ORIGINAL ARTICLE

Safety and efficacy of a novel calcified plaque modification technique — Shockwave Intravascular Lithotripsy — in patients with coronary artery disease: Mid-term outcomes

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Editorial
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ABSTRACT

Background: Coronary interventions in calcified lesions are associated with a higher rate of adverse clinical events. Initial aggressive plaque modification along with post-implantation optimization is pivotal for achieving a favorable outcome of percutaneous coronary intervention (PCI). Recently, the Shockwave C2 Intravascular Lithotripsy (S-IVL) System, a novel acoustic wave-based device designed to modify calcified plaque, has been introduced into clinical practice.

Aims: We evaluated the mid-term safety and efficiency of S-IVL in a cohort of 131 consecutive patients with severely calcified coronary lesions.

Methods: We retrospectively analyzed a total of 131 consecutive S-IVL PCI procedures. The study had two main inclusion criteria — the presence of a calcified resistant lesion (defined by inadequate non-compliant balloon catheter inflation) or a significantly underexpanded stent (more than 20% of reference diameter). The study had two primary endpoints — successful clinical outcome and safety concerns. Clinical success was defined as effective stent deployment or optimization of a previously underexpanded stent (with less than <20% in-stent residual stenosis). Safety outcomes were defined as periprocedural complications, such as device failure and major adverse cardiac and cerebrovascular events (MACCE). Clinical follow-up was performed at the end of hospitalization and 6 months after the index procedure.

Results: In-hospital MACCE was 4.6% with 1.5% target lesion revascularization (TLR) and one case of subacute fatal stent thrombosis. At 6-month follow-up, the MACCE rate was 7.9% with a concomitant TLR rate of 3.8%.

Conclusion: Our mid-term data confirm acceptable safety and efficacy of intravascular lithotripsy as a valuable strategy for lesion preparation and stent optimization in a cohort of 131 consecutive patients with severely calcified coronary lesions.

Key words: calcified lesions, lesion preparation, percutaneous coronary intervention, Shockwave Intravascular Lithotripsy, stent optimization

WHAT'S NEW?

Calcified lesions represent a challenging subset for percutaneous coronary intervention (PCI) with high risk of adverse events. Adequate lesion preparation and post-implantation stent optimization are crucial in achieving satisfactory long-term efficacy. This study is among the first to present real-life data from the Lower Silesia Shockwave Registry (LSSR), which aimed to evaluate the mid-term outcomes of PCI supported by a novel plaque modification method — Shockwave Intravascular Lithotripsy in a cohort of 131 consecutive patients. Our results confirm its feasibility and safety at 6-month follow-up in the high-risk population with advanced coronary artery disease.

INTRODUCTION

Despite undeniable improvement in percutaneous treatment of coronary artery disease resulting from the introduction of the second generation of drug-eluting stents, calcified coronary lesions are still a challenge for interventional cardiology. According to the literature, calcified plaque burden is increasing with age and the prevalence of renal insufficiency, hypertension, and diabetes [1]; it is an independent risk factor for future cardiovascular events [2]. Coronary interventions in calcified lesions are inextricably linked with a higher rate of periprocedural complications (including dissections, perforations, impairment of stent delivery, and deployment) and several long-term adverse events (such as stent failure, thrombosis, restenosis, and repeat revascularization) [3].

Aggressive plaque modification before stent implantation is part of contemporary practice and is crucial in avoiding unfavorable percutaneous coronary intervention (PCI) outcomes [4]. Numerous strategies aiming at appropriate preparation of calcified lesions have been implemented in the PCI armamentarium. Generally, the two main groups can be distinguished — first, balloon-depend technologies (semi-compliant, non-compliant, cutting, and scoring) and second, atheroablative devices (rotational, orbital, and laser) [5]. Although all listed devices can facilitate PCI in calcified lesions, the extent of calcium modification is limited and mainly focused on superficial plaque modification. Additionally, some device-associated periprocedural complications may unexpectedly occur in the course of the procedure.

