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CVN Interview

5-Year Follow-Up of Coronary Revascularization in Diabetic Patients With Multivessel Coronary Artery Disease

Insights From ARTS (Arterial Revascularization Therapy Study)-II and ARTS-I Trials

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Objectives We compared the 5-year outcomes of diabetic patients with multivessel disease treated with sirolimus-eluting stents (SES), bare-metal stents (BMS), and coronary artery bypass graft surgery (CABG) enrolled in the ARTS (Arterial Revascularization Therapy Study) I and II studies.

Background Diabetes is an established risk factor for major adverse cardiac events after revascularization. Recent trials suggest that revascularization with drug-eluting stents has equivalent safety to CABG up to 2 years.

Methods The ARTS I and II studies included 367 diabetic patients (SES: 159, CABG: 96, and BMS: 112) compared with respect to 5-year clinical outcomes.

Results The rate of major adverse cardiovascular and cerebrovascular events was significantly higher in patients treated with BMS (BMS 53.6% vs. CABG 23.4% vs. SES 40.5%; log-rank, $p < 0.01$ for SES vs. BMS and SES vs. CABG). There was no significant difference in mortality among all 3 groups. There was, however, a statistically significant difference in the myocardial infarction rate between BMS and CABG arms (BMS 11.0%, CABG 5.2%, SES 4.8%, $p = 0.04$ for SES vs. BMS and $p = 0.76$ for SES vs. CABG). The rate of repeat revascularization was significantly lower in patients treated with CABG compared with SES (SES 33.2% vs. CABG 10.7%, $p < 0.001$). Revascularization rate of patients treated with SES at 5 years approached that of patients treated with BMS although remained significantly lower. This "catch-up" phenomenon was not apparent in the nondiabetic population.

Conclusions At 5-year follow-up, CABG has comparable safety and superior efficacy compared with BMS and SES in the treatment of diabetic patients with multivessel disease. (J Am Coll Cardiol Intv 2011;4:317–23) © 2011 by the American College of Cardiology Foundation

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Diabetes mellitus is an established risk factor for development and progression of coronary atherosclerosis and is associated with an increased incidence of major adverse cardiac events (MACE) after revascularization (1,2). The difference in MACE between diabetic and nondiabetic patients treated with percutaneous revascularization has consistently been driven by the higher rates of repeat revascularization in diabetic patients (3,4). Similarly, among

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diabetic patients with multivessel disease (MVD) randomized to treatment with percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG), a correspondingly higher rate of repeat revascularization has been seen in those treated with PCI. With respect to mortality, other than the BARI (Bypass Angioplasty Revascularization Investigation) trial, which reported a lower mortality with CABG compared with balloon angioplasty (5), more contemporary studies report equivalent mortality among diabetic patients with MVD treated with CABG or PCI with either bare-metal (BMS) or drug-eluting stents (DES) (4,6–10).

Abbreviations and Acronyms

BMS = bare-metal stent(s)
CABG = coronary artery bypass graft surgery
Ccr = creatinine clearance
DES = drug-eluting stent(s)
MACE = major adverse cardiac event(s)
MACCE = major adverse cardiac and cerebrovascular event(s)
MI = myocardial infarction
MVD = multivessel disease
PCI = percutaneous coronary intervention
SES = sirolimus-eluting stent(s)

At present there are limited data on the long-term follow-up of patients with diabetes and MVD treated with DES. The ARTS-I (Arterial Revascularization Therapy Study Part I) and ARTS-II studies both recruited patients with MVD with the same inclusion criteria (11,12). In the ARTS-I study patients were randomized to treatment with a BMS or CABG, whereas in the single-arm ARTS-II study all patients received a sirolimus-eluting stent (SES). The 3-year outcomes of 367 patients with diabetes from the ARTS-I and ARTS-II studies have been published previously (3). The aim of this report was to describe the 5-year outcomes of this important subgroup of patients, which consequently represents the longest reported follow-up of diabetic patients with MVD treated with DES (3,4).

