

Predictive Ability of the SYnergy Between Percutaneous Coronary Intervention with TAXus and Cardiac Surgery Score II for Long-term Mortality in Patients with Three-vessel Coronary Artery Disease Undergoing Percutaneous Coronary Intervention Treated with Second-generation Drug-eluting Stents

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Abstract

Background: The SYnergy between percutaneous coronary intervention with TAXus and cardiac surgery Score II (SS-II) can well predict 4-year mortality in patients with complex coronary artery disease (CAD), and guide decision-making between coronary artery bypass graft surgery and percutaneous coronary intervention (PCI). However, there is lack of data regarding the utility of the SS-II in patients with three-vessel CAD undergoing PCI treated with second-generation drug-eluting stents (DES). The purpose of the present study was to evaluate the ability of the SS-II to predict long-term mortality in patients with three-vessel CAD undergoing PCI with second-generation DES.

Methods: Totally, 573 consecutive patients with *de novo* three-vessel CAD who underwent PCI with second-generation DES were retrospectively studied. According to the tertiles of the SS-II, the patients were divided into three groups: The lowest SS-II tertile (SS-II ≤ 20), intermediate SS-II tertile (SS-II of 21–31), and the highest SS-II tertile (SS-II ≥ 32). The survival curves of the different groups were estimated by the Kaplan–Meier method. Univariate and multivariate Cox proportional hazard regression analyses were performed to evaluate the relationship between the SS-II and 5-year mortality. The performance of the SS-II with respect to predicting the rate of mortality was studied by calculating the area under the receiver operator characteristic (ROC) curve. The predictive ability of the SS-II for 5-year mortality was evaluated and compared with the SS alone.

Results: The overall SS-II was 27.6 ± 9.0 . Among patients in the lowest, intermediate and the highest SS-II tertiles, the 5-year rates of mortality were 1.6%, 3.2%, and 8.6%, respectively ($P = 0.003$); the cardiac mortality rates were 0.5%, 1.9%, and 5.2%, respectively ($P = 0.014$). By multivariable analysis, adjusting for the potential confounders, the SS-II was an independent predictor of 5-year mortality (hazard ratio: 2.45, 95% confidence interval: 1.38–4.36; $P = 0.002$). The SS-II demonstrated a higher predictive accuracy for 5-year mortality compared with the SS alone (the area under the ROC curve was 0.705 and 0.598, respectively).

Conclusion: The SS-II is an independent predictor of 5-year mortality in patients with three-vessel CAD undergoing PCI treated with second-generation DES, and demonstrates a superior predictive ability over the SS alone.

Key words: Mortality; Percutaneous Coronary Intervention; Predictive Ability; Second-generation Drug-eluting Stents; SYNTAX Score II; Three-vessel Coronary Artery Disease

INTRODUCTION

The anatomical SYnergy between percutaneous coronary intervention with TAXus and cardiac surgery (SYNTAX)

score (SS) is an angiographic scoring system that was developed to quantify the complexity of coronary artery disease (CAD) and guide decision-making between coronary artery bypass graft (CABG) surgery and percutaneous coronary intervention (PCI) in patients with complex CAD.^[1–6] Studies have demonstrated that the SS can predict

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adverse cardiovascular events among patients undergoing PCI, but not among patients undergoing CABG,^[1,7-15] limiting its utility in clinical application. One important limitation of the SS is absence of clinical variables in the scoring algorithm. Patients with equivalent scores may have different short- and long-term outcomes, depending on the presence of comorbidities.^[16] To overcome these limitations, attempts have been made to combine clinical-based scores with the SS.^[17-20] The SS-II was recently developed, combining of the anatomical SS with anatomical and clinical variables that have been shown to modify the threshold value of the SS so that equipoise was achieved between CABG and PCI for long-term mortality in patients with left main (LM) and/or three-vessel CAD.^[21] In a recent validation study, Xu *et al.*^[22] investigated the long-term prognostic value of the SS-II in patients with LM CAD undergoing PCI. In patients with three-vessel disease but no LM involvement, especially undergoing contemporary PCI with second-generation drug-eluting stents (DES), however, the predictive value of the SS-II for long-term mortality has not been evaluated. The purpose of this study is to assess the ability of the SS-II to predict 5-year mortality in patients with three-vessel disease exclusively treated with second-generation DES.

