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The SPIRIT V Study

A Clinical Evaluation of the XIENCE V Everolimus-Eluting Coronary Stent System in the Treatment of Patients With De Novo Coronary Artery Lesions

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Objectives The SPIRIT V (A Clinical Evaluation of the XIENCE V Everolimus-Eluting Coronary Stent System in the Treatment of Patients With De Novo Coronary Artery Lesions) study is a post-market surveillance experience of the XIENCE V (Abbott Vascular, Santa Clara, California) everolimus-eluting stent (EES) in patients with higher-risk coronary anatomy.

Background Previous pre-approval studies have shown the safety and efficacy of EES in highly selected groups of patients.

Methods The SPIRIT V trial is a prospective, open label, single arm, multicenter study. Two thousand seven hundred patients with multiple de novo coronary artery lesions suitable for treatment with a planned maximum of 4 EES were enrolled at 93 centers in Europe, Asia Pacific, Canada, and South Africa. Lesions had a reference vessel diameter between 2.25 and 4.0 mm and a length of ≤28 mm by visual estimation. An independent clinical events committee adjudicated all end point-related events. The primary end point was the composite rate of all death, myocardial infarction (MI), and target vessel revascularization at 30 days. Secondary end points included stent thrombosis and acute success (clinical device and procedure success).

Results At 30 days, the primary composite end point of all death, MI, and target vessel revascularization was 2.7%. At 1 year, rates of cardiac death, overall MI, and target lesion revascularization were 1.1%, 3.5%, and 1.8%, respectively. The cumulative rate of definite and probable stent thrombosis was low at 0.66% at 1 year.

Conclusions Use of EES in patients with multiple, complex de novo lesions yielded 1-year major adverse cardiac events, stent thrombosis, and target lesion revascularization rates that are comparable to those of the more controlled SPIRIT II and SPIRIT III trials—which included patients with restricted inclusion/exclusion criteria—and other all-comer population, physician-initiated studies like the X-SEARCH (Xience Stent Evaluated At Rotterdam Cardiology Hospital) and COMPARE (A Randomized Controlled Trial of Everolimus-eluting Stents and Paclitaxel-eluting Stents for Coronary Revascularization in Daily Practice) trials. (J Am Coll Cardiol Intv 2011;4:168–75) © 2011 by the American College of Cardiology Foundation

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Stenting of de novo lesions in native coronary arteries has been shown to be a safe and effective treatment of coronary atherosclerosis. The application of antiproliferative drugs to the stent is believed to decrease the need for patients to undergo repeat percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG). Drug-eluting stents are used in approximately 50% of procedures in Europe and the U.S. (1).

The feasibility and efficacy of the XIENCE V (Abbott Vascular, Santa Clara, California) everolimus-eluting stent (EES) was investigated for the first time in the SPIRIT FIRST (A Clinical Evaluation of an Investigational Device. The Abbott XIENCE V Everolimus Eluting Coronary Stent System in the Treatment of Patients With de Novo Native Coronary Artery Lesions) trial (n = 60). In this multicenter, single-blind, controlled study the EES was compared with the uncoated MULTI-LINK VISION RX coronary stent (Abbott Vascular) in patients with native de novo coronary artery disease and showed a significant reduction in angiographic in-stent late loss for the EES, relative to the bare-metal stent at 6 and 12 months (2). This was continued out to 5 years without additional target vessel failure events and no very late stent thromboses reported between 1- and 5-year follow-up in the EES arm (3). The EES was further evaluated in the SPIRIT II (4) and SPIRIT III trials (5)—2 randomized comparisons against the TAXUS paclitaxel-eluting stent (PES)—both of which suggested superior clinical outcomes out to 2 years with the EES. Both trials had restrictive angiographic inclusion criteria. The aim of the SPIRIT V study was to continue the assessment of the EES in patients with higher-risk anatomy outside the restrictive inclusion/exclusion criteria used in the SPIRIT II and SPIRIT III trials. In this manuscript we report the 30-day and 1-year clinical results of this study.

