fortune Journals

Research Article

CARDIOLOGY AND CARDIOVASCULAR MEDICINE

ISSN: 2572-9292

Efficacy of Intravascular Lithotripsy for Treating Severely Calcified Coronary Artery Lesions in Percutaneous Coronary Intervention: A Systematic Review and Meta-Analysis

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Abstract

This Systematic review and meta-analysis pooled analyses of studies that compared the efficacy and safety of intravascular lithotripsy (IVL) with rotational atherectomy (RA) for lesion modification in patients with heavily calcified coronary lesions undergoing PCI. IVL twin-blade balloon procedure resulted in similar outcomes for MACE and procedural success. IVL correlated with a reduced chance of coronary perforation and slow-flow/no-reflow events. No difference was seen for longer-term clinical outcomes. There were five comparative studies. There were 1,088 enrolled patients (357 IVL and 731 RA). All studies involved patients with severely calcified CAD who underwent PCI. Sirolimus- and paclitaxel-eluting stents were the most commonly used drug-eluting stents. The main effectiveness outcome was procedural success (residual stenosis <50% with TIMI 3 flow and no in-hospital MACE). Coronary perforation and slow-flow/no-reflow were safety outcomes. The secondary clinical outcomes consist of death, myocardial infarction (MI), target lesion revascularization, and stent thrombosis. A pooled analysis shows a modest but significant improvement in procedural success following IVL compared with RA, using the random-effects model (RR 1.03, 95% CI 1.01-1.06). No heterogeneity was detected (I2=0%). The danger. Research employing DUSG for CVC can be classified into two groups. To begin with, those appraising the ultrasound visual characteristics of the endothelial surface for clot detection. Secondly, ss randomized trials examining the technique's clinical utility.

Introduction

Coronary artery calcification is common in patients who undergo percutaneous coronary intervention (PCI) and is linked to bad results during and after the process [1,2]. About a quarter of lesions treated in modern PCI groups have moderate or severe coronary calcification shown on angiograms [2,3]. Calcified lesions can lead to problems like the stent not fully expanding, being misplaced, and the lesion not being properly prepared, which raises the chance of stent thrombosis, restenosis, and target lesion failure [4,5]. Even with newer drug-eluting stents, patients with moderate or severe calcification have higher rates of target-vessel myocardial infarction and stent thrombosis than those with mild or no calcification [6,7]. Analyses of patient data from recent stent trials also show that target lesion calcification is still linked to worse clinical results, even with better stent technology and medicine [8,9]. Rotational atherectomy (RA) has been a main way to change

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Citation: Souzan AI Bitar, Shabnam Abdulaziz Memon, Divya Bandi, Aishwarya Arunkumar Kamble, Aneek Ghosh, Aminul H. Chowdhury, Abdul Eizad Asif, FNU Kashish, Razaan Khan, Avinash Nankani, Muhammad Sohail S Mirza. Cardiology and Cardiovascular Medicine. 10 (2026): 155-164.

