Letter to the Editor

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Synergy stent for treating unprotected left main stenosis with the large reference vessel diameter

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For many years, unprotected left main stenosis (ULMS) has been remained as the forbidden fruit of interventional cardiology. However, with the remarkable improvement in medical device technology, procedural techniques and antithrombotic agents during the last decades, percutaneous coronary intervention (PCI) with stenting for ULMS has become technically feasible and has exhibited favorable clinical outcomes. In particular, the development of drug-eluting stents (DES) has played an important role. Extensive studies in the DES era, from SYNTAX,^[1] EXCEL^[2] to NOBEL,^[3] have confirmed its safety and efficacy, which is similar to those observed with coronary artery bypass grafting (CABG), at least for patients without very diffuse disease in other coronary segments. Furthermore, a study conducted in 2015 was the first to report that interventional therapy of ULMS is also effective and safe for the elderly patients. $[4]$

Left main stenosis is often calcified and bulky. It can be located at the ostium, but is more frequent at the distal bifurcation.^[5] For any successful interventional therapy, it not only depends on the patient, the lesion selection and the best technique, but also the reasonable stent selection is crucial. ULMS presents a unique challenge for stent: diameters taper markedly from the left main artery to the proximal left anterior descending coronary artery. Therefore, it is improtant to choose a suitable stent that can be extended far above the nominal diameter.^[6] Furthermore, the diameter of the left main artery is usually within 4.5–5.0 mm and the average diameter may reach over 5.5 mm in some patients, according to some imaging studies.[7] This means that most of the present DES platforms do not provide suitable sizes for those anatomies, and require the post-dilatation of at least

0.5–1.5 mm beyond the nominal diameter, in order to ensure the optimal apposition of the stent for these anatomies.^[8] Incomplete stent apposition is generally considered as the predicator of stent thrombosis and adverse outcome.^[9,10] Therefore, the high-pressure post-dilatation of stents has generally been recommended. However, it should be noted that although these DESs can be oversized, this does not imply that it is safe to do so. Indeed, approaching the physical limit of the stent induces changes in mechanical stiffness and drug delivery. Consequently, the performance of the device can be completely altered.[8] To our knowledge, the 4.0 mm of large size design of the Synergy stent (PtCr- EES, Boston Scientific, Natick, Massachusetts, USA) in main stream DES platforms has been labelled for post-expansion to 5.75 mm to accommodate most left main artery anatomies.

Between August 2017 and October 2019, eleven consecutive patients of ULMS with the larger reference vessel diameters were successful implanted the Synergy stent in Beijing Hospital of Traditional Chinese Medicine. Among these patients, both single stenting techniques and double stenting techniques were included, such as the Crush, Tstenting and Culottes technique. The interventional treatment and assessment of ULMS in all patients were completed under the guidance of intravascular ultrasound (IVUS) or optical coherence tomography (OCT). All images were analyzed offline by the experienced investigators, who was uninitiated in the procedural details and outcomes, using the Boston Scientific iReviewTM analysis software and/or RediAnt DICOM Viewer (Medixant, Poznan, Poland).

Of the eleven patients in this study, nine patients were male with the average age of 63 years (range: 45–80 years). Furthermore, among these patients, ten patients were hospitalized for unstable angina and one patient for acute non-ST

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elevation myocardial infarction. Moreover, there were five patients who had previously underwent PCI, nine with hypertension, six with diabetes and nine with hyperlipidemia. The mean LVEF was 64.64% (Table 1).

All eleven patients had serious ULMS, and the mean SYNTAX score was 29.82. Among these patients, eight patients had bifurcation lesions. The mean percentage stenosis area of these patients was 75.64%. However, the mean minimal lumen area (MinLA) was only 4.39 mm^2 . Fibrotic plaques were the main component of these lesions. It noteworthy that the mean maximal vessel diameter (MaxVD) of ULMS reached 5.42 mm (range: 4.73–5.86 mm). According to the anatomic characteristics of these lesions, five patients had received the double stenting techniques. Post- dilation with 5.0-mm non-compliant balloon catheters (Maverick, Boston Scientific, Natick, MA, USA) was required for eight patients. Proximal optimal technique (POT) was applied and optimized for all patients, five of whom underwent kissing balloon. The anatomic characteristics and strategy of the interventional therapy are summarized in Table 2.

