

RESEARCH ARTICLE

Intravascular imaging-guided intracoronary lithotripsy: First real-world experience

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Abstract

Background and Aims: Coronary calcification remains a significant challenge for the contemporary interventional cardiologist. We aim to describe the use of intravascular lithotripsy (IVL) in a range of real-world settings.

Methods: A retrospective two-center analysis of patients treated with IVL between June 2018 and November 2019. Technical and procedural success, as well as procedural complications and 30-day outcomes (death, myocardial infarction, or repeat target vessel revascularization), was recorded.

Results: Sixty-five patients underwent IVL: 80% were male and the mean age was 70.1 ± 12.0 years. 54% of patients presented with acute coronary syndrome (ACS) and 68% of patients had intracoronary imaging. Twelve patients required IVL within pre-existing stents, and 12 underwent IVL in the left main stem. All balloons were successfully delivered with 98.5% procedural success. There was a significant gain in MLA post PCI of $261.9 \pm 100\%$ following IVL. There were two procedural complications. At 30-day follow-up, there was one death, and one patient required a repeat procedure due to stent underexpansion.

Conclusions: In this largest real-world series of imaging-guided IVL for calcified lesions to date, we demonstrate that IVL is deliverable, safe, and effective at calcium modification especially when intracoronary imaging is used.

KEYWORDS

coronary artery disease, lithotripsy, optical coherence tomography, percutaneous coronary intervention

Abbreviations: ACS, acute coronary syndrome; CABG, coronary artery bypass grafting; Cx, circumflex; ISR, in-stent restenosis; IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; LAD, left anterior descending (artery); LMS, left main stem; MLA, minimum lumen area; MSA, minimum stent area; OCT, optical coherence tomography; OFDI, optical frequency domain imaging; PCI, percutaneous coronary intervention; RCA, right coronary artery; VF, ventricular fibrillation.

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1 | INTRODUCTION

Coronary calcification remains a significant challenge for the contemporary interventional cardiologist. Calcified lesions are difficult to dilate and are associated with failure to deliver and expand stents adequately, leading to worse long-term outcomes including stent thrombosis and restenosis.¹ It is therefore crucial to prepare the

lesion adequately through calcium modification. Traditionally, this was attempted with aggressive balloon dilatation with non-compliant balloon and/or modified balloons such as cutting or scoring balloons. However, these balloons are bulky, difficult to deliver, and have higher rate of complications, including coronary perforation.² Other calcium modification techniques include rotational atherectomy, orbital atherectomy, and excimer Laser, but they are highly technical with a steep learning curve and require specialized equipment and training for the team, limiting their use and availability.²

Intravascular lithotripsy (IVL) (Shockwave Medical, Inc, Santa Clara, CA) is a recently approved device for the treatment of calcific coronary lesions. It is evolved from the extracorporeal lithotripsy that has been successfully utilized to treat renal stones since the 1980s.³ The balloon has two emitters that vaporize the saline/contrast solution when expanded, creating bubbles that expand and collapse within the balloon generating bursts of sonic pressure waves. The pressure waves propagate through the coronary tissue and selectively fractures intimal and medial calcium with an effective pressure of 50 atm, while minimizing trauma to the vessel wall.^{4,5} The apposition of the balloon to the vessel wall is essential to facilitate efficient energy transfer and maximize calcium fracture. The disrupt-CAD study demonstrated the effectiveness of the device in fracturing the calcium, achieving significant luminal gain and stent expansion without the complications commonly associated with atherectomy, such as slow-flow and perforation.⁴ Furthermore, IVL calcium modification improved with severity of calcification on imaging, with the greatest effect in the highest tertile suggesting a role of intracoronary imaging in lesion selection.⁴ More recently, IVL has also been utilized to optimize under-expanded stents in heavily calcified vessels, in patients presenting with in-stent restenosis (ISR). Case reports suggest that IVL may be a useful technology in this setting.^{6,7} IVL also has the advantage of short learning curve as it is still essentially a coronary balloon which is familiar to all interventional cardiologists.

