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Editorial

Use of Shockwave in Heavily Calcified Coronary Lesion: Breakthrough or Myth?

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▸ See the article "Coronary Intravascular Lithotripsy Versus Rotational Atherectomy in an Asian Population: Clinical Outcomes in Real-World Patients" in volume 52 on page 288.

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One-third of patients with coronary artery disease have calcified lesions.[1] Especially heavily calcified coronary lesion is a huge obstacle in current coronary intervention because of difficulties in dilating the lesions. Adjunctive balloon dilation with non-compliant, scoring or cutting balloon is initial choice to modify the lesions but these adjunctive balloons are sometimes not effective and deliver intense pressure on coronary vessel wall with potential risk of perforation or rupture. Modifying tool like orbital or rotational atherectomy is another treatment option, however it has many limitations such as high rates of serious procedural complexities and periprocedural complications. The atherectomy techniques with specialized equipment such as Rotablator, rotational atherectomy system (Boston Scientific, Marlborough, MA, USA) and Diamondback 360, orbital atherectomy system (CSI, St. Paul, MN, USA) require a learning curve and a skillful team. Transient atrioventricular block, slow coronary flow, dissection, perforation and closure are serious adverse events in atheroablative procedure.[2]

The latest advance in these devices to treat severely calcified lesion is Shockwave Intravascular Lithotripsy (S-IVL) System with the Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter (Shockwave Medical, Inc., Santa Clara, CA, USA).[3] The US Food and Drug Administration (FDA) has announced the S-IVL System for the treatment of severely calcified coronary artery lesions in 2021. The peripheral lithotripsy system was already cleared by the FDA in 2016 for use in peripheral arterial disease patients with severely calcified lesion. This system consists of the Shockwave C2 Coronary IVL Catheter, IVL Connector Cable, and IVL Generator. The catheter is a device called a balloon catheter that contains integrated lithotripsy emitters, which can breakdown hard components (calcification) that reduces coronary blood flow.[3] S-IVL is used before implanting a stent, to open the coronary arteries that are narrowed or blocked due to severe calcification. The generator is connected to the balloon catheter that has multiple wave transmitters and is working in artery with diameter of 2.5 to 4.0 mm and 12 mm length. The balloon catheter delivers 10 pulses in sequence at a frequency of 1 pulse/second for a maximum of 80 pulses per catheter. It is placed through the calcification and inflated with low pressure (usually 4 atm).[3]

FDA approval was due to results from DISRUPT CAD trials. Especially in the DISRUPT CAD III trial, procedural success was achieved in 92.4% of patients and was limited mainly by

Data Sharing Statement
The data generated in this study is available from the corresponding author(s) upon reasonable request.

in-hospital major adverse cardiovascular event (MACE) (7.0%). After one year, approximately 75% of patients had survived without a heart attack or additional procedure.[4]

Patient-level pooled analysis of the disrupt CAD studies showed the cumulative safety and effectiveness of coronary IVL.[5] The 628 patients were enrolled at 72 sites from 12 countries. Presence of severe calci\xef\xac\x81cation was con\xef\xac\x81rmed in 97.0% of target lesions. The safety endpoint of 30-day MACE (cardiac death, all myocardial infarction, target vessel revascularization) was 7.3% and the effectiveness endpoint, procedural success was achieved in 92.4% of patients. These findings were consistent across all 4 disrupt CAD studies.[5] Aksoy et al.[6] revealed a high success rate (84.6%, calcified de novo lesions) and low procedural complications (no in-hospital MACE and no perforation) in prospective observational registry from Germany. High strategic success rate (90%) and high in-hospital mortality (6%) were reported in retrospective study from Singapore center.[7]

In this issue of the journal, Wong et al.[8] reported the comparisons between their initial IVL experience and rotational atherectomy in high-risk real-world patients for heavily calcified coronary lesions. The issue of S-IVL in coronary intervention would be attractive and the originality of this study would be enough, because very few data were available regarding impact of IVL in Asian population and especially patients with high risk for coronary intervention. They enrolled patients with acute coronary syndrome (56.6%), acute heart failure (17%), end stage renal disease on dialysis (18.9%) and left main coronary arterial lesions, who were excluded from DISRUPT CAD III and IV. This initial IVL experience showed comparable in-hospital adverse outcomes in patients treated with IVL and rotational atherectomy and worse 30-day MACEs with IVL. There are many critical limitations in this study. As authors have mentioned, this is result from the initial experiences of the operators and the small study population made it difficult to interpret the results. A bail-out use of IVL in this complex coronary intervention as adjunctive therapy seemed result in worse outcomes inherently.

Although the small numbers and retrospective nature of this study preclude definitive conclusions, the study by Wong et al.[8] provides valuable insights about the use of IVL in Asian population and patients with heavily calcified high risk coronary lesion. This early experience showed restricted use of the device and more complex lesion were inevitable because of financial constraints and bail-out situations. It is essential to select guide catheter and wire with strong back up support to overcome poor trackability and deliverability of IVL due to its high profile (0.044 inch for a 3.0 mm balloon catheter). In this study they reported 7 patients required adjuvant rotational atherectomy. In 6 out of these 7 patients, IVL which was performed after RA alone had failed to achieve adequate lesion preparation.

In conclusion, the results of this study would be inconclusive due to many critical limitations. However, their early experience in patients with higher risk provides acceptable efficacy of this brand-new device and use with caution to reduce safety concerns.

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