

**Catheter Ablation in Heart
Failure and AFib:
The Latest From CABANA**

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Disclosures

Dr. D. Packer in the past 12 months has provided consulting services for Biosense Webster, Inc., Boston Scientific, CyberHeart, Medtronic, Inc., nContact, Sanofi-Aventis, St. Jude Medical, and Toray Industries. Dr. Packer received no personal compensation for these consulting activities.

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Mayo Clinic and Drs. D. Packer and R. Robb have a financial interest in mapping technology that may have been used at some of the 10 centers participating in this pilot research. In accordance with the Bayh-Dole Act, this technology has been licensed to St. Jude Medical, and Mayo Clinic and Drs. Packer and Robb received annual royalties $> \$10,000$, the federal threshold for significant financial interest.

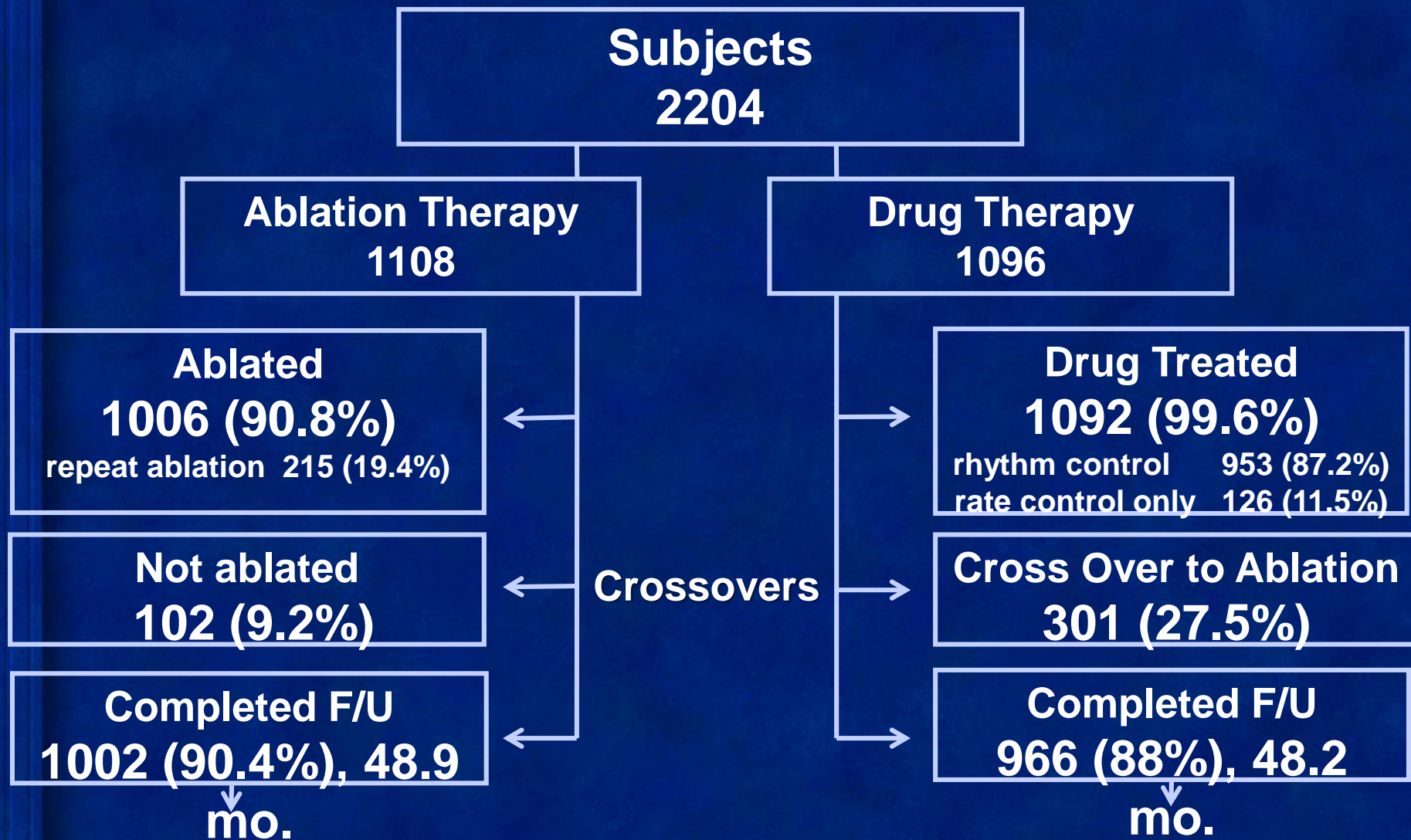
**Catheter ABlation vs ANtiarrhythmic
Drug Therapy in Atrial Fibrillation
(**CABANA**) Trial:**

**Update on Quality of Life, Recurrent
AF, Heart Failure, and Impact of Age**

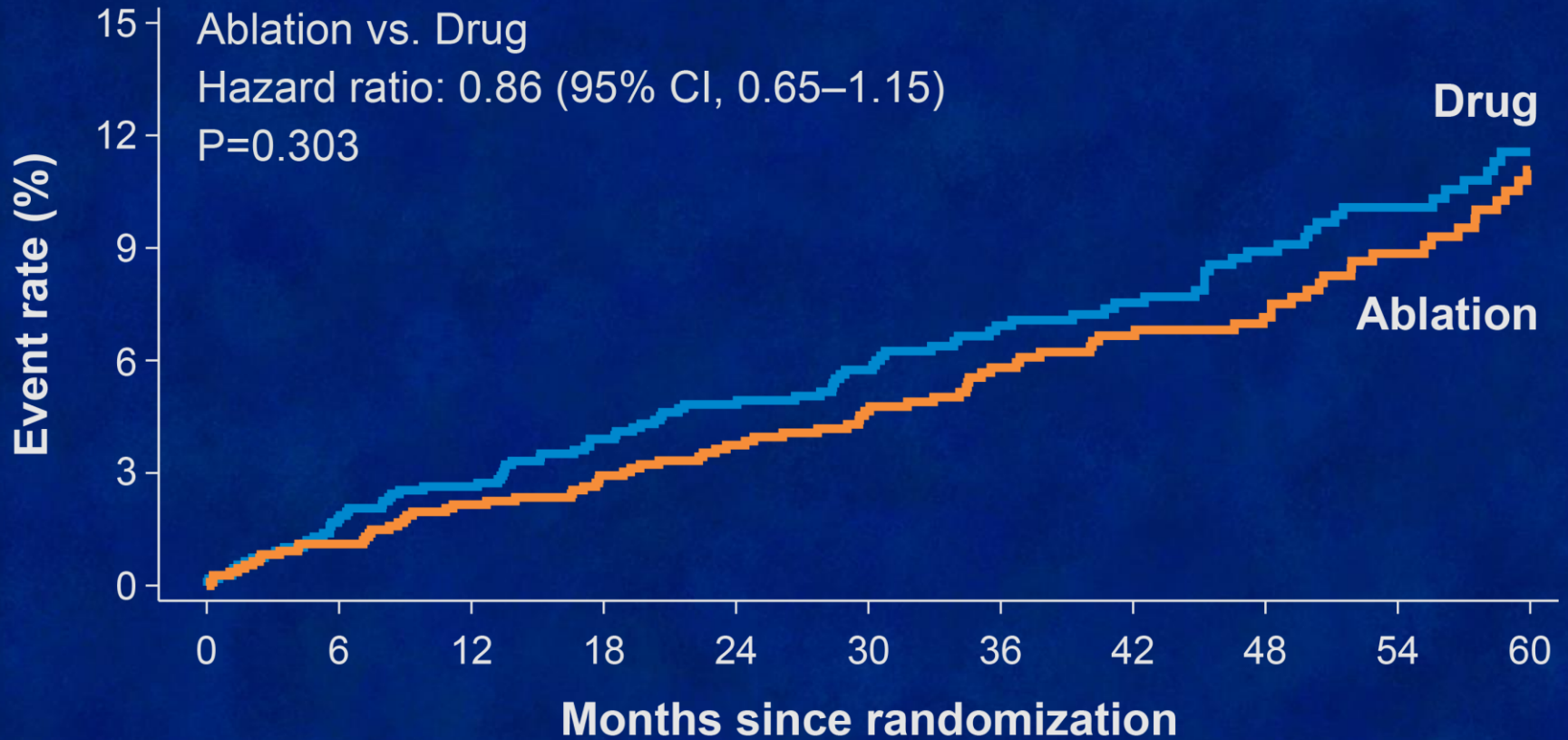
**Douglas L. Packer MD, Kerry L. Lee PhD,
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Kristi Monahan for the CABANA Investigators**

