

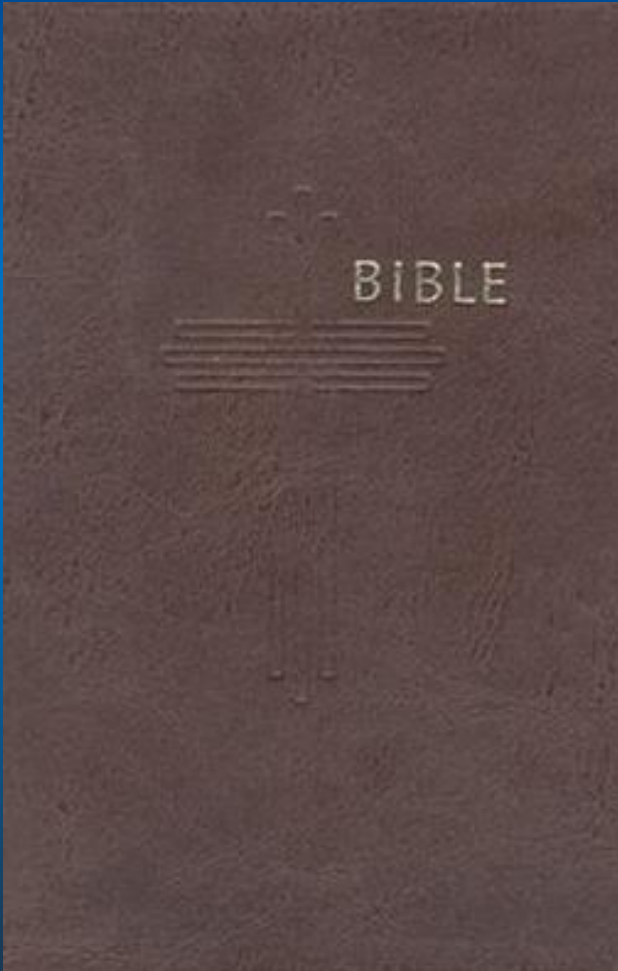
**PACIENT S FIBRILACÍ SÍNÍ  
DOSTAL STENT:  
KLASICKÁ „TRIPLE  
THERAPY“ JE NEZBYTNÁ!**

**Ivo Varvařovský (Pardubice)**

XXV. výroční sjezd české kardiologické společnosti

Brno 9.5.2017

# Stent u pacienta s fibrilací síní: **TRIPLE THERAPY**



1. Já jsem Pán, tvůj Bůh
2. Nebudeš mít jiné bohy mimo mne
3. Nevezmeš jména božího nadarmo
4. Pomni, abys den sváteční světil
5. Cti otce svého i matku svou
6. Nezapomeneš
7. Nesesmilníš
8. Nepromluvíš křivého svědectví
9. Nepožádáš manželky bližního svého
10. Nepožádáš statku bližního svého

# Stent u pacienta s fibrilací síní: TRIPLE THERAPY



European Heart Journal (2016) 37, 2893–2962  
doi:10.1093/eurheartj/ehw210

ESC GUIDELINES

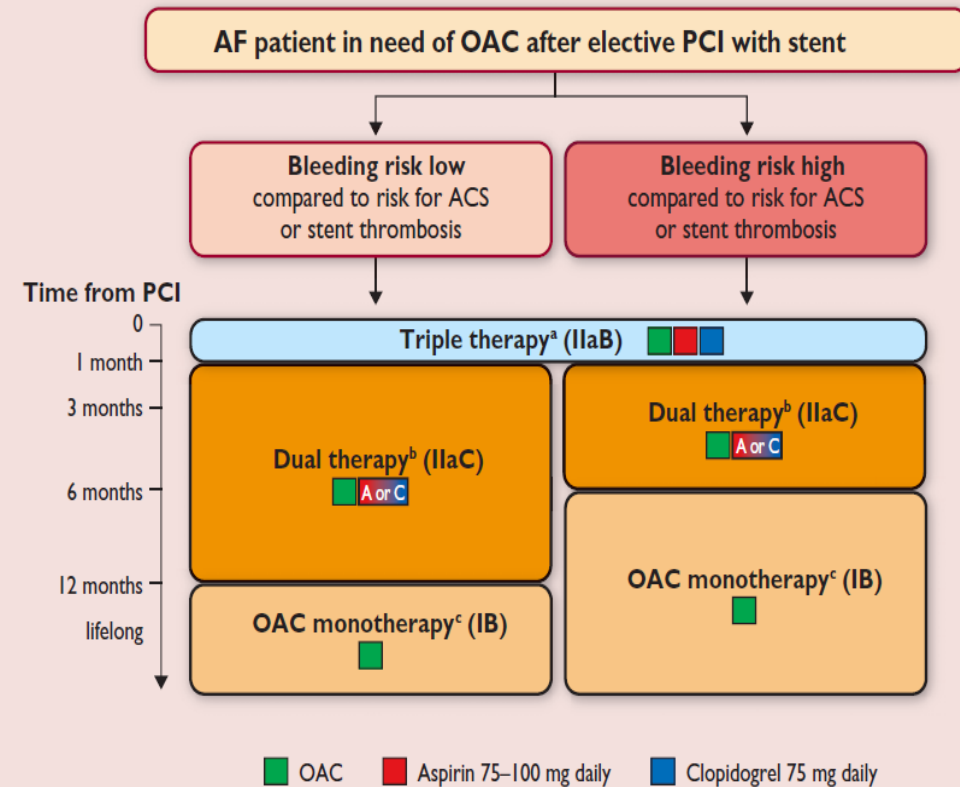
## 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC

Endorsed by the European Stroke Organisation (ESO)

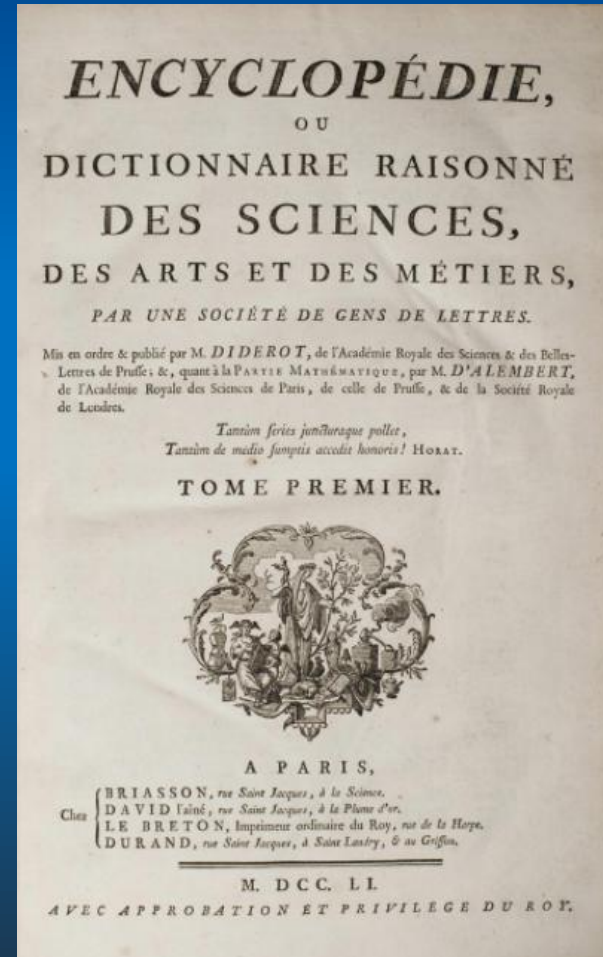
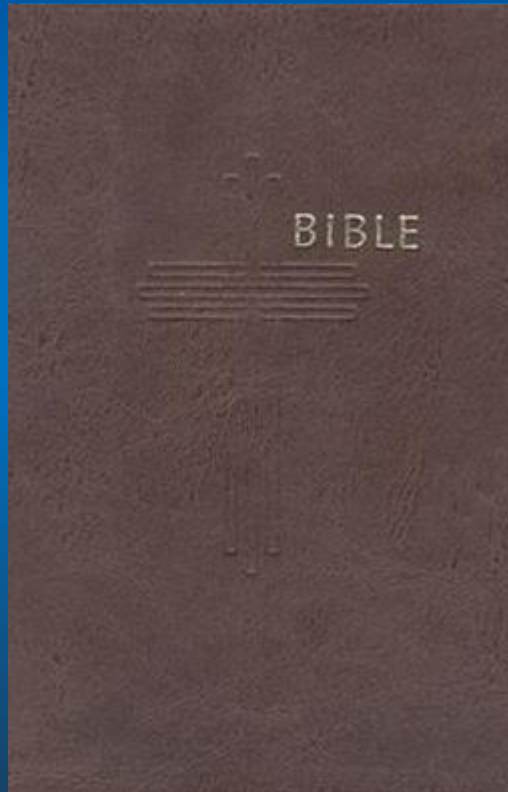
Authors/Task Force Members: Paulus Kirchhof<sup>†\*</sup> (Chairperson) (UK/Germany), Stefano Benussi<sup>‡1</sup> (Co-Chairperson) (Switzerland), Dipak Kotecha (UK), Anders Ahlsson<sup>1</sup> (Sweden), Dan Atar (Norway), Barbara Casadei (UK), Manuel Castella<sup>1</sup> (Spain), Hans-Christoph Diener<sup>2</sup> (Germany), Hein Heidbuchel (Belgium), Jeroen Hendriks (The Netherlands), Gerhard Hindricks (Germany), Antonis S. Manolis (Greece), Jonas Oldgren (Sweden), Bogdan Alexandru Popescu (Romania), Ulrich Schotten (The Netherlands), Bart Van Putte<sup>1</sup> (The Netherlands), and Panagiotis Vardas (Greece)



