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Original Studies

Comparative Long-Term Efficacy and Safety of Drug-Eluting Stent Versus Coronary Artery Bypass Grafting in Ostial Left Main Coronary Artery Disease: Analysis of the MAIN-COMPARE Registry

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Background: To date, drug-eluting stent (DES) implantation has not been compared with coronary artery bypass grafting (CABG) for ostial left main coronary artery (LMCA) lesions. Methods: Of the 263 patients in the MAIN-COMPARE registry with ostial LMCA stenosis, 123 were treated with percutaneous coronary intervention (PCI) with DES and 140 with CABG. We compared their 5-year overall survival, composite outcomes of death, Q-wave myocardial infarction (MI) or stroke, and target vessel revascularization (TVR) rates. Results: Unadjusted analysis showed no significant differences between CABG and DES in overall survival rates (95% confidence interval (CI) for hazard ratio (HR): 0.44 to 1.77, $P = 0.71$), composite outcomes (death, Q-wave MI, or stroke)-free survival rates (95% CI for HR: 0.41–1.63, $P = 0.56$), and TVR-free survival rates (95% CI for HR: 0.79–5.03, $P = 0.14$). Multivariate adjusted Cox regression analysis also showed no significant between-group differences in TVR (95% CI for HR: 0.52–3.79, $P = 0.49$), death (95% CI for HR: 0.79–2.82, $P = 0.22$) and the composite of death, Q-wave MI, or stroke (95% CI for HR: 0.65–2.57, $P = 0.46$). These results were sustained after propensity score adjustment and propensity score matching analysis. Conclusions: DES implantation for ostial LMCA lesions showed similar 5-year outcomes of death, major adverse events, and TVR compared with CABG. Although meticulous adjustments decreased baseline difference between the two treatments, the absence of statistical significance could be attributable to the size of the study sample and hidden bias.

Key words: drug-eluting stent; coronary artery bypass graft; ostial left main coronary artery

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INTRODUCTION

Although aorto-ostial coronary lesions are one of the complex anatomical subsets of percutaneous coronary intervention (PCI), ostial left main coronary arteries (LMCA) have several advantages, including large lumen diameter and less concerns for plaque shift and subsequent stenosis, compared with non-LMCA ostial lesions. Thus, in LMCA disease, nonbifurcation lesions, including ostial and mid shaft lesions, showed favorable outcomes after PCI compared with distal bifurcation lesions [1–3]. Aorto-ostial lesions, however, have certain features, including lesion rigidity and elastic recoil, which may yield suboptimal results and poor long-term outcomes. Thus ostial LMCA disease still remains more challenging for PCI than mid shaft LMCA disease [4].

Drug-eluting stent (DES) implantation for LMCA has been associated with acceptable procedural risks and long-term survival [3–10]. Moreover bifurcations involving the LMCA lesions are more challenging to treat and have a higher rate of revascularization. In contrast to bifurcation LMCA lesions, nonbifurcation LMCA lesions have shown excellent outcomes after introduction of DES [7,11]. These findings, however, were deduced from comparisons of bare-metal stents (BMS) and DES, [12,13] and there have been no studies dedicated to ostial LMCA lesions. Moreover, DES has not been directly compared with coronary artery bypass grafting (CABG), the current standard of treatment for ostial LMCA lesions [14]. We therefore evaluated the long-term (5-year) outcomes of ostial LMCA treated with DES implantation or CABG in patients included in the MAIN-COMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularization) study, which was a nonrandomized trial [5].

METHODS

Patients and Procedures

The protocol of the MAIN-COMPARE study has been described [3]. Briefly, the study enrolled patients with unprotected LMCA stenosis who underwent either CABG or PCI as the index procedure at 12 major cardiac centers in Korea between January 2000 and June 2006. From January 2000 through May 2003, coronary stenting was performed exclusively with bare-metal stents, whereas from May 2003 through June 2006, exclusively drug-eluting stents were used. This study evaluated patients who underwent DES implantation or CABG for ostial lesions of LMCA. All procedures were performed with standard interventional techniques. Use of intravascular ultrasound (IVUS), predilatation, or an intraaortic balloon pump was at the discretion of the operator. Antiplatelet therapy and periprocedural anticoagulation followed standard regimens. Before or during the procedure, patients were administered loading doses of aspirin (300 mg) and clopidogrel (300 or 600 mg) or ticlopidine (500 mg), unless they had previously received antiplatelet medications. After the procedure, patients were maintained on aspirin (100–200 mg once daily) and clopidogrel (75 mg once daily) or ticlopidine (250 mg twice daily) for at least 6 months after DES. This study was approved by the local ethics committee at each hospital. Written informed consent was obtained from all patients for the use of their data.

