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First-in-Man 1-Year Clinical Outcomes of the Catania Coronary Stent System With Nanothin Polyzene-F in De Novo Native Coronary Artery Lesions

The ATLANTA (Assessment of The LAtest Non-Thrombogenic Angioplasty stent) Trial

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Objectives This study sought to assess safety and efficacy of implantation of the Catania Coronary Stent System with Nanothin Polyzene-F (CeloNova BioSciences, Newnan, Georgia) in human coronary arteries with clinical data and comprehensive intracoronary imaging.

Background Novel approaches to modify stents (e.g., bioactive agents, coatings) have been developed to address the limitations of bare-metal and drug-eluting stents (e.g., restenosis, target lesion revascularization [TLR], late thrombosis).

Methods This first-in-man study using the Catania stent is a prospective, single center, nonrandomized, single-arm study of 55 patients with symptomatic ischemic heart disease with de novo, obstructive lesions of native coronary arteries.

Results Acute angiographic success was 100%. A core laboratory analyzed quantitative coronary angiography and intravascular ultrasound data immediately after stenting and at 6-month follow-up. Late lumen loss was 0.60 ± 0.48 mm and the percent neointimal hyperplasia volume was 27.9 ± 16.1%. In 15 of 55 randomly selected patients, 1,904 cross-sections (19,028 struts) were analyzed at 6 months by optical coherence tomography. Overall, 99.5% of struts were covered. Only 29 of 19,028 struts (0.15%) were malapposed. Binary angiographic restenosis was 6.8%. No death, myocardial infarction, or Academic Research Consortium–defined stent thrombosis was observed at 12 months. The incidence of TLR at 12 months was clinically driven TLR 3.6% (2 of 55) and nonclinically driven TLR 7.3% (4 of 55).

Conclusions This first-in-man showed an excellent early and mid-term safety profile and high-level efficacy of the new Catania stent in the treatment of de novo coronary lesions in a fairly complex population. Polyzene-F coated stents may be an alternative to both bare-metal and drug-eluting stents with reduced late loss, restenosis, and the TLR without long-term dual antiplatelet therapy. (J Am Coll Cardiol Intv 2009;2:197–204) © 2009 by the American College of Cardiology Foundation

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Bare-metal stents (BMS) are associated with binary restenosis (BR) rates of approximately 25% at 6 to 9 months and target lesion revascularization (TLR) rates of 10% to 25% at 1 year (1). The Driver BMS (Medtronic Vascular, Santa Rosa, California), for example, had an in-stent BR rate of 32.7% in the ENDEAVOR II (Randomized Comparison of the Endeavor ABT-578 Drug-Eluting Stent with a Bare-Metal Stent for Coronary Revascularization) study (2) and a 15.7% to 26.9% BR was reported for the Multi-Link Vision (Abbott Vascular, Abbott Park, Illinois). Drug-eluting stents (DES) significantly reduce the rates of restenosis and TLR when compared with BMS in patients with symptomatic coronary artery disease (3–5).

Although DES have been shown to decrease restenosis rates, they are associated with an increased risk of 0.13% to 0.18% per year of late stent thrombosis compared with BMS (6). Further, current guidelines suggest that DES implantation should be followed by long-term dual antiplatelet therapy (DAPT) with the attendant increased cost and risk of severe bleeding (7). Therefore, novel approaches modifying stents in a manner or another have been developed to address the limitations of BMS and DES.

Polyzene-F (CeloNova BioSciences, Newnan, Georgia) is a unique and proprietary formulation of poly[bis(trifluoroethoxy)-phosphazene]. It is an inorganic, high molecular weight, ultrapure polymer that can be used to coat multiple substrates and can be applied on stents as an ~40-nm surface modification. Recent animal studies have shown that stents treated with a nanothin surface of Polyzene-F are effective in reducing in-stent restenosis, and when compared with uncoated stents, these coated stents have an optimal profile in terms of thromboresistance and inflammation and promote normal endothelial cell growth (8).

The Catania stent (CeloNova BioSciences) is a flexible, cobalt chromium, balloon-expandable stent. Its Polyzene-F surface is bacteria-resistant and anti-inflammatory, reduces perioperative and post-procedural platelet activation and agglomeration, and helps to prevent tissue reactions that lead to restenosis (8).

