Received: 17 December 2018 | Revised: 20 March 2019 | Accepted: 5 April 2019
DOI: 10.1002/ccd.28287

CASE REPORT

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Coronary lithotripsy for failed rotational atherectomy, cutting balloon, scoring balloon, and ultra-high-pressure non-compliant balloon

Giuseppe Venuti MD | Guido D'Agosta MD | Corrado Tamburino MD, PhD | Alessio La Manna MD

Division of Cardiology, C.A.S.T., Azienda Ospedaliero-Universitaria "Policlinico- Vittorio Emanuele," University of Catania, Catania, Italy

Correspondence
Alessio La Manna, MD, Division of Cardiology, C.A.S.T., Azienda Ospedaliero-Universitaria "Policlinico-Vittorio Emanuele", University of Catania, Catania, Italy, P.O. Gaspare Rodolico, Pad. 8, Via S. Sofia 78, 95125 Catania, Italy.
Email: lamanna.cardio@gmail.com

Abstract

Calcified and undilatable stenosis still represents a challenge in percutaneous coronary interventions (PCI), due to the higher risk of suboptimal result with consequent worse clinical outcomes. Unfortunately, the dedicated technologies and devices, such as specialized balloon and atherectomy systems, do not always provide adequate plaque modification and optimal vessel preparation allowing optimal stent delivery. The intravascular lithotripsy (IVL) is a technology derived from urology that has been tested in peripheral and coronary calcified plaques, with promising preliminary results. We present a case of a patient undergoing planned PCI of the right coronary artery targeting an undilatable lesion, already resistant to both specialized balloons and rotational atherectomy. Using the IVL system, we were able to break the calcium, guarantying optimal stent expansion with good final result.

KEYWORDS
CTO, intravascular lithotripsy, severe calcified lesions

1 | INTRODUCTION

Severely calcified and undilatable lesions are one of the most challenging subsets in percutaneous coronary interventions (PCI), for which the optimal remedy remains demanding.

Calcified stenosis are associated with higher rates of acute and long term stent failure with adverse impact on PCI outcomes; therefore, adequate lesion preparation is pivotal for optimal long term results.[1] Currently, the dedicated devices available on the market include cutting balloons (CB) (The Flextome™ CB™, Boston Scientific, Marlborough, MA), scoring balloons (SB) (AngioSculpt® SB, Spectranetics, Colorado Springs, CO), super high-pressure non-compliant (NC) balloons (OPN, SIS Medical AG, Winterthur, Switzerland), and coronary atherectomy systems.

However, widespread use of these methods is limited due to risk of complications, degree of technical difficulty, operator experience, and cost.

In this scenario, intravascular lithotripsy (IVL) has been rising as a new, user-friendly, and promising technique aiming to overcome limitations of the current devices. The IVL system emits circumferential mechanical energy that disrupts the calcium, minimizing soft tissue injury while aiding stent deployment.[2]

2 | CASE REPORT

A 67-year-old gentleman with history of hypertension, hyperlipidaemia, smoking habit and diabetes as risk factors, mild left ventricular dysfunction, and known coronary artery disease, was admitted at our Institution due to a planned PCI of right coronary artery (RCA).

In 2013, the patient underwent chronic total occlusion PCI of RCA (Figure 1A). A retrograde approach based on reverse CART technique was successfully performed, and two drug eluting stents (DES) were deployed at the distal segment. Despite aggressive NC balloons

