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Sirolimus-Eluting Coronary Stents in Octogenarians

A 1-Year Analysis of the Worldwide e-SELECT Registry

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Objectives The aim of this study was to identify the worldwide practice of Cypher Select (Cordis Corporation, Bridgewater, New Jersey) or Cypher Select Plus sirolimus-eluting stent (SES) in patients 80 years of age (octogenarian) and to identify clinical outcomes in this patient population.

Background The use of drug-eluting stents in elderly patients may have different features compared with younger patients.

Methods Between 2006 and 2008, 15,147 patients from 320 hospitals in 56 countries were enrolled in a registry. Initial implantation and follow-up outcome information obtained at 1-year follow-up in 675 octogenarian patients were compared with those in 14,472 nonoctogenarian patients.

Results Octogenarians had significantly more comorbidities and had higher Charlson comorbidity index scores (1.5 ± 1.6 vs. 1.0 ± 1.3, $p < 0.001$). Rates of cardiac death (3.3% vs. 0.9%, $p < 0.001$), myocardial infarction (2.3% vs. 1.9%, $p = 0.021$), and definite or probable stent thrombosis (2.3% vs. 0.9%, $p = 0.0002$), and major bleeding (2.0% vs. 0.9%, $p = 0.015$) were significantly higher in octogenarians at 1 year; however, there was no significant difference in the rate of target lesion revascularization between the 2 groups (3.2% vs. 2.2%, $p = 0.12$). In octogenarians, a high Charlson comorbidity index was an independent predictor of death and stent thrombosis up to 360 days from the index procedure (hazard ratio: 1.3, 95% confidence interval: 1.1 to 1.5, $p < 0.001$, and hazard ratio: 1.5, 95% confidence interval: 1.3 to 1.8, $p < 0.001$, respectively).

Conclusions Stenting with SES may be an effective therapeutic option in elderly patients, with acceptable rates of complications and a very low rate of repeat revascularization as demonstrated by this e-SELECT (A Multi-Center Post-Market Surveillance Registry) subgroup analysis. (J Am Coll Cardiol Intv 2011;4:982–91) © 2011 by the American College of Cardiology Foundation

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The elderly represent a growing proportion of the population. The increasing prevalence of coronary artery disease associated with aging (1), combined with the rapid growth of percutaneous coronary interventions (PCI), have markedly increased the proportion of octogenarians who undergo implantation of coronary stents (2,3). Although age is a marker of high risk for adverse events (4,5), the elderly have been underrepresented in clinical trials of PCI.

Compared with younger patients, elderly patients undergoing PCI present with more complex lesions, a higher proportion of acute coronary syndromes (ACS), higher comorbidity, and more depressed cardiac function (5–19). The use of drug-eluting stents (DES) in patients ≥80 years of age (octogenarians) may be associated with different outcomes than in younger patients. The purpose of this study was to examine the worldwide utilization of sirolimus-eluting stents (SES), including risk factors, antiplatelet drug regimens, and clinical outcomes in octogenarian patients compared with younger patients.

Methods

Patient population. e-SELECT (A Multi-Center Post-Market Surveillance Registry) is a prospective multicenter observational registry designed to examine the performance of CYPHER Select or CYPHER Select Plus (Cordis Corporation, Bridgewater, New Jersey) according to standard clinical practice and procedural techniques. Between 2006 and 2008, the registry prospectively enrolled 15,147 unselected patients at 320 hospitals in 56 countries worldwide (20). This analysis compares the clinical and coronary angiographic observations, procedural results, complications, and 1-year clinical outcomes in 675 octogenarians with those in 14,472 patients <80 years of age. The registry protocol was approved by the ethics committee of each participating medical center, and the patients granted their consent to participate in the registry after the index procedure.

Study protocol and data collection and management. The investigators were encouraged to follow the instructions for use of the stents, although their off-label use was not disallowed. The lesions could be pre-treated with any technique or device, such as balloon angioplasty, cutting balloon, or atherectomy, though all lesions had to be treated with a SES. All post-operative medical management, including antithrombotic therapy, was prescribed according to usual local practices. The patients were followed at 30, 180, and 360 days by telephone communication, office visit, or by contacts with primary physicians or referring cardiologists. At each evaluation, a determination was made of the occurrence of interim adverse events, and of their possible relationship with the index implantation procedure, the SES, or the antithrombotic regimen.

