

Case report of simultaneous transcatheter mitral valve-in-valve implantation and percutaneous closure of two paravalvular leaks

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Background	Concomitant structural degeneration of surgical mitral bioprostheses and paravalvular leak (PVL) is rare but potentially fatal. Data pertaining to simultaneous transcatheter mitral valve implantation (TMVI) and percutaneous PVL closure are limited, and the optimal treatment strategy remains undetermined. We report a case of simultaneous TMVI and double percutaneous PVL closure in a patient with a degenerated bioprosthetic mitral valve and associated medial and lateral PVLs.
Case summary	A 75-year-old woman who underwent combined aortic (Edwards Perimount Magna 19 mm) and mitral (Edwards Perimount Magna 25 mm) surgical valve replacement 6 years ago was referred for treatment of new-onset orthop- noea and severely reduced exercise capacity. Transoesophageal echocardiography revealed severe mitral stenosis and concomitant moderate to severe mitral regurgitation, originating from two PVLs located medial and lateral from the surgical bioprosthesis. Due to high surgical risk, we performed successful transseptal mitral valve-in-valve (ViV) implantation combined with the closure of two PVLs during the same procedure.
Discussion	Although surgery should be considered as a first-line treatment in this setting, most patients have extremely high or prohibitive surgical risk inherent to repeat open heart surgery. Mitral ViV implantation appears a reasonable treatment option for patients with failed mitral bioprostheses. Furthermore, a recent study of percutaneous PVL closure showed no significant difference in long-term all-cause mortality compared with redo open-heart surgery. Simultaneous TMVI and percutaneous PVL closure appears feasible in selected high-risk patients.
Keywords	Mitral regurgitation • Paravalvular leak • Transcatheter mitral valve implantation • Percutaneous paravalvular leak closure • Case report

Learning points

- Simultaneous transcatheter mitral valve implantation (TMVI) and percutaneous paravalvular leak (PVL) closure can be an option in patients with high surgical risk.
- Pre-procedural planning by multimodality imaging is crucial for a safe intervention when performing combined TMVI and percutaneous PVL.

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Introduction

Concomitant surgical mitral bioprosthesis degeneration and dehiscence leading to paravalvular leak (PVL) is a rare but potentially fatal condition. Although redo open-heart surgery is considered first-line treatment, most patients are at prohibitive surgical risk, due to advanced age and associated comorbidities. Recently, transcatheter mitral valve-in-valve (ViV) implantation via the transseptal access has been proposed as an alternative^{1–3} and may be combined with percutaneous PVL closure in selected patients.⁴ However, published data are limited and optimal strategy remains to be determined.

We report a case of simultaneous transcatheter mitral valve implantation (TMVI) and double percutaneous PVL closure in a patient with degenerated bioprosthetic mitral valve and concomitant medial and lateral PVL. Both step-by-step pre-procedural planning based on multimodal imaging and procedural strategy are presented.

Timeline

Day	Events
6 years ago	Combined aortic and mitral surgical valve replacement
4	Hospitalization
3	Assessment of computed tomography and transoeso-
	phageal echocardiography
0	Simultaneous transcatheter mitral valve implantation
	and percutaneous paravalvular leak closure
1	Intermediate care unit for haemodynamic monitoring
2	Transfer to general ward
5	Discharge without complication

Case presentation

A 75-year-old woman was referred for treatment of general fatigue, new-onset orthopnoea, and severely reduced exercise capacity (New York Heart Association functional Class III). She had undergone combined aortic (Edwards Perimount Magna 19 mm) and mitral (Edwards Perimount magna 25 mm) surgical valve replacement 6 years ago.

Multimodality imaging transoesophageal echocardiography

Transoesophageal echocardiography (TOE) revealed severe mitral stenosis with a mean transvalvular gradient of 16 mmHg (*Figure 1A*; Supplementary material online, *Video S1*). The mitral valve area was 0.5 cm² measured by 3D TOE and 0.73 cm² according to pressure half time (PHT) (Supplementary material online, *Video S2*). In addition, concomitant moderate to severe mitral regurgitation was found, originating from two PVLs located medial and lateral from the surgical

bioprosthesis (*Figure 1B*). Normal function of the surgical aortic valve prosthesis (mean/peak gradient: 14/27 mmHg) as well as normal left ventricular function (ejection fraction: 60%) were documented.

