

## CLINICAL VIGNETTE

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# Bioprosthetic Aortic Valve Paravalvular Leak: Closure During Valve-in-Valve TAVR with an Amplatzer Vascular Plug

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### **Abstract**

A 71-year-old man with severe bioprosthetic aortic valve stenosis was concomitantly found to have severe paravalvular leak, which was subsequently closed using an Amplatzer vascular plug. No clear guidelines exist regarding optimal management of paravalvular leaks after aortic valve replacement. Vascular plugs provide a relatively minimally-invasive alternative to open surgery for paravalvular leak closure, though more safety and efficacy data are needed.

### **Introduction**

The development of transcatheter aortic valve replacement (TAVR) has ushered in a new era of minimally invasive therapy for patients with severe aortic stenosis (AS). The use of TAVR has also extended to those with bioprosthetic valve stenosis after surgical aortic valve replacement (SAVR). Paravalvular leak (PVL) is a known, but rare complication of SAVR and no clear guidelines exist regarding the optimal management of aortic PVLs. We present a patient with severe prosthetic valve AS complicated by PVL. The patient was treated by valve-in-valve TAVR followed by successful PVL closure using an Amplatzer vascular plug (AVP) during the index procedure. The technical details of the case, as well as a mini-review of PVL closure and the current literature, are presented.

### **Case Report**

A 71-year-old man was transferred to our hospital for TAVR evaluation. His medical history was significant for coronary artery disease for which he had undergone three-vessel coronary artery bypass grafting (CABG) as well as placement of a Mitroflow 23mm bioprosthetic valve (Sorin Group, Italy) for critical AS five years prior to this admission. Transthoracic echocardiogram (TTE) had revealed severe stenosis of his aortic valve prosthesis. The patient had a Society of Thoracic Surgeons (STS) risk score of 6% and was evaluated by two cardiothoracic surgeons. Of particular concern was his severe carotid disease as well as extensive calcification of the ascending aorta on chest imaging, factors not captured by the STS score. He was deemed high risk for surgical aortic valve replacement (SAVR).

After extensive discussion with our multidisciplinary cardiac team, a decision was made to proceed with valve-in-valve transfemoral TAVR. Transesophageal echocardiogram (TEE) prior to the procedure confirmed severe stenosis of the bioprosthetic aortic valve (AVA 0.73cm<sup>2</sup>, indexed AVA 0.31cm<sup>2</sup>/m<sup>2</sup>, Vmax 3.2m/s, peak pressure gradient 40.5mmHg, mean pressure gradient 22mmHg). The TEE also revealed severe PVL of the bioprosthetic aortic valve (Figure 1, Panel A), measuring 9x5 mm and originating below the left main ostium, which was not appreciated on his pre-TAVR TTE.

Using TEE and fluoroscopy, a 23mm SAPIEN 3 balloon-expandable valve (Edwards Lifesciences, Irvine, California) was deployed with successful treatment of the aortic stenosis component of the valve disease. Echocardiography demonstrated persistence of the PVL as noted prior to valve deployment (Figure 1, Panel B), and we decided to proceed with post-deployment valve dilatation. A True Dilatation 22 x 50mm balloon (Bard PV, Tempe, AZ) was used to crack the silicone sewing ring of the Mitroflow prosthesis and further dilate the valve, but this did not result in significant improvement in the degree of PVL. Given the severe paravalvular regurgitation and a left ventricular end-diastolic pressure of approximately 30 mmHg, the decision was made to proceed with PVL closure.

Using an Amplatz Left 1 catheter (AL 1), the paravalvular leak was crossed with a Wholey wire, which was advanced into the left ventricle. The Wholey wire was then exchanged for a stiff Lunderquist wire. Then, a 6F multipurpose guide catheter (Medtronic, Dublin, Ireland) was advanced over the Lunderquist wire and a 10mm Amplatzer vascular plug 2 (AVP2) (St. Jude Medical, St. Paul, MN) was delivered within the PVL using the multipurpose guide catheter. After the location and stability of the vascular plug were verified under TEE and fluoroscopic guidance (Figure 1, Panel C), the plug was successfully deployed. A significant decrease in the degree of PVL was noted on TEE with mild residual leak (Figure 1, Panel D). The patient tolerated the procedure well without any complications. Given the stable findings on repeat TTE the following day, the patient was discharged from the hospital without any complications. At 1-month follow-up, the patient

had no complaints and was doing well with good functional capacity and resolution of dyspnea.

