NorthBay HEALTH

Focus on A-Fib

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Overview

- Definitions / Epidemiology
- Evaluation
- Anticoagulation
- Rate Control
- Rhythm Control

Definition

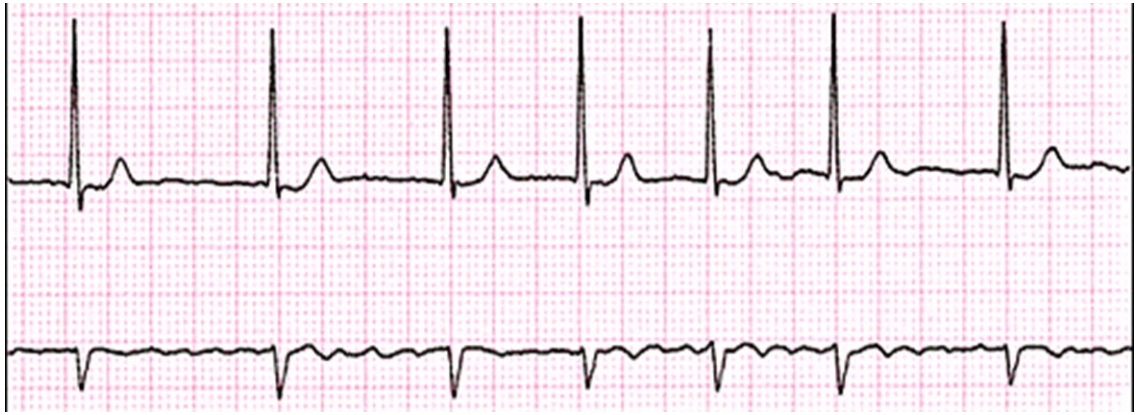
- SVT with uncoordinated atrial electrical activation and ineffective atrial contraction.[1-2]

- Must last ≥ 30 seconds on ECG and typically ≥ 5-6 minutes on pacemaker / ICD interrogation

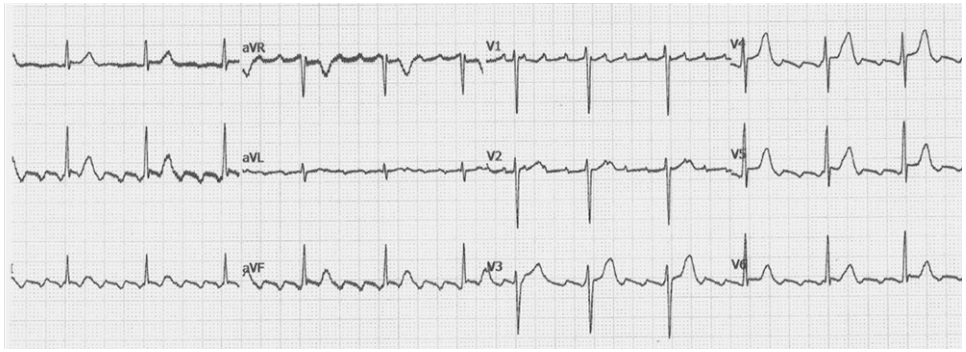
1) *Circulation . 2014 Dec 2;130(23):2071-104*
2) *Eur Heart J . 2021 Feb 1;42(5):373-498*

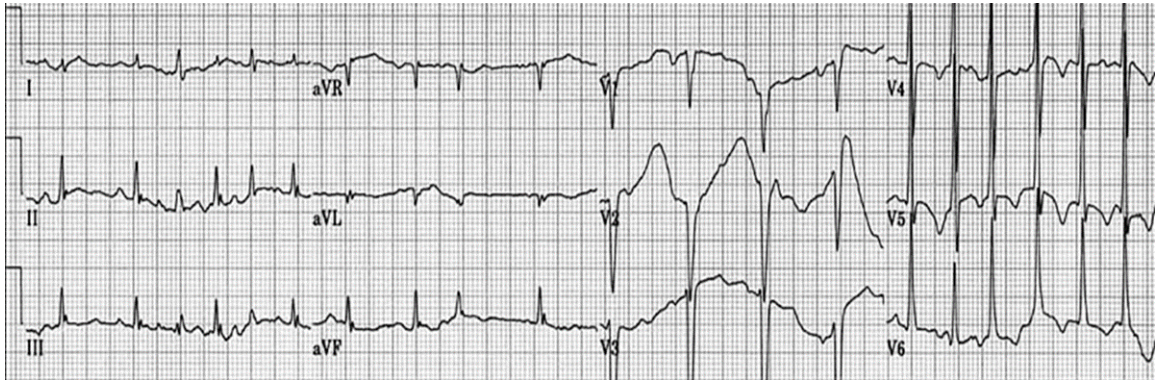
Definition – cont'd

- No identifiable P waves
- Fibrillatory or f waves are present at a rate that is generally between 350 and 600 beats/minute; the f waves vary continuously in amplitude, morphology, and intervals.
- Ventricular response is irregularly, irregular



What is not AF

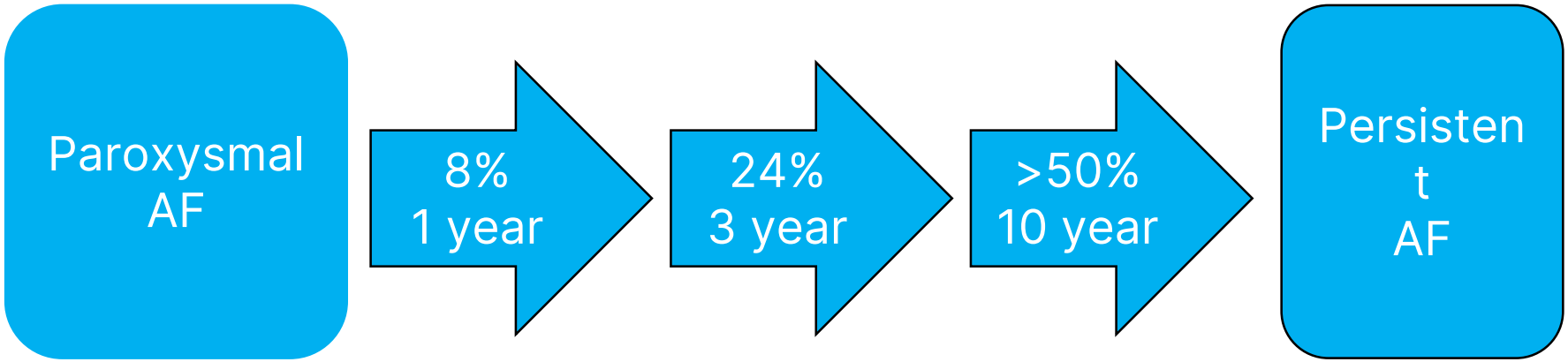




Classification of AF

- **Paroxysmal** – terminated with 7 days
- **Persistent** – continuous AF ≥ 7 days
- **Long-standing persistent** – AF > 12months when pursing rhythm control strategy
- **Permanent** – when a conscious decision has been made not to pursue rhythm control and remain in atrial fibrillation.

Progression of AF

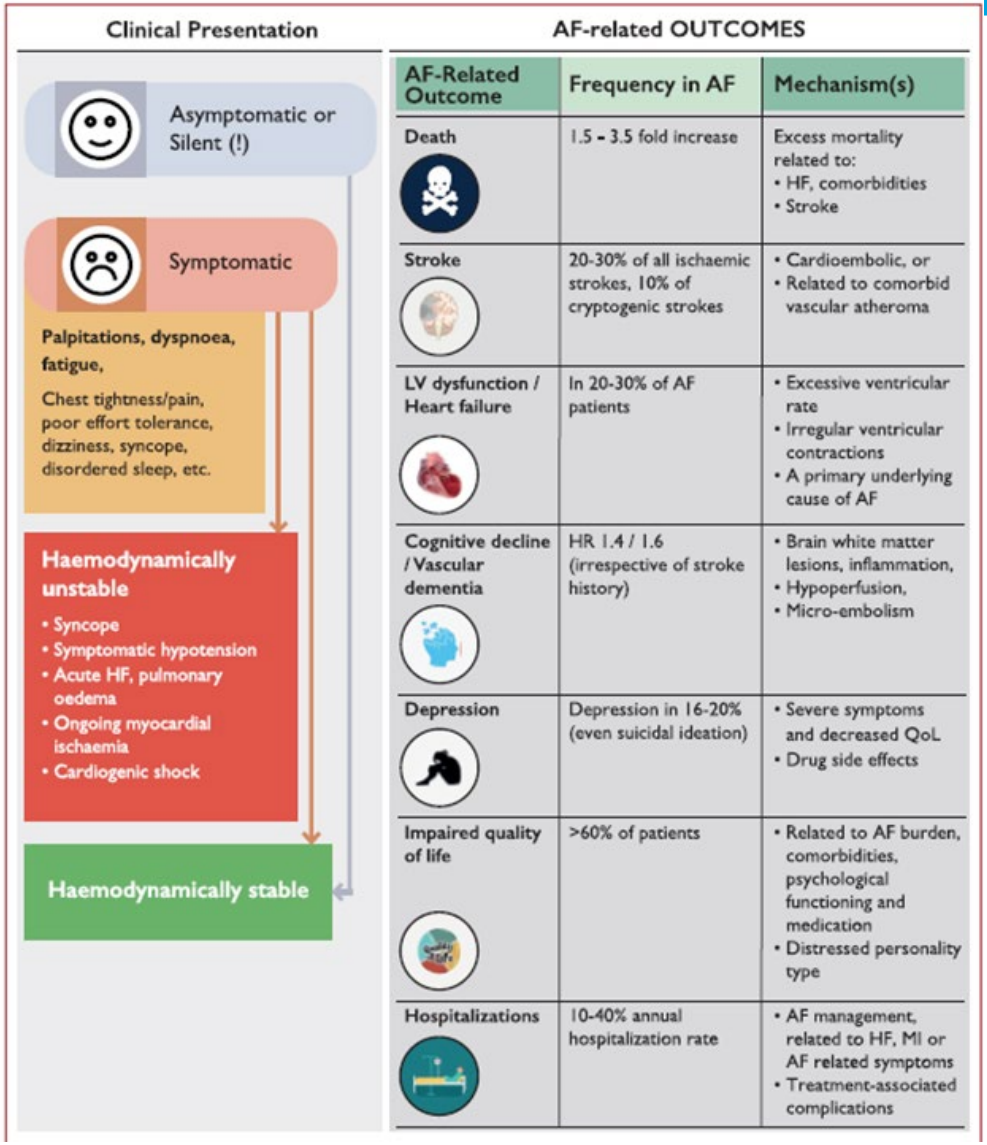


- *Circulation . 2014 Dec 2;130(23):2071-104*
- *Eur Heart J . 2021 Feb 1;42(5):373-498*

- *Heart Rhythm 2008;5:1501–7*
- *Am Heart J 2005;149:489–96*
- *Heart Rhythm 2017;14:801–7*

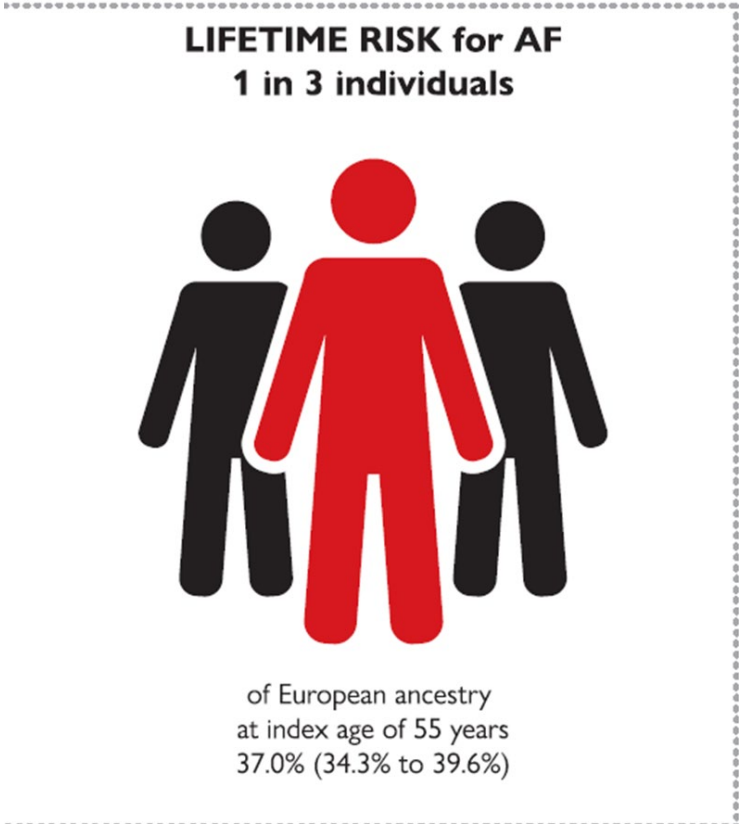
Overview

- AF is the most common abnormal heart rhythm.
- Symptoms: palpitations, fatigue and dyspnea.
- Associated with
  - heart failure
  - Increased risk of death
    - Dementia
    - Hospitalization
    - decreased QOL.



