Journal of the Society for Cardiovascular Angiography & Interventions 2 (2023) 101111

JSCAI

The official journal of the Society for Cardiovascular Angiography & Interventions

Original Research

Novel Lithotripsy-Assisted Transcatheter Aortic Valve Replacement May Reduce Risk of Aortic Root Rupture

Puvi Seshiah, MD [a,b], Joseph Choo, MD [a,b], Santiago Garcia, MD [a,b], Dean J. Kereiakes, MD [a,b,*]

[a] *The Christ Hospital Heart and Vascular Institute, Cincinnati, Ohio;* [b] *The Carl and Edyth Lindner Center for Research and Education at The Christ Hospital, Cincinnati, Ohio*

ABSTRACT

Background: Severe calcific aortic stenosis (AS) can be successfully treated with transcatheter aortic valve replacement (TAVR) using both balloon-expandable valves (BEV) and self-expanding valves. Challenges remain for treatment of AS with TAVR in relation to the severity of calcification involving valve leaflets, aortic annulus, and/or left ventricular outflow tract. Severe calcification presents challenges to TAVR with respect to aortic root/annular rupture and risk for peri-valve leak (PVL).

Methods: Three separate patients with symptomatic severe AS and severely calcified valves underwent TAVR with BEV. Case 1 underwent TAVR without preceding intravascular lithotripsy (IVL) of the native valve and developed annular rupture requiring surgical rescue. Following this experience, TAVR in 2 subsequent cases was preceded by Shockwave IVL using a novel 12-mm × 30-mm L6 balloon placed across the native valve prior to BEV implantation.

Results: Following IVL, cases 2 and 3 had uncomplicated TAVR with excellent valve frame expansion, and no significant residual gradient or PVL.

Conclusions: Severely calcified aortic valves increase the risk of aortic annular rupture and PVL following TAVR. IVL prior to TAVR may enhance leaflet/ annular compliance with the potential to improve the safety and effectiveness of TAVR.

Introduction

Severe calcific aortic stenosis (AS) has been treated with transcatheter aortic valve replacement (TAVR) using balloon-expandable valves (BEV) or self-expanding valves.[1,2] Severe calcification poses challenges to BEV and self-expanding valves of annular rupture during deployment or after dilation as well as increased risk for peri-valve leak (PVL).[3-5]

We recently performed BEV TAVR on a patient with symptomatic severe trileaflet AS and severe valve calcification (calcium score, 5277 mm^3) (Figure 1). Although predilation with an undersized balloon to determine the direction of leaflet calcification movement may be performed, this was not done, and a 29-mm SAPIEN 3 BEV (Edwards Lifesciences) (−1 mL balloon volume, ~8% oversizing) was deployed. During deployment, the heavily calcified noncoronary leaflet moved horizontally in relation to the valve frame during balloon expansion (Figure 2A, Supplemental Video 1). Following deployment, the patient became hypotensive, aortography revealed aortic root rupture (Figure 2B, Supplemental Video 2), and a rapidly enlarging pericardial effusion with associated right atrial compression was visualized by echocardiography. Emergency cannulation, cardiopulmonary bypass, and sternotomy were performed. On exploration of the aorta, rupture was identified due to a calcific shard that penetrated the aortic root at the N-R leaflet commissure. The BEV was explanted, the root was repaired, and a 25-mm INSPIRIS aortic valve (Edwards Lifesciences) was inserted.

In this context, we hypothesized that lithotripsy of heavily calcified aortic valves might fracture calcification, enhance leaflet/valve compliance, and prevent aortic rupture with BEV.

Prior preclinical experiments using a novel lithotripsy device demonstrated fractures in calcified human valve leaflets treated ex vivo and subsequently suggested the safety of similar treatment in pigs.[6] In addition, 2 prior case reports have used 7-mm Shockwave intravascular lithotripsy (IVL) balloons (Shockwave Medical) prior to TAVR and have reported improved leaflet mobility with successful clinical outcomes.[7,8]

Herein, we describe a new, relatively simple technique for delivering lithotripsy therapy to the aortic valve prior to TAVR using a 12-mm × 30-mm Shockwave L6 balloon.

