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Shockwave therapy for coronary calcification: the evolving role of intravascular lithotripsy in coronary interventions

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Abstract

Severely calcified coronary lesions represent a significant challenge during percutaneous coronary interventions (PCI), often limiting optimal stent deployment and increasing the risk of procedural complications. Intravascular lithotripsy (IVL) is an emerging technology designed to modify calcified plaques through the application of acoustic shockwaves, offering a safer and more controlled alternative to traditional atherectomy.

Aim of the Study: This study aims to provide a comprehensive overview of the intravascular lithotripsy (IVL) technique, its mechanism of action, indications, and contraindications. Additionally, it evaluates the procedural efficacy, safety profile, and clinical outcomes of IVL based on current clinical trial data and real-world experience.

Material and Methods: A narrative review was conducted, incorporating findings from major clinical trials (Disrupt CAD I–IV) and observational registries, with a focus on procedural success, complication rates, and major adverse cardiac events (MACE). The review includes comparative analysis of IVL outcomes in de novo lesions, in-stent restenosis (ISR), chronic total occlusions (CTO), and complex anatomical scenarios.

Conclusions: IVL is a highly effective and safe modality for the modification of calcified coronary lesions. It consistently demonstrates procedural success rates exceeding 90%, with a low incidence of complications such as perforation or dissection. Clinical efficacy is sustained in both short- and long-term follow-up, with low MACE rates observed across studies. IVL is particularly valuable in cases resistant to conventional techniques. However, limitations related to cost, access, and certain patient populations necessitate further randomized studies to establish its role as a standard of care.

Keywords: intravascular lithotripsy, calcified coronary lesions, percutaneous coronary intervention, plaque modification,

Glossary of Abbreviations: CVD – cardiovascular diseases; IHD - ischaemic heart disease; PCI – percutaneous coronary interventions; IVL – intravascular lithotripsy; IVUS – intravascular ultrasound; OCT - optical coherence tomography; ISR - in-stent restenosis; MACE - major adverse cardiac events; TVR - target vessel revascularization; CTO - chronic total occlusion; TVMI – target vessel myocardial infraction; ST - stent thrombosis; CCTA – coronary computed tomography angiography

Introduction

According to data published by the World Health Organization (WHO), cardiovascular diseases (CVD) remain the leading cause of death globally, accounting for approximately 17.9 million fatalities annually (*Global Health Estimates*, n.d.). A substantial proportion of these deaths is attributable to ischaemic heart disease (IHD), which primarily results from the formation of atherosclerotic plaques that progressively narrow the arterial lumen and may ultimately lead to complete occlusion of large and medium-sized coronary arteries (Severino et al., 2020).

The aging of the population, combined with the increasing prevalence of comorbidities such as diabetes mellitus, chronic kidney disease, and arterial hypertension, contributes to a rising incidence of advanced and frequently calcified atherosclerotic lesions. These calcifications pose significant technical and clinical challenges during percutaneous coronary interventions (PCI) (M. S. Lee & Shah, 2016).

In response to these difficulties, techniques aimed at modifying calcified plaques are gaining growing attention. Among these, intravascular lithotripsy (IVL) has emerged as a novel and promising method for the effective treatment of coronary calcifications (Cialdella et al., 2023). In recent years, the use of IVL in PCI procedures has expanded rapidly due to its relative ease of application and favorable safety profile, particularly when compared with traditional mechanical atherectomy techniques (Hinton et al., 2024).

The objective of this study is to provide a comprehensive characterization of the intravascular lithotripsy system on the example of the Shockwave C2+, provided by Shockwave Medical Inc., including its structural components and mechanism of action. Furthermore, current indications and contraindications for its use will be discussed in accordance with the recommendations of European and American cardiology societies. A key element of this work will also be the analysis of available evidence concerning the efficacy and clinical safety of IVL in selected medical cases.

System Architecture and Mechanism of Action

The Shockwave intravascular lithotripsy (IVL) system comprises three essential, functional components. The first is a portable, battery-powered generator that produces the electrical energy required to initiate the lithotripsy process. These electrical impulses are transmitted to the system via a connection cable, which terminates in a handheld control interface that allows the operator to manage the procedure in real time.