Eur Heart J . 2021 Feb 1;42(5):373-498

Epidemiology of Atrial Fibrillation



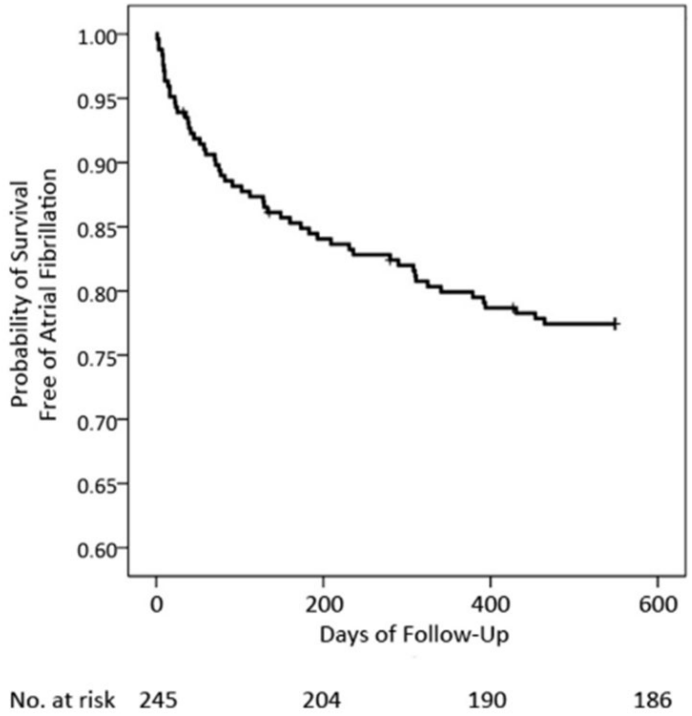
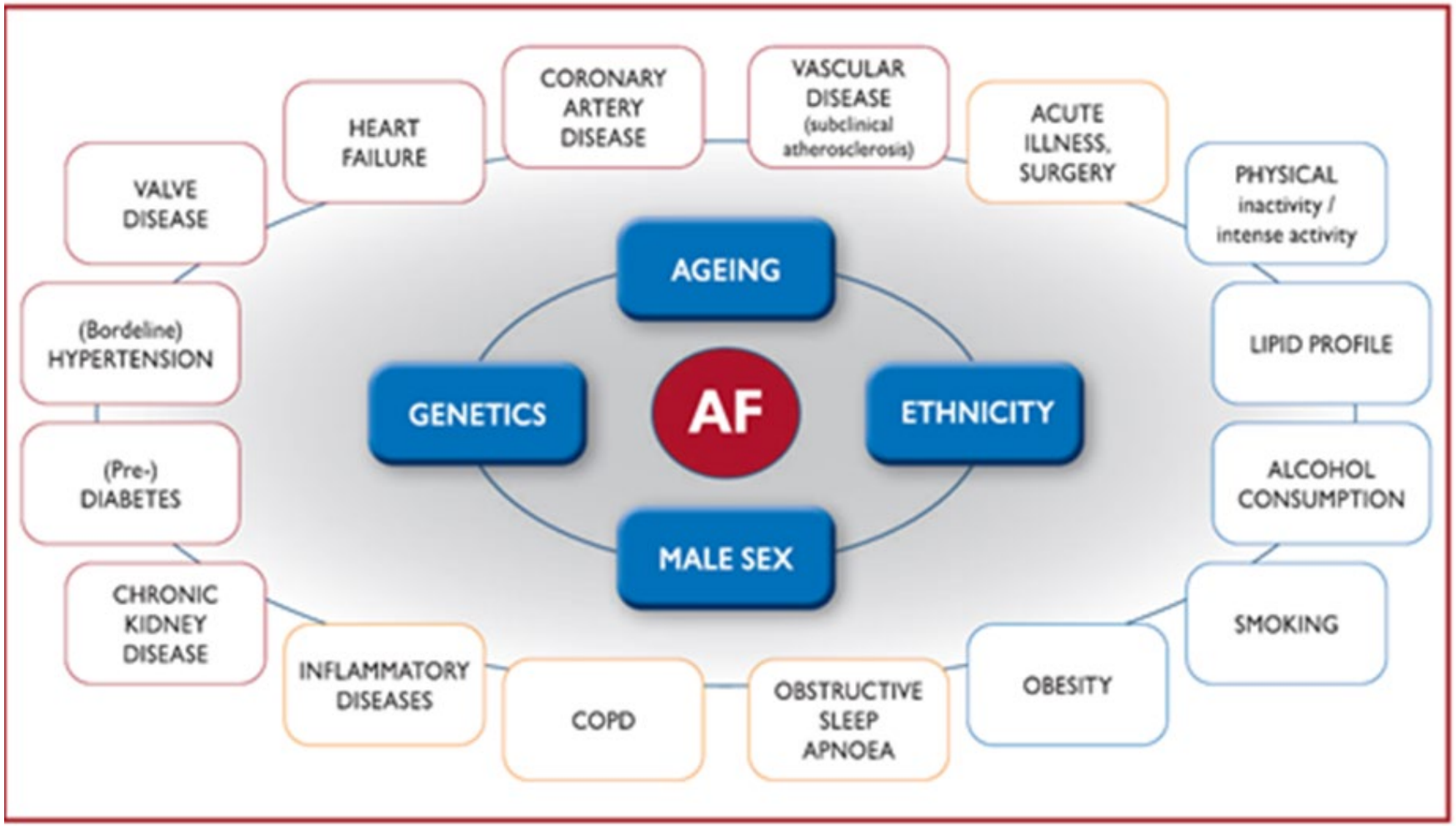


Figure 1 Kaplan-Meier estimates of the probability of survival free of atrial fibrillation. During a mean follow-up of 451 ± 185 days, the incidence of atrial fibrillation was 22.4% (95% confidence interval 17.2%–27.6%).

1) *Circulation . 2014 Dec 2;130(23):2071-104*
2) *Eur Heart J . 2021 Feb 1;42(5):373-498*

Nasir JM, Pomeroy W, Marler A. PREDATE AF Study. Heart Rhythm. 2017 Jul;14(7):955-961

Risk Factors for Atrial Fibrillation



Eur Heart J . 2021 Feb 1;42(5):373-498

Initial Work up

2014 ACC/AHA/HRS Guidelines[1]

- **All patients**: H&P, ECG, TTE, Labs (BMP, LFTs, TSH, CBC)
- **Select patients**: BNP, EPS, sleep study, CXR

2020 ESC Guidelines[2]

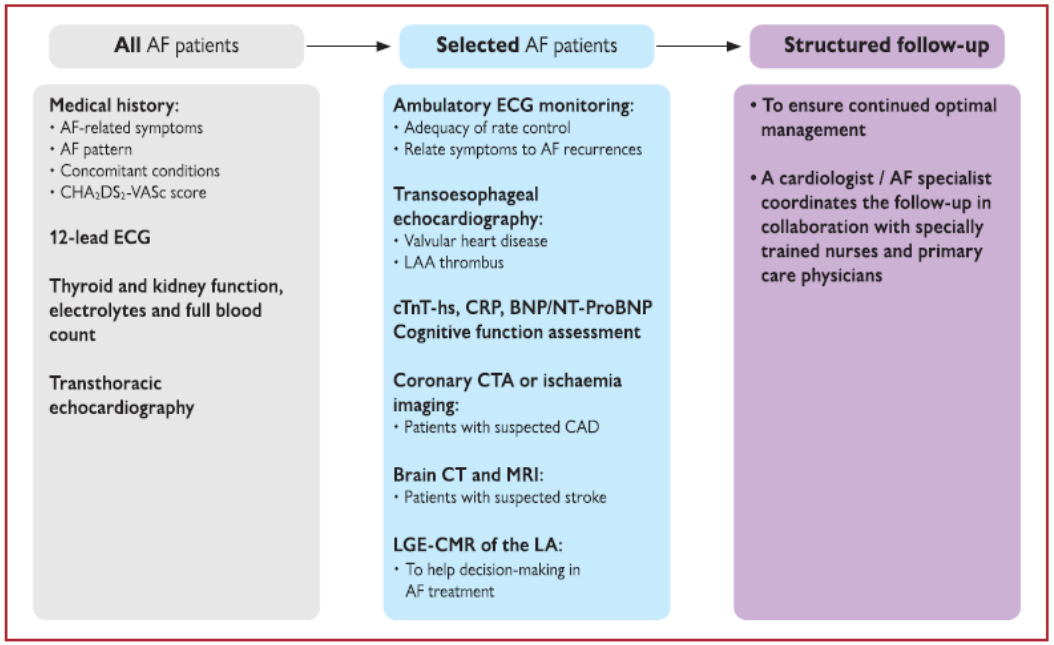


Figure 8 Diagnostic work-up and follow-up in AF patients. AF = atrial fibrillation; BNP = B-type natriuretic peptide; CHA_2DS_2-VASc = Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, Stroke, Vascular disease, Age 65 - 74 years, Sex category (female); CAD = coronary artery disease; CRP = C-reactive protein; CT = computed tomography; CTA = computed tomography angiography; cTnT-hs = high-sensitivity cardiac troponin T; ECG = electrocardiogram; LAA = left atrial appendage; LGE-CMR = late gadolinium contrast-enhanced cardiac magnetic resonance; MRI = magnetic resonance imaging; NT-ProBNP = N-terminal (NT)-prohormone B-type natriuretic peptide.

