Real-World Experience of Coronary Intravascular Lithotripsy in an Asian Population: A Retrospective, Observational, Single-Center, All-Comers Registry

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Abstract

Objectives. To assess the clinical and angiographic outcomes of coronary intravascular lithotripsy (IVL) use in an all-comers population with moderate-to-severely calcified coronary lesions. **Background.** IVL has been shown to modify coronary calcific plaques with minimal vascular complications. **Methods.** This was a retrospective, observational study of patients treated with IVL. The primary endpoint was in-hospital major adverse cardiovascular event (MACE), which included cardiac death, myocardial infarction (MI), and target-vessel revascularization (TVR). Secondary endpoints were clinical success (stent expansion with <30% in-stent residual stenosis and no in-hospital MACE) and angiographic success. **Results.** Between August 2019 and December 2019, a total of 50 calcified lesions were treated in 45 patients using the Shockwave C2 IVL catheter (Shockwave Medical). They were further studied in 3 treatment subgroups: (1) primary IVL group with *de novo* lesions (n = 23 lesions); (2) secondary IVL group in which non-compliant balloon dilation failed (n = 15 lesions); and (3) tertiary IVL group with IVL to underexpanded stents (n = 12 lesions). The mean diameter stenosis of calcified lesions was 63.2 ± 10.2% at baseline, and decreased to 33.5 ± 10.9% immediately post IVL (*P*<.001) and 15 ± 7.1% post stenting (*P*<.001). Mean minimal lumen diameter was 1.1 ± 0.3 mm at baseline, and increased to 1.90 ± 0.5 mm post IVL (*P*<.001) and 2.80 ± 0.50 mm post stenting (*P*<.001). In-hospital and 30-day MACE occurred in 3 and 4 patients, respectively. Overall, clinical success and angiographic success were achieved in 90% and 94% of cases, respectively. **Conclusions.** IVL appears to be a safe, effective, and feasible strategy for calcium modification in an all-comers cohort with high success rate, minimal procedural complications, and low MACE rates.

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Calcified coronary lesions are difficult to treat by percutaneous coronary intervention (PCI) as calcium impedes device crossing,[1] alters drug-elution kinetics,[2] and causes stent malapposition and inadequate stent expansion.[3] This in turn leads to increased risk of stent thrombosis and restenosis.[4] Currently available devices for facilitating PCI in calcific lesions include high-pressure and ultra-high pressure non-compliant (NC) balloons, modified balloons (scoring, cutting balloons), and atherectomy devices such as rotational, orbital, and laser atherectomy.[5] Both NC and modified balloons require high pressure for vessel dilation in severely calcified lesions, which in turn increases angiographic complications.[6-8] Both rotational and orbital atherectomy require specific training and have steeper learning curves. Although the procedural success rates with these devices improve with

expertise, they are still associated with substantial procedural complications and in-hospital adverse cardiac events.[9-11] In this scenario, the intravascular lithotripsy (IVL) device (Shockwave Medical) has been shown to modify coronary calcific plaques with minimal vascular complications.[12,13] It is a novel, balloon-based, percutaneous catheter employing ultrasonic pressure waves for treatment of severely calcified coronary lesions.[14,15] In our study, we present the data of a retrospective, observational IVL registry in an all-comers population with moderate-to-severely calcified coronary lesions.

Methods

Patients and study design. The SingIVL registry is a single-center, retrospective registry of IVL-treated patients that was approved by the Singhealth centralized institutional review board (CIRB). Data were collected by medical record review as part of a clinical audit and received CIRB waiver for patient consent. Data were anonymized by a trusted third party for analysis.

Percutaneous coronary intervention. PCI was performed according to the conventional and local standards in either the same setting or as a staged procedure in patients. All patients were given dual-antiplatelet therapy and received intra-arterial heparin for anticoagulation during the procedure.

