ESC European Society of Cardiology

European Heart Journal - Case Reports (2023) **7**, 1–6
https://doi.org/10.1093/ehjcr/ytad438

CASE REPORT
Structural intervention

Bailout clipping of a leaflet perforation during mitral transcatheter edge-to-edge repair using a larger clip size: a case report

Naoki Nishiura, Shunsuke Kubo *, Takeshi Maruo, and Kazushige Kadota

Department of Cardiovascular Medicine, Kurashiki Central Hospital, 1-1-1, Miwa, Kurashiki, Okayama 710-8602, Japan

Received 22 March 2023; revised 14 August 2023; accepted 30 August 2023; online publish-ahead-of-print 8 September 2023

Background Leaflet tear and perforation are serious complications of transcatheter edge-to-edge repair (TEER) using the MitraClip system for severe mitral regurgitation (MR). However, no optimal bailout strategy has been established.

Case summary An 80-year-old woman developed heart failure due to acute ischaemic severe MR after primary percutaneous coronary intervention. Given the requirement for inotropic drugs and an intra-aortic balloon pump to stabilize her heart failure, we decided to perform TEER using the MitraClip G4 system. The NTW clip was selected considering the limited posterior leaflet, wide central MR, and delivery to the central A2/P2. The leaflet was successfully grasped, and the MR jet dramatically decreased while the clip was closed. However, the MR jet suddenly appeared after completely closing the clip arm. A new eccentric jet was detected coming from the mid-portion of the posterior leaflet, indicating leaflet perforation. We decided to manage the leaflet perforation by covering the perforated portion with a longer type of clip. An XTW clip was then carefully delivered to the previously grasped portion, after which we confirmed that the tip of the clip arm was positioned more posteriorly to the leaflet perforation. After slowly closing the clip, MR decreased to mild, with transoesophageal echocardiography showing no eccentric MR. After her haemodynamics stabilized, she was discharged 28 days after the procedure.

Discussion This case details a successful bailout clipping of a leaflet perforation using an XTW clip. Leaflet anatomy evaluation is important to ensure that the injured portion is covered by the longer clip arm.

Keywords Mitral regurgitation • MitraClip • Valvular heart disease • Complication • Case report

ESC curriculum 2.2 Echocardiography • 4.3 Mitral regurgitation

Learning points

- Transcatheter edge-to-edge repair can cause characteristic leaflet adverse events.
- No optimal bailout strategy has yet been established.
- An XTW clip may be effective for perforations caused by a normal clip type.

Introduction

Transcatheter edge-to-edge repair (TEER) using the MitraClip system (Abbott Vascular, Santa Clara, CA, USA) has become a safe and widespread treatment approach for severe mitral regurgitation (MR).[1,2] The MitraClip G4 system uses four clip types (NT: narrow and short clip arm, NTW: wide and short clip arm, XT; narrow and long clip arm, XTW; wide and long clip arm) to ensure optimal treatment based on mitral valve morphology. However, rare but serious device-related complications have occurred, such as single leaflet device

* Corresponding author. Tel: +81 864 220 210, Email: sk12750@kchnet.or.jp
Handling Editor: Giulio Russo
Peer-reviewers: Andrew Harris; Christoph Hammerstingl
Compliance Editor: Hikmet Kadioglu

attachment, perforation, and leaflet tear, which often require surgical correction. Unfortunately, no optimal bailout strategy has yet been established.

Summary figure

One month before the procedure	The patient underwent primary percutaneous coronary angioplasty for ST-elevation acute myocardial infarction in the left circumflex branch.
A week before the procedure	Congestive heart failure due to severe ischaemic MR was difficult to manage despite using catecholamines and an intra-aortic balloon pump (IABP), prompting transfer to our institution.
Procedure	Transcatheter edge-to-edge repair using the MitraClip device was performed. The NTW clip caused leaflet perforation, which was bailed out using an XTW clip. Post-procedural echocardiography revealed mild MR.
One day later	The IABP was removed after confirming stable haemodynamics.
One week later	Catecholamine was terminated.
One month later	The patient was discharged to a nursing home with good progress.
Eight months later	The patient died due to heart failure.

