CLINICAL OUTCOMES, PROCEDURAL SUCCESS, AND SAFETY OF INTRAVASCULAR LITHOTRIPSY FOR SEVERELY CALCIFIED CORONARY LESIONS: A PROSPECTIVE SINGLE-CENTER REAL-WORLD STUDY

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ABSTRACT

Background: Severe coronary artery calcification remains a major challenge during percutaneous coronary intervention (PCI), often resulting in inadequate lesion preparation, suboptimal stent expansion, and increased procedural complications. Intravascular lithotripsy (IVL) has emerged as a novel calcium-modification technique that uses acoustic pressure waves to fracture vascular calcium and facilitate optimal stent deployment. However, real-world data regarding its effectiveness and safety remain limited.

Objectives: To evaluate the clinical outcomes, procedural success, and safety of IVL-assisted PCI in patients with severely calcified coronary lesions in a prospective single-center real-world setting.

Materials and Methods: This prospective observational study included 110 consecutive patients with severely calcified coronary artery lesions who underwent IVL-assisted PCI at a tertiary care center. Baseline demographic, clinical, angiographic, procedural, and follow-up data were prospectively collected. The primary endpoint was procedural success, defined as successful stent implantation with residual stenosis <30% and final TIMI grade 3 flow without in-hospital major adverse cardiac events (MACE). Secondary endpoints included device success, angiographic success, procedural complications, and 30-day clinical outcomes.

Results: The mean age of the study population was 66.4 ± 9.8 years, and 76.4% were male. Hypertension (73.6%), dyslipidemia (61.8%), and diabetes mellitus (49.1%) were the most prevalent cardiovascular risk factors. Acute coronary syndrome was present in 61.8% of patients. The left anterior descending artery was the most frequently treated vessel (47.3%), while multivessel disease was observed in 43.6% of patients.

Conclusion: Intravascular lithotripsy is a highly effective and safe calcium-modification strategy for the treatment of severely calcified coronary lesions. The high procedural success rates, low complication rates, and favorable short-term clinical outcomes observed in this study support the routine use of IVL in complex calcified coronary artery disease.

Keywords: Intravascular Lithotripsy, Coronary Artery Calcification, Percutaneous Coronary Intervention, Calcified Coronary Lesions, Procedural Success.

INTRODUCTION

Coronary artery calcification (CAC) represents one of the most challenging anatomical substrates encountered during percutaneous coronary intervention (PCI). Severe coronary calcification is increasingly prevalent due to the aging population and the growing burden of diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors.

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Calcified coronary lesions are associated with procedural complexity, impaired device delivery, inadequate lesion expansion, suboptimal stent deployment, and increased rates of restenosis, stent thrombosis, and adverse cardiovascular events [1]. The presence of severe calcium can significantly reduce vessel compliance, limiting balloon expansion and preventing optimal stent apposition, thereby compromising both immediate procedural success and long-term clinical outcomes [2].

Adequate lesion preparation is essential to overcome the mechanical resistance imposed by calcified plaques. Traditionally, plaque modification techniques such as rotational atherectomy, orbital atherectomy, cutting balloons, and scoring balloons have been utilized to facilitate stent delivery and expansion in heavily calcified lesions. Although these technologies have demonstrated effectiveness,

they are associated with several limitations, including procedural complexity, longer learning curves, and risk of vessel perforation, distal embolization, slow-flow or no-reflow phenomena, and procedural complications that may adversely affect patient outcomes [3]. Consequently, there has been increasing interest in the development of safer and more predictable calcium-modification technologies.

Intravascular lithotripsy (IVL) has emerged as a novel and promising strategy for the treatment of severely calcified coronary artery disease. Adapted from extracorporeal lithotripsy used in urology, coronary IVL employs a specialized balloon catheter that emits localized acoustic pressure waves capable of fracturing both superficial and deep calcium deposits within the vessel wall. These microfractures increase vessel compliance, facilitating balloon expansion and optimal stent deployment while minimizing vascular injury to surrounding soft tissues [4]. Unlike atherectomy devices, IVL can be performed over a standard coronary guidewire and does not generate particulate debris, thereby reducing the risk of distal embolization and microvascular obstruction [5].

