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Pulmonary Artery Pseudoaneurysm After Transcatheter Pulmonary Valve Replacement, a Novel Approach for Complication Management

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Transcatheter pulmonary valve replacement (TPVR) using the SAPIEN 3 (Edwards Lifesciences) transcatheter heart valve is increasingly used to treat patients with right ventricular outflow tract (RVOT) dysfunction. Yet, TPVR in patients with calcified RVOT homografts remains challenging and carries a high risk of complications. We present a case of a dysfunctional 24-mm calcified RVOT homograft in a patient with a history of truncus arteriosus and hypoplastic branch pulmonary arteries.

A 31-year-old gentleman with congenital heart disease developed severe pulmonary homograft dysfunction with severe pulmonary valve insufficiency. The patient had truncus arteriosus and hypoplastic branch pulmonary arteries. He underwent a complex neonatal repair at birth. Subsequently, he underwent multiple surgical interventions, including surgical pulmonary valvuloplasty at age 2 years, pulmonary valve replacement with a 24 mm pulmonary homograft at age 13 years, aortic valve replacement with a 24 mm St Jude mechanical bileaflet aortic valve at age 14 years, and bilateral branch pulmonary artery stent placement at age 20 years. Over the last few months before his presentation, he started to complain of increasing dyspnea on exertion. An echocardiogram showed severe pulmonary homograft dysfunction with severe regurgitation. His right ventricle was enlarged (measured right ventricle end-diastolic volume of 260 mL and right ventricle end-systolic volume of 141 mL) with decreased function (right ventricular ejection fraction: 43%). Given the patient's multiple prior surgical interventions, he was deemed to be at very high risk for surgical intervention and was referred to our advanced congenital heart program for consideration of TPVR.

As part of the work-up, the patient underwent cardiac computed tomography angiography (CTA). The previously placed 24 mm homograft was severely calcified with a 360-degree arc of calcification (Figure 1a). The smallest diameter of the homograft was 20.7 mm × 21.7 mm, and the largest diameter was 25.7 mm × 28.6 mm (Figure 1). Given the severity of calcification, there was no pulsatile diameter variation between systole and diastole. The length of the homograft measured 47.3 mm. There was a significant distance between the RVOT conduit and the coronary arteries; thus, the risk of coronary obstruction was low. We planned for balloon rehabilitation of the RVOT homograft followed by deployment of a covered stent to lower the risk of homograft tears, followed by TPVR using a SAPIEN 3 transcatheter heart valve.

The patient underwent a pulmonary angiogram, which confirmed the severity of regurgitation and RVOT homograft dysfunction (Supplemental Video 1). We first performed rehabilitation of the RVOT homograft using 20, 22, and 24 mm compliant balloons in a sequential fashion. At this point, a 24 mm × 3.9 cm CP-covered stent was deployed (Figure 2). A SAPIEN 3 Ultra 26 mm valve was then deployed inside the covered stent. Pulmonary artery angiogram showed moderate paravalvular regurgitation (Supplemental Video 2). This was also confirmed on

Abbreviations: PA, Pulmonary artery; RVOT, right ventricular outflow track; TPVR, Transcatheter pulmonary valve replacement.