The details of the data collection and management in the e-SELECT registry have been described previously (20). In brief, demographic information, general health and cardiovascular history, assessment of angina status, comorbidity (21), lesion and procedure characteristics, procedural outcomes, and cardiac medications and antithrombotic regimens were recorded. The Charlson comorbidity index predicts a variety of patient outcomes, including mortality, post-operative complications, length of stay, and hospital charges (22–26). The data were collected electronically at each participating medical center, transferred to an independent data management organization, and analyzed by an independent clinical research organization. The accuracy of data collection was monitored by an independent organization in 20% of the overall sample, at 100 centers.

Endpoints of the registry. The primary endpoint of the registry was a composite of definite and probable stent thrombosis, as defined by the Academic Research Consortium (27), at 1 year of follow-up. The secondary endpoints at 1 year included major bleeding according to the STEEPLE (Safety and Efficacy of Enoxaparin in Percutaneous Coronary Intervention Patients trial) definition (28) and major adverse cardiac events (MACE) defined as cardiac and noncardiac death, myocardial infarction (MI), and target lesion revascularization. We could determine that "age = 80" is an appropriate cut point since the event rate is statistically significantly higher in patients age ≥80 years compared with patients age <80 years ($p < 0.0001$).

Abbreviations and Acronyms

ACS = acute coronary syndromes
DES = drug-eluting stent(s)
MACE = major adverse cardiac event(s)
MI = myocardial infarction
PCI = percutaneous coronary interventions
SES = sirolimus-eluting stent(s)

Statistics. All eligible patients enrolled in this registry were included in the analysis. Standard statistics were used to describe the baseline clinical and lesion characteristics, and procedural and clinical outcomes. Cumulative rates of adverse clinical events were calculated using event-specific adjusted denominators, meaning that all patients having an event within 360 days, or followed up for at least 330 days after the index procedure, were contributing to the denominator. Continuous variables are presented as mean ± SD. Between-groups comparisons were made by Student *t* test. Discrete variables are presented as counts and percentages, and were compared by Fisher exact test. Kaplan-Meier curves and time-to-event summaries were constructed, using the life-table method, to examine the long-term incidence of clinical and

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safety endpoints. Univariate and multivariate analyses were performed to identify the predictors for the endpoints of thrombosis, major bleeding, and death. The analysis contain 3 steps:

Step 1. Univariate analysis with a simple Cox proportion hazards regression model with a selected endpoint as response variables and baseline characteristics, procedure characteristics, and lesion characteristics as covariates were fitted.

Step 2. Multivariate analysis with a multiple Cox proportional hazards regression model with 1 selected endpoint as response variable and with predictors selected from step 1 was performed. A stepwise procedure with an entry/stay criteria of 0.10/0.15 was applied to select the predictors. The predictors selected from step 1 were based on no more than 15% missing values and followed the proportional hazard assumption.

Step 3. After multivariate analysis for variable selections, 2 or 3 predictors were selected. Considering there were few events (35 deaths, 14 definite and probable stent thrombosis, 12 major bleedings, and 14 noncardiac vascular deaths), selecting only 2 or 3 predictors was reasonable. Otherwise, with the current number of cases, more predictors would cause overfitting problems (for the survival analysis, the number of predictors usually depends on the number of events but not the overall number of patients). A p value of <0.05 was considered significant. No missing value imputation was performed. All statistical analyses were performed with SAS, version 9.1 or higher software (SAS Institute, Cary, North Carolina).

Results

Patients, lesions, and procedural characteristics. Significant differences in baseline characteristics were observed between the 2 study groups (Table 1). The proportion of men and obese patients was lower in the octogenarian group. Sinus rhythm was present on the electrocardiogram of 91.1% of octogenarians versus 96.0% of younger patients ($p < 0.001$). The prevalence of hypertension was significantly higher, whereas that of hyperlipidemia, current smoking, and family history of coronary artery disease was significantly lower in octogenarian than in nonoctogenarians. A higher proportion of octogenarians than younger patients had undergone prior PCI and coronary artery bypass graft surgery. The Charlson comorbidity index was significantly higher in octogenarians than in nonoctogenarians due in particular to a higher prevalence of peripheral vascular disease, cerebrovascular disease, renal dysfunction, and chronic lung disease.

