Previous cerebrovascular disease is an important predictor of clinical outcomes in elderly patients with percutaneous coronary interventions: The Nobori-Biolimus eluting stent prospective multicenter 1-year observational registry in South Korea

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ABSTRACT

Objective: The appropriate selection of elderly patients for revascularization has become increasingly important because these subsets of patients are more likely to experience a major cardiac or cerebrovascular event—percutaneous coronary intervention (PCI). The objective of this study was to determine important independent risk factor for predicting clinical outcomes in the elderly patients after successful PCI, particularly in a series of South Korean population.
Methods: This study is prospective, multicenter, observational cross-sectional study. A total of 1,884 consecutive patients who underwent successful PCI with Nobori® Biolimus A9-eluting stents were enrolled between April 2010 and December 2012. They were divided into two groups according to the age: patients <75 years old (younger patient group) and ≥75 years old (elderly patient group). The primary endpoint was major adverse cardiac or cerebrovascular events (MACCE) at 1-year after index PCI.
Results: The 1-year cumulative incidence of MACCE (12.9% vs. 4.3%, p<0.001) and total death (7.1% vs. 1.5%, p<0.001) was significantly higher in the elderly group than in younger group. Previous cerebrovascular disease was significantly correlated with MACCE in elderly patients 1-year after PCI (hazard ratio, 2.804; 95% confidence interval, 1.290–6.093 p=0.009).
Conclusion: Previous cerebrovascular disease is important independent predictor of the MACCE in elderly patients at 1-year after PCI with Nobori® Biolimus A9-eluting stents especially in a series of South Korean population. Therefore, careful PCI with intensive monitoring and management can improve major clinical outcomes after successful PCI in elderly patients with previous cerebrovascular disease compared with younger patients. *(Anatol J Cardiol 2017; 18: 128-35)*
Keywords: Biolimus A9-eluting stent, clinical outcome elderly patients, percutaneous coronary intervention

Introduction

The number of elderly people is increasing rapidly, as life expectancy increases and overall health improves. Age is one of the major important cardiovascular risk factor, and coronary artery disease (CAD) is the most common cause of death in the elderly (1). Elderly patients have a high prevalence of calcified lesions, tortuous lesions, multi-vessel disease, and left main coronary artery stenosis (2). In the past, elderly patients who had undergone elective percutaneous coronary intervention (PCI) showed lower procedural success rates and higher complication rates (3–5). Notwithstanding the high-risk aspects of PCI, advances in PCI device technology and im-provements in medical therapy have reduced the adverse cardiovascular event rates after PCI in elderly patients (6, 7). PCI is being increasingly performed on elderly patients because of acceptable periprocedural outcomes and long-term survival rates (8).

However, the efficacy of PCI in elderly patients has not been well studied because elderly patients are less commonly enrolled in randomized, controlled clinical trials, and observational studies include only relatively small numbers of elderly patients. The appropriate selection of elderly patients for revascularization is become increasingly important because these subsets of patients are more likely to experience a major cardiac or cerebrovascular event after PCI.

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We aimed to investigate an important determinant risk factor that might predict clinical outcomes following successful PCI with Nobori® Biolimus A9-eluting stents in elderly patients during the 1-year follow-up period, particularly in a series of South Korean population.

Methods

This study was a prospective, multicenter, observational single-arm study that gathered data from 20 centers in South Korea that performed PCI using Nobori stents (Nobori® Biolimus-eluting stent, Terumo, Tokyo, Japan). The Nobori® stent is a new-generation drug-eluting stent (DES) that comprises a stainless steel alloy stent with a strut thickness of 120 μm that is coated on the abluminal surface with a matrix containing the highly lipophilic sirolimus analog, Biolimus A9, and a biodegradable poly-lactic acid polymer (9).

The definition of an elderly person varies among different studies, and while there is no consensus about who should be considered elderly, the 2002 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the management of acute coronary syndromes consider patients aged >75 years to be an "at-risk" group (10).

Detailed patient data were collected from each hospital by a study coordinator or physician who entered the data into a web-based, computerized database. Information about a patient's clinical status at the most recent follow-up assessment was gathered through clinic visits and/or telephone interviews. One year after the index procedure, all patients who had undergone PCI were advised to undergo angiographic follow-up assessments.

