

OPTIMA-AF Trial

XXXIV. výroční sjezd České kardiologické společnosti
HOT LINES

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SHORT DUAL ANTITHROMBOTIC THERAPY AFTER PCI IN PATIENTS WITH ATRIAL FIBRILLATION: OPTIMA-AF TRIAL

 Scientific
Sessions

 OPTIMA-AF

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STUDY DESIGN AND AIM



A prospective, investigator-initiated, nationwide, multicenter, open-label, blinded-endpoint, active-control, randomized, noninferiority-superiority hybrid trial

Experimental arm: 1M dual therapy

AF patients
with CAD
N=1,090
545 vs. 545

R

*Dual
therapy

DOAC monotherapy

*Dual therapy
(DOAC + P2Y₁₂i)

DOAC
monotherapy

Control arm: 12M dual therapy

Primary Endpoints

1 month

Clinical follow-up

12 months

Clinical follow-up

PCI with Xience EES
under imaging guidance
ASA+P2Y12i+DOAC

This trial aims to assess the **safety and efficacy** of a 1-month dual antithrombotic therapy in patients with AF undergoing PCI with contemporary DES, **Xience everolimus-eluting stents**.

* Add-on aspirin is permitted up to 1 month in cases where an attending physician considers more appropriate (e.g. CYP2C19 polymorphism, etc.).

PRIMARY ENDPOINTS AND ANALYSIS



Primary efficacy endpoint

A composite of death or thromboembolic events (myocardial infarction, definite stent thrombosis, stroke, or systemic embolism) at 365 days



Primary safety endpoint

Bleeding (ISTH major or clinically relevant nonmajor bleeding) at 365 days

Noninferiority-Superiority hybrid design

The following three hypotheses were tested step by step using a fixed-sequence procedure to account for multiplicity, controlling the familywise type I error rate at a one-sided α of 0.05.

1. **Non-inferiority** of the primary efficacy endpoint
2. **Superiority** of the primary safety endpoint
3. **Superiority** of the primary efficacy endpoint



If the current hypothesis is met, proceed to the next; otherwise, stop.

PATIENTS' BACKGROUND

	1M dual therapy 542 patients, 737 lesions	12M dual therapy 537 patients, 716 lesions
Age, yr	75.4 (8.1)	74.9 (8.8)
Male sex	80.8%	77.5%
BMI, kg/m ²	24.2 (3.9)	24.4 (3.8)
Diabetes	38.4%	40.2%
Hypertension	86.9%	85.5%
Dyslipidemia	70.5%	73.0%
History of cerebral infarction	13.1%	11.4%
CrCl, mL/min	56 [43, 74]	57 [43, 75]
CHA ₂ DS ₂ -VASc score	4 [3, 5]	4 [3, 5]
Chronic coronary syndrome	94.1%	94.6%
Acute coronary syndrome	5.9%	5.4%
OCT/IVUS use	99.5%	99.7%
Complex PCI	23.1%	23.5%

