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TAVR PROGRAM SPOTLIGHT

Achieving Efficiency in TAVR

A Conversation with Samir Germanwala, DO, FACC, FSCAI

Longview Regional Medical Center, Longview, Texas

Can you tell us about your facility and TAVR program?

Longview Regional Medical Center is a regional hospital in East Texas. Longview itself has about 100,000 people, but our catchment area is closer to 400,000. We are roughly two hours east of Dallas, and that distance was the main reason we launched a local TAVR program ten years ago, just a year or so after the technology received commercial approval.

Patients in this area were reluctant to travel for advanced cardiac care. Many told us they simply wouldn't go to Dallas for a procedure, so we decided to bring it here. We already had a strong foundation, with seven cardiologists (six interventionalists and one electrophysiologist) and a large regional referral network.

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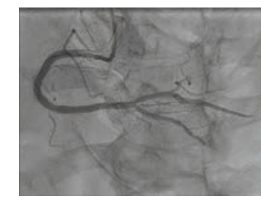
CASE REPORT

When All Else Fails: Devices to Optimize PCI in Calcified and Tortuous Vessels



Boskey Patel, DO, FACC, FSCAI **PAGE 16**

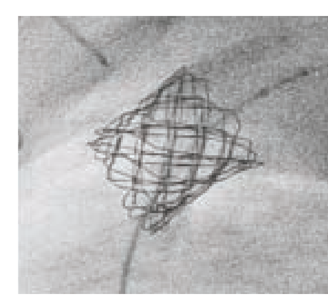
ASK THE EXPERTS

Innovation That Overcomes Radial Access Challenges

Manit Sabharwal with Morton Kern, MD, MSCAI, and Arnold Seto, MD, MPA, FSCAI, FACC, FAHA **PAGE 14**

FROM *JOURNAL OF INVASIVE CARDIOLOGY*

Intravascular Lithotripsy-Assisted Intervention in Patients With Congenital Heart Disease



Zachary L. Steinberg, MD; Lauren N. Carlozzi, MD; Brian H. Morray, MD **PAGE 10**

HMP Global

Intravascular Lithotripsy-Assisted Intervention in Patients With Congenital Heart Disease

Zachary L. Steinberg, MD; Lauren N. Carlozzi, MD; Brian H. Morray, MD

Abstract

Objectives. The use of intravascular lithotripsy (IVL) in patients with calcified coronary and peripheral arterial disease is now commonplace; however, its use in procedures specific to congenital heart disease is rare, with a very limited published case-based experience to date. The authors report the outcomes of four patients with congenital heart disease who underwent IVL-assisted transcatheter procedures, in the effort to inform future operators as to the potential benefits and risks of IVL technology in this patient population. **Methods and Results.** Four patients underwent IVL-assisted transcatheter procedures including branch pulmonary artery stenting, aortic coarctation stenting, and transcatheter pulmonary valve replacement. All four patients underwent successful IVL-assisted implantation of large stents in highly calcified native or surgically implanted biological conduits without significant complications. **Conclusions.** The use of IVL-assisted interventions in patients with severe native or surgical calcified vascular conduits is feasible and may be a useful adjunct in conduit stent implantation and dilation. Vascular injury during angioplasty of calcified vessels and conduits remains a concern despite the use of lithotripsy, and covered stent implantation should be considered prior to aggressive dilation in order to reduce the risk of catastrophic rupture.

Intravascular lithotripsy (IVL) has emerged as a pivotal technology in the management of calcified obstructive vascular disease. Intravascular lithotripsy is composed of miniaturized lithotripsy emitters positioned along the shaft of an angioplasty balloon. Circumferentially aligned emitters produce electric sparks, resulting in the formation of acoustic pressure waves, which are transmitted through the fluid medium of the angioplasty balloon into the surrounding vascular tissue.[1,2] As the acoustic impedance of soft tissue closely approximates that of water, energy is transmitted through the vascular wall without injury. As the pressure wave reaches calcium deposits within the vasculature, changes in acoustic impedance result in calcium fracture, enabling balloon and stent expansion in vessels previously recalcitrant to dilation.[2,3]

The Shockwave IVL catheter (Shockwave Medical), which ranges in diameter from 2.5 to 12 mm, received Federal Drug Administration approval in 2021 following large, prospective, multicenter studies demonstrating safety and efficacy in revascularizing calcified coronary and peripheral arterial obstructions in patients with age-related vascular degeneration.[4,5] While there are limited data demonstrating the use of IVL in patients with congenital heart disease, this technology offers potential therapeutic benefits for a high-risk patient population with heavily calcified native vessels and vascular conduits. We report our experience using the Shockwave IVL catheter to treat calcific vascular disease in four patients with congenital heart disease.