The central therapeutic component is a single-use balloon catheter, compatible with 6 Fr guide catheters (U.S. Food and Drug Administration, 2021). The catheter is available in diameters ranging from 2.5 mm to 4.0 mm (in 0.25 mm increments), with a standard balloon length of 12 mm (Butt et al., 2025). Integrated within the balloon are two piezoelectric emitters positioned axially and spaced 6 mm apart. These emitters generate short bursts of mechanical energy in the form of acoustic shockwaves. The shockwaves propagate through the fluid filling the balloon and directly impact calcified deposits within the vessel wall, leading to their targeted fragmentation. Accurate device positioning is facilitated by two radiopaque markers located at each end of the balloon, which enable precise localization under fluoroscopic guidance (Neleman et al., 2023).

The IVL catheter is advanced into the target vascular segment over a guidewire and positioned across the calcified atherosclerotic lesion, enabling the directional delivery of shockwave energy to the diseased area. The balloon is filled with a mixture of 0.9% sodium chloride solution and radiographic contrast agent in a 1:1 volume ratio. The presence of ionic content in this mixture is essential for the generation of sparks by the piezoelectric emitters, which in turn trigger the formation of shockwaves. The balloon is then inflated to a subnominal pressure of approximately 4 atmospheres, ensuring adequate apposition to the vessel wall (Butt et al., 2025). This contact promotes efficient transmission of mechanical energy from the shockwaves to the vascular tissue, allowing for effective modification of calcified plaques while minimizing trauma to the surrounding healthy vessel wall.

Acoustic pulses are delivered in cyclical sequences lasting 10 seconds, at a frequency of one pulse per second. The number of therapeutic cycles required, depends on the lesion's characteristics - primarily the degree of calcification and the mechanical resistance of the plaque. Although therapy intensity can be tailored to the anatomical complexity of the lesion, the maximum number of pulses deliverable by a single IVL catheter is limited to 80, corresponding to eight complete treatment cycles. This limitation is dictated by both material safety considerations and the need to preserve optimal clinical efficacy during a single-use intervention (Kereiakes et al., 2021), (Forero & Daemen, 2019)

Indications and advantages of intravascular lithotripsy

Approval for the clinical use of the intravascular lithotripsy (IVL) system in the United States was granted in 2021, following the completion of the Disrupt CAD III trial. Due to the relatively recent introduction of this technique into clinical practice, current guidelines issued by cardiovascular societies do not provide uniform recommendations for its routine application. Instead, they cite selected clinical scenarios in which IVL may serve as a feasible adjunctive modality during percutaneous coronary intervention (PCI).

Fibrotic or heavily calcified atherosclerotic lesions remain a significant challenge in interventional cardiology, as they may hinder optimal stent expansion and thereby increase the risk of procedural and long-term complications. In this context, the use of intravascular imaging modalities such as intravascular ultrasound (IVUS) or optical coherence tomography (OCT) becomes crucial in identifying lesions that require plaque modification - particularly when calcium deposits exceed 500 μm in thickness or involve more than 270° of the vessel circumference. In such cases, the application of dedicated techniques to modify lesion morphology prior to stent deployment is strongly recommended (Barbato et al., 2023).

The guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) include IVL among the available strategies for plaque modification before stent implantation in patients with severely calcified coronary lesions (Lawton et al., 2022). Similarly, the European Society of Cardiology (ESC) recognizes IVL as a potential therapeutic approach in the treatment of in-stent restenosis (ISR), particularly when planning balloon angioplasty or reimplantation of a drug-eluting stent in the affected segment (Vrints et al., 2024). he clinical efficacy of IVL has also been confirmed in isolated studies addressing complex cases of restenosis, including multistratified neointimal hyperplasia within previously deployed stents (Kassab et al., 2022).