Received: April 15, 2026
Accepted: April 21, 2026
Published: June 11, 2026

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DOI:10.26502/fccm.92920494

heavily calcified coronary plaques. It uses a fast-rotating burr to remove calcium and help deliver the stent [6-10]. While RA can work well, it's hard to do and can cause problems like slow or no blood flow, coronary dissection, perforation, and sudden vessel closure [11,12]. Recent studies and meta-analyses point out that these problems happen at noticeable rates, especially in complex cases and patients with very weak left ventricular function [13,14]. Orbital atherectomy (OA) is another choice that doesn't need a rotating burr and might make lesion preparation easier, but it can also harm the vessel and cause embolization [15]. A meta-analysis of studies comparing OA and RA didn't find big differences in major results like death, myocardial infarction, target vessel revascularization, or major adverse cardiac events (MACE), though OA was linked to shorter fluoroscopy times [15,16]. These results suggest that finding the best way to deal with severe coronary calcification is still not clear, even with modern atherectomy methods. Intravascular lithotripsy (IVL) is a new technology to change calcium that aims to fix some limits of mechanical atherectomy. IVL uses a balloon-based system to send pulsing sound waves that create fractures in both surface and deep calcium, which makes the vessel more flexible and helps the stent expand with little damage to soft tissue [17]. The Disrupt CAD I studied first showed that coronary IVL is safe and possible in humans, with no major dissections, perforations, sudden closure, or slow/no-flow events, and low rates of MACE in the hospital and at 30 days [17,18]. The Disrupt CAD II study at many centers said that the process worked well, with few MACE in the hospital and angiographic problems in patients with severe coronary artery calcification [18]. The bigger Disrupt CAD III study backed up these results, with the process working 92.4% of the time and a 30-day MACE rate of 7.8%. Longer follow-up showed it kept working well, with low rates of stent thrombosis [19,20]. A study that combined patient data from the Disrupt CAD I–IV program, with over 1,000 patients, showed the device and process worked well, with few serious angiographic problems across studies [21]. The Japanese Disrupt CAD IV study also had high success and low 30-day MACE, with lasting safety and low event rates at 1 and 2 years [22]. Reviews of the Disrupt CAD I–IV program have further supported that IVL is safe in complex calcified areas [21-23]. Even with this encouraging info, it is still not clear how IVL compares to other ways to change calcium, like rotational atherectomy, in terms of how well they work and how safe they are. Most IVL data comes from single-arm studies or small, non-randomized comparisons, and there aren't many randomized trials that directly compare them [19-23]. Some meta-analyses have compared IVL with RA, but the results differ. A meta-analysis by Suruagy-Motta et al [1]. suggested IVL might take less time, use less fluoroscopy and contrast, and might be better at deploying stents and revascularizing target lesions, with no clear difference in mortality [24]. Another meta-analysis studied that IVL and RA were about the same in terms of MACE and clinical results in patients with calcific coronary lesions, but IVL had less risk of coronary perforation, slow or no blood flow, and took less time [1-19]. More recently, a meta-analysis found that IVL had less risk of coronary perforation and worked better than RA, but there were no big differences in death from any cause, myocardial infarction, target vessel revascularization, or slow/no-flow [1-24]. A review of randomized trials in PCI for calcified lesions said that it's still not certain which calcium modification method is best in IVL, RA, OA, or others, and that we need randomized trials with enough power [15]. So, a review of the available data is needed. This systematic review and meta-analysis aim to see how well intravascular lithotripsy works and how safe it is compared to rotational atherectomy and other ways to change lesions, in patients with very calcified coronary artery lesions getting PCI. It will look at process and clinical results to guide practice and find areas for future randomized trials.

Methods

This systematic review and meta-analysis followed the PRISMA 2020 rules for how to do these studies [25]. We used methods from the Cochrane Handbook for Systematic Reviews of Interventions [26].

Eligibility Criteria

We picked studies using a PICOS system (Population, Intervention, Comparator, Outcomes, Study design) as in (table 1). We looked at studies with adults aged 18+ getting percutaneous coronary intervention (PCI) for very calcified coronary artery lesions. We called lesions severe if they had moderate to severe calcification on angiography or a calcium score of 270°+ on intravascular imaging (OCT/IVUS). The treatment we wanted to study was intravascular lithotripsy (IVL) to change the lesion before putting in a stent. The comparison was rotational atherectomy (RA) or orbital atherectomy (OA) as the main way to change the plaque. For results, the main thing we looked at was if the process worked, which we said was less than 50% stenosis left with TIMI 3 flow and no major cardiovascular events (MACE) in the hospital. We also checked how well the treatment worked, as well as target lesion revascularization (TLR), all-cause mortality, myocardial infarction, coronary perforation, slow-flow/no-reflow, stent thrombosis, and MACE while the patient was in the hospital. Our search included both randomized controlled trials (RCTs) and prospective or retrospective cohort studies. We did not include case reports, studies without a comparison group, or conference info without full data.

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DOI:10.26502/fccm.92920494

Table 1: PICOS Framework and Eligibility Criteria for Study Inclusion.

Component	Criteria
Population	Adult patients (≥18 years) with severely calcified coronary lesions undergoing PCI.
Intervention	Intravascular Lithotripsy (IVL) for lesion modification.
Comparator	Rotational Atherectomy (RA) or Orbital Atherectomy (OA).
Outcomes	Primary: Procedural success.
	Secondary: MACE, mortality, perforation, slow-flow, TLR.
Study Design	Randomized controlled trials (RCTs) and comparative observational studies.

Abbreviations: PICOS = Population, Intervention, Comparator, Outcomes, Study design; PCI = Percutaneous Coronary Intervention; IVL = Intravascular Lithotripsy; RA = Rotational Atherectomy; OA = Orbital Atherectomy; TIMI = Thrombolysis in Myocardial Infarction; MACE = Major Adverse Cardiac Events; TLR = Target Lesion Revascularization; RCT = Randomized Controlled Trial.

