

# CABANA

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# CABANA design

Nově zachycená nebo nedostatečně  
léčená FS jakéhokoli typu

&

alespoň jeden faktor CHADS<sub>2</sub>

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

R  
A  
N  
D  
O  
M  
I  
Z  
A  
C  
E

1:1

**Ablace:** izolace  
plicních žil (minimum)

**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

JAMA | **Original Investigation**

JAMA. doi:[10.1001/jama.2019.0693](https://doi.org/10.1001/jama.2019.0693)

# Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on Mortality, Stroke, Bleeding, and Cardiac Arrest Among Patients With Atrial Fibrillation

## The CABANA Randomized Clinical Trial

Douglas L. Packer, MD; Daniel B. Mark, MD, MPH; Richard A. Robb, PhD; Kristi H. Monahan, RN; Tristram D. Bahnson, MD; Jeanne E. Poole, MD; Peter A. Noseworthy, MD; Yves D. Rosenberg, MD, MPH; Neal Jeffries, PhD; L. Brent Mitchell, MD; Greg C. Flaker, MD; Evgeny Pokushalov, MD; Alexander Romanov, MD; T. Jared Bunch, MD; Georg Noelker, MD; Andrey Ardashev, MD; Amiran Revishvili, MD; David J. Wilber, MD; Riccardo Cappato, MD; Karl-Heinz Kuck, MD; Gerhard Hindricks, MD; D. Wyn Davies, MD; Peter R. Kowey, MD; Gerald V. Naccarelli, MD; James A. Reiffel, MD; Jonathan P. Piccini, MD, MHS; Adam P. Silverstein, MS; Hussein R. Al-Khalidi, PhD; Kerry L. Lee, PhD; for the CABANA Investigators

JAMA | **Original Investigation**

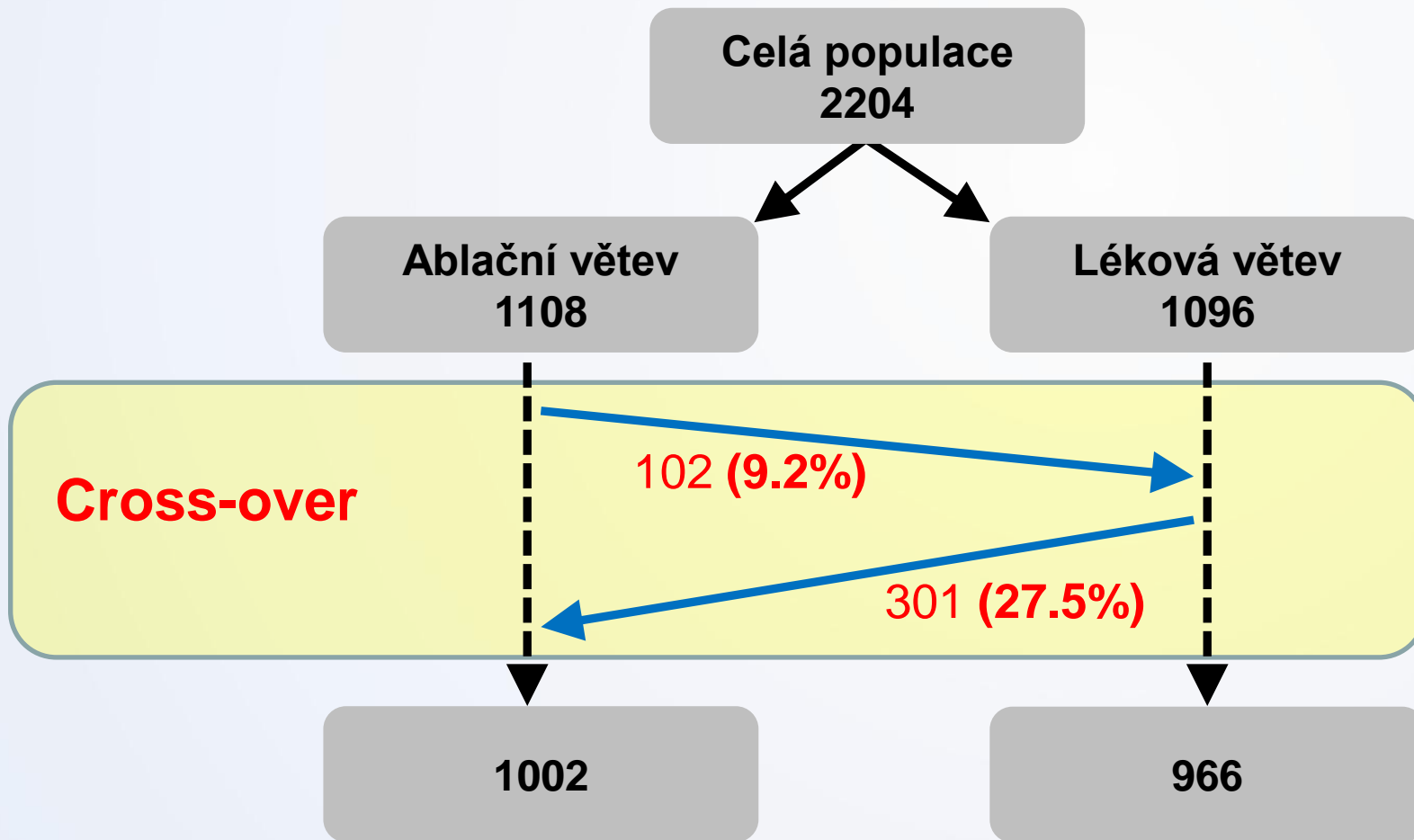
JAMA. doi:[10.1001/jama.2019.0692](https://doi.org/10.1001/jama.2019.0692)