1) *Circulation . 2014 Dec 2;130(23):2071-104*
2) *Eur Heart J . 2021 Feb 1;42(5):373-498*

Screening for CAD

- Many risk factors are the same
- While CAD is associated with new atrial fibrillation in large multivariate models, it is one of the weakest risk factors.
- Guidelines **do not** recommend routine stress tests to screen for CAD with atrial fibrillation.
- *I usually only do stress tests if patient has angina, ECG showed ischemic ST changes, or with cardiomyopathies that don't recover after treating RVR.*

	Risk Factor	Hazard Ratio for AF
C	Congestive Heart Failure	HR 1.72 (p < 0.0001)
H	Hypertension	HR 1.31 (p < 0.0001)
A_2	Age ≥ 75	HR 16.37 (p < 0.0001)
D	Diabetes	HR 1.11 (P < 0.0001)
S_2	Stroke	HR 6.4 (p < 0.001)
V	Coronary Artery Disease	HR 1.21 (p < 0.0001)
A	Age 65-74	HR 4.65 (p < 0.0001)
Sc	Male	HR 1.32 (p < 0.0001)

1) Chyou JY, Hunter TD, Mollenkopf SA, et al. Individual and Combined Risk Factors for Incident Atrial Fibrillation and Incident Stroke: An Analysis of 3 Million At-Risk US Patients. J Am Heart Assoc. 2015 Jul 23;4(7).
2) Sanna T, Diener HC, Passman RS, et al. Cryptogenic stroke and underlying atrial fibrillation. N Engl J Med. 2014 Jun 26;370(26):2478-86.

Risk of Thromboembolism

- AF increases the risk of stroke
- **2019 ACC/AHA/HRS Update[2]**
- CHA2DS2-VASc score recommended to assess stroke risk. (Class I Recommendation, LOE B)

1) *Circulation . 2014 Dec 2;130(23):2071-104*
2) *J Am Coll Cardiol 2019 Jul 9;74(1):104-132*

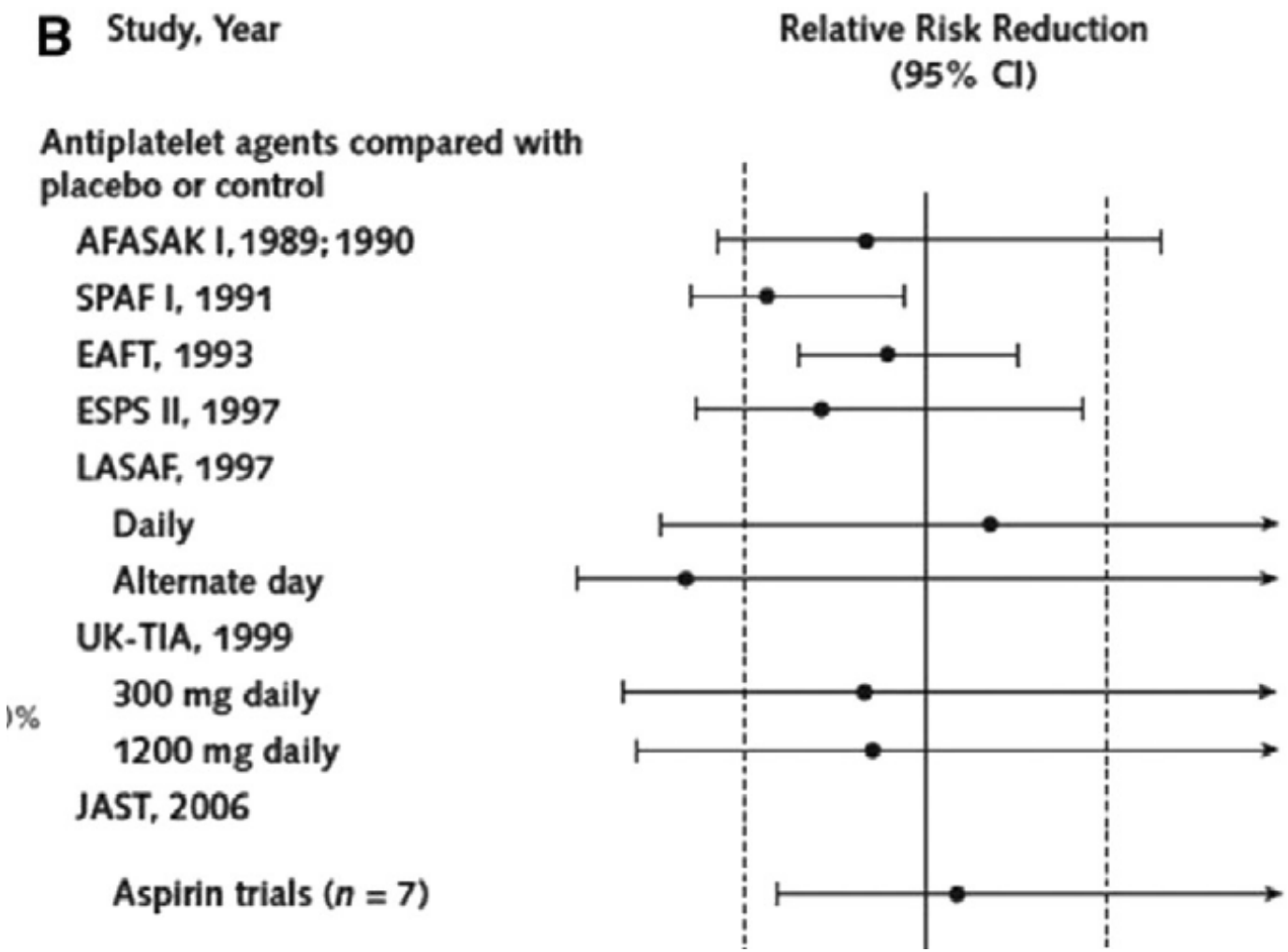
	Score		Adjusted Stroke Rate (% per y)
CHA_2DS_2-VASc		CHA_2DS_2-VASc†	
Congestive HF	1	0	0
Hypertension	1	1	1.3
Age ≥75 y	2	2	2.2
Diabetes mellitus	1	3	3.2
Stroke/TIA/TE	2	4	4.0
Vascular disease (prior MI, PAD, or aortic plaque)	1	5	6.7
Age 65–74 y	1	6	9.8
Sex category (i.e., female sex)	1	7	9.6
Maximum score	9	8	6.7
		9	15.20

1) *Circulation . 2014 Dec 2;130(23):2071-104*
2) *J Am Coll Cardiol 2019 Jul 9;74(1):104-132*

Aspirin

- 2014 ACC/AHA/HRS Guidelines[1]
  - “No studies, with the exception of the SPAF (Stroke Prevention in Atrial Fibrillation)-1 trial, show benefit for aspirin alone in preventing stroke among patients with AF”
- 2020 ESC Guidelines[2]
  - “Antiplatelet therapy alone (monotherapy or aspirin in combination with clopidogrel) is not recommended for stroke prevention in AF”
    - Recommendation: **Class III, LOE A**

1) *Circulation . 2014 Dec 2;130(23):2071-104*
2) *Eur Heart J . 2021 Feb 1;42(5):373-498*


B
Study, Year
Relative Risk Reduction
(95% CI)
Antiplatelet agents compared with placebo or control
AFASAK I, 1989; 1990
SPAF I, 1991
EAFT, 1993
ESPS II, 1997
LASAF, 1997
Daily
Alternate day
UK-TIA, 1999
300 mg daily
1200 mg daily
JAST, 2006
Aspirin trials (n = 7)

Oral Anticoagulation (OAC)

- **2019 ACC/AHA/HRS Update[1]**
  - For patients with AF and CHADS-VASc ≥ 2 in men and ≥ 3 in female, OAC is recommended **(Class I, LOE A)**
  - For patients with AF and CHADS-VASc =1 in men and =2 in female, OAC can be considered recommended **(Class IIb, LOE B-NR)**
  - NOAC are recommended over warfarin for non-valvular AF **(Class I, LOE A)**
- **2020 ESC Guidelines[2]**
  - Same as US guidelines except IIa indication of anticoagulation with CHADS-VASc =1 in men and =2 in female

1) *J Am Coll Cardiol 2019 Jul 9;74(1):104-132*
2) *Eur Heart J . 2021 Feb 1;42(5):373-498*

CHA_2DS_2-VASc		CHA_2DS_2-VASc†	
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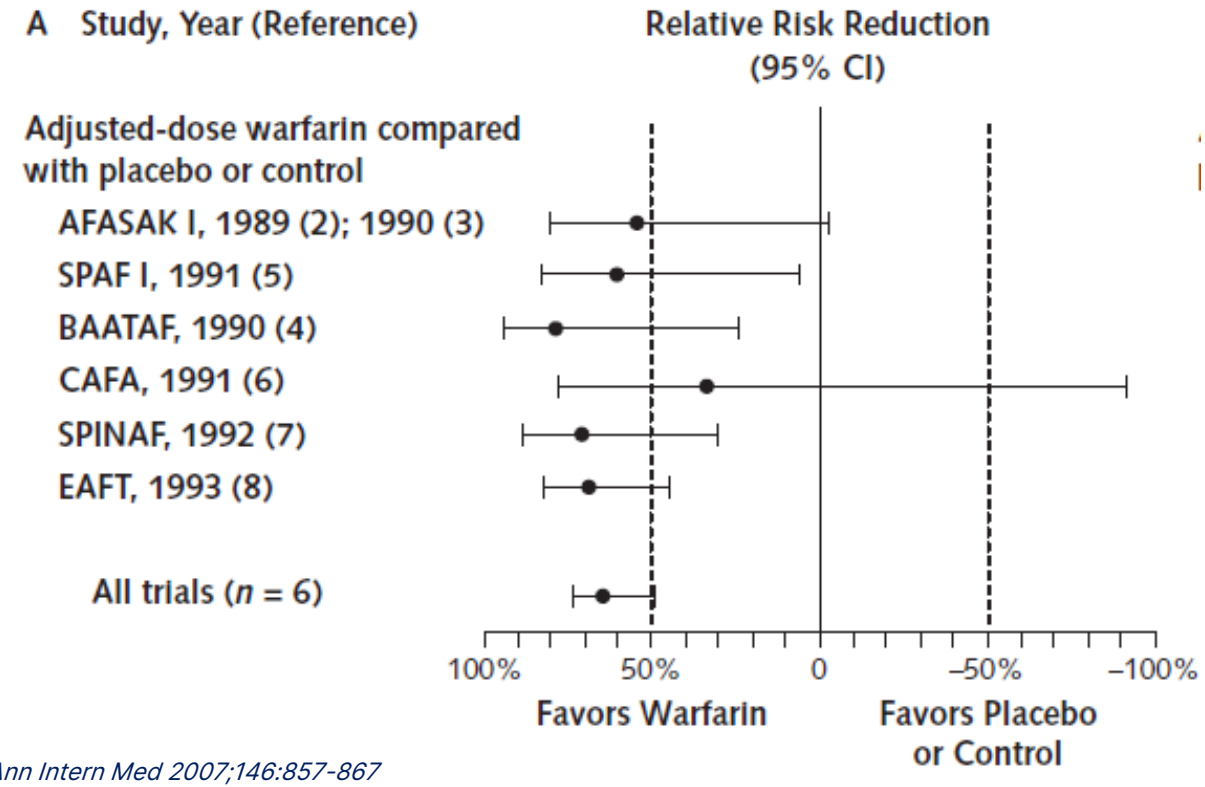
Stroke/TIA/TE	2	4	4.0
Vascular disease (prior MI, PAD, or aortic plaque)	1	5	6.7
Age 65-74 y	1	6	9.8
Sex category (i.e., female sex)	1	7	9.6
Maximum score	9	8	6.7
		9	15.20

Warfarin for AF

- Reduces stroke (by 64%) and all-cause mortality (by 26%) compared with control or placebo.