Intravascular lithotripsy. All patients underwent IVL with the Shockwave C2 balloon-based coronary catheter system. IVL balloon size was chosen based on vessel diameter in a 1:1 ratio and prepared according to the manufacturer's instructions for use. The balloon catheter was then positioned at the target lesion by monorailing over 0.014″ coronary guidewire and inflated to 4 atm. Then, up to 10 impulses were delivered at 1 pulse/second over 10 seconds. The balloon was inflated to 6 atm after delivering the pulses and then deflated to re-establish blood flow. Up to 80 impulses were subsequently delivered with a single IVL catheter. In cases with multiple lesions, each lesion site was treated with a minimum of 20 pulses per site.

In-hospital follow-up. For post-PCI antiplatelet therapy, all patients received 100 mg of aspirin daily. Patients with stable coronary artery disease received 75 mg of clopidogrel for 6 to 12 months and patients with acute coronary syndrome (ACS) received ticagrelor 180 mg/day for 12 months.

Endpoints. The *primary endpoint* was in-hospital *major adverse cardiovascular event (MACE)*, as defined by the Academic Research Consortium (ARC)-2, including cardiac death, myocardial infarction (MI), or target-vessel revascularization (TVR).[16] *Periprocedural MI* was defined per the fourth universal definition for MI.[17]

Secondary endpoints included *clinical success*, defined as residual diameter stenosis <30% after stenting with no evidence of in-hospital MACE; *angiographic success*, defined as success in facilitating stent delivery with <30% residual stenosis and without serious angiographic complications (severe dissection impairing flow [type D–F], perforation, abrupt vessel closure, slow flow or no reflow); and *device success*, defined as the ability to deliver IVL balloon to target site and complete Shockwave pulse delivery. MACE rate was also assessed at 30 days.

Angiographic analysis. Procedural angiograms were digitally recorded and analyzed. Calcification was identified as readily apparent radiopacities within the vascular wall at the site of the stenosis during angiography and graded as moderate or severe as proposed by Mintz et al.[18] Quantitative coronary angiographic analysis (QCA) was performed offline using IMPAX agility imaging software (Agfa Health Care). Measurements were performed using the same single worst-view projection. Contrast-filled non-tapered catheter tip was used for calibration.

Subgroup analysis. The patient cohort were further divided into 3 subgroups: (1) the primary IVL subgroup, in which patients had IVL to *de novo* lesions; (2) the secondary IVL subgroup, in which patients had IVL after failure of non-compliant, high-pressure balloon dilation; and (3) the tertiary IVL subgroup, in which patients had IVL to underexpanded stents.

Statistical analysis. Descriptive statistics including mean, median, and proportion were calculated. Continuous variables are presented as mean ± standard deviation and categorical variables as counts with percentages. We performed paired t-test for comparison of QCA results at baseline and after PCI for overall cohort and subgroups. A *P*-value of ≤.05 was considered statistically significant. Data were analyzed using STATA, version 15.0 (StataCorp LP).

Results

Baseline clinical and procedural characteristics. Between August 2019 and December 2019, a total of 45 patients with 50 calcified lesions were treated with IVL. The baseline characteristics of the overall treatment cohort are shown in Table 1. Mean age was 70 ± 8.8 years, with a high prevalence of male sex (71%) and cardiac risk factors. Prevalence of renal insufficiency was 44%, with 7 patients (16%) in end-stage renal failure. The majority (43 patients) had complex multivessel disease in the form of double-vessel involvement in 22%, triple-vessel involvement in 74%, and left main coronary artery involvement in 29%. Median hospital stay was 3 days (range, 1-6 days). PCI procedural characteristics are shown in Table 2.

Coronary lesion characteristics. Out of 50 coronary lesions, the target artery was the left main coronary artery in 16%, left anterior descending coronary artery in 44%, left circumflex coronary artery in 16%, and right coronary artery in 24%. The

TABLE 1. Baseline clinical and demographic characteristics of overall treatment group.