# Effect of Catheter Ablation vs Medical Therapy on Quality of Life Among Patients With Atrial Fibrillation

## The CABANA Randomized Clinical Trial

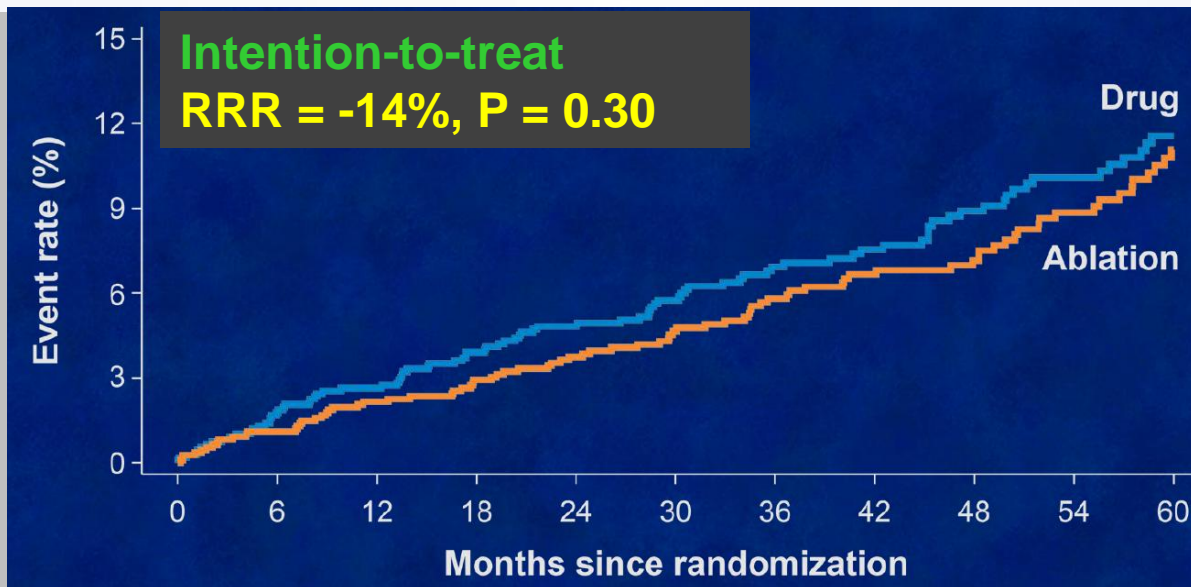
Daniel B. Mark, MD, MPH; Kevin J. Anstrom, PhD; Shubin Sheng, PhD; Jonathan P. Piccini, MD, MHS; Khaula N. Baloch, MPH; Kristi H. Monahan, RN; Melanie R. Daniels, BA; Tristram D. Bahnson, MD; Jeanne E. Poole, MD; Yves Rosenberg, MD, MPH; Kerry L. Lee, PhD; Douglas L. Packer, MD; for the CABANA Investigators

