JACC: CASE REPORTS VOL. 19, 2023

CASE REPORT

ADVANCED

CLINICAL CASE SERIES

Intravascular Lithotripsy for Severe RVOT Calcification to Optimize Transcatheter Pulmonary Valve Replacement

Nabil Sabbak, MD, Kara Denby, MD, Anirudh Kumar, MD, Ghazaleh Goldar, MD, Joanna Ghobrial, MD

ABSTRACT

The presence of severe right ventricular outflow tract calcification may preclude safe and effective transcatheter pulmonary valve replacement in patients with pulmonary allograft stenosis owing to the risk of conduit tear and suboptimal annular expansion. Debulking calcium using intravascular lithotripsy within the right ventricular outflow tract may mitigate this risk and improve valve hemodynamics. (**Level of Difficulty: Advanced.**) (J Am Coll Cardiol Case Rep 2023;19:101926)

Intravascular lithotripsy can effectively modify severe calcification in peripheral and coronary artery disease.[1] Its impact on calcified right ventricular outflow tracts (RVOT) is less understood, particularly because there are no commercially available lithotripsy balloons designed with sufficiently large dimensions.

Transcatheter pulmonary valve replacement (TPVR) is safe option with favorable outcomes to treat homograft dysfunction in patients with previously repaired congenital heart disease or Ross procedure.[2] Severe RVOT calcification increases risk of pulmonary artery (PA) rupture or conduit tear during traditional balloon valvuloplasty and may be a prohibitive risk factor to attempt TPVR. Debulking RVOT calcium using lithotripsy may optimize annular expansion and valve gradient, while decreasing risk of conduit tear after valve implantation.

With patient permission, we present 2 cases using lithotripsy to facilitate successful TPVR within severe RVOT obstruction with heavily calcified allograft stenosis.

LEARNING OBJECTIVES

- To recognize heavy right ventricular outflow tract calcification as a risk factor for conduit tear and suboptimal expansion during transcatheter pulmonary valve replacement.
- To understand the procedural techniques and materials using intravascular lithotripsy to mitigate risk of conduit tear and optimize valve gradients during transcatheter pulmonary valve replacement.

CASE 1

CLINICAL BACKGROUND. A 48-year-old man with a history of tetralogy of Fallot and severe pulmonary allograft stenosis was referred to our tertiary care facility. He underwent repair in infancy followed by RVOT resection and PV replacement (22-mm allograft, CryoLife) at age 16 years, and ultimately developed NYHA functional class III symptoms

From the Cleveland Clinic, Cleveland, Ohio, USA.

Manuscript received February 2, 2023; revised manuscript received May 15, 2023, accepted May 18, 2023.

ISSN 2666-0849 https://doi.org/10.1016/j.jaccas.2023.101926

ABBREVIATIONS AND ACRONYMS

CT = computed tomography

ICE = intracardiac echocardiography

PA = pulmonary artery

RVOT = right ventricular outflow tract

TPVR = transcatheter pulmonary valve replacement

owing to severe RVOT obstruction with pulmonary hypertension.

Cardiac magnetic resonance 2 years prior revealed a peak PV velocity of 3.6 m/s, peak gradient of 48 mm Hg, minimal pulmonary regurgitation, and mild RV dilation. Transthoracic echocardiogram upon referral revealed peak RVOT velocity 4.2 m/s, peak and mean gradients of 69 and 45 mm Hg, respectively, and normal LV function. Cardiac computed tomography (CT) revealed an RVOT annular measurement of 18.6 × 12.8 mm (1.83 cm^2) with severe circumferential calcification extending superiorly into the main PA (**Figure 1**). He was referred for TPVR because of prohibitive surgical risk owing to obesity, obstructive sleep apnea, asthma, tobacco use, and chronic thrombocytopenia.

PROCEDURAL DETAILS. The case was performed under general anesthesia using fluoroscopy and intracardiac echocardiography (ICE). Bilateral femoral venous and left femoral arterial access were obtained. Baseline PA angiography and ICE images were obtained (Videos 1 and 2).

