ORIGINAL ARTICLE

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Clinical safety and effectiveness of the Genoss drug-eluting stent in real-world clinical practice

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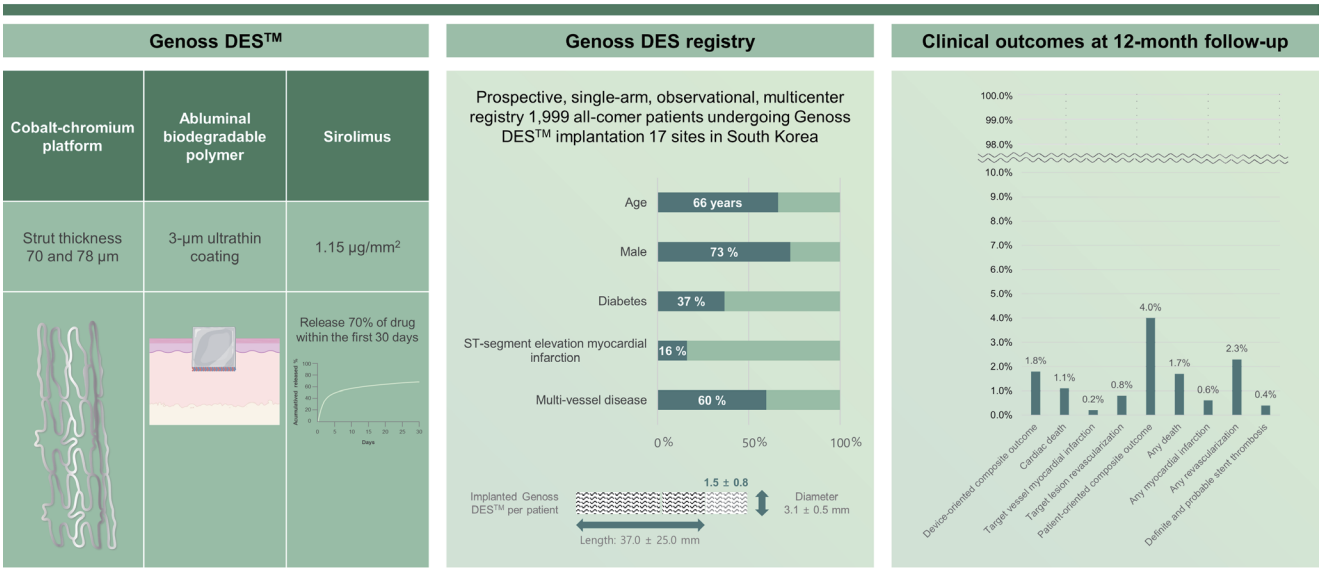
One-year clinical outcomes of all-comer patients treated with the Genoss DES™



Conclusion The results of this study demonstrate the safety and efficacy of the Genoss DES™ in real-world practice among a diverse patient population with complex lesions.

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Background/Aims: The Genoss DES™ is a novel, biodegradable, polymer-coated, sirolimus-eluting stent with a cobalt-chromium stent platform and thin strut. Although the safety and effectiveness of this stent have been previously investigated, real-world clinical outcomes data are lacking. Therefore, the aim of this prospective, multicenter trial was to evaluate the clinical safety and effectiveness of the Genoss DES™ in all-comer patients undergoing percutaneous coronary intervention.
Methods: The Genoss DES registry is a prospective, single-arm, observational trial for evaluation of clinical outcomes after Genoss DES™ implantation in all-comer patients undergoing percutaneous coronary intervention from 17 sites in South Korea. The primary endpoint was a device-oriented composite outcome of cardiac death, target vessel-related myocardial infarction (MI), and clinically driven target lesion revascularization (TLR) at 12 months.
Results: A total of 1,999 patients (66.4 ± 11.1 years of age; 72.8% male) were analyzed. At baseline, 62.8% and 36.7% of patients had hypertension and diabetes, respectively. The implanted stent number, diameter, and length per patient were 1.5 ± 0.8, 3.1 ± 0.5 mm, and 37.0 ± 25.0 mm, respectively. The primary endpoint occurred in 1.8% patients, with a cardiac death rate of 1.1%, target vessel-related MI rate of 0.2%, and clinically driven TLR rate of 0.8%.
Conclusions: In this real-world registry, the Genoss DES™ demonstrated excellent safety and effectiveness at 12 months among all-comer patients undergoing percutaneous coronary intervention. These findings suggest that the Genoss DES™ may be a viable treatment option for patients with coronary artery disease.

