Medtronic News

'IN.PACT Admiral' Drug-Coated Balloon From Medtronic Outperforms Standard Angioplasty In Landmark Study

Interventional Treatment of Lower-Extremity Peripheral Arterial Disease With Novel Medical Device Shows Positive Results in IN.PACT SFA Trial

LONDON -- April 5, 2014 --Patients with peripheral artery disease in the upper leg experienced significantly better outcomes at 12 months after treatment with the IN.PACT Admiral drug-coated balloon from Medtronic, Inc. (NYSE: MDT) than with standard balloon angioplasty, according to a landmark clinical study reported on today for the first time.

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 drug-coated balloon (DCB) or percutaneous transluminal angioplasty (PTA). 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 due to recurrent symptoms related to the treated lesion.
- Per protocol, 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 ($p<0.001$). Primary patency at 360 days was also calculated by Kaplan-Meier survival estimates; at this specific time point, it was 89.8 percent for the DCB group and 66.8 percent for the PTA group. Primary patency means a restoration of adequate blood flow through the treated segment of the diseased artery.

Approximately 650,000 to 700,000 people in the United States and Western Europe undergo an interventional procedure each year for this common form of peripheral artery disease, which typically involves the superficial femoral artery (SFA).

The IN.PACT Admiral drug-coated balloon 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). No drug-coated balloon has received FDA approval.

Presented at the Charing Cross international symposium for vascular surgeons and interventionalists, results of the IN.PACT SFA Trial will soon be submitted by Medtronic to the FDA as part of the company's application for pre-market approval of the IN.PACT Admiral drug-coated balloon.

"The results of this rigorously conducted randomized controlled trial warrant a review of current treatment guidelines for peripheral artery disease in the lower extremities," according to principal investigator Gunnar Tepe, chief of radiology at RoMed Klinikum in Rosenheim, Germany.

"In fact, they should lead to a reconsideration of how we treat patients with claudication, as the highest level of clinical evidence now distinguishes the IN.PACT Admiral drug-coated balloon as a primary therapy for atherosclerosis in the SFA."

To ensure data accuracy and reliability, patency endpoints underwent evaluation by an independent imaging core lab, while all clinical events were adjudicated by an independent clinical events committee. To prevent bias, both the imaging core lab and the clinical events committee were blinded to the patients' randomization assignment.

Study subjects were well matched at the time of enrollment. The vast majority (approximately 95 percent) of the patients had moderate or severe claudication, a condition characterized by leg pain while walking due to restricted blood flow through the SFA or proximal popliteal artery (both in the leg above the knee). The remaining five percent suffered from rest pain because of more advanced arterial disease.

In addition to disease severity, other baseline characteristics -- including diabetes (40.5% vs. 48.6%) and hypertension (91.4%

vs. 88.3%), as well as mean lesion length (8.94 cm vs. 8.81 cm) and percent of total occlusions (25.8% vs. 19.5%) -- were also similar between the two groups, with no statistically significant differences. Clinical outcomes, however, significantly favored the DCB group.

"Based on the addition of these compelling new data to the positive results of previous studies, we see a path to establishing a new standard of care for SFA disease with an optimized and trusted medical technology," said Tony Semedo, a senior vice president at Medtronic and president of the company's Endovascular Therapies business.

"The IN.PACT Admiral drug-coated balloon has the lowest reported revascularization rate of any medical technology for the treatment of SFA disease; and in this particular vessel bed, our device also has the highest reported primary patency rate, with minimal need for durable implants."

To date, 24 clinical studies of the IN.PACT Admiral drug-coated balloon involving more than 4,200 patients have been undertaken. Results presented at medical meetings and published in peer-reviewed medical journals consistently show positive patient outcomes with the novel medical device, which is coated with a drug called paclitaxel that prevents excess scar tissue from forming along the wall of the treated arterial segment and leaves no scaffolding behind.

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. In the legs it frequently results in claudication, a condition characterized by severe pain in calf 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 critical limb ischemia, amputation and premature death.

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.

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