

CASE REPORT

Early surgical aortic bioprosthesis failure caused by cusp tear: A word of caution

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Abstract

Cusp tear is an increasingly described mode of failure of the Trifecta aortic bioprosthesis. Acute aortic regurgitation after implantation of a Trifecta in absence of endocarditis should suggest a cusp tear and be promptly treated with redo surgery.

KEY WORDS

aortic valve replacement, cusp tear, early structural valve degeneration, Trifecta

1 | INTRODUCTION

Among the bioprostheses available for surgical aortic valve replacement (SAVR), the Trifecta valve (Abbott Laboratories) is a stented bioprosthesis with externally mounted bovine pericardial leaflets, renowned for its excellent hemodynamic properties. Midterm as well as recent long-term studies report a low incidence of structural valve deterioration (SVD).^{1,2} However, only recently, we have experienced two cases of acute and severe regurgitation due to cusp tear, 12 and 18 months after initial implantation, respectively. A critical literature research has shown similar current reports. With this depiction, we want to add on a thorough and decisive reconsideration of the valve's features.

2 | CASES PRESENTATION

2.1 | Case n°1

A 69-year-old male patient underwent a combined procedure with SAVR using a 23 mm second-generation Trifecta and mitral annuloplasty, due to severe calcified aortic stenosis and severe mitral prolapse. The procedure was performed in our hospital. Postoperative echocardiography showed neither para- nor intraprosthetic leak and the mean

aortic transvalvular gradient was 12 mm Hg. Eighteen months later, the patient presented to his general practitioner complaining of sudden onset of dyspnea and cough. An empirical antibiotic treatment was initiated as treatment of a presumed pneumonia. Due to worsening of symptoms, the patient was admitted to the regional hospital. Cardiac examination including transesophageal echocardiography (TEE) revealed a severe aortic regurgitation with a floating structure on the noncoronary cusp (Figure 1; Videos S1, Video S2, and Video S3). An infection of the prosthesis was suspected, and the patient was referred to our institution for surgical treatment. Despite negative blood cultures, the decision for urgent redo aortic valve replacement was taken based on a persistent pulmonary edema. The surgical inspection of the Trifecta valve revealed a complete rupture between the noncoronary cusp and the stent along its attachment to the adjacent left cusp (Figure 2). The prosthesis was well seated, and there were no signs of endocarditis. A 23 mm Perimount Magna Ease (Edwards Lifesciences) was alternatively implanted. The intervention was uneventful. The postoperative course was marked by the onset of a ventricular fibrillation on the fourth day, presumably due to a prior nondiagnosed long QT syndrome, for which the patient was successfully resuscitated and an implantable cardioverter-defibrillator was subsequently implanted. The patient was discharged from hospital after 2 weeks without

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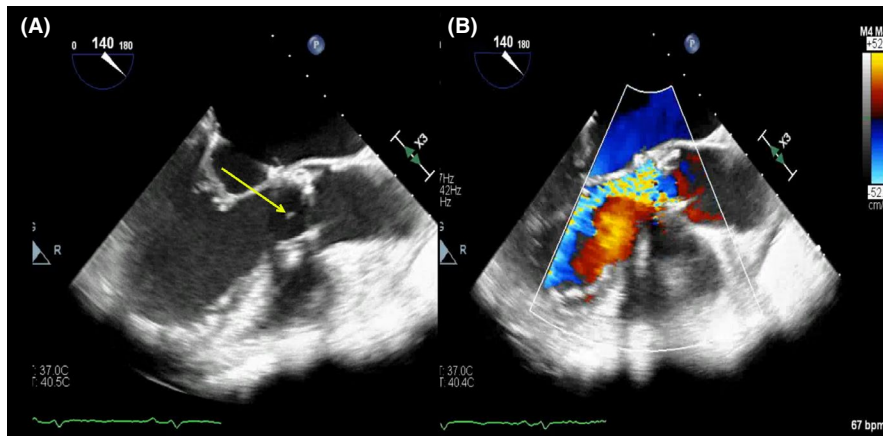


FIGURE 1 Case n°1: A, transesophageal echocardiography 3-chamber view with a floating structure on the ventricular side from the noncoronary cusp during diastole (yellow arrow). B, severe aortic regurgitation with eccentric jet visible with color Doppler