Abbreviations: AS, aortic stenosis; BEV, balloon-expandable valve; IVL, intravascular lithotripsy; LVOT, left ventricular outflow tract; PVL, peri-valve leak; TAVR, transcatheter aortic valve replacement.

Keywords: aortic stenosis; aortic valvuloplasty; lithotripsy; transcatheter aortic valve replacement.

* Corresponding author: djkereiakes@gmail.com (D.J. Kereiakes).

https://doi.org/10.1016/j.jscai.2023.101111

Received 17 May 2023; Received in revised form 23 June 2023; Accepted 13 July 2023

Available online 4 August 2023

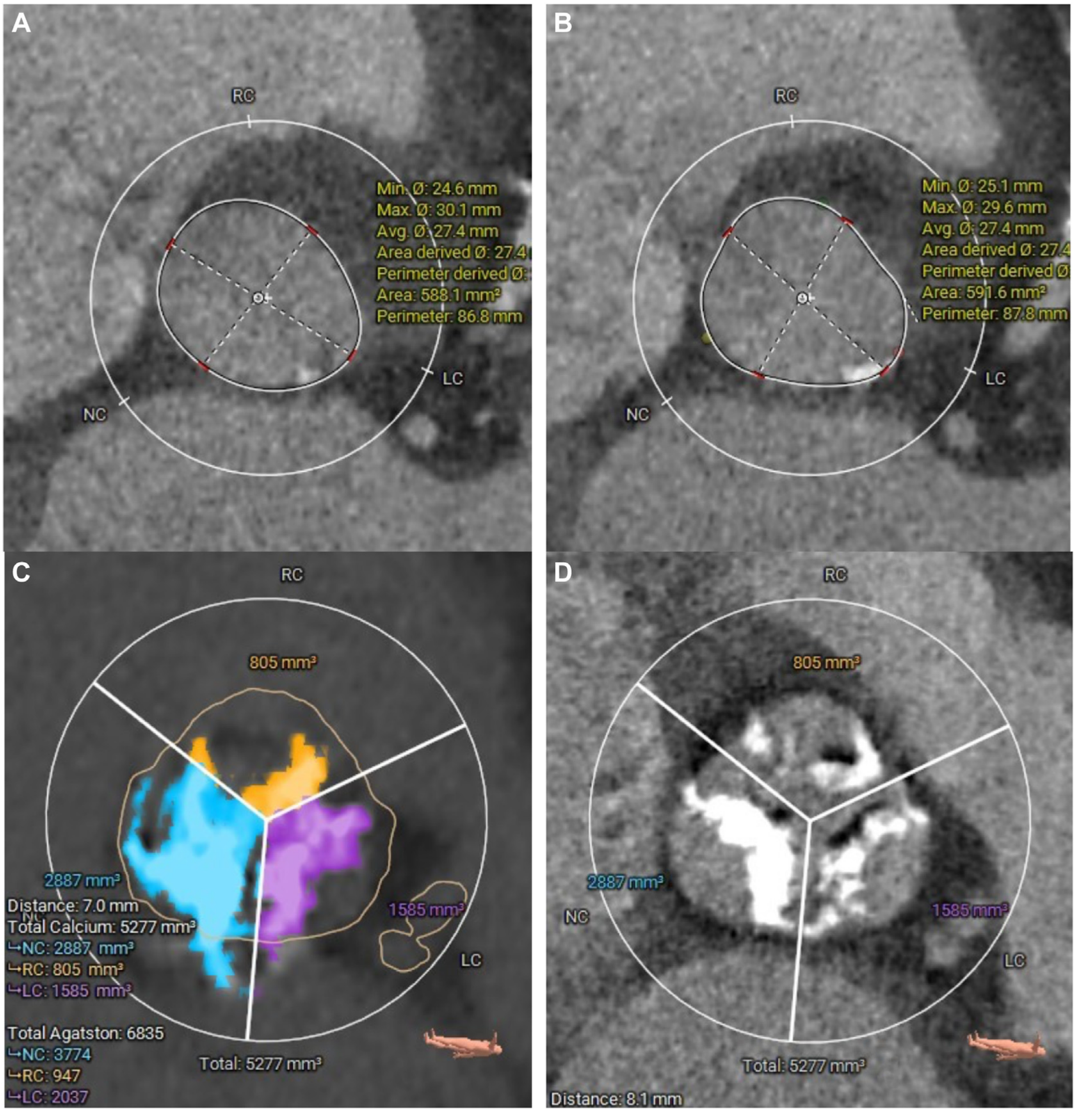


Figure 1.