Intracoronary imaging confirmed that the Synergy stent (4.0 mm) was successfully implanted in all patients and was well-attached to the vessel wall. OCT was performed for the second patient, while the remaining patients received IVUS. After interventional therapy, the mean post-MinLA of the left main artery reached 13.19 mm², which satisfied the supply of the left coronary artery. The cross sectional area of

the Synergy stent with the diameter of 4.0 mm was 12.57 mm², while the mean maximal stent area (MaxSA) reached 17.88 mm² in all patients, increasing by more than 40% after after post-dilation. All stents expanded well above the labelled maximal stent diameter (MaxSD), and achieved the mean post-MaxSD of 5.17 mm, which was 28.25% (range: 13.00%–47.75%) higher than the standard size. For the first and second patients, this reached or even exceeded the labelled MaxSD of 5.75 mm, respectively. However, for the $3rd$, $9th$, and $11th$ patients, the longitudinal length (L-length) of the Synergy stent could not be accurately measured due to the overlapping stent. The L-length of the stents after kissing balloon became elongated, while the others shortened in various degrees. In addition, the deformation length of the stent was less than 1 mm was acceptable. The measurements for the achieved MaxSA, MaxSD and L-length of the Synergy stent are presented in Table 3, and Figures 1 & 2.

The mean follow-up was 21.4 months (10–31 months), and all patients were treated with reference to the present guidelines. Eight patients received the examination for thromboelastography, platelet aggregation rate, and the molecular biological and pathological diagnosis of clopidogrel (Gene Probe). Four of these patients had the moderate-weak metabolism of CYP2C19. However, the standard dose (75 mg) of clopidogrel was still given, considering the potential risk of bleeding. Among all patients, no major adverse cardiovascular event (MACE) occurred during the follow-up.

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Data are presented as means ± SD or *n* (%). "√" Refer to positive. "-" Refer to negative. Bif: bifurcation lesion; Cal: calcified plaque; Dif: diffused lesion; DST: double stenting technology; Fib: fibrotic plaque; JBT: Jailed balloon technique; JWT: Jailed wire technique; Lip: lipidic plaque; LM: left main artery; MaxVD: maximal vessel diameter; MCP: main composition of plaque; MinLA: minimal lumen area; Ost: ostial lesion; PAS: percentage area of stenosis; POT: proximal optimal technique; ULMS: unprotected left main stenosis.

Kissing balloon - √ - √ - √ - √ √ - - 5 (45%) Size, mm 5.0×3.0 4.5×2.5 5.0×3.0 4.5×2.5 5.0×3.0 5.0×3.0 POT √ √ √ √ √ √ √ √ √ √ √ 11 (100%)

Data are presented as means ± SD. "-" Refer to the data cannot be obtained. L-length: longitudinal length; MaxSA: maximal stent area; MaxSD: maximal stent diameter; MinLA: minimal lumen area.

Four patients were re-examined by coronary angiography at one year after the operation, and no restenosis occurred.

The initial investigation of the present study confirms the safety and efficacy of the Synergy stent for treating ULMS with the large reference vessel diameter. Considering that the MaxVD of most patients exceeded 5 mm, achieving stent apposition in this situation always required over-expansion beyond the nominal stent diameter. The data revealed that the large stent diameter of the Synergy stent was achievable, particularly after extreme POT or kissing balloon.

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Figure 1. Coronary angiography and IVUS of the first patient. (A): The patient with serious ULMS was observed by IVUS (arrow); (B): the MaxVD was 5.86 mm measured by IVUS (arrow); (C): the ULMS after implantation of the 4.0-mm Synergy stent from LAD to LM; (D): the measurement of different segments of stent by IVUS; (E): the post-MinLA was 14.87 mm², which was measured distal from the LM (arrow); (F): the MaxSD was 5.75 mm, as measured by the IVUS (arrow); and (G): the L-length was 23.32 mm measured by IVUS. IVUS: intravascular ultrasound; LAD: left anterior descending; LM: left main artery; L-length: longitudinal length; MaxVD: maximal vessel diameter; MaxSD: maximal stent diameter; MinLA: minimal lumen area; ULMS: unprotected left main stenosis.

