Original Article

Clinical and Procedural Outcomes of Image-Guided IVL in Calcified Coronary Lesions: A Retrospective Analysis

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Abstract

Introduction: Imaging-guided coronary intervention by intravascular lithotripsy (IVL) for severe calcification is reported to be a feasible option. In this study, we reported our experience with intravascular lithotripsy for treating severe calcific lesions in both acute and chronic coronary syndromes, comparing procedural success and clinical outcomes.

Methods: This was a single-center, single-operator, retrospective study of all patients treated with image-guided IVL via a radial approach in Bangladesh from January 2022 to January 2024. Both acute coronary syndrome (ACS) and chronic coronary syndrome (CCS) patients were included. Patient demographics, procedural variables for safety/efficacy, in hospital &30-day outcomes were evaluated. The primary endpoints werean in-hospital major adverse cardiovascular event (MACE) including death, myocardial infarction (MI), and target-vessel revascularization (TVR). Secondary endpoints were a clinical **Success:** stent expansion with <30% in-stent residual stenosis & minimum stent area more than distal reference lumen area by imaging with no in-hospital MACE.

Results: During the study period, there were 50 patients (62% male; mean age 67.58±8.38 years) (55 coronary lesions) who underwent image-guided IVL through a radial approach. Among them, 27 (54%) patients presented with ACS (Group A) & the rest of the patients (23) presented with CCS (Group B). Intravascular ultrasound (IVUS)-guided IVL was done in 48 (96%) cases. Two cases (4%) were done by optical coherence tomography (OCT). Procedural-related complications such as coronary dissection occurred in 10 (20%), side branch occlusion was 3 (6%) & slow flow was observed in 1(2%). Angiographic & Imaging success (<30% residual stenosis) occurred in 26 cases (96.3%) in the ACS group & 20 cases (87%) in the CCS group, with no significant difference between them. There was no MACE in-hospital & 30 days after follow-up.

Conclusions: Image-guided IVL is an effective and feasible strategy for calcium modification in both ACS & CCS groups of patients with high success rates and minimal procedural complications.

Keywords: IVL, calcified coronary lesions, trans-radial, imaging guided PCI.

[JNHFB 2026; 15 (2) : 66-70] doi.10.61819/jnhfb.v15i2.57

Introduction

Moderate to severe calcification, which is present in one-third of patients presenting with stable disease or acute coronary syndromes (ACS), portends worse procedural success and an increase in peri-procedural rates of major adverse events and long-term rates of in-stent restenosis, stent thrombosis, and target and lesion revascularization[1,2]. Intravascular lithotripsy (IVL) is an innovative balloon-based technology that employs sound waves to generate local intravascular calcification fractures [3,4]. IVL delivers circumferential, unfocused, and pulsatile energy to disrupt calcium within the target lesion safely. The purpose is to fracture the calcified plaque to allow proper expansion with a balloon to gain enough lumen diameter to pass and deploy the drug-eluting stent (DES) successfully [5]. The ultrasonic waves travel through a balloon-based small-size catheter, disrupting only the superficial and deep calcium deposits with limited risk of vascular rupture or dissection [6,7]. IVL has been shown to offer better safety and lower procedure-related complications.

In this study, we reported our experience of IVL for treating severe calcific lesions in both ACS and chronic coronary syndrome (CCS) to compare the procedural success and clinical outcome.

Methods

This was a single-center single-operator retrospective study of all patients treated with image-guided IVL through radial approach from January 2022 to January 2024 in Bangladesh. Both ACS (Group A) & CCS

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(Group B) patients were included. Patient demographics, procedural variables for safety/efficacy, in hospital &30-day outcomes were evaluated. The primary endpoints were in-hospital major adverse cardiovascular event (MACE), including death, myocardial infarction (MI), and target-vessel revascularization (TVR). Secondary endpoints were a clinical success: stent expansion with <30% in-stent residual stenosis & minimum stent area more than distal reference lumen area by imaging with no in-hospital MACE.

Study population

This was a single-centersingle-operator retrospective study of all patients treated with image-guided IVL through radial approach from January 2022 to January 2024 in Bangladesh. Both ACS &CCS patients were included.