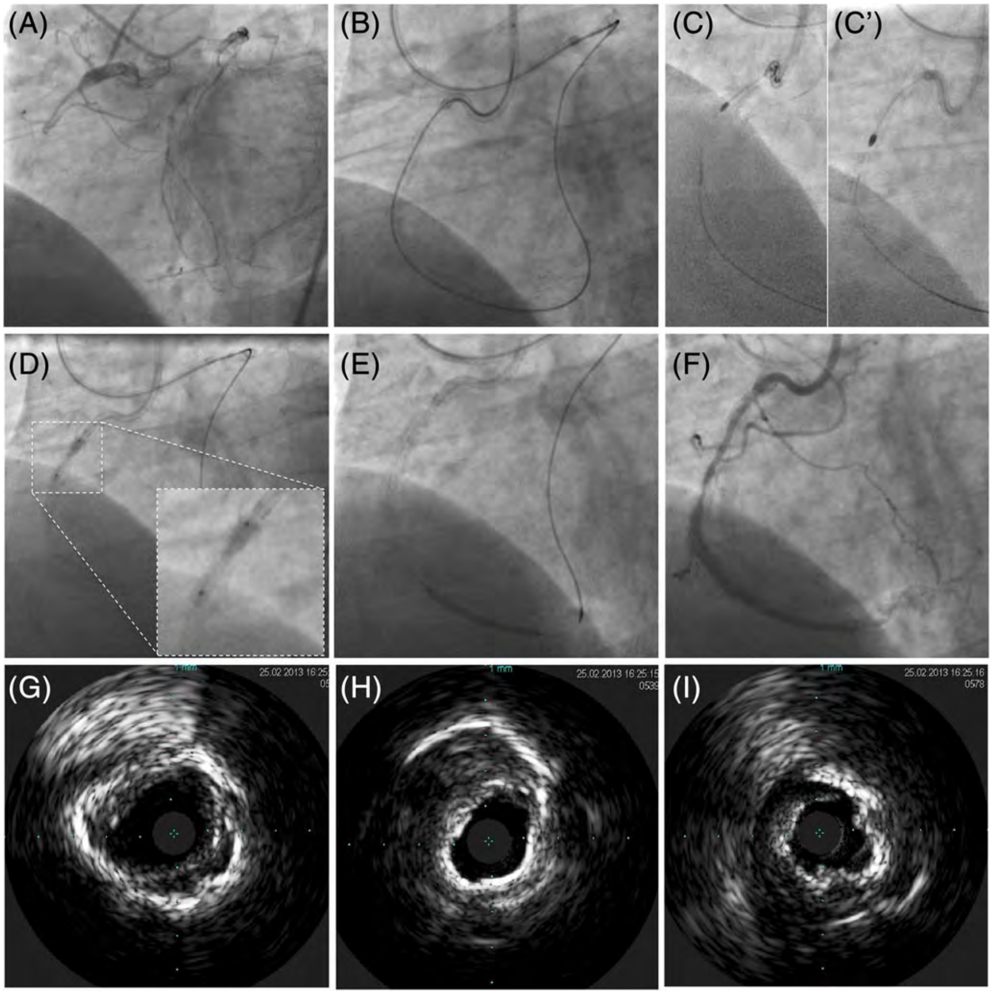

FIGURE 1 (A) Right coronary artery chronic total occlusion. Retrograde approach was performed successfully (B). Lesion preparation was inadequate despite rotablation (1.50 [C] and 1.75 [C′] burr) and 3.5 mm non-compliant balloon resulting in "dog boning effect" (D). Post-rotablation imaging showed calcium rings at the site of the undilatable stenosis (G–I). Two drug eluting stents were then deployed distally (E) with residual severely calcified stenosis at the mid-proximal segment (F) [Color figure can be viewed at wileyonlinelibrary.com]

treatment and plaque modification with rotational atherectomy (RA) with 1.50 and 1.75 burrs that correctly crossed the lesion, an undilatable stenosis remained at the mid-proximal segment. (Figure 1B–F). Post-RA intravascular ultrasound (IVUS) pullback showed rotablation therapy failure with residual concentric calcium deposits (Figure 1G–I).

Again, in 2014 and 2015, the patient was readmitted at our center due to effort angina and underwent re-PCIs of the RCA. Summarizing the two procedures, repeated high-pressure inflations (up to 40 atm) with 3.5 mm OPN balloon and plaque modification strategy with 3.0 and 3.5 mm SB, 2.5 and 3.0 mm CB, and 1.75 and 2.00 mm burrs RA were used unsuccessfully for the undilatable stenosis. During the 2014 procedure, a DES was deployed proximal to the undilatable lesion.

In 2018, the IVL became available for coronary treatment in our institution; therefore, a new PCI on the RCA was planned. The patient was admitted on August 2018, still suffering from effort angina (Canadian Cardiovascular Society class III). The baseline angiogram showed heavily calcified residual stenosis at the mid-proximal segment (Figure 2A).

