FIX AFIB

HEART CARE + AFIB REPAIR

ATRIAL FIBRILLATION

MODIFIABLE RISK FACTORS & TREATMENTS FOR AFIB

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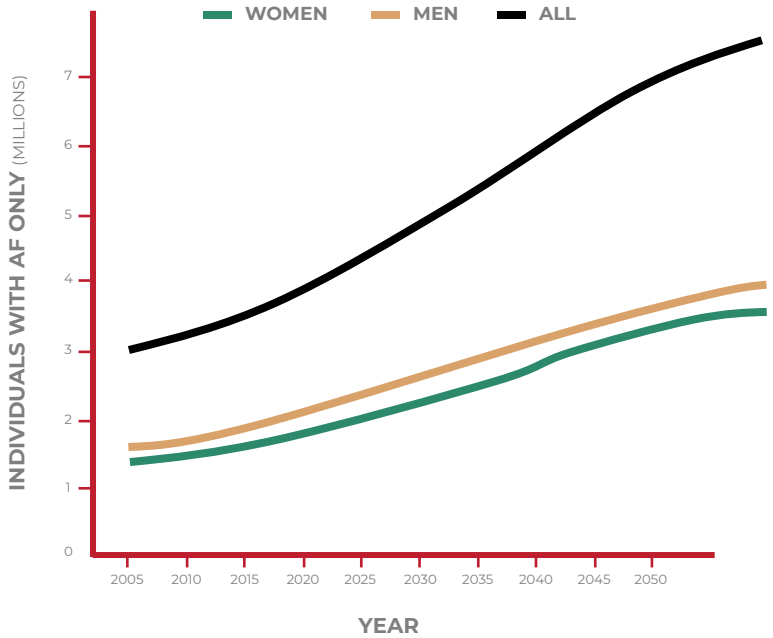
I have no actual or potential conflict of interest in relation to this symposium.

OBJECTIVES

1. Atrial Fibrillation (AFib) Prevalence
2. AFib Classification
3. Modifiable AFib Risk Factors
4. Early Intervention Treatment Strategies

AF PREVALENCE IS LARGE & GROWING



- U.S. AFib prevalence is estimated at 5.2 million and is predicted to grow to 12.1 million by 2030
- Age-adjusted AFib incidence is predicted to grow as a result of increased risk factors – obesity, hypertension, diabetes, sleep apnea and cardiovascular disease