Abbreviations and Acronyms

BMS = bare-metal stent(s)
BR = binary restenosis
DAPT = dual antiplatelet therapy
DES = drug-eluting stent(s)
FIM = first-in-man
IVUS = intravascular ultrasound
LLL = late lumen loss
MI = myocardial infarction
MLD = minimal lumen diameter
NIHV = neointimal hyperplasia volume
OCT = optical coherence tomography
QCA = quantitative coronary angiography
ST = stent thrombosis
TLR = target lesion revascularization
TVR = target vessel revascularization

The purposes of the ATLANTA (Assessment of The LAtest Non-Thrombogenic Angioplasty stent) first-in-man (FIM) prospective study were to assess the feasibility, safety, and efficacy of the Catania Coronary Stent System implantation in human coronary arteries using clinical evaluation, quantitative coronary angiography (QCA), intravascular ultrasound (IVUS), and optical coherence tomography (OCT) follow-up.

Methods

Study design. The study was designed as a prospective, single center, nonrandomized, single-arm study. A total of 55 patients with stable or unstable angina and/or documentation of myocardial ischemia attributable to native coronary artery stenosis, and amenable to treatment by percutaneous stenting, were enrolled in the ATLANTA trial from May 2007 through August 2007. Enrollment criteria included patients older than 30 years and younger than 70 years with up to 2 de novo type A and/or B American Heart Association/American College of Cardiology lesions to be treated with the Catania stent in a vessel with a reference diameter ≥2.5 and ≤3.5 mm by visual assessment. Major clinical/instrumental and angiographic/procedural exclusion criteria are summarized in Table 1. The study was conducted according to the Declaration of Helsinki. The local medical ethics committee approved the protocol and written informed consent was obtained from every patient.

Data collection and core laboratory analyses. All clinically relevant baseline variables were recorded on electronic case report forms. The clinical in-hospital and follow-up data related to medications and clinical status were prospectively collected through scheduled outpatient clinic evaluations. Exercise stress test was scheduled at 5 weeks and 6 months. Referring cardiologists, general practitioners, and patients were contacted whenever necessary for further information. All repeat coronary intervention and rehospitalization data were prospectively collected during follow-up and entered into the centralized computer system of our institution or by directly contacting the hospitals where the patients were admitted or referred. Clinical events were adjudicated by an independent clinical events committee.

All QCA, IVUS, and OCT analyses were performed offline by an independent, validated core laboratory (Rome Heart Research, Rome, Italy) (9,10).

QUANTITATIVE CORONARY ANALYSIS. The QCA images and analyses were obtained following a validated methodology. All angiograms were analyzed using a computer-assisted automated edge-detection algorithm (CMS, Medis, Medical Imaging Systems, BV, Leiden, the Netherlands) using standard qualitative definitions and quantitative coronary angiographic measurements obtained in 2 orthogonal

Table 1. Exclusion Criteria

Clinical
Age <30 or >70 yrs
Life expectancy >1 yr
Chronic renal failure (serum creatinine >2 mg/dl)
Ongoing acute myocardial infarction or myocardial infarction within the last 48 h
Left ventricular ejection fraction <30%
Cardiogenic shock
Documented or suspected systemic and/or infectious disease
Hypersensitivity to cobalt chromium or contrast media
Antithrombotic drug intolerance
Cardiac and/or extracardiac documented disease requiring surgical repair
Patient is not acceptable candidate for emergent coronary artery bypass graft
Primary or secondary pulmonary hypertension (by echo-Doppler)
In-stent restenosis
Recent (<6 months) percutaneous coronary intervention or coronary artery bypass graft
Angiographic
Vessel size <2.5 or >3.5 mm
Lesion length ≥20 mm
Planned >2 stents implantation (except bail-out)
Other type of stent implantation
Visible endocoronary thrombosis
Diffuse, severe coronary calcifications
Use of debulking devices
Extreme vessel tortuosity
Unprotected left main stenosis
Bifurcation lesion
Saphenous vein graft and arterial bypass (internal mammary artery)
Chronic total occlusion

views. The following measured parameters were minimal lumen diameter (MLD), reference vessel diameter, percent diameter stenosis, in-stent late lumen loss (LLL), and BR.

