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ORIGINAL STUDY

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Safety and efficacy of Everolimus-Eluting bioabsorbable Polymer-Coated stent in patients with long coronary lesions: The EVOLVE 48 study

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Abstract

Objectives: The EVOLVE 48 study evaluated the safety and effectiveness of the SYNERGY 48 mm stent for the treatment of long lesions.

Background: Clinical evidence supporting the use of very long stents during percutaneous coronary intervention (PCI) is limited. The bioabsorbable polymer SYNERGY stent has shown good long-term data in a broad population of patients undergoing PCI.

Methods: Patients with lesion length >34- ≤44 mm and reference vessel diameter (RVD) ≥2.5- ≤ 4.0 mm were enrolled in this prospective, multicenter, single-arm study. The primary endpoint was 12-month target lesion failure (TLF; composite of target lesion revascularization [TLR], target-vessel myocardial infarction [TV-MI], or cardiac death) compared to a prespecified performance goal (PG).

Results: A total of 100 patients with mean lesion length of 35.34 ± 7.15 mm (26 patients with lesion length > 40 mm) and mean RVD 2.72 ± 0.44 mm were enrolled. Moderate to severe calcification was present in 30% of the patients and 89% had pre-TIMI flow grade 3. The rates of technical and clinical procedural success were 100%. One-year TLF was observed in 4.1% patients compared to a prespecified PG of 19.5% (95% upper confidence bound = 9.1%; $p < 0.0001$). Cardiac death and TLR were each observed in one patient, and TV-MI in two patients treated with SYNERGY 48 mm stent. Between the 1-2-year timeframe, TV-MI occurred in one additional patient. None of the patients experienced a definite or probable stent thrombosis through 2 years.

Conclusions: PCI of long coronary lesions with the 48 mm SYNERGY stent demonstrated good procedural and clinical outcomes through 2 years, supporting its clinical safety and efficacy.

KEYWORDS
coronary artery disease, drug eluting stent, long lesions, percutaneous coronary intervention–complex PCI

1 | INTRODUCTION

The introduction of drug-eluting stents (DES) that release antiproliferative drugs into the arterial wall to inhibit neointimal proliferation and inflammation, has revolutionized percutaneous coronary intervention (PCI). Due to a reduced risk of restenosis and stent thrombosis (ST), DES are now the recommended treatment of choice for obstructive coronary artery disease (CAD).[1] Additionally, the improved design characteristics of new generation DES have allowed their widespread use in complex CAD, including long coronary artery lesions that represent a significant proportion of PCI cases.[2,3]

Treatment of long lesions typically requires multiple stents with variable overlap, which may contribute to an increased risk of restenosis, side-branch occlusion, and ST.[4-6] The availability of longer-length stents may reduce the need for multiple overlapping stents. Studies suggest that implantation of one long stent instead of two or more shorter overlapping stents reduces both procedural cost and time. Consequently, additional patient benefit accrues from reduced contrast agent use and reduced radiation exposure.[7,8]

The new generation SYNERGY stent combines several design features, including an abluminal everolimus coating (eluted in ~90 days) and bioabsorbable poly(D,L-lactide-co-glycolide) (PLGA) polymer (completely degraded within 4 months), that may improve arterial healing and reduce the occurrence of late/very late ST, as well as the requirement for prolonged dual antiplatelet therapy (DAPT).[9,10] Clinical data from randomized controlled trials and large observational studies have shown promising results with SYNERGY, including low rates of revascularization and thrombotic events.[10-14] The EVOLVE 48 study evaluated the clinical efficacy and safety of the 48 mm SYNERGY stent in patients undergoing PCI for long coronary lesions.

2 | METHODS

EVOLVE 48 was a prospective, multicenter, open label, single-arm study that enrolled 100 patients at 15 clinical sites in the United States, Europe, and New Zealand. The study was conducted in accordance with ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects—Good Clinical Practice (GCP), the Declaration of Helsinki, and all applicable local regulations. Prior to enrollment, all patients provided written informed consent and the Institutional Review Board at each site approved the study protocol. The study is registered at www.clinicaltrials.gov under identifier NCT03350542.

