New data from the EWOLUTION registry presented at EuroPCR 2016 confirms safety of the Boston Scientific WATCHMAN™ Left Atrial Appendage Closure device

Three-months outcomes on more than 1000 patients across Europe focus on post-procedural drug regimen, impact of centre experience and peri-device leakage.

The three-month results from the EWOLUTION REgistry on WATCHMAN Outcomes in Real-Life Utilization found that LAA closure with the Boston Scientific WATCHMAN™ device has a high success rate in complete LAA closure with low periprocedural risk, independently of implanting physicians' experience, thus confirming the safety of the device.

Dual antiplatelet therapy following the implant also appears to be safe.

The data from the prospective multicentre registry was presented by Professor Martin. W. Bergmann, head Interventional Cardiology at Cardiologicum Hamburg, Germany.

Highlights include:

- The implant procedure was successful in 98.5% of cases.
- Independent of centre experience, 99% of implanted devices presented no or minimal (≤5mm) peri-device leakage at the first follow-up, assessed by periprocedural transesophageal echocardiogram (TEE).
- Device or procedure related serious adverse events (SAE) rates at 92 days were similar if patients were treated with warfarin or DAPT (2.6% vs. 4.8%, respectively).
- Rates for bleeding SAE were also similar if warfarin or DAPT was used post-implantation (4.8% vs. 3.6%, respectively).
- Following WATCHMAN implantation, 6% of patients received no anticoagulation, 27% received oral anticoagulation (16% warfarin and 11% novel oral anticoagulants, NOACs), 60% received dual antiplatelet therapy (DAPT) and 7%of patients were on single antiplatelet therapy.
- Stroke (0.4%) and bleeding (4.1%) rates were low overall and did not vary by post-implantation medication.

About EWOLUTION

EWOLUTION included 72% of patients contraindicated to oral anticoagulation, different from previous trials. The majority of patients therefore received dual antiplatelet therapy following the procedure rather than oral anticoagulation. Currently, more than 1000 patients are part of the registry, whose real-world results are expected to complement the amount of randomised clinical trial data, the largest available for a LAAC device.

About the WATCHMAN LAAC Device

The WATCHMAN LAAC Device is a catheter-delivered heart implant designed to close the left atrial appendage (LAA) in order to prevent the migration of blood clots from the LAA, and thus, reduce the incidence of stroke and systemic embolism for higher risk patients with non-valvular AF. The LAA is a thin, sac-like appendix arising from the heart and is believed to be the source of >90% of stroke-causing clots that come from the left atrium in people with non-valvular AF.

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