

Medtronic Drug-Coated Balloon for Peripheral Artery Disease Tops Standard Balloon Angioplasty in Landmark Study

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Results of IN.PACT SFA Trial Published in Circulation

MINNEAPOLIS -- Dec. 22, 2014 -- The results of a landmark study published this month in *Circulation*, the world's leading cardiovascular journal, indicate that a novel medical device from Medtronic, Inc. (NYSE: MDT) called the IN.PACT Admiral drug-coated balloon (DCB) significantly outperformed standard balloon angioplasty in the treatment of symptomatic peripheral artery disease in the upper leg -- specifically, the superficial femoral and proximal popliteal arteries.

To put the results in context, patients in the study's DCB group experienced the highest rate of primary patency and the lowest rate of clinically-driven target lesion revascularization at 12 months ever reported from a study of interventional treatments for this common form of peripheral artery disease.

In their conclusion, the authors of the article state that the IN.PACT Admiral DCB "stands to become an important treatment option for patients with superficial femoral and popliteal artery disease," which affects millions of people worldwide.

The IN.PACT Admiral DCB received the CE (*Conformité Européene*) mark in 2009 but remains an investigational medical device in the United States, where it is under review by the U.S. Food and Drug Administration (FDA). Outside the United States, the device has been used to treat peripheral artery disease in nearly 100,000 patients -- more than any other DCB.

The IN.PACT SFA Trial enrolled 331 subjects at 57 sites across Europe and the United States. All study subjects were randomized to treatment with the DCB or standard balloon angioplasty. On the key endpoints:

- The clinically driven target lesion revascularization (CD-TLR) rates at 12 months were 2.4 percent for the DCB group and 20.6 percent for the PTA group ($p < 0.001$), a highly statistically significant difference. CD-TLR accounts for repeat procedures, or reinterventions, due to recurrent symptoms related to the treated lesion.
- Primary patency rates were assessed at 12 months of follow-up and showed a highly statistically significant difference: 82.2 percent for the DCB group and 52.4 percent for the PTA group ($p < 0.001$). Presented at the Charing Cross international symposium in April, the Kaplan-Meier survival estimates for primary patency at Day 360 were 89.8 percent for the DCB group and 66.8 percent for the PTA group. Primary patency means a sustained restoration of adequate blood flow through the treated segment of the diseased artery.

"In this trial, the IN.PACT Admiral drug-coated balloon resulted in superior efficacy when compared to a plain angioplasty balloon for the treatment of patients with symptomatic superficial femoral and/or proximal popliteal" artery disease, the authors report. "There was significantly better primary patency and a marked reduction in the need for target lesion revascularization at 12 months following treatment with the DCB."

The researchers also explain why drug-coated balloons represent an "attractive alternative" to other treatments for peripheral artery disease (PAD): "Use of DCB (and avoidance of stent implantation) does not limit future treatment options, an important consideration given the chronic and progressive nature of PAD."

The article -- "Drug-Coated Balloon versus Standard Percutaneous Transluminal Angioplasty for the Treatment of

Superficial Femoral and/or Popliteal Peripheral Artery Disease: 12-Month Results from the IN.PACT SFA Randomized Trial," by Tepe et al. -- was published online Dec. 3 and will appear in an upcoming print issue of *Circulation*.

Caused by atherosclerotic plaque formation that narrows the arterial lumen and restricts blood flow, peripheral artery disease affects an estimated 50 million people in the United States and Europe.^{1,2} In the legs -- a common location for the disease to develop -- it frequently results in claudication, a condition characterized by pain in the leg muscles while walking.

More common among men and smokers, claudication has a higher prevalence in the population over age 60. Without effective treatment, claudication can lead to ischemic rest pain in the legs, critical limb ischemia, amputation, and premature death.

Approximately 750,000 to 800,000 people in the United States and Western Europe undergo an interventional procedure each year for the treatment of peripheral artery disease in the superficial femoral or popliteal arteries.

In collaboration with leading clinicians, researchers, and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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¹ National Heart Lung and Blood Institute. Facts About Peripheral Arterial Disease (P.A.D.) 2006. Web. Available at http://www.nhlbi.nih.gov/health/educational/pad/docs/pad_extfctsht_general_508.pdf.

² Fowkes FG, et al .Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet*. 2013 Oct 19;382(9901):1329-40.

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