

CASE REPORT

INTERMEDIATE

CLINICAL CASE SERIES

Plugging Paravalvular Leak in Transcatheter Aortic Valves



Sean M. Conte, BA, MBBS, Katherine Kearney, MBBS, MMED, Pankaj Jain, MBBS, Alasdair Watson, BMED, PhD, Christopher Hayward, MBBS, MD, David W. Muller, MBBS, MD, David A. Roy, MBChB, MD

ABSTRACT

Paravalvular leak can complicate transcatheter aortic valve replacement with important prognostic implications. Correction of defects requires complex planning and execution. Multiple or irregular lesions, calcified annulus, and high sealing skirts on self-expandable devices are especially challenging. Such defects may be approximated using malleable vascular closure devices. (**Level of Difficulty: Intermediate.**) (J Am Coll Cardiol Case Rep 2019;1:696-702)
© 2019 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Paravalvular prosthetic leak (PVL) is a common complication of surgical aortic valve replacement, ring annuloplasty, and transcatheter aortic valve replacement (TAVR) (1). Incident rates

of PVL vary widely but have declined with the development of current generation skirted TAVR devices and now ranges from 1.5% to 7.7% (2,3). PVL has serious consequences, including need for redo valve replacement, heart failure, hemolytic anemia, and increased mortality (4,5). Risk factors for PVL include poor tissue integrity, native valve calcification, prosthetic valve underinflation, prosthetic valve malposition, and incomplete apposition of the prosthesis with the aortic annulus (5). The hemodynamic parameter known as the aortic regurgitation index, representing the ratio of the end-diastolic aortoven-tricular pressure difference to systolic blood pressure multiplied by 100, is a reliable indicator of the severity of PVL. An index of <25 is associated with greater mortality in patients with PVL (6), although this value may be confounded by underlying diastolic dysfunction or significant bradycardia. Thus, a more sensitive and specific marker of aortic regurgitation severity is the modified time-integrated aortic regurgitation index (7). Therapies directed at closure of PVL have been developed and included coated occlusion devices such as Amplatzer vascular plug (AVP) devices (St. Jude Medical, St. Paul, Minnesota).

LEARNING OBJECTIVES

- TAVR-PVL is common and can portend a worse prognosis with higher rates of heart failure and redo valve replacement.
- Multiple or irregular lesions, calcified annulus, low crossing position across frame struts, and high sealing skirts on self-expandable prostheses are especially challenging for crossing defects, wire snaring, and rail formation.
- Looping a wire in the left ventricle and passing it back up into the aorta can provide extra support needed to pass delivery systems.
- Highly stiff wires are often required to cross narrow or irregular defects.
- Irregular defects may be approximated using malleable vascular closure devices that can conform to these shapes.

From the Department of Cardiology, St. Vincent's Hospital Sydney, Darlinghurst, Australia. Dr. Muller has served as a consultant for Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. John W. Hirshfeld, Jr., MD, served as Guest Associate Editor for this paper.

Informed consent was obtained for this case.

Manuscript received September 20, 2019; revised manuscript received October 13, 2019, accepted October 15, 2019.

In the context of TAVR, much of the challenge in PVL closure relates to the prosthetic heart valve apparatus. The very same sealing skirts designed to reduce the risk of PVL can present technical challenges when attempting to cannulate and form wire rails during percutaneous closure. Vascular plug delivery can also be challenging, especially if frame struts are crossed too low, resulting in a narrow aperture through which the device must be passed (8). We present 2 cases of TAVR-PVL, each with unique challenges, and the steps we took to facilitate percutaneous closure.

SEE PAGE 703

CASE 1

PRESENTATION AND PAST MEDICAL HISTORY. The first patient is a 77-year-old man with a history of ischemic cardiomyopathy, atrial fibrillation, prior stroke, chronic kidney disease, type 2 diabetes, hypertension, and severe symptomatic aortic stenosis managed with TAVR with a self-expandable 34-mm Evolut R valve (Medtronic, Dublin, Ireland) in July 2017. Following TAVR, the left ventricular ejection fraction (LVEF) improved to 45% and mild PVL was

demonstrated with anterior and posterior jets. The patient deteriorated clinically over the ensuing 12 months. He was hospitalized with recurrent transudative pleural effusions related to cardiac failure. Despite pleurodesis, he deteriorated in hospital and became inotrope-dependent due to low-output cardiac failure.