Recently a novel technique dedicated to calcified plaque modification has been introduced into clinical practice — Shockwave C2 Intravascular Lithotripsy (S-IVL) (Shockwave Medical Inc, Santa Clara, CA, US). This balloon-based coronary system transforms electrical energy into mechanical (shock wave) leading to profound defragmentation of calcium nodules without affecting the vascular architecture [6]. Although initially small-sized studies confirmed the short-term safety and efficiency [7–11], the mid and long-term data are still missing. Since the subjects recruited to cardiac clinical trials are distinctly different from the "real-world" population of cardiac patients, an assessment of S-IVL in real-life registries seems to be extremely valuable.

METHODS

This study presents data from the Lower Silesia Shockwave Registry (LSSR) that includes all consecutive cases of PCI performed with the support of Shockwave Intravascular Lithotripsy from two cooperating cardiac centers. PCIs were performed between May 2019 and September 2022 in two high-volume centers from the Lower Silesia region of Poland.

All patients in the registry had a clinical indication for PCI, based on the current European Society of Cardiology (ESC) revascularization guidelines, if necessary, with the support of the local Heart Team. Patients enrolled in the study had to meet one of two main inclusion criteria: the presence of a highly calcified resistant lesion or a significantly underexpanded previously implanted stent (regardless of the time of implantation). The lesion was defined as resistant after unsuccessful high-pressure non-compliant (NC) balloon inflation (at least 20% of underexpansion, with at least 16 atm. [16]). The decision regarding initial lesion preparation was left at the operators' discretion and did not indicate a formal recruitment process. Patients meeting the inclusion criteria, who initially underwent advanced debulking procedures (orbital or rotational atherectomy), had also been recruited.

There were no angiographic exclusion criteria regarding lesion anatomy such as its length, tortuosity, severity, or prior stent placement. Operators, based on angiographic assessment, with additional support of intravascular imagining (IVUS/OCT) in the most challenging cases, determined the size of the S-IVL catheter and appropriate number of pulses for optimal vessel preparation or management of an underexpanded coronary stent.

The study had two primary endpoints — successful clinical outcome and safety concerns. Clinical success was defined as effective stent deployment or optimization of the previously not fully expanded stent (with less than <20% in-stent residual stenosis) [12] and the presence of TIMI 3 flow at the end of the procedure.

Safety outcomes were defined as periprocedural final serious angiographic complications (including perforation, abrupt closure, slow flow or no-reflow, unstable ventricular arrhythmias) and device failure (such as inability to cross the lesion, malfunction, or rapture). Also, adverse cardiac and cerebrovascular events (MACCE) were recorded. MAC-

CE involved death, myocardial infarction (MI), acute cerebrovascular events, and repeated revascularization of the target lesion (TLR)[13, 14]. Clinical follow-up was obtained by professional medical staff — personally or by telephone 6 months after the index procedure. On the initial visit (at the end of hospitalization), several data were collected regarding periprocedural characteristics, past medical history, basic laboratory tests at the time of admission, and pharmacotherapy at the time of discharge. The medical history was focused on the burden of cardiovascular disease (including coronary artery disease, hypertension, atrial fibrillation, chronic heart failure, presence of moderate/severe valvular heart disease, and history of stroke) and major cardiovascular risk factors defined according to the applicable definitions [15–17] and including diabetes mellitus and chronic kidney disease. On the first follow-up visit (6 months after the index procedure), data were collected on MACCE and any other revascularization procedures, involving stent thrombosis and restenosis [14]. This study was approved by the local ethics committee (Bioethical Committee at the Lower Silesian Chamber of Physicians — approval number 04/BOBD/2022). The study flowchart is presented in Figure 1.

