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Evaluation of Ultrathin Strut Biodegradable Polymer-Coated Sirolimus-Eluting Stents in an All-Comers Patient Population: 1-Year Results of the S-FLEX Slovakia Registry

ABSTRACT

Background: Supraflex (Sahajanand Medical Technologies Limited, Surat, India) is a new-generation, biodegradable polymer-coated sirolimus-eluting stent (SES) designed on an ultrathin (60 µm) cobalt–chromium platform with a flexible "S-link." The S-FLEX Slovakia registry aimed to assess the safety and effectiveness of Supraflex SES in an all-comers population, with a subgroup of diabetic patients.

Methods: This was a prospective, observational, multi-center, post-market registry conducted between February 2018 and May 2019. All consecutive patients with symptomatic coronary artery disease scheduled for percutaneous coronary intervention with Supraflex SES were enrolled. The primary endpoint was target lesion failure (TLF), defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI), or clinically indicated target lesion revascularization (CI-TLR) by percutaneous or surgical methods at 1-year follow-up. Stent thrombosis was a safety endpoint.

Results: A total of 413 patients was assessed (145 diabetics and 268 nondiabetics). At 1-year follow-up, the primary endpoint of TLF occurred in 5.1% patients, comprised of 3.9% cardiac deaths, 0.5% TV-MI, and 0.7% CI-TLR. Overall stent thrombosis occurred in 0.5% patients at 1-year follow-up. In the subgroup analysis, TLF occurred in 6.2% diabetics and 4.5% nondiabetics ($P = .433$) and comprised 4.8% and 3.4% cardiac deaths ($P = .447$), 0.7% and 0.4% TV-MI ($P = .653$), and 0.7%, and 0.7% CI-TLR ($P = .952$) in diabetics and non-diabetics, respectively. Overall stent thrombosis occurred in 0.7% diabetic and 0.4% non-diabetic patient ($P = .659$).

Conclusion: This registry demonstrates favourable clinical outcomes after the implantation of the ultrathin biodegradable polymer coated Supraflex SES in an all-comers population, with event rates that were similar in diabetic and nondiabetic patients.

Keywords: Coronary restenosis, coronary intervention, drug-eluting stent, percutaneous polymer, stent thrombosis

ORIGINAL INVESTIGATION

INTRODUCTION

Since its inception more than 4 decades ago, the realm of percutaneous coronary intervention (PCI) has witnessed unceasing iteration. Balloon angioplasty—the legacy of Andreas Grüntzig—afforded reduced stenosis and increased lumen diameter, yet abrupt vessel closure and restenosis marred this procedure.[1] Bare-metal stents (BMS) provided vascular scaffolding and attenuated restenosis rates; however, in-stent restenosis and acute stent thrombosis proved to be the Achilles' heel of these metallic scaffolds. Thereafter, BMS were fittingly analogized to a double-edged sword.[2] First-generation drug-eluting stents (DES), comprising a stainless-steel metallic backbone and drug-coated durable polymer, were introduced to overcome these earlier pitfalls. Indeed, these stents succeeded in reducing in-stent restenosis and necessitated the need for revascularization. However, the price to pay was late stent thrombosis.[3,4] Despite imposed adherence to prolonged dual antiplatelet therapy regimens, the compelling need for a better stent spurred further iteration. Thus, second-generation DES, comprising cobalt or platinum–chromium platforms, antiproliferative drugs, and thinner struts, were designed.