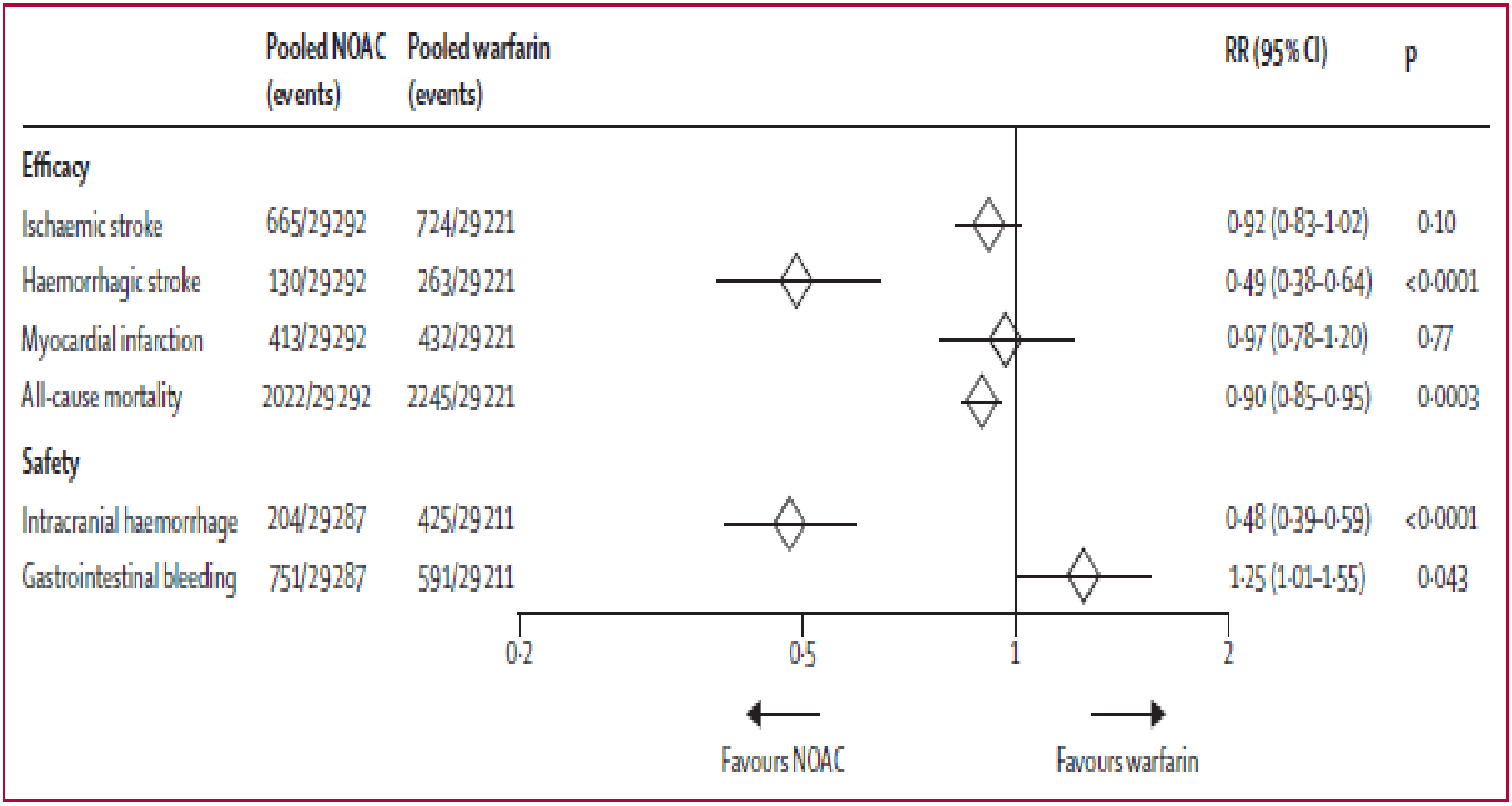
Ann Intern Med 2007;146:857-867

Direct oral anticoagulants (DOACs)

Meta-analysis 42, 411 patients showed DOACs

- Decreased stroke/embolic events by 19%
- Decreased ICH 51%
- Reduced all-cause mortality 10%
- Increased GI bleeding 25%

Lancet 2014;383:955-962.


Pooled NOAC (events)
Pooled warfarin (events)
RR (95% CI)
p
Efficacy
Ischaemic stroke
665/29292
724/29221
0·92 (0·83–1·02)
0·10
Haemorrhagic stroke
130/29292
263/29221
0·49 (0·38–0·64)
<0·0001
Myocardial infarction
413/29292
432/29221
0·97 (0·78–1·20)
0·77
All-cause mortality
2022/29292
2245/29221
0·90 (0·85–0·95)
0·0003
Safety
Intracranial haemorrhage
204/29287
425/29211
0·48 (0·39–0·59)
<0·0001
Gastrointestinal bleeding
751/29287
591/29211
1·25 (1·01–1·55)
0·043
0·2
0·5
1
2
Favours NOAC
Favours warfarin

OAC – Bleeding risk

Assessment of Bleeding Risk

- Formal assessment of bleeding risk
- A **high bleeding risk score should not lead to withholding OAC**

1) *Eur Heart J . 2021 Feb 1;42(5):373-498*

OAC – Bleeding risk

Absolute contraindications to OAC

- Active serious bleeding
- Platelets <50k
- Severe anemia under investigation
- Recent high risk bleeding event such as ICH

Others

- Cerebral amyloid angiopathy

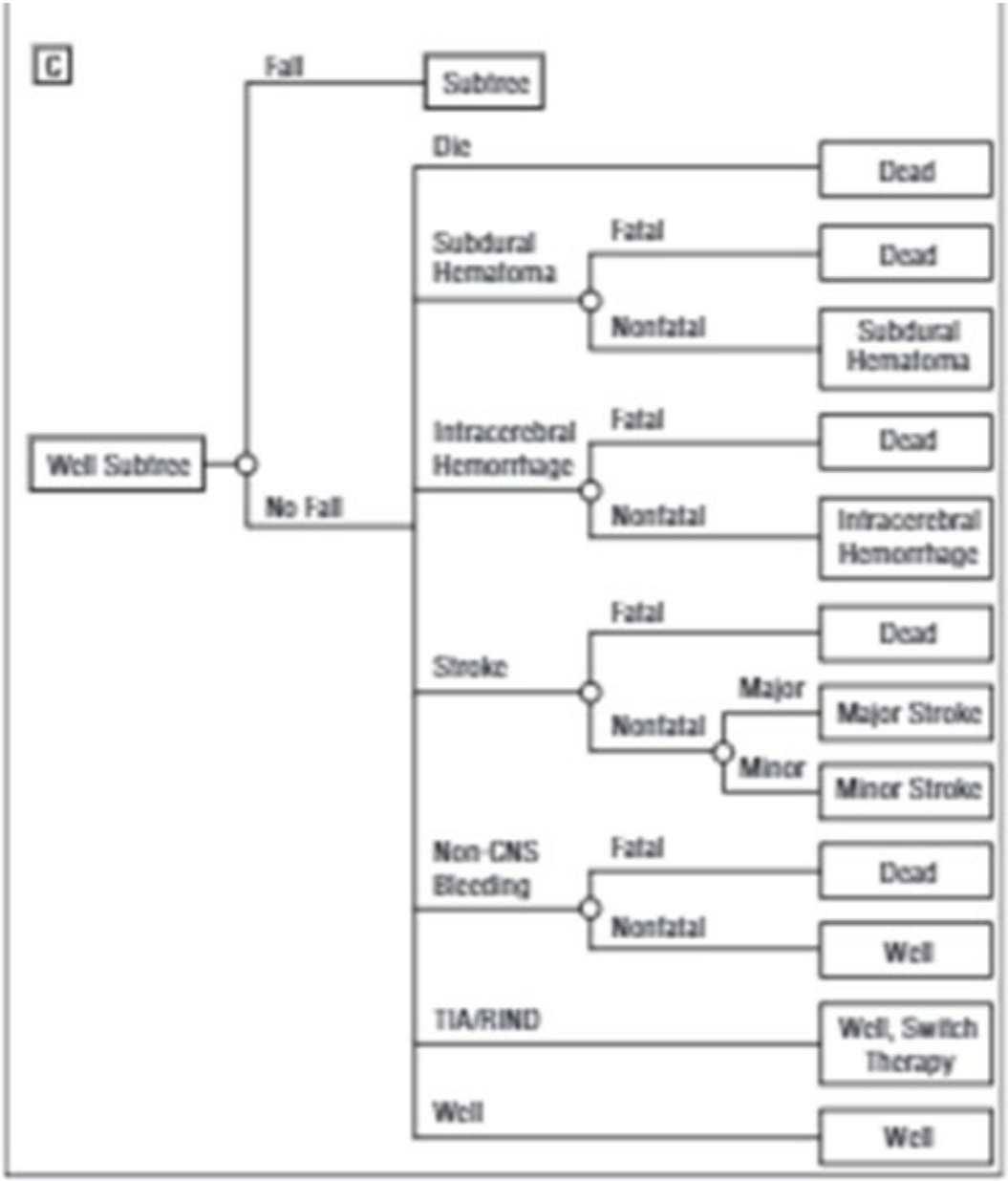
Table 10 Clinical risk factors in the **HAS-BLED score**[395]

Risk factors and definitions		Points awarded
H	**Uncontrolled hypertension** SBP >160 mmHg	1
A	**Abnormal renal and/or hepatic function** Dialysis, transplant, serum creatinine >200 μmol/L, cirrhosis, bilirubin > × 2 upper limit of normal, AST/ALT/ALP >3 × upper limit of normal	1 point for each
S	**Stroke** Previous ischaemic or haemorrhagic[a] stroke	1
B	**Bleeding history or predisposition** Previous major haemorrhage or anaemia or severe thrombocytopenia	1
L	**Labile INR**[b] TTR <60% in patient receiving VKA	1
E	**Elderly** Aged >65 years or extreme frailty	1
D	**Drugs or excessive alcohol drinking** Concomitant use of antiplatelet or NSAID; and/or excessive[c] alcohol per week	1 point for each
Maximum score		**9**

OAC – Fall risk

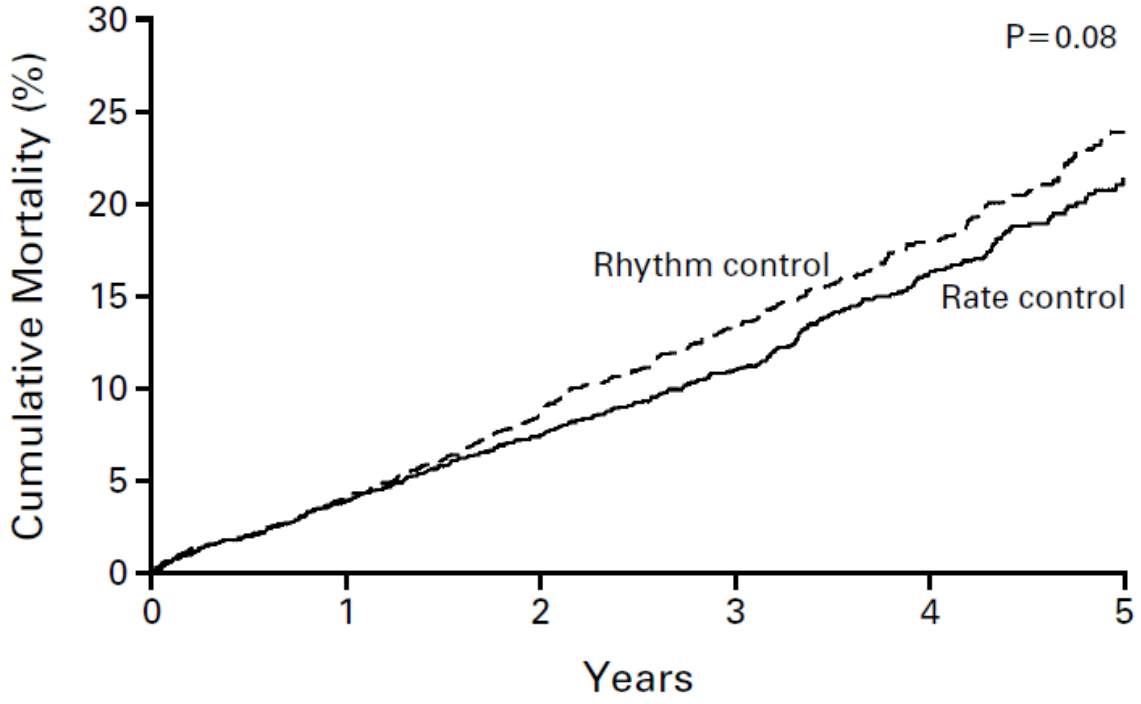
- “Elderly persons who fall have a mean of 1.81 falls per year.
- Given that the risk of SDH must be 535-fold or greater for the risks of warfarin therapy to out-weigh the benefits
- **Persons taking warfarin must fall about 295 (535/1.81) times in 1 year for warfarin to not be the optimal therapy.”**