Statistical analysis

Dependent on the normality of distribution (assessed by the Shapiro-Wilk test), the data were presented as means and standard deviations (SD), or medians and interquartile ranges (IQR). All calculations were made with the R language version 4.0.4

RESULTS

We retrospectively analyzed 131 consecutive S-IVL PCI procedures. Most of the cases were performed in the acute coronary syndrome (ACS) setting (87%) mainly non-ST-segment elevated myocardial infarction (NSTEMI) (74%). The ACS-based procedures (69.4%) were performed between May and September 2022. The study population

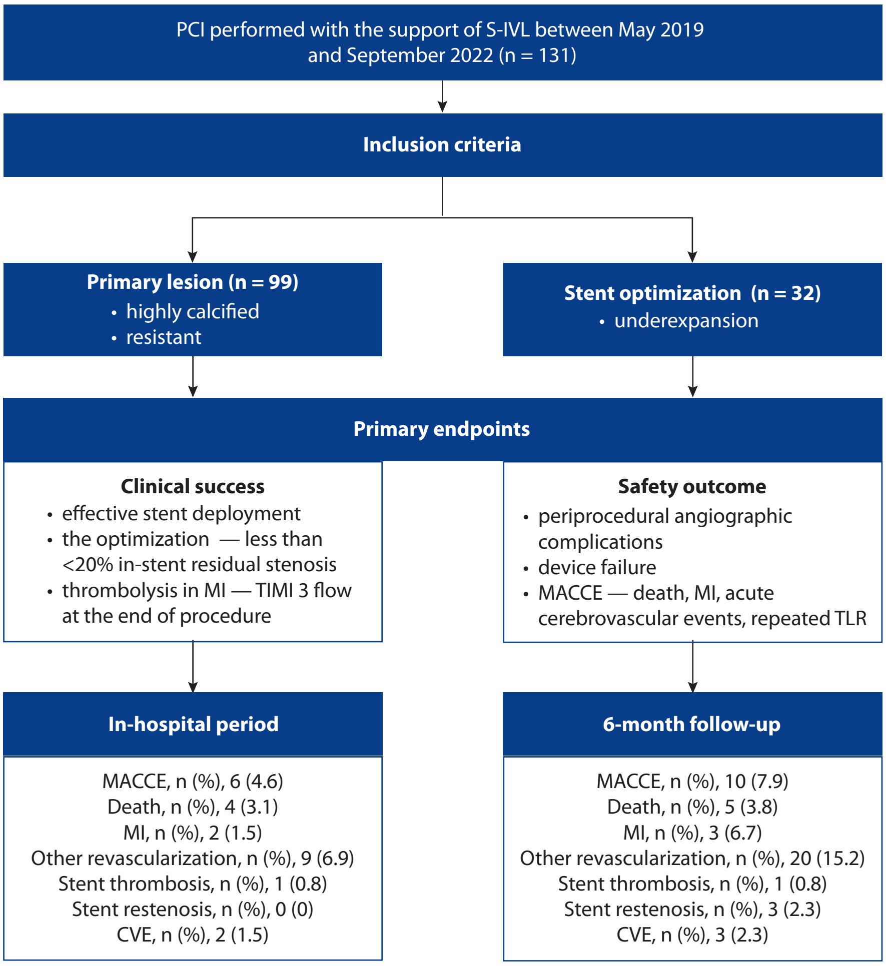

Figure 1. Study flowchart

Abbreviations: CVE, cerebrovascular episodes; MACCE, major adverse cardiac and cerebrovascular event; MI, myocardial infraction; PCI, percutaneous coronary intervention; S-IVL, Shockwave Intravascular Lithotripsy; TIMI, Thrombolysis in Myocardial Infarction; TLR, target lesion revascularization