Morin DP, et al. Mayo Clin Proc. 2016, 91:1778-1810

AF HEALTH RISKS AND COSTS

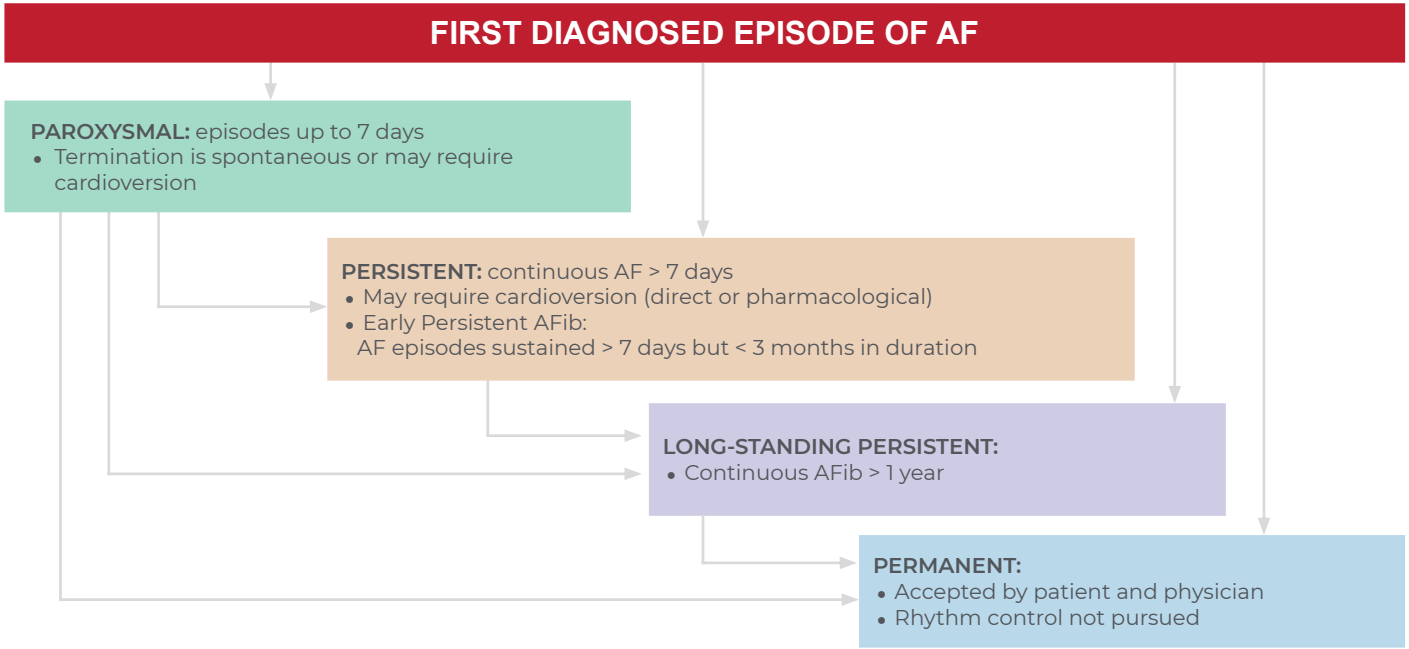
- Negative impact on quality of life [1,2]
- Leading cause of stroke: 5x increased risk [3]
- Increases risk of heart failure [4]
- Increases US healthcare system costs:
  – $28 billion estimated cost to treat AFib[5]

[1] Singh SN, et al. J Am Coll Cardiol. 2006;48:721-730.
[2] Kang Y. Heart Lung. 2006;35:170-177.
[3] Wolf PA, et al. Stroke. 1991;22:983-988.
[4] White PD: Heart disease. New York, NY, The McMillan Co, 1937.
[5] Kornej J, et al. Circulation Research. 2020, 127:4-20

AFIB CLASSIFICATIONS

CLINICAL CLASSIFICATION OF ATRIAL FIBRILLATION

(BASED ON PATTERN)



Hindricks G, et al. *Eur Heart J*. 2021;42:373-498; Calkins H, et al. *J Arrhythm*. 2017;33:369-409.

CONSEQUENCES OF ATRIAL FIBRILLATION PROGRESSION
EARLIER TREATMENT IS IMPORTANT

DECREASED HEALTH-RELATED QUALITY OF LIFE
(EuroQoL-5D) due to worsening AFib symptoms and adverse events (progression vs. no progression)[1]

20%
higher risk of stroke or systemic embolism in patients with persistent/permanent vs. paroxysmal AFib treated with oral anticoagulation[2]

28%
higher risk of death in patients with persistent/permanent vs. paroxysmal AFib treated with oral anticoagulation[2]

2x
prevalence of heart failure (persistent vs. paroxysmal AFib)[3]

~1.5x
increased hospitalizations for cardiovascular problems and 2x for electrical cardioversions (progression vs. no progression)[4]

6.5x
prevalence of stroke (persistent vs. paroxysmal AFib)[3]

[1] Dudink EAMP, et al. *Europace*. 2018;20:929-934.
[2] Zhang W, et al. *Am J Cardiol*. 2019;123:922-928.
[3] Almeida ED, et al. *Arq Bras Cardiol*. 2015;105:3-10.
[4] de Vos CB, et al. *J Am Coll Cardiol*. 2010;55:725-731.

