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Intravascular Lithotripsy for Treatment of Infrapopliteal Lesions

Results from the Disrupt PAD III Observational Study

Disclosure

Speaker name: George Adams, MD

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I have the following potential conflicts of interest to report:

- ☑ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

Endovascular Treatment for Calcified PAD

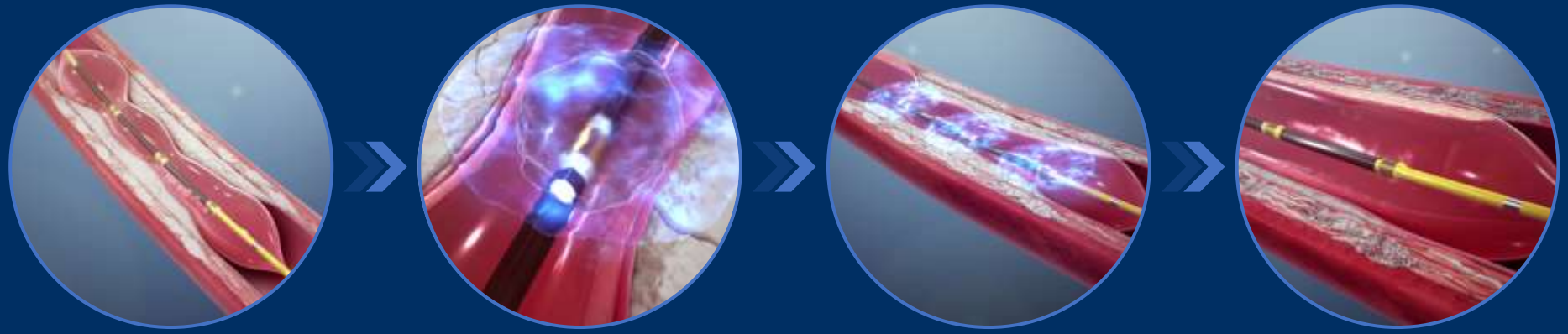
- Infrapopliteal arterial calcium
  - Medial calcification is more prevalent in infrapopliteal arteries
  - Contributes to wall stiffness, vessel recoil and restenosis
  - Leads to increased periprocedural complications

- Percutaneous transluminal angioplasty (PTA) of calcified infrapopliteal lesions is associated with sub-optimal procedural outcomes, results in early recoil, and may contribute to restenosis.

- While promising results with IVL have been reported in a small pilot study, real world evidence from a larger cohort is lacking.

Rocha-Singh et al., *Catheter Cardiovas Interv* 2014; Walker et al., *J. Vasc Surg* 2015

Intravascular Lithotripsy



Deliver catheter and inflate to low pressure

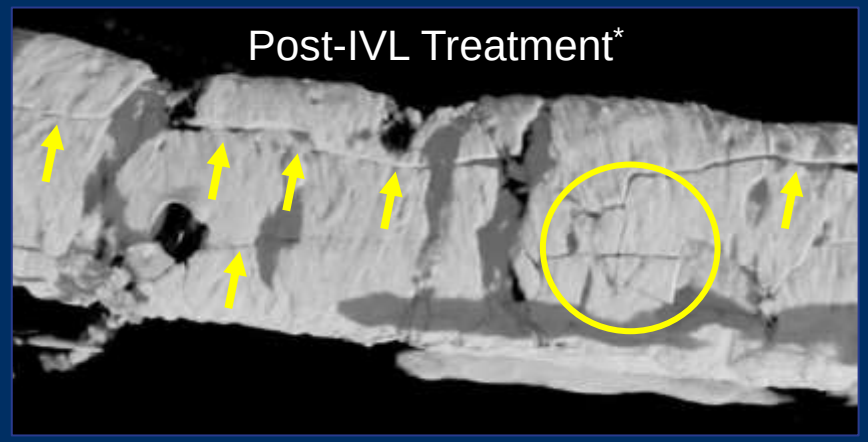
Generate sonic pressure waves using lithotripsy

