SHOCKWAVE | IVL

ROLLING-STONE REGISTRY

The largest prospective multi-center registry comparing the performace of IVL versus atherectomy (AT) in a real-world, all-comers population

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Adapted from: Cerrato, E. (2025, March). Intravascular Lithotripsy And/Or Mechanical Debulking Multicenter Registry For The Treatment Of Complex Calcified Coronary Arteries: Rolling Stone Registry. Cardiovascular Research Technologies (CRT) 2025.

What is the ROLLING-STONE Registry?

ROLLING-STONE compared the procedural success, intraprocedural complications and 30 day and 1 year MACE rates after propensity score matching (PSM) of IVL versus rotational atherectomy (RA) and orbital atherectomy (OA)

Why this Registry Matters?

ROLLING-STONE is the largest, prospective registry (N = 1,005) including IVL, RA and OA with a head-to-head comparison after PSM

Trial Design

Prospective, multi-center, all-comers registry of 1,005 patients with moderate-severe calcification treated with atherectomy or IVL from 23 Italian institutions

Safety Endpoints*

Freedom from MACE at 30 days and 1 year after PSM and Inverse Probability Weighting (IPW)

*Core-lab adjudicated

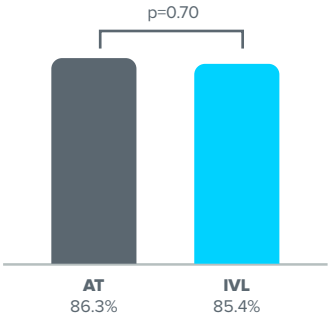
Primary Efficacy Endpoint*

Procedural Success: stent delivery with residual stenosis <30% and absence of in-hospital MACE

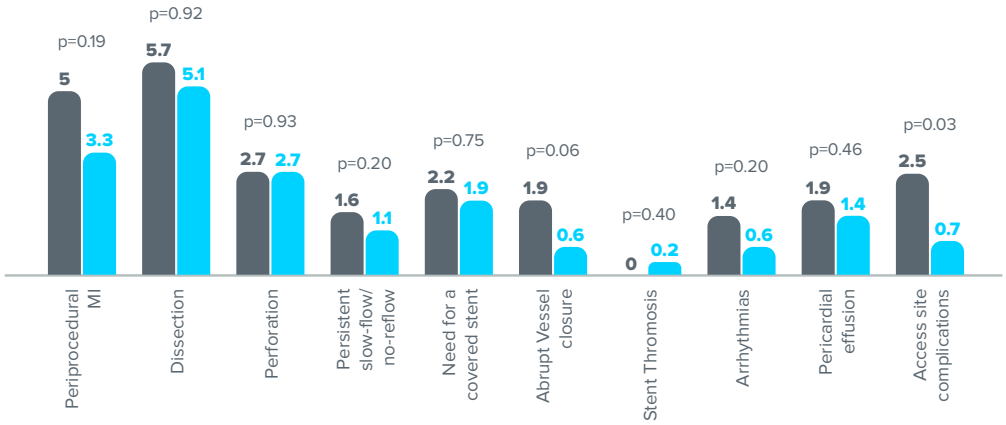
*Core-lab adjudicated

IVL DEMONSTRATES SIMILAR PROCEDURAL SUCCESS WITH NUMERICALLY FAVORABLE INTRAPROCEDURAL COMPLICATIONS AS COMPARED TO ATHERECTOMY

PROCEDURAL SUCCESS

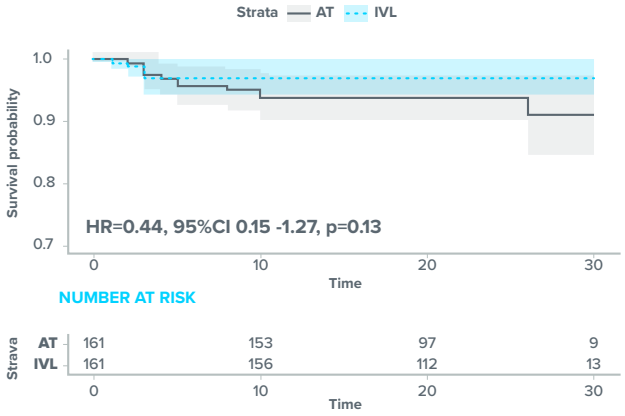


INTRAPROCEDURAL COMPLICATIONS

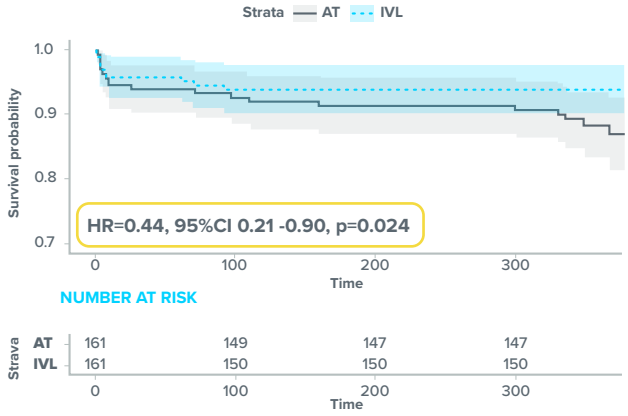


IVL DEMONSTRATES A FAVORABLE 30-DAY MACE AND STATISTICALLY SIGNIFICANT LOWER 1-YEAR MACE AFTER PSM AS COMPARED TO ATHERECTOMY

MACE AT 30 DAYS AFTER PSM



MACE AT 1 YEAR AFTER PSM



ROLLING-STONE adds head-to-head evidence demonstrating IVL's first-in-class safety and supports IVL's utility as front line calcium modification strategy when required

An educational grant was provided by Shockwave Medical for the Rolling-Stone Registry.

Coronary Safety Information

In the United States: Rx only. Indications for Use— The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2+ Coronary IVL Catheter is indicated for lithotripsy enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting. **Contraindications—** The Shockwave C2+ Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries. **Warnings—** Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy. **Precautions—** Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target. **Potential adverse effects consistent with standard based cardiac interventions include–** Abrupt vessel closure - Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion Cardiopulmonary arrest-Cerebrovascular accident (CVA)- Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or nonemergency coronary artery bypass surgery-Emergency or nonemergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention Hematoma at the vascular access site(s)-HemorrhageHypertension/Hypotension-Infection/sepsis/fever-Myocardial Infarction-Myocardial Ischemia or unstable angina-Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke-Thrombus Vessel closure, abrupt-Vessel injury requiring surgical repair Vessel dissection, perforation, rupture, or spasm. **Risks identified as related to the device(s) and its use:** Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture. **Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events. www.shockwavemedical.com/IFU.** Please contact your local Shockwave representative for specific country availability.

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