Clinical presentation

An 80-year-old Japanese woman with a history of chronic renal failure, type 2 diabetes mellitus, and non-disabling cerebral infarction presented with acute chest pain and was diagnosed with ST-elevation acute myocardial infarction at another hospital. Emergency coronary angiography revealed total left circumflex artery (LCX) occlusion, for which primary percutaneous coronary intervention (PCI) was performed. Implantation of a drug-eluting stent at the mid-portion of the LCX promoted Thrombolysis in Myocardial Infarction (TIMI) 3 flow. Post-operative creatinine kinase increased to 11 700U/L, and transthoracic echocardiography (TTE) showed severe MR with severe hypokinesis in the posterior and inferior walls. She developed congestive heart failure after PCI, which was difficult to manage despite using inotropic drugs and an intra-aortic balloon pump (IABP). Two weeks after her primary PCI, she was transferred to our hospital for further heart failure management.

On admission, her vital signs were as follows: heart rate, 92 beats/min; blood pressure, 106/63 mmHg; respiratory rate, 20 breaths/min; and SpO2, 95% under nasal oxygenation (1 L/min), dobutamine (3 μg/kg/h), and IABP. Her oral medications included temocapril (0.25 mg), spironolactone (25 mg), azosemide (30 mg), and prasugrel (2.5 mg). A sinus rhythm and abnormal Q waves in the II/III/aVF induction were noted on 12-lead echocardiography. Chest radiography showed bilateral pulmonary congestion, whereas laboratory findings revealed elevated N-terminal pro-brain natriuretic peptide (to 22 004 pg/mL) and worsening renal function with an estimated glomerular filtration rate of 16.2 mL/min/1.73 m^2. Transthoracic echocardiography showed a left ventricular ejection fraction of 38% with severe hypokinesis in the posterior and inferior walls. The stroke volume reduced to 35 mL (25 mL/m^2 of stroke volume index), suggesting low cardiac output. As the condition of the patient was unstable, an adequate MR quantification with a quantitative method was not performed at the time of TTE examination; however, the average vena contracta width was 9.8 mm, indicating severe MR. The posterior mitral leaflet was tethered due to regional wall motion abnormality, which caused severe MR (*Figure 1*). The patient had a mitral valve area of 4.02 cm^2 measured using 2D planimetry without mitral stenosis and had mild tricuspid regurgitation with a tricuspid regurgitation pressure gradient of 29 mmHg. Transoesophageal echocardiography (TEE) confirmed a severe MR jet coming from the entire A2–P2 due to a restrictive posterior mitral leaflet (PML). The PML length at the grasping zone was 8 mm (*Figure 2*). Given the need for inotropic drugs and an IABP due to low output syndrome caused by severe acute ischaemic MR, interventions for MR were considered. The STS mortality score for mitral annuloplasty was 54.9%. Owing to the prohibitive surgical risk, TEER using the MitraClip G4 system under general anaesthesia was planned as a bailout therapy.

