Medtronic News

New Data Show Medtronic Heli-FX EndoAnchor System Enhances Outcomes and Durability in Complex Aortic Disease

Data from ANCHOR Registry Demonstrate Applicability in Patients with Hostile Aortic Neck Anatomy

DUBLIN and NEW YORK - Nov. 17, 2016 - Medtronic plc (NYSE: MDT) today announced data demonstrating that the company's Heli-FX(TM) EndoAnchor(TM) system enhances outcomes and durability in patients with complex aortic abdominal aneurysm (AAA) anatomy, particularly those who have hostile aortic neck anatomy. The new data were presented in a series of three different presentations during the 43rd Annual Symposium of Vascular and Endovascular Issues (VEITHsymposium) in New York. The findings are based on new sub-analyses from Medtronic's ANCHOR registry - a global, multi-center, multi-arm, prospective, post-market registry evaluating the real-world applicability of the Heli-FX EndoAnchor System in up to 2,000 patients.

ANCHOR Propensity Analysis

Data presented for the first time by Bart Muhs, M.D., Ph.D., a vascular surgeon at The Vascular Experts in Middletown, Conn., demonstrated outcomes in 99 patients who received EndoAnchor implants with the Heli-FX EndoAnchor system along with an approved stent graft during an endovascular aneurysm repair (EVAR) compared with 99 patients who did not receive EndoAnchor implants during EVAR.

Patients in both arms of the ANCHOR propensity analysis (a statistical analysis of observational data) were matched using 19 anatomical and physiological baseline variables.

After a mean follow up of over one year, patients in the ANCHOR test group experienced:

- A statistically significant difference in sac regression: A cumulative sac regression was 28.6 percent in EndoAnchor implant group, and 20.3 percent in the non-EndoAnchor implant group (p=.017).

While not statistically significant, the results also showed:

- Less proximal neck dilation: freedom from neck dilation was 98.4 percent in the EndoAnchor test group versus 94.9 percent in the control group.
- Encouraging low rates of Type Ia endoleaks (an endoleak characterized by a poor seal): freedom from Type 1a endoleak in the EndoAnchor test group was 97.0 percent versus 94.1 percent in the control group.

"This propensity matched data from the ANCHOR registry shows that the Heli-FX EndoAnchor system improves patient outcomes based on key measures of effectiveness," said Dr. Muhs. "Our analysis reflects real-world clinical experience, and provides the next level of clinical evidence supporting this EndoAnchor system in patients with complex, hostile abdominal aortic aneurysms."

ANCHOR Registry

Additional follow up data up from the ANCHOR registry were presented by William Jordan, M.D., professor of surgery and chief, division of vascular surgery and endovascular therapy at Emory University School of Medicine. The data, based on follow up of 604 patients, showed the Heli-FX EndoAnchor system provides additional security when used with approved endovascular stent grafts in patients with hostile AAAs. Patients were evaluated in three groups who either received the Heli-FX EndoAnchor System prophylactically at the same time as an EVAR procedure (n= 314), as a therapeutic primary for a Type Ia endoleak occurring immediately after the EVAR (n=123), or as a therapeutic revision during a follow-up visit to treat a post-EVAR complication (n=167).

In all three groups, patients had very short necks, indicative of the hostile anatomy: median neck length was 11.5mm in the

prophylactic group and 12.1mm in the therapeutic primary and 10.2mm in the therapeutic revision group. Specific results evaluated by a core laboratory at one and two years for all three groups include:

- Favorably low rates of Type Ia endoleaks:
  - One year: prophylactic = 0.6 percent; therapeutic primary = 1.4 percent; therapeutic revision = 19.2 percent
  - Two years: prophylactic = 0.0 percent ; therapeutic primary =2.9 percent; therapeutic revision 11.1 percent
- Positive sac regression despite the hostile anatomy characteristics:
  - One year: prophylactic = 45.6 percent; therapeutic primary = 43.1 percent; therapeutic revision = 16.9 percent
  - Two years: prophylactic = 61.2 percent; therapeutic primary = 51.4 percent; therapeutic revision = 37.9 percent
- High rates of freedom from secondary procedures:
  - One year: prophylactic = 95.9 percent; therapeutic primary = 97.9 percent; therapeutic revision = 84.8 percent
  - Two years: prophylactic = 92.1 percent; therapeutic primary = 92.9 percent; therapeutic revision = 79.9 percent
- High rates of freedom from aneurysm related mortality (ARM), which is notable given the short neck lengths:
  - One year: prophylactic = 98.4 percent; therapeutic primary = 98.4 percent; therapeutic revision = 96.5 percent
  - Two years: prophylactic = 98.4 percent; therapeutic primary = 98.4 percent; therapeutic revision = 92.6 percent

"These data further support the added security and durability of the Heli-FX EndoAnchor System we are seeing in clinical practice," said Dr. Jordan. "With low rates of Type Ia endoleaks and re-intervention rates, positive sac regression and freedom from ARM rates, EndoAnchor implants allow for safe and effective treatment of more complex anatomies, both prophylactically and in conjunction with treatment of a post-EVAR complication, such as a migration or Type Ia endoleak."

In a related presentation, Apostolos Tassiopoulos, M.D., department of surgery, division of vascular and endovascular surgery, Stony Brook University Medical Center, N.Y., presented data demonstrating effects of Heli-FX EndoAnchor system on neck dilation. This additional data from the ANCHOR registry characterized several variables predictive of perioperative neck dilation. The analysis showed that after one year, EndoAnchor implants appear to offer protection against neck dilation.

"We are excited to see the continued, positive data from the ANCHOR registry that demonstrate the strength and durability of our Heli-FX EndoAnchor system when used with EVAR in patients with hostile AAA anatomy," said Daveen Chopra, vice president and general manager of the Aortic business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "Following our acquisition of Aptus Endosystems and its Heli-FX and Heli-FX Thoracic EndoAnchor systems last year, this technology further reflects our commitment in providing solutions for challenging patients with complex aortic disease based on real-world, rigorous clinical data."

Medtronic's Heli-FX EndoAnchorSystems

Medtronic's Heli-FX and Heli-FX(TM) Thoracic EndoAnchor(TM) systems feature an endovascular deployed anchor designed to attach a variety of aortic endografts to the native vessel wall. This off-the-shelf, customized solution minimizes the need for complicated procedures for the select subset of patients who would benefit from supplementary fixation. This may include patients with challenging anatomies, risk factors for a secondary intervention, existing seal complications, as well as in situations where a physician may intraoperatively determine the need for additional security.

The Heli-FX and Heli-FX Thoracic EndoAnchor systems are cleared by the FDA for distribution in the United States and have been granted CE Mark for distribution in the European Union. Both products are also commercialized in other countries worldwide. The Heli-FX and Heli-FX Thoracic EndoAnchor systems can be used with a wide variety of commercially available stent grafts, including Medtronic's Endurant® and Valiant® stent graft systems. Medtronic also plans to pursue approval for use of the Heli-FX EndoAnchor system in patients with infrarenal proximal necks <10mm.

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 VEITHsymposium

Now in its 43rd year, VEITHsymposium provides vascular surgeons, interventional radiologists, interventional cardiologists, and other vascular specialists with a unique and exciting format to learn the most current information about what is new and important in the treatment of vascular disease. The 5-day event features rapid-fire presentations from world renowned vascular specialists with emphasis on the latest advances, changing concepts in diagnosis and management, pressing controversies and new techniques. Press will receive complimentary registration. Please visit www.VEITHpress.org or contact Pauline T. Mayer at +1-561-316-3330.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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