Trial demonstrates safety and effectiveness of intravascular lithotripsy for peripheral artery calcification

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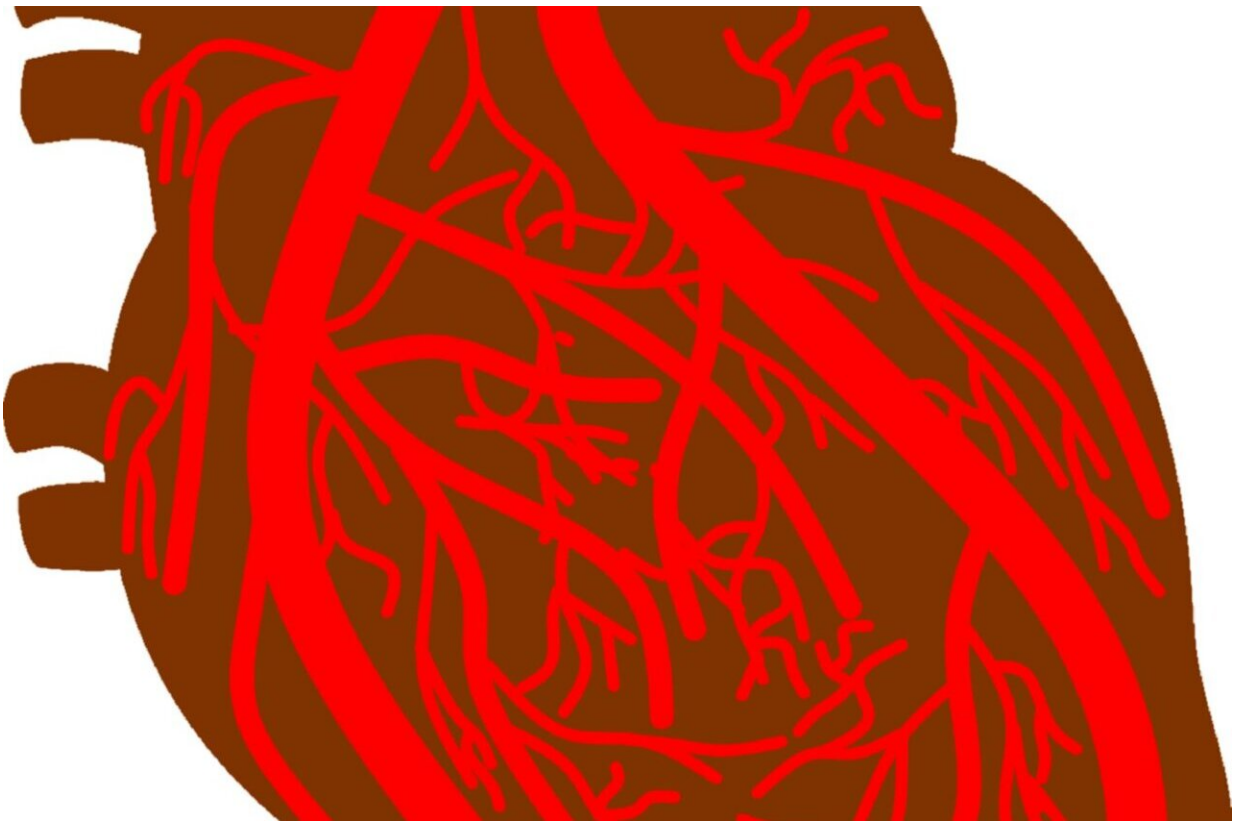

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One year outcomes from the Disrupt PAD III Trial comparing intravascular lithotripsy (IVL) with a drug-coated balloon (DCB) to

percutaneous transluminal angioplasty (PTA) with a DCB was presented today as late-breaking clinical research at the Society for Cardiovascular Angiography & Interventions (SCAI) 2022 Scientific Sessions. The results revealed consistent safety and effectiveness of IVL with durable patency.

Impacting approximately 6.5 million Americans over the age of 40, peripheral arterial disease (PAD) is the narrowing of the peripheral arteries that carry blood away from the heart to other parts of the body. PAD is caused by a buildup of fatty plaque in the arteries and treatment options can including lifestyle changes, medical therapy or surgery depending on the severity of the condition. However, patients with severe calcification are often left out of clinical trials.

The Disrupt PAD III study provides the largest randomized controlled evidence to guide endovascular treatment of severely calcified superficial femoral artery-pop lesions. Looking at 45 global sites, 306 SFA-pop lesions, and, greater than 80% of lesions were defined as severely calcified by the PARC definition with an average calcified length over 125 mm. The goal of the study was to assess long-term primary patency (PP) in patients treated with IVL and DCB compared to patients treated with PTA with a DCB. PP was defined as freedom from clinically driven target lesion revascularization (CD-TLR) by an independent Clinical Events Committee and freedom from restenosis determined by duplex ultrasound (DUS) as assessed by an independent core laboratory. Acute PTA failure requiring a stent during the index procedure was pre-specified per protocol as a loss of PP.

For IVL or PTA arms, PP follow-up is available in 80.4% and 83.7% of patients, respectively. Primary patency at one-year was significantly greater in the IVL arm (80.5% vs. 68.0%). The per protocol requirement for provisional stenting was significantly lower in the IVL group (4.6% vs 18.3%). Freedom from CD-TLR (IVL: 95.7% vs PTA: 98.3%) and

restenosis (IVL: 90.0% vs PTA: 88.8%) were similar between the two groups at 1-year. With IVL, severe complications and the need for additional interventions are reduced compared to PTA.

"This trial offers important new insights because patients with severe PAD are often excluded from trials, resulting in a very limited amount of randomized data to guide treatment," said William A. Gray, M.D., FSCAI, Lankenau Heart Institute/Main Line Health, Wynnewood, PA and lead author of the study. "The trial demonstrated the utility of IVL, rendering these challenging procedures safe and predictable. This offers patients future treatment pathways without the potential long-term risk of adverse clinical events such as stent fracture and restenosis."

Researchers note continued evaluation of IVL for the treatment of calcified PAD in the "real-world" setting is taking place through the Disrupt PAD III Observational Study.

More information: Conference: scai.org/scai2022

Provided by Society for Cardiovascular Angiography and Interventions