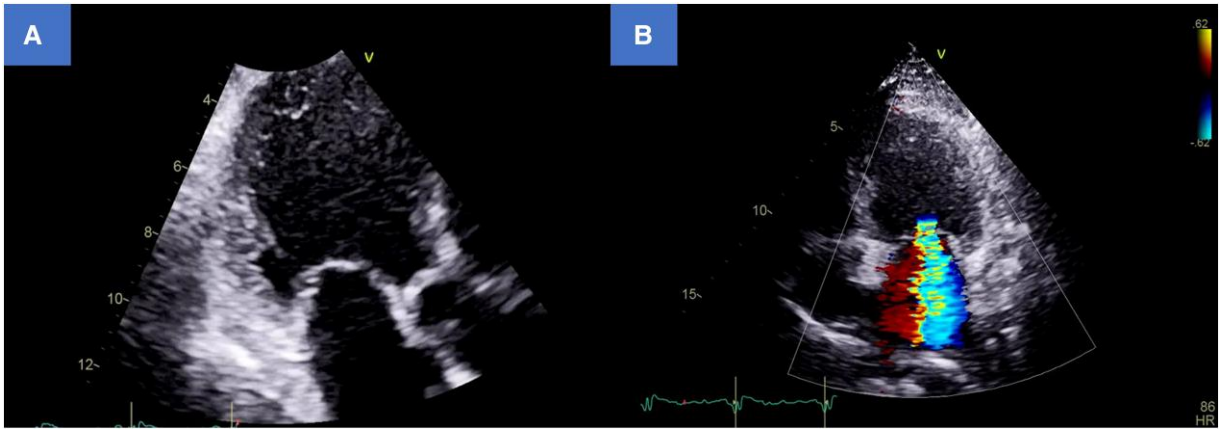

Figure 1 Pre-operative transthoracic echocardiography. Severe mitral regurgitation with tethering of the posterior mitral leaflet. (*A*) Apical three-chamber image, tethering of the posterior mitral leaflet. (*B*) Apical four-chamber image.

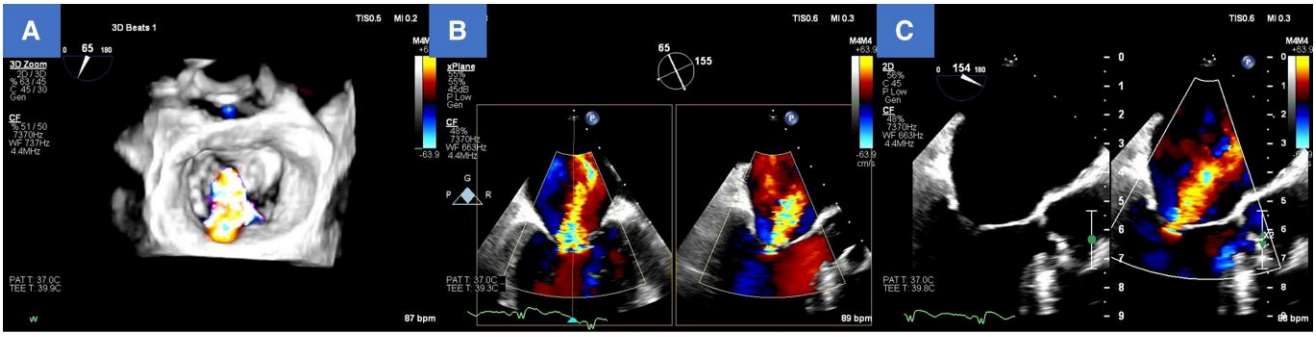

Figure 2 Pre-operative transoesophageal echocardiography. (*A*) Three-dimensional image of the mitral valve showing a central jet from A2–P2. (*B*) Wide regurgitation jet slightly lateral to A2–P2. (*C*) Posterior mitral leaflet was tethering, PML length around 8 mm.

