Intracoronary Lithotripsy in Calcified Coronary Lesions: A Multicenter Observational Study

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Abstract

Objectives. The aim of this study was to evaluate the feasibility, effectiveness, and safety of coronary intravascular lithotripsy (IVL; Shockwave Medical) in the treatment of severe coronary artery calcification (CAC) in a real-world setting. **Background.** Severe CAC can be an arduous obstacle in interventional cardiology, often leading to suboptimal results of percutaneous coronary interventions (PCI). Coronary IVL is a novel technique that modulates severe CAC, thereby facilitating stent implantation. **Methods and Results**. In this multicenter observational study, data from 134 IVL procedures in 5 Belgian hospitals were prospectively obtained. Successful delivery of the IVL catheter was achieved in all cases but 1 (99.3%). The primary endpoint was final overall procedural success, which was obtained in 88.1% of cases, an aggregate of 92.6% in *de novo* lesions and 77.5% in stent underexpansion or in-stent restenosis (ISR). IVL therapy effect was considered successful by the operators in 94% of cases, with 68.7% achieving optimal and 25.3% achieving suboptimal results. The 1-month major adverse cardiovascular event rate was 3%, including 2 cardiovascular deaths (1 in-stent thrombosis and 1 coronary artery perforation). **Conclusions.** This real-world experience suggests that Shockwave IVL is a feasible, effective, and safe technique for the treatment of heavily calcified coronary lesions.

J INVASIVE CARDIOL 2022:34(1):E24-E31. Epub 2021 December 12.

Key words: coronary artery calcification, lesion modification, intravascular lithotripsy, stent underexpansion

Percutaneous coronary intervention (PCI) with stent implantation has been proven to be an effective treatment for coronary artery stenosis.[1] Nevertheless, severe calcification of the arterial wall can hamper preparation of the lesion and deployment of the stent at the lesion site, leading to a higher rate of suboptimal stent expansion. This results in more restenosis, thrombosis, target-vessel failure or target-vessel revascularization (TVR), and myocardial infarction (MI). The prevalence of PCI in lesions with severe coronary artery calcification (CAC) rises because of an aging population and increasing diabetes mellitus, hypertension, and renal insufficiency. Performing PCI in CAC often requires aggressive angioplasty (high-pressure or scoring/cutting balloons and intravascular atherectomy devices) to modify the lesions effectively. Despite these techniques, lesion modification is not always successful and is associated with a higher risk of complications, such as dissections and perforations. Thus, there is a need for novel techniques to facilitate PCI in heavily calcified lesions.

Lithotripsy is a method that uses acoustic shock waves and is extensively used in the treatment of urolithiasis. Recently, a novel device that enables intravascular lithotripsy (IVL; Shockwave Medical) in CAC was introduced to facilitate stent delivery at the lesion site and to treat stent underexpansion, with the latter an off-label indication. Shockwave IVL utilizes a single-use, rapid-exchange catheter with miniaturized and arrayed lithotripsy emitters implemented in a low-pressure balloon. A generator is connected to this catheter, delivering sonic pressure waves, resulting in localized high-pressure bursts. When pulses are generated (programmed delivery per 10 pulses, to a maximum of 80 pulses), calcium fracture occurs within intimal and medial layers without damaging normal vessel tissue (minimal collateral damage).

Recent trials demonstrated the safety and efficacy of IVL for the modification of heavily calcified coronary arteries with low major adverse cardiovascular event (MACE) rates.[2-4] We