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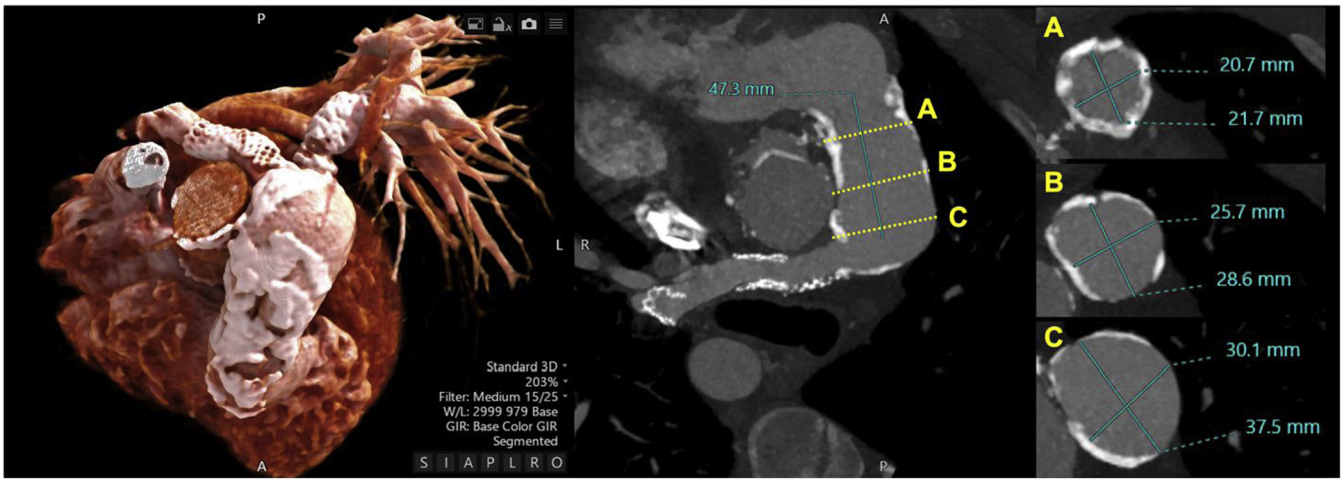

Figure 1. Preprocedural planning computed tomography angiography: A heavily calcified 24 mm pulmonary homograft with a circumferential calcification in the proximal homograft.

intracardiac echocardiogram. Postdilation of the valve was carried on using the valve balloon +2 cc. Final intracardiac echocardiogram showed no residual paravalvular regurgitation.

The patient felt significant improvement overnight; however, he started to complain of left-sided pleuritic sharp chest pain. Blood work-up showed 4 g drop in his hemoglobin. A chest X-ray showed a new left-sided pleural effusion. A repeat CTA showed a new anterolateral pulmonary artery pseudoaneurysm distal to the CP stent (Figure 3). Invasive pulmonary angiogram was performed and confirmed the diagnosis (Supplemental Video 3). No continuous extravasation between the pseudoaneurysm and left pleural space was observed on angiogram, and given clinical and hemodynamic stability, a decision of watchful waiting was made. A left-sided chest tube was placed with removal of 2 L of frank blood. The patient remained hemodynamically stable throughout the hospital course. The next day, the patient's hemoglobin dropped further, and the decision to intervene was made.

