Percutaneous left atrial appendage closure vs. oral anticoagulation: A propensity score matched study of 1000 patients with atrial fibrillation

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I have the following potential conflicts of interest to report:

- Institutional grant/research support:
  GRANTS FROM THE SWISS HEART FOUNDATION and ABBOTT/SJM

BACKGROUND & OBJECTIVES

- LAAC using the Watchman device has been shown to be superior to OAC regarding efficacy and noninferior regarding safety.

- No prospective, randomized trials available for Amplatzer systems.

- To compare net clinical benefit after percutaneous left atrial appendage closure (LAAC) with Amplatzer devices compared to the standard therapy of oral anticoagulation (OAC) in patients with atrial fibrillation (AF).

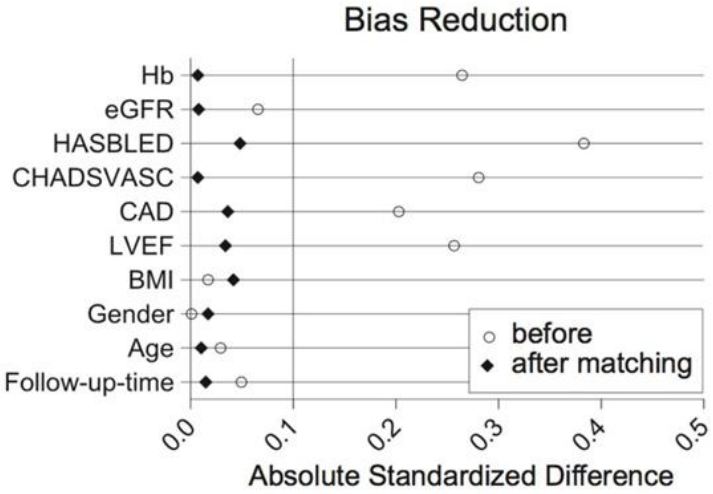
METHODS

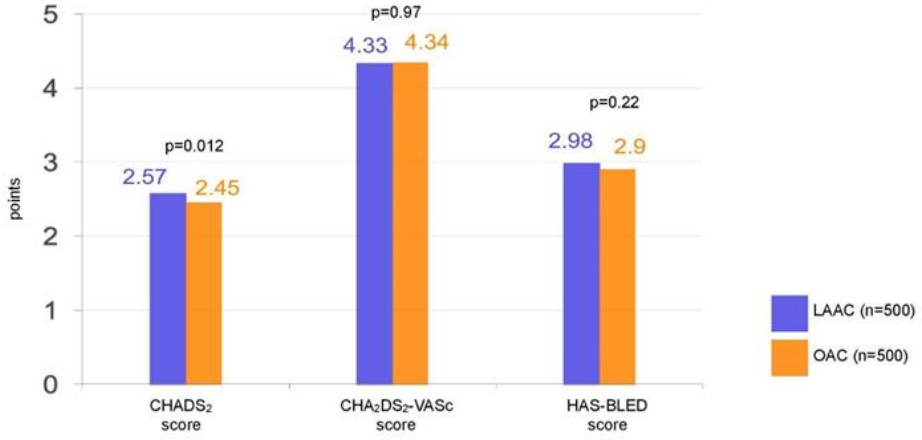
- 1000 Patients: Propensity score matching of 500 patients with any anticoagulation (OAC or NOAC) for AF to 500 consecutive LAAC patients with Amplatzer devices.
- Logistic 4:1 (i.e 500 out of 2000) nearest neighbor propensity score matching.

- Matching criteria: Gender, age, and body mass index, stroke- and bleeding risk (CHA_2DS_2-VASc, HAS-BLED scores), coronary artery disease, left ventricular ejection fraction, renal function, hemoglobin.
- Sweep follow-up from September 2015 to December 2016.
- Predefined endpoints, intention-to-treat analysis.
- Primary efficacy endpoint: Stroke, systemic embolism, and cardiovascular/unexplained death.
- Primary safety endpoint: All major procedural adverse events and major or life-threatening bleeding.
- Combined hazard endpoint (net clinical benefit): Combination of all above mentioned hazards.

RESULTS

- Propensity score matching: Good comparability by excellent bias reduction in all matching categories with absolute standardized differences <0.1.