Methods and Results

The authors confirm that patient consent was waved by our local institutional review board policy due to the retrospective and de-identified nature of this study.

Patient 1. This is a 25-year-old man with a history of D-transposition of the great arteries who underwent staged palliation culminating in an arterial switch procedure with a LeCompte maneuver by one month of age, followed by two subsequent surgical aortic valve replacements (AVR). During the second AVR, he required branch pulmonary artery (PA) reconstruction with homograft material as a result of longstanding bilateral branch PA stenoses. In the setting of progressive bilateral branch PA stenoses, he was brought forward for branch PA stenting. A pre-procedural cardiac computed tomographic angiogram (CTA) revealed severe bilateral ostial PA stenoses measuring 4 x 5 mm and 8 x 15 mm within the right and left PAs with distal reference diameters of 11 x 13 mm and 21 x 25 mm, respectively. Heavy circumferential right PA calcification was present, presumed to be homograft tissue from the prior repair (Figure 1A-C).

The procedure was carried out with bilateral venous access and simultaneous wiring of the branch PAs. Initial angioplasty of the right PA origin with an 8 mm Charger balloon (Boston Scientific) inflated to 10 atmospheres (atm) was without alleviation of a mid-balloon waist. Attempts to place a covered stent prior to a more aggressive angioplasty were unsuccessful because of an inability to deliver a long, 12 French sheath across the heavily calcified lesion. As such, the decision was made to perform IVL to the ostial right PA. An 0.014-inch exchange-length guidewire was advanced into the distal right PA and a 7 mm Shockwave IVL balloon was advanced over the wire and into the right PA. The balloon was inflated to 4 atm and a total of 60 lithotripsy pulses were delivered, resulting in near complete relief of the mid-balloon waist, suggesting adequate lithotripsy (Figure 1D-E). Following IVL, two covered Cheatham-platinum stents (Numed) and a Palmaz 4010 XL stent (Cordis)were implanted and post-dilated with a 12 mm balloon to 30 atm, resulting in a substantial improvement in the right PA caliber to a minimum diameter of 10 mm. Left PA stenting was performed without difficulty, resulting in substantial reduction in the right ventricular systolic pressures and a decrease in the right PA gradient from 55 to 15 mmHg. There were no periprocedural complications and the patient was discharged within 24 hours. A CTA performed several months later demonstrated widely patent branch PA stents (Figure 1F).

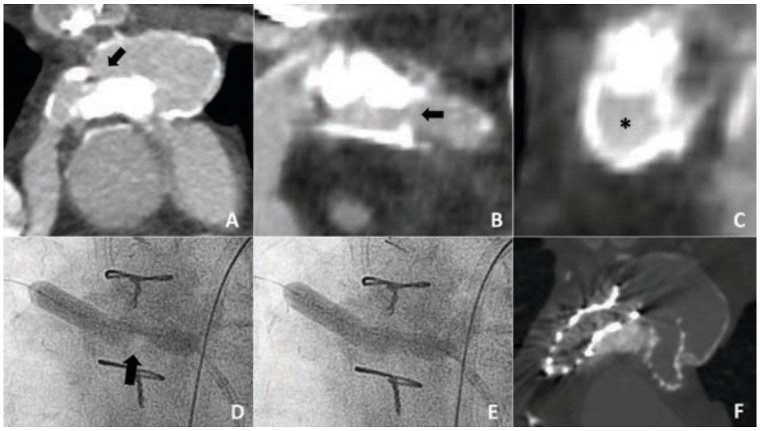


Figure 1. **Pre-, intra-, and post-procedural imaging in Patient 1. Pre-procedural multiplanar reformatted computed tomography angiography (CTA) images in the (A) axial, (B) sagittal, and (C) coronal projections demonstrate heavy calcifications of the ostial right pulmonary artery (black arrows) in a patient with D-transposition of the great arteries post-LeCompte maneuver. (D) At the initiation of intravascular lithotripsy (IVL), a discrete mid-balloon waist was present (black arrow), which (E) fully resolved with the following IVL. (F) A post-procedural CTA reveals patent branch pulmonary artery stents.**