All patients provided written informed consent to participate in this study. The study protocol was reviewed and approved by the institutional review boards of the participating centers.

Study population

From April 2010 to December 2012, a total of 2,012 consecutive patients who underwent successful PCI were enrolled in this study. Among them, 128 patients were excluded because of death, follow-up loss, and not participating (Fig. 1). The remaining 1,884 patients (93.6%) completed 1-year follow-up. We classified them into either younger group (aged <75 years, n=1,519) or the elderly group (aged ≥75 years, n=365). This was an "all-comers" trial of routine clinical practice undertaken in a real-world setting.

PCI procedure and medical treatment

A diagnostic coronary angiography (CAG) and PCI were done through either the femoral or radial artery after an administration of unfractionated heparin (70–100 IU/kg). Patient's activated clotting time was maintained above 250 s during the procedure. Revascularization was considered clinically indicated when the patient had angina and/or signs of ischemia and ≥50% diameter
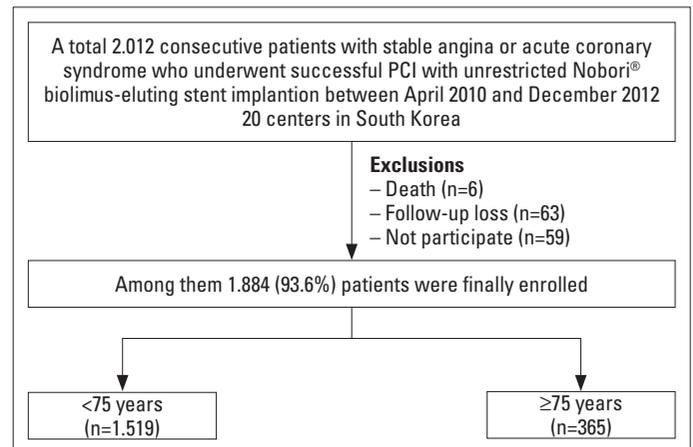
Figure 1. Flowchart of the study patients
PCI - percutaneous coronary intervention

restenosis by angiography or ≥70% diameter restenosis even in the absence of signs and symptoms. The use of cilostazol - Pletaal® (Otsuka Pharmaceutical Co., Tokyo, Japan) or platelet glycoprotein IIb/IIIa receptor blockers was left to the discretion of the individual operators. A successful PCI was defined as the achievement of an angiographic residual stenosis less than 30% and final thrombolysis in myocardial infarction (MI) blood flow grade equal to 3. During hospitalization, enrolled patients had taken cardiovascular beneficial medications, including beta-blockers (BB), angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), calcium channel blockers (CCB), and lipid-lowering agents. After discharge, the patients were encouraged to stay on the same medications they received during hospitalization. Dual anti-platelet therapy, which was the combination of aspirin (100 mg/day) and clopidogrel (75 mg/day), was administered for at least 12 months to patients who had undergone PCI.

Study definitions and clinical follow-up

Patients with systolic blood pressure of at least 140 mm Hg or diastolic blood pressure of at least 90 mm Hg or who were taking antihypertensive medications were defined as having hypertension. Patients with serum low-density lipoprotein cholesterol concentrations of at least 140 mg/dL, high-density lipoprotein cholesterol concentrations <40 mg/dL, triglyceride concentrations were ≥150 mg/dL, or patients who were taking lipid-lowering medication were defined as having dyslipidemia (11). Patients whose fasting blood glucose concentrations were at least 126 mg/dL and/or whose hemoglobin A1c levels were at least 6.5% for at least 1 year before drug or dietary interventions and before they were enrolled in this study or those who were taking anti-diabetic medications were defined as diabetic. Peripheral vascular disease was diagnosed on the basis of the ankle-brachial pressure index (<0.9) or computed tomographic angiographic findings. Renal dysfunction was defined as an estimated glomerular filtration rate (GFR) of <60 mL/min/1.73 m^2.