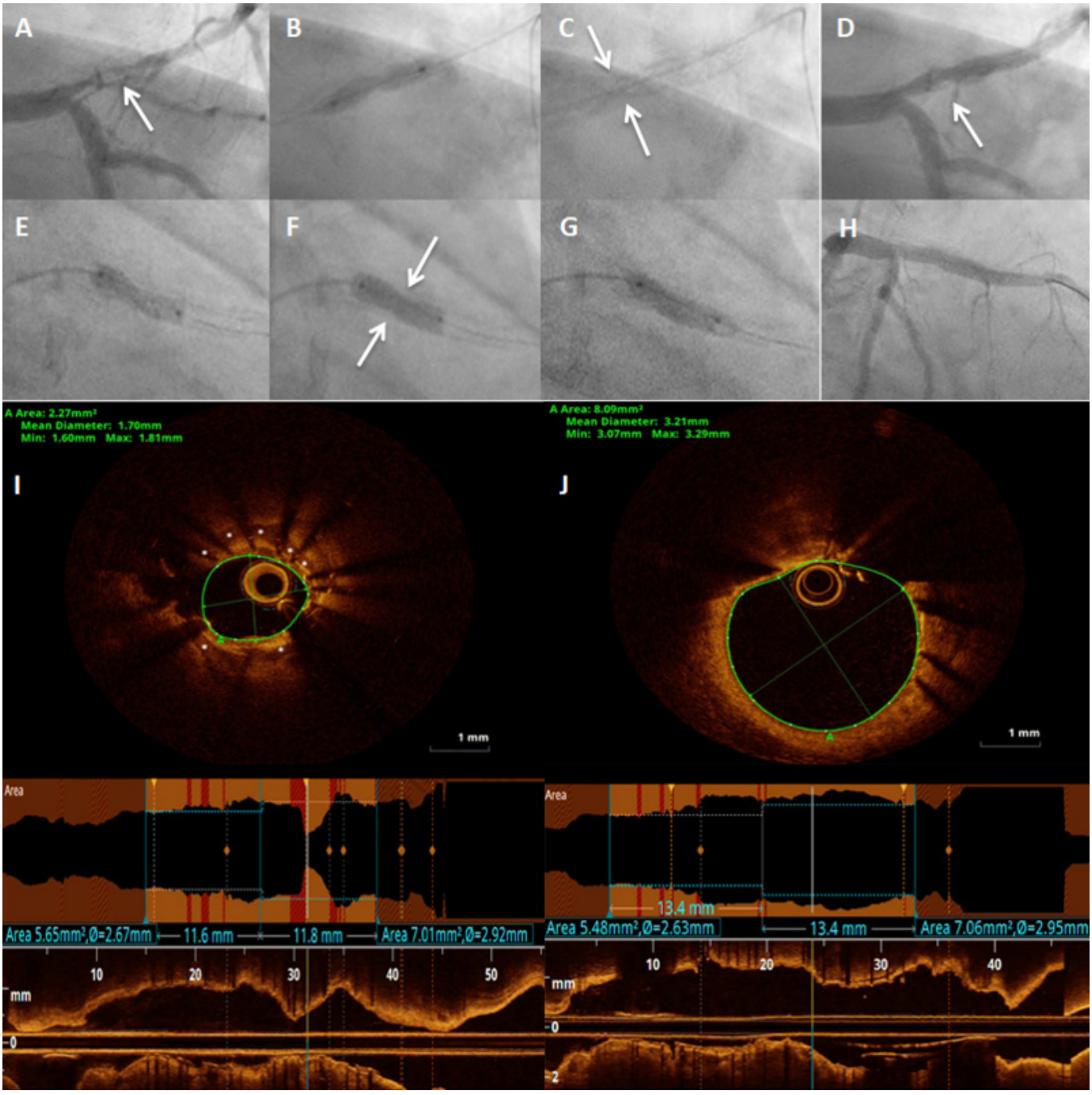

FIGURE 1. A case of suboptimal stent expansion with standard percutaneous coronary intervention techniques (top row) and scheduled reintervention using Shockwave intravascular lithotripsy (second row) and optimal coherence tomography (bottom row). (A, arrow) Significant (>70%) calcified stenosis of the proximal left anterior descending artery. (B) Incomplete balloon expansion with a standard non-compliant balloon. (C) Focal underexpansion of the implanted stent (arrows). (D, arrow) Postdilation with a 3.5 mm non-compliant balloon and cutting balloon did not improve further stent expansion. (E) First Shockwave intravascular lithotripsy balloon after 10 pulses applied with a 3.5 mm diameter and 12 mm length balloon at the site of the suboptimal expanded stent (F, arrows). (G) Minimal balloon waist after the third intravascular lithotripsy application disappearing after postdilation with a non-compliant balloon. (H) Final angiographic result showing complete stent expansion. (I) Optimal coherence tomography findings before applying intravascular lithotripsy — cross-sectional (top) and longitudinal (bottom) images — with severe medial calcification (asterisks) and a minimal stent area of 2.27 mm^2, which represents an expansion rate of 32% (compared with the average of proximal and distal maximal lumen area). (J) Optimal coherence tomography post intravascular lithotripsy — cross-sectional (top) and longitudinal (bottom) images — demonstrates an acute gain of minimal stent area of 5.92 mm^2 resulting in a final minimal stent area of 8.09 mm (129% expansion rate).

TABLE 1. Clinical characteristics.

Characteristics	Patients (n = 134)
Age (years)	73.7 ± 9.1
Male	102 (76.1%)
Diabetes mellitus	45 (33.6%)
Peripheral vascular disease	43 (32.1%)
Previous coronary artery bypass grafting	27 (20.1%)
Multivessel[a]	84 (62.7%)
Clinical presentation	
Stable angina	59 (44.0%)
Unstable angina	22 (16.4%)
Non-ST segment elevation myocardial infarction	18 (13.5%)
ST-segment elevation myocardial infarction	5 (3.7%)
Silent ischemia	30 (22.4%)

Data presented as number (%) or mean ± standard deviation.
[a]Multivessel disease was defined as >1 (angiographically significant) stenosis in >1 coronary artery, judged by the operator.

present an observational, multicenter, Belgian registry of IVL to gain insight into the treatment of heavily calcified lesions in a real-world setting, including its use for in-stent restenosis (ISR), which is considered off-label use.