### Discussion

TAVR has rapidly emerged as a viable alternative to SAVR for the treatment of AS.<sup>1</sup> However, a widely cited drawback of the catheter based approaches has been the higher incidence of PVL after TAVR as compared with SAVR, which is associated with worse outcomes and mortality.<sup>2</sup> Various endovascular techniques for PVL closure have been developed over the years, including balloon dilatation, valve-in-valve replacement, and more recently, the use of vascular plugs.<sup>3</sup>

Data on aortic PVL closure specifically using vascular plugs is accumulating. In one cohort, 24 patients with aortic PVL after TAVR underwent closure; Amplatzer vascular plugs were used in 80% of cases, primarily via a retrograde approach, with an overall success rate of 89%.<sup>4</sup> In another case series of six patients who underwent aortic PVL closure with vascular plugs after TAVR, significant symptomatic improvement and reduction in degree of aortic regurgitation was noted in five patients.<sup>5</sup> Similar success has also been reported in patients with aortic PVL after SAVR who underwent closure with AVP2 and AVP3 devices, with an overall decrease in NYHA functional class, decrease in NT-proBNP levels, and increase in hemoglobin concentration that persisted at three and six month follow-up after PVL closure.<sup>6</sup>

Use of vascular plugs for PVL closure is not without complications. Vascular complications, predominantly femoral pseudoaneurysm, have been noted in approximately 18-28% of patients.<sup>3,6</sup> While PVLs themselves have been associated with hemolysis, incomplete PVL closure can occasionally worsen the degree of hemolysis, though this was observed in a population that underwent closure using Amplatzer occluder devices, rather than vascular plugs.<sup>7</sup> Care must be taken when a PVL is within the vicinity of a coronary ostium, as closure devices can potentially interfere with coronary blood flow.<sup>8</sup> Other reported complications include dislodgement of plugs and embolization, electrocardiographic abnormalities, infection, and hindrance of valve movement.<sup>4,9</sup> Additionally, it is unclear whether use of vascular plugs will affect the integrity of the implanted valve, as long-term follow up is lacking in such patients.

Looking forward, with outcomes from the PARTNER 3 trial, the indications for TAVR will very likely be expanded to include lower-risk patients, with far-reaching implications in the field of valvular disease. Given the expected increase in the number of TAVR cases over the next few years, the optimal management of PVL closure in this population will be of increasing importance. While vascular plugs present an attractive alternative to open surgery for PVL closure, more safety and efficacy data will be needed before there can be more widespread adoption.

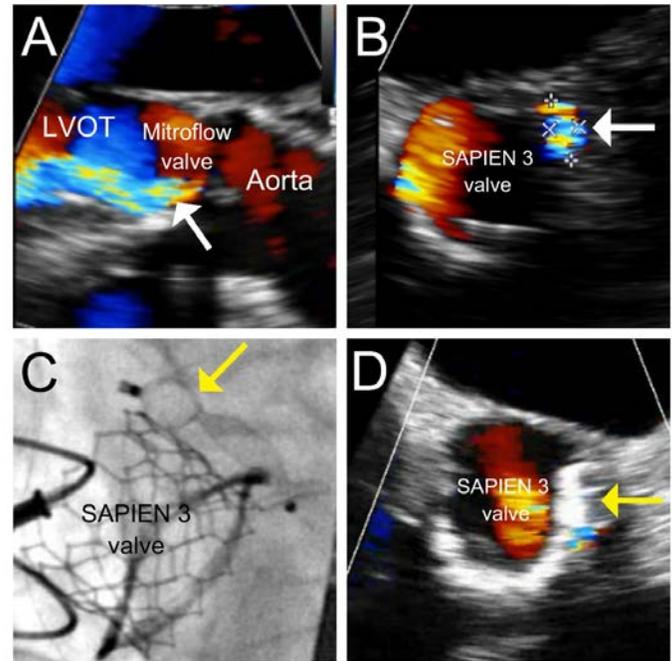


Figure 1. (Panel A) Initial long axis view on TEE, demonstrating severe PVL. (Panel B) Short axis view demonstrating persistence of PVL (white arrow) despite TAVR. (Panel C) Amplatzer vascular plug (yellow arrow) on fluoroscopy following deployment. (Panel D) Positioning of Amplatzer vascular plug (yellow arrow) confirmed on TEE, with mild residual PVL noted.