Furthermore, expert consensus from the Society for Cardiovascular Angiography & Interventions (SCAI) highlights the utility of IVL in specific anatomical contexts, such as ostial lesions, aorto-ostial locations, and bifurcations requiring the presence of multiple guidewires (Riley, Patel, et al., 2024). The use of IVL has also demonstrated favorable outcomes in the treatment of left main coronary artery disease, offering a lower incidence of procedural complications such as the slow/no-reflow phenomenon, compared to traditional mechanical atherectomy techniques (Riley, Miller, et al., 2024).

An emerging body of evidence supports the potential benefit and safety of combining intravascular lithotripsy with mechanical atherectomy, particularly in the context of long, complex, heavily calcified lesions with heterogeneous morphologic and hemodynamic features. In such cases, a single-modality approach may be insufficient to achieve satisfactory procedural results, thus justifying the use of complementary techniques (Riley, Patel, et al., 2024; Wong et al., 2023).

Contraindications for the use of intravascular lithotripsy

Despite the growing clinical significance of intravascular lithotripsy (IVL) in the treatment of calcified coronary artery disease, its application remains limited by clearly defined contraindications. The IVL system is not intended for use within the carotid or cerebrovascular circulation, owing to the absence of safety data regarding its deployment in these vascular territories. Moreover, the use of IVL in recently implanted stents is not recommended due to the potential risk of structural compromise to the stent scaffold and elastic lamina of the vessel wall - a consideration of particular relevance in patients with a recent history of myocardial infarction (Lawton et al., 2022). It is also important to emphasize that IVL was not designed as a platform for stent delivery, but solely as a preparatory modality for plaque modification prior to stent implantation (*Global Health Estimates*, n.d.). Caution is additionally advised when using IVL in saphenous vein grafts (SVGs) following coronary artery bypass grafting (CABG), as current literature provides only a limited number of case reports and small observational studies assessing the safety and efficacy of this approach in such settings (Vrints et al., 2024). Another safety consideration involves the potential for transient electrical discharges generated during device activation, which may interfere with the function of implanted cardiac devices such as pacemakers (PMs) or implantable cardioverter-defibrillators (ICDs). Consequently, the manufacturer advises heightened vigilance in patients with these devices, particularly in cases where the sensing parameters may render them susceptible to electromagnetic interference (Kassab et al., 2022).

Available clinical data, along with the exclusion criteria employed in major trials such as Disrupt CAD III, indicate that IVL should be employed with particular caution in selected patient populations. These include individuals with a limited life expectancy (less than 12 months), decompensated heart failure corresponding to New York Heart Association (NYHA) functional class III–IV, or advanced renal dysfunction (serum creatinine >2.5 mg/dL or ongoing dialysis therapy). Furthermore, relative contraindications encompass a range of systemic and hematologic conditions, including bleeding diatheses, anemia, active systemic infections, and a history of cerebrovascular events such as ischemic stroke, transient ischemic attack (TIA), or intracranial hemorrhage. The presence of such comorbidities may substantially increase the risk of peri- and post-procedural complications. Therefore, the decision to employ IVL in these clinical contexts should be made on a case-by-case basis, guided by a comprehensive assessment of the anticipated risks and therapeutic benefits (U.S. Food and Drug Administration, 2021), (Hill et al., 2020)

Technical and procedural success

A series of prospective clinical trials - Disrupt CAD I through IV, have yielded consistent evidence supporting the efficacy and safety of intravascular lithotripsy (IVL) in the preparation of heavily calcified coronary lesions for stent implantation. Across all four studies, procedural success was defined as achieving a residual stenosis of less than 50% following stent deployment, without the occurrence of major adverse cardiac events (MACE) during hospitalization. MACE included cardiac death, myocardial infarction (MI), and target vessel revascularization (TVR).