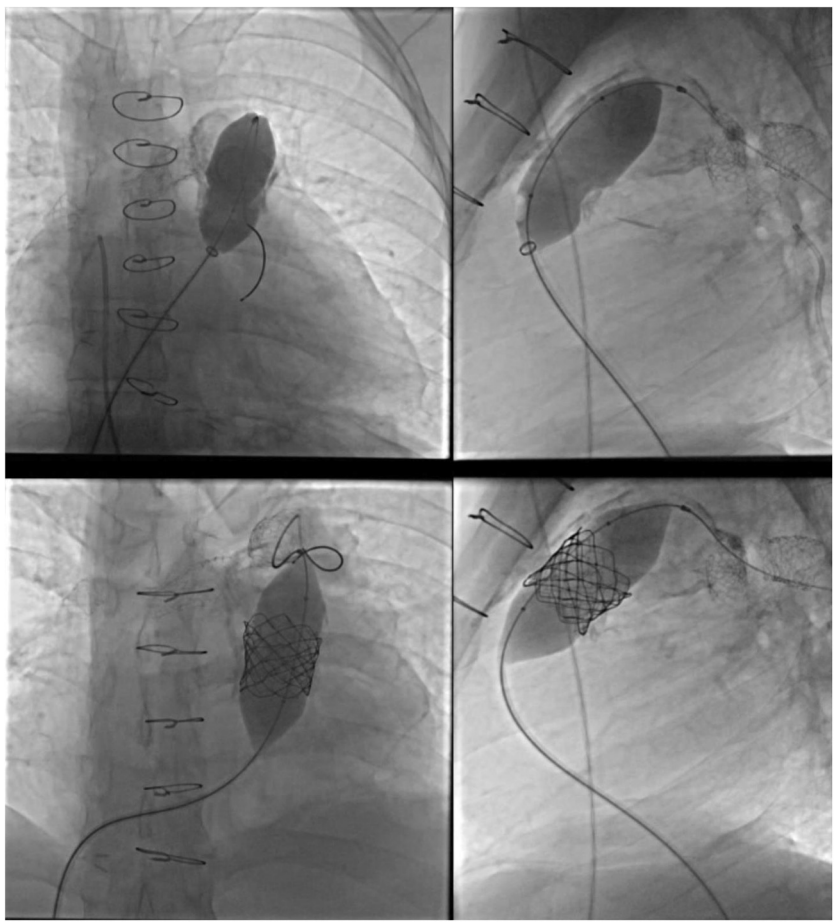

Figure 2. Balloon rehabilitation of the calcified homograft using a noncompliant 24 mm balloon, followed by deployment of a 24 × 39 mm CP stent.

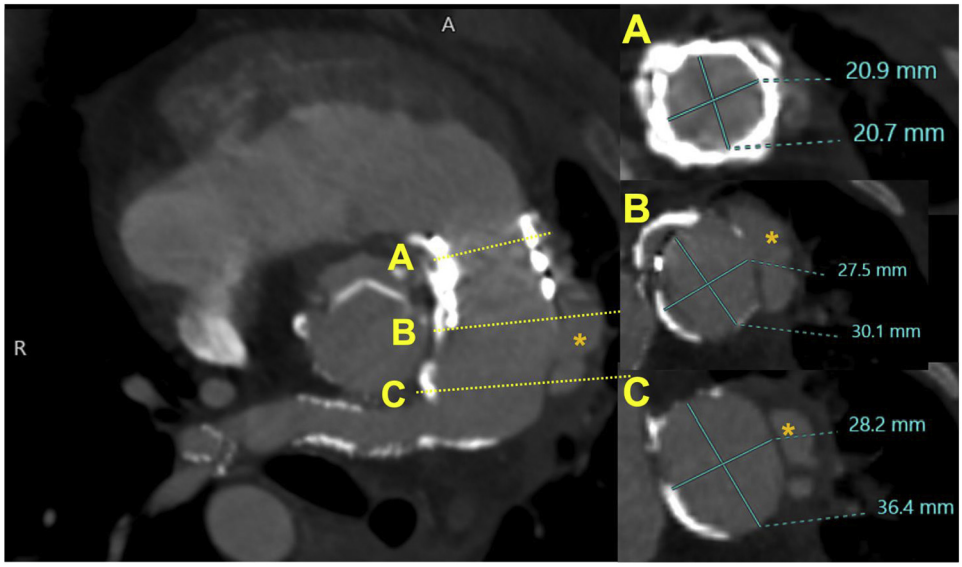

Figure 3. Postprocedural cardiac computed tomography angiography showing the presence of a new pseudoaneurysm at the distal edge of the CP stent (asterisk) with measurements of the conduit/pulmonary artery around it.

The pseudoaneurysm was located at the distal edge of the recently placed CP stent. The main pulmonary artery at this area was measured at 27.5 × 30 mm, but distal to that was up 37 mm (Figure 3). The distance between the pseudoaneurysm and the pulmonary artery bifurcation was 25 mm. The largest commercially available CP stent is 30 mm, which is smaller than what we would need to seal the pulmonary artery. Other covered stents were explored, including Gore abdominal aortic aneurysm endoprosthesis, which is available in variable diameters up to 36 mm, with a length of 45 mm. However, the delivery catheter Gore endograft is only 50 cm in length, which is shorter than the desired location using transfemoral approach. A plan to use surgical cutdown to directly access the external iliac veins was proposed as an option to gain length if needed.