MODIFIABLE AFIB RISK FACTORS

AGGRESSIVE RISK FACTOR MODIFICATION

- Decreases AFib burden and progression
- Improves treatment efficacy

MODIFIABLE RISK FACTORS

- High blood pressure
- Obesity
- Sleep Apnea
- Diabetes
- Excessive alcohol intake
- Smoking

COMPONENTS OF RISK FACTOR MODIFICATION IN ARREST-AF AND LEGACY STUDIES

AGGRESSIVE RISK FACTOR MANAGEMENT

WEIGHT MANAGEMENT AND EXERCISE

- Educate for permanent lifestyle change
- Diet Plan
- Initial target: >10% weight loss. Final target: BMI <27 kg/m2
- Avoid weight fluctuation
- Exercise: 30 minutes for 3-4x per week
- Increase type and duration of activity up to 250 minutes per week

HYPERLIPIDAEMIA

- Initial lifestyle measures
- At 3 months: start statins if LDL > 100 mg/dl
- Add fibrates if TG > 200 mg/dl
- Start fibrates if TG > 500 mg/dl

OBSTRUCTIVE SLEEP APNEA

- Overnight sleep study
- CPAP if AHI > 30; or > 20/h with resistant HT or daytime somnolence
- Check adherence: regular CPAP machine data download

HYPERTENSION

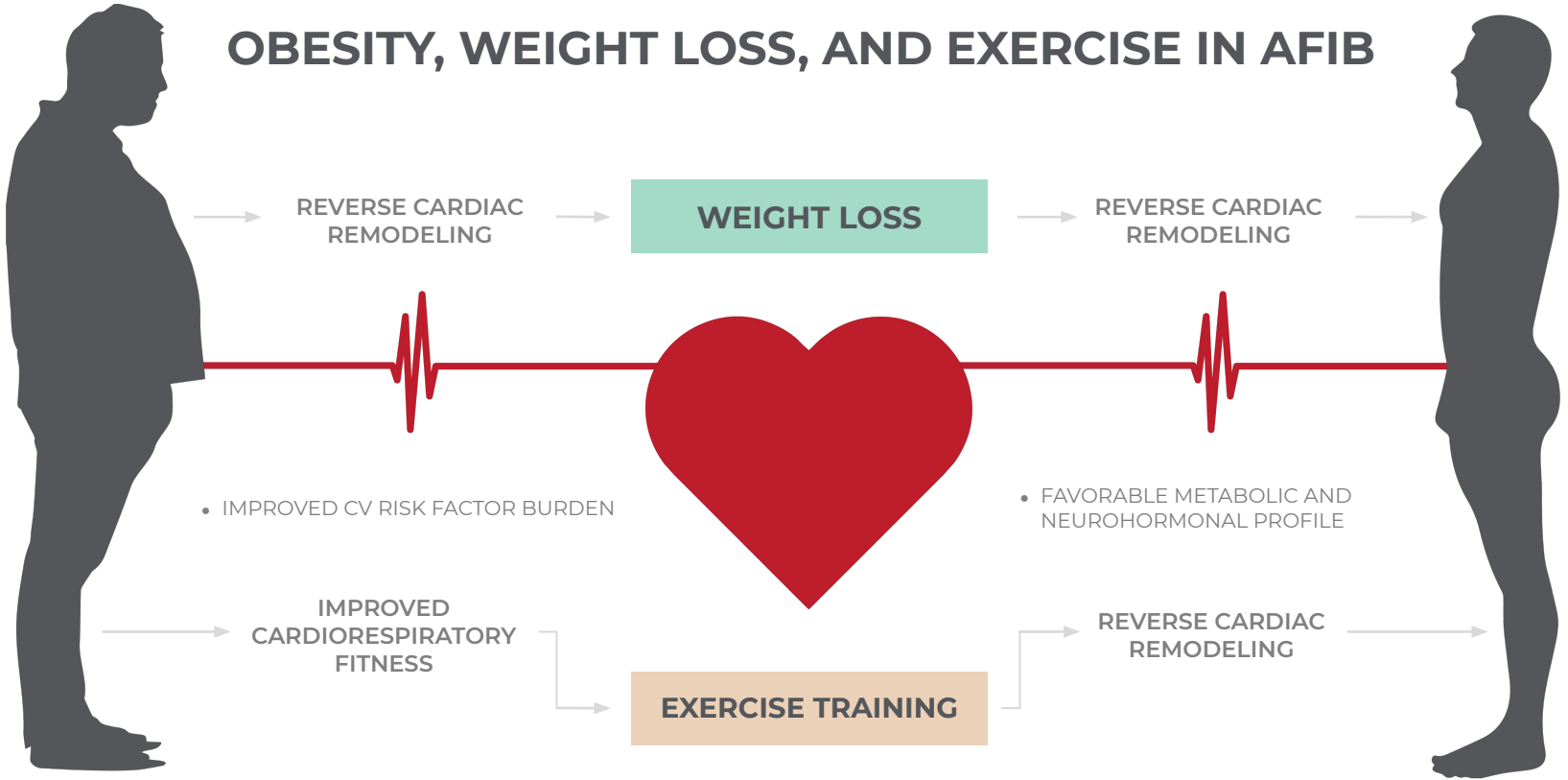
- Home BP diary: 2-3x daily
- Reduce salt
- Start ACEI or ARB
- Target: < 130/80 mmHg (at rest) & < 200/100 mmHg (at peak exercise)

