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Original article

The ultrathin-strut everolimus-eluting stent in a real-world population: the "Everythin" multicenter registry

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ABSTRACT

Introduction and objectives: Ultrathin-strut stents (UTS) represent a significant advancement in percutaneous coronary intervention. This study aimed to evaluate the safety and short- to mid-term outcomes of stenting with the thinnest struts on the market (50 µm) using a biodegradable everolimus-eluting polymer (Evermine 50) in real-world patients with coronary artery disease.
Methods: A single-arm, multicenter, prospective study was conducted in real-world patients. A total of 161 patients with de novo lesions who received at least 1 UTS stent were enrolled. The primary safety endpoint was the occurrence of major adverse cardiovascular events, defined as cardiac death, target-vessel myocardial infarction, or the need for revascularization of the target lesion at 12 months. The incidence of stent thrombosis at 12 months was also analyzed.
Results: The study included 161 patients with a mean age of 64 ± 14 years; 79% were male, 34% had diabetes, and 66% had hypertension. The most common indication for intervention was non-ST-segment elevation myocardial infarction (42%), followed by ST-segment elevation myocardial infarction (22%). The procedural success rate was 100%. At 12 months of follow-up, the incidence of MACE was 2.5%, and the definite stent thrombosis rate was 1.3%.
Conclusions: The use of the 50 µm UTS stent with a biodegradable everolimus-eluting polymer demonstrated a favorable safety profile and good clinical outcomes in unselected patients at 1 year of follow-up.

Keywords: Coronary artery disease. Percutaneous coronary intervention. Ultrathin struts.

Stent de *strut* ultrafino liberador de everolimus en pacientes del mundo real: registro multicéntrico «Everythin»

RESUMEN

Introducción y objetivos: Los *stents* de *struts* ultrafinos (SUF) constituyen una mejora en el campo del intervencionismo coronario percutáneo. El objetivo de este estudio fue evaluar la seguridad y los resultados a corto y medio plazo del *stent* con los *struts* más finos del mercado (50 µm), con polímero biodegradable y liberador de everolimus (Evermine 50), en pacientes del mundo real con enfermedad coronaria.
Métodos: Se diseñó un estudio prospectivo, multicéntrico, de un solo grupo, en pacientes del mundo real. Se incluyeron 161 pacientes con lesiones *de novo* en los que se implantó al menos 1 *stent* de SUF. La variable principal de seguridad fueron los eventos adversos cardiovasculares mayores, compuesto de muerte cardiaca, infarto de miocardio atribuido al vaso diana y necesidad de revascularización de la lesión diana a los 12 meses de seguimiento. También se analizó la incidencia de trombosis del *stent* a los 12 meses del procedimiento.

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Resultados: De los 161 pacientes incluidos (edad media 64 ± 14 años; 79% varones), el 34% eran diabéticos y el 66% eran hipertensos. La indicación más frecuente fue infarto sin elevación del segmento ST (42%), con un 22% de casos en contexto de infarto con elevación del segmento ST. El porcentaje de éxito del procedimiento fue del 100%. A los 12 meses de seguimiento, la incidencia de eventos adversos cardiovasculares mayores fue del 2,5%, con una tasa de trombosis del *stent* definitiva del 1,3%.
Conclusiones: El uso de *stent* con SUF de 50 µm, con polímero biodegradable y liberador de everolimus en pacientes no seleccionados mostró unos buenos resultados clínicos, así como un buen perfil de seguridad a 1 año de seguimiento.

Palabras clave: Enfermedad coronaria. Intervencionismo coronario percutáneo. *Strut* ultrafino.

Abbreviations

MACE: major adverse cardiovascular events. **MI:** myocardial infarction. **PCI:** percutaneous coronary intervention. **ST:** stent thrombosis. **STEMI:** ST-segment elevation myocardial infarction. **UTS:** ultra-thin strut.