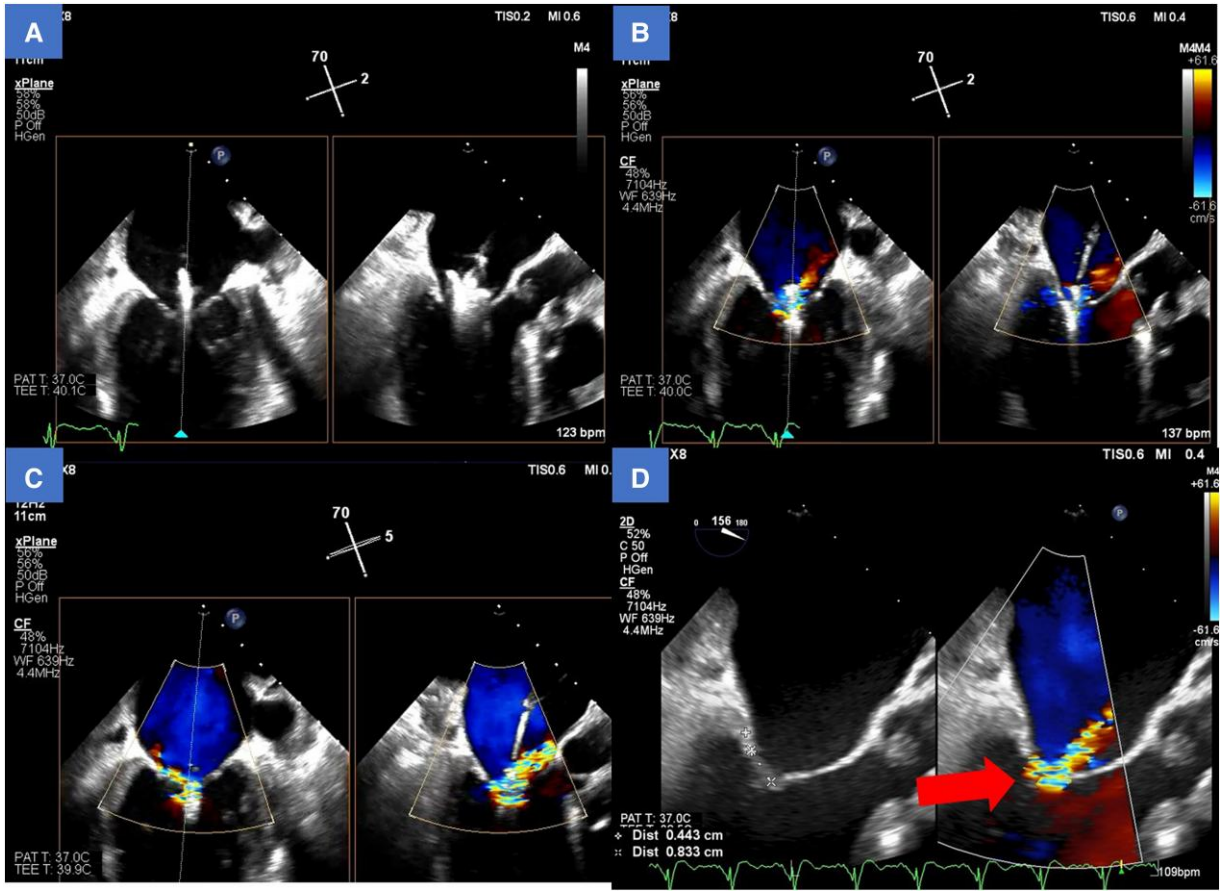

Figure 3 Intraoperative transoesophageal echocardiography until valve leaflet injury was recognized. (*A*) Positioning the NTW clip in line with central jet. (*B*) Mitral regurgitation decreased while the clip arm was closed. (*C*) Once the clip was completely closed, a new mitral regurgitation suddenly appeared. (*D*) The new eccentric jet came from the mid-portion of the posterior leaflet, indicating leaflet perforation caused by the clip arm. The distance from the tip of the posterior leaflet to the perforation site was around 8 mm.

After securing a right femoral venous access, the atrial septum was punctured at the mid/posterior position of the fossa ovalis. The NTW clip was selected given the limited PML length and the need to control for a wide secondary MR. The NTW clip was delivered to the central A2–P2 and inserted into the left ventricle. After confirming that both leaflets were on the clip arm, we dropped gripper down. The MR jet dramatically decreased while the clip was closed but suddenly appeared upon completely closing the clip arm (*Figure 3*). After opening the clip again, valve