Methods

Study design. The ARTS-I and ARTS-II studies have been published previously (11,12). In brief, the ARTS-II study was a multicenter, nonrandomized, open-label trial designed to assess the safety and efficacy of SES in patients with native MVD and to compare the results with historical control subjects enrolled in the ARTS-I study (3,12,13).

The inclusion and exclusion criteria for both studies were the same. Patients with stable or unstable angina or silent ischemia who had ≥2 coronary lesions located in different major epicardial vessels and/or their side-branches (not including the left main stem) that were potentially amenable to stent implantation were eligible for inclusion. All patients were required to have a lesion with a diameter stenosis >50% in the left anterior descending coronary artery and ≥1 other major epicardial coronary artery. Stents with a diameter of 2.5 to 3.5 mm and length up to 33 mm were used. The goal was to achieve complete anatomic revascularization. There was no restriction on the total implanted stent length. Decisions to place stents in lesions with bifurcations, fresh thrombus, calcification, diffuse disease, or complex anatomy or for stenting of side branches were left to the discretion of the operators.

Patients with any prior coronary intervention, left main coronary disease, overt congestive heart failure, or a left ventricular ejection fraction <30% were excluded. Additional exclusion criteria included: history of a cerebrovascular accident, transmural myocardial infarction (MI) in the preceding week, severe hepatic or renal disease, neutropenia or thrombocytopenia, intolerance or contraindication to acetylsalicylic acid or thienopyridines, need for concomitant major surgery, and life-limiting major noncardiac diseases. The study was approved by the ethical committees of each participation institution. All patients signed informed consent before study entry.

Patient population. In total, 367 diabetic patients (20.4% of the overall ARTS I and II population) were studied in this analysis, comprising the 208 diabetic patients enrolled in the ARTS-I trial who were treated with BMS (n = 112) or CABG (n = 96) and the 159 diabetic patients enrolled in the ARTS-II trial treated with SES. In addition, comparison is made with the nondiabetic patient cohort.

Study objectives and end points. The primary objectives of the present analysis were to assess the long-term safety and efficacy of the SES compared with BMS and CABG in patients with diabetes and MVD. Comparison with the nondiabetic population is also provided.

The primary end point of this study was 5-year major adverse cardiac and cerebrovascular events (MACCE)—a composite of death, stroke, MI, and repeat revascularization. Other secondary end points included: death, stroke, MI, repeat revascularization, and stent thrombosis at 5-year follow-up.

End points and definitions. Deaths from all causes were reported. Cerebrovascular events included: stroke, transient ischemic attacks, and reversible ischemic neurologic deficits. Within 7 days after the intervention, a diagnosis of MI was made if new abnormal Q waves (according to the Minnesota code) and either a ratio of serum creatine kinase-myocardial

band isoenzyme/total cardiac enzyme that was >0.1 or a creatine kinase-myocardial band value that was 5× the upper limit of normal were present. Serum creatine kinase levels were measured 6 and 12 hours after the intervention and before discharge. Beginning 8 days after the intervention, either abnormal Q waves or enzymatic changes were sufficient for a diagnosis of MI. This 2-part method of defining MI was developed for the ARTS I study to address the difficulty of diagnosing an MI after surgery. An MI was confirmed only after the relevant electrocardiograms had been analyzed by the electrocardiographic core laboratory. All repeat revascularization procedures were recorded. Events were counted from the time of the start of the initial procedure. All clinical events were adjudicated by the clinical events committee. Five-year clinical follow-up was required in all patients and was obtained via a telephone interview with the patient and, when needed, the physician of the patient. The incidence of stent thrombosis according to the Academic Research Consortium definitions was only available for patients in the ARTS-II study (14). Renal impairment was classified by estimated creatinine clearance (Ccr) calculated by use of the Cockcroft–Gault formula (15): Ccr (ml/min) = ([140 − age] × weight [kg])/(serum creatinine [mg/dl] × 72). The formula was multiplied by a factor of 0.85 for female patients. Patients who had Ccr <60 ml/min were regarded as having renal impairment. Among 1,205 patients in the ARTS I study, 1,062 patients (88%) had their Ccr level before the revascularization, whereas in the ARTS II study, 580 patients (96%) had Ccr level before procedure among 607 patients.