An AL 2 guiding-catheter engaged the RCA ostium, and a workhorse guide-wire was advanced till posterior descending artery. A 3.0 × 12mm Shockwave (Medical Inc. Fremont, CA) IVL balloon catheter was positioned to the target lesion and dilated up to 4 atm followed by the emission of pulsatile mechanical energy (4 runs, 10 pulses per run) (Figure 2B); the subsequent angiogram showed apparently no significant difference compared to the baseline (Figure 2C). At that point, as our default strategy for heavily calcified lesions, we used a 3.5 mm OPN balloon showing optimal expansion already at the pressure of 12 atm (Figure 2D). IVUS was then performed, clearly showing broken calcium rings at the targeted segment (Figure 2H–J). Three overlapping DESs (3.5 × 38, 4.0 × 24, and 5.0 × 12mm), from the distal segment to the ostium, were finally deployed and post-dilated with 4.0 mm NC balloon with good final result (Figure 2E–G). No in-hospital events were recorded. The patient was free from angina at 3-month follow up.

3 | DISCUSSION

Severely fibro-calcified coronary lesions have traditionally represented a very demanding subset for PCI.

Commonly, the main issue related to heavily calcified lesions is the challenging lesion preparation that is related to suboptimal stent delivery and expansion and struts malapposition, which represent the

