New data confirms that the Boston Scientific WATCHMAN™ Left Atrial Appendage Closure Device is safe and effective in reducing the risk of stroke in patients deemed unsuitable for oral anticoagulation

One-year data from the EWOLUTION registry found that left atrial appendage closure (LAAC) with the WATCHMAN™ device followed by dual antiplatelet therapy (DAPT) significantly reduced the risk of stroke and lowered the the risk of major bleeding by more than half as compared to warfarin use.

Highlights of the data presented today as a late-breaking trial at EuroPCR 2017 include:

- 60 per cent of patients who received the implant were prescribed DAPT for a limited period of time.
- The stroke risk in this population was reduced by 81 per cent compared to predicted rates[1] of untreated patients (the annual stroke rate was 1.4 per cent.) This level of stroke risk reduction is similar to that seen in a prior trial of therapy using the non-vitamin K antagonist oral anticoagulant apixaban in a high-risk population.[2]
- The rate of major bleeding in this population was reduced by 52 per cent compared to predicted rates for patients treated with warfarin (the annual major bleeding rate was 2.5 per cent.)
- Excluding periprocedural bleeding, the major bleeding rate was reduced by 60 per cent compared to warfarin (annual major bleeding rate excluding procedural bleeding was 2.1 per cent.)
- Effective sealing of the left atrial appendage at follow-up was achieved in 99.2 per cent of patients (no leak greater than 5mm.)

The prospective, single-arm, multicentre EWOLUTION registry evaluated 1,025 patients with non-valvular atrial fibrillation (AF) who have a high risk for stroke and systemic embolism. More than 70 per cent (73.3) were deemed unsuitable for anticoagulation therapy (OAC) and were not taking any OAC directly after the procedure.

The data adds to the wealth of randomised clinical trial data available on WATCHMAN™, the largest available evidence for any LAAC device. To read the data presented earlier this month at Heart Rhythm 2017 on the whole EWOLUTION population click here.

[1]Lopes RD et al, Efficacy and safety of apixaban compared with warfarin according to patient risk of stroke and of bleeding in atrial fibrillation: a secondary analysis of a randomised controlled trial, Lancet (2012), doi: 10.1016/S0140-6736(12)60986-6. 2CHA2DS2 VASc and HAS-BLED scores have been validated to predict annual rates of ischemic stroke and bleeding, respectively. In order to provide context for the results given the absence of a control group, analyses were performed to compare EWOLUTION event rates to these historical rates for patients of a similar risk profile.

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