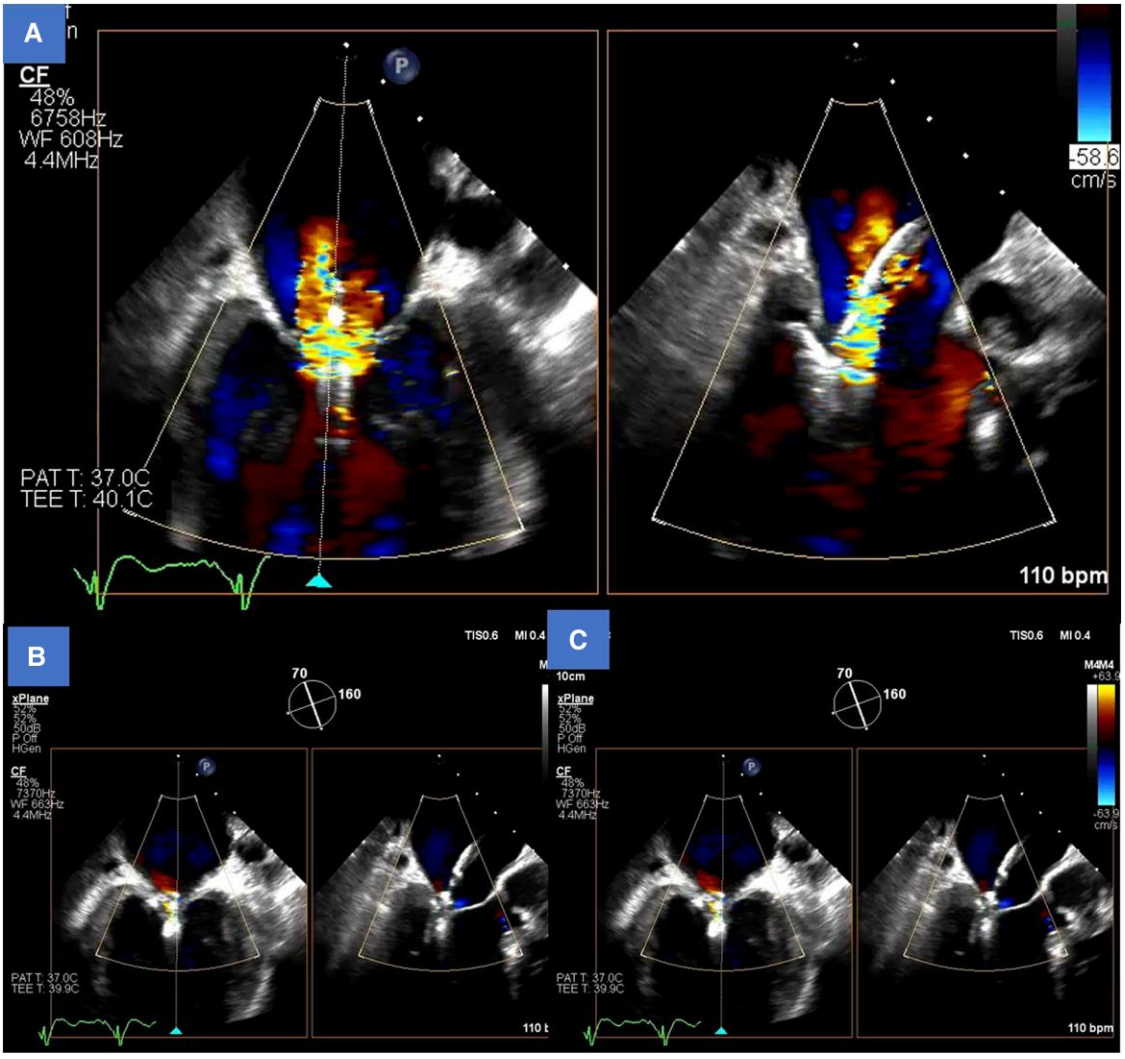

Figure 4 Intraoperative transoesophageal echocardiography after recognizing valve leaflet injury. (*A*) Delivery of the XTW clip to the previously grasped portion, confirming that the tip of the clip arm was positioned more posteriorly to the leaflet perforation before grasping the leaflets. (*B*) After fully closing the clip, the mitral regurgitation decreased to mild. (*C*) Final transoesophageal echocardiography showed mild mitral regurgitation and no stenosis.