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However, durable polymers elicited prolonged inflammation and delayed arterial wall healing, prompting neoatherosclerosis, resulting in-stent restenosis and very late stent thrombosis.[5-8] This observation heralded in biodegradable polymers. Earlier generations of biodegradable polymer DES were thicker and hence less flexible platforms; however, the latest designs have thinner struts to facilitate rapid endothelialization and reduced inflammation, arterial injury, neointimal proliferation, and thrombogenicity. This may translate to reduced thrombogenic events and restenosis.[9]

Diabetes mellitus stimulates endothelial dysfunction and platelet deposition, inducing thrombosis. Hyperglycemia is associated with overexpression of several growth factors, while advanced glycosylation promotes inflammatory cell recruitment and smooth muscle proliferation.[10] These mechanisms cause more accelerated and diffuse coronary artery disease (CAD) in diabetic patients, exposing this specific patient subset to a 2- to 4-fold greater risk of CAD.[11] Although DES have outclassed the performance of BMS in all-comer patients, diabetes mellitus is a challenging subset, and therefore, a one-size-fits-all approach may not be a suitable. Diabetic patients are still in dire need of the best available DES. The S-FLEX Slovakia registry aimed to assess the safety and efficacy of the ultrathin (60 μm) biodegradable polymer-coated Supraflex sirolimus-eluting stents (SES) (Sahajanand Medical Technologies Limited, Surat, India), in an all-comers population along with a subgroup of diabetic patients at 1-year follow-up.

METHODS

Study Design and Patient Population

The S-FLEX Slovakia registry was a prospective, observational, multicenter (2 centers), single-arm, post-market registry conducted between February 2018 and May 2019. All consecutive patients with symptomatic CAD, including stable, unstable, multi-vessel and complex lesions scheduled for PCI with at least 1 Supraflex SES were enrolled. The design and procedures complied with the principles of Good Clinical Practice,[12] and the Declaration of Helsinki.[13] The study was approved by the Institutional Ethics Committee (EC number: 149/10895/2017) on 10/10/2017. All patients provided written informed consent for data collection and its analysis for research purposes.

Description of the Study Stent

The Supraflex SES is a CE-marked new-generation coronary stent and consists of a L605 cobalt–chromium alloy stent platform. The 60 μm squared strut and highly flexible "S-link" connectors are characteristic features of this latest generation DES. The multi-layer coating applied on the conformal surface exhibits a mean thickness of 4-5 μm, comprising sirolimus at a concentration of 1.4 μg/mm^2, blended together with a biodegradable polymeric matrix (poly L-lactide, 50/50 poly-D,L-lactide-co-glycolide, and polyvinyl pyrrolidone). The drug release occurs in 2 phases—approximately 70% of the drug is released within 7 days, and the remainder is released over a period of 48 days. The polymers retain their properties for a limited period and then gradually degrade into biologically inert molecules, excreted via normal metabolic pathways over 9-12 months. Scanning electron microscopic images of the Supraflex SES are shown in Figure 1.

Data Collection and Follow-up

All data on demographic information, cardiovascular history, comorbidities, lesion and procedure characteristics, and antithrombotic regimens were collected from each center. Follow-up was obtained at 1 year (±30 days) after the index procedure by hospital visit or telephonic communication. During follow-up consultations, information about patients' clinical condition, adverse events, hospitalizations, and changes to concomitant (cardiac and antiplatelet) drugs were collected.

Study Endpoints and Definitions

The primary endpoint was target lesion failure (TLF), defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI), or clinically indicated target lesion revascularization (CI-TLR) by percutaneous or surgical methods at 1-year follow-up. The secondary endpoints included (i) overall stent thrombosis, (ii) all-cause death, (iii) any myocardial infarction (MI); (iv) any repeat revascularization; and (v) target vessel failure, a composite endpoint of cardiac death, TV-MI, or CI-TVR.