Methods

Patient selection. This prospective open-label single-arm multicenter study was conducted in 93 clinical sites in several countries in Europe and Asia, also including India, Canada, South Africa, and New Zealand (Online Appendix). Two thousand seven hundred patients were enrolled between November 2006 and November 2007. The study protocol was approved by the medical ethics committee of each participating site before patient enrollment. A prospective single-blind double-arm randomized multicenter substudy, in which diabetic patients were randomized in a 2:1 ratio (EES vs. PES), will be reported separately.

Patients were recruited from the general interventional cardiology population who had been admitted for a PCI procedure. Inclusion criteria were according to the instructions for use, which included patients with age >18 years, evidence of myocardial ischemia, stable or unstable angina, and silent ischemia or a positive functional study or a reversible change in the electrocardiogram consistent with ischemia. Patients were also required to be acceptable for CABG surgery and had to agree to undergo all protocol-required follow-up examinations. Coronary anatomy had to be suitable for optimal planned treatment with a maximum of 4 planned EES in de novo target lesions with a vessel reference diameter between 2.25 and 4.0 mm and a lesion length of ≤28 mm by visual estimation. Patients were not eligible if they had participated in another device or drug study or had completed the follow-up phase of another study within 30 days before enrollment. Eligible patients were asked to provide informed consent, as approved by the local medical ethics committee of each clinical site. Patients meeting the general inclusion/exclusion criteria were asked to provide informed consent and were to be entered into the screening log, whether enrolled in the study or not. Screening failures accounted for 13.6% of the total patients entered in the screening log (425 of 3,125).

Abbreviations and Acronyms

ARC = Academic Research Consortium
CABG = coronary artery bypass grafting
CI = confidence interval
EES = everolimus-eluting stent(s)
ITT = intent-to-treat
MACE = major adverse cardiac event(s)
MI = myocardial infarction
PCI = percutaneous coronary intervention
QCA = quantitative coronary angiography
ST = stent thrombosis
TLF = target lesion failure
TLR = target lesion revascularization
TVR = target vessel revascularization

EES. Details of the device have been published previously (2,4). Briefly, the study device, the XIENCE V EES (Abbott Vascular, Santa Clara, California), comprises the MultiLink VISION stent or the ML MINI VISION stent on a delivery system with a drug-eluting coating. The ML VISION stent is a balloon-expandable stent, which consists of serpentine rings connected by links fabricated from a single piece of medical-grade L–605 cobalt chromium alloy. The drug coating is composed of 2 polymers and the antiproliferative drug everolimus. Everolimus is blended in a non-erodable polymer, coated over another non-erodable polymer primer layer. The coating comprises acrylic and fluorinated copolymers, both approved for use in blood-contacting applications. Everolimus (Certican, Novartis Pharmaceuticals, Basel, Switzerland) is a drug that has been approved for use in conjunction with other medications to prevent heart and renal transplant rejection in many countries worldwide.

Procedural information. Patients were registered via an interactive voice response system (ICON Clinical Research, Eastleigh, United Kingdom) after confirmation of the angiographic inclusion criteria and successful pre-dilation of the first target lesion. Registered patients were considered enrolled in the study and were to remain in the study until completion of the required follow-up period. The process of

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registration was designed to reduce investigator bias with regard to enrollment and/or withdrawal of patients in the study.

The stent was available in diameters of 2.25, 2.5, 2.75, 3.0, 3.5, and 4.0 mm and lengths of 8, 12, 15, 18, 23, and 28 mm. Treatment was with up to a maximum of 4 planned study stents, depending on the number of vessels treated and their respective lesion lengths. Overlapping stents were required to have a minimum overlap of 1 mm and a maximum of 4 mm. All target lesions were to be treated with standard interventional techniques with mandatory pre-dilation and stent implantation at a pressure not exceeding the rated burst pressure. Post-dilation was left to the discretion of the investigator; however, if performed, it was only to be done with balloons sized to fit within the boundaries of the stent. Brachytherapy in any lesion or vessel or any other non-study percutaneous procedure was not allowed at the time of the study procedure. In the event of bailout and additional stent requirement, the EES were to be used.