leaflet evaluation using TEE revealed a new eccentric jet coming from the mid-portion of the posterior leaflet aside from the initial central jet, indicating leaflet perforation caused by the NTW clip arm. We discussed subsequent strategies such as bailout clipping, medical therapy, and bailout surgery. Although performing bailout clipping was associated with potential risks of worsening the leaflet injury and mitral stenosis, our team ultimately decided to perform bailout clipping owing to the lack of alternatives, as the patient already had medical therapy–resistant heart failure despite having IABP with a prohibitive surgical risk. Accordingly, we removed the NTW clip and inserted the XTW clip to cover the perforated portion with its longer clip arm. As the distance between the tip of the posterior leaflet and perforation site was approximately 8 mm, we intended to grasp the posterior annulus and leaflet to prevent further tension on the perforation site. During the procedure, we put the '+ knob' and turned the guide catheter clockwise to grasp a significant portion of the posterior annulus. After confirming that the tip of the clip arm was positioned more posteriorly to the leaflet perforation, we dropped the griper down and slowly closed the clip, following which MR decreased to mild with no eccentric MR was observed on TEE. After releasing the XTW clip, the final TEE showed mild MR, no eccentric jet, and no apparent mitral valve stenosis (*Figure 4*). After the procedure, her haemodynamics improved considerably. The IABP was removed the next day, and the patient was weaned off catecholamine a week after the procedure. Post-operative TTE also showed improvement in mild MR. The patient was ultimately discharged to a nursing home 28 days after the procedure. She received follow-up medical care by a primary care physician. However, she died for heart failure eight months after discharge.

Discussion

Leaflet adverse events during TEER are rare but difficult to manage. Leaflet adverse events can be classified into leaflet injury and single leaflet device attachment. Meanwhile, leaflet injury can be further classified into leaflet tear, leaflet perforation, and shape distortion. In the EXPAND registry, leaflet injuries accounted for only 0.4% of the 1041 patients.[3]

