**CE-538-03**

**INCIDENCE, PREDICTORS, AND CLINICAL OUTCOMES OF PERI-DEVICE LEAK IN SUBJECTS UNDERGOING TRANSCATHETER LEFT ATRIAL APPENDAGE CLOSURE IN THE AMULET IDE TRIAL**

Christopher R. Ellis MD, FHRS; Matthew Price MD; Jens Erik Nielsen-Kudsk MD; David Thaler MD, PhD; Nigel Gupta MD; Konstantinos Koulogiannis MD and Dhanunjaya R. Lakkireddy MD, FHRS

**Background:** The Amulet IDE trial is a prospective, global, randomized (1:1) trial of the Amplatzer (Abbott) occluder versus the Watchman (Boston Scientific) device (Boston Scientific) in subjects with non-valvular AF. Mismatch between LAA anatomy and LAAC device can result in peri-device leaks (PDLs). The association of PDL to stroke has been unclear.

**Objective:** Investigate the incidence, predictors, and clinical outcomes of PDL in subjects in Amulet IDE trial.

**Methods:** Subjects in the Amulet IDE trial were at a high risk of stroke or systemic embolism defined as CHA2DS2-VASc score of ≥3. Protocol mandated transesophageal echocardiography (TEE) was performed at 45 days and 12 months post-procedure. An independent echo core lab analyzed all TEE images for the presence or absence of PDL. PDL was graded as the single largest jet visualized around the device from a minimum of 3 Doppler views. Based on recent literature and the median leak size observed in this study of 3mm, a binary analysis defining PDL as ≥3mm was used in this post-hoc analysis.

**Results:** A total of 1,788 subjects were successfully implanted as randomized with an Amulet™ occluder (N=903) or Watchman™ device (N=885). A total of 1,593 (89%) subjects had an evaluable TEE at 45 days (801 Amulet and 792 Watchman) and 1,291 (72%) at 12 months (673 Amulet and 618 Watchman). Baseline characteristics of subjects with PDL were well-matched between the devices (75.6 ± 6.9 years, 59.0% males, CHA2DS2-VASc 4.8 ± 1.4). Amulet occluder had superior closure (<3mm) compared to Watchman device at both 45 days (89% vs 74%; p<0.001) and 12 months (91% vs 78%; p<0.001). In multivariable analysis, device type (Watchman as opposed to Amulet) and increased CHA2DS2-VASc score identified subjects at increased risk for PDL. In a landmark analysis, subjects with PDL at 45 days had increased rates of ischemic stroke or systemic embolism at 12 months (2.8% vs. 0.9%; p=0.011) with no significant interaction between the device groups (p=0.663).

**Conclusion:** The dual-seal Amulet™ occluder demonstrated superior closure through 12 months compared to the single-occlusive Watchman™ device. PDL at 45 days was associated with a higher incidence of ischemic stroke or systemic embolism. Long-term clinical implications and progression of PDL should be an area of future investigation.

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<th>Table 1: Incidence of bleeding in the presence of competing risks in the intention-to-treat populations</th>
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**CE-538-04**

**INTRACARDIAC ECHOCARDIOGRAPHY-GUIDED LEFT ATRIAL APPENDAGE OCCLUSION WITHOUT CINEANGIOGRAPHY**

Akanibo Da-Wariboko BS, MD; Thomas Flautt; Adi Lador MD; Apoor Patel MD and Miguel Valderrabano MD

**Background:** Left atrial appendage closure (LAAC) with the WATCHMAN device relies on contrast cineangiography of the left atrial appendage. Clinical indications for LAAC commonly overlap with substantial comorbidities including renal dysfunction. An approach to limit or eliminate the use of contrast agents is highly desirable. Intracardiac echocardiography (ICE) has been shown to be effective in guiding LAAC.

**Objective:** We seek to evaluate the safety and feasibility of ICE-guided LAAC without the need of cineangiography of the LAA.

**Methods:** Patients (N=22) with indications for LAAC underwent WATCHMAN device placement entirely guided by intracardiac echocardiography without cineangiography of the left atrial appendage (LAA). Three cases were performed with assisted guidance by a 3D rendition of the LAA. Follow up imaging was performed after 6 weeks to assess device position, presence of leaks or device thrombus.

**Results:** Deployment of LAAC occlusive device was successful in all patients without acute peri-device leak. There were no procedural complications. There was no contrast utilized. Procedural time was 58 ± 31 minutes. Compression rate was 22 ± 8%. Upon follow-up there were no device related thrombus detected. A mild (<3mm) peri-device leak was noted in one patient.

**Conclusion:** ICE-guided WATCHMAN device LAAC without the use of contrast or fluoroscopy is safe and feasible.

**ABSTRACT BS-514:**

**Gene Therapy for Arrhythmias**

Saturday, April 30, 2022
8:00 AM - 9:00 AM

**BS-514-01**

**SCN10ASHORT AS A NOVEL GENE THERAPY TARGET TO TREAT CONDUCTION DEFECTS**

Jianan Wang; Arie O. Verkerk PhD; Mischa Klerk; Annie Boender; Hanno L. Tan MD, PhD; Harsha Devalla; Vincent M. Christoffels PhD; Phil Barnett and Gerard J. Boink MD, PhD

**Background:** Voltage-gated sodium channels play a critical role in the action potential (AP) upstroke velocity and impulse propagation in the heart. Sodium channel gene therapy is challenged by the relatively large transgene size of Sodium.