**Mayo Clinic Rochester
Duke Clinical Research Institute
National Heart, Lung, and Blood Institute**

Patient Randomization in All CABANA Patients



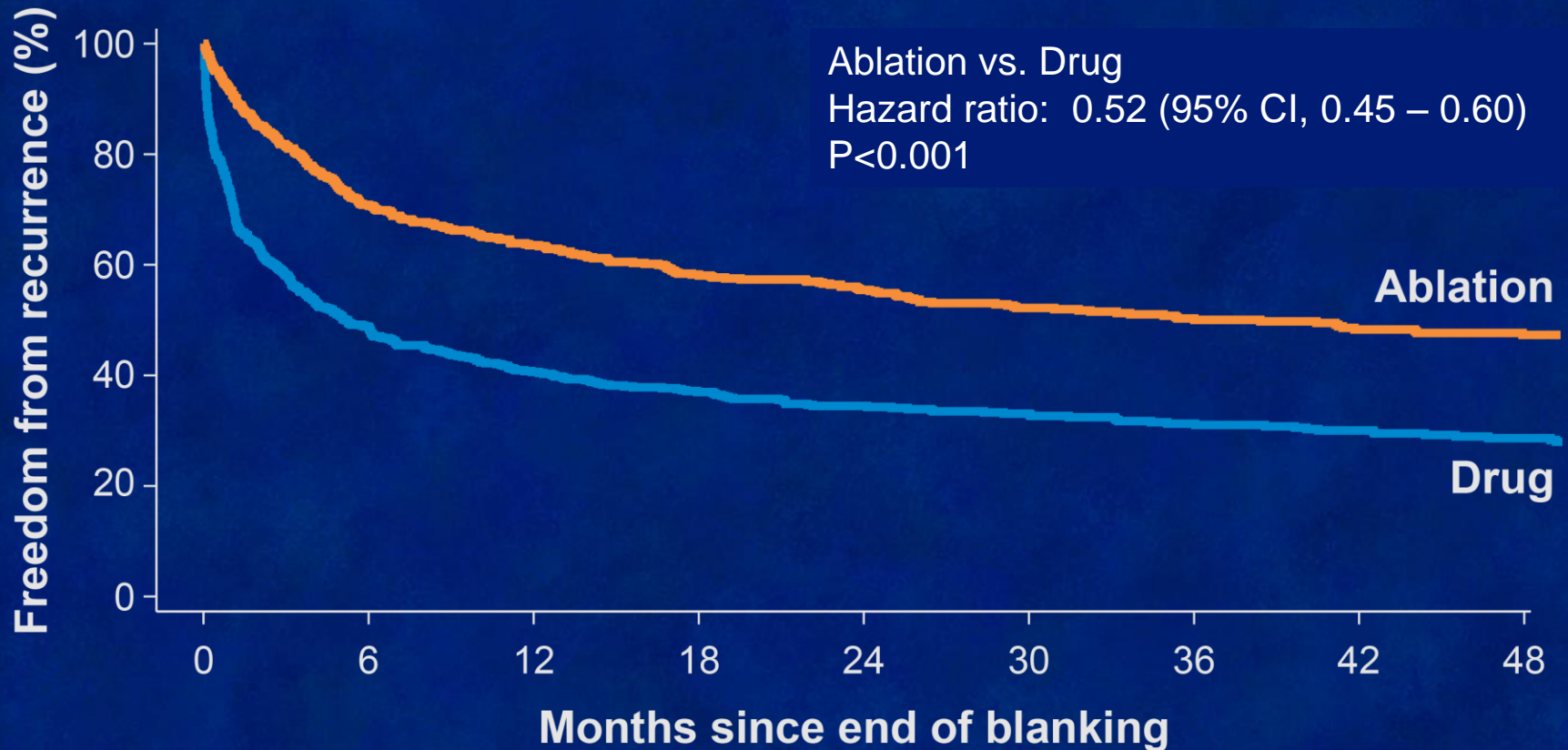
Primary Endpoint (Death, Disabling Stroke, Serious Bleeding, or Cardiac Arrest) (ITT)



Number at risk

	0	6	12	18	24	30	36	42	48	54	60
Drug	1096	1036	1006	970	880	763	652	578	499	418	312
Ablation	1108	1045	1021	996	915	793	700	614	535	432	309

First Recurrence AF – Post Blanking* (ITT)



Number at risk

Drug	629	303	251	211	180	156	130	114	93
Ablation	611	430	380	327	290	239	199	162	133

*Using CABANA Monitors

**Catheter Ablation as First Line
Therapy for AF: Is It Ready For
Prime Time?**

Heart Failure

HF Patient Demographics

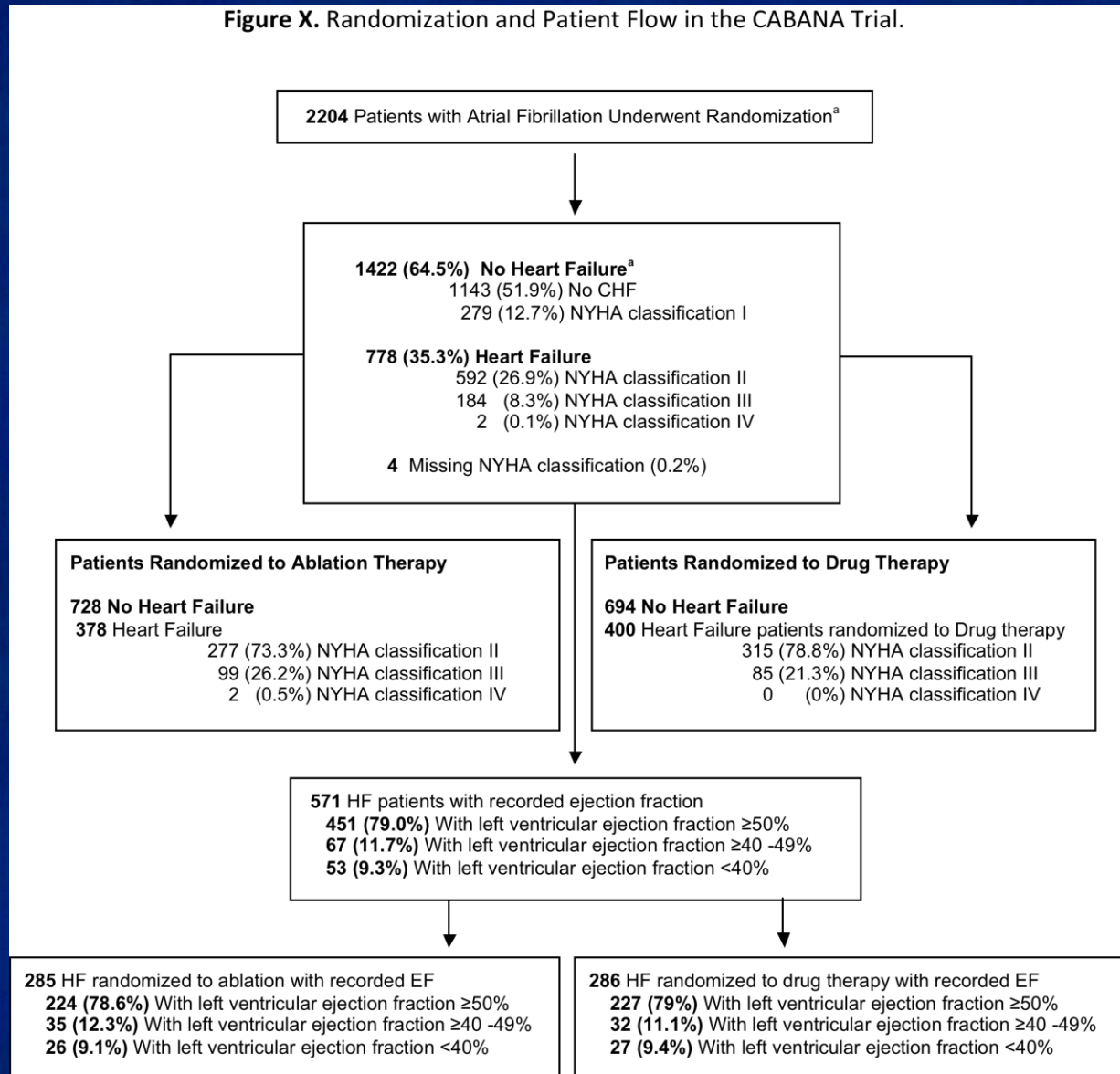
	Non-HF Subjects N=1422	HF Subjects N=778	P-Value
Age, Median (Q1, Q3)	68 (62,72)	68 (62,73)	0.185
<65 yrs	480/1422 (33.8%)	284/778 (36.5%)	
65 to <75yrs	765/1422 (53.8%)	363/778 (46.7%)	
≥ 75	177/1422 (12.4%)	131/778 (16.8%)	
Sex (Female)	472/1422 (33.2%)	345/778 (44.3%)	<.001
Minority	164/1418 (11.6%)	61/778 (7.8%)	0.006
BMI, Median (Q1, Q3)	30 (26,34)	31 (27,35)	0.002

HF Baseline Medical History

	Non-HF Subjects N=1422	HF Subjects N=778	P-Value
Prior CVA or TIA	141/1422 (9.9%)	79/778 (10.2%)	0.858
Hypertension	1110/1422 (78.1%)	665/778 (85.5%)	<.001
Diabetes	365/1422 (25.7%)	195/778 (25.1%)	0.756
CAD	254/1422 (17.9%)	170/778 (21.9%)	0.023
Sleep Apnea	354/1422 (24.9%)	154/778 (19.8%)	0.007
Congestive Heart Failure	105/1422 (7.4%)	229/777 (29.5%)	<.001
NYHA Class			<.001
0	1129/1408 (80.2%)	0/778 (0.0%)	
1	279/1408 (19.8%)	0/778 (0.0%)	
2	0/1408 (0.0%)	592/778 (76.1%)	
3	0/1408 (0.0%)	184/778 (23.7%)	
4	0/1408 (0.0%)	2/778 (0.3%)	
CHADS-VASc Score, Median (Q1, Q3)	3 (2,3)	3 (2,4)	<.001
CHADS-VASc <2	288/1422 (20.3%)	105/778 (13.5%)	
CHADS-VASc ≥ 2	1134/1422 (79.7%)	673/778 (86.5%)	