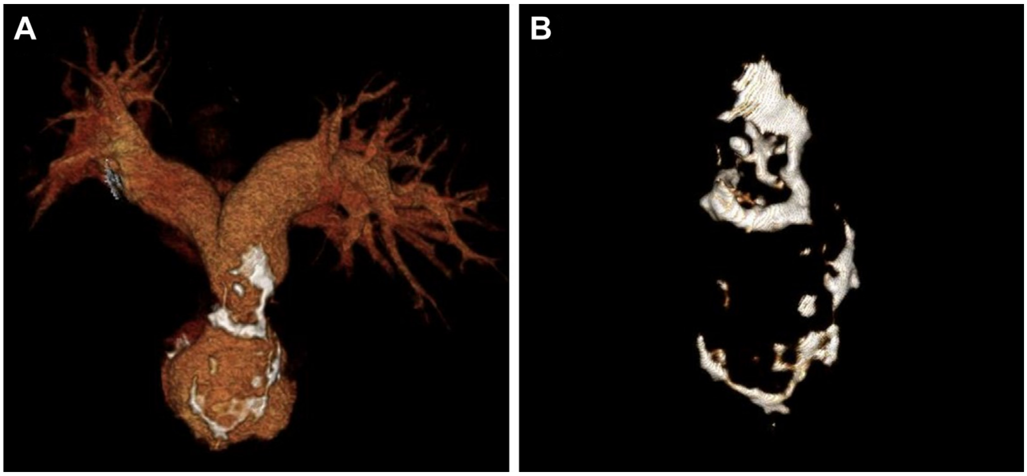
A 7-F balloon wedge catheter was advanced to the distal left PA over a floppy 0.035-inch wire that was exchanged for a stiff wire. The 7-F venous sheath was exchanged for a 20-F sheath. Two 0.014-inch workhorse wires were advanced distally into the PA branches. Two 7 × 60-mm lithotripsy balloons (Shockwave Medical Company) were positioned within the RVOT. A total of 300 pulses were delivered simultaneously, with repositioning of the balloons to allow optimal contact with the calcified tissues in a 360° pattern (**Figure 2**). The RVOT was serially dilated with 16, 18, 20, and 22 × 4 mm balloons (**Figure 3**). Notably, there was significant waist with 18 mm that improved with the larger sizes (**Figure 3**).

A 10 × 45-mm CP stent (NuMED) and 39 × 10-mm Palmaz P4010 stent (Cordis) were loaded onto a 22-mm balloon-in-balloon. The stents were deployed across the RVOT and post-dilated with the balloon-in-balloon (**Figures 4 and 5**, Video 3).

The 20F sheath was exchanged for a 22-F sheathless Melody Ensemble delivery system (Medtronic). The 22-mm Melody valve crimped on a 22-mm balloon-in-balloon was successfully deployed (Video 4). The transpulmonary gradient was 10 mm Hg and residual waist 20 mm; hence, postdilation with a 24-mm balloon was performed, improving the gradient to 7 mm Hg and waist to 22 mm (**Table 1**). Pulmonary angiography (**Figure 6**, Video 5) and ICE (Video 6) revealed a well-expanded valve with trivial regurgitation.

