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# Shockwave intravascular lithotripsy and drug-coated balloon angioplasty in calcified coronary arteries: preliminary experience in two cases

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Heavily calcified coronary arteries are extremely difficult to treat as calcium deposits "hardens" the arteries and alter vascular compliance. Intravascular lithotripsy (IVL) is a new technology consisting of a balloon-based system with miniaturized lithotripsy emitters that create a localised field effect to crack calcium in the arterial wall. Drug-coated balloon (DCB) angioplasty is an alternative treatment option in percutaneous coronary intervention (PCI) with an attractive strategy of leaving nothing behind combined with local drug delivery. In this brief clinical report, we described our early experience of using a novel combination of IVL and DCB angioplasty in two elderly patients with good angiographic results.

Case 1. An 81-year-old male with history of inferior myocardial infarction and previous PCI to right coronary artery (RCA) presented with unstable angina. He has history of diabetes mellitus, hypertension and hyperlipidemia. Echocardiogram showed preserved left ventricular function. Coronary angiography showed widely patent stent in RCA, moderate stenosis in left circumflex artery and significant diffuse stenosis (70%–80%) in the proximal to distal segments of the left anterior descending (LAD) artery (Figure 1A). There was heavy calcification in the proximal-mid LAD segment observed on X-ray fluoroscopy (Figure 1B).

Option of coronary artery bypass surgery was discussed but he refused due to his advanced age. We then proceeded with PCI of LAD. Intravascular ultrasound (IVUS) imaging showed arcs of calcification > 270° (Figure 1C) along these segments. Lesion preparation of the diffuse LAD lesions were performed with the Scoreflex scoring balloon, 2.0 mm × 15 mm. In view of the heavy calcification in the proximal-mid LAD segment, these lesions were treated with the Shockwave Lithotripsy balloon, 3.0 mm × 12 mm (Shockwave Medical Inc, Santa Clara, California, USA) for a total of 80 pulses (Figure 1D). IVUS also showed fracture of the calcified plaques (Figure 1E) with acute gain in minimal lumen area (> 5.0 mm$^2$) in proximal-mid LAD segments. Mid to distal LAD segment was treated with the 2.0 mm × 30 mm Agent DCB (Boston Scientific, Natick, Massachusetts, USA). Proximal-mid LAD calcified segment (Figure 1F) was subsequently treated with the 3.0 mm × 30 mm Agent DCB which was inflated at 7 atmosphere for 60 s. Final angiogram (Figure 1G) showed good angiographic results in LAD with residual stenosis of 30%, no overt dissection and Thrombolysis in Myocardial Infarction (TIMI) 3 flow. There was no acute vessel closure and post PCI complications.

Case 2. A 74-year-old female with history of diabetes mellitus, hypertension and hyperlipidemia presented with anginal symptoms. Myocardial perfusion scan showed perfusion defects in the LAD territory. Total calcium score was 986 with LAD having the highest burden of 683. Echocardiogram showed impaired left ventricular function, ejection fraction of 40%.

Coronary angiography (Figure 2A) showed 70%–80% stenosis in mid LAD segment which was heavily calcified and there was moderate 50% stenosis in ostial left circumflex artery. Mid RCA was totally occluded and received collaterals from left coronary system. Coronary artery bypass surgery was offered to patient but she refused. PCI was then

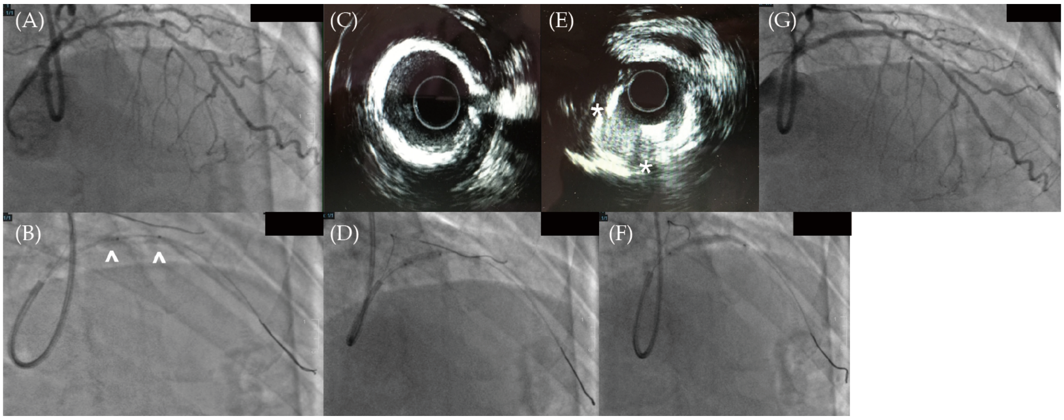


**Figure 1 Coronary angiography results.** (A): Baseline angiography of LAD; (B): baseline angiography of LAD on X-ray fluoroscopy (heavy calcification denoted by small arrows); (C): IVUS of LAD showing concentric ring of calcium; (D): shockwave IVL of calcified LAD segment; (E): post IVL IVUS showing cracks (denoted by pentagram) in calcified plaque; (F): drug-coated balloon angioplasty of proximal-mid LAD segment; and (G): final angiography of LAD. IVL: intravascular lithotripsy; IVUS: intravascular ultrasound; LAD: left anterior descending artery.