Computed tomographic images of the aortic valve. (**A**) Annular (592 mm^2), (**B**) left ventricular outflow tract (LVOT) (588 mm^2) measurements, (**C**) quantitative leaflet calcium measurements and (**D**) sinus of Valsalva (average, 35 mm) measurements prior to balloon-expandable valve transcatheter aortic valve replacement.

IVL Procedure details

Patient 1

A 90-year-old man with critical AS, New York Heart Association class III heart failure, and high surgical risk was referred for TAVR. Computed tomography analysis revealed a valve calcium score of 6094 mm^3 and annulus and left ventricular outflow tract (LVOT) areas of 534 mm^2 and 539 mm^2, respectively, with a sinus of Valsalva average of 34 mm (Figure 3).

After obtaining informed consent, TAVR was performed in a hybrid suite under conscious sedation using Sentinel cerebral

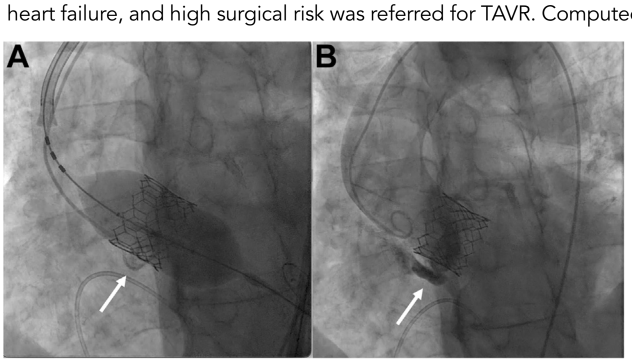


Figure 2.

Noncoronary leaflet movement and aortic root rupture after balloon-expandable valve deployment. Aortic root cine-angiography during and following valve deployment. (**A**) Noncoronary leaflet movement (white arrow). (**B**) Aortic root rupture (white arrow).

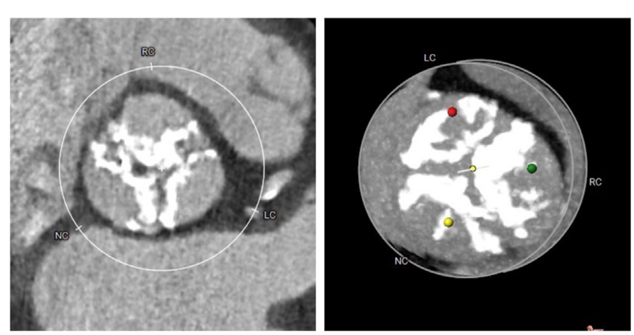


Figure 3.

Patient 1 images prior to balloon-expandable valve transcatheter aortic valve replacement. Computed tomographic images of aortic valve.

