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CASE REPORT

Bail-out edge-to-edge mitral repair for an acute single leaflet device attachment: a case report

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Background An acute single leaflet device attachment (SLDA) may occur during transcatheter mitral valve edge-to-edge repair (TMVr), if an inadequate grasping of the target leaflet and/or a leaflet injury are concomitant. The bail-out TMVr often fails due to the complex pathophysiology.

Case summary We report a case of an acute SLDA after TMVr with the PASCAL Repair System for severe mitral regurgitation (MR) with mixed aetiology, i.e., a thin-appeared posterior leaflet and pseudo-prolapse of the anterior mitral leaflet due to mitral annular dilatation. An acute SLDA occurred 2 min after the deployment, with device detachment of the posterior leaflet. A bail-out TMVr with the MitraClip XTR system led to an optimal MR reduction with the PASCAL stabilized. Despite an adequate leaflet insertion of the 1st device achieved, the posterior leaflet was tear due to its fragile tissue characteristics. At discharge, echocardiography confirmed an optimal MR reduction to mild grade with both devices stabilized.

Discussion The pathology of the mitral valve leaflet is essential to achieve successful TMVr procedure using edge-to-edge repair device. Since the mechanical stress to the target leaflet appears to vary according to the edge-to-edge repair devices, the leaflet tissue characteristics should be respected during device selection.

Keywords Transcatheter edge-to-edge mitral valve repair • Acute single leaflet device attachment • MitraClip • PASCAL • Case report

Learning points

- Tissue characteristics of mitral valve leaflets should be carefully evaluated by transoesophageal echocardiography before transcatheter edge-to-edge mitral valve repair.
- Different edge-to-edge device characteristics can lead to different mechanical strain on mitral valve leaflets.
- Mitral regurgitation mechanisms and quality of mitral leaflet tissue should be respected for selection of transcatheter edge-to-edge mitral valve repair.

Introduction

Transcatheter edge-to-edge mitral valve repair (TMVr) is an effective treatment option for severe mitral regurgitation (MR) if the surgical risk is high or prohibitive. A deep understanding of the MR aetiology is essential for procedural success with an optimal MR reduction. Degenerative MR is often challenging in TMVr, wherein degenerative alterations of the target leaflet show a large variation of the

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pathology. Therein, secondary changes may coexist as the result of the long-standing volume overload of the left ventricle (LV) due to severe MR. In edge-to-edge valve repairs for complicated MR pathologies, a single leaflet device attachment (SLDA) has been concerned because the target leaflet may be fragile due to a degenerative pathology and the risk of leaflet injury is considered high. In initial pivotal studies including the cohort with degenerative MR aetiology, the rate of SLDA was reported as 4–9%.[1–4] The success rate of repeat TMVr for loss of leaflet insertion was reported low as 25%.[5] Moreover, concomitant pathology, such as ring dilatation and leaflet tethering, may reduce the opportunity of optimal leaflet repair.

Nowadays, a variety of percutaneous devices are available for TMVr, in which the device profiles are different. As the differences between PASCAL and MitraClip (Supplementary material online, Figure *S1A* and *B*), the device width, the device material (nitinol vs. cobalt-chrome), and the disposition of frictional elements (or spikes) may influence TMVr procedures and adequate device selection for the underlying MR mechanisms which vary in individuals.

Timeline

Day	Events
2004	Diagnosis of hypertensive heart disease with paroxysmal atrial fibrillation and mild mitral regurgitation (MR)
November 2009	Coronary artery bypass grafting for three-vessel disease (75% stenoses of the proximal left anterior descending and left circumflex arteries, and chronic total occlusion of the proximal right coronary artery)
June 2011	Cardiac arrest due to ventricular fibrillation during exercise, terminated by 2× shocks by automated external defibrillator Implantation of an implantable cardioverter-defibrillator as a secondary prevention
25 March 2020	Acute decompensated heart failure due to severe mitral regurgitation with preserved left ventricular systolic function
20 May 2020	Transcatheter edge-to-edge mitral valve repair using the PASCAL System
11:50	Start of the procedure
12:45	Deployment of the PASCAL with a MR reduction from severe to mild grade
12:47	Single leaflet detachment of the posterior mitral leaflet
13:02	Exchange of the guiding catheters for the bail-out procedure
13:09	Deployment of the MitraClip XTR
13:14	End of the procedure with mild MR and both devices stabilized
22 May 2020	Discharge with mild MR, the transmitral gradient of 4.7 mmHg