Periprocedural pharmacotherapy was administrated according to standard hospital practice. Either unfractionated heparin or bivalirudin was allowed for procedural anticoagulation. The use of glycoprotein IIb/IIIa inhibitors was left to the discretion of the investigator. All patients enrolled in the study were to be pre-treated with a loading dose of ≥300 mg of clopidogrel. After the procedure, the protocol recommended that patients receive clopidogrel 75 mg daily for a minimum of 3 months with ≥75 mg of aspirin for a minimum of 5 years.

Source document verification. In the present study, source document verification was routinely performed in 20% of random cases and 100% of all reported adverse events at the time of the study conduct, resulting in an overall rate of 30%. In addition, sites with low rates of reported events received additional training and monitoring visits to confirm event-reporting. Finally, all reported end points-related events were adjudicated by an independent clinical events committee that had access to source documentation.

Follow-up. Assessment of anginal status, collection of data regarding adverse events, details of any subsequent coronary interventions, Clinical Investigational Plan medications, and use and changes in concomitant medications were collected at 30 days (±7 days) and 1 year (±28 days).

Study end points. The primary end point was the adjudicated composite rate of all death, myocardial infarction (MI), and target vessel revascularization (TVR) at 30 days. In addition to acute success including clinical device and clinical procedure success, secondary end points included adjudicated stent thrombosis (ST) and adjudicated cardiac death, MI, and revascularization (target lesion revascularization [TLR]/TVR/all revascularizations) rates. The adjudicated composite rates of cardiac death, MI not clearly attributed to a nontarget vessel and TLR, and of all death, MI, and any revascularization (TLR/TVR/non-TVR) were reported at 30 days and at 1 year.

Definitions. All study end point events were adjudicated by an independent clinical event committee according to the Academic Research Consortium (ARC) definitions (6). All adverse events were reported bimonthly to an independent data and safety monitoring board that reviewed data to identify any safety issues related to the conduct of the study.

DEATH. All deaths were considered cardiac unless an unequivocal noncardiac cause could be established. Specifically, any unexpected death, even in patients with coexisting potentially fatal noncardiac disease (e.g., cancer, infection), were classified as cardiac.

CARDIAC DEATH. Cardiac death was defined as any death due to immediate cardiac cause (e.g., MI, low-output failure, fatal arrhythmia). Unwitnessed death and death of unknown cause were classified as cardiac death. This included all procedure-related deaths including those related to concomitant treatment.

MI. The MI classification and criteria for diagnosis were defined according to the ARC as follows: for nonprocedural/spontaneous MI, troponin or CK-MB levels had to be >2× upper limit of normal; for peri-PCI, troponin or CK-MB levels had to be ≥3× upper limit of normal; for peri-CABG, troponin or CK-MB levels had to be ≥5× upper limit of normal. The periprocedural period included the first 48 h and 72 h after PCI and CABG, respectively. All late events that were not associated with a revascularization procedure were considered spontaneous. One blood sample was taken from each patient within the post-procedure hospital stay period for the analysis of CK-MB or troponin levels.

TLR. A TLR is defined as any repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion. The target lesion is defined as the treated segment from 5 mm proximal and 5 mm distal to the stent.

TVR. A TVR is defined as any repeat percutaneous intervention or surgical bypass of any segment of the target vessel. The latter is defined as the entire major coronary vessel proximal and distal to the target lesion, including upstream and downstream branches and the target lesion itself.

TARGET LESION FAILURE (TLF). TLF is defined as the composite of cardiac death, target vessel MI, or ischemia-driven TLR (PCI or CABG).

ST. Stent thrombosis was categorized as acute (<1 day), subacute (1 to 30 days), and late (>30 days) and was defined according to the ARC guidelines as follows: definite: acute coronary syndrome and angiographic or pathological confirmation of ST; probable: unexplained death ≤30 days or target vessel MI without angiographic information; and possible: unexplained death >30 days after stent placement.

