Original paper

Procedural advantages of a novel coronary stent design with ultra-thin struts and bioabsorbable abluminal polymer coating in an all-comers registry

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Abstract

Introduction: The implications of novel drug-eluting stent (DES) design modifications including ultra-thin struts and new concepts of polymer coating for procedural efficacy are still unknown.

Aim: To evaluate procedural efficacy and short-term safety of a novel DES design.

Material and methods: In this all-comers registry, 407 consecutive patients were enrolled upon undergoing percutaneous coronary interventions (PCI) with the thin-strut bioabsorbable abluminal polymer-coated SYNERGY stent. These patients were then compared with the previous 407 patients undergoing PCI performed by the same interventionalists using currently established second-generation DES (Promus Element plus, Xience prime, Resolute Integrity). Several clinical and procedural data were compared, and the coronary artery complexity was assessed by the American College of Cardiology/American Heart Association classification and SYNTAX Score.

Results: The study population consisted of 814 patients. A total of 859 Synergy stents were deployed in 480 target vessels in the Synergy group (n = 407), and 904 stents in 469 vessels in the second-generation DES group (n = 407). Coincidentally, target lesions in the Synergy group (A 2.7%, B1 13.8%, B2 38.6%, C 45.0%) were more complex ($p < 0.01$) than those in the second-generation DES group (A 4.9%, B1 18.7%, B2 42.3%, C 34.2%). In cases with severe lesions (B2/C), the median contrast agent amount and fluoroscopy time were significantly lower in the Synergy group, indicating improved deliverability (110 ml vs. 150 ml; $p < 0.01$ and 7.2 min vs. 9.1 min; $p = 0.01$). Rates of in-hospital major adverse cardiovascular events were comparable between the two groups.

Conclusions: In an all-comers, real-world PCI population, novel stent design modifications including ultra-thin struts and abluminal bioabsorbable polymer coating are associated with improved procedural performance.

Key words: coronary artery disease, percutaneous coronary intervention, drug-eluting stent, stent design, bioabsorbable polymer.

Summary

In an all-comers registry, novel drug-eluting stent design advances including ultra-thin struts and bioabsorbable abluminal polymer coating are associated with improved stent deliverability and enhanced procedural performance as reflected by significantly lower contrast agent consumption and shorter fluoroscopy time in comparison to currently established 2nd generation drug-eluting stents with comparable rates of in-hospital major adverse cardiovascular events between both groups. This may positively impact our interventional performance in daily practice, patients' safety, and economic efficiency.

Introduction

During the last 2 decades, coronary stents undergone various improvements, including changes in stent platform design, metal composition, delivery catheter, balloon, polymer coating, and drug loading. In the early stent era, outcome data, including restenosis and stent thrombosis (ST), were the focus of new stent designs. Stent strut geometry showed an impact on stent performance as well as on angiographic and clinical outcomes [1–5]. Early generation bare-metal stents (BMS) with thick-

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er stent struts and larger surface contact area with the coronary arteries were related to higher rates of trauma of the internal elastic lamina and media, eventually inducing peri-strut inflammation, neo-intimal proliferation and in-stent stenosis [6, 7]. First-generation drug-eluting stents (DES) showed superiority compared to BMS in terms of target vessel revascularization and major adverse cardiac events (MACE) [8, 9], leading to adoption of DES as a primary choice for percutaneous coronary interventions (PCI). Nevertheless, there were safety concerns regarding increased rates of ST [10–12], most likely due to drugs and polymers used in the first-generation DES [13, 14]. Thus, second-generation DES were developed including different polymer coatings, different anti-proliferative drugs and enhanced stent platforms, with better clinical results [15]. However, durable polymer coatings were suggested to be a potential source of late (30 days to 1 year) and very late (after 1 year) ST due to prolonged or chronic inflammation [13, 14, 16, 17].

Due to these limitations and because of increasing complex interventions, new DES design modifications were developed with even thinner struts and changes in polymer coating. These novel stent features not only address an improvement in clinical outcome, but shift their focus to safety and simplicity of the procedure, to the increasing demand for suitable stents in very complex and multi-vessel interventions and even to economic efficiency.

The coronary stent which is the focus of this study (Synergy) belongs to this new generation of DES featuring ultra-thin struts as well as reduced bioabsorbable polymer load only to the abluminal side. Several studies have already demonstrated the safety and comparability of these stent innovations in clinical outcome data compared to common second-generation drug-eluting stents [18–20]. However, proof of procedural superiority is still lacking.