Data shown as mean (SD), median [IQR] or %

MEDICATION AT HOSPITAL DISCHARGE

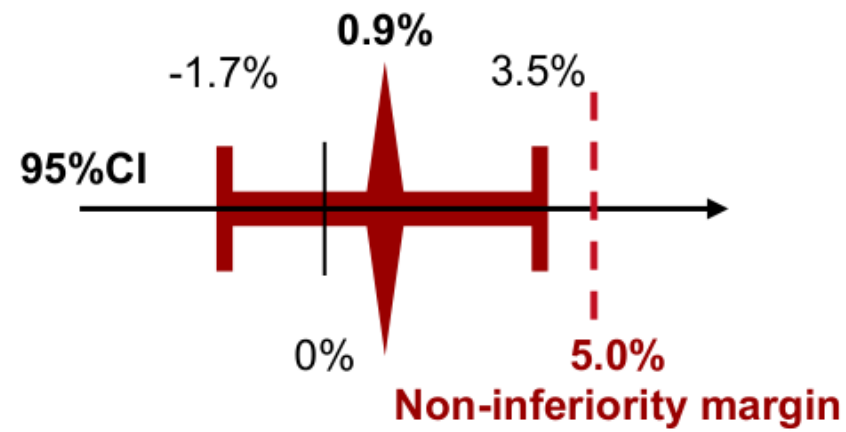
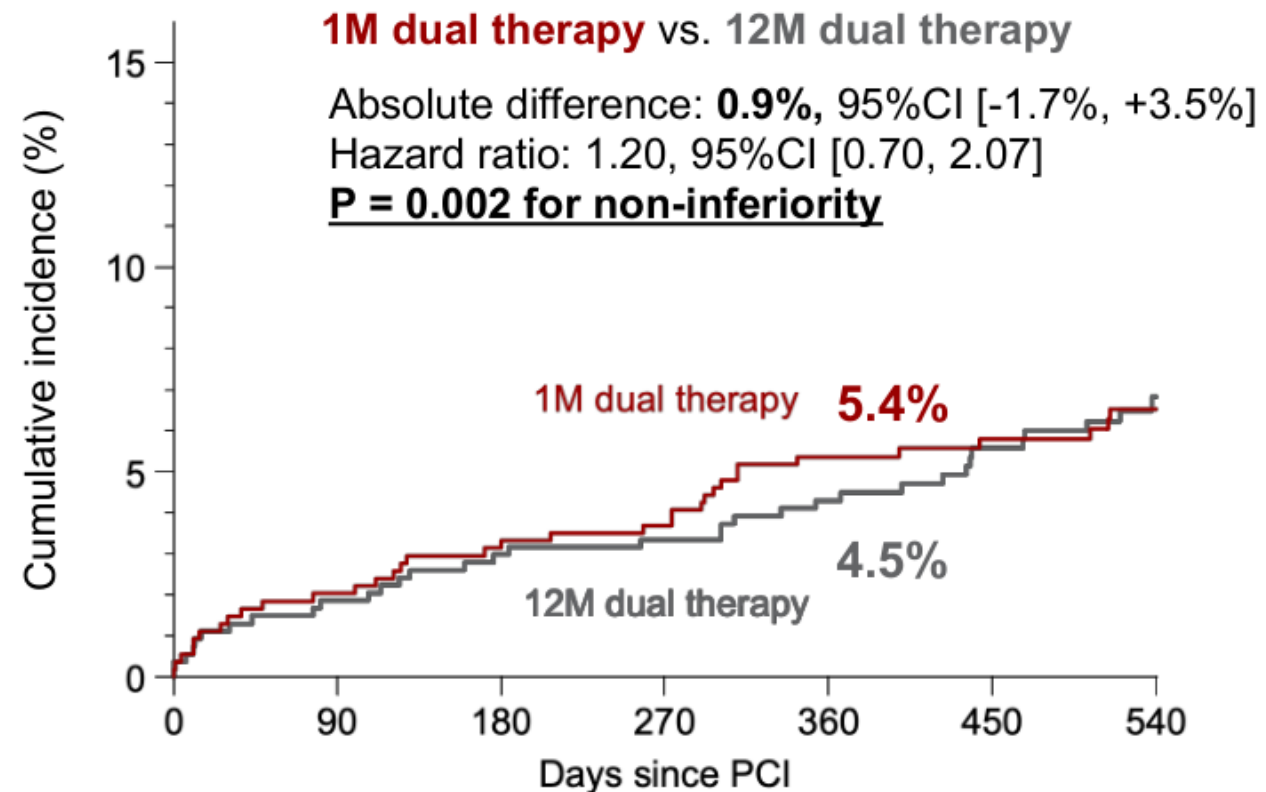
	1M dual therapy 542 patients, 737 lesions	12M dual therapy 537 patients, 716 lesions
Type of antiplatelet agents		
Clopidogrel	48.5%	48.1%
Prasugrel	50.4%	50.9%
Aspirin	4.4%	5.4%
Others	0.6%	0.2%
Type of direct oral anticoagulants		
Dabigatran	4.2%	4.1%
Rivaroxaban	23.2%	22.2%
Apixaban	26.2%	26.5%
Edoxaban	46.3%	47.2%

Data shown as mean (SD), median [IQR] or %

HYPOTHESIS 1

NON-INFERIORITY OF THE PRIMARY EFFICACY ENDPOINT

A composite of death or thromboembolic events (myocardial infarction, definite stent thrombosis, stroke, or systemic embolism) at 365 days.



No. of Patients (censored)