Crack calcium

Safely expand the vessel

IVL

- Delivers 1 pulse/sec with an effective pressure of ~50 atm
- Low balloon inflation pressure
- Fractures both superficial and deep calcium



*Micro-CT scan analysis: R. Virmani, CV Path Institute

Disrupt PAD III Observational Study

Prospective, multicenter,
single-blind, observational study
NCT02923193

Planned enrollment: 1,500 patients
Objective: Assess 'real-world' peri-procedural outcomes of IVL for treatment of calcified, stenotic, peripheral arteries

PAD III OS Sub-study:
IVL treatment of calcified infrapopliteal arteries
Heavily calcified *de novo* infrapopliteal lesions
IVL +/- adjunctive therapy*
July 2018 – Aug 2020
N = 101 patients; 114 BTK lesions; 15 global sites



Sub-study objective: Assess 'real world' peri-procedural outcomes of S^4 IVL treatment of calcified BTK lesions†

Shockwave S^4 IVL Catheter

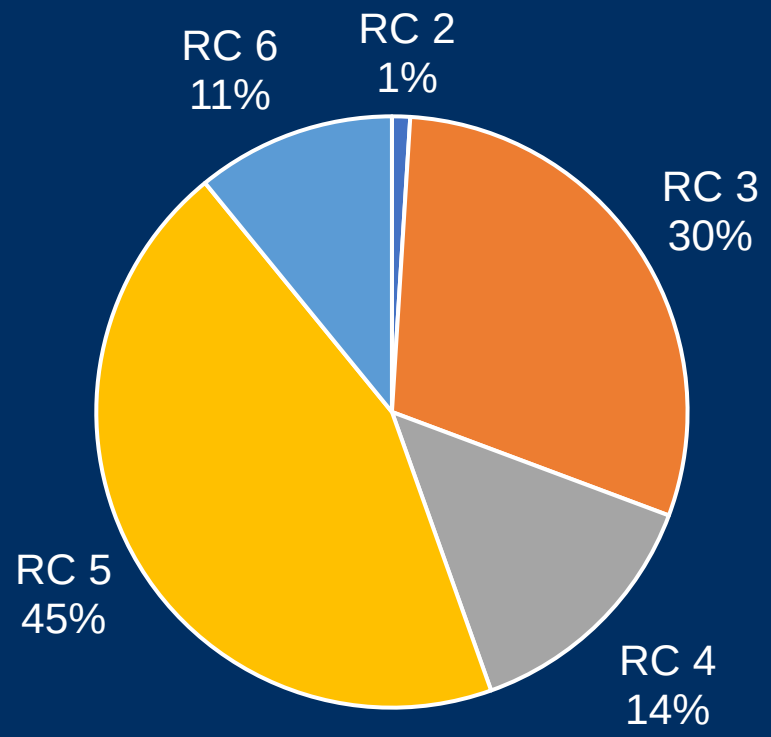
Diameter (mm)	Length (mm)	Pulses/ Cycle	Max Pulse Count
2.5 - 4.0	40	20	160

*No per protocol treatment algorithm; adjunctive therapy use per operator's discretion. †Angiographic core-lab assessment

Baseline Characteristics

Characteristic	Patients N=101
Age	72.5 ± 9.7
Male	75.2%
Hypertension	97.0%
Hyperlipidemia	82.2%
Diabetes Mellitus	74.3%
Current Smoker	18.8%
Prior MI	25.7%
Prior CABG	49.5%
Prior Stroke	14.9%
Renal Insufficiency	48.5%
On Dialysis	23.8%
ABI	0.81 ± 0.33