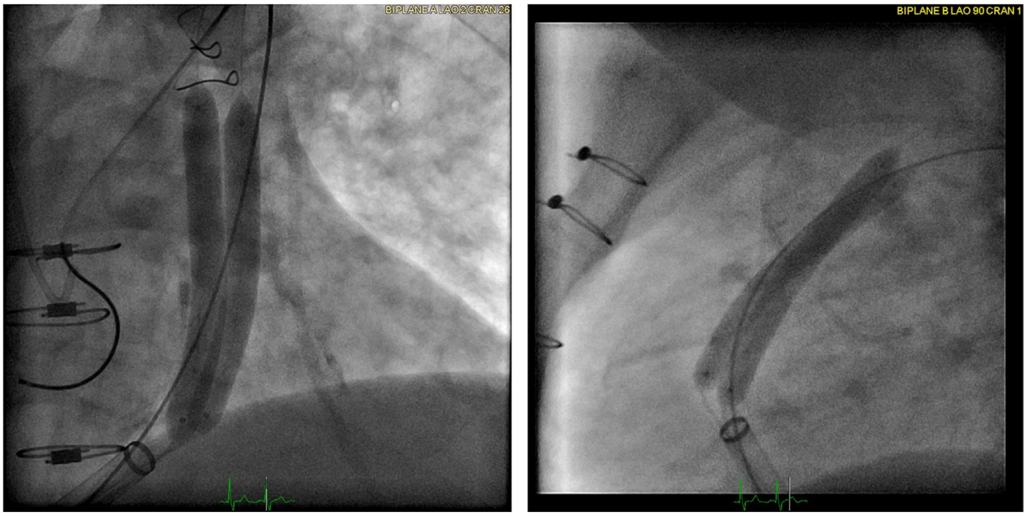
At the 4-month follow-up, the patient endorsed marked symptomatic improvement and had quit smoking. Echocardiogram revealed excellent valve

FIGURE 1 Case 1: Preoperative Computed Tomography Reconstruction of the Right Ventricular Outflow Tract and Pulmonary Arteries



(A) Severe right ventricular outflow tract calcification extending superiorly into the pulmonary artery is shown on computed tomography reconstruction. **(B)** The pattern of calcification without surrounding cardiac structures demonstrates the circumferential pattern.

FIGURE 2 **Case 1: Intravascular Lithotripsy of Calcified Conduit**



Biplane imaging representing 2 adjacent 7-mm lithotripsy balloons positioned across the right ventricular outflow tract as 300 pulses are delivered simultaneously.

function with peak and mean gradients of 29 and 16 mm Hg, respectively, without regurgitation.

CASE 2

CLINICAL BACKGROUND. A 71-year-old man with a history of bicuspid aortic valve disease underwent Ross procedure at age 45 and redo surgical mechanical aortic valve replacement (#25 St. Jude) at age 59. He later developed severe pulmonary homograft stenosis and regurgitation as transthoracic echocardiogram revealed a left ventricular ejection fraction of 62%, normal mechanical aortic valve gradients, right ventricular dilation, and severe pulmonary regurgitation and stenosis with peak and mean gradients of 88 and 56 mm Hg, respectively. CT scan demonstrated heavy homograft calcification with severe RVOT narrowing measuring 13 mm in diameter, with an annular diameter of 23 mm

PROCEDURAL DETAILS. The case was performed under general anesthesia in similar fashion to case 1. Lithotripsy across the RVOT was performed with two 7-mm balloons (**Figure 6**). The RVOT and PV were dilated with 16, 18, 20, and 22 × 4-mm balloons. Subsequent PA angiogram demonstrated evidence of contrast extravasation owing to a conduit tear (Video 7). Covered stenting of the PA was performed immediately using the prepared stent configuration. Pulmonary angiogram revealed complete seal with no evidence of contrast extravasation (Video 8). The 22-mm bioprosthetic PV was then deployed successfully. Pulmonary angiography (Video 9) and ICE (Videos 10 and 11) revealed trivial PR. The transpulmonary gradient was 5 mm Hg (**Table 2**).

Periprocedurally, he required vasopressors and was transferred to the intensive care unit. Postoperative CT scan demonstrated a contained rupture along the leftward aspect of the PV and a small pericardial effusion. With close monitoring and serial CT scans, the patient had an uncomplicated course with resolution of the effusion, and was discharged home.

