Ablace FS a mortalita – kritická analýza studie CABANA

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CABANA design

Nově zachycená nebo nedostatečně léčená FS jakéhokoli typu
&
alespoň jeden faktor CHA_2DS_2

- Srdeční selhání
- Hypertenze s HLK
- Věk >65 let
- Diabetes
- CMP /TIA
- LAd >50mm nebo LAVi >40 ml/m^2

RANDOMIZACE **1:1**

Ablace: PVI (+ ???)

Léky: kontrola rytmu nebo frekvence

POROVNÁNÍ	• Klinické endpointy včetně komplikací léčby • Výskyt arytmií • Symptomy • Kvalita života

Packer DL et al.
American Heart Journal 2018; 199: 192-9

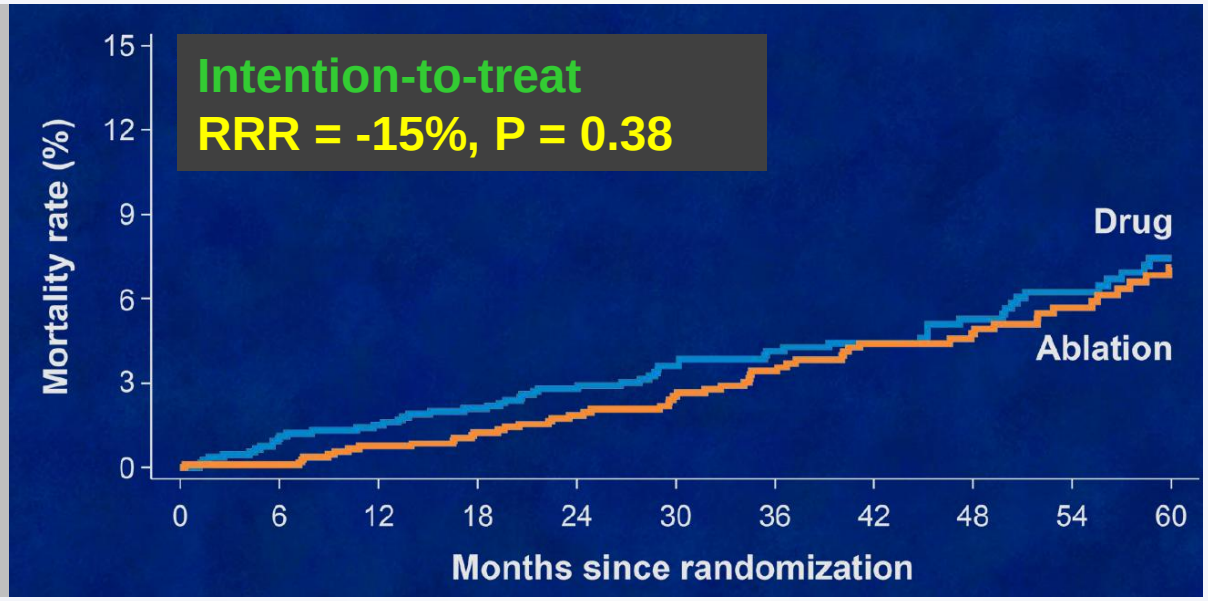
CABANA – major endpoints

All-cause death

Primary endpoint

↓

Secondary endpoint



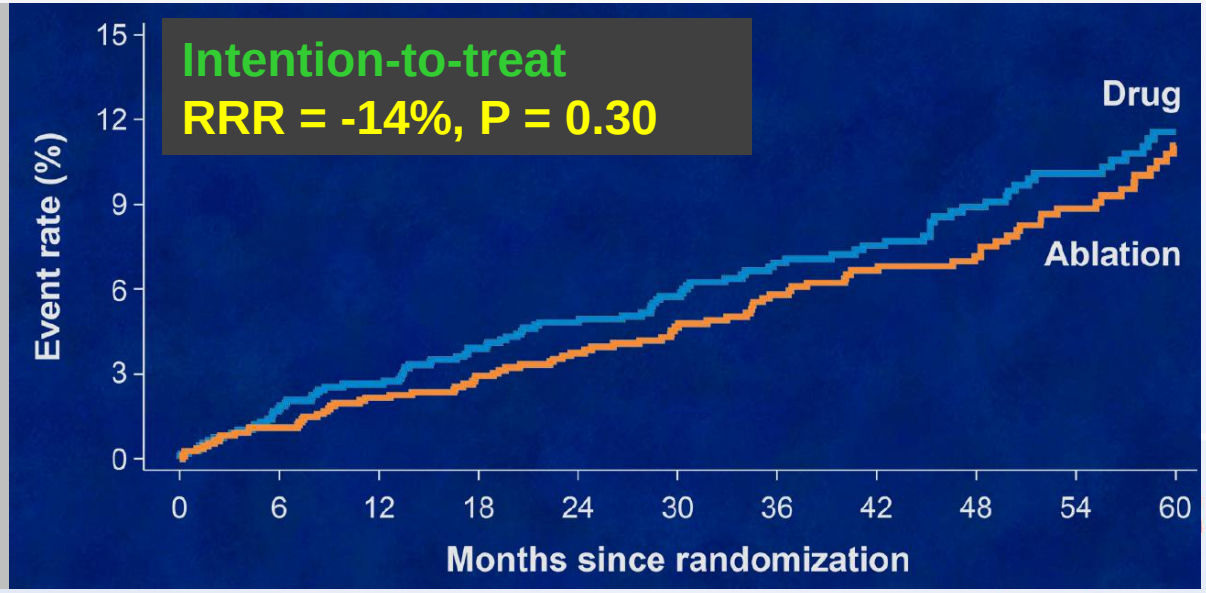
Composite endpoint

- **death**
- **disabling stroke**
- **serious bleeding**
- **cardiac arrest**

Primary endpoint

↑

Secondary endpoint



CABANA – primary composite endpoint (ITT)