A repeat angiogram showed persistent pseudoaneurysm. We first attempted to deliver the Gore endoprosthesis, however, the device was able only to reach the proximal part of the RVOT endograft. We then decided to detach the Gore endoprosthesis from the delivery catheter and use the Dryseal sheath to deliver it across the pseudoaneurysm (Figure 4). Given the endoprosthesis is self-expandable, delivering it inside the sheath, and then unsheathing the endoprosthesis might have helped deploy it in the desired location. A 65 cm GORE DrySeal Flex 24 French Introducer Sheath was then advanced over a 0.035" Lunderquist wire (Cook Medical, Bloomington, IN) and delivered across the pseudoaneurysm to the distal main pulmonary artery. The dilator was removed, and its tip was cut to allow the creation of a blunt end used to push the stent graft out of the Dryseal. The Gore endoprosthesis attached to a string was inserted into the sheath. The string was then pulled to remove the plastic cover of the endoprosthesis, allowing self-expansion inside the sheath. The distal tip of the dilator was then cut and used to push the endoprosthesis to the tip of the sheath (Figure 4). We then unsheathed the endoprosthesis in its location. A 40 mm coda balloon (Cook Medical, Bloomington, IN) was then used to oppose the endoprosthesis to the pulmonary artery wall (Supplemental Video 4). Given the length of the RVOT endograft to the distal pulmonary artery was only 45 mm, and the length of the endograft was 40 mm, we had to cover the previously placed valve leaflets, resulting in wide-open pulmonary insufficiency but sealing of the pseudoaneurysm (Supplemental Video 5). A second SAPIEN 3 Ultra 23 mm valve was then deployed inside the endoprosthesis with excellent results (Figure 5, Supplemental Video 6). The equipment used and the details of the procedure are summarized in Table 1.

The patient recovered well after the second procedure. He was discharged home in 2 days. On 30-day follow-up, the patient underwent a repeat CTA, which showed near resolution of the pseudoaneurysm (Figure 6). The transthoracic echocardiogram showed significant improvement in right ventricular function and size.

TPVR is increasingly used to treat patients with dysfunctional RVOT conduits or surgical bioprosthetic valves.[1] Technical success has been reported up to 97.4% with the use of the balloon-expandable SAPIEN transcatheter heart valve device.[1,2] However, the use of TPVR in native RVOT anatomy or surgical homografts carries significant risk and challenges. The pulsatile nature of RVOT and diameter variation makes sizing very challenging and increases the risk of valve embolization. Furthermore, many congenital heart disease patients have larger RVOT than currently commercially available transcatheter prosthetic valves and therefore require surgical correction with homografts or valve conduits.[3] Pulmonary homografts are frequently used to treat congenital RVOT diseases. Homografts are more prone to calcification and carry significant risk of injury during TPVR. The stepwise approach for RVOT conduit TPVR usually includes conduit rehabilitation, stent placement, and deployment of a transcatheter valve (Melody, or SAPIEN 3).[3] It is essential to carefully evaluate the RVOT conduit for calcification, adherence to the sternum, and risk of coronary obstruction. Fortunately, the risk of RVOT conduit rupture is low and reported to be around 9% in the largest study that included 99 patients undergoing TPVR. About 20% of the patients with homografts and 21% of the patients with moderate to severe conduit calcification had conduit rupture during TPVR.[3] All patients were managed immediately with the deployment of a covered or bare-metal stent. Hemodynamic instability was noted only in 2 patients, and all patients survived the procedure.

The commonly used covered CP stent (Braun Interventional Systems Products) has a delivery system up to 85 cm, which makes it favorable for the pretreatment of the RVOT or the branch pulmonary artery via the femoral venous access. However, the maximum size of the CP stent 10 Zig can go up to 30 mm, which was significantly smaller than the vessel surrounding the pseudoaneurysm in our patient and likely would not have resulted in appropriate sealing. The other alternative option