However, real-world data are still limited, and the only case series published to date included only 26 patients and did not utilize any intracoronary imaging.⁸ In this article, we present our experience of imaging-guided IVL in contemporary real-world patients.

2 | METHODS

In this retrospective analysis, consecutive patients treated with IVL at two high volume centers (the Freeman Hospital, Newcastle Upon Tyne, and Royal Stoke University Hospital, UK) between June 2018 and November 2019 were included. The research was carried out in accordance with the Helsinki Declaration (2013), and patients agreed to their records being used to audit the quality and outcomes of their clinical treatment as part of the written consent for the procedure. Ethical approval was granted by the hospital trusts for audit of outcomes of clinical treatment. There were no specific funding resources for this study.

Following coronary angiography, a decision was made at the discretion of the treating interventional cardiologist to perform percutaneous coronary intervention (PCI) with adjunctive IVL. Although intravascular imaging was not prespecified as an inclusion criterion, in the majority of cases, the target lesion was imaged pre and post PCI by optical coherence tomography (OCT), optical frequency domain imaging (OFDI), or intravascular ultrasound (IVUS), with the choice of imaging modality again at the discretion of the operator.

Baseline demographics and procedural details were collected retrospectively from electronic patient databases. Angiographic calcification was defined as mild (faint radio-opacities noted during cardiac motion before contrast injection), moderate (dense radio-opacities noted before contrast injection), or severe (dense radio-opacities noted before contrast injection comprising both sides of the arterial lumen).⁹

Technical success was defined as successful delivery and deployment of the IVL balloon catheter. Procedural success was defined as residual angiographic stenosis <30%. Angiographic complications were defined as dissection, slow flow, perforation, abrupt closure, or no reflow in the treated artery. Data of 30-day follow-up were collected via the electric patient record system. The outcomes collected were death, myocardial infarction, or repeat target vessel revascularization.

The Shockwave (Santa Clara, CA) C² balloon is a monorail-based device that can be delivered over the standard 0.014 angioplasty wire. The equipment consists of the IVL generator, connector cable, and the catheter. All IVL balloons are compatible with minimum 6F guiding catheters. The balloons range from 2.5-4 mm in diameter, are all 12 mm in length, and each balloon can deliver 80 pulses (8×10 second cycles). The balloon is chosen in a 1:1 ratio relative to the target vessel reference diameter, advanced to the lesion, and inflated slowly over 30 s to 4 atm. Once inflated at 4 atm, IVL is delivered by pressing the button on the handle. A minimum of 20 pulses were delivered to the target lesion, and if the lesion exceeded 12 mm, the balloon was repositioned and the lithotripsy was repeated. Following delivery of the IVL therapy, the balloon is inflated to 6 atm (nominal) before deflation. During delivery of cycles, electric spikes that resemble pacing spikes are often seen on the electrocardiogram trace, and the patient can feel odd vibration sensations in the teeth.

Intravascular imaging was performed (when possible) before and after IVL and after stent optimization. All operators were fully trained in all three imaging modalities. Analysis was performed offline with the researcher blind to any clinical data. The site of minimum lumen area (MLA) was identified on the longitudinal imaging and measured alongside the arc of calcium at this site.¹⁰ Minimal stent area (MSA) was measured post PCI following any postdilatation or further optimization of the stent.

OCT images were obtained using a 2.7F Dragonfly OPTIS catheter (Abbott, USA) connected to the Iliumien PCI Optimization System, in accordance with the protocol from the disrupt-CAD imaging sub-study.⁵ Prior to image acquisition, a short flush of iso-osmolar contrast was administered to ensure the guide catheter was well engaged with the coronary artery, and the catheter was clear of blood.

The system was calibrated, and the pullback was initiated with a contrast flush (10 mL in the right coronary artery and 15 mL in the left coronary artery). OCT images were obtained in 54 mm segments at a pullback rate of 20 mm/s.