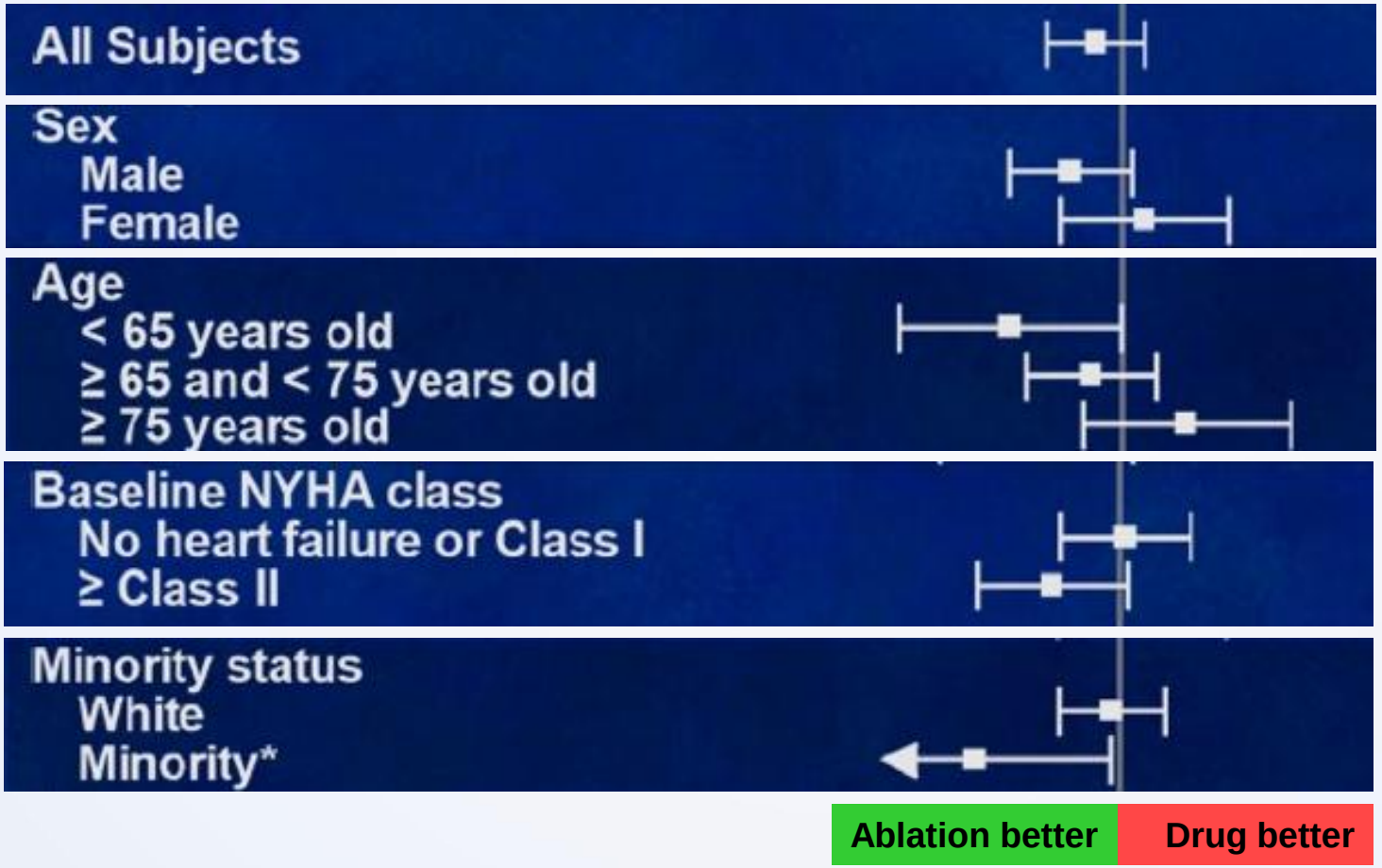
Primary Outcome	Ablation N = 1108	Drug N = 1096	Hazard Ratio (95% CI)	P-Value
Composite:	89 (8.0%)	101 (9.2%)	0.86 (0.65, 1.15)	0.30
Death	58 (5.2%)	67 (6.1%)	0.85 (0.60, 1.21)	0.38
Disabling stroke	3 (0.3%)	7 (0.6%)	0.42 (0.11, 1.62)	0.19
Serious bleeding	36 (3.2%)	36 (3.3%)	0.98 (0.62, 1.56)	0.93
Cardiac arrest	7 (0.6%	11 (1.0%)	0.62 (0.24, 1.61)	0.33

Pokles rizika u pacientů v ablační větvi			
	Absolutní pokles	Relativní pokles	P
COMPOSITE	-1.2%	-14%	0.38
Death	-0.9%	-15%	0.38
Disabling stroke	-0.4%	-58%	0.19
Serious bleeding	0.0%	-2%	0.93
Cardiac arrest	-0.4%	-38%	0.33

Packer DL et al.
HRS Congress, 9-12 May 2018

CABANA – primary composite endpoint (ITT)