Methods

Patients and study design. In this multicenter, observational study, we enrolled 134 consecutive patients from 5 different hospitals from October 2018 to July 2020. The use of IVL, as well as post-IVL lesion treatment — stenting, postdilation, the use of drug-eluting balloons, among others — were at the discretion of the operator, and every patient treated with IVL in these hospitals was included in the registry. Data analysis was approved by all institutional ethical committees. Patient and procedural characteristics were collected by the participating hospitals and analyzed anonymously. Follow-up was performed by medical record review.

Severe calcification was defined as radiopacities seen without cardiac motion before contrast injection, usually affecting both sides of the arterial lumen. *Moderate calcification* was defined as radiopacities noted only during the cardiac cycle before contrast dye injection. *Mild calcification* was defined as radiopacities noted during cardiac cycle at contrast injection. *Multivessel disease* was defined as >1 (angiographically significant) stenosis in >1 coronary artery, judged by the operator. *Multisegment* was defined as a target lesion including >1 segment of the coronary artery.

Study endpoints. The *primary endpoint* was final procedural success. *Optimal final procedural success* was defined as angiographic ≤30% residual stenosis, no coronary artery dissection or perforation, and Thrombolysis in Myocardial Infarction (TIMI) 3 flow. *Suboptimal final procedural success* was defined as angiographic >30% residual stenosis and/or coronary artery dissection, coronary artery perforation, or TIMI <3 flow. *Failed final procedure* was defined as failure to deliver stent or improve vessel lumen relative to the start of the procedure as judged by the operator.

Secondary endpoints included IVL therapy effect, angiographic result post stenting, and MACE. *Optimal IVL therapy effect* was defined as no IVL balloon waist visual on fluoroscopy, no coronary artery dissection or perforation, and TIMI 3 flow. *Suboptimal IVL therapy effect* was defined as IVL balloon waist of approximately 0%-30% on fluoroscopy and/or coronary artery dissection, coronary artery perforation, or TIMI <3 flow. *IVL failure* was defined as IVL balloon waist of >30% on fluoroscopy.

