

The emergence of coronary intravascular lithotripsy

El auge de la litotricia intravascular coronaria

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ABSTRACT

The presence of coronary artery calcification is an independent predictor of poor procedural outcomes. Several techniques, such as cutting or scoring balloons, rotational and orbital atherectomy devices, and excimer laser, are available for plaque modification in the modern catheterization laboratories; however, their use has been associated with increased risk of complications such as vessel dissection, slow or no flow, perforation, or occlusion. Lately, intravascular lithotripsy (IVL) has emerged as a safe and effective tool for the treatment of severely calcified coronary lesions. IVL utilizes spark-gap technology to transform electrical energy to mechanical energy, generating acoustic shock waves that travel transmurally and circumferentially, inducing a therapeutic field effect, and selectively causing fracture of superficial and deep vascular calcium, which is essential for optimal stent expansion. The purpose of this article is to review the mechanism of this novel technology and summarize the pertinent studies leading to its regulatory approvals.

Keywords: intravascular lithotripsy, coronary calcification, atherectomy.

RESUMEN

La presencia de calcificación en las arterias coronarias es un predictor independiente de malos resultados operatorios. En la actualidad, en las modernas salas de hemodinamia, existen diferentes técnicas de modificación de la placa tales como balones de corte o *scoring balloon*, dispositivos de atherectomía orbital y rotacional y el láser Excimer. No obstante, su uso se asocia a un mayor riesgo de complicaciones tales como disecciones del vaso, flujos lentos o fenómenos de *no-reflow*, perforaciones u oclusiones. Últimamente ha aparecido la litotricia intravascular (LIV) como una herramienta segura y efectiva para el tratamiento de lesiones coronarias fuertemente calcificadas. La LIV emplea una tecnología basada en la producción de una chispa eléctrica que transforma la energía eléctrica en energía mecánica generando ondas de choques que viajan transmural y circumferencialmente induciendo un efecto de campo terapéutico que provoca, a nivel selectivo, la fractura del calcio vascular superficial y profundo, algo clave para una expansión óptima del stent. El propósito de este artículo es revisar el mecanismo de esta nueva tecnología y resumir los estudios pertinentes que han hecho que esta tecnología haya sido aprobada por diferentes agencias reguladoras.

Palabras clave: litotricia intravascular, calcificación coronaria, atherectomía.

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INTRODUCTION

The management of coronary artery calcium has been challenging since the inception of percutaneous coronary intervention (PCI). It is one of the strongest markers for the presence of coronary artery disease (CAD) and has been extensively studied since the 1990s.^{1,2} It is encountered in about one-third of cases and is often underdiagnosed with routine coronary angiography.³ Further, moderate to severe coronary calcification is an independent predictor of poor procedural outcomes and increased ischemic target lesion revascularization (TLR) at 1 year.⁴ It not only impedes stent delivery and expansion but could damage the polymer or drug coating resulting in increased risk of stent thrombosis.⁵ Stent underexpansion is considered a strong predictor of future adverse events such as stent thrombosis and restenosis.⁶ Thus, proper lesion preparation with the use of ablative techniques is strongly recommen-

ded for plaque modification and optimal stent implantation.^{7,8} However, the use of these techniques comes at the expense of increased risk of complications such as vessel dissection, slow or no flow, perforation, or occlusion.^{9,10} While cutting or scoring balloons lack robust trial data and may be biased toward noncalcified segments of the artery leading to dissection, rotational and orbital atherectomy-mediated calcium modification may be limited by guidewire bias.^{11,12} Lately, intravascular lithotripsy (IVL; Shockwave Medical Inc., Santa Clara, California, USA) has emerged as a promising technique for the treatment of severely calcified coronary lesions. It works on the principle of generating shock waves (acoustic or pressure waves) that traverse through a medium with peak positive and negative pressure phases, causing tensile stress, shear forces, and cavitation, which modifies calcified plaque.¹³ It is a novel technique derived from established extracorporeal shockwave lithotripsy (ESWL) treatment for nephrolithiasis. The technique has been streamlined for the coronaries by arranging multiple emitters in a series along the shaft of the coronary balloon to deliver adequate compressive force for calcium modification while mitigating vascular parenchymal injury.¹⁴ It offers unique advantages, including no requirement for specific training in comparison to conventional atherectomy devices. Also, IVL eliminates guidewire bias as seen with other ablative techniques.