The recordings of cardiovascular risk factors and past medical histories were based on patient self-report. All deaths were

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classified cardiac in origin unless a non-cardiac cause could be documented. MI was defined as the presence of clinical symptoms, electrocardiographic changes, or abnormal imaging findings of MI, combined with an increase in the creatine kinase myocardial band fraction above the upper normal limits or an increase in troponin-T/troponin-I to greater than the 99th percentile of the upper normal limit. Target lesion revascularization (TLR) was defined as a revascularization of the target lesion due to restenosis or reocclusion within the stent or 5 mm in and adjacent of the distal or proximal segment. Target vessel revascularization (TVR) was defined as revascularization of the target vessel or any segment of the coronary artery containing the target lesion. The primary endpoint of this study was major adverse cardiac or cerebrovascular events (MACCE) at 1 year. Major adverse cardiac events (MACE) were defined as the composite of total death, non-fatal MI, TLR, TVR, and non-TVR. All participants were required to visit the outpatient department of cardiology at the end of the first month and then every 3 to 6 months after the index PCI procedure as well as whenever angina-like symptoms occurred. The cumulative incidence of various MACCE during 1 year was compared between the 2 groups. In this study, all patients completed 1-year clinical follow-up through face-to-face interviews at the outpatient clinic, medical chart review, and telephone contacts. In some ambiguous cases, we compared patient's biological information with data from the Korean National Statistical Office.

Statistical analysis

PASW Statistics for Windows, Version 18.0 (SPSS Inc., Chicago, IL, USA) was used for all statistical analyses. Continuous variables were presented as means±standard deviations or as medians (interquartile ranges) and were compared using Student's t test or Mann–Whitney U test after appropriate testing for normal distributions. Categorical variables, presented as numbers and percentages, were compared using the chi-square test on the basis of an expected frequency of >5, Fisher's exact test, or Pearson's chi-square test, as appropriate. Univariate and multivariate logistic regression analyses were performed to determine the risk factors associated with the adverse events. Two-tailed p values <0.05 were considered statistically significant. Cox proportional hazards regression was used to determine the independent predictors of 1-year mortality and MACCE.

Results

A total of 1,884 consecutive patients who underwent successful PCI with Nobori® Biolimus A9-eluting stents were enrolled and 1,519 (80.6%) patients were <75 years old and 365 (19.4%) were ≥75 years old. Patient's baseline clinical characteristics are summarized in Table 1. The mean age of the younger patient group was 60.8±9.3 years, and the mean age of the elderly group was 79.4±3.8 years. The elderly group had a higher number of hypertension, previous cerebrovascular disease, decreased

Table 1. Baseline characteristics

	<75 years (n=1.519)	≥75 years (n=365)	P
Age, y	60.8±9.3	79.4±3.8	<0.001
Men, n (%)	1129 (74.3)	198 (54.2)	<0.001
Hypertension, n (%)	912 (60.0)	257 (70.4)	0.001
Dyslipidemia, n (%)	1197 (78.8)	253 (64.3)	<0.001
DM, n (%)	570 (37.3)	143 (39.2)	0.820
Smoker (C-F), n (%)	718 (47.2)	99 (27.1)	<0.001
Previous MI, n (%)	75 (4.9)	17 (4.7)	0.707
Previous CVD, n (%)	136 (9.0)	53 (14.5)	0.005
Previous PCI, n (%)	291 (19.2)	65 (17.8)	0.833
Previous CABG, n (%)	35 (2.3)	11 (3.0)	0.714
PVD, n (%)	70 (4.5)	23 (6.1)	0.421
Family history of CAD, n (%)	68 (4.5)	8 (2.2)	0.134
LVEF (%)	57.98±13.1	54.5±14.1	<0.001
NYHA classification			
Class I	1165 (76.7)	286 (78.4)	0.498
Class II	235 (15.5)	52 (14.2)	0.559
Class III	109 (7.2)	22 (6.0)	0.439
Class IV	10 (0.7)	5 (1.4)	0.154
BMI, kg/m²	25.5±19.4	23.1±3.4	0.024
Estimated GFR [<60 mL/min/1.73 m², n (%)]	402 (26.5)	285 (78.0)	<0.001
Stable angina, n (%)	668 (44.0)	156 (42.7)	0.696
ACS, n (%)	851 (56.0)	209 (57.2)	0.650
Unstable angina, n (%)	409 (26.9)	96 (26.3)	0.863
NSTEMI, n (%)	164 (10.8)	61 (16.7)	0.002
STEMI, n (%)	278 (18.3)	52 (14.2)	0.054

