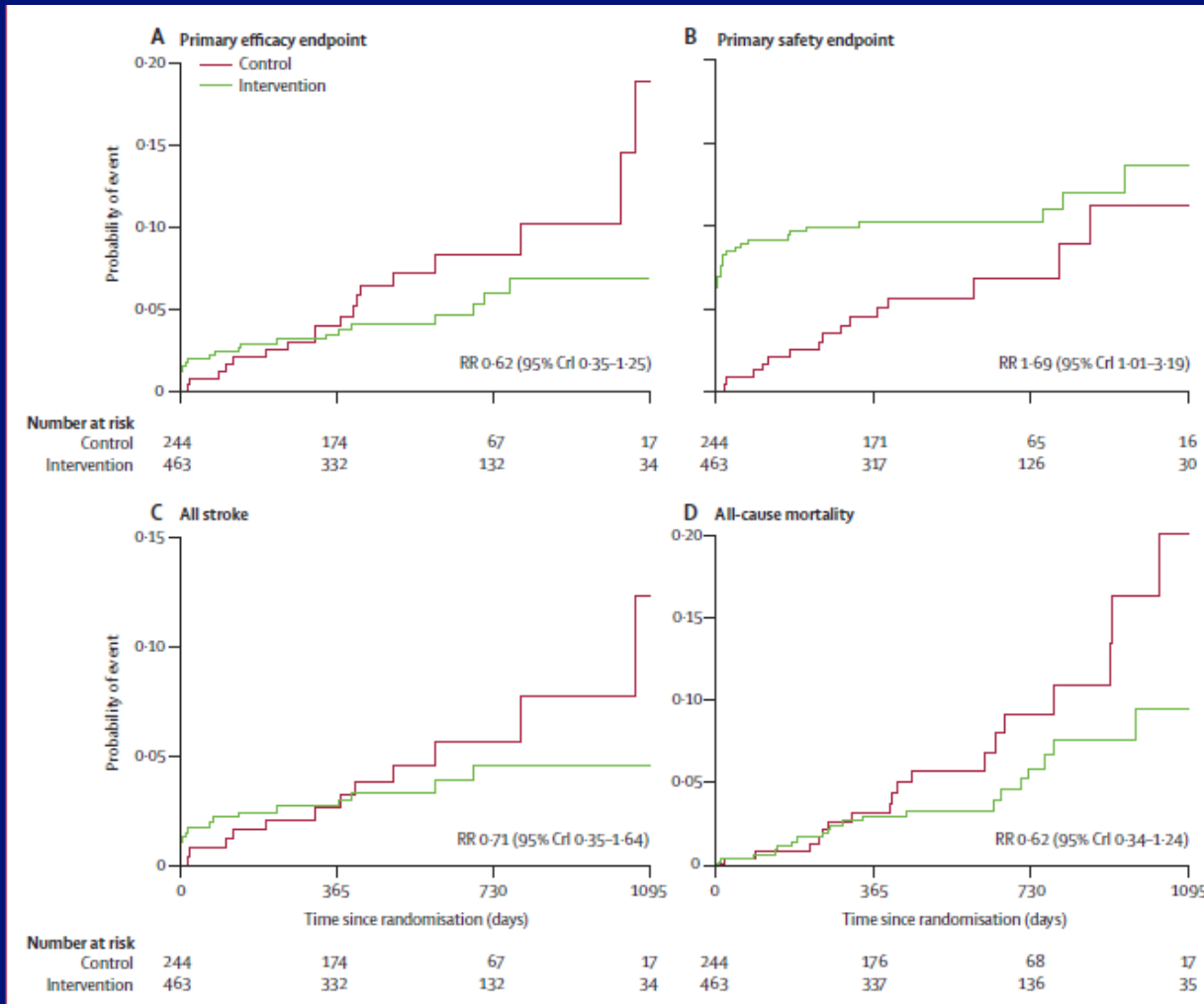


Outcomes (% per year)							
	Warfarin (n = 6022)	Dabigatran 150 (n = 6076)	Dabigatran 110 (n = 6015)	Warfarin (n = 7133)	Rivaroxaban (n = 7131)	Warfarin (n = 9081)	Apixaban (n = 9120)
		(RR, 95% CI; P value)	(RR, 95% CI; P value)		(HR, 95% CI; P value)		(HR, 95% CI; P value)
Stroke/systemic embolism	1.69	1.11 (0.66, 0.53–0.82; P for superiority <0.001)	1.53 (0.91, 0.74–1.11; P for non-inferiority <0.001)	2.4	2.1 (0.88, 0.75–1.03; P for non-inferiority <0.001, P for superiority = 0.12) (ITT)	1.6	1.27 (0.79, 0.66–0.95; P <0.001 for non-inferiority, P = 0.01 for superiority)
Ischaemic stroke	1.2	0.92 (0.76, 0.60–0.98; P = 0.03)	1.34 (1.11, 0.89–1.40; P = 0.35)	1.42	1.34 (0.94; 0.75–1.17; P = 0.581)	1.05	0.97 (0.92, 0.74–1.13; P = 0.42)
Haemorrhagic stroke	0.38	0.10 (0.26, 0.14–0.49; P <0.001)	0.12 (0.31, 0.17–0.56; P <0.001)	0.44	0.26 (0.59; 0.37–0.93; P = 0.024)	0.47	0.24 (0.51, 0.35–0.75; P <0.001)
Major bleeding	3.36	3.11 (0.93, 0.81–1.07; P = 0.31)	2.71 (0.80, 0.69–0.93; P = 0.003)	3.4	3.6 (P = 0.58)	3.09	2.13 (0.69, 0.60–0.80; P <0.001)
