Catheter Ablation versus Drug Therapy for Rhythm Control of Atrial Fibrillation

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Relationships with Industry

- Consultant/ Lecture Honoraria: Biosense, Boston Scientific, Medtronic, Abbott Medical, Boehringer Ingelheim, AtriCure

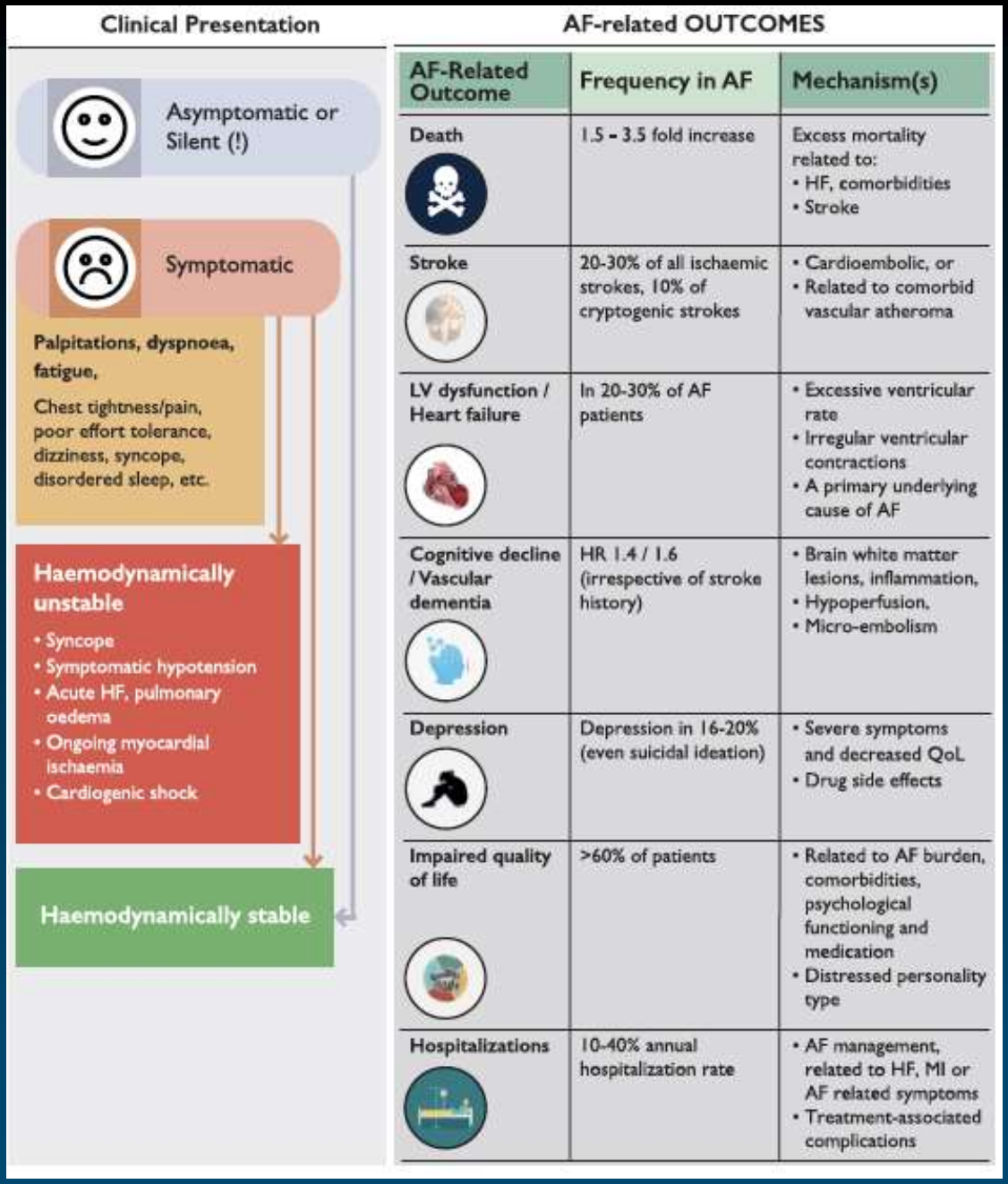
Case Presentation

- 67 year old man
- Highly symptomatic paroxysmal AF
- Failed Toprol
- Normal echocardiogram
- BMI 25
- Otherwise healthy

Case Presentation
What Would You Recommend?