Data are presented as the means±standard deviations or as numbers and percentages. ACS - acute coronary syndrome; C-F - current or former; CVD - cerebrovascular disease; BMI - body mass index; CABG - coronary artery bypass graft; CAD - coronary artery disease; DM - diabetes mellitus; GFR - glomerular filtration rate; LVEF - left ventricular ejection fraction; MI - myocardial infarction; NYHA - New York Heart Association; NSTEMI - non-ST segment elevation myocardial infarction; PCI - percutaneous coronary intervention; PVD - peripheral vascular disease; STEMI - ST segment elevation myocardial infarction

left ventricular ejection fraction (LVEF), decreased body mass index (BMI), renal dysfunction, and non-ST segment elevation MI (NSTEMI) compared with the younger group. In contrast, the younger group contained more smokers and more dyslipidemic individuals.

The younger patients were more likely to have one-vessel disease but multi-vessel diseases were more frequent in the elderly patients. There were no significant differences between the groups with respect to the distributions of the ACC/AHA lesion types, bifurcation lesions, or treated vessels or with respect
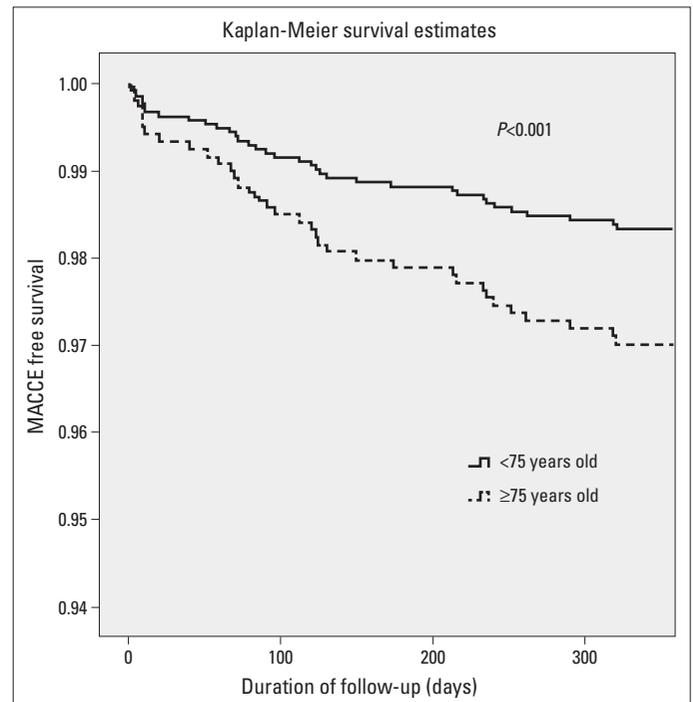
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Table 2. Lesion characteristics

	<75 years (n=1.519)	≥75 years (n=365)	P
Number of diseased vessels			0.062
1, n (%)	738 (48.6)	153 (42.0)	0.022
2, n (%)	440 (28.9)	115 (31.5)	0.339
≥3, n (%)	341 (22.4)	97 (26.6)	0.094
Multi-vessel disease	781 (51.4)	212 (58.1)	0.022
Number of treated vessels			
1, n (%)	1519 (100.0)	365 (100)	1.000
2, n (%)	145 (9.5)	31 (8.5)	0.535
≥3, n (%)	41(2.7)	8 (2.2)	0.584
Number of lesions			0.647
1, n (%)	1169 (77.0)	274 (75.1)	0.444
2, n (%)	291 (19.2)	76 (20.8)	0.471
3, n (%)	48 (3.2)	15 (4.1)	0.365
4, n (%)	11 (0.7)	0 (0.0)	1.000
Number of treated lesions			
1, n (%)	1519 (100.0)	365 (100.0)	1.000
2, n (%)	132(8.7)	23 (6.3)	0.136
3, n (%)	25 (1.6)	5 (1.4)	0.795
4, n (%)	3 (0.2)	0 (0.0)	1.000
Target vessel location			
Left main, n (%)	52 (3.4)	9 (2.5)	0.575
Left anterior descending, n (%)	811 (53.4)	205 (56.2)	0.104
Left circumflex, n (%)	241 (15.9)	54 (14.8)	0.469
Right coronary, n (%)	415 (27.3)	97 (26.6)	0.567
ACC/AHA type, B2, C lesion, n (%)	1197 (78.8)	291 (79.7)	0.717
IVUS	310 (20.4)	59 (16.2)	0.186
Bifurcation lesions, n (%)	95 (6.3)	24 (6.6)	0.825
Mean number of stents, n	1.10±0.29	1.08±0.27	0.198
Mean total stent length, mm	21.1±7.7	21.6±5.1	0.261
Mean stent diameter, mm	3.07±0.9	3.0±1.3	0.417