In the pilot study Disrupt CAD I (n = 60), procedural success was achieved in 95% of patients, with a 5% incidence of periprocedural myocardial infarction and no other reported MACE events (Brinton et al., 2019). Disrupt CAD II (n = 120) confirmed the high procedural efficacy, with a success rate of 94.2%, only two minor non-flow-limiting dissections, and a 5.8% incidence of non-Q wave myocardial infarctions (Ali et al., 2019). The largest registry-based study, Disrupt CAD III (n = 431), demonstrated a procedural success rate of 92.4%, with successful stent delivery in 99.2% of cases. The overall incidence of MACE during hospitalization was 7%, including myocardial infarction in 6.8%, TVR in 0.5%, and cardiac death in 0.3%. The rate of intraprocedural complications was only 0.5%, reflecting a favorable safety profile (Hill et al., 2020). Comparable outcomes were reported in Disrupt CAD IV, conducted in a Japanese cohort (n = 64), where procedural success was achieved in 93.8% of cases. MACE occurred in four patients (6.3%), exclusively in the form of non-Q wave myocardial infarctions, with no deaths or need for repeat revascularization (Saito et al., 2021).

Aziz et al. (2020) conducted a retrospective analysis aimed at evaluating the efficacy and safety of intravascular lithotripsy (IVL) in the management of atherosclerotic lesions in the coronary arteries. The study encompassed 190 patients who underwent a total of 200 percutaneous coronary interventions (PCI) using IVL across six centers between 2018 and 2020. Angiographic success was defined as the achievement of TIMI 3 flow and residual stenosis of less than 30% following balloon dilation or stent deployment. This criterion was met in 189 patients, corresponding to a success rate of 99%. The incidence of intraprocedural complications was 3%, including six cases of coronary artery perforation - none of which were directly attributable to the use of IVL. One patient died within two hours of the procedure, resulting in an in-hospital mortality rate of 0.5%. Apart from the perforation events, no other periprocedural complications were reported (Aziz et al., 2021).

In 2022, Jattari et al. published a prospective study designed to assess the feasibility, efficacy, and safety of intravascular lithotripsy (IVL) in the treatment of heavily calcified coronary artery lesions. The analysis included 134 patients who underwent percutaneous coronary intervention (PCI) with the use of IVL across five Belgian centers between 2018 and 2020. The primary endpoint was defined as final procedural success. Optimal procedural efficacy was characterized by the attainment of TIMI 3 flow and residual stenosis ≤30%, without the occurrence of vessel dissection or perforation. Suboptimal outcomes were defined by residual stenosis >30%, TIMI flow <3, and/or the presence of vascular complications.

IVL was utilized for the treatment of de novo lesions in 70.1% of cases and in-stent restenosis (ISR) in 29.9%. Optimal procedural success was achieved in 88.1% of the overall cohort, with suboptimal results observed in 9% of patients. Subgroup analysis demonstrated optimal success in 92.6% of patients with de novo lesions and in 77.5% of those with ISR. Procedural complications were infrequent; rupture of IVL balloons occurred in 13 cases (9.7%), none of which resulted in adverse clinical consequences. One case of arterial dissection was managed with stent implantation, and a single instance of vessel perforation necessitated emergency coronary artery bypass grafting (CABG), which ultimately resulted in patient death (El Jattari et al., 2022).

In 2020, Iwańczyk et al. presented the findings of a study evaluating the efficacy and safety of intravascular lithotripsy (IVL) in a cohort of 46 patients with hemodynamically significant, heavily calcified coronary artery lesions. Technical success was defined as the successful delivery of the IVL balloon to the target lesion, achievement of TIMI 3 coronary flow, and residual stenosis below 30% following stent implantation. These criteria were met in 45 patients (97.8%). Procedural efficacy - defined as the combination of technical success and the absence of major periprocedural complications leading to major adverse cardiovascular events (MACE), such as death, myocardial infarction, or target vessel revascularization, was confirmed in 95.6% of the study population.

During hospitalization, one case of a transient ischemic attack (TIA) was recorded, with no lasting neurological sequelae. Additionally, one coronary artery dissection occurred, necessitating bailout stenting but without further clinical complications. Importantly, no vessel perforations related to IVL use were observed. (Iwańczyk et al., 2021)

In 2021, Øksnes and colleagues published the results of a retrospective analysis evaluating the efficacy and safety of intravascular lithotripsy (IVL) during percutaneous coronary interventions (PCI) in patients with chronic total occlusions (CTO) of the coronary arteries. The study encompassed 55 patients who underwent PCI with IVL applied to CTO lesions across five centers in the United Kingdom and Norway. Definitions of procedural endpoints were based on the CTO-ARC consensus recommendations (Ybarra et al., 2021).