Optimal result post stenting was defined as angiographic ≤30% residual stenosis, no coronary artery dissection or perforation, and TIMI 3 flow. *Suboptimal result post stenting* was defined as angiographic >30% residual stenosis and/or coronary artery dissection, perforation, or TIMI <3 flow. *Failure* was defined as no visible angiographic effect of IVL therapy on lumen diameter (off-label in ISR and stent underexpansion).

MACE was defined as the composite of all-cause mortality, myocardial infarction, target-vessel failure or TVR, stroke, and stent thrombosis at 1 month post IVL.

Statistical analysis. Data analysis was performed via SPSS, version 26.0 (SPSS), using descriptive analysis. Categorical variables are expressed as count (percentage) and continuous variables are expressed as mean ± standard deviation.

Results

Patient and procedural characteristics. Between October 1, 2018 and July 31, 2020, at total of 134 consecutive patients were treated with IVL. Baseline clinical, lesion, and procedural characteristics are presented in **Table 1**, **Table 2**, and **Table 3**, respectively. Patients were predominantly male (76.1%); diabetes mellitus (33.6%), peripheral vascular disease (32.1%), and previous coronary artery bypass grafting (20.1%) were common comorbidities. The indications for coronary angiography (CAG) were diverse (stable angina in 44%, acute coronary syndrome in 33.6%, and silent ischemia in 22.4% of cases) (**Table 1**).

IVL was used to treat *de novo* lesions in 70.1% of cases and to treat in-stent (re)stenosis in 29.9% of cases. The left anterior descending artery was the most common target vessel (45.5%). In this cohort, target lesions were judged to be severely calcified in 64.9% and moderately calcified in 29.5% of cases by the operator on fluoroscopy. In the majority of lesions (65.7%), the calcification

TABLE 2. Lesion characteristics.

Characteristics	Patients (n = 134)
De novo	94 (70.1%)
In-stent	40 (29.9%)
Stent layers[a]	
1 stent layer	31 (77.5%)
2 stent layers	2 (5.0%)
Unknown	7 (17.5%)
Age of stent[a]	
Periprocedural	13 (32.5%)
<3 months	2 (5.0%)
3-12 months	6 (15.0%)
>12 months	18 (45.0%)
Unknown	1 (2.5%)
Distribution of calcium	
Concentric[b]	88 (65.7%)
Eccentric[c]	45 (33.6%)
Unknown/missing value(s)	1 (0.7%)
Ostial lesion	32 (23.9%)
Bifurcation	28 (20.9%)
Lesion length >20 mm	68 (50.7%)
Calcification	
Severe[d]	87 (64.9%)
Moderate[e]	36 (29.5%)
Mild[f]	9 (7.4%)
No	2 (1.6%)
Target location	
Left main artery	9 (6.7%)
Left anterior descending artery	61 (45.5%)
Circumflex artery	17 (12.7%)
Intermediary	2 (1.5%)
Right coronary artery	43 (32.1%)
Venous bypass graft	1 (0.75%)
Left internal mammary artery	1 (0.75%)
Vessel segment	
Proximal	98 (73.1%)
Mid	34 (25.4%)
Distal	2 (1.5%)
Multisegment[g]	24 (17.9%)
Imaging performed	26 (19.4%)
Imaging modality[h]	
Intravascular ultrasound	15 (61.9%)
Optical coherence tomography	11 (38.1%)
Calcium distribution[h]	
Calcium into media	6 (23.1%)
Calcium cirumference	
0°-180°	3 (11.5%)
180°-240°	12 (46.2%)
>240°	9 (34.6%)
Unknown	2 (7.7%)