INTRODUCTION

Percutaneous coronary intervention (PCI) has grown exponentially along with the technological evolution associated with this procedure. The continuous advancement of technology has enabled the development of stents with thinner struts, which offer a series of advantages over stents with thicker struts. One of the advantages of these new stents is the improved device profile—with increased flexibility—providing better navigability and greater lesion crossing capability. On the other hand, ultra-thin struts (UTS) cause fewer disturbances to normal laminar blood flow at target lesion level, due to the reduced protrusion of material into the vascular lumen. This seems to be associated with a lower degree of platelet activation and muscle cell proliferation,—the processes involved in stent failure—in terms of stent thrombosis (ST) and in-stent restenosis.[1,2] In lesions located in small caliber vessels (≤ 2.5 mm), the use of UTS could provide additional advantages due to a higher ratio between the size of the struts and the lesion luminal area.[3] Furthermore, UTS stents seem to be associated with less acute damage to the vascular endothelium during stent deployment. This reduced initial aggression could diminish the barotrauma-related inflammatory response and, therefore, prevent in-stent restenosis and promote faster device endothelialization.[4,5] Studies have indicated that the use of UTS stents could be associated with lower rates of in-stent restenosis and a reduced need for new revascularizations.[6,7]

The Evermine 50 EES stent (Meril Life Sciences, India) is a UTS (50 µm) stent with CE marking consisting of a cobalt-chromium alloy platform with an everolimus-eluting biodegradable polymer. The aim of this study was to evaluate the 1-year safety and efficacy outcomes after UTS stent deployment in real-world patients with coronary artery disease.

METHODS

We conducted a prospective, non-randomized, multicenter study with patients who underwent UTS stent deployment at 4 different Spanish hospitals (data from the "Everythin" Registry). To be included in the study, patients had to be older than 18 years, with available coronary angiographies in the context of chronic or acute coronary syndrome, and have, at least, 1 target lesion with a 2 mm up to 4.5 mm reference vessel diameter on visual estimation. Overlapping stents was ill-advised and, if necessary, the overlap length should be ≤ 2 mm. PCI in multiple vessels and lesions during the same surgical act was allowed, and deferred procedures within the first 90 days since the initial procedure were also accepted. In these cases, any further procedures were not coded as an event—i.e. need for new revascularization—but as scheduled procedures. Only 1 case—1 target lesion treated with UTS stent deployment—was counted per patient. Deploying the study UTS stent was not mandatory in any of the other treated lesions, only in the target lesion/vessel.

The study followed the privacy policy of each research center, including regulations for the appropriate use of data from patient research. The study was approved by the Ethics Committee for Drug Research of the coordinating center. Moreover, the study was conducted in full compliance with the terms set forth in the Declaration of Helsinki. All patients signed specific informed consent forms prior to being included in the study.

Study device and procedure

The Evermine 50 EES (Meril Life Sciences, India) is a UTS (50 µm) stent with a cobalt-chromium platform coated with a biodegradable polymer composed of poly-L-lactic acid and poly(lactic-co-glycolic) acid. The Evermine stent—which has a hybrid design with an open cell in its central part and a closed cell at the edges—releases everolimus (1.25 µg/mm²) as the antiproliferative drug. The stent has received the corresponding CE marking and is available in several lengths from 8 mm up to 48 mm with diameters ranging from 2 mm up to 4.5 mm. The main features of the Evermine 50 EES device are illustrated in figure 1.

PCI was performed following each center routine practice within the recommendations outlined in the clinical practice guidelines.[8] The PSP algorithm (predilation, sizing [stent size selection], and postdilation) was recommended for optimal device implantation. The study protocol recommended postdilation, especially in cases where any degree of underexpansion was identified immediately after device implantation. Although the study protocol recommended the use of intravascular imaging modalities to guide the procedure, this was left to the operator's discretion. All patients received a 300 mg loading dose of acetylsalicylic acid prior to the intervention followed by a loading dose of a second antiplatelet agent—clopidogrel, prasugrel, or ticagrelor—after the PCI, which was maintained for 3 up to 12 months and left to the discretion of the responsible investigator of the center.