Technical success was defined as achieving TIMI flow grade ≥2 in distal branches of the vessel with a reference diameter ≥2.5 mm and residual stenosis <30% within the CTO segment. This criterion was met in 53 patients (96%). Procedural success - defined as technical success without in-hospital major adverse cardiovascular events (MACE), including death, myocardial infarction, or target vessel revascularization, was achieved in 51 patients (93%).

Reported complications included three cases (5%) of target vessel perforation, one instance of femoral access site bleeding requiring blood transfusion, one case of atrioventricular block necessitating pacemaker implantation, and a single ventricular septal perforation managed with percutaneous coil embolization. (Øksnes et al., 2021)

Clinical outcomes

Based on the findings from the Disrupt CAD I–IV studies, intravascular lithotripsy (IVL) demonstrates a favorable clinical safety profile in the treatment of hemodynamically significant calcified coronary lesions. In the Disrupt CAD I trial, the primary safety endpoint - defined as the absence of major adverse cardiovascular events (MACE) within 30 days, was achieved in

95% of patients. At six months, the total MACE rate reached 8%, primarily due to events deemed unrelated to the IVL procedure (Brinton et al., 2019). Similar results were observed in the Disrupt CAD II trial, where the 30-day MACE rate was 7.6%, comprising non–Q wave myocardial infarctions, in-stent thrombosis, isolated cases of target vessel revascularization, and cardiac death (Ali et al., 2019).

In Disrupt CAD III, which evaluated the 30-day safety endpoint in a cohort of 384 patients, MACE occurred in 7.8% of cases. The majority were myocardial infarctions (7.3%), while cardiac death and target vessel revascularization occurred in 0.5% and 1.6% of patients, respectively (Hill et al., 2020). Long-term follow-up, with a median duration of two years and involving 347 patients from the same cohort, revealed an overall MACE rate of 18.9%, primarily driven by non-Q wave myocardial infarctions (11.3%). Ischemia-driven target lesion revascularization (ID-TLR) was required in 6.4% of cases, and stent thrombosis was observed in 1.4% (Kereiakes et al., 2023). In contrast, the Disrupt CAD IV study, conducted in a Japanese population, reported achievement of the primary safety endpoint in 93.8% of patients. All recorded MACE events were limited to non-Q wave myocardial infarctions occurring during hospitalization, none of which led to further clinical complications (Saito et al., 2021)

In the research undertaken by Aziz and colleagues, in addition to evaluating procedural efficacy and safety, the incidence of major adverse cardiovascular events (MACE) during follow-up was also analyzed. The median duration of follow-up was 222 days. During this period, a total of five MACE events (2.6%) were recorded. These included two cardiovascular deaths (1%) and three cases of target vessel revascularization (TVR, 1.5%), one of which involved a myocardial infarction related to the previously treated segment (TVMI, 0.5%) (Aziz et al., 2021).

Similarly, in the study conducted by Jattari and colleagues, a 30-day follow-up was performed to assess the incidence of major adverse cardiovascular events (MACE), defined as a composite endpoint including all-cause mortality, myocardial infarction, target vessel failure, target vessel revascularization (TVR), stroke, and stent thrombosis. During the observation period, MACE occurred in four patients (3.0%), all of which were fatalities. Two deaths were attributed to cardiovascular causes - one resulted from unsuccessful emergent coronary artery bypass grafting (CABG) following vessel perforation, while the other was due to acute stent thrombosis occurring several hours after completion of the PCI procedure. The remaining two deaths were not directly related to the intervention. No additional major cardiovascular events were recorded during the follow-up period (El Jattari et al., 2022).