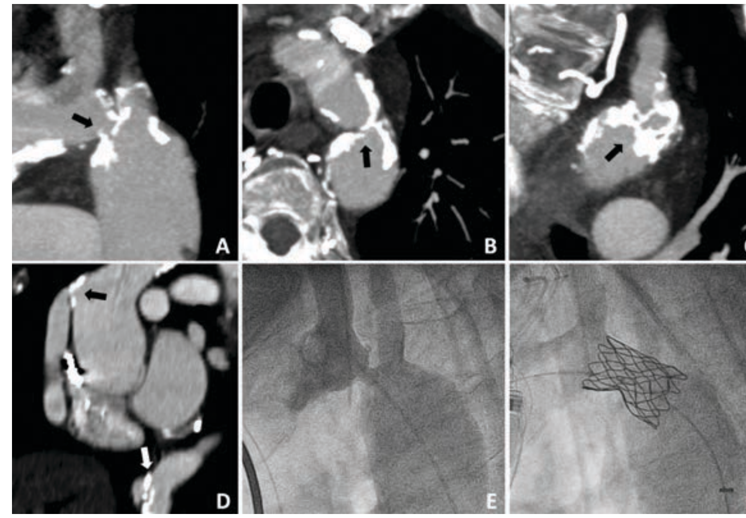


Figure 2. **Pre- and post-procedural imaging in Patient 2. Pre-procedural multiplanar reformatted CTA images in the (A) sagittal, (B) axial, and (C) coronal projections demonstrate a heavily calcified native aortic coarctation (black arrows). (D) A separate coronal view reveals severe calcified stenoses of the proximal (black arrow) and distal (white arrow) ascending to descending aortic conduit. (E) Pre- and (F) post-procedural angiography reveal a significant improvement in coarctation caliber.**

Patient 2. This is a 71-year-old man with a history of aortic coarctation and a bicuspid aortic valve status post-patch angioplasty of his aortic coarctation at age 2, patch revision at age 10, and implantation of a 16 mm ascending-to-descending aortic bypass graft at age 30. Following decades of limited cardiovascular follow-up, he presented with systolic blood pressures of 160 mmHg, an echocardiography-derived aortic arch mean gradient of 48 mmHg, and a CTA demonstrating a severely calcified transverse arch stenosis (<5 mm) with severely stenotic proximal and distal bypass conduit stenoses (Figure 2A-D). The decision was made to proceed with lithotripsy-assisted native coarctation stenting.

A 12 x 30 mm Shockwave lithotripsy balloon was advanced over an 0.018-inch wire, inflated to 3 atm within the coarcted segment under rapid pacing conditions, and 30 consecutive lithotripsy pulses were delivered prior to balloon deflation. This process was repeated 9 times for a total delivery of 300 pulses. A 3.4 cm covered Cheatham-platinum stent was advanced over an 0.035-inch wire and deployed within the coarctation over a 14 mm balloon at 6 atm. Stent post dilation was carried out with a 12 mm noncompliant balloon to 8 atm, intentionally leaving a mild mid-stent waist to avoid aortic wall injury. A 20 mm Z-MED balloon (B. Braun) was advanced into the stent and inflated to 5 atm with the sole intent of flaring the proximal stent to improve aortic wall apposition; however, at low pressure, the minimum diameter of the covered Cheatham-platinum stent expanded from 12 to 15 mm. Stent strut jailbreaking of the covered left subclavian artery was performed and the procedure was concluded. Final angiography showed no evidence of aortic wall injury, and the arch gradient was reduced from 42 mmHg to 4 mmHg (Figure 2E-F). There were no procedural complications and the patient was discharged the following day.