Arch Intern Med 1999 Apr 12;159(7):677-85


C
Well Subtree
Fall
Subtree
No Fall
Die
Dead
Subdural Hematoma
Fatal
Dead
Nonfatal
Subdural Hematoma
Intracerebral Hemorrhage
Fatal
Dead
Nonfatal
Intracerebral Hemorrhage
Stroke
Fatal
Dead
Nonfatal
Major
Major Stroke
Minor
Minor Stroke
Non-CNS Bleeding
Fatal
Dead
Nonfatal
Well
TIA/RIND
Well, Switch Therapy
Well
Well

AFFIRM

- **DESIGN**: Multicenter, parallel-group, randomized, controlled trial 4060 patient
- **COMPARED**: rate-control strategy (resting HR < 80, 6minute walk <110 bpm) vs rhythm control
- **PRIMARY OUTCOME**: mortality
- **FOLLOW-UP**: mean 3.5 years
- **CONCLUSION**: no survival benefit of rhythm control

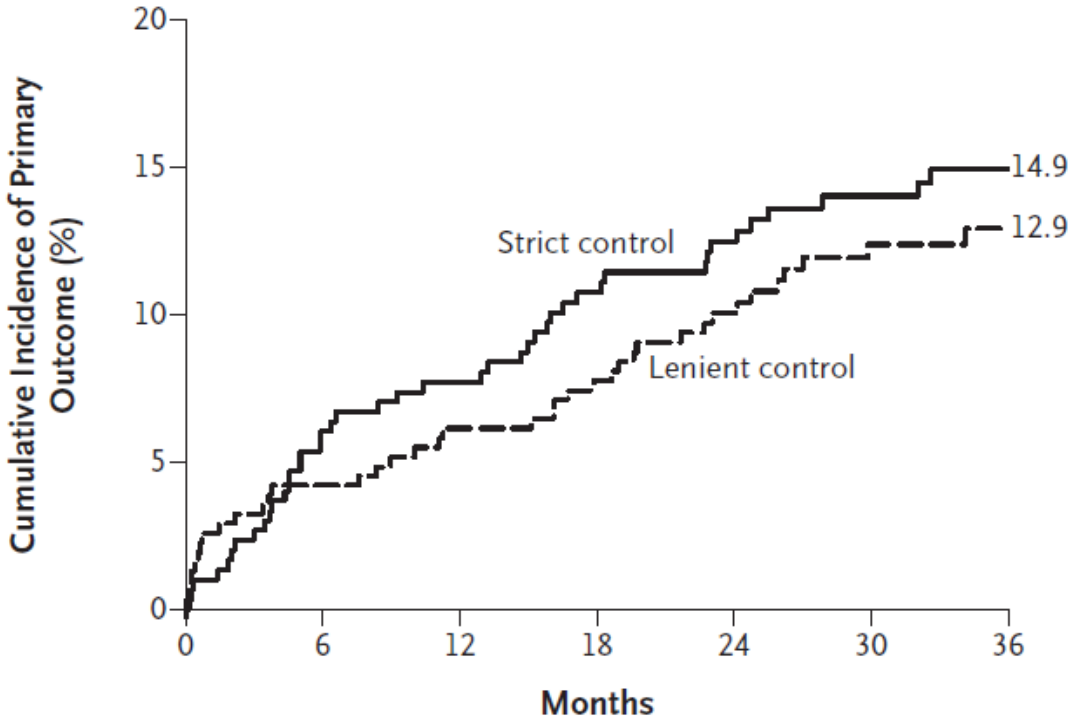


No. of Deaths		number (percent)				
Rhythm control	0	80 (4)	175 (9)	257 (13)	314 (18)	352 (24)
Rate control	0	78 (4)	148 (7)	210 (11)	275 (16)	306 (21)

N Engl J Med 2010;362:

RACE-II Trial

- **DESIGN**: Prospective, multicenter RCT 614 of patients with permanent atrial fibrillation
- **COMPARED**: lenient rate-control strategy (resting HR < 110 bpm) or a strict rate control strategy (resting HR <80 bpm and HR during moderate exercise <110 bpm).
- **PRIMARY OUTCOME**: composite of death from cardiovascular causes, hospitalization for heart failure, and stroke, systemic embolism, bleeding, and life-threatening arrhythmic events.
- **FOLLOW-UP**: 2 - 3 years
- **CONCLUSION**: lenient rate-control strategy was noninferior ($p<0.001$)



No. at Risk

Strict control	303	282	273	262	246	212	131
Lenient control	311	298	290	285	255	218	138

Figure 2. Kaplan–Meier Estimates of the Cumulative Incidence of the Primary Outcome, According to Treatment Group.

The numbers at the end of the Kaplan–Meier curves are the estimated cumulative incidence of the primary outcome at 3 years.

N Engl J Med 2010;362:

Rate control – Guidelines

2014 ACC/AHA/HRS Guidelines[1]

- A heart rate control (resting heart rate <80 bpm) strategy is reasonable for symptomatic management of AF (IIA, LOE B)

- A lenient rate-control strategy (resting heart rate <110 bpm) may be reasonable when patients remain asymptomatic and LV systolic function is preserved (IIA, LOE B)

2020 ESC Guidelines[2]

- A resting heart rate of <110 bpm (i.e. lenient rate control) should be considered as the initial heart rate target for rate control therapy.

1) Circulation . 2014 Dec 2;130(23):2071-104 2) Eur Heart J . 2021 Feb 1;42(5):373-498

Rate control – RATAF Study

- 60 patient took each medicine for 3 weeks
  1. Metoprolol succinate 100 mg/d
  2. Diltiazem SR 360 mg/d
  3. Verapamil SR 240 mg QAM
  4. Carvedilol 25 mg QAM.
- Diltiazem was the most effective drug regimen for reducing the ventricular rate.

Am J Cardiol. 2013; 111:225–230

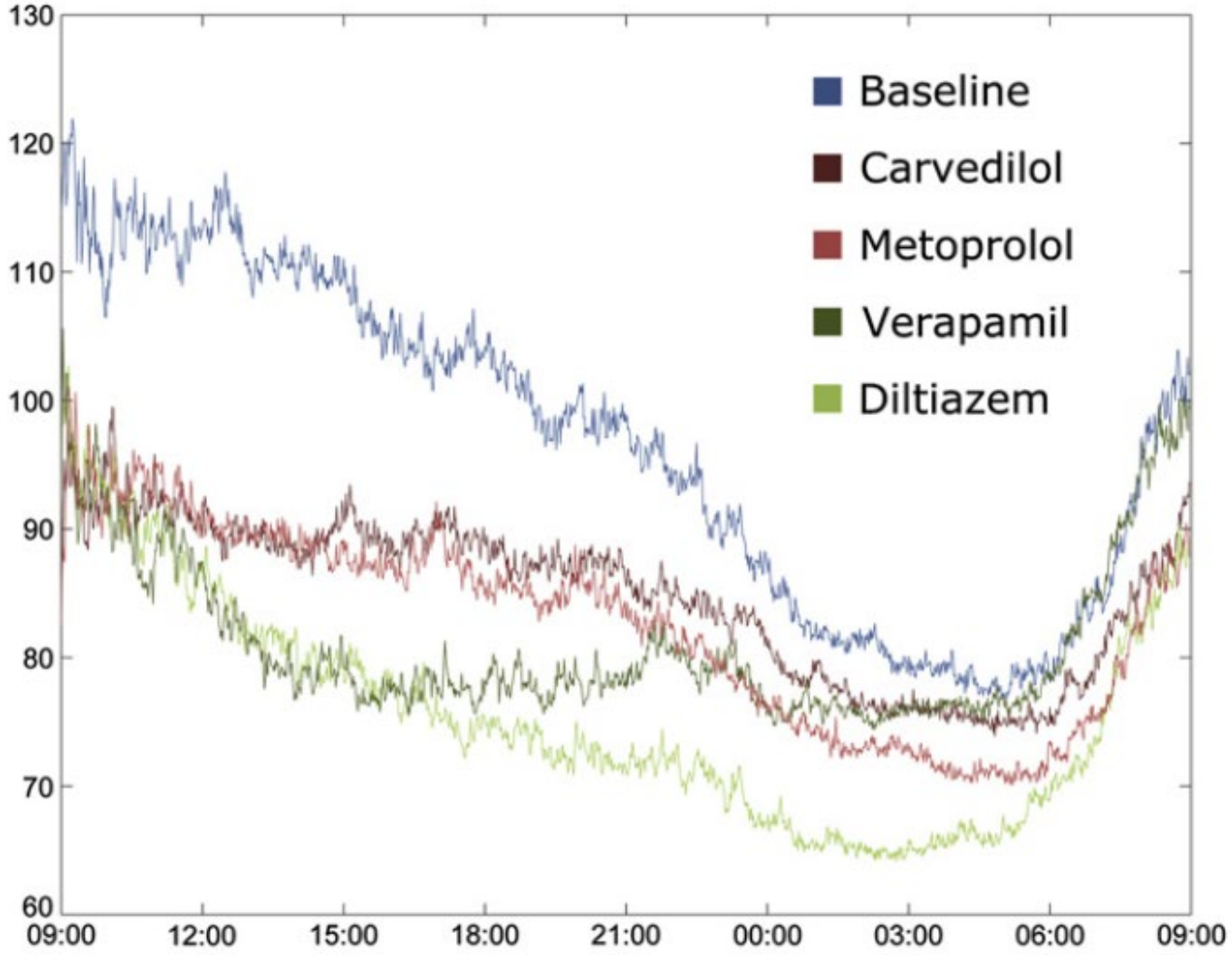


Figure 2. Minute-by-minute heart rate during the day at baseline and during treatment. HR = heart rate.

Rate control – Digoxin

Out of favor

RE-ANALYSIS OF DIG TRIAL[1]

- 44% of the 6800 patients in the DIG trial had been treated with digoxin before randomization, and half of them were randomly withdrawn from digoxin treatment.
- These patient had a higher mortality regardless of treatment arm strongly suggesting that digoxin use just identifies a higher risk group of patients.

RATE-AF TRIAL[2]

- 160 patients permanent AF randomized to bisoprolol or digoxin for rate control
- Similar change in HR but over 6 to 12 months, improvement in NYHA class and NTproBNP level was significantly greater in the digoxin arm

1) European Heart Journal, Volume 40, Issue 40, 21 October 2019, Pages 3336–3341
2) JAMA 2020;324:2497-508

Rate control – Amiodarone

2014 ACC/AHA/HRS Guidelines[1]

- IV amiodarone can be useful for rate control in critically ill patients without pre-excitation (IIA, LOE B)
- Oral amiodarone may be useful for ventricular rate control when other measures are unsuccessful or contraindicated. (IIB, LOE C)

2020 ESC Guidelines[2]

- In patients with haemodynamic instability or severely depressed LVEF, intravenous amiodarone may be considered for acute control of heart rate. (IIB, LOE B)

Amiodarone can be useful as a last resort when heart rate cannot be controlled with combination therapy in patients who do not qualify for non-pharmacological rate control, i.e. atrioventricular node ablation and pacing, notwithstanding the extracardiac adverse effects of the drug[504] (*Table 13*).