IVUS. The IVUS examinations were performed in all patients at the completion of the stenting procedure and at 6-month follow-up. The IVUS images were obtained with mechanical ultrasound imaging catheters at 40 MHz (Atlantis 2.9-F, Boston Scientific Corp., Natick, Massachusetts). Images were obtained after intracoronary administration of 200 μg of nitroglycerin to prevent possible vasospasm. The imaging probe was positioned distally to the target lesions and withdrawn at a constant speed of 0.5 mm/s using a motorized pullback device. Offline analyses were done with the EchoPlaque software (INDEC Medical Systems, Santa Clara, California). Lumen, stent, and external elastic membrane contours were analyzed at a distance of 0.5 mm in the stented segment. The following measurements were obtained: mean stent volume, lumen volume, neointimal hyperplasia volume (NIHV), and percentage of NIHV.

OCT. Fifteen patients were randomly assigned to OCT examination at the completion of the stenting procedure and at 6-month follow-up.

The M2 LightLab OCT wire (ImageWire, Light Imaging Inc., Westford, Massachusetts) was used. ImageWire has an outer diameter of 0.019 inches and contains a 0.006-inch fiberoptic imaging core (<0.4 mm in diameter) and a distal radiopaque spring tip, similar to conventional guidewires.

The OCT images were obtained with a recently developed nonocclusive technique (11,12). Briefly, OCT image acquisition was performed after coronary cannulation with a 7-F guiding catheter and intravenous administration of 50 U/kg of heparin. The OCT image wire was then positioned in the target vessel and pulled back at 2-mm/s speed; OCT frames were acquired at a frame rate of 15.6/s. The infusion protocol requires a manual injection of iodixanol 320 (Visipaque, GE Health Care, Cork, Ireland) from the guiding catheter at an infusion rate between 2 and 4 cc/s, based on the run-off of the artery and the online assessment of OCT image quality. Consistent with IVUS assessment, OCT cross-sections were analyzed at 0.5-mm intervals. Using a published methodology (13–15), stent strut coverage and malapposition was evaluated.

Device description. The Catania stent is made of a cobalt chromium alloy and is surface treated with Polyzene-F, a proprietary, biocompatible, biostable formulation of poly-[bis(trifluoroethoxy) phosphazene]. The surface treatment measures approximately 40 nm thick. In its highly purified form, Polyzene-F effectively reduces glycoprotein IIb/IIIa receptor density on thrombocytes, diminishes activation of the clotting and complement systems, reduces adhesion, minimizes activation and accumulation of platelets, decreases the infiltration of inflammatory cells, and reduces foreign body reactions (16,17). Polyzene-F is a drug-free surface treatment that promotes healthy endothelial cellular growth. The decline in the amount of thrombocyte deposition on the arterial wall is associated with diminished neointimal formation in humans (18). The stent strut architecture is designed to promote polymer integration and reduce strain concentration in the critical strut area. The Catania stent has a modified open cell design with struts of 65-μm thickness in the 2.0- to 2.75-mm diameters and 74 μm in the 3.0- to 4.0-mm diameters, a very flexible design and a low crossing profile (from ≤1.0 mm for the 2.5-mm stent to ≤1.05 mm for the 4.0-mm stent). By comparison, DES have strut thicknesses of 81 to 140 μm and polymer thicknesses of 5.3 to 16 μm (more than 1,000 times the thickness of the Polyzene-F surface treatment). The stent is mounted on a 0.014-inch guidewire-compatible rapid exchange stent delivery system.

Implantation procedure. Interventional procedures were performed and adjuvant therapies were given according to accepted guidelines (19). All patients were pre-treated with aspirin (75 to 300 mg daily) and clopidogrel (600-mg loading dose 6 h before or during the procedure). During the procedure, all patients received intravenous unfraction-

ated heparin (50 to 150 IU/kg) to maintain activated clotting time ≥200 s. An intracoronary dose of nitroglycerin 200 μg was administered before the first and the last reference angiogram. Pre-dilation or direct stenting was performed at the discretion of the operator. Angiographic optimization was performed by high-pressure dilation to achieve <30% residual stenosis by visual estimate after stent implantation. All patients were advised to maintain lifelong aspirin therapy. Thienopyridine therapy (clopidogrel 75 mg/day or ticlopidine 250 mg twice daily) was discontinued 4 weeks after the procedure.