Multimodality imaging—computed tomography

Due to the complexity of the disease, cardiac multi-slice computed tomography (CT) was used for valve sizing, and assessment of the risk of left ventricular outflow tract (LVOT) obstruction. According to CT sizing, a bioprosthetic surface of 400.0 mm, a 3D annulus perimeter of 72.4 mm, a projected annulus perimeter of 71.4 mm, and an internal diameter of 22.4 mm were measured (*Figure 2A*). A 26 mm Edwards Sapien 3 valve was simulated for evaluation of the risk of LVOT obstruction (*Figure 2B*). LVOT area was 457.6 mm², whereas the neo-LVOT area was 385.2 mm² (*Figure 2C*) with minimal protrusion of the valve into the LVOT. This corresponds to a minimal relative LVOT reduction of 16%, almost excluding the risk of obstruction, Furthermore, the aortic–mitral angle was favourable with a value of 131.8°.

Heart team discussion

After completion of the pre-procedural workup, a multidisciplinary heart team evaluated the therapeutic recommendation. Risk scores were indicative of high surgical risk [Society of Thoracic Surgery-Predicted Risk Of Mortality (STS-PROM) score 9.6% and EuroSCORE II 10.01%], mainly because of pre-operation, previous stroke, and chronic kidney disease (glomerular filtration rate 36 mL/min). The decision was made to perform a transseptal mitral ViV procedure combined with the treatment of both PVLs using plug implantation via the same access. Written informed consent was obtained for the intervention and the publication.

Procedure

The intervention was performed under general anaesthesia and TOE-guidance. A 8.5-Fr transseptal sheath and needle (BRK^{TM}) Transseptal needle; Abbott/St. Jude Medical) were introduced into the right femoral vein and advanced over a guiding wire into the right atrium. Transseptal puncture was performed at the postero-superior part of the fossa ovalis under TOE-guidance. An Agilis[™] NxT Steerable Introducer (Abbott/St. Jude Medical, St. Paul, MN, USA) was used to orientate a multipurpose catheter towards the degenerated bioprosthesis. Subsequently, the prosthesis was crossed and a pre-shaped stiff wire (SAFARI² Guidewire small curve; Boston Scientific, Marlborough, MA, USA) was positioned in the apex of the left ventricle using a pigtail catheter. The sheath was exchanged for a 14-Fr eSheath (Edwards Lifescience). Atrial septostomy was performed using a 40×14 mm balloon (XXL Balloon Dilatation Catheter; Boston Scientific). The 26 mm Edwards SAPIEN 3 transcatheter heart valve was advanced into the degenerated mitral bioprosthesis using both fluoroscopy- and TOE-guidance to facilitate crossing of the septum (Figure 3A). The Sapien 3 valve was then slowly deployed under rapid pacing (160/min) taking care to align both valve inflows (Figure 3B). Mean transmitral gradient decreased to 3 mmHg.

For PVL closure, a straight guidewire (EMERALD[®] Fixed-Core Guidewire; Cordis, Baar, Switzerland) supported by a 4 Fr straight

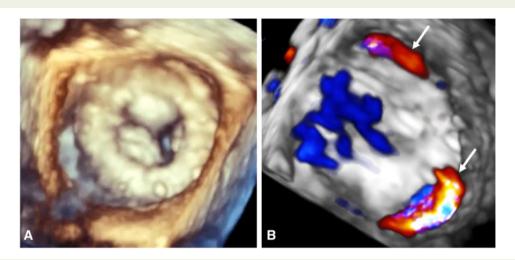


Figure I Baseline echocardiographic assessment. (A) Pre-procedural transoesophageal echocardiography 3D atrial view from the surgical mitral bioprosthesis showing severe stenosis. (B) 3D Doppler atrial view showing the localization of the paravalvular leaks. White arrows indicate the location of paravalvular leak.