1) *Circulation . 2014 Dec 2;130(23):2071-104*
2) *Eur Heart J . 2021 Feb 1;42(5):373-498*

Rate control – Ablate and Pace

2014 ACC/AHA/HRS Guidelines[1]

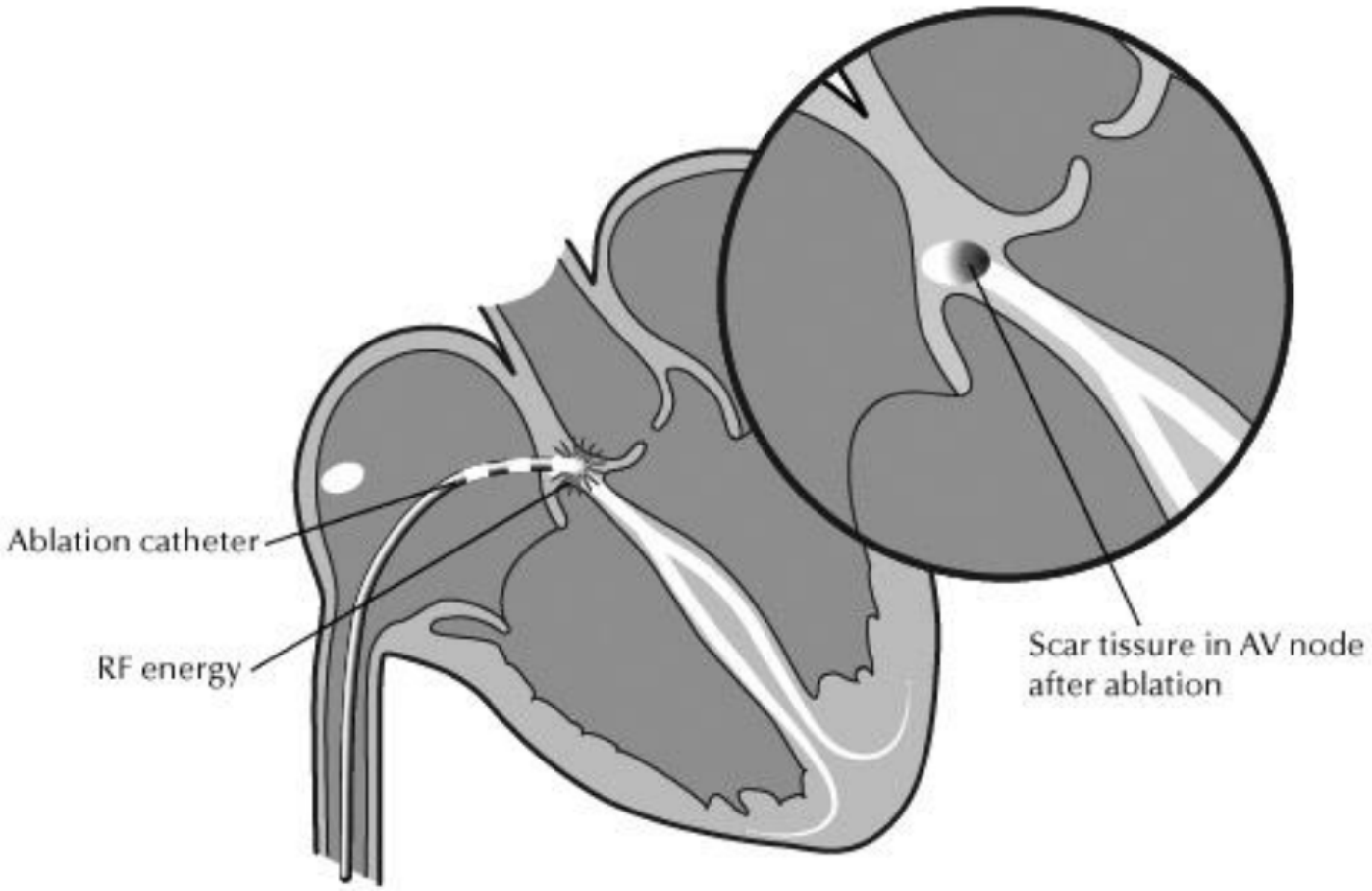
"AV nodal ablation with permanent ventricular pacing is reasonable to control heart rate when pharmacological therapy is inadequate and rhythm control is not achievable"

- Class IIa, LOE B

2020 ESC Guidelines[2]

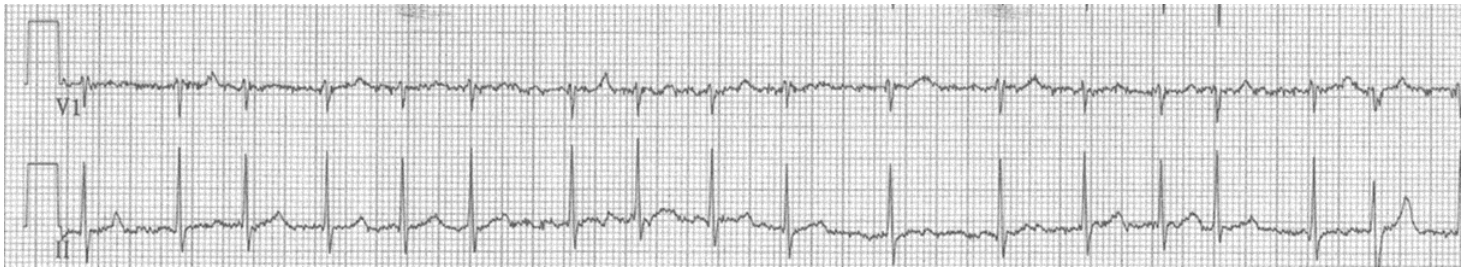
- "Atrioventricular node ablation should be considered to control heart rate in patients unresponsive or intolerant to intensive rate and rhythm control therapy, and not eligible for rhythm control by LA ablation, accepting that these patients will become pacemaker dependent"
- Class IIa, LOE B

1) *Circulation . 2014 Dec 2;130(23):2071-104*
2) *Eur Heart J . 2021 Feb 1;42(5):373-498*


Ablation catheter
RF energy
Scar tissure in AV node
after ablation

Rhythm Control

- New onset atrial fibrillation
- Symptomatic atrial fibrillation
- Asymptomatic atrial fibrillation with LV systolic dysfunction



New Onset Atrial Fibrillation

- RACE II - 46% patients in both rate and rhythm control groups were symptomatic.[3]

- RACE trial - all patients had undergone DCCV prior to inclusion in rate control trial.[2]

1) *Eur Heart J . 2021 Feb 1;42(5):373-498*
2) *N Engl J Med 2002;347:1834-40*
3) *N Engl J Med 2010;362:1363-73.*

In patient with AF, it is recommended to:

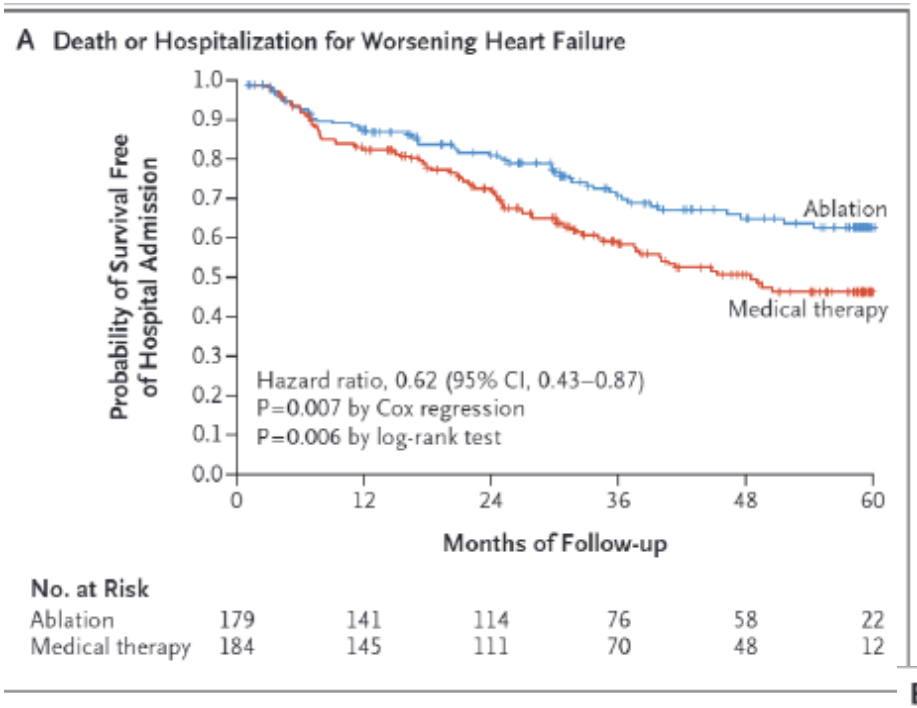
Recommendation	Class[a]	Level[b]
Evaluate AF-related symptoms (including fatigue, tiredness, exertional shortness of breath, palpitations, and chest pain) an quantify the patient symptom status using the modified EHRA symptom scale before and after initiation of treatment. [230, 232]	I	C
Evaluate AF-related symptoms before and after cardioversion of persistent AF to aid rhythm control treatment decisions. [230,232]	I	C

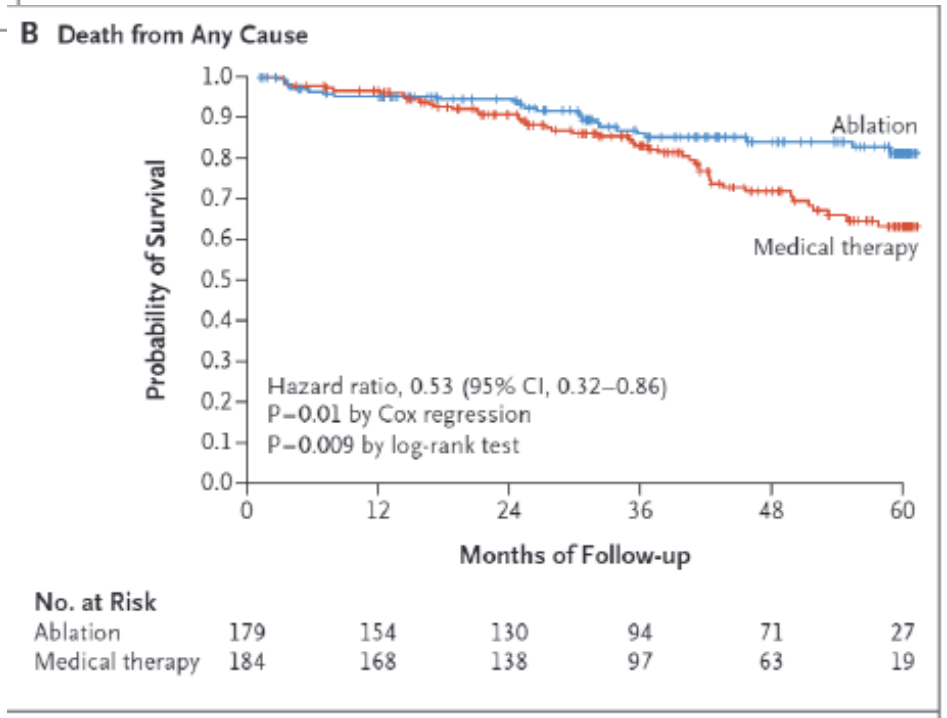
AF + LV dysfunction

CASTLE AF TRIAL - Prospective RCT 398 patients with AF and HFrEF (LVEF ≤ 35%) randomized to ablation or medical therapy (predominately rhythm control). Ablation showed a