The safety and efficacy of IVL have been evaluated in a series of prospective multicenter studies known as the Disrupt CAD trials. The Disrupt CAD II study demonstrated that IVL could be safely performed in patients with severe coronary artery calcification, achieving high procedural success with minimal complications and significant calcium fracture as assessed by intracoronary imaging [6]. Subsequently, the Disrupt CAD III study confirmed high procedural success rates exceeding 90% and low rates of major adverse cardiac events (MACE), supporting the effectiveness of IVL as a calcium-modification strategy prior to stent implantation [7]. Long-term follow-up data from the Disrupt CAD III study further demonstrated sustained clinical benefits and favorable one-year outcomes after IVL-assisted PCI [8].

Similarly, the Japanese Disrupt CAD IV study reported excellent procedural outcomes and low rates of adverse cardiovascular events among patients with severely calcified coronary lesions undergoing IVL-assisted PCI [9]. Extended follow-up demonstrated durable safety and efficacy through one and two years, suggesting that optimal calcium modification achieved by IVL may contribute to favorable long-term vessel patency and clinical outcomes [10]. Furthermore, pooled patient-level analyses from multiple Disrupt CAD studies have shown consistently high procedural success rates and low complication rates across diverse patient populations and lesion characteristics, reinforcing the reproducibility of IVL outcomes in routine clinical practice [11].

Despite the encouraging evidence generated from clinical trials, real-world data remain essential because patients encountered in daily practice often present with greater anatomical complexity, multiple comorbidities, diffuse calcification, bifurcation disease, left main involvement, and other high-risk characteristics that may be underrepresented in controlled studies. Real-world investigations provide valuable information regarding procedural feasibility, device performance, safety, and clinical effectiveness in broader patient populations. Recent registry-based studies have demonstrated favorable technical success and acceptable clinical outcomes of IVL in complex calcified lesions, including bifurcation and left main coronary artery disease, thereby expanding its potential applicability in contemporary interventional cardiology [12, 13].

Given the increasing adoption of IVL in the management of severe coronary calcification and the need for evidence reflecting routine clinical practice, further prospective real-world studies are warranted. Evaluating procedural success, clinical outcomes, and safety profiles in unselected patient populations can provide important insights into the effectiveness of IVL beyond controlled clinical trial settings. Therefore, the present prospective single-center real-world study was undertaken to assess the clinical outcomes, procedural success, and safety of intravascular lithotripsy in patients undergoing PCI for severely calcified coronary lesions.

MATERIALS AND METHODS

Study Design and Setting

This prospective, observational, single-center real-world study was conducted at **[Institution/Hospital Name, City, Country]** between **[Month Year] and [Month Year]**. The study aimed to evaluate the clinical outcomes, procedural success, and safety of intravascular lithotripsy (IVL) in patients undergoing percutaneous coronary intervention (PCI) for severely calcified coronary lesions. Consecutive eligible patients presenting during the study period were enrolled to minimize selection bias and to reflect routine clinical practice.

Sample Size

A total of 110 patients with severely calcified coronary artery lesions requiring PCI and IVL-assisted lesion preparation were included in the study. The sample size was based on consecutive patient recruitment during the study period and was considered adequate to evaluate procedural success, clinical outcomes, and safety endpoints in a real-world setting.

Study Population

Patients aged ≥18 years who underwent IVL-assisted PCI for severely calcified coronary artery disease were screened for inclusion.

Inclusion Criteria

1. Age ≥18 years.
2. Presence of symptomatic coronary artery disease or objective evidence of myocardial ischemia requiring PCI.
3. Angiographically severe coronary artery calcification, defined as radiopacities noted without cardiac motion before contrast injection involving both sides of the arterial wall or confirmed by intravascular imaging.
4. Lesions considered suitable for treatment with coronary intravascular lithotripsy according to operator discretion.
5. Provision of informed consent.

Exclusion Criteria

1. Cardiogenic shock at presentation.
2. Active systemic infection or severe inflammatory disease.
3. Known hypersensitivity to contrast media not amenable to premedication.
4. Life expectancy less than one year due to non-cardiac comorbidities.
5. Inability or unwillingness to provide informed consent.
6. Participation in another interventional clinical study that could influence outcomes.

Clinical Assessment

Baseline demographic, clinical, laboratory, angiographic, and procedural characteristics were prospectively recorded. Data collected included age, sex, body mass index, hypertension, diabetes mellitus, dyslipidemia, smoking status, chronic kidney disease, previous myocardial infarction, prior PCI, prior coronary artery bypass grafting, left ventricular ejection fraction, and presenting clinical syndrome.

Clinical presentation was categorized as stable ischemic heart disease, unstable angina, non-ST-segment elevation myocardial infarction (NSTEMI), or ST-segment elevation myocardial infarction (STEMI).