Patient 3. This is a 38-year-old man with a history of tetralogy of Fallot who underwent staged intracardiac repair of unknown type, which was completed by age 3. He underwent two subsequent right ventricle-pulmonary artery (RV-PA) conduit interventions, the last of which was at age 20 with a 23 mm homograft. In the setting of progressive conduit stenosis, with an echocardiography-derived mean gradient of 47 mmHg, the patient was brought forward for transcatheter conduit rehabilitation. A preprocedural chest CTA revealed heavy circumferential conduit calcifications with a minimum luminal diameter of 8 mm (Figure 3A-C).

Due to concerns over conduit fracture with angioplasty alone, and concerns related to the efficacy of conduit angioplasty following covered stent placement, the decision was made to proceed with IVL prior to implantation of a covered stent. Coronary angiography demonstrated the coronary arteries to be remote from the conduit. A 12 x 30 mm Shockwave lithotripsy balloon was advanced into the conduit over an 0.018-inch wire and inflated to 4 atm. No balloon waist was appreciated; however, the balloon remained in a stable position with a drop in systemic blood pressure, indicating appropriate apposition to the vessel wall. Thirty lithotripsy pulses were delivered to the calcified homograft, followed by balloon deflation, allowing for systemic blood pressure recovery. This process was repeated 4 times for a total delivery of 150 pulses. A 4.5 cm covered Cheatham-platinum stent was deployed within the conduit

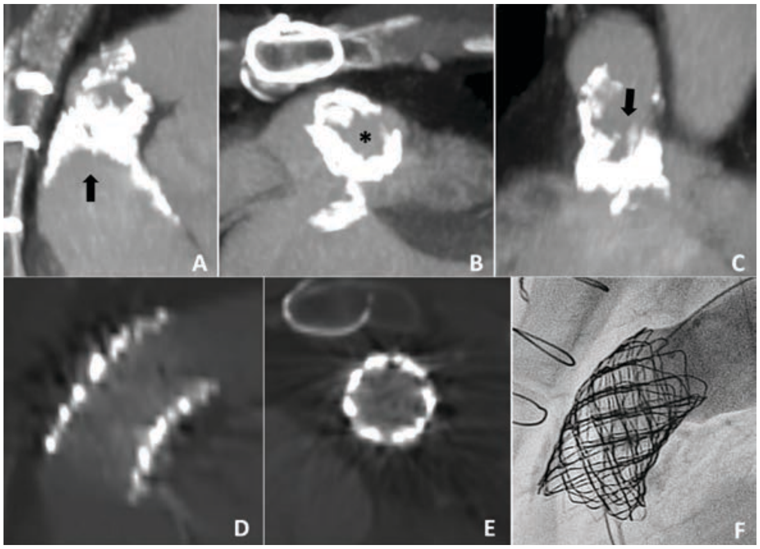


Figure 3. **Pre- and post-procedural imaging in Patient 3. Pre-procedural multiplanar reformatted CTA images in the (A) sagittal, (B) axial, and (C) coronal projections demonstrate a heavily calcified right ventricle-pulmonary artery conduit (black arrows and asterisk). A post-procedural CTA in the (D) sagittal and (E) axial projections reveals a widely patent stented conduit. (F) Post-procedure angiography reveals widely patent stents, a competent pulmonary valve, and no residual conduit dissection.**

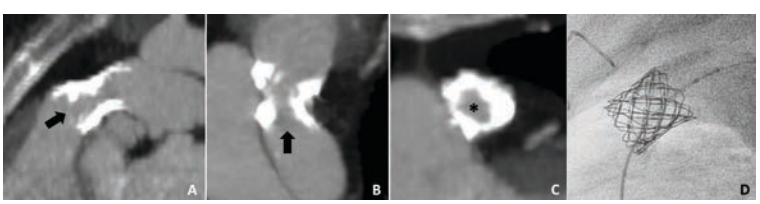


Figure 4. **Pre- and post-procedural imaging in Patient 4. Pre-procedural multiplanar reformatted CTA images in the (A) sagittal, (B) axial, and (C) coronal projections demonstrate a heavily calcified right ventricle-pulmonary artery conduit (black arrows and asterisk). (D) Post-procedure angiography reveals widely patent stents and a competent pulmonary valve.**

