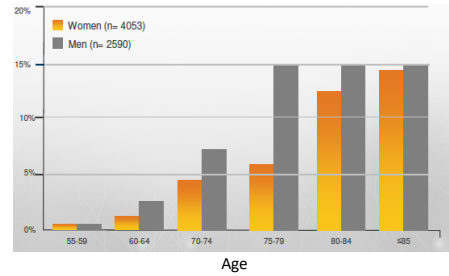


## Left Atrial Appendage Closure (LAAC): Evidence and patient selection

Lars Sondergaard, MD, DMSc  
Professor of Cardiology  
Rigshospitalet, University of Copenhagen  
Denmark

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### Prevalence of atrial fibrillation



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### CHA<sub>2</sub>DS<sub>2</sub>-VASc Score

CHA <sub>2</sub> DS <sub>2</sub> -VASc	Score	Score	Adjusted stroke rate (%/year)
Congestive heart failure/ LV dysfunction	1	0	0
Hypertension	1	1	0.7
Age ≥75 years	2	2	1.9
Diabetes mellitus	1	3	4.7
Stroke/TIA/TE	2	4	2.3
Vascular disease (prior MI, PAD, or aortic plaque)	1	5	3.9
Age 65–74 years	1	6	4.5
Female sex	1	7	10.1
	Max=9	8	14.2
		9	100

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### CHA<sub>2</sub>DS<sub>2</sub>-VASc Score

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	Max=9	8	14.2
		9	100

Oral anti-coagulation indicated if  
CHA<sub>2</sub>DS<sub>2</sub>-VASc Score ≥2

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### Risk of serious bleeding

Risk factors	Points
<b>H</b> - Hypertension	1
<b>A</b> - Abnormal renal or/and liver function	1 or 2
<b>S</b> - Stroke	1
<b>B</b> - Bleeding	1
<b>L</b> - Labile INR	1
<b>E</b> - Elderly (age >65 years)	1
<b>D</b> - Drugs or alcohol abuse	1 or 2
<b>Max score</b>	<b>9 points</b>

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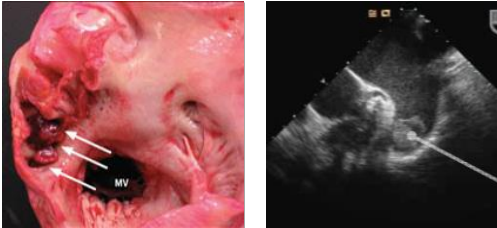
### Oral anti-coagulation



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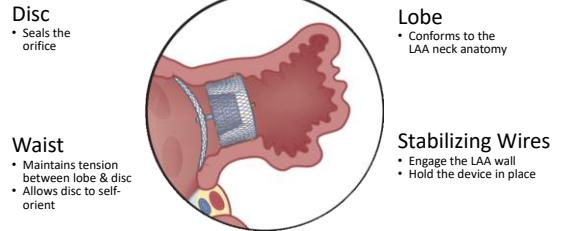
Thrombus in left atrial appendage

Cause of 90% of strokes in AFib



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Amplatzer Amulet device (Abbott)



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Case example

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63 years old male. 175 cm, 107 kg, BMI 34.9 kg/m<sup>2</sup>

Medical history:

- Peripheral polyneuropathy
- Basal ganglion hemorrhage - with R hemiparesis
- HT
- Permanent AF

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2016 ESC Guidelines for management of AFib

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>
After surgical occlusion or exclusion of the LAA, it is recommended to continue anticoagulation in stroke patients with AF for stroke prevention.	I	B
LAA occlusion may be considered for stroke prevention in patients with AF and contra-indications for long-term anticoagulant treatment (e.g. those with a previous life-threatening bleed without a reversible cause)	IIIb	B
Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients with AF undergoing cardiac surgery.	IIIb	B
Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients undergoing thoracoscopic AF surgery.	IIIb	B

