Interventional procedure overview of intravascular lithotripsy to treat calcified coronary arteries during percutaneous coronary intervention

Contents

Table 1 Abbreviations

Abbreviation	Definition
ACS	Acute coronary syndrome
CCS	Chronic coronary syndrome
CL	Coronary lithotripsy
HR	Hazard ratio
IVL	Intravascular lithotripsy
MACE	Major adverse cardiovascular events
MI	Myocardial infarction
PCI	Percutaneous coronary intervention
RA	Rotational atherectomy
S-IVL	Shockwave intravascular lithotripsy
SMD	Standardised mean difference
TIMI	Thrombolysis in myocardial infarction

The condition, current treatments, unmet need and procedure

Information about the condition, current treatments, unmet need and the procedure is available in section 2 of NICE's interventional procedures guidance for intravascular lithotripsy to treat calcified coronary arteries during percutaneous coronary intervention.

Outcome measures

The main outcomes focused on procedural success, clinical success and safety outcomes. The measures used are detailed in the following paragraphs.

Procedural and clinical success

Procedural success rate

Defined as completing the procedure with full expansion of the balloon or stent with residual stenosis of less than 30%, or both, and TIMI III flow without any serious angiographic complications.

Clinical success rate

Defined as the ability of IVL to achieve a residual stenosis of less than 50% after stent implantation and freedom from MACE.

Safety measures

Major adverse cardiovascular events (MACE)

Defined as the composite of death, MI, and target-vessel revascularisation occurring within a specified follow-up period (for example, in-hospital, 30-days).

Evidence summary

NICE has identified studies and reviews relevant to IVL for calcified coronary arteries during PCI from the medical literature. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

Population and studies description

This interventional procedure overview is based on about 8,400 people from 2 systematic reviews and meta-analyses (Sagris, 2024; Caminiti, 2023), 1 small randomised controlled trial (Zou, 2024), 2 pooled analyses of prospective studies (Frampton, 2023; Hussain, 2022), 5 prospective studies (Cubero-Gallego, 2022; Aziz, 2020; Rodriguez-Leor, 2024; Aksoy, 2019; Zhao, 2024), 2 retrospective cohort studies (Wiens, 2021, Sukul, 2024) and 2 case reports (Jacobsen, 2024; Mahanta, 2024). There was significant overlap between the studies included in the meta-analyses. Among the included studies, IVL was the main intervention including some comparator interventions. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This overview presents 14 studies as the key evidence in table 2 and table 3, and lists other relevant studies in appendix B, table 5. Table 2 presents study details.

The key evidence includes explicit comparisons between IVL and other procedures used for treating calcified coronary lesions. This is the reason for including several meta-analyses even if some or all studies overlap. The systematic review and meta-analysis by Sagris (2024) included 38 studies comparing IVL for lesion preparation before stent implantation. The systematic review and meta-analysis by Caminiti (2023) included 13 studies focusing on IVL for treating underexpanded stents.

The review by Sagris (2024) involved 2,977 people, predominantly men, with heavily calcified coronary lesions, with comorbidities such as hypertension,

diabetes mellitus, hyperlipidaemia, chronic kidney disease, and previous MI and PCI. Similarly, Caminiti (2023) focused on 354 people with underexpanded coronary stents, also predominantly men and with a high mean age.

The prospective studies, such as those by Cubero-Gallego (2022), Aziz (2020) and Frampton (2023) provided detailed insights into the procedural success and long-term clinical outcomes of IVL. These studies included people with significant comorbidities and varying clinical presentations, such as acute coronary syndromes and multivessel disease.

The retrospective cohort studies by Sukul (2024) and Wiens (2021) added a real-world perspective. Sukul (2024) included more than 3,000 people who had PCI and either IVL, atherectomy or both during an inpatient hospitalisation or as an outpatient. Wiens (2021) focused on 50 people with highly calcified lesions, including those with ACS, stent failure, and left main coronary artery lesions.

Figure 1 Flow chart of study selection

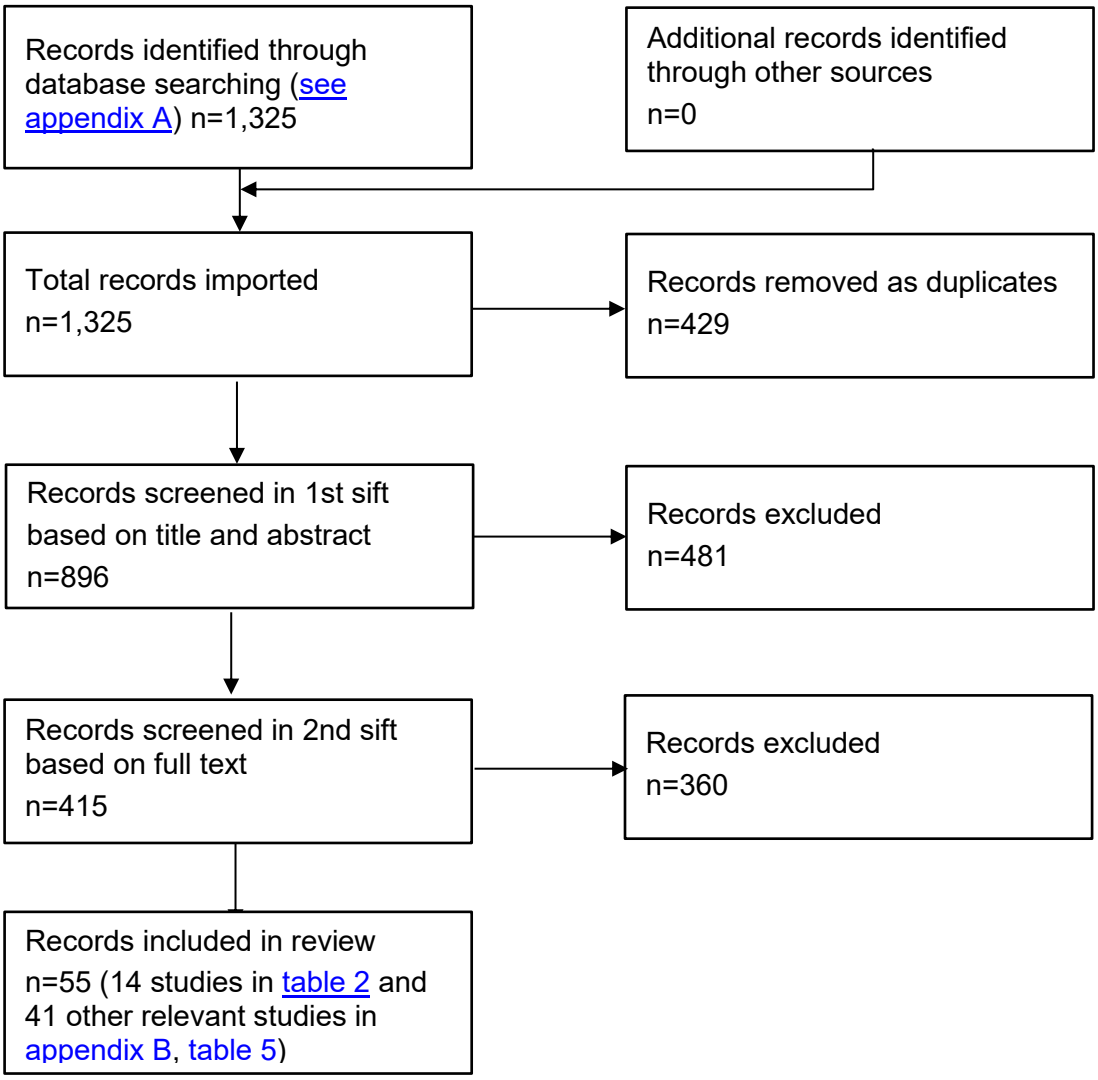

Table 2 Study details

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
1	Sagris M, 2024	2,977 patients with heavily calcified coronary lesions. Mean age: 72.2 plus or minus 9.1 years. Majority were men (77.5%). Comorbidities included hypertension, diabetes mellitus, hyperlipidaemia, chronic kidney disease, and previous myocardial infarction and PCI.	Multicentre systematic review and meta-analysis.	Prospective/retrospective analyses of patients undergoing IVL before stent implantation. Studies reporting short- and/or late-outcomes. Studies published up to February 23, 2023.	IVL for lesion preparation before stent implantation. 69% of procedures used radial artery access and 32% used the femoral artery.	In-hospital and 30-day follow-up.
2	Caminiti R, 2023 Italy	354 patients with under expanded coronary stents due to calcified plaques. Mean age: 71.3 years. 77% males.	Systematic review and meta-analysis	Studies reporting on IVL for under expanded stents	IVL for stent under expansion treatment	Mean follow-up of 2.6 months
3	Zou G-X, 2024 China	40 people with severe coronary artery calcification lesions who needed PCI and were hospitalised Mean age, IVL: 67.6, plus or minus 7.08 years	Randomised controlled trial	Primary lesions and coronary artery lesions in situ as the target lesion	IVL: 20 Conventional PCI: 20	In-hospital, 6 months