Data presented as number (%).
[a]Stent layers ascertained in 40 patients.
[b]Distribution of calcium >180°
[c]Distribution of calcium <180°
[d]*Severe calcification* defined as radiopacities seen without cardiac motion before contrast injection usually affecting both sides of arterial lumen.
[e]*Moderate calcification* defined as radiopacities noted only during the cardiac cycle before contrast dye injection.
[f]*Mild calcification* defined as radiopacities noted during cardiac cycle at contrast injection.
[g]*Multisegment* defined as target lesion including >1 segment of the coronary artery.
[h]Calcium distribution ascertained in 26 patients.

was concentric. Intravascular imaging techniques were used in 19.4% of the procedures (**Table 2**).

Target-lesion predilation was performed in 93.7% of procedures, mostly with non-compliant balloons. In 39.5% of cases, additional devices — such as rotational atherectomy and cutting balloon — were used prior to IVL. IVL balloon delivery was successful in all cases but 1 (99.3%) (**Table 3**).

Procedural outcomes. Final procedural success in all 134 patients was considered optimal in 88.1% and suboptimal in 9% of cases. When *de novo* lesions and ISR lesions were analyzed separately, final procedural success was optimal in 92.6% of *de novo* lesions and in 77.5% of ISR lesions (**Table 4**).

Based on angiography, overall IVL therapy effect was successful in 94% of cases, comprised of 68.7% optimal (no IVL balloon waist) and 25.3% suboptimal results (≤30% IVL balloon waist). IVL outcome in *de novo* lesions was successful in 94.7% (74.5% optimal vs 20.2% suboptimal) and IVL outcome (off-label use) in stent underexpansion and ISR was successful in 92.5% (55% optimal vs 37.5% suboptimal) (**Table 4**).

Additional lesion preparation post IVL was performed in 61.9% of procedures, mainly using a non-compliant balloon.

TABLE 3. Procedural characteristics.

Characteristic	Patients (n = 134)
Access site	
Radial	97 (72.4%)
Femoral	36 (26.9%)
Brachial	1 (0.7%)
Catheter size	
6 French	94 (70.1%)
7 French	36 (26.9%)
8 French	4 (3.0%)
Predilation before IVL treatment	
Semicompliant balloon	9 (6.7%)
Non-compliant balloon	114 (85.1%)
High-pressure balloon	1 (0.75%)
No predilation	9 (6.7%)
Missing value(s)/unknown	1 (0.75%)
Additional device before IVL treatment	
Cutting balloon	21 (15.7%)
High-pressure balloon	5 (3.7%)
Scoring balloon	7 (5.2%)
Rotablation	18 (13.4%)
Laser therapy	2 (1.5%)
No additional device used before IVL	81 (60.5%)
Second additional device before IVL treatment	4 (3.0%)
Average balloon diameter (mm)	2.76 ± 0.53
Average balloon length (mm)	14.54 ± 3.40
Average highest balloon pressure (bar)	19.57 ± 3.73
IVL delivery	133 (99.3%)
IVL catheter type	
C2IVL2512	29 (21.6%)
C2IVL3012	39 (29.1%)
C2IVL3512	50 (37.3%)
C2IVL4012	16 (12.0%)
Number of pulses delivered (n)	
≤20	8 (6.0%)
>20 to ≤40	21 (15.7%)
>40 to ≤60	34 (25.4%)
>60 to ≤80	70 (52.2%)
Missing value(s)/unknown	1 (0.7%)
Number of pulses needed to open the lesion (n)	
≤20	11 (8.2%)
>20 to ≤40	14 (10.4%)
>40 to ≤60	39 (29.1%)
>60 to ≤80	32 (23.9%)
Missing value(s)/unknown	30 (22.4%)
Lesion not opened by IVL	8 (6.0%)
Post IVL lesion preparation	
No dilation	51 (38.1%)
Non-compliant balloon	62 (46.3%)
High-pressure balloon	11 (8.2%)
Scoring balloon	2 (1.5%)
Cutting balloon	4 (3.0%)
Rotablation	3 (2.2%)
Missing value(s)/unknown	1 (0.7%)
Drug-eluting balloon	5 (3.7%)
Stenting	104 (78.2%)
Average stent size (mm)	3.25 ± 0.52
Average stent length (mm)	9.59 ± 9.97
Post-stenting treatment[a]	
No dilation	28 (26.9%)
Non-compliant balloon	70 (67.3%)
High-pressure balloon	4 (3.8%)
Intracoronary lithotripsy	1 (0.75%)
Rotablation	1 (0.75%)
Average highest balloon pressure (bar)	20.43 ± 3.73