DIABETES

- Glucose tolerance test
- Lifestyle measures
- At 3 months: Metformin if HbA1c > 6.5%
- Diabetes clinic

SMOKING CESSATION & ALCOHOL ABSTINENCE (OR REDUCTION TO 30G PER WEEK)

OBESITY, WEIGHT LOSS, AND EXERCISE IN AFIB

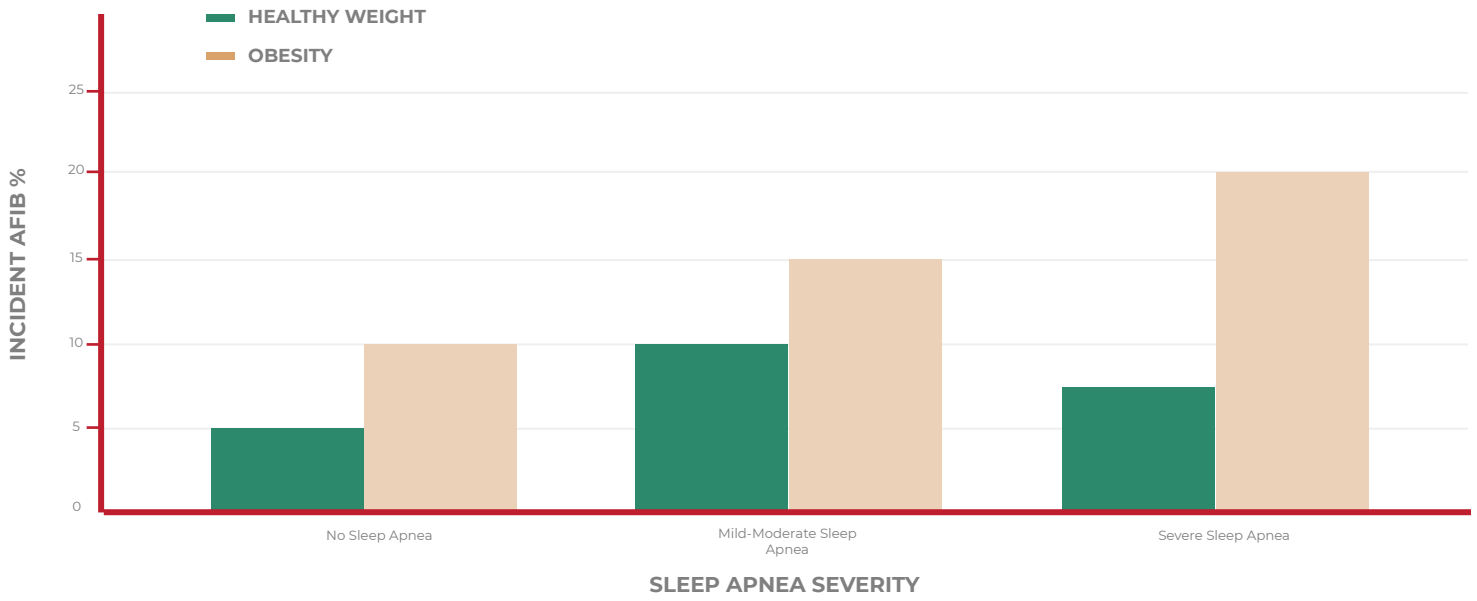


OBESITY AND AFIB

LOWER AFIB RECURRENCE

Lavie, C.J. et al. J Am Coll Cardiol, 2017;70(16):2022-35.