- Catheter ablation
- Flecainide
- Amiodarone
- AV node ablation and PPM

In 2023 I Believe that Rhythm Control is the Preferred Strategy for AF Management



European Heart Journal (2020) **00**, 1 – 126

Why Rhythm Control is Best

Proven Benefits of Rhythm Control

1) Eliminate AF and /or reduce AF burden
2) Improve quality of life

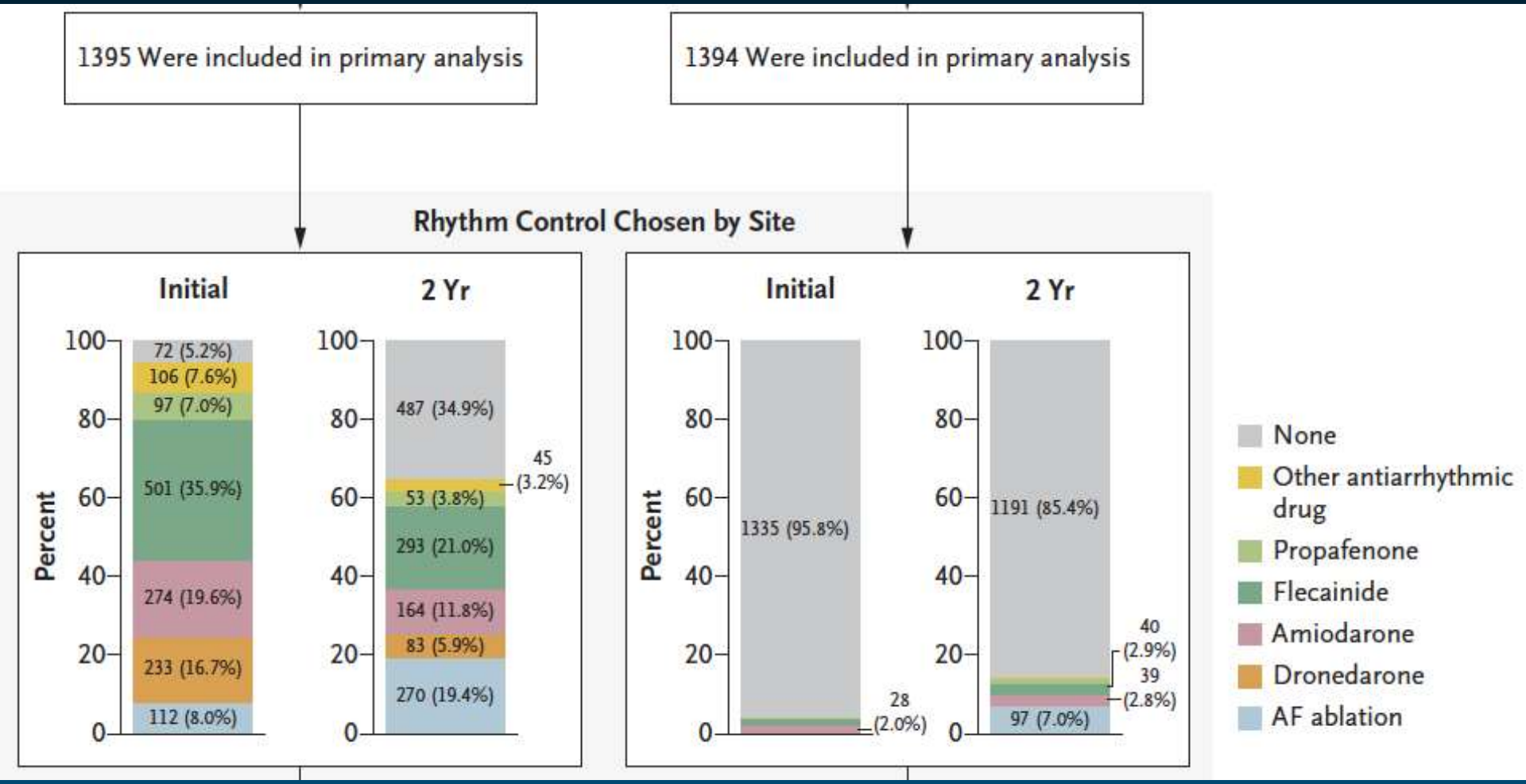
Unproven / Potential Benefits of AF ablation

1) Reduce stroke risk
2) Prevent dementia
3) Improve cardiac function / prevent heart failure
4) Prolong life
5) Prevent a lifetime of AF due to a remodeled atrium