Importantly, the present study did not reveal any serious events including catastrophic stent failure, intraprocedural complication, or MACE with the size of the ULMS, which further highlights the requirement for the overexpansion of the Synergy stent beyond the nominal diameter. In addition, no clinical restenosis was found during the follow-up.

The important developments in the stent platform, including design, structure and composition, have resulted in significant technical advances and clinical benefits. The ideal stent is considered to be a highly transportable stent with thin struts, low-profile flexible design, high radiopacity, high radial strength and minimal recoil.^[11] For ULMS with large reference vessel diameter, the overexpansion capacity of the stent is an important performance index. The details of the available DES designs in China are presented in Table 4.

The Synergy stent is the last addition to the family of platinum-chromium everolimus-eluting stent (PtCr-EES), and it consists of a thinner-strut platinum chromium stent platform that delivers everolimus from an ultrathin (4 um) bioabsorbable poly-DL-lactide-co-glycolide polymer applied only to the outer (abluminal) stent surface. Synergy stent has made several modifications to the PROMUS Element

platform, including the use of rounder struts (2.25– 2.75 mm, 0.074 mm; 3.00–3.50 mm, 0.079 mm; 4.00 mm, 0.081 mm) to reduce the strut thickness and changes in the connector angle, with the presence of two additional proximal and distal connectors, and changes in the peak radius. These modifications were intended to improve the crimp profile, flexibility, compliance and longitudinal robustness.^[12] In addition, in terms of safety and effectiveness, the Synergy stent is noninferior to the PROMUS Element.^[13]

Thinner struts resulted in lower restenosis rates than the thicker struts, according to the ISAR-STEREO trial.^[14] Although the Synergy stent reduced the strut thickness, it still maintains the expansion capacity and radiopacity, which may be related to its material. The material of the Synergy stent is PtCr alloy, which consists of 33% platinum, 33% iron, 18% chromium, 9% nickel, 3% molybdenum and a trace of manganese. Alloys with 33% Pt seems to provide an optimal balance between processability, mechanical properties, strength, stability and radiopacity (density: 9.9 g/cm^3). Compared to 316L-SS and cobalt chromium (CoCr) alloys, the PtCr alloy has excellent yield strength and tensile strength compared with 316L-SS, which can reduce the

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Figure 2. Coronary angiography and OCT of the second patient. (A): The patient with serious bifurcation lesions was observed by OCT and the MinLA was 5.69 mm² (arrow); (B): the MaxVD was 5.71 mm measured by OCT (arrow); (C): the ULMS after implantation of the 4.0-mm Synergy stent from LAD to LM; (D): the MaxSD was 5.79 mm, as measured by OCT (arrow); (E): the cross-section of the Synergy stent after POT simulation by 3D-OCT; and (F): the longitudinal perspective of the Synergy stent, as simulated by 3D-OCT. LAD: left anterior descending; LM: left main artery; MaxVD: maximal vessel diameter; MaxSD: maximal stent diameter; MinLA: minimal lumen area; OCT: optical coherence tomography; ULMS: unprotected left main stenosis.

Co-Cr: cobalt-chromium; DES: drug-eluting stents; NA: not applicable; PBMA: poly-n-butyl-methacrylate; PDLLA: poly-D-L-lactic acid; PLA: poly-lactic acid; PLGA: poly-lactide-co-glycolide; PLLA: poly-L-lactic acid; Pt-Cr: platinum-chromium; PVDF-HFP: poly vinylidenefluoride-hexafluoro propylene; SS: stainless steel.

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thickness of the pillar while maintaining the radial strength and providing improved radiopacity.^[15]

At present, there is no literature on the over-expansion ability of Synergy stents *in vivo*. A study tested the results of Synergy stent overexpansion under an oversized post-dilatation *in vitro*, and measured changes in stent geometry and lumen diameter using an optical microscope.^[8] For the 4.0 mm Synergy stent, the MaxSD observed after the overexpansion of balloon to a 6.0 mm size (14 atmospheres) was 5.7 mm. In these patients, with the use of the 5-mm non-compliant balloon, the maximum post-dilatation diameter of the Synergy stent reached 5.75 mm and 5.79 mm, respectively; which was consistent with the maximum diameter of the label dimension, which may be the expansion pressure of 28 atmospheres or kissing balloons related.

