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CASE SERIES
Coronary heart disease

Treatment of heavily calcified coronary artery stenosis using 3.5 mm peripheral intravascular lithotripsy balloon: case series

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Background Prevalence of coronary artery calcification is high among patients with advanced age, chronic kidney disease, and diabetes. Percutaneous coronary intervention of heavily calcified coronary artery remains a significant challenge for interventional cardiologists. Although there are several modalities available in treating calcified coronary arteries, lesion preparation of certain heavily calcified vessels remains inadequate prior to stent deployment and/or often associated with worse periprocedural adverse outcomes.

Case summary We report feasibility and safety of 3.5 mm peripheral intravascular lithotripsy (IVL) for the treatment of severely calcified coronary stenosis in two patients after orbital atherectomy failed to debulk calcified plaque to enable stent deployment.

Discussion Intravascular lithotripsy has recently emerged as a therapeutic option in treating calcified peripheral artery disease. However, coronary IVL is currently available only in a few centres in the USA. Studies are ongoing in the safety and efficacy of this technology in treating coronaries.

Keywords Coronary artery disease • Intravascular ultrasound • Atherectomy • Case series

Learning points

- Treating severely calcified coronary artery stenosis is challenging. Lesion preparation is the key to a successful percutaneous coronary intervention.
- Numerous modalities of treating these heavily calcified vessels are available, albeit they all have certain limitations. Intravascular lithotripsy is a newer tool which is more feasible and safer way of treating these complex lesions.

Introduction

With aging and increased prevalence of diabetes and renal insufficiency in coronary artery disease (CAD) population, the recent demand to treat complex calcified coronary artery stenosis by percutaneous coronary intervention (PCI) is increasing dramatically.[1] The current modalities for treating moderate to severe calcified coronaries include high-pressure angioplasty with non-compliant balloon, scoring balloons, cutting balloons, rotational atherectomy,

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orbital atherectomy, and laser atherectomy. While these modalities have increased the success rates of PCI in calcified coronary arterial stenosis, these rates remain lower. Periprocedural and long-term major adverse cardiac events are noted to be higher than that for PCI of non-calcific lesions.[1–5] In addition, adverse coronary anatomy (tortuosity, presence of major side branch, and excessive angulation) often preclude use of many such technologies particularly the atherectomy devices. As such, major enthusiasm remains for exploring alternative techniques for the successful treatment of calcified coronary lesions. One such technology that is currently available for treating calcified lesions in peripheral artery disease (PAD) is the use of IVL. Studies of IVL in PAD have shown encouraging results in reducing residual stenosis and achieving greater average acute lumen gain compared to other modalities.[6] However, IVL is commercially available and approved in the USA only for the treatment of PAD. The efficacy and safety of this technology in treating calcified coronary stenosis remain unknown. Accordingly, we report the feasibility and limited safety of peripheral IVL for the treatment of severely calcified coronary stenosis in two patients after orbital atherectomy failed to debulk calcified plaque and enable stent deployment.

Figure 1 Case 1: pre-intervention angiogram.

Timeline

Patient 1	
30 January 2019	Diagnostic coronary angiogram
13 February 2019	Patient was deemed poor candidate for surgical revascularization, patient was brought back to undergo percutaneous coronary intervention. Orbital atherectomy and balloon angioplasty showed poor expansion of the balloon, hence a intravascular lithotripsy (IVL) was performed followed by successful stent implantation.
Patient 2	
3 February 2019	Diagnostic angiogram and intervention of the left circumflex during an acute coronary syndrome presentation.
7 February 2019	Staged intervention of left anterior descending coronary artery: orbital atherectomy and balloon angioplasty but poor expansion of the balloon, hence no stent was deployed.
11 March 2019	Patient was brought back to undergo IVL prior to successful stent implantation.

Case presentation

Case 1

An 81-year-old male with a history of hypertension, hyperlipidaemia, and former smoker underwent a cardiac catheterization for evaluation of severe CAD manifested as atypical angina and syncope suspicious for ventricular tachycardia. His physical exam revealed normal blood pressure and heart rate. There was no jugular venous distension. Cardiac exam showed normal heart sounds. His electrocardiogram showed sinus rhythm with right bundle branch block. Echocardiogram showed basal to mid-anterolateral and inferolateral wall hypokinesia with an ejection fraction of 50–55%. Coronary angiogram revealed heavily calcified proximal to mid-left anterior descending coronary artery (LAD) 90% stenosis as well as a 90% stenosis in the diagonal 1 branch. He also had 50–60% stenosis in the mid and distal right coronary artery.