Data are presented as the means±standard deviations or as numbers and percentages. ACC/AHA - American College of Cardiology/American Heart Association; IVUS - intravascular ultrasound

Figure 2. Kaplan-Meier curved analysis of MACCE free survival
MACCE - major adverse cardiac or cerebrovascular events

Table 3. One year cumulative incidence of adverse cardiac or cerebrovascular events

	<75 years (n=1.519)	≥75 years (n=365)	Total (n=1.884)	P
Death				
Total, n (%)	23 (1.5)	26 (7.1)	49 (2.6)	<0.001
Cardiac, n (%)	7 (0.5)	17 (4.7)	24 (1.3)	<0.001
Non-cardiac, n (%)	16 (1.1)	9 (2.5)	25 (1.3)	0.034
MI, n (%)	9 (0.6)	12 (2.5)	21 (1.1)	<0.001
Revascularization, n (%)	26 (1.7)	6 (1.6)	32 (1.7)	0.928
TLR, n (%)	10 (0.7)	3 (0.8)	13 (0.7)	0.732
TVR, n (%)	23 (1.5)	5 (1.4)	28 (1.5)	0.838
Non-TVR, n (%)	8 (0.5)	2 (0.5)	10 (0.5)	1.000
CVA, n (%)	8 (0.5)	3 (0.8)	11 (0.6)	0.506
Recurrent CVA, n (%)†	2/136 (1.5)	2/53 (3.8)	4/189 (2.1)	0.201
MACE, n (%)	57 (3.8)	44 (12.1)	101 (5.4)	<0.001
MACCE, n (%)	65 (4.3)	47 (12.9)	112 (5.9)	<0.001

Values are numbers and percentages. The p value is for categorical data from chi-square test or Cox proportional hazard models. CVA - cerebrovascular accidents; MACE - major adverse cardiovascular events; MACCE - major adverse cardiovascular events or cerebrovascular events; MI - myocardial infarction; TLR - target lesion revascularization; TVR - target vessel revascularization. †Number of newly established CVA/number of previous cerebrovascular disease

to the mean numbers of stents per patient, the mean total stent lengths, or the mean stent diameters (Table 2).

Figure 2 shows the Kaplan–Meier MACCE-free survival estimates for the elderly patients and the younger patients. The cumulative 1-year incidence of MACCE was 5.9%; when stratified according to age; the 1-year incidence was 4.3% in the younger group and 12.9% in the elderly group (p<0.001). The cumulative 1-year mortality rate was 2.6% (49 patients); when stratified according to age, the 1-year mortality rate was 1.5% (23 patients) in the younger patient group and 7.1% (26 patients) in the elderly patient group (p<0.001). The rates of MI was 0.6% (nine patients) in

the younger patient group and 2.5% (12 patients) in the elderly patient group (p<0.001). However, the revascularization rates (TLR, TVR, non-TVR) and cerebrovascular accident (CVA) rates did not differ significantly between the groups (Table 3). Table 4 shows

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Table 4. Multivariate analysis of all-cause mortality and MACCE at 1-year after index PCI

	All-cause mortality		MACCE	
	HR (95% CI)	*P*	HR (95% CI)	*P*
Age, ≥75 y (n=365)	3.380 (1.771–6.450)	<0.001	2.634 (1.702–4.077)	<0.001
Men (n=1.327)	0.485 (0.244–0.965)	0.039	0.695 (0.451–1.070)	0.098
Previous cerebrovascular disease (n=189)	2.775 (1.312–5.870)	0.008	2.118 (1.119–4.008)	0.021
Estimated GFR (<60 mL/min/1.73 m²) (n=687)	2.303 (1.138–4.662)	0.020	1.405 (0.904–2.185)	0.131
Stable angina (n=824)	0.564 (0.310–1.027)	0.061	0.680 (0.454–1.020)	0.062
Unstable angina (n=505)	0.243 (0.092–0.643)	0.004	0.396 (0.226–0.694)	0.001
Left main CAD (n=61)	4.250 (1.579–11.44)	0.004	2.381 (1.012–5.603)	0.047
Right coronary artery lesion (n=824)	0.661 (0.318–1.374)	0.267	1.090 (0.741–1.603)	0.663
One-vessel disease (n=891)	0.700 (0.394–0.700)	0.473	0.925 (0.637–1.341)	0.680
Multi-vessel disease (n=993)	1.427 (0.804–2.536)	0.225	1.081 (0.746–1.569)	0.527
Number of diseased vessels	0.823 (0.392–1.727)	0.606	0.900 (0.545–1.484)	0.679
Number of treated vessels	2.052 (0.747–5.636)	0.163	1.434 (0.759–2.710)	0.266
Number of lesions	0.507 (0.152–1.693)	0.270	0.746 (0.391–1.424)	0.374
Number of treated lesions	1.589 (0.489–3.416)	0.429	1.487 (0.764–2.893)	0.243