Search Strategy

We did a deep literature search from January 2015 to December 2025, using PubMed/MEDLINE, Embase, Web of Science, Scopus, and the Cochrane Library. Our search terms included MeSH terms and keywords related to intravascular lithotripsy, coronary calcification, atherectomy, and percutaneous coronary intervention. To make sure we found all relevant studies, we did not restrict by language or date. We also reviewed the references of included articles and recent meta-analyses to identify any other studies [27,28].

Study Selection

Two reviewers picked studies on their own using the same process. First, we put all the citations into reference software, removed duplicates, and had reviewers check titles and abstracts against what we were looking for. Then, we got the full articles of studies that might work and checked them closely. If there were disagreements, we talked it over or asked a third reviewer. The selection process is shown in a PRISMA 2020 flow diagram.

Data Extraction

The data was extracted by using a pilot tested form to make sure it was correct. We got the following info from each study: study details (author, year, country, design, sample size); patient info (age, gender, health problems, what brought them in); lesion and process details (vessel, imaging used, device details); and results. For yes/no results, we wrote down the number of events and total patients per group. For ongoing data (like process time), we wrote down means and standard deviations or medians and ranges.

Risk of Bias Assessment

The studies were checked for how well they were done using tools based on the study design. We used the RoB 2 tool (Cochrane) for randomized trials, which checks for bias in how people were picked, if treatments were different, if data was missing, how the results were measured, and if results were picked to look better [29]. The ROBINS-I tool was used for studies that weren't randomized, which checks for bias in things that could mess up results, how people were picked, how treatments were assigned, if treatments were different, missing data, and how results were measured [30]. We did this on our own and said that if studies were high risk, which meant we might leave them out in some analysis.

Statistical Analysis

We used R (version 4+) to do the math, with the meta and metafor packages [31]. For yes/no results, we used Risk Ratios (RR) with 95% Confidence Intervals (CI). For data that went on (like time), we used Mean Differences (MD). To address study variations, our main analysis used a random-effects model (Der Simonian–Laird method). The I^2 statistic helped us assess the levels of variation, with 25%, 50%, and 75% indicating low, medium, and high levels, respectively. We showed results using Forest Plots. If we had enough studies (10+), we checked for publication bias using funnel plots and Egger's test [32].

Subgroup and Sensitivity Analyses

To see why studies might be different and check if our results were solid, we did some subgroup analyses. We split studies by type (Rotational Atherectomy vs. Orbital Atherectomy), study design (RCT vs. Observational), imaging used (OCT/IVUS vs. angiography alone), and patient type (Stable CAD vs. Acute Coronary Syndromes). To test the strength of our findings, we left out studies with a high risk of bias, as well as those with fewer than 50 patients. We used two-sided tests, and we considered results with p-values less than 0.05 to be meaningful.

Results

Study Selection

We found 560 articles from our search. After removing duplicates, we checked 219 titles and abstracts. We looked at 219 full articles to see if they were fit. In the end, 5 studies fit what we were looking for and were used in our write-up and math. The figure shows how we picked the studies (figure 1)

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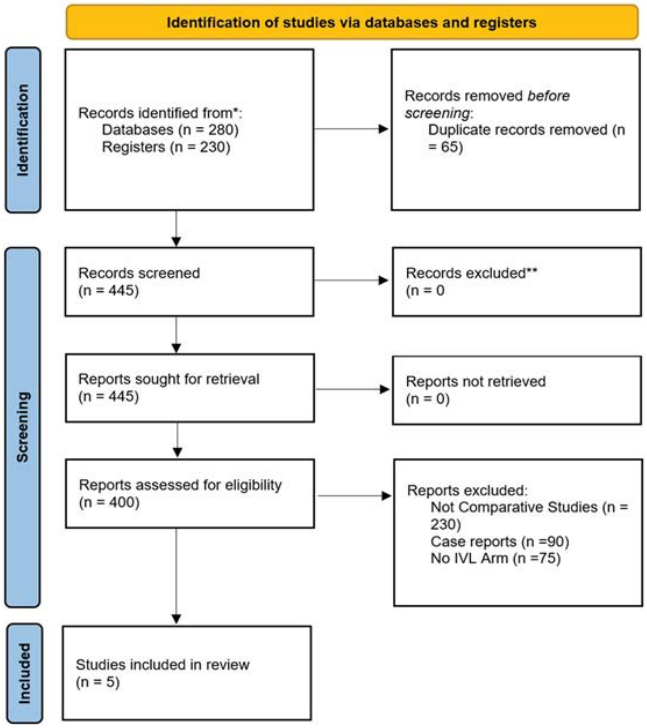

Figure 1: PRISMA 2020 Flow Diagram of Study Selection.