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Mean age, conventional PCI: 71 plus or minus 8.20 years Men, IVL: 9 (45%) Men, conventional PCI: 13 (65%)				
4	Aksoy A, 2019, Germany and Spain	71 patients with 78 calcified coronary lesions. Mean age: 76 (9.7 years range). High prevalence of male sex (71.8%) and comorbidities including hypertension (92.9%), hypercholesterolemia (63.4%), and diabetes (33.8%).	Prospective, observational, multicentre registry	Patients with significant coronary lesions and angiographically graded moderate or severe calcification.	IVL using the Shockwave C2 balloon	In-hospital, 30-day, and ongoing 12-month follow-up
5	Aziz A, 2020, European study	190 patients with 200 calcified coronary lesions. Mean age: 72 years. High rates of comorbidities including diabetes (50%) and chronic kidney disease (16%). Acute-coronary syndrome in 48% of cases.	Prospective, multicentre, single-arm study	All patients had treatment with IVL between November 2018 and February 2020 at 6 centres.	IVL for treating calcified coronary lesions.	Median follow-up of 222 days.
6	Cubero-Gallego H, 2022 Spain	109 patients with 128 calcified coronary lesions. Mean age: 74 years. High rates of comorbidities including diabetes (58%), renal	Real-world registry. Prospective, multicentre,	Patients more than 18 years old with severe stenosis and severe calcified coronary lesions	CL for treating calcified coronary lesions.	In-hospital, 30-day follow-up, and long-term follow-up (median

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		insufficiency (32%), multivessel disease (76%).	single-arm study	in vessels with diameter 2.5 mm or more.		of 20 months [IQR, 14.5 to 25]).
7	Frampton J, 2023 France, Germany, Japan, UK, US	448 people with stable or unstable angina or silent ischaemia Mean age, men: 71, plus or minus 8.5 years Mean age, women: 73.9, plus or minus 8.6 years 76% men Women were less likely to be smokers. Women had smaller reference vessel diameters, as well as shorter lesion length and total calcified length when compared with men.	Pooled subgroup analysis of 2 non-comparative studies	De novo severely calcified coronary artery lesions	Coronary IVL-facilitated stenting	In-hospital, 30 days, 1 year
8	Hussain Y, 2022 Australia, Belgium, Denmark, France,	628 people with stable or unstable angina or silent ischaemia Mean age, men: 71.1, plus or minus 8.8 years	Pooled subgroup analysis of 4 non-comparative studies	Target lesion must be a de novo coronary lesion that has not been previously treated with any interventional procedure	Coronary IVL-facilitated stenting	In-hospital, 30 days

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
	Germany, Italy, Japan, Netherlands, Spain, Sweden, UK, US	Mean age, women: 74.2, plus or minus 9.0 years 77% men Women more frequently had hyperlipidemia and renal insufficiency than men. Women had a smaller reference vessel diameter and less side branch involvement, but severe calcification and calcium length were not different compared with men.				
9	Rodriguez-Leor, 2024, Spain	426 patients with calcified coronary lesions. High prevalence of hypertension, diabetes, dyslipidaemia, and prior myocardial infarction (MI) and percutaneous coronary intervention (PCI).	Prospective, multicentre, single-arm, open-label conducted in 26 hospitals	Patients with calcified coronary artery disease requiring PCI and deemed necessary for coronary IVL Exclusion criteria: refusal to participate, life expectancy less than 1 year or haemodynamic instability with Killip class III or IV	IVL with coronary IVL system	30 days

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
10	Sukul D, 2024US	3,073 people who had PCI and either IVL, atherectomy or both during an inpatient hospitalisation or as an outpatient Mean age, IVL: 71.85, plus or minus 9.90 years Mean age, atherectomy: 72.54, plus or minus 9.48 years Mean age, IVL and atherectomy: 72.62, plus or minus 9.73 years Men, IVL: 69.8% Men, atherectomy: 69.5% Men, IVL and atherectomy: 72.5% The left anterior descending artery was the most frequently treated artery in each group. People who had IVL were more likely to have previously had PCI before. They more frequently had NSTEMI and STEMI compared with people	Multicentre registry study	PCI attempted on 1 or more lesions treated with IVL, atherectomy, or both.	IVL: 1,090 Atherectomy: 1,743 IVL and atherectomy: 240	To discharge

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		who had atherectomy. People who had IVL were more likely to have PCI performed using radial artery access and have intracoronary imaging used for PCI optimization.				
11	Wiens EJ, 2021 Canada	50 patients with highly calcified coronary lesions. Median age: 71.5 Majority were men (64%). Comorbidities included ACS, stent failure, and left main coronary artery lesions.	Retrospective cohort study	Patients undergoing IVL for calcified lesions. Real-world settings.	IVL for treatment of calcified coronary lesions.	In-hospital and 30-day follow-up.
12	Zhao Y, 2024 China	390 people with severe coronary artery calcification Mean age, IVL: 65, plus or minus 8 years Mean age, rotational atherectomy: 66, plus or minus 8 years Men, IVL: 75.0% Men, rotational atherectomy 65.5%	Single-centre, non-randomised comparative study	Severe coronary artery calcification defined as radiographic opacities on both sides of the arterial wall	IVL: 152, rotational atherectomy: 238	To discharge

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Unstable angina was the primary indication for PCI in over 60% of the patients in both groups. Smoking and previous PCI was more common in the IVL grouped compared with the rotational atherectomy group.				
13	Jacobsen L, 2024 Denmark	A 75-year-old woman with a heavily calcified chronic total occlusion of the right artery	Case report	Not applicable	S-IVL	To discharge
14	Mahanta D, 2024 India	A 75-year-old man with nodular calcium in the left main coronary artery bifurcation	Case report	Not applicable	Intravascular lithotripsy	1 month

Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Sagris M, 2024	Overall clinical success rate of 93% (95% CI: 91% to 95%). Procedural success rate of 97% (95% CI: 95% to 98%). There was a significant increase in vessel diameter immediately after IVL application (SMD: 2.47, 95% CI: 1.77 to 3.17, I^2 96%) and a	In-hospital and 30-day MACE incidence was 8% (95% CI: 6% to 11%, I^2 84.5%). Myocardial infarction incidence was 5% (95% CI: 2% to 8%, I^2 85.6%).

First author, date	Efficacy outcomes	Safety outcomes
	decrease in diameter stenosis (SMD: −3.44, 95% CI: −4.36 to −2.52, I^2 97.5%). Further reduction in diameter stenosis (SMD: −6.57, 95% CI: −7.43 to −5.72, I^2 95.8%) and an increase in vessel diameter (SMD: 4.37, 95% CI: 3.63 to 5.12, I^2 96.7%) and calculated lumen area (SMD: 3.23, 95% CI: 2.10 to 4.37, I^2 98%) were observed after stent implantation. Stenosis, diameter, and lumen area improvements were maintained after stent implantation. Meta-regression analysis showed no significant effect of baseline characteristics on the outcomes.	Mortality rate was 2% (95% CI: 1% to 3%, I^2 69.3%). Periprocedural complications were rare: perforations (1%), dissections (2%), slow flow (0%), or no-reflow phenomena (0%).
Caminiti R, 2023	The study evaluated the efficacy of intravascular lithotripsy (IVL) therapy on 360 treated lesions, with the left anterior descending artery being the most involved vessel (45.9%, 95% CI 36.6% to 55.3%), followed by the right coronary artery (31.8%, 95% CI 24.5% to 39.5%), left circumflex artery (10%, 95% CI 6% to 14.6%), and left main artery (7.9%, 95% CI 4.3% to 12.2%). Lesion preparation before IVL therapy involved noncompliant balloon pre dilatation in 82.6% (95% CI 69.6% to 93%) of patients and the use of a very high–pressure balloon in 29.8% (95% CI 12.2% to 50.5%). Post dilatation following IVL was performed in 83.8% (95% CI 75% to 91.2%) of patients.	Procedural complications and major adverse cardiac events (MACEs) were reported across 13 studies, with a pooled procedural complication rate of 1.6% (95% CI 0.3 to 2.9). Specific complications included 2 cases of dissection (types D and F), 1 perforation (Ellis type III), and 1 periprocedural myocardial infarction due to IVL balloon rupture. The heterogeneity for these complications was low (I^2 0%), indicating consistent findings.

First author, date	Efficacy outcomes	Safety outcomes
	During the IVL procedure, the mean IVL balloon diameter was recorded at 3.4 mm (95% CI 3.2 to 3.5), with an average of 70.9 lithotripsy pulses (95% CI 62.2 to 79.6) and a mean maximum balloon pressure of 5.2 atmospheres (95% CI 4.3 to 6.2). Intravascular ultrasound imaging was used in 33.1% (95% CI 20.1% to 47.4%) of patients, while optical coherence tomography was performed in 23.7% (95% CI 10.9% to 39%). The mean follow-up period was 2.6 months (95% CI 1 to 15.3). Post-IVL outcomes showed statistically significant improvements: the average minimal stent area increased from a baseline value of 3.4 mm^2 (95% CI 3 to 3.8) to 6.9 mm^2 (95% CI 6.5 to 7.4). The percent diameter stenosis, assessed by quantitative coronary analysis, reduced from 69.4% at baseline (95% CI 60.7 to 78.2) to 14.6% post-IVL therapy (95% CI 11.1 to 18). Additionally, the mean minimum luminal diameter increased from 1.1 mm (95% CI 0.8 to 1.4) pre-IVL to 2.9 mm (95% CI 2.6 to 3.2) post-IVL. The primary efficacy endpoint, procedural success, was reported in 12 studies with a total of 342 lesions undergoing IVL, achieving success in 289 lesions (88.7%, 95% CI 82.3 to 95.1). Meta-regression analysis suggested a negative influence of left main lesions on procedural success (β −0.91	