Early Rhythm-Control Therapy in Patients with Atrial Fibrillation

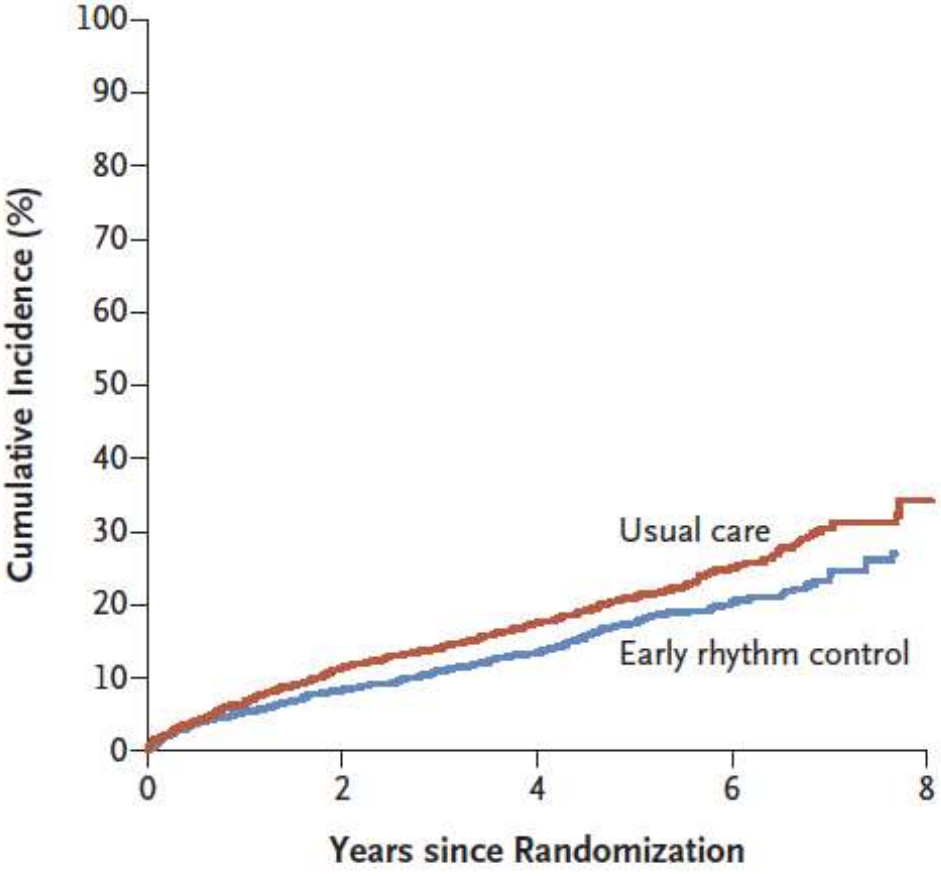
P. Kirchhof, A.J. Camm, A. Goette, A. Brandes, L. Eckardt, A. Elvan, T. Fetsch, I.C. van Gelder, D. Haase, L.M. Haegeli, F. Hamann, H. Heidbüchel, G. Hindricks, J. Kautzner, K.-H. Kuck, L. Mont, G.A. Ng, J. Rekosz, N. Schoen, U. Schotten, A. Suling, J. Taggeselle, S. Themistoclakis, E. Vettorazzi, P. Vardas, K. Wegscheider, S. Willems, H.J.G.M. Crijns, and G. Breithardt, for the EAST-AFNET 4 Trial Investigators*

East Trial
2700 patients with early AF (< 1 yr) randomized to rhythm control or usual care



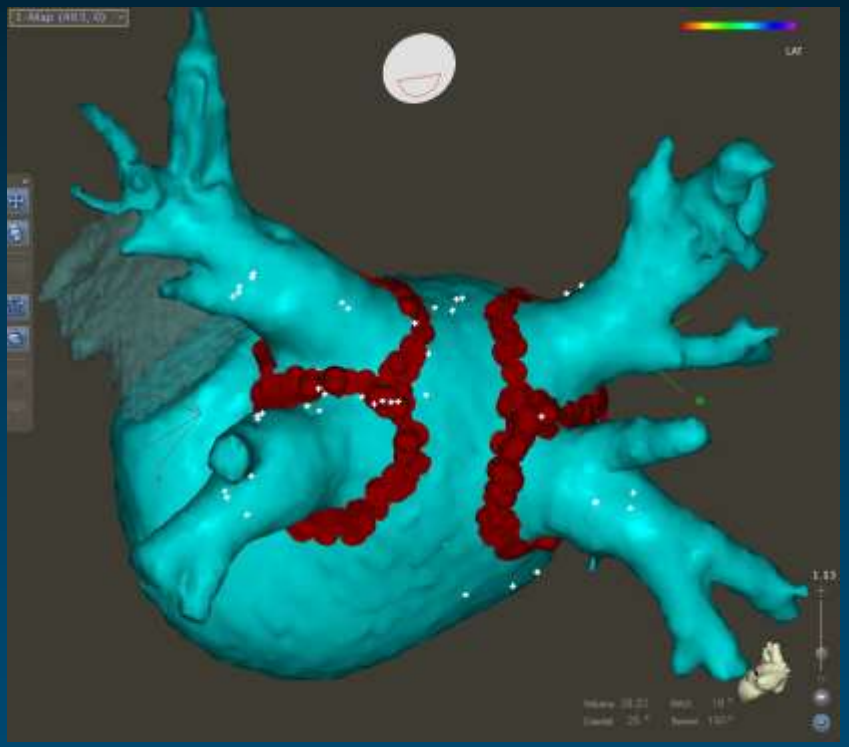
Primary outcome was a composite of CV death, stroke, heart failure hospitalization, or ACS

3.9 vs 5.0 per 100 pt years (p < 0.01)



No. at Risk					
Usual care	1394	1169	888	405	34
Early rhythm control	1395	1193	913	404	26

Drugs versus Ablation for Rhythm Control ?