The baseline coronary angiographic observations and procedural outcomes in each study group are shown in Table 2. The mean number of vessels and lesions treated during the index procedure were 1.2 ± 0.4 and 1.4 ± 0.6, respectively, in the octogenarian group, versus 1.2 ± 0.4 and 1.3 ± 0.6, respectively, in nonoctogenarian group ($p = NS$ for both comparisons). A higher proportion of octogenarians than nonoctogenarians were treated for lesions located in bypass grafts, for restenotic lesions, or for left main coronary artery disease. Calcified lesions, but not bifurcation lesions, were significantly more prevalent in the octogenarians than in the younger group, whereas the percentages of lesions >30 mm in length and reference vessel diameter <2.25 mm were 12.6% and 3.7% in the octogenarian group, respectively, versus 13.5% and 3.9% in the nonoctogenarian group, respectively ($p = NS$ for both comparisons). Triple-vessel disease was significantly more prevalent in the octogenarian than in the nonoctogenarian group.

Direct stenting was performed less frequently and the mean maximum pressure applied per stent was significantly higher in the octogenarian group than in the nonoctogenarian group. Multiple stents were deployed more frequently and the stent diameter was significantly smaller in the octogenarians than in the younger group. The procedural success was derived from the information on the case report form: post-procedure percent diameter stenosis and adjudicated in-hospital MACE. There was no significant difference in procedural success rate between the octogenarian and nonoctogenarian groups (98.6% [629 of 638] vs. 98.6% [13,184 of 13,373], $p = 1.000$).

Antithrombotic regimen. The antithrombotic regimens administered at the time of discharge from the hospital and at 1-month of follow-up were nearly identical in both study groups. However, at 6 months and at 1-year follow-up, a lower proportion of octogenarians than nonoctogenarians were treated with a dual antiplatelet regimen. At 1-year follow-up, 73% of octogenarians versus 80% of nonoctogenarians remained on a dual antiplatelet regimen ($p < 0.001$).

Clinical outcomes. The cumulative, 1-year rate of major adverse events was significantly higher ($p < 0.001$) in octogenarians than in nonoctogenarians (Fig. 1). The rates of death, MI, definite and probable stent thrombosis, and major bleeding were significantly higher in octogenarians than in the nonoctogenarians. It is, however, noteworthy, that the need for repeat revascularization was similar in both groups (Fig. 2). The incidence of acute and subacute stent thrombosis was significantly higher in octogenarians (1.3% vs. 0.5%, $p = 0.015$), though the incidence of acute stent thrombosis was similar in both groups (0.15% vs. 0.06%, $p = 0.37$). There was a trend toward a higher incidence of late stent thrombosis in octogenarians (0.8% vs. 0.3%, $p = 0.056$). All stent thromboses in octogenarians occurred within 6 months after the index procedure (Fig. 3). Conversely, the risk of major bleeding events was prolonged during the first year and significantly higher in octogenarians (2.0%) than in nonoctogenarians (0.9%, $p = 0.015$) (Fig. 3).

Table 1. Baseline Characteristics of the Study Groups

	Study Groups		
	Age ≥80 Yrs (n = 675)	Age <80 Yrs (n = 14,472)	p Value
Age, yrs	82.5 ± 2.4	61.2 ± 10.1	<0.001
Male	392 (58.1)	11,031 (76.2)	<0.001
Left ventricular ejection fraction <30%	14 (2.4)	232 (1.9)	NS
Body mass index ≥30 kg/m^2	86 (12.8)	3,587 (24.9)	<0.001
Heart rate (beats/min)	68.4 ± 12.3	70.0 ± 13.0	0.003
Systolic blood pressure (mm Hg)	139 ± 26	134 ± 24	<0.001
Diastolic blood pressure (mm Hg)	71 ± 14	75 ± 13	<0.001
Indications for index procedure			
Asymptomatic	18 (2.7)	349 (2.4)	NS
Silent ischemia	30 (4.4)	672 (4.6)	NS
Stable angina	244 (36.1)	6,062 (41.9)	0.003
Unstable angina	183 (27.1)	3,739 (25.8)	NS
Non–ST-segment myocardial infarction	111 (16.4)	1,570 (10.8)	0.001
ST-segment myocardial infarction	45 (6.7)	1,017 (7.0)	NS
Old myocardial infarction	44 (6.5)	989 (6.8)	NS
Medical history			
Diabetes mellitus	210 (31.1)	4,367 (30.3)	NS
Insulin-nondependent	162 (24.0)	3,177 (22.0)	NS
Insulin-dependent	48 (7.1)	1,190 (8.2)	NS
Hypertension	522 (77.3)	9,649 (67.0)	<0.001
Hyperlipidemia	419 (62.1)	9,870 (68.5)	<0.001
Current smoking	241 (35.7)	7,819 (54.3)	<0.001
Coronary artery disease in the family	103 (15.3)	4,694 (32.6)	<0.001
Percutaneous coronary interventions	251 (37.2)	4,599 (31.9)	0.005
Coronary artery bypass graft surgery	83 (12.3)	1,287 (8.9)	0.004
Myocardial infarction	238 (35.3)	4,616 (32.0)	0.08
Peripheral vascular disease	72 (10.7)	869 (6.0)	<0.001
Cerebral vascular accident	63 (9.3)	580 (4.0)	<0.001
Chronic obstructive lung disease	55 (8.1)	542 (3.8)	<0.001
Congestive heart failure	60 (8.9)	570 (4.0)	<0.001
Hemiplegia	4 (0.6)	31 (0.2)	NS
Dementia	8 (1.2)	23 (0.2)	<0.001
Gastroduodenal ulcer	20 (3.0)	403 (2.8)	NS
Serum creatinine >177 μmol/l	24 (4.0)	327 (2.6)	0.034
Moderate to severe liver disease	1 (0.1)	27 (0.2)	NS
Any type of cancer	36 (5.3)	287 (2.0)	<0.001
AIDS	0 (0.0)	4 (0.03)	NS
Mean Charlson index score	1.45 ± 1.59	1.03 ± 1.29	<0.001
Charlson index score ≥3	130 (19.3)	1,416 (9.8)	<0.001

