JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 10, NO. 23, 2017

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2017.08.050

The DELTA 2 Registry

A Multicenter Registry Evaluating Percutaneous Coronary Intervention With New-Generation Drug-Eluting Stents in Patients With Obstructive Left Main Coronary Artery Disease

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ABSTRACT

OBJECTIVES The aim of this study was to evaluate clinical outcomes of unprotected left main coronary artery percutaneous coronary intervention (PCI) with new-generation drug-eluting stents in a "real world" population.

BACKGROUND PCI of the unprotected left main coronary artery is currently recommended as an alternative to coronary artery bypass grafting (CABG) in selected patients.

METHODS All consecutive patients with unprotected left main coronary artery stenosis treated by PCI with second-generation drug-eluting stents were analyzed in this international, all-comers, multicenter registry. The results were compared with those from the historical DELTA 1 (Drug Eluting Stent for Left Main Coronary Artery) CABG cohort using propensity score stratification. The primary endpoint was the composite of death, myocardial infarction (MI), or stroke at the median time of follow-up.

RESULTS A total of 3,986 patients were included. The mean age was 69.6 ± 10.9 years, diabetes was present in 30.8%, and 21% of the patients presented with acute MI. The distal left main coronary artery was involved in 84.6% of the lesions. At a median of 501 days (≈17 months) of follow-up, the occurrence of the primary endpoint of death, MI, or cerebrovascular accident was lower in the PCI DELTA 2 group compared with the historical DELTA 1 CABG cohort (10.3% vs. 11.6%; adjusted hazard ratio: 0.73; 95% confidence interval: 0.55 to 0.98; $p = 0.03$). Of note, an advantage of PCI was observed with respect to cerebrovascular accident (0.8% vs. 2.0%; adjusted hazard ratio: 0.37; 95% confidence interval: 0.16 to 0.86; $p = 0.02$), while an advantage of CABG was observed with respect to target vessel revascularization (14.2% vs. 2.9%; adjusted hazard ratio: 3.32; 95% confidence interval: 2.12 to 5.18; $p < 0.0001$).

CONCLUSIONS After a median follow-up period of 17 months, PCI with new-generation drug-eluting stents was associated with an overall low rate of the composite endpoint of death, MI, or cerebrovascular accident. (J Am Coll Cardiol Intv 2017;10:2401–10) © 2017 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass grafting

CI = confidence interval

CVA = cerebrovascular accident

DES = drug-eluting stent(s)

HR = hazard ratio

MACCE = major adverse cardiac and cerebrovascular events(s)

MI = myocardial infarction

PCI = percutaneous coronary intervention

TLR = target lesion revascularization

TVR = target vessel revascularization

ULMCA = unprotected left main coronary artery

Percutaneous treatment of unprotected left main coronary artery (ULMCA) disease evolved over time and currently is accepted as an alternative to coronary artery bypass grafting (CABG) in selected patients (1). In this challenging subset of patients, percutaneous coronary intervention (PCI) with drug-eluting stents (DES) has been demonstrated to be feasible and safe at midterm clinical follow-up (2–21).

The noninferiority of PCI compared with CABG in terms of major adverse cardiac and cerebrovascular events (MACCE) in patients with ULMCA disease was reported in the randomized SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) trial in the era of first-generation DES (22,23). Recently, the EXCEL (Evaluation of XIENCE Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) trial demonstrated the noninferiority of PCI with second-generation DES versus CABG in patients with ULMCA disease and intermediate to low SYNTAX scores with respect to death, cerebrovascular accident (CVA), or myocardial infarction (MI) at 3 years (24). Conversely, higher rates of the primary endpoint of death, CVA, MI, or any repeat coronary revascularization with PCI were reported in the NOBLE (Nordic-Baltic-British Left Main Revascularization Study) trial at 5 years of follow-up (25).

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Patterns of use and clinical outcomes of PCI with new-generation DES in real-world practice remain unclear. Therefore, the aim of the present study was to evaluate clinical outcomes of ULMCA PCI with second-generation DES in a "real world" setting and compare these with CABG from the historical DELTA 1 (Drug Eluting Stent for Left Main Coronary Artery) registry (2).

METHODS

The DELTA 2 registry included "all comers" patients with ULMCA disease treated with PCI and new-generation DES between March 2006 and December 2015 at 19 centers in 7 countries. New-generation DES included in the registry were the following: everolimus-eluting stents (XIENCE, Abbott Vascular, Santa Clara, California; PROMUS, Boston Scientific, Natick, Massachusetts; and SYNERGY Boston Scientific), zotarolimus-eluting stents [Endeavor, Resolute Integrity, and Resolute Onyx, Medtronic, Santa Rosa, California), biolimus-eluting stents (Nobori, Terumo, Tokyo, Japan; and BioMatrix, Biosensors, Newport Beach, California), and sirolimus-eluting stents (Ultimaster, Terumo; and Orsiro, Biotronik, Bülach, Switzerland).

At all institutions, patients were evaluated by both interventional cardiologists and cardiac surgeons, and the decision to perform PCI or CABG was made as in the DELTA 1 registry on the basis of: 1) hemodynamic conditions; 2) lesion characteristics; 3) vessel size; 4) the presence of comorbidities; 5) quality of arterial and/or venous conduits for grafting; and 6) patient and/or referring physician preferences. In all cases, the selected revascularization approach seemed suitable to guarantee complete revascularization (2). All data related to hospital admissions, procedures, and outcomes were collected at each center within the hospital recording network. Information on clinical status at the latest clinical follow-up was collected by clinical visits, telephone interviews, and referring physicians. Dual-antiplatelet therapy was administered according to hospital and physician practice. Angiographic follow-up was scheduled according to hospital practice or if a noninvasive evaluation or clinical presentation suggested ischemia.

DEFINITIONS. Study definitions of the DELTA 2 registry were consistent with the previously published DELTA 1 registry (2). The following events were analyzed cumulatively at the latest clinical follow-up available: all-cause and cardiac death, MI, CVA, target lesion revascularization (TLR), and target vessel revascularization (TVR). The occurrence of stent

Menarini, and Abbott Vascular. Dr. Stefanini has received institutional research grant support from Boston Scientific; and speaking and consulting fees from Boston Scientific, B. Braun, and Edwards Lifesciences. Dr. Erglis has received consulting fees and honoraria from Abbott Vascular, Biosensors, Biotronik, Boston Scientific, and Johnson & Johnson/Cordis. Dr. Mehran has received institutional research grant support from The Medicines Company, Bristol-Myers Squibb, Sanofi, Eli Lilly, and AstraZeneca; has received consulting fees from AstraZeneca, Bayer, CSL Behring, Janssen Pharmaceuticals, Merck, Osprey Medical, and Watermark Research Partners; serves on the advisory board of Abbott Laboratories, Boston Scientific, Merck, Covidien, Janssen Pharmaceuticals, The Medicines Company, and Sanofi; and is an equity owner of Claret Medical and Elixir Medical Corporation. Dr. Van Mieghem is a consultant for Abbott Vascular. Dr. Varbella is on the advisory board and has received lecture fees from AstraZeneca, Bayer, Daiichi-Sankyo, Pfizer, and Boehringer; and has received institutional research grants from Boston Scientific, Sanitex, Abbott, St. Jude Medical, Biotronik, and Cardia. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received May 15, 2017; revised manuscript received August 24, 2017, accepted August 25, 2017.