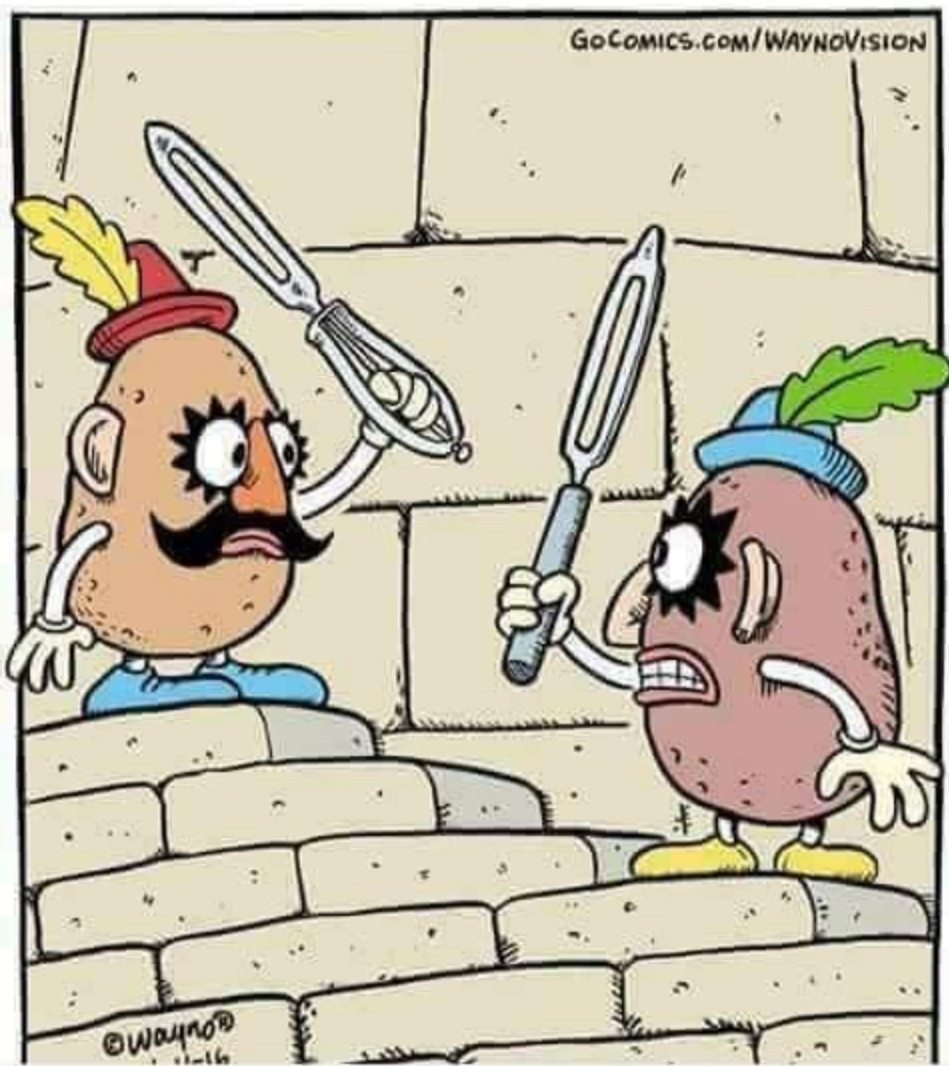
Consort Diagram For HF Type

Figure X. Randomization and Patient Flow in the CABANA Trial.