over a 22 mm balloon at 6 atm, followed by implantation of a Palmaz XL 4010 within the covered Cheatham-platinum stent. Post dilation was carried out with a 24 mm Atlas Gold balloon (BD) to 8 atm with full expansion of the stent complex. Follow-up angiography revealed a small, contained distal conduit tear, prompting placement of a second covered Cheatham-platinum stent, which successfully sealed the injury. A Melody valve (Medtronic) was implanted within the stented conduit over a 22 mm Ensemble delivery system (Medtronic) with a reduction in the final conduit gradient from 44 to 4 mmHg (Figure 3F). The patient experienced a left hemothorax, which was discovered several hours post procedurally, with a CTA showing a fully intact conduit with widely expanded stents (Figure 3D-E) and a bleeding source within the periphery of the left pulmonary vasculature, likely due to a distal wire perforation. The patient was monitored with spontaneous resolution of the bleed within 12 hours and was brought forward for a video-assisted thoracoscopic surgery 3 days post procedure for hematoma evacuation.

Patient 4. This is a 38-year-old man with a history of congenital aortic valve stenosis status post-Ross procedure with a 24 mm RV-PA homograft at the age of 15. He was lost to follow-up for many years, returning to care in the setting of new onset atrial flutter. At that time, he was discovered to have mixed conduit disease by echocardiography with a mean gradient of 36 mmHg and moderate regurgitation with mild right ventricular dysfunction, prompting referral for transcatheter conduit rehabilitation. A pre-procedure CTA revealed heavy circumferential calcifications with a minimum luminal diameter of 14 mm (Figure 4A-C).

Like Patient 3, there was concern over both conduit fracture with angioplasty prior to covered stent implantation and inability to adequately relieve the outflow tract gradient with stenting and angioplasty alone. Therefore, IVL-assisted conduit stenting was performed up front. Coronary angiography demonstrated a remote position from the RV-PA conduit, and coronary compression testing was not performed. A 12 x 30 mm Shockwave lithotripsy balloon was advanced over an 0.018-inch wire and into the RV-PA conduit. Given a minimum luminal area of greater than 12 mm, an 8 x 40 mm Armada balloon (Abbott) was advanced into the conduit over an 0.035-inch wire alongside the IVL balloon to ensure its adequate apposition to the vessel wall. A total of 150 pulses were delivered in 30 pulse increments, allowing intermittent systemic pressure recovery. A 3.9 cm covered Cheatham-platinum stent followed by a Palmaz XL 4010 stent was deployed within the conduit over 18 mm balloons inflated to 6 atm. Post dilation was carried out with a 24 mm Atlas Gold balloon to 8 atm, fully expanding the stent complex. A Melody valve was implanted within the stented conduit on a 22 mm Ensemble delivery system with a reduction in the conduit gradient from 70 to 6 mmHg. Final angiography showed no evidence of conduit disruption (Figure 4D). There were no procedural complications, and the patient was discharged within 24 hours.

Discussion

The presence of circumferential intravascular calcium is known to be a risk factor for vascular injury during coronary artery interventions because of reduced vascular compliance and the need for high-pressure angioplasty to relieve the obstruction.[6,7] While data in the congenital space is lacking, heavy vessel and conduit calcifications are recognized risk factors for vascular disruption, and calcification remodeling has theoretic benefits for conduit- and large-vessel interventions.

There are few intraprocedural markers of successful IVL, as heavy shadowing limits the utility of intravascular ultrasound imaging and, while optical coherence tomography may show evidence of some calcium fracture, the true effect of calcium modification with IVL is best observed with micro-computed tomographic imaging.[8] Clinically, relief of a balloon waist during IVL has been used as a marker of successful lithotripsy; however, the presence or absence of this angiographic finding is not necessarily indicative of procedural success. IVL was employed following unsuccessful attempts at vessel dilation in only one of our four cases (Patient 1), obscuring the true efficacy of IVL in the remaining three cases. IVL was performed on Patients 2, 3, and 4 a priori, as there are no data on the efficacy of IVL performed through an existing covered stent. As a result, there is no way to ascertain whether IVL truly had any effect on procedural outcomes; however, the procedures on Patients 2, 3, and 4 resulted in excellent hemodynamic outcomes following relatively low-pressure angioplasty post IVL despite heavy calcification. While there is no way to determine whether this outcome would have been identical without the use of IVL, its use may have allowed for relief of obstruction with lower pressure angioplasty.