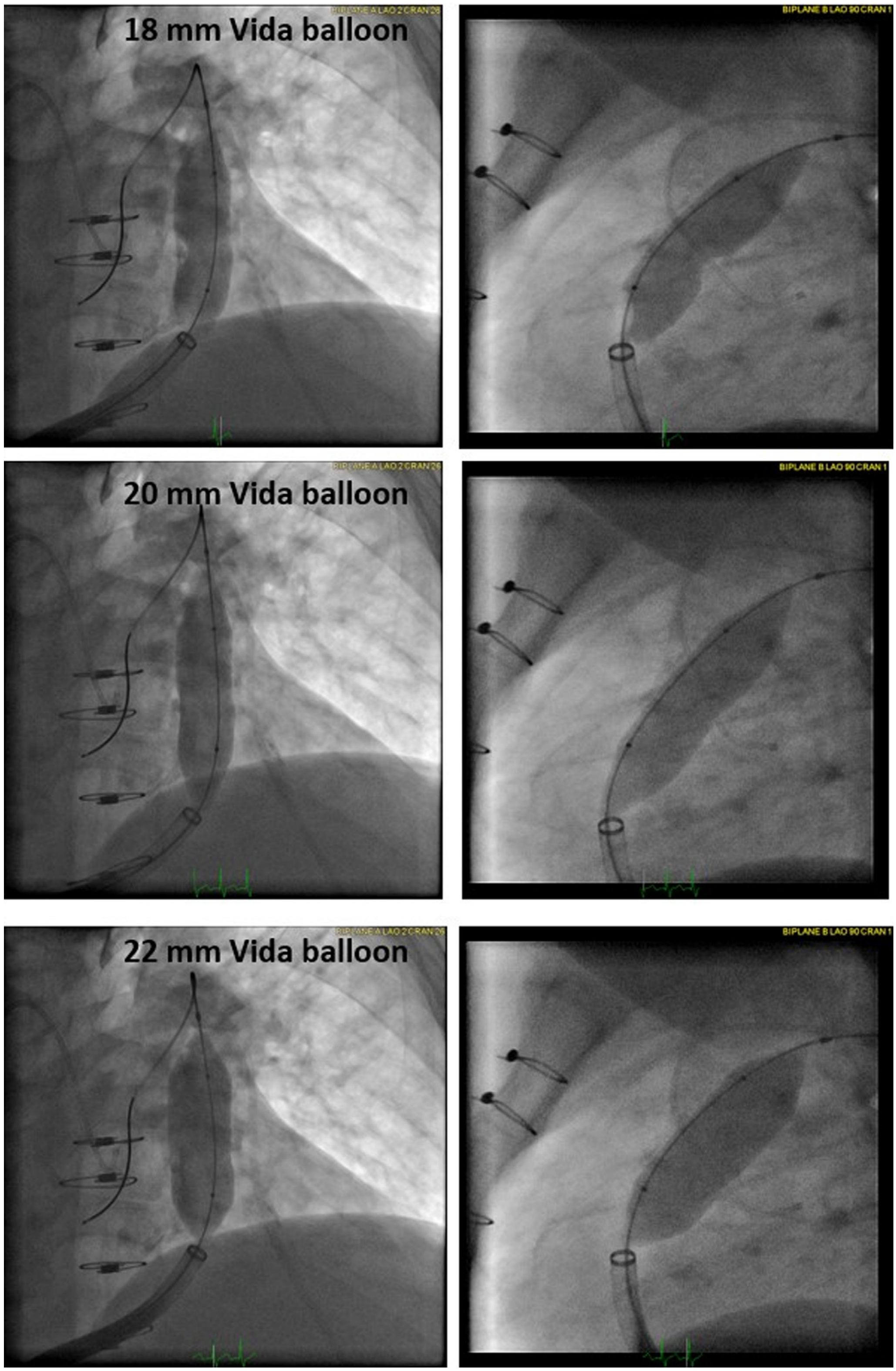
At the 4-month follow-up, he endorsed marked symptomatic improvement. CT angiography demonstrated resolution of the contained rupture. Echocardiogram demonstrated excellent valve function with peak and mean gradients of 13 and 5 mm Hg, respectively.