Values are mean ± SD or n (%) of observations in the corresponding group.
Abbreviations as in Table 1.

The types of major bleeding events or their consequences are shown in Figure 4.

MACE rate was significantly higher in acute coronary syndrome (ACS) patients compared with non-ACS patients overall and in the nonoctogenarian group (5.3% [352 of 6,665] vs. 3.8% [319 of 8,482], $p < 0.0001$, and 5.0% [318 of 6,326] vs. 3.6% [296 of 8,146], $p < 0.0001$, respectively), but the MACE rate was not significantly different between ACS patients and non-ACS patients in octogenarian groups (10.0% [34 of 339] vs. 6.9% [23 of 336], $p = 0.1661$).

Predictors of major adverse events. The independent predictors of death, stent thrombosis, and major bleeding up to 360 days after the index procedure are shown in Table 3. A high Charlson comorbidity index was a predictor of death and of stent thrombosis, and there is a stronger correlation

Table 2. Coronary Angiographic Observations and Procedural Outcomes in Each Study Group

	Study Groups		
	Age ≥80 Yrs (n = 675 Patients; 905 Lesions; 1,095 Stents)	Age <80 Yrs (n = 14,472 Patients; 19,083 Lesions; 22,397 Stents)	p Value
Reference vessel diameter, mm	2.89 ± 0.46	2.92 ± 0.45	0.07
Lesion length, mm	19.47 ± 10.76	20.27 ± 11.62	0.043
Target vessel			
Native coronary artery	863 (95.6)	18,701 (98.3)	<0.001
Left main	33 (3.8)	416 (2.2)	0.005
Left anterior descending	444 (51.4)	9,537 (51.0)	NS
Left circumflex	183 (21.2)	4,108 (22.0)	NS
Right coronary artery	217 (25.1)	4,859 (26.0)	NS
Bypass graft	40 (4.4)	331 (1.7)	<0.001
Lesion subsets			
De novo	751 (83.7)	16,586 (88.4)	<0.001
Restenotic	146 (16.3)	2,168 (11.6)	<0.001
Ostial	130 (14.5)	2,346 (12.5)	0.09
Bifurcation	149 (16.6)	2,682 (14.3)	NS
Moderately/severely calcified	319 (37.9)	3,883 (22.9)	<0.001
Chronic total occlusion	15 (1.7)	602 (3.2)	0.008
Number of diseased vessels			
1	306 (45.3)	7,972 (55.1)	<0.001
2	194 (28.7)	4,048 (28.0)	NS
3	175 (25.9)	2,452 (16.9)	<0.001
ACC/AHA lesion type			
A	82 (9.2)	2,182 (11.8)	0.021
B1	260 (29.3)	5,919 (31.9)	NS
B2	324 (36.5)	5,931 (32.0)	0.005
C	221 (24.9)	4,514 (24.3)	NS
Intravascular ultrasound used	18 (2.1)	695 (3.8)	0.006
Percent diameter stenosis			
Pre-procedure	84.59 ± 11.99	84.51 ± 12.37	NS
Post-procedure	1.05 ± 5.47	1.33 ± 6.74	NS
Direct stenting	276 (30.8)	6,736 (35.9)	0.002
Maximum stenting pressure, atm	15.8 ± 3.2	15.5 ± 3.3	0.003
Adjunct balloon angioplasty	383 (36.5)	7,673 (36.1)	NS
Multiple stents implanted	160 (23.7)	2,746 (19.0)	0.003
Number of stents per patient	1.62 ± 0.86)	1.55 ± 0.86	0.028
Mean stent diameter per lesion, mm	2.86 ± 0.37	2.91 ± 0.39	<0.001
Total stent length per patient, mm	33.5 ± 19.9	33.5 ± 21.0	NS
Number of vessels treated during index procedure	1.2 ± 0.4	1.2 ± 0.4	NS
Number of lesions treated during index procedure	1.4 ± 0.6	1.3 ± 0.6	NS