My Perspective on Antiarrhythmic Drugs

- They are effective (40% to 70%)
- They are inexpensive
- They are widely available.
- There is no delay in starting therapy.
- The risks are well known and largely avoidable.
- Fifty percent of patients referred for AF ablation will continue to need AA meds

My Perspective on Catheter Ablation

- Catheter ablation is effective (30% to 80%)
- Catheter ablation is more effective than AA meds.
- Catheter ablation has a 1 – 2% incidence of major complications.
- Catheter ablation is resource intensive.
- The wait times for AF ablation are long.
- Some patients prefer procedures.
- Some patients are reluctant to have procedures and prefer medications

Catheter Ablation Outcomes in 2023

	Single Procedure	Multiple Procedure
Optimal Candidate:	60-80%	70-90%
Moderate Candidate	45-65%	55 – 75%
Poor candidate	35 – 50%	45 – 60%

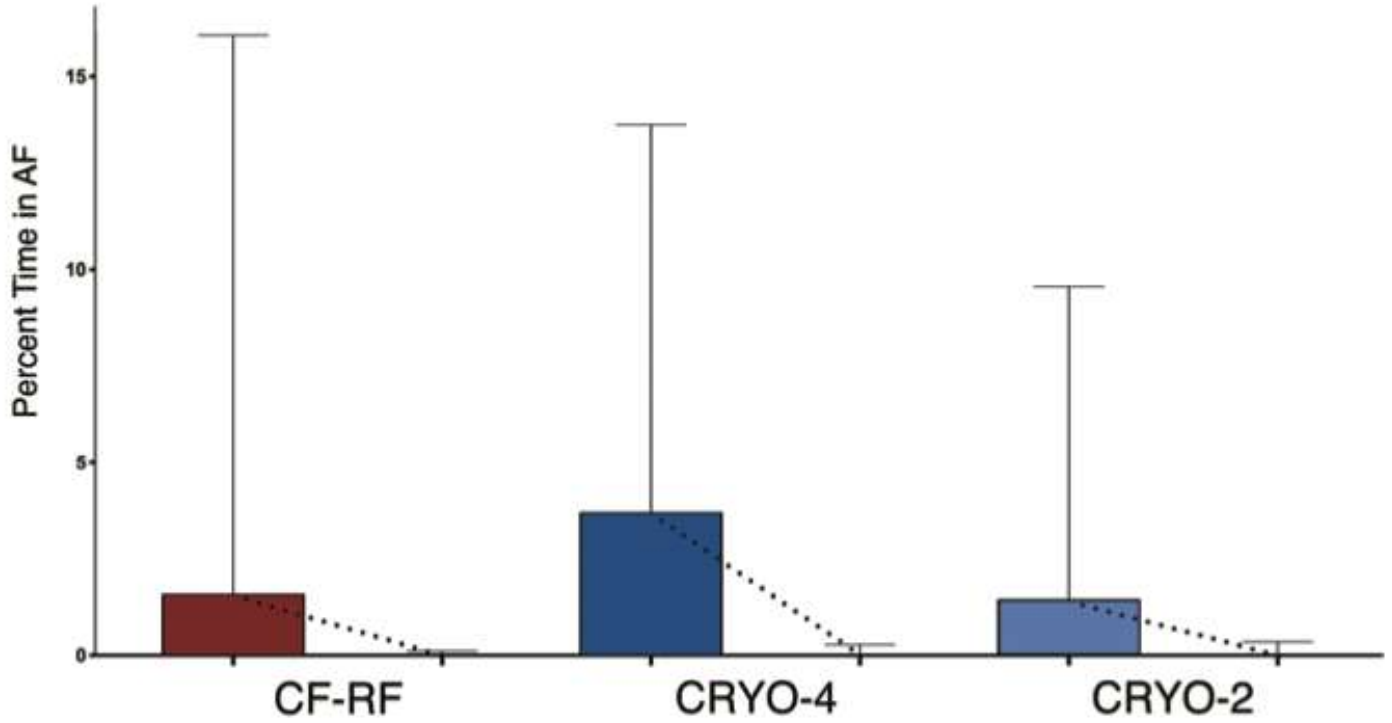
- *Success is defined as freedom from symptomatic AF at 12 months of follow-up.*

Circulation

ORIGINAL RESEARCH ARTICLE

Cryoballoon or Radiofrequency Ablation for Atrial Fibrillation Assessed by Continuous Monitoring