OFDI imaging was performed using a FastView imaging catheter (Terumo Corp., Japan) connected to a mobile LUNAWAVE imaging system. Following contrast administration in a similar fashion to OCT imaging, the OFDI catheter is pulled back on an automated pullback motor over a longitudinal distance of up to 150 mm at a rate of 20 mm/s.¹¹

IVUS images were obtained using the 3.0F 40MHz Opticross imaging catheter (Boston Scientific, USA) connected to the mobile POLARIS multimodality guidance system. Image acquisition was performed at a pullback speed of 1 mm/s using the automated MDU5 motor drive unit.

3 | RESULTS

In the 18 months between June 2018 and November 2019, 6740 patients underwent PCI at Freeman and Royal Stoke University Hospitals, of which 211 required excimer laser or rotational atherectomy for severe calcification (3.1%). During this time, 65 patients underwent IVL

during PCI. Table 1 details their demographics. Eighty percent of patients were male, and the mean age was 70.1 ± 12.0 years. The majority of patients presented with ACS.

Table 2 demonstrates the procedure-related details. All balloons were successfully delivered to the lesion, and 53 patients underwent IVL to de novo coronary lesions, with 12 requiring IVL within pre-existing stents. One patient received IVL in both the left anterior descending (LAD) and circumflex arteries. There was a heavy burden of calcification when measured by angiography alone, and the majority of patients underwent intracoronary imaging both pre and post PCI, with three patients undergoing both OCT and IVUS imaging. One IVL balloon burst during inflation due to heavy calcification of the lesion.

In the sub-group of 44 patients with invasive intracoronary imaging (Table 3), 25 had imaging pre-PCI, 27 post-PCI, and 23 had both pre- and post-PCI imaging. IVUS was the imaging modality of choice overall and for patients with ACS, while patients with ISR were imaged exclusively with OCT or OFDI (to identify the pathophysiology of ISR). The mean calcium arc at the MLA was near circumferential in most patients, demonstrating that IVL is being used in the most heavily calcified of lesions. There was significant positive change in

TABLE 1 Baseline characteristics

	Total N = 65
Age (y)	70.1 ± 12.0
Male sex	80.0
ACS	53.8
Angina classification:	
• None	6.7
• I	10.0
• II	36.7
• III	46.7
• IV	0
Diabetes	43.1
Hypertension	81.5
Hyperlipidaemia	55.4
Previous MI	44.6
Previous PCI	36.9
Previous CABG	9.2
Previous stroke/TIA	1.5
Smoking status:	
• Current	1.5
• Ex-smoker	64.6
• Never	32.3
Renal insufficiency	16.9

Note: Values are % of the total or mean ± SD.

Abbreviations: ACS, acute coronary syndrome; CABG, coronary artery bypass grafting; MI, myocardial infarction; PCI, percutaneous coronary intervention; TIA, transient ischemic attack.

TABLE 2 Procedural details

	Total N = 65
Radial access	84.1
Artery treated:	
• LMS	12
• LAD	23
• Cx	8
• RCA	23
In-stent restenosis	18.5
Angiographic calcification:	
• None	3.8
• Mild	11.3
• Moderate	22.6
• Severe	62.2
Pre dilation	86.2
Number of IVL balloons per lesion	1.09
Size of IVL balloon:	
• 2.5 mm	5
• 3 mm	18
• 3.5 mm	26
• 4 mm	19
Number of pulses delivered	64.5 ± 29.8
Number of stents	1.73 ± 0.99
Post dilation	92.3
Contrast volume (mL)	208 ± 82

Note: Values are % of the total or mean ± SD.

