Amulet occluder shows promise against Watchman device in atrial fibrillation

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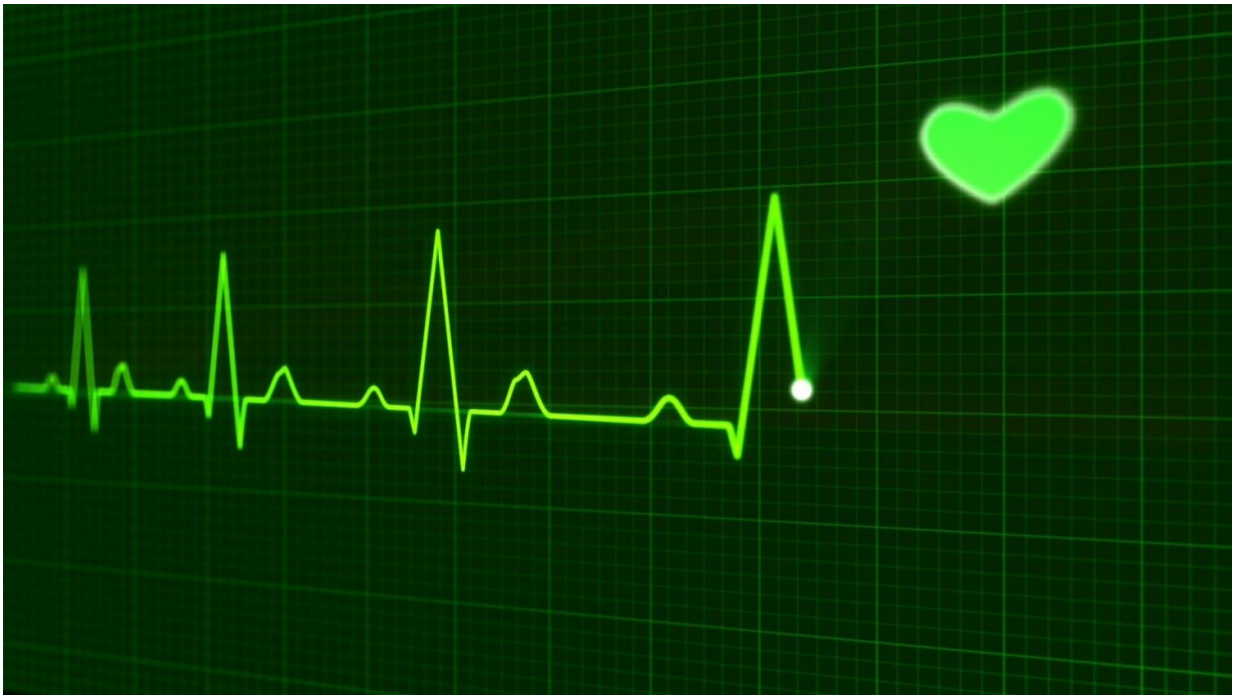

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The Amplatzer Amulet Left Atrial Appendage Occluder has shown superior left atrial appendage (LAA) closure and noninferior safety and effectiveness for stroke prevention in patients with non-valvular atrial fibrillation (NVAF) compared to the Watchman device. That's the finding of late breaking research presented in a Hot Line session today at ESC Congress 2021.

Patients with NVAF are at increased risk for ischaemic stroke. Oral anticoagulation is recommended to reduce stroke risk, but percutaneous LAA occlusion may be considered in patients with contraindications to long-term anticoagulation due to risk of bleeding.

The Amulet IDE trial was the first multicentre randomized trial comparing the Amulet LAA occluder head-to-head with the Watchman device. Both are percutaneous transcatheter devices intended to prevent the migration of blood clots from the LAA and reduce the incidence of thromboembolic events in patients with NVAF. While both devices close off the LAA, the mechanism differs. The Amulet LAA occluder dual-seals the LAA by two mechanisms using the device's lobe and disc: 1) filling the neck of the LAA with the lobe and 2) covering the LAA ostium with the disc. In contrast, the Watchman device only fills the body of the LAA.

The trial enrolled patients 18 years of age or older with paroxysmal, persistent, or permanent NVAF and at a high risk of stroke or systemic embolism defined as CHA_2DS_2-VASc score of 3 or higher or a $CHADS_2$ score of 2 or higher. Patients were screened with transoesophageal echocardiography to ensure suitable LAA anatomy for implanting either device prior to enrolment. As required by the directions for use of the Watchman device, patients had to be suitable for anticoagulation therapy for six weeks post-implantation.

A total of 1,878 patients were randomized 1:1 to receive an Amulet LAA occluder or a Watchman device. All patients were required to complete clinical follow-up at discharge, 45 days, 3, 6, 9, 12 and 18 months, and 2, 3, 4 and 5 years. Follow-up beyond 18 months is currently ongoing.

The trial had three primary endpoints. The primary safety endpoint was a composite of procedure-related complications, all-cause death, or

major bleeding through 12 months. The primary effectiveness endpoint was a composite of ischaemic stroke or systemic embolism through 18 months. The primary mechanism of action endpoint was device based LAA closure (residual jet around the device 5 mm or less) as assessed by an independent core laboratory on transoesophageal echocardiography at the 45-day visit. This endpoint provided an indication of how well the device was sealing off the LAA.

The average age of participants was 75 years and 60% were men. Patients most frequently sought an alternative to anticoagulation therapy due to a history of major or minor bleeding (~54%) or high bleeding risk (~21%). Patients were at a high risk of stroke, with a mean CHA_2DS_2-VAScscore of ~4.6. The device was successfully implanted as randomized in 98.4% of Amulet patients and 96.4% of Watchman patients. Most (82.0%) Watchman patients were discharged on warfarin plus aspirin. In contrast, 75.7% of Amulet patients were discharged on dual antiplatelet therapy (aspirin and clopidogrel) and 20.0% were on anticoagulation plus aspirin.

Device based LAA closure rates were higher and demonstrated superiority of the Amulet LAA occluder compared with the Watchman device (98.9% versus 96.8%; difference=2.03; 95% confidence interval [CI] 0.41–3.66; p