We first used orbital atherectomy 1.25 mm burr in the proximal and mid-LAD. After three rounds of atherectomy, angiography revealed significant residual stenosis (*Figure 1*). We then performed balloon angioplasty with an over the wire compliant balloon 2.5 mm $\times$ 15 mm. Intravascular ultrasound (IVUS) catheter placement was attempted; however, it could not cross proximal LAD due to heavy calcification. We then used a non-compliant 3.0 mm $\times$ 15 mm balloon with multiple high-pressure dilatations, but we still could not break residual calcified disease. Therefore, we then elected to use a peripheral Shockwave 3.5 mm $\times$ 40 mm lithotripsy balloon and inflated up to 4 atm and 20 pulses followed by another 40 pulses at 6 atm. Then, we were finally able to advance the IVUS catheter, which revealed 270° heavily calcified vessel with successful full thickness fractures associated with hinge motion in the proximal and mid-LAD (*Figure 2*). We then were able to deploy two Everolimus 2.75 mm and 3.0 mm drug-eluting stents (DES) in the mid- and proximal LAD, respectively (*Figures 3* and *4*) with excellent angiographic result. Patient was followed up on 14 March 2019 and has been doing well.

Case 2

A 79-year-old female underwent a cardiac catheterization due to acute coronary syndrome presentation. Catheterization showed

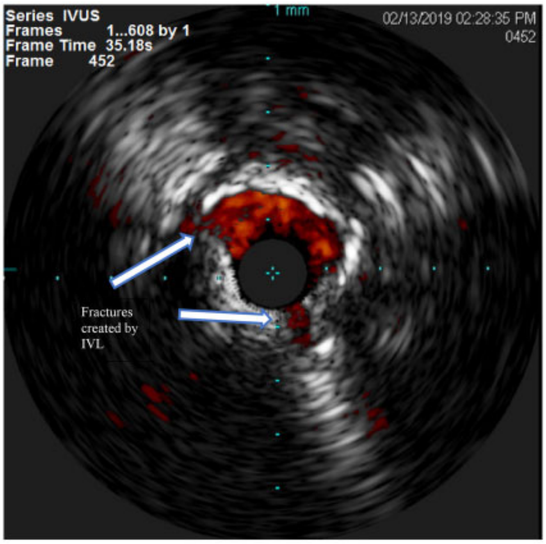

Figure 2 Case 1: IVUS post-IVL. IVUS, intravascular ultrasound; IVL, intravascular lithotripsy.

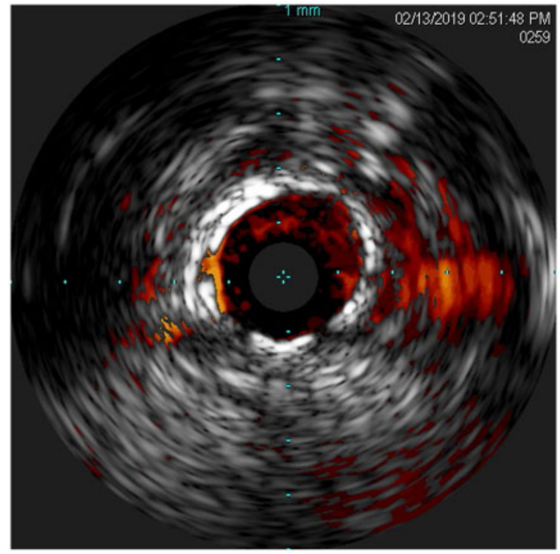

Figure 4 Case 1: IVUS post-stenting. IVUS, intravascular ultrasound.

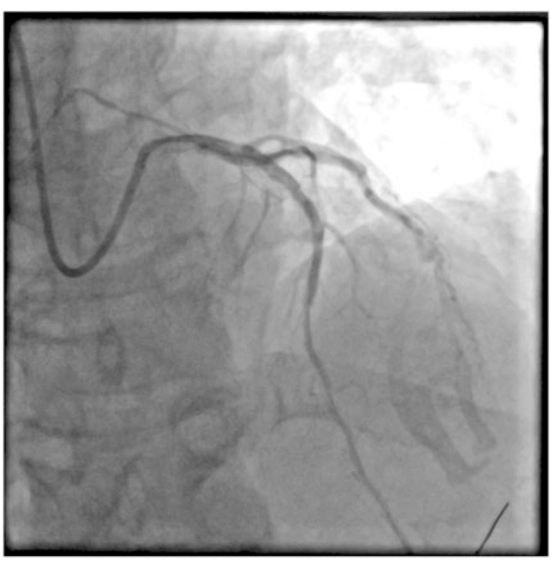

Figure 3 Case 1: post-intervention angiogram.

