Cook Medical Sponsors First Clinical Study to Examine New Endovascular Technique

Clinical investigators are for the first time examining the retrograde tibiopedal interventional approach, an endovascular technique that has the potential to reduce the rate of leg amputations by as much as 50 percent[1] in patients with critical limb ischemia (CLI), a manifestation of peripheral arterial disease (PAD). Cook Medical [1], a global pioneer in interventional medical device technologies, is sponsoring the Tibiopedal Access for Crossing Infrainguinal Artery Occlusions study.

With the retrograde tibiopedal approach, a physician gains vascular access at the foot and advances wire guides and catheters up the leg to reach and cross arterial blockages. Individuals[1] and single centers[2] have reported initial success with the technique, which is often tried after a traditional antegrade approach fails. This is the first prospective, multicenter study to collect data on this technique.

“This endovascular approach developed by leading physicians has the demonstrated potential to address life-limiting and lower-limb-threatening occlusions,” said Rob Lyles, vice president and global leader of Cook’s Peripheral Intervention business unit. “We are committed to enhancing the delivery of quality patient care and look forward to the initial study results in 2013.”

An estimated 27 million people in Europe and North America suffer from PAD,[3] which can lead to CLI, a severe obstruction of the arteries that decreases blood flow to the extremities, producing pain and skin ulcers or sores. CLI, which affects up to 300,000 people a year in the U.S.[4] is the end stage of lower-extremity PAD and poses a significant risk for limb loss. Currently, 25 percent of CLI patients undergo amputation as a primary treatment.[4] Within two years of treatment, 25 percent of these patients die and another 30 percent experience additional lower-limb amputation.[4] The mortality rate at five years following amputation can be as high as 68 percent.[5]

Twelve sites in the United States and Europe will participate in the Tibiopedal Access for Crossing Infrainguinal Artery Occlusions study led by global principal investigator, Craig Walker, M.D., founder, president and medical director of the Cardiovascular Institute of the South [2] in Louisiana. Up to 200 patients with a totally occluded lower-limb artery will be enrolled, and physicians will assess the technical success rates of the new procedure both for gaining vascular access via the foot and for crossing the lesion. Patient follow-up will consist of a telephone interview approximately 30 days after the procedure. J.A. Mustapha, M.D., director of endovascular intervention at Metro Health Hospital [3], has enrolled and treated the first patients in this study. Drs. Walker and Mustapha are compensated by Cook Medical for educational lectures they present to physicians on the tibiopedal access procedure.

[1] Kavteladze Z. Retrograde recanalization of tibial CTOs. Presented at: TCT 2010; September 21-25, 2010; Washington, DC.

[2] Montero-Baker M, Schmidt A, Bräunlich S, et al. Retrograde approach for complex popliteal and tibioperoneal occlusions. J Endovasc Ther. 2008;15(5):594-604.

[3] Belch JJ, Topol EJ, Agnelli G, et al. Critical issues in peripheral arterial disease detection and management: a call to action. Arch Intern Med. 2003;163(8):884-892.

[4] Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33(suppl 1):S1-S75.

[5] Reiber GE, Boyko EJ, Smith DG. Lower extremity foot ulcers and amputations in diabetes. In: Harris MI, Cowie CC, Stern MP, et al., eds. Diabetes in America. 2nd ed. Washington, DC: National Institute of Diabetes and Digestive and Kidney Diseases, 1995:409-428.

Source URL (retrieved on *07/30/2014 - 9:52am*):
http://www.mdtmag.com/news/2012/06/cook-medical-sponsors-first-clinical-study-examine-new-endovascular-technique

Links:
[1] http://www.cookmedical.com/home.do
[2] http://www.cardio.com/site1.php
[3] http://metrohealth.net/