Characteristic	Patients (n = 45)
Age (years)	70 ± 8.8
Gender	
Male	32 (71%)
Female	13 (29%)
Body mass index (kg/m^2)	26 ± 4.1
Current smoker	8 (18%)
Diabetes mellitus	28 (62%)
Hypertension	42 (93%)
Hyperlipidemia	43 (96%)
Chronic kidney disease[a]	20 (44%)
End-stage renal failure	7 (16%)
Prior myocardial infarction	24 (53%)
Prior percutaneous coronary intervention	24 (53%)
Prior transient ischemic attack/stroke	5 (11%)
Stable angina	17 (38%)
Functional class I	3 (7%)
Functional class II	14 (31%)
Acute coronary syndromes	28 (62%)
Unstable angina	7 (16%)
Non-ST segment elevation myocardial infarction	14 (31%)
ST-segment elevation myocardial infarction	7 (16%)
Acute heart failure at presentation	9 (20%)
Left ventricular ejection fraction (%)	46 ± 14.7
Emergency percutaneous coronary intervention	8 (18%)
Coronary artery disease	
Single-vessel disease	2 (4%)
Double-vessel disease	10 (22%)
Triple-vessel disease	33 (74%)
Left main stenosis ≥50%	13 (29%)
Creatinine (µmol/L)	162 ± 195
Hospital stay (days)	3 (1-6)

Data presented as mean ± standard deviation, count (percentage), or median (range).
[a]Defined as glomerular filtration rate <60 mL/min.

TABLE 2. PCI procedural characteristics of overall treatment group.

Characteristic	Patients (n = 45)
Total procedural time (minutes)	83 ± 30
Total fluoroscopy time (minutes)	28.8 ± 12.8
Total contrast (mL)	178 ± 68
Vascular access	
Radial	22 (49%)
Femoral	23 (51%)
Intravascular lithotripsy indication	
Primary	21 (47%)
Secondary	14 (31%)
Tertiary	10 (22%)
Image-guided percutaneous coronary intervention	20 (45%)
Intravascular ultrasound	17 (38%)
Optical coherence tomography	3 (7%)

Data presented as mean ± standard deviation or count (percentage).

majority of lesions were proximally located (82%) and severely calcified (76%), with mean length of 28.5 ± 12.5 mm. Concentric calcium and eccentric calcium were present in 76% and 24% of lesions, respectively (Table 3).

IVL procedural characteristics. IVL-related procedural characteristics are presented in Table 3. Pre-IVL and post-IVL balloon dilation were done in the majority of lesions (82% and 78%, respectively). Modified balloons, like scoring balloon (22%), cutting balloon (6%), and ultra-high pressure OPN balloon (22%), were also used in specific cases for lesion preparation and optimal stent expansion. Rotational atherectomy was performed in 1 patient before IVL. The majority of lesions (96%) were treated with drug-eluting stent and 2 in-stent restenosis lesions were treated with drug-coated balloon. Representative examples of IVL treatment are presented in Figures 1 and 2.

Quantitative coronary angiography. Mean diameter stenosis of calcified lesions was 63.2 ± 10.2% at baseline, and decreased to 33.5 ± 10.9% immediately post IVL (P<.001) and 15 ± 7.1% post stenting (P<.001). Mean minimal lumen diameter was 1.1 ± 0.3 mm at baseline, and increased to 1.90 ± 0.5mm post IVL (P<.001) and 2.80 ± 0.50 mm post stenting (P<.001) (Table 4).

Clinical and angiographic outcomes of IVL. Successful IVL treatment of the target lesion was performed in 48 lesions (96%). IVL balloons ruptured in 2 cases in the primary IVL subgroup after

Table 3. Lesion and intravascular lithotripsy procedural characteristics of overall treatment group and subgroups.