Following a 30-day follow-up of patients enrolled in the study conducted by Iwańczyk et al., one major adverse cardiovascular event (MACE) was recorded, corresponding to 2.2% of the study population. This event was a cardiovascular death, most likely related to stent thrombosis. In 32 patients (69.6%), extended follow-up up to six months was possible. During this extended observation period, one additional case of target vessel and lesion revascularization was documented, increasing the cumulative MACE rate to 6.2% (two patients) (Iwańczyk et al., 2021).

By comparison, in the study conducted by Øksnes and colleagues, patients were followed for a longer period, with a median follow-up of 13 months (range: 4–21 months). During this time, two cases of peri-procedural myocardial infarction were observed (4%). In addition, two patients required target vessel revascularization (TVR) due to in-stent restenosis (ISR). No other major adverse cardiovascular events were documented over the course of the follow-up. (Øksnes et al., 2021)

Discussion

Intravascular Lithotripsy (IVL) is a modern technique for modifying calcified atherosclerotic plaques. Its growing popularity stems from the limitations of traditional methods such as cutting balloons, scoring balloons, or atherectomy. Unlike classical mechanical decalcification techniques, IVL utilizes mechanical waves that penetrate tissue and selectively fracture calcifications without damaging the healthy vessel wall. This approach is particularly valuable in clinical situations where calcifications are deep, circumferential, or located in areas that are difficult to access with atherectomy.

In the Disrupt CAD I–IV studies, IVL demonstrated high technical efficacy. Across all study groups, >99% success was achieved in delivering the IVL balloon to the lesion and enabling stent implantation. For example, El Jattari et al. reported successful device delivery in 99.3% of cases and overall procedural success (angioplasty/stent success) in 88.1% of patients (92.6% in de novo lesions; 77.5% in ISR). Similarly, Aziz et al., in a European multicenter registry, observed a 99% procedural success rate with a very low complication rate (3%). This indicates that IVL offers a consistently high stent expansion rate even in heavily calcified lesions, and - unlike ablative techniques, its success is less dependent on operator experience.

Clinical outcomes following IVL have also been favorable, both in the short and long term. Low MACE (Major Adverse Cardiac Events) rates were observed across all studies (Disrupt and observational registries). In the Disrupt CAD III trial, 92.2% of patients were free from MACE at 30 days (MACE = cardiac death, myocardial infarction, or target vessel revascularization [TVR]). In longer follow-up, MACE rates remained consistently low (2-year data from Disrupt III indicated sustained low complication rates). Registry data (e.g., Aziz et al.) support these findings - their patients (median follow-up of 222 days) experienced serious events at low rates (cardiac death 1%, TVMI 0.5%, repeat revascularization 1.5%), resulting in an overall MACE rate of ~2.6%. No significant episodes of acute stent thrombosis were recorded, aside from a single case reported by Jattari et al. (one ST among two deaths). Overall, short-term adverse events (including TVMI) dominate the complications spectrum, while long-term TVR and ST rates remain very low. These outcomes are comparable to or better than those seen with conventional PCI in heavily calcified lesions.

Data from randomized Disrupt CAD trials are consistent with real-world clinical practice outcomes. A pooled analysis of Disrupt CAD I–III showed high procedural success rates (≥92% successful stent implantation) and low 30-day cardiac mortality (<1%). Real-world registries report similar parameters. Even though patients in everyday clinical practice were often older and had more comorbidities (e.g., 50% with diabetes in the Aziz study), procedural success and event profiles remained very similar. This is especially evident in safety assessments - 93% of procedures in Disrupt CAD III were free of in-hospital MACE, and only 2.6% of patients in the European registry experienced a composite event over a median of 7 months. Differences appear primarily in more specialized subgroups: IVL is clearly less effective in treating ostial lesions or highly fibrotic in-stent restenosis (ISR), with procedural success rates of ~77-80% compared to ~92-95% in de novo lesions. This underscores that while IVL has been primarily studied in de novo lesions, its real-world effectiveness also extends to complex patient cohorts, with ISR remaining one of the key challenges.