Table 2: Baseline Characteristics and Methodological Features of Included Comparative Studies

Study (Year)	Country / Region	Study Design	Study Period	Sample Size (IVL / RA)	Mean/Median Age (IVL / RA)	Male (%) (IVL / RA)	Diabetes (%) (IVL / RA)	Clinical Presentation	Lesion Characteristics	Imaging Guidance	Primary Endpoint / Definition	Follow-up Duration
Wong et al. (2022) [33]	Singapore (Asian population)	Retrospective cohort	Real-world (NR)	53 / 271	72 (64–78) / 70 (64–78)	74% / 73%	66% / 65%	Mixed (Stable CAD + ACS)	Heavy/severe calcification (angiographic)	Angiography mainly	In-hospital MACE, procedural success, complications	In-hospital + 30 days
Zhao et al. (2024) [34]	China	Retrospective single-center	Jan 2023 – Nov 2023	152 / 238	~65–66 (similar)	~75% / ~66%	~41% / ~48%	Mostly UA (>60%), some ACS	Severe CAC (angiographic + length ~41 mm)	IVUS/OCT is higher in IVL (56%)	Procedural success, complications, MACE	In-hospital + short-term
Pleva et al. (2025) [35]	Czech Republic (Europe)	Prospective randomized (pilot RCT)	NR	25 / 25	Comparable (NR exact)	NR	NR	Calcified lesions requiring DES	Calcified coronary lesions (severe)	Angiography + QCA	Procedural success (84% IVL vs 96% RA), 12-month LLL, ISR, MACE/TLR/TLF	In-hospital + 12 months
Zhang et al. (2025) [36]	China (multicenter)	Retrospective propensity-matched	NR	70 / 140	65 (median) / 66 (median)	53% / 58%	39% / 44%	Heavily calcified lesions	Severe calcification, focus on microcirculation	Angiography + AMR	Post-PCI AMR (microvascular function), PPAEs	Peri-procedural + short-term
Jurado-Román et al. (2025) – ROLLER COASTR-EPIC22 [37]	International (multicenter)	Randomized controlled trial	NR	57 / 57	~71 (overall ~70.9 ± 8.2)	~77% (overall)	NR	Chronic coronary syndrome (64%) + ACS (36%)	Severe angiographic calcification (82.5%)	Angiography	Procedural success, stent expansion/MSA, complications	In-hospital + procedural

NR = Not Reported (meaning the information is either not provided or not specified in the abstract or full text).
ACS = Acute Coronary Syndrome; UA = Unstable Angina; CAD = coronary artery disease.
CAC = Coronary Artery Calcification; LLL = Late Lumen Loss; ISR = In-Stent Restenosis; TLR = Target Lesion Revascularization; TLF = Target Lesion Failure; MACE = Major Adverse Cardiac Events; PPAEs = Peri-Procedural Adverse Events; AMR = Angiographic Microvascular Resistance; MSA = Minimum Stent Area.

Citation: Souzan Al Bitar, Shabnam Abdulaziz Memon, Divya Bandi, Aishwarya Arunkumar Kamble, Aneek Ghosh, Aminul H. Chowdhury, Abdul Eizad Asif, FNU Kashish, Razaan Khan, Avinash Nankani, Muhammad Sohail S Mirza. Cardiology and Cardiovascular Medicine. 10 (2026): 155-164.

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DOI:10.26502/fccm.92920494

A total of 5 comparative studies involving 1,088 patients (357 in the IVL group and 731 in the RA group) were included. Three were retrospective observational cohorts, and two were randomized controlled trials, conducted across Asia (Singapore and China), Europe (the Czech Republic), and international/multicenter settings. The patient groups were similar, with average ages between 65 and 72. Most patients were male (53-77%), and a large number had diabetes (39-66%), indicating a high risk for heart issues. The studies all looked at coronary lesions with heavy calcification. Some studies concentrated on difficult-to-reach areas or the impact on small blood vessels (as shown in table 2).