2.1 | Device description

A detailed description of the SYNERGY stent has been published elsewhere.[15] In brief, SYNERGY is a thin strut (74–81 μm), platinum chromium metal alloy stent with an ultrathin (4 μM) bioabsorbable polymer designed to release everolimus (100 μm/cm^2) on the abluminal side only. Drug release and polymer degradation are completed in parallel within 4 months,[16] leaving behind a biocompatible bare metal platform.

2.2 | Study design and procedure

Patients ≥18 years of age were eligible if they had either (1) symptomatic CAD with coronary stenosis ≥70%, abnormal fractional flow reserve, elevated cardiac biomarkers or an abnormal stress or imaging stress test, or (2) silent ischemia based on abnormal fractional flow reserve (FFR), abnormal stress or imaging stress test, or elevated biomarkers prior to the procedure. The main angiographic inclusion criteria were lesion length >34 to ≤44 mm in a native coronary artery with a reference vessel diameter (RVD) ≥2.5 to ≤4.0 mm (both by visual estimation), target lesion with visually estimated stenoses ≥50% and < 100% and Thrombolysis in Myocardial Infarction (TIMI) flow >1, and successful predilatation of the target lesion. Patients with acute STEMI, left main or saphenous vein graft lesions, chronic total occlusion, in-stent restenosis, and bifurcations requiring >1 stent were excluded. Eligible patients who met the inclusion criteria were enrolled and treated with a single 48 mm SYNERGY stent. Treatment of one nontarget lesion in one nontarget vessel was allowed during the index procedure.

Dual antiplatelet therapy (DAPT) with aspirin and a P2Y12 inhibitor was prescribed following PCI for at least 6 months (12 months in patients with acute coronary syndrome). All patients were required to take aspirin through 2 years of follow-up. Clinical follow-up was required in hospital, at 30 days, 6- and 12-months following PCI, and then at 2 years. Protocol-specified coronary angiography assessment was required during index procedure, but not at follow up.

2.3 | Study endpoints

The primary endpoint was the rate of 12-month target lesion failure (TLF), defined as the composite of any ischemia-driven revascularization of the target lesion (TLR), myocardial infarction (MI, Q-wave and non-Q-wave)[17] related to the target vessel, or any cardiac death. Secondary clinical endpoints evaluated at both 1- and 2 years included target vessel failure (TVF; composite of ischemia-driven target vessel revascularization [TVR], target vessel-related MI [TV-MI] or death), all-cause death, individual components of TLF, and Academic Research Consortium defined stent thrombosis

(ST).[18] ST, TVR, MI, and death were adjudicated by an independent clinical events committee (CEC). Technical success was defined as successful delivery and deployment of the study stent into the target vessel, without balloon rupture or stent embolization, and postprocedure diameter stenosis of <30% with TIMI 3 flow in the target lesion (as visually assessed by the physician). Clinical procedural success was defined as postprocedure diameter stenosis <30%, TIMI 3 flow in the target lesion without the occurrence of in-hospital MI, cardiac death or TVR. All procedural angiograms were evaluated by an independent angiographic core laboratory (Beth Israel Deaconess Medical Center, Boston, MA).

2.4 | Data availability statement

The data for this clinical trial may be made available to other researchers in accordance with the Boston Scientific Corporation (BSC) Data Sharing Policy (http://www.bostonscientific.com/en-US/data-sharing-requests.html).