In the S-FLEX Slovakia registry, any death due to a cardiac cause such as MI, low-output failure, lethal arrhythmia or unwitnessed death, death of unknown reason, and all procedure-related deaths linked to concomitant treatment were defined as cardiac death, whereby noncardiac death included any death where a noncardiac cause was well established. Myocardial infarction was defined according to the third universal definition. Target vessel myocardial infarction was defined as an MI with evidence of myocardial necrosis in the vascular territory of the previously treated target vessel.[14] Clinically indicated target lesion revascularization was described as any revascularization procedure in the target lesion with stenosis >50% in association with clinical or functional ischemia (positive functional study, electrocardiographic changes, or ischemic symptoms), or stenosis >70% in the absence of clinical or functional

HIGHLIGHTS

- The S-FLEX Slovakia registry was a prospective, observational, multi-center, post-market registry that enrolled 413 consecutive patients (145 diabetics and 268 nondiabetics) with symptomatic coronary artery disease (CAD) who underwent percutaneous coronary intervention with the ultrathin biodegradable polymer-coated Supraflex sirolimus-eluting stent (SES).
- At 1 year, the primary endpoint of target lesion failure (TLF) occurred in 5.1% patients, and overall stent thrombosis in 0.5% patients. In the subgroup analysis, TLF occurred in 6.2% diabetics and 4.5% nondiabetics.
- Overall stent thrombosis occurred in 0.7% diabetic and 0.4% nondiabetic patient, respectively.
- Supraflex SES is a safe and effective treatment option in the all-comers CAD population.

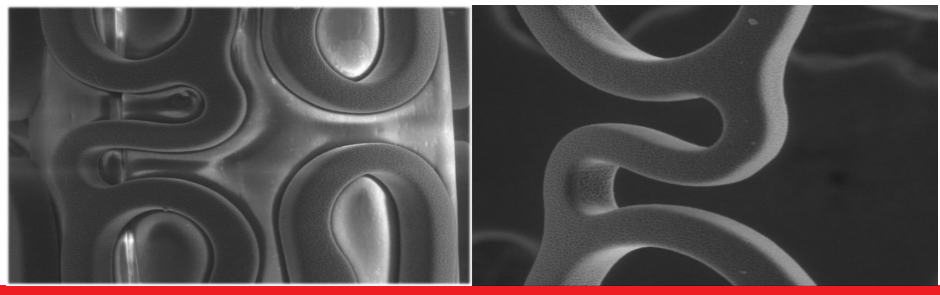

Figure 1. Scanning electron microscopy images of Supraflex sirolimus eluting stent.

ischemia.[15] Clinically indicated target lesion revascularization was described as any revascularization procedure in the target vessel with stenosis >50% in association with clinical or functional ischemia (positive functional study, electrocardiographic changes, or ischemic symptoms), or stenosis >70% in the absence of clinical or functional ischemia.[15] Device success was defined as the successful delivery, deployment, and withdrawal of the assigned device at the intended target lesion with a final in-stent residual stenosis of <30% by visual estimation. Procedural success was defined as device success of all intended target lesions without the occurrence of TLF during the index procedure hospital stay.[15]