METHODS

Study design and patient population

From December 2008 to January 2010, 573 consecutive patients with *de novo* three-vessel CAD undergoing PCI and exclusively treated with second-generation DES including zotarolimus-eluting stent ENDEAVOR, zotarolimus-eluting stent RESOLUTE (Medtronic Inc., Santa Rosa, California, USA), and everolimus-eluting stent (Abbott Vascular, Santa Clara, California, USA) in Beijing Anzhen Hospital, China were retrospectively analyzed. Patients with previous PCI or CABG or presenting with acute myocardial infarction (MI) were excluded. Patients were pretreated with 100 mg/d of aspirin and a loading dose of 300 mg of clopidogrel or 75 mg/d clopidogrel for at least 3-day prior to PCI. After the procedure 100 mg/d of aspirin and 75 mg/d of clopidogrel in combination were continued for at least 12 months, aspirin alone was used indefinitely. Follow-up clinical status was documented through hospital records review, telephone interviews, or office visits to the outpatient clinic after the index procedure.

SYnergy between percutaneous coronary intervention with TAXus and Cardiac Surgery score II

The SS-II has been described in detail previously.^[22] Briefly, in the present study, the baseline SS was calculated using dedicated software as previously reported,^[5] and according to the predefined algorithm, points were added taking into account 6 other clinical variables (age, sex, left ventricular ejection fraction, creatinine clearance, chronic obstructive pulmonary disease, and peripheral vascular disease) leading to the SS-II. The baseline SS for each angiogram was assessed by two experienced investigators who were blinded as to procedural data and clinical outcome. In case of

disagreement, the opinion of a third observer was obtained, and the final decision was made by consensus. According to tertiles of the SS-II for PCI, the patients were divided into three groups: The lowest SS-II tertile, intermediate SS-II tertile, and the highest SS-II tertile.

Study endpoints

The primary objective of the present study was to evaluate the impact of the SS-II for PCI on the risk of all-cause mortality in patients with three-vessel disease undergoing PCI. The primary endpoint of this analysis was all-cause mortality at 5-year follow-up. The secondary endpoints included the rates of cardiac death, MI, cerebrovascular event, any repeat revascularization, and major adverse cardiac and cerebrovascular events (MACCE) defined as a composite of all-cause death, cerebrovascular event, MI, and repeated revascularization. Death was defined as any postprocedural death and was considered of cardiac origin unless there was documentation of another cause. A cerebrovascular event was defined as an ischemic neurologic deficit lasting more than 24 h. Repeated revascularization was defined as a subsequent revascularization procedure by percutaneous intervention or surgery after PCI.

Statistical analysis

Continuous variables are presented as mean \pm standard deviation (SD) and were compared using the Student's *t*-test or the Mann–Whitney rank sum test when appropriate. Categorical data are expressed as frequency (percent) and were compared with the Chi-square or Fisher's exact test. Survival curves were generated for time-to-event variables using Kaplan–Meier estimates, and differences in survival were compared using the log-rank test. Patients lost to follow-up were considered at risk until the date of last contact, at which point they were censored. In addition to SS-II risk score, relationships of all-cause death to covariates, utilizing previously published baseline and peri- and post-procedural characteristics, were investigated with univariate Cox regression models. The statistically significant correlates of worse prognosis identified in univariable analyses were then introduced into a multivariable model using the forced enter method, with a variable entry criterion of 0.05. Receiver operator characteristic (ROC) curves were constructed to assess the predictive accuracy of the SS-II for 5-year all-cause mortality. The minimized absolute value of sensitivity-specificity was chosen as the optimal ROC cut-off point. All tests were two-tailed, and a $P < 0.05$ was considered as statistically significant. All analyses were performed using SPSS 17.0 for Windows (SPSS, Inc., Chicago, IL, USA).

RESULTS

Baseline clinical, angiographic and procedural characteristics

Among the entire cohort, the mean \pm SD of the overall SS and SS-II were 26.8 ± 11.5 and 27.6 ± 9.0 , respectively.

According to the tertiles of SS-II, the patients were divided into three groups: The lowest SS-II tertile (SS-II ≤ 20), intermediate SS-II tertile (SS-II of 21–31), and the highest SS-II tertile (SS-II ≥ 32). Baseline clinical, angiographic, and procedural characteristics of the study population, stratified according to SS-II tertiles, are shown in Table 1. Compared with patients in the lower tertile, those in the upper tertile were older, more frequently female, and with higher incidence of hypertension, and diabetes. They were also more likely to have had a previous MI, peripheral vascular disease, or stroke and were more often nonsmokers with lower pre-PCI creatinine clearance. In addition, the mean number of diseased lesions, treated lesions, and stents per patient in those in the upper tertile were significantly higher compared with that of those in the lower tertile as shown in Table 1.