Statistical analysis. Baseline characteristics were compared for diabetic patients in both the ARTS-I and ARTS-II trial. Continuous variables are reported as mean ± SD. Binary variable are reported as percentages with 95% confidence intervals. Two group *t* tests and Fisher tests were used for continuous and discrete variables, respectively. Time-to-event variables are presented as Kaplan-Meier curves generated with log-rank test. To compensate for differences in baseline and procedural characteristics between patients enrolled in the ARTS-I and ARTS-II trials, outcomes were adjusted with a Cox regression analysis with adjustments made for the potential confounding factors: age, sex, previous MI, history of revascularization, CABG, insulin dependence (only for diabetic patients), current smoking, dyslipidemia, and hypertension. Post-hoc Bonferroni correction was performed for analysis of variance. All analyses were performed with SPSS software (SPSS, Chicago, Illinois).

Results

Baseline characteristics of diabetic patients. Baseline and procedural characteristics of the 367 diabetic patients enrolled in the ARTS-I and ARTS-II trials are summarized in Table 1. Patients treated with SES were significantly more likely to be hypertensive and have hypercholesterolemia and complex coronary artery disease (type C lesions)

Table 1. Baseline Clinical and Angiographic Characteristics

	Diabetic Patients				Nondiabetic Patients			
	BMS (n = 112)	SES (n = 159)	CABG (n = 96)	p Value	BMS (n = 509)	SES (n = 448)	CABG (n = 488)	p Value
Age in yrs, mean	63	65	63	0.12	60	62	61	0.01
Ejection fraction	61	60	60	0.81	61	60	60	0.66
Male	73	67	69	0.53	78	80	77	0.56
Diabetes insulin-treated	21	18	17	0.78				
Hypertension	64	80	56	<0.01	40	63	43	<0.01
Hypercholesterolemia	55	74	49	<0.01	59	74	59	<0.01
Renal impairment*	15	5	15	<0.01	13	4	14	<0.01
Previous MI	41	30	49	<0.01	41	36	41	0.02
Previous PCI	2	0	2	0.17	1	1	2	0.10
Current smoking	21	12	17	0.15	30	22	28	0.02
Unstable angina	38	32	33	0.64	38	38	38	1.00
Stable angina	59	54	63	0.35	56	53	57	0.45
Silent ischemia	4	15	4	<0.01	7	9	5	0.04
2-vessel disease	65	49	64	0.01	69	45	67	<0.01
3-vessel disease	31	50	35	<0.01	27	55	29	<0.01
Total number of implanted stent	3.0 ± 1.5	3.6 ± 1.5		<0.01	2.7 ± 1.2	3.7 ± 1.5		<0.01
Total stented length in mm	52.7 ± 25.6	73.9 ± 31.9		<0.01	46.4 ± 20.6	72.0 ± 32.1		<0.01
Max. stent pressure in atm	14.9 ± 2.9	16.2 ± 2.7		<0.01	14.6 ± 2.8	16.4 ± 2.9		<0.01

Values are % or mean ± SD, unless otherwise indicated.

BMS = bare-metal stent(s); CABG = coronary artery bypass graft; MI = myocardial infarction; PCI = percutaneous coronary intervention; SES = sirolimus-eluting stent(s). *Patients who had Ccr <60 ml/min (calculated by Cockcroft-Gault formula) were regarded as having renal impairment.

compared with historical control subjects from the ARTS-I trial. Consequently, a greater number of stents and an overall longer total length was implanted in the ARTS-II cohort. In addition, reported completeness of revascularization was lower for patients treated with SES versus BMS (68.6% for BMS vs. 59.9% for SES-treated patients and 77.4% for CABG-treated patients with diabetes; p = 0.017).