Table 1. Baseline Clinical Characteristics of the Registry Population

Characteristics	Overall (n = 413)	Diabetes (n = 145)	Non-diabetic (n = 268)	*P*
Age (years)	65.1 ± 11.2	67.0 ± 10.2	64.0 ± 11.6	.010
Male	291 (70.5%)	77 (53.1%)	214 (79.9%)	<.001
Height (cm)	170.4 ± 12.8*	166.8 ± 16.4	172.6 ± 8.7	<.001
Weight (kg)	85.6 ± 16.2*	86.4 ± 16.4	84.9 ± 15.0	.560
Body mass index (kg/m^2)	29.3 ± 4.4*	30.8 ± 4.7	28.4 ± 4.0	<.001
Underweight (≤18.5 kg/m^2)	2 (0.5%)*	1 (0.7%)	1 (0.4%)	<.001
Normal weight (18.5-24.9 kg/m^2)	60 (14.6%)*	11 (7.6%)	49 (18.3%)	
Overweight (25-29.9 kg/m^2)	191 (46.4%)*	57 (39.6%)	134 (50.0%)	
Obesity (≥30 kg/m^2)	159 (38.6%)*	75 (52.1%)	84 (31.3%)	
Systolic blood pressure, mm Hg	136.3 ± 20.5	138.6 ± 21.8	135.0 ± 19.7	.440
Diastolic blood pressure, mm Hg	80.6 ± 12.2	80.7 ± 12.6	80.5 ± 12.0	.778
Medical history				
Hypertension	320 (77.5%)	133 (91.7%)	187 (69.8%)	<.001
Hypercholesterolemia	269 (65.1%)	118 (81.4%)	151 (56.3%)	<.001
Smoker	158 (38.3%)	28 (19.3%)	130 (48.5%)	<.001
Family history of CAD	140 (33.9%)	50 (34.5%)	90 (33.6%)	.487
Peripheral vascular disease	38 (9.2%)	14 (9.7%)	24 (9.0%)	.568
Congestive heart failure	29 (7.0%)	8 (5.5%)	21 (7.8%)	.109
Renal insufficiency	22 (5.3%)	14 (9.7%)	8 (3.0%)	.010
Transient ischemic attack	7 (1.7%)	1 (0.7%)	6 (2.2%)	.496
Previous myocardial infarction	86 (20.8%)	37 (25.5%)	49 (18.3%)	.016
Previous stroke	27 (6.5%)	15 (10.3%)	12 (4.5%)	.043
Previous PCI	95 (23.0%)	34 (23.4%)	61 (22.8%)	.806
Previous CABG	19 (4.6%)	7 (4.8%)	12 (4.5%)	.985
Anginal status				
Stable angina	90 (21.8%)	32 (22.1%)	58 (21.6%)	.920
Unstable angina	58 (14.0%)	22 (15.2%)	36 (13.4%)	.627
NSTEMI	159 (38.5%)	44 (30.3%)	115 (42.9%)	.012
STEMI	89 (21.5%)	41 (28.3%)	48 (17.9%)	.014
Silent ischemia	4 (1.0%)	1 (0.7%)	3 (1.1%)	.670

All values are expressed as number (percentage) or mean ± SD.
CABG, coronary artery bypass grafting; CAD, coronary artery disease; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.
*Variable available in 412 of 413 patients.

Statistical Analysis

All data were analyzed using the R statistical computing software version 4.3.2. Continuous variables are presented as mean ± standard deviation and were compared using independent *t*-test or Mann–Whitney *U*-test, depending on the normality of the data, which was verified by the Shapiro–Wilk test. Categorical variables are presented as counts and percentages and were compared using chi-square test or Fisher exact test. Cumulative rates of events were estimated using the Kaplan–Meier method and compared using the log-rank test. All *P* values were two sided, and statistical significance was set at a value of less than 0.05.

RESULTS

Baseline, Lesion, and Procedural Characteristics

A total of 413 patients with a mean age of 65.1 ± 11.2 years were assessed in the S-FLEX Slovakia registry. The registry population was reflective a real-world clinical scenario, and comorbidities such as obesity/overweight, hypertension, hypercholesterolemia, smoking, and diabetes mellitus were found in 350 (85.0%), 320 (77.5%), 269 (65.1%), 158 (38.3%), and 145 (35.1%) patients, respectively. Clinical presentation was non-ST-segment elevation myocardial infarction in 159 (38.5%) patients, stable angina in 89 (21.5%) patients, and ST-segment myocardial infarction (STEMI) in 89 (21.5%) patients. A total of 468 Supraflex SES (1.13 ± 0.4 stent/patient) were implanted to treat 435 coronary lesions (1.08 ± 0.28 stent/lesion). Lesion complexity was defined by 255 (58.6%) type B2/C lesions, 105 (24.1%) total occlusions, 55 (12.6%) bifurcations, and 14 (3.2%) restenotic lesions. Device success was 99.8%, while procedural success was 99.0%. At hospital discharge, 393 (95.2%) patients and at the 1-year follow-up, 298 (72.2%) patients adhered to a dual antiplatelet therapy regimen. Baseline patient, lesion, and procedural characteristics, and pharmacological therapy details of overall, diabetic, and nondiabetic patients are elaborated in Tables 1, 2, and 3, respectively.