First author, date	Efficacy outcomes	Safety outcomes
	[−1.46 to −0.37], p=0.001), while predilatation with OPN showed a positive influence (β 0.27 [0.02 to 0.53], p=0.035). The heterogeneity for these outcomes was high (I^2 75.7%).	
Zou G-X, 2024	Surgical success rate (residual stent stenosis less or equal to 30%, TIMI grade III of forward flow, and no in-hospital MACE) was 100% in both IVL and the conventional PCI groups.	There were no MACEs during hospitalisation or within the 6 months follow up. There were no significant differences between the 2 groups in terms of procedural complications (slow flow or no reflow, coronary artery dissection, coronary artery perforation or cardiac tamponade: 2 [10%] in IVL versus. 1 [5%] in the conventional PCI group, p-value more than 0.05).
Aksoy A, 2019	The primary efficacy endpoint, defined as successful stent delivery with less than 20% residual stenosis, was achieved in 78.2% of the lesions. Specifically, success rates were 84.6% for primary IVL (de-novo lesions), 77.3% for secondary IVL (failed high-pressure balloon dilatation), and 64.7% for tertiary IVL (in-stent restenosis due to under expanded stents). Mean minimal lumen diameter (MLD) increased from 1.01 (range of 0.49 mm) at baseline to 2.88 (range of 0.56 mm) after stenting, indicating effective lesion preparation and improved stent expansion across all groups.	The primary safety endpoint, which included procedural complications and in-hospital MACE, reported no in-hospital MACE in the entire cohort. Procedural complications were low, with 4 type B dissections and 7 balloon ruptures occurring without further adverse outcomes. The overall rate of device-related complications was minimal, demonstrating a favourable safety profile for IVL in treating severely calcified coronary lesions. This study indicates that IVL is a feasible and safe method for lesion preparation, with high success rates and low procedural complications in a diverse patient population.
Aziz A, 2020	Procedural success in 99% of cases.	MACE rate at median follow-up of 222 days was 2.6%. Rare complications: 2 cases of cardiac

First author, date	Efficacy outcomes	Safety outcomes
		deaths (1%), 1 case of target vessel MI (0.5%), and 3 cases of target lesion revascularisation (1.5%).
Cubero-Gallego H, 2022	Procedural success rate of 99% in treating calcified coronary lesions using CL. Patients showed clinical improvements, including enhanced left ventricular ejection fraction and better Canadian Cardiovascular Society angina class, with 78% of patients in class 0 to 1 at long-term follow-up. The long-term follow-up, with a median duration of 20 months, revealed a MACE rate of 5.6%. Additionally, the target-lesion revascularisation (TLR) rate was 1.85%, suggesting effective maintenance of vessel patency and low rates of restenosis in this high-risk population.	CL was characterised by minimal procedural complications. In-hospital and 30-day follow-up data showed a freedom from MACE rate of 98%, with a few instances of coronary dissection, all managed with stenting. There were no reports of slow-flow/no-reflow phenomena, coronary perforation, or target-lesion failure. Long-term follow-up indicated a cardiac death rate of 3.7% and an all-cause death rate of 15%, reflecting the advanced age and comorbidities of the study population. The low TLR rate and absence of significant adverse events, such as stent thrombosis or major bleeding, further support the safety of CL in managing calcified coronary lesions in a high-risk, unselected patient cohort.
Frampton J, 2023	Post-IVL angiographic outcomes including acute gain, minimum lumen diameter, and residual diameter stenosis were similar between men and women. 30-day procedural success with residual stenosis less than 30% was 93.0% for men and 90.6 for women (p=0.41).	In-hospital MACE was 6.4% for men and 8.5% for women (p=0.47) Serious angiographic complications, defined as a composite of severe dissection, perforation, abrupt closure, slow flow, or no-reflow, were similar between women and men (2.2% versus 2.6%, p=0.85). There was no difference in post-IVL severe dissection (type D to F) (3.8% versus 6.7%, p=0.27).

First author, date	Efficacy outcomes	Safety outcomes
	30-day procedural success with residual stenosis less than 50% was 93.3% for men and 90.6% for women (p=0.35).	30-day MACE rate was 7.0% men and 9.4% for women (p=0.42). 30-day target lesion failure was 6.7% for men and 9.4% for women (p=0.35). 30-day stent thrombosis (definite or probable) was 0.9% for men and 0.0% for women (p=0.33%). 1-year MACE was 13.2% for men and 12.3% for women (p=0.52). 1-year target lesion failure was 11.2% men and 10.4% for women (p=0.43). After adjustment for major clinical and angiographic covariates, sex was not an independent predictor of MACE at 1 year (hazard ratio [HR] 1.24, p=0.52). Independent predictors for MACE at 1 year included lesion length (HR 1.45, p-value less than 0.01) and bifurcation lesions (HR 2.96; p-value less than 0.01). Similarly, after adjustment, sex was not an independent predictor of target lesion failure at 1 year (HR 1.34, p=0.43). Independent predictors for target lesion failure at 1 year were lesion length (HR 1.44, p-value less

First author, date	Efficacy outcomes	Safety outcomes
		than 0.01) and bifurcation lesions (HR 2.40, p-value less than 0.01).
Hussain Y, 2022	Immediately after IVL, acute gain and residual diameter stenosis were similar in women and men. The rate of successful IVL delivery, target lesion predilatation, and post-IVL and poststent dilatation was similar in women and men. Procedural success (less or equal to 30% without in-hospital MACE) was 92.6% for men and 91.7% for women (p=0.72).	In-hospital MACE rate was 6.2% for men and 7.6% for women. Severe angiographic complications immediately after IVL treatment were infrequent in women and in men (1.6% versus 2.3%, p=0.75) and included low rates of flow-limiting dissection and slow flow, with no perforations, abrupt closure, or no reflow after IVL. Final poststent serious angiographic complications occurred in 0.0% of women and 0.4% of men. 30-day MACE was 7.1% for men and 8.3% for women (p=0.61) 30-day target lesion failure was 6.8% for men and 8.3% for women (p=0.35) 30-day stent thrombosis (definite or probable) was 1.0% for men and 0.0% for women (p=0.33)
Sukul D, 2024	Procedural success was defined as all the lesions treated with a calcium modification device having residual stenosis less than 50% and TIMI flow grade 3, with all de novo lesions treated with	In-hospital MACE rate was similar among people who had IVL compared with atherectomy: 4.3% (95% CI 3.2% to 5.7%) versus 5.4% (95% CI 4.4% to 6.6%), p=0.231.

First author, date	Efficacy outcomes	Safety outcomes
	calcium modification devices had successful stent implantation, without in-hospital MACE. In-hospital procedural success was similar among people who had IVL and people who had atherectomy: 89.4% (95% CI 87.4% to 91.1%) versus 89.1% (95% CI 87.5% to 90.5%), p=0.314. In the small subset of people who had both IVL and atherectomy, the rate of procedural success was lower: 86.2% (95% CI: 81.2% to 90.3%). Of the 3,073 people, 479 (15.6%) met the inclusion and exclusion criteria similar to the Disrupt CAD III trial. This trial-like subgroup included 169 people who had IVL, 286 who had atherectomy, and 24 people who had both. In-hospital procedural success rate in this subset was 94.7% (95% CI 90.1% to 97.5%) for IVL and 91.6% (95% CI 87.8% to 94.5%) for atherectomy (p=0.302). Of the 3,073 people, 378 had PCI to treat in-stent restenosis. This group included 243 people who had IVL, 96 who had atherectomy and 39 who had both. The in-hospital procedural success rate was 91.8% (95% CI 87.6% to 94.9%) for IVL and 83.3% (95% CI 74.4% to 90.2%) for atherectomy (p=0.038).	There were similar rates of adverse outcomes among people who had IVL and people who had atherectomy except for perforation. This was significantly higher among people who had atherectomy (2.1% versus 1.0%, p=0.047). No reflow was also significantly higher in atherectomy (1.4% versus 0.3%, p=0.006) In the trial-like subgroup the rate of in-hospital MACEs was 0% (95% CI 0.0% to 2.2%) for IVL and 2.1% (95% CI 0.8% to 4.5%) for atherectomy (p=0.142). In the in-stent restenosis group, the rate of in-hospital MACEs was 3.3% (95% CI 1.4% to 6.4%) for IVL and 10.4% (95% CI 5.1% to 18.3%) for atherectomy (p=0.018). In the acute myocardial infarction group, the rate of in-hospital MACEs was 8.9% (95% CI 5.8% to 12.9%) for IVL and 8.3% (95% CI: 5.5% to 11.9%) for atherectomy (p=0.903).

First author, date	Efficacy outcomes	Safety outcomes
	Of the 3,073 people, 652 had PCI to treat acute myocardial infarction (NSTEMI or STEMI). This group included 281 people who had IVL, 314 who had atherectomy and 57 who had both. Procedural success rate was 85.1% (95% CI 80.3% to 89.0%) for IVL and 86.9% (95% CI 82.7% to 90.5%) for atherectomy (p=0.585).	
Rodriguez-Leor, 2024	The procedural success rate for IVL delivery was 99%. The primary efficacy endpoint, defined as successful PCI with residual stenosis less than 20% and no in-hospital MACE, was achieved in 66% of patients. There were no statistically significant differences in angiographic success between patients with CCS and those with ACS, indicating that IVL effectively facilitated stent implantation in severely calcified lesions across different patient subsets.	The primary safety endpoint, defined as freedom from MACE at 30 days, was observed in 96.4% of patients. The overall 30-day MACE rate was 3%, with a higher, though not statistically significant, incidence in ACS patients compared to CCS patients (5% versus. 1%, p=0.073). In-hospital complications included a 0.7% incidence of coronary perforation and a 2.4% incidence of coronary dissection, all of which were managed successfully. There were 7 deaths (1.7%) within 30 days, with 4 being cardiovascular-related. Additionally, 3 cases of stent thrombosis (1.1%) occurred, all in ACS patients. These findings suggest that IVL is associated with a low complication rate in a real-world setting, even among high-risk patients with complex coronary lesions.