Keywords: Drug-eluting stents; Percutaneous coronary intervention; Prospective studies; Registries

INTRODUCTION

Coronary artery disease (CAD) is commonly treated with percutaneous coronary intervention (PCI) using metallic stents. New-generation drug-eluting stents (DESs) have improved clinical outcomes compared with first-generation DESs by using newer or reduced doses of active drugs, biocompatible durable polymer, or biodegradable polymers, and thinner struts [1-4]. However, adverse outcomes such as stent thrombosis (ST) and restenosis remain a concern, leading to the development of newer stent technologies aimed at reducing these events [5,6].

The Genoss DES™ (Genoss Company Limited, Suwon, Korea) is a novel sirolimus-eluting stent designed to improve vascular healing after implantation with its thin strut and abluminal biodegradable polymer. Previous first-in-man trials have shown similar angiographic and clinical outcomes to the Promus Element stent (Boston Scientific, Natick, MA, USA) at 9 months and 5 years of follow-up [7,8]. However, the sample size of those trials was too small to provide robust evidence for the safety and efficacy of the Genoss DES™.

To address this gap, we conducted a prospective Genoss DES registry study to evaluate the clinical safety and effectiveness of Genoss DES™ in unselected patients, reflecting real-world practice. We previously reported on the interim analysis of this registry [9], and here we present the final analysis of the Genoss DES registry.

METHODS

Genoss DES™

The Genoss DES™ is a sirolimus-eluting stent with an abluminal biodegradable polymer and a cobalt-chromium platform, designed to release nearly 70% of its initial drug payload (1.15 mg/mm^2) within the first 30 days after implantation [7]. The stent features an open-cell design with a uniform architecture for enhanced conformability and resistance to shortening. The strut thickness is 70 and 78 μm for stents with diameters of 2.25–2.50 mm and 2.75–5.00 mm, respectively. A 3-μm ultrathin coating is applied only to the abluminal side of the stent to achieve the desired drug release profile and minimize the amount of polymer used. The biodegradable coating comprises a proprietary blend of poly(lactic-co-glycolic acid) and poly(L-lactic acid) and is almost completely degraded within nine months. The Genoss DES™ was approved by the Korean Food and Drug Administration in 2016. It has also received the Conformité Européenne Mark and is available in certain Asian and Latin American countries.

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Genoss DES registry

The Genoss DES registry (ClinicalTrials.gov identifier: NCT03045913) is a prospective, single-arm, observational, multicenter, sponsor-initiated trial to enroll 2,000 patients from 17 sites in South Korea. The trial aimed to collect baseline clinical characteristics and angiographic and procedural data of consecutive patients with CAD treated with Genoss DES™ for at least one significant coronary stenosis. Patients aged ≥ 19 years presented with stable angina or acute coronary syndrome were eligible. The exclusion criteria included intolerance to medication, allergy to stent components, surgery planned within 12 months of the index PCI, cardiogenic shock during the index PCI, and life expectancy < 12 months. Clinical follow-up visits were scheduled for 1, 6, and 12 months after the index PCI. All patients were followed up either via office visits or via telephone, as necessary. Data quality was assessed via independent monitoring, and all events were adjudicated by an independent clinical event committee. All patients provided written informed consent for participation. The Institutional Review Boards of Wonju Severance Christian Hospital (CR216010) and each participating center approved this study. The trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines.