Table 1. Study population baseline clinical characteristics

Shockwave intravascular	N = 131
Clinical features	
Age, mean (SD)	70.8 (7.5)
Sex, male, n (%)	92 (70.2)
Stable angina, n (%)	17 (13)
Unstable angina, n (%)	6 (4.6)
NSTEMI, n (%)	97 (74.0)
STEMI, n (%)	11 (8.4)
Diabetes mellitus, n (%)	75 (57.3)
Chronic heart failure, n (%)	64 (48.9)
Hypertension, n (%)	121 (92.4)
Hyperlipidemia, n (%)	127 (96.9)
Atrial fibrillation, n (%)	40 (30.5)
History of PCI, n (%)	68 (51.9)
History of MI, n (%)	63 (48.1)
History of CABG, n (%)	11 (8.4)
COPD, n (%)	13 (9.9)
History of stroke, n (%)	11 (8.4)
Moderate/severe valvular heart disease, n (%)	26 (19.8)
Chronic kidney disease, n (%)	31 (23.7)
LVEF, %, mean (SD)	48.2 (15.5)
Creatinine level, µmol/l, median (IQR)	82 (71–76.8)
Post-procedural pharmacotherapy	
Acetylsalicylic acid, n (%)	125 (95.4)
Clopidogrel, n (%)	78 (59.5)
Ticagrelor, n (%)	42 (32.1)
Prasugrel, n (%)	11 (8.4)
Statins, n (%)	125 (95.4)
NOAC/VKA, n (%)	37 (28.2)
ACEI/ARB, n (%)	115 (87.8)
β-blocker, n (%)	119 (90.8)
CCB, n (%)	42 (32.1)
Diuretic, n (%)	50 (38.1)
Oral antidiabetic, n (%)	64 (48.8)
Insulin, n (%)	22 (16.8)

Abbreviations: ACEI, angiotensin-converting-enzyme inhibitors; ARB, angiotensin receptor blockers; CABG, coronary artery bypass grafting; CCB, calcium channel blocker; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; NOAC, non-vitamin K antagonist oral anticoagulants; NSTEMI, non-ST-segment elevation myocardial infraction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infraction; VKA, vitamin K antagonists; β-blocker, beta blocker

Table 2. Baseline procedural features of the study population

Shockwave intravascular	N = 131
Vessel treated	
LM, n (%)	27 (20.6)
LAD, n (%)	45 (34.3)
LCx, n (%)	18 (13.7)
RCA, n (%)	41 (31.2)
SYNTAX I score, median (IQR)	15.5 (9–25.7)
SYNTAX II PCI score, mean (SD)	37.5 (12.8)
SYNTAX II PCI four-year mortality, median (IQR)	18.2 (5.8–21.6)
SYNTAX II CABG score, mean (SD)	34.4 (10.2)
SYNTAX II CABG year mortality, median (IQR)	13.0 (6–15.4)
Primary lesion, n (%)	99 (75.6)
Stent underexpansion, n (%)	32 (24.4)
CTO lesions, n (%)	6 (4.6)
Post-atherectomy debulking, n (%)	18 (13.7)
Initial predilatation, n (%)	122 (93.1)
Predilatation pressure, atm, mean (SD)	19.5 (4.4)
Initial stenosis grade, %, mean (SD)	81.8 (11.7)
Final stenosis grade, %, mean (SD)	7.2 (13)
S-IVL diameter, mm, mean (SD)	3.22 (0.44)
S-IVL pulses, median (IQR)	50 (30-80)
Postdilatation, n (%)	101 (77.1)
Postdilatation pressure, atm, mean (SD)	19.3 (3.1)
Number of DES per procedure, mean (SD)	1.53 (0.4)
Total DES length per procedure, mm, median (IQR)	40.8 (26–66)
Number of DEB inflation, n (%)	21 (16)
Intravascular guidance, n (%)	31 (23.7)
Clinical success, n (%)	126 (96.1)
S-IVL perforations, n (%)	3 (2.3)
Radial access, n (%)	118 (90.0)
6 F guide catheter, n (%)	96 (73.2)
7 F or larger guide catheter, n (%)	35 (26.7)
Radiation dose, mGy, median (IQR)	1435.9 (663.3–1866.7)
Contrast volume, n (%), median (IQR)	230.2 (150–260.7)

Abbreviations: CABG, coronary artery bypass grafting; CTO, chronic total occlusion; Cx, circumflex artery; DEB, drug eluting balloon; DES, drug-eluting stent; LAD, left anterior descending; LM, left main; MACCE, major adverse cardiac and cerebrovascular event; PCI, percutaneous coronary intervention; RCA, right coronary artery; S-IVL, Shockwave Intravascular Lithotripsy

was dominated by male subjects (70.2%) at an average age of 70.8 years. The study cohort was characterized by a high prevalence of cardiovascular risk factors: hypercholesterolemia (96.7%), hypertension (92.4%), and diabetes mellitus (57.3%). Nearly one in two subjects had a history of myocardial infarction, and 60.3% underwent previous revascularization. The baseline clinical characteristics of the study cohort are presented in Table 1.