Our four cases of IVL-assisted conduit- and large-vessel interventions raise many questions about the efficacy and safety of this technology in this patient population. Included among them is the question of how many lithotripsy impulses are required to achieve the appropriate calcium modification in calcified homografts and large vessels. In only one procedure (Patient 1) did we achieve angiographic feedback, via balloon waist relief, that calcium modification had likely been achieved. The remaining three cases all received a set number of impulses with no interpretable angiographic feedback. Patient 2 received 300 impulses — the full amount achievable for a 12 mm Shockwave balloon. Patients 3 and 4 only received 150 impulses, yet complete relief of high-grade stenoses was achieved in both cases at only 8 atm. Future ex vivo research will aid in determining the depth of lithotripsy penetration and the number of impulses needed to achieve adequate calcium fracture in these larger vascular structures.

Equally as important, assuming adequate calcium fracture has been achieved, is to determine whether IVL-assisted angioplasty reduces the risk of conduit- and/or large-vessel injury. This has particularly important implications in patients undergoing RV-PA conduit interventions in whom coronary compression testing is required prior to stenting. Coronary compression was not a concern in our two cases of RV-PA conduit stenting, permitting covered-stent implantation prior to dilation. Yet one patient still experienced a non-full-thickness conduit tear distal to the covered stent, requiring placement of a second covered stent. In their early experience, Sabbak et al reported on two patients who underwent IVL-assisted RV-PA conduit interventions, one of whom experienced a full-thickness conduit disruption during sequential conduit angioplasty, requiring emergent covered-stent implantation.[9] This early combined experience suggests that continued caution with dilation of heavily calcified conduits is appropriate, regardless of whether IVL is employed.

One potential drawback to the use of IVL in conduit and aortic interventions is the need to fully occlude the vascular structure for the duration of the lithotripsy impulses. The larger diameter IVL balloons are capable of delivering up to 30 lithotripsy impulses over a period of 1 second per impulse. Balloon deflation is then necessary to permit reperfusion before the process can be repeated. In our experience, Patients 2, 3, and 4 all tolerated the 30-second balloon inflation with only a minimal drop in systemic blood pressure. This may be due to incomplete balloon apposition to the surrounding vessel as a result of the presence of irregular calcifications and/or the use of two balloons in Patient 4, allowing for flow around the balloon. IVL has the potential to result in significant systemic hypotension and fewer consecutive impulses with longer periods of recovery may be necessary in select cases.

Balloon sizing remains an important limitation to the use of IVL in larger conduits and vessels. The recent introduction of a 12 mm balloon has expanded applications for its use; however, the simultaneous use of additional balloons to achieve adequate vessel apposition is a technique that may prove effective at achieving IVL in stenoses larger than 12 mm. In Patient 4, we used a second, non-IVL "buddy" balloon to achieve adequate vessel contact with the IVL balloon. Alternatively, Sharma et al reported a successful balloon mitral valvuloplasty procedure on a heavily calcified valve with the use of three adjacent 7 mm IVL balloons; also, Sabbak et al used two adjacent 7 mm IVL balloons for their two RV-PA conduit interventions, noting that 7 mm balloons were the largest size available at the time of these interventions.[9,10] While cost is a major advantage to the use of a non-IVL "buddy" balloon (IVL balloons are priced well above standard angioplasty balloons), noncircumferential calcium modification may increase the risk of conduit rupture due to asymmetric dilation. The limited experience to date does not address this question.

Conclusions

IVL offers promise for increasing the efficacy of transcatheter therapies across a wide spectrum of cardiovascular diseases, including patients with congenital heart disease. The early experience with this technology suggests that IVL may be a useful adjunct in stenting severely calcified vessels and conduits. However, additional study is needed to investigate the efficacy of calcium modification, the safety of IVL-assisted stenting, and the optimal procedural technique in patients with congenital heart disease undergoing transcatheter intervention on large vascular structures. ■

References for Steinberg et al are available with the article online:

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