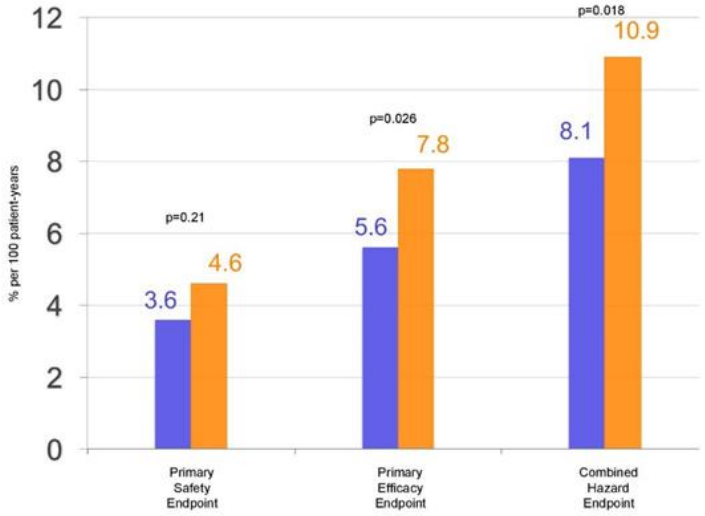




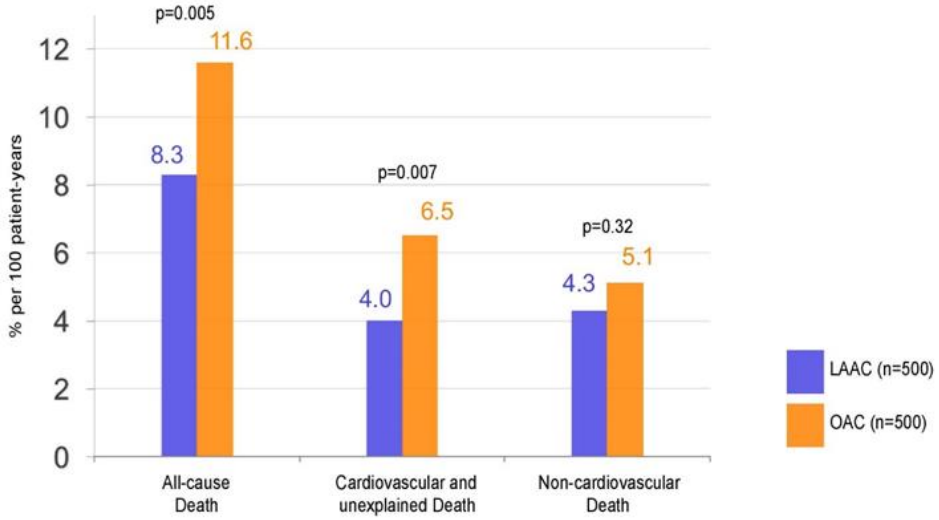
RESULTS: Predefined endpoints at a glance

- 1000 patients (500 vs. 500)
- mean follow-up of 2.7 ± 1.5 years
- 2,645 patient-years