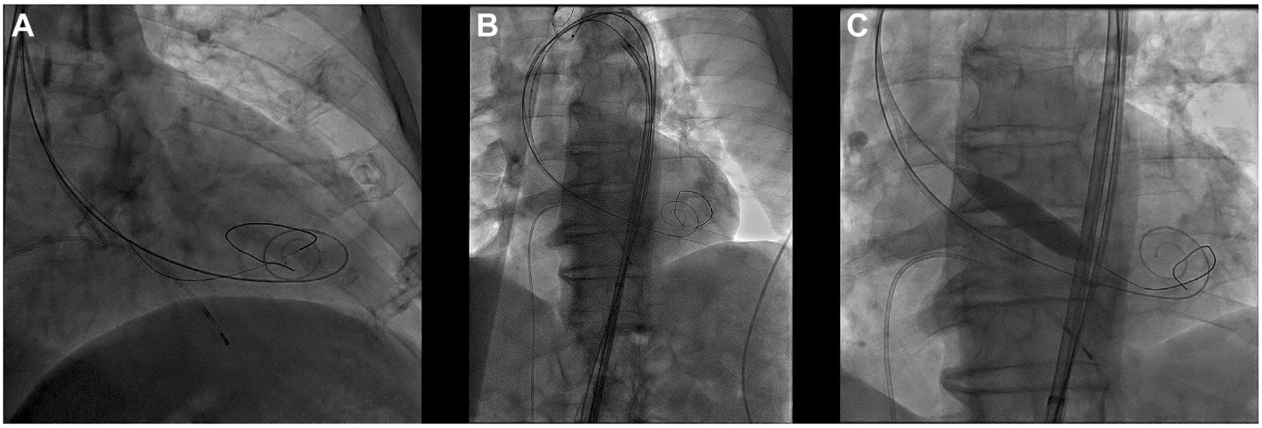


Figure 4.
Cinefluoroscopy of guidewire, guide catheter, and Shockwave balloon. Angiography during the procedure showing (**A**) Safari and Platinum Plus wires at LV apex, (**B**) Oscar Destino sheath in aortic arch (**C**) IVL being delivered via L6 balloon. IVL, intravascular lithotripsy; LV, left ventricle.

protection (Boston Scientific). A 14F E-sheath (Edwards Lifesciences) was placed via right femoral access, the aortic valve was crossed using an Amplatz left 1 diagnostic catheter, and a Safari wire (Boston Scientific) was placed at the left ventricular apex. Mean gradient was 62 mm Hg. From the left femoral access, the aortic valve was crossed, and a 6F Judkins right 4 guide catheter was placed into the left ventricle through which a preshaped 0.018-inch Platinum Plus wire (Boston Scientific) was delivered. Both Safari and Platinum Plus wires were seen at the left ventricular apex (Figure 4A). The Judkins right 4 guide was exchanged for a 10F Destino sheath (OSCOR Inc), which was advanced into the ascending aorta over the 0.018-inch Platinum Plus wire (Figure 4B, Supplemental Video 3). A 12-mm × 30-mm L6 IVL balloon was advanced over the 0.018-inch wire and positioned across the valve. Shockwave lithotripsy was performed (Figure 4C, Supplemental Video 4) using 4 cycles of 30 pulses administered during 3- to 4-atm balloon inflations. Rapid ventricular pacing was not required to keep the balloon in position due to the stability provided by the Destino sheath.

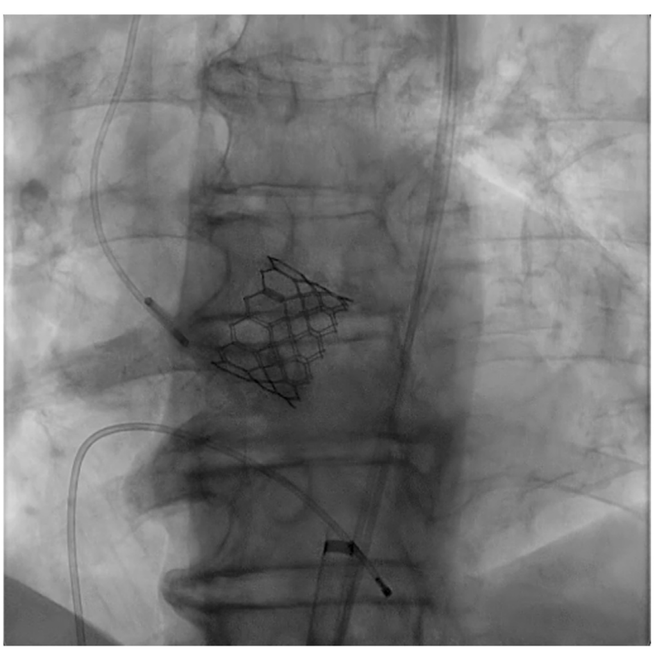


Figure 5.
Deployment of a 26-mm SAPIEN 3 valve. Valve deployment.

The balloon and 0.018-inch wire were removed, and a 26-mm SAPIEN 3 valve was advanced across the aortic annulus and deployed without difficulty during rapid pacing at 160 bpm (Figure 5). The valve was interrogated by echocardiography, which revealed absence of PVL and a mean gradient of 5 mm Hg. Percutaneous vascular closure followed; the patient remained neurologically intact and was discharged home the following day.