	Overall Lesions (n = 50)	Primary IVL Lesions (n = 23)	Secondary IVL Lesions (n = 15)	Tertiary IVL Lesions (n = 12)
Vessel treated				
Left main coronary artery	8 (16%)	4 (17%)	4 (27%)	0 (0%)
Left anterior descending coronary artery	22 (44%)	12 (52%)	5 (33%)	5 (42%)
Left circumflex coronary artery	8 (16%)	4 (18%)	3 (20%)	1 (8%)
Right coronary artery	12 (24%)	3 (13%)	3 (20%)	6 (50%)
Lesion localization				
Proximal	41 (82%)	21 (91%)	14 (93%)	6 (50%)
Mid	7 (14%)	2 (9%)	1 (7%)	4 (33%)
Distal	2 (4%)	0 (0%)	0 (0%)	2 (17%)
Lesion length (mm)	28.5 ± 12.5	29.6 ± 11.4	28.1 ± 15.0	26.9 ± 11.8
Calcification				
Moderate	12 (24%)	7 (30%)	2 (13%)	3 (25%)
Severe	38 (76%)	16 (70%)	13 (87%)	9 (75%)
Lesion assessment				
Concentric	38 (76%)	16 (70%)	13 (87%)	9 (75%)
Eccentric	12 (24%)	7 (30%)	2 (13%)	3 (25%)
IVL procedural time (min)	5.8 ± 2.7	5.9 ± 3.4	5.4 ± 2.2	6.2 ± 1.5
Total pulses delivered	61 ± 24	55 ± 22	62 ± 21	72 ± 27
Number of IVL catheters				
1	48 (96%)	23 (100%)	14 (93%)	11 (92%)
2	2 (4%)	0 (0%)	1 (7%)	1 (8%)
Diameter of IVL balloon (mm)	3.2 ± 0.4	3.2 ± 0.4	3.2 ± 0.2	3.3 ± 0.5
Maximal IVL balloon inflation pressure (atm)	5.2 ± 1.1	5.0 ± 1.2	5.5 ± 1.2	5.3 ± 1.0
Pre-IVL dilation	41 (82%)	15 (65%)	15 (100%)	11 (92%)
Largest diameter of predilation balloon (mm)	2.7 ± 0.5	2.3 ± 0.4	2.9 ± 0.3	3.0 ± 0.6
Mean predilation pressure (atm)	20 ± 6.4	17 ± 4.5	20 ± 5.2	23 ± 8.2
Post-IVL dilation	39 (78%)	19 (83%)	10 (67%)	10 (83%)
Largest diameter of postdilation balloon (mm)	3.2 ± 0.5	3.2 ± 0.5	3.1 ± 0.3	3.4 ± 0.6
Mean postdilation pressure (atm)	20 ± 5.7	17 ± 3.1	20 ± 3.7	25 ± 7.5
Adjunctive devices				
Scoring balloon	11 (22%)	6 (26%)	2 (13%)	3 (25%)
Cutting balloon	3 (6%)	1 (4%)	1 (7%)	1 (8%)
OPN non-compliant balloon	11 (22%)	1 (4%)	3 (20%)	7 (58%)
Rotational atherectomy	1 (2%)	0 (0%)	1 (7%)	0 (0%)
Number of stents used (n)	1.7 ± 0.8	1.6 ± 0.7	1.9 ± 1.0	1.5 ± 0.9
Use of drug-coated balloon	2 (4%)	0 (0%)	0 (0%)	2 (17%)

Data presented as mean ± standard deviation or count (percentage).
IVL = intravascular lithotripsy.

TABLE 4. Quantitative coronary analysis of lesions treated with intravascular lithotripsy.

Measurement	Overall Lesions (n = 50)	Primary IVL Lesions (n = 23)	Secondary IVL Lesions (n = 15)	Tertiary IVL Lesions (n = 12)
Reference vessel diameter (mm)	3.2 ± 0.5	3.2 ± 0.6	3.4 ± 0.4	3.0 ± 0.5
Baseline MLD (MLD1, mm)	1.1 ± 0.3	1.2 ± 0.3	1.0 ± 0.2	1.3 ± 0.4
Baseline % DS (DS1)	63.2 ± 10.2	63.6 ± 8.4	69.4 ± 5.4	54.9 ± 12.5
Post-IVL MLD (MLD2, mm)	1.9 ± 0.5[a]	1.9 ± 0.5[a]	1.9 ± 0.4[a]	1.9 ± 0.5[b]
Post-IVL luminal gain (LG1, mm)	0.8 ± 0.4	0.8 ± 0.3	0.9 ± 0.4	0.6 ± 0.4
Post-IVL % DS (DS2)	33.5 ± 10.9[a]	32.7 ± 11.0[a]	36.1 ± 9.2[a]	32 ± 12.8[c]
Post-PCI MLD (MLD3, mm)	2.8 ± 0.5[a]	2.8 ± 0.5[a]	2.9 ± 0.3[a]	2.5 ± 0.6[a]
Post-PCI luminal gain (LG2, mm)	1.6 ± 0.5[a]	1.6 ± 0.5[a]	2.0 ± 0.4[a]	1.2 ± 0.5[b]
Post-PCI % DS (DS3)	15 ± 7.1[a]	14.5 ± 6.0[a]	14.2 ± 5.8[a]	17 ± 10[a]