Case presentation

A 78-year-old male presented to our hospital with a recent history of acute decompensated heart failure due to severe MR, based on long-standing ischaemic heart disease which had been treated by coronary bypass and implantable cardioverter defibrillator for secondary prevention. At presentation, an auscultatory examination revealed a holosystolic murmur of a grade IV/VI was audible at the left fifth mid-clavicular line with radiation to the left axilla. No peripheral oedema was documented. The exertional dyspnoea was graded in New York Heart Association functional Class II. Six-minute walk distance was 403 m. N-terminal pro brain-type natriuretic peptide was 990 ng/L (normal < 486 ng/L). The prescribed medication was torasemide 20 mg, bisoprolol 10 mg, and amlodipine 10 mg and dabigatran 150 mg.

Transoesophageal echocardiography demonstrated an A2 segment pseudo-prolapse with an eccentric MR jet to the posterior direction, which appeared to result from mitral annular enlargement due to left atrial dilatation (volume 49 mL/m^2) with the anteroposterior diameter of 38 mm, but no relevant LV cavity enlargement with the end-diastolic diameter of 52 mm and the ejection fraction of 64% (*Figure 1A–D*, *Video 1*). As a result, the coaptation angle of both leaflets increased to 148°, where the angles between the mitral annular plane and leaflets reduced to 21° as to the anterior leaflet, comparing the posterior leaflet with 28°, in absence of relevant apical leaflet tethering (coaptation depth 6 mm) (Supplementary material online, *Figure S2*). A three-dimensional colour Doppler echocardiography revealed a large MR orifice area of 0.78 cm^2 with the width of 17 mm (*Figure 1D*).

Due to a prohibitive risk for redo surgery, the local multidisciplinary heart team decided to treat the patient using TMVr. In consideration of pathoanatomy of MV and a regurgitation width of 17 mm, we selected the PASCAL® Transcatheter Valve Repair System (Edwards Life Scientific, Irvine, CA, USA). The PASCAL was placed successfully between segments A2 and P2 (*Figure 2A*). The target posterior leaflet showed a thick basal part of 12.1 mm and a thin distal part of 4.7 mm with a total of 16.8 mm. The clasped length was 9.1 mm (*Figure 2B–D*, *Video 2*). After PASCAL release, the MR severity was reduced to mild (*Figure 2E* and *F*); however, an acute SLDA occurred 2 min later (*Figure 3A–C*). The posterior leaflet was shortened to 12.3 mm (*Figure 3B*), and the device was moving back and forth instable, while the residual MR remained unchanged because the large-profile device worked like as a central spacer for the coaptation defect (*Figure 3D*, *Video 3*). The mean transmitral gradient was 2 mmHg after PASCAL implantation. Due to the limited MV orifice area for a second PASCAL device with device width of 10 mm, we decided to stabilize the PASCAL device and both leaflets by a MitraClip XTR® (Abbott Vascular Structural Heart, Menlo Park, CA) with a device width of