2.5 | Statistical methods

The study was powered to assess the primary endpoint of 12-month TLF compared to a prespecified performance goal of 19.5%, which was based on EVOLVE II-like patients with lesion length >34 and ≤44 mm from PROMUS Element Plus US Post-Approval Study[19] and PE-Prove Study.[20] The expected 12-month TLF rate of 9.2% was based on results from EVOLVE II RCT[15] for SYNERGY and assumed a relative 20% increase in rates for every 10 mm increase in mean lesion length. A one-group Clopper–Pearson exact test was used to test whether the 12-month TLF rate for SYNERGY was less than the performance goal. If the *p*-value was <0.05 in both perprotocol and intent-to-treat (ITT) populations, SYNERGY 48 mm stent would be concluded to successfully meet the performance goal with respect to the 12-month TLF rate. This corresponds to the one-sided 95% upper confidence bound (UCB) on the observed 12-month TLF rate from SYNERGY being less than the performance goal. Given a performance goal of 19.5% and one-sided test significance level of 0.05, a minimum of 95 patients would provide at least 80% power for TLF after adjusting for attrition (5%). Discrete variables were reported as percentages (%) and continuous variables as mean ± standard deviation. Clinical outcomes were evaluated by the Kaplan–Meier method. Confidence intervals were evaluated using normal approximation. Statistical analyses were conducted using SAS® Version 9.0 or later (SAS Institute, Cary, NC, USA).

3 | RESULTS

3.1 | Patients and enrollment

The EVOLVE 48 study enrolled 100 patients between April 2018 and January 2019 at 15 clinical sites (Figure 1). Baseline clinical and lesion characteristics are listed in Tables 1 and 2. The average age was 65 years, 40% were female, 27% had medically treated diabetes mellitus, 14% had unstable angina and 24% had MI diagnosed prior to the index PCI (Table 1). All patients had lesion length >34 mm based on site assessment, which was one of the main eligibility criteria for inclusion. Angiographic core lab adjudicated mean lesion length and RVD were 35.34 ± 7.15 and 2.72 ± 0.44 mm, respectively (Table 2). A total of 20 patients had a nontarget lesion treated during the index procedure. Mean stent length implanted was 50.96 ± 7.25 mm (Table 3). Site-reported technical and clinical procedural success rates were 100%. The core lab confirmed the angiographic data for site-reported clinical procedural success. Postprocedural angiographic results were available in all 100 lesions (Table 3). Mean postprocedure in-stent diameter stenosis was 9.74% ± 7.19% and minimum lumen diameter was 2.47 ± 0.40 mm. Additional angiographic outcomes are shown in Table 3. At 2 years follow-up, 91% patients were on aspirin (Figure 2). DAPT usage decreased from 99% postimplantation to 72% at 1-year and 41% at 2 years.

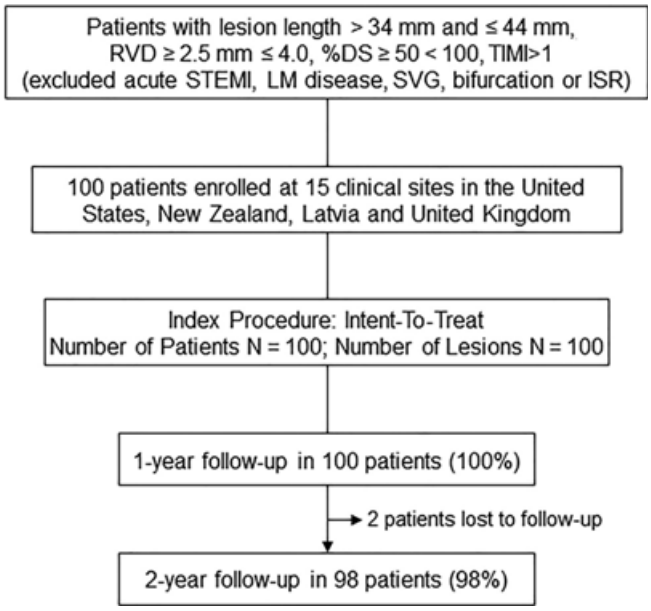

FIGURE 1 EVOLVE 48 study enrollment and follow-up. DS, diameter stenosis; ISR, in-stent restenosis target lesion; LM, left main; RVD, reference vessel diameter; STEMI, ST-segment elevation myocardial infarction; SVG, saphenous vein graft target lesion; TIMI, thrombolysis in myocardial infarction

3.2 | Clinical outcomes

The trial primary endpoint of 1-year TLF analyzed by ITT and perprotocol was observed in 4.1% of SYNERGY 48 mm treated patients and the one-sided 95% UCB was 9.1%, significantly less than the performance goal of 19.5% ($p < 0.0001$; Figure 3). Cardiac mortality was reported in one patient (318 days postprocedure). Two patients had a non-Q-wave-MI related to the study stent (111- and 292-days postprocedure) and one patient underwent TLR that was treated with PCI (259 days postprocedure).