Procedure

Standard interventional techniques for PCI were employed. The number, diameter, and length of the stents used were not restricted. The use of various agents, devices, and techniques such as glycoprotein IIb/IIIa inhibitors, heparin, thrombectomy devices, intravascular ultrasound (IVUS), optical coherence tomography, and pressure wires were at the operator's discretion. Plain old balloon angioplasty (POBA) with or without a drug-coated balloon (DCB) in conjunction with Genoss DES™ implantation was permitted in cases of multivessel or bifurcation PCI. Lesion success was defined as a residual stenosis ≤ 20% and a final Thrombolysis in Myocardial Infarction flow grade of 3 by visual estimation. The clinicians were encouraged to determine the selection, dose, and duration of dual antiplatelet therapy (DAPT) with aspirin plus P2Y12 inhibitor (clopidogrel, prasugrel, or ticagrelor) according to the current guidelines [10,11].

Clinical endpoints

The primary endpoint was a 12-month device-oriented composite outcome (DOCO) comprising cardiac death, target vessel-related myocardial infarction (MI), and clinically indicated target lesion revascularization (TLR). The secondary endpoints were a patient-oriented composite outcome (POCO) comprising any death, any MI, and any revascularization, each component of the DOCO and the POCO, and Academic Research Consortium-defined ST, all determined at the 12-month clinical follow-up. All definitions of the above endpoints are provided elsewhere [12]. Periprocedural MI was not included in this endpoint because periprocedural cardiac biomarkers are not routinely collected. Lesion and procedural characteristics were reported according to visual estimation. Core laboratory–adjudicated quantitative coronary angiography was not conducted.

Statistical analysis

We expressed continuous variables as means ± standard deviations and categorical variables as numbers (percentages). Event-free survival was assessed using the Kaplan–Meier method, with patients being censored at 12 months or at the time of death, whichever occurred first. Patients lost to follow-up were censored at the time of last contact. The patient population was stratified into subgroups based on age, sex, acute MI, hypertension, diabetes, chronic kidney disease, smoking, prior MI, PCI for any in-stent restenosis (ISR) lesion, PCI for any chronic total occlusion lesion (CTO), PCI for any bifurcation lesion, use of IVUS, concomitant use of a DCB or POBA, use of any stent with a diameter ≤ 2.5 mm, and use of any stent with a length > 30 mm. In each subgroup, the event-free survival of DOCO and TLR at 12 months of follow-up was assessed using the Kaplan–Meier method. We considered *p* values less than 0.05 as clinically significant. Statistical analyses were conducted using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, NY, USA).

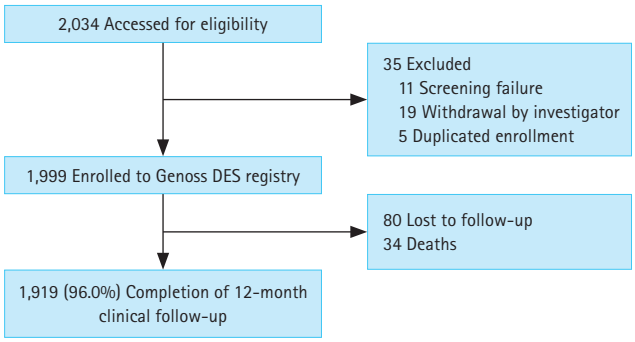

Figure 1. The study flow diagram. DES, drug-eluting stent.

Table 1. Baseline clinical, angiographic, and procedural characteristics of patients (n = 1,999)

Variable	Value
Age, yr	66.4 ± 11.1
Sex, male	1,456 (72.8)
Hypertension	1,256 (62.8)
Diabetes mellitus	733 (36.7)
Insulin dependent	85 (4.3)
Dyslipidemia	1,067 (53.4)
Chronic kidney disease	296 (14.8)
Dialysis dependent	37 (1.9)
Current or ex-smoker	979 (49.0)
Previous MI	126 (6.3)
Previous PCI	326 (16.3)
Previous CABG	15 (0.8)
Previous stroke	166 (8.3)
Indication for PCI	
Stable angina	390 (19.5)
Unstable angina/NSTEMI	1,178 (58.9)
STEMI	322 (16.1)
Others	109 (5.5)
Disease extent	
1-VD	810 (40.5)
2-VD	658 (32.9)
3-VD	531 (26.6)
Transradial intervention	1,620 (81.0)
Elective PCI	1,397 (69.9)
Primary PCI	291 (14.6)
Treated territory	
Left anterior descending artery	1175 (58.8)
Left circumflex artery	506 (25.3)
Right coronary artery	753 (37.7)
Left main coronary artery	65 (3.3)
Multi-vessel PCI	463 (23.2)
Implanted Genoss DES™ per patient	
Number	1.5 ± 0.8
Diameter, mm	3.1 ± 0.5
Length, mm	37.0 ± 25.0