End point and definitions. Primary end points included cardiac death, index vessel-related nonfatal myocardial infarction (MI), TLR, target vessel revascularization (TVR), non-TLR, and stent thrombosis (ST). Secondary end points included procedural success, overall mortality, BR, LLL, and percent NIHV.

CLINICAL END POINTS. A non–Q-wave MI was defined as creatine kinase-myocardial band enzyme elevation ≥3 times the upper limit of the normal value; a Q-wave MI was defined as occurrence of new pathological Q waves in the electrocardiogram in addition to enzyme elevation. Target lesion revascularization was defined as any clinically driven repeat percutaneous revascularization or surgical bypass of the original target lesion site. We defined clinically driven revascularizations as those in which the patient had a positive functional study, ischemic electrocardiogram change at rest in a distribution consistent with the target vessel, or ischemic symptoms, and an in-lesion diameter stenosis ≥50% by QCA. Revascularization of a target lesion with an in-lesion diameter stenosis ≥70% (by QCA) in the absence of the previously mentioned ischemic signs or symptoms is also considered clinically driven. Nonclinically driven TLRs were those in which the patient undergoes a nonemergent revascularization for a diameter stenosis >50% and <70% (by QCA).

We defined TVR as a reintervention driven by any lesion located in the same coronary artery and included coronary artery bypass graft involving the infarct-related artery. Stent thrombosis was defined as an acute coronary syndrome with angiographic documentation of either vessel occlusion or thrombus within or adjacent to a previously successfully stented vessel. According to the Academic Research Consortium classification (20), ST was defined as definite (symptoms suggestive of an acute coronary syndrome and angiographic or pathologic confirmation of ST), probable (unexplained death within 30 days after the procedure or target vessel–related MI without angiographic confirmation of ST), and possible (any unexplained death after 30 days).

Stent thromboses were also categorized according to the timing of the event into intraprocedural, subacute thrombosis (from the end of the procedure to 30 days), and late stent thrombosis (>30 days).

ANGIOGRAPHIC END POINTS. Lesion length was measured as the length of contiguous coronary narrowing (defined as percent diameter stenosis >20%) containing both the target hemodynamically obstructive and adjacent nonobstructive plaque. Minimal lumen diameter was defined as the mean MLD derived from 2 orthogonal views by QCA angiography. Percent diameter stenosis was defined as: (1 − (MLD/reference vessel diameter) × 100). Acute gain was defined as the change in MLD from pre- to post-intervention, LLL was defined as the change in MLD between post-intervention and 6-month follow-up. Binary restenosis was defined as a diameter stenosis of ≥50% within the stent. Angiographic success was defined as the achievement of <30% residual stenosis by visual estimate after stent implantation. Procedural success was defined as an angiographically successful procedure without death, MI, or repeat revascularization until hospital discharge.

IVUS END POINTS. Mean stent area and lumen area were calculated from manually traced contours using serial cross-sections with an axial distance of 0.5 mm throughout the stented segment. Stent volume and lumen volume were calculated using Simpson's rule. Neointimal hyperplasia volume was computed as stent volume minus lumen volume. Percentage NIHV was also measured as (NIHV × 100/stent volume).

OCT END POINTS. Neointimal hyperplasia thickness of >0 μm was defined as covered (13–15). A maximum distance of 75 μm (polymer and stent strut thickness) plus OCT resolution (21,22) between the inner strut surface and adjacent vessel surface was defined as malapposition. Intracoronary thrombus was defined as a protruding mass beyond the stent strut into the lumen.

Statistical analysis. The trial was designed to minimize the number of patients exposed to this investigative device while still providing enough information for evidence of safety and efficacy.