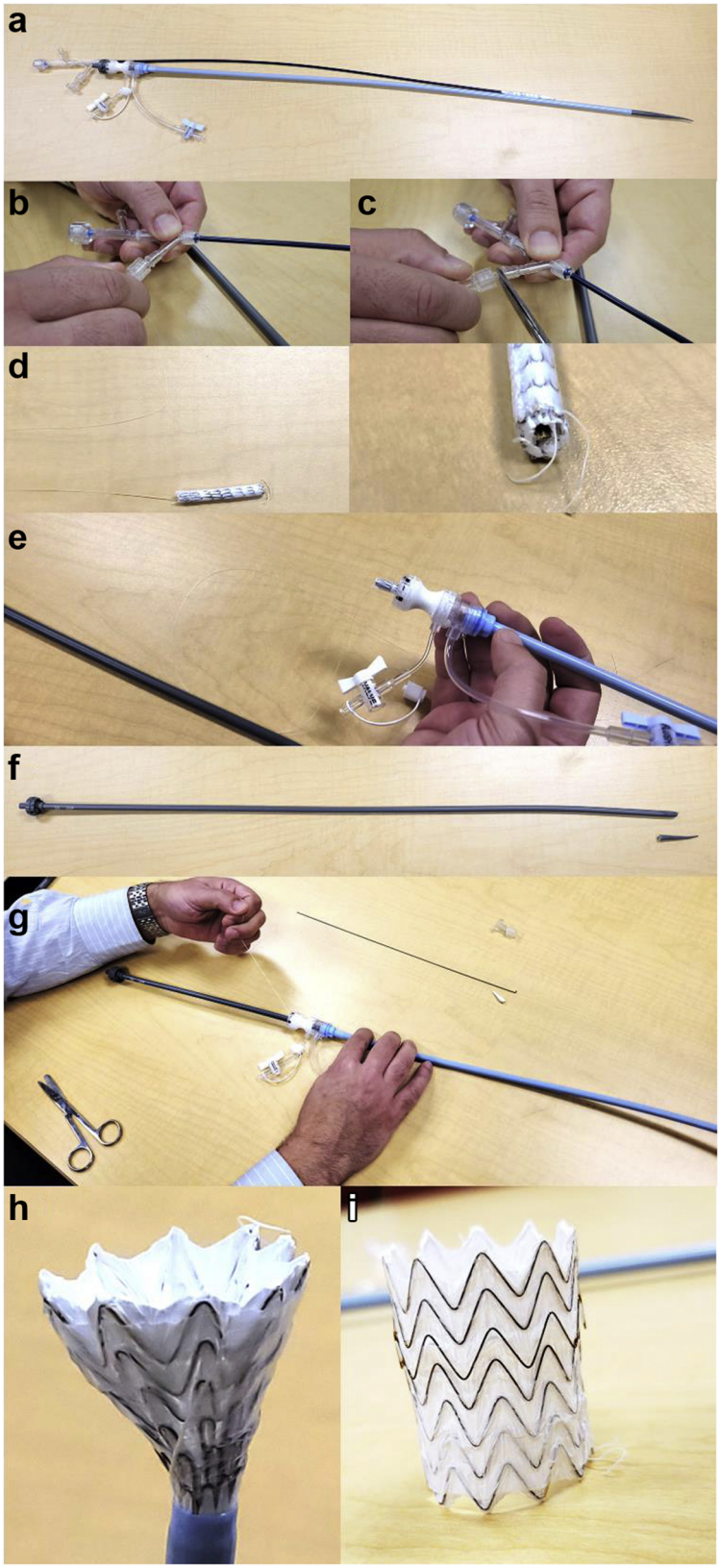

Figure 4. Preparing the Gore abdominal aortic endoprosthesis to treat the pseudoaneurysm step by step. (a) The length of the endoprosthesis is shorter (50 cm) than the delivery 65 cm Gore Dryseal sheath. (b and c) The side arm of the endoprosthesis delivery system was detached, and the string was cut to release the endoprosthesis. (d) The endoprosthesis is covered with a plastic cover that is attached to a string. (e) The endoprosthesis was inserted into the delivery sheath. (f and g) The distal tip of the dilator was cut, and the dilator was used to push the endoprosthesis. Once the endoprosthesis is inside the sheath, the string attached to the endoprosthesis was then pulled to break the plastic cover around the endoprosthesis allowing self-expansion. (h and i) Demonstrate the self-expanded endoprosthesis.

available is to use the Gore endoprosthesis, which is commonly used to treat abdominal and thoracic aortic aneurysm. The abdominal endoprosthesis (cuff extension) is available in a wide variety of sizes up to 36 mm in diameter and with a maximum length of 4.5 cm, which makes it favorable to deploy in the main pulmonary artery with a caveat of short delivery system of 50 cm. The thoracic endoprosthesis, on the other hand, has a variety of sizes between 21 and 45 mm in diameter and longer delivery system up to 65 cm. However, the minimum length of