Data presented as mean ± standard deviation. DS = diameter stenosis; IVL = intravascular lithotripsy; MLD = minimal lumen diameter.
[a]Indicates *P*<.001 for MLD2 vs MLD1, MLD3 vs MLD2, DS2 vs DS1, DS3 vs DS1, LG2 vs LG1 in overall, primary, and secondary IVL groups and MLD3 vs MLD1, DS3 vs DS1 in tertiary IVL group. [b]Indicates *P*<.001 for MLD2 vs MLD1, LG2 vs LG1 in tertiary IVL. [c]Indicates *P*<.001 for DS2 vs DS1 in tertiary IVL.

TABLE 5. Clinical and angiographic outcomes of lesions treated with intravascular lithotripsy.

Outcomes	Overall Lesions (n = 50)	Primary IVL Lesions (n = 23)	Secondary IVL Lesions (n = 15)	Tertiary IVL Lesions (n = 12)
Clinical success	45 (90%)	23 (100%)	13 (87%)	9 (75%)
Angiographic success	47 (94%)	22 (96%)	15 (100%)	10 (83%)
Facilitated stent delivery	50 (100%)	23 (46%)	15 (30%)	12 (100%)
Device success	48 (96%)	21 (91.3%)	15 (100%)	12 (100%)
Device failure	2 (4%)	2 (9%)	0 (0%)	0 (0%)
Final angiographic complications	19 (38%)	11 (48%)	8 (53%)	0 (0%)
Dissection	18 (36%)	10 (43%)	8 (53%)	0 (0%)
A	2 (4%)	2 (9%)	0 (0%)	0 (0%)
B	15 (30%)	7 (30%)	8 (53%)	0 (0%)
C	1 (2%)	1 (4%)	0 (0%)	0 (0%)
D-F	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Perforation	1 (2%)	1 (4%)	0 (0%)	0 (0%)
Abrupt vessel closure	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Slow/no flow	0 (0%)	0 (0%)	0 (0%)	0 (0%)
In-hospital MACE	3 (6%)	0 (0%)	2 (13%)	1 (8%)
MI	2 (4%)	0 (0%)	1 (7%)	1 (8%)
TVR	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Cardiac death	1 (2%)	0 (0%)	1 (7%)	0 (0%)
30 day MACE (MI/TVR/cardiac death)	4 (8%)	0 (0%)	2 (13%)	2 (17%)
Stent thrombosis (definite or probable)	1 (2%)	0 (0%)	0 (0%)	1 (8%)

Data presented as count (percentage). In total, at 30 days, there were 5 MACE in 4 patients.
IVL = intravascular lithotripsy; MACE = major adverse cardiovascular event; MI = myocardial infarction; TVR = target-vessel revascularization.