# CABANA – flowchart



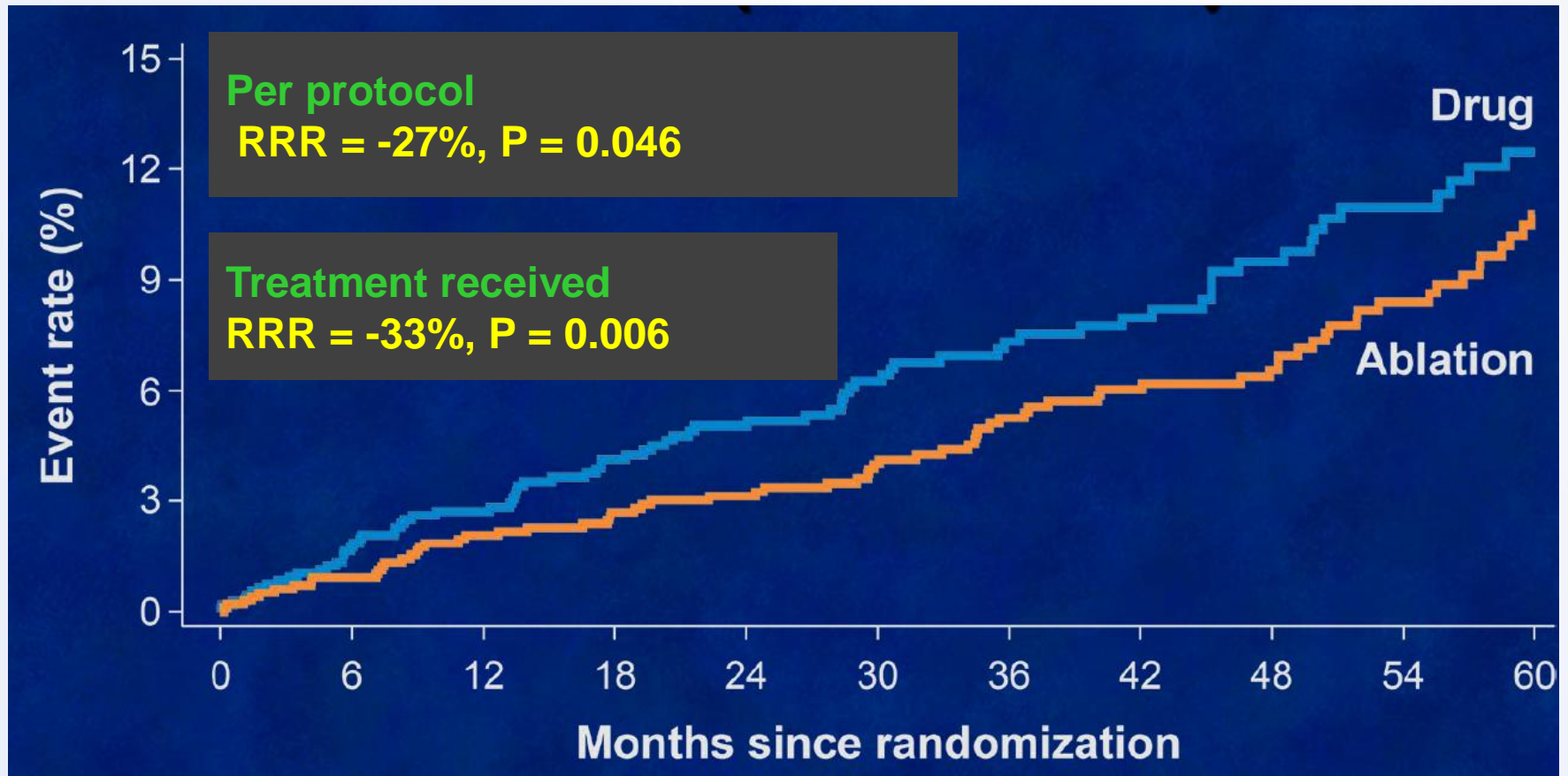
# CABANA – primary composite endpoint

- death
- disabling stroke
- serious bleeding