INCIDENCE OF AFIB BASED ON SEVERITY OF SLEEP APNEA AND OBESITY



[1] Apoor SG, et al. JACC, 2007,49,5:565-57

ALCOHOL ABSTINENCE IN AFIB PATIENTS

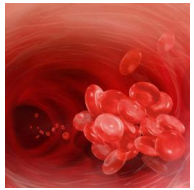
Abstaining from alcohol can decrease the risk of episode recurrence and hospital admissions in patients with AFib.

ABSTINENCE VS USUAL DRINKING	ABSTINENCE	USUAL DRINKING
AFIB EPISODE RECURRENCE	53%	73%
MODERATE TO SEVERE AFIB SYMPTOMS	10%	32%
AFIB HOSPITAL ADMISSIONS	9%	20%

[A] Voskoboinik et al. 10.1056/NEJMoa1817591, Copyright 2020 Massachusetts Medical Society

AFIB TREATMENT STRATEGIES & EARLY INTERVENTION

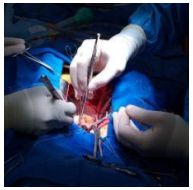
AF TREATMENT OPTIONS



Anticoagulation therapy to prevent clots from forming

Medication to control the heart rate or rhythm

Restoration of normal heart rhythm through an electrical cardioversion or medication



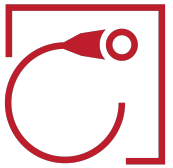
Surgery to create lines of scar tissue to block abnormal electrical circuits causing AFib

Pacemakers and defibrillators may be used in conjunction with medication or catheter ablation

Radiofrequency or Cryoablation to help keep the heart in a normal rhythm

TREATMENT STRATEGIES TO CONTROL AFIB SYMPTOMS

- Rate control
- Rhythm Control



EARLY RHYTHM CONTROL

- Results in better cardiovascular outcomes [1]
- Catheter ablation is more effective than drug therapy at preventing AFib progression [2]
- Catheter ablation decreases time spent in AFib [3,4]
- Early ablation increases procedural effectiveness [5]
- Early ablation decreases cardiovascular hospitalizations [5]

[1] Kirchhof P, et al. N Engl J Med. 2020;383:1305-1316.
[2] Kuck KH, et al. Europace. 2021;23:362-369.
[3] Andrade JG, et al. Circulation. 2019;140:1779-1788.
[4] Blomstrom-Lundqvist C, et al. JAMA. 2019;321:1059-1068.
[5] Kawaji T, et al. Int J Cardiol. 2019;291:69-76.

SUMMARY OF GUIDELINES FOR CATHETER ABLATION OF SYMPTOMATIC PAROXYSMAL AF PRIOR TO AAD FAILURE

2014 AHA/ACC/HRS Guideline for the Management of Patients with AFib	2017 HRS/EHRA/APHRS/SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of AFib	2020 ESC Management of Atrial Fibrillation Guidelines	
In patients with recurrent symptomatic paroxysmal AFib, catheter ablation is a reasonable initial rhythm control strategy prior to therapeutic trials of antiarrhythmic drug therapy, after weighing risks and outcomes of drug and ablation therapy (IIa, B)[1]	Catheter ablation is reasonable prior to initiation of AADs (IIa, B-R)[2]	AFib catheter ablation for PVI should be considered for rhythm control after one failed or intolerant to beta-blocker treatment (IIa, B)[3]	Should/may be considered as first-line rhythm control therapy to improve symptoms in selected patients with symptomatic paroxysmal AFib episodes (IIa, B)[3]

[1] January CT, et al. *Circulation*. 2014;130:2071-2104.
[2] Calkins H, et al. *Europace*. 2018;20:e1-e160.
[3] Hindricks G, et al. *Eur Heart J*. 2021;42:373-498.