Podskupinové analýzy

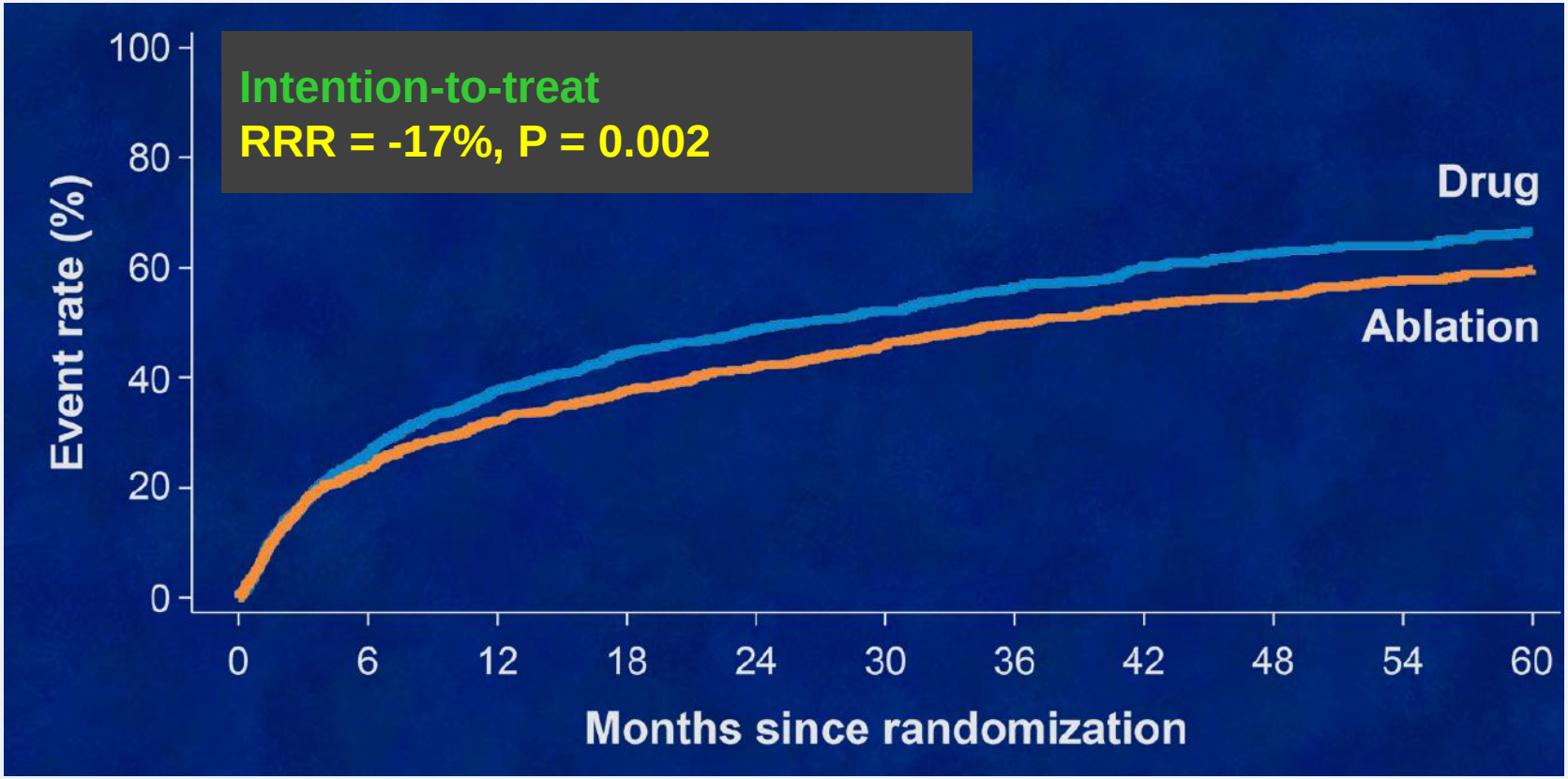


ALE !!

Packer DL et al.
HRS Congress, 9-12 May 2018

CABANA – „minor“ secondary endpoint (ITT)

All-cause mortality + cardiovascular hospitalization



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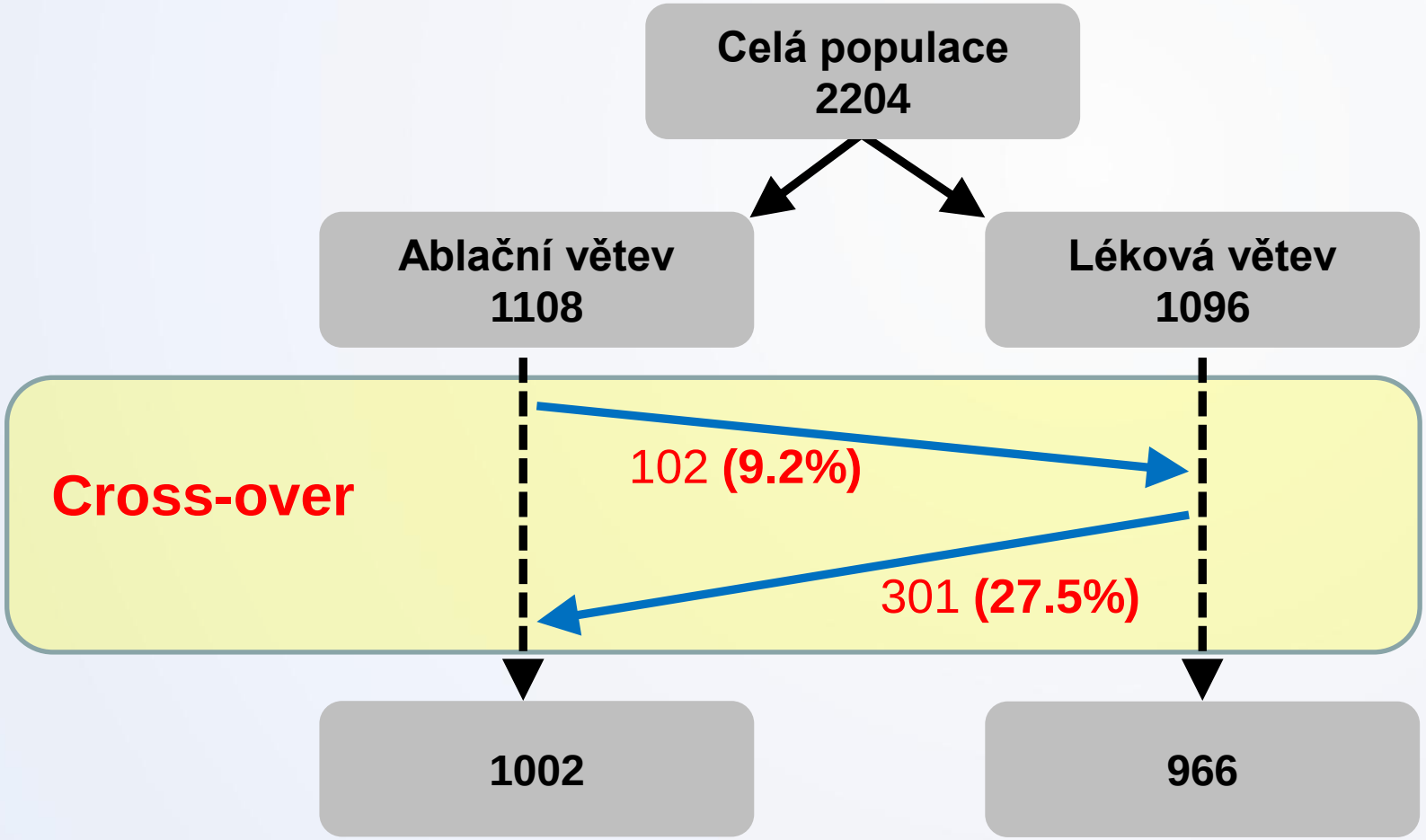
CABANA – flowchart



