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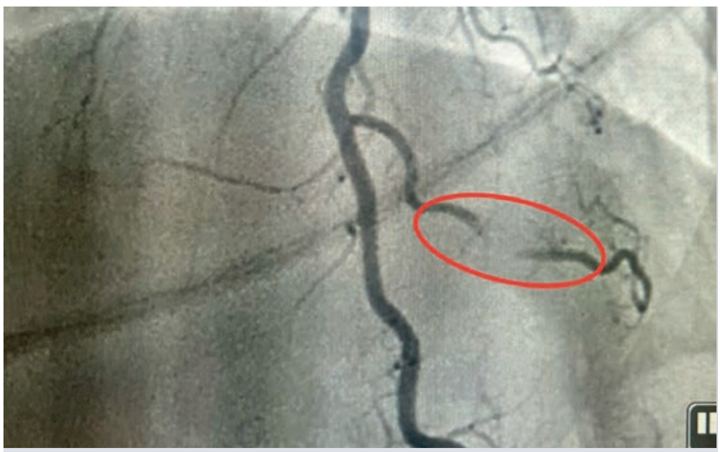

CASE REPORT

Rare Case of Myocardial "Milking" in a Diagonal Branch Artery

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Myocardial bridging is a very common anomaly, which can be found in more than 30% of the population, based on autopsy studies.[1] It happens when a segment of a major epicardial coronary artery runs intramural through the myocardium. It is a common congenital anomaly sometimes referred to as a "tunneled artery." Systolic compression during filling can result in hemodynamic changes that may be associated with angina, myocardial ischemia, acute coronary syndrome, left ventricular dysfunction, arrhythmias, and even sudden cardiac death.[2]

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HMP Global

Cracking Calcium With the C2+ Lithotripsy Balloon

Can Greater Pulse Availability Translate to Enhanced Procedural Outcome Whilst Maintaining a High Safety Profile?

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Coronary artery calcification is a common challenge in percutaneous coronary intervention (PCI), often leading to stent under-expansion and failure.[1-5] Intravascular lithotripsy (IVL) has emerged as a safe and effective tool for calcium modification, with the DISRUPT CAD trials showing favorable outcomes even in complex lesions.[6-10] IVL uses acoustic waves to fracture calcium and improve vessel compliance, and its balloon-based delivery system offers a short learning curve and ease of use compared to atherectomy.

While IVL has shown promise in a range of scenarios, including STEMI, eccentric lesions in combination with rotational atherectomy, and stent failure due to calcific under-expansion,[12-20] limitations remain, such as balloon crossing profile and the pulse cap of the C2 balloon (80 pulses) (Shockwave Medical). Registry data suggest higher pulse counts may improve outcomes.[21] This analysis evaluates patient and procedural characteristics, along with medium-term outcomes, from early experience with the C2+ IVL balloon (Shockwave Medical), which delivers up to 120 pulses.

Method

Study participants and data collection

This is a retrospective analysis of consecutive patients treated with IVL for coronary calcification using the C2+ Shockwave balloon from its implementation in November 2022 through December 2023, with comparison to consecutive patients in the preceding year undergoing C2 Shockwave balloon treatment, taking place across the three hospitals (University Hospital Dorset, University Hospital Bristol & Weston, and St. George's University Hospital). This analysis received approval from each of the local audit/service evaluation groups. Baseline demographics, comorbidity details, and details of the procedure were taken from the British Cardiovascular Intervention Society database. Target vessel revascularization (TVR) and mortality during the analysis were also recorded.

Procedure

Patients were included in this cohort if the treating interventional cardiologist felt that

Table 1. Patient demographics and comorbidities.

