



ATRIAL FIBRILLATION  
NETWORK

AXAFA – AFNET 5

STUDIENDESIGN

Catheter ablation is an effective and increasingly used treatment to maintain and restore sinus rhythm in patients with symptomatic atrial fibrillation.

It is recommended to perform atrial fibrillation ablation on continuous anticoagulation to minimize periprocedural strokes.

One small and one medium-sized controlled clinical trial in patients undergoing atrial fibrillation ablation found that bleeding risk is similar with rivaroxaban and dabigatran compared to vitamin K antagonists.

High resolution diffusion weighted magnetic resonance brain imaging identifies small acute brain lesions in approximately 25% of patients undergoing atrial fibrillation ablation.

Cognitive decline has been reported 90 days after atrial fibrillation ablation.

Benamer K et al. *AJNR Am J Neuroradiol*; 27:1987-9.(2006)

Herm J et al. *Circ Arrhythm Electrophysiol*. 6:843-850 (2013)

Nakamura T et al. *Europace*;19:1681-8.(2017)

Medi C et al. *J Am Coll Cardiol*; 62:531-9.(2013)

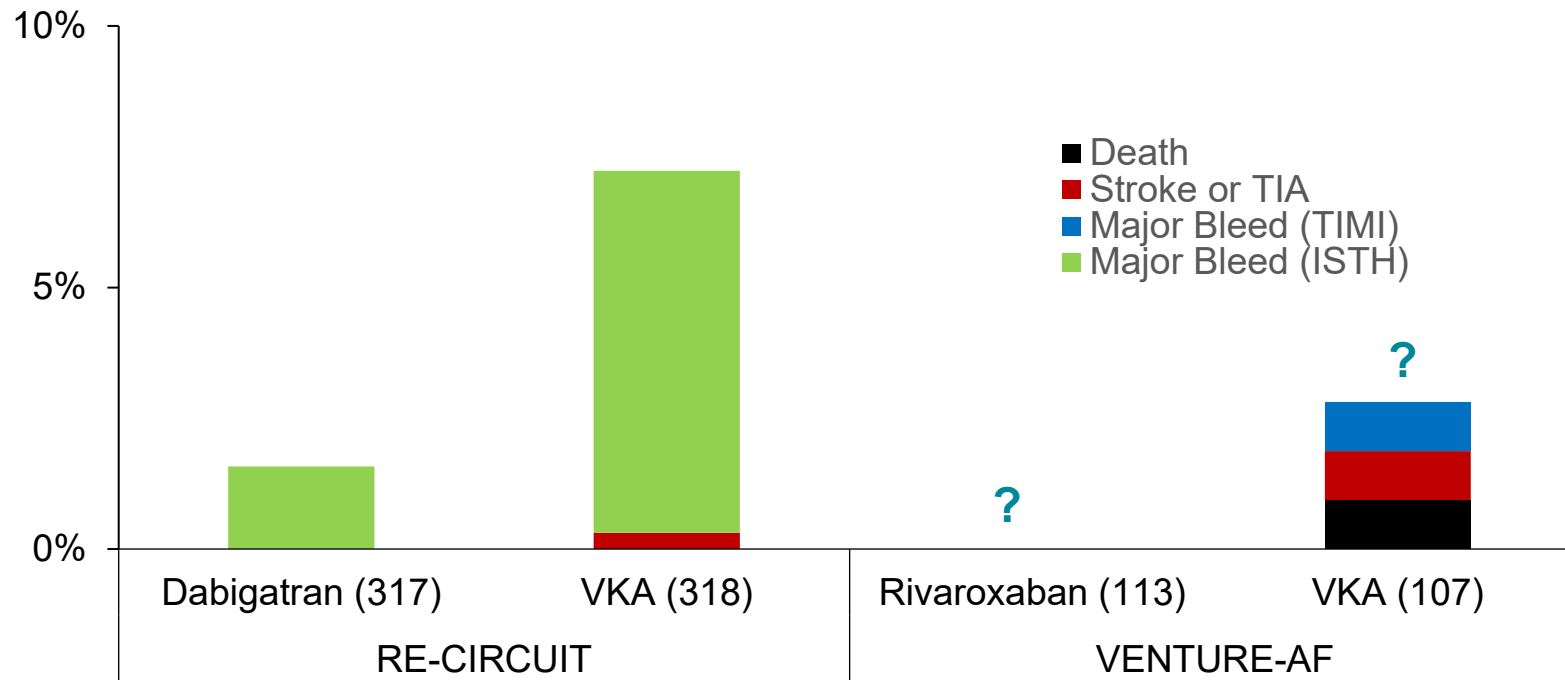
2016 ESC AF Guidelines. *Eur Heart J* 37:2893-962 (2016)