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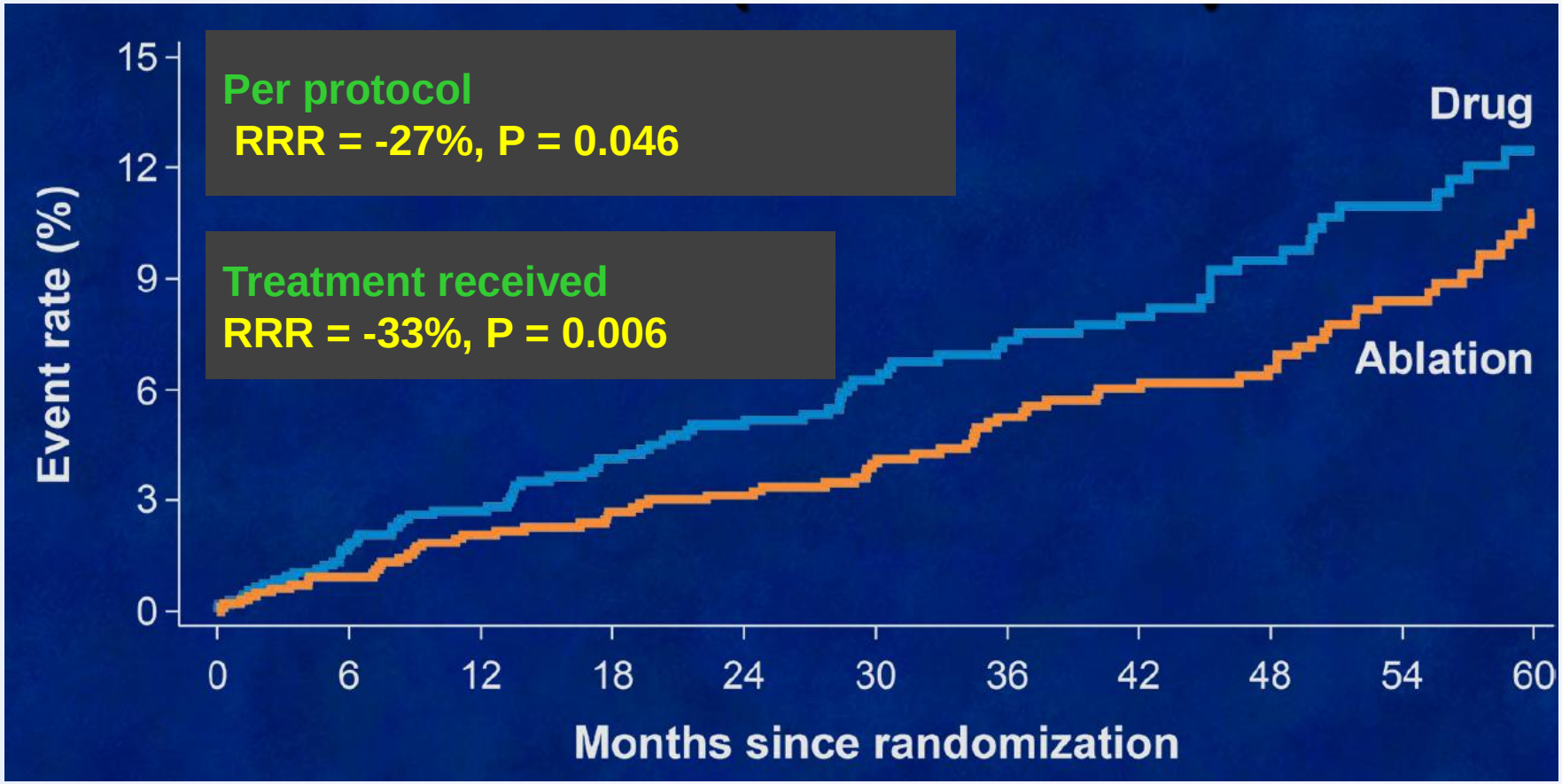
CABANA – exploratory analyses

Primary composite endpoint



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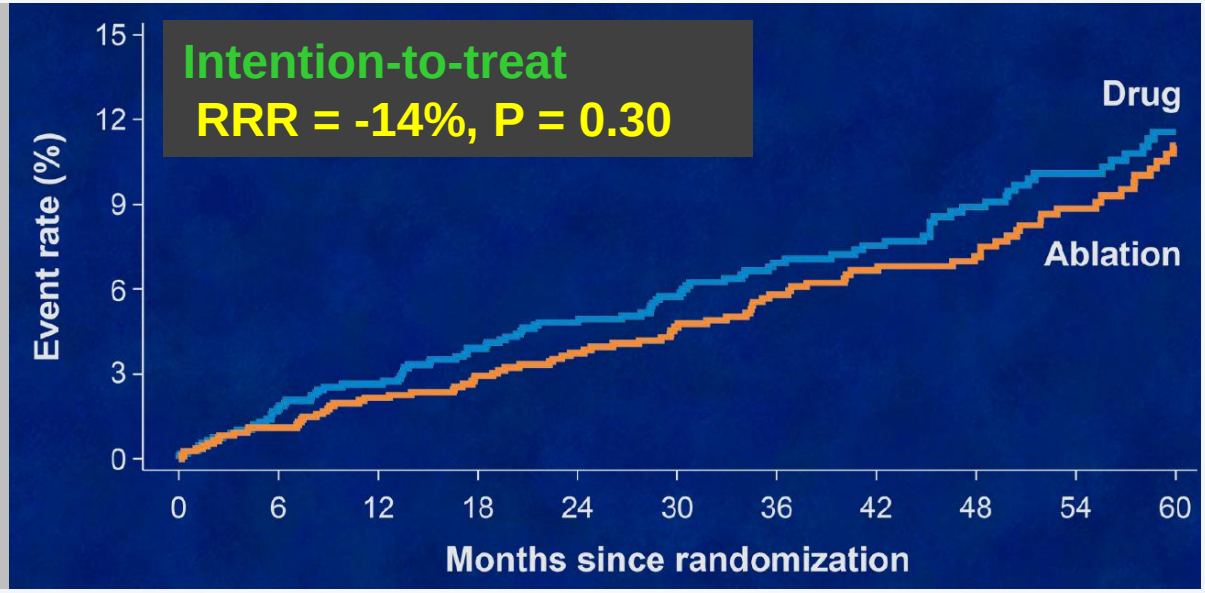
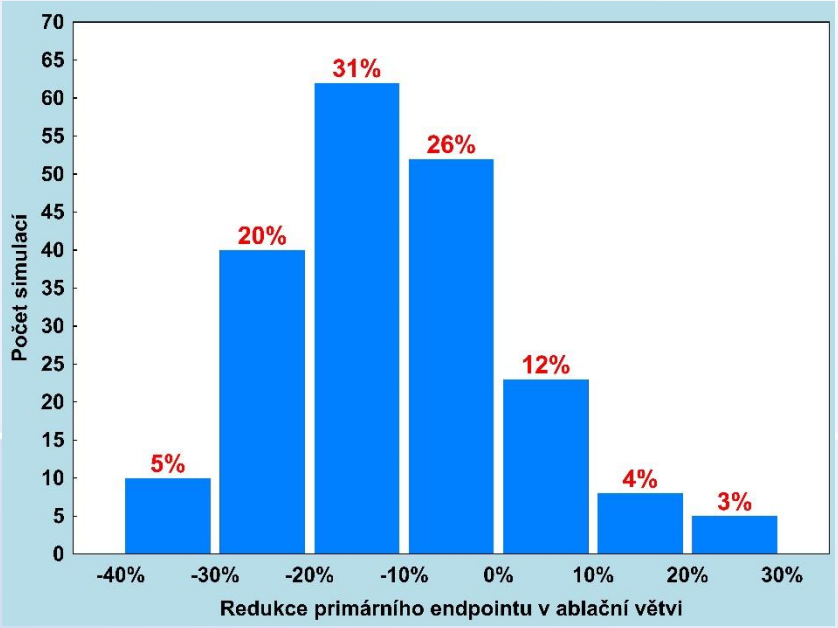
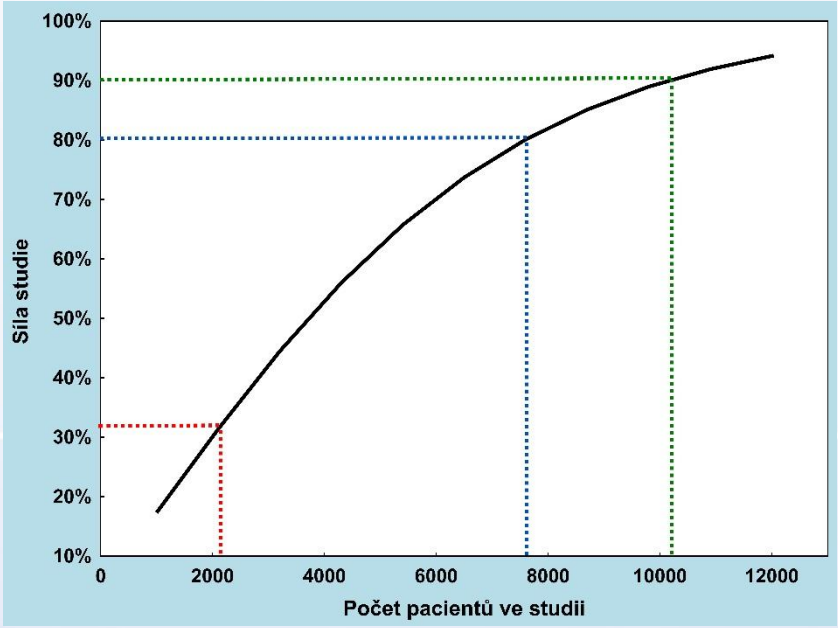
CABANA – simulace