Data presented as number (%) or mean ± standard deviation.
[a]Post-stenting treatment in 104 patients. IVL = intravascular lithotripsy.

Occasionally (in 6.7%), scoring balloons, cutting balloons, or rotational atherectomy were deemed necessary (**Table 4**).

A stent was deployed in 104 patients and optimal result post stenting was achieved in 79.8% of procedures. Postdilation after PCI was performed in 73.1% of patients, almost always with a non-compliant balloon (**Table 4**).

An illustrative case where IVL clearly showed its value is presented in **Figure 1**.

Clinical outcomes. MACE occurred in 4 cases (3.0%), all caused by death. Two deaths were cardiovascular in origin. One death was due to failed urgent coronary artery bypass grafting for a

TABLE 4. Procedural outcome.

Outcomes	Patients (n = 134)		
	Overall	*De novo* Lesions[d]	ISR[e]
Primary endpoint (final procedural success)			
Optimal[a]	118 (88.1%)	87 (92.6%)	31 (77.5%)
Suboptimal[b]	12 (9.0%)	4 (4.3%)	8 (20%)
>30% stenosis	11 (91.7%)	3 (75%)	8 (100%)
Dissection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Perforation	1 (8.3%)	1 (25.0%)	0 (0.0%)
TIMI flow <3	0 (0.0%)	0 (0.0%)	0 (0.0%)
Failure[c]	4 (2.9%)	3 (3.1%)	1 (2.5%)
Secondary endpoint (IVL therapy effect)			
Optimal[f]	92 (68.7%)	70 (74.5%)	22 (55%)
Suboptimal[g]	34 (25.3%)	19 (20.2%)	15 (37.5%)
Failure[h]	8 (6.0%)	5 (5.3%)	3 (7.5%)
	Overall	De novo lesions[j]	ISR[k]
Angiographic result post stenting[i]			
Optimal[a]	83 (79.8%)	73 (82.0%)	10 (66.7%)
Suboptimal[b]	21 (20.2%)	16 (18.0%)	5 (33.3%)
>30% stenosis	21 (100%)	16 (100%)	5 (100%)
Dissection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Perforation	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIMI flow <3	0 (0.0%)	0 (0.0%)	0 (0.0%)
Failure[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)

Data presented as number (%).
[a]*Optimal* defined as angiographic ≤30% residual stenosis, no coronary artery dissection or perforation and TIMI 3 flow.
Suboptimal defined as angiographic >30% residual stenosis and/or coronary artery dissection, coronary artery perforation or TIMI <3 flow.
[c]*Failure* defined as failure to deliver stent or improve vessel lumen relative to the start of the procedure as judged by the operator.
[d]*De novo* lesions n = 94.
[e]ISR lesions n = 40.
[f]*Optimal* defined as no IVL balloon waist visual on fluoroscopy, no coronary artery dissection or perforation and TIMI 3 flow.
[g]*Suboptimal* defined as IVL balloon waist of approximately 0%-30% on fluoroscopy and/or coronary artery dissection, coronary artery perforation or TIMI <3 flow.
[h]*Failure* defined as IVL balloon waist of >30% on fluoroscopy.
[i]Angiographic result post stenting n = 104.
[j]*De novo* lesions n = 89.
[k]ISR lesions n = 15.
ISR = in-stent restenosis; TIMI = Thrombolysis in Myocardial Infarction.