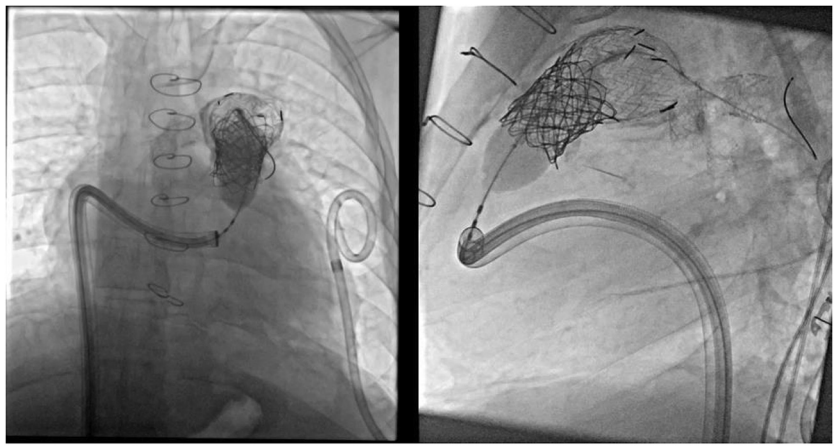

Figure 5. After deployment of a 36 mm endoprosthesis, a SAPIEN 3 Ultra 23 mm valve was deployed.

Table 1
Equipment and description of the procedure

A) Equipment used for the procedure		
Equipment	Size	Length
Dryseal sheath	24 French	65 cm
Balloon wedge catheter	7 French	110 cm
Pigtail catheter	6 French	125 cm
Lunderquist Extra-Stiff Wire Guide, Cook Medical	0.035"	260 cm
Gore Excluder AAA endoprosthesis	36 × 45 mm	Delivery system of 50 cm
Coda balloon, Cook Medical	40 mm	Delivery system of 120 cm
Tuohy Y adapter with hemostatic valve		

B) Description of the procedure
1) Obtain femoral venous access using a 7 French sheath
2) Using a balloon wedge catheter, access the right pulmonary artery
3) Advance a 0.035" lundrquest catheter to the right pulmonary artery
4) Advance a 7 French Pigtail catheter over the lunderquest wire. While maintaining wire position, connect a Tuohy Y adapter with a hemostatic valve and perform main pulmonary angiogram using power injector.
5) Remove the pigtail catheter and the 7 French venous sheath
6) Advance a 24 French 65 cm Dryseal to the distal end of the desired position of the endoprosthesis
7) Detach the Gore Excluder AAA endoprosthesis (Figure 4b and c)
8) Cut the Dryseal dilator to form a blunt end (Figure 4f)
9) Advance the endoprosthesis in the dryseal using the blunt dilator while holding on the white string (Figure 4g)
10) Pull the endoprosthesis string to break the plastic cover
11) Advance the endoprosthesis to the distal tip of the dryseal sheath
12) Unsheath the endoprosthesis allowing self-expansion
13) Postdilate the endoprosthesis using Coda balloon to achieve wall apposition
14) Perform pulmonary angiogram to confirm sealing of the pseudoaneurysm

AAA = abdominal aortic aneurysm.

these endoprostheses is 10 cm, which will result in either protrusion into the right ventricle or jailing one of the pulmonary arteries. We detached the abdominal endoprosthesis and advanced it using the Dryseal dilator to the desired site and post dilated it resulting in a complete sealing of the pseudoaneurysm. It is very important to note that once the endoprosthesis is released, it will not be retrievable. Synchronized maneuvers of lining up the distal edge of the device with the end of the sheath, maintaining the blunt dilator end at the proximal part, and unsheathing the endoprosthesis are required. Precise positioning of the endoprosthesis using biplane was needed, which made the femoral rather than the jugular access more favorable in our patient.