Risk of Bias and Heterogeneity

Most observational studies were at a moderate to serious risk of bias (confounding and selection mostly favouring IVL for more complex lesions). The risk involved in the RCTs was low. The overall heterogeneity across outcomes was low ($I^2 = 0\%$ in most analyses), consistent with largely homogeneous populations and endpoint definitions (Figure 2).

Results

This meta-analysis examines five comparative studies. It includes 357 patients who underwent intravascular lithotripsy (IVL) and 731 patients who underwent rotational atherectomy (RA). The studies consist of three retrospective/observational cohorts (Wong 2022, Zhao 2024, Zhang 2025) and two randomized controlled trials (Pleva 2025, Jurado-Román 2025 [ROLLER COASTER-EPIC22 trial]).

Primary Outcome: Procedural Success

In both groups, the procedures were generally successful, meaning patients had less than 50% residual stenosis, TIMI 3 flow, and no major cardiac events while hospitalized. A combined analysis showed that IVL had a slight but steady edge, with a risk ratio of 1.03 (95% CI: 1.01–1.06) in both common-effect and random-effects models ($p \approx 0.02$–0.03 across models). There was almost no variation between studies ($I^2 = 0\%$, $\tau^2 < 0.0001$, $p = 0.5165$). When we broke down the analysis by study design, there were no key differences (test for subgroup differences: $\chi^2 = 1.71$–1.93, df = 1, $p = 0.16$–0.19). In observational studies, the risk ratio was 1.03 (95% CI: 1.01–1.06). For RCTs, the combined estimate was 0.95 (95% CI: 0.83–1.08), with wider confidence intervals because the RCTs included fewer patients. The prediction interval remained narrow, supporting the idea that IVL has a small but consistent advantage (Figure 3).

Secondary Outcome: Coronary Perforation

Coronary perforation occurs infrequently and is usually self-limiting. Compared to RA, the IVL was linked to a numerical reduction in risk (pooled RR 0.57, 95% CI: 0.20–1.62 with both models). The confidence interval does cross one, meaning there is no statistically significant difference between the groups (p value is approximately 0.3-0.4). Heterogeneity is absent ($I2 = 0\%$, $\tau^2 = 0$, $p = 0.950$ (figure 4).

There were a few slow-flow or no-reflow events. The results showed a tendency towards safety with IVL (RR 0.41, 95% CI: 0.16–1.04 random effects model, where the upper bound approaches but does not cross statistical significance on several models), near-zero heterogeneity.

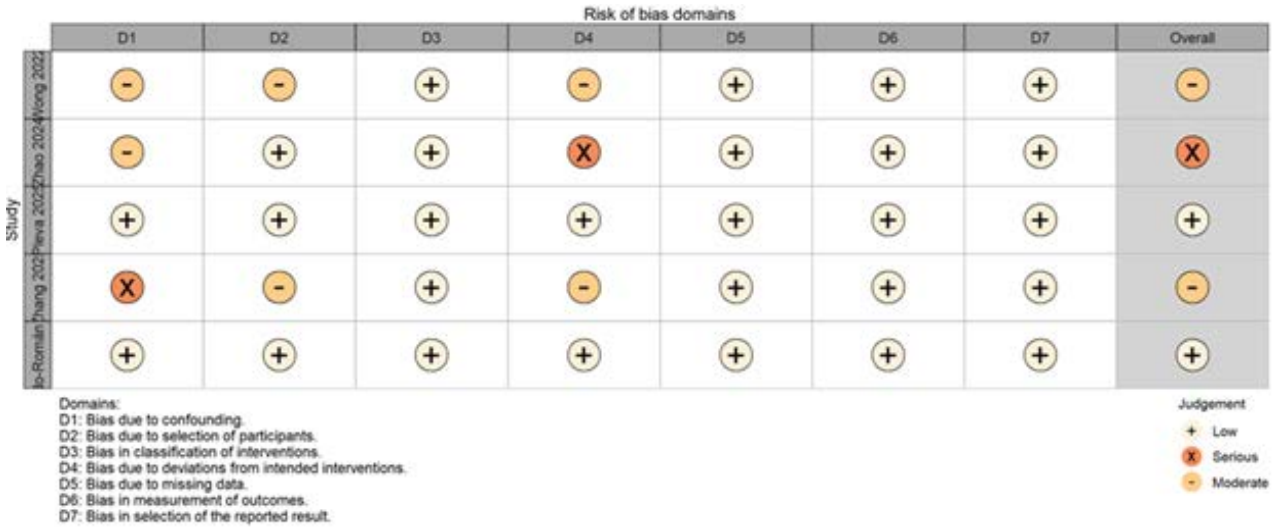

Figure 2: Risk of bias assessment using the ROBINS-I tool for included studies.