Rutherford Category
N=101 Patients

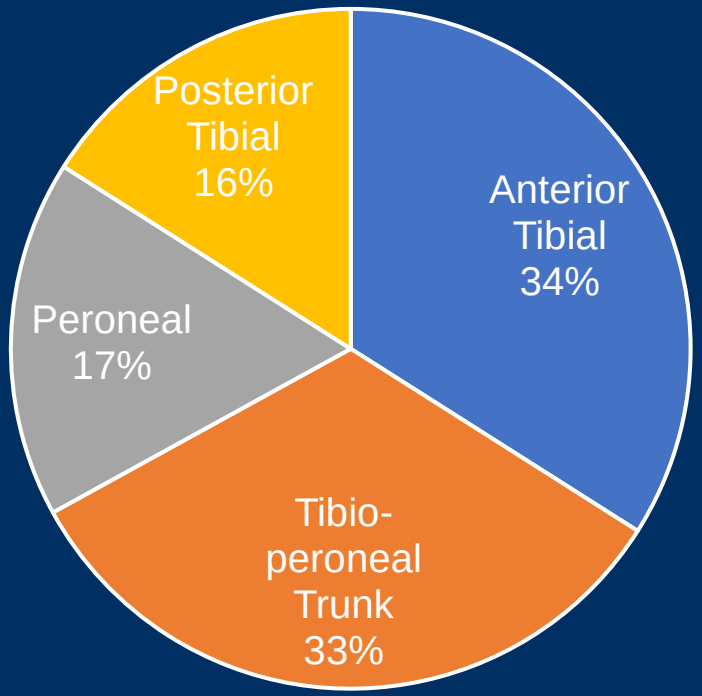


70% of patients with critical limb ischemia

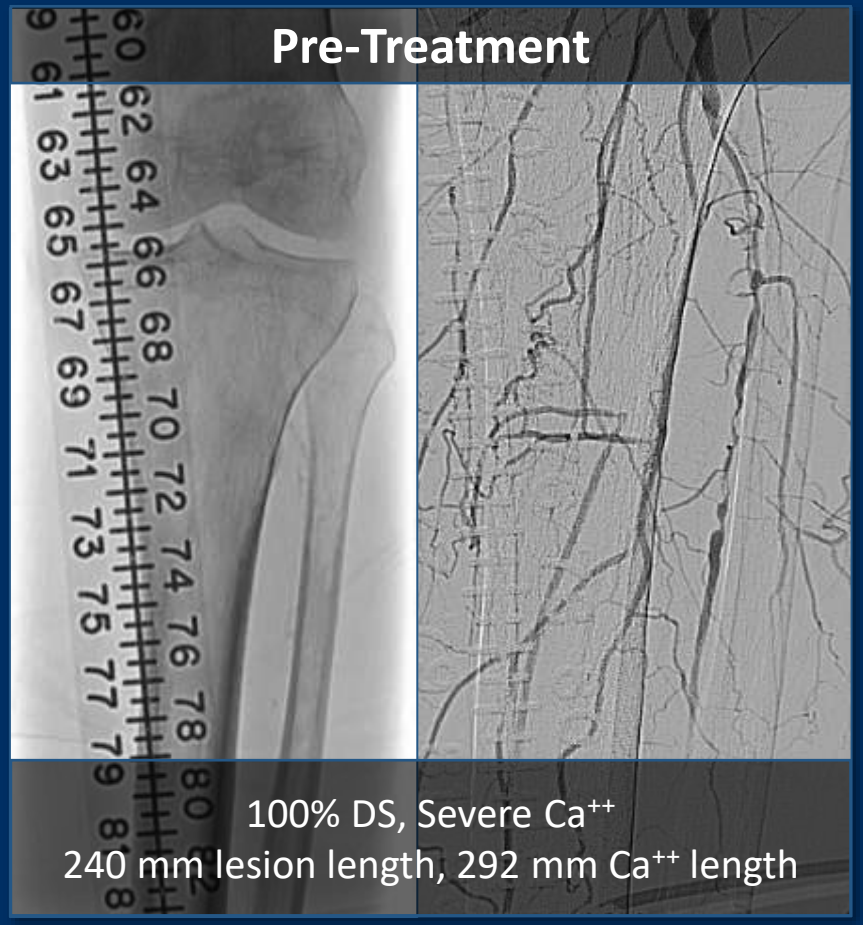
Lesion Characteristics
(Core Lab Adjudicated)