Primary Composite Endpoint

- death
- disabling stroke
- serious bleeding
- cardiac arrest





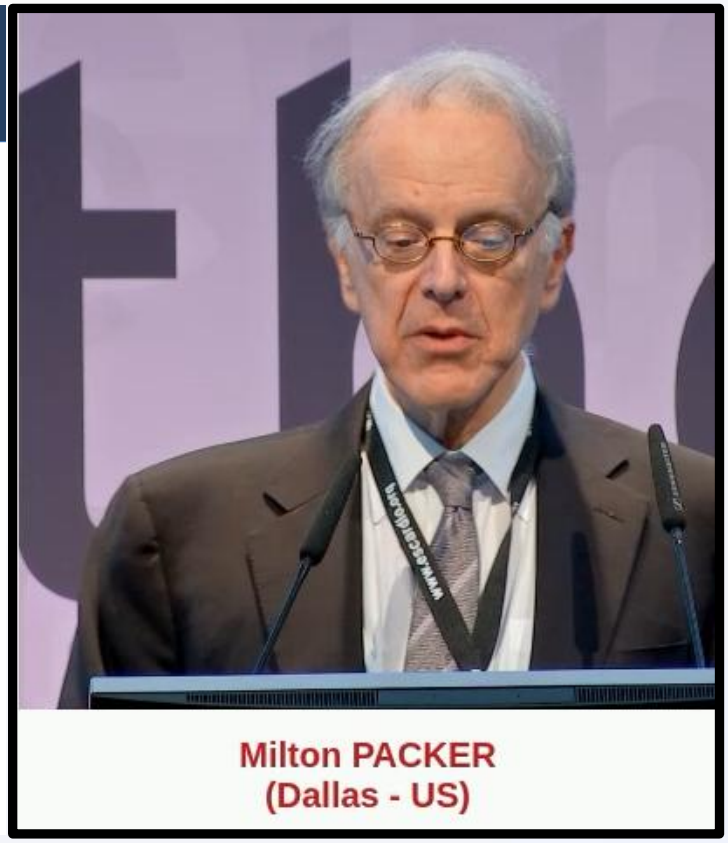


What CABANA does not tell us

A critical appraisal

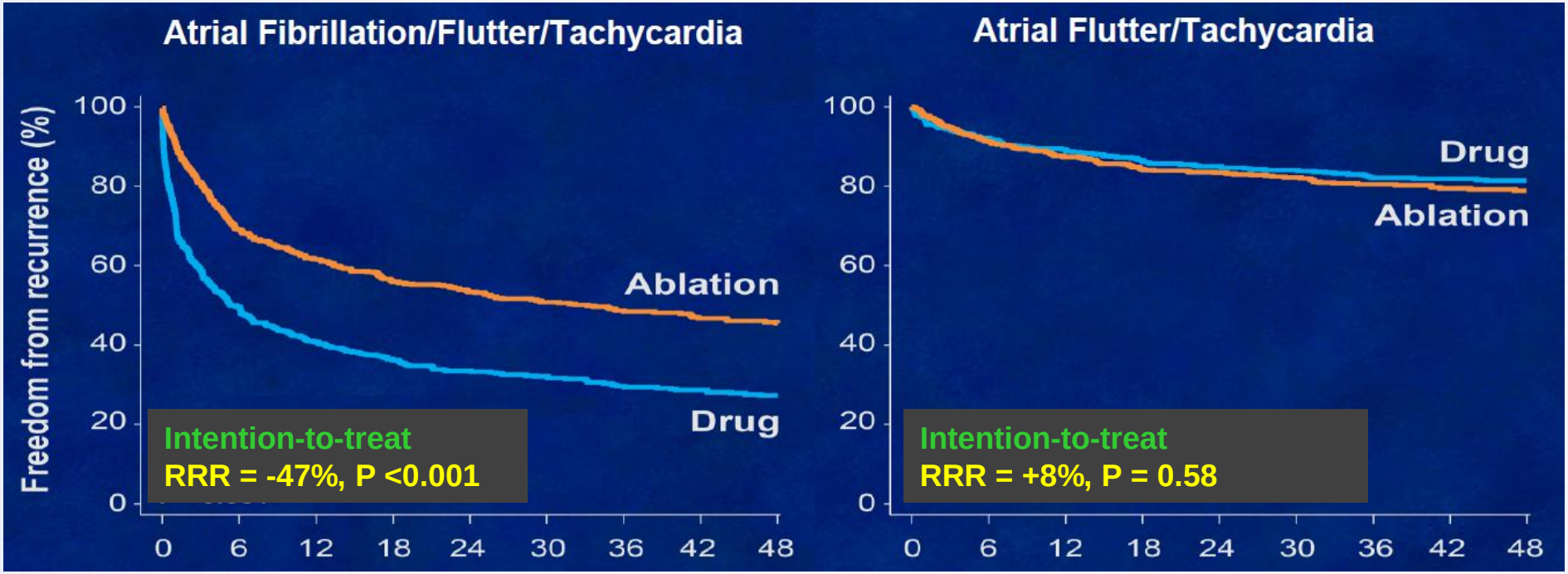
Conclusions of the CABANA Trial

- The CABANA trial is an important study that yielded a clear result, i.e. ablation does ***not*** prevent the serious consequences of atrial fibrillation.
- If CABANA were a trial of a new drug, we would reject the on-treatment analyses due to their bias.
- Since ablation is expensive, carries risks and is available to very few, evaluation of its efficacy should ***not*** be held to a lower standard of evidence than evaluation of the efficacy of drugs.