DISCUSSION

To our knowledge, this case series is the first to publish intravascular lithotripsy-facilitated TPVR. The rationale to use this technology was to optimize

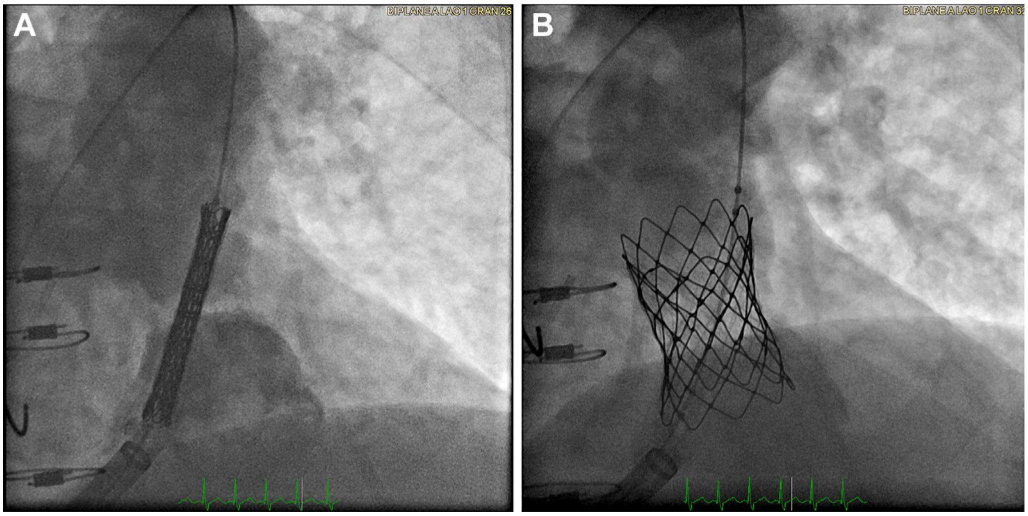
JACC: CASE REPORTS, VOL. 19, 2023
AUGUST 2, 2023:101926

FIGURE 3 **Case 1: Serial Angioplasty With Resolution of the Calcified Waist**



Serial balloon dilation with Vida balloons with waist at 18 mm that improved with 20 and 22 mm.

FIGURE 4 **Case 1: Covered Stenting of the Calcified Homograft**

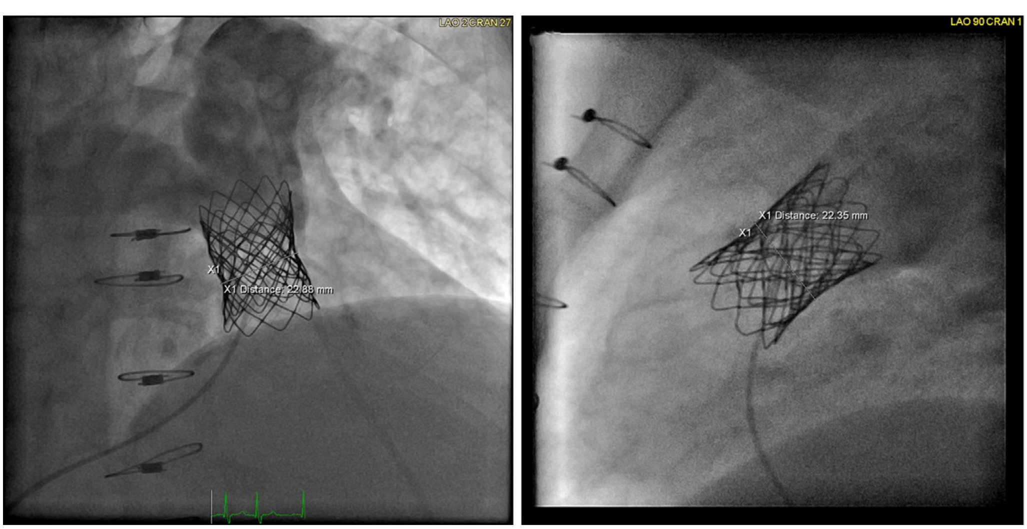


The 10 × 45 mm CP and 39 × 10 mm Palmaz P4010 stents were positioned across the **(A)** right ventricular outflow tract and **(B)** deployed.