INVESTIGATIONS. Transesophageal echocardiogram in early August 2018 demonstrated moderate-grade posterior PVL and mild anterior PVL (Figure 1) around the TAVR prosthesis with an LVEF 35% and moderately dilated left ventricle, with diffuse spontaneous echo contrast within the left ventricle. Coronary angiography demonstrated mild proximal left anterior descending artery stenosis and a chronic total occlusion of the right coronary artery, with collaterals from a large patent left circumflex artery. The decision was made by our hospital's multidisciplinary heart team to offer percutaneous PVL closure.

MANAGEMENT AND FOLLOW-UP. In late August 2018, the patient underwent PVL closure under transesophageal echocardiogram guidance. The

ABBREVIATIONS AND ACRONYMS

- AVP** = Amplatzer vascular plug
- LVEF** = left ventricular ejection fraction
- PVL** = paravalvular prosthetic leak
- TAVR** = transcatheter aortic valve replacement
- TTE** = transthoracic echocardiogram

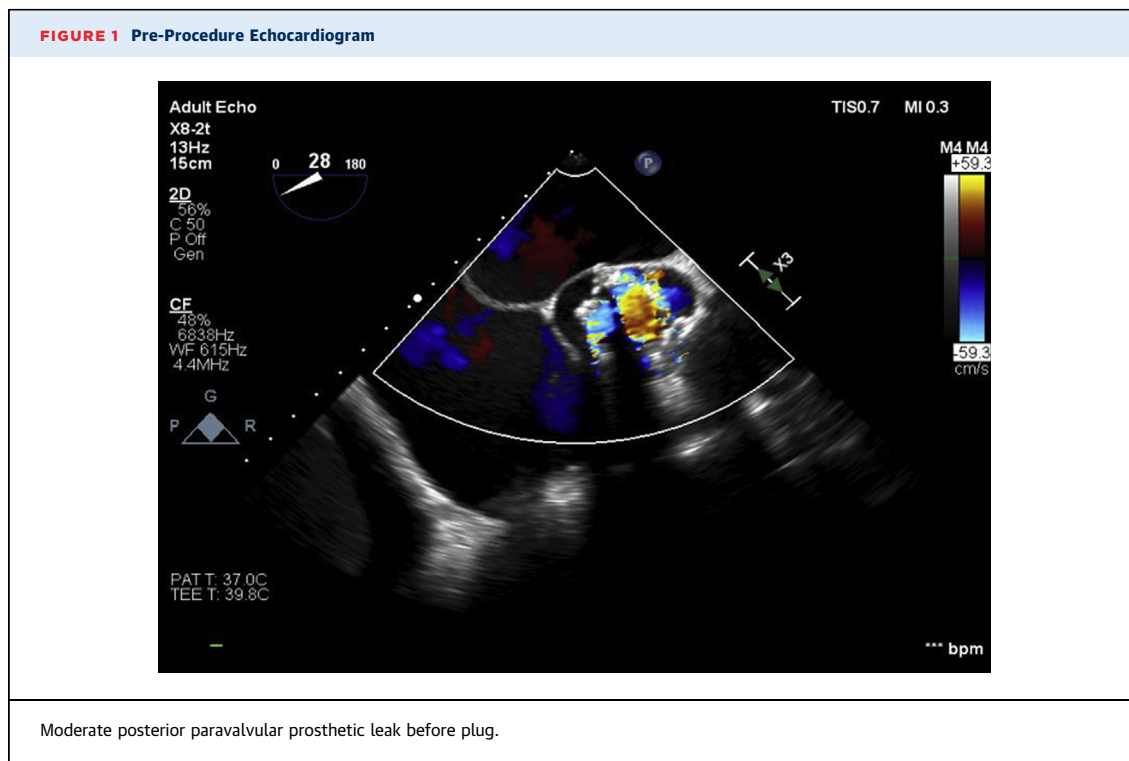
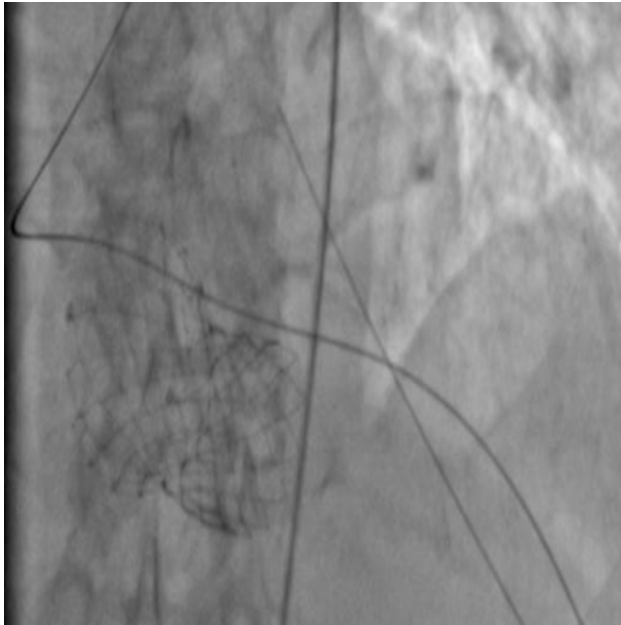