Values are presented as mean ± standard deviation or number (%).
CABG, coronary artery bypass grafting; DES, drug-eluting stent; MI, myocardial infarction; NSTEMI, non- stent thrombosis-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, stent thrombosis-segment elevation myocardial infarction; VD, vessel disease.

RESULTS

Among the 2,034 patients screened from November 2016 to November 2021, 1,999 were analysed for clinical outcomes after 35 were excluded (Fig. 1).

The baseline clinical, angiographic, and procedural characteristics of the patients are summarized in Table 1. The

Table 2. Angiographic and procedural characteristics of lesions (n = 2,544)

Variable	Value
In-stent restenosis lesion	133 (5.2)
Moderate to severe proximal tortuosity	121 (4.8)
Moderate to severe angulation	117 (4.6)
Moderate to severe calcification	309 (12.1)
Thrombotic lesion	237 (9.3)
Treated territory	
Left anterior descending artery	1,197 (47.1)
Left circumflex artery	509 (20.0)
Right coronary artery	772 (30.3)
Left main coronary artery	66 (2.6)
PCI for chronic total occlusion lesion	75 (2.9)
PCI for bifurcation lesion	475 (18.7)
With two-stent strategy	34 (1.3)
Use of intravascular ultrasound	703 (27.6)
Thrombectomy	135 (5.3)
PCI method	
Genoss DES™ only	2,429 (95.5)
Genoss DES™ + POBA or DCB	47 (1.8)
Others	68 (2.7)
Implanted Genoss DES™ per lesion	
Number	1.2 ± 0.5
Diameter, mm	3.0 ± 0.5
Length, mm	29.7 ± 16.2
Lesion success	2,473 (97.2)
TIMI flow grade 0-1, pre-procedure	610 (24.0)
TIMI flow grade 3, post-procedure	2,496 (98.1)
Diameter stenosis, pre-procedure, %	85.4 ± 12.2
Diameter stenosis, post-procedure, %	7.9 ± 7.8

Values are presented as mean ± standard deviation or number (%).
DCB, drug-coated balloon; DES, drug-eluting stent; PCI, percutaneous coronary intervention; POBA, plain old balloon angioplasty; TIMI, Thrombolysis in Myocardial Infarction.

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mean age of the patients was 66.4 ± 11.1 years, and the majority (72.8%) were male. Common comorbidities included hypertension (62.8%), dyslipidemia (53.4%), and diabetes mellitus (36.7%). The majority of patients underwent PCI for unstable angina or non-ST-segment elevation MI (NSTEMI) (58.9%), followed by stable angina (19.5%) and STEMI (16.1%). The mean number of Genoss DES™ stents implanted per patient was 1.5 ± 0.8, with a mean diameter of 3.1 ± 0.5 mm and a mean length of 37.0 ± 25.0 mm. Transradial intervention was used in 81.0% of cases.

The angiographic and procedural characteristics of the lesions are summarized in Table 2. A total of 2,544 lesions were treated, with the majority being ACC/AHA type B2/C lesions (78.5%) and located in the left anterior descending artery (47.1%). The use of IVUS was reported in 27.6% of cases, and thrombectomy was performed in 5.3%. The majority of lesions were treated with Genoss DES™ only (95.5%). The mean implanted Genoss DES™ per lesion was 1.2 ± 0.5, with a mean diameter of 3.0 ± 0.5 mm and mean length of 29.7 ± 16.2 mm. Lesion success was achieved in 97.2% of cases, and post-procedure TIMI flow grade 3 was reported in 98.1%. The mean diameter stenosis post-procedure was 7.9 ± 7.8%.