Demographic/comorbidity	C2+ patients (264 patients)	C2 patients (286 patients)	*P*-value for comparison
Median age (IQR)	74 years (67 – 80 years)	74 years (65 – 80 years)	.988
Female	61 (23.1%)	64 (22.5%)*	.856
Median body mass index (kg/m²) (IQR)	26.7 (24.3 – 30.5) 58 missing	27.2 (24.3 – 30.8) 26 missing	.552
Median creatinine (IQR)	90 (80 – 104) 36 missing	85 (70 – 102) 43 missing	.004
Previous myocardial infarction	95 (36.0%)	92 (32.2%)	.345
Previous CABG	32 (12.2%)	26 (9.1%)	.248
Previous PCI	119 (45.1%)	114 (39.9%)	.216
Diabetes mellitus	90 (34.1%)	96 (33.6%)	.897
Peripheral vascular disease	20 (7.6%)	19 (6.6%)	.670
Hypertension	184 (69.7%)	182 (63.6%)	.132
Dyslipidaemia	148 (56.1%)	156 (54.5%)	.721
Previous stroke/TIA	17 (6.4%)	16 (5.6%)	.677
Left ventricular function			.606
Normal	81 (30.7%)		
Moderate	46 (17.4%)		
Severe	10 (3.8%)		
Unknown	127 (48.1%)		
Smoking status			.371
Never	108	94	
Previous	86	24	
Current	17	79	
Unknown	53	89	

*Note: One C2 patient lacked recorded sex information; sex-based statistics reflect the remaining 285 patients in this group.
IQR = interquartile range; CABG = coronary artery bypass graft surgery; PCI = percutaneous coronary intervention; TIA = transient ischemic attack

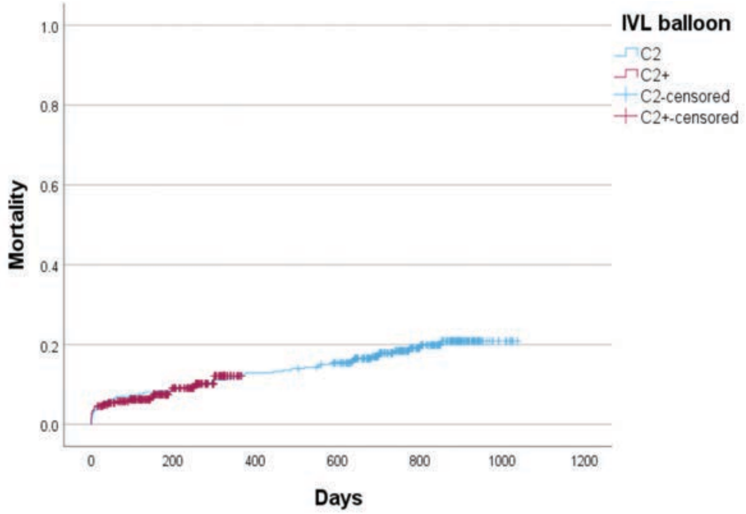


Figure 1. **Kaplan-Meier curve of mortality comparing C^2 (blue) and C^{2+} (red) cohorts, *P*=.950.**

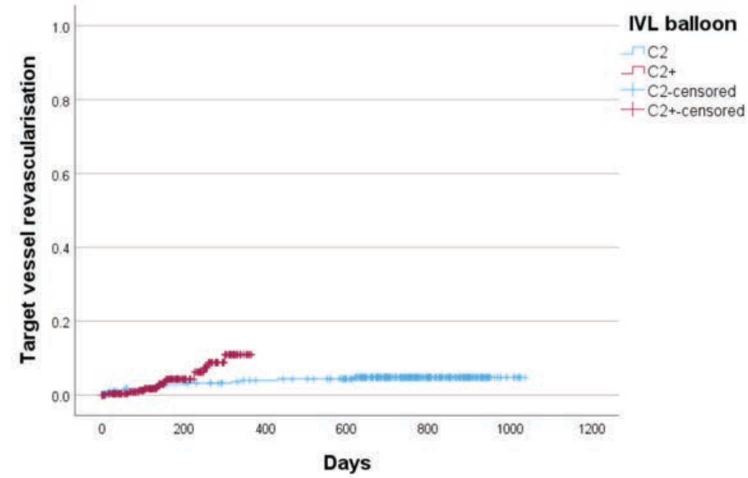


Figure 2. **Kaplan-Meier curve of target vessel revascularization (TVR) comparing across C^2 (blue) and C^{2+} (red) cohorts, *P*=.035.**