PRIMARY PUBLICATIONS

CRYO-FIRST [1]

Primary results published in *Europace*, March 17, 2021

STOP AFIB FIRST [2]

Primary results published in *The New England Journal of Medicine*, January 2021

EARLY-AFIB [3]

Primary results published in *The New England Journal of Medicine*, January 2021

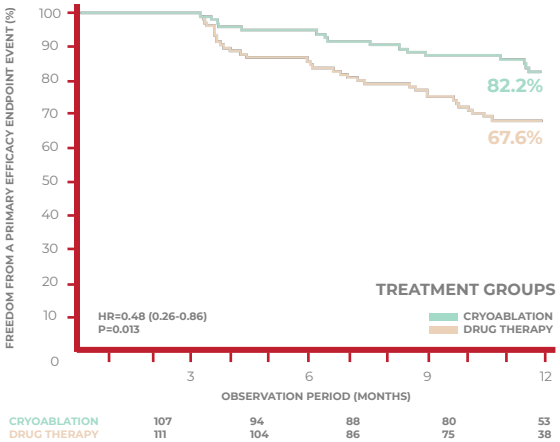
[1] Kuniss M, et al. *Europace*. Published online March 17, 2021.
[2] Wazni OM, et al. *N Engl J Med*. 2021;384(4):316-324.
[3] Andrade JG, et al. *N Engl J Med*. 2021;384(4):305-315.

PRIMARY EFFICACY RESULTS

Cryoablation was superior to AAD therapy for the prevention of atrial arrhythmia recurrence over 12 months.

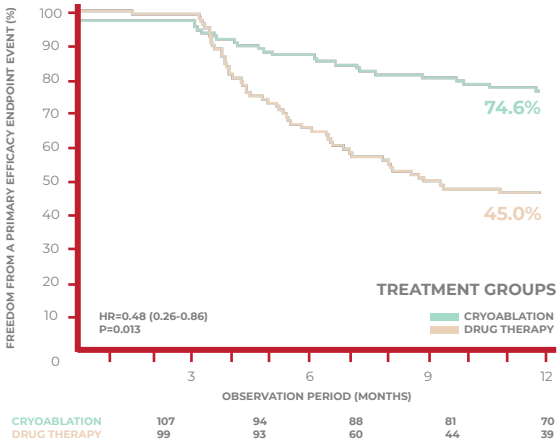
CRYO-FIRST [1]

7-Day Holters every 3 months



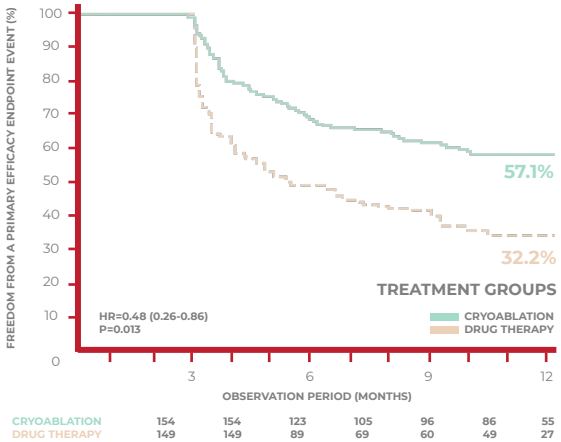
STOP AFIB FIRST [2]

TTMs weekly and when symptomatic,
24-hour ambulatory monitoring at 6 & 12



EARLY-AFIB [3]

