







## ORIGINAL STUDY

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# Intravascular lithotripsy for treatment of calcific coronary lesions in ST elevation myocardial infarction

Claudia Cosgrove MBBS<sup>1</sup>  | Colm G Hanratty MD<sup>2</sup> | Jonathan M Hill MD<sup>3</sup> | Kalaivani Mahadevan MBBS<sup>4</sup> | Jonathan Mailey MBChB<sup>5</sup>  | Margaret McEntegart MD, PhD<sup>6</sup>  | Peter O'Kane MD<sup>7</sup> | Novalia Sidik MBChB<sup>6</sup> | Julian W Strange MD<sup>4</sup> | Simon J Walsh MD<sup>5</sup> | Simon Wilson MBChB<sup>1</sup>  | Julian Yeoh MBBS<sup>8</sup>  | James C Spratt MBChB, MD<sup>1</sup> 

<sup>1</sup>Department of Cardiology, St George's University Hospitals NHS Foundation Trust, London, UK

<sup>2</sup>Department of Cardiology, Mater Private Hospital, Dublin, UK

<sup>3</sup>Department of Cardiology, Royal Brompton and Harefield NHS Foundation Trust, London, UK

<sup>4</sup>Department of Cardiology, Bristol Heart Institute, Bristol, UK

<sup>5</sup>Department of Cardiology, Belfast Health and Social Care Trust, Belfast, UK

<sup>6</sup>Department of Cardiology, Golden Jubilee Hospital, Clydebank, UK

<sup>7</sup>Department of Cardiology, Royal Bournemouth Hospital, Bournemouth, UK

<sup>8</sup>Department of Cardiology, Kings College Hospital NHS Foundation Trust, London, UK

## Correspondence

Dr Claudia Cosgrove, Department of Cardiology, St George's University Hospitals NHS Foundation Trust, Blackshaw Road, London, SW17 0QT, UK.  
Email: claudia.cosgrove@nhs.net

## Abstract

**Aims:** To describe the utility and safety of intravascular lithotripsy (IVL) in the setting of primary percutaneous coronary intervention (PCI) for ST elevation myocardial infarction (STEMI).

**Methods and results:** We performed a retrospective analysis, across six UK sites of all patients in whom IVL was used for coronary calcium modification of the culprit lesion during primary PCI for STEMI. The 72 patients were included. IVL was used in de-novo culprit lesions in 57 (79%) of cases and culprit in-stent restenoses in 11 (15%) of cases. In four cases (6%) it was used in a newly deployed stent when this was under-expanded due to inadequate calcium modification. Of the 30 cases in which intracoronary imaging was available for stent analysis, the average stent expansion was 104%. Intra-procedural stent thrombosis occurred in one case (1%), and no-reflow in three cases (4%). The 30 day MACE rates were 18%.

**Conclusion:** IVL appears to be feasible and safe for use in the treatment of calcific coronary artery disease in the setting of STEMI.

## KEYWORDS

coronary artery disease, calcium, percutaneous coronary intervention, ST elevation myocardial infarction

## 1 | INTRODUCTION

Primary PCI is increasingly performed in older and more co-morbid patients,<sup>1,2</sup> with more calcified and complex coronary artery disease. Angiographic coronary artery calcium (CAC) is frequent in target lesions in STEMI,<sup>3</sup> associated with worsened epicardial flow, a poorer response to fibrinolytic therapy, and is an independent risk factor for increased cardiovascular major adverse events (MACE).<sup>4</sup>

Existing tools for calcium modification have limitations in STEMI which may restrict their use. Repeated high pressure balloon dilatation in a thrombotic lesion can cause distal embolization. Although data are scarce on the use of rotational atherectomy in STEMI, it is relatively contraindicated due to the risk of no-reflow caused by embolization of atheromatous debris. This risk is likely to be greater in the highly thrombotic milieu of STEMI, where the microvasculature may already be congested. There is also a risk of increased platelet activation by the heat generated

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by the rapidly rotating burr. Perhaps as a consequence, the use of rotational atherectomy is low in non ST elevation myocardial infarction (NSTEMI) and STEMI- 0.7% in a pooled analysis of the HORIZONS-AMI and ACUITY trials.<sup>3</sup>

Coronary intravascular lithotripsy (IVL; Shockwave Medical, CA, USA) is an emerging treatment modality for vascular calcium that may offer advantages over existing therapies. IVL has been shown to be safe and effective in patients with calcific disease requiring revascularization for stable clinical syndromes.<sup>5</sup>

Coronary calcium is a major risk factor for stent underexpansion and subsequent stent failure.<sup>3,6-8</sup> In addition to facilitating optimal stent expansion in de-novo lesions,<sup>5</sup> IVL has demonstrated utility in the management of under-expanded stents due to coronary calcification,<sup>9</sup> and may be of particular use in this subset of patients presenting with STEMI. As a balloon-based therapy, IVL has a reduced learning curve compared to other calcium modification techniques, and with the potential for low complication rates, may have an advantage over these existing tools.<sup>5</sup>

Here we present the first description of procedural characteristics and safety outcomes following IVL use in STEMI.