- cardiac arrest



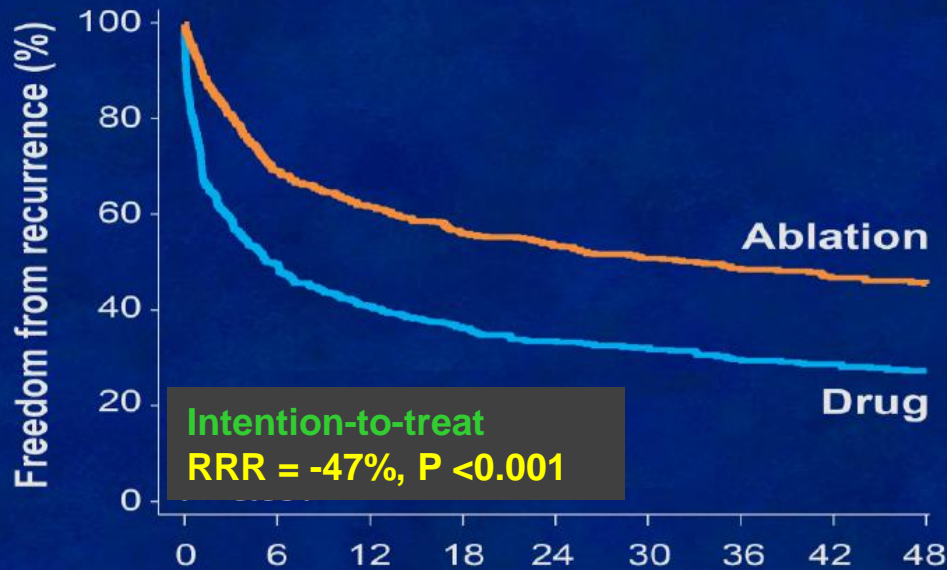
# CABANA – exploratory analyses

## Primary composite endpoint