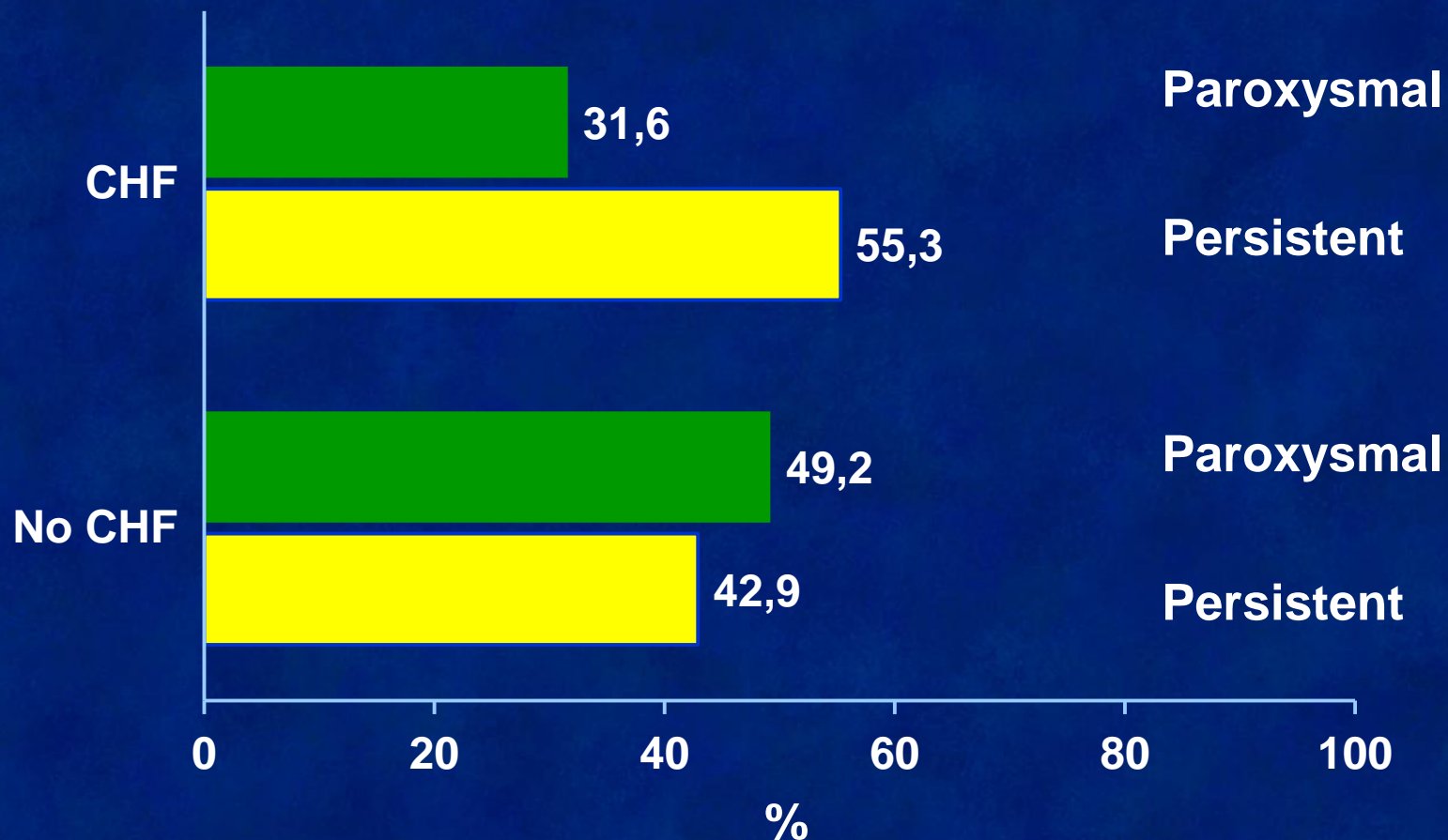


Heart failure is defined as baseline NYHA class

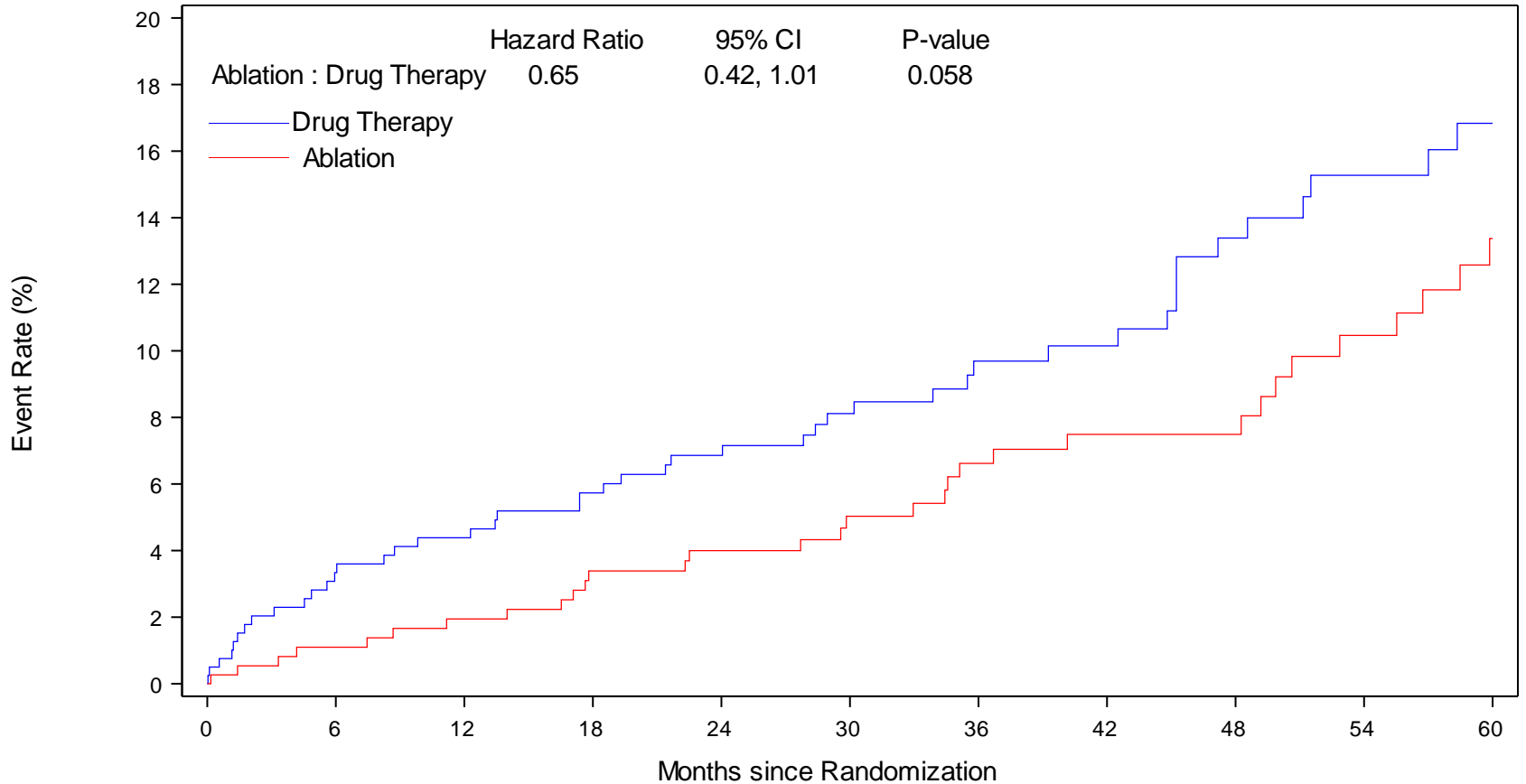
My name is Idaho Montoya. You peeled my father. Prepare to fry.



AF Type at Enrollment in CABANA:HF

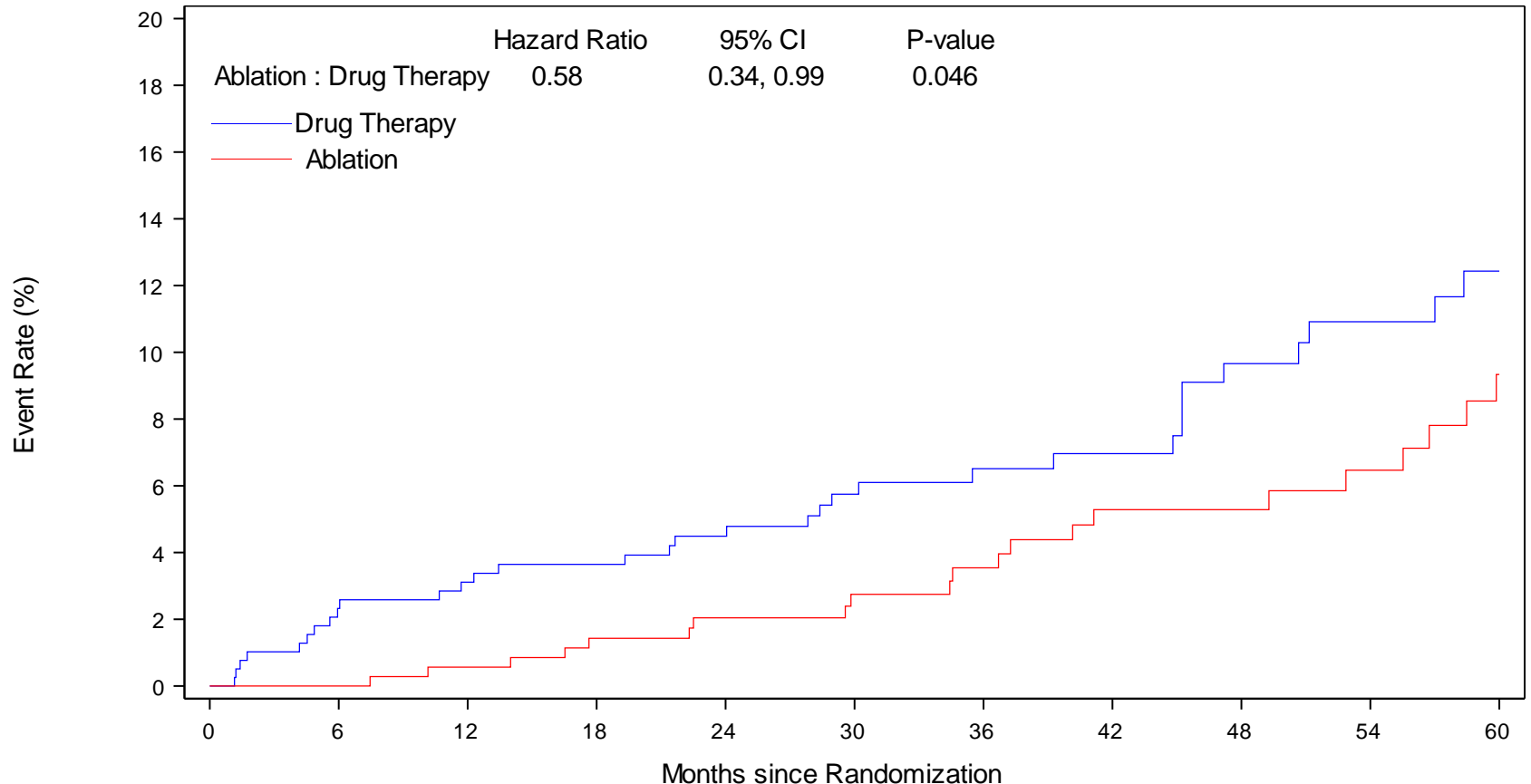


All-Cause Mortality, Disabling Stroke, Serious Bleeding, or Cardiac Arrest (ITT): In HF Patients



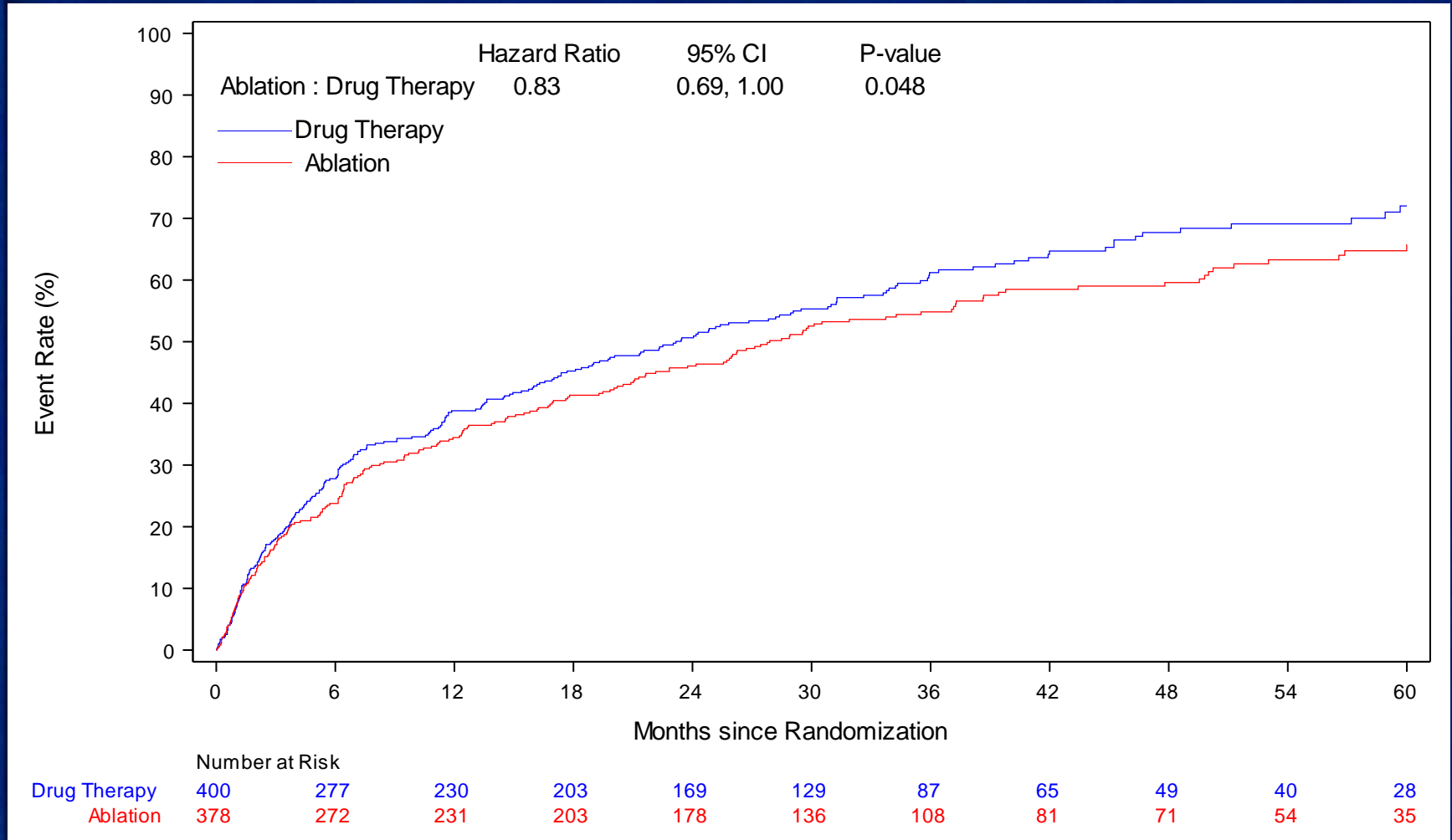
	Number at Risk										
	0	6	12	18	24	30	36	42	48	54	60
Drug Therapy	400	371	359	345	317	264	210	179	149	121	97
Ablation	378	353	344	332	311	265	228	193	171	137	108