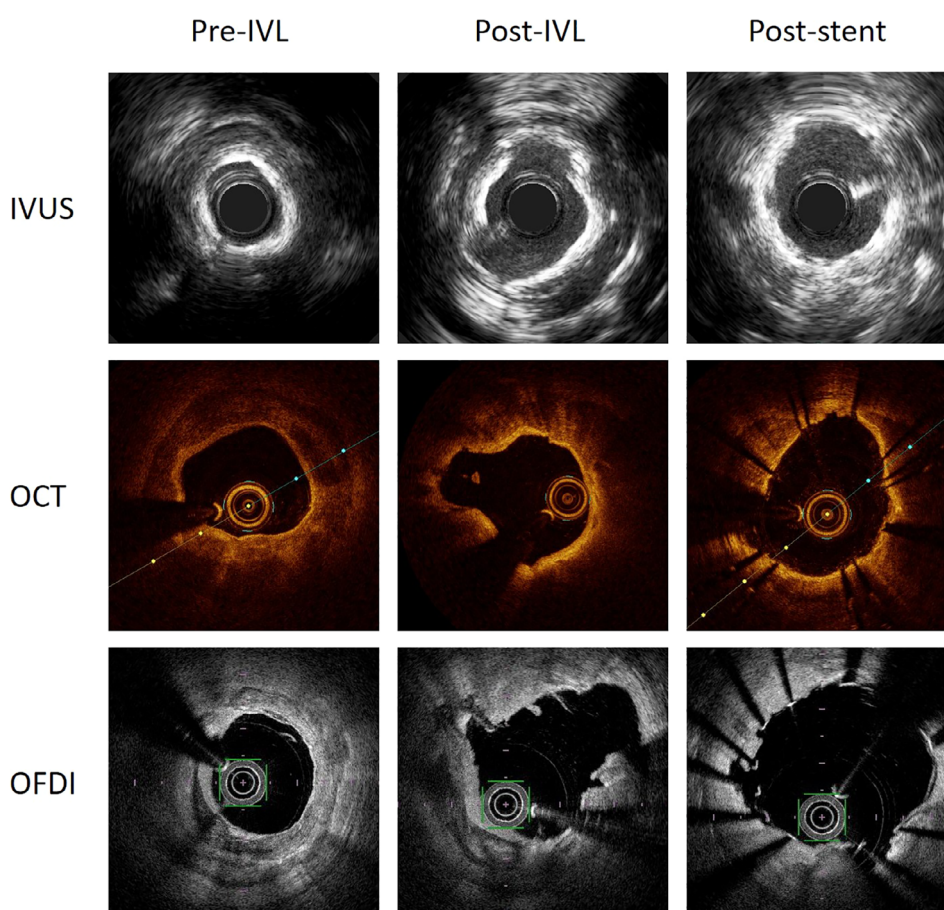
Abbreviations: Cx, circumflex artery; IVL, intravascular lithotripsy; LAD, left anterior descending artery; LMS, left main stem; RCA, right coronary artery.

TABLE 3 Intravascular imaging characteristics

	Total N = 44	ACS N = 23	ISR N = 8
Imaging modality:			
• OCT	43.2	39.1	62.5
• OFDI	15.9	4.3	50.0
• IVUS	47.7	60.9	0
MLA pre PCI (mm ²)	3.07 ± 1.10	3.23 ± 1.16	3.46 ± 1.26
Arc of calcium at MLA (degrees)	305 ± 70	300 ± 74	264 ± 89
% change in MLA post PCI	261.9 ± 100	260.2 ± 104.4	235.2 ± 141.6
Minimal stent area post PCI (mm ²)	7.83 ± 2.75	7.90 ± 2.58	6.72 ± 3.12

Note: Values are % of the total or mean ± SD.

Abbreviations: ACS, acute coronary syndrome; ISR, in-stent restenosis; IVUS, intravascular ultrasound; MLA, minimum luminal area; OCT, optical coherence tomography; OFDI, optical frequency domain imaging; PCI, percutaneous coronary intervention.

**FIGURE 1** Calcium fracturing pre and post IVL on IVUS, OCT, and OFDI

the MSA post PCI, demonstrating the efficacy of IVL, although patients with ISR had a smaller MSA post PCI than those with de novo lesions requiring IVL. Figure 1 exemplifies the calcium fracturing seen on all three imaging modalities.

Table 4 details the outcomes in our cohort. In one case, the IVL balloon burst on inflation; this was the only technical failure of the IVL system. Overall, 86.4% of patients achieved procedural success with a post-PCI stenosis <30%. There were two procedural complications (a distal wire perforation in the IVL treated artery and a

ventricular fibrillation [VF] arrest during an IVL treatment). There was one death (due to the previously mentioned distal wire perforation, cardiac tamponade, and multiorgan failure despite adequate pericardial drainage) and one patient that required further IVL and laser coronary angioplasty to the target vessel due to stent underexpansion. One patient was readmitted with a troponin-negative ACS and underwent coronary artery bypass grafting (CABG) to a nontarget vessel. No patients required temporary or permanent pacing or mechanical support during their procedure or hospitalization.