Five-year clinical outcomes. Overall MACCE, death, MI, cerebrovascular accident, and repeat revascularization rates at 5

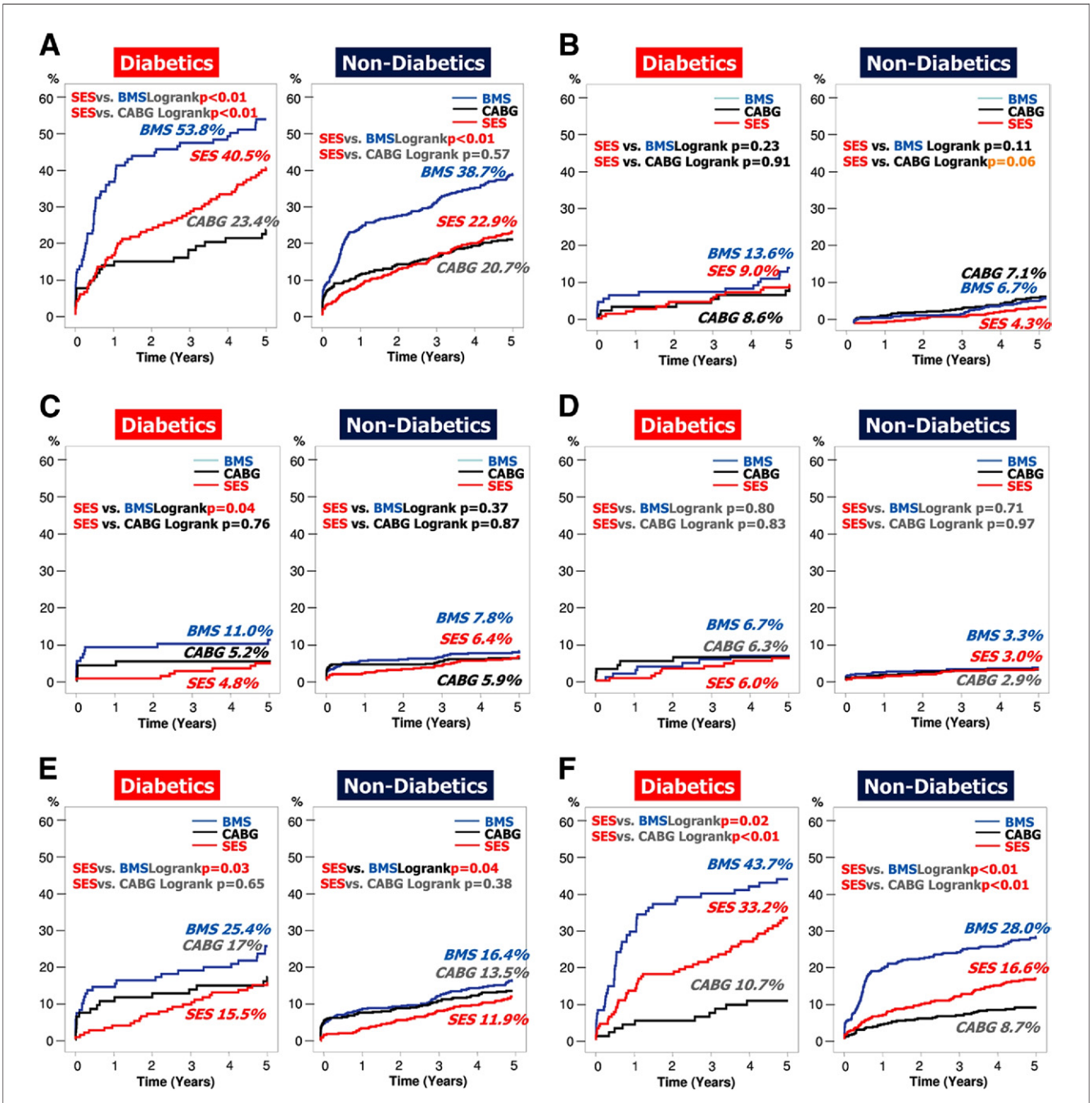

Figure 1. Cumulative Kaplan-Meier Incidence Estimates Up to 5 Years

Cumulative Kaplan-Meier incidence estimates up to 5 years in diabetic subjects and in nondiabetic subjects: 1) for major adverse cardiac and cerebrovascular events (a composite of all-cause mortality, myocardial infarction [MI], cardiovascular accident, or revascularization) **(A)**; 2) for all-cause mortality **(B)**; 3) for MI **(C)**; 4) for cerebrovascular accidents **(D)**; 5) for a composite end point of death, cerebrovascular accidents, or MI **(E)**; and 6) for any revascularization **(F)**. BMS = bare-metal stent(s); CABG = coronary artery bypass graft; SES = sirolimus-eluting stent(s).