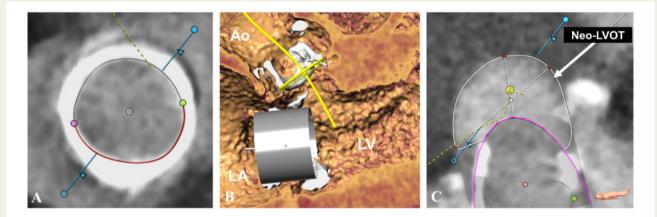


Figure 2 Pre-procedural computed tomography assessments. (*A*) Measurements of the bioprosthesis using a short-axis reconstruction. (*B*) Virtual valve simulation (26 mm Edwards Sapien 3) in the mitral position (the yellow circle indicates the plane of the aortic bioprosthesis). (*C*) Reconstruction and measurement of the anticipated neo-left ventricular outflow tract after mitral valve-in-valve implantation.

catheter (Heartrail II straight; Terumo, Leuven, Belgium) was used to cross the medial PVL first. After exchange for an 8 French AmplatzerTM TorqvueTM 45° delivery system (Abbott/St. Jude Medical, Plymouth, MN, USA), a 10/5 mm Amplatzer Vascular Plug III (AVP III; Abbott/St. Jude Medical, Plymouth, MN, USA) was implanted reducing PVL to trace (*Figure 3C and D*). In the same way, a second AVP III (8/4 mm) was positioned into the lateral PVL (*Figure 3E and F*). At the end of the intervention overall mitral regurgitation was reduced to trace (Supplementary material online, *Videos* S3 and S4).

No post-procedural complication occurs and the patient was discharged after 5 days under oral anticoagulation and acetylsalicylic acid 100 mg/day.

Discussion

Pre-procedural planning

Functional assessment of the valve and PVL localization typically requires (3D) TOE. The exact differentiation between valvular and paravalvular regurgitation jets as well as the appreciation of the stability of the dehiscent surgical implant are of central importance to determine the treatment strategy. In addition, given the complexity of the procedure, appropriate planning using CT scan appears crucial. In our case, CT was used to measure the true diameter of the surgical valve and assess LVOT. Valve simulation emerges as an important tool in this setting for preventing the occurrence of LVOT obstruction during TMVI.⁵ Indeed, implantation of a valve in mitral position provokes the displacement of the anterior (in that case

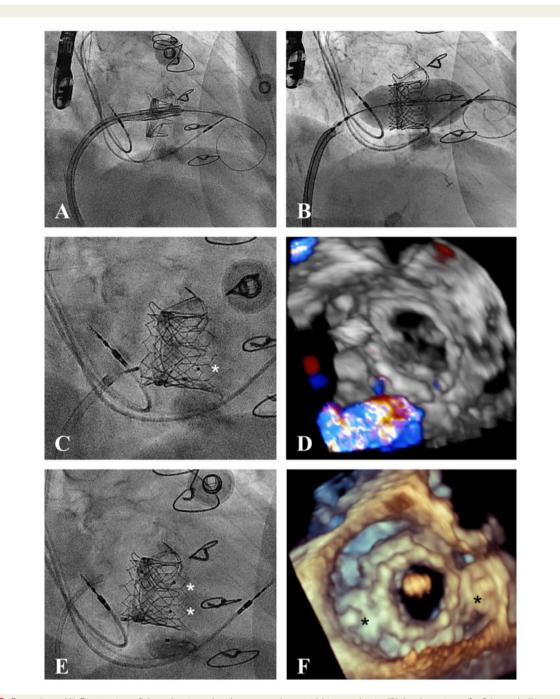


Figure 3 Procedure. (A) Positioning of the valve into the degenerated surgical bioprosthesis. (B) Implantation of a 26 mm balloon-expandable valve. (C) Occlusion the medial paravalvular leak (10/5 mm Amplatzer Vascular Plug III; asterisk). (D) Three-dimensional Doppler atrial view showing the result after implantation of the first plug and the remaining wide lateral jet. (E) Closure of the lateral paravalvular leak (8/4 mm Amplatzer Vascular Plug III; second asterisk). (F) Three-dimensional transoesophageal echocardiography view showing the final result after valve-in-valve implantation of two plugs (asterisks).

bioprosthetic) valve leaflet that may protrude into the LVOT and leads to haemodynamic relevant or even life-threatening obstruction. This risk is more pronounced for valve-in-mitral annular calcification (MAC) or valve-in-ring interventions and lowest during ViV procedures. Protrusion of the valve into the LVOT creates a smaller neoLVOT with a subsequent flow acceleration that is inversely proportional to the smallest cross-sectional area. Additional factors influencing the size of the neo-LVOT include the aorto-mitral angle, the length of the anterior leaflet, the presence of a septum bulge as well as the implantation height.⁶