A Randomized Clinical Trial

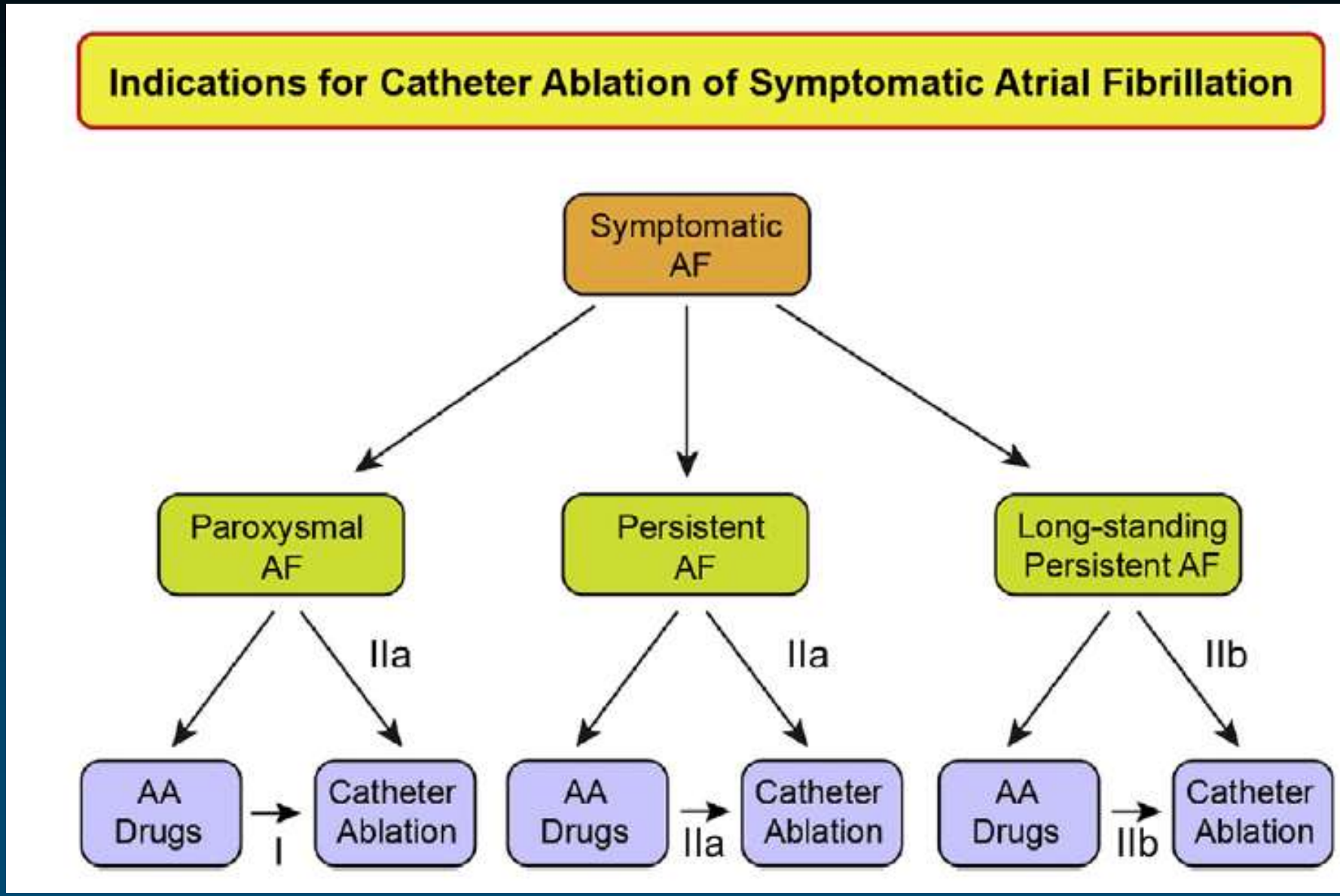


	CF-RF		CRYO-4		CRYO-2	
	Pre	Post	Pre	Post	Pre	Post
AF Burden median (IQR)	1.57 (0.08, 16.09)	0.00 (0.00, 0.11)	3.71 (0.22, 13.78)	0.00 (0.00, 0.24)	1.46 (0.09, 9.17)	0.01 (0.00, 0.34)
Median reduction in AF burden compared to baseline	99.34% (67.76, 100.00)		99.93% (65.31, 100.00)		98.40% (56.24, 100.00)	

Complications in 2023
Overall Complication Rate: 1% - 2%

Stroke /TIA	0.2% - 1%
Cardiac perforation / tamponade	0.5% - 2%
Vascular injury / bleeding	1.0% - 2%
Phrenic nerve injury	0.1% - .5%
PV Stenosis	0.2% - 0.5%
Atrial esophageal fistula	0.1%
Death	< 0.1%

What do the Guidelines Tell Us?