TABLE 1 Baseline Clinical Characteristics

	Synergy 48 N = 100 patients
Patient Charactersitics	
Age (yr) ± *SD*	64.99 ± 10.57 (100)
Female	40.0% (40)
Caucasian	85.0% (85)
Medical history	
Smoking status	
Current	14.0% (14)
Previous	37.0% (37)
Medically treated diabetes	27.0% (27)
Insulin dependent	8.0% (8)
Hyperlipidemia	82.0% (82)
Hypertension	76.0% (76)
Cardiac history	
Myocardial infarction	24.0% (23)
Congestive heart failure	8.0% (8)
Stable angina	62.6% (62)
Unstable angina	14.1% (14)
Silent ischemia	7.4% (6)
PCI	32.7% (32)
CABG	6.0% (6)
Arrhythmia	9.1% (9)
Multivessel disease	42.9% (42)
History of renal disease	10.0% (10)
History of peripheral vascular disease	10.1% (10)

Note: Values are mean ± *SD* or % (n), Intent-to-treat analysis.
Abbreviations: CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

TABLE 2 Baseline lesion characteristics (Adjudicated by the Angiographic Core Lab)

	Synergy 48 N = 100 patients
Number of lesions	100
Target vessel treated	
LAD	40.0% (40)
LCx	14.0% (14)
RCA	46.0% (46)
Lesion length (mm)	35.34 ± 7.15 (98)
≤34 mm	40.8% (40)
>34 – 40 mm	32.7% (32)
>40 – 44 mm	17.3% (17)
>44 mm	9.2% (9)
Reference vessel diameter (mm)	2.72 ± 0.44 (100)
3.0 mm	76.0% (76)
3.0 – 3.5 mm	20.0% (20)
>3.5 mm	4.0% (4)
Minimum lumen diameter (mm)	0.78 ± 0.43 (100)
% diameter stenosis	71.23 ± 14.98 (100)
Pre-TIMI flow grade 3	89.0% (89)
Modified AHA/ACC B2/C	100.0% (100)
Calcification, moderate/severe	30.0% (30)

Note: Values are mean ± SD or % (n), Intent-to-treat analysis.

Kaplan–Meier curves for the occurrence of TLF and its individual components (cardiac death, MI and TVR) through 2 years are shown in Figure 4. One additional patient experienced target vessel related non-Q-wave MI between the 1-2-year timeframe (624 days postprocedure). None of the patients experienced a definite or probable ST through 2 years. Secondary clinical outcomes at 2 years poststent implantation are shown in Table 4.

4 | DISCUSSION

EVOLVE 48, a prospective, single-arm, global study, met the primary endpoint of 1-year TLF in patients with long coronary lesions. Despite the angiographic complexity of long lesions treated per protocol in EVOLVE 48, the rates of technical and clinical procedural success were 100%. The 2-year rates of TLF, target vessel MI, cardiac death, and TLR remained relatively low. No ST was observed in any of the patients implanted with the SYNERGY 48 mm stent through 2 years of follow-up.