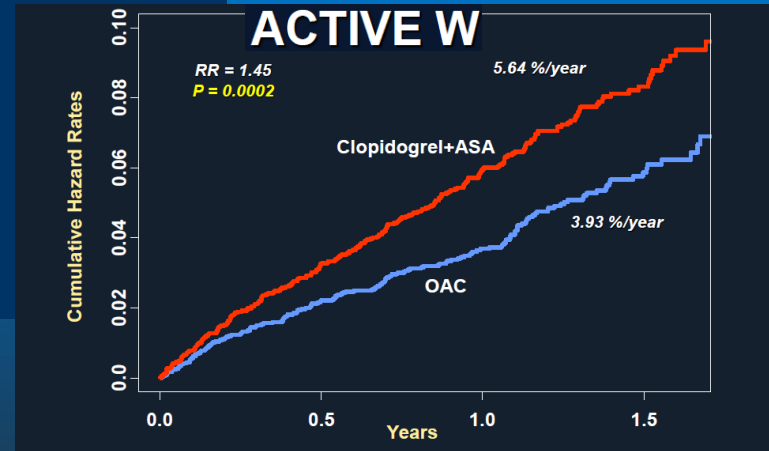
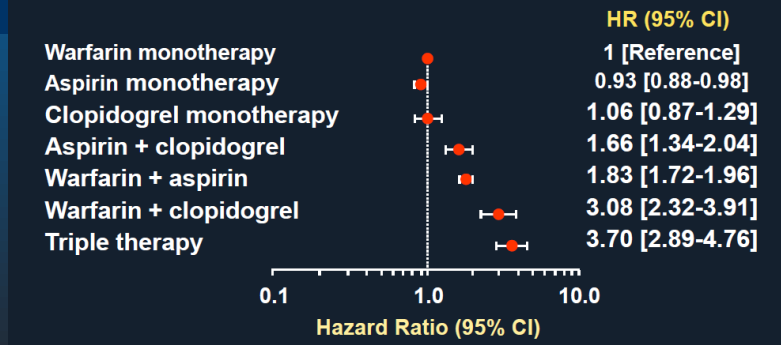
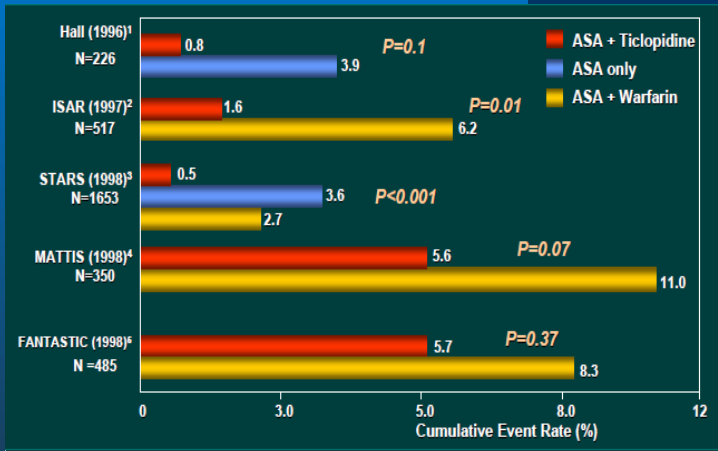
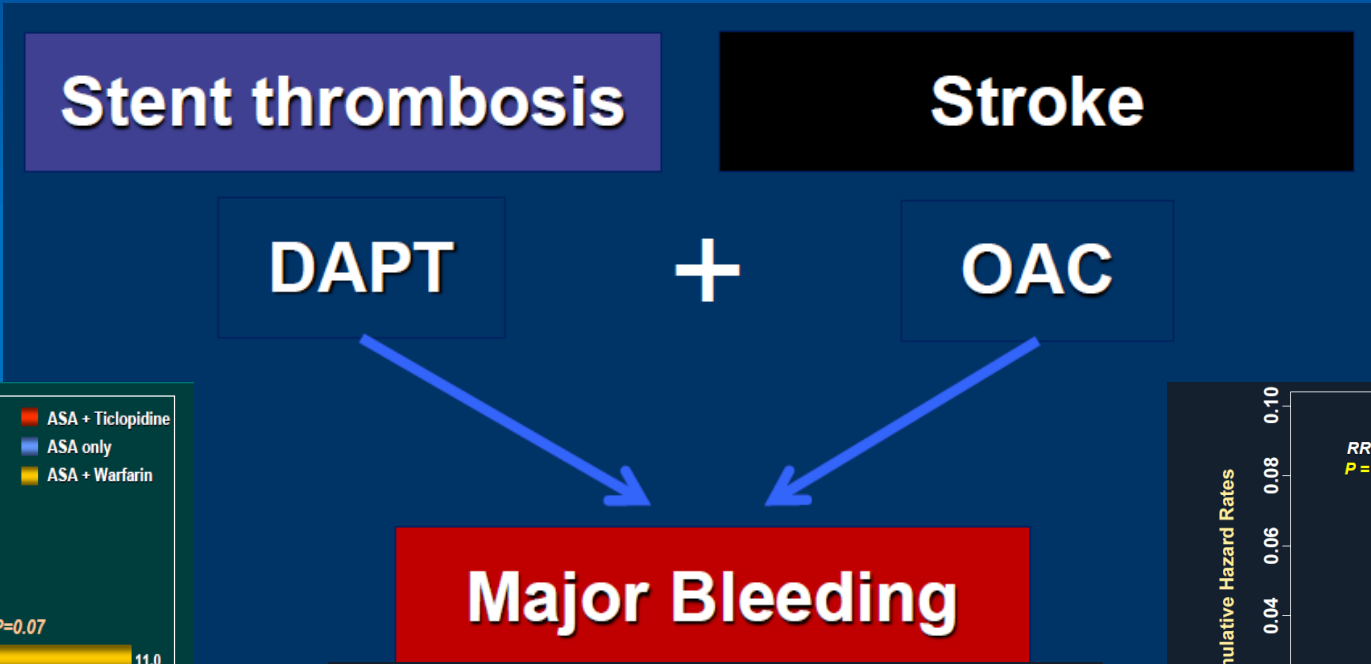
Stent u pacienta s fibrilací síní: **TRIPLE THERAPY**