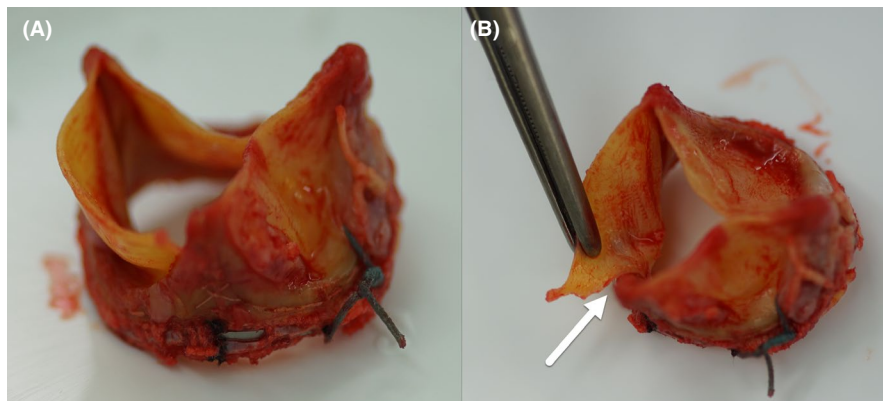


FIGURE 2 Case n°1: A, explanted prosthesis (Trifecta 25 mm). B, cusp tear (arrow) along the commissure causing the prolapse

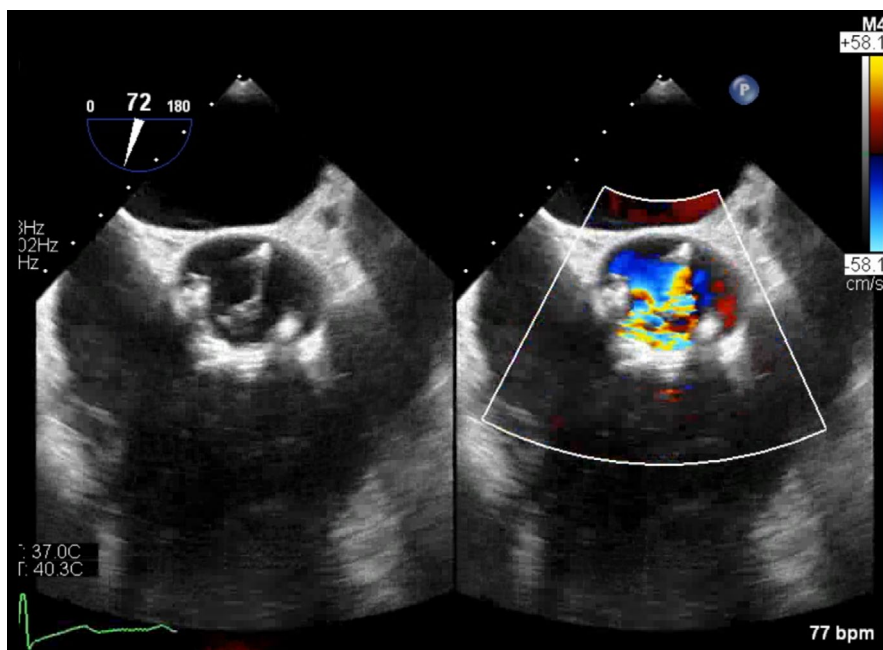


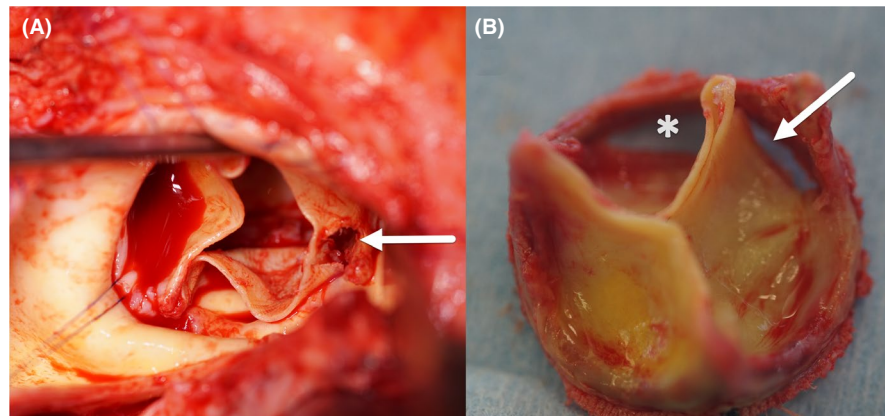
FIGURE 3 Case n°2: transesophageal echocardiography short-axis view through the aortic valve showing severe aortic regurgitation due to complete prolapse, presumably of the noncoronary cusp; with and without color Doppler (left and right, respectively)

further complications. Microbiologic analyses of the prosthesis including a eubacterial polymerase chain reaction as well as Q fever, Brucella and Bartonella serology remained negative.

