

## THE SAFETY OF PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE FOR STROKE PREVENTION IN ATRIAL FIBRILLATION (AF) PATIENTS: IS THERE EVIDENCE FOR A LEARNING CURVE?

i2 Oral Contributions

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**Background:** PROTECT AF randomized trial compared warfarin with left atrial appendage (LAA) closure using a filter device (WATCHMAN) in AF pts with CHADS<sub>2</sub> ≥ 1. While the primary endpoint of stroke/systemic embolism/cardiovascular death favored LAA closure (RR = 0.71, 95%CI 0.44 - 1.30), safety complications of LAA closure compared to control- predominantly peri-procedural events of pericardial effusion and procedure-related stroke (largely related to air embolism). Herein, we report the influence of LAA closure experience on the acute safety event rate.

**Methods:** The analysis cohort included patients in the PROTECT AF trial that underwent LAA closure, and patients enrolled in a subsequent non-randomized CAP registry (Continued Access PROTECT AF). The incidence of procedure or device related safety adverse events (and the subtypes of acute serious pericardial effusion and procedure-related stroke) was assessed and their timing was compared between the two studies. All data were adjudicated by an independent Clinical Events Committee (CEC).

**Results:** This analysis includes 542 and 566 patients undergoing LAA closure at 59 and 26 centers in the PROTECT-AF and CAP studies, respectively. The procedural complication rates declined significantly over the course of the two studies.

**Conclusions:** As with all novel procedures, there is a learning curve to LAA closure. With experience, the serious pericardial effusion rate is 2.1% and the procedure-related stroke rate is zero.

Events Within 7 Days	PROTECT-AF	PROTECT-AF		CAP	p-value <sup>a</sup>	p-value <sup>b</sup>
		1 <sup>st</sup> Half	2 <sup>nd</sup> Half			
Any Procedure/Device Related Safety Adverse Event	42/542 (7.7)	27/271 (10.0)	15/271 (5.5)	22/566 (3.9)	0.005	0.006
Serious Pericardial Effusion	27/542 (5.0)	17/271 (6.3)	10/271 (3.7)	12/566 (2.1)	0.010	0.010
Procedure-related Stroke	5/542 (0.9)	3/271 (1.1)	2/271 (0.7)	0/566 (0.0)	0.022	0.022

Values presented are N Events/Patients (%). P-values are from Chi-square tests. <sup>a</sup>P-values are from Chi-square tests comparing the PROTECT-AF cohort with CAP. <sup>b</sup>P-values are from Mantel-Haenszel Chi-square tests for differences across three groups (each half of PROTECT-AF and CAP).