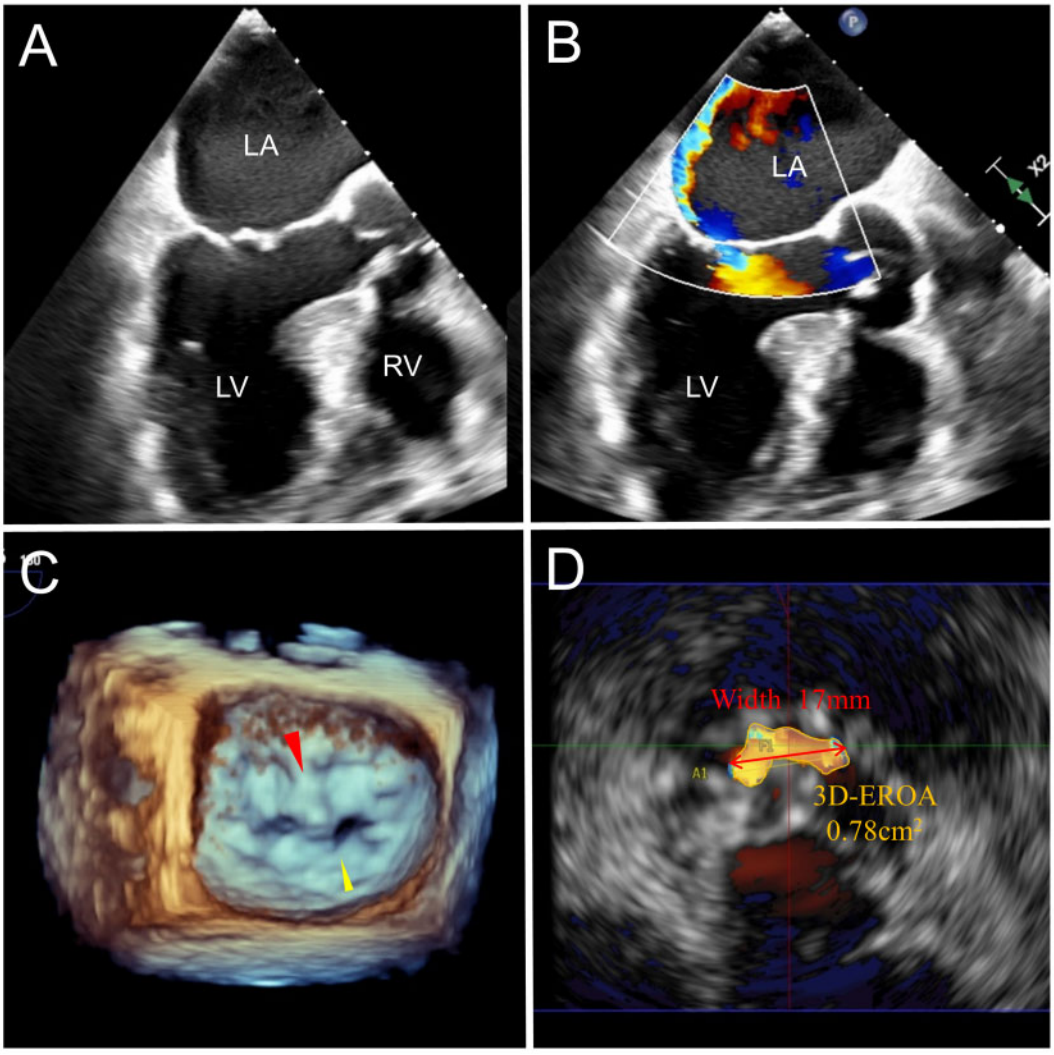
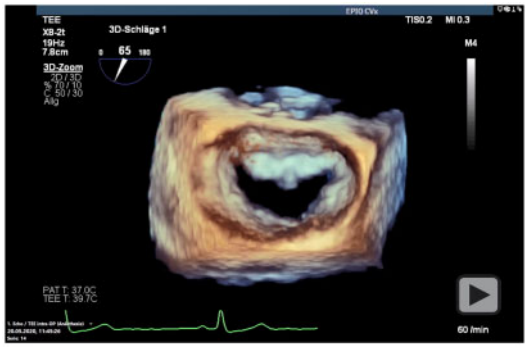


Figure 1 Baseline echocardiographic characteristics of the mitral regurgitation. (*A*,*B*) Transoesophageal echocardiography (TOE) demonstrated A2 pseudo-prolapse (*A*) and an eccentric regurgitation jet (*B*). (*C*) Three-dimensional TOE from the atrial view: a red arrow head indicates A2 pseudo-prolapse, a yellow arrow head indicates a P2–P3 indentation. (*D*) Multiplanar colour Doppler TOE from the ventricular view [vena contracta width of 17 mm and three-dimensional effective regurgitation orifice area (3D-EROA) of 0.78 cm^2]. 3D-EROA, three-dimensional effective regurgitant orifice area; LA, left atrium; LV, left ventricle; RV, right ventricle; TOE, transoesophageal echocardiography

