Journal of Cardiology xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc

Original Article

Comparison of clinical outcomes between biodegradable polymer sirolimus-eluting stents and durable polymer everolimus-eluting stents in octogenarian patients

Masaki Kushi (MD) [a,b], Yuichi Ozaki (MD, PhD, FJCC) [b,*], Keiya Komatsu (MD) [a], Ryo Hikida (MD) [c], Kenichi Komukai (MD, PhD) [d], Yosuke Katayama (MD, PhD) [b], Keisuke Satogami (MD, PhD) [b], Masahiro Takahata (MD, PhD) [b], Teruaki Wada (MD, PhD) [b], Manabu Kashiwagi (MD, PhD) [b], Yasutsugu Shiono (MD, PhD) [b], Akio Kuroi (MD, PhD) [b], Takashi Yamano (MD, PhD) [b], Takashi Tanimoto (MD, PhD, FJCC) [b], Shintaro Kuki (MD, PhD) [c], Yasushi Ino (MD, PhD) [a], Yasushi Hayashi (MD) [d], Hironori Kitabata (MD, PhD, FJCC) [b], Atsushi Tanaka (MD, PhD) [b]

[a] Department of Cardiovascular Medicine, Shingu Municipal Medical Center, Shingu, Japan
[b] Department of Cardiovascular Medicine, Wakayama Medical University, Wakayama, Japan
[c] Department of Cardiovascular Medicine, Hashimoto Municipal Hospital, Wakayama, Japan
[d] Department of Cardiovascular Medicine, Wakayama Rosai Hospital, Wakayama, Japan

ARTICLE INFO

Article history:
Received 18 November 2025
Received in revised form 23 February 2026
Accepted 16 March 2026
Available online xxxx

Keywords:
Biodegradable polymer sirolimus-eluting stent
Durable polymer everolimus-eluting stent
Octogenarian patients

ABSTRACT

Background: Biodegradable polymer sirolimus-eluting stents (BP-SESs) have provided similar clinical outcomes including cardiac death, myocardial infarction (MI), and target lesion revascularization to second-generation durable polymer everolimus-eluting stents (DP-EESs). However, safety and efficacy of BP-SES in patients aged ≥80 years remain unknown. The aim of this study was to investigate the 1-year clinical outcomes between BP-SES and DP-EES in patients aged ≥80 years.

Methods: We retrospectively analyzed 213 patients aged ≥80 years who underwent percutaneous coronary intervention (PCI) with BP-SES or DP-EES between April 2020 and March 2022. The primary endpoint was a 1-year composite of all-cause death, MI, target vessel revascularization (TVR), cerebrovascular accident (CVA), and definite or probable stent thrombosis (ST). To minimize stent selection bias, propensity score matching was conducted. Multivariable logistic regression was used to identify factors associated with the 1-year primary endpoint in the matched cohort.

Results: Among 213 patients treated with BP-SES ($n = 93$) and DP-EES ($n = 120$), the 1-year rates of MI, TVR, CVA, ST, and bleeding events were similar between the two groups. After propensity score matching, 1-year event-free survival for the primary endpoint was similar between the BP-SES and DP-EES groups [hazard ratio, 0.893; 95% confidence interval (CI), 0.345–2.315; $p = 0.816$]. Multivariable analysis demonstrated that acute coronary syndrome [odds ratio (OR), 3.478; 95% CI, 1.019–14.190; $p = 0.047$] was independently associated with a higher incidence of the 1-year primary endpoint, whereas angiographic success (OR, 0.058; 95% CI, 0.008–0.347; $p = 0.002$) and angiotensin-converting enzyme inhibitor or angiotensin II type 1 receptor blocker use at discharge (OR, 0.229; 95% CI, 0.057–0.858; $p = 0.029$) were independently associated with a lower incidence.

Conclusions: In patients aged ≥80 years, 1-year clinical outcomes after PCI with BP-SES were generally consistent with those with DP-EES.

© 2026 Japanese College of Cardiology. Published by Elsevier Ltd. All rights are reserved, including those for text and data mining, AI training, and similar technologies.

Introduction

Due to recent advances in health care, elderly populations are rapidly growing and will increase in the future three decades. Therefore, the proportion of elderly patients undergoing percutaneous coronary intervention (PCI) for coronary artery disease is also gradually increasing in daily clinical practice [1]. In Japan, in particular, the crude

* Corresponding author at: Department of Cardiovascular Medicine, Wakayama Medical University, 811-1 Kimiidera, Wakayama, 641-8509, Japan.
E-mail address: yozaki@wakayama-med.ac.jp (Y. Ozaki).

https://doi.org/10.1016/j.jjcc.2026.03.015
0914-5087/© 2026 Japanese College of Cardiology. Published by Elsevier Ltd. All rights are reserved, including those for text and data mining, AI training, and similar technologies.