FIGURE 2 Crossing the Valve Frame

The self-expandable transcatheter aortic valve replacement prosthesis was crossed first by passing through the upper cells of the valve frame.

FIGURE 3 Support Wire in Aorta

A stiff slippery wire was looped in the left ventricle and passed back up into the aorta for support, which allowed passage of the delivery sheath and closure device system.

defect was difficult to cross due to the high sealing skirt and valve frame. By passing through the upper cells of the valve frame and then passing behind the valve at the level of the skirt using an AL-1 catheter (Cordis, Zug, Switzerland) and a slippery wire the defect was eventually crossed (**Figure 2**). However, the delivery sheath would not pass over a standard wire. A 4-F GLIDECATH (Terumo, Shibuya, Tokyo, Japan) was used to pass a stiff slippery wire that was looped and passed back through the prosthetic aortic valve into the ascending aorta for extra support (**Figure 3**). This allowed passage of the 6-F delivery system and then a 12 × 5 mm AVP III (**Figure 4**). Post-procedural transthoracic echocardiogram (TTE) confirmed the resolution of the posterior PVL (**Figure 5**) and, over the next 24 h, inotropic support was weaned. The patient was discharged home 3 days after the procedure and was clinically and echocardiographically stable at 6-month follow-up.

CASE 2

PRESENTATION AND PAST MEDICAL HISTORY. The second patient is a 77-year-old former Olympic weightlifter with ischemic cardiomyopathy, biventricular implantable cardioverter-defibrillator for ventricular tachycardia, previous cigarette smoking and chronic obstructive pulmonary disease, hypertension, dyslipidemia, and severe symptomatic aortic stenosis managed with TAVR with a balloon-expandable 26-mm SAPIEN 3 prosthesis (Edwards Lifesciences, Irvine, California) in August 2017. Following TAVR, TTE demonstrated an LVEF of 35% with a moderately dilated left ventricle and trivial anterior PVL. Unfortunately, there was only slight improvement in his heart failure, and he clinically deteriorated over the next 18 months.

INVESTIGATIONS. In November 2018, TTE revealed moderate-to-severe anteromedial PVL (**Figure 6**). Coronary angiography undertaken in early March 2019 demonstrated severe native triple-vessel disease and patent left internal mammary artery to left anterior descending and right internal mammary artery to obtuse marginal grafts. An aortogram disclosed moderate total aortic regurgitation. A heart team decision was made to offer percutaneous closure.

MANAGEMENT AND FOLLOW-UP. Percutaneous PVL closure was undertaken with transesophageal guidance in late March 2019. The irregularly shaped defect was initially crossed using a slippery wire and JR4 (Cordis) catheter, but neither the 6-F delivery sheath nor the long 6-F Cook sheath (Cook Medical, Bloomington, Indiana) could pass (**Figure 7**). This was overcome by exchanging the slippery wire via an AL-1

catheter for a very stiff Lunderquist wire (Cook Medical) (Figure 8) over which the delivery sheath could advance. A 14 × 5 mm AVP III was deployed with excellent effect (Figure 9). There was trivial residual PVL on the post-procedure echocardiogram (Figure 10). Six-month follow-up TTE demonstrated stable trivial PVL and left ventricular size reduction, and the patient experienced marked clinical improvement.