First author, date	Efficacy outcomes	Safety outcomes
Wiens EJ, 2021	Angiographic success in 98% of patients (residual stenosis less than 50%, TIMI 3 flow). More than 90% of patients were free of angina at 30 days.	In-hospital mortality unrelated to IVL: 3 patients. No occurrences of MACE up to 30 days. Rare complications: no cases of distal embolisation, coronary perforation, or dissection.
Zhao Y, 2024	In-hospital procedural success (successful stent implantation, residual vascular stenosis less than 30% and no in-hospital MACE) was 99.3% for IVL versus 95.8% for rotational atherectomy (p=0.80)	In-hospital MACE rate was 0.8% for IVL and 2 for rotational atherectomy (p-value more than 0.9). Procedural complications (flow-limiting dissection, perforation, slow/no reflow, cardiac tamponade) were higher in the rotational atherectomy group than the IVL group (5.5% versus 0.7%, p=0.027).
Jacobsen L, 2024	Not reported	A 75-year-old woman with a heavily calcified chronic total occlusion of the right artery developed ventricular fibrillation twice during S-IVL. Because of post-procedure ECG with very long QT interval, she stayed in hospital overnight for heart rhythm monitoring. There were no further arrhythmias and she was discharged the next day. The authors suggest that in this case the combination of S-IVL, sinus bradycardia and long QT interval might explain the complications and electrocardiography synchronised S-IVL may help avoid the complications.
Mahanta D, 2024	Nodular calcium in the left main coronary artery bifurcation of a 75-year-old man was successfully cracked with pulses of intravascular lithotripsy.	The man developed bradyarrhythmia with significant hypotension and severe angina after delivering 50 shock wave pulses so the full 80 pulses were not delivered. After the procedure, he developed hypotension with minimal pericardial

First author, date	Efficacy outcomes	Safety outcomes
		effusion. This resolved in the next 72 hours. The man was discharged and was doing well in follow-up after 1 month.

Procedure technique

Of the 14 studies, all detailed the procedure technique and devices used. The most common approach involved the use of IVL for lesion preparation before stent implantation. The technique was consistent across the studies, with minor variations in balloon size and pressure settings based on the severity of the calcification and specific vessel characteristics. The primary device used for IVL was the Shockwave C2 balloon catheter, which delivers pulsatile sonic pressure waves to fracture the calcified plaque and improve vessel compliance.

Efficacy

Procedural and clinical success

Procedural success rate

The procedural success rate is defined as the completion of the procedure with full expansion of the balloon or stent with residual stenosis of less than 30%, or both, and TIMI III flow without any serious angiographic complications. The procedural success rate was reported in 9 studies and ranged from 92% to 100% (2 studies reported partly from the same population). In the 2 studies that compared IVL and either rotational atherectomy or conventional PCI, the success rate in both groups were similar.

Clinical success rate

The clinical success rate, defined as the ability of IVL to achieve a residual stenosis of less than 50% after stent implantation and freedom from major adverse cardiovascular events (MACE), was reported in several studies. Sagris (2024) reported an overall clinical success rate of 93% (95% CI 91% to 95%). Cubero-Gallego (2022) reported a clinical success rate of 99%, and Wiens (2021) noted that over 90% of people were free of angina at 30 days, suggesting a high rate of clinical success. Frampton (2023), pooled data from 2 prospective

studies and reported less than 50% residual stenosis for 93% of men and 91% of women. In a large real-world registry study by Sukul (2024), clinical success rate was 89% (95% CI 87% to 91%). In this study, in a subgroup similar to the population in Frampton (2023), the rate was 95% (95% CI 90% to 98%). Success rate was similar in both the IVL and rotational atherectomy group.

Vessel diameter and stenosis

Vessel diameter increase

The increase in vessel diameter, measured by the change before and after IVL application and typically reported as a standardised mean difference (SMD), was reported in several studies. Sagris (2024) found a statistically significant increase in vessel diameter (SMD 2.47, 95% CI 1.77 to 3.17, I^2 96%) and a decrease in diameter stenosis (SMD −3.44, 95% CI −4.36 to −2.52, I^2 97.5%) immediately after IVL application. Caminiti (2023) reported a mean increase in minimal luminal diameter from 1.1 mm (95% CI 0.8 to 1.4 mm) pre-IVL to 2.9 mm (95% CI 2.6 to 3.2 mm) post-IVL. Aksoy (2019) also found a statistically significant increase in vessel diameter following IVL, with mean minimal lumen diameter increasing from 1.01 mm at baseline to 2.88 mm after stenting. In Hussain (2022), acute gain in minimum lumen diameter was 0.84 plus or minus 0.50 mm for men and 0.78 plus or minus 0.40 mm for women after IVL (p=0.21), and 1.71 plus or minus 0.48 mm for men and 1.59 plus or minus 0.40 mm for women after stenting (p=0.002).

Diameter stenosis reduction

The reduction in diameter stenosis, assessed by the percentage reduction in vessel stenosis following IVL and stent implantation, was reported in several studies. Sagris (2024) found a statistically significant reduction in diameter stenosis (SMD -3.44, 95% CI -4.36 to -2.52, I^2 97.5%). Cubero-Gallego (2022) reported a mean reduction in diameter stenosis of 17.5%. Aksoy (2019) also reported a reduction in diameter stenosis, with a mean reduction of 17.5%.

Caminiti (2023) reported a reduction in diameter stenosis from 69.4% (95% CI 60.7% to 78.2%) pre-IVL to 14.6% (95% CI 11.1% to 18%) post-IVL. In Hussain (2022), the mean residual diameter stenosis before IVL was 63.9% for men and 63.2% for women (p=0.52). It reduced to the mean of 35.8% for men and 34.1% for women after IVL (p=0.18), and to the mean of 12.3% for men and 11.4% for women after stenting (p=0.18).

Safety

Major adverse cardiovascular events (MACE)

Major adverse cardiovascular events (MACE), defined as the composite of death, myocardial infarction (MI), and target-vessel revascularisation within a specified follow-up period, were reported in 12 studies. Zhao (2024) reported a rate of in-hospital MACE of 0.8% and Sukul (2024) a rate of in-hospital MACE of 4.3% (95% CI 3.2% to 5.7%). In Sukul (2024), the in-hospital MACE rate was slightly higher, 8.9% (95% CI 5.8% to 12.9%), for people with acute myocardial infarction (STEMI or NSTEMI). Sagris (2024) reported an in-hospital and 30-day MACE incidence of 8% (95% CI 6% to 11%). Caminiti (2023) reported a pooled MACE rate of 11%. Rodriguez-Leor (2024) found a 30-day MACE rate of 3% and Hussain (2022) a 30-day MACE rate of 7.1% for men and 8.3% for women (p=0.61). Cubero-Gallego (2022) found a 30-day MACE rate of 2%, with a long-term MACE rate of 5.6% at a median follow-up of 20 months. Aziz (2020) reported a MACE rate of 2.6% at a median follow-up of 222 days. Rodriguez-Leor (2024) found a 30-day MACE rate of 3%, with a higher incidence (not statistically significant) in people with ACS than in people with CCS (5% versus. 1%, p=0.073). Frampton (2023) reported a 1-year MACE rate of 13.2% for men and 12.3% for women (p=0.52). In the 2 studies that reported on both IVL and rotational atherectomy, the MACE rates in both groups were similar. There were no MACE during hospital stay in Aksoy (2019), within 30 days in Wiens (2021) or within 6 months in Zou (2024).

Myocardial infarction

The incidence of MI during or after the procedure, assessed within the follow-up period, was reported in several studies. In Sukul (2024), there were 10 (0.9%) MI during hospital stay. Zhao (2024) reported 1 (0.4%) non-fatal MI. Sagris (2024) reported an MI incidence of 5% (95% CI 2% to 8%). Caminiti (2023) reported a target vessel MI rate of 3%. Cubero-Gallego (2022) included MI within the overall MACE but did not report it separately. Aziz (2020) reported 1 target vessel MI (0.5%). Rodriguez-Leor (2024) reported a 30-day MI incidence of 2.4%, all occurring in people with ACS. In Hussain (2022), 32 (7%) men and 11 (8%) women had MI within 30 days of IVL (p=0.67). In Frampton (2023), 10% of men and 8% women had MI within 1 year. In the 2 studies that reported on IVL and rotational atherectomy, the MI rates in both groups were similar. Aksoy (2019) and Zou (2024) reported no cases of MI.