Angiographic and Procedural Characteristics

All procedures were performed according to current international guidelines and institutional protocols by experienced interventional cardiologists.

Coronary angiography was performed using standard techniques. Lesion characteristics including target vessel, lesion length, and reference vessel diameter, degree of stenosis, lesion morphology, and calcium severity were assessed by quantitative coronary angiography and/or intravascular imaging whenever available.

Following guidewire crossing of the target lesion, an appropriately sized coronary IVL balloon catheter (Shockwave Medical, Santa Clara, California, USA) was advanced across the lesion. The balloon was inflated to low pressure (approximately 4 atm), and lithotripsy pulses were delivered according to manufacturer recommendations. Additional balloon dilatation, adjunctive plaque modification techniques, and drug-eluting stent implantation were performed at the discretion of the treating operator. Final post-dilatation was undertaken when necessary to optimize stent expansion.

Study Endpoints

Primary Endpoint

The primary endpoint was **procedural success**, defined as successful stent delivery and deployment with residual stenosis <30% and final Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow in the absence of in-hospital major adverse cardiac events (MACE).

Secondary Endpoints

Secondary endpoints included:

1. Device success.
2. Angiographic success.
3. In-hospital MACE.
4. Thirty-day MACE.
5. Individual adverse cardiovascular events.
6. Procedural complications.

Definitions

Device Success: Successful delivery, activation, and retrieval of the IVL catheter with effective lesion modification.

Angiographic Success: Residual stenosis <30% with restoration of TIMI grade 3 flow after PCI.

Major Adverse Cardiac Events (MACE): Composite of cardiac death, myocardial infarction, and target vessel revascularization.

Safety Outcomes: Included coronary perforation, severe dissection, abrupt vessel closure, no-reflow phenomenon, slow-flow, stent thrombosis, ventricular arrhythmias, stroke, major bleeding, vascular access complications, and contrast-induced nephropathy.

Follow-Up

Patients were monitored throughout hospitalization and underwent clinical follow-up at 30 days following the procedure. Follow-up data were obtained through outpatient visits, hospital records, and structured telephone interviews. Any occurrence of adverse cardiovascular events was documented and adjudicated by independent investigators.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 26.(IBM Corp., Armonk, NY, USA)**.**Continuous variables were tested for normality using the Shapiro–Wilk test. Normally distributed variables were expressed as mean ± standard deviation, whereas non-normally distributed variables were reported as median with interquartile range. Categorical variables were presented as frequencies and percentages.

Comparisons between groups were performed using the independent Student's t-test or Mann–Whitney U test for continuous variables and the Chi-square test

or Fisher's exact test for categorical variables. Clinical outcomes were reported with corresponding 95% confidence intervals. A two-tailed p-value <0.05 was considered statistically significant.

RESULTS

A total of 110 patients with severely calcified coronary artery lesions underwent intravascular lithotripsy (IVL)-assisted percutaneous coronary intervention during the study period. The mean age of the study population was 66.4 ± 9.8 years, with males constituting 76.4% of patients. Hypertension was present in 73.6%, diabetes mellitus in 49.1%, and chronic kidney disease in 12.7% of patients. Most patients presented with acute coronary syndrome (61.8%), while 38.2% had stable ischemic heart disease.

Table 1. Baseline Demographic and Clinical Characteristics (N=110)

Characteristic	Number (%)
Age (years), mean ± SD	66.4 ± 9.8
Male sex	84 (76.4)
Hypertension	81 (73.6)
Diabetes mellitus	54 (49.1)
Dyslipidemia	68 (61.8)
Current/Former smoker	39 (35.5)
Chronic kidney disease	14 (12.7)
Previous PCI	31 (28.2)
Previous MI	26 (23.6)
Previous CABG	8 (7.3)
LVEF (%)	51.8 ± 8.9

Table 1 summarizes the baseline demographic and clinical characteristics of the study population. A total of 110 patients with severely calcified coronary lesions underwent IVL-assisted PCI. The mean age of the cohort was 66.4 ± 9.8 years, with a predominance of male patients (76.4%). Hypertension (73.6%), dyslipidemia (61.8%), and diabetes mellitus (49.1%) were the most common cardiovascular risk factors. Chronic kidney disease was present in 12.7% of patients. Previous coronary interventions and myocardial infarction were reported in 28.2% and 23.6% of patients, respectively. The mean left ventricular ejection fraction was 51.8 ± 8.9%, indicating relatively preserved ventricular function in most patients.