Heart Rhythm. 2017 Oct;14(10):e275-e444

2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society

Developed in Collaboration With the Society of Thoracic Surgeons

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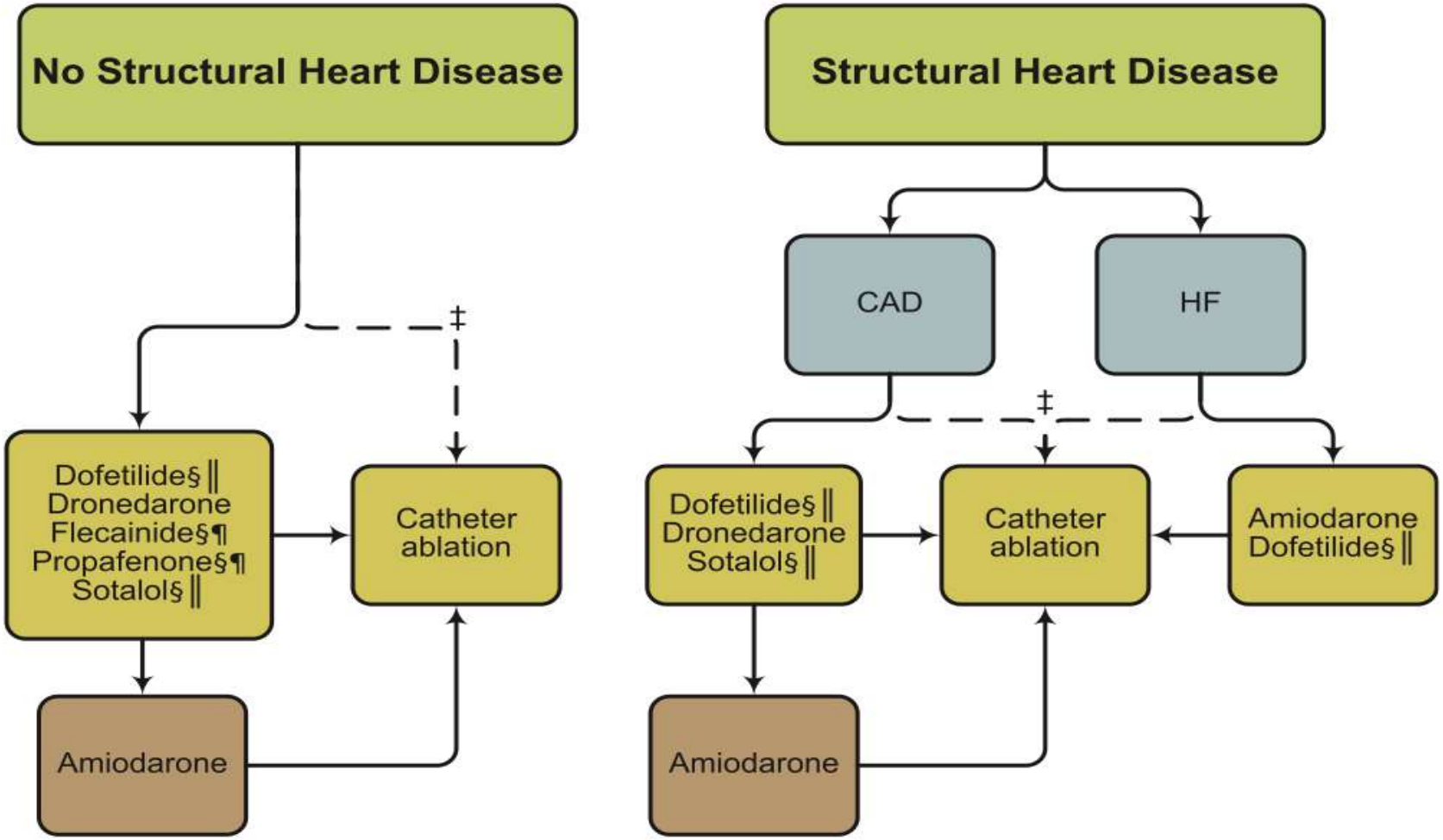

No Structural Heart Disease
‡
Dofetilide§ ‖
Dronedarone
Flecainide§¶
Propafenone§¶
Sotalol§ ‖
Catheter ablation
Amiodarone
Structural Heart Disease
CAD
HF
‡
Dofetilide§ ‖
Dronedarone
Sotalol§ ‖
Catheter ablation
Amiodarone
Dofetilide§ ‖
Amiodarone

6.3. AF Catheter Ablation to Maintain Sinus Rhythm: Recommendations

CLASS I

1. AF catheter ablation is useful for symptomatic paroxysmal AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication when a rhythm-control strategy is desired (363,392-397). *(Level of Evidence: A)*
2. Before consideration of AF catheter ablation, assessment of the procedural risks and outcomes relevant to the individual patient is recommended. *(Level of Evidence: C)*

CLASS IIa

1. AF catheter ablation is reasonable for some patients with symptomatic persistent AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication (394,398-400). *(Level of Evidence: A)*
2. In patients with recurrent symptomatic paroxysmal AF, catheter ablation is a reasonable initial rhythm-control strategy before therapeutic trials of antiarrhythmic drug therapy, after weighing the risks and outcomes of drug and ablation therapy (401-403). *(Level of Evidence: B)*

CLASS IIb

1. AF catheter ablation may be considered for symptomatic long-standing (>12 months) persistent AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication when a rhythm-control strategy is desired (363,404). *(Level of Evidence: B)*
2. AF catheter ablation may be considered before initiation of antiarrhythmic drug therapy with a class I or III antiarrhythmic medication for symptomatic persistent AF when a rhythm-control strategy is desired. *(Level of Evidence: C)*

CLASS III: HARM

1. AF catheter ablation should not be performed in patients who cannot be treated with anticoagulant therapy during and after the procedure. *(Level of Evidence: C)*
2. AF catheter ablation to restore sinus rhythm should not be performed with the sole intent of obviating the need for anticoagulation. *(Level of Evidence: C)*

Have Randomized Studies Been Done ?