Clinical Outcomes

The 1 year outcomes were available for all 413 patients. At 1 year, the primary endpoint of TLF occurred in 21 (5.1%) patients, comprised of 16 (3.9%) cardiac deaths, 2 (0.5%) TV-MIs, and 3 (0.7%) CI-TLRs. According to the ARC-2 definition, overall stent thrombosis occurred in 2 (0.5%) patients, comprising 2 (0.5%) definite stent thromboses and no incidents of probable stent thrombosis. Cumulative TLF-free survival at 1-year follow-up, estimated by the Kaplan–Meier method, is displayed in Figure 2. The 1 year outcomes of the overall population and for the subgroup of diabetic and nondiabetics patients are shown in Table 4.

DISCUSSION

The present study provides the first all-comers assessment of the safety and efficacy of the ultrathin (60 µm) biodegradable polymer-coated Supraflex SES in a Slovakian population. A subgroup of diabetic patients was also assessed. The main findings of this national registry analysis are outlined as follows: (a) a low 1-year TLF event rate of 5.1% in the overall study population. (b) a low 1e-year TLF rate of 6.2%

Table 2. Procedural and Lesion Characteristics

Characteristics	Overall (n = 413)	Diabetes (n = 145)	Non-diabetic (n = 268)	*P* value
Target oronary artery	435 lesions	153 lesions	282 lesions	
Left anterior descending artery	180 (41.4%)	58 (37.9%)	122 (43.3%)	.773
Right coronary artery	150 (34.5%)	57 (37.3%)	93 (33.0%)	
Left circumflex artery	96 (22.1%)	34 (22.2%)	62 (22.0%)	
Left main artery	3 (0.7%)	1 (0.7%)	2 (0.7%)	
Saphenous vein graft	6 (1.4%)	3 (2.0%)	3 (1.1%)	
Lesion complexity				
Type B2/C	255 (58.6%)	84 (54.9%)	171 (60.6%)	.246
Total occlusion	106 (24.4%)	26 (17.0%)	80 (28.4%)	.008
Bifurcation	55 (12.6%)	10 (6.5%)	45 (16.0%)	.005
Restenotic lesion	14 (3.2%)	3 (2.0%)	11 (3.9%)	.274
Pre-dilation	241 (55.4%)	88 (57.5%)	153 (54.3%)	.631
Post-dilation	218 (50.1%)	80 (52.3%)	138 (48.9%)	.504
Stents	n = 468 stents	n = 167 stents	n = 301 stents	
Overlapping stents	76 (16.2%)	33 (19.8%)	43 (14.3%)	.097
No. of stents per patient (mm)	1.13 ± 0.4	1.11 ± 0.3	1.15 ± 0.4	.464
No. of stents per lesion (mm)	1.08 ± 0.3	1.09 ± 0.3	1.07 ± 0.3	.411
Stent length per patient (mm)	22.35 ± 7.5	21.90 ± 7.8	22.60 ± 7.3	.179
Mean stent length (mm)	22.27 ± 7.6	22.31 ± 7.7	22.24 ± 7.5	.895
Mean stent diameter (mm)	2.97 ± 0.5	2.89 ± 0.5	3.02 ± 0.5	.004
Device success	434 (99.8%)	153 (100.0%)	281 (99.6%)	.461
Procedure success	409 (99.0%)	143 (98.6%)	266 (99.3%)	.531

All values are expressed as number (percentage) or mean ± SD.