RVOT expansion and mitigate the risk of conduit tear by debulking heavy calcification. In case 1, there was a significant waist with the 18 mm predilation that improved with larger balloons (Figure 3). Theoretically, up-front lithotripsy facilitated this expansion without resulting in conduit tear.

Despite a similar strategy, conduit tear occurred in case 2. The skewed distribution of calcification within

FIGURE 5 **Case 2: Angiography After Transcatheter Pulmonary Valve Implantation**



Pulmonary angiography after deployment of the 22-mm Melody valve revealed optimal expansion with no regurgitation.

TABLE 1 Case 1: Periprocedural Valve Hemodynamics

	Baseline Pressure (mm Hg)	Post-Valve Deployment Pressure (mm Hg)
Right atrium	20	-
Right ventricle	60/20	52/25
Pulmonary artery	34/22 (26)	45/30 (38)
Pulmonary wedge	20	-
Pulmonary valve gradient	26	7

TABLE 2 Case 2: Periprocedural Valve Hemodynamics

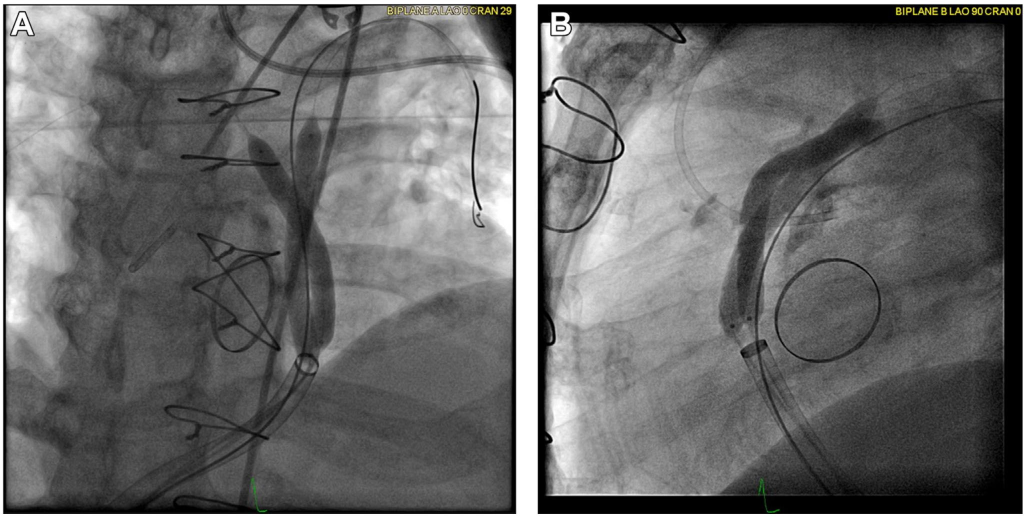
	Baseline Pressure (mm Hg)	Post-Valve Deployment Pressure (mm Hg)
Right atrium	13	15
Right ventricle	80/13	50/10
Pulmonary artery	32/12 (22)	45/20 (30)
Pulmonary wedge	20	-
Pulmonary valve gradient	48	5

the RVOT resulting in a counter-force along the contralateral wall during balloon valvuloplasty may have driven this outcome (**Figure 7**). It is also possible that shifting forces from the mechanical aortic valve played a role. Follow-up CT scan demonstrated deviation of the prestent away from the bulk of the calcification (**Figure 8**). Anticipation and prompt delivery of the prepared covered stent was imperative to avoid any further adverse event.

Long-term TPVR registry outcomes suggest the greatest predictors of repeat TPVR include age and postimplant gradient.[3] Without lithotripsy, the only available method to optimize gradient would be balloon expansion. As demonstrated in case 2, this technique is fraught with the potential of conduit tear in calcified homografts. We serially dilated up to 22 mm to optimize orifice area relative to measured annular dimensions. With each balloon size, we assess for conduit tear and coronary compression. Hypothetically without debulking, angioplasty alone may lead to rupture at an earlier stage in serial dilation, leading to covered stenting at a smaller diameter, precluding maximal valve diameter, with potentially higher final gradients.