Medications at discharge and antithrombotic agents at the 12-month follow-up among the survivors at discharge (n = 1,985) are presented in Supplementary Table 1. The majority of patients (98.1%) were discharged on DAPT, with aspirin and clopidogrel being the most commonly used combination (62.9%). Other medications prescribed at discharge included statins (96.3%), renin-angiotensin-system blockers (61.5%), and nitrates or nicorandil (62.3%). At 12-month follow-up, 56.0% of patients were still on DAPT, while 17.1% were on a P2Y12 inhibitor only and 15.8% were on aspirin only. A small proportion of patients were on oral anticoagulant therapy in combination with either DAPT or a P2Y12 inhibitor, or on oral anticoagulant therapy alone.

Clinical outcomes at the 12-month follow-up are presented in Table 3. A 12-month follow-up was completed in 96.0% of patients. The DOCO occurred in 36 (1.8%) of patients, with 21 (1.1%) cardiac deaths, 3 (0.2%) target vessel-related MI, and 16 (0.8%) TLR. The POCO occurred in 4.0% of patients, with 34 (1.7%) any deaths, 12 (0.6%) any MI, and 45 (2.3%) any revascularizations. Definite and probable ST occurred in 8 (0.4%) of patients, with 6 (0.3%) being MI-related. The Kaplan–Meier survival plots of the DOCO, POCO, TLR, and target vessel-related MI are illustrated in Figure 2.

The results of the subgroup analysis for the DOCO and TLR at the 12-month follow-up are presented in Table 4. Some subgroups showed significant differences in the incidence of DOCO and TLR, including age ≥ 65 years, CKD, and any ISR lesion. However, most subgroups did not show significant differences in the incidence of DOCO and TLR.

Table 3. Clinical outcomes at 12-month follow-up (n = 1,999)

Variable	Value
Device-oriented composite outcome	36 (1.8)
Cardiac death	21 (1.1)
In-hospital cardiovascular death	8 (0.4)
Target vessel myocardial infarction	3 (0.2)
Target lesion revascularization	16 (0.8)
Patient-oriented composite outcome	80 (4.0)
Any death	34 (1.7)
Any myocardial infarction	12 (0.6)
Any revascularization	45 (2.3)
Target vessel revascularization	21 (1.1)
Definite stent thrombosis	7 (0.4)
Myocardial infarction related	5 (0.3)
Definite and probable stent thrombosis	8 (0.4)
Myocardial infarction related	6 (0.3)

Values are presented as number (%).

DISCUSSION

The study presented here reports on the safety and effectiveness of the Genoss DES™ in real-world practice, with low clinical event rates observed at the 12-month follow-up. The primary results were as follows: 1) treatment of patients with CAD with the Genoss DES™ resulted in low clinical event rates, with a DOCO rate of 1.8% and a definite and probable ST rate of 0.4% at the 12-month follow-up; 2) the rates of target vessel-related MI and clinically driven TLR were 0.2% and 0.8%, respectively, at the 12-month follow-up.

In the first-in-man random trial, patients treated with the Genoss DES™ (n = 38) were compared to those treated with the Promus Element stent (n = 39). At the 9-month follow-up, the in-stent late lumen loss did not differ significantly between the groups (0.11 ± 0.25 mm vs. 0.16 ± 0.43 mm,