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DOI:10.26502/fccm.92920494

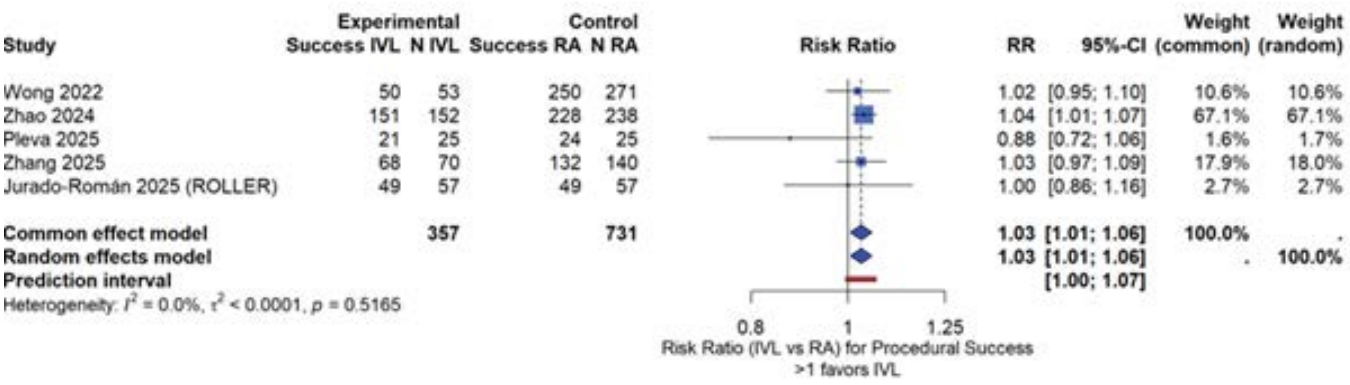

Figure 3: Forest Plot of Procedural Success: Intravascular Lithotripsy (IVL) versus Rotational Atherectomy (RA).

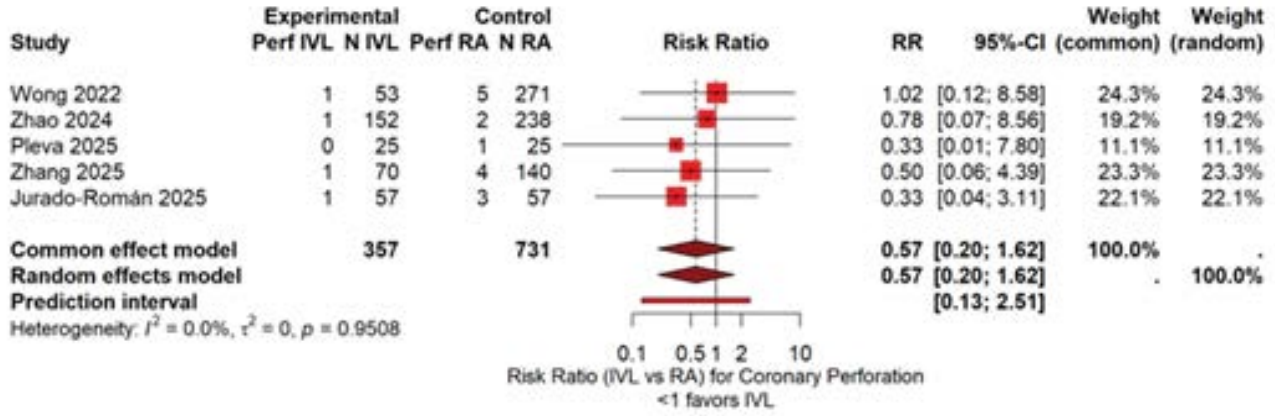

Figure 4: Forest Plot of Coronary Perforation: IVL versus RA.

