Shockwave Intravascular Lithotripsy in all-comers with resistant *de novo* calcified coronary disease or stent underexpansion: Growing evidence

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Over the past few years, the number of percutaneous coronary interventions (PCI) performed in patients with severely calcified coronary artery disease (CAD) has significantly increased [1]. Heavily calcified lesions are challenging in terms of adequate lesion preparation, equipment delivery, and optimal stent deployment [2]. Several PCI adjunctive tools for plaque modification have been introduced to deal with severely calcified lesions safely and effectively [3].

Shockwave Intravascular Lithotripsy (S-IVL) has emerged as a novel therapy for the treatment of vascular calcification [2]. The Shockwave Medical Coronary IVL catheter (Santa Clara, CA, US) consists of a 0.014-inch guidewire-compatible balloon catheter with two lithotripsy emitters incorporated into the shaft of a 12-mm-long balloon [4]. The IVL catheter is delivered, inflated, and deflated as any other balloon. During brief and low-pressure balloon inflation, 10 IVL pulses are delivered creating acoustic shockwaves that spread circumferentially and transmurally with minimal effect on soft tissue while imparting compressive stress on calcified plaques [4]. Each balloon catheter can deliver up to 80 pulses or 120 with the latest generation Shockwave C^{2+} system with interval deflations to allow distal coronary perfusion [4].

The safety and efficacy of the S-IVL system have been supported by the company-sponsored single-arm prospective DISRUPT CAD studies (I, II, III, and IV) [5]. In a patient-level pooled analysis of these studies reporting results from 628 patients across 72 sites in 12 countries, the primary safety (i.e., absence of in-hospital major adverse cardiovascular events) and effectiveness (i.e., procedural success) endpoints were achieved in 92.7% and 92.4% of patients, respectively [5]. At 30 days, the rates of target lesion failure, cardiac death, and stent thrombosis were 7.2%, 0.5%, and 0.8%, respectively. Rates of post-IVL and final serious angiographic complications were 2.1% and 0.3%, with no IVL-associated perforations, abrupt closures, or episodes of no reflow [5].

In this issue of *Kardiologia Polska* (*Polish Heart Journal*), Rola et al. [6] present data from the Lower Silesia Shockwave Registry (LSSR). The registry includes 131 PCI cases where the S-IVL system was used between May 2019 and September 2022 in two high-volume Polish cardiac centers. S-IVL was used either for calcium modification in resistant calcified lesions before stent deployment (76% of recruited cases) or for stent optimization in significantly underexpanded previously implanted stents (25% of cases). The study evaluated procedural success and clinical outcomes in-hospital and in 6-month follow-up. Procedural success was met in 96% of cases, with 3 cases of device failure (i.e., S-IVL balloon rupture) without clinical consequences. Regarding clinical outcomes, in-hospital MACE was 4.6% and 7.9% at 6 months.

Several clinical and procedural aspects of the study are important and add to the existing literature. Firstly, 87% of the patients presented with acute coronary syndrome (ACS)

(8.4% ST-segment elevation myocardial infarction [STEMI] and 74% non-STEMI [NSTEMI]). ACS was essentially an exclusion criterion for the DISRUPT CAD studies. Nevertheless, ACS cases represent a significant part of PCI procedures in high-volume cardiac centers. Calcified culprit lesions are frequent in NSTEMI and STEMI patients undergoing urgent or emergency PCI and directly impact future target lesion failure [7, 8]. Having an easy, safe, and effective method for calcium modification is important, and the current study supports S-IVL use in this cohort.

In 1 of 4 cases in the LSS Registry, S-IVL was used to treat significant underexpansion of previously implanted stents. Although initially an "off-label" use, S-IVL for stent restenosis secondary to underexpansion became a popular strategy for this challenging clinical scenario with limited therapeutic options [9–11]. The LSSR data show that S-IVL is a relatively safe and effective approach when dealing with stent underexpansion.

The previous use of rotational or orbital atherectomy was not an exclusion criterion for the study, and 13.7% of the patients had atherectomy debulking before S-IVL use. The occasional complementary use of the 2 calcium-modifying modalities should be noted, a strategy that appeared to be safe and effective in a recently published report from the international multicenter Rota-Shock Registry [12]. Finally, the left main artery constituted 20.6% of the treated vessels in the study, adding to previous reports [13, 14] that supported S-IVL use to treat LM lesions (another exclusion criterion in the DISRUPT CAD studies).

The current study carries the inherent limitations of registry-based studies such as potential selection bias, retrospective data collection, and lack of a control group or adjudication for procedural and clinical endpoints. From a procedural perspective, the lack of universal post-dilation (applied in 77% of cases) and the relatively low use of intracoronary imaging for the specific cohort (23.7%) should be noted.

Nevertheless, the study by Rota et al. provides real-life data in a high-risk population supporting the use of S-IVL as an everyday tool for calcium modification. This kind of data are necessary for S-IVL to demonstrate its safety and efficacy outside the "sterile" environment of clinical studies where several exclusion criteria are applied. In conclusion, the Lower Silesia Shockwave Registry showed short- and long-term safety and efficacy for S-IVL in the treatment of resistant *de novo* calcified coronary disease and stent underexpansion. Still, the lack of comparative studies in the literature regarding S-IVL is striking. Studies comparing S-IVL with other calcium/plaque modifying techniques are needed. Furthermore, the high price of the device compared to alternative modalities, merits cost-effectiveness analysis and adequate reimbursement policies [15].

Article information

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