Table 2. Clinical Presentation

Clinical Presentation	Number (%)
Stable Ischemic Heart Disease	42 (38.2)
Unstable Angina	23 (20.9)
NSTEMI	31 (28.2)
STEMI	14 (12.7)
Acute Coronary Syndrome (Total)	68 (61.8)

Table 2 presents the clinical presentation of patients at the time of PCI. Acute coronary syndrome was the predominant indication for intervention, accounting for 61.8% of cases. Among these, NSTEMI constituted 28.2%, unstable angina 20.9%, and STEMI 12.7% of presentations. Stable ischemic heart disease was observed in 38.2% of patients. These findings indicate that IVL was frequently utilized in complex and high-risk clinical scenarios requiring urgent coronary revascularization.

Table 3. Angiographic and Lesion Characteristics

Variable	Value
Left Anterior Descending Artery (LAD)	52 (47.3%)
Right Coronary Artery (RCA)	29 (26.4%)
Left Circumflex Artery (LCX)	18 (16.4%)
Left Main Coronary Artery	11 (10.0%)
Multivessel Disease	48 (43.6%)
Bifurcation Lesions	21 (19.1%)
Mean Lesion Length (mm)	31.6 ± 11.2
Reference Vessel Diameter (mm)	3.28 ± 0.54

Diameter Stenosis (%)	84.2 ± 8.6
IVUS/OCT Utilization	67 (60.9%)

Table 3 illustrates the angiographic and lesion-related characteristics of the study cohort. The left anterior descending artery was the most commonly treated vessel (47.3%), followed by the right coronary artery (26.4%), left circumflex artery (16.4%), and left main coronary artery (10.0%). Multivessel coronary artery disease was present in 43.6% of patients, while bifurcation lesions accounted for 19.1% of cases. The mean lesion length was 31.6 ± 11.2 mm, and the average diameter stenosis was 84.2 ± 8.6%, reflecting the severe complexity of coronary lesions included in the study. Intravascular imaging using IVUS or OCT was employed in 60.9% of procedures to optimize lesion assessment and stent deployment.

Table 4. Procedural Characteristics and Success Rates

Variable	**Number (%)**
Device Success	108 (98.2)
Angiographic Success	106 (96.4)
Procedural Success	104 (94.5)
Drug-Eluting Stent Implantation	110 (100)
Post-dilatation Performed	98 (89.1)
Mean Number of IVL Pulses	67.3 ± 18.5
Mean Stent Length (mm)	36.8 ± 12.1
Mean Stent Diameter (mm)	3.24 ± 0.47

Table 4 summarizes procedural outcomes and success rates following IVL-assisted PCI. Device success was achieved in 98.2% of patients, demonstrating excellent deliverability and functionality of the IVL system. Angiographic success was observed in 96.4% of cases, while overall procedural success was achieved in 94.5%. Drug-eluting stents were implanted in all patients. Post-dilatation was performed in 89.1% of lesions to optimize stent expansion. The mean number of lithotripsy pulses delivered was 67.3 ± 18.5. These findings indicate that IVL provided effective calcium modification, facilitating successful PCI in the majority of severely calcified lesions.

Table 5. Procedural and in-Hospital Safety Outcomes

Safety Outcome	**Number (%)**
Coronary Dissection	4 (3.6)
Slow Flow/No-Reflow	2 (1.8)
Coronary Perforation	1 (0.9)
Ventricular Arrhythmia	2 (1.8)
Major Bleeding	1 (0.9)
Contrast-Induced Nephropathy	3 (2.7)
Stroke	0 (0.0)
In-Hospital Death	1 (0.9)
Any Procedural Complication	10 (9.1)

Table 5 presents procedural and in-hospital safety outcomes. The overall incidence of complications was low. Coronary dissection occurred in 3.6% of patients, while slow-flow/no-reflow phenomena were observed in 1.8%. Coronary perforation, one of the most feared complications of complex PCI, occurred in only one patient (0.9%). Ventricular arrhythmias and major bleeding were each reported in less than 2% of patients. Contrast-induced nephropathy developed in 2.7% of cases, whereas no strokes were recorded. In-hospital mortality was limited to one patient (0.9%). These findings support the favorable safety profile of IVL in real-world clinical practice.