Aim

This study aimed at evaluating procedural efficacy and short-time safety of those recent stent design advances including ultra-thin struts and bioabsorbable abluminal polymer in comparison with currently established second-generation DES in an all-comers registry.

Material and methods

Study design

The Synergy stent has been available at our institution since August 2013. Initially, it was solely used as a bailout stent. This all-comers study was prospectively initiated in January 2015, starting to exclusively use the Synergy stent in patients receiving PCI. To avoid any training-related bias, only the 4 most experienced interventional cardiologists participated in this study. They were randomly assigned to various days, performing PCI with the Synergy stent only. Patient recruitment was finalized in December 2015 after enrolling a minimum of 400 patients in the Synergy group. We then retrospectively collected the same number of patients who previously received PCI by the same interventional cardiologists just before January 2015. During that period (January 2014 to December 2014), the same interventionalists were also randomly assigned to various days, performing PCI with established second-generation DES, including PROMUS Element plus (Boston Scientific Corp., Natick, Massachusetts), XIENCE prime (Abbott Vascular, Santa Clara, California), and RESOLUTE Integrity (Medtronic Cardiovascular, Santa Rosa, California). Patients who received a BMS or scaffold were excluded. However, with less than 10 such patients, this number was negligible.

All PCI decisions were made for symptomatic patients with ≥ 75% stenosis, or with positive tests including stress echocardiography, stress cardiac magnetic resonance imaging, abnormal fractional flow reserve, or with signs of myocardial infarction. Percutaneous coronary intervention strategies and techniques as well as choice of guide wires, balloons and second-generation DES were left at the discretion of the interventionalist. The reference vessel diameter of treated coronary lesions ranges between 2.25 mm and 4.0 mm.

To evaluate procedural performance, major endpoints were contrast agent use, fluoroscopy time, and dose area product (DAP). Minor endpoints were in-hospital major adverse cardiac and cerebrovascular event (MACCE) rates, number of balloons prior to stent implantation and the use of additional wires ("buddy wire"). Parameters such as fluoroscopy time, contrast agent consumption and DAP were only assessed for the PCI and not for the preceding diagnostic angiography (starting with the change of the sheath or introduction of a guiding catheter).

The study was performed in accordance with the Helsinki Declaration and was approved by the local ethics board. Patients provided written consent for every procedure included in this study. Clinical trial registration (http://www.clinicaltrials.gov) unique identifier NCT02881216.

Study device

The SYNERGY coronary stent (Boston Scientific Corporation, Massachusetts, USA) is a thin-strut (74–81 µm) platinum-chromium stent platform delivering everolimus from an ultrathin (4 µm) bioabsorbable poly-lactic-co-glycolic acid (PLGA) polymer coating applied only to the abluminal (i.e. outer surface) side of the stent [18]. Endothelialization was reported to be complete within 4 weeks after stent implantation in a porcine coronary artery model [21], whereas the polymer degrades into carbon dioxide and water within 4 months [18], leaving a bare-metal platform behind.

Complexity of coronary artery disease

Coronary artery lesions were categorized according to the American College of Cardiology/American Heart Association (ACC/AHA) classification. The extent of the coronary artery disease (CAD) was reflected by calculation of the SYNTAX Score. All diagnostic coronary angiograms in this study were scored according to the SYNTAX Score algorithm and were grouped into pre-specified categories indicating low (0–22 points), intermediate (23–32 points) and high (≥ 33 points) risk [22]. A higher SYNTAX Score is indicative of a more complex CAD. Since some patients had previous bypass surgery, prohibiting SYNTAX score calculation, and since the overall SYNTAX score also includes lesions that were not necessarily treated in the same setting, a lesion-specific "pathway" score was calculated, which would characterize the challenge of deploying a stent to the target coronary lesion.

Statistical analysis

Continuous data were reported as means (± standard deviation – SD) or medians (interquartile range – IQR) if not normally distributed (Kolmogorov-Smirnov test). Group comparison was done either by the *t* test or by the two-tailed Mann-Whitney test as appropriate. Categorical variables were expressed as absolute numbers (percentages) and were tested using the χ^2 or Fisher's exact test. All tests were 2-tailed and *p*-values < 0.050 were considered statistically significant. Statistical analysis and creation of figures were carried out using MedCalc software (Version 16.4.3).