DISCUSSION

PVL is a common and potentially dangerous complication of TAVR. Clinicians should screen for PVL immediately after TAVR deployment with TTE and aortography keeping in mind that without sufficient volume of contrast dye, many defects will be missed. PVL of moderate severity or worse should be managed with either valve repositioning (post-dilation) or percutaneous closure. Should percutaneous closure of PVL complicating a self-expandable prosthesis be attempted during the index TAVR procedure, the top of the prosthesis can be snared to prevent potential movement, dislodgement, or embolization. Progression or failure of improvement of heart failure symptoms and the emergence of peripheral stigmata of aortic regurgitation after TAVR should raise suspicion for hemodynamically significant PVL. Although medical therapy is first line,

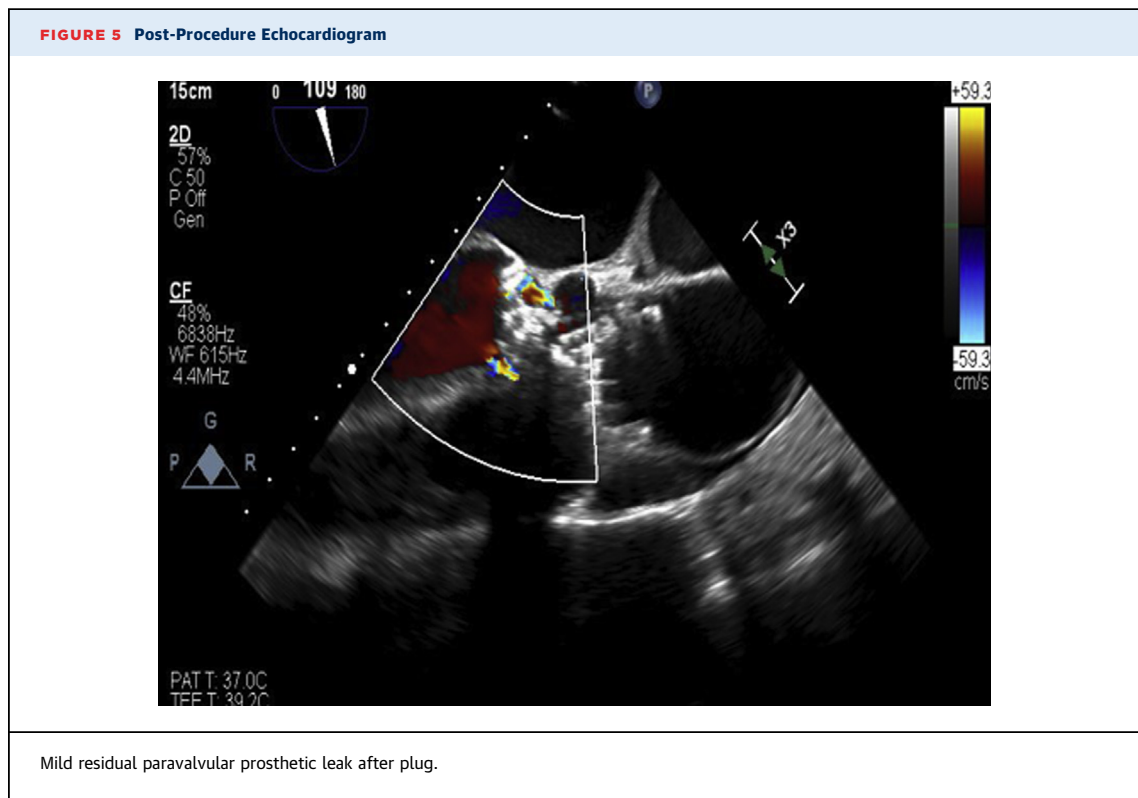
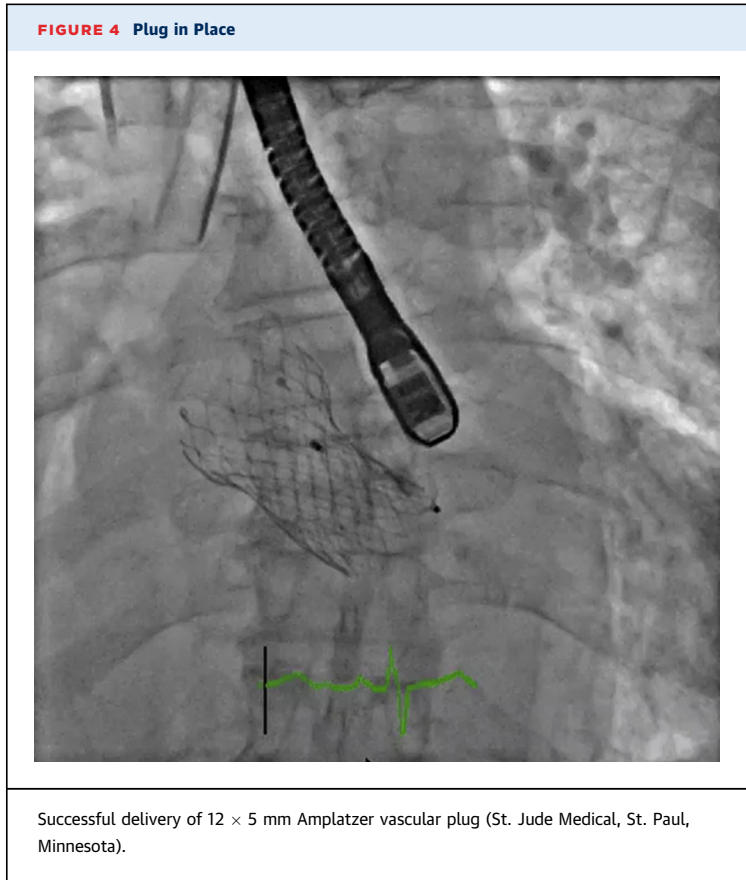
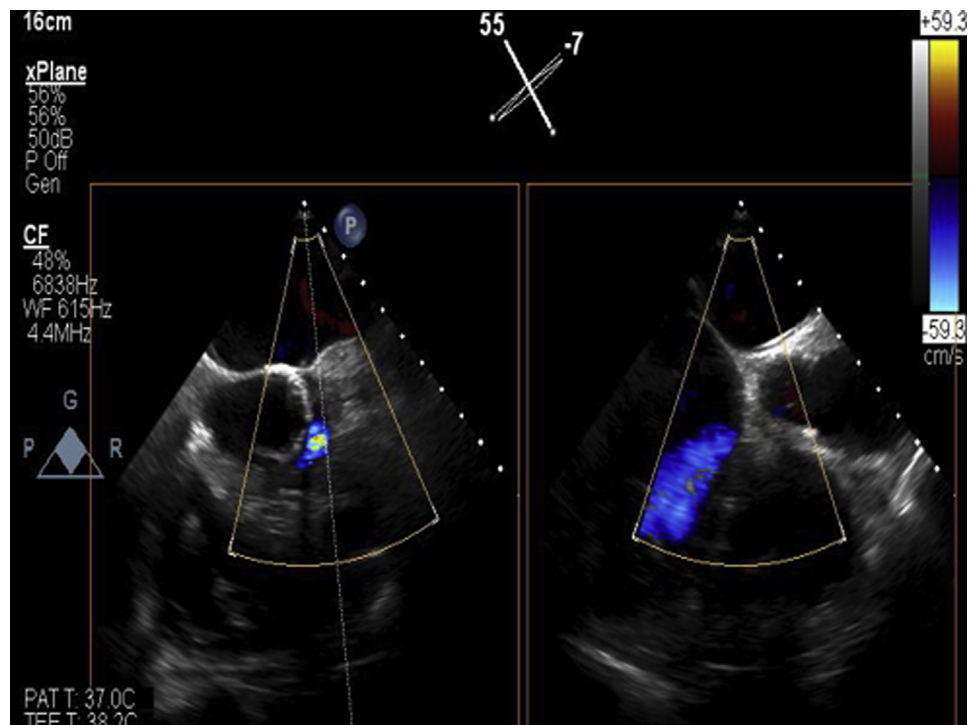
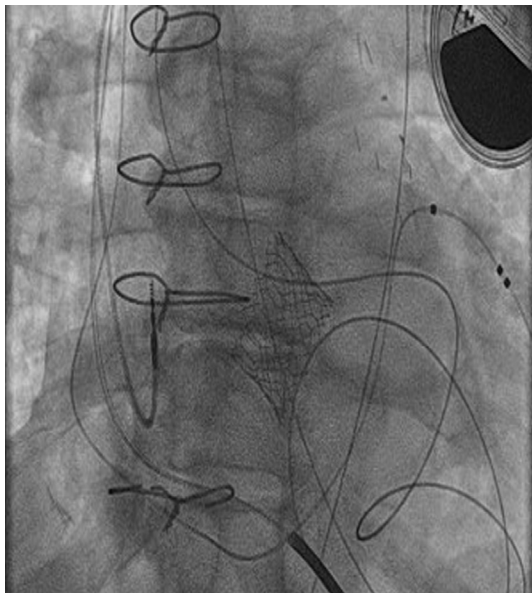