Please cite this article as: M. Kushi, Y. Ozaki, K. Komatsu, et al., Comparison of clinical outcomes between biodegradable polymer sirolimus-eluting stents and durable polymer everolimus-eluting stents in octogenarian..., Journal of Cardiology, https://doi.org/10.1016/j.jjcc.2026.03.015

mortality rate from cardiovascular disease has been increasing in recent years in parallel with the population aging [2].

Second-generation drug-eluting stents (DESs) have addressed the concern of stent thrombosis (ST) compared to first-generation DESs [3–5], in addition to their improved restenosis rate compared to bare-metal stents (BMSs) [6]. In particular, the use of second-generation durable polymer everolimus-eluting stents (DP-EESs) versus BMS has been shown to improve global cardiovascular outcomes including cardiac survival, myocardial infarction (MI), and ST [7–10]. One randomized trial demonstrated that, in patients aged ≥80 years, DP-EESs were superior to BMSs in terms of MI and target vessel revascularization (TVR), without increased risk of bleeding or ST [11]. Furthermore, the 1-year safety and efficacy outcomes of DP-EES in octogenarians were comparable to younger populations [12].

The biodegradable polymer sirolimus-eluting stent (BP-SES) is a third-generation DES which is based on an ultra-thin cobalt-chromium stent. The BIOFLOW trials have demonstrated that BP-SESs showed non-inferiority for in-stent late lumen loss compared to DP-EESs [13], and provided similar clinical outcomes including cardiac death, MI, and target lesion revascularization (TLR) and its non-inferiority to DP-EESs [14,15]. However, the patients aged ≥80 years were excluded in the BIOFLOW trials; therefore, the safety and efficacy of BP-SES in this population remain to be elucidated. The aim of this study was to compare 1-year clinical outcomes between BP-SES and DP-EES in patients aged ≥80 years.

Materials and methods

Study design and population

This is a multicenter retrospective study of patients treated with BP-SES or DP-EES. Between April 2020 and March 2022, a total of 1816 patients underwent PCI in our institutions. Of these, 1426 patients aged <80 years were excluded, and then 390 patients aged ≥80 years remained. Among these, 213 patients who were treated for de-novo lesions with an ultrathin-strut (60 μm for stent diameters ≤3.0 mm and 80 μm for stent diameters ≥3.5 mm) BP-SES (Orsiro, Biotronik AG, Bülach, Switzerland) or a contemporary thin-strut (81 μm) DP-EES (Xience, Abbott Vascular, Santa Clara, CA, USA) were retrospectively included in this study (Fig. 1).

Clinical and demographic data, as well as clinical events during hospitalization, were collected from the hospital charts and reviewed by qualified personnel blinded to the objectives of the study. Every patient underwent 1-year clinical follow-up by qualified personnel via telephone contacts or during office visits. All clinical events were classified and adjudicated by a physician who was not involved in the follow-up process.

This study was in compliance with the Declaration of Helsinki with regard to investigation in humans, and the protocol was approved by the institutional ethics committee of all participating institutes. Written informed consent was waived by each institutional ethics committee because of the retrospective design of the study.

PCI procedure

PCI was performed in the standard manner according to clinical guidelines at the time of the procedure. The procedural approach, stent selection, and use of intracoronary imaging were at the operator's discretion. In case of stable angina pectoris, pre-PCI antiplatelet treatment consisted of aspirin (100 mg/day) and thienopyridines (clopidogrel 75 mg/day or prasugrel 3.75 mg/day) for at least 5 days. In case of ST-segment elevation MI (STEMI), non-STEMI, or unstable angina, all patients received aspirin 200 mg before the procedure and a loading dose of clopidogrel 300 mg or prasugrel 20 mg before or during the procedure. During PCI, patients received anticoagulation therapy with unfractionated heparin (70–100 U/kg bolus with an additional dose to achieve an activated clotting time of 250–300 s). Unless a bleeding event occurred, dual antiplatelet therapy (DAPT) was generally continued in accordance with Japanese Circulation Society guidelines [16]; however, the final decision was left to the discretion of the attending physician or primary care physician.