Risk of All-Cause Mortality (ITT): In HF Patients

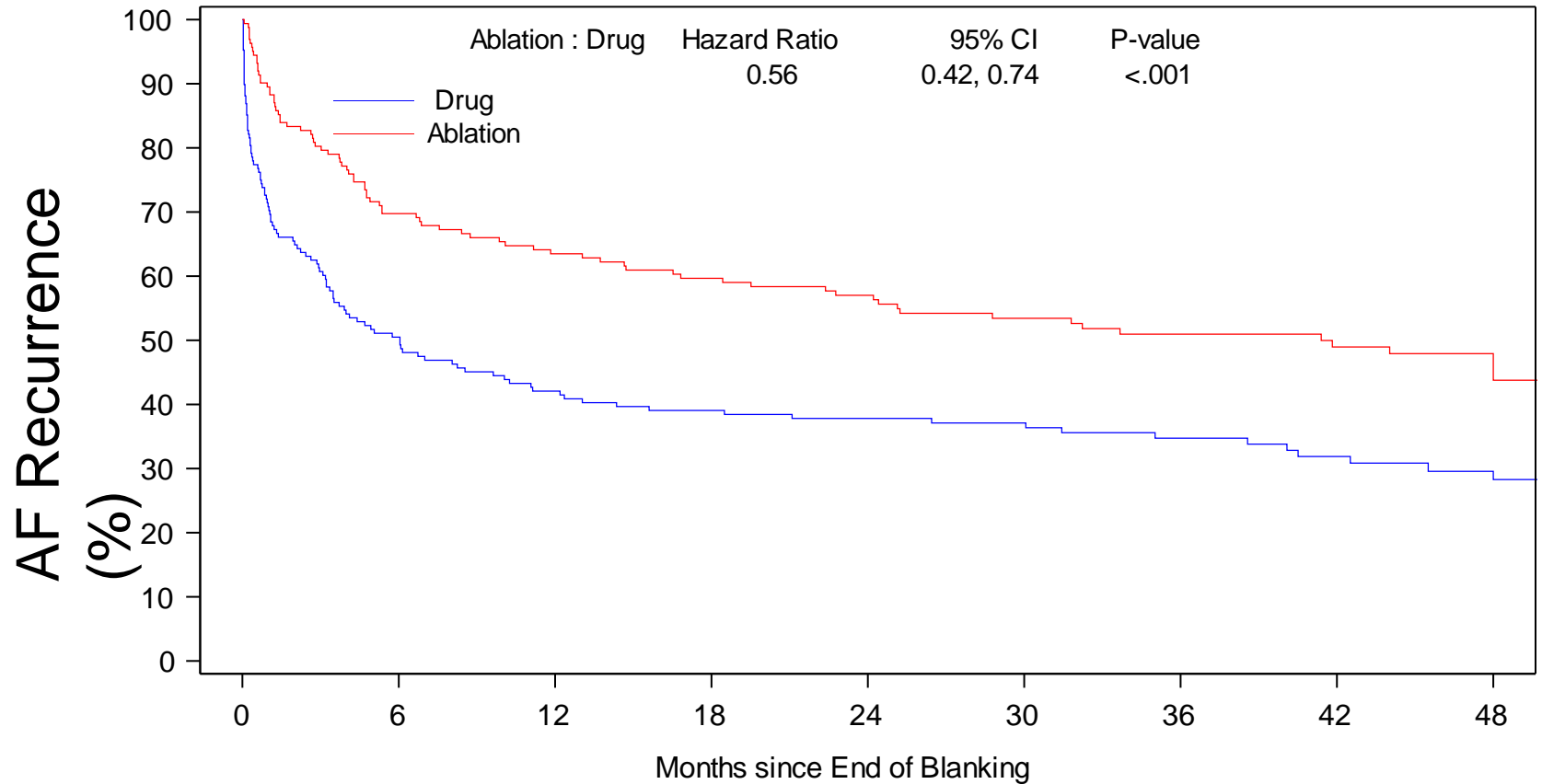


	Number at Risk										
	0	6	12	18	24	30	36	42	48	54	60
Drug Therapy	400	375	365	355	326	271	219	188	157	130	106
Ablation	378	359	349	339	316	272	237	200	177	146	113

Risk of Mortality and CV Hospitalization (ITT): In HF Patients

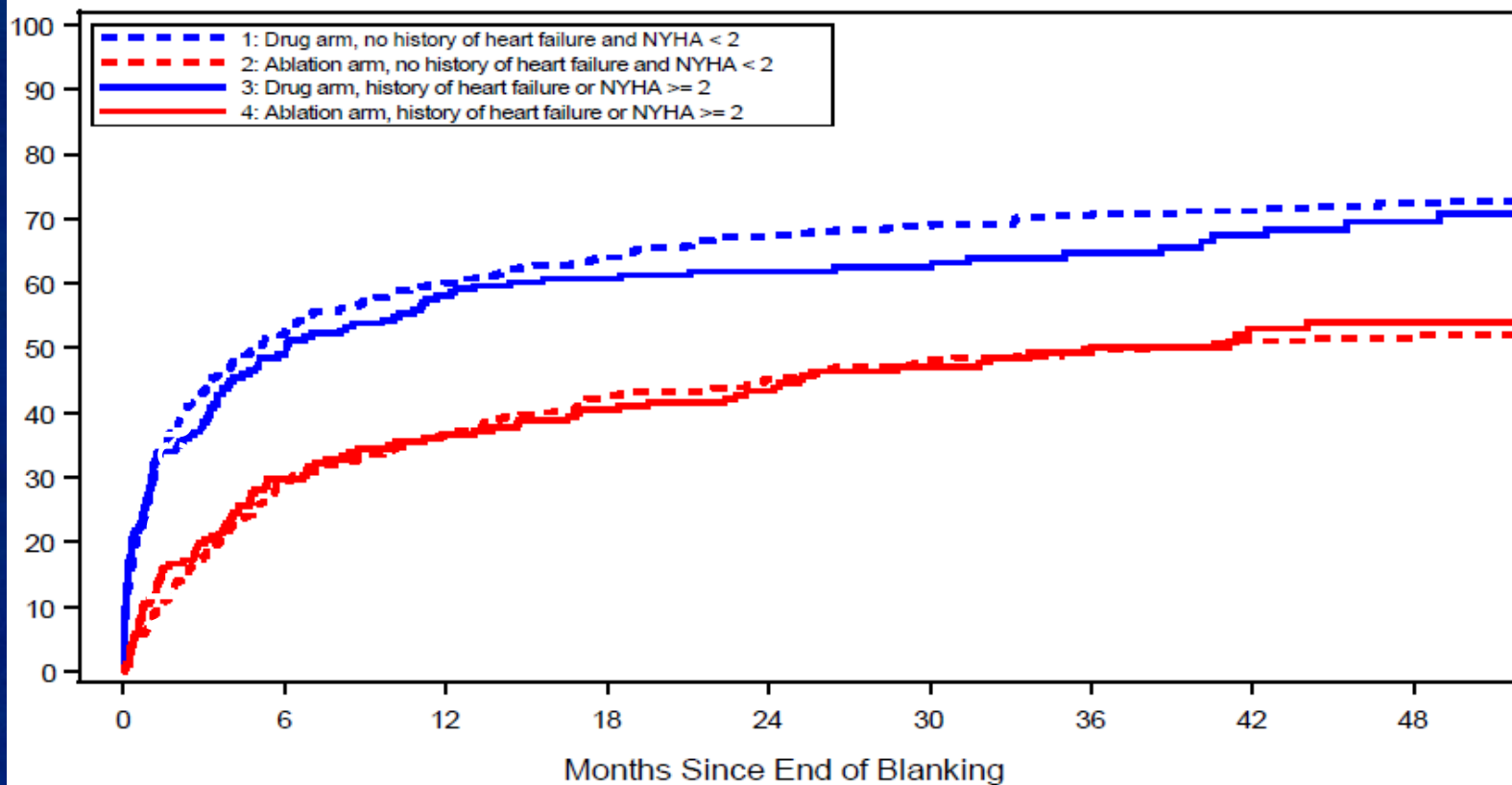


Cumulative Risk of AF Recurrence In HF Patients (ITT)



	Number at Risk								
	0	6	12	18	24	30	36	42	48
Drug Therapy	168	83	68	60	54	47	37	29	21
Ablation	162	113	101	92	83	66	55	44	38