## 2 | METHODS

### 2.1 | Study design and patient population

We performed a retrospective analysis of all patients in whom IVL was used during primary PCI at six UK sites between June 2018 and September 2020. Inclusion criteria were presentation fulfilling criteria for STEMI (chest discomfort or other symptoms suggestive of ischemia and ST segment elevation in at least two contiguous ECG leads) and the use of IVL in the culprit lesion during the primary PCI. All patients received IVL as part of standard care, with therapy administered as per the manufacturer's recommendations.

### 2.2 | Procedure

Interventional strategy was determined by anatomy and operator preference. Antithrombotic therapy was prescribed according to current guidelines.

### 2.3 | Endpoints

The primary safety endpoint was procedural complications and in-hospital major adverse cardiac events (MACE), defined as all-cause death, non-fatal myocardial infarction (MI) or target vessel revascularization (TVR).<sup>10</sup>

### 2.4 | Definitions

An undilated lesion was defined as a lesion which failed to yield despite high pressure (>18 atm) inflation of a non-compliant (NC) balloon sized 1:1 to the vessel. Severe angiographic calcification was defined as radiopacities seen before contrast injection, appearing to involve both sides of the arterial lumen on angiography. Concentric calcium was defined as >270° calcium arc seen on intracoronary imaging. Thrombolysis in Myocardial Infarction (TIMI) criteria was used to describe coronary flow, and has been defined previously.<sup>11</sup> No reflow (TIMI 0-1) was defined as a persistent reduction in coronary flow in the absence of dissection, spasm, stenosis or thrombus of the epicardial vessel.<sup>12</sup> Stent expansion was defined as the minimum stent area (MSA) divided by the distal reference area, expressed as a percentage. Stent underexpansion was defined as stent expansion <90%. Target lesion revascularization (TLR) was defined as repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion.<sup>10</sup> Bleeding was defined as BARC Type 3 bleeding.<sup>13</sup> Significant bystander lesions were defined as major epicardial arteries with >70% angiographic stenosis.

### 2.5 | Statistical analysis

Continuous data are expressed as a mean ± SD, categorical data are expressed as total number and percentage unless otherwise stated.

**TABLE 1** Patient characteristics

	All patients (n = 72)
Age, years (SD)	72.9 (10.9)
Male	85% (61)
Hypertension	64% (46)
Diabetes	22% <sup>14</sup>
Smoking (current/previous)	53% (38)
Renal impairment <sup>a</sup>	36% (26)
Previous CABG	4% <sup>3</sup>
Previous PCI	25% <sup>15</sup>
Statin therapy	47% (34)
Warfarin/DOAC pre-admission	10% <sup>7</sup>
BMI, kg/m <sup>2</sup> (SD)	26.3 (4.8)
LVEF<55%	72% (52)
LVEF<35%	29% <sup>16</sup>

Abbreviations: CABG, coronary artery bypass grafting; BMI, body mass index; DOAC, direct oral anticoagulant; LVEF = left ventricular ejection fraction; PCI, percutaneous coronary intervention.

<sup>a</sup>eGFR<60 ml/min.