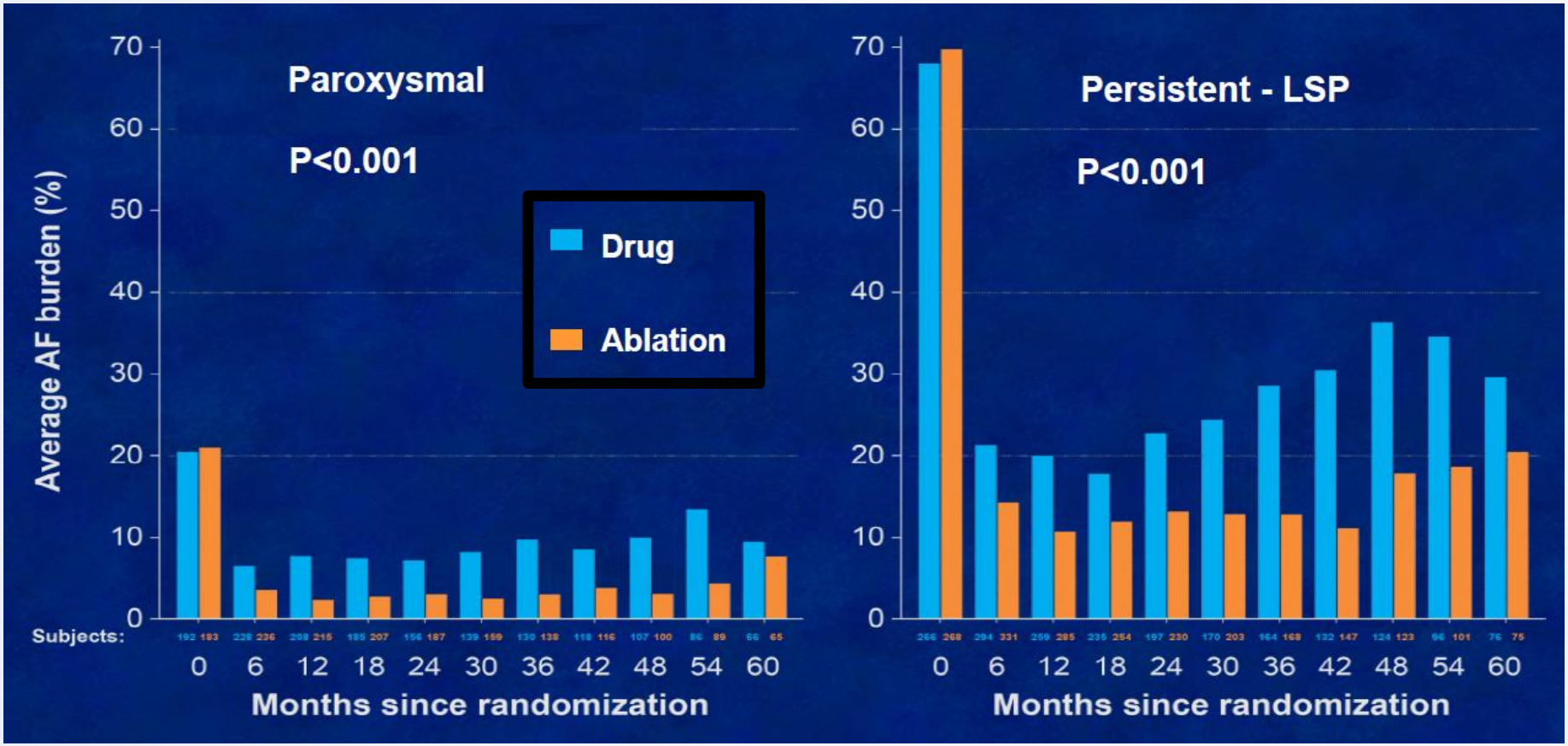
Milton PACKER
(Dallas - US)

CABANA – Rhythm Outcome (ITT)



Poole JE et al.
ESC Congress, 25-29 August 2018

CABANA – Rhythm Burden (ITT)



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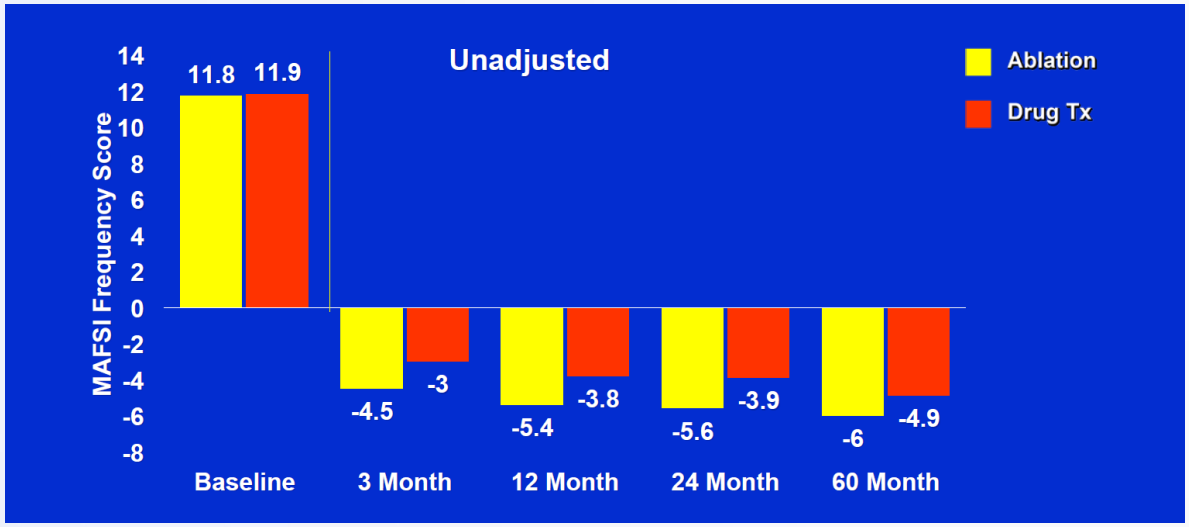
CABANA – symptomy (MAFSI)