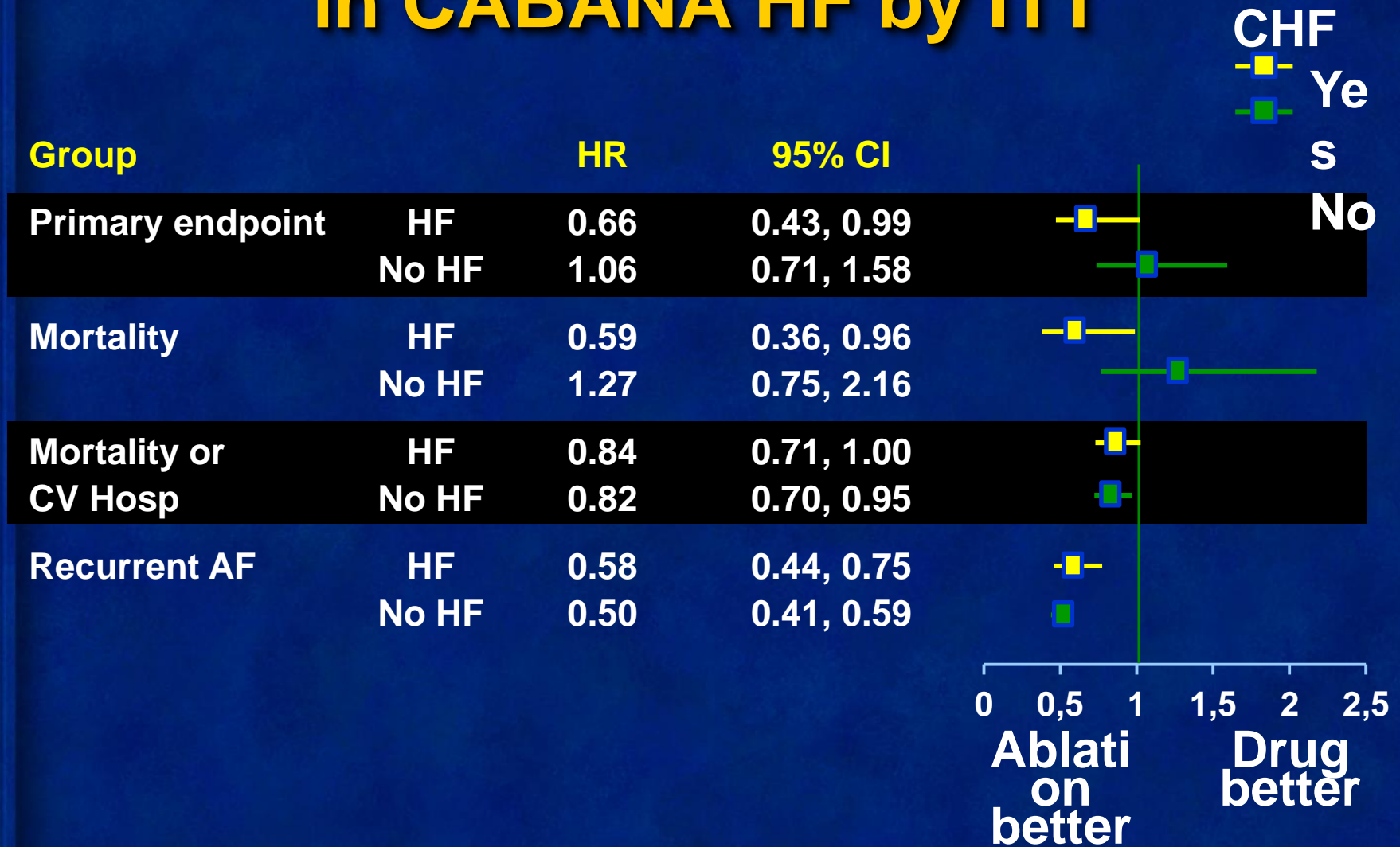
KM Estimates of Cumulative Risk of AF Recurrence In HF Patients (ITT)



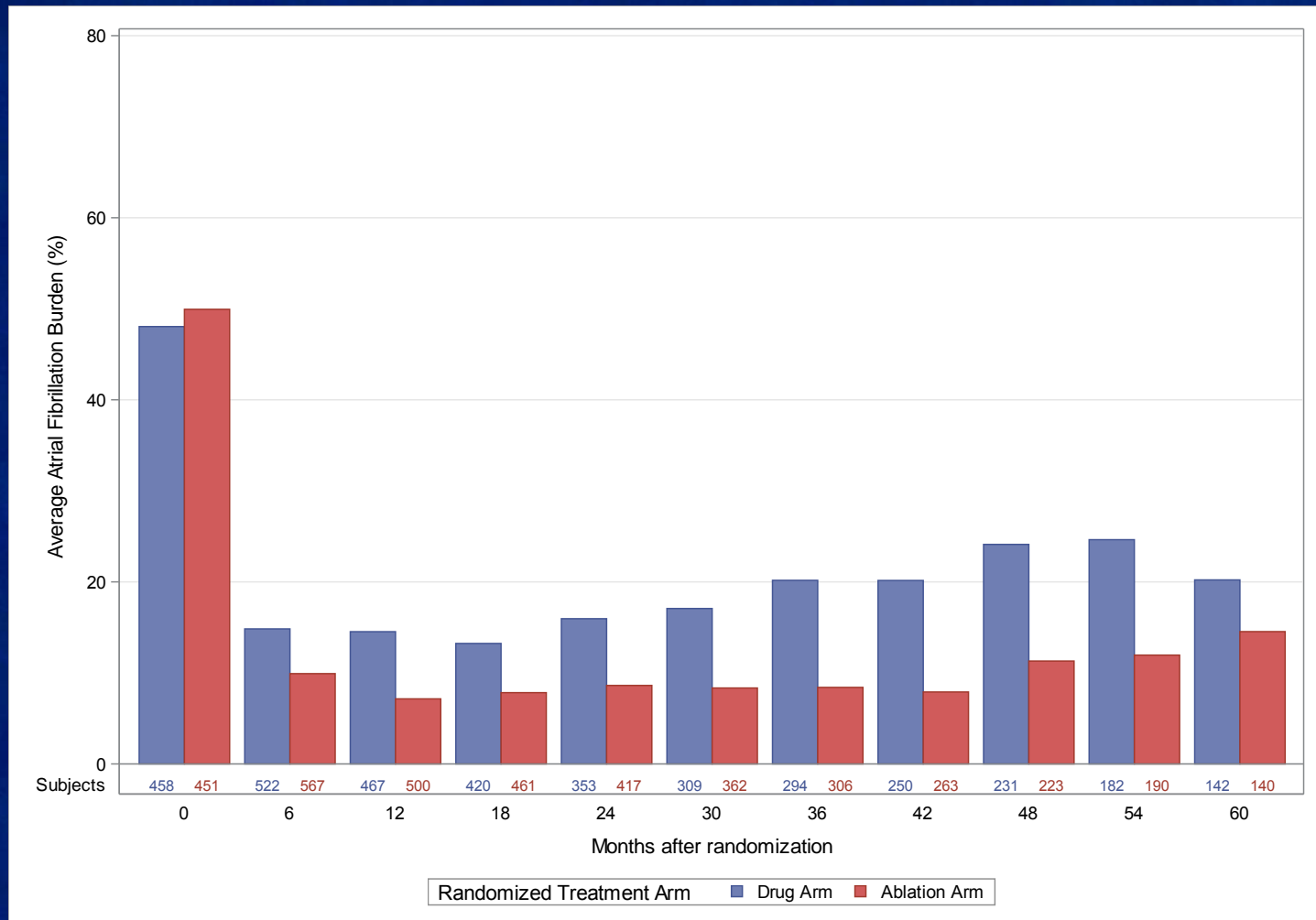
Number at risk:

1	432	206	172	141	118	102	88	79	66
2	419	296	262	221	195	162	136	114	92
3	197	97	79	70	62	54	42	35	27
4	192	134	118	106	95	77	63	48	41