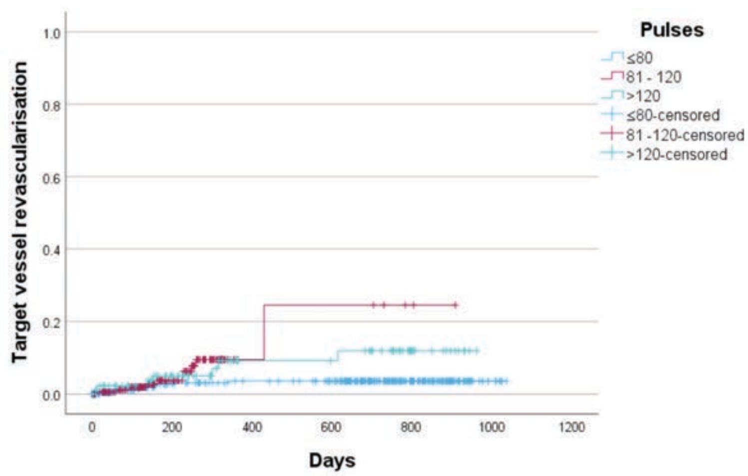


Figure 3. **Kaplan-Meier curve of target vessel revascularization (TVR) depending on the total number of pulses delivered (≤80 pulses versus 81-120 pulses, *P*=.015; ≤80 pulses versus >120 pulses, *P*=.025; 81-120 pulses versus >120 pulses, *P*=.614).**

there was significant calcification requiring modification with IVL. The size of IVL balloon and number of pulses delivered was at the discretion of the supervising interventional cardiologist. IVL was performed using the Shockwave C^2 system as per the standard IVL technique using the C^2 or C^{2+} balloon.[22]

Statistical analysis

Patient demographics and comorbidities are reported per patient, while procedural data are reported per procedure to account for patients who underwent more than one IVL procedure. Continuous variables are shown as medians with interquartile ranges (IQR), and compared between C^2 and C^{2+} groups using the Mann-Whitney U test. Categorical variables are reported as counts and percentages, with group comparisons made using the Chi-squared test.

Target vessel revascularization (TVR) is presented per lesion, and mortality is presented per patient, both analyzed using Kaplan-Meier curves. Given prior data linking higher pulse counts with lower TVR, TVR was also analyzed per procedure by grouping total IVL pulses into ≤80 pulses, 81-120 pulses, and >120 pulses as categories. Additional TVR comparisons were made by sex and use of intracoronary imaging.

Kaplan-Meier analyses were also used to compare TVR in the entire cohort across several subgroups: acute coronary syndrome (ACS) versus chronic coronary syndrome (CCS, also known as stable ischemic heart disease), ST-elevation myocardial infarction (STEMI) versus non STEMI, IVL with versus without adjunctive atherectomy or cutting balloon, and treatment of in-stent restenosis versus de novo lesions. Log-rank tests were used for all group comparisons. Analyses were conducted using SPSS v29.0 (IBM Corp).

Results

Patients

A total of 264 patients were treated with the C^{2+} IVL balloon, accounting for 274 procedures, while 286 patients received the C^2 balloon in the preceding year, totaling 296 procedures. The median age of the overall cohort was 74 years (interquartile range [IQR] 65-80), and 22.7% were female. Baseline characteristics were generally well-matched between groups, with the only significant difference being a higher median creatinine level in the C^{2+} group (90 µmol/L versus 85 µmol/L, *P*=.004). Full demographic and comorbidity data are summarized in Table 1.

Presentation and procedures

There was a balanced distribution of ACS and CCS presentations, with no significant difference between the C^2 and C^{2+} cohorts. IVL was used in previously stented segments in 8.8% of cases, again with similar rates between groups. Left main PCI was more frequent in

Table 2. Presentation and procedural characteristics.