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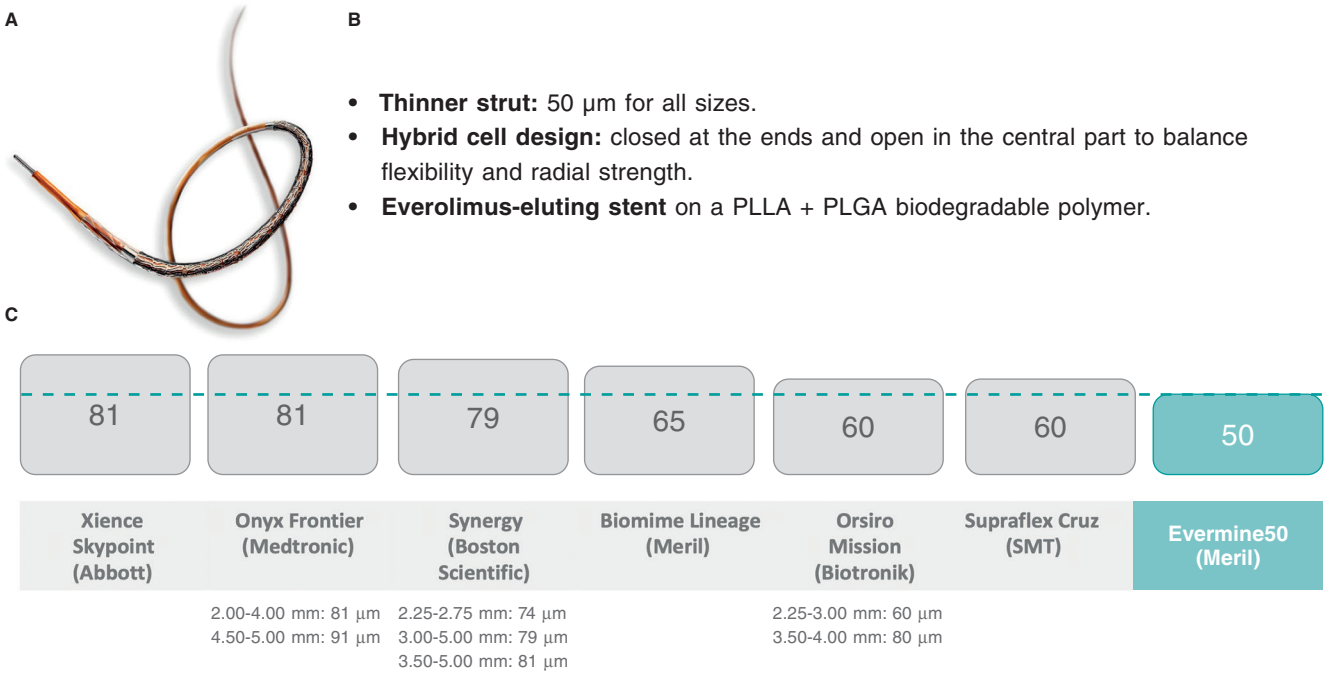

Figure 1. A: illustrative image of the Evermine 50 stent (Meril Life Sciences, India). **B:** description of the main characteristics of the stent. **C:** comparison of the study stent strut thickness vs major competing next-generation stents. PLGA, poly(lactic-co-glycolic acid); PLLA, poly-L-lactic acid (Images courtesy of Meril Life Sciences. Images reproduced with permission from Meril Life Sciences or its affiliates.)

Endpoints and definitions

The primary endpoint of the study was the occurrence of major adverse cardiovascular events (MACE) at 12 months. MACE were defined as the composite of cardiac death, non-fatal target vessel myocardial infarction (MI), or the need for target lesion revascularization. Secondary endpoints included each individual component of the composite endpoint, the overall mortality and ST (both definite and probable) according to the definitions of the Academic Research Consortium[9] 12 months after implantation. Additionally, the rates of device and procedural success were taken into consideration. Device success was defined as the deployment of the study stent in the target lesion with a final percent diameter residual stenosis < 30% by visual estimation. Procedural success was defined as the success of the device without any in-hospital complications, including death, MI, and target lesion revascularization.