CLINICAL DEVICE SUCCESS. Clinical device success was defined as successful delivery and deployment of the study

stent (in an overlapping stent setting, a successful delivery and deployment of the first and following study stent) at the intended target lesion and successful withdrawal of the stent delivery system with attainment of final residual stenosis of <50% of the target lesion by quantitative coronary angiography (QCA) (by visual estimation if QCA unavailable), without use of a device outside the assigned treatment strategy. Bailout patients were included as clinical device success only if the aforementioned criteria were met.

CLINICAL PROCEDURE SUCCESS. Clinical procedure success was defined as successful delivery and deployment of the study stent or stents at the intended target lesion and successful withdrawal of the stent delivery system with attainment of final residual stenosis of <50% of the target lesion by QCA (by visual estimation if QCA unavailable) and/or with any adjunctive device without the occurrence of cardiac death, MI not clearly attributed to a nontarget vessel, and/or clinically indicated TLR during the hospital stay with a maximum of first 7 days after index procedure. In a multiple lesions setting, each lesion must have met clinical procedure success criteria.

Statistical analysis. All analyses were performed on the intent-to-treat (ITT) population. The sample size for the study was based on the primary end point of the composite rate of all death, MI, and TVR at 30 days. A sample size of 2,700 patients would produce a narrow 2-sided 95% confidence interval (CI) around the clinical end points estimates. The one-half width of the 2-sided CI around the primary end point would be between 0.6% and 0.9%, assuming a true rate between 3% and 6%. Binary variables are presented as percentages. Mean and SD are presented for continuous variables.

Subgroup analysis with TLF as outcome is represented with descriptive measurements (absolute percentage difference), 95% CI, and post hoc p value (with normal approximation), with subgroups created according to sex: women (n = 580) versus men (n = 2,020); vessel diameter: ≤2.75 mm (n = 1,046) versus >2.75 mm (n = 1,554); number of target vessels treated: single vessel (n = 2,125) versus multiple vessels (n = 475); lesion length: ≥20 mm (n = 889) versus <20 mm (n = 1,711); diabetes status: patients with (n = 768) versus patients without diabetes or unknown diabetes status (n = 1,832); and bifurcation C, D, F, G lesions: patients with (n = 502) versus patients without C, D, F, G bifurcation lesions (n = 2,098).

Results

A total of 2,700 patients were enrolled in the study. As defined by the protocol, all results are presented for the ITT population. Thirty-seven patient records were excluded from the ITT population due to enrollment errors, lack of informed consent, and/or no attempt to implant an EES during the index procedure, leaving an ITT population of 2,663 patients (Fig. 1).

Baseline demographic data (Table 1) showed that 30% of patients were diabetic, 82% of lesions were class B2 or C classification according to the American College of Cardiology/American Heart Association, and 29% of patients had more than 1 target lesion treated.

Lesions, as assessed by the treating physician, had a mean reference vessel diameter of 3.0 mm and mean lesion length of 15.6 mm (Table 2). Most treated lesions were in the left anterior descending artery (46%). Patients were treated according to standard interventional techniques with high acute device and procedure success rates (99% and 98%, respectively). The mean number of lesions treated/patient was 1.4, and the mean number of devices implanted was 1.5.

At 30 ± 7 days, the primary end point of adjudicated composite rate of all death, MI, and TVR was 2.7% (Table 3). The overall death rate was 0.5%, and the MI rate was 2.2% with 0.2% Q-wave MI and 2.0% non–Q-wave MI. Because there was no angiographic follow-up in the study, all revascularizations were considered ischemic-driven, and the TLR rate at 30 days was 0.3%. At 1 year ± 28 days the composite rate of cardiac death, MI not clearly attributed to a nontarget vessel, and TLR was 5.1% (Fig. 2). The cardiac death rate was 1.1%, the MI rate was 3.5%, and the rate of any revascularization was 5.9% (including TLR 1.8%, TVR (excluding TLR) 1.5%, TVR (including TLR) 2.8%, and non-TVR 3.9%).