Baseline characteristics of patients were summarized in terms of frequencies and percentages for categorical variables and by means with standard deviations for continuous variables. Continuous variables were compared using Student's unpaired *t* test. All data were processed using the Statistical Package for Social Sciences, version 15 (SPSS Inc., Chicago, Illinois).

Results

A total of 55 patients were recruited to the ATLANTA trial, and a total of 76 lesions were treated with 89 implanted stents. To date, baseline demographic and lesion characteristics of all patients have been analyzed as well as 1-, 6-, and 12-month clinical outcomes for all 55 patients (100% follow-up). At 6 months, 1 asymptomatic patient with no evidence of myocardial ischemia refused angiographic follow-up (98% follow-up), 52 patients had techni-

Table 2. Patient Characteristics (N = 55)

Age, mean ± SD, yrs	58.6 ± 8.6
Male, n (%)	41 (75)
Diabetes mellitus, n (%)	19 (34)
Insulin-dependent diabetes mellitus, n (%)	6 (11)
Hypertension, n (%)	33 (60)
Hypercholesterolemia, n (%)	30 (55)
Current smoker, n (%)	23 (42)
Stable angina, n (%)	13 (24)
Unstable angina, n (%)	35 (63)
Silent ischemia, n (%)	1 (2)
Recent MI (>48 h, <4 weeks), n (%)	6 (11)
Previous MI, n (%)	38 (69)
Baseline LVEF, mean ± SD, %	52.2 ± 6.7

LVEF = left ventricular ejection fraction; MI = myocardial infarction.

cally successful IVUS (95% follow-up), and all pre-assigned patients had technically successful OCT.

The mean patient age was 58.6 ± 8.6 years. Thirty-four percent of patients had diabetes mellitus, 63% had unstable angina, and 11% had evidence of recent MI (Table 2). Of the 76 lesions treated, 89.5% were classified as American Heart Association/American College of Cardiology (10) type B lesions by visual estimate before the procedure. After QCA analysis, the core laboratory reclassified 15 lesions as type C lesions because of a longer length than visually estimated (Table 3). The left anterior descending artery was the target vessel in 51.3% of cases. A high number (64%) of small vessels ≤2.75 mm were enrolled with an overall reference vessel diameter of 2.75 mm. The combination of these factors makes the patient population for a FIM study unusually complex. Forty-three procedures (48%) were accomplished with direct stenting and 46 (52%) with predilation.

Initial angiographic and procedural success was achieved in 100% of patients.

CLINICAL OUTCOME. The in-hospital incidence of death, MI, TVR, and/or stent thrombosis was 0%. Table 4 summarizes the adverse event rates at 30 days, 6 months, and 12 months. No events were observed during the first 30 days, but at 6 months, 1 asymptomatic patient (1.8%) had clinically driven TLR, 4 patients (7.3%) had nonclinically driven TLR, and 2 patients (3.6%) experienced TVR non-TLR. One additional clinically driven TLR (1.8%) occurred at 9 months.

QUANTITATIVE CORONARY ANALYSIS. Table 5 summarizes QCA results at baseline, immediately after the procedure and at 6 months. Binary angiographic restenosis was observed in 5 of 74 lesions (6.8%) and in-stent LLL was 0.60 ± 0.48 mm.

IVUS ANALYSIS. The IVUS analysis data are listed in Table 6. Overall percent NIHV was 27.9%. Notably, no differences were observed between diabetics and nondiabetics based upon all IVUS measurements.

Table 3. Angiographic and Procedural Characteristics (Lesion-Based) (N = 76)

Vessels treated, n (%)	
Left anterior descending artery	39 (51.3)
Left circumflex artery	17 (22.4)
Right coronary artery	20 (26.3)
Lesions characteristics, n (%)	
Type A	8 (10.6)
Type B	53 (69.7)
Type C	15 (19.7)
Procedural characteristics, mean ± SD	
Lesion length, mm	13.0 ± 4.3
Stents per lesion, n	1.2 ± 0.4
Stented segment length	19.2 ± 7.6

Table 4. Early, Mid-, and Long-Term Outcomes (N = 55)