Primary Outcomes and Definitions

Clinical outcomes were censored at 5 years to reduce followup bias. The primary end point was the composite of death, Q-wave myocardial infarction (MI) or stroke, and target vessel revascularization (TVR) for 5 years after the index procedure. Death was defined as death from any cause. Q-wave MI was defined as the documentation of a new abnormal Q wave after the index revascularization. Stroke was confirmed by a neurologist on the basis of imaging analyses. TVR was defined as repeat revascularization of the treated vessel, including any segments of the left anterior descending artery and the left circumflex artery [3]. For systematic risk stratification before the procedure, standard European System for Cardiac Operative Risk Evaluation (EuroSCORE) was measured, with a score ≥ 6 defined as high risk [13,14].

Statistical Analysis

Categorical variables are presented as raw numbers, and percentages and were compared with the chi-square test and Fisher's exact test. Continuous variables are presented as mean $\pm$ standard deviation and were compared by Student's *t*-test. Kaplan-Meier analysis was used to determine event-free survival rate, and the difference between groups were analyzed by log-rank test. For adjustment of baseline differences in patient characteristics, we performed a multivariable Cox proportional hazards regression modelsPatients' demographics, risk factors, coexisting conditions, left ventricular function, and clinical indications were adjusted. We observed that some of variables such as syntax scores, hypertension and previous heart failure indication had missing values. In particular, about 23% of syntax score values in the data were missing. Because syntax score is a clinically meaningful variable, we decided to use the syntax score variable by

TABLE I. Baseline Characteristics of the DES and CABG Groups

Variable	DES ($n = 123$)	CABG ($n = 140$)	P value
Clinical characteristics			
Age (years), mean ± SD	59 ± 13	63 ± 10	0.01
Men (%)	69 (56)	95 (68)	0.05
Diabetes mellitus (%)	32 (26)	50 (36)	0.09
Hypertension (%)	54 (44)	68 (49)	0.39
Body mass index (kg/m^2)	24 ± 3	24 ± 3	0.79
Current smoker (%)	30 (24)	36 (26)	0.81
Hypercholesterolemia (%)	31 (25)	38 (27)	0.72
Chronic lung disease (%)	3 (2.4)	1 (0.7)	0.34
Previous PCI (%)	19 (15)	12 (8.6)	0.08
Previous heart failure (%)	3 (2.4)	7 (5.0)	0.35
Previous stroke (%)	5 (4.1)	7 (5.0)	0.72
Peripheral artery occlusive disease (%)	1 (0.8)	5 (3.6)	0.22
Acute coronary syndrome (%)	66 (54)	107 (76)	<0.001
Syntax Score	22.1(11.6)	39.3(14.9)	<0.001
Renal failure (%)	3 (2.4)	8 (5.7)	0.18
Medications			
Aspirin (%)	122 (99)	131 (94)	0.02
Clopidogrel or Ticlopidine (%)	116 (94)	105 (75)	<0.001
GP IIb/IIIa inhibitor (%)	3 (2.4)	2 (1.4)	0.67
Warfarin (%)	1 (0.8)	9 (6.4)	0.02
Statin (%)	67 (55)	56 (40)	0.02
Beta blocker (%)	91 (74)	94 (68)	0.26
ACEI or ARB (%)	50 (41)	66 (47)	0.29
Calcium channel blocker (%)	75 (61)	96 (69)	0.20

All results for continuous or categorical variables were presented as mean ± standard deviation (SD) or frequency (%).

CABG, coronary artery bypass graft; DES, drug-eluting stent; SD, standard deviation; PCI, percutaneous coronary intervention; GP, glycoprotein; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

resorting to a multiple imputation method. Imputing incomplete multivariate data was conducted by fully conditional specification approach which specifies a multivariate imputation model on a variable-by-variable basis by a set of conditional densities. Because the multivariate imputation model uses a certain chained equations instead of MCMC type techniques, it is computationally fast. Furthermore, propensity-score methods using covariate adjustment and matching technique were used to reduce selection bias and potential confounding. Propensity scores were estimated from a logistic regression model for DES implantation versus CABG. The discrimination and calibration ability of the propensity score model was assessed using the *C*-statistic and the Hosmer-Lemeshow statistic. For propensity-covariate adjustment, individual propensity scores were incorporated into Cox proportional hazards regression models as a covariate to calculate the adjusted hazard ratios (HR). Propensity matching was done with the Greedy algorithm, and comparisons were completed with Cox regression models, with robust standard errors that accounted for the clustering of matched pairs. The details of the propensity-score matching and analytic methods have been described previously [5]. All analyses were performed on a per patient basis. A probability value <0.05 was considered statistically significant. All statistical analyses were conducted in the statistical software R. Especially we used R packages of MatchIt and Mice for the propensity score matching and the multiple imputations