procedure-related perforation in a native ostial left anterior descending coronary artery lesion. In this case, no high-pressure dilation, scoring/cutting balloon, or intravascular atherectomy devices were used, indicating that the perforation was likely caused by IVL. A non-compliant balloon was used to dilate the lesion before and after IVL. The other cardiovascular death was due to acute in-stent thrombosis, which occurred a few hours post PCI, despite optimal final result after PCI. Two other deaths were unrelated to the procedure (1 Covid-19, 1 abdominal aortic aneurysm rupture) (**Table 5**).

Complications. IVL complications were rare. Thirteen IVL balloons (9.7%) ruptured without further consequences, 1 coronary artery dissection was successfully stented, and 1 coronary artery perforation required urgent coronary artery bypass grafting (and resulted in death, as mentioned above).

Discussion

In an aging population, the number of PCIs performed in patients with CAC increases. In the past, a number of techniques have been developed to dilate severely calcified lesions and facilitate stent implantation. One of these techniques employs cutting balloons — eg, Flextome cutting balloon (Boston Scientific) — which are non-compliant balloons with 3-4 microblades mounted longitudinally on the surface.[5] Cutting balloon angioplasty achieved a larger luminal gain than standard balloon angioplasty in calcified lesions, but 6-month follow-up showed no difference in restenosis despite a higher rate of perforation.[6] Another technique uses scoring balloons — eg, AngioSculpt RX (Spectranetics) — which are semicompliant balloons covered with 3 external nitinol spiral scoring wires. Scoring balloons are more flexible than cutting balloons and are often used to treat ISR because of the higher stability.[7] Data on scoring balloons in CAC are limited, although they seem less effective than cutting balloons in these lesions.[8] Another well-established technique is coronary rotational atherectomy — eg, Rotapro (Boston Scientific). Rotablation is effective in opening calcified lesions that cannot be crossed readily with regular balloons. Nevertheless, rotational atherectomy has a number of potential complications, such as perforation, dissection, burr entrapment, complete heart block, and distal embolization of plaque microparticles.[9] A meta-analysis of randomized controlled trials showed that lesion modification with cutting-balloon, scoring-balloon angioplasty, and rotational atherectomy resulted in similar short-term and improved long-term outcomes compared with controls.[10]

Recently, a new technique has been introduced to treat CAC and is based on IVL through the use of acoustic shock waves. Herein, we present data from 134 consecutive patients treated with Shockwave IVL at 5 cardiac centers in Belgium. Overall, IVL therapy effect was optimal in 68.7% and final angiographic result post stenting was optimal in 88.1% of cases. These results are encouraging, because Shockwave was mainly used as bail-out strategy after initial balloon angioplasty failure.

Table 5. Clinical outcome (major adverse cardiovascular event).

1-Month Outcomes	Patients (n = 134)
Death	4 (3.0%)
Cardiac death	2 (50.0%)
Non-cardiac death	2 (50.0%)
Myocardial infarction	0 (0.0%)
Non-Q wave myocardial infarction	0 (0.0%)
Q-wave myocardial infarction	0 (0.0%)
Target-vessel failure	0 (0.0%)
Target-vessel revascularization	0 (0.0%)
Cerebrovascular accident/transient ischemic attack	0 (0.0%)
Stent thrombosis	1 (0.7%)

Data presented as number (%).