Characteristic	Lesions N=114
Lesions per Patient	1.1 ± 0.3
Reference Vessel Diameter, mm	3.1 ± 0.8
Minimum Lumen Diameter, mm	0.5 ± 0.6
Diameter Stenosis, %	85% ± 15%
CTO, %	35.1%
Lesion Length, mm	65 ± 55
Calcified Length, mm	53 ± 43
Moderate-Severe Calcification	
Site-Reported	100%
Core Lab Adjudicated	69.3%
Eccentric	14.0%

Lesion Location
N=114

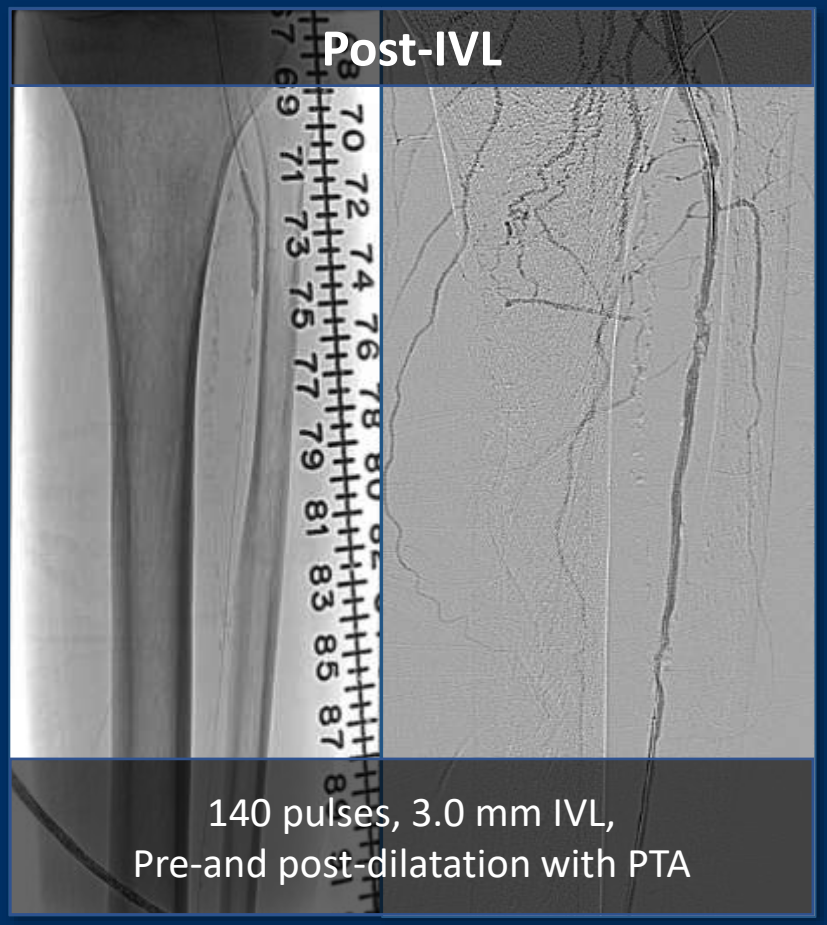


IVL Treatment: Anterior Tibial



Pre-Treatment

100% DS, Severe Ca^{++}
240 mm lesion length, 292 mm Ca^{++} length



Post-IVL

140 pulses, 3.0 mm IVL,