Results

The study population consisted of 814 patients, with 407 patients in each study arm. Age and gender distribution was similar in both groups (Synergy group: 71 (62–78) years, 74.9% male; DES group: 72 (62–78) years, 76.9% male). A total of 859 Synergy stents were deployed in 480 target vessels in the Synergy group, and 904 stents in 469 vessels in the second-generation DES group. Coincidentally, target lesions in the Synergy group (A 2.7%, B1 13.8%, B2 38.6%, C 45.0%) were significantly more complex ($p < 0.01$) than those in the second-generation DES group (A 4.9%, B1 18.7%, B2 42.3%, C 34.2%), while the median SYNTAX score for "pathway" to lesion was comparable in both groups (11 vs. 10 points, $p = 0.17$). Significantly more patients in the Synergy group had previous bypass surgery (18.2% vs. 11.5%; $p < 0.01$). Fewer ST-elevation myocardial infarctions (STEMI) but considerably more cases of non-ST-elevation acute coronary syndrome (NSTE-ACS) were treated in the Synergy group (Tables I and II).

Major endpoints of this study were amount of contrast agent consumed, fluoroscopy time and DAP as surrogate parameters for procedural simplicity of PCI. Interestingly, despite coincidentally more complex coronary lesions in the Synergy group, median contrast agent use and median DAP were significantly lower in the Synergy group (Contrast agent: Synergy 100 (70–170) ml vs. second-generation DES 120 (90–200) ml; $p < 0.01$. DAP: Synergy 29.3 (14–52) Gy · cm² vs. second-generation DES 36.8 (14–52) Gy · cm²; $p < 0.01$). Fluoroscopy time was non-significantly shorter in the Synergy group. Looking at the subgroup of the most complex lesions (B2 or C lesions), these procedural advantages for the Synergy stent were even more pronounced, reaching statistical significance even for a lower fluoroscopy time in the Synergy group (Contrast agent: Synergy 110 (100–120) ml vs. second-generation DES 150 (120–160) ml; $p < 0.01$. Fluoroscopy time: Synergy 7.2 (4.45–14) min vs. second-generation DES 9.1 (8.17–10.63) min; $p < 0.01$. DAP: Synergy 31.9 (16–56) Gy · cm² vs. second-generation DES 40 (25–70) Gy · cm²; $p < 0.01$) (Figure 1; Table III).

To further understand the potential for easier deployment of the Synergy stent, lesion preparation and use of coronary wires were analyzed. Despite more complex lesions in the Synergy group, significantly fewer "buddy wires" were used (Synergy 17.9% vs. second-generation

Table I. Baseline characteristics

Parameter	Study population	Synergy	Control	*P*-value
Study population, *N*	814	407	407	
Male, *n* (%)	618 (75.9)	305 (74.9)	313 (76.9)	0.51
Age, median (IQR) [years]	72 (62–78)	71 (62–78)	72 (62–78)	0.97
Previous CABG, *n* (%)	121 (14.9)	74 (18.2)	47 (11.5)	< 0.01
Procedure indication, *n* (%):				
STEMI	123 (15.1)	45 (11.1)	78 (19.2)	< 0.01
NSTE-ACS	335 (41.2)	205 (50.4)	130 (31.9)	
Stable CAD	356 (43.7)	157 (38.6)	199 (48.9)	

CABG – coronary artery bypass grafting, CAD – coronary artery disease, IQR – interquartile range, NSTE-ACS – non-ST-elevation acute coronary syndrome, STEMI – ST-elevation myocardial infarction.

Table II. Classification of coronary artery lesions

Variable	Study population	Synergy	Control	*P*-value
Target vessel:	(*n* = 949)	(*n* = 480)	(*n* = 469)	
Right coronary artery	261 (27.5)	126 (26.3)	135 (28.8)	0.02
Left anterior descending artery	361 (38.0)	179 (37.3)	182 (38.8)	< 0.01
Circumflex coronary artery	210 (22.1)	103 (21.5)	107 (22.8)	0.75
Left main	79 (8.3)	48 (10.0)	31 (6.6)	0.04
Coronary artery graft	38 (4.0)	24 (5.0)	14 (3.0)	0.10
Syntax score:				
Target lesion, median (IQR)	10 (5.0–17.0)	10 (5.0–17.5)	10 (5.0–17.0)	0.65
Lesion "pathway", median (IQR)	11 (5–17)	11 (5–18)	10 (5–17)	0.17
Total CAD score*, median (IQR)	22.0 (14–32)	22 (13–33)	23 (21–24)	0.94
Risk category 1, *n* (%)	351 (43.1)	175 (43.0)	176 (43.2)	0.05
Risk category 2, *n* (%)	171 (21.0)	73 (17.9)	98 (24.1)	
Risk category 3, *n* (%)	292 (35.9)	159 (39.1)	133 (32.7)	
ACC/AHA classification, *n* (%):				
Coronary lesion type A	31 (3.8)	11 (2.7)	20 (4.9)	< 0.01
Coronary lesion type B1	132 (16.2)	56 (13.8)	76 (18.7)	
Coronary lesion type B2	329 (40.4)	157 (38.6)	172 (42.3)	
Coronary lesion type C	322 (39.6)	183 (45.0)	139 (34.2)	