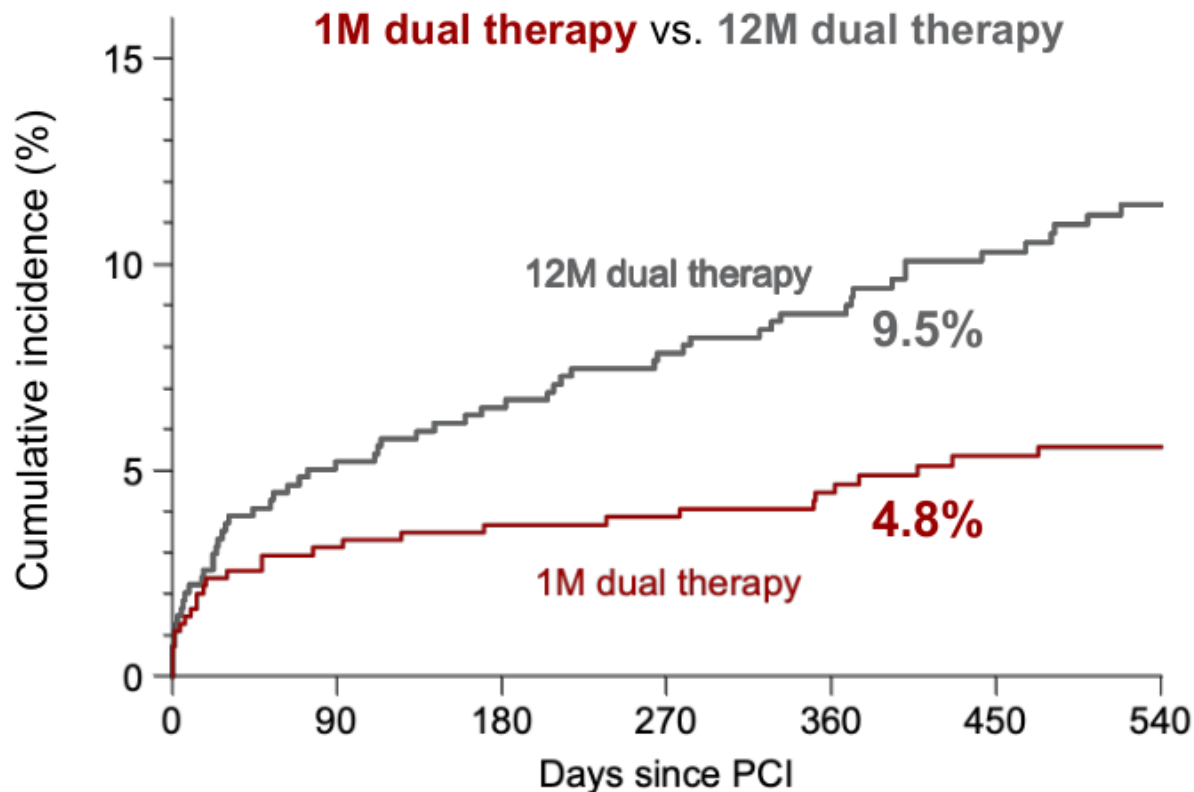
1M dual therapy	542(0)	531(1)	524(1)	520(3)	475(39)	423(89)	247(508)
12M dual therapy	537(0)	528(0)	521(1)	516(4)	477(38)	438(71)	258(503)



HYPOTHESIS 2

SUPERIORITY OF THE PRIMARY SAFETY ENDPOINT

Bleeding (ISTH major or clinically relevant nonmajor bleeding) at 365 days



Absolute difference: -4.7% 95%CI [-7.8%, -1.6%]
Hazard ratio: 0.50, 95%CI [0.31, 0.80]
P = 0.004 for superiority

No. of Patients (censored)