Intracranial bleeding	0.74	0.30 (0.40, 0.27–0.60; P <0.001)	0.23 (0.31, 0.20–0.47; P <0.001)	0.7	0.5 (0.67; 0.47–0.93; P = 0.02)	0.80	0.33 (0.42, 0.30–0.58; P <0.001)
Extracranial bleeding	2.67	2.84 (1.07, 0.92–1.25; P = 0.38)	2.51 (0.94, 0.80–1.10; P = 0.45)	–	–	–	–
Outcomes (% per year)							
Gastrointestinal bleeding	1.02	1.51 (1.50, 1.19–1.89; P <0.001)	1.12 (1.10, 0.86–1.41; P = 0.43)	2.2	3.2 (P <0.001)	0.86	0.76 (0.89, 0.70–1.15; P = 0.37)
Myocardial infarction	0.64	0.81 (1.27, 0.94–1.71; P = 0.12)	0.82 (1.29, 0.96–1.75; P = 0.09)	1.1	0.9 (0.81; 0.63–1.06; P = 0.12)	0.61	0.53 (0.88, 0.66–1.17; P = 0.37)
Death from any cause	4.13	3.64 (0.88, 0.77–1.00; P = 0.051)	3.75 (0.91, 0.80–1.03; P = 0.13)	2.2	1.9 (0.85; 0.70–1.02; P = 0.07)	3.94	3.52 (0.89, 0.80–0.99; P = 0.047)
% Discontinuation at the end of follow-up	10.2	15.5	14.5	22.2	23.7	27.5	25.3
% Discontinuation/year	5.1	7.8	7.3	11.7	12.5	15.3	14.1

# Watchman vs Warfarin



1065 patient-years FU

Primary efficacy endpoint  
(stroke, CV death, systemic  
Embolism):