Cardiology society guidelines clearly emphasize the need for lesion preparation before stent implantation. According to the 2023 EAPCI/Euro4C consensus, any significant calcification should be pre-assessed using imaging (IVUS/OCT or CCTA) and appropriately modified using specialized techniques. IVL (or ablation) is indicated when standard balloon predilatation fails in moderately or severely calcified lesions. If the lesion cannot be crossed even with a standard wire, rotational atherectomy is recommended. If the balloon can cross but fails to adequately expand the lesion, IVL is considered either as an alternative or adjunct to other methods. Similarly, U.S. guidelines and expert consensus (SCAI) highlight an algorithmic approach to calcification, where IVL is one of the tools to "crack" calcium and enable optimal stent expansion. Both the European and American perspectives regard IVL as a safe and effective adjunctive technique, though they do not recommend it as a standalone solution.

The limitations of IVL should also be discussed. Most importantly, the procedure requires catheter access - extremely tight or highly tortuous lesions may need pre-treatment with rotational atherectomy to achieve passage. As shown in data from Jattari et al., IVL's efficacy in ISR is limited (success rate ~77.5%), possibly due to the different nature of the tissue (dense scarring, fibrosis). Technically, the IVL balloon can rupture if misused (e.g., overinflation beyond recommendations), which - though rare - has been reported in cases of type E dissections or balloon fragmentation (T. J. Lee et al., 2021). Clinically, IVL has not yet been sufficiently studied in certain populations (e.g., patients with acute STEMI, massive atherosclerosis, or invasive coronary revascularization in oncology). Existing studies also lack continuous two-year follow-up data in specific populations (e.g., severe renal failure, related procedures on femoral vessels, etc.). Cost and equipment availability must also be considered. In summary, although IVL significantly expands interventional options for calcified lesions, it should be used as part of a broader treatment algorithm, taking into account its technical limitations and the clinical context of the patient.

Conclusions

1. Intravascular lithotripsy (IVL) is a highly effective method for modifying calcified coronary lesions. Clinical trial data clearly confirm its ability to improve vessel preparation for stent implantation, achieving procedural success rates exceeding 90%.
2. IVL is characterized by a very favorable safety profile. In the Disrupt CAD studies, the incidence of serious intraprocedural complications (such as perforations or dissections) was low and often comparable to, or even lower than, that observed with other calcium modification techniques.
3. The clinical efficacy of IVL is sustained in both mid- and long-term follow-up, as evidenced by the 2-year outcomes from the Disrupt CAD III trial, which showed low rates of cardiac death, revascularization, and target vessel myocardial infarction (TV-MI).
4. IVL is applicable not only in classic de novo lesions, but also in challenging cases such as in-stent restenosis (ISR), chronic total occlusions (CTO), and ostial lesions, where other methods often fail or carry higher risk.
5. Despite its high efficacy, further research - ideally randomized controlled trials - is necessary to definitively establish IVL’s superiority over other techniques and confirm the durability of its therapeutic effects in the general population.

6. Cost and availability remain limiting factors for IVL, making optimal patient selection essential to ensure the rational and effective use of this technology.

Disclosure:

Author's contribution:

Author's contribution: Conceptualization: Piotr Jóźwiak, Maria Wysieńska; Methodology: Adam Rybak, Weronika Biaduń, Kinga Rogowska; Software: Adam Rybak, Aleksandra Romanowska, Paweł Arkadiusz Malmur, Maria Wysieńska; Check: Piotr Jóźwiak, Weronika Biaduń; Formal analysis: Adam Rybak, Kinga Rogowska; Investigation: Maria Wysieńska, Paweł Arkadiusz Malmur, Aleksandra Romanowska, Piotr Jóźwiak; Resources: Maria Wysieńska; Data curation: Piotr Jóźwiak, Maria Wysieńska; Writing - rough preparation: Piotr Jóźwiak, Maria Wysieńska, Adam Rybak; Writing - review and editing: Kinga Rogowska, Weronika Biaduń, Aleksandra Romanowska; Visualization: Paweł Arkadiusz Malmur, Kinga Rogowska; Supervision: Maria Wysieńska; Project administration: Adam Rybak, Piotr Jóźwiak, Aleksandra Romanowska, Weronika Biaduń.

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