Cryoballoon Ablation as Initial Treatment for Atrial Fibrillation

JACC State-of-the-Art Review

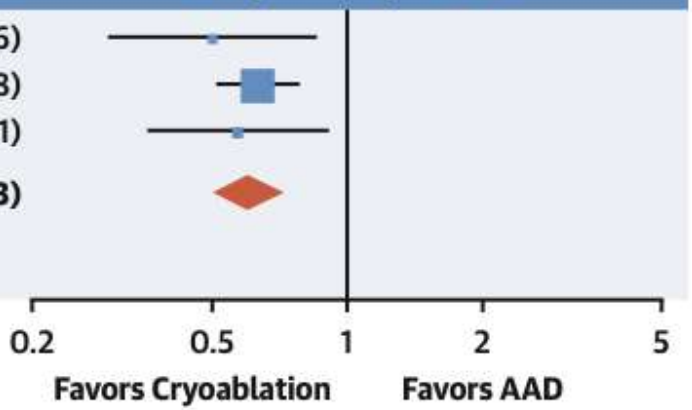
Jason G. Andrade, MD,[a,b,c] Oussama M. Wazni, MD,[d] Malte Kuniss, MD,[e] Nathaniel M. Hawkins, MD,[a,b] Marc W. Deyell, MD, MSc,[a,b] Gian-Battista Chierchia, MD,[f] Steven Nissen, MD,[d] Atul Verma, MD,[g] George A. Wells, PhD,[h] Ricky D. Turgeon, PharmD[a]

	Cryo-FIRST	EARLY-AF	STOP-AF First
Design	Prospective, multicenter, randomized	Prospective, multicenter, randomized	Prospective, multicenter, randomized
Setting (number of centers)	Australia, Europe, Latin America (20)	Canada (18)	United States (24)
Enrollment	2014-2018	2017-2018	2017-2019
Blanking period	90 days from cryoablation procedure or AAD initiation	90 days from cryoablation procedure or AAD initiation	90 days from cryoablation procedure or AAD initiation
Follow-up duration	12 months	12 months	12 months
Primary outcome	Any recurrence of atrial tachyarrhythmia (AF, AT, AFL) lasting longer than 30 seconds	Any recurrence of atrial tachyarrhythmia (AF, AT, AFL) lasting longer than 30 seconds	Any recurrence of atrial tachyarrhythmia (AF, AT, AFL) lasting longer than 30 seconds
Key secondary outcomes	• Quality of life (AFEQT) • Symptoms • Health care use • Adverse events	• Quality of life (AFEQT, EQ5D) • Symptoms • Health care use • Adverse events	• Quality of life (AFEQT) • Health care use • Adverse events

A Any Atrial Tachyarrhythmia

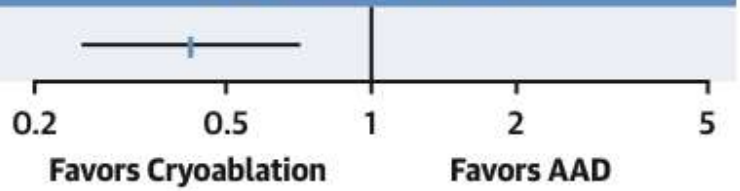
Study	Cryoablation Events	Cryoablation Total	AAD Events	AAD Total	Weight	Risk Ratio M-H, Random, 95% CI
Cryo-FIRST	16	107	33	111	11.6%	0.50 (0.29-0.86)
EARLY-AF	66	154	101	149	73.0%	0.63 (0.51-0.78)
STOP-AF First	21	104	35	99	15.3%	0.57 (0.36-0.91)
Total (95% CI)		**365**		**359**	**100.0%**	**0.61 (0.51-0.73)**
Total events	103		169			

Heterogeneity: Tau^2 = 0.00; chi-square = 0.72, df = 2 (P = 0.70); I^2 = 0%
Test for overall effect: Z = 5.38 (P < 0.00001)



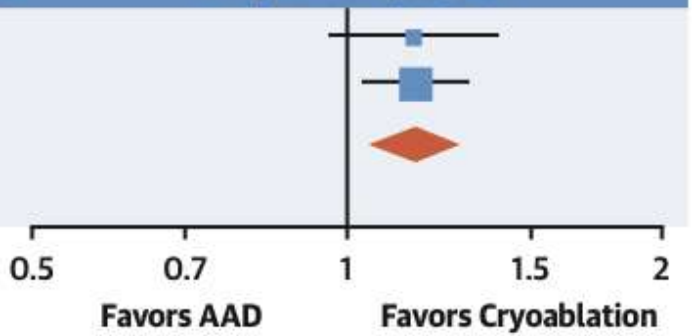
B Symptomatic Atrial Tachyarrhythmia

Study	Cryoablation Events	Cryoablation Total	AAD Events	AAD Total	Risk Ratio M-H, Random, 95% CI
EARLY-AF	17	154	39	149	0.42 (0.25-0.71)



A Asymptomatic at 12 Months

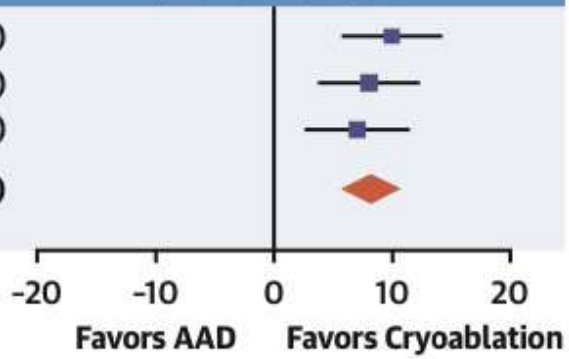
Study	Cryoablation Events	Cryoablation Total	AAD Events	AAD Total	Weight	Risk Ratio M-H, Random, 95% CI
Cryo-FIRST	77	107	69	111	28.3%	1.16 (0.96-1.40)
EARLY-AF	131	154	109	149	71.7%	1.16 (1.03-1.31)
Total (95% CI)		**261**		**260**	**100.0%**	**1.16 (1.05-1.28)**
Total events	208		178			



