

Apixaban vs. Aspirin for the prevention of stroke due to subclinical AF in patients with an implanted cardiac monitor: Analysis from the ARTESiA Trial

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Background - 1

Subclinical atrial fibrillation (SCAF) is detected in approximately one-third of patients with implanted pacemakers and defibrillators (ASSERT-I)

Detected at similar rates in patients with implanted cardiac monitors (ICM) in patients without an indication for pacemaker or ICD (ASSERT-II)

The NOAH-AFNET 6 and ARTESiA trials show a reduction in stroke using oral anticoagulation among patients with SCAF and additional stroke risk factors, which is balanced by an increase in bleeding risk



Background -

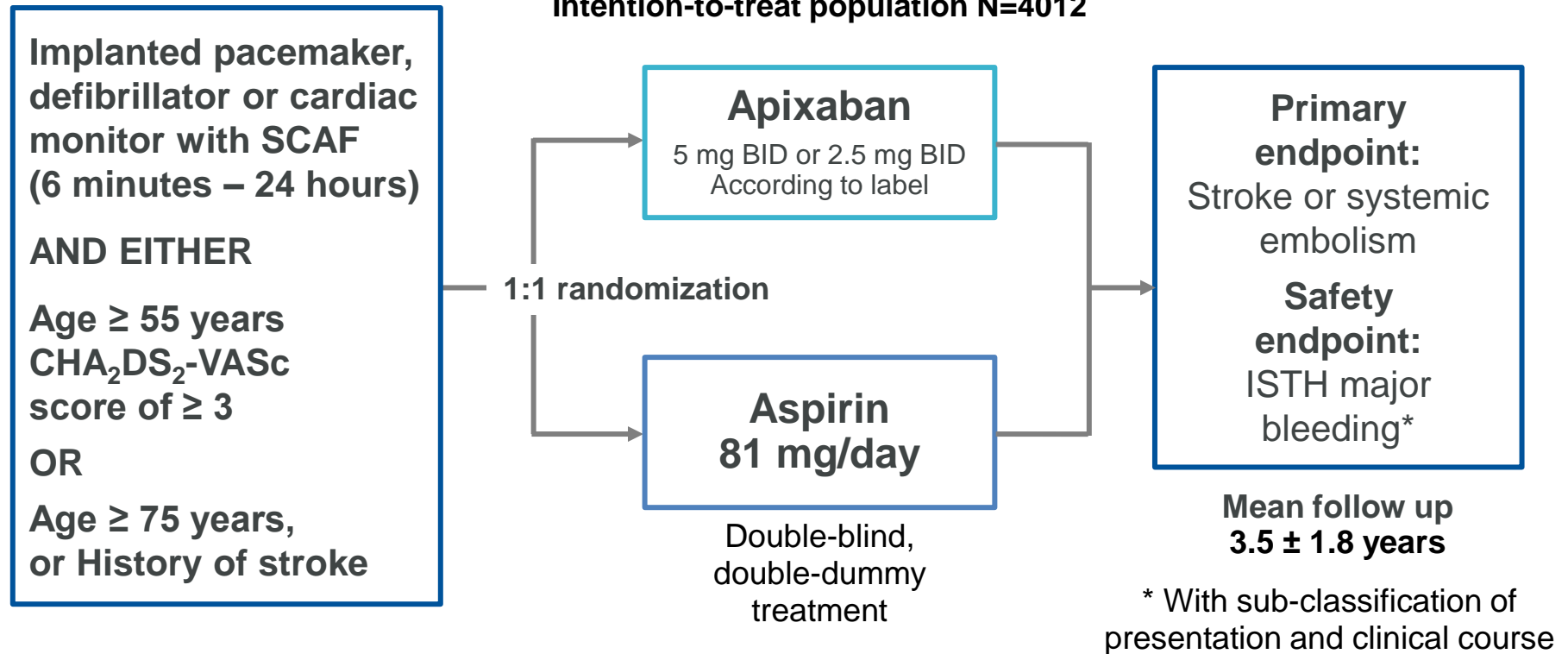
ARTESiA included enrolled 200 individuals with SCAF detected by an ICM

This analysis sought to determine if ARTESiA patients with SCAF detected by an ICM:

1. Have similar stroke risk factors as other patients in the trial?
2. Have a similar rate of stroke and systemic embolism?
3. Derive similar benefit from apixaban?