4 mm. After exchanging the guide catheters, the leaflets adjacent to the PASCAL device were captured by the MitraClip XTR (*Figure 4A–D*), in which the residual length of the posterior leaflet was 5.5 mm after closing the clip (*Figure 4E and F*). The PASCAL device was stabilized (*Figure 5A–C*, Supplementary material online, *Video S1*) and the residual MR remained mild with a mean transmitral gradient of 3 mmHg (*Figure 5D–F*). The patient was successfully discharged 2 days after the procedure with mild MR, stable devices implanted and no post-procedural mitral stenosis with the mean gradient of 4.7 mmHg.



Video 1 A2 prolapse and P2–P3 indentation in the three-dimensional transoesophageal echocardiography.

Discussion

In this reported case, the mechanisms of the acute SLDA could be assumed that the spike anchors were exactly positioned on the hinge

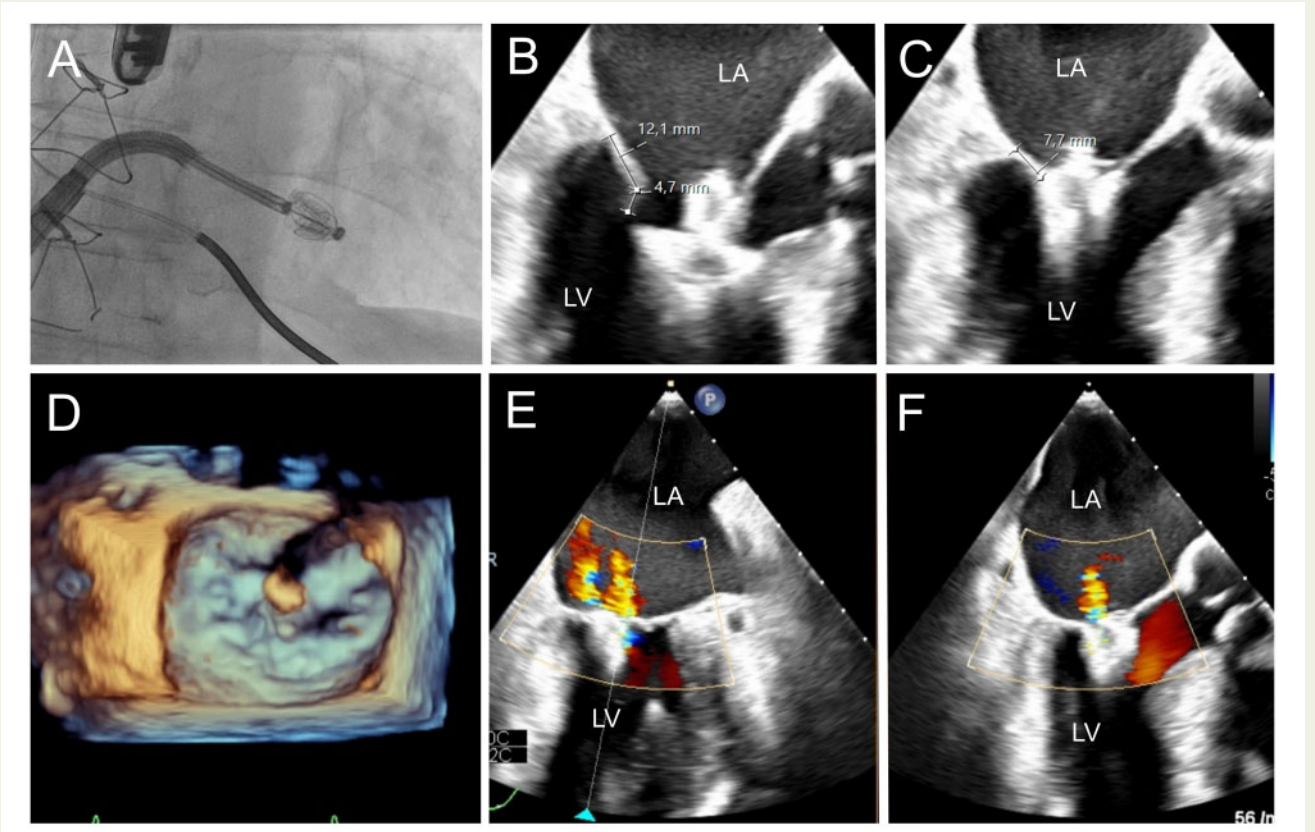
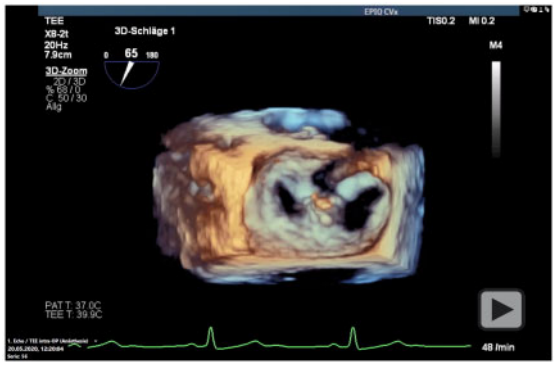


