



New Shockwave Coronary IVL Publications Confirm Safety and Efficacy Across Multiple Calcium Morphologies

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Clinical Research Validates Utility of IVL in Complex Nodular and Eccentric Calcium

SANTA CLARA, Calif., Oct. 19, 2023 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development and commercialization of transformational technologies for the treatment of cardiovascular disease, announced today that two new publications reported excellent and consistent outcomes with coronary intravascular lithotripsy (IVL) in both nodular and eccentric calcium. The publications each reported separate patient-level pooled optical coherence tomography (OCT) sub-analyses of the company-sponsored Disrupt CAD clinical studies.

"While the majority of the robust, core-lab adjudicated evidence supporting coronary IVL to date has studied concentric calcium, we are beginning to see a shift in evidence reinforcing IVL use across all calcium morphologies, both in retrospective analyses and 'real-world' prospective registries," said Keith D. Dawkins, MD, Chief Medical Officer of Shockwave Medical. "This new evidence showing the consistency of IVL confirms that this platform technology has a critical role to play in not just concentric calcium, but in modifying challenging coronary calcium across all morphologies – whether concentric, eccentric, nodular or mixed."

IVL in Eccentric Calcium

Published in [Circulation: Cardiovascular Intervention](#) and titled, "Impact of Calcium Eccentricity on the Safety and Effectiveness of Coronary Intravascular Lithotripsy: Pooled Analysis from the Disrupt CAD studies," the eccentric analysis divided individual patient-level data (N=230) analyzed by an independent OCT core laboratory into quartiles from eccentric to concentric based on maximum continuous calcium arc.

While there were no differences in pre-procedure minimum lumen area (MLA), diameter stenosis, or maximum calcium thickness across the different calcium arcs, the calcium length and overall volume index increased progressively with concentric calcium, and a higher minimum calcium thickness was increased with eccentric calcium. Post-procedure, the number of calcium fractures, fracture depth and width increased with increasing concentricity; however, there were no significant differences in mean stent area (7.39mm² vs 7.22mm² vs 7.26mm² vs 8.09mm²; p= 0.07) or stent expansion (98.7% vs 100.3% vs 95.4% vs 101.9%; p=0.74) across quartiles at the site of maximum calcification. These excellent results were achieved in the absence of any procedural complications.

"IVL was initially adopted in clinical practice because of its ability to modify concentric calcium in a safe and predictable manner, and we are now seeing the utility increase as the consistency of the safety and efficacy outcomes related to IVL expand across calcium arcs," said Dr. Ziad Ali, MD, DPhil, Director of the DeMatteis Cardiovascular Institute at St Francis Hospital & Heart Center in Roslyn, NY, USA, and first author on the publication.* "This shift in clinical practice has been key to addressing the limitations of atherectomy technologies in modifying eccentric calcium due to wire bias and the concerns with perforations associated with high pressure balloons in eccentric lesions at the interface between the calcium and the healthy tissue. With IVL, we now have a tool that can modify the eccentric calcium and increase the vascular compliance to greatest effect while minimizing procedural risk."

IVL in Nodular Calcium

Published in [JACC: Cardiovascular Interventions](#) and titled, "Safety and Effectiveness of Coronary Intravascular Lithotripsy for Treatment of Calcified Nodules," the patient-level pooled analysis from the Disrupt CAD studies was the first investigation of IVL in calcified nodules, examining 54 nodules found within 248 lesions (22%) analyzable by OCT. In lesions with calcific nodules, IVL was found to be highly effective in modifying the calcium prior stent implantation, reducing stenosis to a residual area of less than 15 percent with an acute gain of 1.8 mm² in a safe manner with no major procedural complications.

When comparing lesions with and without calcific nodules treated with IVL, there were no significant differences in minimum stent area (6.3mm² vs 6.0 mm²), mean stent area (8.3mm² vs 7.9 mm²), or stent expansion at the maximum site of calcification (104.9% vs 99.4%). There was a trend toward more calcium fractures (78.7% vs 65.2%; p=0.07) in lesions with calcific nodules as well as an increased fracture length (5.2mm vs 3.6mm p=0.02) in nodular lesions.

"These new acute data with IVL are very encouraging and reconfirm the safety of IVL with no procedural complications in lesions with calcific nodules, which is generally a high-risk setting, however, there is still a lot to learn about this challenging calcium morphology to reduce long-term events associated with calcific nodular protrusion into the stent," said Dr. Ali, the first author on the publication. "Given the relatively low prevalence of nodules, it has been challenging to perform large prospective controlled studies. The collection of more 'real-world data' in nodules across calcium arcs with intravascular imaging can help determine the optimal treatment algorithm – whether standalone IVL or IVL with concomitant technologies – for lesions with calcified nodules, so that we can improve both short- and long-term PCI outcomes."

About Shockwave Medical, Inc.

Shockwave Medical is a leader in the development and commercialization of innovative products that are transforming the treatment of cardiovascular disease. Its first-of-its-kind Intravascular Lithotripsy (IVL) technology has transformed the treatment of atherosclerotic cardiovascular disease by safely using sonic pressure waves to disrupt challenging calcified plaque, resulting in significantly improved patient outcomes. Shockwave has also recently acquired the Neovasc Reducer, which is limited for investigational use in the United States and is CE Marked in the European Union and the United Kingdom. By redistributing blood flow within the heart, the Reducer is designed to provide relief to the millions of patients worldwide suffering from

refractory angina. Learn more at www.shockwavemedical.com and www.neovasc.com.

Forward-Looking Statements

This press release contains statements relating to our expectations, activities, programs, goals, events or developments that we expect, believe or anticipate will or may occur, which are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, are statements that could be deemed forward-looking. In some cases, you can identify these statements by forward-looking words such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” or “continue,” and similar expressions, and the negative of these terms. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current plans, expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware.

Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly in peripheral artery disease, coronary artery disease and aortic stenosis; our ability to successfully execute our commercialization strategy for our approved or cleared products; and our expected future growth. These factors, as well as others, are discussed in our filings with the Securities and Exchange Commission (SEC), including in Part I, Item 1A - Risk Factors in our most recent Annual Report on Form 10-K filed with the SEC, and in our other periodic and other reports filed with the SEC. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations.

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*Dr. Ali is a paid consultant of Shockwave Medical. He has not been compensated in connection with this press release.



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