CI - confidence interval; GFR - glomerular filtration rate; HR - hazard ratio; MACCE - major adverse cardiac or cerebrovascular events; PCI - percutaneous coronary intervention

Table 5. Multivariate Cox regression analysis of MACCE in the elderly at 1-year post-PCI

	<75 y (n=1.519)		≥75 y (n=365)	
	HR (95% CI)	*P*	HR (95% CI)	*P*
Previous cerebrovascular disease	1.326 (0.405–4.334)	0.641	2.804 (1.290–6.093)	0.009
Men	0.581 (0.300–1.125)	0.107	0.787 (0.437–1.418)	0.425
Estimated GFR <60 mL/min/1.73 m²	1.682 (0.975–2.900)	0.061	0.868 (0.436–1.730)	0.688
Stable angina	0.730 (0.430–1.237)	0.242	0.667 (0.349–1.278)	0.222
Unstable angina	0.315 (0.142–0.698)	0.004	0.576 (0.258–1.284)	0.178
Left main CAD	2.823 (0.979–8.142)	0.055	2.020 (0.455–8.969)	0.355
Right CAD	1.458 (0.876–2.426)	0.147	0.740 (0.401–1.366)	0.336
One-vessel disease	0.907 (0.557–1.477)	0.695	1.087 (0.611–1.931)	0.777
Multi-vessel disease	1.103 (0.677–1.795)	0.514	0.920 (0.518–1.636)	0.581
Number of diseased vessels	0.773 (0.372–1.606)	0.490	0.866 (0.407–1.842)	0.709
Number of treated vessels	1.566 (0.704–3.482)	0.271	1.675 (0.527–5.321)	0.382
Number of lesions	0.751 (0.344–1.639)	0.472	0.694 (0.209–2.305)	0.551
Number of treated lesions	1.758 (0.778–3.969)	0.175	0.856 (0.274–2.671)	0.789

CI - confidence interval; GFR - glomerular filtration rate; HR - hazard ratio; MACCE - major adverse cardiac or cerebrovascular events; PCI - percutaneous coronary intervention

the multivariate analysis of all-cause mortality and MACCE at 1-year. Age [hazard ratio (HR), 3.380; 95% confidence interval (CI), 1.771–6.450; p<0.001] and previous cerebrovascular disease (HR, 2.634; 95% CI, 1.702–4.077; p=<0.001) were independent predictors for 1-year MACCE. Also, cardiac death and previous cerebrovascular disease showed significant correlation (HR, 2.338; 95% CI, 1.024–4.962, p=0.018). Table 5 shows multivariate Cox regression analysis of MACCE in the elderly group at 1-year after PCI. Previous cerebrovascular disease was the only independent predictor (HR, 2.804, 95% CI, 1.290–6.093, p=0.009) in this age group.

Only one patient, a 66-year-old male who had undergone an ST elevation MI, experienced an acute stent thrombosis after PCI; therefore, we did not include stent thrombosis as an outcome parameter in our study.

Discussion

The main findings from this prospective, multicenter, observational single-arm study showed that previous cerebrovascular disease is important independent predictor of MACCE in elderly

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patients 1-year after PCI with Nobori® Biolimus A9-eluting stents especially in a series of South Korean population.

The 1-year cumulative rate of all-cause mortality was 2.6% (cardiac mortality was 1.3%) in this study. These rates were similar with the rates reported from the SORT OUT V trial (2.4%) and the LEADERS trial (3%) (12, 13).

