

**DISRUPT
CAD III**

**MAKING
BIG WAVES
IN COMPLEX CALCIUM**

**Largest and
Most Rigorous
Shockwave Study**

SHOWCASES SAFETY, EFFECTIVENESS & EASE OF USE OF CORONARY IVL

CAD III By The Numbers

384

Patients at
47 Sites

100%

Severe Ca++

47.9mm

Calcium Length

98%

IVL Crossing &
Therapy Delivery

99%

Stent Delivery

0.3%

Final Major
Dissections

0.3%

Final Perforations

0.3%

Abrupt Closure

0%

Slow Flow/
No Reflow

11.9%

Residual
Stenosis

1.7 mm

Acute Gain

Presented at TCT Connect and Simultaneously Published in JACC: J. Hill, D. Kereiakes, et al. "Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease: The Disrupt CAD III Study." JACC 2020.

Key Findings

CAD III confirms IVL safety with low rates of major peri-procedural clinical and angiographic complications, setting a new bar for safety in complex coronary lesions.

- 92.2% of patients were free from MACE at 30 days, a composite of CD (0.5%), MI (7.3%), or TVR (1.6%)
 - Primary MACE driver was in-hospital non-Q-wave MI (5.7%)
- Low risk of perforation (0.3%), major dissection (0.3%), abrupt closure (0.3%), and slow flow/no reflow (0.0%) at the end of procedure

CAD III showcases IVL effectiveness with large lumen gains that facilitate stent delivery and optimize stent expansion.

- 92.4% procedural success rate, defined as successful stent delivery (99%) residual stenosis <50% (100%), & without in-hospital MACE (93%)
- Successful IVL crossing & therapy delivery in 98% of lesions, correlating to 99% stent delivery
- 1.7mm acute gain and 11.9% final in-stent residual stenosis

CAD III demonstrated Coronary IVL's ease of use and quick learning curve to achieve consistently predictable outcomes.

- Despite >80% of operators having no prior experience with IVL, MACE, procedural success and device crossing success were similar between first roll-in first case and pivotal cohort



DISRUPT CAD III Design & Patient Demographics

Stable angina, unstable angina or silent ischemia



Heavily calcified, de novo coronary lesions
RVD 2.5 – 4.0 mm, stenosis ≥50%,
Lesion length ≤40 mm

Objective: Prospective, multicenter, single-arm global IDE to evaluate the safety and effectiveness of coronary IVL

Primary Safety Endpoint: Freedom from MACE at 30 days

- Cardiac death, Myocardial infarction, or Target vessel revascularization

Primary Effectiveness Endpoint: Procedural success

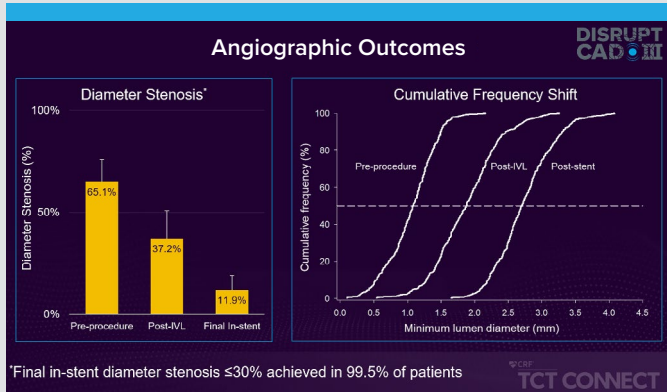
- Successful stent delivery with residual stenosis <50% and without in-hospital MACE

Secondary Performance Endpoints: Clinical and Angiographic Success

Baseline Characteristics:

71 yo	65% DS	57% LAD, 13% LCX, 29% RCA, 1% LM
40% DM	48mm Ca++ length	292 Ca++Arc @ Max Ca++ Site
3.0mm RVD	25mm Lesion Length	.96mm Thick Ca++ @ Max Ca++ Site

Large Circumferential Lumen Gains to Facilitate Stent Delivery, Apposition & Expansion