4 | DISCUSSION

Our results were compared very favorably to a prospective registry of 78 IVL cases in Germany, which demonstrated a successful PCI strategy (residual stenosis <20%) in 84.6% of calcified de novo lesions, 77.3% of lesions in which noncompliant balloon dilatation failed, and

64.7% of patients with stent underexpansion.¹² Our results also were compared well to clinical success rates (defined as residual stenosis <50% and no periprocedural complications) for rotablation in a large (966 patients) contemporary European registry (91.9%).¹³ Utilizing intracoronary imaging, our results establish the efficacy of IVL in treating highly calcified coronary lesions in a range of real-world patients (Figure 2), comprising many lesions (eg, LMS, ISR, unstable lesions in ACS) that were not included in the original DISRUPT-CAD trials of IVL.^{4,14} Furthermore, we have demonstrated the calcium fracturing effect of IVL on intracoronary calcium on three different intravascular imaging modalities, confirming early OCT studies that showed circumferential modification of calcium.⁵ Although the crossing profile of the IVL balloons is somewhat bulky (0.044-0.046"), all balloons were successfully delivered to the culprit lesion.

A previous case series highlighted the capacity of IVL to precipitate ventricular ectopics, "shocktopics," and asynchronous cardiac pacing,¹⁵ and there was one patient in our cohort who had VF during IVL delivery and was successfully shocked back to sinus rhythm with no sequelae. The patient who died as a consequence of a distal wire perforation was a high-risk patient with complex calcified coronary disease and left ventricular dysfunction and is a cogent reminder that coronary calcification is an independent predictor of major bleeding events.¹⁶

TABLE 4 Angiographic and 30-day outcomes

	Patients N = 65
Technical success	98.5
Procedural success	86.4
Angiographic complications:	
• Dissection	0
• Slow flow	0
• Perforation	1.5
• Abrupt closure	0
• No reflow	0
30-d complications:	
• Death	1.5
• Myocardial infarction	0
• Repeat target vessel revascularization	1.5

Note: Values are % of the total.