Values are mean ± SD or n (%) of observations in the corresponding group.
ACC/AHA = American College of Cardiology/American Heart Association.

between the Charlson comorbidity index and mortality at 1 year for octogenarian patients compared with younger patients (Fig. 5). Conversely, a history of hyperlipidemia was a negative predictor of death. A pre-procedural reference vessel diameter <2.25 mm and statin use at baseline were powerful, positive and negative predictors, respectively, of stent thrombosis.

Independent predictors of major bleeding were presence of thrombus at the index procedure, body mass index >30 kg/m^2, and lesion length >30 mm. More patients with no thrombus than those with thrombus were taking antiplatelet medication at most of the visits, excluding post-procedure. More patients with lesion length ≥30 mm than those with lesion length <30 mm were taking antiplatelet medication

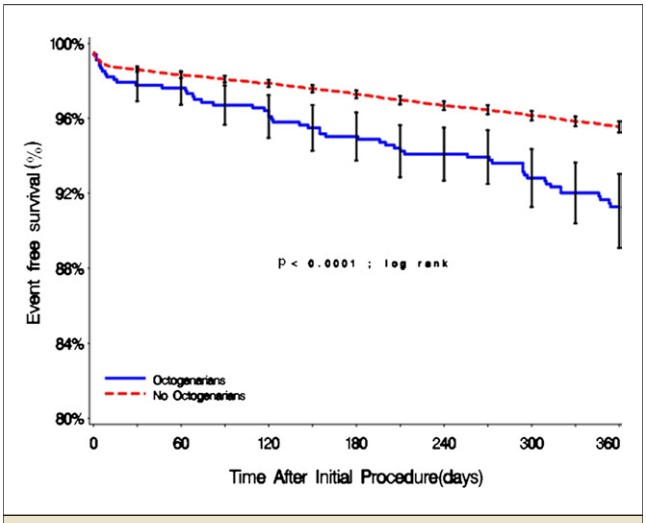

Figure 1. Survival Free From All MACE in Each Study Group

The cumulative, 1-year rate of major adverse cardiac events (MACE) was significantly higher in octogenarians than in nonoctogenarians.

during the procedure, at discharge, and at 6 months visit. In contrast, more of the patients with lesion length <30 mm than those with lesion length ≥30 mm were taking antiplatelet medication during post-procedure, at 1-month visit, and at 1-year visit. None of differences, however, are statistically significant.

The noncardiac death rate at 12 months in octogenarian patients was 2.3% (14 of 609). The multivariate predictors of noncardiac death within 0 to 360 days in octogenarian patients included total number of lesions treated (hazard ratio: 2.47, 95% confidence interval: 1.50 to 4.09, $p < 0.001$] and Charlson comorbidity index (hazard ratio: 1.32, 95% confidence interval: 1.03 to 1.70, $p = 0.029$).

Discussion

Several observations were made in this subanalysis of the e-SELECT registry. First, the prevalence of concomitant disorders was significantly higher in octogenarians than in the younger study group, and the Charlson comorbidity index was the most powerful predictor of death and stent thrombosis in octogenarians. Second, the rates of death, MI, stent thrombosis, and major bleeding were all higher in octogenarians, an observation reflecting the higher overall risk represented by aging. Third, no definite or probable stent thrombosis occurred beyond 6 months of follow-up in octogenarians, despite a significantly lower use of dual antiplatelet therapy at 1 year compared with younger patients. Finally, the need for repeat revascularization was similar in both groups.