Pre-and post-dilatation with PTA

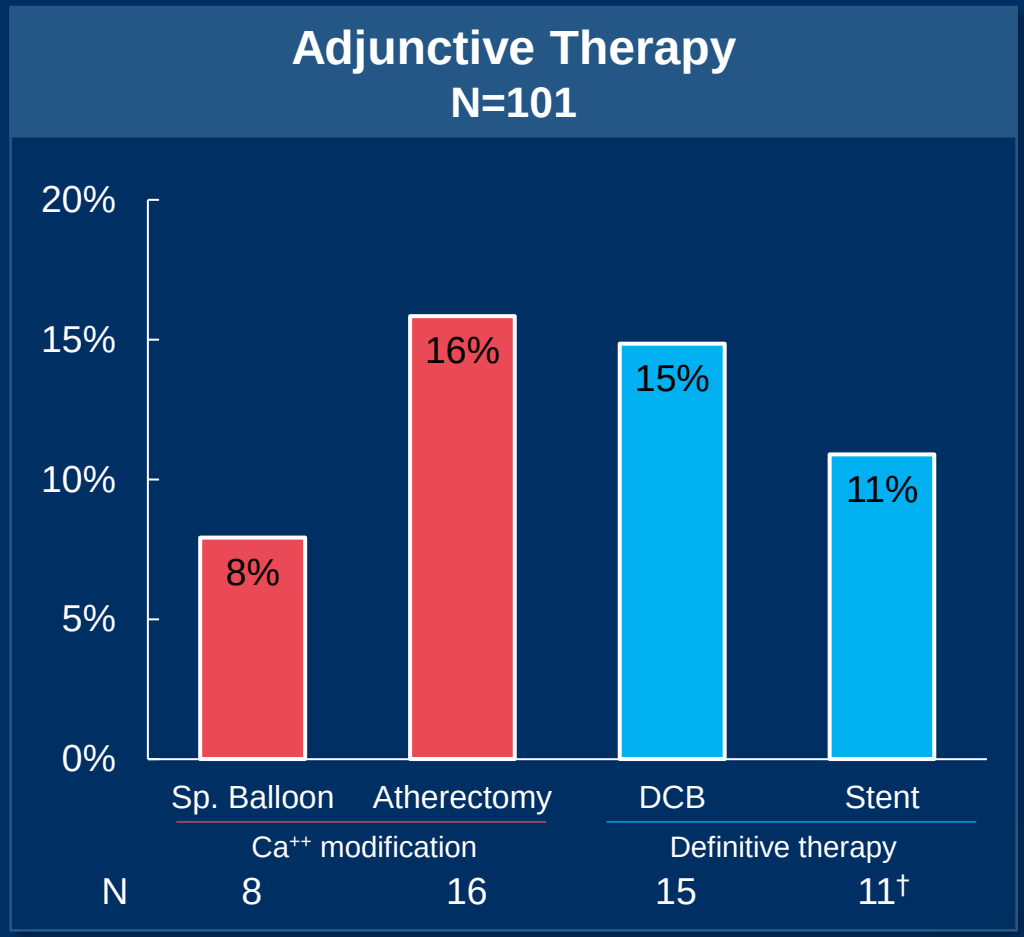
Final

26% DS
No complications or stent placement

Treatment with the S^4 IVL catheter resulted in marked improvement in diameter stenosis

Procedural Characteristics

Characteristic	Patients N=101
Procedure Time, min	88 ± 46
Contrast Volume, ml	147 ± 77
Fluoroscopy Time, min	21 ± 11
Embolic Protection	3.0%
Pre-Dilatation	27.7%
Post-IVL Dilatation	50.5%
IVL Catheters	1.1 ± 0.3
IVL Pulses	139 ± 54
Stand-Alone IVL Therapy*	77%
IVL + Adjunctive Ca^{++} Modifying Therapy*	23%