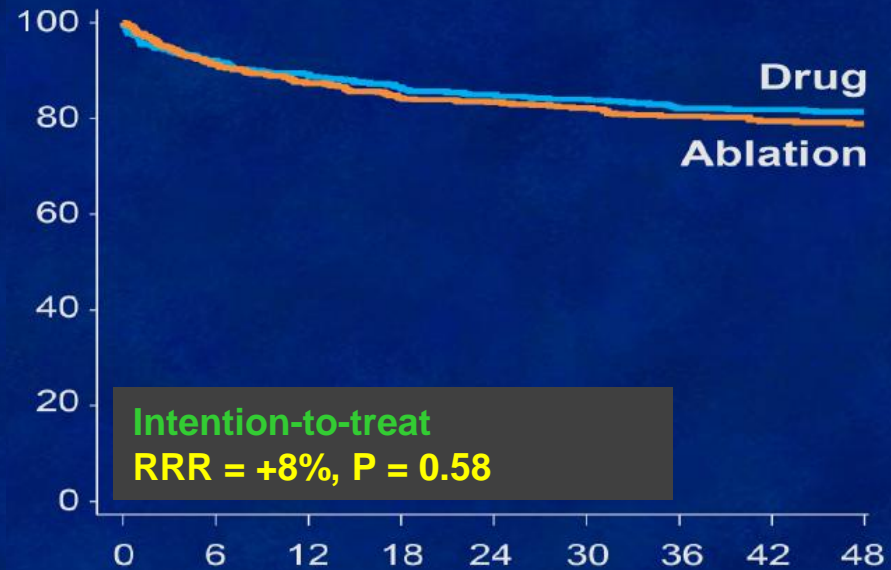


# CABANA – rhythm outcome (ITT)

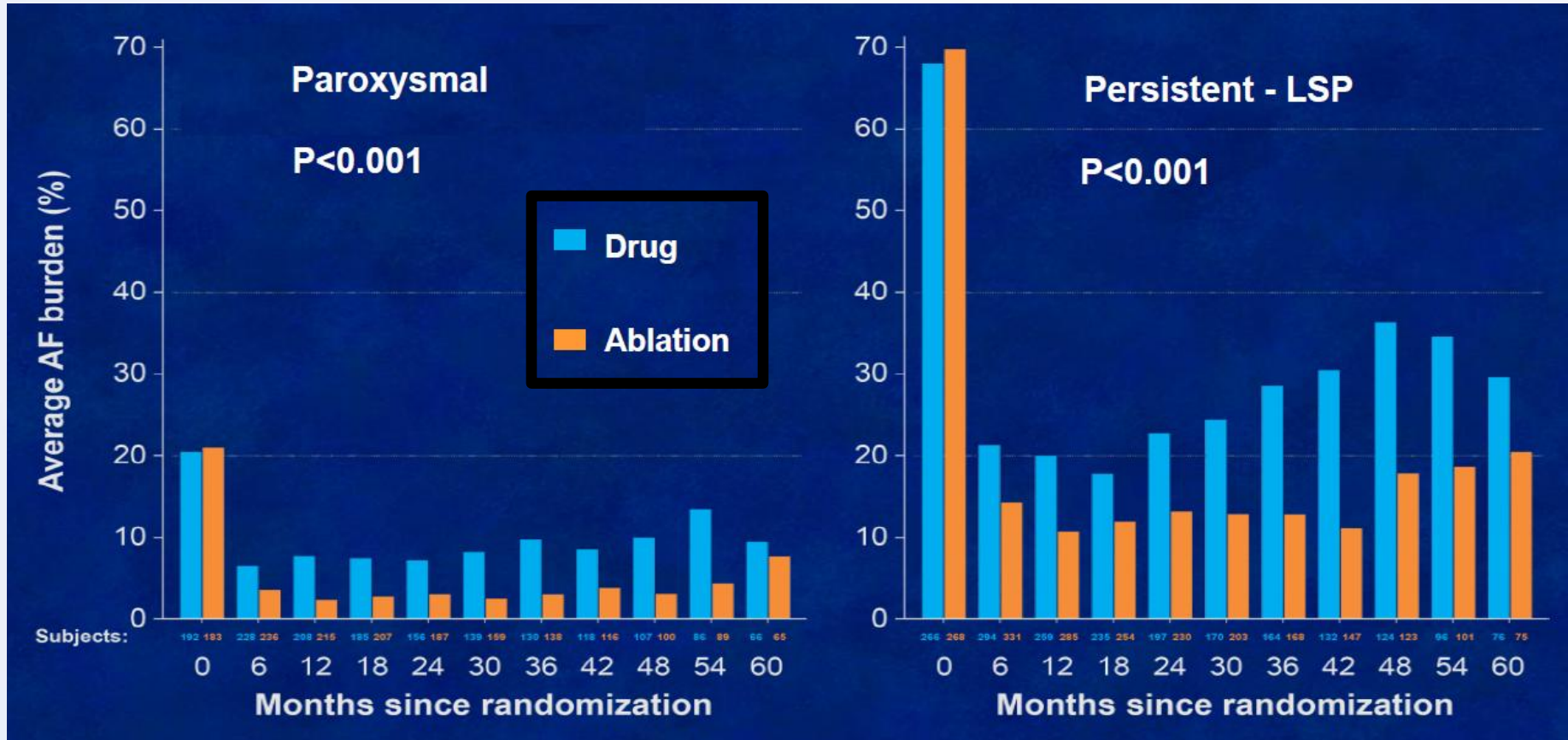
## Atrial Fibrillation/Flutter/Tachycardia