Statistical analysis

Quantitative variables are expressed as mean and standard deviation or as median and interquartile range [IQR], depending on their distribution. Categorical variables are expressed as number and percentage. All analyses were performed using the statistical tool STATA 12 (StataCorp LLC, United States).

RESULTS

Demographic and baseline clinical characteristics

A total of 161 patients were included in the study from November 2020 through April 2022 whose demographic data and clinical characteristics are shown in table 1. The mean age was 64 ± 14 years, and 79% were male. A total of 66% of the patients were hypertensive; 53% had dyslipidemia; 34%, diabetes mellitus, and 59% a history of smoking. A total of 20% of the patients had experienced a prior MI, and 22% a previous PCI. The most common indication for the intervention was the diagnosis of non-ST-segment elevation acute myocardial infarction (42%), followed by ST-segment elevation myocardial infarction (STEMI) (22%) and chronic coronary syndrome (21%).

Angiographic and procedural characteristics

The lesion angiographic characteristics, and the results of the intervention are shown in table 2. Most patients had significant single-vessel disease (71%), being the presence of 2 or 3-vessel disease far less common (20% and 9%, respectively). The most widely treated vessel was the left anterior descending coronary artery (54%), followed by the right coronary artery (27%) and the left circumflex artery (17%). The target lesion median percent diameter stenosis by visual estimation was 90% [IQR, 75-99]. A total of 29% of the target lesions showed some degree of calcification on angiography. Intracoronary imaging modalities (7% optical coherence tomography) were used to guide the PCI in 11% of the cases. The mean number of stents deployed per lesion was 1.04 ± 0.22, with a median stent diameter of 3.0 mm [IQR 2.75-3.5] and a median stent length of 19 mm [IQR 19-24]. Pre- and postdilation were performed in 71% and 39% of the cases, respectively. The device and procedural success rates were 100%, without any procedure-related complications being reported in patients treated during the inpatient period.

Clinical outcomes at the follow-up

The 12-month follow-up was completed in 158 patients (98%). One year after implantation, 4 patients exhibited MACE (2.5%), and 3

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Table 1. Baseline characteristics of the study population

Basal characteristics	Patients (n = 161)
Age (years) ± SD	64 ± 14
Male, n (%)	126 (79)
BMI (kg/m²)	28 ± 3.5
Hypertension, n (%)	106 (66)
Dyslipidemia, n (%)	86 (53)
Diabetes mellitus, n (%)	55 (34)
Smoking status, n (%)	
Non-smoker	65 (40)
Former smoker	49 (30)
Current smoker	47 (29)
Previous AMI, n (%)	33 (20)
Previous stroke, n (%)	2 (1.2)
Atrial fibrillation, n (%)	7 (4.3)
Peripheral vascular disease, n (%)	10 (6.2)
Previous coronary angioplasty, n (%)	36 (22)
Previous coronary artery bypass grafting, n (%)	4 (2.5)
COPD, n (%)	13 (8)
Chronic kidney disease, n (%)	14 (9)
Glomerular filtration rate (mL/min/1.73 m²)	61 ± 10
Left ventricular function, (%)	55 ± 11
Indication for coronary angiography, n (%)	
Chronic coronary syndrome	34 (21)
Unstable angina	24 (15)
NSTEMI	67 (42)
STEMI	36 (22)

AMI, acute myocardial infarction; BMI, body mass index; COPD, chronic obstructive pulmonary disease; NSTEMI, non-ST-segment elevation acute myocardial infarction; SD, standard deviation; STEMI, ST-segment elevation myocardial infarction.

patients died (1.9%). The cause of death was cardiac in 1 patient (due to a probable ST 7 days after the procedure) and non-cardiac in the remaining 2 (one due to lung neoplasm and the other to multiple organ failure). There were 2 non-fatal MIs (1.3%), both due to late definite ST (1 occurred 8 months after stent deployment and was associated with the study UTS stent, while the other one occurred 9 months after deployment due to a different thrombosed non-UTS stent implanted in a lesion of the target lesion same vessel. Only 2 patients required target lesion revascularization at the follow-up (1 due to ST and the other one due to in-stent restenosis).