**Excluding CABG patients, IQR – interquartile range, CAD – coronary artery disease.*

DES 23.6%; $p = 0.04$), fewer "jailed" wire techniques were applied (Synergy 8.4% vs. second-generation DES 15.2%; $p < 0.01$), and significantly more direct stent implantations without predilatation were achieved (Synergy 14.7% vs. second-generation DES 6.9%; $p < 0.01$). No significant differences between the groups were seen in the number of bifurcation stentings and the percentage of a successful final "kissing-balloon" technique. The mean stent length was similar with 20 ±8.8 mm for Synergy and 19.5 ±8.4 mm for second-generation DES.

In-hospital short-term MACCE rates were comparable between the two groups (Table IV).

Discussion

The development of second-generation DES has led to significant clinical improvements [15]. Today, several such second-generation DES are established in interventional coronary therapy, with excellent clinical results. The advances in newer coronary stent designs, with even lower profiles and increased flexibility, may have a positive impact on long-term clinical outcome. However, from a strictly procedural perspective, advantages of newer stent design modifications are expected, but limited data are presently available. A recent study demonstrated superior clinical 1-year outcomes in a cohort utilizing contemporary diagnostic and PCI methods, including implantation of thin strut bioresorbable-polymer DES, after heart team derived decision making based on the SYNTAX II algorithm [23]. Further investigations are expected in the coming years.

In this all-comers registry, we compared procedural parameters of established second-generation DES with the Synergy stent, representing the new generation of DES with a lower profile. The expected enhanced deliverability of this new stent is based on several changes to its design, including thinner stent struts and only abluminal polymer coating. To prove the procedural advantages, we chose contrast agent use, fluoroscopy time and DAP as major endpoints, since easy stent deployment should be recognized by short procedure time and less need of filming.

Despite coincidental more complex coronary lesions in the Synergy group, both contrast agent consumption and DAP were significantly lower for the patients treated with the Synergy stent, suggesting robust data and reliable procedural benefits. In the subgroup analysis of the most complex coronary lesions, the advantages of the Synergy stent were more pronounced, with significantly lower levels even for fluoroscopy time. This seems plausible, since in a simple lesion, a stent can be easily and perfectly deployed. However, with more complex lesions differences in stent deliverability will become more no-