Clinical endpoints

The primary endpoint was the 1-year rate of a composite of all-cause death, MI, TVR, cerebrovascular accident (CVA), and definite or probable ST. Secondary endpoints included each component of the primary endpoint, TLR, and major or minor bleeding at 1-year follow-up. Angiographic success was defined as residual stenosis <30% in the presence of Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 after the procedure. All-cause death was defined as death from any cause, cardiac as

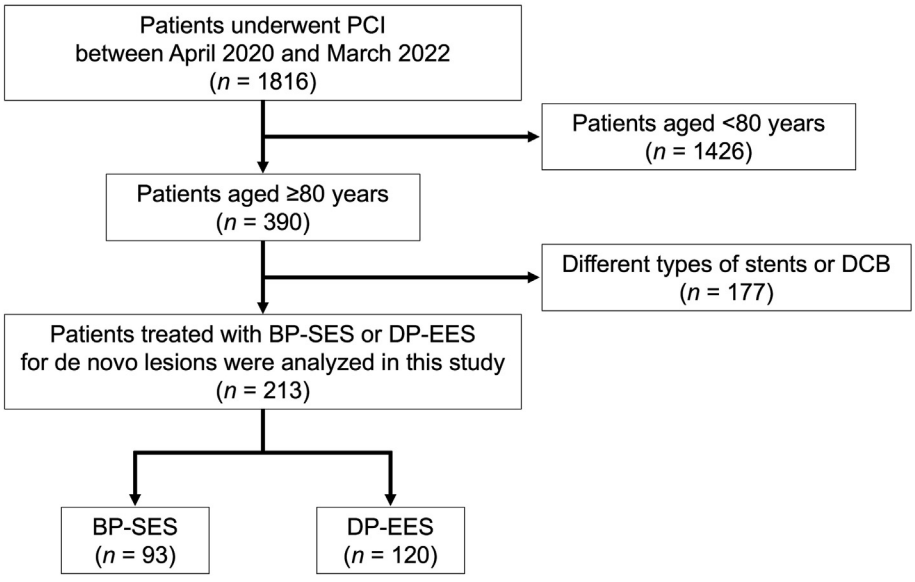

Fig. 1. Flow of this study population.
BP-SES, biodegradable polymer sirolimus-eluting stent; DCB, drug-coated balloon; DP-EES, durable polymer everolimus-eluting stents; PCI, percutaneous coronary intervention.

Table 1
Baseline clinical characteristics.

	BP-SES ($n = 93$)	DP-EES ($n = 120$)	p-value
Age (years)	83 (82–87)	84 (81–87)	0.775
Male	49 (52.7)	68 (56.7)	0.563
HT	77 (82.8)	106 (88.3)	0.249
DM	40 (43.0)	49 (40.8)	0.749
DLP	56 (60.2)	78 (65.0)	0.473
Smoking	23 (24.7)	54 (45.0)	0.002
FH	6 (6.5)	14 (11.7)	0.196
BMI (kg/m^2)	22.4 (19.6–25.2)	21.4 (19.2–23.8)	0.145
Prior MI	21 (22.6)	34 (28.3)	0.341
Prior CABG	6 (6.5)	3 (2.5)	0.155
History of HF	20 (21.5)	28 (23.3)	0.752
CKD[a]	51 (54.8)	55 (45.8)	0.192
HD	4 (4.3)	4 (3.3)	0.713
eGFR (mL/min/1.73 m^2)	50.2 (37.1–66.6)	48.6 (38.8–60.1)	0.352
BNP (pg/mL)	122.2 (59.4–329.7)	136.9 (62.5–330.2)	0.985
LVEF (%)	52 (42–60)	50 (45–58)	0.381
Clinical presentation			0.005
STEMI	22 (23.7)	47 (39.2)	
NSTEMI/UAP	17 (18.3)	30 (25.0)	
SAP	54 (58.1)	43 (35.8)	
Medication at discharge			
Aspirin	90 (96.8)	113 (94.2)	0.372
P2Y12 inhibitor	93 (100)	119 (99.2)	0.378
Warfarin/DOAC	9 (9.7)	11 (9.2)	0.899
ACEI/ARB	63 (67.7)	102 (85.0)	0.003
Statin	66 (71.0)	110 (91.7)	<0.001
β-blocker	51 (54.8)	78 (65.0)	0.132
MRA	17 (18.3)	26 (20.2)	0.541