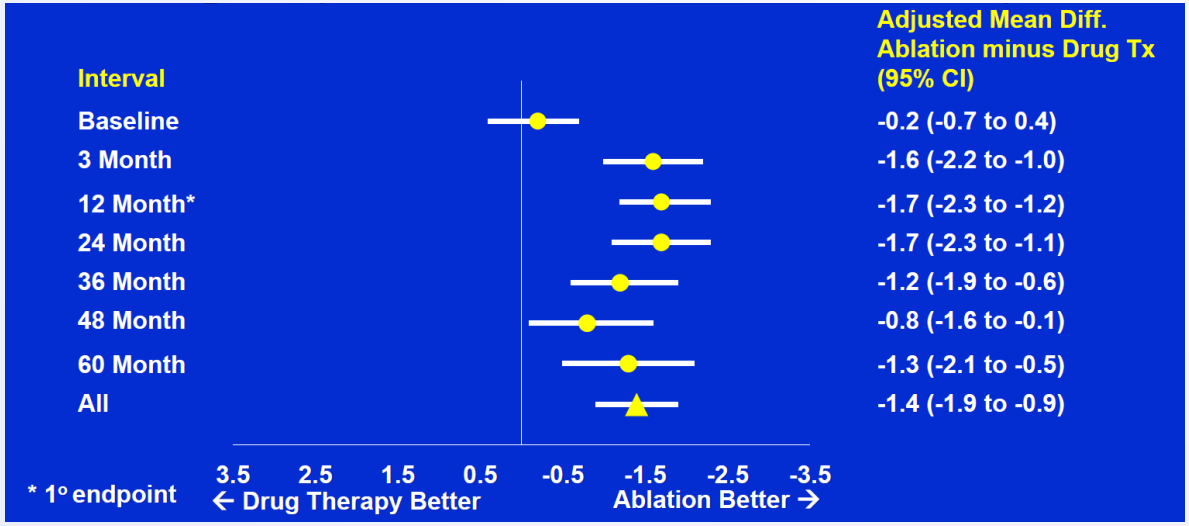


Mayo Clinic Atrial Fibrillation Specific Symptom Inventory

Symptomy:

0 = žádné

40 = nejhorší



Pokles MAFSI (ve 12. měsíci)

Léky: -3.8 bodu

Ablace: -5.4 bodu

Delta: -1.6 bodu (42%)

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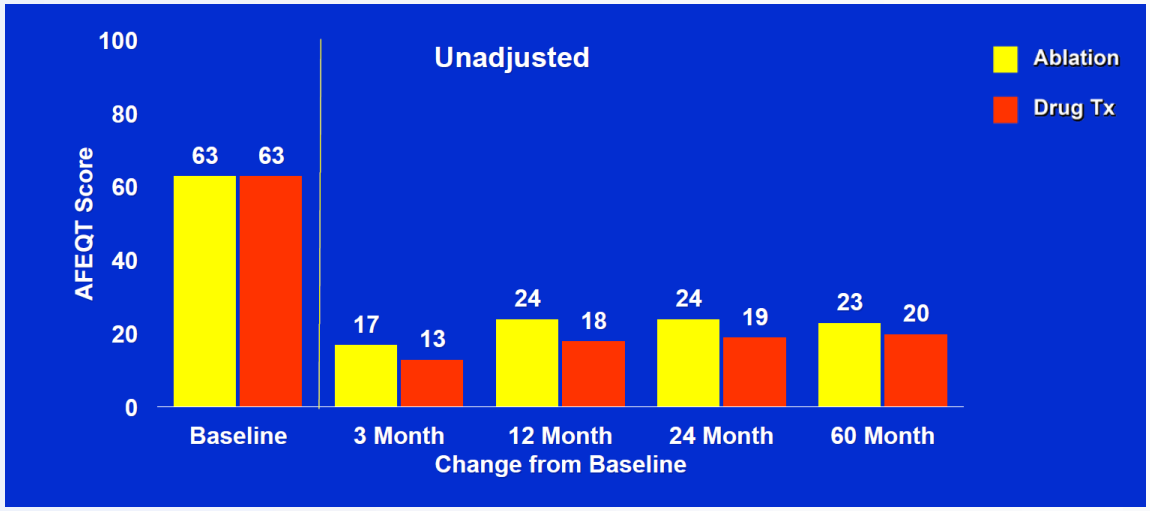
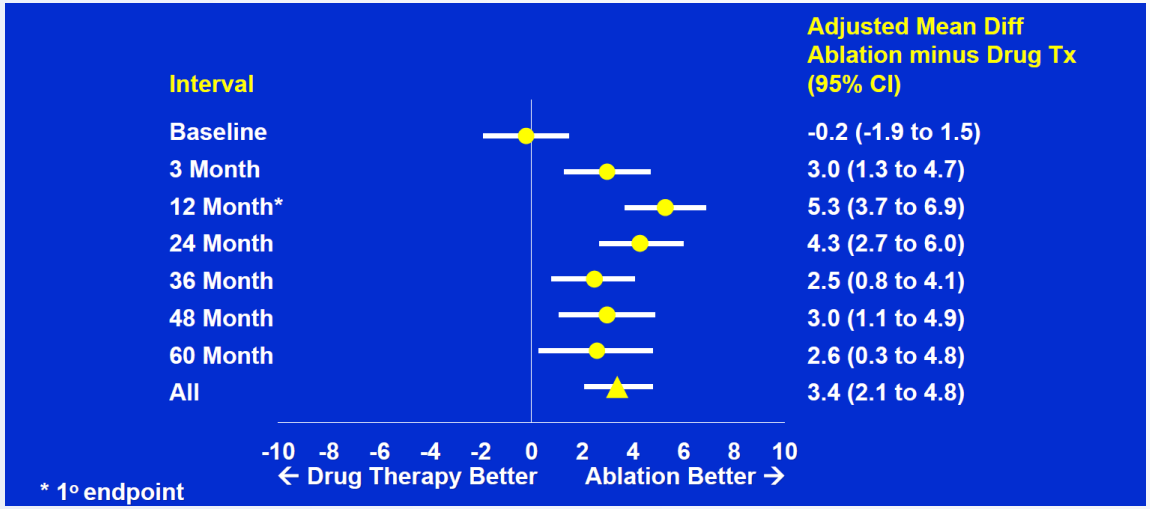
CABANA – kvalita života (AFEQT)





Atrial Fibrillation Effect on Quality of Life

Kvalita života:
0 = nejhorší
100 = nejlepší

Vzestup EFEQT (ve 12. měsíci)

Léky: +18 bodů
Ablace: +24 bodů

Delta: +6 bodů (33%)

