Boston Scientific Next Generation Acurate Neo2™ Aortic Valve System Demonstrates Favorable Outcomes In Clinical Practice

Advanced Sealing Technology May Reduce Rates of Paravalvular Leakage

A new study evaluating the safety and performance of the Boston Scientific ACURATE neo2™ Aortic Valve System, a next generation transcatheter aortic valve implantation (TAVI) system, demonstrated a high procedural success rate and a low rate of paravalvular aortic regurgitation at 30 days post procedure.

Results from the ACURATE neo2 CE-Mark Study, a single-arm, multi-center study, were presented at the annual congress of PCR London Valves, in London. Core laboratory adjudicated data showed 97% of patients had mild or less occurrence of paravalvular aortic regurgitation (PVL), defined as leakage of blood at the site of the valve implantation which at high rates can indicate increased risk of mortality. Data also demonstrated that the new ACURATE neo2 Valve System could be implanted with a high procedural success rate of over 97%, very short device usage times and low complication rates.

In the ACURATE neo2 CE-Mark Study, key 30-day results include the following:

- All-cause mortality rate was 3.3%; disabling stroke was 1.7%.
- Approximately 97% of patients had mild or less PVL, 3% had moderate PVL and no cases of greater than moderate PVL were observed.
- Procedural data showed a high procedural success rate of 97.5% with a very short average device usage time of 3.9 minutes.[i]
- Patients experienced marked hemodynamic improvement with the mean pressure gradients and effective orifice areas (EOA), measures used to assess the hemodynamic performance of the valve, were 7.9 +/- 3.2mmHg and 1.7 cm2, respectively.

The ACURATE neo2 Valve system maintains key features of the original ACURATE neo™ Aortic Valve System including a self-expanding nitinol frame, supra-annular positioning and a two-step, top-down deployment method. New to ACURATE neo2 is the incorporation of an annular sealing technology, intended to further reduce occurrences of PVL. The ACURATE neo2 Delivery System also features a new radiopaque marker designed to enhance visibility of positioning and ease of use by clinicians to further improve procedural safety and efficiency.

“We are very pleased with the initial performance of the ACURATE neo2 Valve System and the low paravalvular regurgitation rates, lower than previously reported with ACURATE neo, which can be attributed to the new advanced sealing technology,” said Ian Meredith, M.D., executive vice president and global chief medical officer, Boston Scientific. “Boston Scientific is committed to gathering clinical evidence that advances transcatheter heart valve therapies and expands our reach in patient care, especially in addressing unique patient pathologies and anatomies.”

The ACURATE neo2 Aortic Valve System is an investigational device and not available for sale.

About Aortic Valve Disease

Aortic valve disease results in dysfunction of the aortic valve, one of the four valves that control the flow of blood in and out of the heart. Aortic valve stenosis is the process of thickening and stiffening of the valve, resulting in restricted valve opening and reduction in blood flow. Aortic stenosis is a common problem affecting approximately three percent of the population over age 65 and five percent of people older than 75. From the onset of aortic stenosis symptoms, the average survival rate is 50 percent at two years and 20 percent at five years.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.eu and connect on Twitter and Facebook.

References

i Defined as time from insertion of delivery system into sheath to delivery system removal post implant

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https://news.bostonscientific.eu/2018-09-10-Boston-Scientific-Next-Generation-Acurate-Neo2-TM-Aortic-Valve-System-Demonstrates-Favorable-Outcomes-In-Clinical-Practice