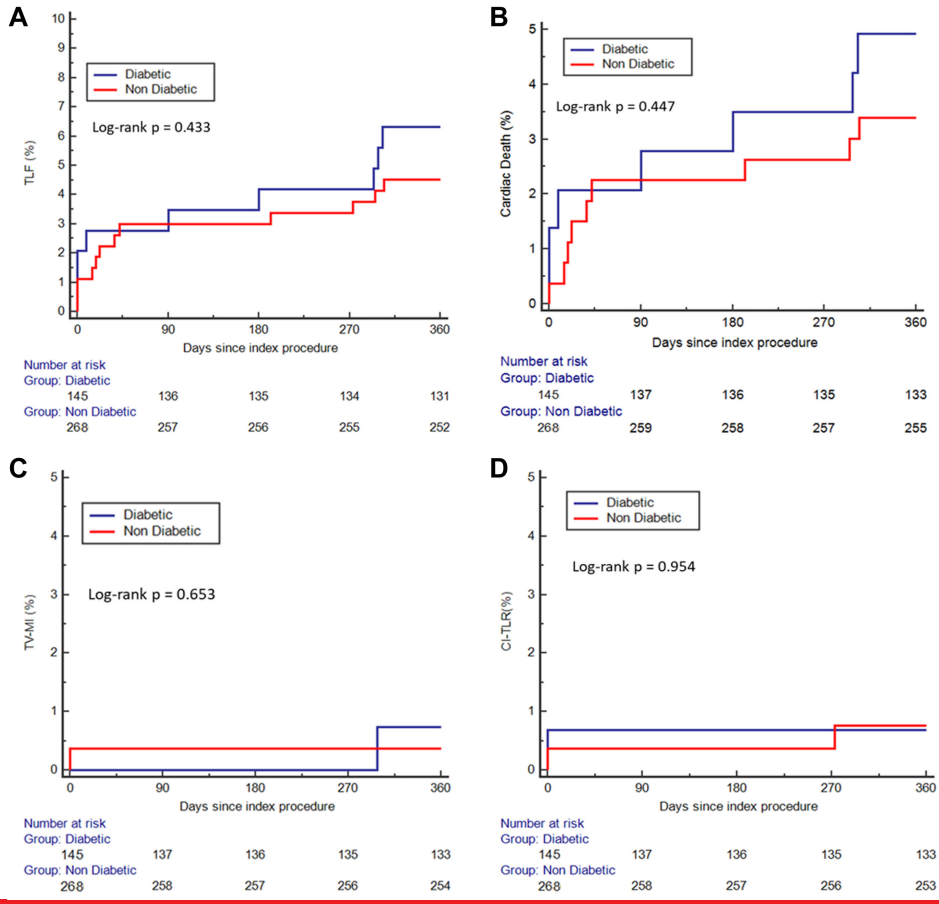

Figure 2. Kaplan–Meier graphs for target lesion failure (A) and its individual components—cardiac death (B), target vessel myocardial infarction (C), and target lesion revascularization (D).

in the diabetic subgroup. (c) Outcomes in the diabetic subgroup do not differ significantly from that of the nondiabetic subgroup.

The primary endpoint of the present registry was TLF, defined as a composite of 3 individual event components of safety (cardiac death and TV-MI) and efficacy (CI-TLR) with different mechanisms and time courses. This aptly reflects the spectrum of device and lesion-related adverse events that may occur during follow-up. At 1-year follow-up, TLF occurred in 5.1% of patients in the overall study population. This clinical outcome is concordant with several earlier registries and randomized controlled trials assessing the safety and efficacy of very thin and ultrathin biodegradable polymer SES in all-comer populations.[16-22] This comparison indicates that results of these studies are in agreement with a growing and evolving body of evidence specific to very thin and ultrathin strut biodegradable polymer SES that have demonstrated superiority compared with alternative DES.