In terms of post-discharge pharmacotherapy, notably, a relatively large proportion of patients (59.5%) received clopidogrel as part of dual anti-platelet therapy (DAPT). The anatomical complexity of coronary artery disease (CAD) was relatively high, and the SYNTAX score I reached a median of 15.5 (9–25.7) with subsequent SYNTAX II — PCI score of 37.5 (12.8); estimated 4-year mortality reached 18.2%. The vast majority of PCI procedures were related to *de novo* lesions (75.6%), and the remaining 32 were concerned with significantly underexpanded stents. In 13.7% of all cases, S-IVL was used despite initial aggressive lesion preparation (orbital or rotational atherectomy). Clinical success criteria were met in 96.1% of cases. Notably, we noticed only 3 device failures (perforation of S-IVL catheter) without serious clinical consequences. The predominant vascular access point was the radial artery (90%). All procedural features are presented in Table 2.

During the hospitalization period, the MACCE rate was 4.6%. There were four deaths in the study cohort during this period. Most occurred in patients with advanced heart failure. The first fatality was a 71-year-old man with multiple comorbidities, coronary artery disease, with a history of MI previously treated with PCI, advanced heart failure with reduced ejection fraction, and implanted cardioverter-defibrillator (ICD), who was admitted because of cardiogenic shock in the course of STEMI.

He received PCI of the left anterior descending artery (LAD) (culprit lesion) and a few days later, due to symptoms of recurrent angina, we performed right coronary artery (RCA) PCI supported by S-IVL. The patient died several days later with symptoms of persistent cardiogenic shock despite implementing an intensive care protocol. The second death was observed in a 65-year-old man with a history of alcohol abuse and multiple organ dysfunction. He was admitted with NSTEMI and underwent PCI of the LAD supported by S-IVL. He was transferred to the Intensive Care Unit (ICU) directly after the procedure and died several days later from multiorgan dysfunction and clinical symptoms of stroke. The third case involved a 72-year-old woman with multiple comorbidities and advanced heart failure, who was admitted to the hospital with STEMI and pre-hospital arrest and treated with rescue PCI of the left main (LM). Approximately 24 hours later, the patient experienced another cardiac arrest. PCI of the RCA was performed, as the last possible revascularization procedure, with S-IVL support. The patient died several days later with symptoms of persistent cardiogenic shock. The last in-hospital death in our study was a 76-year-old woman with NSTEMI and advanced CAD. She underwent rescue PCI of the LM/LAD/Cx supported by S-IVL. Five days after PCI, ventricular fibrillation occurred, and control angiography revealed stent thrombosis, and, despite the second rescue PCI and prolonged resuscitation, the patient died. During this follow-up period, we also had an additional case of TLR in a 60-year-old man with NSTEMI and advanced highly calcified CAD. During the index procedure, the patient underwent rota-lithotripsy after unsuccessful initial lesion preparation with rotational atherectomy (presence of significant NC balloon underexpansion post-atherectomy). A few days later, the patient underwent additional PCI of the target lesion due to a symptomatic distal edge dissection. One elderly patient with high comorbidity was found to have suffered a stroke while hospitalized. However, it was not directly related to the periprocedural period.