Our study contributes to recent IVL studies. Askoy et al investigated the safety and success rates of IVL in 71 patients.[11] Wong et al published a single-center study on the first experiences with IVL in 26 patients.[12] The authors from these papers concluded that IVL had a high success rate in lesion preparation in severely calcified coronary lesions and had few procedural complications or MACE. Data from DISRUPT CAD I, II, and III are also available. The DISRUPT CAD I investigators demonstrated the feasibility of IVL for modification of severe CAC in a multicenter study, which included 60 patients. The results were promising, with 95% clinical success rate, 98.3% device success rate, and 100% stent delivery success rate. In DISRUPT CAD I, there were no MACE after 30 days.[2] In DISRUPT CAD II, the aim was to confirm safety and efficacy of IVL in a prospective, multicenter, single-arm, post-approval study; the primary endpoint of in-hospital MACE occurred in 5.8% of patients. There were no procedural complications and successful delivery and use of the IVL catheter was achieved in all patients.[3] In Disrupt CAD III, Hill et al suggested that coronary IVL can safely (primary safety endpoint of 92.2%) and effectively (primary effectiveness endpoint of procedural success was 92.4%) facilitate stent implantation in severely calcified lesions.[4]

The results of our real-world registry match these findings, confirming the feasibility, safety, and effectiveness of the Shockwave device, even when IVL is used as a bail-out strategy. It is important to note that the population included in our study differs from the population undergoing PCI in daily clinical practice. All patients were enrolled in tertiary centers, resulting in procedures with higher complexity. Furthermore, compared with "standard" populations in these tertiary centers, patients were older (73.7 years vs 68.3 years), and had more diabetes (33.6% vs 26.0%), coronary artery bypass grafting (20.1% vs 10.7%), and peripheral arterial disease (32.1% vs 14.9%). The use of intravascular imaging (19.4%) was also much higher than in regular Belgian clinical practice, indicating once more the complexity of the lesions in this registry. Compared with the DISRUPT CAD trials, our patient population was older (73.7 vs. 72.1 in DISRUPT CAD I and II vs. 71.2 years in DISRUPT CAD III) and a larger fraction of them previously underwent CABG (20.1 vs. 9.4% in DISRUPT CAD III). The proportion of male patients and patients with diabetes mellitus was similar to DISRUPT CAD.

Rotablation was used as an adjunctive treatment modality in 14.2% of cases before IVL and in 2.2% following IVL. This suggests that atheroablative technologies may still be required in specific situations to facilitate IVL balloon placement or in case IVL was unable to (fully) crack the lesion. Therefore, Shockwave IVL and rotational atherectomy should be considered complementary — rather than interchangeable — techniques. The frequent use of rotablation in this registry confirms that the population had severely calcified and highly stenotic lesions. In contrast, no rotational atherectomy was performed in the DISRUPT CAD trials.

Regarding the safety endpoints, 1 dissection and 1 perforation occurred during IVL treatment. The distal dissection was successfully stented. The IVL-induced perforation, however, led to cardiac tamponade and death after failed emergency coronary artery bypass grafting. To date, only 1 case of a coronary artery perforation following Shockwave IVL has been published.[13]

Study limitations. This is a real-life registry, including only a few procedures with intracoronary imaging, due to a lack of reimbursement in Belgium. Consequently, many parameters were evaluated angiographically, including severity of calcification and the assessment of the results (suboptimal vs optimal). Similar to all studies published thus far on IVL, the main limitations are that this study is not randomized and that no long-term follow-up can be provided. In addition, no analysis was performed for periprocedural troponin rise/myocardial infarction or acute cardiac injury.

Conclusion

Coronary IVL is a feasible, effective, and safe technique for the treatment of severely calcified coronary lesions. IVL has been shown to facilitate stent implantation and correct stent underexpansion without the conventional risks associated with rotational atherectomy. A high success rate combined with a low complication rate positions IVL as a key player for CAC disease, especially when conventional techniques fail. Further prospective and randomized studies are needed to confirm the added value when used upfront or after failure of the initially applied conventional techniques.

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Funding: This work was supported by a Senior Clinical Investigator fellowship (to VFS, 1842219N) of the Fund for Scientific Research Flanders.

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.

Manuscript accepted February 21, 2021.

The authors report patient consent for the images used herein.

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