Figure 2 Implantation of the PASCAL® Transcatheter Valve Repair System. (*A*) Fluoroscopic image of the device delivery system. (*B*) An independent grasping of the posterior leaflet. (*C*) After grasping of both mitral leaflets. The rest leaflet length was 7.7 mm. (*D*) Three-dimensional transoesophageal echocardiography before the device release. (*E*,*F*) Mild residual mitral regurgitation was observed after the device deployment. LA, left atrium; LV, left ventricle.



Video 2 Final position of the PASCAL device in the three-dimensional transoesophageal echocardiography.

Video 3 An acute single leaflet device attachment of the PASCAL device with residual mild regurgitation in the three-dimensional transoesophageal echocardiography.

between the thick and the thin part of the segment P2, following that the mechanical stress by the grasping device led to an injury of the posterior leaflet. We hypothesize that the posterior leaflet was thinned out due to degenerative processes through during the long history of MR. Moreover, the pseudo-prolapse resulted from that shallow angles of leaflets to the mitral annulus alter the position of the leaflet tip through a ring dilatation despite preserved LV systolic function, mimicking a functional atrial MR. Device selection for TMVr in this type of pathology is crucial. Percutaneous mitral annuloplasty could be an option for the treatment of annular enlargement only. Due to the pseudo-prolapse of A2, we selected an edge-to-edge TMVr