ARTESIA Study Design

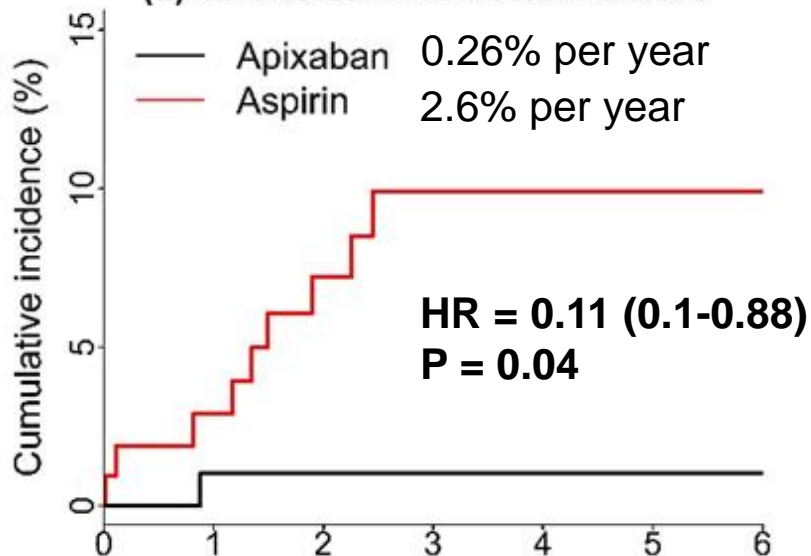


Baseline Characteristics

	Patients with ICM (n=209)	Patients with PM/ICD (n=3803)	P-value
Age (mean \pm SD)	74.9 \pm 7.9	76.9 \pm 7.6	<0.001
Male sex (%)	49.8	64.7	<0.001
Body mass index	28.1 \pm 5.2	28.9 \pm 5.8	0.046
Longest SCAF episode (median, IQR)	0.8 hours (0.2 - 3.0 hours)	1.5 hours (0.2 – 5.0 hours)	0.074
CHADS-VASc score (mean)	3.9 \pm 1.2	3.9 \pm 1.1	0.92
Hypertension	78.9%	81.6%	0.33
Diabetes Mellitus	20.6%	29.6%	0.005
Congestive Heart Failure	8.6%	29.4%	<0.001
Prior stroke or TIA	24.9%	7.7%	<0.001
Prior systemic embolism	1.4%	0.3%	0.04
Coronary artery disease	16.3%	3.8%	<0.001
Vascular disease	11.5%	8.2%	0.09

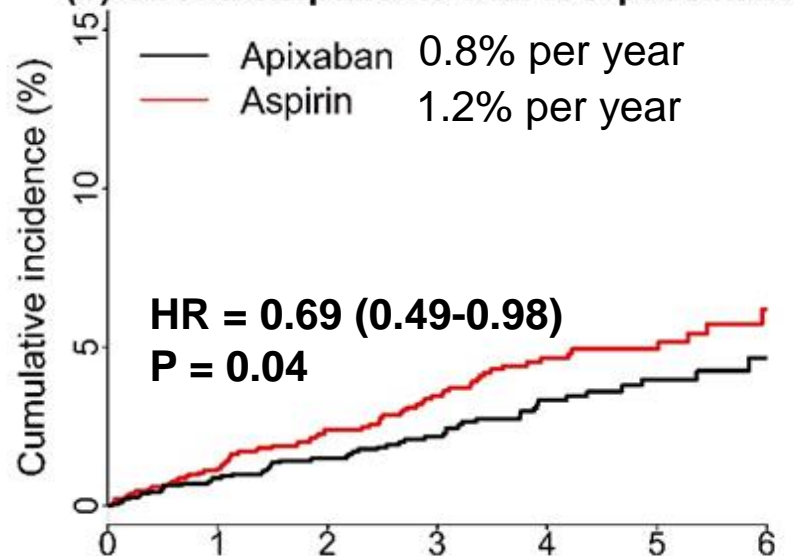
Stroke/SE by Device Type

(a) Stroke/SE:ICM-detected SCAF



No. at Risk	Years since Randomization						
	0	1	2	3	4	5	6
Apixaban	103	95	86	69	43	24	10
Aspirin	106	94	79	52	38	22	14

(b) Stroke/SE:patients with ICD/pacemaker



No. at Risk	Years since Randomization						
	0	1	2	3	4	5	6
Apixaban	1912	1691	1470	1088	779	450	204
Aspirin	1891	1683	1460	1069	741	446	186

P-Interaction = 0.08

Conclusions

1. Despite an identical CHADS-VASc score, patients with ICM-detected SCAF had a very different risk factor profile

Younger, with a greater history of stroke/TIA/SE (26%), and CV disease
Less diabetes and heart failure

2. Aspirin-treated patients with ICM-detected SCAF had a greater risk of stroke/SE than patients with a pacemaker or ICD

3. Patients with SCAF detected by and ICM had a significant reduction in stroke/SE with apixaban

Which appeared larger in absolute and relative terms than among patients with SCAF detected by a pacemaker or ICD

First demonstration of reduction in stroke/SE in patients with ICM-detected SCAF using oral anticoagulation