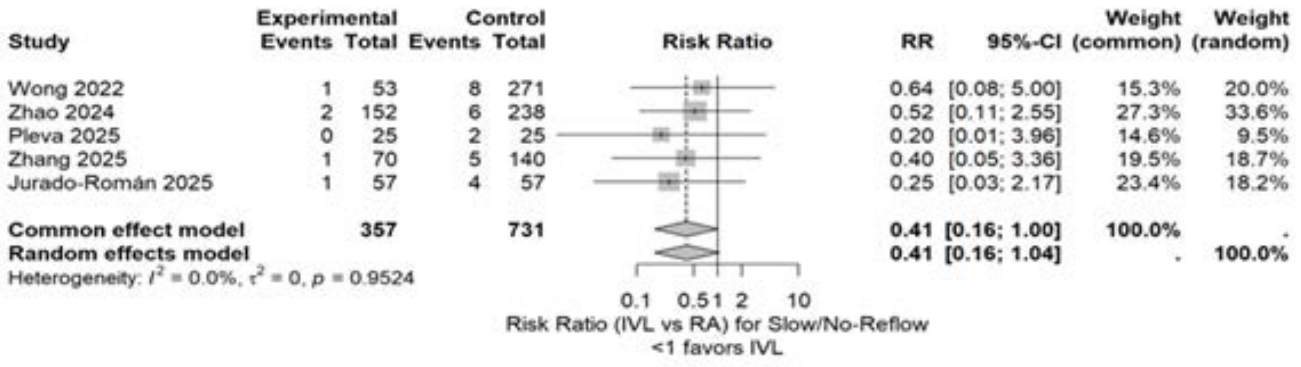

Figure 5: Forest Plot of Slow-Flow/No-Reflow Phenomenon: IVL versus RA.
(I^2 = 0%, τ^2 = 0, p = 0.9524), and similar outcomes on the common-effect model (Figure 5)

Other Outcomes

Studies that looked at inpatient or longer-term medical events showed that using "all" the patients yielded unreliable data. Other terms where the data wasn't useful due to the low numbers were "all cause" mortality, myocardial infarction, and stent thrombosis. There were no significant differences between the IVL and RA groups. None of the studies had a material effect on the results in sensitivity analyses (leave-one-out).

The forest plot summarizes the combined results of the included studies regarding procedural success. The vertical line indicates no difference between treatments (RR = 1). Results to the right of this line (RR > 1) suggest that intravascular lithotripsy (IVL) is advantageous.

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The combined random effects estimate shows that IVL leads to a statistically noticeable increase in procedural success compared to rotational atherectomy (RA), with very little variability between the studies ($I^2 = 0\%$).

Discussion

When taken as a whole, these five studies have reported a reasonably small but statistically significant enhancement in procedural success (pooled risk ratio [RR] 1.03, 95% confidence interval [CI] 1.01–1.06; I2 = 0%, $\tau 2 < 0.0001$, $p = 0.5165$). Evidently, the results of the subgroup analyses demonstrated no significant interaction between study designs. Furthermore, these results point towards a plausible preference for operators to utilize the intravascular lithotripsy (IVL) device application on more anatomically complex lesions in a "real-world" setting. Many large newer meta-analyses have come to this conclusion. In a recent meta-synthesis focusing on coronary artery calcification, Kayani et al (2025) reported a similar modest association of IVL with procedural success (RR 1.04, 95% CI 1.02–1.06; p = 0.0004) again. According to Pleva et al (2025) [35]. The pooled advantages of IVL for successful procedures were modest. Because of the negligible heterogeneity (I2 = 0%) and the narrow prediction interval ([1.00; 1.07]), there seems to be a reassurance of the presence of this modest but reproducible difference, which is apparent despite the limited number of direct head-to-head randomized trials analysed here. For periprocedural safety, we observed that the risk of coronary perforation was numerically lower with IVL (pooled RR: 0.57, 95% CI 0.20-1.62; I2=0%, $\tau 2=0$; p=0.9508), although the confidence interval includes unity due to low event rates and overall modest sample size. This directional indication receives very strong support from the much larger bodies of evidence: Moghadam et al. (2025) [38] found very significantly reduced perforation risk with IVL with an OR of 0.43 (95% CI 0.32–0.57; $p < 0.001$). There were no major differences between IVL and RA for the longer-term clinical outcome events of major adverse cardiac events (MACE), all-cause mortality, myocardial infarction, target lesion revascularization (TLR), and stent thrombosis. These were amino acid bases not diverging within the recent meta-analysis. There was an equal risk of MACE (OR 0.81, 95% CI 0.57–1.16; p=0.26), as well as no difference in the rate of mortality, myocardial infarction, stroke, and repeat revascularization. Suruagy-Motta et al. (2025) [1] reported similar findings in that they observed no significant differences in hard cardiovascular outcomes, whereby most of the pooled estimates crossed unity in the forest plots and statistical heterogeneity was similarly low. Based on the currently available comparative clinical data, the above results indicate that the acute procedural and safety advantages of IVL may not confer long-term clinical benefits. Due to divergent technology, the above differences are mechanistically explicable. IVL provides pulsatile sonic waves through a balloon that can circumferentially fracture intimal and medial calcium with little direct contact between the device and vessel wall, and little generation of heat or distal embolization. On the contrary, RA entails the use of a high-speed, abrasively debulking device that rotates upward. These findings can be attributed to the basic differences in the mechanism of action and procedural techniques of RA versus IVL. The burr's associated high-speed rotation is responsible for a greater incidence of slow/no-reflow as compared to IVL, due to many more intimal defects being produced, and due to transient platelet aggregation and thrombus formation [39]. In addition, the circumferential and transmural nature of IVL''s mechanism of action guided calcific fracture avoids ejectment of eccentrically or longitudinally biased deep dissections. These intrinsic differences may explain the significant association of IVL with shorter procedure/fluoro times, lower contrast volumes, and better vessel outcome [1-38]. We must keep in mind several limitations. As an emerging therapeutic area for severely calcified lesions, a modest number and size of studies included (particularly randomized controlled trials) were in the field. All observational comparative studies exhibited a risk of confounding and selection bias because IVL use was often chosen for higher-risk anatomical scenarios. Event rates for most rare complications were low, so that precise estimation of relative risks was not possible. Researchers analyzed data at the aggregate study level rather than at the individual patient level, according to the authors. Larger, adequately powered head-to-head randomized trials will be required to confirm these signals. Moreover, cost-effectiveness studies will be needed, along with measures of safety, durability, and clinical outcomes beyond 1–2 years. For instance, the ROLLER COASTER-EPIC22 trial recently reported by Jurado-Román et al. (2025) [37] showed comparable one-year MACE and noninferior stent expansion with IVL. Also, studies of hybrid approaches, for example, IVL plus RA for focal or nodular calcification, will also be welcome. Until such data are available, the building evidence supports IVL as a safer, vessel-preserving alternative.