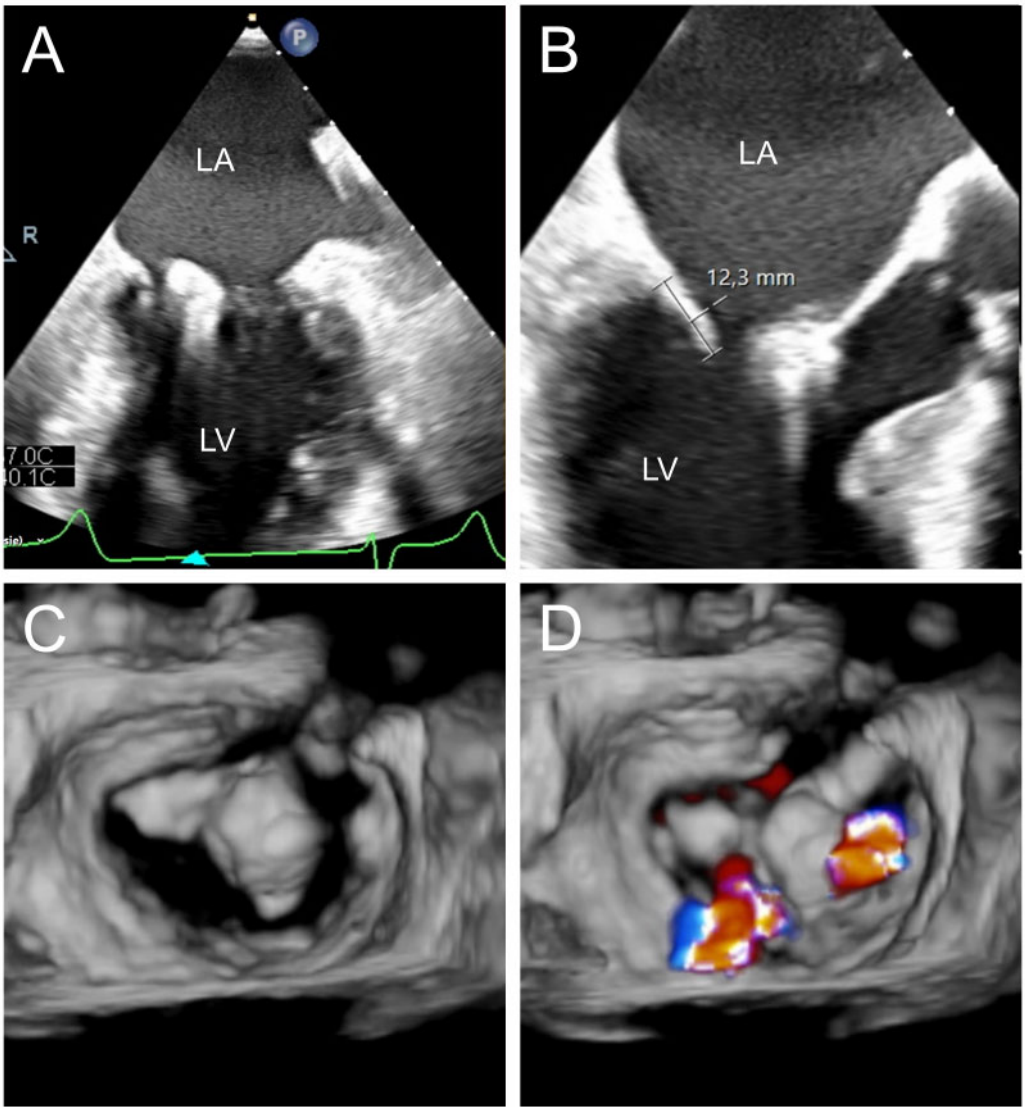


Figure 3 An acute single leaflet device attachment (SLDA) with the shortened posterior leaflet. (*A, B*) The device was attached only at the anterior leaflet, and the posterior leaflet length was shortened from 16.8 mm to 12.3 mm. (*C,D*) Three-dimensional transoesophageal echocardiography showed an SLDA with the device attached on the anterior leaflet (*C*) and the regurgitation of mild grade (*D*). LA, left atrium; LV, left ventricle; SLDA, single leaflet device attachment.

technique with the objective to achieve a large zone of coaptation between both leaflets in segment 2. In consideration of pseudo-prolapse of anterior mitral leaflet with a regurgitation width of 17 mm, selecting the PASCAL Repair System was considered reasonable because the leaflet capture was enabled even if both paddles completely open up to the angle of 180°. Both clasps of the PASCAL system have four spikes which are positioned 3 mm inside from the tip. Indeed, the length of the thick basal posterior leaflet and the remaining length during grasping with the PASCAL system were 12.1 mm and 7.7 mm, meaning that only 4.4 mm length of the thick basal leaflet was clasped and that its spikes were positioned on the hinge of thick and thin posterior leaflet and finally led to the SLDA (Supplementary material online, *Figure S3A* and *B*). On the other hand, the MitraClip® has 4–6 frictional elements which are straightforwardly positioned along each gripper. Therefore, quality of leaflet tissue should be respected for device selection, given that the different clasping manner is critical for an adequate device deployment, in particular for patients with complex MR pathologies.