INTRAVASCULAR LITHOTRIPSY SYSTEM

The IVL system consists of a rechargeable and portable generator, a connector cable with a push button for activation, and a catheter available in both over-the-wi-

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re and rapid exchange systems that is advanced over a 0.014-inch wire. The sterile, disposable, single-use catheter is available in 2.5- to 4.0-mm range diameters (0.5-mm increments) and is 12 mm in length. The device is default preset to deliver approximately 10 pulses in a sequence, at a frequency of 1 pulse per second for a maximum of 80 pulses per catheter.¹⁵ The distal end of the catheter system has a novel semi-compliant balloon containing a 50:50 mixture of contrast and fluid and incorporates multiple arrayed lithotripsy emitters in a longitudinal manner. The balloon is sized in a 1:1 ratio to the reference coronary vessel, often guided with the use of intracoronary imaging. Once electrically stimulated, the emitters vaporize the fluid within the balloon, creating shock waves in a circumferential fashion, generating a therapeutic field effect, which selectively fractures superficial and deep vascular calcium.¹⁵ The balloon inflation is restricted to 4 atm to limit the barotrauma while the fluid within the balloon mitigates the thermal injury, keeping the underlying vessel architecture unperturbed. After the delivery of therapy, the balloon is inflated to 6 atm prior to deflation. As the energy is delivered in a circumferential and unfocused manner, the pressure effect reduces with the distance traveled. The pulse duration of these waves is 0.6 - 1.2 μ s, delivered at frequency of 1 pulse/s (1 Hz), and produces low amounts of energy (8 - 10 μ J) without introducing electrical components into the localized tissue.¹⁴

Figure 1 represents a case example of calcium modification by the use of IVL. The severely calcified lesion in the left anterior descending artery was identified on angiography and confirmed via optical coherence tomography (OCT) imaging (luminal area 1.18 mm²). There was a significant luminal gain post IVL (4.29 mm²) with multiple calcium fractures and optimal stent expansion (luminal area 5.60 mm²).

THE USE OF IVL IN CAD

Disrupt CAD I (Shockwave Coronary Rx Lithoplasty® Study) was the initial study testing the feasibility of IVL in CAD patients.¹⁵ It was a prospective, multicenter, single-arm pilot study of 60 patients with ≥ 1 heavily calcified lesion on both sides of the vessel wall. The primary outcome was major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction (MI), or target vessel revascularization (TVR). The study reported a procedural success rate of 95% facilitating the delivery of stents in all patients. The primary endpoint was observed in 8.3% at 30 days, and there was no unresolved dissection, slow/no flow, embolization, or perforations.¹⁵ The OCT substudy identified intraplaque calcium fracture in 43% of lesions; mean acute area gain was 2.1 mm² and minimal stent area was 5.94 ± 1.98 mm².¹⁶ It also revealed the distinct mechanism of IVL causing circumferential calcium modification independent of calcium thickness in contrast to the guidewire-dependent course of rotational and orbital atherectomy devices.¹⁶ Also, the number of calcium fractures was proportional to the severity of vascular calcification. On the basis of this study, IVL was granted CE mark approval for the treatment of severely calcified coronary lesions.

Following this, Disrupt CAD II (Shockwave Coronary Lithoplasty® Study) was conducted on 120 patients to evaluate safety and efficacy of IVL. The primary endpoint of MACE (cardiac death, MI, or TVR) was observed in 5.8% of patients, including 7 non-Q-wave MIs.¹⁷ The post-IVL acute lumen gain was 0.83 ± 0.47 mm, and residual stenosis of $7.8 \pm 7.1\%$ after stent deployment confirmed the effectiveness of IVL in optimal stent expansion.¹⁷ The OCT substudy identified calcium fracture in 78.7% of lesions, with multiple fracture in more than half of lesions and approximately 3.4 ± 2.6 fractures per lesion, results consistent with the Disrupt CAD I. Disrupt CAD II showed successful delivery of IVL across all the lesions with no concerns of slow or no reflow, abrupt closure, or perforations during the procedure. Disrupt CAD III (Disrupt CAD III With the Shockwave Coronary IVL System) was a US Food and Drug Administration (FDA) Investigational Device Exemption (IDE) study designed for possible regulatory approval of coronary IVL. It was comparatively a larger study that enrolled 384 patients who had severely calcified de-novo coronary artery lesions and used an intention-to-treat analysis. The primary safety endpoint of freedom from MACE (a composite of cardiac death, MI, and TVR) occurred in 92.2% patients, and the primary effectiveness endpoint of procedural success (successful stent deployment with $<50\%$ residual stenosis without in-hospital MACE) was achieved in 92.4% patients.¹⁸ The OCT substudy included 100 patients and confirmed severe calcification of vascular lesions, with calcium angle of 292.5 ± 76.5 degrees and calcium thickness of 0.96 ± 0.25 mm at the site of maximum calcification. Calcium fractures were observed circumferentially and longitudinally in 67.4% patients, with multiple fractures in 67.7% of patients with fractures. Minimal stent area, area stenosis, and stent expansion were comparable via OCT irrespective of presence or absence of calcium fractures. Overall, the study successfully achieved safety and effectiveness endpoints with low rates of peri-procedural and angiographic complications, leading to FDA approval on February 12, 2021.