Stent thrombosis is a rare yet life-threatening clinical event. In this study, definite/probable stent thrombosis was 0.5% at the 1-year follow-up. This rate is on par with the 0.5% definite/probable stent thrombosis documented in the BIOFLOW-III Italian Satellite registry.[23] Additionally, this is comparable to the T-FLEX registry,[24] Thailand Orsiro registry,[25] and BIONYX trial,[26] which reported rates of definite/probable stent thrombosis as 0.6%, 0.7%, and 0.7%, respectively. The SORT OUT IX trial[27] reported 1.1% definite/probable stent thrombosis, which is numerically more than double

Table 3. Pharmacological Therapy of Registry Population

Medication	Overall (n = 413)	Diabetes (n = 145)	Non-Diabetic (n=268)	*P* value
At hospital discharge				
Aspirin	393 (95.2%)	135 (93.1%)	258 (96.3%)	.098
Thienopyridine	411 (99.5%)	143 (98.6%)	268 (100.0%)	.054
Clopidogrel	162 (39.2%)	59 (40.7%)	103 (38.4%)	.654
Ticagrelor	181 (43.8%)	62 (42.8%)	119 (44.4%)	.748
Prasugrel	68 (16.5%)	22 (15.2%)	46 (17.2%)	.602
Aspirin + Thienopyridine	393 (95.2%)	135 (93.1%)	258 (96.3%)	.153
At 1-year follow-up				
Aspirin	341 (82.6%)	113 (78.0%)	228 (85.1%)	.258
Thienopyridine	331 (80.1%)	112 (77.2%)	219 (81.7%)	.659
Clopidogrel	114 (27.6%)	43 (29.7%)	71 (26.5%)	.493
Ticagrelor	153 (37.0%)	47 (32.4%)	106 (39.6%)	.152
Prasugrel	64 (15.5%)	22 (15.2%)	42 (15.7%)	.894
Aspirin + Thienopyridine	298 (72.2%)	97 (66.9%)	201 (75.0%)	.079

All values are expressed as number (percentage).

Table 4. Clinical Outcomes at 1-Year Follow-Up

Clinical outcomes	Overall (n = 413)	Diabetes (n = 145)	Non-Diabetic (n = 268)	*P* value
Patient followed-up	413 (100%)	145 (100%)	268 (100%)	
All-cause death	25 (6.1%)	12 (8.3%)	13 (4.9%)	.163
Cardiac death	16 (3.9%)	7 (4.8%)	9 (3.4%)	.447
Noncardiac death	9 (2.2%)	5 (3.4%)	4 (1.5%)	.190
All myocardial infarction	6 (1.5%)	3 (2.1%)	3 (1.1%)	.430
Target-vessel myocardial infarction	2 (0.5%)	1 (0.7%)	1 (0.4%)	.653
Nontarget-vessel myocardial infarction	4 (1.0%)	2 (1.4%)	2 (0.7%)	.515
Clinically indicated TLR	3 (0.7%)	1 (0.7%)	2 (0.7%)	.954
Clinically indicated TVR	7 (1.7%)	4 (2.8%)	3 (1.1%)	.213
Any stent thrombosis	2 (0.5%)	1 (0.7%)	1 (0.4%)	.659
Definite stent thrombosis	2 (0.5%)	1 (0.7%)	1 (0.4%)	
Acute (0-1 days)	2 (0.5%)	1 (0.7%)	1 (0.4%)	
Subacute (2-30 days)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Late (31-360 days)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Probable stent thrombosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Target lesion failure	21 (5.1%)	9 (6.2%)	12 (4.5%)	.433
Target vessel failure	25 (6.1%)	12 (8.3%)	13 (4.9%)	.160

All values are expressed as number (percentage) for each event calculated according to patients followed-up.
TLR, target lesion revascularization; TVR, target vessel revascularization.