RESULTS

Baseline and Procedural Characteristics

Among the 2,240 patients in MAIN-COMPARE registry, 422 (19%) had been treated for ostial LMCA lesions, including 282 with PCI and 140 with CABG. In the PCI group, 159 (56%) patients received BMS and 123 (44%) received DES. Of the latter 103 (84%) received sirolimus-eluting stents and 20 (16%) received paclitaxel-eluting stents. Among 123 DES group, 103 (84%) patients underwent intravascular ultrasound guided PCI. The mean stent length was 18 ± 13 mm, and the average stent diameter was 3.4 ± 0.2 mm. The mean total number of stents implanted (including left main and other vessels) was 1.8 ± 1.2. IVUS were used in 86% (106/123) of patients.

In the CABG group, 57 patients (41%) underwent off-pump surgery and 138 (99%) received at least one arterial conduit. The average number of grafts used per patient was 2.9 ± 1.0 (2.1 ± 0.9 arterial grafts and 0.8 ± 0.8 venous grafts).

The baseline characteristics according to revascularization procedure are shown in Table I. Patients undergoing CABG were significantly older (63 ± 10 years vs. 59 ± 13 years, $P = 0.01$), had lower ejection fractions (56% ± 13% vs. 59% ± 12%, $P = 0.05$), and were more likely to present with acute coronary syndrome. Table II shows procedural characteristics of the two patient groups. Incidence of three-vessel disease or involvement of the right coronary artery was higher in patients with CABG. Patients receiving DES had tougher lesion characteristics. The percentage of patients with a EuroSCORE ≥ 6 did not differ significantly. The median followup was 4.3 ± 0.9 years in the DES group and 4.3 ± 1.3 years in the CABG group. In-hospital stay was significantly longer in the CABG group (19 ± 12 days vs. 5.9 ± 4.6 days, $P <$ 0.001). Following propensity-score matching for the entire population, we identified a total of 60 matched-pairs. In this matched cohort, there was no longer any significant difference between the DES and CABG groups in any covariate.

TABLE II. Procedural Characteristics of the DES and CABG Groups

Variable	DES ($n = 123$)	CABG ($n = 140$)	P value
EuroSCORE	3.7 ± 2.2	4.5 ± 2.3	0.003
EuroSCORE ≥ 6 (%)	25 (20)	40 (29)	0.12
Peak CK-MB	13 ± 32	41 ± 53	<0.001
Extent of diseased vessel			<0.001
Left main only (%)	47 (38)	18 (13)	
Left main plus one-vessel disease (%)	25 (20)	15 (11)	
Left main plus two-vessel disease (%)	24 (20)	27 (19)	
Left main plus three-vessel disease (%)	27 (22)	80 (57)	
Right coronary artery disease (%)	41 (33)	98 (70)	<0.001
Lesion length of left main (mm)	6.9 ± 3.1	4.6 ± 3.3	<0.001

All results for continuous or categorical variables were presented as mean ± standard deviation (SD) or frequency (%).

CABG, coronary artery bypass graft; DES, drug-eluting stent; SD, standard deviation

TABLE III. Unadjusted and Adjusted Hazard Ratios of Clinical Outcomes of DES Compared With CABG

		DES vs. CABG	
Outcomes	Event/total	Hazard ratio (95% confidence interval)	P value
Unadjusted			
Death	32/263	0.88 (0.44–1.77)	0.71
Death/QMI/stroke	34/263	0.82 (0.41–1.63)	0.56
TVR	19/263	1.99 (0.79–5.03)	0.14
Death/QMI/stroke/TVR	53/263	1.09 (0.64–1.88)	0.74
Multivariable adjusted			
Death	32/263	1.49 (0.79–2.82)	0.22
Death/QMI/stroke	34/263	1.30 (0.65–2.57)	0.46
TVR	19/263	1.41 (0.52–3.79)	0.49
Death/QMI/stroke/TVR	53/263	1.59 (0.94–2.68)	0.09
Propensity score adjusted			
Death	32/263	1.29 (0.47–3.54)	0.62
Death/QMI/stroke	34/263	1.22 (0.47–3.15)	0.68
TVR	19/263	3.43 (0.65–18.19)	0.15
Death/QMI/stroke/TVR	53/263	1.78 (0.78–4.09)	0.17
Propensity score matching			
Death	9/78	2.01 (0.47–8.57)	0.35
Death / QMI / stroke	10/78	1.46 (0.38–5.56)	0.58
TVR	6/78	1.94 (0.33–11.38)	0.46
Death/QMI/stroke/TVR	16/78	1.60(0.59–4.29)	0.35

TVR, target vessel revascularization; TLR, target lesion revascularization; QMI, Q-wave myocardial infarction.