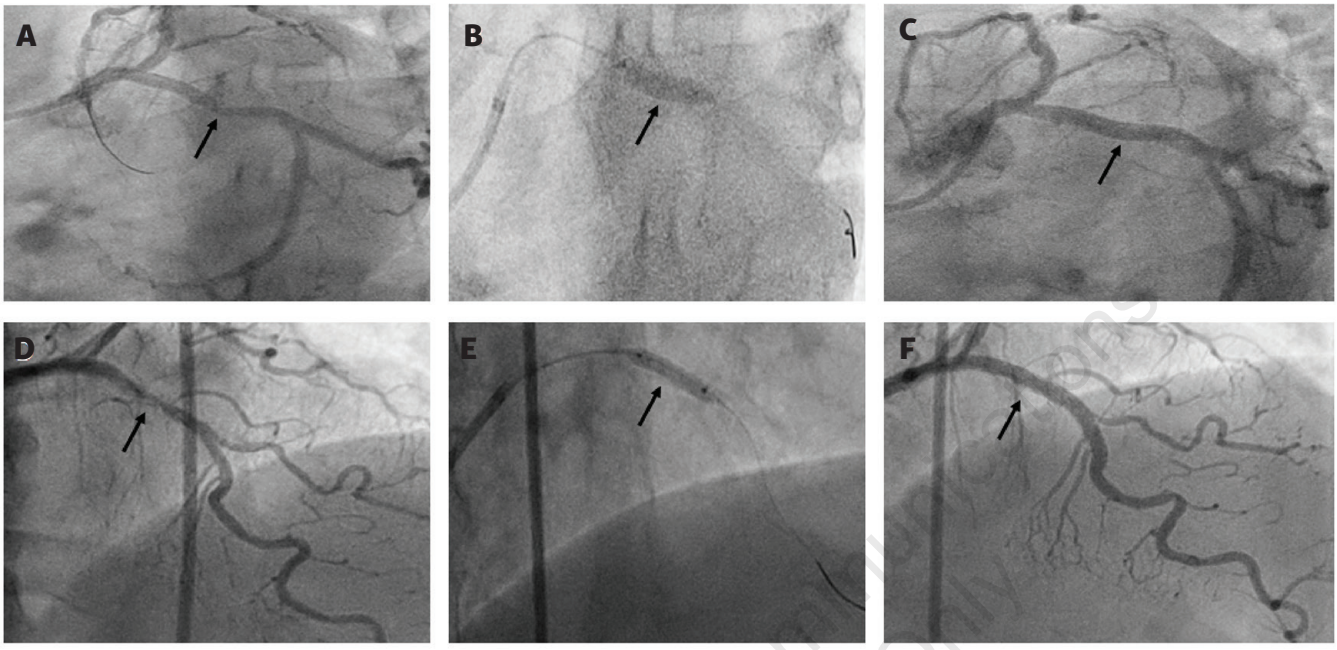

FIGURE 1. Representative examples of primary and secondary intravascular lithotripsy (IVL) treatment groups. Primary IVL group: (A) calcific lesion at baseline; (B) post IVL therapy; (C) final result after stenting. Secondary IVL group: (D) calcific lesion at baseline; (E) post IVL therapy; (F) final result after stenting (arrows).

delivering 15 pulses and 30 pulses, respectively, without further sequelae. Minor dissections (type A to C dissections) occurred in 18 lesions (36%). One patient had major coronary perforation, which was managed successfully with covered stent. The perforation in this case did not occur after IVL. After IVL, both cutting balloon and OPN balloon were used for vessel dilation at high pressure, which may have contributed to the perforation. There were no cases of abrupt vessel closure, slow flow and no reflow. Out of 50 treated lesions, angiographic success was achieved in 94% and clinical success was achieved in 90% of cases.

The primary endpoint of in-hospital MACE occurred in 3 patients (6%), which included 2 non-ST elevation MIs with troponin I increase and 1 death due to cardiogenic shock. One patient died due to sepsis after prolonged hospital stay of 40 days and was excluded from our MACE data due to non-cardiac mortality. A total of 5 MACEs occurred in 4 patients at 30 days (8%). One patient in the tertiary IVL subgroup had ST-elevation MI secondary to subacute stent thrombosis after hospital discharge and underwent PCI with drug-coated balloon to the target vessel. No MACEs occurred in the primary IVL subgroup at 30 days (Table 5).

Subgroup analysis. In the primary IVL subgroup, the average diameter stenosis reduced from 63.6 ± 8.4% at baseline to 14.5 ± 6% post PCI (*P*<.001), with final acute luminal gain of 1.6 ± 0.5 mm. Clinical success was achieved in all 23 lesions (100%) and 1 patient had coronary perforation. In the secondary IVL subgroup, mean diameter stenosis reduced from 69.4 ± 5.4% at baseline to 14.2 ± 5.8% post PCI (*P*<.001), with final acute luminal gain of 2 ± 0.4 mm. Clinical success was achieved in 13 of 15 lesions (87%). In the tertiary IVL subgroup, mean diameter stenosis reduced from 54.9 ± 12.5% at baseline to 17 ± 10% post PCI (*P*<.001), with final acute luminal gain of 1.2 ± 0.5 mm. Clinical success was achieved in 9 of 12 lesions (75%); 2 lesions did not achieve final residual diameter stenosis <30% and 1 lesion was in a patient who had periprocedural MI that was medically treated (Tables 4 and 5).