Table 6. Thirty-Day Clinical Outcomes

Outcome	**Number (%)**
Cardiac Death	2 (1.8)
Myocardial Infarction	3 (2.7)
Target Vessel Revascularization	2 (1.8)
Stent Thrombosis	1 (0.9)

Major Adverse Cardiac Events (MACE)	7 (6.4)
Event-Free Survival	103 (93.6)

Table 6 summarizes the short-term clinical outcomes observed during the 30-day follow-up period. Cardiac death occurred in 1.8% of patients, while myocardial infarction was reported in 2.7%. Target vessel revascularization was required in 1.8% of patients, and definite stent thrombosis occurred in one patient (0.9%). The overall incidence of major adverse cardiac events was 6.4%. Importantly, event-free survival was achieved in 93.6% of patients, indicating favorable short-term clinical effectiveness following IVL-assisted PCI. These outcomes are consistent with previously reported studies demonstrating high procedural success and low adverse event rates in patients with heavily calcified coronary artery disease.

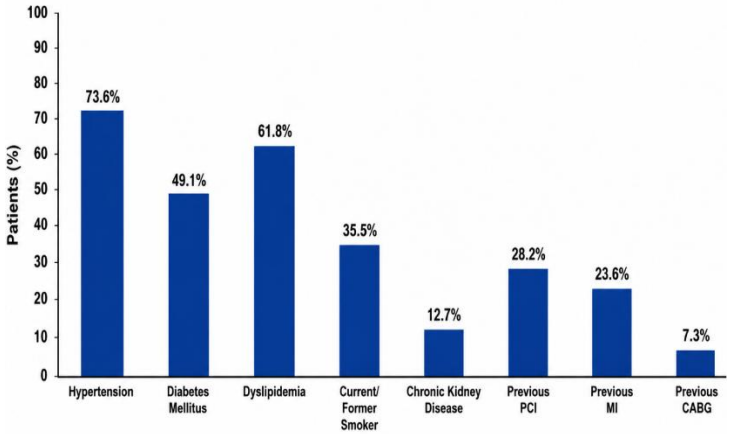

Figure 1. Distribution of Baseline Cardiovascular Risk Factors among Study Participants Undergoing IVL-Assisted PCI

Figure 1 illustrates the distribution of baseline cardiovascular risk factors among the 110 patients included in the study who underwent intravascular lithotripsy (IVL)-assisted percutaneous coronary intervention (PCI) for severely calcified coronary lesions. Hypertension was the most prevalent risk factor, affecting 73.6% of patients, followed by dyslipidemia (61.8%) and diabetes mellitus (49.1%). A history of current or former smoking was observed in 35.5% of participants. Previous PCI and previous myocardial infarction were reported in 28.2% and 23.6% of patients, respectively. Chronic kidney disease was present in 12.7% of the study population, while previous coronary artery bypass grafting (CABG) was the least common risk factor, occurring in 7.3% of patients. Overall, the study cohort demonstrated a high burden of cardiovascular comorbidities, reflecting the complex clinical profile typically associated with severe coronary artery calcification requiring advanced plaque modification techniques such as IVL.

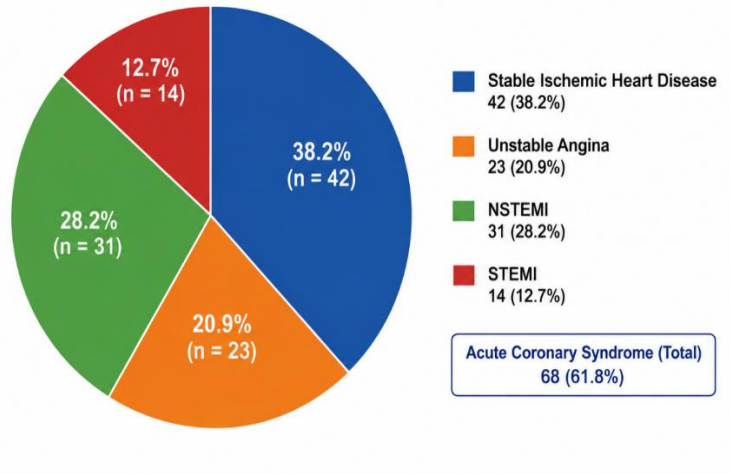

Figure 2. Clinical Presentation of Patients Treated With Intravascular Lithotripsy for Severely Calcified Coronary Lesions

Figure 2 depicts the clinical presentation of the 110 patients who underwent intravascular lithotripsy (IVL)-assisted percutaneous coronary intervention for severely calcified coronary lesions. Stable ischemic heart disease (SIHD) was the most common individual presentation, accounting for 42 patients (38.2%). Among acute coronary syndrome (ACS) presentations, NSTEMI was observed in 31 patients (28.2%), followed by unstable angina in 23 patients (20.9%) and STEMI in 14 patients (12.7%). Overall, ACS constituted the majority of cases, affecting 68 patients (61.8%). These findings indicate that IVL was frequently employed in patients presenting with both stable and acute manifestations of coronary artery disease, reflecting its applicability across a broad spectrum of complex clinical scenarios involving severe coronary calcification. The predominance of ACS presentations further highlights the clinical importance of effective calcium modification strategies to facilitate successful revascularization in high-risk patients.