Mortality rate

The mortality rate occurring within the follow-up period, whether related to the procedure or from other causes, was reported in several studies. Sagris (2024) reported an in-hospital mortality rate of 2% (95% CI 1% to 3%) and Sukul (2024) of 2.7%. Mortality rates between IVL and rotational atherectomy were similar. Caminiti (2023) did not report specific mortality rates in their study. Wiens (2021) reported in-hospital mortality unrelated to IVL in 3 people. Cubero-Gallego (2022) reported a long-term mortality rate of 4% (cardiac death) at a median follow-up of 20 months. Aziz (2020) reported 2 cardiac deaths (1%). Rodriguez-Leor (2024) reported a 30-day mortality rate of 1%. Hussain (2022) reported that 2 (0.4%) men and 1 woman (0.7%) died within 30 days. Frampton (2023) reported that 3 men and 1 woman died within 1 year. Zhao reported no deaths during hospital stay and Zou (2024) reported no deaths within 6 months.

Periprocedural complications

Periprocedural complications, including perforations, dissections, slow flow and no-reflow phenomena, were reported during or immediately after the procedure across multiple studies. Sagris (2024) reported rare complications, including perforations (1%), dissections (2%), slow flow (0%) and no-reflow phenomena (0%). Wiens (2021) found no cases of distal embolisation, coronary perforation or dissection. Caminiti (2023) reported procedural complications with a pooled rate of 2% (95% CI 0.3% to 3%), including specific cases of dissection and perforation. Cubero-Gallego (2022) noted rare periprocedural complications, including dissections (2.8%) and no instances of slow flow or no-reflow. Aksoy (2019) reported no cases of perforation, slow flow or no-reflow phenomena, but observed 7 balloon ruptures during treatment without any adverse sequelae. In addition, Rodriguez-Leor (2024) reported a 1% incidence of coronary perforation and a 2% incidence of coronary dissection, all managed successfully. In Frampton (2023) and Hussain (2022) the rate of serious angiographic complications was between 2% and 3% in men and 2% in women (populations overlapped). In Zhao (2024), there were fewer procedural complications in the IVL 1% compared with the rotational atherectomy group (6%, p-value for difference = 0.027). In Sukul (2024), there were fewer perforations in IVL compared with atherectomy (1% in IVL and 2% in atherectomy, p=0.047). No reflow was also less common in IVL (1% in IVL and 0.3% in atherectomy, p=0.006). Zou found no significant differences in procedural complications in IVL (1 in 20) and conventional PCI group (2 in 20).

There were 2 case reports on arrhythmia events during IVL. In one case the complication was ventricular fibrillation. In the other case the complication was bradyarrhythmia with significant hypotension and severe angina followed by hypotension with minimal pericardial effusion after the procedure. These complications were not reported in the larger trials. Both resolved within 1 to 3 days of hospitalisation.

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

Six professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

Validity and generalisability

Sample size and follow-up

The studies collectively included a total of about 8,300 people, with follow-up periods varying from in-hospital to several months. The longest follow-up period reported was a median of 20 months in the prospective study by Cubero-Gallego (2022). Frampton (2023) also reported clinical outcome data at 1 year after the procedure. Most studies, such as the multicentre systematic review and meta-analysis by Sagris (2024) and the retrospective cohort study by Wiens (2021), reported follow-up data at 30 days. The systematic review and meta-analysis by Caminiti (2023) included a mean follow-up of 2.6 months.

Sources of bias

The retrospective nature of some studies, such as those by Wiens (2021) and Sukul (2024), introduces potential bias because of the reliance on previously recorded data and the lack of randomisation. Also, the non-randomised design of studies like Caminiti (2023) and Aksoy (2019) can contribute to selection bias and limit the generalisability of the findings.

Variability in inclusion and exclusion criteria

There was significant variability in the inclusion and exclusion criteria across the studies. For example, some studies, such as Caminiti (2023) and Rodriguez-Leor (2024), included people with specific comorbidities such as diabetes mellitus and chronic kidney disease, whereas others, such as Wiens (2021), excluded patients with certain conditions or lesions. This variability can affect the generalisability of the results, as IVL may work differently in different patient populations. The diverse inclusion and exclusion criteria across studies necessitate careful consideration when interpreting the overall efficacy and safety outcomes of IVL.

Other considerations

The diversity in study design, patient populations and settings provides a broad perspective on the use of IVL in treating calcified coronary lesions.

Ongoing trials

- Registry of Coronary Lithotripsy in Spain NCT04298307.
- Evaluate the Safety and Efficacy of Intracoronary Lithotripsy Balloon Catheter and Intracoronary Lithotripsy Apparatus NCT05649488.
- Rotablation versus Intravascular Lithotripsy in Calcified Coronary Lesions NCT04960319
- FORWARD PAD IDE Study With the Shockwave Mini S IVL Catheter (FORWARD PAD) NCT05858905
- Intravascular Lithotripsy and/or Mechanical Debulking for Severely Calcified Coronary Artery Lesions (ROLLING-STONE) NCT05016726
- Use of Shockwave M5+ IVL Catheter (Intravascular Lithotripsy) in Hostile and Calcified Iliac Access (SHOCK-ACCESS) NCT05880641
- Balloon Lithoplasty for Preparation of Severely Calcified Coronary Lesions (BALI) NCT04253171
- Intravascular Balloon Lithotripsy in Left Main Stem Percutaneous Coronary Intervention NCT04319666

- Intravascular Lithotripsy in High Risk Calcified Iliac Anatomy for Transfemoral TAVR (ILIT) NCT05862558
- ROtational Atherectomy, Lithotripsy or LasER for the Treatment of CAlcified STEnosis (ROLLERCOASTR) NCT04181268
- Coronary Intravascular Lithotripsy System in Patients With Coronary Artery Calcification (VIGOUR) NCT05818098
- A Clinical Trial to Assess the Elixir Medical LithiX Coronary Hertzian Contact Lithotripsy Catheter (PINNACLE-I) NCT05828173
- Coronary Calcification Study - Intravascular Lithotripsy for Calcified Lesions (CCS) NCT04428177
- ComparIson of Strategies to PrepAre SeveRely CALCified Coronary Lesions 2 (ISAR-CALC2) NCT05072730
- Shockwave Lithoplasty Compared to Cutting Balloon Treatment in Calcified Coronary Disease - A Randomized Controlled Trial (Short-Cut) NCT06089135
- Atherectomy versus Intravascular Lithotripsy (RAINBOW) NCT04013906
- CRUSTAL Study in China NCT05828186
- Shockwave Induced Attenuation of Calcified Plaques Quantified NCT05973994
- Equity in Modifying Plaque Of WomEn With UndeRtreated Calcified Coronary Artery Disease (EMPOWER CAD) NCT05755711
- Shockwave C2+ 2Hz Coronary IVL Catheter in Calcified Coronary Arteries (Disrupt CAD DUO) NCT05966662
- Clinical Trial of T-wave™ Coronary Lithotripsy Catheter System NCT05552131
- The GISE (Società Italiana di Cardiologia Interventistica) - ShockCalcium Registry NCT05455515
- ShOckwave ballooN or Atherectomy With Rotablation in Calcified Coronary Artery Lesions, the SONAR Trial (SONAR) NCT05208749
- The Value of IVL Compared To OPN Non-Compliant Balloons for Treatment of RefractorY Coronary Lesions (VICTORY) Trial (VICTORY) NCT05346068
- The Lower Silesia Shockwave Registry (LSSR) NCT05916898
- BASIL Study: A randomised comparison study on the treatment of calcified (hard and concrete-like) coronary artery using the conventional balloon angioplasty prior

stenting versus the use of Shockwave Intravascular Lithotripsy (S-IVL) prior to stenting ACTRN1260000086965

- EMPOWER CAD: Equity in modifying plaque of women with undertreated calcified coronary artery disease NCT05755711
- Shockwave IVL to aid DCB only PCI [Germany] NCT05626997

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

Bioresorbable stent implantation to treat coronary artery disease (2022) NICE interventional procedures guidance 732. (Recommendation: only in research).

Optical coherence tomography to guide percutaneous coronary intervention (2014) NICE interventional procedures guidance 481. (Recommendation: only in special arrangements).

Percutaneous laser coronary angioplasty (2011) NICE interventional procedures guidance 378. (Recommendation: standard arrangements).

Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency (2004) NICE interventional procedure guidance 98. (Recommendation: standard arrangements).

Technology appraisals

Drug-eluting stents for the treatment of coronary artery disease (2008) NICE technology appraisal guidance 152

Guidance on the use of coronary artery stents (2003) NICE technology appraisal guidance 71

Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease (2019) NICE technology appraisal guidance 607

Clinical guidelines

Recent-onset chest pain of suspected cardiac origin: assessment and diagnosis (2010) NICE clinical guideline 95

Stable angina: management (2011) NICE clinical guideline 126

NICE guidelines

Acute coronary syndromes (2020) NICE guideline 185

Medical technologies guidance

HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography (2017) NICE medical technologies guidance 32

MiraQ for assessing graft flow during coronary artery bypass graft surgery (2011) NICE medical technology guidance 8

Diagnostics guidance

New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners (2012, updated 2017) NICE diagnostics guidance 3

Professional societies

- British Cardiovascular Intervention Society (BCIS)

- British Cardiovascular Society (BCS)
- Royal College of Physicians (Edinburgh)
- Royal College of Surgeons (Edinburgh)
- Royal College of Physicians London
- The Royal College of Physicians and Surgeons of Glasgow

Company engagement

A structured information request was sent to 1 company who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the interventional procedures technical team and any relevant points have been taken into consideration when preparing this overview.

