

Abbott's stent system gets FDA approval

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Singapore: The US FDA approved Abbott's Omnilink Elite Vascular Balloon-Expandable Stent System for the treatment of iliac artery disease, a form of peripheral artery disease (PAD) that affects the lower extremities.

The FDA approval is supported by positive clinical data from the MOBILITY (Omnilink Elite or Absolute Pro Stent used in the iliac artery) study. The MOBILITY study demonstrated that Omnilink Elite is safe and effective, including when used for patients who are difficult-to-treat due to complex disease resulting from severely calcified lesions.

The Omnilink Elite stent is based on the proven, market-leading MULTI-LINK stent design with a next-generation cobalt chromium alloy. Cobalt chromium is stronger and more radiopaque than stainless steel, making the stent easy to see under X-ray while maintaining thin, flexible struts. These features are designed to enable the physician to navigate the stent in complex anatomy and facilitate accurate placement of the device, which is important for long-term patient outcomes.

Dr Tony S Das, co-principal investigator of the MOBILITY study, and director, peripheral vascular interventions, cardiology section, Presbyterian Heart Institute, Dallas, Texas, said that, "The MOBILITY study demonstrated that treatment with Omnilink Elite resulted in an increase in quality of life in a difficult-to-treat patient population that is reflective of real clinical practice. At nine months, patients experienced significant improvements in walking distance and speed, and were able to climb more stairs than they could before treatment."

The MOBILITY study, which is a prospective, non-randomized, two-arm, multi-center study conducted at 48 centers in the US, evaluated the effectiveness of two Abbott stents, (including Absolute Pro Vascular Self Expanding Stent System and Omnilink Elite Vascular Balloon Expandable Stent System) in patients who had iliac artery disease with intermittent claudication or critical limb ischemia, including complex lesions.

Of the 304 patients enrolled in the study, 151 were treated with Absolute Pro and 153 were treated with Omnilink Elite. The study met its primary endpoint, which was a nine-month major adverse event rate of 6.1 percent for patients treated with Absolute Pro and 5.4 percent for patients treated with Omnilink Elite. These rates were significantly below the primary

endpoint goal of 19.5 percent ($p < 0.0001$), which was developed from published literature on previous iliac artery stenting studies.

Dr Charles A Simonton, divisional vice president, medical affairs, and chief medical officer, Abbott Vascular, said that, "Low rates of target lesion revascularization and significant improvements in walking ability reinforce the use of Omnilink Elite in real-world patients. The approval of Omnilink Elite and the recent FDA approval of Absolute Pro add to Abbott's already robust portfolio of advanced endovascular products for the treatment of PAD."