At 6-month follow-up, MACCE was reported (7.9%) with a concomitant TLR rate of 3.8% (all undiscussed cases were related to in-stent restenosis; two of three were recurrent restenoses in underexpanded stents). Two additional deaths occurred. The first was an unexplained death 14 days after discharge in a patient with a high number of comorbidities and low left ventricular ejection fraction (LVEF of 25%) initially planned for implantation of a cardioverter-defibrillator (ICD) following 3-month optimal medical treatment of HF after complete revascularization. The second patient, who suffered from multiple comorbidities and advanced heart failure (LVEF, 15%–20%) with an ICD, died approximately 5 months after discharge. In this case, a second patient with newly diagnosed COVID-19 was admitted to the emergency department (ED) and died a few hours later with symptoms of acute cardiorespiratory failure. All the clinical follow-up data are summarized in Table 3.

Table 3. Clinical follow-up data of study cohort

Shockwave Intravascular N-131	
In-hospital period	
MACCE, n (%)	6 (4.6)
Death, n (%)	4 (3.1)
Myocardial infarction, n (%)	1 (0.8)
Target lesion revascularization, n (%)	2 (1.5)
Any other revascularization, n (%)	9 (6.9)
Stent thrombosis, n (%)	1 (0.8)
Stent restenosis, n (%)	0 (0)
Cerebrovascular episodes, n (%)	2 (1.5)
6-month follow-up	
MACCE, n (%)	10 (7.9)
Death, n (%)	6 (4.6)
Myocardial infarction, n (%)	3 (6.7)
Target lesion revascularization, n (%)	5 (3.8)
Any other revascularization, n (%)	20 (15.2)
Stent thrombosis, n (%)	1 (0.8)
Stent restenosis, n (%)	3 (2.3)
Cerebrovascular episodes, n (%)	3 (2.3)

Abbreviations: MACCE, major adverse cardiac and cerebrovascular event

DISCUSSION

Initially, the Shockwave C2 I-VL catheter was introduced into clinical practice in the field of peripheral interventions and has already undergone several clinical trials in various peripheral vascular beds [18]. Nevertheless, the history of S-IVL as a therapeutic tool in coronary artery disease is much shorter — S-IVL has been commercially available in Europe since 2018 and in the US and Japan since 2021. The scientific evidence for the efficacy of this technology in treating CAD is mainly based on small cohorts of patients who were recruited for the pre-market evaluation studies focused mainly on short-term outcomes and designed by the manufacturer [19, 20]. In this study, we present, as one of the first, "real-life" data from the Lower Silesia Shockwave Registry (LSSR), which evaluate the mid-term outcomes of S-ILV-assisted PCI in a cohort of 131 consecutive patients.

Coronary calcifications reduce vascular compliance, severely affecting both short- and long-term clinical outcomes in patients undergoing percutaneous revascularization [21]. Percutaneous interventions in calcified lesions are associated with increased periprocedural complications (dissection, perforation, MI) as well as suboptimal PCI outcomes, mainly concerning stent delivery and deployment, leading to malapposition, underexpansion, or stent fracture and potentially compromising drug adhesion and delivery [22]. This can lead to an increase in late adverse events such as restenosis, stent thrombosis, and the need for repeat revascularization [23]. Contemporary practice has evolved a variety of devices and strategies for treatment of coronary calcifications.

The well-established balloon-dependent methods (such as non-compliance, cutting, scoring) [24] together with the atherectomy devices (both, rotational and orbital) [25, 26] ensure that the success rate of the procedure can exceed 90%. A combination of the mentioned methods can result in an even higher success rate [27–31]. However, all of them have inherent limitations and may increase the risk of complications.

Intravascular lithotripsy (IVL) is a novel therapeutic strategy based on the use of acoustic pressure waves to treat calcium deposits in the vascular wall, similar to the method previously used in renal calculi. Lithotripsy emitters (source of acoustic pressure waves) are incorporated into the shaft of a balloon angioplasty catheter that delivers precisely localized acoustic pressure waves via a standard angioplasty wire. A unique property of S-IVL is the fact its action affects also deep calcium deposits in opposition to athero-ablation or the classical pressure-depend balloon methods mainly focused on superficial plaque modification. The recently published reports on the safety and efficacy of S-IVL are encouraging but have been concerned mainly with short-term outcomes of intravascular lithotripsy [7, 11, 31–34], with few data on longer-term follow-up [35].