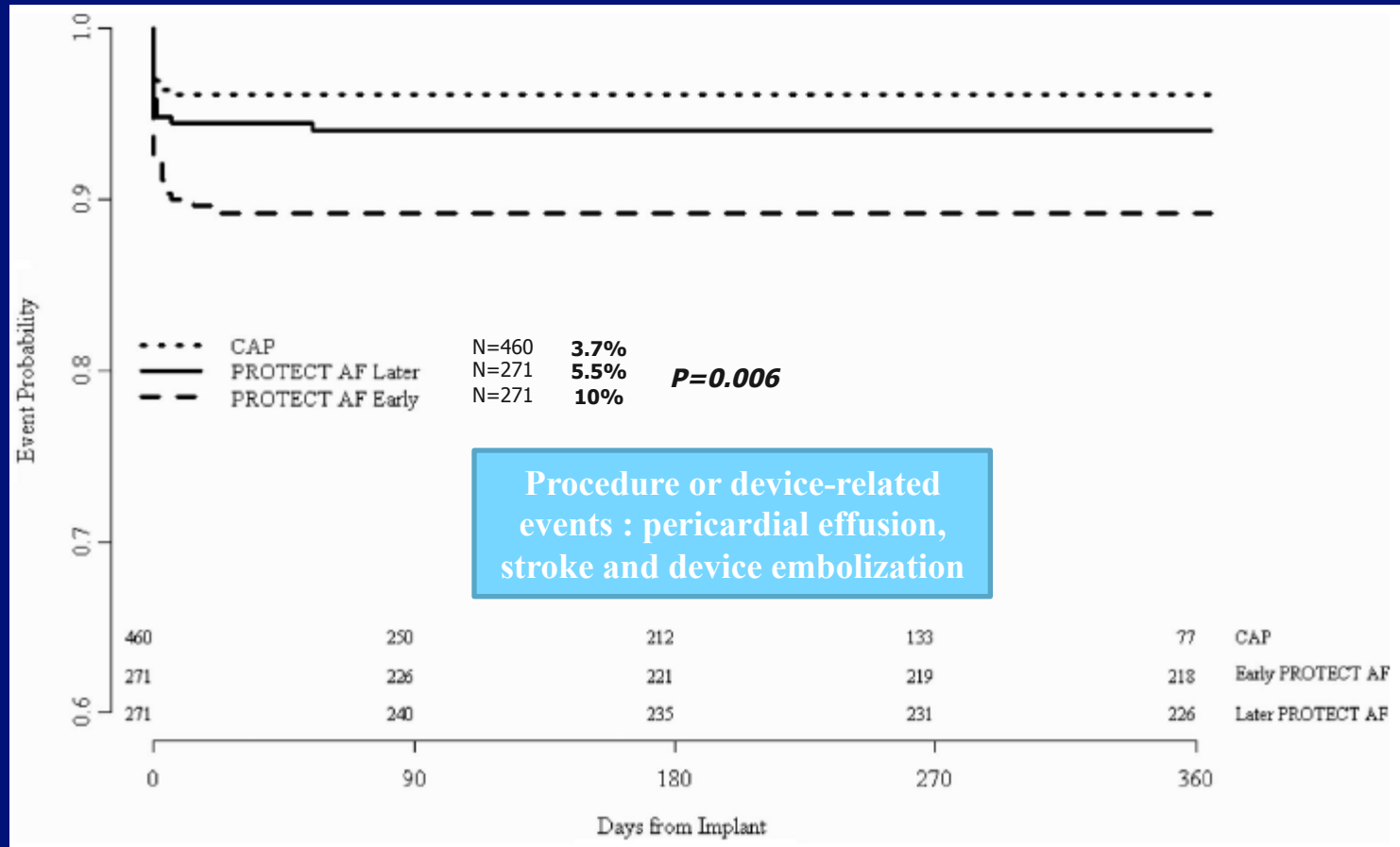
3 per 100 patient-years vs  
4.9 per 100 patient-years;  
Probability of non-inferiority  
>99.9%

Primary safety endpoint  
(PE, device embolization,  
Major bleeding):