2.2 | Case n°2

A 58-year-old male patient underwent aortic valve replacement with a 27 mm second-generation Trifecta due to a

FIGURE 4 Case n°2: A, intraoperative view of the destructed Trifecta (arrow). B, explanted prosthesis (Trifecta 27 mm). The arrow marks the initial tear between the cusp and the stent along the commissure. The tear marked with * was due to the explantation of the prosthesis



severe stenotic, bicuspid aortic valve in our hospital. The decision to implant a bioprosthesis had been influenced by the patient's reluctance to a lifelong anticoagulation. Postoperative echocardiography showed neither para- nor intraprosthetic leak and the mean aortic transvalvular gradient was 6 mm Hg. Twelve months later, the patient was urgently admitted to his regional hospital due to the sudden onset of chest pain. A computed tomography ruled out a pulmonary embolism. The patient was further referred to our institution, where a complete cardiac examination including TEE demonstrated a severe aortic regurgitation due to a complete cusp prolapse, presumably on the noncoronary side (Figure 3; Videos S4 and Video S5). The patient denied fever. Blood cultures were negative. The decision was taken in our heart team to perform a valve-in-valve transcatheter aortic valve implantation (TAVI) into the faulty Trifecta prosthesis via a transfemoral approach. However, the TAVI implantation (Portico 29 mm, Abbott) failed, with an ultimate migration of the device into the proximal aorta. An urgent sternotomy was performed, and the TAVI-prosthesis was extracted under cardiopulmonary bypass. The surgical examination of the Trifecta confirmed the tear of the noncoronary cusp along the commissure adjacent to the right cusp (Figure 4). There were no signs of infection. A 25 mm Inspiris Resilia (Edwards Lifesciences) was implanted. The procedure was uneventful. The patient was discharged on the sixth postoperative day. Microbiologic analyses revealed a single colony-building unit of *Propionibacterium acnes*, which was interpreted as a contamination by our infectious disease specialists.

3 | DISCUSSION

Since its release on the market in 2011, the Trifecta has aroused interest for SAVR due to its excellent dynamic performance. Regarding its durability, a recent cohort study involving 1241 patients reported a freedom from reoperation due to SVD of 93.3% at 8 years.² The precise SVD mechanisms were not specified. A thorough review of the literature

between 2014 and 2020 reveals 15 cases among 11 publications of parastent cusp tear as a cause of acute aortic regurgitation after implantation of a Trifecta valve, for which urgent redo surgery was mandatory.³⁻¹³ In all cases, neither extrinsic damage nor evidence of endocarditis could explain the cusp tear. Table 1 lists the reported cases with relevant clinical and operative details. Based on the data provided by these reports, the median time was 43 months (range 8-72 months) between the implantation of the valve and the occurrence of the cusp tear (ie, durability).

In 2017, Goldmann & al.¹⁴ also reported one case of pure regurgitation due to noncalcified leaflet tear as a cause of explantation in a prospective, nonrandomized observational study involving 710 patients. In 2019, Fukuhara & al.¹⁵ demonstrated a 13.3% incidence of SVD at 7 years in a retrospective comparative study involving 1058 patients after bioprosthetic SAVR in the Trifecta group (n = 508). Among the explanted failed prostheses, the authors reported seven cases of pure regurgitation, the mechanism of which being a cusp tear. Also in 2019, Kilic & al.¹⁶ reported three cases out of 1953 implantations of early failed Trifecta due to cusp tear. Our two present cases add up to the aforementioned with an unfavorably early occurrence.