References

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3. Zou GX, Zhang GW, Wang ZD et al. (2024) A comparative study of shockwave intravascular lithotripsy and conventional percutaneous coronary intervention in the treatment of severe coronary artery calcification lesions. Journal of Cardiothoracic Surgery 19: 434
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6. Cubero-Gallego H, Calvo-Fernandez A, Tizon-Marcos H et al. (2022) Real-World Multicentre Coronary Lithotripsy Registry: Long-Term Clinical Follow-Up. Journal of Invasive Cardiology 10: E701-E708

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8. Hussain, Y, Kearney KE, Abbott JD et al. (2022). Sex-Specific Outcomes After Coronary Intravascular Lithotripsy: A Patient-Level Analysis of the Disrupt CAD Studies. Journal of the Society for Cardiovascular Angiography & Interventions 1(1): 100011

9. Jakobsen L, Christiansen EH & Thim T (2024) A case report of ventricular fibrillation following Shockwave intravascular lithotripsy during percutaneous coronary intervention. BMC Cardiovascular Disorders 24: 219

10. Mahanta D, Deb P, Mohanan S, Acharya D et al. (2024) The Unique Role of Intravascular Lithotripsy (IVL) in Debulking the Nodular Calcium in Left Main Coronary Artery Bifurcation. Cureus 16(6): e62439

11. Rodriguez-Leor O, Cid-Alvarez AB, Lopez-Benito M et al. (2024) A Prospective, Multicentre, Real-World Registry of Coronary Lithotripsy in Calcified Coronary Arteries. The REPLICA-EPIC18 Study. JACC: Cardiovascular Interventions 17(6)

12. Sukul D, Seth M, Madder RD et al. (2024) Contemporary Trends and Outcomes of Intravascular Lithotripsy in Percutaneous Coronary Intervention: Insights From BMC2. JACC Cardiovascular Interventions 17(15): 1811-1821

13. Wiens EJ, Sklar JC, Wei YH et al. (2021) Real-world outcomes in treatment of highly calcified coronary lesions with intravascular shockwave lithotripsy. Indian Heart Journal 73: 653-655

14. Zhao Y, Wang P, Zheng Z et al. (2024) Comparison of intravascular lithotripsy versus rotational atherectomy for the treatment of severe coronary artery calcification. BMC Cardiovascular Disorders 24: 311

Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention from the medical literature.

Search strategy design and peer review

This search report is informed by the Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension (PRISMA-S).

A NICE information specialist ran the literature searches on 28/03/2024 and updated on 27/09/2024. See the search strategy history for the full search strategy for each database. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The principal search strategy was developed in MEDLINE ALL (Ovid interface). It was adapted for use in each of the databases listed in table 4, taking into account the database's size, search functionality and subject coverage. The MEDLINE ALL strategy was quality assured by a NICE senior information specialist. All translated search strategies were peer reviewed to ensure their accuracy. The quality assurance and peer review procedures were adapted from the Peer Review of Electronic Search Strategies (PRESS) 2015 evidence-based checklist.

Review management

The search results were managed in EPPI-Reviewer version 5 (EPPI-R5). Duplicates were removed in EPPI-R5 using a 2-step process. First, automated deduplication was done using a high-value algorithm. Second, manual deduplication was used to assess low-probability matches. All decisions about inclusion, exclusion and deduplication were recorded and stored.

Limits and restrictions

The CENTRAL database search removed trial registry records and conference material. The Embase search excluded conference material.

English language limits were applied to the search when possible in the database. This is standard NICE practice for review topics.

The main search was limited from 13/11/2023 to 28/03/2024. The date limit was included to update an earlier search for this topic undertaken as part of surveillance activity. The update search was date limited from the date of the main search to current.

The limit to remove animal studies in the searches is standard NICE practice, which has been adapted from Dickersin et al. (1994).

Table 4 Literature search strategy

Databases	Date searched	Version/files
MEDLINE ALL (Ovid)	27/09/2024	1946 to September 26, 2024
EMBASE (Ovid)	27/09/2024	1974 to September 26, 2024
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	27/09/2024	Issue 8 of 12, August 2024
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	27/09/2024	Issue 8 of 12, August 2024
International HTA database (INAHTA)	27/09/2024	-

Search strategy history

For the updated searches there was no change to the strategy apart from the date limit from 28/03/2024 to 27/09/2024. (So, the rerun strategies have not been included.)

MEDLINE ALL search strategy

1 Coronary Artery Disease/
2 Acute Coronary Syndrome/

3 Myocardial Infarction/
4 exp Angina Pectoris/
5 Myocardial Ischemia/
6 Vascular Calcification/
7 Plaque, Atherosclerotic/
8 Coronary Stenosis/
9 ((coronar* or isch?em*) adj4 (arter* or heart* or vasc*) adj4 (diseas* or disord* or lesion* or stenos* or calcium*)).tw.
10 (coronar* adj4 (arterioscleros* or atheroscleros*)).tw.
11 (Myocardial* adj4 (infarct* or isch?emia* or stenos*)).tw.
12 (heart adj4 attack*).tw.
13 (acute* adj4 coronar* adj4 syndrome*).tw.
14 angina*.tw.
15 (calcif* adj4 (coronar* or heart* or vasc*) adj4 (lesion* or stenon* or arter* or plaque*)).tw.
16 (vascular* adj4 (calcific* or calcinos*)).tw.
17 atheroma*.tw.
18 fibroatheroma*.tw.
19 (atheroscler* adj4 plaque*).tw.
20 (arterial adj4 fat* adj4 streak*).tw.
21 (CHD or CAD or MI or ACS or PCI).tw.
22 Percutaneous Coronary Intervention/
23 (percutan* adj4 coronar* adj4 intervention*).tw.
24 PCI.tw.
25 or/1-24
26 Lithotripsy/
27 (lithotrip* or litholapax* or lithoplast*).tw.
28 shockwave*.tw.
29 (IVL or S-IVL).tw.
30 (calcif* and (plaque* adj4 modif*)).tw.
31 or/26-30
32 25 and 31
33 animals/ not humans/
34 32 not 33
35 limit 34 to english language
36 limit 35 to dt=20231130-20240328
37 limit 35 to ed=20231130-20240328
38 36 or 37

Appendix B: Other relevant studies

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Table 5 Additional studies identified

Study	Number of people and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Achim A, Jambrik Z, Nagy F et al. (2024) Subintimal intravascular lithotripsy to optimize external crush stenting. European Heart Journal - Case Reports 8(5)	Case report (n=1)	Subintimal IVL was safely used during in-stent chronic total occlusion PCI within heavily calcified vessels in a 72-year-old man to facilitate external crush stenting.	Tables 2 and 3 include larger studies and systematic reviews.
Bawamia B, Kuzemczak M, Lipiecki J et al. (2024). The role of intra-vascular imaging in patients undergoing intravascular lithotripsy: insights from the COIL registry. Catheterization & Cardiovascular Interventions 1–8.	Subgroup analysis of a multicentre registry (n=102, complex lesions=27, non-complex lesions=75)	IVL was successfully used in both complex (left main, true bifurcation, long lesion or IVL used together with athero-ablative therapy) and non-complex lesions. People with complex lesions had worse 1-year clinical outcomes because of a higher rate of target vessel revascularisation. In the complex lesion group, the event rate was lower for those	Small subgroup analysis. Tables 2 and 3 include larger studies and systematic reviews.

		who had intracoronary imaging after IVL compared those without imaging.	
Blachutzik F, Meier S, Blachutzik M et al. (2024) Comparison of interventional treatment options for coronary calcified nodules: A sub-analysis of the ROTA.shock trial. Cardiovascular Revascularization Medicine: in press	Non-randomised study (n=19)	Using IVL or rotational atherectomy did not reduce the volume of calcified nodules. There were no complications during PCI.	Tables 2 and 3 include larger studies and systematic reviews.
Corl JD, Frizzell JD, Bohrer CA, Kereiakes DJ (2022) Shock Buddy Technique for Intravascular Lithotripsy of Severe Eccentric Arterial Calcification	Case report n=1 patient	The “shock buddy” technique was used successfully to treat severe, eccentric arterial calcification in an 80-year-old man. The procedure involved the use of two balloons to optimize the positioning of the IVL balloon, resulting in successful plaque modification and improved vessel compliance without intraprocedural complications	Larger studies added to table 2
Costoya IR, Marcos HT, Montilla BV et al. (2019) Coronary lithoplasty: initial experience in coronary calcified lesions. Rev Est Cardio (article in press)	Case report n=3 patients with multivessel coronary artery disease had IVL.	The lithoplasty balloon was successfully used to treat 6 severely calcified lesions. There were no intraprocedural complications such	Larger studies added to table 2.

		as dissections or perforations	
De Silva K, Roy J, Webb I et al. (2019) A calcific, undilatable stenosis; Lithoplasty – a new tool in the box? JACC: Cardiovascular Interventions 10(3): 304- 6	Case report A 69-year-old man with severe calcific disease in the right coronary artery had PCI after balloon dilation. He had PCI with adjunctive lithotripsy for calcium debulking.	OCT done pre and post lithoplasty showed the calcium 'cracking' effect of the technique. The segment of disease was then treated with a stent with good angiographic result.	Larger studies added to table 2.
Fedele M, (2021) Shockwave Intravascular Lithotripsy in the Treatment of Under-expanded Coronary Stents	2 patients with 12 month follow up	Both patients showed good angiographic results and uneventful follow ups after 12 months	Small sample size (n=2) limits the ability to generalise results.
Gonzalez IC, Ferreiro RG, Moreiras JV et al. (2019) Facilitated transfemoral access by shockwave lithoplasty for transcatheter aortic valve replacement. JACC: Cardiovascular Interventions 12(5): e35- 8	Case report n=1 patient with severe aortic stenosis, coronary artery disease (CAD) and severe peripheral artery disease had IVL to help transfemoral transcatheter aortic valve replacement.	Results showed a significant reduction in stenosis severity with high acute gain, no major adverse events.	Larger studies added to table 2
Gupta A, Shrivastava A, Chhikara S et al. (2024) Safety, efficacy, and optical coherence tomography insights into intravascular lithotripsy for the modification of noneruptive calcified nodules: A prospective	Single-centre, non-comparative study (n=21)	IVL resulted in excellent lesion modification, and favourable 30-day and 1-year outcomes. There were no major procedural complications.	Tables 2 and 3 include larger studies and systematic reviews.