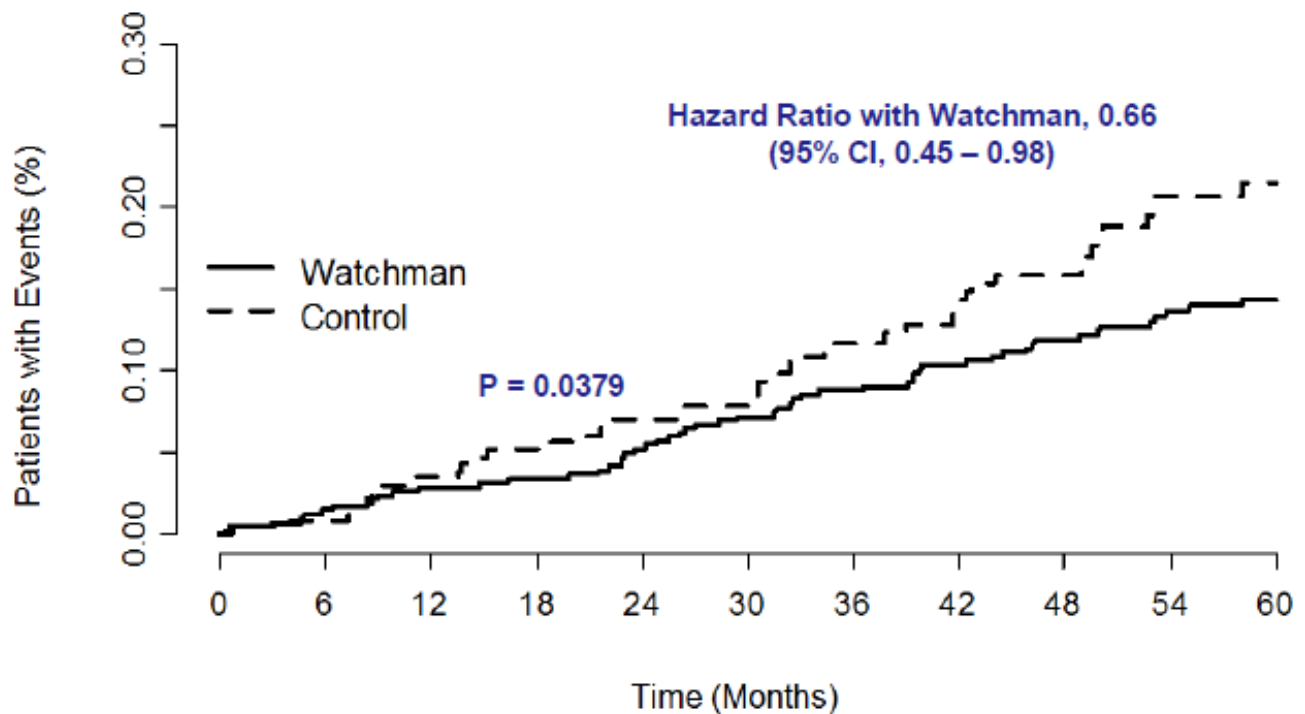
7.4 per 100 patient-years vs  
4.4 per 100 patient-years

Holmes DR et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with Atrial fibrillation: a randomized non-inferiority trial. Lancet 2009;374:534-42

# Learning Curve Effect



# Long-term Effect-All-cause Mortality



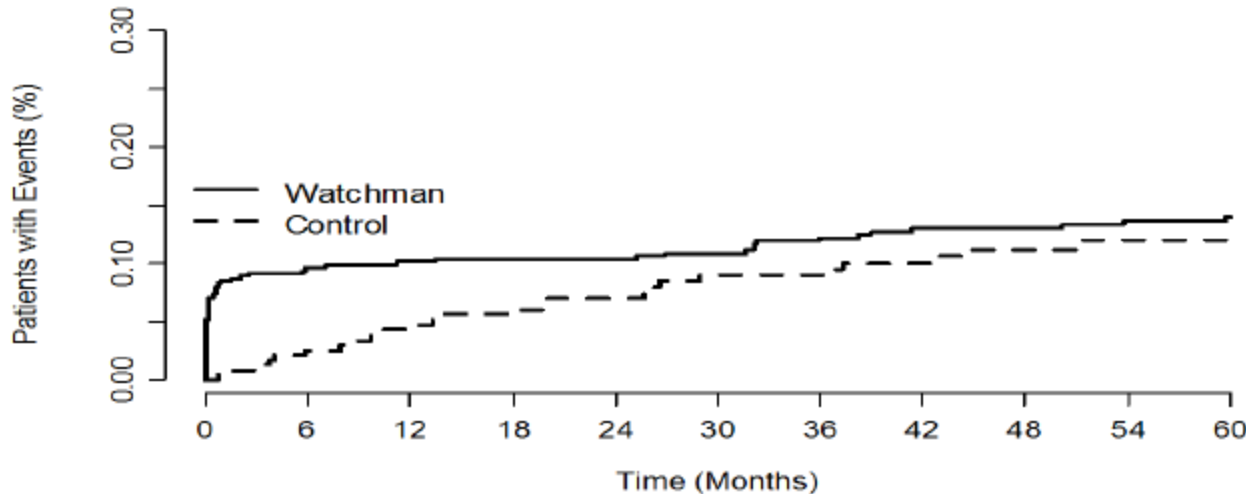
No. at Risk	0	6	12	18	24	30	36	42	48	54	60
Watchman	463	404	389	381	373	360	352	341	330	294	202
Control	244	233	222	216	204	193	177	163	150	125	92

Cause	Watchman Group (n=463)	Warfarin Group (n=244)	p value
Cardiovascular	13 / 2.8%	12 / 4.9%	0.1973
Cancer	10 / 2.2%	3 / 1.2%	0.5584
Pulmonary	9 / 1.9%	9 / 3.7%	0.2082
Neurologic	5 / 1.1%	3 / 1.2%	1.0000
Multisystem organ failure	5 / 1.1%	1 / 0.4%	0.6700
Hemorrhagic Stroke	2 / 0.4%	7 / 2.9%	0.0098
Other	9 / 1.9%	6 / 2.5%	0.7844

Reddy VY, et al. Long-term results of Protect AF  
HRS LBCT 2013.

