

# Feasibility of the intravascular lithotripsy in coronary artery disease. Short-term outcomes of the Lower-Silesia Shockwave Registry

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## INTRODUCTION

The presence of calcified lesions has a substantial impact on percutaneous coronary intervention (PCI) outcomes. The severity of calcifications impairs stent crossing and correlates with a higher rate of periprocedural complications including vessel dissection or perforation, acute or chronic in-stent thrombosis as well as in-stent restenosis. A response to these unfavorable clinical events is aggressive plaque modification prior to coronary stent implantation.

Numerous strategies aiming at the appropriate preparation of calcified plaques have been implemented [1]. The two main techniques include the balloon-dependent and the atherectomy devices. Even though they remain an essential part of contemporary practice, all of them have some limitations [2]. To overcome them, a new balloon-based coronary system for IVL — Shockwave C2 Intravascular Lithotripsy (S-IVL) (Shockwave Medical Inc, Santa Clara, CA, USA) has been introduced. It is a novel method of calcified plaque modification, which transforms electrical energy into mechanical one, leading to calcium nodules defragmentation. In this brief report, we present the short-term outcomes of the S-IVL registry — the Lower-Silesia Shockwave Registry (LSSR).

## METHODS

We retrospectively enrolled patients from the two cooperating Cardiac Departments in the Lower Silesia Region with a clinical indication for PCI, where due to a presence of “undilatable” lesion, advanced plaque modification methods were needed. Undilatable lesion was defined

as a lesion after unsuccessful high-pressure inflation (20% diameter at least 18 atm) of a non-compliant (NC) balloon catheter (sized 1:1 to the reference vessel diameter balloon), with or without prior plaque preparation with smaller NC balloon or rotational atherectomy (RA).

There were no angiographic exclusion criteria regarding lesion anatomy, such as the length, tortuosity, severity, or prior stent placement. Angiography was used to determine the appropriate number of pulses and the size of the S-IVL catheter for optimal vessel preparation. Subsequent stent implantation and percutaneous coronary intervention optimization (including the use of intravascular imaging) were performed at the discretion of the operator.

The study had two primary endpoints: clinical success and safety outcomes. Clinical success was defined as an effective stent deployment or optimization of the previously implanted not fully expanded stent (with less than <20% in-stent residual stenosis) and the presence of Thrombolysis in Myocardial Infarction (TIMI) 3 flow at the end of the procedure.

Safety outcomes were defined as the absence of procedural complications (coronary perforation, slow- or no-reflow, new coronary thrombus, ventricular arrhythmias, vessel closure), and device failure (inability to cross the lesion, malfunction, or rupture). Also, major adverse cardiac and cerebrovascular events (MACCE) were recorded. MACCE was defined as acute coronary syndrome, cerebrovascular events, major bleeding, need for repeated re-

vascularization, or death. Clinical follow-up was obtained by telephone 30-day after the index procedure (additional 6- and 12-month follow-up is ongoing and will be reported when completed).

The study was based on retrospective registry data. No ethics committee approval nor patient consent was required.

### Statistical analysis

The data is presented as the mean with the standard deviation (SD) or the median with the interquartile range (IQR), dependent on the normality of distribution, assessed previously using the Shapiro-Wilk test, as appropriate. All calculations were made with the R language.

## RESULTS AND DISCUSSION

From May 2019 to January 2021, we enrolled 52 patients (54 treated lesions) — 35 males and 17 females with an average age of 71.2 (7.3) years with a high prevalence of cardiovascular risk factors and comorbidities (hypertension 90.3%, hypercholesterolemia 96.1%, diabetes mellitus 57.7%). Most S-IVL procedures were performed in acute coronary syndrome (ACS) settings (82.7%) — mainly at the time of the index PCI. Forty-one procedures were related to lesions that had not undergone prior coronary angioplasty, the remaining 13 concerned in-stent restenosis due to significant stent under-expansion. The majority (69.2%) of these cases were treated with additional prolonged inflation of the drug-eluting balloon (DEB) — the rest (4 out of 13 — 30.8%) required additional DES implantation due to the operator's decision. **Table 1** provides the details on the clinical, procedural, and postprocedural characteristics.

The median SYNTAX score was 11 (7–24) points. In six cases, before S-IVL, a rotational atherectomy was performed as a part of lesion preparation. The average S-IVL balloon catheter size was 3.3 (0.4) and a median of 40 (30–80) sonic pulses was delivered. Hospital observation revealed three procedure-related complications. In the first case, the patient developed a ventricular arrhythmia during the procedure, which was interrupted by ALS and electrical defibrillation. The second case was related to the rupture of the S-IVL balloon after 30 pulses. In the third case, we observed failure of S-IVL therapy — residual stenosis of more than 50% — after 100 sonic pulses. This patient was qualified for coronary artery bypass grafting. One stroke was recognized during the index hospitalization. Two major bleedings in the postprocedural period were recorded. The first patient required transfusion of 6 units of packed red blood cells for gastrointestinal bleeding. The second patient required transfusion of 2 units of packed red blood cells due to vascular access complications. No other MACCE were recorded for 30 days after hospital discharge.