Study device

The Shockwave Medical IVL catheter and its technique for use have been previously described [3,4]. The catheter consists of a 0.014-inch guidewire-compatible, fluid-filled balloon angioplasty catheter with 2 lithotripsy emitters incorporated into the shaft of the 12–mm–long balloon segment. Each catheter can provide up to 80 IVL pulses and is intended for single use. The IVL balloon catheter is connected via a cable to a portable, battery-powered generator. Following delivery to the target lesion, the balloon is inflated to low pressure (4 atm), and the lithotripsy emitters are energized. Electrical energy delivered to the emitters initiates the formation of steam bubbles within the balloon that expand and collapse, creating transient (~1 ms) circumferential acoustic pressure pulses/sonic pressure waves that deliver ~50 atm of instantaneous pressure to fracture superficial and deep calcium within the arterial wall selectively. These sonic pressure waves are delivered circumferentially and transmurally through the vessel wall, resulting in calcium microfractures due to transient shear mechanisms.

Study procedures

Patients who signed informed consent were enrolled before IVL catheter insertion. Preparation of the lesion with a noncompliant balloon, high-pressure balloon, cutting balloon, scoring balloon, and rotational atherectomy before IVL was left at the operator's discretion. All patients underwent pre &post-procedural radiology imaging before IVL.

Coronary angiography analysis

Two experienced interventional cardiologists performed coronary angiography analysis. All study lesions were serially analyzed at pre-intervention, post-IVL, and post-intervention. Quantitative coronary angiographic analysis was performed in matched segments according to the post-intervention stent segment. The interpolated reference vessel diameter was automatically estimated by the software at the site of the minimal lumen diameter, but analysts were allowed to manually modify it in cases of long lesions with different reference vessel locations across the 3 serial analyses, as appropriate [8].

Study endpoints

The primary endpoints were in-hospital MACE, including death, MI, and TVR. Secondary endpoints were a clinical success: stent expansion with <30% in-stent residual stenosis & minimum stent area more than distal reference lumen area by imaging with no in-hospital MACE.

Statistical analysis

Patient demographics, procedural variables for safety/efficacy, in hospital & 30-day outcomes were evaluated according to clinical presentation as ACS or CCS. Continuous variables are expressed as mean ± SD (standard deviation) (or if the values do not follow a normal distribution, as median [IQR]). Categorical variables are expressed as frequencies and percentages. The data obtained were analyzed using the unilateral analysis of variance for continuous variables, and the Fisher exact test or the chi-square test for categorical variables, when appropriate. Nonparametric tests were used with variables without a normal distribution or when normalization was not possible. A p value of 0.05 was considered to set statistical significance. All analyses were performed with the use of SPSS 23.

Results

During the study period 50 patients (62% male; mean age 67.58±8.38 years) (55 coronary lesions) underwent image-guided IVL through a radial approach. Out of 50 patients, 27 (54%) patients presented with ACS (Group A) & the rest of the patients presented with CCS (Group B). The baseline and clinical demographics were outlined in Table 1. Intravascular ultrasound (IVUS)-guided IVL was done in 48 (96%) cases. Two cases (4%) were done by optical coherence tomography (OCT). The lesion characteristics were delineated in Table 2. In most of the cases target vessel was left anterior descending artery in both groups. Bifurcation lesion was more common in group B (9) than group A (5). Procedural characteristics were described in Table 3 and Figure 1 & Figure 2. In both groups clinical success was 100%. Angiographic success was 20.83% in group A and 22.92% in group B. Procedural-related complications such as coronary dissection occurred in 10 (20%), side branch occlusion was 3 (6%) & slow flow was observed in 1(2%) (Table 4). Angiographic & Imaging success (<30% residual stenosis) occurred in 26 cases (96.3%) in the ACS group & 20 cases (87%) in the CCS group, with no significant difference between them. There was no in-hospital MACE, including 30 days after follow-up.

Table 1: Baseline and clinical demographics (n=50)

Variables	All groups (n=50)	Group A (n=27)	Group B (n=23)	p-value
Age (mean±SD)	67.58±8.39	67.15±9.55	68.09±6.95	0.697
Gender				
Male	32 (64%)	13 (48.1%)	19 (82.6%)	0.011
Female	18 (36%)	14 (51.9%)	4 (17.4%)	
BMI	26.94±8.99	25.11±7.21	29.09±10.47	0.120
DM	37 (74%)	20 (74.1%)	17 (73.9%)	0.990
HTN	47 (94%)	26 (96.3%)	21 (91.3%)	0.459
Dyslipidemia	50 (100%)	27 (100%)	23 (100%)	1.000
Current smoker	3 (6%)	1 (3.7%)	2 (8.7%)	0.459
Prior MI	14(28%)	5 (18.5%)	9 (39.1%)	0.106
Prior CABG	8(16.3%)	2 (7.7%)	6(26.1%)	0.082
eGFR<60	20 (40%)	12 (44.4%)	8 (34.8%)	0.487
ESRD	3 (6.1%)	3 (11.1%)	0 (0%)	0.242
LVEF	53.45±6.29	51.80±5.57	55.88±6.67	0.037
NSTEMI	14(28%)	14(48.1%)	0(0%)	0.001
STEMI	7(14%)	7(25.9%)	0(0%)	0.008
Stable CAD	22 (44%)	0 (0%)	22 (95.7%)	<0.001

