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	**1.7mm** 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

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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

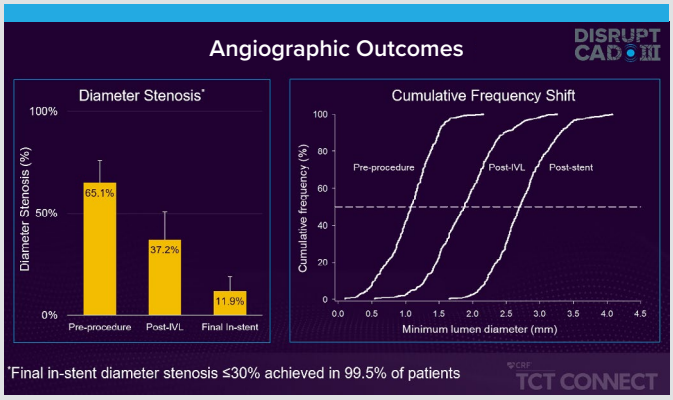
- Successful stent delivery with residual stenosis <50% and without in-hospital MACE

Secondary Performance Endpoints: Clinical and Angiographic Success

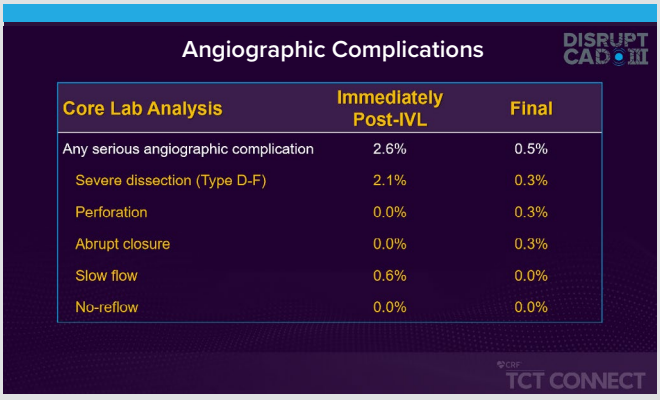
Baseline Characteristics:

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



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