- 16.1% absolute reduction in death or hospitalization for heart failure when compared to medical therapy (rate or rhythm control).
- 11.6% absolute reduction in death 15.2% absolute reduction in hospitalization for CHF.
- greater improvement in LVEF

N Engl J Med. 2018 Feb 1;378(5):417-427

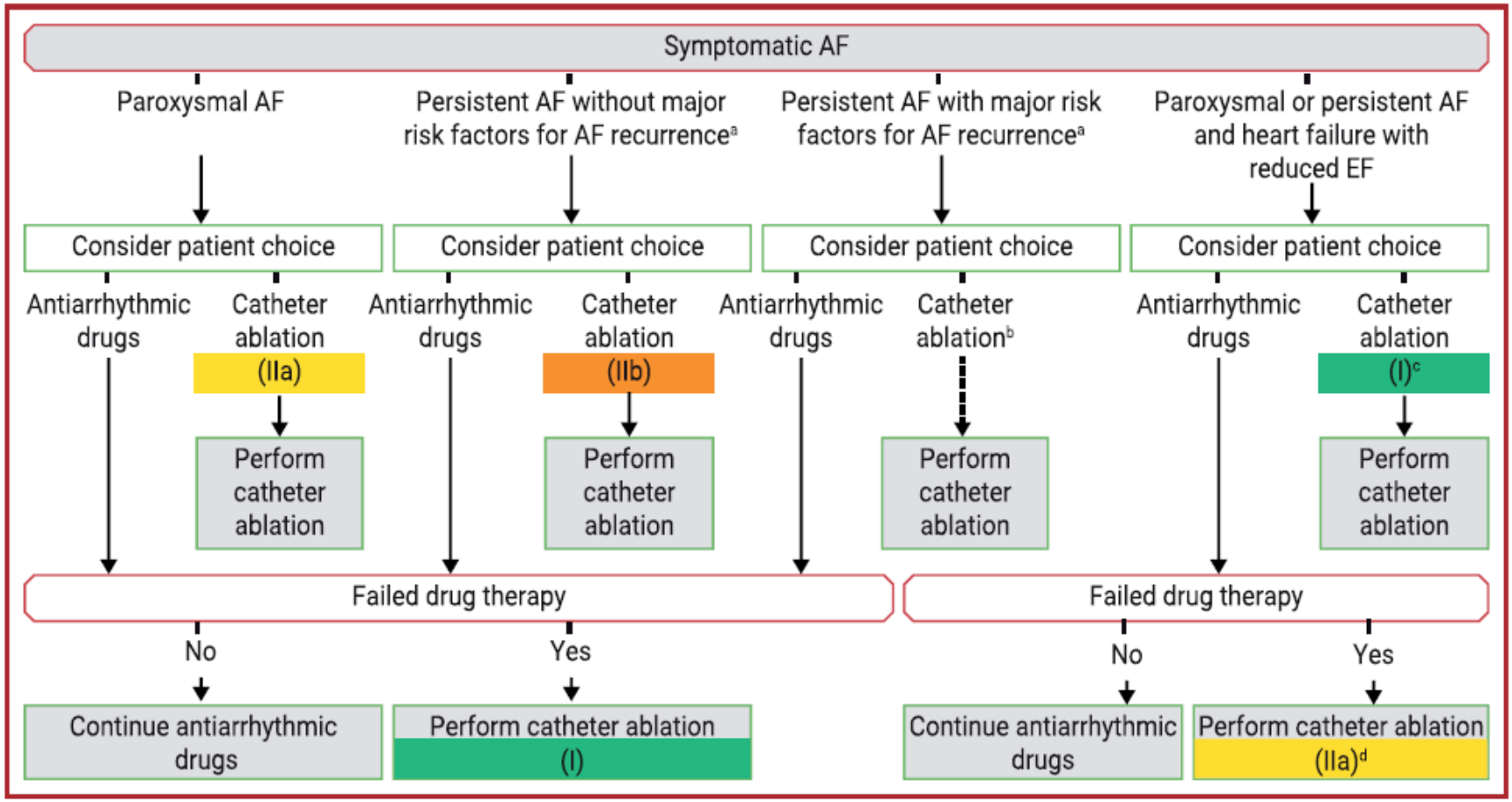

A Death or Hospitalization for Worsening Heart Failure
Probability of Survival Free of Hospital Admission
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
Ablation
Medical therapy
Hazard ratio, 0.62 (95% CI, 0.43–0.87)
P=0.007 by Cox regression
P=0.006 by log-rank test
0
12
24
36
48
60
Months of Follow-up
No. at Risk
Ablation 179 141 114 76 58 22
Medical therapy 184 145 111 70 48 12


B Death from Any Cause
Probability of Survival
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
Ablation
Medical therapy
Hazard ratio, 0.53 (95% CI, 0.32–0.86)
P=0.01 by Cox regression
P=0.009 by log-rank test
0
12
24
36
48
60
Months of Follow-up
No. at Risk
Ablation 179 154 130 94 71 27
Medical therapy 184 168 138 97 63 19

Symptomatic AF

- Rhythm control is usually preferred.
- Options:
  - intermittent DCCV, AAD, ablation, and combinations of all three

Eur Heart J . 2021 Feb 1;42(5):373-498


Symptomatic AF
Paroxysmal AF
Persistent AF without major risk factors for AF recurrence[a]
Persistent AF with major risk factors for AF recurrence[a]
Paroxysmal or persistent AF and heart failure with reduced EF
Consider patient choice
Consider patient choice
Consider patient choice
Consider patient choice
Antiarrhythmic drugs
Catheter ablation
(IIa)
Perform catheter ablation
Antiarrhythmic drugs
Catheter ablation
(IIb)
Perform catheter ablation
Antiarrhythmic drugs
Catheter ablation[b]
Perform catheter ablation
Antiarrhythmic drugs
Catheter ablation
(I)[c]
Perform catheter ablation
Failed drug therapy
Failed drug therapy
No
Yes
No
Yes
Continue antiarrhythmic drugs
Perform catheter ablation
(I)
Continue antiarrhythmic drugs
Perform catheter ablation
(IIa)[d]
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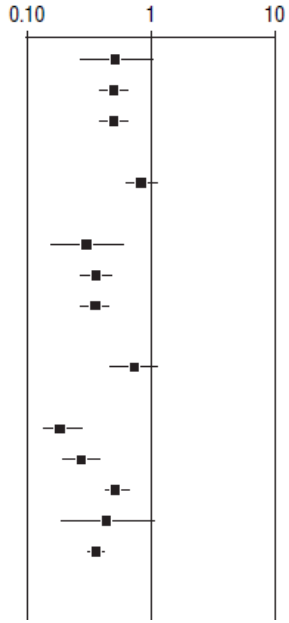
Antiarrhythmic Drugs

- AAD significantly reduce AF recurrence
- Have side effects

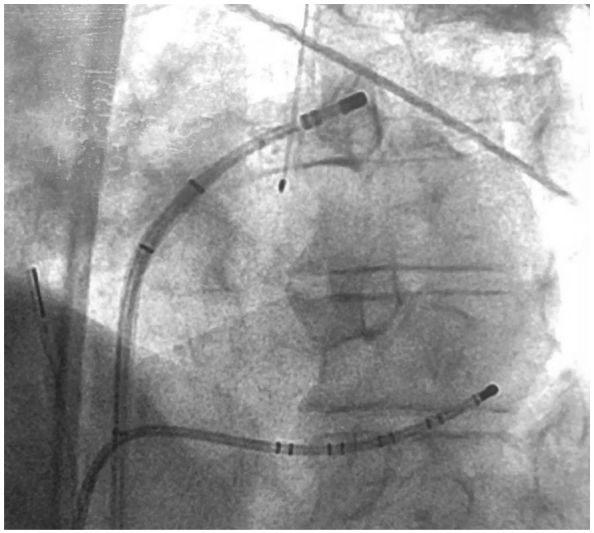
Drugs Studied	No. of Studies	No. of Events/Total		Peto OR (95% CI)	*P* Value
		Antiarrhythmic	Control		
Antiarrhythmic vs Control					
Class IA					
Disopyramide hydrochloride	2	40/75	49/71	0.52 (0.27-1.01)	.05
Quinidine sulfate	7	741/1106	417/518	0.51 (0.40-0.65)	<.001
All class IA	8	781/1118	449/564	0.51 (0.40-0.64)	<.001
Class IB					
All: aprindine hydrochloride, bidisomide	2	639/781	453/540	0.84 (0.63-1.13)	.26
Class IC					
Flecainide acetate	3	31/71	56/78	0.31 (0.16-0.60)	<.001
Propafenone hydrochloride	5	376/720	276/378	0.37 (0.28-0.48)	<.001
All class IC	9	443/843	342/466	0.36 (0.28-0.45)	<.001
Class II					
All: metoprolol tartrate	1	127/197	140/197	0.74 (0.49-1.13)	.16
Class III					
Amiodarone	4	200/428	209/245	0.19 (0.14-0.27)	<.001
Dofetilide	2	252/431	274/325	0.28 (0.20-0.38)	<.001
Sotalol hydrochloride	9	916/1391	622/815	0.53 (0.44-0.65)	<.001
Dronedarone	1	116/151	43/48	0.45 (0.20-1.02)	.06
All class III	15	1484/2401	1148/1433	0.37 (0.32-0.43)	<.001



Arch Intern Med. 2006;166:719-728

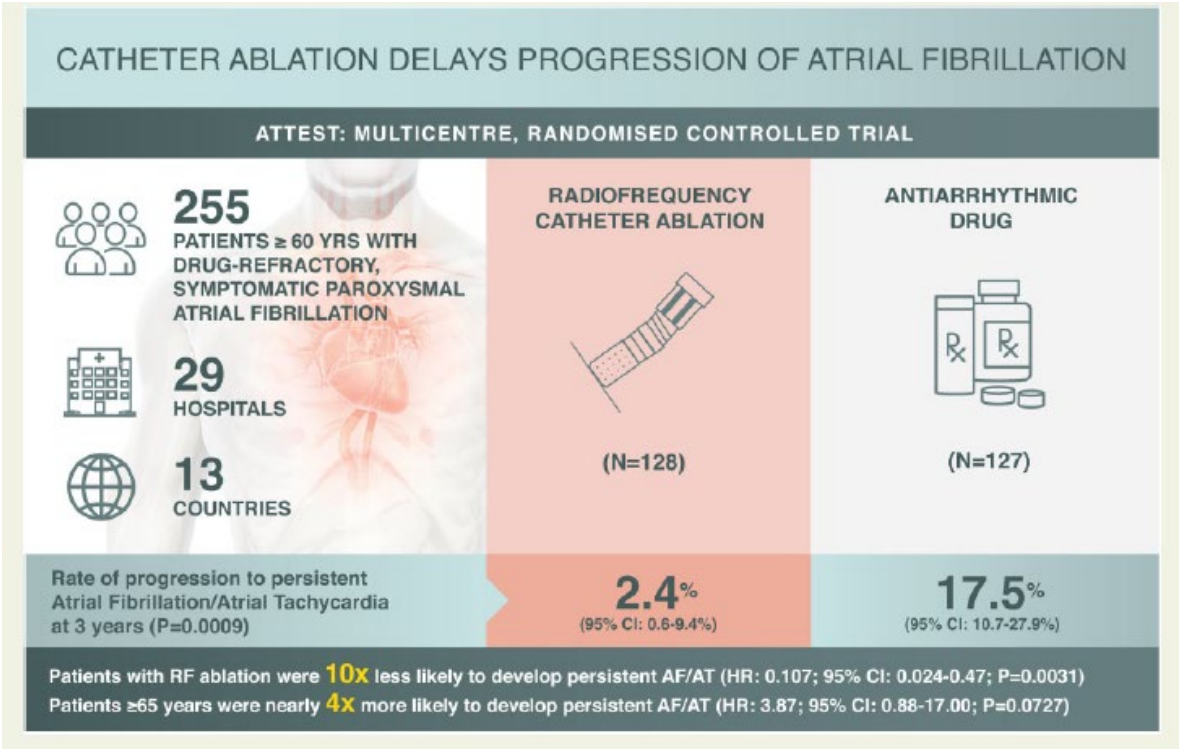
Atrial Fibrillation Ablation

- Outpatient procedure that takes <2 hours
- Not a cure but reduces symptomatic episodes