Long-term follow-up outcome

Among the 573 eligible patients enrolled, 41 patients were lost to follow-up, and clinical data were obtained in 92.8% of the overall cohort. At 5-year follow-up, the rates of all-cause death, cardiac death, MI, stroke, any repeat revascularization, and MACCE in the overall cohort were 4.4%, 2.4%, 6.6%, 3.7%, 21.8%, and 27.7%, respectively. Clinical outcomes stratified according to SS-II tertiles are shown in Table 2 and Figure 1a-e. The incidences of all-cause death, cardiac death, and MI at 5-year were significantly increased among patients with the highest SS-II tertile as compared to those with intermediate or the lowest

SS-II tertiles. No significant difference existed between the intermediate and the lowest tertiles. In univariate Cox regression analysis, the SS-II, SS, age, left ventricular ejection fraction, previous MI, peripheral vascular disease, and serum creatinine clearance significantly predicted the rate of 5-year all-cause mortality. In multivariate analysis, after adjusting for potential confounders, the SS-II was an independent predictor of 5-year mortality (hazard ratio [HR]: 2.45, 95% confidence interval [CI]: 1.38–4.36; $P = 0.002$). The other independent predictors included SS, age, left ventricular ejection fraction, and serum creatinine clearance as shown in Table 3.

Receiver operator characteristic analysis

Receiver operator characteristic curve analysis showed a significant association between the SS-II and 5-year all-cause mortality with an area under the curve (AUC) of 0.705 (95% CI: 0.599–0.811, $P = 0.001$). The AUC demonstrated a substantially higher predictive accuracy of the SS-II for 5-year all-cause death, compared with the anatomical SS alone (AUC = 0.598, 95% CI: 0.502–0.694, $P = 0.003$) as shown in Figure 2.

DISCUSSION

To the best of our knowledge, the current study is the first to evaluate specifically the SS-II for prediction of long-term mortality in patients with three-vessel disease exclusively treated with second-generation DES. The following are