Primary endpoints



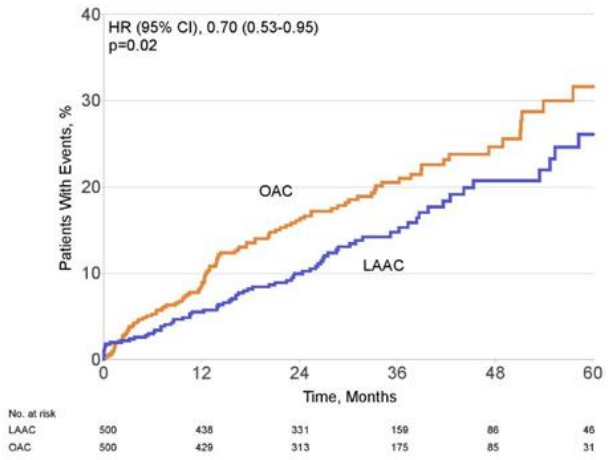
Mortality



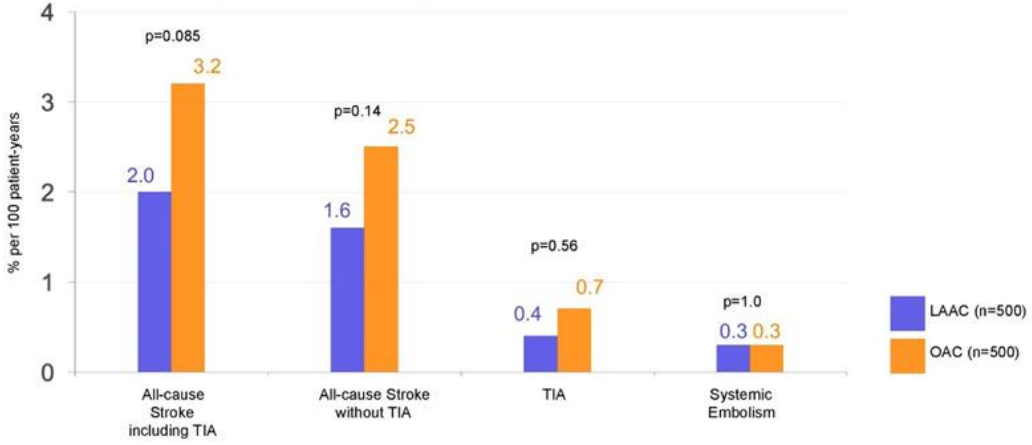
RESULTS: Efficacy

- 75/1342 (5.6%) vs. 102/1303 (7.8%) per 100 patient-years
- Hazard ratio (HR): 0.70
- 95% confidence interval (CI): 0.53-0.95, p=0.02