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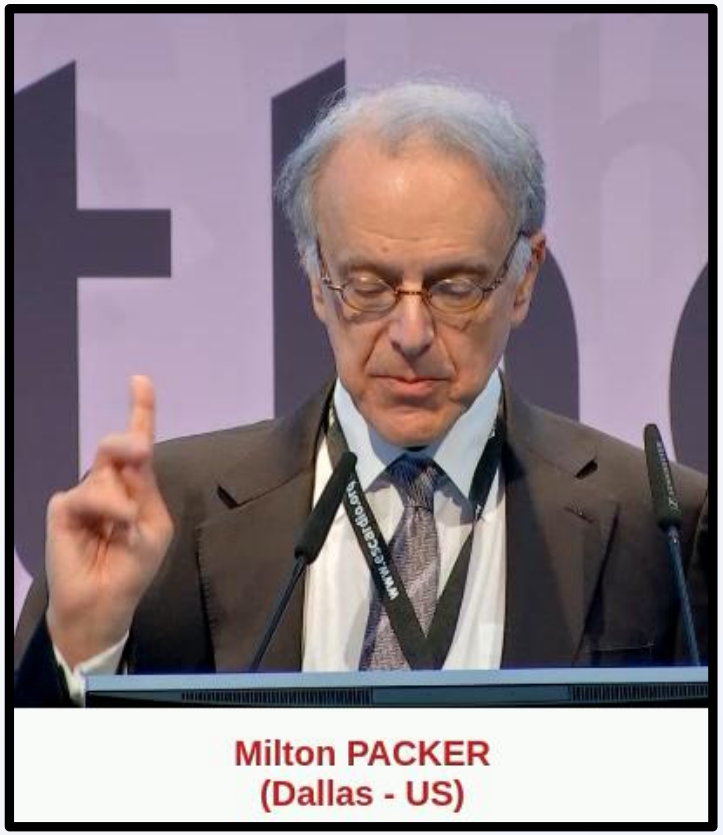
What CABANA does not tell us

A critical appraisal

Major Take-Home Points From the CABANA Trial

- Catheter ablation may be a reasonable therapeutic choice for patients with distressing symptoms of atrial fibrillation (particularly if recent onset) if they have not responded to (or would like to avoid) taking anti-arrhythmic drugs.
- There is no clear or unbiased evidence that catheter ablation prevents any of the serious consequences of atrial fibrillation (death, stroke or heart failure) in patients at high risk of cardiovascular events.



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Závěry

- **Ablační léčba FS (v porovnání s léky)**
  - signifikantně **snižuje arytmickou zátěž**
  - signifikantně **zlepšuje kvalitu života**
  - neovlivňuje signifikantně mortalitu ani výskyt dalších závažných klinických událostí
- **Ablační léčba FS je bezpečná**
- **Ablaci pro fibrilace síní je plošně indikovat jako léčbu první volby**

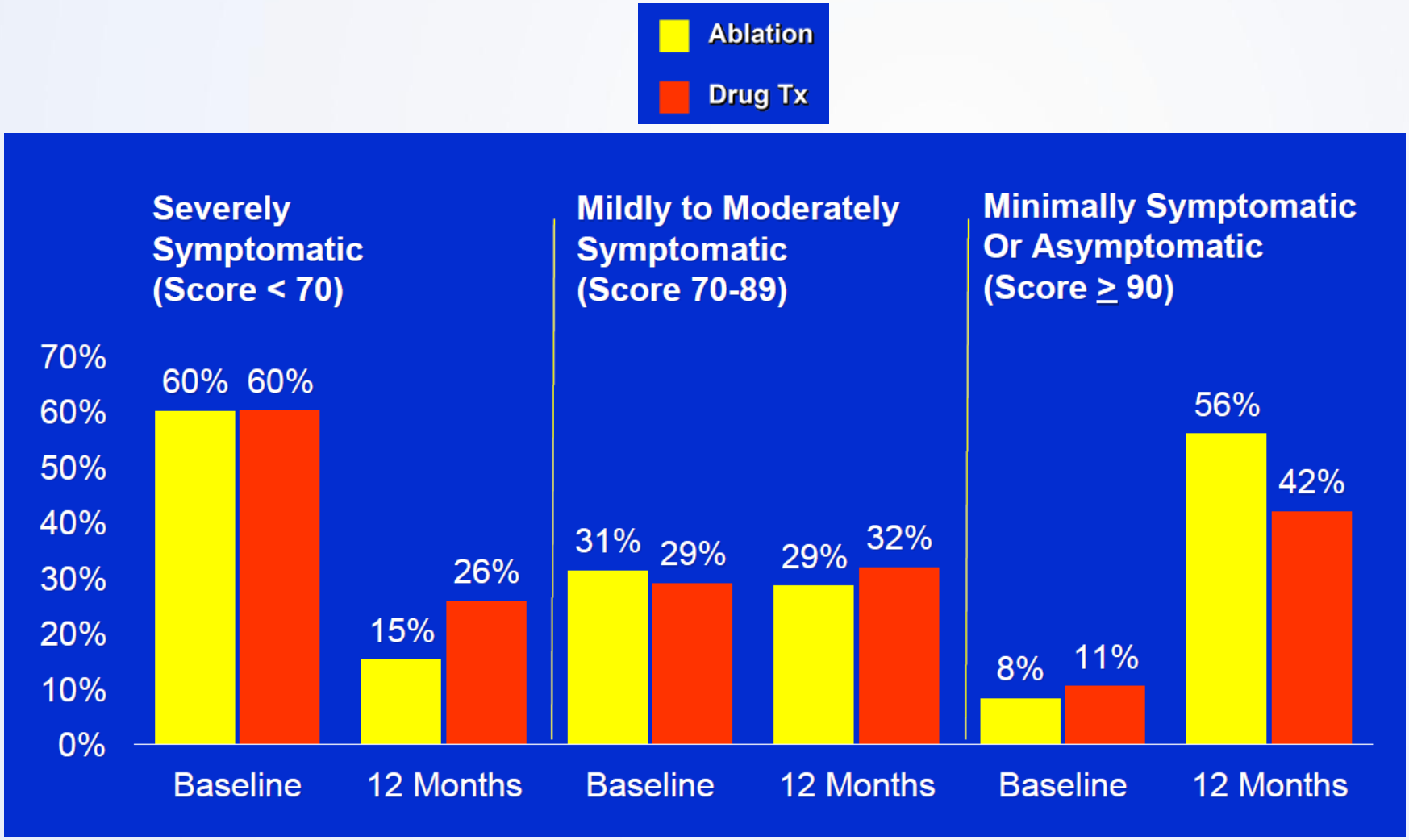
Adverse Events in CABANA

	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.

CABANA – AFEQT



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