Transcatheter mitral valve implantation

In a retrospective international registry including 248 patients at 25 centres, TMVI was shown to be a safe and very effective procedure for patients with a degenerated bioprosthesis in mitral position.² Procedural complications, in particular, LVOT obstruction or valve embolization, occurred rarely (3.2 and 1.6%, respectively). However, patients with valve-in-ring exhibited a higher risk of mortality at 1 year, compared to those with ViV, mainly because of lower procedural success and comorbidities. Differences in access site (transseptal vs. transapical), did not affect clinical outcomes. A majority of patients were discharged under oral anticoagulation, while antiplatelet therapy alone appears insufficient in preventing incidental valve thrombosis.

Percutaneous paravalvular leak closure

Mitral PVL following surgical prosthesis placement is observed in 7-17% of all cases^{7,8} and has been linked to a significant risk of heart failure and haemolysis.⁹ In the past decade, percutaneous PVL closure has emerged as an alternative approach due to the high risk of mortality related to redo procedures for surgical PVL closure.^{10,11} However, it remains a technically challenging procedure in particular due to the need for precise procedural imaging. Echocardiographicfluoroscopic fusion imaging has been proposed to facilitate the navigation in the left atrium and localization of the defect(s).¹² In a recent report including 381 patients who underwent percutaneous or surgical mitral PVL closure, a higher rate of adverse events occurred in the surgical group, while no significant difference in long-term (average follow-up: 85.1 ± 115.6 months) survival was found after adjusting for comorbidities.¹³ Successful percutaneous PVL closure, which was defined as a residual PVL of mild or less, was associated with improved 1-year survival.¹⁴

Combined transcatheter mitral valve implantation and percutaneous paravalvular leak closure

Only limited data exist concerning the combination of both procedures. Kliger *et al.* reported a single-centre case series of TMVI with concomitant percutaneous PVL closure.⁴ Five patients with high or prohibitive surgical risk factors underwent this specific treatment, using the transseptal or transapical approach. PVL closure was successful in all patients with no residual regurgitation using one or two closure devices. However, in one patient who underwent TMVI using the Melody valve (Medtronic, Minneapolis, MN, USA) emergent conversion to open-heart surgery was necessary due to valve embolization. The remaining four patients had no complications. One of the specific challenge of the combined procedure is to avoid interactions between the different implanted devices to ensure unrestricted function of the valve leaflets. Appropriate sizing as well as careful intraprocedural guiding are essential to achieve this goal.

Conclusions

In conclusion, complex mitral valve degeneration affects mainly elderly patients at high surgical risk. In experienced centre, advancements in interventional and imaging techniques enable safe and effective percutaneous treatment producing equivalent technical results compared to surgery. Careful pre-procedural planning using multimodality imaging is essential.

Lead author biography



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Supplementary material

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

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

Consent: The author/s confirm that written consent for submission and publication of this case report including image(s) and associated text has been obtained from the patient in line with COPE guidance.

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References

- Dvir D, Webb JG, Bleiziffer S, Pasic M, Waksman R, Kodali S, Barbanti M, Latib A, Schaefer U, Rodés-Cabau J, Treede H, Piazza N, Hildick-Smith D, Himbert D, Walther T, Hengstenberg C, Nissen H, Bekeredjian R, Presbitero P, Ferrari E, Segev A, de Weger A, Windecker S, Moat NE, Napodano M, Wilbring M, Cerillo AG, Brecker S, Tchetche D, Lefèvre T, De Marco F, Fiorina C, Petronio AS, Teles RC, Testa L, Laborde J-C, Leon MB, Kornowski R. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. *JAMA* 2014;**312**: 162–170.
- 2. Yoon S-H, Whisenant BK, Bleiziffer S, Delgado V, Schofer N, Eschenbach L, Fujita B, Sharma R, Ancona M, Yzeiraj E, Cannata S, Barker C, Davies JE, Frangieh

