SHOCKWAVE | IVL

ROLLING-STONE REGISTRY

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

Enrico Cerrato and the ROLLING-STONE investigators

Adapted from: Cerrato et al. Intravascular Lithotripsy or Mechanical Debulking in Complex Calcified Coronary Arteries: Multicenter, Prospective ROLLING-STONE Study. J Am Coll Cardiol Intv. 2026

WHAT

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

WHY

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

The ROLLING-STONE registry prospectively enrolled patients treated with Shockwave IVL and/or atherectomy across 23 Italian centers

1,005	23	56%	25%	23%
Patients	Italian Centers	Acute Coronary Syndrome	CTO	Left Main Disease

SAFETY ENDPOINTS*

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

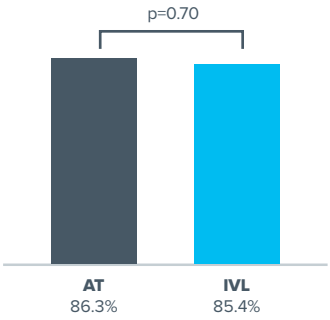
PRIMARY EFFICACY ENDPOINT

Procedural success: residual stenosis <30% and absence of in-hospital major adverse cardiac events MACE

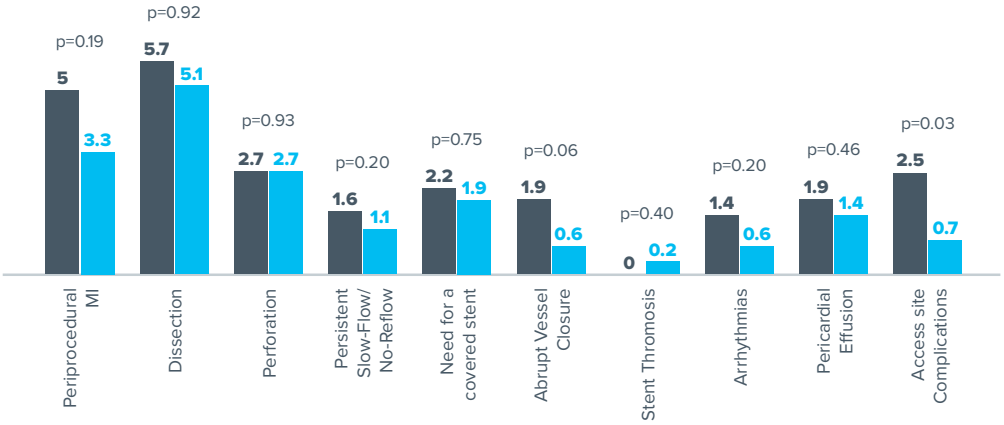
*Core-lab adjudicated

SHOCKWAVE IVL: PROVEN PROCEDURAL SUCCESS WITH FAVORABLE INTRAPROCEDURAL SAFETY VS ATHERECTOMY

PROCEDURAL SUCCESS



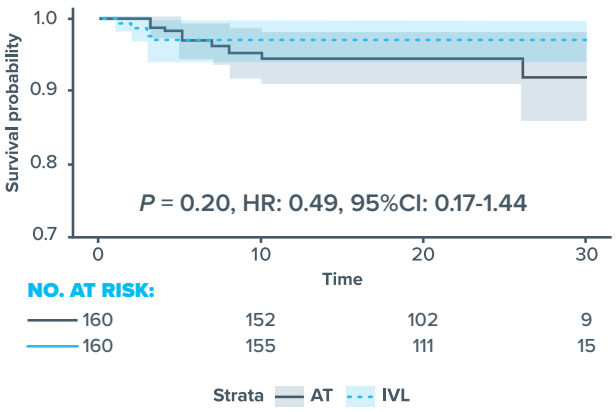
INTRAPROCEDURAL COMPLICATIONS



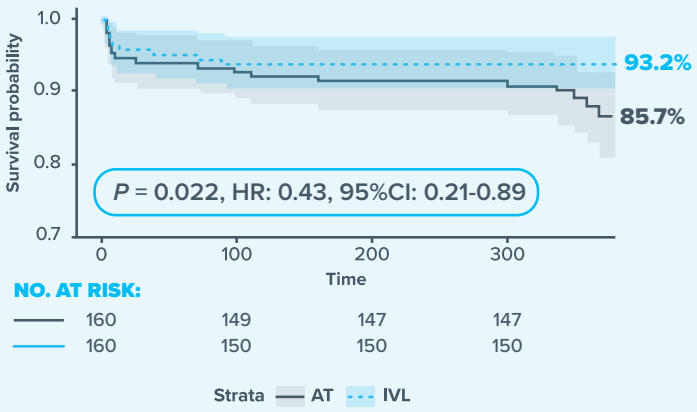
SHOCKWAVE IVL SHOWS FAVORABLE EARLY OUTCOMES, SIGNIFICANTLY LOWER 1-YEAR MACE VS ATHERECTOMY

SAFETY ENDPOINTS IN PROPENSITY MATCHED COHORT (N=320)

MACE AT 30 DAYS AFTER PSM



MACE AT 1 YEAR AFTER PSM



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

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

Shockwave C2, Shockwave C2+, and Shockwave C2 Aero Safety Information Indications for Use— The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2, Shockwave C2+, and Shockwave C2 Aero Coronary IVL Catheters is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting. **Contraindications—** The Shockwave C2, Shockwave C2+, and Shockwave C2 Aero Coronary IVL Systems are contraindicated for the following: These devices rea not intended for stent delivery. These devices are 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 5 mm of target lesion IVL pulses may potentially interfere with certain implanted electrical devices (e.g., ventricular support systems). **Cautions—** Shockwave C2 and Shockwave C2+ should not be re-inserted once they are pulled out of the patient's body. Shockwave C2 Aero may be re-inserted up to 3 times in the same patient when used in accordance with the IFU. **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 non- emergency coronary artery bypass surgery-Emergency or non- emergency 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)-Hemorrhage- Hypertension/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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