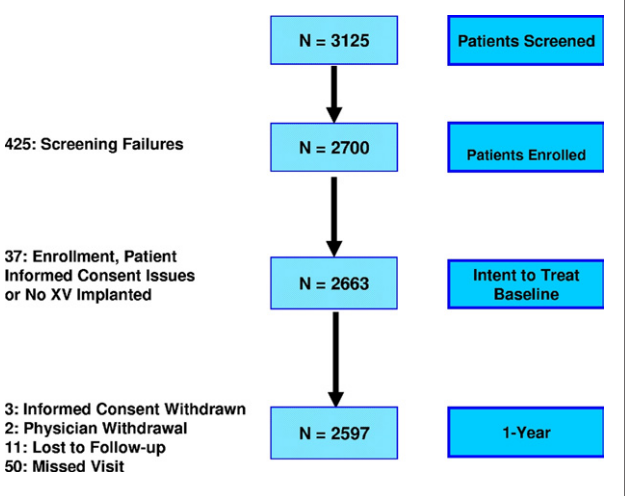

Figure 1. ITT Population Through 1 Year

A total of 2,700 patients with multiple de novo coronary artery lesions were enrolled at 93 centers in Europe, Asia Pacific, Canada, and South Africa. A total of 37 patient records were excluded from the intent-to-treat (ITT) population due to enrollment errors, lack of informed consent, and/or no attempt to implant an everolimus-eluting stent during the index procedure, leaving an ITT population of 2,663 patients. At 1 year, 3 patients had withdrawn informed consent, 2 patients were withdrawn by the physician, 11 patients were lost to follow-up, and 50 patients missed the follow-up visit, leaving a population of 2,597 patients.

Table 1. Baseline Characteristics of the Intent-to-Treat Population (n = 2,663)

Age (yrs)	63 ± 11
Men, n	78
Current tobacco use	24
All diabetes mellitus	30
Diabetes mellitus requiring medication	26
Diabetes mellitus requiring insulin	7
Hypertension requiring medication	64
Hypercholesterolemia requiring medication	59
All prior cardiac intervention	25
Prior cardiac intervention on target vessel(s)	9
Family history of coronary artery disease	34
MI within 2 months	13
Stable angina	46
Unstable angina	33
Silent ischemia	5
Number of diseased vessels	
Single-vessel	58
Double-vessel	27
Triple or more vessels	14
Number of target lesions	
1	71
2	22
3	5

Values are mean ± SD or %.
MI = myocardial infarction.

Target lesion failure (defined as composite of cardiac death, MI related to the target vessel, and TLR) rates at 1 year did not significantly differ between the high-risk subgroups studied and their fewer complex counterparts, with the exception of patients with multiple vessels treated (Fig. 3). Patients with multivessel treatment had significantly higher 1-year TLF rates compared with those who had a single vessel treated (absolute difference: 3.06%, 95% CI: 0.52% to 5.60%, p = 0.011).

Table 2. Procedural Characteristics (n = 2,663)

Acute procedure success	98
Acute device success	99
LAD	46
LCX	25
RCA	28
Lesion class B2/C	82
Reference vessel diameter (mm)	3.0 ± 0.4
Lesion length (mm)	15.6 ± 6.2
Stented length (mm)	29.4 ± 17.1
Number of target lesions	1.4 ± 0.7
Stents implanted/patient	1.5 ± 0.8
Most frequent stent length implanted (18.0 mm)	25
Most frequent stent diameter implanted (3.0 mm)	41

Values are % or mean ± SD. Most frequent stent length and diameter are based on 4,091 implanted study stents. Reference vessel diameter and lesion length are based on 3,645 lesions.
LAD = left anterior descending artery; LCX = left circumflex artery; RCA = right coronary artery.

The definite and probable subacute and late ST rates at 1 year were 0.3% and 0.2%, respectively (Fig. 4). The cumulative definite and probable ST rate to 1 year was 0.66%. At 1 year, 86% and 97% of patients were taking clopidogrel and aspirin, respectively.

Discussion

The EES have been shown to be safe and effective in randomized trials of carefully selected patients. The objective of the SPIRIT V trial was to evaluate whether this also holds true in patients with more complex lesion types that were selected under less-restrictive criteria and thus more closely resembling the real-world situation. As investigator reported, the population in the SPIRIT V trial included a high proportion of complex patients, including 30% of diabetic patients, 82% with class B2 or C lesions, and 29% with more than 1 target lesion treated.