Heterogeneity: $Tau^2 = 0.00$; chi-square = 0.00, df = 1 ($P = 0.97$); $I^2 = 0\%$
Test for overall effect: Z = 2.94 ($P = 0.003$)

B Mean Difference in AFEQT Score

Study	Cryoablation Mean	Cryoablation SD	Cryoablation Total	AAD Mean	AAD SD	AAD Total	Weight	Mean Difference IV, Random, 95% CI
Cryo-FIRST	88	14.8	89	78.1	14.8	92	33.7%	9.90 (5.59-14.21)
EARLY-AF	88.3	19.1	154	80.3	19.1	149	33.9%	8.00 (3.70-12.30)
STOP-AF First	91.9	15.4	99	84.9	15.4	90	32.4%	7.00 (2.60-11.40)
Total (95% CI)			**342**			**331**	**100.0%**	**8.32 (5.81-10.82)**

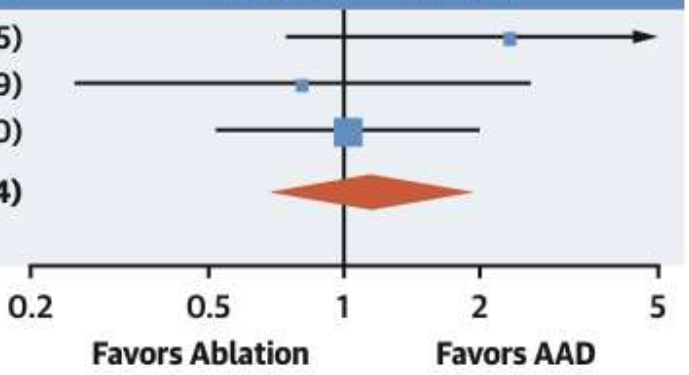


Heterogeneity: $Tau^2 = 0.00$; chi-square = 0.88, df = 2 ($P = 0.64$); $I^2 = 0\%$
Test for overall effect: Z = 6.51 (P < 0.00001)

A Serious Adverse Event

Study	Cryoablation Events	Total	AAD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Cryo-FIRST	9	107	4	111	20.6%	2.33 (0.74-7.35)
EARLY-AF	5	154	6	149	19.9%	0.81 (0.25-2.59)
STOP-AF First	15	104	14	99	59.5%	1.02 (0.52-2.00)
Total (95% CI)		**365**		**359**	**100.0%**	**1.15 (0.69-1.94)**
Total events	29		24			

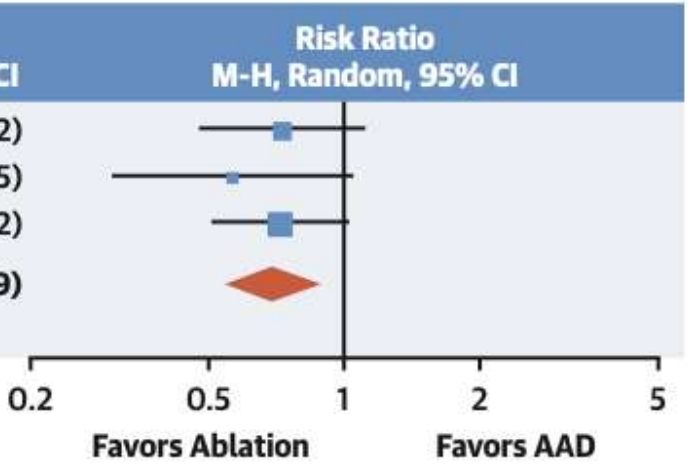
Heterogeneity: $Tau^2 = 0.00$; chi-square = 1.95, df = 2 ($P = 0.38$); $I^2 = 0\%$
Test for overall effect: Z = 0.54 ($P = 0.59$)



B Any Safety Endpoint

Study	Cryoablation Events	Total	AAD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Cryo-FIRST	26	107	37	111	33.9%	0.73 (0.48-1.12)
EARLY-AF	14	154	24	149	16.0%	0.56 (0.30-1.05)
STOP-AF First	34	104	45	99	50.1%	0.72 (0.51-1.02)
Total (95% CI)		**365**		**359**	**100.0%**	**0.70 (0.54-0.89)**
Total events	74		106			

Heterogeneity: $Tau^2 = 0.00$; chi-square = 0.53, df = 2 ($P = 0.77$); $I^2 = 0\%$
Test for overall effect: Z = 2.88 ($P = 0.004$)



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Case Presentation
What Would You Recommend?

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Case Presentation
What Would You Recommend?

- Catheter ablation
- Flecainide
- Amiodarone
- AV node ablation and PPM

Conclusion

- Rhythm control is preferred over rate control.
- Rhythm control can be accomplished with AA drugs or ablation.
- Efficacy for both strategies is < 80%
- Catheter ablation is more effective.
- AA therapy is more available
- Patient preference is important


THANK YOU!