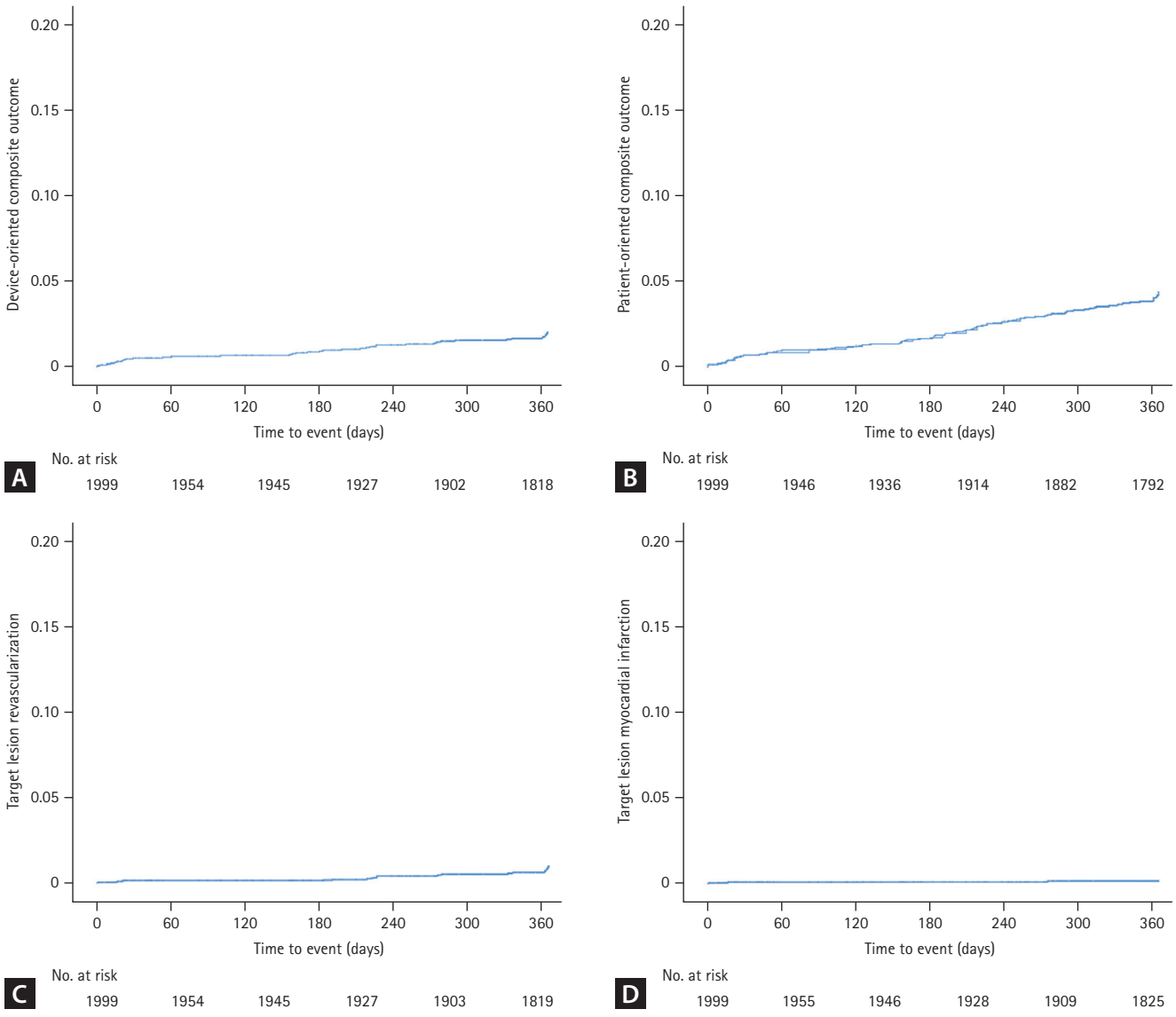

Figure 2. Kaplan–Meier survival curves. Event rates were estimated based on the unadjusted Kaplan–Meier method. (A) Device-oriented composite outcome, (B) patient-oriented composite outcome, (C) target lesion revascularization, and (D) target lesion myocardial infarction.

p = 0.567), nor did the rates of death, MI, TLR, and target vessel revascularization [7]. After 5 years, the Genoss DES™ yielded comparably low rates of major adverse cardiac events (5.3% vs. 12.8%, p = 0.431) and TLR (2.6% vs 2.6%, p > 0.999) to the Promus Element stent [8]. The Genoss DES registry includes high-risk patients with acute MI, CTO lesions, ISR lesions, left main disease, or diffuse long lesions. Nevertheless, the 12-month adverse event rate was low. Thus, with this study, we confirmed the results of the first-in-man trial in the real-world setting. Currently, a few Korea-made DES, such as D+Storm™ stent (CG Bio Co., Ltd., Seoul, Korea) and Centum™ stent (Osstem Cardiotec Co., Seoul, Korea), are available. However, there is limited evidence of the safety and efficacy of these DESs [13,14]. Genoss DES registry provides the most extensive evidence of the Genoss DES™.