Table 2. Unadjusted Nonhierarchical Event Rates Up to 1,800 Days and HRs

	Diabetic Patients						Nondiabetic Patients					
	BMS	SES	CABG	HR (95% CI) CABG vs. SES	p Value	HR (95% CI) BMS vs. SES	p Value	BMS	SES	CABG	HR (95% CI) CABG vs. SES	p Value	HR (95% CI) BMS vs. SES	p Value
MACCE	60 (53.6%)	63 (39.6%)	22 (22.9%)	0.54 (0.34–0.88)	0.014	1.65 (1.16–2.35)	0.006	187 (38.3%)	102 (22.8%)	103 (20.5%)	0.93 (0.70–1.22)	0.575	1.94 (1.53–2.47)	<0.001
Death	15 (13.4%)	14 (8.8%)	8 (8.3%)	0.95 (0.40–2.27)	0.911	1.56 (0.76–3.24)	0.229	32 (6.6%)	19 (4.2%)	35 (7.0%)	1.70 (0.97–2.97)	0.063	1.57 (0.89–2.78)	0.118
CVA	7 (6.3%)	9 (5.7%)	6 (6.3%)	1.24 (0.42–3.65)	0.70	1.33 (0.49–3.59)	0.58	16 (3.3%)	13 (2.9%)	14 (2.8%)	0.99 (0.45–2.18)	0.99	1.34 (0.81–2.23)	0.25
MI	12 (10.7%)	7 (4.4%)	5 (5.2%)	1.20 (0.38–3.78)	0.754	2.65 (1.01–6.51)	0.048	37 (7.6%)	28 (6.3%)	29 (5.8%)	0.96 (0.57–1.61)	0.866	1.25 (0.76–2.04)	0.379
Revasc.	47 (42.0%)	50 (31.4%)	10 (10.4%)	0.29 (0.15–0.57)	<0.001	1.58 (1.06–2.35)	0.025	134 (27.5%)	73 (16.3%)	42 (8.4%)	0.51 (0.35–0.74)	<0.001	1.88 (1.41–2.50)	<0.001

CI = confidence interval; CVA = cerebrovascular accident; HR = hazard ratio; MACCE = major adverse cardiac and cerebrovascular events (a composite of all-cause mortality, MI, cardiovascular accident, or revascularization); Revasc. = revascularization; other abbreviations as in Table 1.

years are reported in Kaplan-Meier curves (Figs. 1A to 1F), while crude event rates with unadjusted hazard ratios are presented in Table 2. The event rates were higher than those reported for the overall ARTS-I and ARTS-II populations (16). The MACCE rate was the highest in patients treated with BMS (BMS 53.8% vs. SES 40.5% vs. CABG 23.4%; log-rank, p values for SES vs. BMS and SES vs. CABG, $p < 0.001$). Cumulative incidence of all-cause mortality was 13.6%, 9.0%, and 8.6% for patients treated with BMS, SES, and CABG, respectively (log-rank for SES vs. BMS, $p = 0.23$; SES vs. CABG, $p = 0.91$). The rate of MI was highest (11.0%) for BMS, versus 4.8% for SES-treated patients and 5.2% for CABG patients (log-rank SES vs. BMS, $p = 0.04$; SES vs. CABG, $p = 0.76$), with a statistically significant difference between SES and BMS. There were no differences in the rates of cerebrovascular events between treatment groups at 5 years. Rates of repeat revascularization were the highest in the BMS revascularization group at 43.7% versus 33.2% in the SES-treated group and 10.7% in the CABG group (log-rank SES vs. BMS, $p = 0.02$; SES vs. CABG, $p < 0.01$).