Patient 2

A 77-year-old man with symptomatic severe trileaflet AS, a valve calcium score of 4900 mm^3, annulus and LVOT areas of 668 mm^2 and 687 mm^2, respectively, a sinus of Valsalva average of 37 mm, and intermediate surgical risk was referred for TAVR. Mean gradient was 45 mm Hg. He had lithotripsy performed in a similar fashion using a 12-mm × 30-mm L6 Shockwave balloon followed by successful and uneventful placement of a 29-mm SAPIEN 3 valve. Sentinel cerebral embolic protection was employed. Postdeployment echocardiogram demonstrated a mean gradient of 4 mm Hg and no significant PVL.

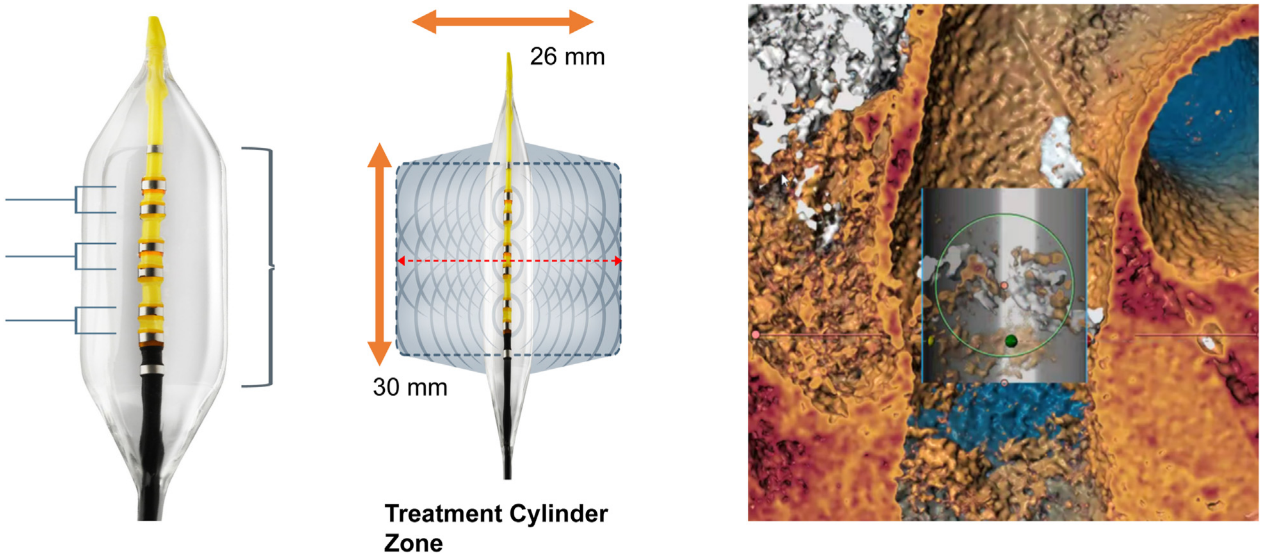
Discussion

Shockwave lithotripsy, which has been used to modify calcium in the coronary and peripheral vasculature, works by sonic disruption of calcium with creation of multiplane fractures. IVL has also been used to facilitate mitral valvuloplasty and transcatheter mitral valve replacement in patients with severe mitral annular calcification.[9]

Prior case reports have described IVL balloon pretreatment of severely calcified aortic valve leaflets prior to TAVR either using a single 7-mm Shockwave balloon[8] or with the simultaneous use of 3 7-mm Shockwave balloons.[7] A single 7-mm balloon is inadequate to effectively treat the average aortic valve area due to the limited distance encompassed by the sonic energy profile. Using 3 Shockwave balloons simultaneously is technically cumbersome and expensive.