**TABLE 2** Procedural characteristics

		All patients (n = 72)
Time of day	8 a.m.–8 p.m.	68% (49)
	8 p.m.–8 a.m.	32% <sup>17</sup>
Culprit artery	LMS	5% <sup>4</sup>
	LAD	51% (37)
	LCX	15% <sup>11</sup>
	Ramus	2% <sup>1</sup>
	RCA	27% <sup>18</sup>
Access radial		88% (63)
TIMI flow at start	0	37
	1	8
	2	11
	3	16
TIMI flow at end	0	1
	1	3
	2	5
	3	63
Onset to reperfusion time, min (SD)		272 (375)
LV support- IABP		4% <sup>3</sup>
Aspiration thrombectomy		8% <sup>6</sup>
GIIb/IIIa inhibitor		26% <sup>18</sup>
IVL use	Culprit- denovo lesion	80% (57)
	Culprit-in-stent	15% <sup>11</sup>
	Under-expanded newly-placed stent	5% <sup>4</sup>
IVL indication	Undilatable lesion	71% (51)
	Under-expanded stent	21% <sup>19</sup>
	Concentric calcium on intracoronary imaging	4% <sup>3</sup>
	Severe calcium on angiography	4% <sup>3</sup>
Calcium arc (degrees) (n = 29)		314
Max IVL balloon size, mm (SD)		3.28 (0.5)
Other calcium modification	NC	76% (55)
	Cutting/scoring	28% <sup>20</sup>
	Rotational atherectomy	7% <sup>5</sup>
Intravascular imaging	None	44% (32)
	IVUS	49% (35)
	OCT	7% <sup>5</sup>
No. stents implanted, culprit lesion (SD)		1.8 (1.0)
Max stent diameter, culprit lesion, mm (SD)		3.5 (0.5)
Total stent length, culprit lesion, mm (SD)		56.4 (27)
Stent expansion (%) (n = 30)		104
Bystander disease	None	43% (31)
	PCI at index procedure	39% (28)
	Staged PCI	10% <sup>7</sup>
	CABG	3% <sup>2</sup>

(Continues)

**TABLE 2** (Continued)

		All patients (n = 72)
Medical management		5% <sup>4</sup>
Antithrombotic therapy	DAPT – aspirin + ticagrelor	82% (59)
	DAPT – aspirin + clopidogrel	5% <sup>4</sup>
	Aspirin + DOAC/warfarin	3% <sup>2</sup>
	Triple therapy – aspirin + clopidogrel + DOAC/warfarin	10% <sup>7</sup>
Procedure time, min (SD)		99 (42)
Screening time, min (SD)		26 (12)

Abbreviations: CABG, coronary artery bypass grafting; DAPT, dual anti-platelet therapy; DOAC, direct oral anti-coagulant; LMS, left main stem; LAD, left anterior descending; LCX, left circumflex; RCA, right coronary artery TIMI, thrombolysis in myocardial infarction; LV, left ventricle; IABP, intra-aortic balloon pump; IVL, intravascular lithotripsy; NC, non-compliant; IVUS, intravascular ultrasound; OCT, optical coherence tomography; PCI, percutaneous coronary intervention.

**TABLE 3** Outcomes

All patients (n = 72)		
Procedural complications	No reflow	4% <sup>3</sup>
	Stent thrombosis	1% <sup>1</sup>
	Perforation	0% (0)
	VT/VF	4% <sup>3</sup>
In-hospital death		11 (15%)
In-hospital stroke		3 (4%)
In-hospital TVR		0 (0%)
In-hospital bleeding		5 (7%)
30-day death		12 (17%)
30-day MI		1 (1%)
30-day TVR		1 (1%)
30-day MACE (death/MI/TVR)		18%

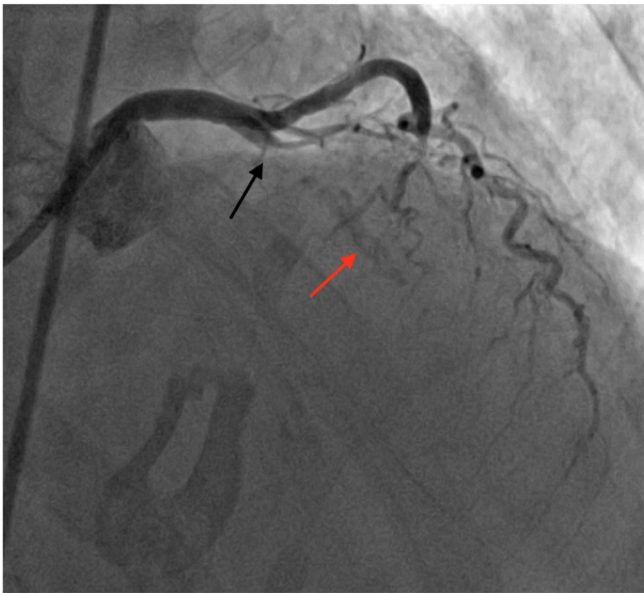
Abbreviations: VT, ventricular tachycardia; VF, ventricular fibrillation; TVR, target lesion revascularization; MI, myocardial infarction; MACE, major adverse cardiovascular events.