Long coronary artery lesions constitute a significant proportion of PCI cases, in which approximately a third of the population need multiple overlapping stents due to the lesion length exceeding that of the longest available or deliverable stent.[3] Treatment of long lesions is challenging due to difficult stent deliverability and the need for stent overlap, which may lead to geographical miss and in-stent restenosis.[21] Both stent length and stent overlap are predictors of adverse clinical outcomes following DES implantation.[6] As such, the availability of longer-length stents can reduce the need for multiple overlapping stents and associated procedural costs as well as adverse angiographic and clinical outcomes. Further, reduction of the number of stents used to treat a lesion reduces intervention time, need for contrast agent, radiation exposure for both the patient and the operator, and may impact long-term outcomes.[3,8]

The introduction of new stent technologies with improved design and antiproliferative drugs eluting from a bioabsorbable polymer may have decreased the impact of the previously reported association between stent length and restenosis.[3] However, there are limited data supporting the use of new generation DES with longer stent lengths. SYNERGY, a newer generation bioabsorbable polymer stent, incorporates specific design characteristics that enhance deliverability and facilitate healing. Long-term safety and efficacy of SYNERGY have been established in a broad population of patients undergoing PCI.[12,14] Data from the present study compare well with those from previous studies on the SYNERGY stent in patients with moderate complexity and implanted stent length ≤34 mm.[11,14,22] The 1-year rates of TLF (4.0%), TVR (1.0%) and ST (0.0%) in patients implanted with the 48 mm SYNERGY stent were similar to or lower than those

TABLE 3 Procedural and postprocedural characteristics

	Synergy 48 N = 100 patients N = 100 lesions
Procedural characteristics	
Technical success	100.0% (100)
Clinical procedural success	100.0% (100)
Time from sheath placement to last guide catheter removal (min)	52.47 ± 24.29 (100)
Stents per patient	
Total stent length implanted[a], mm	50.96 ± 7.25 (100)
Predilatation	99.0% (99)
Postdilatation	99.0% (99)
Max pressure overall (atm)	19.02 ± 3.82 (100)
Postprocedural characteristics	
Reference vessel diameter (mm)	2.74 ± 0.43 (99)
Minimum lumen diameter (mm)	
In-stent	2.47 ± 0.40 (99)
In-segment	2.18 ± 0.44 (99)
Acute gain (mm)	
In-stent	1.68 ± 0.51 (99)
In-segment	1.39 ± 0.52 (99)
% diameter stenosis	
In-stent	9.74 ± 7.19 (99)
In-segment	20.83 ± 8.69 (99)

Note: Values are mean ± *SD* or % (n).
[a]Includes the 48 mm study stent and any nonstudy stents implanted; Intent-to-treat analysis.

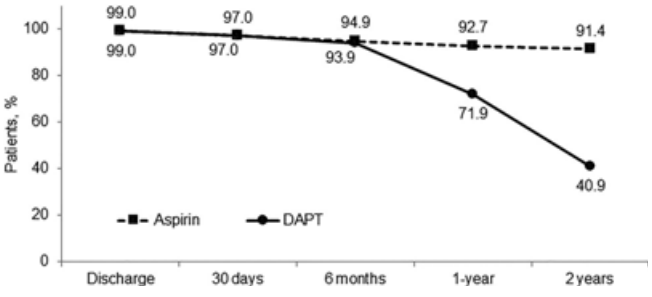

FIGURE 2 Antiplatelet medications through 2-year follow-up. Aspirin and dual antiplatelet therapy (DAPT) use for the SYNERGY 48 mm stent at discharge, 30 days, 6 months, 1 and 2 years poststent implantation

reported in prior studies evaluating the performance of stents up to 38 mm in size.[7,23] In the RESOLUTE 38 mm sub-study[23] evaluating the use of the 38 mm durable polymer Resolute zotarolimus-eluting stent among real-world patients, the rate of 1-year TVR was low (2.7%), with no patients developing ST after 30 days (0.9%). The study met the primary endpoint of 1-year TLF (5.4%), which was significantly below the prespecified performance goal of 19.0%.[23] Comparable rates of TVR (3.9%) and ST (1.0%) were observed at 1-year in the