DISCUSSION

The present study prospectively and multicentrically evaluates the safety and efficacy profile of implanting an UTS stent in a real-world population. Its main findings are that the UTS stent demonstrated a high procedural success rate, without in-hospital

Table 2. Angiographic, procedural and clinical follow-up characteristics of the cohort

Angiographic and procedural characteristics	Patients (n = 161)
Radial access, n (%)	158 (98)
Diseased vessels, n (%)	
1-vessel disease	114 (71)
2-vessel disease	32 (20)
3-vessel disease	15 (9)
Target lesion location, n (%)	
Left main coronary artery	3 (1.8)
Proximal left anterior descending coronary artery	37 (23)
Mid left anterior descending coronary artery	40 (24.8)
Distal left anterior descending coronary artery	10 (6.2)
Proximal left circumflex artery	10 (6.2)
Mid left circumflex artery	11 (6.8)
Distal left circumflex artery	6 (3.7)
Proximal right coronary artery	13 (8)
Mid right coronary artery	18 (11.2)
Distal right coronary artery	13 (8)
Bifurcation lesions, n (%)	12 (7.5)
Calcified lesions, n (%)	46 (29)
Visual percent diameter stenosis, median [IQR]	90 [75-99]
Predilation, n (%)	114 (71)
Postdilation, n (%)	63 (39)
Intracoronary imaging modalities, n (%)	18 (11)
Optical coherence tomography	11 (7)
Intravascular ultrasound	7 (4)
No. of stents deployed, mean ± SD	1.04 ± 0.22
Stent diameter (mm), median [IQR]	3.0 [2.75-3.5]
Stent length (mm), median [IQR]	19 [19-24]
Device success, n (%)	161 (100)
Procedural success, n (%)	161 (100)
Antiplatelet therapy after PCI, n (%)	
Acetylsalicylic acid	161 (100)
Clopidogrel	78 (48)
Ticagrelor	68 (42)
Prasugrel	15 (9)
Clinical follow-pp	
12-month follow-up, n (%)	158 (98)
MACE, n (%)	4 (2.5)
Cardiac death	1 (0.6)
Target vessel MI	2 (1.3)
Target lesion revascularization	2 (1.3)
Overall mortality, n (%)	3 (1.9)
Stent thrombosis, n (%)	
Definite	2 (1.3)
Probable	1 (0.6)

IQR, interquartile range; MACE, major adverse cardiovascular events; MI, myocardial infarction; PCI, percutaneous coronary intervention; SD, standard deviation.

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complications, acceptable midterm clinical outcomes, and a 2.5% rate of MACE 12 months after implantation.

The baseline characteristics of the study population are similar to the ones reported in previous studies that analyzed various stent technologies in patients with atherosclerotic coronary artery disease.[10-12] However, it is noteworthy that in this study, 79% of cases were performed in the context of an acute coronary syndrome, including 22% of patients diagnosed with STEMI. In acute coronary syndrome—especially STEMI—there are factors associated with poorer outcomes of the implanted device, both in the short and long term. Firstly, the state of generalized vasoconstriction of the coronary tree and high thrombotic burden can complicate the appropriate selection of the size of the stent, thus leading to the implantation of smaller devices in relation to the actual size of the vessel, a mechanism involved in ST and in-stent restenosis. Furthermore, in the context of acute lesions, there is a higher risk of embolization and no-reflow or slow-flow phenomena, which can sometimes condition suboptimal final outcomes in terms of distal coronary flow, involving a greater risk of further ST. In our study, no ST occurred in patients with an early diagnosis of STEMI. Although it is worth mentioning that the results of the study stent were good—even in demanding contexts such as STEMI—the absolute number of STEMI patients included was low, meaning that data should be contrasted in larger series.