Presentation / Procedural Characteristic	C^{2+} patients (274 patients)	C^2 patients (296 patients)	*P*-value for comparison
Chronic coronary syndrome (CCS)	138 (50.4%)	140 (47.3%)	.464
STEMI	24 (8.8%)	32 (10.8%)	.411
In-stent restenosis	29 (10.6%)	21 (7.1%)	.141
Chronic total occlusion	12 (4.4%)	10 (3.4%)	.535
Intravascular ultrasound	227 (82.9%)	242 (81.8%)	.733
Optical coherence tomography	18 (6.6%)	11 (3.7%)	.121
Any intracoronary imaging	243 (88.7%)	249 (84.1%)	.113
Pressure wire	24 (8.8%)	19 (6.4%)	.291
Rotational atherectomy	41 (13.5%)	10 (3.4%)	<.001
Cutting/scoring balloon	94 (34.3%)	78 (26.4%)	.039
Excimer laser atherectomy	2 (0.7%)	5 (1.7%)	.299
Mechanical hemodynamic support			.924
Intra-aortic balloon pump	9 (3.3%)	9 (3.0%)	
Impella (Abiomed)	2 (0.7%)	2 (0.7%)	
Target vessel			
Left main	56 (20.4%)	38 (12.8%)	.015
Left anterior descending	148 (54.0%)	185 (62.5%)	.040
Right coronary artery	80 (29.2%)	74 (25.0%)	.260
Circumflex/intermediate	61 (22.3%)	54 (18.2%)	.232
Vein graft	2 (0.7%)	0 (0.0%)	.141
Number of IVL balloons			.591
1	218 (79.6%)	243 (82.1%)	
2	49 (17.9%)	49 (16.6%)	
3	6 (2.2%)	4 (1.4%)	
4	1 (0.4%)	0 (0.0%)	
Largest IVL balloon utilized			.028
2.5 mm	16 (5.8%)	23 (7.8%)^	
3.0 mm	75 (27.4%)	105 (35.7%)	
3.5 mm	136 (49.6%)	108 (36.7%)	
4.0 mm	47 (17.2%)	47 (15.9%)	
Two-stent bifurcation	29 (10.6%)	23 (7.8%)	
Median number of pulses (IQR)	120 (95-120)*	80 (70-80)*	<.001
Median stent length (IQR)	43 mm (30-60 mm)~	38 mm (30-55 mm)~	.164

(* = one C^{2+} and two C^2 cases did not have the number of pulses available; ^ = two C^2 cases did not have a record of the largest IVL balloon used; ~ = stent length was missing in 46 C^{2+} cases and 65 C^2 cases). IQR = interquartile range; CABG = coronary artery bypass graft surgery; PCI = percutaneous coronary intervention; TIA = transient ischemic attack

the C^{2+} cohort (20.4% versus 12.8%, *P*=.015), and use of adjunctive devices such as rotational atherectomy (13.5% versus 3.4%, *P*<.001) and cutting balloons (34.3% versus 26.4%, *P*=.039) was also higher in the C^{2+} group.

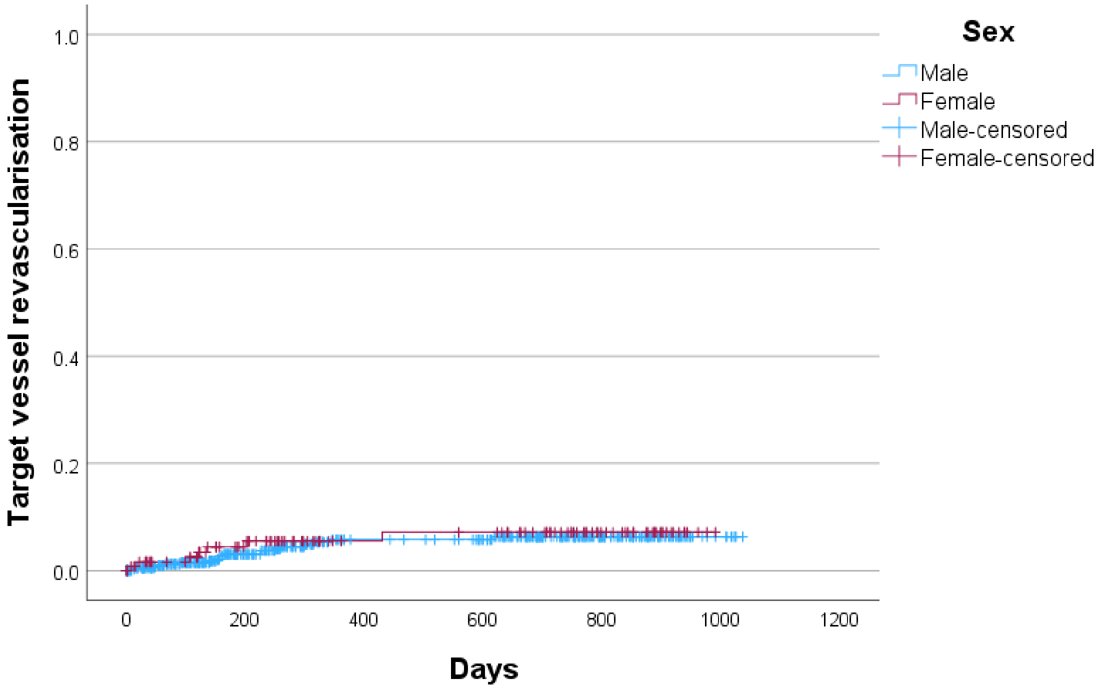
Intravascular imaging was widely used (86.3% overall), with no significant difference between groups. The C^{2+} cohort had significantly higher total IVL pulse counts than the C^2 cohort (median 120 versus 80 pulses, *P*<.001), reflecting the C^{2+} balloon's expanded capacity. Although most cases used a single IVL balloon, larger balloon sizes were more frequently used in the C^{2+} group. There was also a non-significant trend toward longer stent lengths in the C^{2+} cohort.

