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: To 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 significant (>3mm) leak (mean age: 74 ± 9 years; 66.9% males; CHA2DS2-VASc: 4.4 ± 1.7; HAS-BLED: 3.1 ± 1) underwent LAA leak coiling. The expected annual TE risk was estimated based on the patients’ CHA2DS2-VASc and compared with the annualized incidence observed before and after coiling (Fig 1B).

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: 2-10)]. 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.

CE-538-02

LEFT ATRIAL APPENDAGE CLOSURE IS ASSOCIATED WITH REDUCED NON-PROCEDURAL BLEEDING COMPARED TO NOAC TREATMENT: A SUB-ANALYSIS OF THE 4-YEAR FOLLOW-UP OF THE PRAGUE-17 TRIAL

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Background: In PRAGUE-17, the first randomized controlled trial comparing non-vitamin K oral anticoagulants (NOACs; ~ 95% Apixaban) with LAAC (Amulet or Watchman) in high-risk patients with nonvalvar AF, LAAC was noninferior to NOACs in preventing the composite endpoint of major AF-related cardiovascular, neurological or bleeding events.

Objective: To compare the type and severity of bleeding events with NOAC vs LAAC.

Methods: The primary endpoint in PRAGUE-17 was a composite of a cardioembolism (stroke, TIA, systemic embolism), cardiovascular death, procedural complications and ISTH major (MB) or clinically-relevant non-major bleeding (CRNMB) - the latter defined as bleeding requiring hospitalization or an invasive procedure/device related. In the primary modified ITT analysis, LAAC was associated with similar rates of ISTH major and non-major bleeding (Table). The rate of non-procedural ISTH- MB/CRNMB was significantly reduced in the LAAC group (sHR 0.55, 95%CI 0.31-0.97, p = 0.039). The rates of non-procedural MB were not significantly different between groups (0.69, 95%CI 0.34-1.39, p = 0.3); but the rate of non-procedural CRNMB was lower in the LAAC group (sHR 0.43, 95%CI 0.18-1.03, p = 0.059). Per protocol and on-treatment analyses revealed similar results. Gastrointestinal bleeding represented the most common type of bleeding (~ 50%) in both groups.

Conclusion: After a 4 year follow-up period in the PRAGUE-17 randomized trial, LAAC was associated with a reduced rate of non-procedural bleeding - a reduction that was mainly driven by a decrease in clinically-relevant non-major bleeding. On the one hand, this is not surprising given the relatively good safety profile of NOACs; on the other hand, clinically-relevant non-major bleeding is not benign, as it leads to hospitalization and often leads to NOAC discontinuation.