**Děkuji za pozornost !**

# Stent u pacienta s fibrilací síní: **TRIPLE THERAPY**



ACTIVE W: **warfarin** je pro prevenci **CMP** při fibrilaci síní lepší než DAPT  
 STARS: **DAPT** je pro prevenci **trombózy stentu** lepší než OAC+aspirin



PCI u nemocných s antikoagulační léčbou: součástí „triple therapy“

**Aspirin** v dávce do 100 mg

**Clopidogrel** 75mg má přednost před prasugrelem nebo ticagrelorem

**Warfarin** s cílovým INR 2.0 – 2.5

**NOAC** v nižší účinné dávce

(dabigatran 2x110mg, rivaroxaban 15mg, apixaban 2x2,5mg)

**Inhibitory protonové pumpy**

# Stent u pacienta s fibrilací síní: TRIPLE THERAPY

## WOEST Study Design

### Inclusion criteria

- Indication for OAC for ≥1 year
- PCI of a single coronary lesion

### 1:1 Randomization:

Double therapy group:

OAC + 75mg Clopidogrel qd

Triple therapy group

OAC + 75mg Clopidogrel qd + 80mg Aspirin qd

1 month minimum after BMS

1 year after DES

Follow up: 1 year

1 month minimum after BMS

1 year after DES

Primary Endpoint: The occurrence of all bleeding events (TIMI criteria) (powered for a reduction from 12% to 5%)

### Secondary Endpoints:

- Combination of stroke, death, myocardial infarction, stent thrombosis and target vessel revascularisation

## ISAR-TRIPLE: Study Organization

### TEST HYPOTHESES:

6-week superior to 6-month therapy; Primary Endpoint 10%, Risk reduction 60% with 6-week therapy; Power = 80%, alpha = 0.05; 283 patients per group

### PRIMARY ENDPOINT:

- Death, myocardial infarction, definite stent thrombosis, stroke or TIMI major bleeding at 9 months

### SECONDARY ENDPOINTS:

- Ischemic complications: Cardiac death, myocardial infarction, definite stent thrombosis or ischemic stroke
- Bleeding complications (TIMI major)

614 patients with DES implantation  
3 European centers  
(September 2008 – December 2013)

Aspirin and VKA

6-week  
Clopidogrel  
(n=307)

6-month  
Clopidogrel  
(n=307)

Clinical follow up at 9 months in  
606 patients (98.7%)



## XARELTO® (rivaroxaban) Use in Patients With AF Undergoing PCI: PIONEER AF-PCI



- Primary endpoint: TIMI major, minor, and bleeding requiring medical attention
- Secondary endpoint: CV death, MI, stroke, and stent thrombosis



## PCI u nemocných s antikoagulační léčbou

Závěry studií WOEST, ISAR - TRIPLE, PIONEER AF:  
„dual therapy“ je bezpečnější a srovnatelně účinná.

**ALE !**

**Žádná ze studií nebyla koncipována na průkaz non-inferiority z hlediska účinnosti léčby pro snížení ischemických komplikací po PCI**

# PCI u nemocných s antikoagulační léčbou

Cardiovasc Drugs Ther (2016) 30:611–622

DOI 10.1007/s10557-016-6692-z



ORIGINAL ARTICLE

## **Risk and Benefits of Triple Therapy in Patients Undergoing Coronary Stent Implantation Requiring Oral Anticoagulation: A Meta-Analysis of 16 Studies**

Lucia Barbieri<sup>1</sup> · Monica Verdoia<sup>1</sup> · Alon Schaffer<sup>1</sup> · Harry Suryapranata<sup>2</sup> ·  
Giuseppe De Luca<sup>1</sup>