	30-Day Follow-Up	6-Month Follow-Up	12-Month Follow-Up
Death	0 (0)	0 (0)	0 (0)
Cardiac death	0 (0)	0 (0)	0 (0)
Index vessel–related MI	0 (0)	0 (0)	0 (0)
Q-wave MI	0 (0)	0 (0)	0 (0)
Non–Q-wave MI	0 (0)	0 (0)	0 (0)
TLR clinically driven	0 (0)	1 (1.8)	2 (3.6)
CABG	0 (0)	0 (0)	0 (0)
PCI	0 (0)	1 (20)	2 (33)
TLR nonclinically driven	0 (0)	4 (7.3)	4 (7.3)
CABG	0 (0)	0 (0)	0 (0)
PCI	0 (0)	4 (80)	4 (67)
TVR non-TLR	0 (0)	2 (3.6)	2 (3.6)
Stent thrombosis	0 (0)	0 (0)	0 (0)

CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention; TLR = target lesion revascularization; TVR = target vessel revascularization; other abbreviations as in Table 2.

Table 5. Quantitative Coronary Angiography

	In-Stent
Reference vessel diameter, mm, mean ± SD	
Baseline	2.75 ± 0.52
After procedure	2.87 ± 0.48
At 6 months	2.55 ± 0.50
Minimal lumen diameter, mm, mean ± SD	
Baseline	1.00 ± 0.41
After procedure	2.50 ± 0.40
At 6 months	1.91 ± 0.64
Stenosis, % of lumen diameter, mean ± SD	
Baseline	64.5 ± 11.7
After procedure	12.2 ± 6.6
At 6 months	26.0 ± 16.6
Acute gain, mm, mean ± SD	1.51 ± 0.49
Late lumen loss, mm, mean ± SD	0.60 ± 0.48
Binary restenosis, n (%)	5 (6.8)

Table 6. Intravascular Ultrasound Measurements at Follow-Up

	All Patients (N = 55)	Patients With Diabetes (n = 19)	Patients Without Diabetes (n = 36)	p Value
Stent volume, mm^3, mean ± SD	127.0 ± 59.1	123.2 ± 43.1	128.6 ± 65.3	0.735
Luminal volume, mm^3, mean ± SD	89.3 ± 40.2	89.7 ± 40.4	89.1 ± 40.6	0.955
NIHV, mm^3, mean ± SD	37.7 ± 37.6	33.5 ± 22.7	39.5 ± 42.7	0.610
Percent NIHV, mean ± SD	27.9 ± 16.1	28.1 ± 15.9	27.7 ± 16.6	0.932

NIHV = neointimal hyperplasia volume.

OCT ANALYSIS. A total of 1,904 cross-sections were analyzed (19,028 struts) by OCT. Of these, 18,933 struts (99.5%) showed evidence of coverage. The vast majority of patients (5 of 6) with incomplete coverage exhibited a percentage of strut coverage greater than 99%. Malapposition was found only in 29 struts (0.15%) and was present in 3 patients, in which 4 stents with a total of 4,020 struts were analyzed. A single patient accounted for 81% and 59% of all noncovered and malapposed struts, respectively.

Discussion

DES have been shown to reduce the risks of both restenosis and TLR after elective percutaneous coronary intervention, as compared with BMS (3–5). However, DES may be associated with lack of or delayed endothelialization, stent malapposition, inflammatory or hypersensitivity reactions, and an increased risk of late stent thrombosis and very late stent thrombosis (23), and usually require long-term DAPT with consequent bleeding risk and increased cost. The CHARISMA (Clopidogrel for High Atherothrombotic Risk, Ischemic Stabilization, Management, and Avoidance) study group suggested that long-term DAPT with aspirin and clopidogrel is associated with a 2.1% risk of moderate bleeding requiring transfusion (24). In addition, the cost of DAPT to patient or health care system is estimated to be $1,540 (€982) per year (6). Moreover, biocompatible polymer coatings used as drug-elution matrices may induce hypersensitivity and/or inflammatory reactions. Thus, a strong effort is still devoted to develop new stents with ideal features such as decreased restenosis rates with decreased thrombogenicity and without the need for long-term DAPT.