# Long-term Effect

Event	Watchman Group (n = 463)		Warfarin Group (n = 244)		Posterior Probabilities		
	Events/ Patient-Years	Observed Rate (Events per 100 Patient-Years) (95% CrI)	Events/ Patient-Years	Observed Rate (Events per 100 Patient-Years) (95% CrI)	Rate Ratio (Watchman/Warfarin) (95% CrI)	Non- inferiority	Superiority
Primary Safety Endpoint	60/1666.2	3.6 (2.8, 4.6)	27/878.2	3.1 (2.0, 4.3)	1.17 (0.78, 1.95)	0.980	0.196



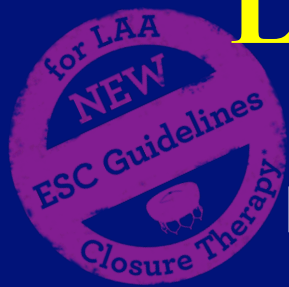
No. at Risk											
Watchman	463	376	364	357	353	341	332	320	310	277	190
Control	244	228	214	207	195	183	169	153	139	117	86

Event	Watchman Group (n = 463)			Warfarin Group (n = 244)
	Total Events No. (%)	Early Events No. (%)	Late Events No. (%)	Events No. (%)
Serious pericardial effusion	22 (4.8%)	22 (4.8%)	0 (0.0%)	---
Major bleeding	22 (4.8%)	3 (0.6%)	19 (4.1%)	18 (7.4%)
Procedure-related stroke	6 (1.3%)	5 (1.1%)	1 (0.2%)	---
Device embolization	3 (0.6%)	3 (0.6%)	0 (0.0%)	---
Hemorrhagic stroke	3 (0.6%)	0 (0.0%)	3 (0.6%)	9 (3.7%)
Other	4 (0.9%)	4 (0.9%)	0 (0.0%)	---

Reddy VY, et al. Long-term results of Protect AF  
HRS LBCT 2013.