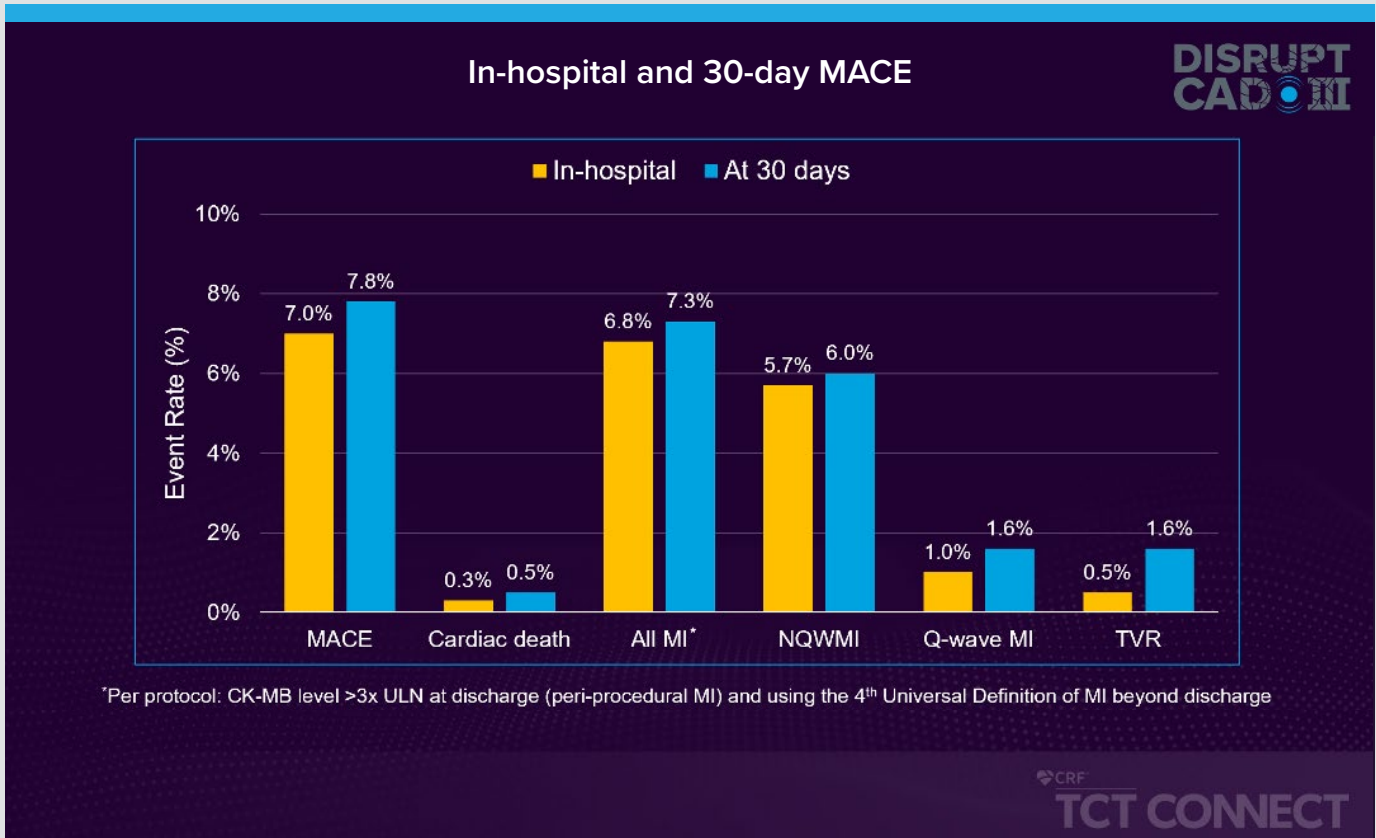


Low Rates of Complications, Similar to DISRUPT CAD I & II

Angiographic Complications

Core Lab Analysis	Immediately Post-IVL	Final
Any serious angiographic complication	2.6%	0.5%
Severe dissection (Type D-F)	2.1%	0.3%
Perforation	0.0%	0.3%
Abrupt closure	0.0%	0.3%
Slow flow	0.6%	0.0%
No-reflow	0.0%	0.0%

Low Rates of MACE, Mostly Driven by In-Hospital NQWMI



For use outside the U.S. only. Caution: In the United States, Shockwave C² Coronary IVL catheters are investigational devices, limited by United States law to investigational use. Shockwave C² Coronary IVL catheters are commercially available in certain countries outside the U.S. Please contact your local Shockwave representative for specific country availability. The Shockwave C² Coronary IVL catheters are indicated for lithotripsy-enhanced, low-pressure balloon dilatation of calcified, stenotic de novo coronary arteries prior to stenting. Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events. Contact Shockwave Medical at customerservice@shockwavemedical.com