## Atrial Flutter/Tachycardia



# CABANA – rhythm burden (ITT)



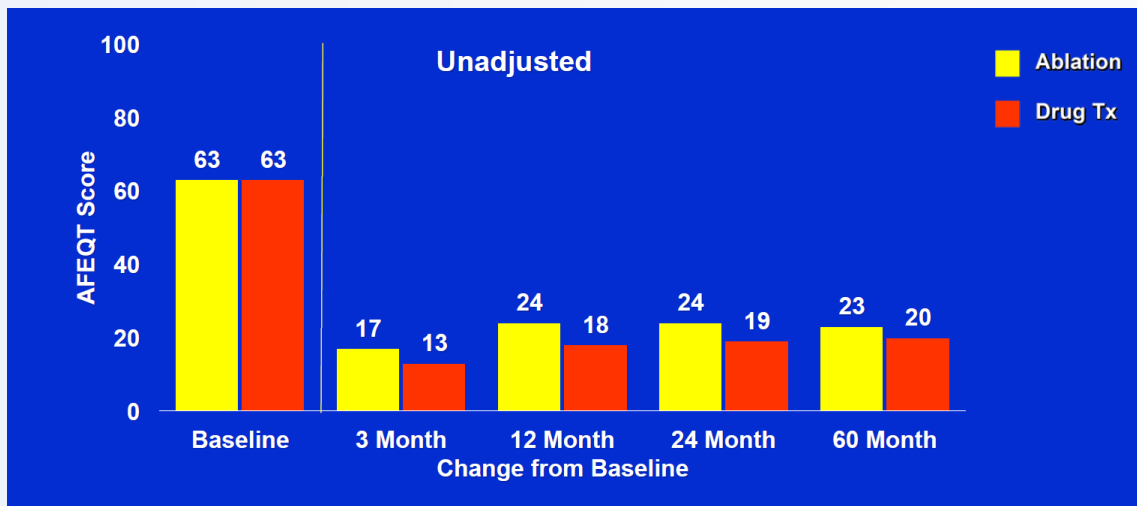
Poole JE et al.  
ESC Congress, 25-29 August 2018

INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDICÍNY  
KLINIKA KARDIOLOGIE



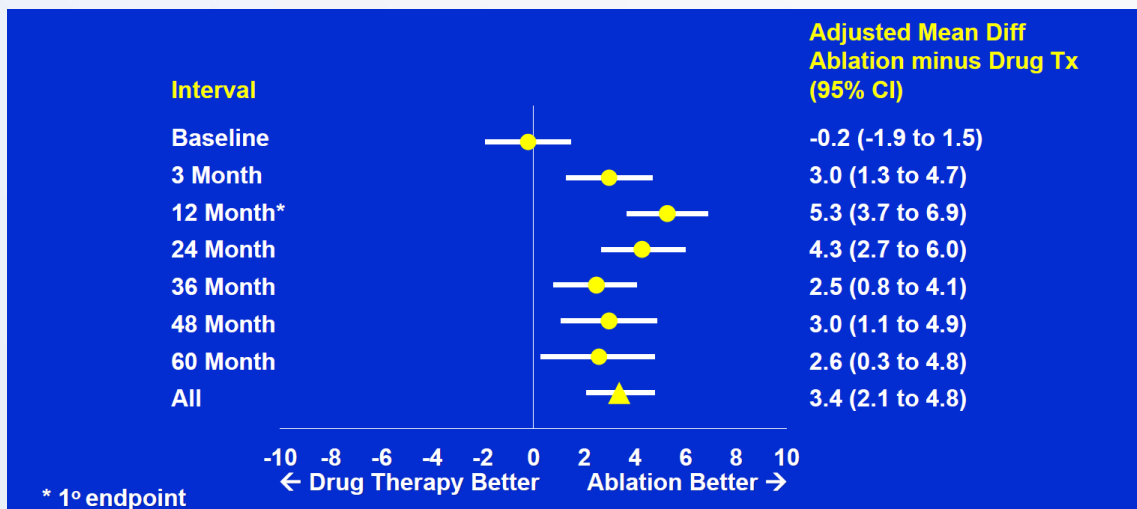


# CABANA – quality of life (AFEQT)



## Atrial Fibrillation Effect on Quality of Life

Kvalita života:  
0 = nejhorší  
100 = nejlepší





# Adverse Events in CABANA

Event	Ablation n = 1006 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

Event	Pts Receiving Drug n = 1092 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.

# Závěry

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