In our real-world high-risk cohort (87% of patients with ACS), clinical success was even higher than that one presented in the pooled data from all Disturb trials (96.1% vs. 92.6%) [32]. Similar favorable results were observed in terms of in-hospital MACCE (4.6% vs. 6.5%), yet the in-hospital TLR rate was slightly higher than in the Disturb studies (1.5% vs. 0.3%). Interestingly, the high level of clinical success was maintained despite the high prevalence of patients with underexpansion of previously implanted stents (24.4%) and chronic total occlusion (4.6%), both well-known risk factors for adverse clinical outcomes [34, 36]. Especially in the case of patients in whom high-pressure dilatation of a non-compliant balloon failed to expand the stent, clinical success is generally lower [34, 37]. Currently, there are limited therapeutic options for refractory stent underexpansion [38]. Based on the data presented so far [39, 40], S-IVL appears to be a relatively safe and effective approach, which is related to its unique mechanism of action – an atraumatic balloon-based treatment that may help to avoid mechanical vascular trauma often observed with classic high-pressure balloon postdilatation. Another alternative to treat incomplete stent expansion is to perform debulking atherectomy. However, these challenging procedures are associated with high risk of acute complications [41, 42].

Notably, no in-hospital MACCE occurred despite the high anatomical complexity of treated lesions (SYNTAX Score 15.5 [9–25.7], total drug-eluting stent (DES) length per procedure 40.8 [26–66] mm). This might be partially related to the relatively common use of additional debulking methods (rotational or orbital atherectomy devices). Nevertheless, in our study cohort, S-IVL was used only in the setting of initial inadequate lesion preparation with an atherectomy device followed by NC balloon inflation. This suggests that the lesions treated with rota-lithotripsy were extremely challenging with deep calcium deposits. As a result, initial burr atheroablation most likely only pulverized superficial portions of calcified deposits without interacting with deep calcium [43]. The different mechanisms of S-IVL action, focusing on the disruption of the deep calcium plaque [6], allowed us to achieve adequate lesion preparation in this highly challenging cohort. This comprehensive approach has been previously reported [28–30, 44, 45]. Alternative approaches would be associated with an increase in burr size, which could seriously compromise the safety of this procedure [46].

The 6-month outcomes observed in our study are also encouraging: we noted a low number of TLR (3.8%), mainly related to the recurrent in-stent restenosis due to its previous underexpansion (3 of 5). This number of TLR is comparable to other alternative debulking methods — orbital atherectomy (1-year TLR, 4.7%) [47, 48], rotational atherectomy (9-month TLR 2, 11.7%) [49], or cutting/scoring balloon (9-month TLR 7%). Furthermore, if we excluded from our study cohort the patients who underwent the S-IVL procedure for post-stenting optimization, the TLR would decrease to 2%.

In our cohort study, we observed an encouraging safety profile (lack of vessel perforation or no-reflow phenomena), which may be related to a high number of low-size (6 F) (73.2%) radial access sites (90.0%), which has been shown to increase the safety of PCI procedures [50]. Additionally, during all analyzed PCI procedures, we observed only 3 cases of device failure (Shockwave catheter perforation) without any clinical consequences for the patient.

Our study has several limitations. First, it has a non-randomized retrospective study design lacking a control group. The second limitation is a relatively low number of intravascular imagining studies and a lack of external core lab analysis. Finally, heterogeneity, high number of stent optimization procedures, and additional use of an atherectomy device can complicate the analysis of study results.

CONCLUSIONS

The mid-term data from the Lower Silesia Shockwave Registry (LSSR) confirm the acceptable safety and efficacy of intravascular lithotripsy, which was a valuable strategy for lesion preparation and stent optimization in a cohort of 131 consecutive patients with severely calcified coronary lesions. Larger randomized trials are needed to evaluate fully this novel treatment modality. A head-to-head comparison with other advanced debulking techniques would be particularly valuable.

Article information

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