FIGURE 6 Pre-Procedure Echocardiogram

Moderate-to-severe paravalvular prosthetic leak before plug.

FIGURE 7 Initial Cross With Slippery Wire

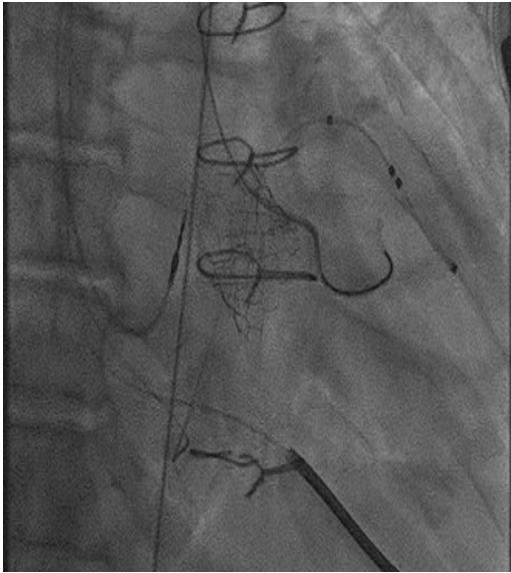
Defect initially crossed with slippery wire and JR4 catheter but could then not cross with 6-F delivery sheath or long 6-F Cook sheath (Cook Medical, Bloomington, Indiana).

hemodynamically significant PVL often results in progressive heart failure and thus requires definitive management with percutaneous closure. After TAVR, PVL of moderate or worse grade echocardiographically results in a greater mortality compared with mild, trace, or no PVL. Many defects are irregularly shaped, often forming in crescents around the prosthetic valve perimeter. This makes crossing them challenging and a combination of slippery guidewires and very stiff catheters may be required to do so. Retroflexion and antegrade passage of the catheter through the prosthetic aortic valve up into the aorta provides extra support for delivery of a vascular occlusion device. The presence of high sealing skirts on self-expandable TAVR devices are challenging for wire snaring and rail formation and often require extreme angles to visualize wire progress. PVL cannulation in the context of balloon-expandable valves is typically less challenging.

CONCLUSIONS

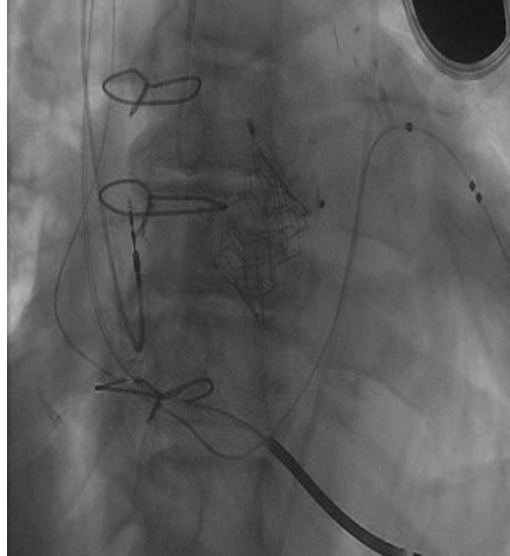
TAVR-PVL is common and can portend a worse prognosis, owing to higher rates of progressive heart failure and need for redo valve replacement.