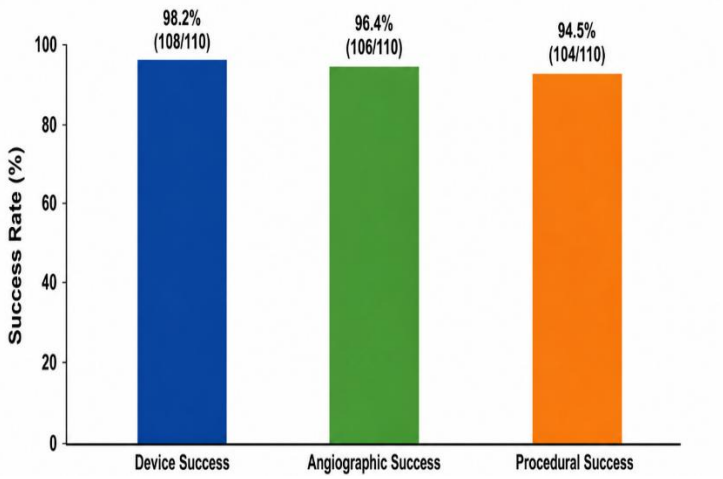

Figure 3. Device Success, Angiographic Success, and Procedural Success Rates Following IVL-Assisted PCI

Figure 3 illustrates the rates of device success, angiographic success, and overall procedural success following intravascular lithotripsy (IVL)-assisted percutaneous coronary intervention in the study cohort. Device success was achieved in 108 of 110 patients (98.2%), indicating excellent deliverability, activation, and retrieval of the IVL catheter with effective lesion modification. Angiographic success was observed in 106 patients (96.4%), reflecting successful restoration of coronary blood flow with residual stenosis less than 30% following intervention. Overall procedural success was achieved in 104 patients (94.5%), demonstrating a high rate of successful stent implantation and optimal procedural outcomes without major in-hospital adverse cardiac events. The consistently high success rates across all procedural endpoints highlight the effectiveness of IVL in facilitating PCI in severely calcified coronary lesions and support its role as a safe and reliable calcium-modification strategy in contemporary interventional cardiology practice.

DISCUSSION

The present prospective single-center real-world study evaluated the procedural success, clinical outcomes, and safety of intravascular lithotripsy (IVL) in patients undergoing percutaneous coronary intervention (PCI) for severely calcified coronary lesions. The principal findings of this study were the high rates of device success (98.2%), angiographic success (96.4%), and procedural success (94.5%), accompanied by a low incidence of procedural complications and favorable short-term clinical outcomes. These findings further support the growing evidence that IVL is an effective and safe calcium-modification strategy for the management of heavily calcified coronary artery disease.

The baseline demographic profile observed in the present study is consistent with the epidemiology of severe coronary artery calcification. The mean age of 66.4 years and the predominance of male patients reflect previous reports indicating that calcified coronary artery disease is more frequently encountered in elderly individuals with longstanding cardiovascular risk factors [1]. Hypertension, dyslipidemia, and diabetes mellitus were highly prevalent in our cohort, affecting 73.6%, 61.8%, and 49.1% of patients, respectively. These findings are

in agreement with earlier studies demonstrating a strong association between metabolic disorders and progressive vascular calcification [2]. Similar patient characteristics were reported in the Disrupt CAD II and Disrupt CAD III studies, confirming that our study population is representative of patients commonly encountered in routine interventional practice [6,7].

Acute coronary syndrome constituted 61.8% of clinical presentations in the present study, indicating that IVL was frequently utilized in urgent and complex clinical scenarios. This proportion is higher than that reported in the pivotal Disrupt CAD trials, where stable coronary artery disease predominated [6,7]. Nevertheless, the favorable procedural outcomes observed in our cohort suggest that IVL can be effectively employed in both stable and acute coronary syndromes when severe coronary calcification is present. The inclusion of a substantial proportion of ACS patients enhances the real-world relevance of our findings and demonstrates the feasibility of IVL in high-risk clinical settings.