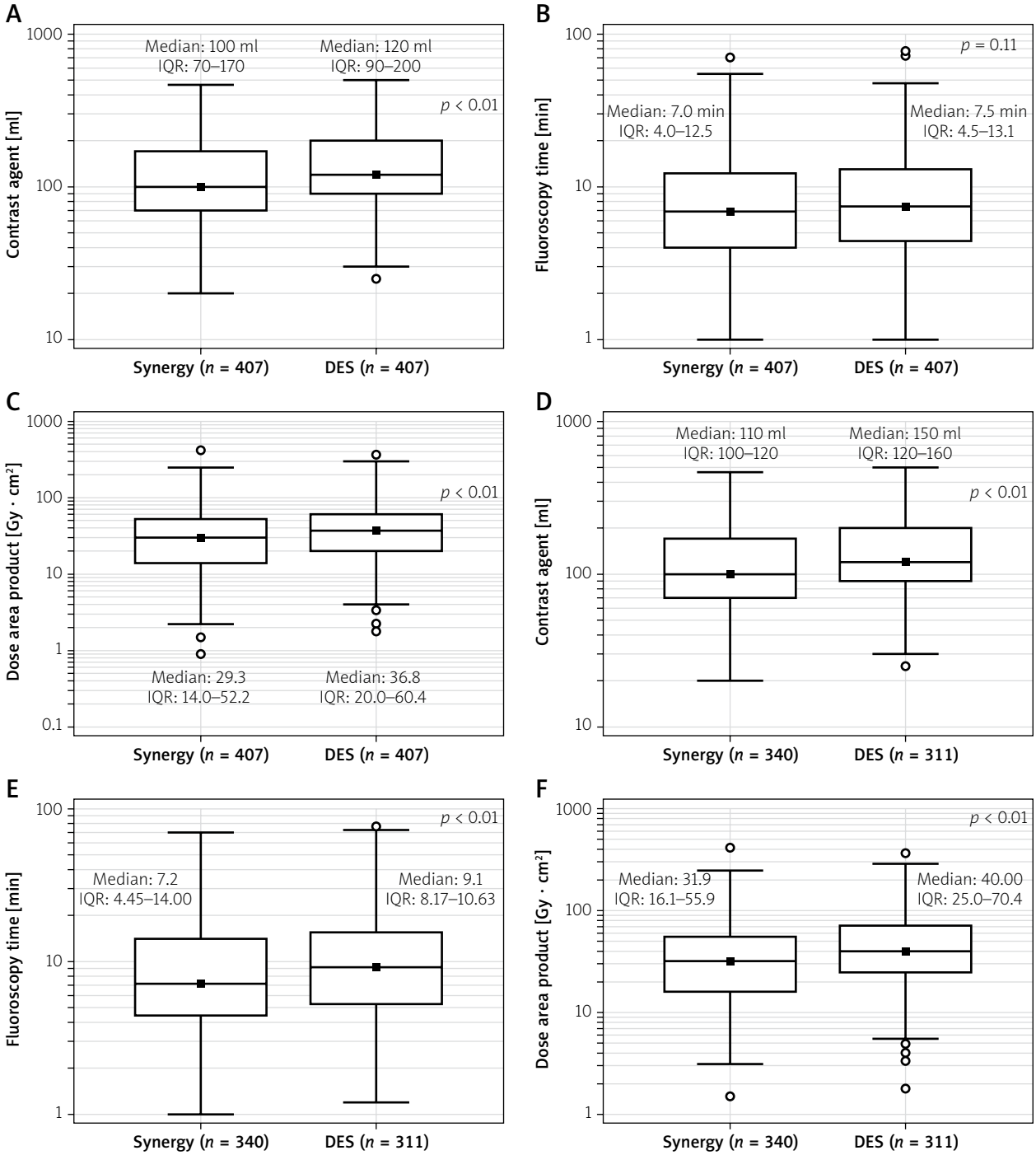

Figure 1. Comparison of contrast agent consumption (**A**), fluoroscopy time (**B**), and dose area product (**C**) between both groups for the entire study population and for those with moderate to severe coronary artery disease (**D–F**)

DES – drug-eluting stent, IQR – interquartile range.

ticeable. Some other parameters that can indicate more difficult stent implantations, such as the use of supportive techniques (for example "buddy" or "jailed" wiring), were significantly lower in the Synergy group. And finally, considerably more Synergy stents could be implanted without prior lesion preparation.

All these differences not only indicate enhanced deliverability, but could also potentially improve patients' safety as a consequence of limited manipulation, shorter fluoroscopy time and less injected contrast medium. In addition, this may have economic implications, since less time and fewer materials are needed for a complex procedure.