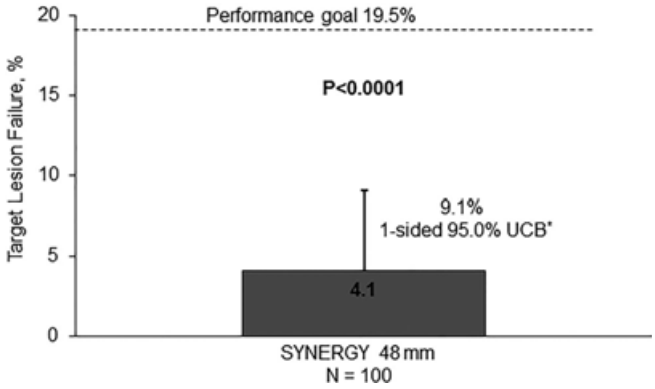

FIGURE 3 Primary endpoint of target lesion failure (TLF) at 1 year. TLF in the SYNERGY 48 mm intent-to-treat and perprotocol patient populations was compared to a 19.5% performance goal. One-sided 95.0% upper confidence bound (UCB*) is indicated by the error bar. *p*-value was calculated using the Clopper–Pearson Exact test

real-world P38 registry[7] that enrolled patients treated with at least one 38 mm durable polymer Xience Prime everolimus-eluting stent (EES). Despite the use of a very long stent, the absence of ST in the present study population suggests that the bioabsorbable polymer together with the optimal combination of platinum-chromium metal alloy, thinner struts and everolimus coating play an important role in defining the safety of the SYNERGY 48 mm stent. Also, everolimus is eluted in ~90 days and bioabsorbable PLGA polymer is completely degraded within 4 months leaving behind a bare metal platform, which may help prevent the occurrence of late/very late ST.[9]

Recently conducted trials studying the use of very long stents have reported good clinical outcomes in retrospective analyzes of real-world population undergoing PCI. Jurado-Román et al.[3] compared the use of very long stents (≥40 mm), including the new generation SYNERGY 48 mm size, to overlapping stents. The rates of TLR were significantly lower with the use of one very long stent (0.9%) versus overlapping stents (4.7%; $p = 0.01$). No between-group differences in cardiac death, acute MI or ST were observed at 20 months. Also, procedure and fluoroscopy time were lower with the use of very long stents, and required less contrast volume.[3] A single center study evaluating the performance of 48 mm Xience Expedition durable polymer EES showed favorably low incidence of major adverse cardiac events (3.3%) and ST (1.3%) at 1-year.[24] Two-year TLF rate in an observational registry for patients treated with a single long 48 mm Xience Expedition stent was 5.3% and probable ST was 0.9%.[25] It must be noted that between the 1-2-year timeframe, TLF occurred in only one additional patient treated with the 48 mm SYNERGY stent (2-year TLF: 5.0%), which was primarily driven by MI related to the target vessel. There were no additional cardiac deaths or the occurrent of very late ST. Acknowledging the limitations of comparing trials, the event rates in previous studies align with those observed in EVOLVE 48; although the rate of ST appears to be lower in patients treated with 48 mm SYNERGY stent.[3,24,25]

Honda et al.[26] evaluated the performance of both durable and bioabsorbable polymer stents that were ultra-long (>50 mm) and long (20–50 mm), and compared outcomes to those of short stents (<20 mm). The

