Comparison of Percutaneous Coronary Intervention (With Drug-Eluting Stents) Versus Coronary Artery Bypass Grafting in Women With Severe Narrowing of the Left Main Coronary Artery (from the Women−Drug-Eluting stent for LefT main coronary Artery disease Registry)

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Women typically present with coronary artery disease later than men with more unfavorable clinical and anatomic characteristics. It is unknown whether differences exist in women undergoing treatment for unprotected left main coronary artery (ULMCA) disease. Our aim was to evaluate long-term clinical outcomes in women treated with percutaneous coronary intervention (PCI) with drug-eluting stents versus coronary artery bypass grafting (CABG). All consecutive women from the Drug-Eluting stent for LefT main coronary Artery disease registry with ULMCA disease were analyzed. A propensity matching was performed to adjust for baseline differences. In total, 817 women were included: 489 (59.8%) underwent treatment with PCI with drug-eluting stents versus 328 (40.2%) with CABG. Propensity score matching identified 175 matched pairs, and at long-term follow-up there were no differences in all-cause (odds ratio [OR] 0.722, 95% confidence interval [CI] 0.357 to 1.461, p = 0.365) or cardiovascular (OR 1.100, 95% CI 0.455 to 2.660, p = 0.832) mortality, myocardial infarction (MI; OR 0.362, 95% CI 0.094 to 1.388, p = 0.138), or cerebrovascular accident (CVA; OR 1.200, 95% CI 0.359 to 4.007, p = 0.767) resulting in no difference in the primary study objective of death, MI, or CVA (OR 0.711, 95% CI 0.387 to 1.308, p = 0.273). However, there was an advantage of CABG in major adverse cardiovascular and cerebrovascular events (OR 0.429, 95% CI 0.254 to 0.723, p = 0.001), driven exclusively by target vessel revascularization (OR 0.185, 95% CI 0.079 to 0.432, p <0.001). In women with significant ULMCA disease, no difference was observed after PCI or CABG in death, MI, and CVA at long-term follow-up. **(Am J Cardiol 2014;113:1348−1355)**

Only a few reports have evaluated optimal revascularization strategies in women with coronary artery disease,[1,2] who typically present later than men with potentially more co-morbidities and unfavorable angiographic characteristics. Data are even more limited on outcomes of percutaneous coronary intervention (PCI) versus coronary artery bypass grafting (CABG) in women with complex coronary anatomy, including unprotected left main coronary artery (ULMCA)

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See page 1354 for disclosure information.

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0002-9149/14/$ - see front matter
http://dx.doi.org/10.1016/j.amjcard.2014.01.409

Table 1
Baseline clinical characteristics in the overall population

Variable	PCI (n = 489)	CABG (n = 328)	p Value
Age (yrs)	67.4 ± 12.6	67.9 ± 11.6	0.562
Hypertension	359 (73.4)	240 (72.9)	0.111
Hypercholesterolemia	323 (66.1)	232 (70.5)	0.680
Smoker	122 (24.9)	55 (16.7)	0.041
Diabetes mellitus	161 (32.9)	101 (30.7)	0.504
Chronic kidney disease	28 (5.7)	9 (2.7)	0.044
Unstable angina pectoris	160 (32.7)	163 (49.5)	<0.001
Non−ST elevation myocardial infarction	66 (13.5)	34 (10.4)	0.181
ST elevation myocardial infarction	10 (2.0)	2 (0.6)	0.094
Previous CABG	51 (10.4)	13 (4.0)	0.001
Previous PCI	123 (25.2)	48 (14.6)	<0.001
Left ventricular ejection fraction	54.8 ± 12.2	54.5 ± 11.0	0.731
EuroSCORE	5.6 ± 4.0	5.4 ± 2.6	0.395

Results are expressed as n (%) or mean ± SD as appropriate.

Hypertension is defined as a sustained systolic pressure of >140 mm Hg or a diastolic pressure of >90 mm Hg, requiring antihypertensive therapy. Hypercholesterolemia is defined as total cholesterol >240 mg/dl, requiring lipid-lowering treatment.

EuroSCORE = European System for Cardiac Operative Risk Evaluation.

disease.[1,2] In general, women are largely underrepresented in randomized clinical trials; specifically, in the Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery (SYNTAX) trial, in the ULMCA subgroup, women made up 10.3% of the overall population.[3] Registries are hence the ideal setting to appraise the comparative effectiveness of different procedures in patients who are not adequately represented in randomized clinical trials. The aim of the present study was to evaluate if women had improved long-term clinical outcomes after ULMCA revascularization using PCI with drug-eluting stents (DES) compared with CABG, from the large Drug-Eluting stent for LefT main coronary Artery disease (DELTA) registry.

Methods

The DELTA registry included consecutive "all comers" with ULMCA disease treated in 14 multinational centers, by either PCI with DES or CABG, from April 2002 to April 2006.[4] The W-DELTA is a subset analysis focusing on women from the DELTA registry.

Patients enrolled in the registry were evaluated by a multidisciplinary team including interventional cardiologists and cardiothoracic surgeons, and the choice of technique was deemed suitable to ensure complete revascularization. The decision was based on (1) the hemodynamic state, (2) lesion characteristics, (3) vessel size, (4) co-morbidities, (5) quality of arterial and/or venous conduits for grafting, and (6) patient and/or referring physician preference. Coronary angioplasty and stent implantation, including bifurcation strategy in the case of distal disease, were performed according to the operator's preference with the aim of complete coverage of the diseased segment.

The use of dual antiplatelet therapy was recommended for at least 12 months in all patients undergoing PCI, consisting of aspirin 100 mg/day and clopidogrel 75 mg/day or ticlopidine 250 mg twice daily. Aspirin 100 mg/day was continued indefinitely thereafter. In the Korean center, cilostazol was additionally prescribed. Information regarding compliance was obtained in all patients. Angiographic follow-up was not mandatory unless there were clinical symptoms or subjective evidence of ischemia on functional testing.

All data relating to hospital admission, procedures, and follow-up were collected and adjudicated in each center according to local policy. Full written informed consent was obtained for the procedure and for subsequent data collection.

The events analyzed during hospital stay and at clinical follow-up were death, both all-cause and cardiovascular, myocardial infarction (MI), cerebrovascular accident (CVA), target lesion revascularization (TLR), and target vessel revascularization (TVR). Major adverse cardiovascular and cerebrovascular event (MACCE) was defined as a composite of death, MI, CVA, and TVR.[4] The primary study objective was the composite of death, MI, and CVA at long-term follow-up (1,185 days). The secondary study objectives were MACCE and each of the individual components of death, CVA, MI, and TVR at long-term follow-up.

Continuous variables are expressed as mean ± SD and were analyzed with the Student *t* test or Wilcoxon rank sum test depending on the variable distribution. Categorical variables were compared with the chi-square test with Yates' correction for continuity or Fisher's exact test, as appropriate.

Because of the nonrandomized nature of the study, to reduce the effect of treatment selection bias and potential confounding in this observational study, we performed rigorous adjustment for significant differences in the baseline characteristics of patients with propensity score matching. A propensity score was calculated by performing a parsimonious multivariate logistic regression using the following covariants: age, family history, hypertension, hypercholesterolemia, smoker, diabetes mellitus, unstable angina, left ventricular ejection fraction, chronic kidney disease, previous PCI, previous CABG, multivessel disease, right coronary artery disease, and distal disease. The C-statistic for the propensity score model was 0.77,