Disrupt CAD IV (Disrupt CAD IV With the Shockwave Coronary IVL System) was a prospective, multicenter study that enrolled 64 patients with similar eligibility criteria to Disrupt CAD III and was designed to assess the safety and effectiveness of coronary IVL for Japanese regulatory approval. These patients were compared to a propensity-score-matched subgroup of Disrupt CAD III patients for primary endpoints, which served as the control group (IVL control) for Disrupt CAD IV. The primary endpoint of freedom from 30-day MACE (cardiac death, MI, or TLR) was accomplished in 93.8% of IVL patients vs. 91.2% of control ($p=0.008$), and the primary effectiveness endpoint of procedural success was achieved in 93.8% of IVL patients vs. 91.6% of control ($p=0.007$). Consistent with prior studies, no perforations, abrupt closures, or slow or no-reflow phenomena occurred during the procedures.¹⁹ An OCT analysis showed that calcium fractures were observed in 53.5%, with multiple fractures in 60.5% of patients with fractures. The mean acute gain was 1.42 ± 0.42 mm and minimal stent area was 5.65 ± 1.45 mm².

Recently, a patient-level pooled analysis of all 4 trials ($n=628$) reported that the primary safety outcome

TABLE 1. Coronary intravascular lithotripsy study details.

Studies	Disrupt CAD I	Disrupt CAD II	Disrupt CAD III	Disrupt CAD IV
Study Aim	Feasibility testing	Safety and effectiveness	Regulatory approval	Japanese regulatory approval
Identifier	NCT02650128	NCT03328949	NCT03595176	NCT04151628
Number of patients enrolled (n)	60	120	384	64
Number of sites	7	15	47	8
Primary endpoint	MACE as a composite of cardiac death, MI, or TVR.	MACE as a composite of cardiac death, MI, or TVR.	MACE as a composite of cardiac death, MI, or TVR.	MACE as a composite of cardiac death, MI, or TVR
Criterios de inclusión	<ul style="list-style-type: none"> • Patients with moderate to severely calcified de novo coronary artery disease presenting with stable or unstable angina and silent ischemia with: • $\geq 50\%$ stenosis • Lesion length ≤ 32 mm • RVD 2.5-4.0 mm 	<ul style="list-style-type: none"> • Patients with moderate to severely calcified de novo coronary artery disease presenting with stable or unstable angina and silent ischemia with: • $\geq 50\%$ stenosis • Lesion length ≤ 32 mm • RVD 2.5-4.0 mm 	<ul style="list-style-type: none"> • Patients with moderate to severely calcified de novo coronary artery disease presenting with stable or unstable angina and silent ischemia with: $\geq 70\%$ to $<100\%$ stenosis or Visually assessed $\geq 50\%$ to 70% stenosis with evidence of positive stress test, or FFR ≤ 0.80, or iFR < 0.90 or IVUS or OCT MLA ≤ 4.0 mm² Lesion length ≤ 32 mm RVD 2.5-4.0 mm 	<ul style="list-style-type: none"> • Patients with moderate to severely calcified de novo coronary artery disease presenting with stable or unstable angina and silent ischemia with: $\geq 70\%$ to $<100\%$ stenosis or visually assessed $\geq 50\%$ to 70% stenosis with evidence of positive stress test, or FFR ≤ 0.80, or iFR < 0.90 or IVUS or OCT MLA ≤ 4.0 mm² Lesion length ≤ 32 mm RVD 2.5-4.0 mm