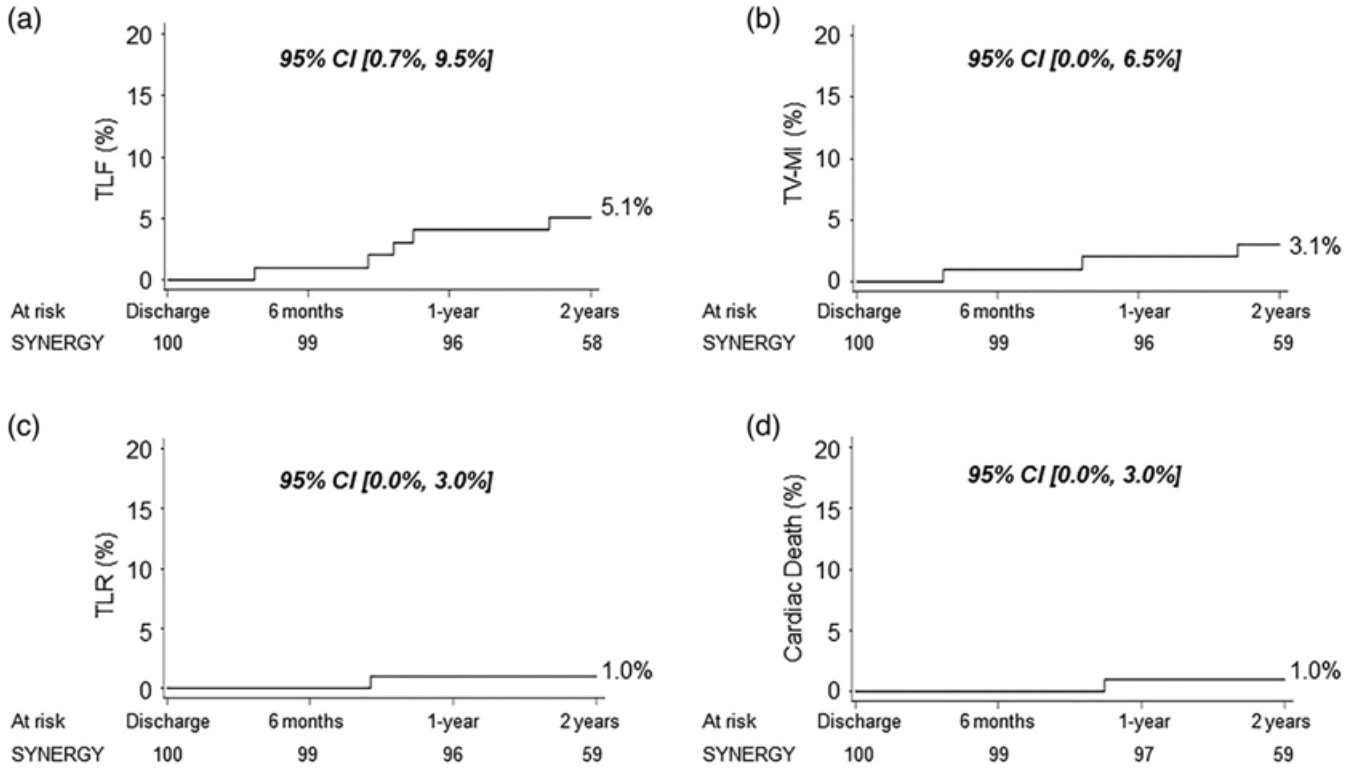

FIGURE 4 Kaplan–Meier curves for target lesion failure (TLF) and individual components through 2 years. (A) TLF, (B) target vessel-related myocardial infarction (TV-MI), and (C) target lesion revascularization (TLR), and (D) cardiac death. CI, confidence intervals

TABLE 4 Clinical endpoints through 2 years

	1-year(N = 100)		2 years (N = 100)	
Events	**Rate**	**95% CI**	**Rate**	**95% CI**
Death	5.0% (5)	[1.6%, 11.3%]	5.0% (5)	[1.6%, 11.3%]
Cardiac death	1.0% (1)	[0.0%, 5.4%]	1.0% (1)	[0.0%, 5.4%]
Noncardiac death	4.0% (4)	[1.1%, 9.9%]	4.0% (4)	[1.1%, 9.9%]
Myocardial infarction	2.0% (2)	[0.2%, 7.0%]	4.0% (4)	[1.1%, 9.9%]
Q-wave	0.0% (0)	[0.0%, 3.6%]	1.0% (1)	[0.0%, 5.4%]
Related to target vessel	0.0% (0)	[0.0%, 3.6%]	0.0% (0)	[0.0%, 3.6%]
Non-Q-wave	2.0% (2)	[0.2%, 7.0%]	3.0% (3)	[0.6%, 8.5%]
Related to target vessel	2.0% (2)	[0.2%, 7.0%]	3.0% (3)	[0.6%, 8.5%]
Target vessel revascularization	1.0% (1)	[0.0%, 5.4%]	1.0% (1)	[0.0%, 5.4%]
PCI	1.0% (1)	[0.0%, 5.4%]	1.0% (1)	[0.0%, 5.4%]
CABG	0.0% (0)	[0.0%, 3.6%]	0.0% (0)	[0.0%, 3.6%]
Target lesion revascularization	1.0% (1)	[0.0%, 5.4%]	1.0% (1)	[0.0%, 5.4%]
PCI	1.0% (1)	[0.0%, 5.4%]	1.0% (1)	[0.0%, 5.4%]
CABG	0.0% (0)	[0.0%, 3.6%]	0.0% (0)	[0.0%, 3.6%]
Non-TLR TVR	1.0% (1)	[0.0%, 5.4%]	1.0% (1)	[0.0%, 5.4%]
PCI	1.0% (1)	[0.0%, 5.4%]	1.0% (1)	[0.0%, 5.4%]
CABG	0.0% (0)	[0.0%, 3.6%]	0.0% (0)	[0.0%, 3.6%]
Target lesion failure	4.0% (4)	[1.1%, 9.9%]	5.0% (5)	[1.6%, 11.3%]
Target vessel failure	4.0% (4)	[1.1%, 9.9%]	5.0% (5)	[1.6%, 11.3%]
ARC stent thrombosis	0.0% (0)	[0.0%, 3.6%]	0.0% (0)	[0.0%, 3.6%]