Our data show that, in this complex patient population, the rates of cardiac death, MI, and TLR were low at 30 days and remained low at 1 year. This is evidenced by the low composite rate of cardiac death, target vessel-related MI, TLR, late definite and probable ST, as well as cumulative rates of ST out to 1 year. In addition, 1-year TLF rates in complex patient subgroups did not significantly differ from those observed in their fewer complex counterparts, with the exception of the 1-year TLF rate in patients with multiple vessels treated, which was significantly higher than that in patients with a single vessel treated. Importantly, because there was no angiographic follow-up, all revascularizations

Table 3. Major Adverse Cardiac Events at 30 Days and 1 Year in the Intent-to-Treat Population

	30 Days (n = 2,663)	1 Yr (n = 2,600)
Nonhierarchical events		
All death	0.5	1.7
Cardiac death	0.4	1.1
Myocardial infarction	2.2	3.5
Q-wave	0.2	0.3
Non–Q-wave	2.0	3.2
TLR	0.3	1.8
TVR (non-TLR)	0.1	1.5
TVR (including TLR)	0.3	2.8
Non-TVR	0.9	3.9
Any revascularizations	1.2	5.9
Composite events		
Composite all death, MI, and TVR	2.7	6.8
Composite cardiac death, MI (not clearly attributed to non-TV), and TLR	2.5	5.1

Values are %.
MI = myocardial infarction; TLR = target lesion revascularization; TV = target vessel; TVR = target vessel revascularization.

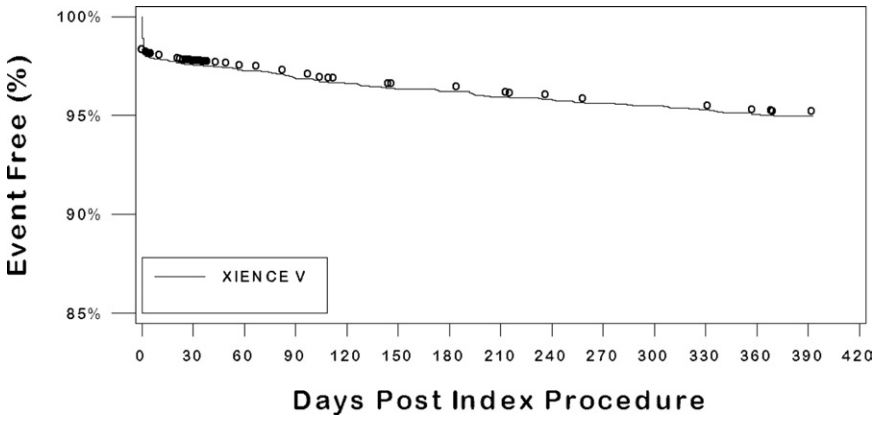

Figure 2. Kaplan-Meier Curve for Target Lesion Failure

Freedom from target lesion failure (cardiac death, myocardial infarction attributed to the target vessel and target lesion revascularization) through 1 year.

were considered ischemia-driven and not driven by the result of a protocol-mandated catheterization procedure. The rates of periprocedural MI were low, despite the use of the ARC definitions allowing the use of troponin or CK-MB levels for event adjudication.

The data presented here are in line with those previously reported in the SPIRIT II and III studies with very restricted enrollment criteria, allowing only patients with no more than 2 de novo coronary artery lesions. At 1 year, the SPIRIT II study reported major adverse cardiac events (MACE) and cardiac death rates in EES-treated patients of 2.7% and 0.0%, respectively (7), and clinical safety was sustained at 2 years (8). In the SPIRIT III study, patients treated with the EES had improved event-free survival, TVF (8.6% vs. 11.3%, hazard ratio: 0.75, 95% CI: 0.49 to 1.14, p = 0.18), and MACE (cardiac death, MI, or TLR; 6.0% vs. 10.3%, hazard ratio: 0.57, 95% CI: 0.36 to 0.90, p = 0.01) at 1-year follow-up (9).