ATTEST Trial

- Prospective RCT comparing AAD vs ablation
- Radiofrequency ablation is superior



Europace (2021) 23, 362–369a

EARLY AF Trial

- Prospective RCT comparing starting with AAD vs ablation
- Initial treatment of paroxysmal atrial fibrillation with catheter ablation was associated with a lower incidence of persistent atrial fibrillation or recurrent atrial tachyarrhythmia over 3 years of follow-up

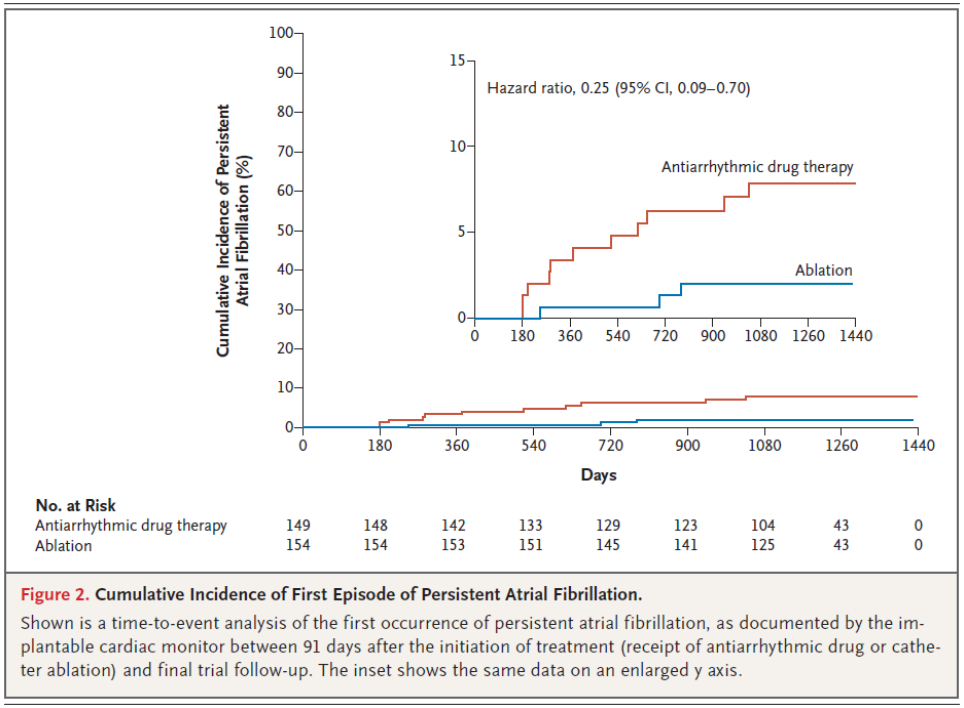


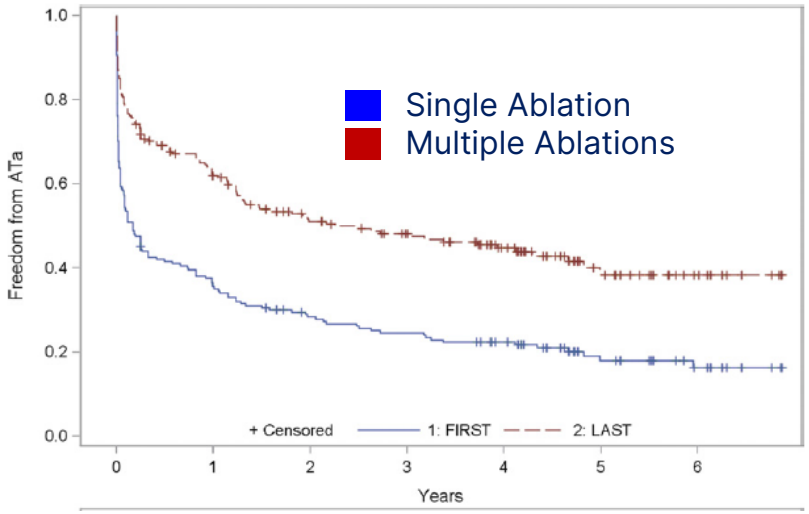
Figure 2. Cumulative Incidence of First Episode of Persistent Atrial Fibrillation.
Shown is a time-to-event analysis of the first occurrence of persistent atrial fibrillation, as documented by the implantable cardiac monitor between 91 days after the initiation of treatment (receipt of antiarrhythmic drug or catheter ablation) and final trial follow-up. The inset shows the same data on an enlarged y axis.

N Engl J Med 2023;388:105-16.

Long Standing Persistent Atrial Fibrillation

Hamburg Sequential Ablation Strategy Study

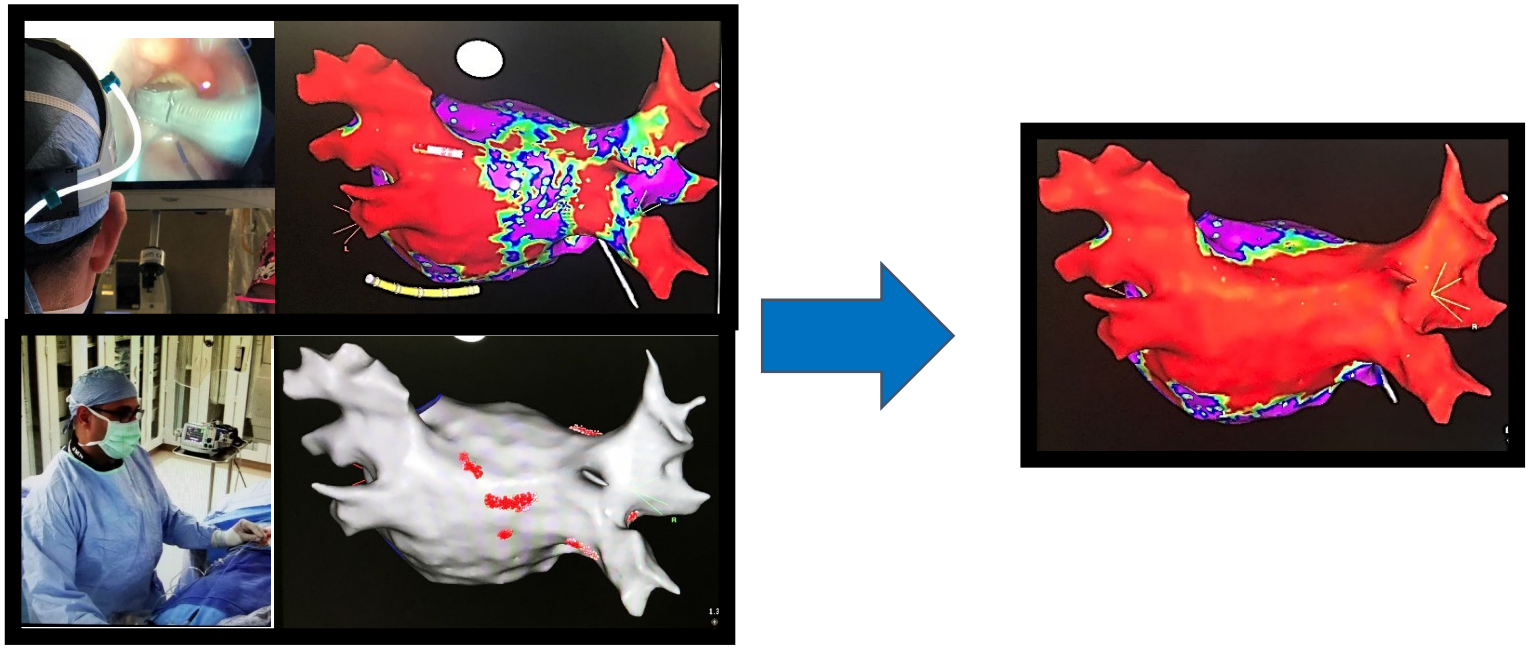
- Prospective study of 202 sequential patients with LSPAF.
- PVI in all. CFAEs if unable to DCCV or recurrence and veins were isolated.
- During 5-year follow-up, single- and multiple ablation procedure success was 20% and 45%,



J Am Coll Cardiol. 2012 Nov 6;60(19):1921-9

Javed Nasir, MD

Convergent AF Ablations



CONVERGE Trial

- Prospective RCT comparing catheter vs convergent ablation
- Convergent ablation is superior

Circ Arrhythm Electrophysiol. 2020;13:e009288.

Hybrid Convergent Procedure Vs Endocardial Catheter Ablation for the Treatment of Drug Refractory Persistent and Longstanding Persistent AF (CONVERGE Trial)

PROSPECTIVE RANDOMIZED CONTROLLED MULTICENTER TRIAL

27

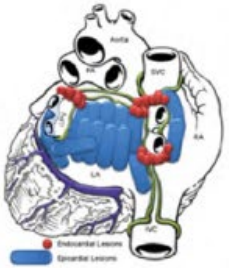
US & UK Sites

153

Patients with drug refractory symptomatic persistent and longstanding persistent AF

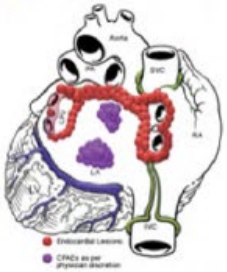
LESION SET

HYBRID CONVERGENT arm



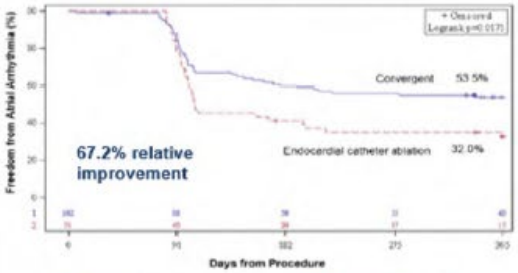
2:1 randomization

Endocardial catheter ablation arm

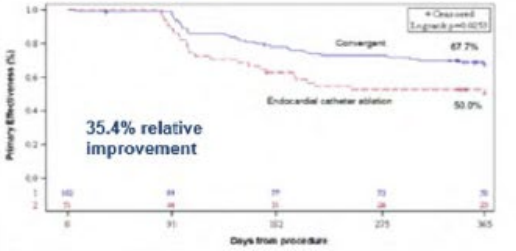


OUTCOMES THROUGH 12 MONTHS

21.5 % absolute improvement (P = 0.013) – Off AADs



17.7% absolute improvement (P = 0.036) off new/increased dose of failed AADs



Safety rate of 2.9% through 7days & 7.8% through 30 days