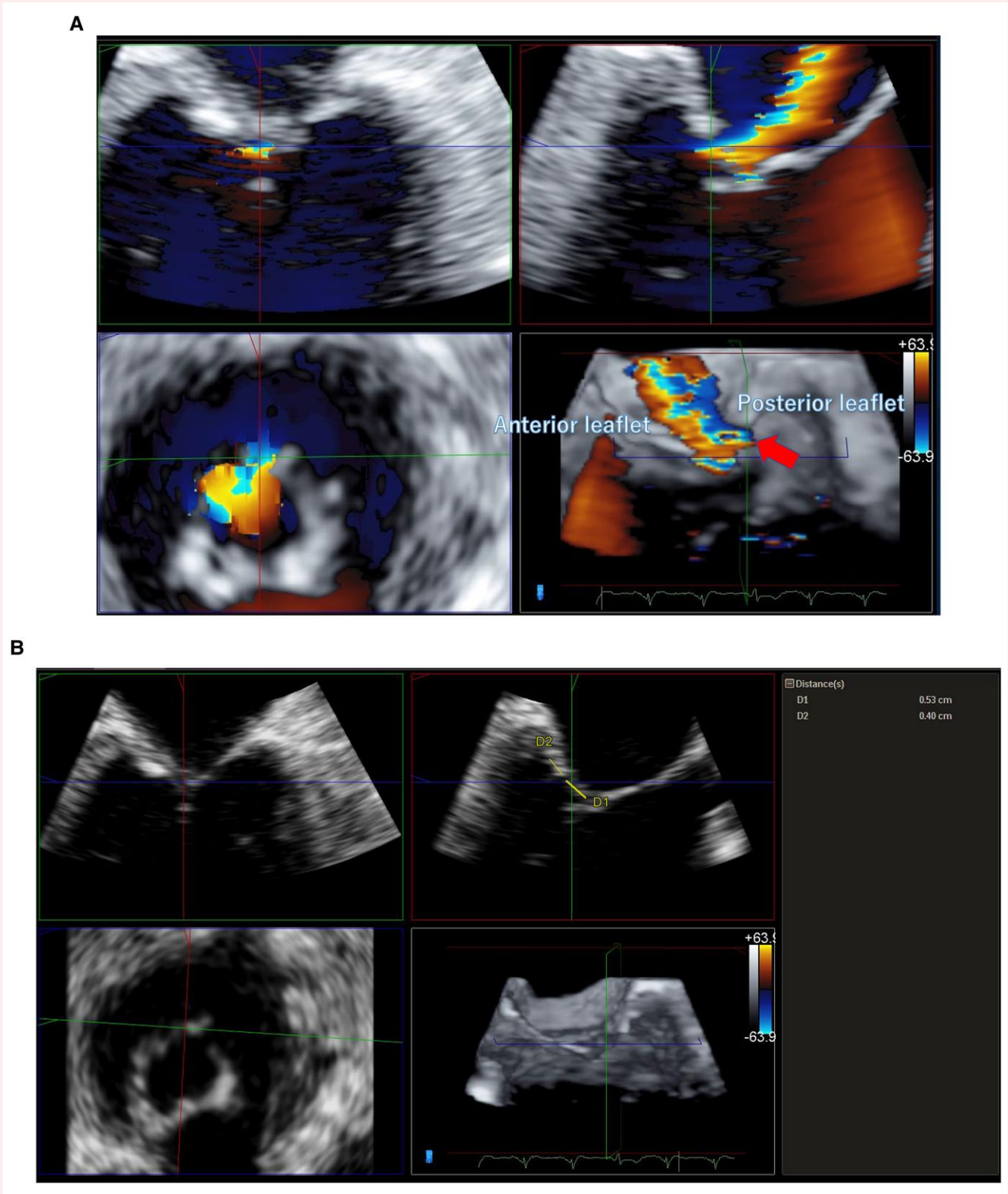

Figure 5 Three-dimensional multiplanar reconstruction image at the time of leaflet injury. (*A*) Regurgitant blood flow from the middle portion of the posterior leaflet (arrow). (*B*) The distance to the injured part was 5.3 mm from the leaflet tip and 4 mm from the base of the posterior leaflet.

The tip of a clip arm creates tension on the leaflet, potentially injuring the leaflet tissue by grasping, especially in thin or fragile leaflets or those with mitral annular calcification. To prevent leaflet damage, surgeons should avoid multiple grasping and slightly advance the clip towards the ventricular direction during careful and slow clip closure.[3,4] In our case, the leaflet injury occurred at the mid-portion of the posterior leaflet during the first grasping. In the EXPAND registry, all patients with leaflet injury exhibited 3+ or 4+ MR and resulted in mitral valve surgery and/or death. Therefore, cardiac team discussions are required to determine the appropriate treatment of the leaflet perforation. Although surgical treatment is the most common approach for leaflet injuries, we decided to implant an additional clip given the extremely high surgical risk.

No optimal bailout strategy has yet been established for leaflet tears and perforations. While a few case series have reported that plug closure was effective for the clip-related tears, some issues were presented, such as frequent haemolysis and device embolization after the plug implantation.[5] Transcatheter mitral valve replacement with or without cutting the leaflet attached with the clip is another option for patients with TEER failure.[6] However, there are still some technical issues associated with transcatheter mitral valve replacement such as left ventricular outflow tract obstruction, valve durability, leaflet thrombosis, and access site. In addition, there is still less experience with transcatheter mitral valve replacement in native valves compared to valve-in-valve and valve-in-ring cases. Therefore, it should only be considered in selected patients who exhibit anatomical suitability. In the current case, an XTW clip was used to cover the damaged area of the posterior leaflet. On TEE, the distance from the tip of the posterior leaflet to the perforation site was around 8 mm, whereas the length of the XTW clip arm was 12 mm, theoretically suggesting that the perforated area can be completely covered by the XTW clip. Considering that additional clipping could worsen the leaflet injury, a comprehensive assessment of the leaflet is crucial to determine whether the injured portion can be covered using the additional clipping. During the procedure, the distance between the tip and injured part was approximately 8 mm. However, it was difficult to measure the distance directly in line with the injury site in the long-axis image. Therefore, we retrospectively examined the three-dimensional (3D) image obtained via multiplanar reconstruction (MPR). The 3D MPR image clearly showed that the MR PISA from the middle portion of the posterior leaflet was separated from the original MR, indicating leaflet perforation (*Figure 5A*). We also found that distances to the perforation site from the leaflet tip and base of the posterior leaflet were 5.3 and 4 mm, respectively (*Figure 5B*). Therefore, it seems reasonable to infer that the leaflet injury was caused by the tip of the NTW clip, probably because of the excessive tension on the insufficiently inserted posterior leaflet. Although not performed at the time, intraoperative 3D MPR could have helped in understanding the detailed anatomy of leaflet injury during TEER procedure. Surgeons should confirm that the perforated portion is just above the clip arm and that tip of the clip arm is positioned more posteriorly to the perforation before dropping the gripper down.