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Candidates for LAAC

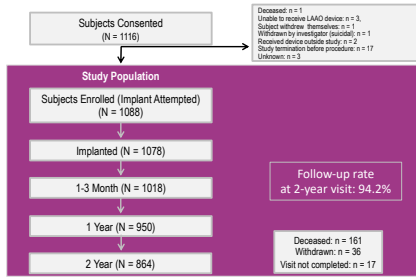
Europe:

Patients with *absolute* contra-indications for OAC

- severe bleeding episode

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### Global Amulet observational registry



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### Demographics

Baseline Characteristic	All enrolled (N = 1,088)
Age (years)	75.2 ± 8.5
Gender - Male	64.5%
CHA <sub>2</sub> DS <sub>2</sub> -VASc Score	4.2 ± 1.6
HAS-BLED Score	3.3 ± 1.1
Prior Stroke	27.5%
Prior TIA	10.6%
Previous Major Bleed	71.7%
Contraindication to OAC	82.8%

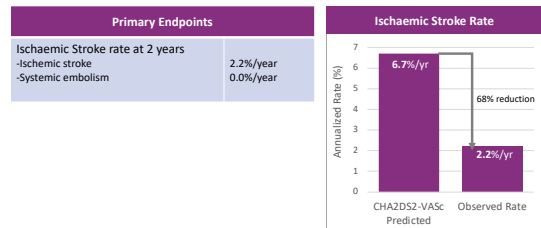
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### Safety end-points

Primary Endpoints	
<b>Early SAEs (0-7 days)</b>	
Pericardial effusion or tamponade	1.5%
Major vascular complication	0.9%
Ischemic stroke	0.4%
Death	0.3%
Device embolization	0.2%
<b>Late SAEs (related to procedure/device; &gt;7 days)</b>	
Device-related thrombus (DRT)	1.6%
Major bleeding event	0.5%

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### Efficacy end-points



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### Candidates for LAAC

**Europe:**

Patients with *absolute* contra-indications for OAC  
 • severe bleeding episode

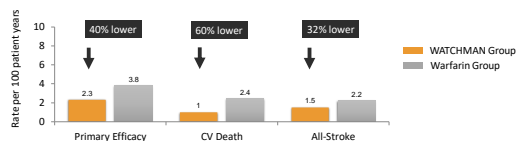
**US:**

Patients with *relative* contra-indication for OAC  
 • high bleeding risk

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### PROTECT-AF @ 4Y

	WATCHMAN Observed Rate per 100 pt-yr	Warfarin Observed Rate per 100 pt-yr	% Reduction (vs Warfarin)	
Primary Endpoint	2.3	3.8	40%	SUPERIOR
CV Death	1.0	2.4	60%	SUPERIOR
All Stroke	1.5	2.2	32%	NON-INFERIOR
Hemorrhagic Stroke	0.2	1.1	85%	SUPERIOR
Fatal/Disabling Stroke	0.5	1.2	63%	SUPERIOR



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Pre-procedural planning


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ECG: AF 60 bpm

Bld results: eGFR >90, INR 1.8, Plt 294

Cardiac CT on 22/5/2018

- Chicken wing morphology
- No intracardiac thrombus



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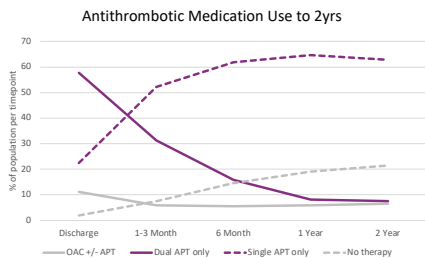
LAAC procedure

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Post-procedural anti-thrombotic therapy



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LAAC with the Amulet device

- The observed rate of ischaemic stroke was 2.2%/yr, a 68% reduction compared to the CHA<sub>2</sub>DS<sub>2</sub>-VASc predicted rate.
- For patients unable to take anticoagulants, the Amplatzer™ Amulet™ device offers high levels of protection from ischaemic stroke.
- 84% of patients were on single APT or no antithrombotic medications 2 years post-LAAO.

**LAAC with the Amplatzer™ Amulet™ occluder is a safe and effective means to reduce the risk of ischaemic stroke without the need for long-term anticoagulation.**

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