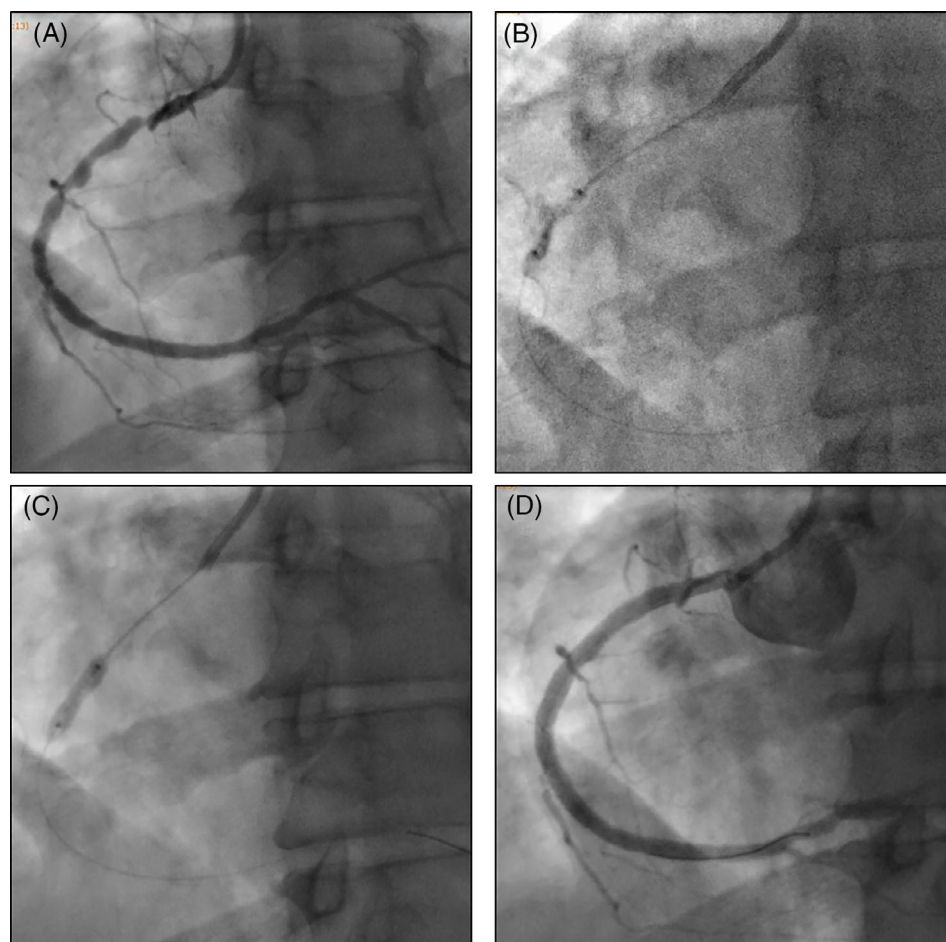


FIGURE 2 Angiographic images of a right coronary artery undergoing IVL treatment. A, before treatment, B, underexpansion of noncompliant balloon due to heavy calcification, C, IVL balloon expansion, and D, final result after stenting