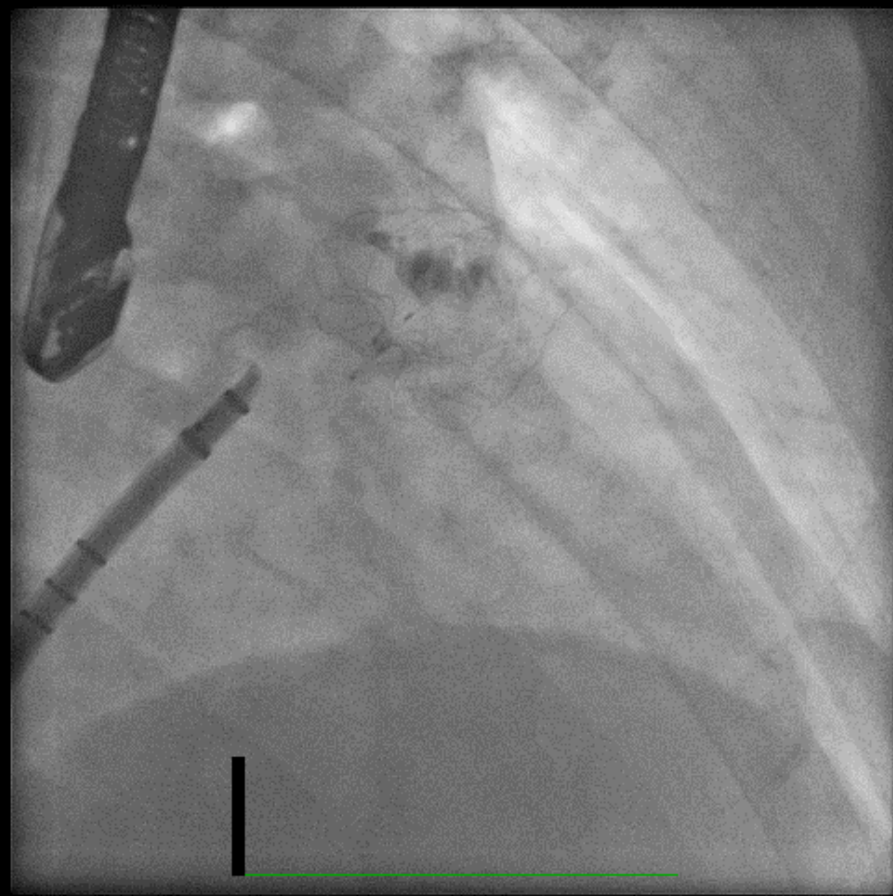
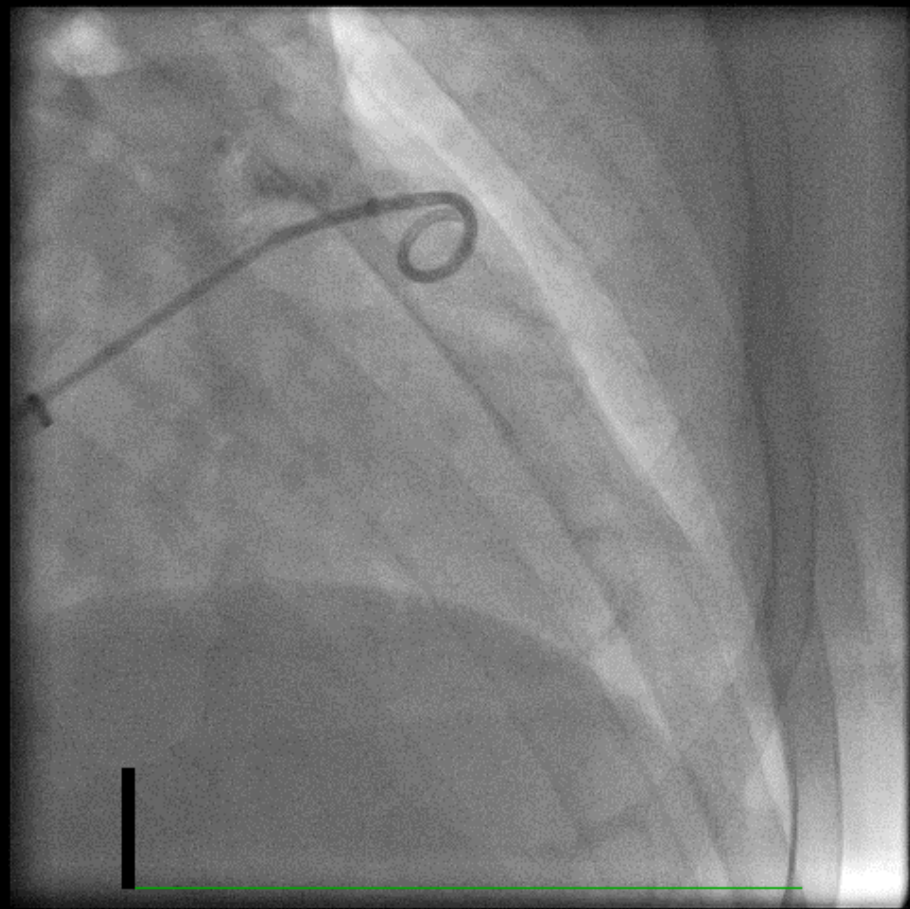
# ESC A-Fib Guidelines 2012