The angiographic characteristics of the study population further highlight lesion complexity. Nearly half of the patients had multivessel coronary artery disease, while bifurcation lesions were present in approximately one-fifth of cases. Furthermore, the mean lesion length exceeded 30 mm and the mean diameter stenosis was greater than 80%, indicating extensive calcific disease. Similar lesion characteristics have been reported in pooled analyses of the Disrupt CAD studies, where diffuse calcification, long lesions, and multivessel disease were frequently encountered [11]. These observations emphasize the importance of effective lesion preparation before stent implantation in heavily calcified vessels.

One of the most important findings of the present study was the exceptionally high device success rate of 98.2%. This result is comparable to the findings of the Disrupt CAD II and Disrupt CAD III studies, where device success rates exceeded 98% [6,7]. The high deliverability and ease of use of the IVL system may explain these favorable outcomes. Unlike atherectomy-based technologies, IVL utilizes a balloon-based platform that can be delivered using conventional PCI techniques without requiring specialized guidewires or extensive operator experience [4]. The acoustic pressure waves generated by IVL effectively fracture both superficial and deep calcium deposits, thereby improving vessel compliance and facilitating optimal lesion expansion.

Similarly, the angiographic success rate of 96.4% and procedural success rate of 94.5% observed in our study are highly encouraging and consistent with previously published evidence. Hill et al. reported procedural success exceeding 92% in the Disrupt CAD III study, while Saito et al. demonstrated similarly favorable outcomes in the Japanese Disrupt CAD IV study [7,9]. Adequate calcium modification is essential for achieving optimal stent expansion and apposition, both of which are critical determinants of long-term PCI outcomes. Optical coherence tomography studies have demonstrated that IVL creates multiple calcium fractures, thereby reducing vessel rigidity and improving stent expansion [4]. Moreover, inadequate stent expansion has been identified as an important predictor of restenosis, stent thrombosis, and recurrent ischemic events [14].

The safety profile observed in the present study was highly favorable. Coronary dissection occurred in only 3.6% of patients, while coronary perforation was limited to a single patient (0.9%). Slow-flow or no-reflow phenomena were uncommon and occurred in only 1.8% of cases. These complication rates compare favorably with those reported for rotational and orbital atherectomy, which have historically been associated with higher rates of distal embolization, slow-flow, and vessel injury [3]. The mechanism of IVL may explain these findings, as calcium modification is achieved through acoustic energy rather than tissue ablation, thereby minimizing vascular trauma and reducing particulate debris generation [5].

In-hospital outcomes were also favorable. Only one in-hospital death was recorded, and no strokes occurred during hospitalization. Contrast-induced nephropathy developed in 2.7% of patients despite the presence of chronic kidney disease in a subset of the study population. Similar safety outcomes have been reported in pooled analyses of the Disrupt CAD program, which demonstrated low rates of major procedural complications and excellent procedural tolerability [11]. These findings suggest that IVL can be safely applied even in patients with multiple comorbidities and complex coronary anatomy.

Short-term follow-up outcomes were similarly encouraging. At 30 days, the overall major adverse cardiac event rate was 6.4%, while event-free survival exceeded 93%. These findings are consistent with previous IVL studies demonstrating low rates of early adverse cardiovascular events following successful calcium modification and stent implantation [8,12]. Long-term follow-up from the Disrupt CAD III study has further demonstrated sustained clinical benefit and favorable one-year outcomes after IVL-assisted PCI [8]. The favorable short-term outcomes observed in our study therefore support the durability of procedural success beyond hospital discharge.

The present study has important clinical implications. Severe coronary artery calcification remains one of the most challenging lesion subsets

in contemporary interventional cardiology. As the prevalence of diabetes, chronic kidney disease, and aging populations continues to increase worldwide, the burden of calcified coronary artery disease is expected to rise further. The high procedural success rates and low complication rates observed in the present study support the incorporation of IVL into routine PCI practice as a reliable and reproducible calcium-modification strategy. Furthermore, the simplicity of the technique and compatibility with standard PCI workflows may facilitate broader adoption across centers with varying levels of expertise.

Several limitations should be acknowledged. First, this was a single-center study with a relatively modest sample size, which may limit the generalizability of the findings. Second, the absence of a comparator group precludes direct comparison with alternative calcium-modification strategies such as rotational or orbital atherectomy. Third, the follow-up period was limited to 30 days, preventing assessment of long-term outcomes such as target lesion failure and late stent thrombosis. Nevertheless, the prospective design and inclusion of consecutive real-world patients strengthen the validity and clinical relevance of the findings.