Clinical Outcomes in CABANA HF by ITT



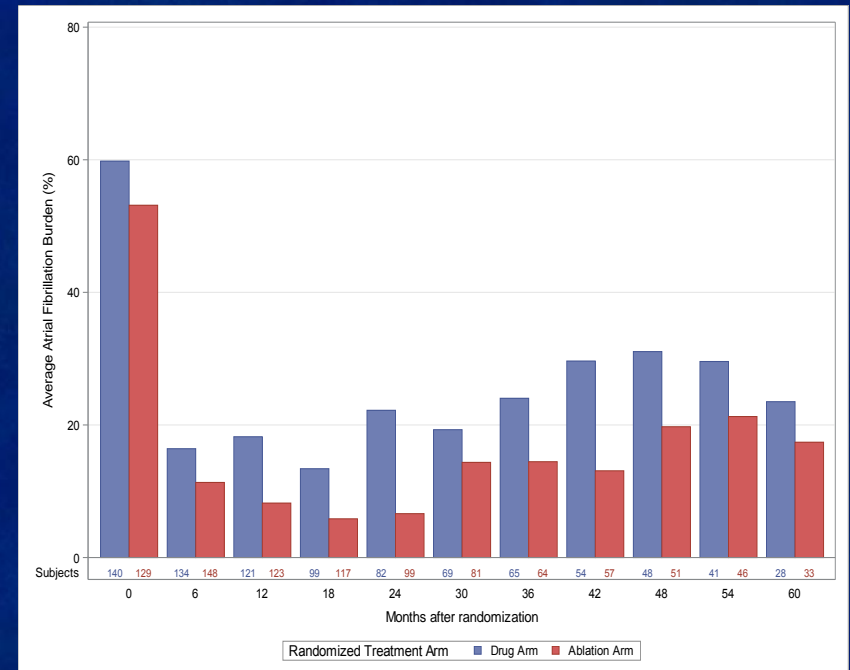
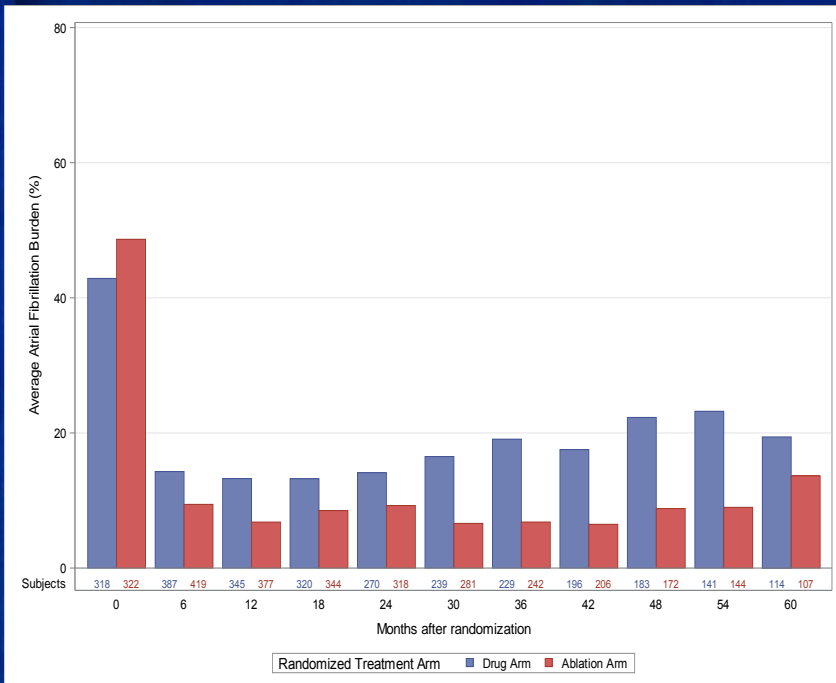
AF Burden by Time and Randomization in All CABANA pts



AF Burden by Time and Randomization in CABANA Patients

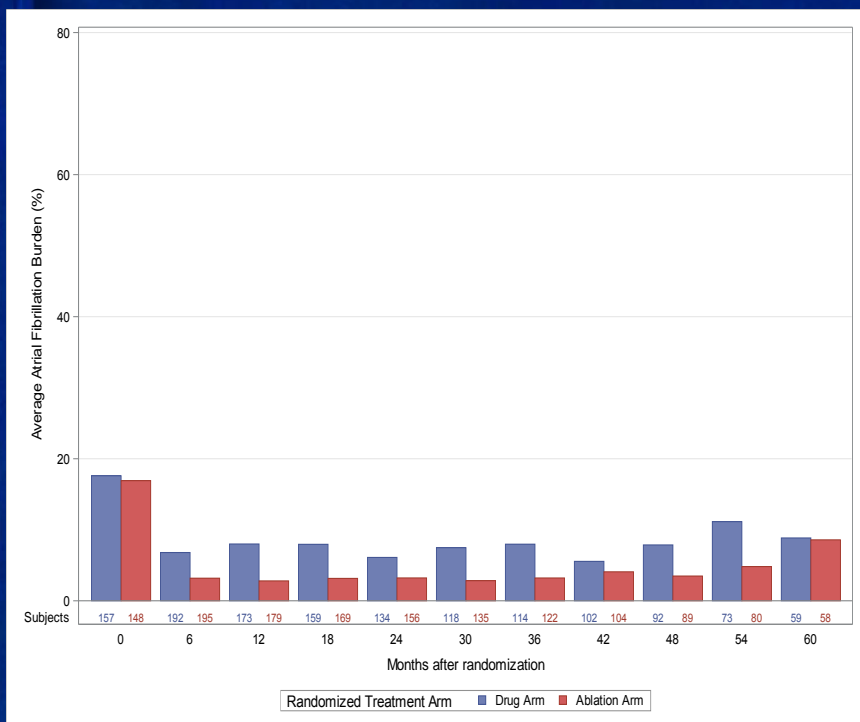
No HF

HF

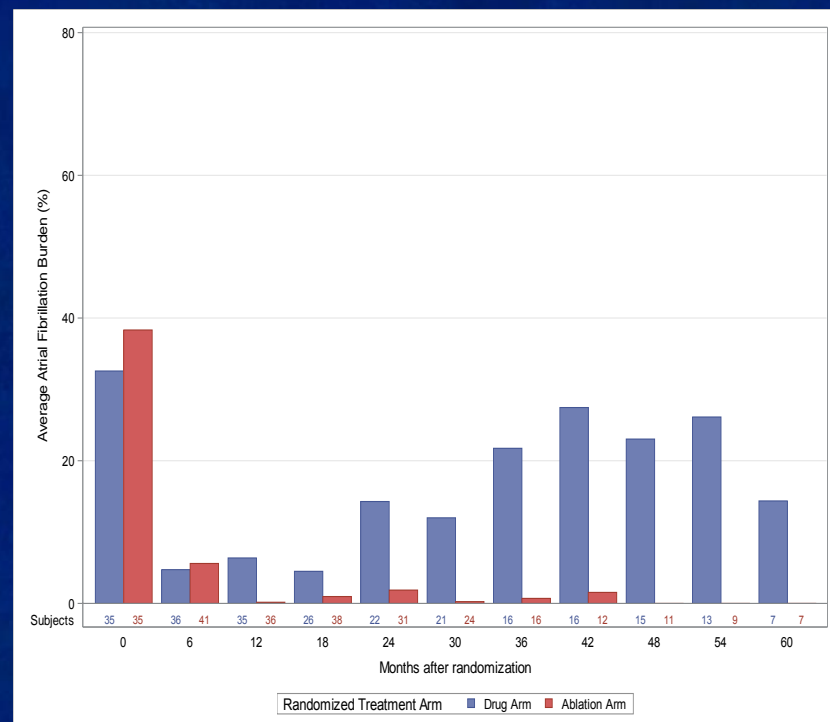


AF Burden by Time and Randomization in Paroxysm AF in CABANA

No HF



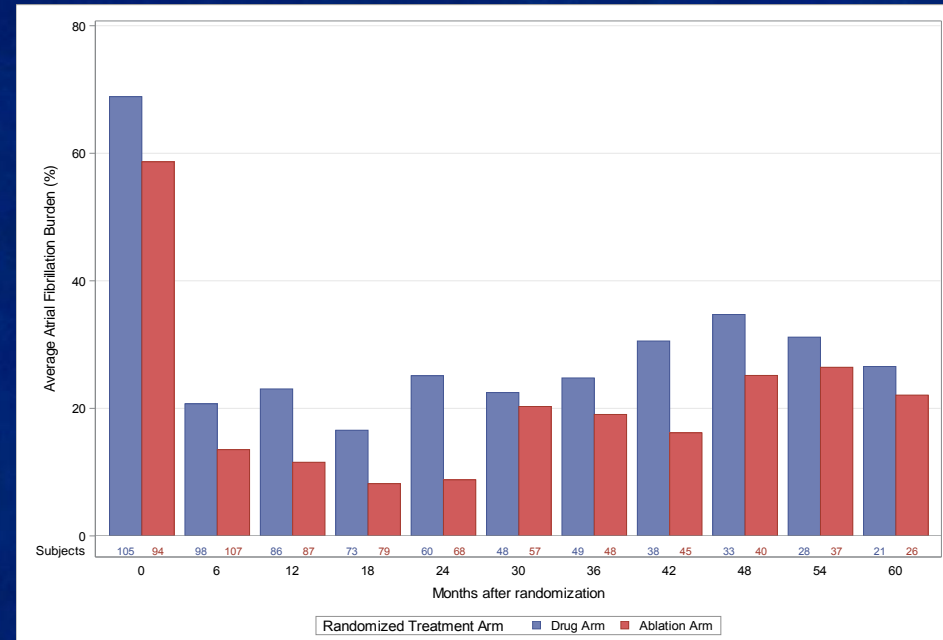
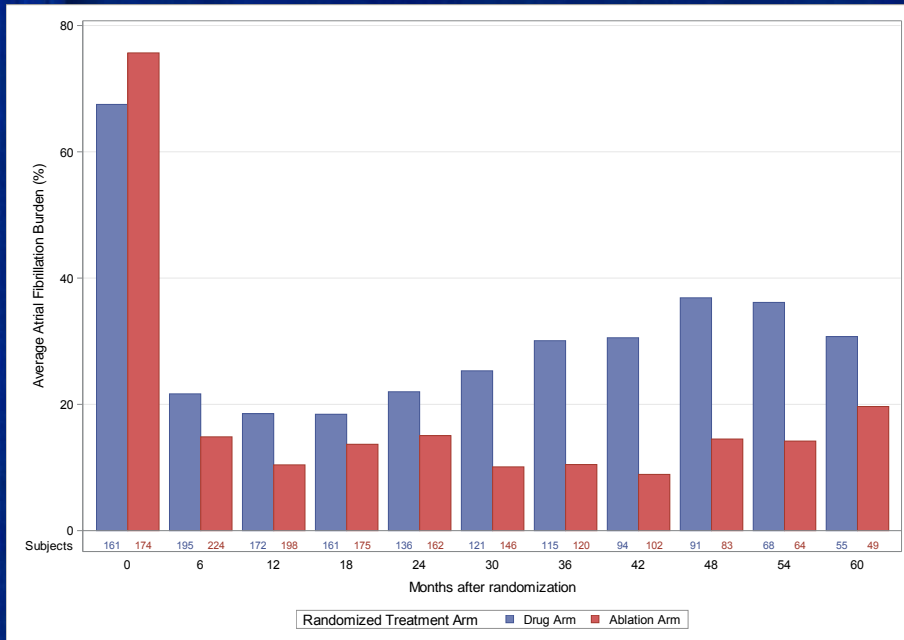
HF