### 3 | RESULTS

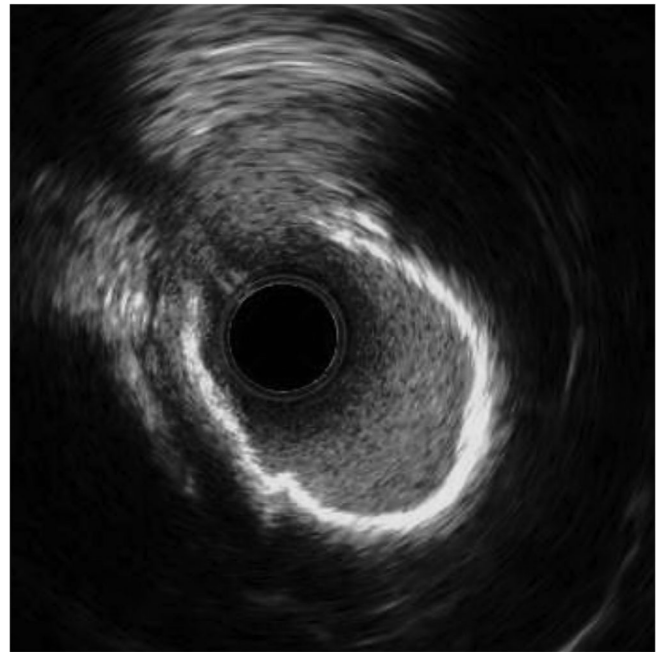
We identified 72 eligible patients, over a 2 year period, representing 1% of total STEMI procedures undertaken across the six sites. The total annual STEMI number of the sites is 3,328, the total annual number of PCIs 11,912, and the total annual number of IVL cases 503.

Patient characteristics are shown in Table 1.

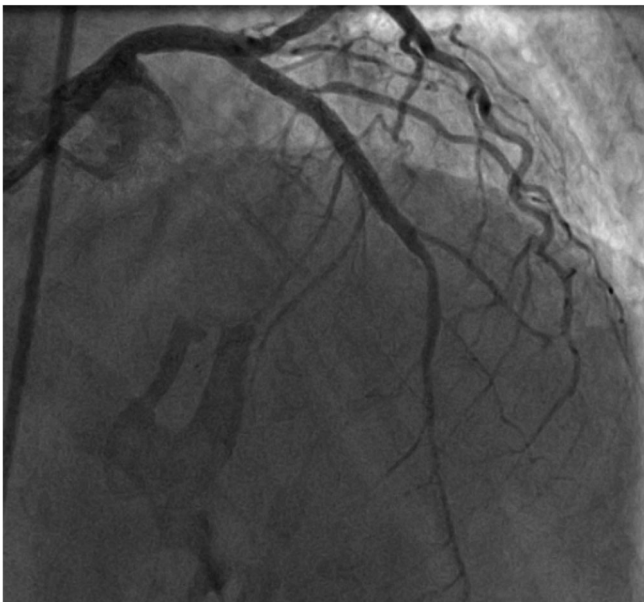
Procedural characteristics are shown in Table 2. IVL was used in de-novo culprit lesions in 57 (79%) of cases and culprit in-stent restenoses in 11 (15%) of cases. In four cases (6%) it was used in a newly deployed, under-expanded stent when this was due to inadequate calcium modification. In 71% of cases, IVL was used



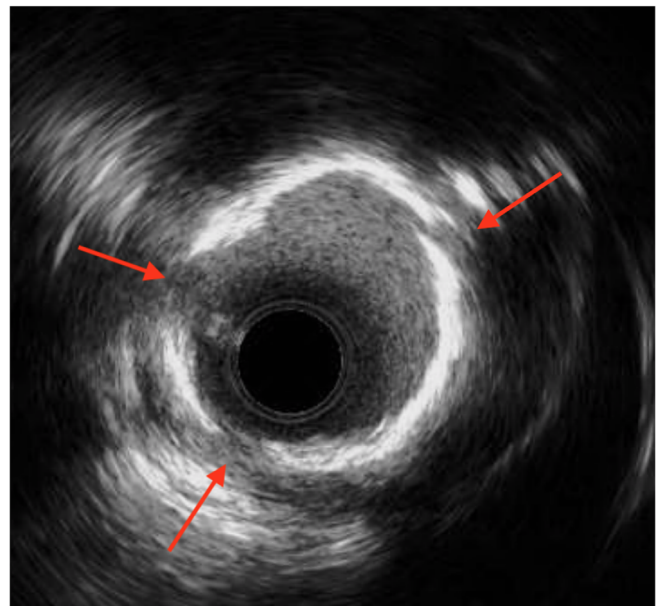
**FIGURE 1** Coronary angiogram showing occluded left anterior descending (LAD) (Black arrow) and calcification within the occluded vessel (Red arrow) [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