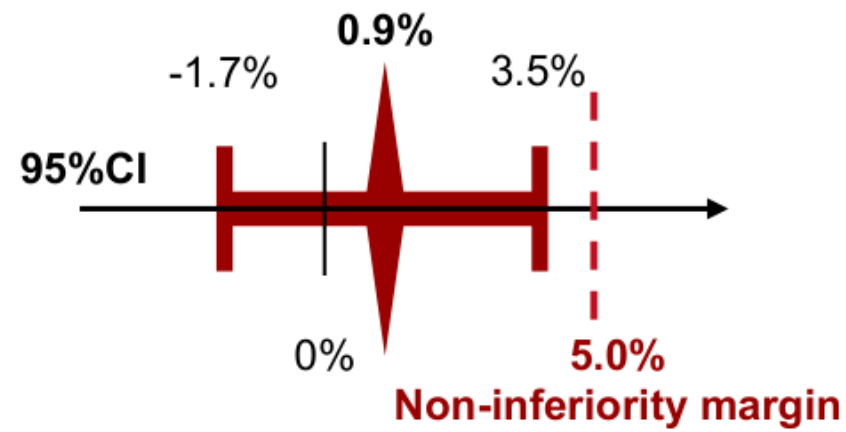
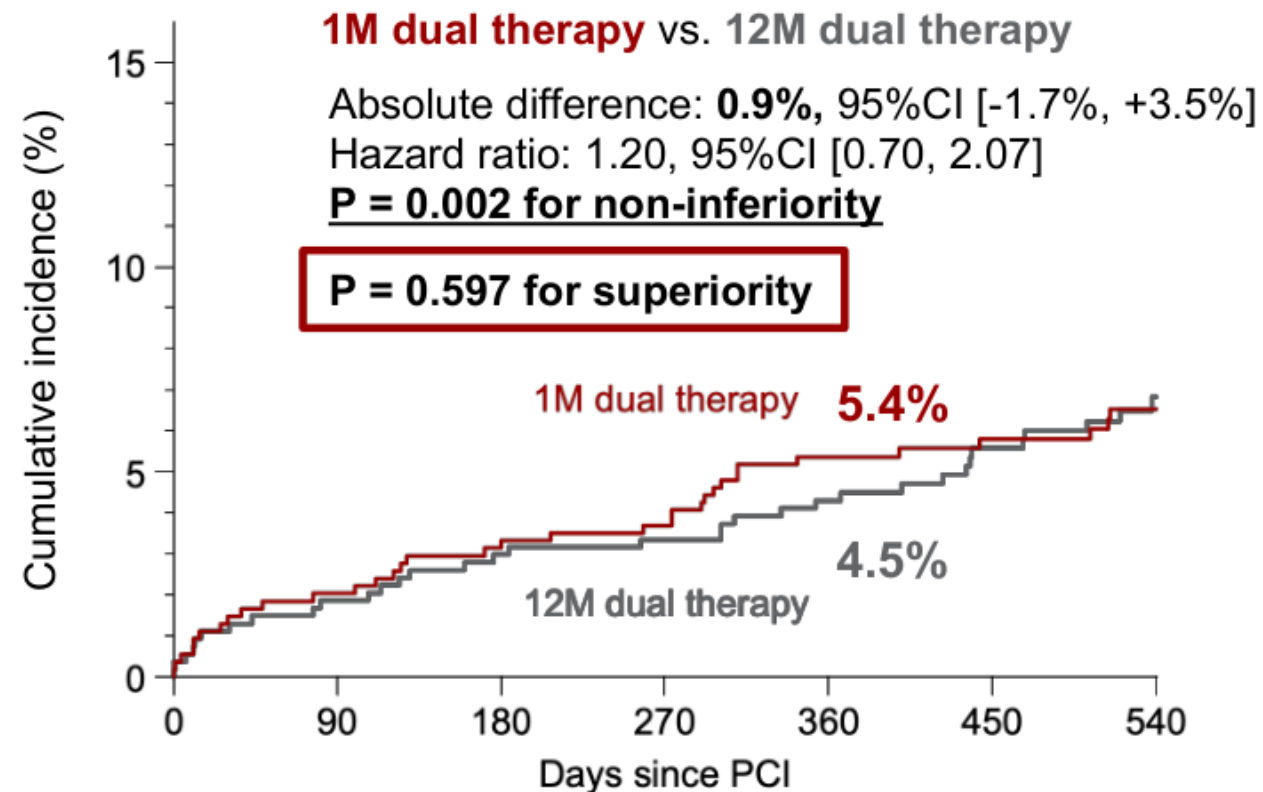
1M dual therapy	542(0)	522(4)	515(8)	511(11)	466(53)	411(104)	240(513)
12M dual therapy	537(0)	507(3)	498(5)	486(10)	445(46)	407(77)	236(478)



HYPOTHESIS 3

SUPERIORITY OF THE PRIMARY EFFICACY ENDPOINT

A composite of death or thromboembolic events (myocardial infarction, definite stent thrombosis, stroke, or systemic embolism) at 365 days.



No. of Patients (censored)

1M dual therapy	542(0)	531(1)	524(1)	520(3)	475(39)	423(89)	247(508)
12M dual therapy	537(0)	528(0)	521(1)	516(4)	477(38)	438(71)	258(503)



LIMITATIONS

- The open-label design posed a potential risk of reporting and performance bias.
- **Almost all PCI procedures in our trial were performed with intracoronary imaging guidance**, which may limit the generalizability of our findings to angiography-guided PCI.
- Although the trial met the prespecified non-inferiority margin, the observed event rate was substantially lower than expected, making the fixed absolute margin disproportionately large relative to the actual risk. Overall, the clinical profile appears acceptable. However, **the efficacy findings warrant cautious interpretation.**
- Our trial primarily involved **an East Asian population**, which is recognized for having a distinct predisposition to ischemic and bleeding complications compared with Western populations.

ZÁVĚR

1měsíční duální antitrombotická a antikoagulační léčba po PCI u pacientů s AF oproti 12 měsíčnímu režimu:

- je **non-inferiorní** z hlediska ischemických příhod
- a **významně** snižuje riziko krvácení

Velmi krátká duální terapie trvající jeden měsíc se jeví jako bezpečná a zároveň dostatečně účinná strategie.

Děkuji za pozornost!

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