New - Data from the Imperial Clinical Program demonstrates ELUVIA more effective in diabetic patients

Boston Scientific today announced diabetic subanalysis results from the IMPERIAL trial in which patients treated with the ELUVIA™ Drug-Eluting Vascular Stent System demonstrated statistically significant lower rates of target lesion revascularization (TLR) and stent thrombosis when compared to those treated with the Zilver® PTX® Drug-Eluting Peripheral Stent. These results were presented during a first data session at Leipzig Interventional Course (LINC) in Leipzig, Germany.

Over 400 million people worldwide suffer from diabetes, which raises their risk of heart attacks, stroke and peripheral artery disease (PAD).[1] PAD occurs when fatty or calcified atherosclerotic material, called plaque, builds up on the walls of the arteries of the legs, restricting blood flow and causing pain, swelling, ulceration and in some cases, the need for amputation of the affected limb.

In the IMPERIAL subgroup analysis, diabetic patients in the Eluvia arm of the study experienced more than 70 percent reduction in TLR (3.7 percent for Eluvia compared to 13.6 percent for Zilver PTX) as well as achieved a nine-fold, statistically significant lower rate of stent thrombosis (0.9 percent for ELUVIA vs 8.1 percent for Zilver PTX) at 12 months. Those treated with the Eluvia stent also experienced a primary patency rate of 87.4 percent versus 80.2 percent for those who received Zilver PTX.[2]

“We observed excellent vessel patency and a good safety profile, after one year in patients with diabetes treated in IMPERIAL,” explains Professor Stefan Müller-Hülsbeck, M.D., PhD, co-principal investigator and chairman, Vascular Center Diako Flensburg and Head of the Department of Diagnostic and Interventional Radiology / Neuroradiology, Academic Hospitals Flensburg, Germany, and co-principal investigator of the IMPERIAL trial. “These strong clinical outcomes reinforce what has been demonstrated in the IMPERIAL RCT and long-lesion study in that the Eluvia stent is a viable and effective treatment option for patients who present with some of the most challenging lesion and disease state characteristics.”

The IMPERIAL trial is a global, multi-center, randomized controlled trial that included 465 patients with superficial femoral artery (SFA) and proximal popliteal artery (PPA) lesions up to 140mm in length. It is the first head-to-head drug-eluting stent trial in the SFA evaluating both the Eluvia and Zilver PTX stent systems in patients with symptomatic PAD.

The Eluvia Stent System received FDA approval in September of 2018 and CE Mark in February of 2016.

1. https://www.who.int/news-room/fact-sheets/detail/diabetes Accessed January 16, 2019

2. Kaplan- Meier