Stent thrombosis is the most feared complication of DES implantation. Although the incidence of acute stent thrombosis was similar in both study groups, subacute and late stent thromboses were significantly higher in octogenarians. However, all stent thromboses in octogenarians occurred within 6 months after the index procedure, suggesting that elderly patients might benefit from a more effective antiplatelet therapy during the first 30 or 180 days after SES implantation but that this therapy may not need to be prolonged. In the present study, a high Charlson comorbidity index, a small reference vessel diameter, and the

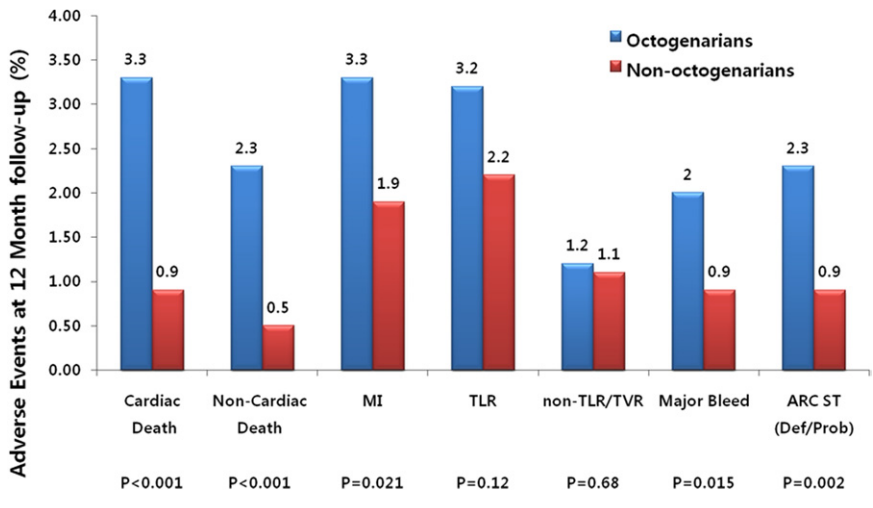

Figure 2. The Incidences of MACE at 1-Year Follow-Up

The rates of death, myocardial infarction (MI), stent thrombosis (ST), and major bleeding were significantly higher in octogenarians than in the nonoctogenarians. It is, however, noteworthy that the need for target lesion revascularization (TLR) was similar in both groups. ARC = Academic Research Consortium; Def/Prob = definite/probable; MACE = major adverse cardiac events; TVR = target vessel revascularization.

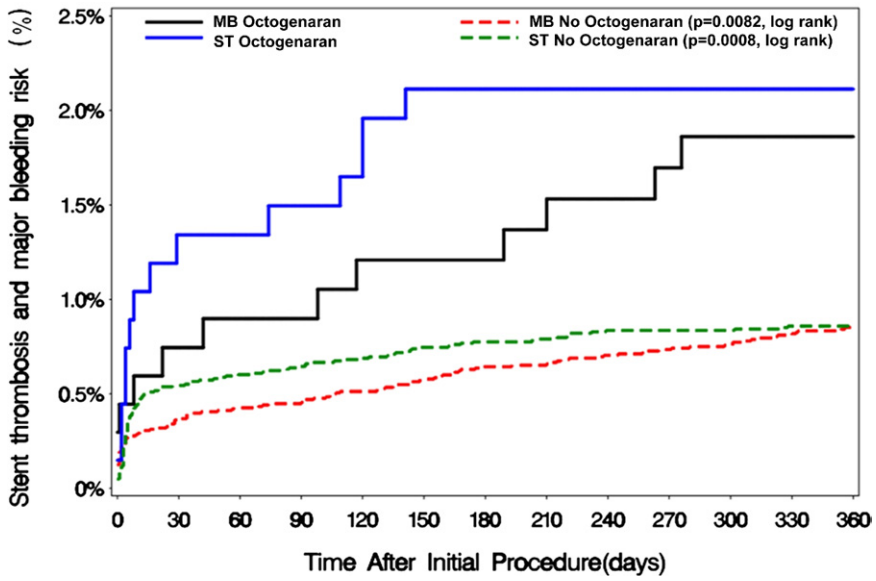

Figure 3. Cumulative Incidences of ST and MB

All stent thrombosis (ST) in octogenarians occurred within 6 months after the index procedure. Conversely, the risk of major bleeding (MB) events was prolonged during the first year and significantly higher in octogenarians than in nonoctogenarians.