FIGURE 8 Cross With Lunderquist Wire



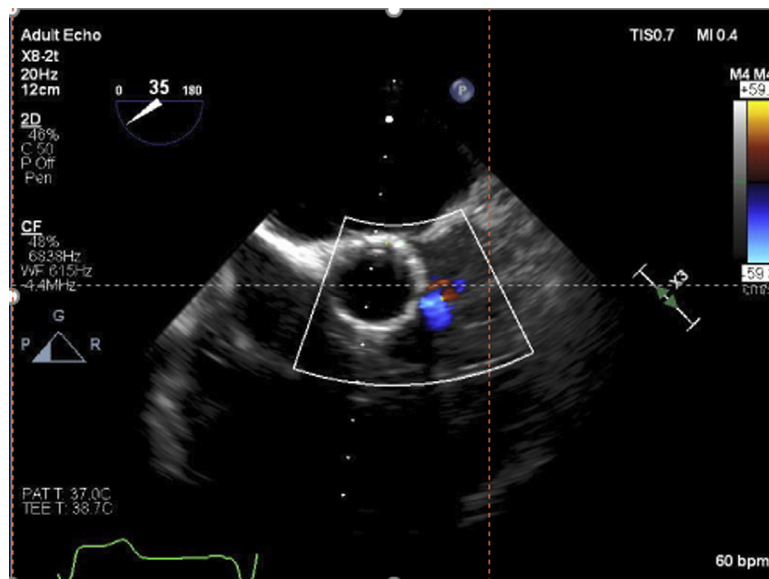
Highly stiff Lunderquist wire (Cook Medical, Bloomington, Indiana) used to cross defect which allowed passage of 6-F delivery sheath.

FIGURE 9 Plug in Place



Successful delivery of 14 x 5 mm Amplatzer vascular plug (St. Jude Medical, St. Paul, Minnesota).

FIGURE 10 Post-Procedure Echocardiogram



Mild residual paravalvular prosthetic leak after plug.

TAVR-PVL should be screened for and the diagnosis considered in patients who fail to improve after TAVR and in those who subsequently deteriorate. Echocardiography is the mainstay for identifying and monitoring for TAVR-PVL but is often difficult due to interference from the valve frame. TAVR-PVL correction requires complex planning and execution. PVL owing to valve malposition or under-expansion can be treated with valve-in-valve or balloon post-dilation whereas PVL due to asymmetric calcification is more amenable to vascular plugs. Multiple or irregular lesions, calcified annulus, low crossing position across frame struts, and the presence of high sealing skirts on self-expandable TAVR

devices are especially challenging with regard to crossing defects, wire snaring, and rail formation. Highly stiff wires are often required to cross narrow or irregular defects. Such defects are best approximated using malleable vascular closure devices that can conform to crescent shaped defects such as the AVP III. Transcatheter plugging of TAVR-PVL is achievable with careful planning with excellent results.

ADDRESS FOR CORRESPONDENCE: Dr. Sean M Conte, Department of Cardiology, St. Vincent's Hospital Sydney, 1 Turner Street, Redfern, New South Wales 2016, Australia. E-mail: sean.m.conte@gmail.com.

REFERENCES

1. Ionescu A, Fraser AG, Butchart EG. Prevalence and clinical significance of incidental paraprothestic valvar regurgitation: a prospective study using transoesophageal echocardiography. *Heart* 2003;89:1316-21.
2. Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. *Lancet* 2016;387:2218-25.
3. Kalra SS, Firoozi S, Yeh J, et al. Initial experience of a second-generation self-expanding transcatheter aortic valve: the UK & Ireland Evolut R Implanters' Registry. *J Am Coll Cardiol Intv* 2017;10:276-82.
4. Thourani VH. Five-year outcomes from the PARTNER 2A trial: transcatheter vs. surgical aortic valve replacement in intermediate-risk patients. Presented at: TCT 2019; September 28, 2019; San Francisco, CA.
5. Sponga S, Perron J, Dagenais F, et al. Impact of residual regurgitation after aortic valve replacement. *Eur J Cardiothorac Surg* 2012;42:486-92.
6. Wilczek K, Bujak K, Reguta R, Chodór P, Osadnik T. Risk factors for paravalvular leak after transcatheter aortic valve implantation. *Kardiochir Torakochirurgia Pol* 2015;12:89-94.
7. Sinning JM, Vasa-Nicotera M, Chin D, et al. Evaluation and management of paravalvular aortic regurgitation after transcatheter aortic valve replacement. *J Am Coll Cardiol* 2013;62:11-20.
8. Abdelghani M, Soliman Oll, Schultz C, Vahanian A, Serruys PW. Adjudicating paravalvular leaks of transcatheter aortic valves: a critical appraisal. *Eur Heart J* 2016;37:2627-44.

KEY WORDS aortic valve, complication, valve replacement