Procedural and follow-up outcomes

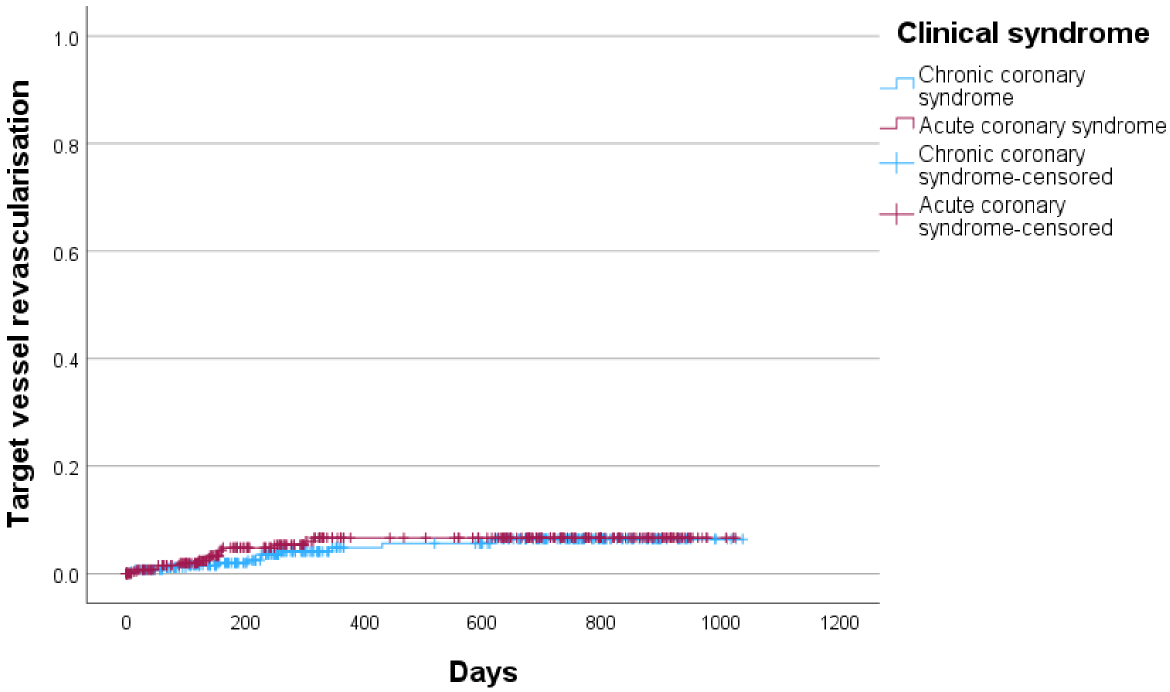
In terms of vessel perforation (as opposed to distal wire perforation), there were three (1.0%) perforations in the C^2 cohort and three (1.1%) perforations in the C^{2+} cohort. In the entire cohort, at a median follow-up of 324 days, there were 76 deaths. Median follow-up in C^{2+} cohort was 172 days (IQR 101-264 days) and median follow up in C^2 cohort was 752 days (IQR 643-859 days), with 54 deaths in C^2 cohort and 22 deaths in the C^{2+} cohort. There was no difference in mortality between the C^2 and C^{2+} cohorts on Kaplan-Meier curve and log rank analysis (Figure 1). There was a significant increase in the frequency of TVR with the use of the C^{2+} when comparing the C^2 and C^{2+} cohorts, but the split in the curves occurred after around 200 days (Figure 2). When the two cohorts were combined, those patients with ≤80 pulses had significantly lower TVR when compared with those with 81-120 pulses and >120 pulses (Figure 3).