Table III. Procedural data

Parameter	Study population	Synergy	Control	*P*-value
Access site, *n* (%):				
Radial	378 (46.4)	196 (48.2)	182 (44.7)	0.33
Femoral	436 (53.6)	211 (51.8)	225 (55.3)	
Procedure data:				
Contrast agent, median (IQR) [ml]	110 (80–190)	100 (70–170)	120 (90–200)	< 0.01
Fluoroscopy, median (IQR) [min]	7.0 (4.2–13.0)	7.0 (4.0–12.5)	7.5 (4.5–13.1)	0.11
Dose area product, median (IQR) [Gy · cm^2]	33.8 (17.0–57.15)	29.3 (14.0–52.2)	36.8 (20.0–60.4)	< 0.01
Procedure data (Stenosis B2 and C):	*n* = 651	*n* = 340	*n* = 311	
Contrast agent, median (IQR) [ml]	120 (85–200)	110 (100–120)	150 (120–160)	< 0.01
Fluoroscopy, median (IQR) [min]	8.1 (5–15)	7.2 (4.45–14.00)	9.1 (8.17–10.63)	0.01
Dose area product, median (IQR) [Gy · cm^2]	36.85 (20.0–61.7)	31.9 (16.1–55.9)	40.0 (25.0–70.4)	< 0.01
Technical features:				
Rotational atherectomy	48 (5.9)	24 (5.9)	24 (5.9)	1.00
CTO PCI	48 (5.9)	21 (5.2)	27 (6.6)	0.37
Buddy wiring	169 (20.8)	73 (17.9)	96 (23.6)	0.05
Caged wire	96 (11.8)	34 (8.4)	62 (15.2)	< 0.01
Bifurcation stenting:				
Culotte technique PTCA	18 (2.2)	11 (2.7)	7 (1.7)	0.34
T-stenting	14 (1.7)	8 (2.0)	6 (1.5)	0.59
Stent crush	74 (9.1)	36 (8.8)	38 (9.3)	0.81
Attempted "final-kiss"-PTCA	100 (12.3)	57 (14.0)	43 (10.6)	0.14
Successful	78 (9.6)	44 (10.8)	34 (8.4)	0.23
Failed	23 (2.8)	14 (3.4)	9 (2.2)	0.29
Lesion preparation:				
Balloon pre-dilation:	726 (89.2)	347 (85.3)	379 (93.1)	< 0.01
1 balloon	529 (65.0)	268 (65.8)	261 (64.1)	
2 balloons	127 (15.6)	50 (12.3)	77 (18.9)	
≥ 3 balloons	70 (8.6)	29 (7.1)	41 (10.1)	
Balloon post-dilation	396 (48.6)	218 (53.6)	178 (43.7)	< 0.01
Number of stents per patient:				
1 stent	297 (36.5)	157 (38.6)	140 (34.4)	0.49
2 stents	223 (27.4)	108 (26.5)	115 (28.3)	
3 stents	195 (24.0)	99 (24.3)	96 (23.6)	
4 stents	69 (8.5)	31 (7.6)	38 (9.3)	
5 stents	21 (2.6)	7 (1.7)	14 (3.4)	
6 stents	9 (1.1)	5 (1.2)	4 (1.0)	
Stent types:	*n* = 1,763	*n* = 859	*n* = 904	
SYNERGY, *n* (%)	859 (48.7)	859 (100)	–	–
DES, *n* (%):	904 (51.3)		904 (100)	
Xience Prime		–	462 (51.1)	< 0.01
Promus Element Plus		–	317 (35.1)	
Resolute Integrity		–	125 (13.8)	
Stent length [mm]:				0.12
SYNERGY	20.0 ±8.8	20.0 ±8.8	–	
DES:	19.5 ±8.4	–	19.5 ±8.4	
Xience Prime		–	20.8 ±9.4	
Promus Element Plus		–	18.5 ±7.2	
Resolute Integrity		–	17.7 ±6.7	

CTO – chronic total occlusion, DES – drug-eluting stent, IQR – interquartile range, PCI – percutaneous coronary intervention, PTCA – percutaneous transluminal coronary angioplasty.

Table IV. In-hospital major adverse cardiac and cerebrovascular event (MACCE)

Parameter	Synergy	2nd gen DES	*P*-value
Myocardial infarction*, *n* (%)	4 (1.0)	8 (2.0)	0.25
Stent thrombosis, *n* (%)	2 (0.5)	2 (0.5)	–
Re-PCI target lesion, *n* (%)	2 (0.5)	2 (0.5)	–
Cardiac death, *n* (%)	11 (2.7)	8 (2.0)	0.49
Non-cardiac death, *n* (%)	5 (1.2)	7 (1.7)	0.56
Stroke, *n* (%)	1 (0.2)	1 (0.2)	–

**Assessed only for patients with normal baseline troponin levels.*

Conclusions

In this all-comers, real-world PCI registry, novel coronary stent design advances including ultra-thin struts and abluminal bioabsorbable polymer coating are associated with improved deliverability as compared to currently established second-generation drug-eluting stents with comparable in-hospital rates of major adverse cardiac and cerebrovascular events between the two groups. This may have a positive impact on patients' safety and economic efficiency. These findings will have to be confirmed in future randomized trials, which should be justified by these encouraging results.

Conflict of interest

HAS and RB received travel support from Boston Scientific. RB received speaker's honoraria from Boston Scientific. The other authors have no conflict of interests to declare.

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