absence of statin administration at baseline were independent 1-year predictors of stent thrombosis. In octogenarians, the risks and benefits of PCI should be carefully evaluated, taking into account comorbidities, lesion characteristics, and bleeding risks with prolonged dual antiplatelet therapy. Although clopidogrel reduces the risk of late DES thrombosis, its long-term administration increases the risk of bleeding (29–32). Latib et al. (33) reported: 1) a 1.9% overall rate of bleeding, an 0.8% rate of major bleeding; 2) a 2.57 per 100 person-year rate of any bleeding complication between 30 days and 18 months; 3) a 1.10 per 100 person-year rate in patients treated with dual antiplatelet

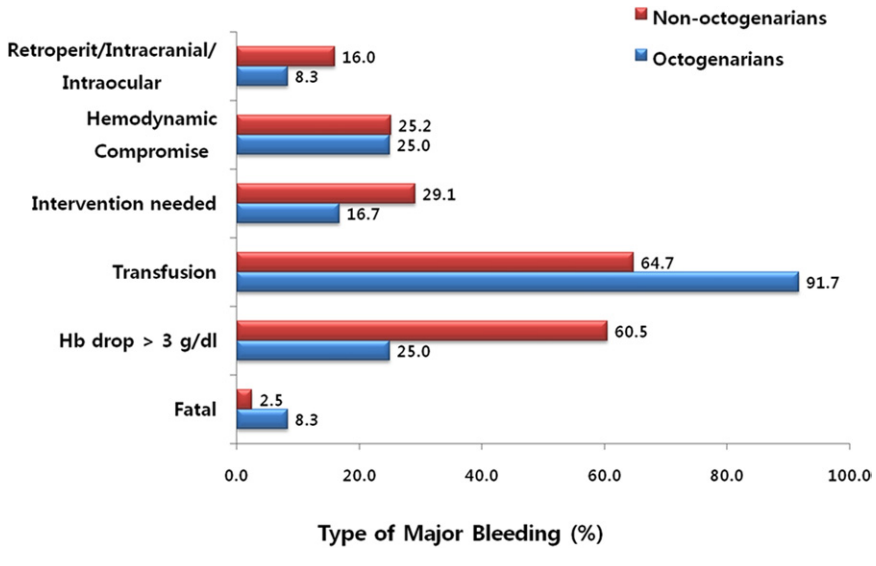

Figure 4. Types or Consequences of MB Events

The rate of transfusion and the incidence of fatal bleeding were significantly higher in octogenarians than in nonoctogenarians. Hb = hemoglobin; MB = major bleeding; Retroperit = retroperitoneal.

Table 3. Independent Predictors of Death, Stent Thrombosis, and Major Bleeding at 1 Year in Octogenarians

	Hazard Ratio	95% Confidence Interval	p Value
Death			
Charlson comorbidity index, in 1-point increments	1.3	1.1–1.5	<0.001
History of hyperlipidemia	0.3	0.2–0.7	0.002
Stent thrombosis			
Charlson comorbidity index, in 1-point increments	1.5	1.3–1.8	<0.001
Pre-procedure reference vessel diameter <2.25 mm	7.4	1.5–36.1	0.014
Statin use at baseline	0.3	0.1–1.0	0.05
Major bleeding			
Presence of thrombus	8.4	2.0–35.9	0.004
Body mass index >30 kg/m^2	5.5	1.5–20.6	0.011

The sample population for the endpoints depended on the number of patients with no missing data for the predictors selected: death (n = 658); stent thrombosis (n = 625), and major bleeding (n = 594).

therapy; and 4) dual antiplatelet therapy and age >65 years as independent predictors of bleeding after DES implantation. In the present study, although octogenarians suffered a higher rate of major bleeding complications than nonoctogenarians, the 1-year, independent predictors of major bleeding were the angiographic presence of a thrombus, obesity, and long lesions. The rate of major bleeding was relatively low in octogenarians, probably because patients perceived to be at high risk underwent implantation of bare-metal stents and were not entered in this registry, and because the indications to undergo the procedure were elective in most patients.