SD: standard deviation; BMI: body mass index; DM: diabetes mellitus; HTN: hypertension; MI: myocardial infarction; CABG: coronary artery bypass grafting; eGFR: estimated glomerular filtration rate: ESRD: end stage renal disease; LVEF: left ventricular ejection fraction; NSTEMI: non-ST elevation myocardial infarction; STEMI: ST elevation myocardial infarction; CAD: coronary artery disease.

Table 2: Distribution of study subjects according to the lesion characteristics (n=50)

Variable		All groups (n=50)	Group A (n=27)	Group B (n=23)
Total number of lesions		55	29	26
Target vessels	Left main	8	3	5
	LAD	26	16	10
	LCx	5	4	1
	RCA	8	3	5
	2 target vessels	3	2	1
Bifurcation lesion		14	5	9
CTO lesion		6	3	3
SB involvement		3	1	2
Reference vessel diameter (mm)		3.06±0.38	3.09±0.45	3.03±0.31
Pre-IVL vessel stenosis		85.37±9.5	89.39±.99	81.35±92
Lesion length (mm)		28.65±14.2	29.5±11.6	27.8±16.8
Calcified length		43.26±18.427	44.37±16.027	41±21.199
SB involvement		3	1	2

LAD: left anterior descending; LCX: left circumflex; RCA: right coronary artery; CTO: chronic total occlusion; SB: side branch; IVL: intravascular lithotripsy.

Table 3: Distribution of study subjects according to the table performance outcome (n=50)

Variable	Group A (n=27)	Group B (n=23)
Clinical success	100%	100%
Angiographic success (residual stenosis <30%)	20.83%	22.92%
Stent delivery	100%	100%
Residual diameter stenosis <50%	100%	100%
Mean residual stenosis	8.65±9.6	10.38±8.7

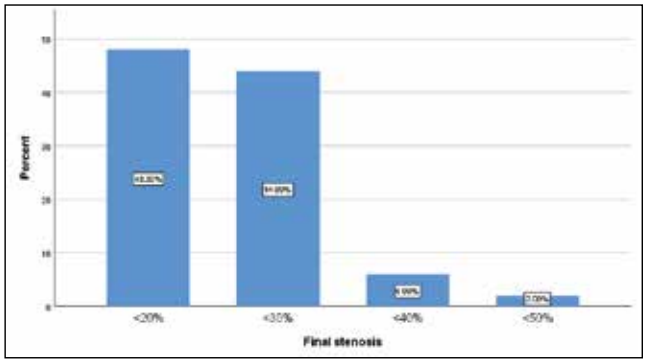


Figure 1: Histogram showing final stenosis (n=50)

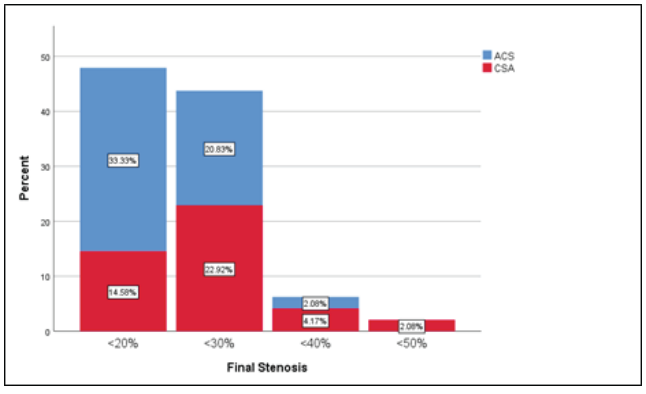


Figure 2: Histogram showing final stenosis (n=50)

Table 4: Distribution of study subjects according to clinical status (n=50)

Procedure-related complications	All groups (N=50)	Group A (n=27)	Group B (n=23)	p-value
IVL-induced coronary dissection	10 (20%)	4 (14.8%)	6 (26.1%)	0.322
Coronary perforation	0 (0%)	0 0%)	0 0%)	
SB occlusion	3 (6%)	1 (3.7%)	2 (8.7%)	0.459
Abrupt vessel closure	0 (0%)	0 0%)	0 0%)	
Slow flow	1 (2%)	1 (3.7%)	0 (0%)	0.352
No flow, MACE (Cardiac death, AMI, TVR, stroke) Stent thrombosis & restenosis, Non-cardiac death			0 (0%)	

IVL: intravascular lithotripsy; SB: side branch; MACE: major adverse cardiovascular event; AMI: acute myocardial infarction; TVR: target-vessel revascularization.