Therefore, to provide a biologically inert barrier between the stent surface, circulating blood, and endothelial wall, a variety of different stent coatings have been evaluated in multiple study registries, nonrandomized and randomized trials (25).

The present FIM feasibility single center study assessed the safety and efficacy of the new Catania stent in the treatment of de novo coronary lesions. Angiographic success and procedural success were 100%. Comprehensive clinical follow-up was achieved in all patients at 30 days, with no observed cardiac events.

At 12-month clinical follow-up, the total TLR per patient rate was 10.9% (7.3% nonclinically driven and 3.6% clinically driven) and there was no occurrence of death, MI, stroke, ST, or need for surgical revascularization. This compares very favorably with 12-month BMS TLR rates of 14.7% in the TAXUS IV (Treatment of de Novo Coronary Disease Using a Single Paclitaxel-Eluting Stent) study and 20% in the SIRIUS (Sirolimus-Eluting Stent in Coronary Lesions) study and reasonably well against DES TLR rates of 4.2% in TAXUS IV, 4.9% in SIRIUS (26–28). The 0% death rate compares very favorably with BMS (0.7% to 1.5%) to paclitaxel-eluting stents (1.5%) and to sirolimus-eluting stents (1.1%) at 12 months. The 0% MI rate also compares very favorably to BMS (1.8% to 2.2%), to paclitaxel-eluting stents (0.8%) and to sirolimus-eluting stents (1.3%) at 12 months (27).

Moreover, the 6-month BR rate of 6.8% in the present study was far lower than the rate reported for stents with nonpolymeric coatings (29–32). Another pilot study assessing the short- and mid-term performance of a polyphosphazene-coated coronary stent reported a 15.6% rate of restenosis at 6-month angiographic follow-up (33) but with a different stent platform of 120-μm strut thickness. The LLL of 0.60 mm was lower than those of BMS (34–36) and was in the range of some currently available DES (37). Overall, with the baseline reference vessel diameter of 2.75 ± 0.52, the restenosis pattern is considered focal and mild. Of the 5 of 55 (9.1%) patients undergoing TLR at 6 months, all were asymptomatic with 1 procedure meeting the criteria for clinically driven with a BR rate >70%. The remaining 4 patients had QCA BR >50% and <70%.

Intravascular ultrasound at follow-up showed a mild percentage of neointimal proliferation that compares well with other IVUS studies on BMS (38). Interestingly, we observed that diabetes seems not to influence volumetric IVUS assessment of neointima in patients treated with the Catania stent. This is a very intriguing finding that needs further confirmation.

Data from OCT analysis showed extremely low rates of malapposition suggesting an optimal healing process. Complete vessel healing visualized by OCT with evidence of stent strut coverage in 99.5% of struts is a remarkable finding and justifies the absence of ST reported in the study. The investigators believe this to be the first FIM study to include an OCT arm and the only study to date with a strut-by-strut analysis of vessel healing.

Finally, the safety profile appeared excellent, as there was no incidence of stent thrombosis from the index procedure to 180 days of clinical and angiographic follow-up, despite the fact that 1 patient discontinued aspirin 1 week after implantation and another patient discontinued both aspirin and ticlopidine 2 weeks after implantation. The absence of stent thrombosis confirms the strong preclinical evidence that a Polyzene-F surface treatment is associated with reduced thrombogenicity and inflammatory reactions in animal models (8,39). This is of clinical relevance because, in contrast to restenosis, which is not usually associated with increased mortality, ST is a potentially catastrophic event that might manifest as MI and sudden death (22). It is important to also note that at 12-month clinical follow-up on all 55 patients, there were no deaths, stroke, or MIs reported. These preliminary results should be confirmed using a larger cohort of patients, but are undoubtedly very promising. The Catania stent, due to its safety profile may also represent a reliable alternative for patients who are not eligible for long-term thienopyridine regimen.

In summary, this FIM experience showed a favorable early and mid-term safety profile and a high-level efficacy of the new Catania stent in the treatment of de novo coronary lesions in a real-world patient population. The use of Polyzene-F coated stents may be an alternative to both BMS and DES, with reduced LLL, restenosis, and TLR without increased risk of late and very late ST and no requirement for long-term DAPT.

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