AH, Deuschl F, Podlesnikar T, Asami M, Dhoble A, Chyou A, Masson J-B, Wijeysundera HC, Blackman DJ, Rampat R, Taramasso M, Gutierrez-Ibanes E, Chakravarty T, Attizzani GF, Kaneko T, Wong SC, Sievert H, Nietlispach F, Hildick-Smith D, Nombela-Franco L, Conradi L, Hengstenberg C, Reardon MJ, Kasel AM, Redwood S, Colombo A, Kar S, Maisano F, Windecker S, Pilgrim T, Ensminger SM, Prendergast BD, Schofer J, Schaefer U, Bax JJ, Latib A, Makkar RR. Transcatheter mitral valve replacement for degenerated bioprosthetic valves and failed annuloplasty rings. *J Am Coll Cardiol* 2017;**70**:1121–1131.

 Praz F, Windecker S, Huber C, Carrel T, Wenaweser P. Expanding indications of transcatheter heart valve interventions. JACC Cardiovasc Interv 2015;8:1777–1796.

 Kliger C, Angulo R, Maranan L, Kumar R, Jelnin V, Kronzon I, Fontana GP, Plestis K, Patel N, Perk G, Ruiz CE. Percutaneous complete repair of failed mitral valve prosthesis: simultaneous closure of mitral paravalvular leaks and transcatheter mitral valve implantation—single-centre experience. *EuroIntervention* 2015;**10**: 1336–1345.

 Blanke P, Naoum C, Dvir D, Bapat V, Ong K, Muller D, Cheung A, Ye J, Min JK, Piazza N, Theriault-Lauzier P, Webb J, Leipsic J. Predicting LVOT obstruction in transcatheter mitral valve implantation: concept of the neo-LVOT. *JACC Cardiovasc Imaging* 2017;**10**:482–485.

 Bapat V, Pirone F, Kapetanakis S, Rajani R, Niederer S. Factors influencing left ventricular outflow tract obstruction following a mitral valve-in-valve or valve-inring procedure, part 1. *Catheter Cardiovasc Interv* 2015;86:747–760.

7. Hammermeister K, Sethi GK, Henderson WG, Grover FL, Oprian C, Rahimtoola SH. Outcomes 15 years after valve replacement with a mechanical versus a bioprosthetic valve: final report of the Veterans Affairs randomized trial. J Am Coll Cardiol 2000;**36**:1152–1158.

- Hwang HY, Choi JW, Kim HK, Kim KH, Kim KB, Ahn H. Paravalvular leak after mitral valve replacement: 20-year follow-up. *Ann Thorac Surg* 2015;**100**: 1347–1352.
- Gafoor S, Steinberg DH, Franke J, Bertog S, Vaskelyte L, Hofmann I, Sievert H. Tools and techniques—clinical: paravalvular leak closure. *EuroIntervention* 2014;9: 1359–1363.
- Rihal CS, Sorajja P, Booker JD, Hagler DJ, Cabalka AK. Principles of percutaneous paravalvular leak closure. *JACC Cardiovasc Interv* 2012;5:121–130.
- Taramasso M, Maisano F, Denti P, Guidotti A, Sticchi A, Pozzoli A, Buzzatti N, De Bonis M, La Canna G, Alfieri O. Surgical treatment of paravalvular leak: longterm results in a single-center experience (up to 14 years). J Thorac Cardiovasc Surg 2015;149:1270–1275.
- Thaden JJ, Sanon S, Geske JB, Eleid MF, Nijhof N, Malouf JF, Rihal CS, Bruce CJ. Echocardiographic and fluoroscopic fusion imaging for procedural guidance: an overview and early clinical experience. J Am Soc Echocardiogr 2016;29:503–512.
- Alkhouli M, Rihal CS, Zack CJ, Eleid MF, Maor E, Sarraf M, Cabalka AK, Reeder GS, Hagler DJ, Maalouf JF, Nkomo VT, Schaff HV, Said SM. Transcatheter and surgical management of mitral paravalvular leak: long-term outcomes. *JACC Cardiovasc Interv* 2017;**10**:1946–1956.
- Alkhouli M, Zack CJ, Sarraf M, Eleid MF, Cabalka AK, Reeder GS, Hagler DJ, Maalouf JF, Nkomo VT, Rihal CS. Successful percutaneous mitral paravalvular leak closure is associated with improved midterm survival. *Circ Cardiovasc Interv* 2017;**10**:e005730.