Discussion

In this contemporary real-world cohort, we evaluated the safety and efficacy of image-guided IVL delivered via a trans-radial approach in patients withseverely calcified coronary lesions presenting with both ACS and CCS. The principal findings are threefold. First, imaging-guided IVL achieved consistently high procedural and angiographic success across clinical presentations. Second, procedural complications were acceptable and did not translate intoadverse short-term clinical outcomes. Third, there were no in-hospital or 30-day MACE, despite inclusion of complex lesion subsets such asleft main disease, bifurcations, and chronic total occlusions.

Coronary artery calcification remains one of the most important predictors of PCI failure.Severe calcification is associated with impaired balloon compliance, stent underexpansion, malapposition, restenosis, and stent thrombosis.

Even in the era of contemporary drug-eluting stents, inadequate lesion preparation continues to be a dominant mechanism ofearly and late stent failure. Therefore, effective and controlled calcium modification is critical for optimizing both acute procedural success and long-term vessel patency.

IVL represents a mechanistically distinct approach to plaquemodification. By generating circumferential acoustic pressure waves that propagatetransmurally, IVL induces controlled microfractures in both superficial and deep calciumwhile minimizing injury to surrounding soft tissue. Unlike atherectomy-based debulkingtechniques, IVL does not rely on differential cutting or sanding and therefore may reducedistal embolization and microvascular compromise. The low incidence of slow flow andabsence of no-reflow in our study supports this mechanistic advantage.

A key strength of our experience is the near-universal use of intravascular imaging (IVI). Imaging guidance enables precise assessment of calcium arc, thickness, and lesion length, ensuringappropriate balloon sizing and confirmation of adequate calcium fracture before stentimplantation. Imaging-defined procedural success was achieved in the vast majority ofpatients, underscoring the importance of integrating IVL within an imaging-guided PCIstrategy. Optimal stent expansion—rather than device selection alone—remains central todurable PCI outcomes.

The inclusion of ACS patients is particularly noteworthy. Calcium modification in ACS is inherently challenging due to thrombus burden, plaque instability, and heightenedinflammatory milieu. Historically, there has been caution regarding plaque-modifyingdevices in unstable settings due to concerns about distal embolization. In our cohort, angiographic and imaging success was comparable between ACS and CCS groups, with noexcess periprocedural complications or MACE in the ACS subgroup. These findings suggestthat IVL may safely extend into selected unstable clinical scenarios when careful imagingassessment and procedural planning are applied.Importantly, all procedures were performed via the transradial approach. Radial access is associated with reduced bleeding and vascular complications, particularly in ACSpopulations. Demonstrating the technical feasibility of IVL delivery through radialaccess—even in complex calcified lesions—supports its integration into contemporaryradial-first PCI programs.

The favorable safety profile observed in this study is clinically meaningful. Coronarydissections were manageable and did not result in perforation, abrupt vessel closure,emergency surgery, or clinical sequelae. The absence of coronary perforation is particularlyreassuring given the vulnerability of heavily calcified vessels to rupture during aggressivehigh-pressure balloon dilation or atherectomy. These findings reinforce the concept thatIVL provides controlled calcium modification with a predictable safety margin.From a broader clinical perspective, the global increase in aging populations, diabetes, andchronic kidney disease predicts a rising burden of calcified coronary disease. In such alandscape, reproducible and safe calcium-modifying technologies will become increasinglyimportant. Our findings support IVL as a valuable addition to the interventionalarmamentarium, particularly when combined with IVI.

Limitations: Several limitations warrant consideration. This was a retrospective, single-center, single-operator study, which introduces inherent selection and performance bias. The sample size was small, limiting statistical power for subgroup analyses. Follow-up was restricted to30 days, precluding evaluation of long-term outcomes such as restenosis, late stentthrombosis, and repeat revascularization. Additionally, the absence of a comparator armlimits conclusions regarding relative efficacy versus atherectomy or other calcium-modifying strategies.

Conclusions: Image-guided IVL is an effective and feasible strategy for calcium modification in both ACS & CCS groups of patients with high success rates and minimal procedural complications.

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