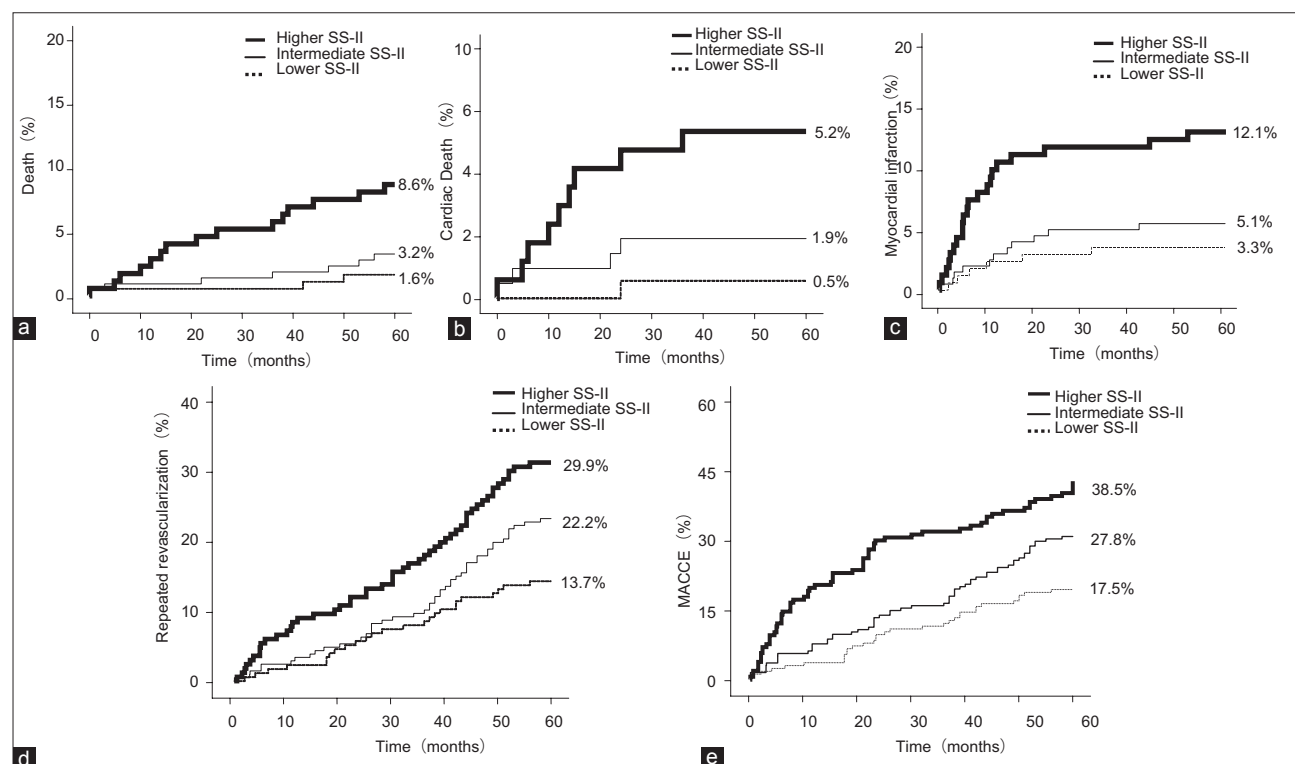


Figure 1: Kaplan–Meier curves showing event rates stratified by the SYnergy between percutaneous coronary intervention with TAXus and cardiac surgery score-II (SS-II) through 5-year all-cause death (a); cardiac death (b); myocardial infarction (c); repeated revascularization (d); major adverse cardiac and cerebrovascular events (MACCE), defined as a composite of all-cause death, cerebrovascular event, myocardial infarction, and repeated revascularization (e) stratified by tertiles of SS-II.

the main findings of this study: (1) The SS-II was an independent predictor of 5-year all-cause mortality (*HR*: 2.45, 95% *CI*: 1.38–4.36, *P* = 0.002) in patients with three-vessel disease undergoing PCI, with higher SS-II associated with increased all-cause mortality. (2) The

SS-II demonstrated a superior ability over the anatomical SS alone in predicting 5-year mortality in a patient population with three-vessel disease undergoing PCI. (3) The incidences of 5-year all-cause death, cardiac death, MI, and MACCE were significantly higher in the upper SS-II tertile than in the lower 2 tertiles. However, the rate of 5-year stroke was not significantly different among SS-II tertiles.

Table 1: Baseline clinical, angiographic and procedural characteristics of the study population

Variables	SS-II			P
	≤20 (n = 183)	≥21–31 (n = 216)	≥32 (n = 174)	
Age, years	51.4 ± 6.4	60.9 ± 8.3	71.0 ± 5.9	<0.0001
Male	177 (96.7)	164 (75.9)	91 (52.3)	<0.0001
Previous MI	7 (3.8)	22 (10.2)	13 (7.5)	<0.0001
Hypertension	105 (57.4)	158 (73.1)	133 (76.4)	0.005
Diabetes	57 (31.1)	66 (30.6)	69 (39.7)	0.544
Hypercholesterolemia	75 (41.0)	66 (30.6)	42 (24.1)	0.008
Current smoker	93 (50.8)	101 (46.8)	37 (21.3)	<0.0001
Previous stroke	9 (4.9)	24 (11.1)	24 (13.8)	0.019
Peripheral vascular disease	0 (0)	2 (0.9)	19 (10.9)	<0.0001
COPD	1 (0.1)	3 (1.4)	4 (2.3)	0.417
LVEF	63.6 ± 6.6	63.5 ± 7.2	62.8 ± 10.4	0.605
Creatinine clearance, ml/min	123.3 ± 28.7	107.2 ± 28.8	73.1 ± 27.1	<0.0001
Clinical presentation				
Unstable angina	128 (69.9)	161 (74.5)	140 (80.5)	0.072
Stable angina	50 (27.3)	48 (22.2)	32 (18.4)	0.129
Silent ischemia	5 (2.6)	7 (3.3)	2 (1.1)	0.395
Number of diseased lesions	3.4 ± 1.4	5.1 ± 1.9	5.3 ± 1.9	<0.0001
Number of treated lesions	1.58 ± 0.76	1.91 ± 0.80	2.11 ± 0.98	<0.0001
Number of stents per patient	1.75 ± 0.94	2.20 ± 1.07	2.60 ± 1.45	<0.0001
DAPT >1-year	179 (97.8)	210 (97.2)	171 (98.3)	0.673
Baseline SS	19.3 ± 6.9	33.2 ± 10.9	32.4 ± 12.9	<0.0001
SS-II	18.1 ± 1.8	26.6 ± 2.7	38.9 ± 5.7	<0.0001

Values are n/N(%) or mean ± SD. COPD: Chronic obstructive pulmonary disease; DAPT: Dual-antiplatelet therapy; LVEF: Left ventricular ejection fraction; SS: SYNTAX score; SS-II: SYNTAX score II; SYNTAX: SYNergy between percutaneous coronary intervention with TAXus and cardiac surgery; MI: Myocardial infarction; SD: Standard deviation.