Published online: 18 October 2016

## PCI u nemocných s antikoagulační léčbou: metaanalýza 16 studií

	Triple therapy	Dual therapy	OR [95 % CI]
Celková mortalita	10,4%	16,3%	0,73 (0,66 – 0,80)
Infarkt myokardu	6,4%	9,8%	0,74 (0,65 - 0,84)
CMP	1,8%	3,9%	0,55 (0,45 – 0,68)
Závažné krvácení	10,8%	8,5%	1,38 (1,25 – 1,53)

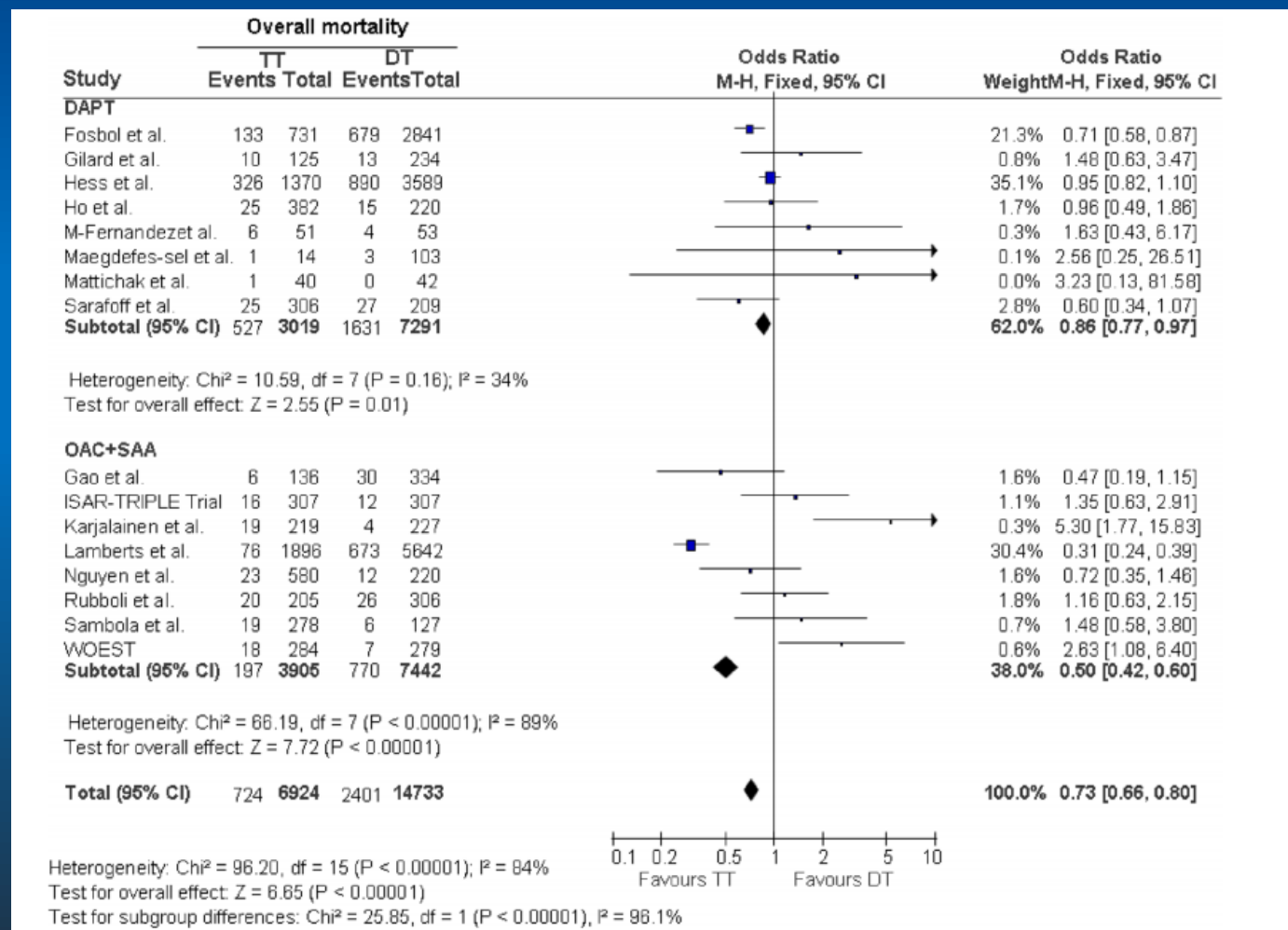
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**Risk and Benefits of Triple Therapy in Patients Undergoing Coronary Stent Implantation Requiring Oral Anticoagulation: A Meta-Analysis of 16 Studies.**