The SPIRIT IV trial of 3,690 patients with up to 3 de novo lesions reported a 1-year rate of TLF (cardiac death, target vessel MI, and ischemia-driven TLR), the primary end point, of 3.9% and ARC-defined definite and probable

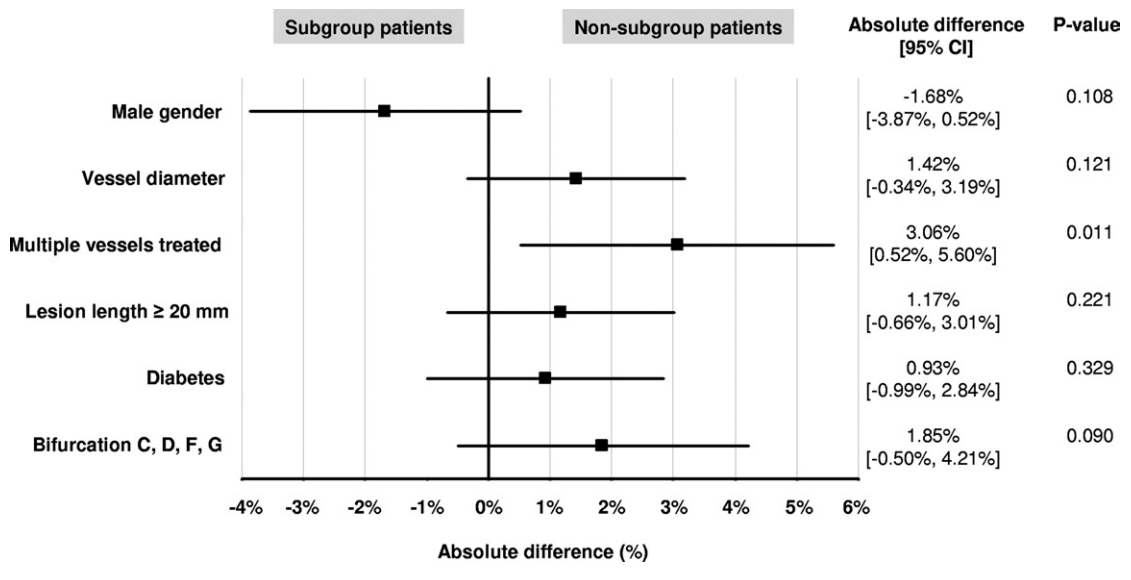

Figure 3. Subgroup Analysis of the 1-Year Target Lesion Failure Rates

The absolute differences in 1-year target lesion failure rates (defined as the composite of cardiac death, myocardial infarction attributed to the target vessel and target lesion revascularization) are plotted for the different subgroups. Data were stratified according to number of target vessels treated, vessel diameter, lesion length, bifurcation status, diabetes mellitus status, and sex. CI = confidence interval.

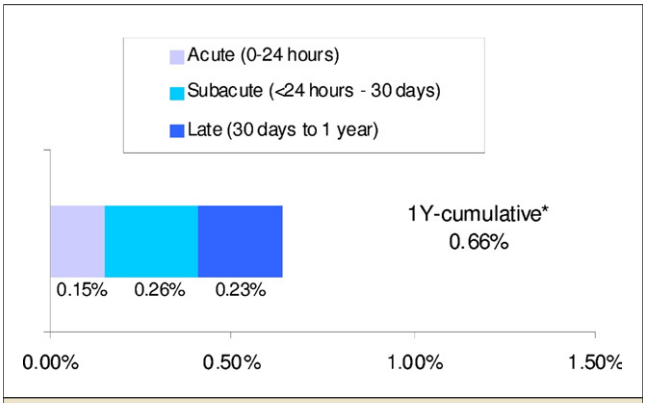

Figure 4. Definite and Probable Stent Thrombosis Rates to 1 Year

Stent thrombosis rates were defined according to the Academic Research Consortium guidelines (see Methods section) and were categorized as acute (<1 day), subacute (1 to 30 days), and late (>30 days to 1 year). *86% of patients on clopidogrel and 97% on aspirin at 1-year follow-up.