**FIGURE 3** Intravascular ultrasound (IVUS) of the left anterior descending (LAD), showing  $>270^\circ$  arc of calcium



**FIGURE 2** Coronary angiogram following PCI after calcium modification with IVL

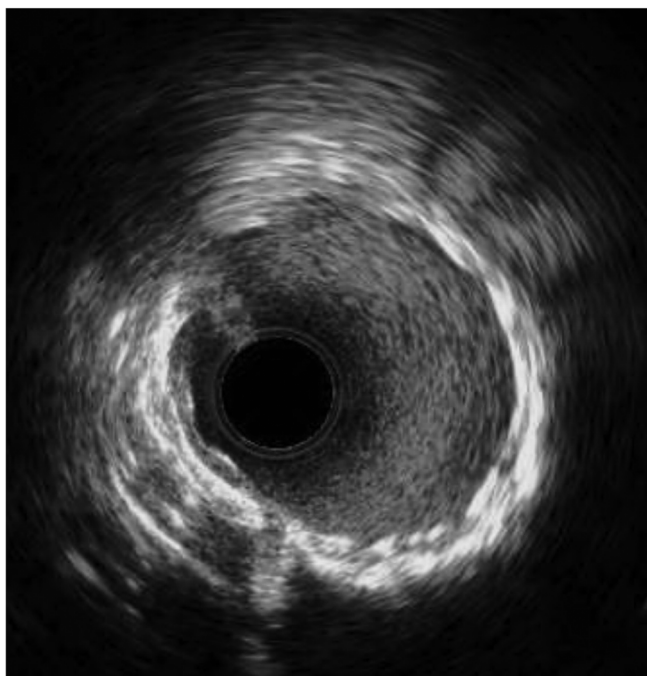


**FIGURE 4** Intravascular ultrasound (IVUS) demonstrating calcium fractures (Red arrows) following delivery of IVL [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

after the culprit lesion failed to yield to high pressure NC balloon inflation. In 21% of cases, IVL was used in an under-expanded stent (whether a previously or newly placed). In 4%, IVL was used prior to any other calcium modification, based on the presence of concentric calcium seen on intracoronary imaging, and in 4%, the operators elected to use IVL prior to any other calcium modification, because severe calcification was identified on angiography.

Procedural and clinical outcomes are shown in Table 3. Intra-procedural stent thrombosis occurred in one case (1%), and no-reflow

in three cases (4%), two of which occurred immediately after delivery of IVL, in cases with TIMI 0–1 flow at the start of the case. The third instance of no-reflow occurred in a patient with initially TIMI 3 flow, following repeated high pressure inflations with an NC balloon (prior to IVL). 30-day all-cause death occurred in 12 (17%) of patients. There was one case of repeat infarction requiring TVR, due to stent thrombosis of an inadequately expanded stent (due to inadequate calcium



**FIGURE 5** Intravascular ultrasound (IVUS) demonstrating satisfactory stent expansion within the heavily calcified segment of left anterior descending (LAD)

modification during the index procedure). Overall 30-day MACE rates were 18%.

## 4 | DISCUSSION

This retrospective analysis describes the procedural characteristics and safety outcomes in patients treated with IVL during STEMI.

Although STEMI is most commonly caused by rupture of thin capped lipid rich plaque, in 8% of STEMI the culprit lesion is an eroded calcified nodule. As CAC increases with age,<sup>21</sup> the incidence of calcification (54%) within all STEMIs<sup>19</sup> and eroded calcific nodules are also likely to increase.

Dealing with CAC in the context of STEMI may carry a higher risk of procedural complications and, if CAC is inadequately treated, a higher risk of stent failure. Existing technologies such as high pressure balloon inflation, scoring or cutting balloons and rotational atherectomy are associated with increased rates of slow/no reflow, severe dissection and perforation. This may translate to a reluctance to modify calcium within STEMI and explain the low use of these technologies. We hypothesize that these risks may be reduced with IVL, due to the low pressure inflations used (4–6 atm) and the absence of distal embolization of calcific remnants.<sup>14</sup> Our findings were consistent with this hypothesis and demonstrated low rates of procedural complications or inpatient adverse events. Rates of no-reflow were low (4%, compared to reported rates of 20–30%<sup>17,22</sup>) with no cases of perforation reported in keeping with safety rates previously published for IVL.<sup>23</sup> The low incidence of

no-reflow may reflect a lower need for repeated high pressure balloon inflation to achieve lesion expansion.