Continuous monitoring with an icm

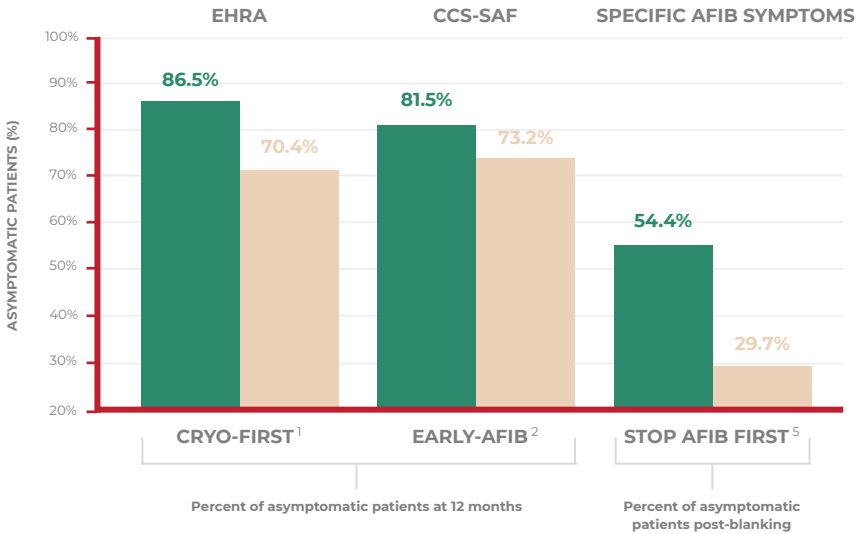


[1] Kuniss M, et al. *Europace*. Published online March 17, 2021.
[2] Wazni OM, et al. *N Engl J Med*. 2021;384(4):316-324.
[3] Andrade JG, et al. *N Engl J Med*. 2021;384(4):305-315.

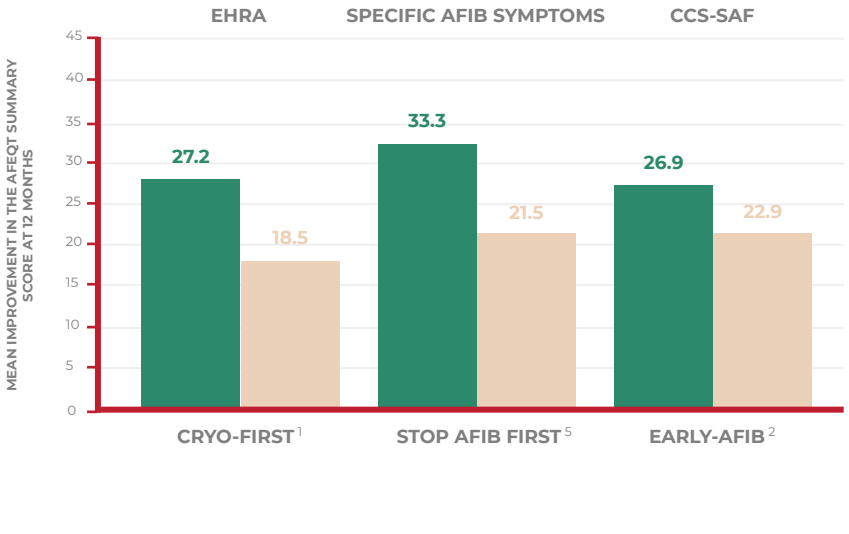
HIGHER RATE OF PRIMARY ENDPOINT FAILURE WITH MORE ROBUST CARDIAC MONITORING DURING FOLLOW-UP

QUALITY OF LIFE AND SYMPTOMS

Significantly more patients in the cryoballoon vs. AAD arm were asymptomatic at either 12 months or post-blanking.[1-3]



Larger improvements in AFib-specific quality of life were observed with cryoballoon ablation vs. AAD.[2,4,5]



*Early AF results are based on a mixed effects model for repeated measures.

[1] Kuniss M, et al. *Europace*. Published online March 17, 2021.

[2] Andrade JG, et al. *N Engl J Med*. 2021;384(4):305-315.