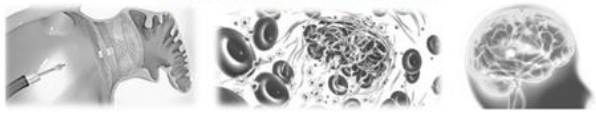
Primary efficacy endpoint

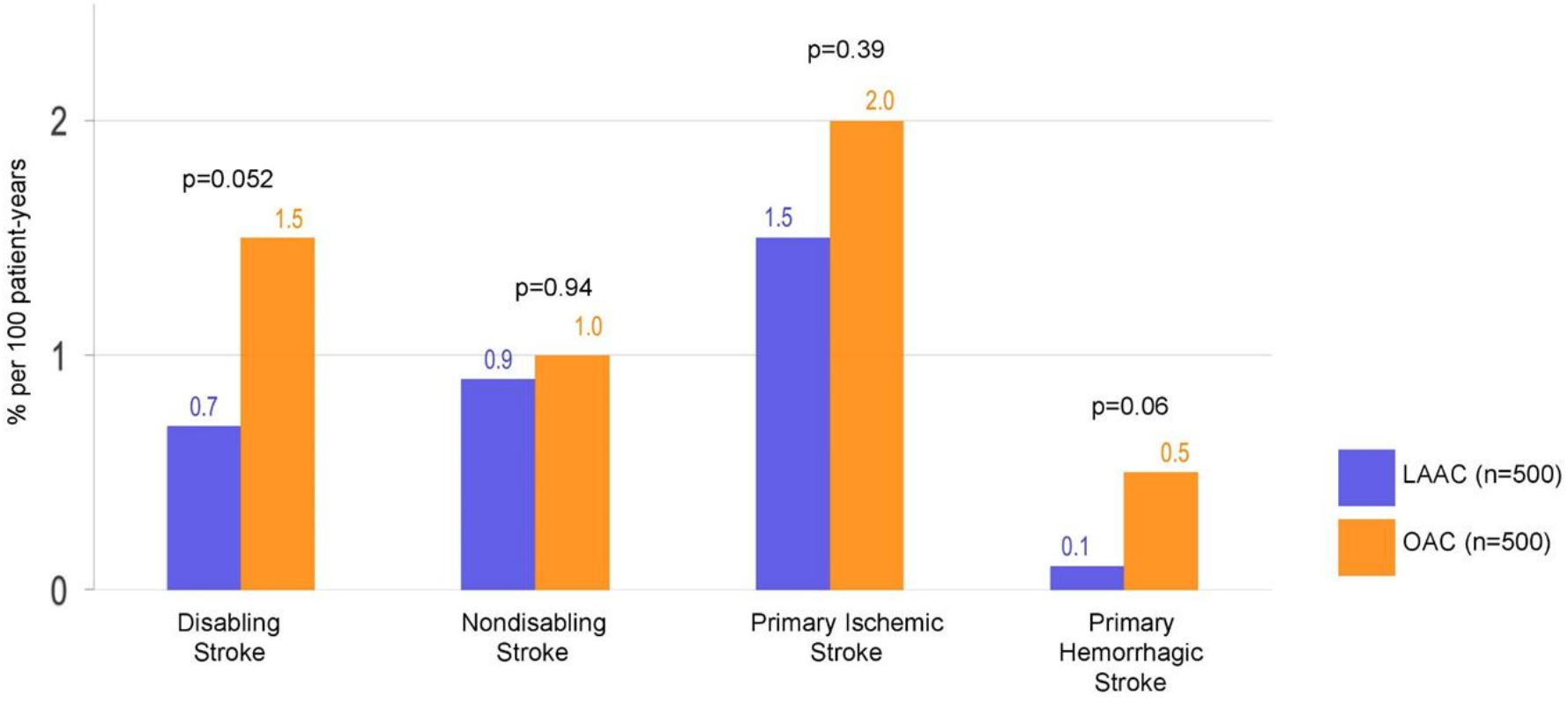


Stroke, TIA and systemic embolism

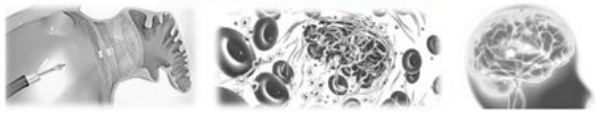


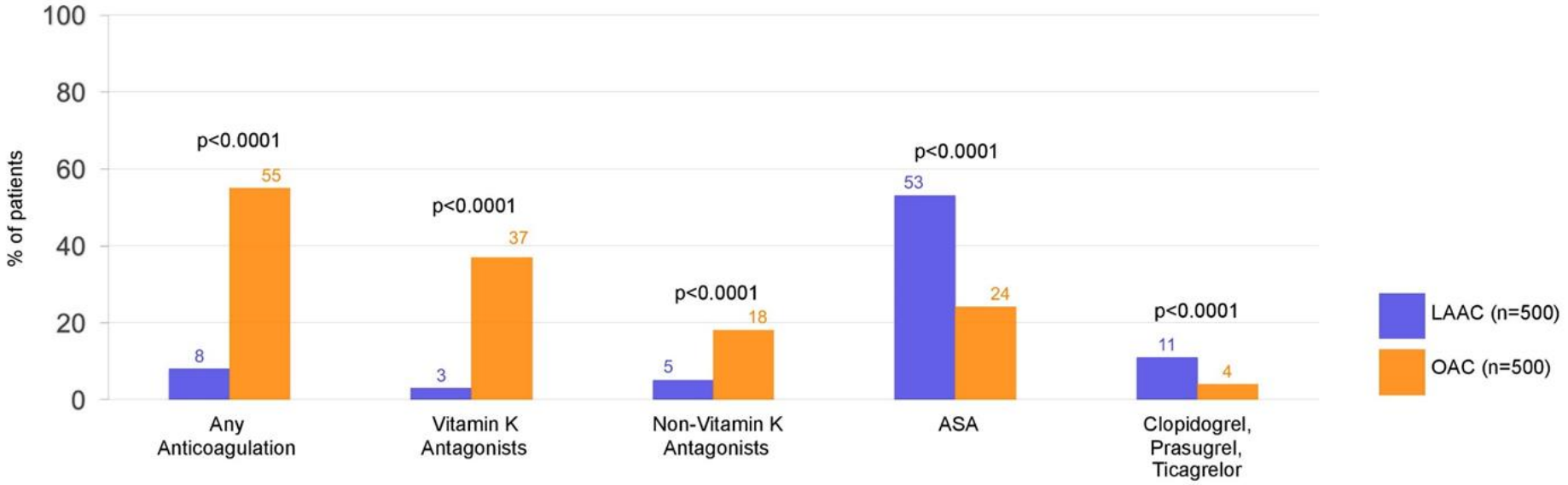
STROKE TYPES