Overall, the present study demonstrates that intravascular lithotripsy is associated with excellent device performance, high procedural success, and a favorable safety profile in patients with severely calcified coronary artery disease. These findings are consistent with contemporary clinical trial evidence and support the expanding role of IVL in the management of complex calcified coronary lesions.

Conclusion

intravascular lithotripsy (IVL) demonstrated high procedural efficacy and a favorable safety profile in the treatment of severely calcified coronary lesions undergoing percutaneous coronary intervention. In this prospective real-world study, IVL achieved excellent device success, angiographic success, and overall procedural success rates, while maintaining low rates of procedural complications and adverse clinical events. The technology proved effective across a complex patient population characterized by a high prevalence of cardiovascular risk factors, multivessel disease, and acute coronary syndrome presentations.

REFERENCES

1. Lee MS, Shah N. The impact and pathophysiologic consequences of coronary artery calcification on percutaneous coronary interventions. J Invasive Cardiol. 2016;28(4):160-167.
2. Barbato E, Shlofmitz E, Milkas A, Shlofmitz R, Azzalini L, Colombo A. State of the art: evolving concepts in the treatment of heavily calcified and undilatable coronary stenoses. EuroIntervention. 2017;13(6):696-705.
3. Chambers JW, Behrens AN, Martinsen BJ. Atherectomy devices for the treatment of calcified coronary lesions. IntervCardiolClin. 2016;5(2):143-151.
4. Ali ZA, Brinton TJ, Hill JM, Maehara A, Matsumura M, KarimiGalougahi K, et al. Optical coherence tomography characterization of coronary lithoplasty for treatment of calcified lesions. JACC Cardiovasc Imaging. 2017;10(8):897-906.
5. Gupta A, Sharma A, Kaul U. Coronary intravascular lithotripsy in contemporary practice. Indian Heart J. 2024;76(3):193-201.
6. Ali ZA, Nef H, Escaned J, Werner N, Banning AP, Hill JM, et al. Safety and effectiveness of coronary intravascular lithotripsy for treatment of severely calcified coronary stenoses: the Disrupt CAD II study. CircCardiovascInterv. 2019;12(10):e008434.
7. Hill JM, Kereiakes DJ, Shlofmitz RA, Klein AJ, Riley RF, Price MJ, et al. Intravascular lithotripsy for treatment of severely calcified coronary artery disease: the Disrupt CAD III study. J Am CollCardiol. 2020;76(22):2635-2646.
8. Kereiakes DJ, Hill JM, Ben-Yehuda O, Maehara A, Shlofmitz RA, Riley RF, et al. Intravascular lithotripsy for treatment of severely calcified coronary lesions: 1-year results from the Disrupt CAD III study. J SocCardiovascAngiogrInterv. 2022;1(4):100410.
9. Saito S, Yamazaki S, Takahashi A, Namiki A, Kawasaki T, Kajita AH, et al. Intravascular lithotripsy for vessel preparation in severely calcified coronary arteries prior to stent placement: primary outcomes from the Japanese Disrupt CAD IV study. Circ J. 2021;85(6):826-833.
10. Saito S, Yamazaki S, Takahashi A, Namiki A, Kawasaki T, Kajita AH, et al. Japanese Disrupt CAD IV study: 2-year outcomes following coronary intravascular lithotripsy. Circ Rep. 2023;5(11):537-545.
11. Kereiakes DJ, Virmani R, Hokama JY, Illindala U, Mena-Hurtado C, Holden A, et al. Patient-level pooled analysis of the Disrupt CAD studies. JACC CardiovascInterv. 2021;14(12):1337-1348.
12. Oliveri F, Franchin L, de Winter RJ, Knaapen P, Claessen B, Stella PR, et al. Intravascular lithotripsy for calcific coronary bifurcations: technical success and clinical outcomes from

the BENELUX-IVL registry. Catheter CardiovascInterv. 2025;105(2).
13. Lee MS, Torguson R, Waksman R. Intravascular lithotripsy for calcified left main artery disease. CardiovascRevasc Med. 2023;56:120-126.
14. Fujino A, Mintz GS, Matsumura M, Lee T, Kim SY, Hoshino M, et al. Stent underexpansion and adverse clinical outcomes in calcified coronary lesions. JACC CardiovascInterv. 2018;11(7):615-623.

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