ABSTRACT CE-538:
Left Atrial Appendage Occlusion: Trials and Tribulations

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CE-538-01
TRANSCATHETER LEAK OCCLUSION WITH ENDOVASCULAR COILS FOLLOWING LEFT ATRIAL APPENDAGE CLOSURE: PROCEDURAL SUCCESS AND OUTCOMES BEFORE AND AFTER LEAK CLOSURE
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Background: Whether residual peri-device leaks after left atrial appendage occlusion (LAAO) portend a higher risk of thromboembolism (TE), it is still a matter of debate.

Objective: We report the TE risk in patients with incomplete LAA closure before and after leak closure with endovascular coils.

Methods: One hundred twenty-four Watchman patients with a CHA2DS2-VASc: 4.4; HAS-BLED: 3.1 underwent LAAO and were followed-up with TEE at 1 year. The primary endpoint was a composite of major AF-related cardiovascular, neurological or bleeding events.

Results: The time between LAAO and leak coiling was 8 ± 6 months [83 patients-year (PY)]; before leak closure, 6 (4.8%) patients had a TE event (annualized rate: 7.2%). Coil deployment was successful in all cases [median n. of coils deployed: 5 (IQR: 3-10)]. Procedure time was 79 ± 40 min; the mean volume of iodinated contrast medium used was 80 ± 43mL. The overall complication rate was 2.4% (1 pericardial tamponade, 2 pericardial effusion). Follow-up TEE after 61 ± 14 days revealed complete LAA sealing or a negligible leak in 117 cases (94.4%); the remaining 7 patients had a moderate leak. During 14 ± 6 months post-coiling (145 PY), 1 (0.8%) patient suffered from stroke. The incidence of TE events was significantly lower after leak closure than before coiling (0.8% vs 4.8%; log-rank p = 0.02; fig.1A). The annualized TE rates were 7.2% before and 0.7% after leak closure (Fig. 1B). According to the expected rate estimated from the patients’ CHA2DS2-VASc (9.8%), LAAO with and without significant leaks yielded to a risk reduction of 26.5% and 92.9% (Fig. 1B).

Conclusion: Transcatheter leak occlusion via endovascular coils was safe. LAA leak closure led to a significant reduction in TE events.
IN THE AMULET IDE TRIAL
TRANSCATHETER LEFT ATRIAL APPENDAGE CLOSURE
PERI-DEVICE LEAK IN SUBJECTS UNDERGOING
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 AmuletTM 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 compared to those without PDL. PDL 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.

Conclusion: The dual-seal AmuletTM 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.

CE-538-04

INTRACARDIAC ECHOCARDIOGRAPHY-GUIDED LEFT ATRIAL APPENDAGE OCCLUSION WITHOUT CINEANGIOGRAPHY

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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 LAA 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.