There was no difference in TVR between sexes (Supplementary Figure 1, online). There was no difference in TVR when ACS cases were compared with CCS cases (*P*=.622) and STEMI cases with the remainder of the cohort (Supplementary Figures 2-3, online) (*P*=.706). The TVR frequency was significantly higher in patients treated with IVL within a previously stented segment compared with de novo disease (Supplementary Figure 4, online) (*P*=.005). Finally, there was no difference in TVR in cases where IVL was used alone

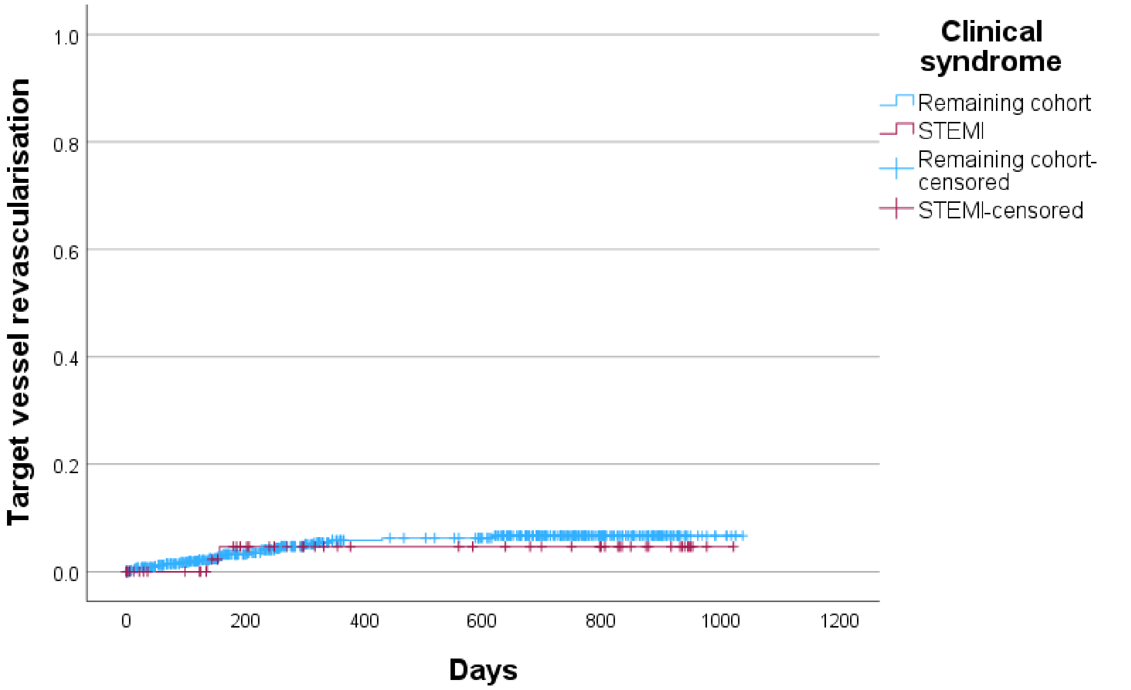
Supplementary figures



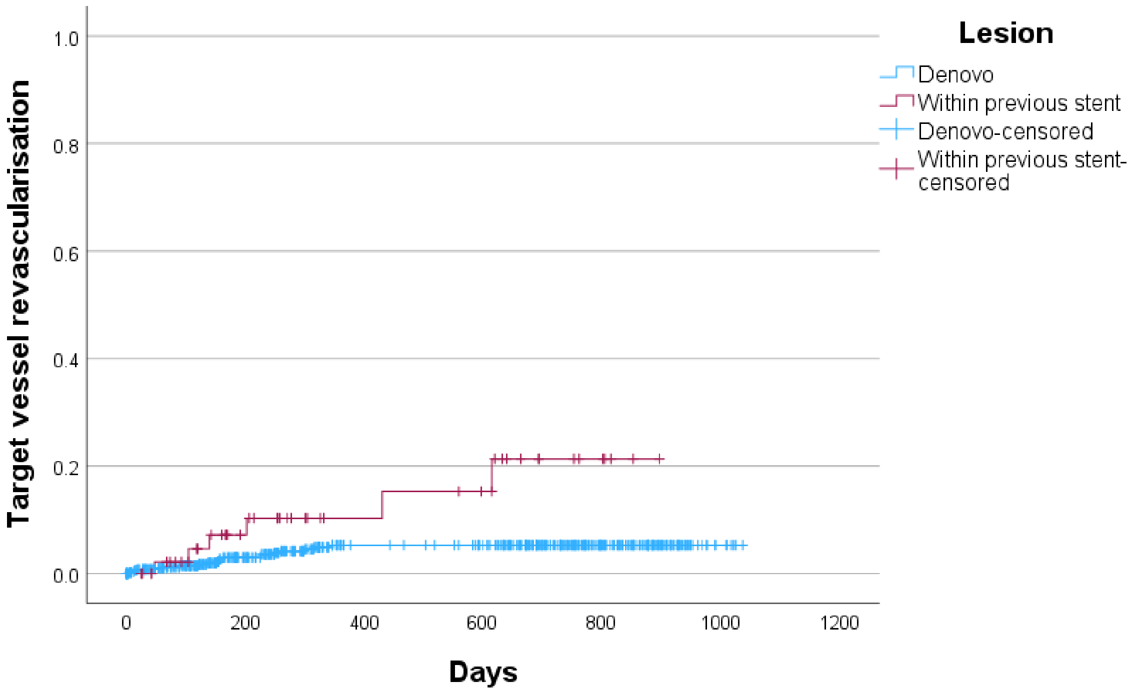
Supplementary Figure 1. Kaplan-Meier curve comparing target vessel revascularization between the sexes, *P*=.613.



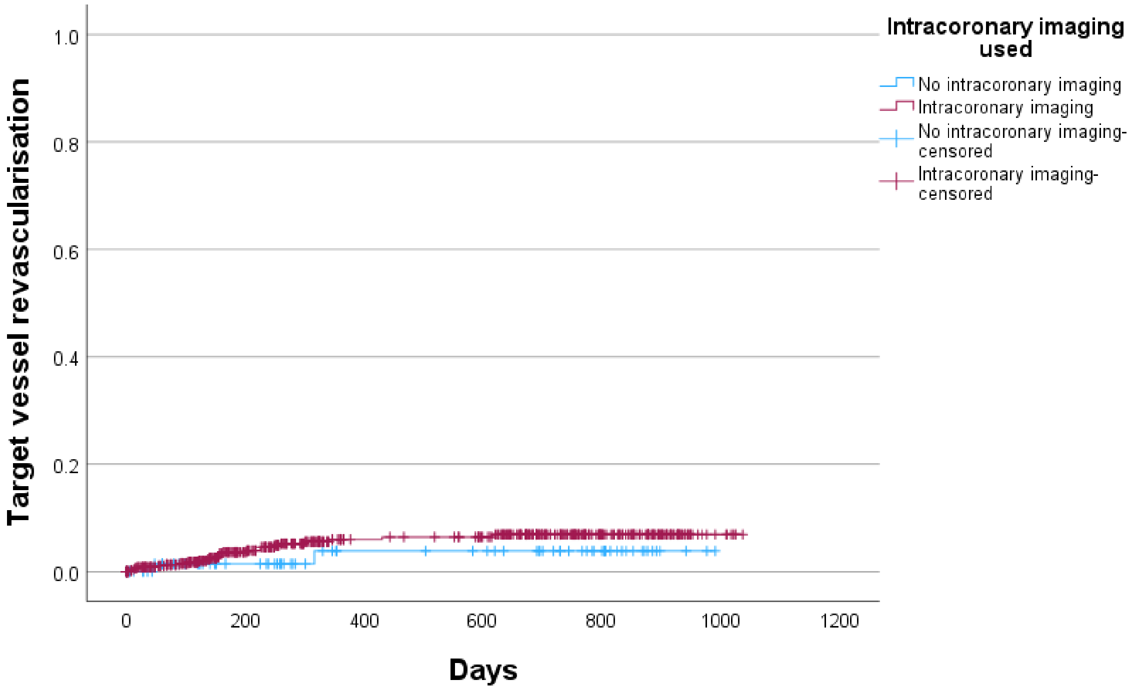
Supplementary Figure 2. Kaplan-Meier curve comparing TVR in all cases across CCS and ACS, *P*=.622.