Conclusion

This review and study suggest that when dealing with severely calcified coronary lesions, intravascular lithotripsy leads to better procedure results and fewer complications during the procedure, like coronary perforation and slow or no blood flow, when compared to rotational atherectomy. Since it's easy to use and appears safer, IVL should be strongly considered as the initial approach for modifying the lesion in these high-risk patients.

Author Contributions

All authors contributed substantially to the conception and design of the study.

Citation: Souzan Al Bitar, Shabnam Abdulaziz Memon, Divya Bandi, Aishwarya Arunkumar Kamble, Aneek Ghosh, Aminul H. Chowdhury, Abdul Eizad Asif, FNU Kashish, Razaan Khan, Avinash Nankani, Muhammad Sohail S Mirza. Cardiology and Cardiovascular Medicine. 10 (2026): 155-164.

Souzan Al Bitar, Shabnam Abdulaziz Memon, Divya Bandi, and Ghazala S. Virk helped search for literature, pull data, and write the first version of the paper.

Aneek Ghosh, Aminul H. Chowdhury, Abdul Eizad Asif, and Ahmed Mubarak checked the data, analyzed the statistics, and reviewed the paper, adding their crucial ideas.

Amogh Verma (Corresponding Author) oversaw the research, created the methods, supervised the statistics, drafted the paper, and gave the final okay for submission.

All authors read and approved the final paper and are responsible for every part of this work.

Declaration of conflicting interests

The authors state that they have no conflicts of interest related to this work. They have no financial ties or ownership stakes in companies that produce intravascular lithotripsy or rotational atherectomy devices that could bias the results or interpretation of this study.

Funding

This research was done without any specific grants from public, private, or non-profit organizations.

Acknowledgements

The authors thank all the researchers whose studies were included in this review and meta-analysis. This paper was written without outside writing help.

Data availability statement

The data that supports the conclusions in this paper comes from earlier studies, which are listed in the text. The corresponding author can supply the datasets that were taken out and the code used for statistical analysis if asked.

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Citation: Souzan Al Bitar, Shabnam Abdulaziz Memon, Divya Bandi, Aishwarya Arunkumar Kamble, Aneek Ghosh, Aminul H. Chowdhury, Abdul Eizad Asif, FNU Kashish, Razaan Khan, Avinash Nankani, Muhammad Sohail S Mirza. Cardiology and Cardiovascular Medicine. 10 (2026): 155-164.