Di Biase L, et al. *Circulation*. 129:2638-2644 (2014)

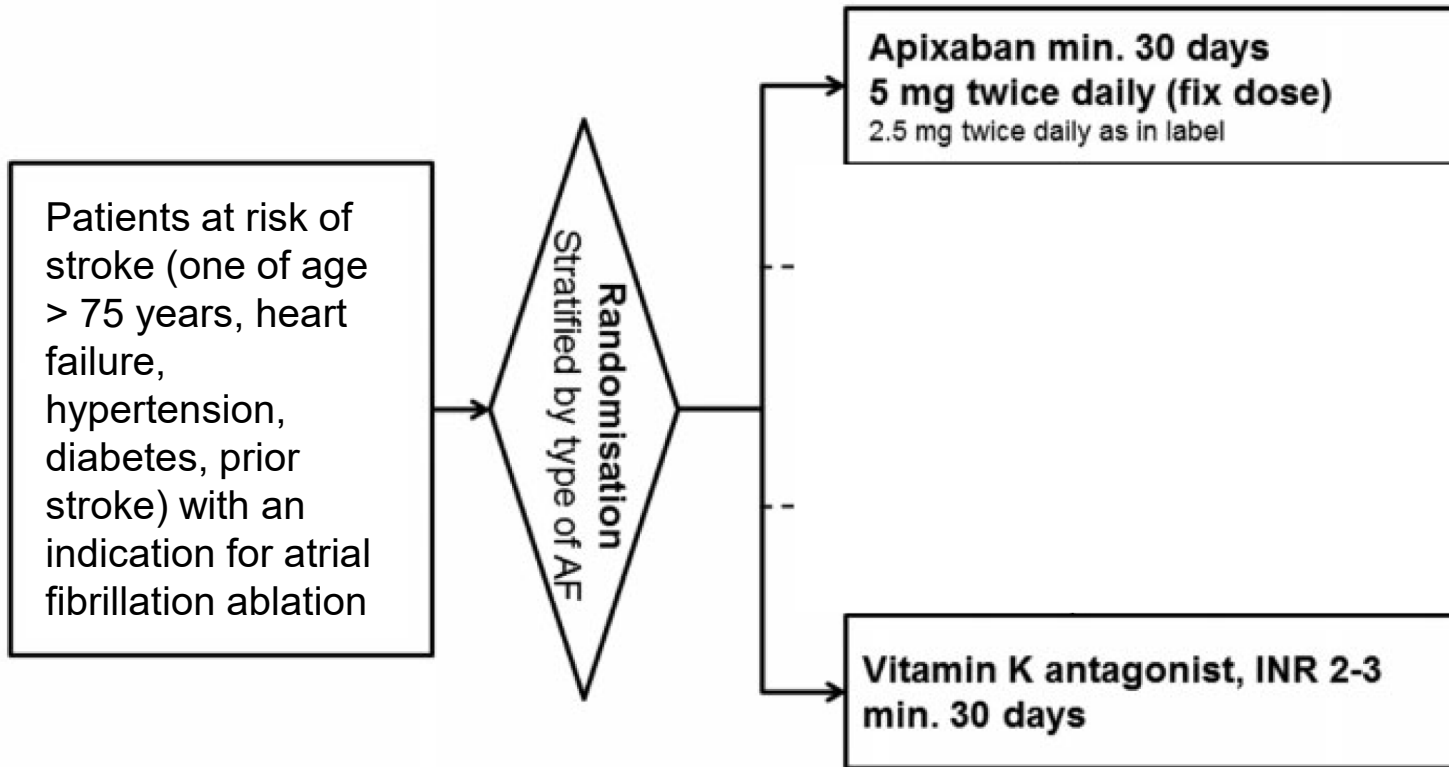
Cappato R et al. *Eur Heart J*; 36:1805-11.(2015)

Calkins H et al. *N Engl J Med*; 376:1627-36.(2017)

# Event rates in controlled trials of continuous NOAC and VKA therapy



# Study Design



49 sites in Europe and the USA  
650 patients planned

Day 0

Day 90  
+ 14 days

# Main outcomes

## Primary outcome:

Composite of death, stroke, or bleeding (BARC 2-5)

The sample size was determined based on a 7.5% absolute non-inferiority margin (1.44 relative margin)

## Selected secondary outcomes:

Components of the primary outcome (adjudicated, descriptive)

ISTH and TIMI major bleeds (adjudicated, descriptive)

Quality of life (SF-12, Karnofsky scale) at end of study, change compared to baseline

MRI substudy: patients with HR-DWI lesions, number of lesions per patient

Cognitive function at 90 days, change compared to baseline

# CONSORT diagram