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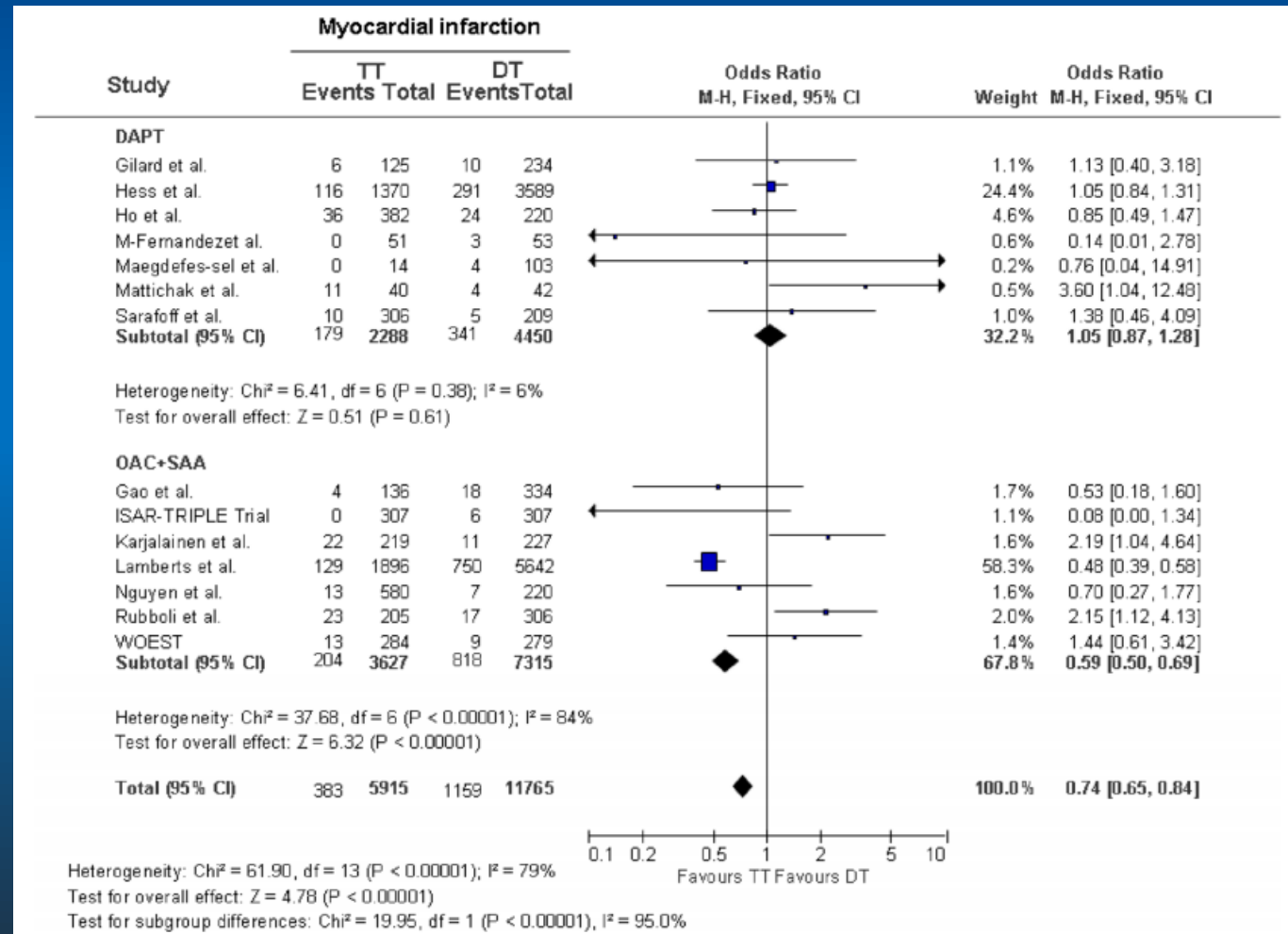
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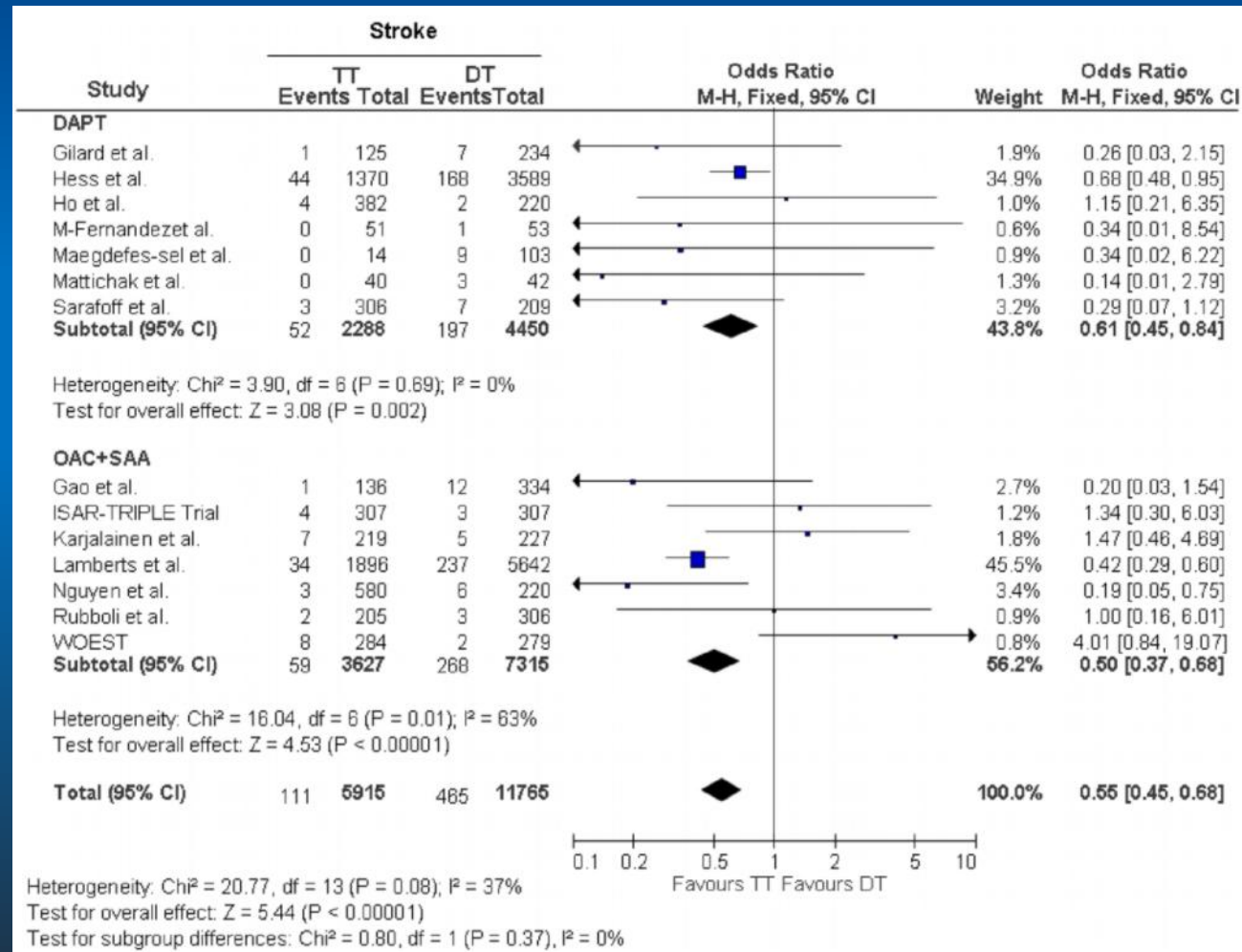
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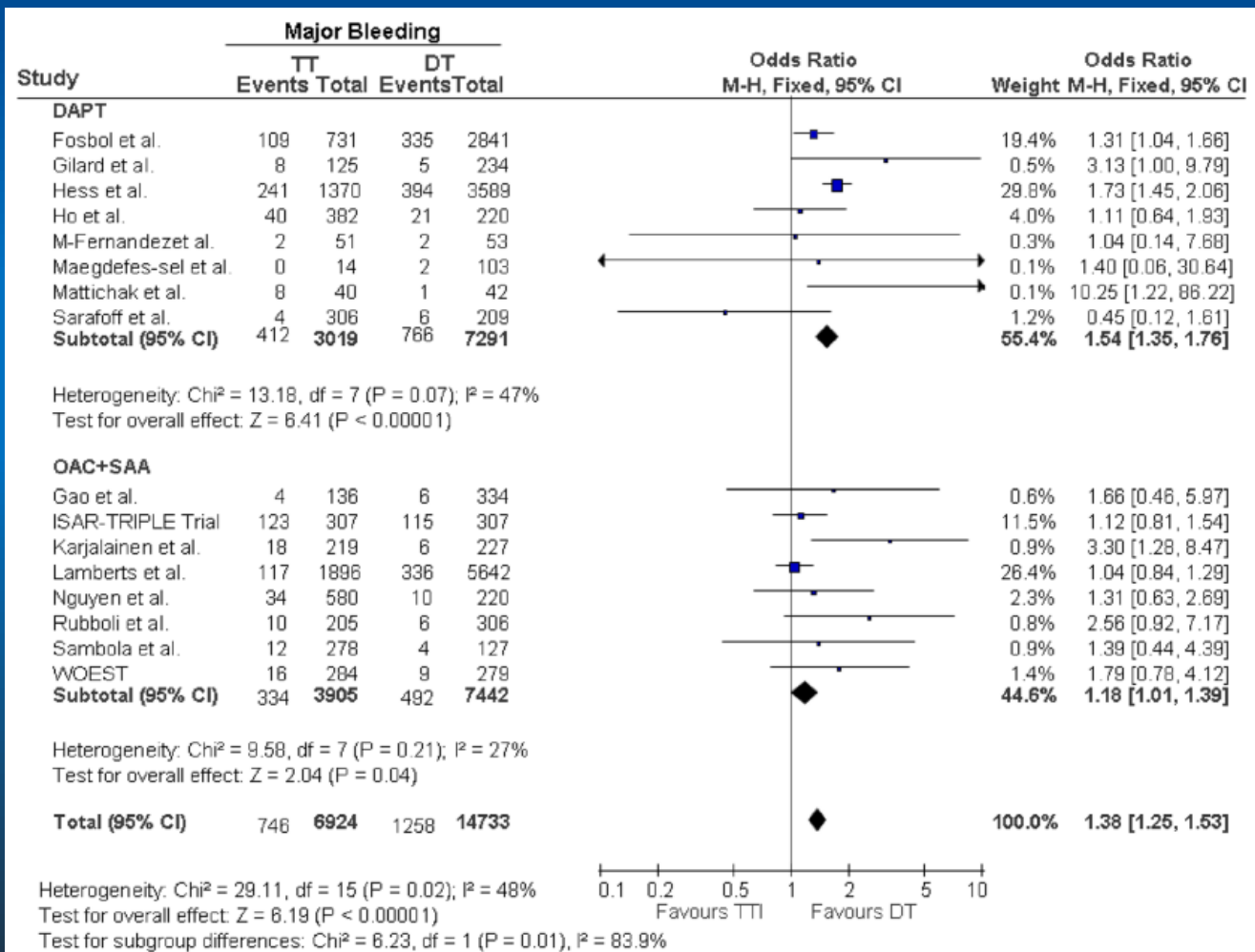
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# Zkrácení období „triple/dual thrapy“: **volba stentu !** 1-měsíční léčba aspirin + clopidogrel