Key exclusion criteria	<ul style="list-style-type: none"> Concomitant use of atherectomy, special balloons LVEF $< 40\%$ BP $> 180/110$ mmHg Acute MI Cardiogenic shock NYHA class III and IV Target vessel diameter < 2.4 mm Target lesion length > 32 mm Unprotected LM $> 50\%$ stenosis CTO 	<ul style="list-style-type: none"> Concomitant use of atherectomy, special balloons LVEF $< 40\%$ BP $> 180/110$ mmHg Acute MI Cardiogenic shock NYHA class III and IV Target vessel diameter < 2.4 mm Target lesion length > 32 mm Unprotected LM $> 50\%$ stenosis CTO 	<ul style="list-style-type: none"> Concomitant use of atherectomy, special balloons LVEF $< 25\%$ BP $> 180/110$ mmHg Acute MI Cardiogenic shock NYHA class III and IV Target vessel diameter < 2.4 mm Target lesion length > 32 mm Unprotected LM $> 30\%$ stenosis CTO 	<ul style="list-style-type: none"> Concomitant use of atherectomy, special balloons LVEF $< 25\%$ BP $> 180/110$ mmHg Acute MI Cardiogenic shock NYHA class III and IV Target vessel diameter < 2.4 mm Target lesion length > 32 mm Unprotected LM $> 30\%$ stenosis CTO
Target vessels	LM: 2% LAD: 47% LCx: 13% RCA: 38%	LM: 0,8% LAD: 62,5% LCx: 11,7% RCA: 25%	LM: 1,6% LAD: 56,5% LCx: 12,8% RCA: 29,2%	LM: 1,6% LAD: 75% LCx: 6,3% RCA: 17,2%
MACE at 30 days	5%	7,6%	7,8%	6,2%
Acute gain (mean)	1,7 \pm 0,4 mm	1,6 \pm 0,49 mm	1,7 \pm 0,48 mm	1,42 \pm 0,42 mm
Dissection	0%	1,7%	0,3%	0%
Perforation	0%	0%	0,3%	0%
Abrupt closure	0%	0%	0,3%	0%
No flow or slow flow	0%	0%	0%	0%
Stent delivery	100%	100%	99,2%	100%

FFR: fractional flow reserve, iFR: instantaneous wave free ratio, IVUS: intravascular ultrasound, OCT: optical coherence tomography, MLA: minimum lumen area, MACE: major adverse cardiac events, LM: left main, LAD: left anterior descending artery, LCx: left circumflex artery, RCA: right coronary artery, RVD: reference vessel diameter, CTO: chronic total occlusion, MI: myocardial infarction, TVR: target vessel revascularization, BP: blood pressure, LVEF: left ventricular ejection fraction, NYHA: New York Heart Association, IVL: intravascular lithotripsy.

was accomplished in 92.7% of patients, and the primary effectiveness outcome was achieved in 92.4% of patients.²⁰ The target lesion failure rate was 7.2%, cardiac death was 0.5%, and stent thrombosis was 0.8% at 30 days. There were lower rates of angiographic complications with no perforation, abrupt closure, or no reflow.²⁰ Although all the studies (summarized in **Table 1**) were prospective and multicentered, still the major concerns were the absence of a control arm and possibility of proceduralist preferences for the selective cases suited for IVL. Also, long term data would provide more insight into later procedural complications, such as in-stent restenosis. Further, we do not know whether some of these lesions were compatible with high-pressure balloons to begin with. It would be reasonable to conduct further studies with a control arm (preferably rotational or orbital atherectomy) and the use of intracoro-

nary imaging to better define calcium lesions better suited for IVL compared to other ablative techniques, especially given the higher cost associated with it. Moreover, the data regarding the effect of IVL on nodular and eccentric calcium remain limited. A patient-level pooled analysis of the Disrupt CAD I and II trials (n=180) with 47 eccentric lesions (26%) showed comparable angiographic outcomes and complications between the eccentric and concentric lesion groups (21). While the preliminary data appear promising, it would be interesting to see whether further studies provide consistent results regarding the role of IVL in the treatment of nodular calcification. Further, randomized clinical trials are warranted to validate the superiority or non-inferiority of IVL against other atherectomy devices or high non-compliant pressure balloon angioplasty.