Given the strong association of CAC with age and diabetes it is not surprising that the patients described within this cohort were older (73, compared to the average age of STEMI in the United Kingdom (UK)-63 for men, 72 for women within the UK registry<sup>2</sup>) and had a high incidence of diabetes (22%, compared to 20.5% of men and 22.4% of women presenting with STEMI within the UK registry.<sup>2</sup>) In total, 57% of patients in this cohort had significant bystander disease, slightly higher than previously published rates of between 28 and 53% of multivessel disease in patients presenting with STEMI.<sup>15,18,24</sup>

IVL was used within the culprit lesion in all these patients, and included in this were culprit lesions occurring in previously placed stents (15%), and in cases in which the newly deployed stent remained underexpanded despite high pressure post-dilatation (6%). Overall, IVL was used for under-expanded stents (whether newly placed or pre-existing) in 21% of cases, an indication which has previously been described.<sup>9</sup> The threshold of appropriate use for IVL remains poorly defined, within our series high pressure NC balloons were used unsuccessfully in 76% of cases prior to IVL.

Coronary angiography is insensitive for the diagnosis of CAC which may explain the high incidence of intravascular imaging within our cohort (55%, compared to 2.7% in a large US registry of all acute myocardial infarctions, and compared to 9% in all PCI in the UK.

(20, 21)). Intravascular imaging is a sensitive way of identifying the need for calcium modifying therapies and assessing both the response to therapy and the final stent result. Of the 29 cases in which intracoronary imaging was performed prior to IVL, there was an average calcium arc of 314°, indicating appropriate use of IVL. One such representative case is shown in Figures 1–5. A further potential advantage of IVL is the ability to modify deep wall and / or medial coronary calcium and thereby restore vessel compliance, this may in turn translate into larger MSAs and a lower incidence of stent failure. Indeed, of the 30 cases in which intracoronary imaging was available for stent analysis, the average stent expansion was 104%, indicating satisfactory mechanical results achieved in these heavily calcified lesions.

The majority of cases (68%) were performed between 8 a.m. and 8 p.m. Overnight, when priority is placed on performing shorter procedures and the interventional team is smaller this may translate to a reluctance to use adjunctive, particularly complex technology such as rotational atherectomy. The short learning curve of IVL and relative ease of use may circumnavigate this potential barrier.

Our findings were consistent and demonstrated low rates of procedural complications or inpatient adverse events related to the PCI. Rates of no-reflow were low (4%, compared to reported rates of 20%–30%<sup>17,22</sup>) with no cases of perforation reported in keeping with safety rates previously published for IVL.<sup>23</sup> The low incidence of no-reflow may reflect a lower need for repeated high pressure balloon inflation to achieve lesion expansion.

The 30 day mortality rate of this cohort was 17%, significantly higher than 30 day mortality rates for STEMI of 9% from both UK and Swedish national registries.<sup>2,25</sup> Of the 12 deaths, eight were cardiac

deaths, and all due to cardiogenic shock or ventricular arrhythmia in patients with severe LV impairment, most of whom were older than 80 years. The non-cardiac deaths included one due to hypoxic brain injury complicating out of hospital arrest, two were due to malignancy and one perforated cholecystitis.

Although this study is limited by the lack of control group and modest sample size, it provides a “real-world” demonstration of the utility and safety of IVL use in STEMI and adds to the growing body of evidence of the important role of IVL in coronary calcium modification.

## 5 | CONCLUSION

In the setting of primary PCI for STEMI, IVL appears to be a safe and effective tool for modification of calcified coronary lesions prior to stent implantation.

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### DATA AVAILABILITY STATEMENT

Data available on request from the authors: The data that support the findings of this study are available from the corresponding author upon reasonable request.

### ORCID

Claudia Cosgrove  <https://orcid.org/0000-0003-1754-4680>

Jonathan Mailey  <https://orcid.org/0000-0002-9013-5720>

Margaret McEntegart  <https://orcid.org/0000-0001-5135-3322>

Simon Wilson  <https://orcid.org/0000-0002-1999-5103>

Julian Yeoh  <https://orcid.org/0000-0003-4957-186X>

James C Spratt  <https://orcid.org/0000-0001-8719-4538>

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