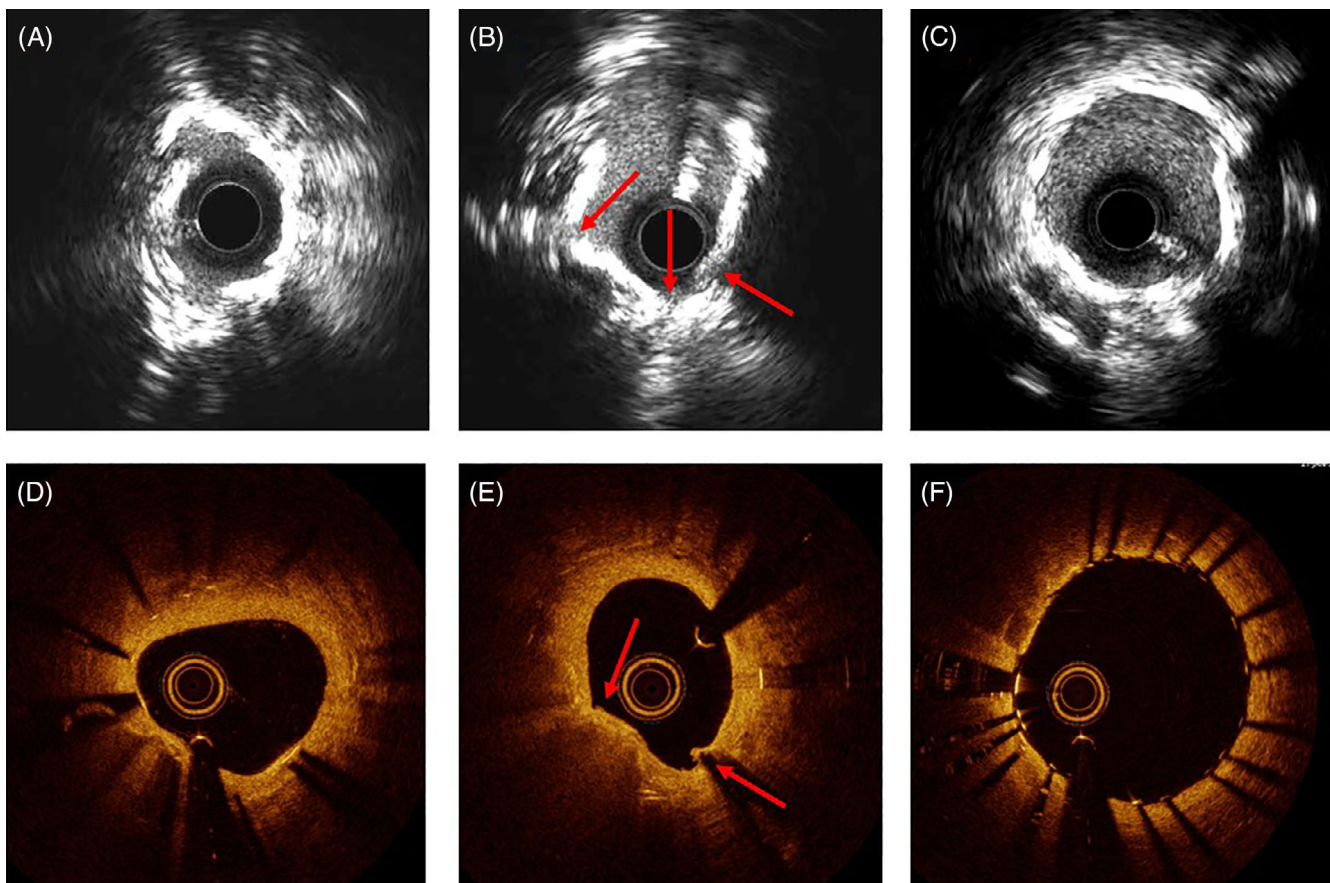


FIGURE 3 IVUS and OCT images of in-stent restenosis before IVL (A and D), after IVL (B and E—red arrows showing calcium fracturing), and after stenting (C and F)

Previous case reports have detailed the utilization of IVL in stent underexpansion due to calcified plaque.^{6,7,17} Our series of 12 patients with calcific ISR (Figure 3) treated by IVL is the largest to date and demonstrates the utility of this technology where previously interventional cardiologists had only high-pressure noncompliant balloons and excimer laser angioplasty in their armamentarium. Indeed, the one patient in our series that required repeat target vessel revascularization underwent successful repeat IVL and laser angioplasty to an underexpanded stent. A significant number ($n = 12$) of our cases successfully utilized IVL in the LMS (mainly treating distal LMS and bifurcation disease), demonstrating its effectiveness despite the largest balloon diameter of 4 mm.

This is a relatively small observational case series from two UK centers, detailing our experience with IVL in patients not included in the feasibility and efficacy trials. As such, there are several limitations. IVL was chosen at the operator's discretion, and we did not have any comparison groups utilizing other calcium-modifying techniques such as rotational atherectomy or laser angioplasty. Use of intravascular imaging was also only at the operator's discretion, and therefore any conclusions from this are purely hypothesis generating. In addition, as this was a retrospective study, there may have been an element of selection bias in the choice of IVL vs other calcium debulking device following the acquirement of preprocedural

angiographic or intravascular images (noting that the pre-IVL MLA in our cohort was relatively large, suggesting that it was not used in the tightest lesions). Finally, follow-up was limited to 30 days, and longer-term outcomes remain to be seen.

5 | CONCLUSIONS

IVL appears effective in calcium modification in a range of clinical settings, including de novo lesions, acute coronary syndrome, left main stem/bifurcation lesions, and calcified in-stent restenosis. Intravascular imaging demonstrates calcium fracturing as the mode of action of IVL and is useful in both quantifying the arc of calcium pre-IVL and confirming adequate calcium modification prior to stent implantation. IVL is deliverable and safe and is a useful adjunct when other, more technical, calcium modification approaches are unavailable.

CONFLICT OF INTEREST

None of the authors has any conflicts of interest to disclose.

AUTHOR CONTRIBUTIONS

Conceptualization: Hannah Sinclair, Lampson Fan, Javed Ahmed
Data curation: Hannah Sinclair, Lampson Fan

Formal analysis: Hannah Sinclair, Lampson Fan

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Methodology: Hannah Sinclair, Javed Ahmed

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Writing—original draft: Hannah Sinclair, Lampson Fan

Writing—review and editing: Hannah Sinclair, Lampson Fan, Eoin Fahy, Farhan Shahid, Karim Ratib, James Nolan Mamas Mamas, Javed Ahmed

All authors have read and approved the final version of the manuscript.

Javed Ahmed had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

TRANSPARENCY STATEMENT

Javed Ahmed affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article.

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