Discussion

This study is the first IVL registry from an Asian region, and shows IVL to be a safe and effective modality for calcium modification in an all-comers cohort. The main findings of our study are as follows. (1) In our all-comers population with calcified coronary lesions, IVL showed device success in 96% of cases and facilitated stent delivery in 100% of cases. (2) Angiographic success was achieved in 94% of cases, while clinical success (defined as final residual stenosis <30% with no in-hospital MACE) was achieved in 90% of cases. (3) IVL was highly effective across all treatment subgroups, with clinical success of 100% in the primary IVL subgroup, 87% in the secondary IVL subgroup, and 75% in the tertiary IVL subgroup. (4) IVL was safe, with no major angiographic complications in 98% of cases. (5) Three patients had in-hospital MACE and 4 patients

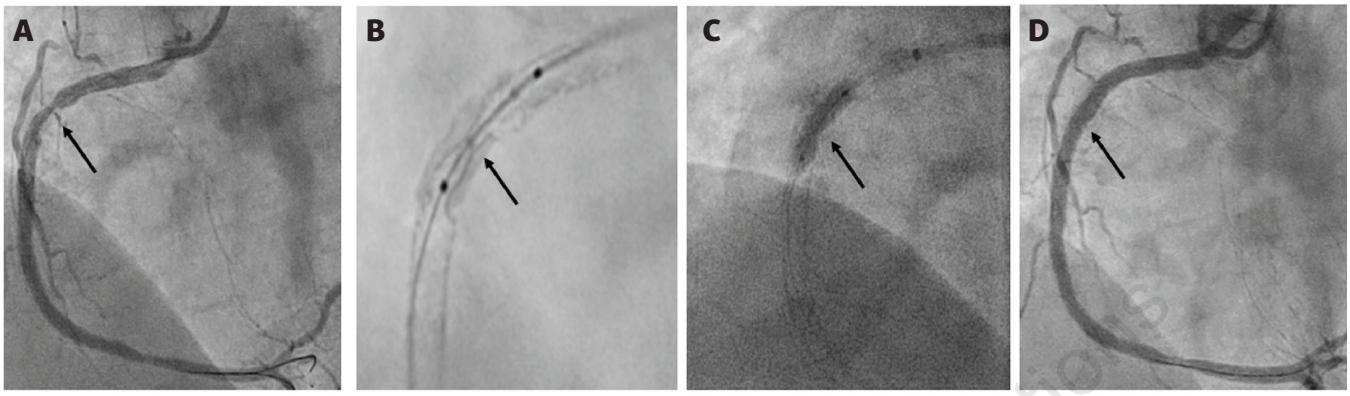

FIGURE 2. Representative example of tertiary intravascular lithotripsy (IVL) treatment group: (A) acute stent underexpansion; (B) stent boost enhancement showing underexpanded stent; (C) post IVL therapy; (D) final result showing well-expanded stent (arrows).

had MACE at 30 days. (6) IVL balloon rupture occurred in 2 cases (4%) without any sequelae.

Currently used devices for calcium modification include NC high-pressure and ultra-high pressure balloons, scoring or cutting balloons, as well as atheroablative techniques such as rotational, orbital, and laser atherectomy.[5] These devices usually act by either tissue compression or tissue debulking. Success rates with modified balloons (scoring or cutting balloons) have been reported in a range from 81%-100%, along with increased risk of vessel dissection (7%-9.3%) and coronary perforation (0%-2%).[6,8] Contemporary studies on rotational atherectomy[6,9] have shown success rates varying from 92.5%-98%, with in-hospital MACE varying between 2%-4.3%, and the procedure has been associated with major angiographic complications such as coronary artery dissection (3%-3.3%), perforation (1.7%-4%), and pericardial effusion (0.8%-3%).