## Left Atrial Appendage Closure

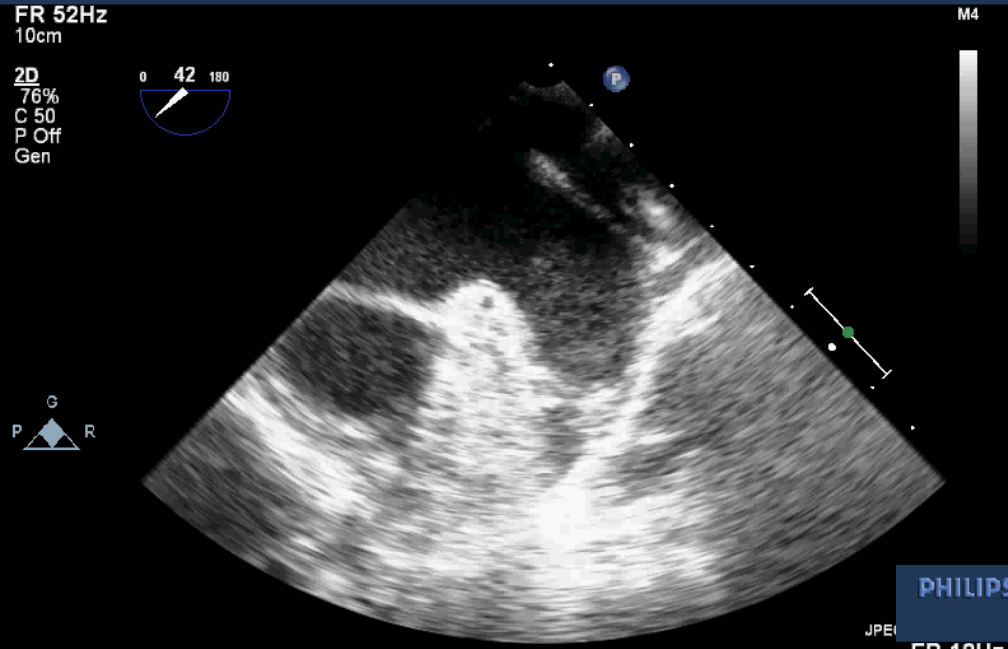


### Recommendations for LAA closure/occlusion

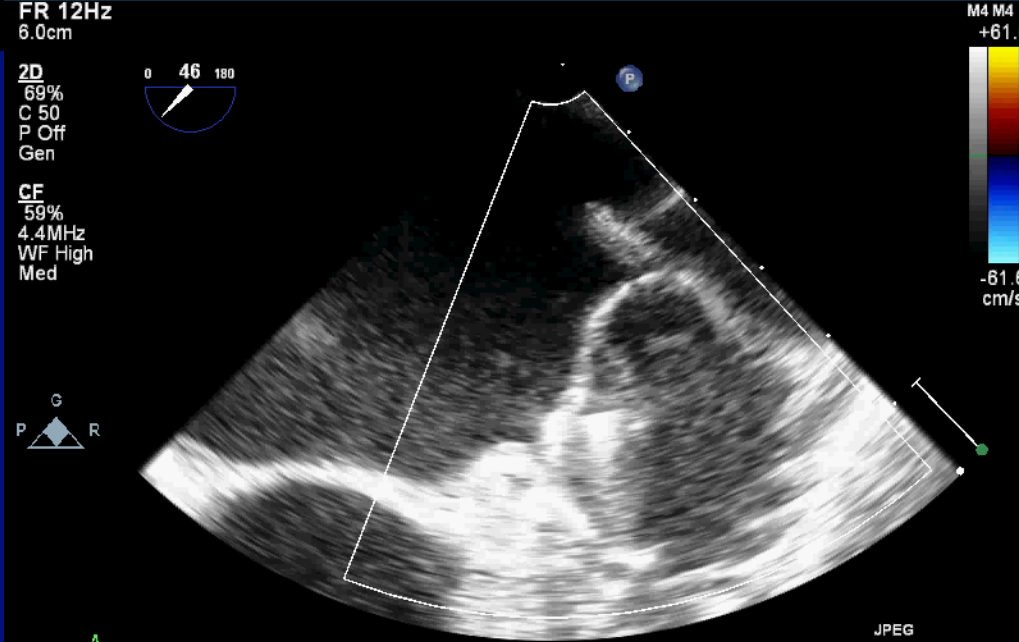
Recommendations	Class	Level
Interventional, percutaneous LAA closure may be considered in patients with a high stroke risk and contraindications for long-term oral anticoagulation	<b>IIb</b>	<b>B</b>
Surgical excision of the LAA may be considered in patients undergoing open heart surgery	<b>IIb</b>	<b>C</b>







PAT T: 37.0C  
TEE T: 38.8C



A  
PAT T: 37.0C  
TEE T: 38.2C

67 bpm



# Conclusions

- AF management starts with clinical classification, identification of underlying pathology and assessment of symptom severity
- Rate control is non-inferior to rhythm control approach by antiarrhythmic drugs in elderly population at risk of stroke

# Conclusions

- Rhythm control can be achieved with poor to modest success with antiarrhythmic drugs
- Rhythm control with catheter ablation is more effective than with antiarrhythmic drugs
- Catheter ablation is indicated in drug-refractory PAF and can be considered as first-line therapy in symptomatic PAF

# Conclusions

- Stroke prevention in AF can be achieved with warfarin, novel anticoagulants or left atrial appendage occlusion