observational study. Catheterization & Cardiovascular Interventions 4(104): 1–9			
Kassimis G, Raina T, Kontogiannis N et al. (2019) How should we treat heavily calcified coronary artery disease in contemporary practice? From atherectomy to intravascular lithotripsy. Cardiovascular Revascularization Medicine. Available January 2019	Review	With the introduction of several adjunctive PCI tools, like cutting and scoring balloons, atherectomy devices, and intravascular lithotripsy technology, the treatment of calcified coronary lesions has become feasible, predictable and safe. This review highlights the techniques in the clinical setting and gives examples of how best to apply them through better patient and lesion selection, with the main objective being optimising drug eluting stent delivery and implantation, and subsequent improved outcomes	Review
Kereiakes et al. (2021) "Intravascular Lithotripsy for Treatment of Calcified Coronary Lesions"	628 patients with 30-day follow-up.	The study demonstrated that IVL is safe and effective for facilitating stent implantation in severely calcified coronary lesions. The primary safety	Focus on short term outcomes

		and effectiveness endpoints were achieved in 92.7% and 92.4% of patients, respectively. The incidence of serious angiographic complications was low.	
Kereiakes et al. (2021) “Principles of Intravascular Lithotripsy for Calcific Plaque Modification” JACC Cardiovascular Interventions	Review – does not specify participant numbers of follow up details	IVL is a promising and effective technique for treating vascular calcification. It provides a comprehensive summary of the physics, preclinical, and clinical data supporting IVL’s safety and efficacy in modifying calcified plaque to facilitate stent expansion and improve luminal gain.	Review article summarising existing data rather than presenting original clinical trial results with specific participant data and follow-up periods. Therefore, it does not provide the direct clinical evidence necessary for inclusion in a main evidence summary focused on clinical trial outcomes.
Kereiakes DJ, Hill JM, Shlofmitz RA et al. (2022) Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Lesions: 1-Year Results From the Disrupt CAD III Study. Journal of the Society for Cardiovascular Angiography &	Non-comparative multicentre study (n=384)	At 1 year, MACE occurred in 13.8% of patients and target lesion failure in 11.9%. Stent thrombosis (definite or probable) occurred in 1.1% of patients including 1 event (0.3%) beyond 30 days.	Disrupt CAD III study is discussed in Sagris systematic review

Interventions 1: 100001			
Khan S, Li B, Salata K, et al. (2019) The current status of lithoplasty in vascular calcifications: A systematic review. Surgical Innovation: 1- 11	Systematic review n=9 studies 211 patients with vascular calcification lesions had lithoplasty. Follow up: 5.5 months.	Most lesions (72%, 152/212) were in peripheral artery beds, with the remainder occurring in coronary vessels. Lesioned vessels typically had severe calcium burden 62.6% (131/210), with an average initial stenosis of 76.6% (range, 68.1% to 77.8%). After treatment, the average residual stenosis was 21.0% (range, 13.3% to 26.2%), with a mean acute gain of vessel diameter of 2.5 mm. A limited number of type D dissections occurred, with a total of 2.4% (5/211) of patients needing stent implantation. Recent studies suggest that lithoplasty is a promising intervention to decrease vessel stenosis in both peripheral artery disease and coronary artery disease, with minimal occurrence of major adverse	The review included both peripheral and coronary circulation studies. Evidence is from limited quality case series, case reports, and conference abstracts. Peripheral artery disease is out of the remit of this guidance.

		events. Further research studies, with more rigorous study designs, are needed to determine the effectiveness of lithoplasty in vascular calcifications.	
Lee MS, Kereiakes DJ, Shlofmitz RA et al. (2023) Intravascular Lithotripsy for Calcified Left Main Artery Disease. Journal of the Society for Cardiovascular Angiography & Interventions 2: 101126	Review (29 non-randomised studies and case reports)	IVL for severe coronary artery calcification of the left main artery seems to be a reasonable and feasible approach for plaque modification, especially given its ease of use compared to coronary atherectomy. IVL was associated with high procedural success rates. Intravascular imaging prior to PCI to determine the severity and distribution of the calcification is highly recommended.	Tables 2 and 3 include systematic reviews on wider indications.
Legutko J, Niewiera L, Tomala M et al. (2019) Successful shockwave intravascular lithotripsy for severely calcified undilatable lesion of the left anterior descending coronary artery in patient with	Case report n=1 patient with severely calcified, critical narrowing of left anterior descending coronary artery associated with a history of recurrent myocardial infarction had IVL	Angiography, intravascular ultrasound and OCT confirmed optimal PCI result with perfect stent expansion and apposition. No complications occurred during hospitalisation and patient was	Larger studies included in table 2.

recurrent myocardial infarction. Kardiologia Poloska (published online June 6)		discharged home 48 hours after the procedure free of angina and ventricular arrhythmia	
Mathias B, Federico M, Stefan T et al. (2019) The effect of lithoplasty on coronary arteries. Cardiovascular medicine 22:02013	Case report 79-year-old man with non-ST-elevation myocardial infarction and a heavily calcified bifurcation stenosis of the left anterior descending artery (LAD) had IVL	The subsequent OCT showed calcium containing cracks in the intima and the media of the LAD. The bifurcation lesion was treated with 2 stents. The final OCT showed good stent expansion and apposition.	Larger studies included in table 2.
Oliveira C, Vilela M, Nobre Menezes M et al. (2024) Coronary Intravascular Lithotripsy Effectiveness and Safety in a Real-World Cohort. Journal of Personalised Medicine 14(4): 438	Single-centre, prospective, non-comparative study (n=111)	IVL was an effective and safe technique for treating calcified coronary lesions. Peri-procedural complications were minimal and successfully resolved. 30-day adverse clinical event rates were low.	Tables 2 and 3 include studies with longer follow up and systematic reviews.
Oliveri F, Meijer M, van Oort MJH et al. (2024) Procedural and clinical impact of intracoronary lithotripsy in heavily calcified aorto-ostial coronary lesions. Catheterization & Cardiovascular Interventions, 1-10	Subgroup analysis of a multicentre registry (n=321, aorto-ostial lesions=48, other heavily calcified lesions=273)	IVL had similar device success, and procedural and 6-month clinical outcomes in heavily calcified aorto-ostial lesions and other heavily calcified lesions, despite a higher incidence of in-hospital MACE in people with aorto-ostial lesions.	Subgroup analysis with similar outcomes for subgroups. Population overlaps with Oliveri et al. (2024) subgroup analysis on chronic total occlusion.

Oliveri F, van Oort MJH, Al Amri I, et al. (2024) Intravascular lithotripsy in heavily calcified chronic total occlusion: procedural and one-year clinical outcomes. Catheterization & Cardiovascular Interventions 104(4): 1–9	Subgroup analysis of a multicentre registry (n=404, chronic total occlusion=33, other heavily calcified lesions=371)	IVL had similar device and procedural success and clinical outcomes during hospitalisation, and at 30-day and 1-year follow up in heavily calcified chronic total occlusion and other heavily calcified lesions.	Subgroup analysis with similar outcomes for subgroups. Population overlaps with Oliveri et al. (2024) subgroup analysis on aorto-ostial lesions.
Oliveri F, van Oort M, Al Amri I et al. (2024) Invasive evaluation of coronary artery compliance modification after intracoronary lithotripsy. Journal of Cardiovascular Medicine 25(9)	Non-comparative single-centre registry study (n=33)	IVL improves coronary artery compliance calcified lesions. IVL balloon delivery to the target lesion and therapy administration without serious complications was high and there were no intraprocedural deaths.	Tables 2 and 3 include larger studies and systematic reviews. Population potentially overlaps with Oliveri et al. (2024) subgroup analyses on chronic total occlusion and aorto-ostial lesions.
Riley R et al. (2023) SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions	The study provides expert consensus rather than individual patient data	Consensus outlines strategies for managing calcified coronary lesions using various calcium modification tools. It emphasises the importance of intravascular imaging and provides guidelines for using balloons, atherectomy, and IVL.	This study provides expert consensus and guidelines rather than empirical data from patient trials, making it more suitable for clinical guidance rather than direct comparison in the main evidence summary.