Leaflet injury or partial clip detachment has been the leading mechanism in recurrent MR or repeat TMVr.[5] As the sequelae, an acute SLDA was reported as 3.7% of the MitraClip XTR[4] and 1.6–4.3% of the PASCAL.[3,6] Nowadays, several types of edge-to-edge valve repair devices are available; hence, the 4th-generation MitraClip devices have a wide variation of arm length (9 mm or 12 mm) and of device width (4 mm or 6 mm), while the PASCAL-Ace Repair System has recently emerged with a smaller device width than the conventional

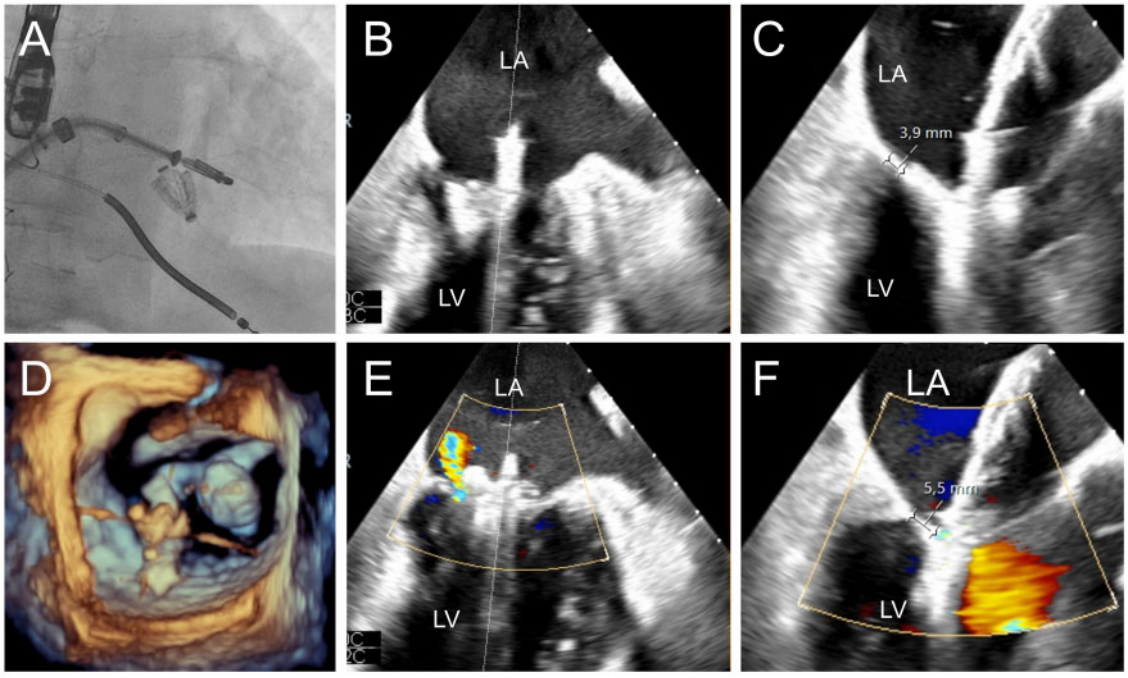


Figure 4 Bail-out transcatheter edge-to-edge mitral repair using the MitraClip XTR® for an acute single leaflet device attachment of the PASCAL® System. (*A*) Fluoroscopic image of the device delivery system. (*B*, *C*) Leaflet gripping by the MitraClip XTR® adjacent to the PASCAL® device (the rest leaflet length was 3.9 mm). (*D*) Clip orientation. (*E*, *F*) Leaflet grasp minimized the regurgitation with the rest posterior leaflet length of 5.5 mm. LA; left atrium, LV; left ventricle.