Note: Values are % (n), Intent-to-treat analysis.
Abbreviation: CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

rate of TLR at 1-year was significantly higher in the ultra-long group (13.5%) compared to the long (7.2%) and short (6.0%) DES groups ($p = 0.001$). No significant differences were noted between groups for individual cardiac events and ST. These data support the safety and efficacy of long stents up to 50 mm in size.[26] Furthermore, the safety and effectiveness of bioabsorbable polymer DES for treatment of long (≥25 mm) coronary lesions has been established in the Long Drug-Eluting Stent (LONG-DES) V multicenter, prospective randomized controlled trial.[2] The primary endpoint of 9-month angiographic in-segment late luminal loss was comparable between biolimus-eluting bioabsorbable Nobori versus everolimus-eluting durable Promus Element stents (0.14 ± 0.38 versus 0.11 ± 0.37 mm; $p = 0.03$ for a noninferiority margin of 0.11, $p = 0.45$ for superiority). There were no significant between-group difference in the rates of TLF (16.3% versus 16.5%; $p = 0.97$), TLR (3.3% versus 2.0%; $p = 0.44$) and ST (1.2% versus 0.0%; $p = 0.12$).[2] Although not directly comparable due to differences in the inclusion/exclusion criteria, low revascularization and ST rates were observed in the present study despite the use of longer implanted stent sizes than in LONG-DES-V, validating the safety and performance of the SYNERGY 48 mm stent.

5 | STUDY LIMITATIONS

The 2-year outcomes from the EVOLVE 48 study demonstrate low rates of adverse cardiac events, with no ST. However, this was a non-randomized trial that did not include an active comparator or a control group and comparing these results to clinical outcomes with other contemporary DES is challenging. The relatively small sample size may have limited the ability to assess rare clinical adverse outcomes, such as ST. Also, this study was not powered to evaluate individual clinical endpoints at 2 years. Patients with very high lesion complexity were not enrolled, and therefore this study does not fully represent real-world patients. In addition, adequate predilatation was specified in the protocol and postdilatation was optional yet performed in almost all implanted DES. As such, postdilatation may have significantly contributed to the high technical and procedural success rates, as well as the excellent 2-year clinical outcomes, and should therefore be considered when treating long coronary lesions. Finally, use of intravascular imaging or ancillary devices was neither prespecified nor captured in the present study; nevertheless, it should be considered in all complex PCI cases with long lesions.

6 | CONCLUSIONS

The EVOLVE 48 study demonstrated good procedural and clinical outcomes among patients undergoing PCI for long lesions and met the prespecified primary endpoint at 12 months, with no incidence of ST through 2 years. These data support the safety and efficacy of the SYNERGY 48 mm EES for the treatment of long coronary artery lesions.

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