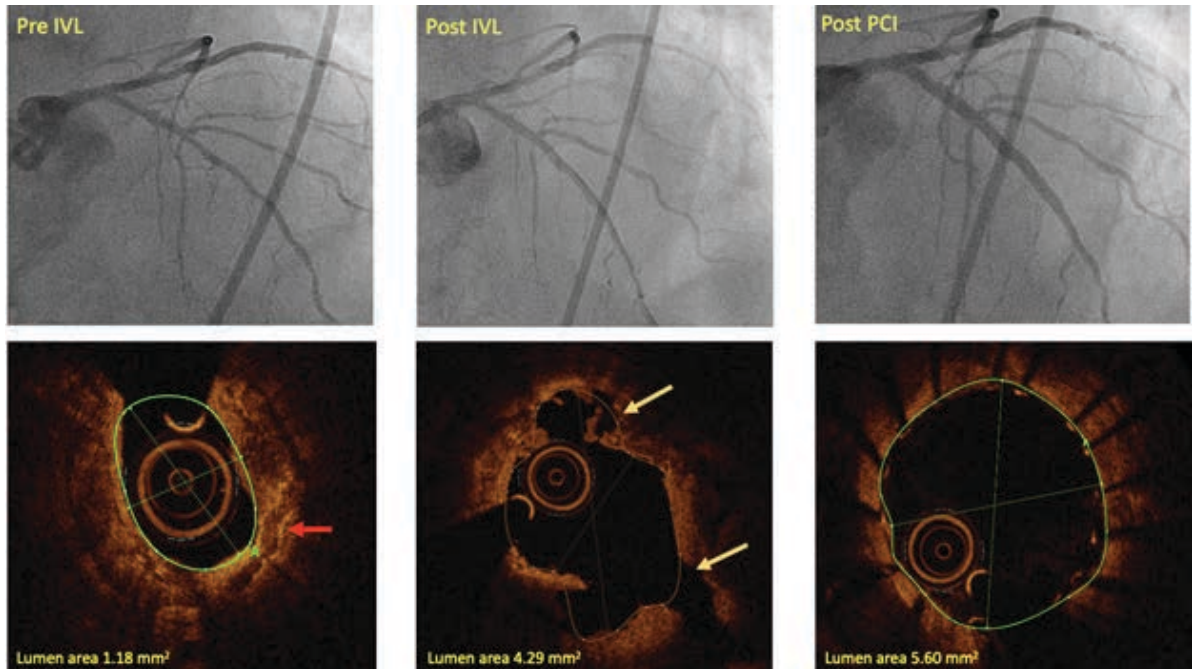


Figure 1. A case example with angiographic images (pre-IVL, post-IVL, and post-PCI) and corresponding OCT images showing severe calcification (red arrow, pre IVL), fractured calcium at 1 and 4 o'clock post-IVL therapy (yellow arrows), and post-PCI images showing optimal stent expansion. OCT: optical coherence tomography; IVL: intravascular lithotripsy; PCI: percutaneous coronary intervention.

IVL EFFECT ON CARDIAC ELECTRICAL ACTIVITY

One major concern regarding coronary IVL is its effect on cardiac rhythm, as was already evident in the past, even with ESWL(22). IVL's pulsatile shock waves can cause localized myocardial depolarization, resulting in an isolated ventricular ectopic ("shocktopics") or asynchronous cardiac pacing (≥ 2 successive beats)(23). A retrospective study of 54 patients found a higher incidence (77.8%) of ventricular capture, with heart rate being an independent predictor and 16-fold increased likelihood of IVL-induced myocardial capture with heart rate < 65 beats per min(23). It was further evaluated systematically in Disrupt CAD III, and the use of IVL was found to be safe, without increased risk of sustained ventricular arrhythmias. The study found the incidence of IVL-induced capture was

41.1% and male sex, total number of IVL pulses delivered, and heart rate ≤ 60 beats per min were independent predictors(18). The drop in systolic blood pressure was comparable between the IVL-capture versus no-IVL-capture groups. Taken together, although there is a theoretical risk of potential arrhythmias with IVL, no malignant arrhythmias have been reported so far, further solidifying its safety.

CONCLUSION

Coronary IVL is a novel technique, emerging as a safe and effective alternative for the treatment of moderate to severely calcified coronary lesions. However, further studies, preferably with a control group, are warranted to better define the calcified lesions best suited for IVL compared to other techniques.

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