Figure 5 Case 2: pre-intervention angiogram.

occluded mid-left circumflex and severe calcified residual stenosis in the LAD. She underwent intervention of the left circumflex coronary artery. She was subsequently brought to the catheterization lab for staged intervention of the LAD; however, the intervention was unsuccessful despite orbital atherectomy and angioplasty. Her vital signs were normal and cardiac physical exam revealed normal heart sounds. Electrocardiogram showed sinus rhythm with no significant abnormalities prior to ensuing attempt to intervene the LAD. Angiography revealed proximal to mid-95% severely calcified stenosis in the LAD (*Figure 5*). We wired the LAD with a regular workhorse wire, then IVL was performed with a 3.5 mm × 40 mm balloon. A total of 40 pulses were delivered. Intravascular ultrasound was performed which showed a remnant 87% proximal stenosis with a minimal luminal area of 1.9 mm^2; however, significant full-thickness

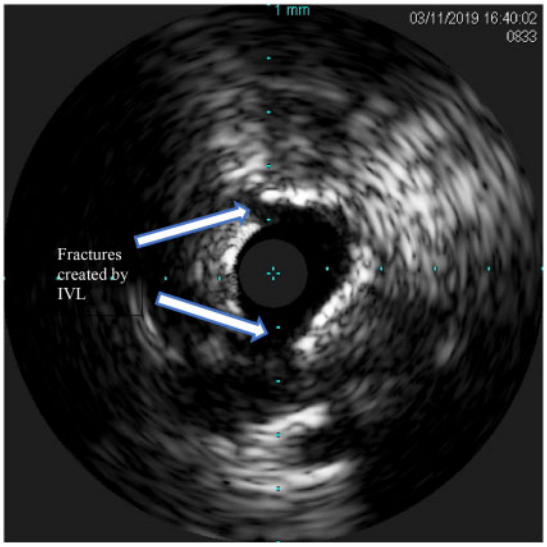

Figure 6 Case 2: IVUS post-IVL. IVUS, intravascular ultrasound; IVL, intravascular lithotripsy.

Figure 7 Case 2: post-intervention angiogram.

fracturing of the concentric calcification associated with a hinge motion was noted (*Figure 6*). Balloon angioplasty was then performed with a non-compliant 3.0 mm × 20 mm balloon distal to proximal. Stenting was then performed with an everolimus 3.0 mm × 38 mm DES (*Figure 7*). Repeat IVUS was performed which showed a post-minimal stent area of 4.3 mm^2. Post-dilation was performed by a non-compliant 3.5 mm × 15 mm balloon. Repeat IVUS was performed which showed luminal area had increased to 5.2 mm^2 in the area of the tightest lesion (*Figure 8*). Patient was followed up on 9 April 2019 and has been doing well.

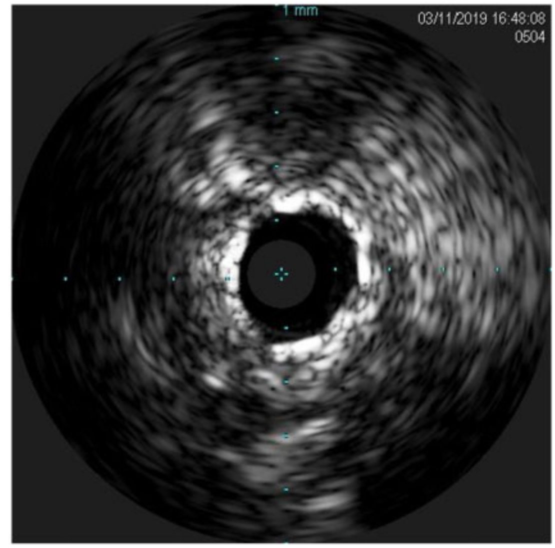

Figure 8 Case 2: IVUS post-stenting. IVUS, intravascular ultrasound.