Five-Year Outcomes

During the 5 years of followup, 32 (12%) patients (14 in the DES group and 18 in the CABG group) died, whereas 19 (7.2%) underwent TVR (12 in the DES group and 7 in the CABG group). Composite outcomes occurred in 34 (13%) patients (14 in DES group and 20 in CABG group). Both crude and multivariable adjusted Cox regression analysis showed no significant between group differences in the rates of death, TVR, the composite of death, Q-wave MI or stroke, and the composite of death, Q-wave MI, stroke, or TVR (Table III). Overall survival rates ($P = 0.71$, Fig. 1A), composite outcome-free survival rates ($P = 0.56$, Fig. 1B), and TVR-free survival rates ($P = 0.14$, Fig. 1C) were similar in the DES and CABG groups. Even after adjustment for propensity score and propensity-score matching (Supporting Information Appendix), the death, TVR, and composite outcome rates did not differ significantly (Table III). Propensity-adjusted survival curves were shown in Fig. 2.

DISCUSSION

Using rigorous adjustments, we found no significant differences in long-term survival rates and the composite outcome of death, Q-wave MI, or stroke in patients treated with DES implantation and CABG for ostial LMCA lesions. In addition, the rates of TVR were similar in the two groups, a novel finding compared with other studies in LMCA patients. To our knowledge, this study is the first to demonstrate that an anatomical subgroup of patients with LMCA, ostial lesions, shows comparable long-term outcomes for TVR, death, and composite outcomes in patients treated with DES and CABG.

There were no differences between patients with bifurcation LMCA lesions and those with ostial and mid shaft LMCA lesions treated with one stent [3]. Furthermore, a meta-analysis of patients undergoing DES for LMCA lesions showed a wide variation in clinical outcomes among trials according to clinical and angiographic characteristics [9]. Of nonbifurcation LMCA lesions treated with PCI, ostial lesions are more challenging than mid shaft LMCA lesions owing to lesion rigidity and elastic recoil. Therefore, there is an increasing need to determine optimal treatments for patients with ostial LMCA lesions, and that is the reason why we limited our analysis to ostial disease only rather than ostial and shaft disease as in most studies.

Results from the MAIN-COMPARE registry showed similar composite outcomes for DES and CABG [5]. Therefore, our findings suggest that DES implantation in LMCA lesions, including ostial lesions, may be an effective alternative therapeutic option in patients with suitable anatomy for PCI.

Results from the MAIN-COMPARE registry showed that CABG was more effective than DES in reducing the need for TVR. In contrast, we found no difference in TVR rate between the DES and CABG groups in patients with ostial LMCA lesions. Ostial LMCA lesions have several advantages, including large lumen

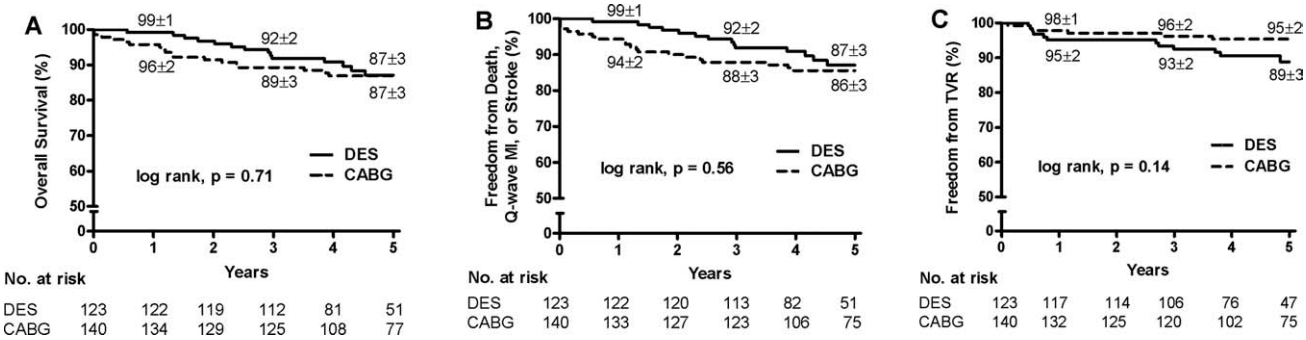

Fig. 1. Kaplan-Meier comparisons of 5-year outcomes in the DES and CABG groups. Unadjusted (A) overall survival rates; (B) freedom from death, Q-wave myocardial infarction, or stroke; (C) freedom from target-vessel revascularization. CABG, coronary-artery bypass grafting; DES, drug-eluting stent; MI, myocardial infarction; TVR, target-vessel revascularization.