This report describes the successful bailout clipping of a leaflet perforation using an XTW clip. Careful evaluation of the anatomy of the injured leaflet is important to ensure that the perforated portion is covered by the additional clip. From our experience and previous studies, we proposed the following approach for leaflet injury.

When leaflet injury is suspected, anatomical evaluation using TEE and 3D MPR should be performed to accurately identify the injured site and damaged aetiology.

(1) When the patient is operable, a bailout open-heart surgery should be considered.

(2) When catheter-based bailout procedure is selected, the following options can be considered.

  (a) When leaflet perforation is detected, transcatheter insertion of an occluder may be considered.

  (b) When the distance between the injured part and leaflet tip is within 10 mm, it may be covered by additional implantation of XTW or XT clip.

  (c) When the distance between the injured part and leaflet tip is >10 mm, the first clip should be placed at the uninjured part to improve the coaptation gap of the injured part, and then the second clip should be implanted to cover the injured part. If the residual MR is observed between the two clips, additional implantation of an occluder between the clips can be considered.

  (d) If the mitral valve and left ventricular anatomy is suitable, transcatheter mitral valve replacement may be another option.

Lead author biography

The lead author graduated from Kobe University in 2017 and currently works as a cardiologist at Kurashiki Central Hospital, Japan. His areas of interest include echocardiography and valvular disease.

Supplementary material

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

Consent: The patient's husband signed the informed consent form on 13 February 2023, which confirmed that he received the information sheet, was adequately informed, and consented to use of health-related data and biological material for research purposes. The authors confirm that written consent for submission and publication of this case report, including the images and associated text, have been obtained from the patient in accordance with COPE guidance.

Conflict of interest: Shunsuke Kubo and Takeshi Maruo are clinical proctors at Abbott Vascular.

Funding: None.

Data availability

The data underlying this article cannot be shared publicly due to the privacy of individuals that participated in the study.

References

1. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, *et al.* 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J* 2022;**43**:561–632.
2. McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Böhm M, *et al.* ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J* 2021;**2021**:3599–3726.
3. Asch FM, Little SH, Burkhard Mackensen G, Grayburn PA, Sorajja P, Rinaldi MJ, *et al.* Incidence and standardised definitions of mitral valve leaflet adverse events after transcatheter mitral valve repair: the EXPAND study. *EuroIntervention* 2021;**17**:e932–e941.
4. Schnitzler K, Hell M, Geyer M, Kreidel F, Münzel T, von Bardeleben RS. Complications following MitraClip implantation. *Curr Cardiol Rep* 2021;**23**:131.
5. Naeim HA, Abuelatta R. Tear of posterior mitral valve leaflet during MitraClip, successful bailout using vascular plugs. *JACC Case Rep* 2021;**1**:197–201.
6. Russo G, Gennari M, Gavazzoni M, Pedicino D, Pozzoli A, Taramasso M, *et al.* Transcatheter mitral valve implantation: current status and future perspectives. *Circ Cardiovasc Interv* 2021;**14**:e010628.