The anatomical SS is an important instrument in helping clinicians to establish the optimum revascularization approach in patients with complex CAD.^[1-5] However, the absence of clinical variables to guide decision-making between CABG and PCI is a major limitation of the SS. In previous reports, other scoring systems combining both the anatomical SS and clinical variables (such as the global risk classification, the clinical SS, and the logistic clinical SS, etc.) have been shown to have superior ability in predicting adverse outcomes than the SS alone in patients with complex CAD undergoing PCI.^[17-20] Recently, the SS-II was developed by incorporating clinical variables into anatomical SS and thereby allowing individualized approach to mortality prediction. It was internally validated in the SYNTAX trial and externally validated in the DELTA registry.^[21] In patients with unprotected LM disease, the EXCEL study^[23] demonstrated that the SS-II can predict 4-year mortality in both PCI and CABG arms, and forecasted at least an equipoise for long-term mortality between CABG and PCI. In the another study, Xu *et al.*^[22] reported that the SS-II possesses better long-term predictive power, mainly in terms of 4-year mortality, compared with the SS alone. Similar results were reported by Farooq *et al.*^[21] and Campos *et al.*^[24] although the population of their studies were patients with LM and/or three-vessel disease undergoing PCI. The result of the present study is consistent with that of the studies mentioned above. However, there are several notable differences: (1) Different study population. In the EXCEL study,^[23] study population were a cohort of subjects with LM disease only and low-intermediate anatomical SS (<33). The subjects of our study were patients with three-vessel disease only but no LM involvement. The

Table 2: Patient clinical outcomes at 5-year follow-up

Variables	SS-II			Trend	P		
	≤20 (n = 183)	≥21–31 (n = 216)	≥32 (n = 174)		1 versus 2	1 versus 3	2 versus 3
All-cause mortality	3 (1.6)	7 (3.2)	15 (8.6)	0.003	0.309	0.003	0.022
Cardiac mortality	1 (0.5)	4 (1.9)	9 (5.2)	0.014	0.242	0.008	0.030
Noncardiac mortality	2 (1.1)	3 (1.4)	6 (3.4)	0.206	0.791	0.133	0.178
Stroke	5 (2.7)	7 (3.2)	9 (5.2)	0.429	0.782	0.238	0.332
MI	6 (3.3)	11 (5.1)	21 (12.1)	0.002	0.377	0.002	0.011
Repeated revascularization	25 (13.7)	48 (22.2)	52 (29.9)	0.001	0.034	<0.0001	0.067
MACCE	32 (17.5)	60 (27.8)	67 (38.5)	<0.0001	0.017	<0.0001	0.012

Values are n/n (%). MACCE: Major adverse cardiac cerebrovascular events (the composite of all-cause mortality, stroke, MI, or any repeated revascularization); MI: Myocardial infarction; SS-II: SYNTAX score II; SYNTAX: SYNergy between percutaneous coronary intervention with TAXus and cardiac surgery.

Table 3: Univariate and multivariate analysis of predictors of 5-year mortality

Variables	P	HR	95% CI
Univariate Cox regression analysis			
Age (per 10-year increase)	<0.0001	2.25	1.49–3.41
Male	0.590	1.31	0.49–3.50
LVEF (per 10% increase)	<0.0001	0.51	0.43–0.61
Previous MI	<0.0001	6.28	2.71–14.55
Hypertension	0.310	1.21	0.56–2.74
Diabetes	0.110	1.89	0.86–4.14
Current smoker	0.410	1.34	0.63–3.04
Stroke	0.740	0.78	0.18–3.30
Peripheral vascular disease	0.040	3.55	1.06–11.85
Creatinine clearance (per 10% increase)	0.012	0.85	0.75–0.97
COPD	0.270	3.10	0.42–22.94
Baseline SS (per 10-point increase)	0.001	1.91	1.31–2.76
SS-II (per 10-point increase)	0.001	2.00	1.35–2.96
Multivariable Cox regression analysis			
Age (per 10-year increase)	0.001	2.85	1.57–5.17
LVEF (per 10% increase)	<0.0001	0.46	0.36–0.58
Previous MI	0.850	1.12	0.32–3.91
Creatinine clearance (per 10% increase)	0.019	0.75	0.58–0.95
Peripheral vascular disease	0.220	2.58	0.58–11.57
Baseline SS (per 10-point increase)	0.006	2.03	1.23–3.35
SS-II (per 10-point increase)	0.002	2.45	1.38–4.36