The incidence of left main CAD increases with age (14). Thus, elderly patients are more likely to develop left main CAD than younger patients. Recent guidelines have considered PCI to be a compelling alternative to coronary artery bypass grafting (CABG) for left main coronary artery stenosis (15). At a median follow-up duration of 1,088 days, with respect to death, CVA, or MI, there were no differences between octogenarians who had been vascularized using PCI or CABG (16). Therefore, the long-term clinical outcomes following PCI in elderly patients appear to be acceptable. The present study also showed that left main CAD was not an independent predictor of MACCE in elderly patients one year after PCI (Table 4). According to our results, the authors carefully agree that PCI may provide greater benefit compared to CABG in elderly patients with left main CAD because they typically have more comorbidities and higher surgery risk than younger patients.

Patients who previously experienced cerebral infarctions are at high-risk of CAD (17), and CAD is a key cause of death in these patients (18). The findings from previous studies that have involved DES in CAD have shown reductions in the incidence of cardiac events associated with recurrent ischemia and lower rates of angiographic restenosis compared with bare metal stents (19, 20). However, Sasao et al. (21) reported that the long-term clinical outcomes were worse in patients with CAD who had experienced previous cerebral infarctions compared with those who had not experienced previous cerebral infarctions. Patients with cerebral infarction typically had motor dysfunction and could not perform a sufficient exercise stress test for assessment of ischemic heart disease. Early detection of CAD occurs less frequently in these patients. Therefore, early diagnosis and treatment of CAD in patients who have experienced previous cerebral infarctions is very important.

Another study showed that patients who had experienced previous cerebral infarctions had a higher incidence of coronary risk factors and high-risk coronary anatomy, and poorer prognosis after PCI than patients who had not experienced cerebral infarctions (22). Our study showed that previous cerebrovascular disease in elderly patients, who had undergone PCI, was a predictor of MACCE at 1-year (HR, 2.804; 95% CI, 1.290–6.093; p=0.009; Table 5). Previous cerebrovascular disease was one of the major determinants of all-cause mortality in our study (HR, 2.775; 95% CI, 1.312–5.870; p=0.008; Table 4). Previous cerebral infarction is known to be another risk factor for recurrent cerebral infarction. Uchiyama et al. (23) reported that patients with CAD who had coexisting atherothrombotic disease were at high-risk of recurrence. The 1-year cumulative incidence of cerebrovascular disease in our study was 0.5% (eight patients) for the younger patient group
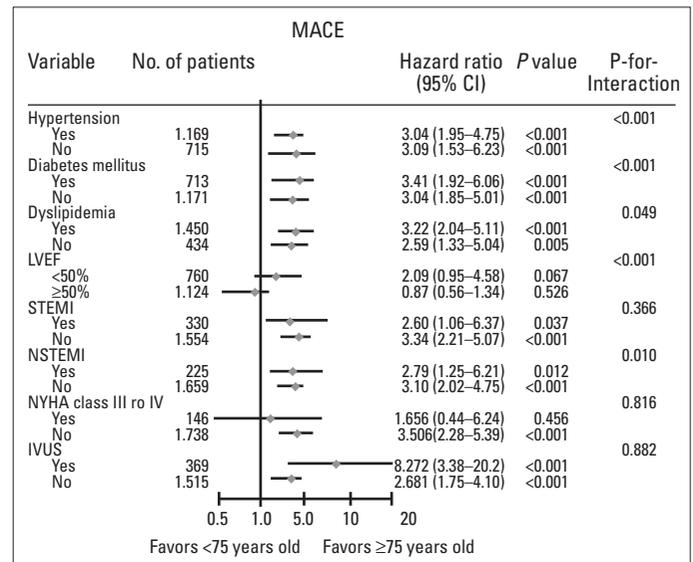
Figure 3. Subgroup analysis for MACCE