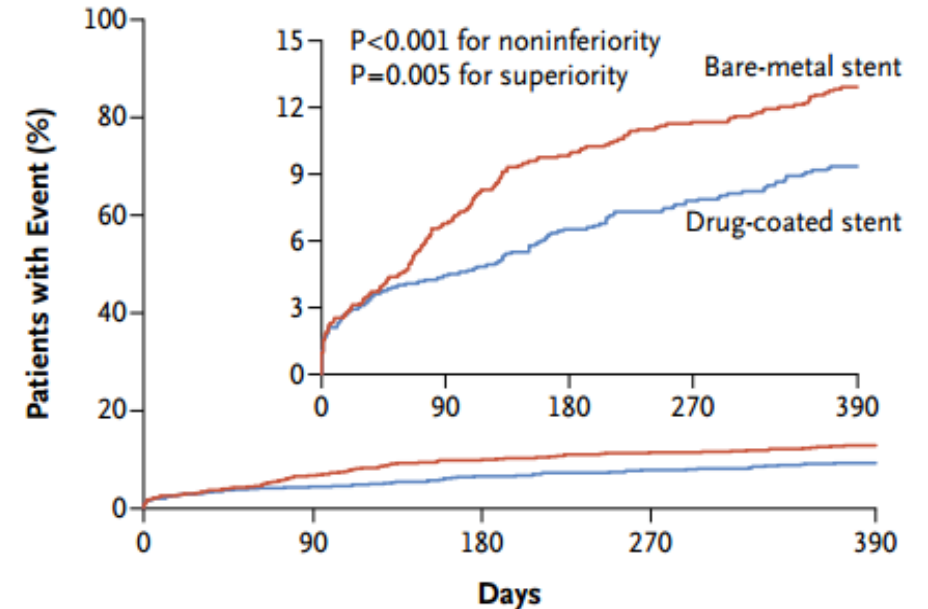
N Engl J Med. 2015 Nov 19;373(21):2038-47. doi: 10.1056/NEJMoa1503943. Epub 2015 Oct 14.

## Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk.

Urban P<sup>1</sup>, Meredith IT, Abizaid A, Pocock SJ, Carrié D, Naber C, Lipiecki J, Richardt G, Iñiguez A, Brunel P, Valdes-Chavarrí M, Abdellaoui M, Eberli F, Oldroyd K, Zambahari R, Gregson J, Greene S, Stoll HP, Morice MC; LEADERS FREE Investigators.

1. Adjunctive oral anticoagulation treatment planned to continue after PCI
2. Age  $\geq$  75 years old
3. Baseline Hemoglobin  $<$ 11 g/dl (or anemia requiring transfusion during the 4 weeks prior to randomization)
4. Any prior intra-cerebral bleed
5. Any stroke in the last 12 months
6. Hospital admission for bleeding during the prior 12 months
7. Non skin cancer diagnosed or treated  $<$  3 years
8. Planned daily NSAID (other than aspirin) or steroids for  $>$ 30 days after PCI
9. Planned surgery that would require interruption of DAPT (within next 12 months)
10. Renal failure defined as calculated creatinine clearance  $<$ 40 ml/min

## A Primary Safety End Point



### No. at Risk

Drug-coated stent	1221	1146	1105	1081	1045
Bare-metal stent	1211	1115	1066	1037	1000



# Stent u pacienta s fibrilací síní: **TRIPLE THERAPY**

## Giordano Bruno (1547 – 1600)

- dominikánský mnich, učitel na různých univerzitách.
- Bruno zastával Koperníkovu teorii
- ani Slunce není středem vesmíru, vesmír je nekonečný, existuje nekonečně mnoho sluncí s planetami a každá planeta je světem, jako je náš.
- V roce 1593, když se vrátil z ciziny do Itálie byl zatčen, souzen inkvizicí za kacířské názory a po sedmi letech věznění upálen.