In the SES group, clopidogrel use at 5 years was 13.2% in diabetic patients and 23.2% in nondiabetic patients ($p = 0.008$). Aspirin use was 68.6% in the diabetic patients and 77.7% in the nondiabetic patients ($p = 0.03$).

Cox regression analysis. The HRs (adjusted for baseline characteristics) for CABG versus SES and BMS versus SES are shown in Table 3. Treatment with BMS conferred significantly higher risk of MACCE, death, MI, and repeat revascularization than treatment with SES. Coronary artery bypass graft surgery offered no advantage over treatment with SES in terms of mortality or risk of MI. There was a reduced risk of repeat revascularization and overall (revascularization driven) MACCE with CABG compared with treatment with SES in diabetic patients. Similar analysis in the nondiabetic population (Table 3) showed equivalent HRs for MACCE and MI between CABG and SES and higher mortality for CABG. Revascularization rates remained higher in the SES group when compared with CABG, although the HR was 0.54 in the nondiabetic population versus 0.31 in the diabetic population. The interaction, however, between treatment type and diabetic status was nonsignificant for all clinical end points.

Stent thrombosis. In diabetic patients treated with SES there were 17 stent thrombosis events (10.7%), with 6 definite, 6 probable, and 5 possible stent thrombosis events. This is higher than the overall stent thrombosis rates reported for the ARTS-II population of 9.4% and 8.7% for the nondiabetic subgroup. The rate of definite stent thrombosis in both the diabetic and nondiabetic patient population was 3.8%. Two late and 2 very late stent thrombosis cases occurred in the diabetic patient population. Two patients with diabetes receiving SES (1.3% of 159) and 12

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Table 3. Adjusted HRs

	Diabetic Patients				Nondiabetic Patients			
	HR (95% CI) CABG vs. SES	p Value	HR (95% CI) BMS vs. SES	p Value	HR (95% CI) CABG vs. SES	p Value	HR (95% CI) BMS vs. SES	p Value
Death	1.11 (0.47–2.66)	0.81	1.77 (0.85–3.67)	0.137	1.99 (1.12–3.53)	0.02	1.88 (1.05–3.38)	0.04
CVA	1.24 (0.42–3.65)	0.70	1.33 (0.49–3.59)	0.58	0.99 (0.45–2.18)	0.99	1.15 (0.53–2.50)	0.72
MI	1.19 (0.38–3.76)	0.76	2.55 (1.00–6.47)	0.049	1.01 (0.60–1.73)	0.96	1.34 (0.81–2.23)	0.25
Death/CVA/MI	1.33 (0.70–2.50)	0.38	2.09 (1.21–3.62)	<0.01	1.26 (0.83–1.72)	0.33	1.49 (1.05–2.11)	0.03
Any Revasc.	0.31 (0.16–0.62)	0.001	1.61 (1.08–2.41)	0.02	0.54 (0.37–0.80)	<0.01	2.01 (1.49–2.71)	<0.01
MACCE	0.58 (0.36–0.95)	0.03	1.80 (1.25–2.57)	0.001	0.97 (0.75–1.32)	0.97	2.10 (1.64–2.70)	<0.01

The Cox regression models are constructed to adjust the following variables: age, sex, previous MI, history of revascularization, CABG, insulin dependence (only for diabetic patients), current smoking, dyslipidemia, and hypertension.

Abbreviations as in Tables 1 and 2.

patients without diabetes receiving SES (2.7% of 448) suffered from very late stent thrombosis.