The favorable results of this study may be associated with the biodegradability of the polymer and the thinness of the strut. In a meta-analysis of 10 randomized controlled trials, ultrathin-strut DESs (strut thickness < 70 μm) reduced the target lesion failure (relative risk [RR] 0.84; 95% confidence interval [CI]: 0.72–0.99) and MI (RR 0.80; 95% CI: 0.65–0.99) rates compared with thicker-strut second-generation DESs [15]. In another meta-analysis of 9 randomized con-

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Table 4. Subgroup analysis for device-oriented composite outcome and target lesion revascularization at 12-month follow-up (n = 1,999)

Subgroup		Patients (n)	DOCO	Log rank *p* value	TLR	Log rank *p* value
Age ≥ 65 yr	Yes	1,124	27 (2.4)	0.018	9 (0.8)	0.920
	No	875	9 (1.0)		7 (0.8)	
Sex, male	Yes	1,456	28 (1.9)	0.485	14 (1.0)	0.177
	No	543	8 (1.5)		2 (0.4)	
AMI	Yes	736	18 (2.4)	0.094	6 (0.8)	0.951
	No	1,263	18 (1.4)		10 (0.8)	
Hypertension	Yes	1,256	19 (1.5)	0.210	6 (0.5)	0.037
	No	743	17 (2.3)		10 (1.3)	
Diabetes	Yes	733	14 (1.9)	0.788	6 (0.8)	0.942
	No	1,266	22 (1.7)		10 (0.8)	
CKD	Yes	296	12 (4.1)	0.002	4 (1.4)	0.246
	No	1,703	24 (1.4)		12 (0.7)	
Any smoking	Yes	979	19 (1.9)	0.680	9 (0.9)	0.591
	No	1,020	17 (1.7)		7 (0.7)	
Prior myocardial infarction	Yes	126	3 (2.4)	0.549	2 (1.6)	0.262
	No	1,873	33 (1.8)		14 (0.7)	
Any ISR lesion	Yes	123	6 (4.9)	0.006	5 (4.1)	< 0.001
	No	1,876	30 (1.6)		11 (0.6)	
Any CTO PCI	Yes	75	2 (2.7)	0.540	1 (1.3)	0.534
	No	1,924	34 (1.8)		15 (0.8)	
Any bifurcation PCI	Yes	446	5 (1.1)	0.202	1 (0.2)	0.111
	No	1,553	31 (2.0)		15 (1.0)	
Use of IVUS	Yes	566	6 (1.1)	0.104	3 (0.5)	0.360
	No	1,433	30 (2.1)		13 (0.9)	
Any use of DCB or POBA	Yes	123	3 (2.4)	0.614	2 (1.6)	0.305
	No	1,876	33 (1.8)		14 (0.7)	
Any use of stent diameter ≤ 2.5 mm	Yes	472	8 (1.7)	0.812	3 (0.6)	0.621
	No	1,527	28 (1.8)		13 (0.9)	
Any use of stent length > 30 mm	Yes	682	14 (2.1)	0.588	8 (1.2)	0.202
	No	1,317	22 (1.7)		8 (0.6)	

Values are presented as number only or number (%).
AMI, acute myocardial infarction; CKD, chronic kidney disease; CTO, chronic total occlusion; DCB, drug-coated balloon; DOCO, device-oriented composite outcome; ISR, in-stent restenosis; IVUS, intravascular ultrasound; PCI, percutaneous coronary intervention; POBA, plain old balloon angioplasty; TLR, target vessel revascularization.

trolled trials, biodegradable-polymer DESs showed a trend of the low incidence of definite or probable ST (RR 0.78; 95% CI: 0.59–1.01) and similar clinical outcomes compared with durable-polymer DES [16].