Our technique, using a single 12-mm L6 balloon, should provide a calcium-modifying sonic energy field that extends to at least 7 mm beyond the inflated balloon edge, thereby creating a cylindrical "treatment volume" diameter of 26 mm, which should be sufficient to impact most aortic valvular and LVOT calcium (Central Illustration). In addition, unlike the M5/M5+ IVL balloons (Shockwave Medical), which have a variable energy profile between emitters, the L6 balloon has 6 emitters spaced evenly over 30 mm, which provides a uniform high energy profile across the entire balloon length.[10]

Although use of a 10F, tip-deflecting sheath made delivery and stability of the balloon more controlled due to additional support in



Central Illustration.
Shockwave L6 intravascular lithotripsy balloon sonic pressure wave treatment volume. A uniform sonic pressure wave profile extends for at least 7 mm beyond the surface of the inflated L6 balloon. Shockwave L6 balloon and effective calcium modification treatment zone.

these cases, different types of guide catheter support might have been useful as well. Because the L6 balloon delivers 30 pulses per cycle at 1 pulse/s, the stabilizing sheath obviated the need for long pacing runs. Balloon position was reasonably stable during IVL therapy, and both patients remained hemodynamically stable.

Shockwave IVL of severely calcified aortic valves prior to TAVR may improve leaflet and annular pliability and mitigate the risk of annular/aortic root rupture.

Although anecdotal, these cases will hopefully prompt a larger-scale evaluation of IVL-facilitated TAVR in severely calcified valves to facilitate safe and effective TAVR.

Peer review statement

Deputy Editor Dean J. Kereiakes had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Associate Editor Sandeep Nathan.

Declaration of competing interest

Dean J. Kereiakes is a consultant for Shockwave Medical.

Funding sources

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethics statement and patient consent

This research adhered to all relevant ethical guidelines, and adequate informed patient consent was obtained.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2023.101111.

References

1. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019;380(18):1706–1715. https://doi.org/10.1056/NEJMoa1816885
2. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380(18):1695–1705. https://doi.org/10.1056/NEJMoa1814052
3. Guimarães L, Ferreira-Neto AN, Urena M, et al. Transcatheter aortic valve replacement with the balloon-expandable SAPIEN 3 valve: impact of calcium score on valve performance and clinical outcomes. *Int J Cardiol*. 2020;306:20–24. https://doi.org/10.1016/j.ijcard.2020.02.047
4. Pio SM, Bax J, Delgado V. How valvular calcification can affect the outcomes of transcatheter aortic valve implantation. *Expert Rev Med Devices*. 2020;17(8):773–784. https://doi.org/10.1080/17434440.2020.1789456
5. Salem MA, Ismail AS, Donkol RH, Reyad MA, Ramadan AM. Aortic valve calcium score in prediction of post-TAVI complications in an Egyptian cohort. *Egypt J Radiol Nucl Med*. 2022;53(1):260. https://doi.org/10.1186/s43055-022-00946-2
6. Bernava G, Fermi E, Gelpi G, et al. Lithotripsy of calcified aortic valve leaflets by a novel ultrasound transcatheter-based device. *Front Cardiovasc Med*. 2022;9:850393. https://doi.org/10.3389/fcvm.2022.850393
7. Sharma A, Bertog S, Mbai M. Transcatheter aortic valve lithotripsy in severely calcified bicuspid aortic stenosis prior to transcatheter aortic valve implantation. *Eur Heart J*. 2021;42(4), 358-358. https://doi.org/10.1093/eurheartj/ehaa829
8. Sardella G, Salvi N, Bruno E, Colantonio R, Mancone M. Lithotripsy-assisted aortic valvuloplasty during TAVR. *J Am Coll Cardiol Intv*. 2019;12(15):e131–e132. https://doi.org/10.1016/j.jcin.2019.05.018
9. Seshiah P, Garcia S, Choo J, et al. Lithotripsy-assisted transcatheter mitral valve replacement for severe mitral annular and valve calcification. *J Soc Cardiovasc Angiogr Interv*. 2023;2(1):100540. https://doi.org/10.1016/j.jscai.2022.100540
10. Corl JD, Flynn D, Henry TD, Kereiakes DJ. First human use of Shockwave L6 intravascular lithotripsy catheter in severely calcified large vessel stenoses. *J Soc Cardiovasc Angiogr Interv*. 2023;2(4):100969. https://doi.org/10.1016/j.jscai.2023.100969