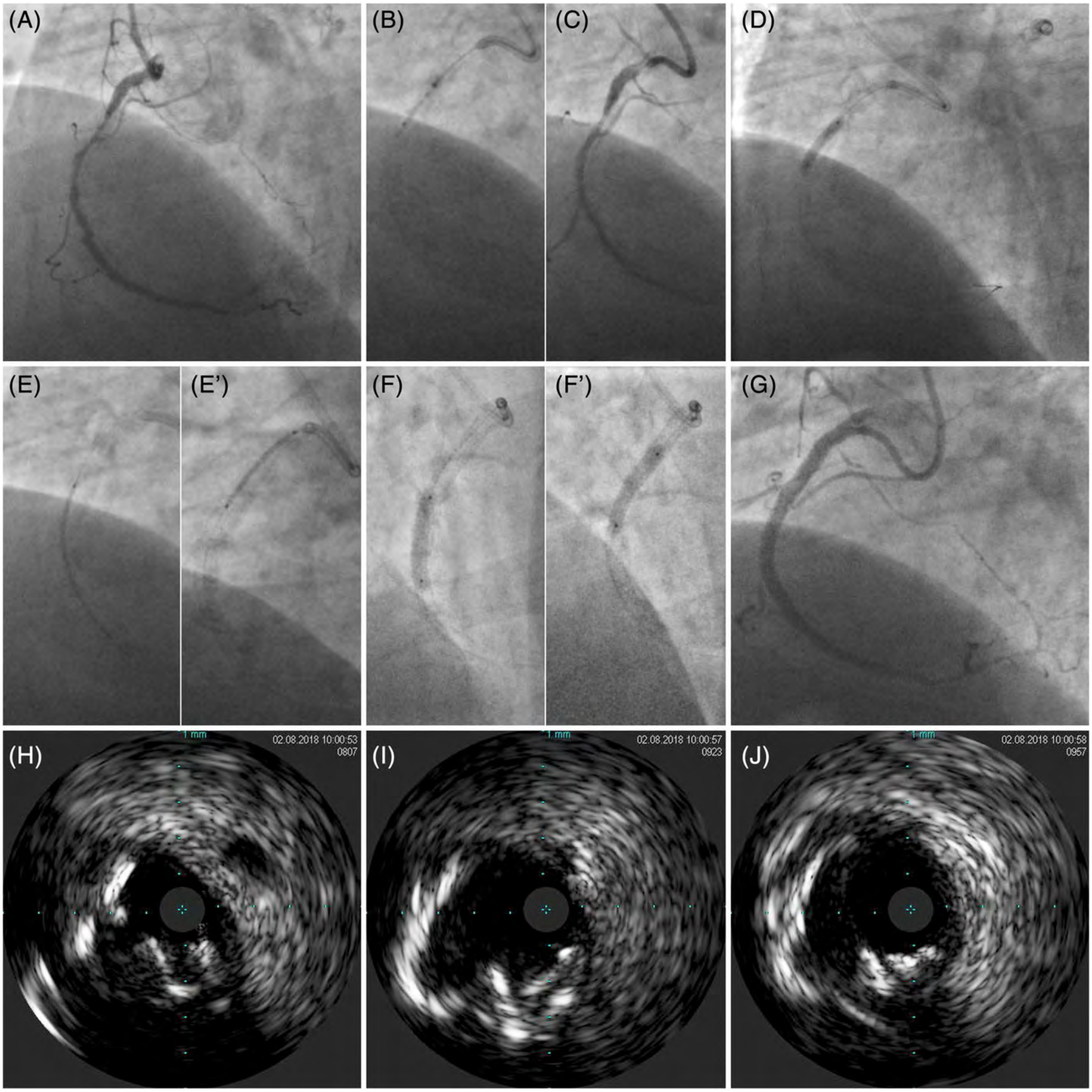

FIGURE 2 (A) Right coronary artery with heavily calcified residual stenosis at the mid-proximal segment. Intravascular lithotripsy (B) with 3.0 mm balloon catheter was performed. Although the subsequent angiogram (C) showed apparently, no significant difference compared to the baseline, the following dilation with 3.5 mm OPN balloon was successful (D). Moreover, imaging showed calcium rings breakage (H–J). Three overlapping drug eluting stents were then implanted (E, E′) and optimized with 4.0 mm non-compliant balloon post-dilatation (F, G), with excellent final result (H) [Color figure can be viewed at wileyonlinelibrary.com]

triggers of higher rates of stent thrombosis, in-stent restenosis (ISR), and target lesion revascularization.[1]

When heavily calcified lesions are resistant to multiple high-pressure inflations with conventional balloons, the adjective "undilatable" is commonly used. Moreover, balloon undilatable lesions can be also balloon "uncrossable," which means that cannot be crossed with a balloon after successful guidewire crossing. Therefore, dedicated devices, ranging from specialized balloons to atherectomy devices, have been designed.

Either de novo or ISR lesions can be heavily calcified and suitable for debulking treatment, although with some cautions. On the one hand, orbital atherectomy (OA) is discouraged in the setting of ISR lesions, whereas laser atherectomy (ELCA) is attractive in ISR but underused in de novo lesions due to the risk of dissections or perforations. On the other hand, RA is effective in both settings, although is related to higher risk for complications in ISR.[3,4] Furthermore, intravascular imaging plays an essential role in the management of calcified lesion, providing pivotal information including calcium deposits location and distribution, optimal/suboptimal vessel preparation, stent sizing, and optimization.[3]

Between 2013 and 2015, the dedicated devices available at our unit were OPN balloon, CB and SB, and RA. All of them were used repeatedly and unsuccessfully in our report.

The rationale of OPN in heavily calcified lesions consists in massive vessel dilatation and calcium breakage due to its tolerance to very high pressure. It was designed for very high pressures inflation with uniform expansion, aiming for virtually very low dog—boning effect and reduced risk of vessel injury. The major device limitation is its high profile that may compromises recrossing attempts. The OPN can be used for both lesion preparation and post-dilatation purpose with safe and effective results also in undilatable lesions.[5,6]

Conversely, CB and SB modify the plaque with microblades and abrasive surfaces, respectively, which cause calcium dissection allowing further expansion with conventional balloons.

CB balloon catheter is armed with three/four microblades mounted on the outer surface. The balloon may be delivered with difficulty due to its high crossing profile. During dilation, the device scores into the plaques creating endovascular radial breaches through the tissue. CB angioplasty is more effective in reducing plaque burden and acute lumen gain in calcified lesion setting compared to plain old balloon angioplasty (POBA).[7] Perforation and blade entrapment are the most feared complications with CB angioplasty.[7]

SB consists of a semi-compliant balloon, surrounded by three nitinol spiral scoring wires. This device has increased deliverability and crossing profile compared to CB. The controlled expansion of the balloon reduces the risk of barotrauma and critical coronary dissection and perforation, and moreover, it helps to prevent balloon slippage and allows higher inflation pressures. Different studies proved the SB performance and safety in different complex scenarios, with satisfying results.[3] CB and SB cut and score the plaque acting mainly on its surface, resulting ineffective in case of deeper calcium deposit.