Despite the all-comer nature of the study population, event rates in this trial were low, which may be explained as follows: First, patients with periprocedural MI were excluded, which may have reduced the rate of MI compared with previous studies. Second, transradial intervention was used in 81% of patients. Transradial access is well-known

to be associated with a lower risk of adverse clinical events than femoral access, particularly in patients with ST-segment elevation MI [17]. Third, ethnic or genetic protective factors may affect the clinical event rate [18]. In the recently published BIODEGRADE trial, in which Korean patients were enrolled, Orsiro stents (Biotronik, Bülach, Switzerland) were non-inferior to the BioMatrix stent (Biosensors, Singapore) in terms of target lesion failure (2.1% vs. 2.9%) at the 18-month follow-up [19]. Considering the similar properties between the Genoss DES™ and Orsiro stents, the event rate in this study was in line with that of the BIODEGRADE trial.

Limitations

This study has several limitations. One major limitation is the lack of a control group for a direct comparison, which may affect the interpretation of the results. Another limitation is that only patients from Korea were enrolled in the registry, which may limit the generalizability of the findings to other ethnicities and regions. Additionally, the follow-up period was relatively short (12 months), and the potential long-term benefits of the biodegradable polymer should be investigated in future studies. The use of operator-reported angiographic data instead of adjudicated data by an independent core laboratory is also a limitation. However, we provided detailed instructions to the participating hospitals on how to measure and record the angiographic data. We believe that this minimized the interobserver variability in angiographic measurements. Finally, the authors did not collect data on cases in which the stent failed to pass the lesion, which may underestimate the adverse events related to the stent. We believe that the delivery of the Genoss DES is generally acceptable.

Conclusions

The results of this study demonstrate the safety and efficacy of the Genoss DES™ in real-world practice among a diverse patient population with complex lesions. The low rates of adverse events and the consistent outcomes across different subgroups suggest that the biodegradable polymer and ultrathin strut design of the Genoss DES™ are associated with favorable clinical outcomes. However, further randomized controlled studies with larger sample sizes and longer follow-up periods are needed to confirm these findings and to evaluate the potential benefits of the biodegradable polymer over an extended period.

KEY MESSAGE

1. The Genoss DES™ is a novel sirolimus-eluting stent with an abluminal biodegradable polymer and a cobalt-chromium platform with thin strut.
2. The Genoss DES registry is a prospective, single-arm, observational, multicenter trial to enroll 2,000 consecutive patients with coronary artery disease treated with the Genoss DES™ with minimal exclusion criteria from 17 sites in South Korea.
3. In this real-world registry, the Genoss DES™ demonstrated excellent safety and effectiveness at 12 months among all-comer patients undergoing percutaneous coronary intervention.

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Supplementary Table 1. Discharge medications and antithrombotic agents at 12-month follow-up among survivors at discharge (n = 1,985)

Variable	Value
Discharge medications	
DAPT	1,947 (98.1)
Aspirin + clopidogrel	1,248 (62.9)
Aspirin + ticagrelor	629 (31.7)
Aspirin + prasugrel	70 (3.5)
OAC	81 (4.1)
Vitamin K antagonist	8 (0.4)
Non-vitamin K antagonist	73 (3.7)
Statin	1,911 (96.3)
Calcium channel blocker	543 (27.4)
Beta blocker	1,089 (54.9)
ACEi or ARB	1,221 (61.5)
Nitrate or nicorandil	1,237 (62.3)
Antithrombotic agents at 12-month follow-up	
DAPT	1,112 (56.0)
P2Y12 inhibitor only	339 (17.1)
Aspirin only	314 (15.8)
OAC plus DAPT	27 (1.4)
OAC plus P2Y12 inhibitor	52 (2.6)
OAC plus aspirin	7 (0.4)
OAC only	29 (1.5)

Values are presented as number (%).
ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; DAPT, dual antiplatelet therapy; OAC, oral anticoagulant.