ANTI-THROMBOTIC THERAPY AT FOLLOW-UP

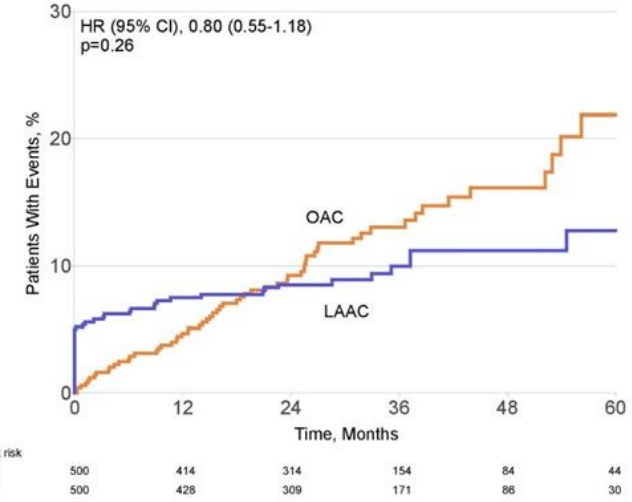




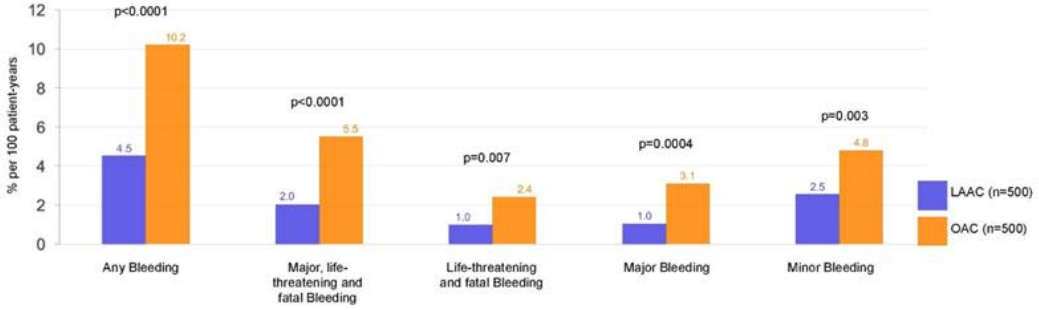
RESULTS: Safety

- 48/1342 (3.6%) vs. 60/1303 (4.6%) per 100 patient-years
- HR: 0.80
- 95% CI: 0.55-1.18, p=0.26.