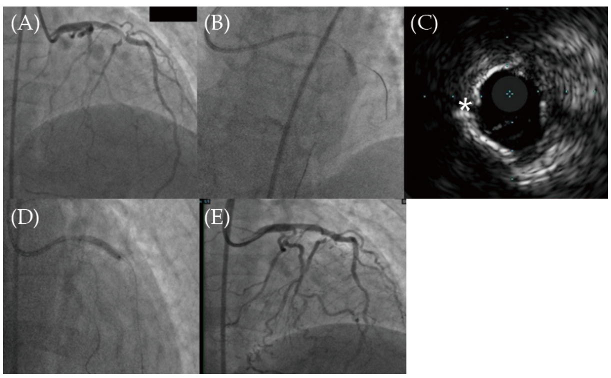


**Figure 2 Coronary angiography results.** (A): Baseline angiography of LAD; (B): shockwave IVL of calcified mid LAD segment; (C): post IVL IVUS showing crack (denoted by pentagram) in calcified plaque; (D): drug-coated balloon angioplasty of mid LAD segment; and (E): final angiography of LAD. IVL: intravascular lithotripsy; IVUS: intravascular ultrasound; LAD: left anterior descending artery.

performed to LAD. Attempted to perform IVUS imaging but the catheter could not advance past the mid LAD calcified segment. Lesion preparation of the LAD lesion was performed with the non-compliant balloon, 2.5 mm × 15 mm. This was followed by the use of Shockwave Lithotripsy balloon, 3.0 mm × 12 mm (Shockwave Medical Inc, Santa Clara, California, USA) for a total of 50 pulses (Figure 2B) and further plaque modification with Scoreflex scoring balloon, 2.75 mm × 15 mm.

IVUS pullback was successfully performed and it showed fracture of the calcified plaques (Figure 2C) with minimal lumen area of > 6.0 mm$^2$ in the mid LAD segment.

Mid LAD segment was treated with the 3.0 mm × 20 mm Sequent Please DCB (B Braun, Melsungen, Germany) (Figure 2D) which was inflated at 8 atmosphere for 50 s. Final angiogram (Figure 2E) showed good angiographic results in LAD with residual stenosis of 30%, no overt dissection and TIMI 3 flow. There was no acute vessel closure and post PCI complications.

To our knowledge, these are the first two reported cases of successful use of a novel combination of IVL and DCB angioplasty for treatment of calcified coronary arteries. Both elderly patients remained clinically well on 15 months of follow-up.

PCI of calcified lesions are often associated with higher rate of periprocedural complications, restenosis and long term adverse events. Studies have shown that the higher calcium burden in the coronary arteries,[1,2] adequate stent expansion may not be achieved. This can result in increased rates of restenosis and stent thrombosis.

The existing devices used to treat heavily calcified coronary arteries include cutting balloons and atherectomy devices with the diamond coated burr/crown.[3,4] Cutting balloon has limited capacity to treat heavily calcified arteries whereas atherectomy devices are associated with complications like coronary perforation, no reflow and death.

There is a clinical need to use a novel technology like IVL to treat heavily calcified arteries in an efficacious and much safer manner.[5,6] IVL utilizes pulsatile mechanical energy to disrupt calcified lesions with adaptation of the technology used in lithotripsy of renal stones. The safety and feasibility of IVL for modification of severely calcified coronary vessels was demonstrated in the Disrupt CAD I and Disrupt CAD II studies (Disrupt Coronary Artery Disease).[7,8] IVL was safely performed with high procedural success, minimal complications and resulted in substantial calcific plaque fracture in most lesions.

Paclitaxel-based DCB has emerged as a feasible treatment option in PCI with an attractive strategy of leaving nothing behind.[9] There is accumulating evidence to support its use in de-novo lesions and high bleeding risk patients.[10,11] DCB has several advantages over drug-eluting stent as it inhibits excessive neointimal hyperplasia following balloon angioplasty without leaving the permanent metallic frame, eliminate the risk of stent thrombosis and reduce the duration of dual anti-platelet therapy.

Our novel "all-balloon" approach of combining the use of IVL and DCB angioplasty in PCI is based on the principles of lesion modification and local drug delivery on lesion site. There has been some precedent in this approach as there were prior studies which evaluated the use of rotablation and DCB angioplasty in calcified coronary vessels.[12,13] Preliminary results were favorable and showed that debulking of calcified plaques by rotablation followed by DCB angioplasty was safe and feasible. Although we have shown that the novel combination of IVL and DCB angioplasty is feasible, more data are required to establish the long term safety and efficacy of this approach in calcified coronary vessels.

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