Atherectomy modifies the calcific plaques by lasing or diamond-surfaced burr rotation with increased probability of better luminal gain and complete balloon and stent expansion.[3,8]

The atherectomy devices currently available are: RA, OA, and ELCA.

Since the 1990, The Rotablator® system (Boston Scientific) has been the most used atherectomy device worldwide and its functioning is already well-known.[3] Recently, Boston Scientific has presented the new generation of RA system, the ROTAPRO™, which seems more use-friendly compared to the old generation, indeed the pedal is no more needed due to the controls that are localized on the advancer.

Contemporary observational studies and registries have demonstrated favorable results of DES implantation in heavily calcified lesions after lesion preparation with RA, although no randomized trials are available that demonstrated superiority of RA versus conventional balloon lesion preparations.[3,8]

However, atherectomy does not always provide adequate plaque modification, especially in case of thick, deep or eccentric calcifications.[9,10] Moreover, RA is also associated with potentially serious complications including slow/no-flow phenomenon, vessel dissection, or perforation.[3] Therefore, interventional cardiologists may still face undilatable lesions that cannot be effectively treated despite any attempt with current conventional devices.

In this scenario, recently transferred from urology to the vascular setting, the Shockwave Medical Rx Lithotripsy System may represent the ultimate solution. IVL consists of three main components: IVL catheters, connector cables and a generator. The balloon catheter-based device has radiopaque markers to guide positioning and is mounted with a 12 mm length balloon in seven balloon sizes ranging from 2.5 and 4.0 mm in diameters with increments of 0.25 mm. The catheter utilizes sonic pressure waves to disrupt both intimal and medial calcium. The connector cable mediates connection between the catheters and the IVL generator. Once delivered, IVL catheter is expanded to 4 atm. A button command initiates the emissions along the balloon of settled level of pulsatile mechanical energy (one pulse for second for 10 seconds) creating a series of fractures, increasing the likelihood of complete balloon dilatation to reference vessel size and full stent expansion. A maximum of eight therapy cycles can be delivered per catheter. For lesions longer than 12 mm, the catheter needs to be repositioned to treat the full lesion. As evidenced, the energy released induces circumferential calcium modification. The calcium fragments remain in situ avoiding microvascular impairment.[2] The performance and the safety of this technology were evaluated in the DISRUPT CAD trial (multicentre, prospective, single-arm study), whose results showed 95.0% clinical success. Stent apposition was achieved in 100% of the cases with reduction in residual stenosis to less than 50% in all patients despite more than 90% having moderate or severe calcifications. There were no major intraprocedural complications. MACE rates at 30-day and 6 months were 5% and 1.7%, respectively.[11] IVL seems to be safe and effective for the treatment of undilatable coronary lesions, although balloon rupture and vessel dissections may occur.[12]

Recently, Tajti et al. created an algorithm including all devices and techniques available for the management of undilatable stenosis in CTO PCI.[4] According to that algorithm, ELCA could have been a valid tool in such a case for plaque modification, although not available in our institute. Moreover, subintimal lesion crossing and NC balloon plaque "crushing," similar to the so called "external cap crush" technique for uncrossable lesions could have been attempted at the time of CTO PCI.[13]

4 | CONCLUSION

Notwithstanding the availability of different dedicated devices, undilatable coronary lesions still remain a difficult subset of stenosis with higher rates of acute and long-term failures.

As demonstrated in our case, IVL may represent a new alternative tool for the treatment of undilatable lesions, overcoming the limitations of already existing technology.

ACKNOWLEDGMENT

We would like to show our gratitude to Professor Masahiko Ochiai (MD, Showa University Northern Yokohama Hospital, Yokohama, Japan) for sharing his pearls of expertise and wisdom with us.

ORCID

Giuseppe Venuti https://orcid.org/0000-0003-3486-1039

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Venuti G, D'Agosta G, Tamburino C, La Manna A. Coronary lithotripsy for failed rotational atherectomy, cutting balloon, scoring balloon, and ultra-high-pressure non-compliant balloon. *Catheter Cardiovasc Interv*. 2019;1–5. https://doi.org/10.1002/ccd.28287