Supplementary Figure 3. Kaplan-Meier curve comparing TVR in all cases across STEMI and other presentations, *P*=.399.



Supplementary Figure 4. Kaplan-Meier curve comparing TVR in all IVL cases treated for ISR and de novo lesions, *P*=.005.



Supplementary Figure 5. Kaplan-Meier curve comparing TVR in all IVL cases comparing those performed with and without intracoronary imaging, *P*=.374.

This is a retrospective analysis of consecutive patients treated with IVL for coronary calcification using the C^{2+} Shockwave balloon (120 pulses) from its implementation in November 2022 through December 2023, with comparison to consecutive patients in the preceding year undergoing C^2 Shockwave balloon (80 pulses) treatment, taking place across three hospitals.

versus in conjunction with rotational/orbital atherectomy, cutting balloons, or intracoronary imaging (Supplementary Figure 5, online).

Discussion

This is the first analysis comparing the C^{2+} IVL balloon (120 pulses) with the standard C^2 (80 pulses). Use of the C^{2+} was associated with more complex cases, including higher rates of left main PCI and adjunctive atherectomy, and a higher frequency of target vessel revascularization (TVR). This may reflect selection bias, as operators possibly used C^{2+} in more complex anatomy, supported by longer stent lengths and greater use of imaging. While both cohorts showed good acute outcomes, the difference in TVR became apparent beyond 200 days, and longer follow-up is warranted.

Compared with the DISRUPT CAD III and IV trials, which enrolled shorter, more focal lesions (≤40 mm),[8-10] our study population presented with more complex disease, evident in the longer stents and broader use of adjunctive tools. Intriguingly, while the FRANCE-LILI registry showed reduced TVR with more pulses,[21] our analysis showed the opposite. However, the widespread use of intracoronary imaging in our study likely led to higher pulse counts in more advanced disease, making pulse number a surrogate for lesion complexity rather than an independent predictor of outcome.

IVL showed favorable results in ACS and STEMI patients, with similar TVR rates compared to CCS cases. This is notable given the limited data on plaque modification in STEMI due to concerns around embolization with atherectomy.[8,9,15,20,23] IVL may provide an accessible, safe alternative in this setting, especially for operators without atherectomy experience.

Despite more pulses with the C^{2+}, operators used more adjunctive tools, suggesting evolving practice toward hybrid strategies such as "rotashock." While promising, evidence supporting the added benefit of multimodality plaque modification, especially involving IVL, remains limited.[24-27]

We also observed frequent IVL use for stent under-expansion. Although this subgroup had higher TVR, as expected for restenosis cases, the one-year TVR rate (22.2%) was in line with other cohorts.[12,18,20,28-31] These findings support the real-world safety and utility of IVL in previously stented segments.

Lastly, the perforation rate in this analysis was slightly higher (1.0% with C^2 and 1.1% with C^{2+}) compared with the Disrupt CAD III and IV trials, which reported perforation rates of 0.3% and 0.0%, respectively.[8,9] This difference is likely attributable to the more complex lesions and use of larger balloons in our study, rather than any specific safety concern with the C^{2+} device.

Limitations

This analysis has several limitations. First, although data were collected from three sites, all were early adopters of the C^{2+} balloon with established calcium modification programs, limiting generalizability, especially in settings with low use of intracoronary imaging. Second, this was a retrospective analysis based on data from the British Cardiovascular Intervention Society database, which lacks formal adjudication. Additionally, TVR events may be underreported if patients sought care outside the contributing institutions. Lastly, the C^{2+} cohort had a median follow-up of only 172 days, reducing the power to assess medium-term outcomes compared to the C^2 cohort.

Conclusion

The C^{2+} IVL balloon's greater pulse availability has been shown to be as safe as the C^2 IVL balloon and similarly, is suitable for a broad range of presentations and calcific lesion subsets. The use of the C^{2+} IVL balloon is associated with good clinical outcomes in a complex, real-world cohort of patients with severe calcification. However, from this retrospective analysis, efficacy does not appear to correlate with the number of pulses used at a lesion level. ■

Supplementary Figures 1-5 and cited references are available with Hinton et al online:

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Online Only

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