### REFERENCES

1. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, Thourani VH, Tuzcu EM, Miller DC, Herrmann HC, Doshi D, Cohen DJ, Pichard AD, Kapadia S, Dewey T, Babaliaros V, Szeto WY, Williams MR, Kereiakes D, Zajarias A, Greason KL, Whisenant BK, Hodson RW, Moses JW, Trento A, Brown DL, Fearon WF, Pibarot P, Hahn RT, Jaber WA, Anderson WN, Alu MC, Webb JG; PARTNER 2 Investigators. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med.* 2016 Apr 28;374(17):1609-20. doi: 10.1056/NEJMoa1514616. Epub 2016 Apr 2. PubMed PMID: 27040324.
2. Généreux P, Head SJ, Hahn R, Daneault B, Kodali S, Williams MR, van Mieghem NM, Alu MC, Serruys PW, Kappetein AP, Leon MB. Paravalvular leak after transcatheter aortic valve replacement: the new Achilles' heel? A comprehensive review of the literature. *J Am Coll Cardiol.* 2013 Mar 19;61(11):1125-36. doi: 10.1016/j.jacc.2012.08.1039. Epub 2013 Jan 30. Review. PubMed PMID: 23375925.
3. Cruz-Gonzalez I, Rama-Merchan JC, Arribas-Jimenez A, Rodriguez-Collado J, Martin-Moreiras J, Cascon-Bueno M, Luengo CM. Paravalvular leak closure with the Amplatzer Vascular Plug III device: immediate and short-term results. *Rev Esp Cardiol (Engl Ed).* 2014 Aug;67(8):608-14. doi: 10.1016/j.rec.2013.09.031. Epub 2014 Feb 11. PubMed PMID: 25037539.

4. **Saia F, Martinez C, Gafoor S, Singh V, Ciuca C, Hofmann I, Marrozzini C, Tan J, Webb J, Sievert H, Marzocchi A, O'Neill WW.** Long-term outcomes of percutaneous paravalvular regurgitation closure after transcatheter aortic valve replacement: a multicenter experience. *JACC Cardiovasc Interv.* 2015 Apr 27;8(5):681-8. doi: 10.1016/j.jcin.2014.11.022. PubMed PMID: 25946440.
5. **Feldman T, Salinger MH, Levisay JP, Smart S.** Low profile vascular plugs for paravalvular leaks after TAVR. *Catheter Cardiovasc Interv.* 2014 Feb;83(2):280-8. doi: 10.1002/ccd.25202. Epub 2013 Oct 19. PubMed PMID: 24038981.
6. **Smolka G, Pysz P, Wojakowski W, Ochala A, Peszek-Przybyła E, Roleder T, Jasinski M, Gasior Z.** Clinical manifestations of heart failure abate with transcatheter aortic paravalvular leak closure using Amplatzer vascular plug II and III devices. *J Invasive Cardiol.* 2013 May; 25(5):226-31. PubMed PMID: 23645046.
7. **Hein R, Wunderlich N, Robertson G, Wilson N, Sievert H.** Catheter closure of paravalvular leak. *EuroIntervention.* 2006 Nov;2(3):318-25. PubMed PMID: 19755307.
8. **Rihal CS, Sorajja P, Booker JD, Hagler DJ, Cabalka AK.** Principles of percutaneous paravalvular leak closure. *JACC Cardiovasc Interv.* 2012 Feb;5(2):121-30. doi: 10.1016/j.jcin.2011.11.007. PubMed PMID: 22361595.
9. **Webb JG, Pate GE, Munt BI.** Percutaneous closure of an aortic prosthetic paravalvular leak with an Amplatzer duct occluder. *Catheter Cardiovasc Interv.* 2005 May;65(1):69-72. PubMed PMID: 15800890.