Discussion

Shock wave technology has been used safely for urological lithotripsy in treating urolithiasis for several decades. The system consists of a generator, a connector cable, and a catheter that houses an array of lithotripsy emitters enclosed in an integrated balloon. The generator produces energy that travels through the connector cable and catheter to the lithotripsy emitters located near the calcified lesion. With the integrated balloon expanded to ultra-low pressure, a small electrical discharge at the emitters vaporizes the fluid within the balloon, creating a rapidly expanding bubble that collapses within microseconds. The bubble's expansion and collapse generate a series of sonic pressure waves up to 50 atm that travel through the fluid-filled balloon and pass through soft vascular tissue, selectively cracking any hardened calcified plaque inside the vessel wall. After the calcium has been fractured, the integrated balloon can be expanded, performing angioplasty safely at low pressures. Peripheral IVL balloons are available in the USA from 3.5 mm with 0.5 mm increment up to 7 mm in diameter with the capability of total of 180 pulses of 50 atm pressure waves delivery for treatment of calcific PAD.[6]

Current modalities such as balloon angioplasty either with non-compliant or scoring or cutting balloon, rotational atherectomy, and orbital atherectomy are being used widely for lesion preparation prior to stent deployment. However, they all have certain limitations such as requirement of device-specific wires, inability to protect side branch by additional wire, high risk of perforation or dissection, higher rate of no-reflow phenomena, steep learning curve, to name a few.

Using IVL balloons to treat complex calcified vessels can be simpler and safer but, they also have limitations such as limited availability of sizes, their bulkiness, and poorer deliverability compared to coronary dedicated balloons. The smallest size peripheral IVL currently available in the USA is 3.5 mm × 40 mm balloon. However, in our limited experiences, this balloon appears to be used safely in angiographically smaller appearing coronary arteries such as shown in our series because balloon needs to be inflated only to ultra-low pressures just enough to have the balloon surface to touch the coronary lumen and the bulk of the job of cracking the heavily calcified lesions are done by shock waves transmitted through the fluid-filled lumen of the balloon, delivering 50 atm powerful shock waves. We have not seen any significant dissection outside of the target lesions; however, caution and judicious usage are warranted to use this device to smaller vessels. Poor deliverability due to the bulkiness of the balloon sometimes requires preparation by orbital or rotational atherectomy to facilitate the IVL delivery.

The two cases we presented illustrate the feasibility and limited safety for using a 3.5 mm peripheral IVL device to treat severely calcified coronary artery stenosis using peripheral IVL balloons. Although, definitive conclusions regarding its potential advantage over other technology cannot be inferred from these case reports, we can speculate certain potential advantages over other technology for treating calcified coronary lesions, particularly atherectomy devices.

These advantages and the potential efficacy and safety of IVL for treating calcified coronary stenosis remain to be proven in future randomized clinical trial. DISRUPT-CAD III is an ongoing trial, that is likely to provide insight into this missing information on the safety and efficacy of using coronary IVL as a tool to treat complex CAD.[7] Till the results of such trials are available and the use of coronary IVLs approved for use in treating calcified coronary lesions, the peripheral IVL may have the potential for being used judiciously in selected cases as an alternative for treating heavily calcified coronary arteries.

Conclusions

Patients with heavily calcified coronaries remain to be a challenging cohort with regards to PCI success. Despite the availability of various devices in plaque modification, PCI success and outcomes remain suboptimal for calcified compared to that for non-calcified coronary lesions. Intravascular lithotripsy may have the potential as a promising tool in treatment of these lesions. While we demonstrated the feasibility and limited safety of this technique for treating calcified coronary stenosis, results of ongoing clinical trial are likely to guide the future uptake of this technology in contemporary clinical practice in the community at large.

Lead author biography

Dr. Karthik Mekala is an Interventional Cardiologist in Christus Good Shepherd Medical Center, Longview, Texas. He is a member of American College of Cardiology. Dr. Mekala is Board Certified in Internal Medicine, Cardiovascular Diseases, Echocardiography and Nuclear Cardiology.

Supplementary material

Supplementary material is available at *European Heart Journal - Case Reports* online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The author/s confirm that written consent for submission and publication of this case report including image(s) and associated text has been obtained from the patients in line with COPE guidelines.

Conflict of interest: none declared.

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