Coronary artery disease is highly prevalent and is the cause of most deaths in elderly patients. It has been hypothesized that the high mortality associated with increasing age is due to greater comorbidity, more severe coronary artery disease, and a reduced cardiac and general physiological reserve (5–19). Few reports of current PCI practices and outcomes in elderly patients have been published. Douglas et al. (34) reported significantly lower rates of death and MI after DES than after bare-metal stent implantation in elderly patients. Floyd et al. (35) observed higher rates of death, new MI, urgent revascularization, and other serious adverse events after DES implantation in patients >75 years of age than in younger patients, concluding that advanced age remains a predictor of adverse outcomes after PCI, despite the advent of DES. Kataoka et al. (36) found higher rates of MACE after bare-metal stent implantation in women >75 years of age than in younger patients or in elderly men, although they found lower rates of death from all causes and of target vessel revascularization after SES implant. In the present study, the cardiac mortality was significantly higher in octogenarians than in nonoctogenarians. However, the rate of any death up to 1 year and the Charlson comorbidity index were higher in octogenarians. Despite this high-risk profile, the rate

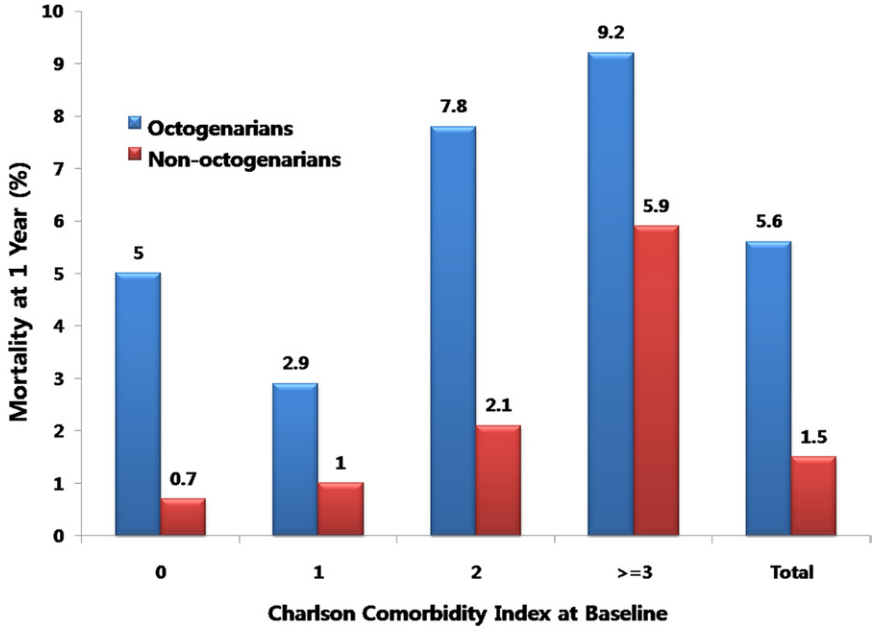

Figure 5. Relation Between Charlson Comorbidity Index and Mortality at 1 Year

There is a stronger correlation between the Charlson comorbidity index and mortality at 1 year for octogenarian patients compared with younger patients.

of repeat revascularization was similar, and the incidences of adverse events were only slightly higher than that of nonoctogenarians.

The Charlson comorbidity index has been prospectively tested and predicts a variety of patient outcomes, including mortality, post-operative complications, length of stay, and hospital charges (22–26). To our knowledge, the e-SELECT registry is the first study to prospectively study the relationship between the Charlson index and outcome after PCI. The Charlson index was significantly higher in octogenarians and was a strong predictor for adverse events. Careful assessment of comorbidities in elderly patients who are candidates for coronary revascularization is recommended. The use of the Charlson index could further improve the screening process of elderly patients for coronary revascularization by allowing a simple and comprehensive quantification of comorbidities.

Study limitations. First, as in the case of several other large cardiovascular registries, the e-SELECT database was not externally validated. However, all institutions had agreed to a strict adherence to the specific a priori definitions of the study variables. Furthermore, institution-specific outcomes were not released outside each institution, encouraging a trustworthy reporting of outcomes. Second, the results of this study are only applicable to selected octogenarians undergoing PCI by experienced operators in high-volume medical centers. Third, the clinical follow-up, limited to 1 year, precluded the evaluation of very late stent thrombosis and adverse events.

Conclusions

Although event rates were higher than in younger patients, octogenarians had markedly more comorbidities than younger patients. If the risks and benefits of PCI are carefully evaluated, taking into account comorbidities, lesion characteristics, and bleeding risks with prolonged dual antiplatelet therapy, stenting with SES may be an effective therapeutic option in elderly patients with acceptable rates of MACE and complications, and a low rate of repeat revascularization compared with younger patients as demonstrated by this e-SELECT registry subgroup analysis.

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Key Words: coronary artery disease ■ hemorrhagic complication ■ octogenarian ■ percutaneous coronary intervention ■ sirolimus-eluting stent ■ stent thrombosis.