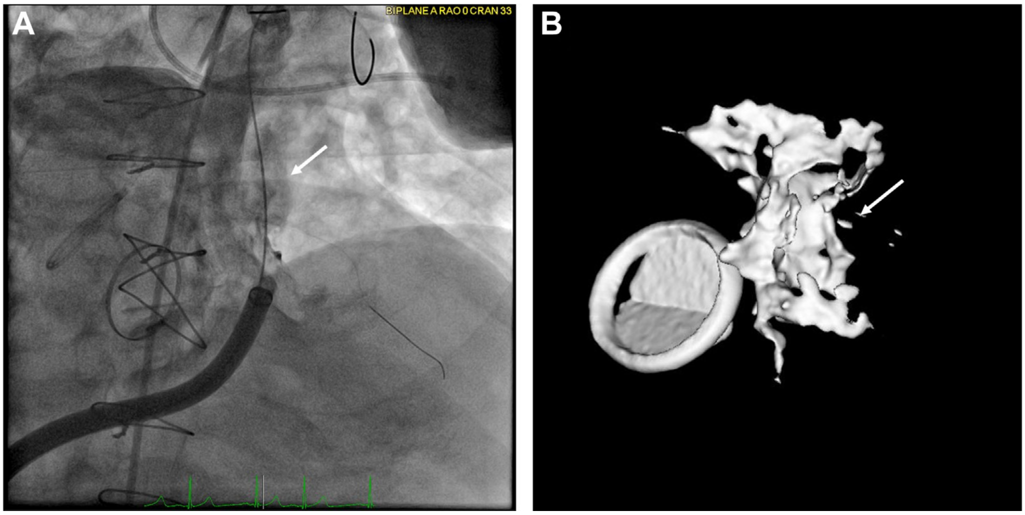
The strategy to use 2 adjacent lithotripsy balloons to deliver pulses within the RVOT should be limited to severe, near circumferential calcification (Videos 12 and 13), yet has limitations. Similar methods to facilitate mitral balloon valvuloplasty in patients with rheumatic and calcific mitral stenosis have been

FIGURE 6 Case 2: Intravascular Lithotripsy of Calcified Conduit



Two adjacent 7-mm lithotripsy balloons are positioned within the severely calcified right ventricular outflow tract, represented in biplane imaging with straight **(A)** cranial and **(B)** lateral projections. One may appreciate the severe degree of homograft calcification, particularly posteriorly in the lateral view.

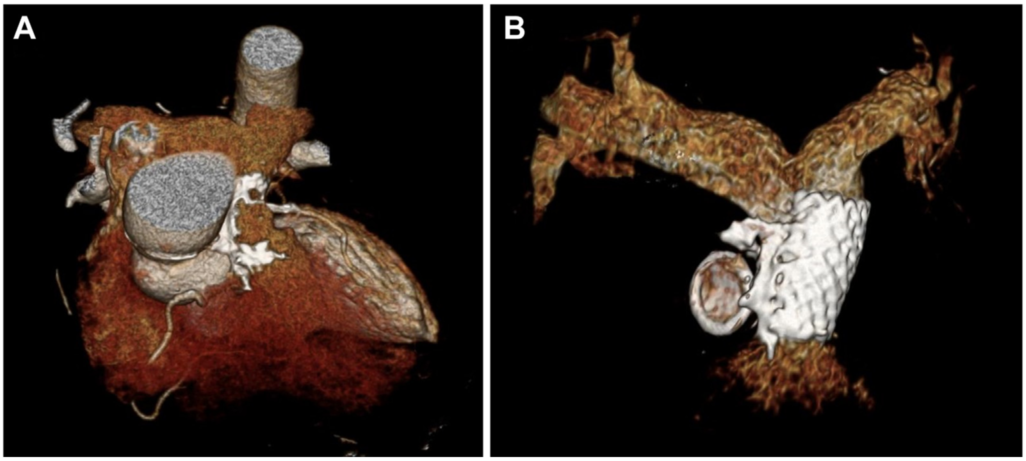
FIGURE 7 Case 2: Angiography Demonstrating Focal Conduit Rupture and Computed Tomography Demonstrating Calcification Pattern of the Conduit