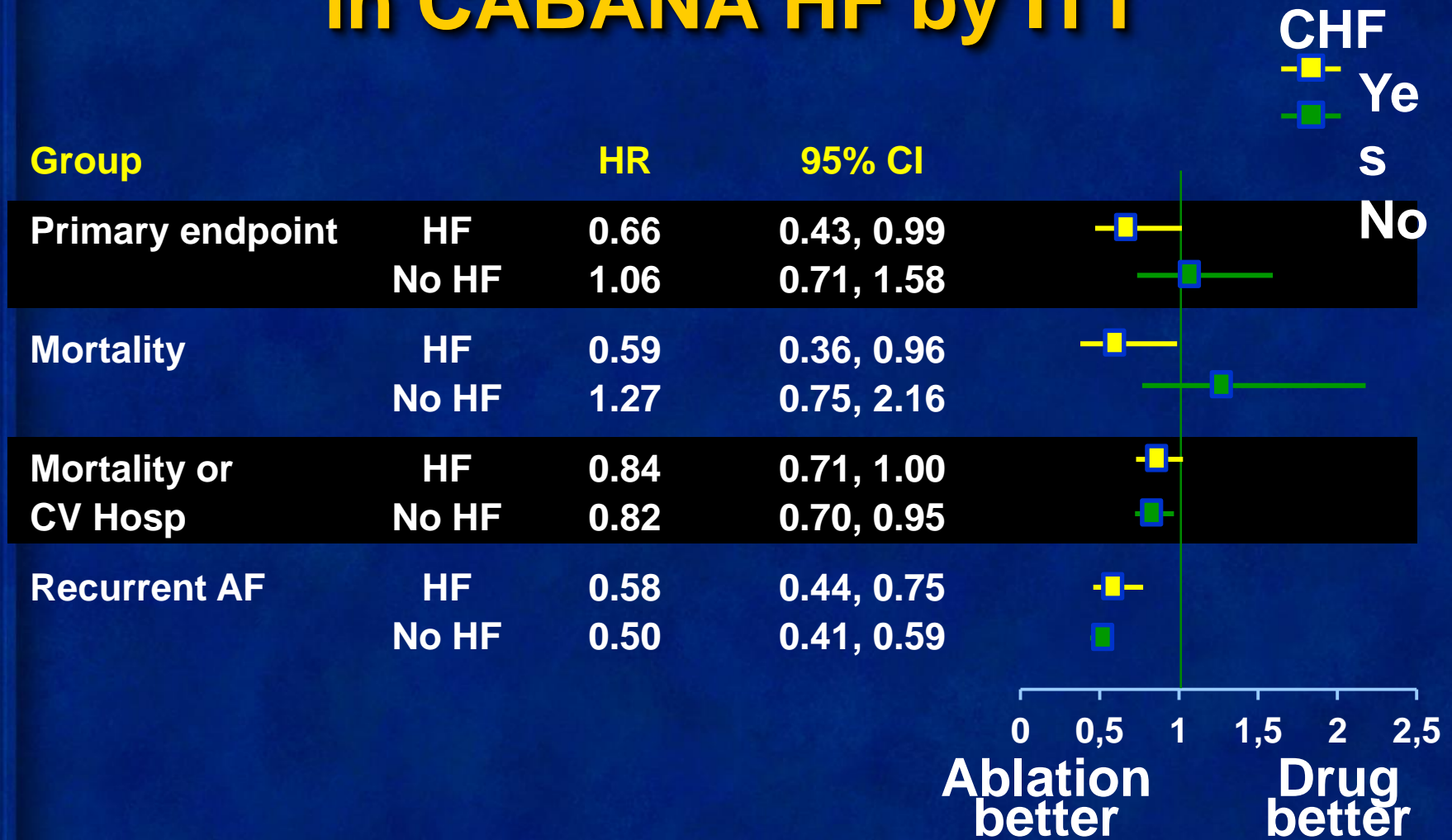
AF Burden by Time and Randomization in Persistent/LSP AF HF Subjects

No HF

HF



Clinical Outcomes in CABANA HF by ITT



Adverse Events in CABANA

	Ablation n = 1006
Event	n (%)*
Catheter Insertion	39 (3.9)
Hematoma	23 (2.3)
Pseudo aneurysm	11 (1.1)
Atrial venous fistula	4 (0.4)
Pneumothorax	1 (0.1)
Sepsis	1 (0.1)
DVT	0
Pulmonary embolus	0
Catheter Manipulation Within the Heart	34 (3.4)
Pericardial effusion not requiring intervention	22 (2.2)
Cardiac tamponade with perforation	8 (0.8)
TIA	3 (0.3)
Coronary occlusion	0
Myocardial infarction	1 (0.1)
Complete heart block	0
Valvular damage	0
Ablation-related Events	18 (1.8)
Severe pericardial chest pain	11 (1.1)
Esophageal ulcer	5 (0.5)
Pulmonary Vein Stenosis > 75%	1 (0.1)
Phrenic nerve injury	1 (0.1)
Atrial esophageal fistula	0
Medication-related Events	0
Heparin induced bleeding	0

	Pts Receiving Drug n = 1092
Event	n (%)*
Hyper- or hypothyroidism	17 (1.6)
Hypotension	3 (0.3)
Major proarrhythmic event (VT,VF)	9 (0.8)
Torsades des pointes	0
Atrial proarrhythmic event	1 (0.1)
Heart failure	0
Allergic reaction	7 (0.6)
Gastrointestinal abnormality	3 (0.3)
Moderate or severe diarrhea	0
Liver injury/failure	3 (0.3)
Pulmonary toxicity	1 (0.1)
Blindness	0
Kidney damage	0
Renal failure	0
Severe headache	0

* n (%) = number (percent) of patients who reported drug-related adverse event.
Percent is calculated among all patients that have received drug.

Changing Times and Approaches

1998:

"Don't get in a car with strangers"

2008:

"Don't meet people from the internet alone."

2018:

UBER...
Order yourself a stranger from the internet to get into a car with alone.



The Latest AF Ablation Trials

Conclusions

What Does or Doesn't CABANA Say About Ablation?

Confirms prior observational and RTC studies	★★★★★
Is an effective way of eliminating AF	★★★★★
Ablation is acceptably safe	★★★★
Reduces mortality or CV hospitalization	★★★
Is effective in persistent AF	★★★★
Is highly effective as first-line Rx	★★★★★
Ablation is no different than drug Rx for reducing mortality, disabling stroke, bleeding, or CA by ITT	★ ★
Ablation is no different than anti-arrhythmic Rx for reducing mortality by ITT	★ ★
Ablation may reduce mortality by TR or PP, particularly in CHF	★★★★

Recommendations for Catheter Ablation

Recommendations	Class ^a	Level ^b	Ref ^c	After CABANA
Catheter ablation of symptomatic paroxysmal AF is recommended to improve AF symptoms in patients who have symptomatic recurrences of AF on antiarrhythmic drug therapy (amiodarone, dronedarone, flecainide, propafenone, sotalol) and who prefer further rhythm control therapy, when performed by an electrophysiologist who has received appropriate training and is performing the procedure in an experienced centre.	I	A	585-587, 713,727	+ Pers.
Ablation of common atrial flutter should be considered to prevent recurrent flutter as part of an AF ablation procedure if documented or occurring during the AF ablation.	IIa	B	827	
Catheter ablation of AF should be considered as first-line therapy to prevent recurrent AF and to improve symptoms in selected patients with symptomatic paroxysmal AF as an alternative to antiarrhythmic drug therapy, considering patient choice, benefit, and risk.	IIa	B	585	I A
All patients should receive oral anticoagulation for at least 8 weeks after catheter (IIaB) or surgical (IIaC) ablation.	IIa	B C	727	
Anticoagulation for stroke prevention should be continued indefinitely after apparently successful catheter or surgical ablation of AF in patients at high-risk of stroke.	IIa	C		
When catheter ablation of AF is planned, continuation of oral anticoagulation with a VKA (IIaB) or NOAC (IIaC) should be considered during the procedure, maintaining effective anticoagulation.	IIa	B C	760,768	
Catheter ablation should target isolation of the pulmonary veins using radiofrequency ablation or cryotherapy balloon catheters.	IIa	B	585,715, 716,734, 735	
AF ablation should be considered in symptomatic patients with AF and heart failure with reduced ejection fraction to improve symptoms and cardiac function when tachycardiomyopathy is suspected.	IIa	C	185, 226-228, 720, 777-779, 828	II A- I B
AF ablation should be considered as a strategy to avoid pacemaker implantation in patients with AF-related bradycardia.	IIa	C	829,830	
Catheter or surgical ablation should be considered in patients with symptomatic persistent or long-standing persistent AF refractory to AAD therapy to improve symptoms, considering patient choice, benefit and risk, supported by an AF Heart Team.	IIa	C	468,735, 777,831, 832,1040	