Riley RF, Miller LE, Davies R et al. (2024) Retrospective Multicenter Analysis of Intravascular Lithotripsy Use During Calcified Left Main Coronary Artery Percutaneous Coronary Interventions. Journal of the Society for Cardiovascular Angiography & Interventions 3(2)	Non-comparative multicentre study (n=187)	IVL for calcified left main coronary artery lesions was safe and had high technical success rates. Angiographic complications were rare and clinical adverse events during hospitalisation and at 30 days were. In-hospital MACE was 4.4% and 30-day MACE was 8.8%. Procedural success at 30 days was 90.6%.	Tables 2 and 3 include larger studies and systematic reviews on wider indications with similar results.
Rola P, Kulczycki JJ, Włodarczak A et al. (2022) Intravascular Lithotripsy as a Novel Treatment Method for Calcified Unprotected Left Main Diseases–Comparison to Rotational Atherectomy–Short-Term Outcomes. International Journal of Environmental Research and Public Health, 19(15): 9011	Retrospective study (n=44)	High procedural success rates in both IVL and rotational atherectomy groups during hospital stay. Both techniques were found to be safe with no significant differences in complications.	Tables 2 and 3 include larger studies and systematic reviews on with similar results.
Roy S, Kumar P, Kidambi BR (2024) The Uncrossable STEMI – Calcific Eruptive Nodule in Elderly Women. Indian Journal of Cardiovascular Disease in Women 9(1): 40	Case report (n=1)	IVL was done safely during PCI after rotablation for a 78-year-old woman with inferior wall myocardial infarction and high-grade stenotic lesions with both	Tables 2 and 3 include larger studies and systematic reviews.

		superficial and deep calcium.	
Sattar Y, Ullah W, Ul Hasan Virk H et al. (2021) Coronary intravascular lithotripsy for coronary artery calcifications	Review	Shockwave intravascular lithotripsy (S-IVL) may be used in cases of the calcified disease to gain vessel lumen in order to deploy drug-eluting stents with PCI. The success of the DES implantation of IVL can be 100% with a minimal complication rate	Review
Sgueglia GA, Gioffre G, Piccioni F et al. (2019) Slender distal radial five French coronary shockwave lithotripsy. Catheter cardiovascular Interventions 1-4	Case report 72-year-old man with calcific atherosclerosis of the left anterior descending artery with stenosis had IVL PCI using a 5 French guiding catheter.	Procedure was successful with optimal stenting results and reported no complications at 6 months follow up.	Larger studies added to table 2
Shavadia JS, Minh NV, Kevi B. 2018 Challenges with severe coronary artery calcification in percutaneous coronary intervention: A Narrative Review of Therapeutic Options. Canadian Journal of Cardiology, 3 (12): 156-72	Review	Summary of the principles, technique, and contemporary evidence for the currently approved devices designed to treat severe coronary calcific lesions.	Review
Salazar C, Escaned J, Tirado G et al. (2019) Undilatable calcific coronary stenosis causing stent under	Case report n=71-year-old man with repeat STEMI had PCI. A suboptimal under expansion was achieved by	A good final angiography result was achieved. The case showed effectiveness of IVL to modify	Larger studies added to table 2

expansion and late stent thrombosis. A complex scenario successfully managed with intravascular lithotripsy. JACC: Cardiovascular Interventions. 12(15): 1510-3	coronary calcification. A new PCI using IVL was done to modify calcific plaques.	calcific plaques and act through a previously implanted stent.	
Tassone EJ, Tripolino C, Morabito G et al. (2018) When calcium gets tough, the tough cardiologist starts to play. Cardiology, 141: 167-71	Case report n=60-year-old man with calcific restenosis of a previously stented or treated lesion (left coronary artery) had coronary shockwave lithotripsy.	IVUS after 3 cycles showed a significant area gain more than 6 mm2 . There was an excellent postprocedure angiographic result and a minimal lumen area on final IVUS. The patient was discharged after 48 hours in good condition and without symptoms.	Larger studies added to table 2.
Teira Calderón A., Sans-Roselló J., Fernández-Peregrina E. et al. (2024) Impact of the use of plaque modification techniques on coronary microcirculation using an angiography-derived index of microcirculatory resistance. The International Journal of Cardiovascular Imaging 40: 1671–1682	Comparative multicentre study (n=162, IVL=80, RA=82)	IVL and RA seemed to have an effect on coronary microcirculation status. Procedural success between the groups was similar but higher rate of periprocedural PCI complications was observed in the RA compared to the IVL group mainly because of higher rates of shock developed during PCI. Clinical adverse events during hospitalisation and at 1 year were	Tables 2 and 3 include larger studies and systematic reviews. Some baseline characteristics were slightly unbalanced between the groups.

		similar between the groups.	
Thirumurugan E, Gomathi K, Karthick R et al. (2023) Shockwave intravascular lithotripsy: The future of coronary intervention? Research in Cardiovascular Medicine 12: 103–7.	Review (13 non-randomised studies)	IVL can be safely done with a high rate of procedural success and a low incidence of complications.	Tables 2 and 3 include systematic reviews.
Tovar Forero, MN, Wilschut J, Van Mieghem NM et al. (2019) Coronary lithoplasty: a novel treatment for stent under expansion. European Heart Journal. 40, 2: 221	Case report n=74-year-old man with a heavily calcified stenotic lesion in the proximal left anterior descending coronary artery and under expanded stent resistant to conventional noncompliant balloons had coronary shockwave lithotripsy.	Full expansion was achieved after 2 lithoplasty therapies. OCT imaging showed multiple calcium fractures. The procedure completed without any complications.	Larger studies added to table 2.
Umeh CA, Harpreet K, Paknoosh S (2024) Intravascular lithotripsy in coronary arteries: a review of case reports. The Egyptian Heart Journal 76:121	Review of case reports 70 case reports and case series (n=84)	IVL showed nearly 100% clinical and angiographic success in heavily calcified coronary artery lesions in different clinical scenarios including in-stent restenosis of native coronary arteries, saphenous vein grafts, and under-expanded stents.	Tables 2 and 3 include systematic reviews of larger studies.
Vainer J, Lux A, Ilhan M et al. (2019) Smart solution for hard times: successful lithoplasty of an	Case report n=70-year-old woman with unsuccessful PCI with high-pressure balloons and rotational	Lithoplasty effectively resulted in plaque modification and a significant increase in diameter. OCT	Larger studies added to table 2.

undilatable lesion. Neth Heart J 27:216-7	atherectomy had lithoplasty-assisted PCI.	showed typical calcium tears and a large dissection. To cover the lesion, a drug-eluting stent was implanted. Proper stent expansion and apposition were confirmed with OCT.	
Van Oort MJH, Al Amri I, Bingen BO et al. (2024) Current applications, procedural and 1-year outcomes of Rotatripsy for the treatment of calcified coronary lesions. Catheterization & Cardiovascular Interventions 104(2): 203–212	Multicentre registry study (n=114)	Device success, technical success and procedural success were high when IVL was used before or after rotational atherectomy (Rotatripsy). Over a 1-year follow-up period, Rotatripsy was safe and effective, predominantly using RA electively before IVL.	Tables 2 and 3 include larger studies and systematic reviews. Population potentially overlaps with Oliveri et al. (2024) subgroup analyses on chronic total occlusion and aorto-ostial lesions.
Venuti G, D'Agosta G, Tamburino C et al. (2019). Coronary lithotripsy for failed rotational atherectomy, cutting balloon, scoring balloon and ultra-highpressure non-compliant balloon. Catheter Cardiovascular Interventions 1-5	Case report n=67-year-old man having planned PCI of the right coronary artery targeting an undilatable lesion already resistant to multiple specialised balloons and rotational atherectomy had coronary lithotripsy and new PCI on the RCA.	Calcium modification at the target segment was seen and 3 stents were deployed with a good final result. No intra hospital complications reported. Patient was free from angina at 3 months follow up.	Larger studies added to table 2.
Wong B, El -Jack S et al. (2019) Shockwave intravascular lithotripsy of	Case series n=3 patients having PCI for ST-elevation myocardial infarction (STEMI) using IVL	The 3 presented cases include an upfront use of S-IVL in a right coronary artery, an	Larger studies added to table 2. (cases also reported in study 3 in table 2)

calcified coronary lesions in ST-elevation myocardial infarction: first in-man experience. Journal of invasive cardiology 31 (5), e73-5	as an adjunct procedure.	in-stent restenosis, and a community cardiac arrest/ST-elevated myocardial infarction equivalent when S-IVL was used as a bailout technique to help stent delivery in a tortuous calcified vessel. Early experience has been favourable	
Wong B, El -Jack S, Khan S et al. (2019) Treatment of heavily calcified unprotected left main disease with lithotripsy-the first case series. The journal of invasive cardiology, 31 (6): E143-7	Case series n=3 the use of S-IVL in a patient with left main-coronary artery disease (LM-CAD) with multivessel disease who declined surgery, a patient with an isolated LM-CAD and severe cardiomyopathy, and a late nonagenarian patient when surgical revascularisation was not an option reported.	No patients had procedural complications or major adverse events (stroke, myocardial infraction, death) during the index admission or within the first 30 days post discharge	Larger studies included in table 2
Yeoh J, Hill J, Spratt JC et al. (2019) Intravascular lithotripsy assisted chronic total occlusion revascularization with reverse controlled antegrade retrograde tracking. Catheter Cardiovasc Interv, 93:1295-7	Case report 81-year-old female with heavily calcified right coronary artery chronic total occlusion (CTO) had PCI via reverse controlled antegrade/retrograde tracking (RCART).Standard balloon inflation failed to create communication by	IVL was used to help connection in R-CART to complete the CTO PCI when heavy calcification was present at the site of chronic occlusion. Multiple fractures helped connection between intimal and subintimal tissue planes.	Larger studies added to table 2

	modifying plaque and guidewire failed. So IVL was used in controlled antegrade/retrograde tracking.		