ST of 0.29% as derived from Kaplan-Meier estimates and log-rank test (10).

Although patients in the SPIRIT V trial were of a more complex type, it can be argued whether they really reflect the real-world patient population, because of the presence of broad selection criteria. Interestingly, the X-SEARCH (Xience Stent Evaluated At Rotterdam Cardiology Hospital) registry and the prospective randomized COMPARE trial (A Randomized Controlled Trial of Everolimus-eluting Stents and Paclitaxel-eluting Stents for Coronary Revascularization in Daily Practice), both performed in an all-comer population, recently reported an efficacy and safety of the EES similar to those observed in the SPIRIT V study. The X-SEARCH study showed subacute and late definite ST rates of 0.3% and 0%, respectively, at 6-month follow-up (11), whereas in the COMPARE trial at 1 year, the rates of subacute and late ST were 0.1% and 0.4%, respectively (12). The rates of cardiac death of 1.1% and MI of 2.2% (of which 0.2% were Q-wave MI and 2% were non–Q-wave MI) at 1-year follow-up in the SPIRIT V study closely resemble those obtained in the COMPARE trial (cardiac death: 2%; MI: 3%; Q-wave MI: 0.3%; and non–Q-wave MI: 2%). The data obtained in the SPIRIT V study support that of the real-world populations of the X-SEARCH and COMPARE studies.

Registries of PCI using other drug-eluting stents have shown results similar to the SPIRIT V study. The e-Cypher Registry (13), a registry of 15,157 patients treated with the sirolimus-eluting Cypher stent (Cordis Corporation, Warren, New Jersey) with no pre-specified inclusion or exclusion criteria reported a MACE rate (all death, MI, and TLR) of 1.36% at 30 days and 5.8% at 1 year. The 1-year protocol-defined definite and likely cumulative ST rate was 0.87%. The WISDOM (Web-based TAXUS Intercontinental obServational Data transitiOnal program) registry (14) of 778 patients treated with the Express^2 PES (Boston Scientific Corporation, Boston, Massachusetts) reported a 12-month MACE rate (death, MI, and TLR) of 5.2% and a protocol-defined ST rate of 0.6%. The combined ARRIVE (The TAXUS Peri-Approval Registry: A Multi-center Safety Surveillance) 1 and ARRIVE 2 (15) registry population of 7,492 patients who underwent deployment of the TAXUS Express^2 PES had a 1-year MACE rate (cardiac death, MI, TVR) of 9.5% and ARC-defined definite and probable ST rate of 1.8%.

These outcomes in first-generation drug-eluting stents (Taxus Express^2, Liberté, and Cypher) suggest that, when compared with the XIENCE V, EES might have a better safety and efficacy outcome both in controlled trials with strict inclusion/exclusion criteria and in less-selected patient populations.

Study limitations. This study was limited by the single-arm nature of the design and the inherent lack of a control arm for direct comparison. Lesion characteristics were assessed and reported by the investigator at the time of the procedure without core laboratory evaluation of lesion morphology.

Although this was designed as an all-comers registry, patients were enrolled according to relatively broad inclusion/exclusion criteria. Some inclusion limitations existed due to the specifications of the Instructions For Use and device availability. Although consecutive eligible patients were to be enrolled, it cannot be excluded that the low event rates might be related to selection bias in favor of low-risk patients and event under-reporting.

Conclusions

At 30 days, the primary end point of death, MI, and TVR showed a low rate of 2.7% in this complex patient population. This confirmed the acute safety of the XIENCE V EES.

The 1-year clinical results in the SPIRIT V study indicate that the use of the XIENCE V EES in a close-to-real-world population with complex lesions is safe and effective and results in 1-year MACE, ST, and TLR rates that are comparable to those of the more-controlled SPIRIT II and III trials.

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Key Words: drug-eluting stent (DES) ■ everolimus ■ percutaneous coronary intervention (PCI) ■ stent.

APPENDIX

For a list of participating investigators and institutions, please see the online version of this article.