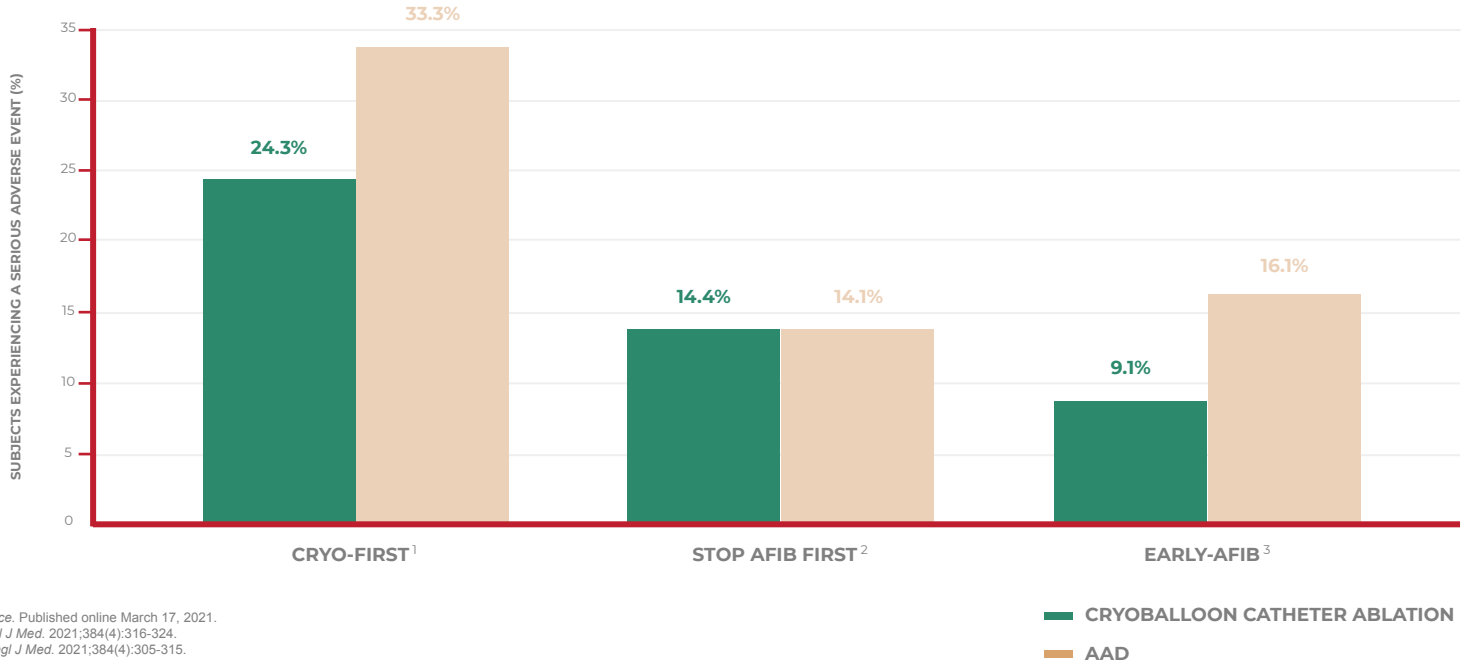
[3] Data on file.

[4] Pavlovic N, et al. *Circulation*. 2020;142:A13916-A13916.

[5] Wazni OM, et al. *J Am Coll Cardiol*. 2021;77:225.

SAFETY RESULTS

There was not a higher proportion of subjects in the ablation arm who experienced a serious adverse event, despite ablation being an invasive procedure.[1-3]



[1] Kuniss M, et al. *Europace*. Published online March 17, 2021.
[2] Wazni OM, et al. *N Engl J Med*. 2021;384(4):316-324.
[3] Andrade JG, et al. *N Engl J Med*. 2021;384(4):305-315.

SUMMARY OF PATIENT BENEFITS

- Earlier treatment with catheter ablation has been shown to reduce atrial arrhythmia recurrence.
- Patients can now be referred for a cryoablation without the need for drug therapy failure.
- Cryoballoon is a safe and effective choice.
- Study after study shows ablations are more effective than medicines in minimizing AFib burden
- Now, ablations are covered by health care insurance as a first line of therapy to prevent AFib recurrence

LONG-TERM OUTCOMES AFTER ABLATION PROCEDURE, FIX AFIB CLINIC

Patients followed at our clinic report less AFib burden in their activities of daily living after an ablation procedure.

75%

Of subjects with paroxysmal AF remain free from AFib at 2 years as evidence by Kaplan-Meier analysis

Rare serious adverse events through hospitalization: 2 patients with persistent AFib experienced pericardial effusion