Overexpansion ability of the Synergy stent could ensure the optimal apposition of the stent in ULMS with large reference vessel diameter, while several low probability mechanisms of stent failure remained, which were associated with adverse clinical outcomes. For these patients, no stent failure was observed during the interventional therapy, including stent fracture, longitudinal deformation, and acute recoil.

Despite the improvements in stent design, stent fracture (SF) may still occur in present generation stents, with an observed incidence ranging within $0.8\% - 8.0\%$.^[16] Autopsy studies have suggested that the rate of SF can reach up to 29%.[17] The likelihood of superimposed ISR on SF ranges from 15% to nearly 90% in the available literature.^[18] A larger stent size may be associated with lower risk of SF. Importantly, there was no relationship between stent deployment inflation pressure or the use of post-dilation, and the risk of subsequent $SF^[19]$ A previous study in which the Synergy stent was fractured at 2.5 mm after post-dilation and lodged against the middle with a 3.5 mm balloon had been reported.^[20] However, this situation was not found in the present study. Furthermore, there was no further literature on SF of the Synergy stent, when referred to other families of PtCr-EES. One study used a repetitive bend test to compare the durability and fracture of different stent designs and found that the PREMIER Element did not fracture after completing 10 million cycles.^[21] A retrospective study reported that the rate of SF after using the PROMUS Element was 1.7%.[22] Coronary vessel tortuosity and angulation play an important role in $SF₁^[23]$ and some studies have shown that the majority of SF occurs when stent angulation exceeds 45°.^[18] One study described that more than 90% of SF occurs when the stent angulation exceeds 75° in the blood vessel.[24] The angle between the left main artery and left anterior descending or left circumflex artery was large

in some patients. Hence, the situation of stent fracture needs to be given more attention in clinical practice.

Longitudinal stent deformation may be associated with serious clinical consequences, including interference with the passage of other device, resulting in stent thrombosis and compromised drug delivery, and even predispose to restenosis.[25–28] A bench study revealed that the Element stent with two connectors was more likely to distort under longitudinal loads and the angulation of the connectors was related to the offset, and the in-phase hoop peaks may contribute to the lesser resistance to longitudinal distortion.[29,30] In response to these concerns, the Synergy stent has been upgraded to make the connector angle smoother, and additiona proximal and distal end connectors were placed, and the out-phase hoop peaks would help improve longitudinal robustness. In the bench test, the design of the Synergy stent demonstrated higher longitudinal resistance than the Element stent.[31,32] For the current study, the Synergy stent exhibited satisfactory longitudinal robustness.

In previous clinical trials, the acute stent recoil varied between 4.3% and 21.3%, which was the most important predictors of the post-procedure severity events.[33] Some studies have revealed that the reduced thickness of the reduced strut will reduce the radial strength, resulting in more acute stent recoil.^[34] However, the major concerns of these studies were stainless steel and CoCr platforms. The radial strength of the thin strut PtCr-DES remains similar to that of the 316L-SS stent or CoCr stent with the thicker strut.^[30,35] One study revealed that acute stent recoil more frequently occurred with the CoCr-DES, when compared to the PtCr-DES.^[36] In the present study, no acute stent recoil was occurred. This may be correlated to the extreme post-expansion through the multiple and large-size non-compliant balloon, thereby overcoming the radial compressive force exerted by the vessel itself.

Studies of a series of interventional therapies have confirmed that ULMS with the large reference vessel diameter is not rare, and can achieve overexpansion of the Synergy stent, and appears to be effective and safe over the mean follow-up of 21.4 months. Although several theoretical concerns have been raised when over-expanding the present DES platforms, these problems seemed negligible compared to the risk of restenosis caused by stent malposition and under-expansion, and when stenting back into the large ULMS. Although these data require more extensive validation, they still emphasize the requirements for the use of a dedicated DES platform for the left main artery with the larger reference vessel diameter, as well as the requirements for further manufacturing of matching large size post-balloon catheters. This also concluded that for ULMS with the

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MaxVD less than 4.5 mm, most of the current stents can be used. For lesions with the diameter of 4.50–5.75 mm, the Synergy stent may be an ideal choice. For the lesions with the diameter more than 5.75 mm, the kissing stenting technique is an option.^[37] In a word, when we encounter ULMS with the large reference vessel diameter during PCI, we should be able to think of Synergy stent with the maximum post-expansion diameter of 5.75 mm as an effective and safe weapon.

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