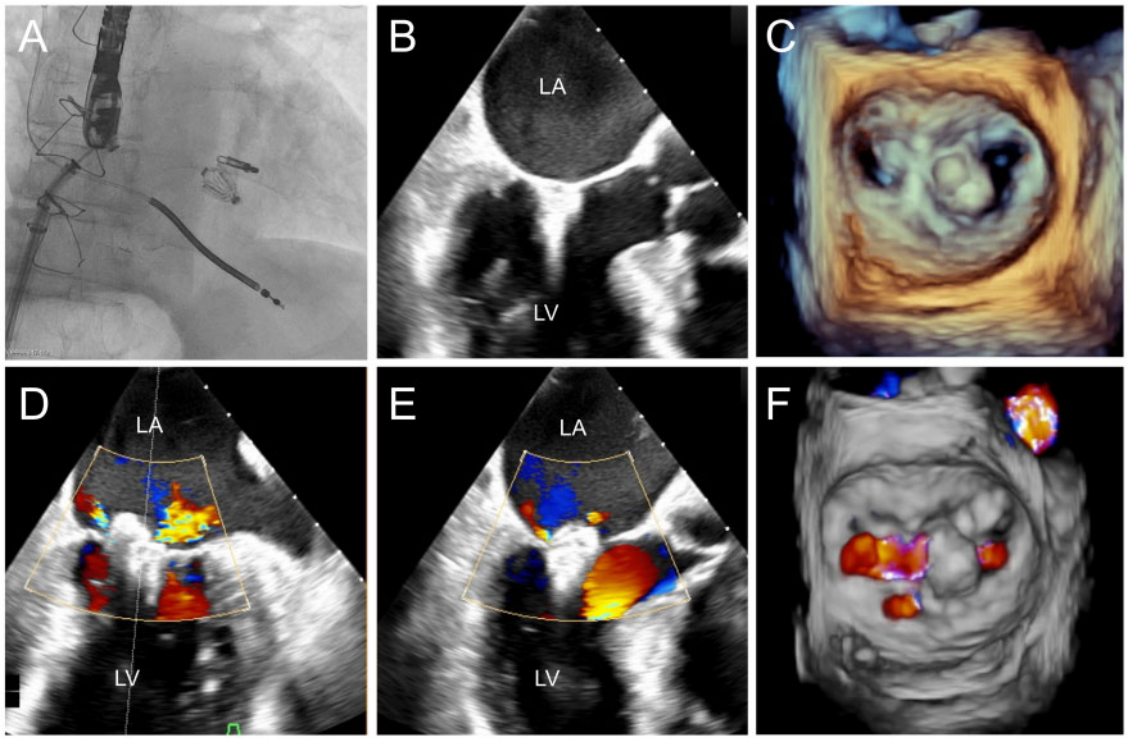


Figure 5 Final results after PASCAL® device and MitraClip XTR® implantation. (*A*) Fluoroscopic image of both devices deployed. (*B*, *C*) Stable deployment of the MitraClip XTR® with the PASCAL® device stabilized. (*D*–*F*) Transoesophageal Doppler echocardiography of the residual regurgitation at the end of procedure. LA, left atrium; LV, left ventricle.

PASCAL device (5 mm vs. 10 mm). The PASCAL series are made of nitinol with a central spacer facilitating the coaptation enhancement as designed to minimize the mechanical stress to the target leaflets. Noteworthy, the frictional elements (or spikes) for the leaflet capture vary between the MitraClip and the PASCAL devices (Supplementary material online, *Figure S1A* and *B*).

To prevent SLDA in TMVr, MR mechanisms and quality of leaflet should be respected for device selection, and a thin-appeared leaflet should be avoided to be captured by an edge-to-edge repair device.

Conclusion

In this case, a bail-out TMVr with the MitraClip-XTR was successfully performed without hemodynamic deterioration after an acute SLDA of the PASCAL system. No recurrent severe MR occurred despite SLDA with injury of the posterior leaflet as a sequelae, where the central spacer appeared to maintain the effect of coaptation enhancement. Meticulous imaging analysis of leaflets and understandings of the device design were crucial to elaborate the mechanisms of SLDA and to complete the confidential procedure of the bail-out TMVr.

Lead author biography

Mitsunobu Kitamura, MD is currently a clinical fellow in Heart Center Leipzig at University of Leipzig, Germany. Until 2015, he was working as an interventional cardiologist in Tokyo, Japan. His interests are haemodynamic alterations and imaging analyses in transcatheter interventions for heart failure. Since 2016, he is working as a fellow for interventional cardiology in Germany, practicing percutaneous valvular interventions and clinical researches.

Supplementary material

Supplementary material is available at *European Heart Journal - Case Reports* online.

Slide sets: A fully edited slide set detailing these cases and suitable for local presentation is available online as Supplementary data.

Consent: The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient in line with COPE guidance.

Conflict of interest: None declared.

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