(A) Pulmonary angiography demonstrates contrast extravasation signifying evidence of conduit tear **(white arrow)**. Preprocedural computed tomography reconstruction of the calcium within the right ventricular outflow tract **(B)** in the same projection shows that the area of conduit tear **(white arrow)** is opposite to the bulk of calcification. This pattern may portend higher risk of conduit tear. The mechanical valve is also represented left of the right ventricular outflow tract calcium on the computed tomography scan.

described.[4,5] The summative diameter of adjacent balloons approximated the calculated conduit area, so as to make optimal tissue contact. This geometry, however, inherently creates zones of zero contact with the outflow tract, despite attempts at rotating the balloons' positions. Presumably, larger balloons designed specifically for valvular lithotripsy would enhance calcium modification. Because these devices are not available commercially, positioning 3 adjacent lithotripsy balloons at a later stage in the dilation

FIGURE 8 Case 2: Computed Tomography Angiography of Final Prestented Transcatheter Valve Within Conduit



(A) Preprocedural computed tomography scan demonstrating severe right ventricular outflow tract calcification. **(B)** Postdeployment computed tomography scan reveals the stented right ventricular outflow tract deviated away from the bulk of calcification.

process so as to not exceed the narrowest conduit area may have improved tissue contact.

CONCLUSIONS

Intravascular lithotripsy before TPVR within a calcified homograft may improve annular expansion and decrease risk of conduit tear. Although both cases were successful ultimately, a conduit tear occurred in case 2, with a skewed, bulkier calcium distribution. These cases highlight the limitations in treating heavily calcified pulmonary homografts in nonsurgical candidates and demonstrate a role for the development of lithotripsy balloons designed specifically for valvuloplasty.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

Dr Sabbak has consulted for Medtronic and is a proctor for Harmony (outside this submitted work). All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

ADDRESS FOR CORRESPONDENCE: Dr Joanna Ghobrial, Cleveland Clinic, Mail Code J2-4, 9500 Euclid Avenue, Cleveland, Ohio 44195, USA. E-mail: ghobrij@ccf.org.

REFERENCES

1. Hill JM, Kereiakes DJ, Waksman R, Stone GW, et al, Disrupt CAD III Investigators. Intravascular lithotripsy for treatment of severely calcified coronary artery disease. *J Am Coll Cardiol*. 2020;76:2635–2646.

2. Shahanavaz S, Qureshi A, Levi D, et al. Transcatheter pulmonary valve replacement with the melody valve in small diameter expandable right ventricular outflow tract conduits. *J Am Coll Cardiol Intv*. 2018;11:554–564.

3. Eng MH, Villablanca P, Wang DD, Frisoli T, Lee J, O'Neill WW. Lithotripsy-facilitated mitral balloon valvuloplasty for senile degenerative mitral valve stenosis. *J Am Coll Cardiol Intv*. 2019;12:e133–e134.

4. McElhinney D, Zhang Y, Levi D, et al. Reintervention and survival after transcatheter pulmonary valve replacement. *J Am Coll Cardiol*. 2022;79:18–32.

5. Sharma A, Kelly R, Mbai M, Chandrashekhar Y, Bertog S. Transcatheter mitral valve lithotripsy as a pretreatment to percutaneous balloon mitral valvuloplasty for heavily calcified rheumatic mitral stenosis. *Circ Cardiovasc Interv*. 2020;13:e009357.

KEY WORDS congenital heart disease, pulmonary allograft stenosis, Ross procedure, shockwave lithotripsy, transcatheter pulmonary valve replacement, tetralogy of Fallot

APPENDIX For supplemental videos, please see the online version of this paper.