Abstract



JAMA. 2013 Dec 18;310(23):2510-22. doi: 10.1001/jama.2013.282183.

# Three vs twelve months of dual antiplatelet therapy after zotarolimus-eluting stents: the OPTIMIZE randomized trial.

Feres F, Costa RA, Abizaid A, Leon MB, Marin-Neto JA, Botelho RV, King SB 3rd, Negoita M, Liu M, de Paula JE, Mangione JA, Meireles GX, Castello HJ Jr, Nicolela EL Jr, Perin MA, Devito FS, Labrunie A, Salvadori D Jr, Gusmão M, Staico R, Costa JR Jr, de Castro JP, Abizaid AS, Bhatt DL; OPTIMIZE Trial Investigators.

**Collaborators (183)**

## Abstract

**IMPORTANCE:** The current recommendation is for at least 12 months of dual antiplatelet therapy after implantation of a drug-eluting stent. However, the optimal duration of dual antiplatelet therapy with specific types of drug-eluting stents remains unknown.

**OBJECTIVE:** To assess the clinical noninferiority of 3 months (short-term) vs 12 months (long-term) of dual antiplatelet therapy in patients undergoing percutaneous coronary intervention (PCI) with zotarolimus-eluting stents.

**DESIGN, SETTING, AND PATIENTS:** The OPTIMIZE trial was an open-label, active-controlled, 1:1 randomized noninferiority study including 3119 patients in 33 sites in Brazil between April 2010 and March 2012. Clinical follow-up was performed at 1, 3, 6, and 12 months. Eligible patients were those with stable coronary artery disease or history of low-risk acute coronary syndrome (ACS) undergoing PCI with zotarolimus-eluting stents.

**INTERVENTIONS:** After PCI with zotarolimus-eluting stents, patients were prescribed aspirin (100-200 mg daily) and clopidogrel (75 mg daily) for 3 months (n = 1563) or 12 months (n = 1556), unless contraindicated because of occurrence of an end point.

**MAIN OUTCOMES AND MEASURES:** The primary end point was net adverse clinical and cerebral events (NACCE; a composite of all-cause death, myocardial infarction [MI], stroke, or major bleeding); the expected event rate at 1 year was 9%, with a noninferiority margin of 2.7%. Secondary end points were major adverse cardiac events (MACE; a composite of all-cause death, MI, emergent coronary artery bypass graft surgery, or target lesion revascularization) and Academic Research Consortium definite or probable stent thrombosis.

**RESULTS:** NACCE occurred in 93 patients receiving short-term and 90 patients receiving long-term therapy (6.0% vs 5.8%, respectively; risk difference, 0.17 [95% CI, -1.52 to 1.86]; P = .002 for noninferiority). Kaplan-Meier estimates demonstrated MACE rates at 1 year of 8.3% (128) in the short-term group and 7.4% (114) in the long-term group (HR, 1.12 [95% CI, 0.87-1.45]). Between 91 and 360 days, no statistically significant association was observed for NACCE (39 [2.6%] vs 38 [2.6%] for the short- and long-term groups, respectively; HR, 1.03 [95% CI, 0.66-1.60]), MACE (78 [5.3%] vs 64 [4.3%]; HR, 1.22 [95% CI, 0.88-1.70]), or stent thrombosis (4 [0.3%] vs 1 [0.1%];

HR, 3.97 [95% CI, 0.44-35.49]).

**CONCLUSIONS AND RELEVANCE:** In patients with stable coronary artery disease or low-risk ACS treated with zotarolimus-eluting stents, 3 months of dual antiplatelet therapy was noninferior to 12 months for NACCE, without significantly increasing the risk of stent thrombosis.

**TRIAL REGISTRATION:** clinicaltrials.gov Identifier: NCT01113372.

### Comment in

Antiplatelet therapy: DAPT for 3 months is sufficient. [Nat Rev Cardiol. 2014]
Dual antiplatelet therapy after stent implantation--reply. [JAMA. 2014]
Dual antiplatelet therapy after stent implantation. [JAMA. 2014]

PMID: 24177257 [PubMed - indexed for MEDLINE]

### Publication Types, MeSH Terms, Substances, Secondary Source ID

### LinkOut - more resources

## PubMed Commons

PubMed Commons home

0 comments

How to join PubMed Commons