UTS stents provide better navigability, flexibility, and conformity to the vessel geometry. However, there may be doubts on whether the presence of UTS can lead to a reduction of the stent radial strength, which could have further implications for treating more unfavorable lesions, such as calcified lesions. Although, in the present study, 29% of the treated lesions showed some degree of calcification on angiography, the success rate of the stent reached 100%. This demonstrates the good performance of this UTS stent across different scenarios, achieving excellent radial strength even in the most challenging situations, such as calcified coronary lesions. These results are especially relevant in the specific context of the study, where, despite the recommendation for systematic postdilation, the final rate of stent postdilation was relatively low (39%).

Previous studies have consistently shown good clinical follow-up results for UTS stents with low rates of ST.[13-15] The reason for this low rate of ST would be strut thickness *per se*, which would favor early neointimal coverage, thereby reducing the risk of ST (especially late and very ST).[4] In the specific case of the study device (Evermine 50 EES), Patted et al.[13] described the 6-month follow-up results of 251 patients. In this single-center, prospective experience, the authors describe a 6-month rate of MACE of 0.8%, with no ST at the follow-up. Regarding differences with respect to our series, nearly one-third of the cases were procedures in asymptomatic patients or with silent ischemia. Additionally, the rate of postdilation (57%) was higher than that of our cohort, which may have influenced the ST outcomes. The same group retrospectively described the results of 171 patients treated with the Evermine 50 EES stent,[16] with 2-year rates of procedural success and MACE of 100% (same as in our study) and 2.4%, respectively. Again, the authors noted the absence of definite or probable ST at the follow-up. In this single-center cohort, the rate of stent postdilation was not reported, which may have implications for the prevention of MACE, especially ST. A meta-analysis that analyzed various types of UTS stents found no significant differences in the likelihood of stent failure, including ST across different stents with struts < 70 µm.[17] In the present study, although the 1-year rate of definite ST after stent deployment was 1.3%, only 1 of these STs was attributed to the study device. The rate of ST is similar to that of other real-world experiences with second and third-generation stents,[18-20] which confirms the good performance of the Evermine 50 EES in unselected real-world patients.

Limitations

The main limitations of the study are the relatively low number of patients included, and the absence of a comparator group. Furthermore, although the events reported at the follow-up were reviewed by the principal investigator of the coordinating center based on the case reports submitted by each principal investigator from the collaborating centers, these events were not allocated by an independent event adjudication committee. The fact that, in our cohort, few intracoronary imaging modalities were used to guide the PCI—reflecting real clinical practice—could be interpreted as a limitation of the study.

CONCLUSIONS

With data from a prospective, multicentric study of real-world patients, the PCIs performed with a 50 µm UTS stent, with a biodegradable polymer and everolimus elution had good clinical outcomes and a favorable safety profile at the 12-month follow-up.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

The study was approved by the Drug Research Ethics Committee of the coordinating center. The study was conducted in full compliance with the terms outlined in the Declaration of Helsinki. All patients signed specific informed consent forms prior to the intervention and before being included in the study.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence was used for this work.

AUTHORS' CONTRIBUTIONS

J. Casanova-Sandoval and M. García-Guimarães participated in the conception and design of the study, analysis and interpretation of results, and drafting the manuscript. G. Miñana Escrivà, E. Bosch-Peligero, J.F. Muñoz-Camacho, D. Fernández-Rodríguez, K. Rivera, A. Fernández-Cisnal, and D. Valcárcel-Paz participated in data acquisition and critically reviewed the content of the manuscript. All authors gave their final approval for the publication of the latest draft of the manuscript.

CONFLICTS OF INTEREST

None declared.

WHAT IS KNOWN ABOUT THE TOPIC?

- The use of UTS stents may be associated, through various mechanisms, with better clinical outcomes compared with thicker-strut stents. Previous studies suggest that UTS stents are associated with less stent failure, preventing in-stent restenosis and ST.

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WHAT DOES THIS STUDY ADD?

– In this prospective, multicentric study of real-world patients, the use of a 50 µm UTS stent with a biodegradable polymer and everolimus elution was associated with good clinical outcomes, and a favorable safety profile at the 12-month clinical follow-up.

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