COPD: Chronic obstructive pulmonary disease; LVEF: Left ventricular ejection fraction; SS: SYNTAX score; SS-II: SYNTAX score II; SYNTAX: SYNERgy between percutaneous coronary intervention with TAXus and cardiac surgery; HR: Hazard ratio; CI: Confidence interval; MI: Myocardial infarction.

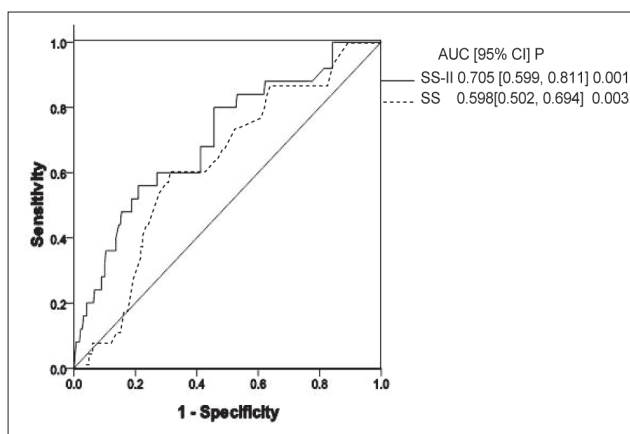


Figure 2: Receiver-operating characteristic curve analyses comparing the SYNERgy between percutaneous coronary intervention with TAXus and cardiac surgery score (SS) with the SS-II for the predictability of long-term mortality.

SS in the present study was higher than that in the studies of Xu *et al.*^[22] and Campos *et al.*,^[24] representing anatomically more complex CAD. The higher SS may also reflect a patient population with more advanced systemic atherosclerosis and, therefore, are at greater longer-term cardiovascular and cerebrovascular risk. (2) The use of

different stents. Second-generation DES were developed to overcome safety concerns with first-generation devices, and many data suggest significantly improved clinical outcomes in patients undergoing PCI with these new stents.^[25–27] Some studies even demonstrated remarkably lower long-term mortality with second-generation DES as compared with first-generation DES.^[28–30] Presently, second-generation DES were widely applied in patients with CAD undergoing PCI in clinical practice. With the exception of the EXCEL study,^[23] all other previous studies^[21,22,24] have enrolled patients entirely or mostly treated with first-generation DES. Some even included a small amount of bare metal stents. Therefore, the ability of the SS-II to predict long-term mortality in patients treated with second-generation DES implantation remains unknown. The result of the current study confirms the ability of the SS-II to independently predict long-term mortality in patients treated with second-generation DES. It provides important evidence to support the use of the SS-II in contemporary practice. (3) Different duration of follow-up. Our study evaluated the ability of the SS-II to predict 5-year mortality in patients with three-vessel disease undergoing PCI. To the best of our knowledge, this is the longest duration of follow-up among similar previous studies.^[21–24]

Study limitations

The current study has some limitations. First, it is a retrospective study. As a retrospective analysis, the results should be considered hypothesis generating. Second, it represents a single-center experience, which may affect the generalizability of our findings. In addition, the relatively small number of patients, further diminished by separation into SS-II tertiles, may influence the results. Third, the decision for PCI is based on the clinical judgment of the treating cardiologists, and thus may lead to selection bias. Fourth, although multivariable adjustments were performed for significant confounders ($P < 0.05$), the possibility of other unmeasured confounders affecting the results cannot be excluded. In addition, as all correlates that were significantly associated with increased mortality on univariable analyses were included in the multivariable model, this may have resulted in over-fitting. Fifth, the calculation of the anatomical SS is associated with inter and intraobserver variability, which is inherent in the subjective nature of its derivation from coronary angiography. Finally, there is no CABG comparative arm with three-vessel disease in this study.

In conclusion, in patients with three-vessel disease but no LM involvement undergoing PCI with second-generation DES, the SS-II is an independent and superior predictor of 5-year mortality, compared with the anatomical SS alone. As such, the SS-II may be a useful instrument for risk stratification in this patient population.

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