Artery calcification remains one of the greatest challenges in the management of coronary artery disease. Armamentarium for optimal lesion preparation includes the pre-dilation with NC or ultrahigh-pressure balloons, utilization of scoring or cutting balloons, and RA devic-

**Table 1.** Clinical, procedural, and postprocedural characteristics of the study population

	Overall (n = 52)
Age, mean (SD)	71.2 (7.3)
Male, n (%)	35 (67.3)
Diagnosis	
Stable angina, n (%)	9 (17.3)
Unstable angina, n (%)	2 (3.8)
NSTEMI, n (%)	38 (73.0)
STEMI, n (%)	3 (5.9)
Hypercholesterolemia, n (%)	50 (96.1)
Diabetes, n (%)	29 (55.7)
Hypertension, n (%)	47 (90.3)
Kidney failure, n (%)	10 (19.2)
Post PCI status, n (%)	35 (67.3)
Primary diagnosis MI, n (%)	28 (53.8)
Syntax score, median (IQR)	11 (7–24)
LVEF, %, mean (SD)	52.3 (13.8)
Treated vessel	10 (19.2)
LM, n (%)	18 (34.6)
LAD, n (%)	6 (11.6)
Cx, n (%) RCA, n (%)	18 (34.6)
Primary lesion, n (%)	41 (78.8)
Stent underexpansion, n (%)	13 (25)
CTO lesions, n (%)	5 (9.6)
Primary rotablation, n (%)	6 (11.5)
Previously predilatation, n (%)	43 (82.6)
Predilatation pressure, atm, mean (SD)	19.8 (4.2)
Initial diameter stenosis, %, mean (SD)	83.3 (9.7)
Final diameter stenosis, %, median (IQR)	5 (0–14)
IVL diameter, mm, mean (SD)	3.3 (0.4)
Number of pulses, median (IQR)	40 (30–80)
Postdilatation, n (%)	49 (94.2)
Postdilatation pressure, atm, mean (SD)	18.5 (5.0)
Number of DES per procedure, mean (SD)	1.4 (0.3)
Total DES length per procedure, median (IQR)	38 (26–71)
Number of DEB inflation, n (%)	9 (17.3)
OCT/IVUS guided PCI, n (%)	11 (21.2)
Clinical success, n (%)	51 (98.1)
Radial access, n (%)	48 (88.8)
Femoral access, n (%)	6 (12.2)
6F guide catheter, n (%)	32 (59.2)
7F guide catheter, n (%)	22 (40.8)
Radiation doses, mGy, median (IQR)	1334 (699–2105)
Contrast amount, ml, median (IQR)	180 (135–230)
In-hospital MACCE, n (%)	3 (5.7)
30-days after procedure MACCE, n (%)	3 (5.7)

Abbreviations: CTO, chronic total occlusion; Cx, circumflex artery; DEB, drug eluting balloon; DES, drug eluting stent; IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; MACCE, major adverse cardiac and cerebrovascular events; LAD, left anterior descending; LM, left main; LVEF, left ventricular ejection fraction; NSTEMI, no ST-elevation myocardial infarction; OCT, optical coherence tomography; RCA, right coronary artery; STEMI, ST-elevation myocardial infarction

es. Success rates using these strategies are high and reach over 90.0% [3, 4]. Nevertheless, some limitations are still observed. In the presence of eccentric calcium, the dilation force of the balloon is limited and may be redirected to less resistant, noncalcified parts of the vessel. Rotational devices perform atheroablation by sanding/abrasion, resulting in pulverization of the superficial plaque. However, the deep calcifications may remain untouched [5]. S-IVL could respond to the aforementioned superficial mech-

anisms of plaque modification. It generates sonic pulses that propagate through the lesion and selectively interact even with profound calcified plaques. The efficiency and safety of S-IVL were initially confirmed in a Disrupt II study [6]. Although preliminary data are encouraging [7, 8], convincing clinical evidence from randomized trials is missing.

We obtained a higher clinical success rate, in comparison to the previously described (98.1% vs. 84.6%–95.0%) [7, 8]. This finding might be related to the simultaneous use of RA and S-IVL (6 cases) in the most challenging lesions. Rota-lithotripsy is a novel bail-out strategy used for resistant lesions. Only a few case reports [9–11] regarding this method are available. A high rate of clinical success was maintained despite the relatively high prevalence of patients with under-expansion of previously implanted stents in our registry (25.0% vs. 21.7%) [7]. A clinical success rate in these non-option patients is overall lower (64.7% vs. 87.1%) [7, 8, 12]. The severity of coronary artery disease (median of SYNTAX score, 11) with coexisting complexity of PCI procedures (5 CTO, 6 Rota-lithotripsies) included in the LSSR led to the relatively high average use of contrast volume (median of 180 ml) and radiation dose (median of 1334 mGy). These findings are partially consistent with previously reported data [7, 8, 12]

Preliminary safety outcomes are also encouraging. We observed one balloon ruptured during treatment without any sequelae, as well as one episode of ventricular arrhythmias probably connected to ongoing ischemia induced by ACS (high-risk patient with NSTEMI and multivessel disease-accumulated SYNTAX score, 33.5). However, in view of the reports suggesting that S-IVL can induce ventricular arrhythmias [13], future studies are necessary. Probably due to the high prevalence of trans-radial access (88.8%) with accompanying predominance of 6F guiding catheter (59.2%), we observed only one access-related bleeding in this high-risk group. These data might suggest that wider use of S-IVL may reduce the number of complex PCI performed with femoral access and decrease the rate of access points complications [14].

Retrospectively the data collected from the LSSR suggest intravascular lithotripsy is relatively safe and effective as a method of modifying calcified plaque in short-term observation, especially when performed via radial access. Moreover, subsequent studies are needed to evaluate the long-term results.

### Article information

**Conflict of interest:** None declared.

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