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Novel '3D' Stent Improves Clinical Status in Femoropopliteal Disease Patients

PARIS, France—A "3D" helical stent that mimics the natural vascular curvature helps improve clinical symptoms and walking distance at 12 months in patients with femoropopliteal disease, according to results presented Tuesday, May 21 at EuroPCR 2013.

For the Mimics study, researchers led by Stephan H. Duda, MD, of Jewish Hospital Berlin (Berlin, Germany), randomized 76 patients with Rutherford 1to 4 occlusions of the SFA/proximal popliteal artery to receive the BioMimics 3D stent (Veryan, Horsham, United Kingdom) or a control stent (24/26 LifeStent, CR Bard, Murray Hill, NJ).

The BioMimics 3D stent features a 3-dimensional design that mimics the natural helical geometry of the human vascular system. The intention is to improve blood flow characteristics in the stented segment that may confer a vasoprotective effect and enhance biomechanical performance. The stent is also designed to promote swirling flow to elevate wall shear stress.

At 12 months, event-free survival (freedom from MAE, amputation, or clinically driven TLR) was 89.3% with BioMimics vs. 92.3% with control stents (P = 0.191), while Kaplan Meier primary patency was 80.4% with BioMimics vs. 72.0% with control stents (P = 0.105).

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Good Safety, No Fractures

There were no major adverse peripheral vascular events with BioMimics, which showed a 91.2% rate of freedom from clinically-driven reintervention. There have been no stent fractures reported to date.
Using bi-planar X-rays, the researchers determined that there was no loss of patency when mean stent curvature was greater than 0.02 mm-1. In addition, mean stent curvature was 26% greater with the BioMimics stent vs. controls when the leg was straight, and 30% greater when the leg was bent (90 degrees). Curvature promotes swirling flow, Dr. Duda explained, which leads to protective wall shear stress.

Rutherford clinical category improved by a value of 1 or more in 86% of BioMimics patients vs. 81% of controls at 12 months. In addition, 81% of BioMimics patients demonstrated an increase in walking distance from baseline to 12 months compared with 73% of controls. In BioMimics patients, mean ankle brachial index was 0.93 ± 0.17 at 12 months, a significant increase from baseline.

"Mimics data support the hypothesis that a 3D helical stent promotes swirling flow and elevates wall shear stress, which is 'patency protective,'" Dr. Duda concluded.

Next Stop: Popliteal Artery?

One panel member called the BioMIMICS stent a "very nice concept of helical design to address the flexion and geometry changes in segments in which stents are particulary stressed." According to Dr. Duda, the next logical step would be to target the popliteal artery itself with the novel stent.

Questions were raised, however, as to whether the BioMIMIC stent would behave in the same manner in a different location of the SFA or the femoropopliteal artery, and how short or how extensively one needs to stent with the device.

"It's always wise to stay as short as possible," Dr. Duda replied. "But when you go down the SFA obviously this stent concept would make sense, whereas the upper two-thirds of the SFA it cannot be shown to be as valuable."
Dr. Duda also addressed the stent's design and ability to withstand calcified lesions. "The stent has a particular feature, which is to taper down the radial stiffness to the proximal and distal ends in order not to have such a big transition of radial force," he explained. "So the radial force is biggest in the middle segment of the stent and there it can withstand easily any calcified force, but not at the very ends."

Source:

Duda SH. Mimics Study: Results at 12 months. A randomized, controlled trial of the BioMimics 3D nitinol stent system in femoropopliteal intervention with 24-month follow-up evaluation. Presented at: EuroPCR; May 21, 2013; Paris, France.