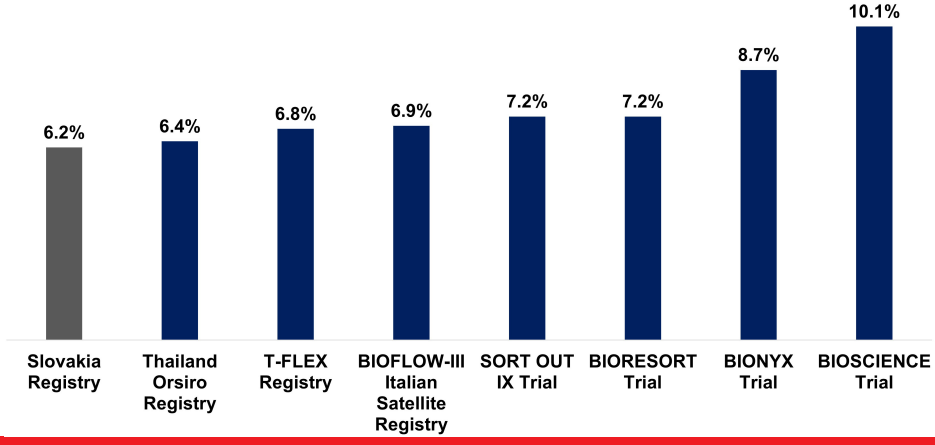

Figure 3. Comparison of 1 year target lesion failure rates of the present registry and other registries and trials assessing safety and efficacy of ultrathin biodegradable polymer sirolimus-eluting stents in diabetic patient subsets.

that observed in the present registry at the 1-year follow-up. Thus, the results of the S-FLEX Slovakia registry affirm favorable safety at 1 year with Supraflex ultrathin biodegradable polymer-coated SES.

Since the inception of the BMS, continuous iterations have paved the way to latest generation DES implementing refinements in features such as the metallic platform, strut thickness, polymer biocompatibility and thickness, and drug efficacy and elution profile. One of the more impactful iterations is the reduction in strut thickness. Coronary stents have undergone a transition from 130 to 140 μm stainless steel struts to 81-91 μm cobalt–chromium struts and recently to 60 μm cobalt–chromium struts. Thinner stent struts are more beneficial in small coronary arteries as thicker struts and smaller minimum in-stent lumen diameter are independent predictors of restenosis in coronary stents.[28] Diabetic patients typically present with diffuse lesions and small coronary artery diameter and thus are the most fitting subset to assess the safety and efficacy of the latest generation ultrathin DES. In the present registry, at the 1-year follow-up, TLF occurred in 6.2% of patients in the diabetic subgroup. This outcome is favorable when compared with TLF rates of 6.4%-10.1% reported in the Thailand Orsiro registry, T-FLEX registry,[24] BIOFLOW-III Italian Satellite registry,[23] SORT OUT IX trial,[27] BIORESORT trial,[28] BIONYX trial,[29] and BIOSCIENCE trial.[30] The comparison of 1 year TLF among these studies is displayed in Figure 3.

A few study limitations must be noted. First, the nonrandomized, observational, and single-arm study design, along with the relatively small patient population, holds inherent limitations. Secondly, the follow-up time of 1 year was relatively short and might have led to an underestimation of the

benefits of the study stent. Long-term follow-up is warranted to assess the true event rates.

CONCLUSION

Prospective evaluation from the S-FLEX Slovakia registry demonstrates favorable outcomes after the implantation of the ultrathin biodegradable polymer-coated Supraflex SES in an all-comers population, with the diabetic subgroup at the 1-year follow-up.

Ethics Committee Approval: The study was approved by the institutional Ethics Committee (EC number: 149/10895/2017; date: October 10, 2017).

Informed Consent: The written informed consent was obtained from all the patients.

Peer-review: Internally peer-reviewed.

Author Contributions: Concept – M.H., A.K., P.G.; Design – M.H., A.K., P.G.; Supervision – M.H., A.K., P.G.; Resources – M.H., A.K., P.G.; Materials – M.H., A.K., P.G.; Data Collection and/or Processing – M.H., A.K., P.G.; Analysis and/or Interpretation – M.H., A.K., P.G.; Literature Search – M.H., A.K., P.G.; Writing – M.H., A.K., P.G.; Critical Review – M.H., A.K., P.G.

Declaration of Interests: The authors have no conflicts of interest to declare.

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