Primary safety endpoint

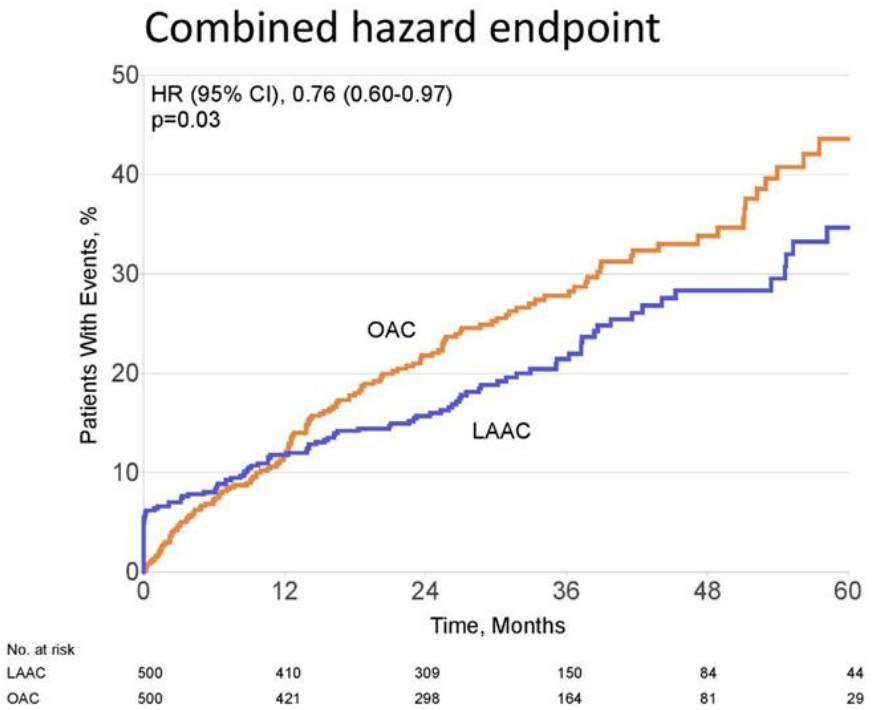


Bleedings



RESULTS: Net clinical benefit

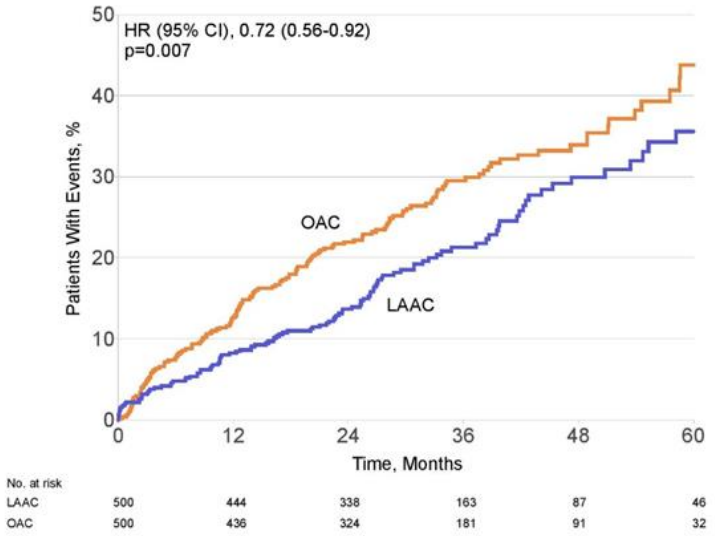
- 109/1342 (8.1%) vs. 142/1303 (10.9%) per 100 patient-years
- HR: 0.76
- 95% CI: 0.60-0.97, p=0.03.



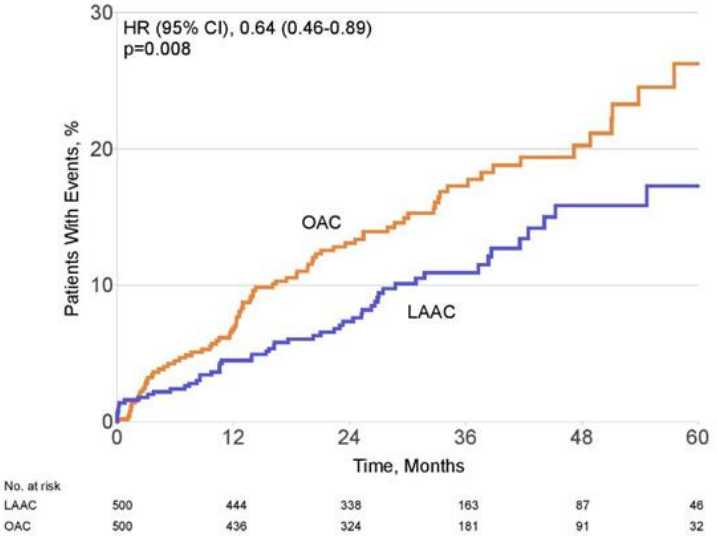
RESULTS: Mortality

- All-cause mortality: 111/1342 (8.3%) vs. 151/1303 (11.6%)
  HR: 0.72, 95% CI: 0.56-0.92, p=0.007
- Cardiovascular mortality: 54/1342 (4.0%) vs. 84/1303 (6.5%)
  HR: 0.64, 95% CI: 0.46-0.89, p=0.008.

All-cause mortality



Cardiovascular mortality



CONCLUSIONS

After 2.7 years of follow-up among patients with nonvalvular AF, in this propensity score matched study of 1,000 patients with 2,645 patient-years

LAAC with Amplatzer devices showed

a net clinical benefit over OAC and NOAC

-by superior efficacy

-similar safety

a benefit in all-cause and cardiovascular mortality.