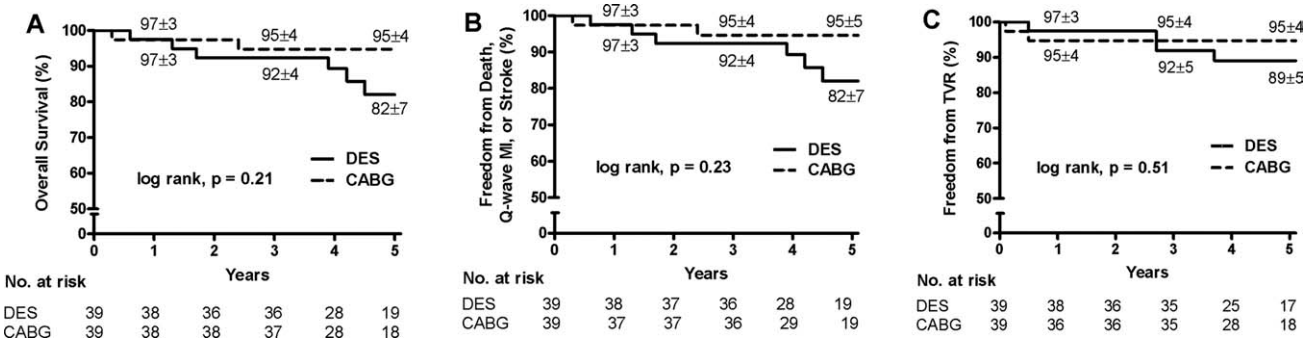

Fig. 2. Kaplan-Meier comparisons of 5-year outcomes in the DES and CABG groups matched for propensity scores. (A) overall survival rates; (B) freedom from death, Q-wave myocardial infarction, or stroke; (C) freedom from target-vessel revascularization. CABG, coronary-artery bypass grafting; DES, drug-eluting stent; MI, myocardial infarction; TVR, target-vessel revascularization.

diameter and no concerns about plaque shift and subsequent stenosis after stenting compared with other aorto-ostial lesions. Moreover, ostial LMCA lesions are usually treated with single/simple stenting, which may partially explain the comparable TVR rates we observed in the PCI and CABG groups. A previous study, although not exclusive to patients with ostial LMCA lesions, found that most restenosis occurred in patients with bifurcation LMCA lesions [15]. Similarly, the risk of TVR was found to be significantly lower in nonbifurcation than in bifurcation stenosis (3% versus 13%) [2]. A multicenter observational study of 147 patients with unprotected nonbifurcation LMCA lesions (77 ostial, 41 shaft, and 29 ostial and shaft lesions) demonstrated favorable long-term outcomes with DES [11]. Procedural success was achieved in 99% of patients, and none experienced Q-wave MI or died during hospitalization. The mean late lumen loss in the 106 patients who underwent angiographic followup at 4–6 months was only 0.01 mm, and restenosis occurred in only one patient (0.9%). At a mean followup of 886 days, there were five deaths (3.4% cumulative mortality) and seven TVRs (4.7%); of the latter, only one patient had a target lesion revascularization. These findings were in good agreement with the comparable rate of TVR we observed in our DES and CABG groups.

The MAIN-COMPARE registry is the largest multicenter cohort for LMCA lesions. In performing a subgroup analysis of patients with ostial lesions, we found that, compared with CABG, DES implantation had similar clinical outcomes for TVR, mortality, and the composite outcome of death, Q-wave MI, or stroke. These findings provide reasonable evidence for PCI in patients with LMCA lesions.

The major limitation of this study was that we evaluated observational data, with treatment strategy not based on randomized assignment. The choice of revascularization was at the discretion of the treating physician and/or patient. Analytically, our findings may be subject to selection bias and confounding with respect to the relative severity of preprocedural risks among patients who underwent PCI and CABG. To minimize these possible biases, we used several statistical

methods. Nevertheless, hidden bias may remain because of the influence of unmeasured confounders. A final caveat is that, although this study is the first to compare DES with CABG for ostial LMCA lesions, the sample size was relatively small. Thus our analysis was underpowered to detect clinically significant differences in TVR and composite outcomes. Given these issues and the findings of our study, we believe that a randomized trial comparing DES versus CABG is warranted in a larger population of individuals with ostial unprotected left main disease, who are candidates for revascularization.

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