Transcatheter options that could have been used to treat the pseudoaneurysms are coils or septal occluder device. Given the presence of left hemothorax, we felt the pseudoaneurysm might be communicating with the left pleural space, and coils could migrate to the pleural space or cause significant irritation/adhesion. The use of septal occluder has been reported before in the literature; however, it was unsuccessful.[3] Vascular plugs were used before to treat subacute to chronic pseudoaneurysm in the aortic location.[4] In our patient, the size of the pseudoaneurysm ostium, acute nature, and RV-RVOT-pseudoaneurysm angulation made this approach less favorable.

It is important for congenital heart disease operators to be familiar with bailout strategies for the management of patients with dysfunctional RVOT conduits. With the increasing utilization of TPVR to treat congenital RVOT dysfunction, new bailout tools may be needed. Recently, the Food and Drug Administration has approved the self-expanding Harmony TPVR (Medtronic, Minneapolis, MN) for pulmonary valve regurgitation in native or surgically repaired RVOT based on

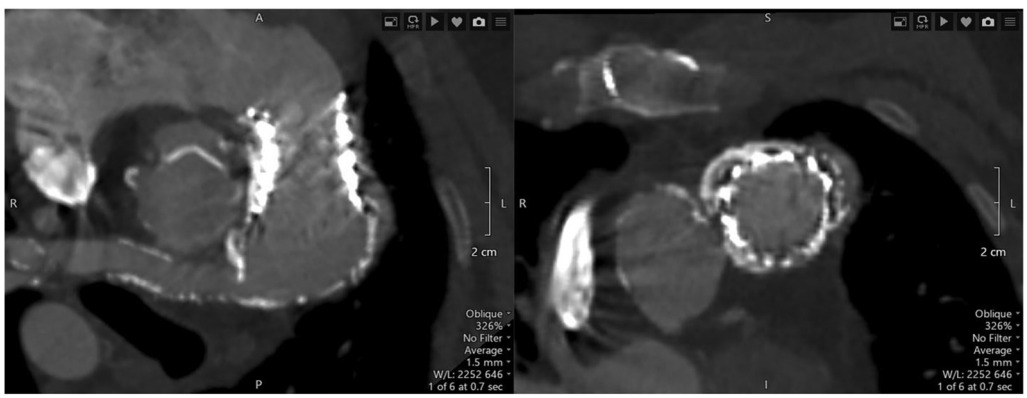

Figure 6. A 30-day follow-up CTA showed complete resolution of the pseudoaneurysm.

the favorable outcomes in the pivotal trial.[5] Similarly, the Alterra Adaptive Prestent aims to remodel dysfunctional RVOTs before implantation of SAPIEN 3 valve. Both devices have the potential to increase the indications and safety of TPVR.[5]

Consent Statement

Consent was obtained from the patient for publication of this report and any accompanying images.

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Supplementary Material

Supplemental data for this article can be accessed on the publisher's website.

References

1 Morray BH, McElhinney DB. Semilunar valve interventions for congenital heart disease: JACC state-of-the-art review. *J Am Coll Cardiol.* 2021;77(1):71-79. https://doi.org/10.1016/j.jacc.2020.10.052

2 Shabana S, Zahn EM, Levi DS, et al. Transcatheter pulmonary valve replacement with the sapien prosthesis. *J Am Coll Cardiol.* 2020;76(24):2847-2858. https://doi.org/10.1016/j.jacc.2020.10.041

3 Boudjemline Y, Malekzadeh-Milani S, Patel MB, et al. Predictors and outcomes of right ventricular outflow tract conduit rupture during percutaneous pulmonary valve implantation: a multicentre study. *EuroIntervention.* 2016;11(9):1053-1062.

4 Tang L, Lesser JR, Gössl M, et al. Transcatheter closure of complex ascending aortic pseudoaneurysms after cardiac surgery. *Circ Cardiovasc Interv.* 2018;11(9), e007052. https://doi.org/10.1161/CIRCINTERVENTIONS.118.007052

5 Bergersen L, Benson LN, Gillespie MJ, et al. Harmony feasibility trial: acute and short-term outcomes with a self-expanding transcatheter pulmonary valve. *JACC Cardiovasc Interv.* 2017;10(17):1763-1773. https://doi.org/10.1016/j.jcin.2017.05.034