MACCE - major adverse cardiac or cerebrovascular events; LVEF - left ventricular ejection fraction; STEMI - ST-segment elevation myocardial infarction; NSTEMI - non-ST-segment elevation myocardial infarction; NYHA - New York Heart Association; IVUS - intravascular ultrasound

and 0.8% (three patients) for the elderly patient group (p=0.506). Among the younger patients group, two had experienced hemorrhagic strokes (intraventricular hemorrhage and subdural hemorrhage) and six were ischemic stroke patients; whereas in the elderly patient group, one patient had experienced hemorrhagic stroke (cerebral hemorrhage) and two patients were ischemic stroke patients. The above three hemorrhagic stroke patients received operation. Six ischemic stroke patients of the younger patient group received thrombolytic therapy with intravenous (IV) or intra-arterial (IA) recombinant tissue plasminogen activator (rt-TPA, alteplase). Two ischemic stroke patients of the elderly patient group were treated with conventional anticoagulation therapy due to contraindication of thrombolytic therapy (≥75 years). The incidence of recurrent CVA was higher in elderly patients than in younger patients but was not statically significant (3.8% vs. 1.5%, p=0.201; Table 3). Moreover, polyvascular disease is associated with increased event rates when compared with atherothrombotic disease in a single vascular bed (24). Pre-PCI cerebrovascular risk factor assessment as a part of an assessment to determine preventive intervention or increased monitoring may reduce the risk of future cerebrovascular events.

Also, the proportion of patients with acute coronary syndrome in our study was 56.0% in the younger patient group and 57.2% in the elderly patient group (Table 1), and subgroup analysis for MACCE is shown in Figure 3. Our study included a large number of high-risk patients; therefore, we expect the current results to be meaningful.

Although our study showed that previous cerebrovascular disease was an important independent predictor of MACCE in elderly patients 1 year after PCI, large, randomized, controlled clinical trials that include high-risk elderly patients will be re-

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quired to guide decision-making and improve PCI outcomes in this population.

Study limitations

This study was limited because of its non-randomized design with short-term follow-up and the absence of another type of DES to facilitate direct comparisons. Furthermore, and like every "real-world" registry, there may have been some under-reporting and/or data might have been missing which is more likely to reflect physician selection bias toward patients with relatively good survival. Because the present study registry was conducted using only the Nobori® stent, the translation of our results in the present-day clinical practice may be inappropriate.

Conclusion

Previous cerebrovascular disease is important independent predictor of MACCE in elderly patients during 1-year follow-up period after successful PCI with Nobori® Biolimus A9-eluting stents especially in a series of South Korean population. Therefore, careful PCI with intensive monitoring and management can improve major clinical outcomes after successful PCI in elderly patients with previous cerebrovascular disease compared with younger patients.

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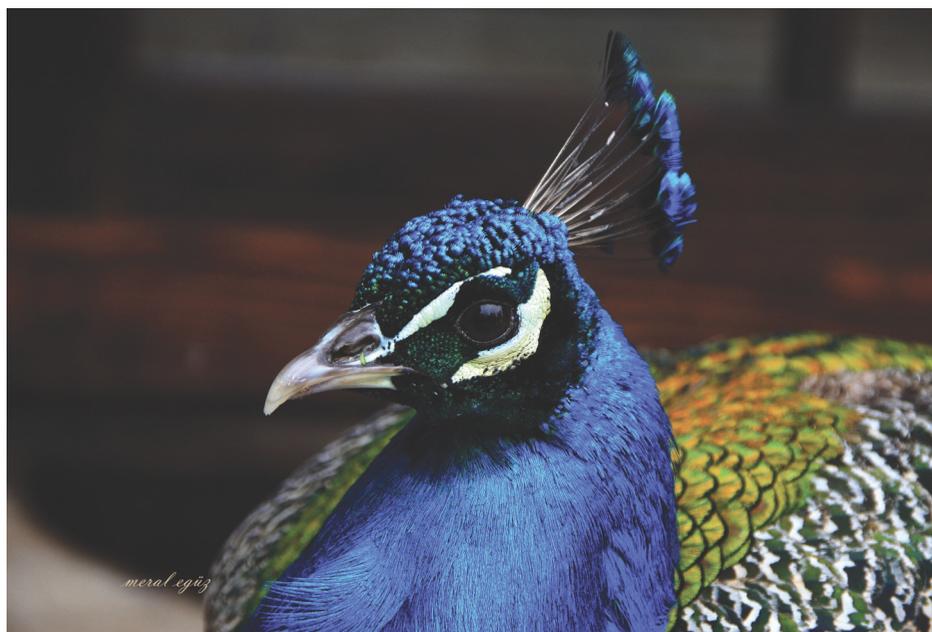
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