Discussion

In this analysis we present the 5-year outcomes of PCI with the SES in diabetic patients with MVD. At 3-year follow-up of the ARTS-II trial, patients treated with SES had lower MACCE rates than patients treated with BMS PCI, and CABG in the ARTS-I trial, although the differences did not reach statistical significance (3). In contrast, at 5-year follow-up, MACCE rates were lowest for diabetic patients treated with CABG in the ARTS-I trial. Patients treated with SES had a MACCE rate lower than that of patients treated with BMS PCI in the ARTS-I trial but considerably higher than that of patients treated with CABG. As illustrated by the Kaplan-Meier curves for MACCE (Fig. 1A), although the event rate for patients treated with BMS and CABG reach an asymptotic value at 1 year, events continue to accumulate for patients treated with SES in the ARTS-II trial. After 2 years this increase in events is partly explained by an increase in MI rates (Fig. 1B). This "catch-up" phenomenon is much more apparent in the diabetic population compared with nondiabetic patients (Table 3). The rate of repeat revascularizations also continues to accumulate, approaching closer to that of the BMS-treated patients at 5 years (Fig. 1F). Cox regression model HRs suggest an advantage of CABG over SES in reducing repeat revascularization procedures but equivalence of the 2 procedures in terms of mortality and MI risk after adjusting for baseline covariates in patients with diabetes (Table 3). The SES clearly reduced the risk of MI, repeat revascularization, and overall MACCE but had only a nonsignificant effect on mortality compared with treatment with BMS. Overall stent thrombosis rate in the diabetic population treated with DES is 10.7% at 5 years, which is somewhat higher than that observed in the overall ARTS-II population (9.4%). The rates of definite stent thrombosis in diabetic and nondiabetic patients are the same at 3.8% with two-thirds of the cases classified as late or very late stent thrombosis.

Our analysis at 5-year follow-up agrees with other recent trials, such as the CARDIA (Coronary Artery Revascularisation in Diabetes) and SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) trials, which also demonstrate equivalent mortality of PCI with DES and CABG in patients with diabetes at 1-year follow-up (4,9,10). Both of these studies also demonstrate consistently higher revascularization rates in the PCI arms versus CABG arm. The SYNTAX diabetic subgroup analysis might have, however, been underpowered to detect differences in mortality at 1 and 2 years. Our results are also consistent with the BARI-2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes) trial findings, where survival rates were similar between PCI-treated and CABG-treated groups (86.4% for CABG vs. 89.2% for PCI) at 5 years. The differences in the MACE-free survival rate in patients with MVD randomized to CABG versus medical therapy were statistically significant, but no such difference was appreciated in patients randomized to PCI versus medical therapy. Effectiveness of PCI over medical therapy versus CABG will be assessed in the FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) trial, the first properly powered prospective trial of revascularization strategies in diabetic patients.

Study limitations. This study is a sub-analysis of the main ARTS-I and ARTS-II trials and hence suffers from inherent limitations, such as the lack of sufficient power because of the limited number of patients in the subgroups to provide definite answers. Although the protocol required that the lesions in the ARTS-II trial be potentially treatable by CABG, the absence of dialogue with the surgeons before the intervention might have caused a selection bias. Another potential bias of this study is that a 5-year time difference exists between the groups that were being compared, and

technology and medical practice have improved with time, as have surgical mortality rates. The study is nonrandomized, and consequently statistical adjustment is required to correct for the differences between the current study population and the historical ARTS-I population.

However, the results of the study after adjustment for differences in risk factors did not substantially differ from the unadjusted outcome, because the patients enrolled in the ARTS-II trial were in fact more complex in terms of demographic data and lesion characteristics than those included in the ARTS-I trial. In addition, some of the factors such as stent length used or willingness of the operator to treat more complex lesions with DES or use of dual antiplatelet agents could not be adjusted for and can be a confounding factor in the analysis. Given low numbers of events in some of the subgroups, the multivariate model might have been overfitted.

Conclusions

When compared with the outcome of the diabetic patients with MVD treated with either PCI or CABG, the overall MACCE-free survival rate at 5 years in patients treated with SES is higher than in patients treated with CABG and, although still more favorable than in patients treated with BMS, it seems to approach the rate of events in the BMS-treated group. The MACCE rate in diabetic patients treated with SES is predominantly driven by the rate of repeat revascularization. The mortality in the SES-treated population is similar to that of CABG patients at 5 years. Myocardial infarction rate was 2-fold higher in diabetic patients treated with BMS than in patients treated with either SES or CABG. At 5-year follow-up, CABG seems to have better outcomes than PCI in a diabetic patient population by virtue of reducing repeat revascularization rates, making CABG the preferred treatment for this subgroup of patients with MVD.

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