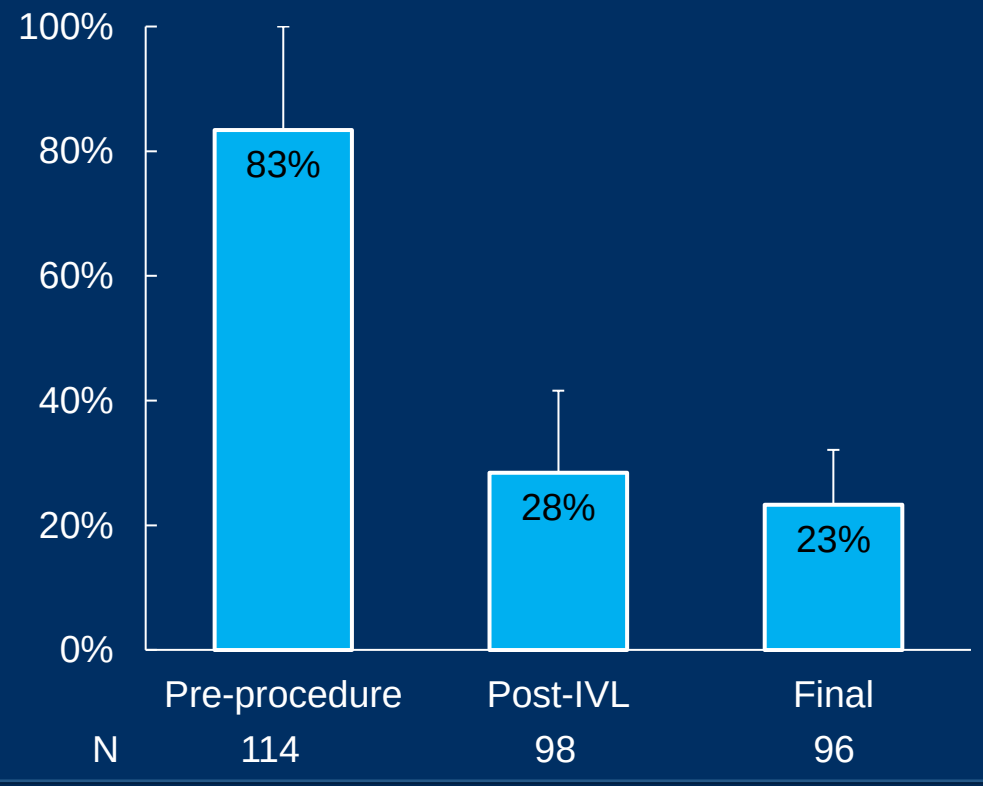


Multiple adjunctive therapies used in 9 subjects

*IVL stand-alone therapy includes pre- or post-dilatation with PTA; Calcium-modifying therapy includes specialty balloons and/or atherectomy. DCB and/or stents used in both groups.
†9/11 stents placed in CTO cases

Angiographic Outcomes
(Core Lab Adjudicated)

Diameter Stenosis*



Complications	Post-IVL N=98	Final N=96
Dissections D-F	3.1%†	0%
Perforation	0%	0%
Distal Emboli	1.0%	0%
Slow Flow/ No Reflow	0%	0%
Abrupt Closure	0%	0%

* Comparison across all time points: p<0.001; †3 events, all occurred in CTO lesions

Conclusions

- This sub-study from the ‘real world’ Disrupt PAD III Observational Study represents the largest cohort for IVL treatment of heavily calcified infrapopliteal arteries and the initial experience using the Shockwave S^4 IVL catheter

- Acute outcomes following IVL treatment demonstrated:
  - Significant reduction in diameter stenosis immediately following IVL treatment
  - Minimal vascular complications, with no serious angiographic complications at the end of the procedure

- Treatment approach was per operator’s discretion in this ‘real world’ study
  - Ca^{++} modifying adjunctive therapy was used in 23% of cases in this initial S^4 IVL BTK treatment experience
  - 95% of cases were performed in the U.S. - data may be more reflective of U.S. current practice

- Future studies with longer-term follow-up are needed to understand the durability of IVL treatment in calcified infrapopliteal arteries