The exact mechanism of the tear remains unclear. We did not notice any significant amount of calcification, pannus, or any signs of endocarditis, neither macroscopically nor with microbiological analysis, as an explanation for prosthesis failure. We assume, these tears resulted from mechanical fatigue of the cusp tissue at its fulcrum on the stent post, where mechanical stress is notoriously high.¹⁷ Cusp tear is a well-documented issue of externally mounted leaflets bioprostheses from previous generations, described after explantation of both Ionescu-Shiley, Hancock I, and first-generation Mitroflow (A11) valves.¹⁸⁻²⁰ Recent in vitro works suggest the specificity of cusp tear secondary to mechanical abrasion at the commissural region in externally mounted leaflets valves.²¹ Besides, fixation as well as anticalcification treatment differ between manufacturers and may affect the valve durability.²² Whether their ethanol-based anti-calcification

TABLE 1 Trifecta failure cases due to cusp tear reported in the lit

Case n°	Authors	Date	Age (years)	Gender	Valve Size (mm)	Clinical presentation	Durability (months)	Tear localization	Other pathologic findings	Therapy	Blood cultures	Explant culture
1	Campisi & al.	2014	74	M	23	Left ventricular heart failure	8	Between left & noncoronary	ND	SAVR w/CEPME 23 mm	ND	Negative
2	Piñón & al.	2014	71	F	21	Pulmonary congestion	34	Noncoronary	ND	SAVR w/St Jude Epic 21 mm	Negative	Negative
3	Yoshida & al.	2016	77	F	ND	Dyspnea on exertion	19	Between right & noncoronary	ND	SAVR w/CEPME	Negative	ND
4	Zhu & al.	2017	76	M	23	Left ventricular heart failure	33	Between left & noncoronary	ND	SAVR w/CEPME 23 mm	Negative	ND
5	Schaefer & al.	2017	83	M	23	Cardiogenic shock	72	ND	ND	SAVR	ND	ND
6	Hamamoto & al.	2017	76	F	21	Pulmonary congestion	24	Right coronary	Circumferential pannus ingrowth on the inflow side	SAVR w/porcine bioprosthesis	ND	Negative
7	Tamura & al.	2017	77	M	23	Dyspnea on exertion	31	Left coronary	ND	SAVR	ND	ND
8	Eichinger & al.	2018	73	F	21	Severe, acute dyspnea	43	Noncoronary	ND	SAVR w/bovine bioprosthesis 21 mm	ND	Negative
9	Eichinger & al.	2018	66	F	23	Pulmonary congestion	51	Right coronary	ND	SAVR w/bovine bioprosthesis 21 mm	ND	Negative
10	Chengalath & al.	2018	56	M	23	Severe aortic regurgitation	44	Between left & right coronary	ND	SAVR	ND	ND
11	Hara & al.	2019	69	M	23	Dyspnea	48	Left coronary	ND	SAVR w/CEPME 23 mm	ND	ND
12	Kaneyuki & al.	2020	64	F	21	Dyspnea on exertion	72	Noncoronary	Pannus formation	SAVR w/bovine bioprosthesis 21 mm	ND	ND
13	Kaneyuki & al.	2020	71	F	19	Dyspnea on exertion	71	Noncoronary	Pannus formation	SAVR w/bovine bioprosthesis 19 mm	ND	ND
14	Kaneyuki & al.	2020	68	M	21	Dyspnea on exertion	56	Noncoronary	Pannus formation	SAVR w/bovine bioprosthesis 21 mm	ND	ND
15	Kaneyuki & al.	2020	73	M	21	Dyspnea on exertion	37	Noncoronary	ND	SAVR w/bovine bioprosthesis 21 mm	ND	ND

Abbreviation: CEPME, carpentier-edwards perimount magna ease; ND, not documented, SAVR, surgical aortic valve replacement.

treatment weakens the Trifecta's leaflets overtime, remains hypothetical.

An announcement was made to the Swiss national surveillance organization for implanted medical devices (*Swissmedic*). Due to our current experience and the latest adverse reports, we have decided to discontinue the implantation of the Trifecta bioprosthesis.

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Not applicable.

CONFLICT OF INTEREST

The authors report no conflict of interest.

AUTHOR CONTRIBUTION

TS: wrote the manuscript. DB: performed the surgical procedure (Case n°1). OR: performed the surgical procedure (Case n°2) and revised the manuscript. All authors read and approved the final manuscript.

ETHICAL APPROVAL

Written informed consent for publication was obtained from both patients.

DATA AVAILABILITY STATEMENT

The data are available from the corresponding author on reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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