In this scenario, IVL is a novel, balloon-based treatment modality for calcium modification that was introduced in 2016 and offers several potential advantages in the form of its easy applicability, ability to modify both superficial and deep calcium at lower balloon inflation pressures with less vessel barotrauma and distal atheromatous embolization, elimination of guidewire bias, and provision of side-branch guidewire protection during calcium modification.[12] Compared with modified balloons and rotational atherectomy, IVL had shown comparable procedural success rate (90%) and in-hospital MACE rate (6%) in treating calcified coronary lesions with minimal angiographic complications in our study cohort. IVL appears to be safe and effective along with the adjunctive use of modified balloons (scoring balloon, 22%; cutting balloon, 6%) and ultra-high pressure balloons (OPN balloon, 22%), attaining residual diameter stenosis <50% in all patients and resulting in no major angiographic complications in 98% of cases. However, the use of these aggressive adjunctive therapies caused minor type B dissections in 5 cases and coronary perforation in 1 case.

Our IVL procedural success rate of 90% was similar to orbital atherectomy as reported in the ORBIT II study (88.9%),[11] but with slightly lower rate of in-hospital MACE (6% vs 9.8%, respectively) and 30-day MACE (8% vs 10.4%, respectively).

As compared with the DISRUPT CAD II study, our patient cohort had more comorbidities, complex multivessel disease with left main coronary artery involvement, and longer coronary lesions, and also included both *de novo* and in-stent restenosis lesions. Angiographic success in our study was slightly lower (94% vs 100% in the DISRUPT CAD II study) and clinical success was lower (90% vs 94.2% in the DISRUPT CAD II study).[13] This difference can be explained by our relatively high-risk patient cohort, stringent angiographic criteria for clinical success, aggressive pre-IVL balloon dilation (82% vs 41.7% in the DISRUPT CAD II study), and use of adjunctive devices such as modified balloons.

In a prospective IVL registry with 78 IVL-treated lesions by Aksoy et al,[19] strategic success with residual stenosis <20% was noted in 78.2% of cases vs 90% (residual stenosis <30%) in our study. Similarly, higher strategic success was noted across all 3 treatment subgroups in our cohort — primary IVL (100% vs 84.6%), secondary IVL (87% vs 77.3%), and tertiary IVL (75% vs 64.3%). Comparatively, higher in-hospital (6% vs 0%) and 30-day MACE (8% vs 1.3%) in our cohort may be explained by the presence of longer coronary lesions (mean lesion length, 28.5 mm vs 21 mm), more patients with ACS presentation (62% vs 28.2%), and aggressive lesion preparation with both pre-IVL (82% vs 41.7%) and post-IVL balloon dilation (78% vs 32%) in our study vs the registry by Aksoy, et al.[19]

Our primary and secondary IVL subgroups achieved final residual stenosis <30% with clinical success in 100% and 87%, respectively. Both subgroups had significant acute luminal gain after IVL and achieved similar average residual stenosis (14.5 ± 6% vs 14.2 ± 5.8%) after PCI. In our tertiary IVL subgroup of 12 lesions, 3 lesions had acute stent underexpansion and 9 lesions had late target-lesion failure presenting as in-stent restenosis. Clinical success was achieved in 9 lesions (75%). Stent underexpansion due to incomplete lesion preparation is a clinically relevant

problem with fewer treatment options and increases the risk of stent thrombosis and restenosis.[20,21] IVL appears to be useful in this subgroup, as it fractures both superficial and deep calcium beyond stent struts, thereby increasing the compliance of the artery and allowing for optimal stent expansion. Currently, only limited data are available with regard to IVL use in stent underexpansion and these initial reports show promising results.[19,22] However, systematic IVL studies with long-term follow-up are needed for this group. In all 3 treatment subgroups, IVL appears to be a safe and effective treatment for calcium plaque modification with minimal vascular complications.

Study limitations. This is a retrospective, single-arm registry with short-term follow-up to 30 days. Our small study cohort of 50 IVL-treated lesions had fewer patients in each treatment subgroup; hence, results of the subgroup analyses should be considered exploratory and hypothesis generating.

Conclusion

IVL is a safe, effective, feasible strategy for calcium modification in an all-comers cohort with moderate-to-severely calcified coronary lesions with high success rate, minimal procedural complications, and low MACE rates. Larger randomized studies of IVL with long-term follow-up are needed to confirm these initial study results in the future.

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