Data are expressed as median (interquartile range) or number (%).
ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin II type 1 receptor blocker; BMI, body mass index; BNP, brain natriuretic peptide; BP-SES, bioresorbable polymer sirolimus-eluting stent; CABG, coronary artery bypass grafting; CKD, chronic kidney disease; DLP, dyslipidemia; DM, diabetes mellitus; DOAC, direct oral anticoagulant; DP-EES, durable polymer everolimus-eluting stents; eGFR, estimated glomerular filtration rate; FH, family history; HD, hemodialysis; HF, heart failure; HT, hypertension; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MRA, mineralocorticoid receptor antagonist; NSTEMI, non-STEMI; SAP, stable angina pectoris; STEMI, ST-segment elevation MI; UAP, unstable angina pectoris.
[a] eGFR <60 mL/min/1.73 m^2.

well as noncardiac. MI was defined according to the universal definition [17]. TLR was defined as clinically-driven any repeat percutaneous intervention or bypass grafting of the treated lesion including in-stent and in-segments 5-mm proximal or distal to the initial stent edges, and TVR as clinically-driven any percutaneous intervention or bypass grafting of the target vessel. CVA was defined as a new neurological deficit lasting >24 h confirmed with appropriate imaging abnormality [11]. ST was defined according to the Academic Research Consortium definition [18]. Bleeding events were defined as major or minor according to TIMI bleeding criteria [19].

Statistical analysis

Data are expressed as mean ± standard deviation for normally distributed variables and median (interquartile range) for skewed variables. Categorical data are presented as number (%). Continuous variables were compared using an unpaired Student's t-test for normally distributed variables; nonparametric Wilcoxon rank sum test for skewed variables; and chi-squared test or Fisher's exact test as appropriate for categorical variables. To minimize potential stent selection bias, propensity score matching was performed using gender, smoking, chronic kidney disease (CKD), target vessel, and acute coronary syndrome (ACS) as covariates. Variables that differed significantly between the two groups and those considered clinically relevant to stent selection were included in the propensity score model. After propensity score matching, a multivariable logistic regression model was used to identify factors associated with the 1-year primary endpoint. Variables showing $p < 0.10$ in the univariate analysis of the 1-year primary endpoint were included in the multivariable regression analysis. Results were expressed as odds ratios (ORs) with 95% confidence intervals (CIs). The cumulative event-free survival for the primary endpoint was estimated using the Kaplan–Meier method, and differences between the groups were evaluated with the log-rank test. Values of $p < 0.05$ were considered statistically significant. All statistical analyses were conducted using JMP Pro version 18.0 (SAS Institute, Cary, NC, USA).

Results

Patients' characteristics

Among 213 patients treated with BP-SES ($n = 93$) and DP-EES ($n = 120$), 1-year clinical follow-up was completed for all patients in both groups. The baseline clinical characteristics are summarized in Table 1. There were no significant differences in terms of gender, coronary risk factors except for smoking, including hypertension, diabetes mellitus, and dyslipidemia, and CKD between the two groups. However, ACS was more frequent in patients treated with DP-EES, whereas stable angina pectoris was more common in those treated with BP-SES ($p = 0.005$). The rates of angiotensin-converting enzyme inhibitor or angiotensin II type 1 receptor blocker (ACEI/ARB) and statin use at discharge were higher in the DP-EES group than in the BP-SES group.

Angiographic and procedural characteristics

Angiographic and procedural characteristics are shown in Table 2. Radial artery (RA) approach was used in 84% of all cases, with no significant difference between the two groups. Procedural factors including pre- and post-balloon dilatation and debulking devices were not different between the two groups. Furthermore, the use of mechanical support device, including intra-aortic balloon pumping, Impella

Table 2
Lesion-based angiographic and procedural characteristics.

	BP-SES ($n = 103$)	DP-EES ($n = 134$)	p-value
Target vessel			0.012
LMT	0 (0)	5 (3.7)	
LAD	41 (39.8)	56 (41.8)	
LCX	27 (26.2)	18 (13.4)	
RCA	33 (32.0)	55 (41.0)	
SVG	2 (1.9)	0 (0)	
Mechanical support device[a]	6 (6.5)	10 (8.3)	0.605
Bifurcation lesion	35 (34.0)	46 (34.3)	0.955
Chronic total occlusion	0 (0)	4 (3.0)	0.077
Lesion type (ACC/AHA classification)			0.562
Type A	14 (13.6)	11 (8.2)	
Type B1	32 (31.1)	41 (30.6)	
Type B2	37 (35.9)	51 (38.1)	
Type C	20 (19.4)	31 (23.1)	
Angiographic calcification	31 (30.1)	54 (40.3)	0.105
Radial approach[b]	81 (87.1)	98 (81.7)	0.283
IVUS or OCT use	102 (99.0)	131 (97.8)	0.453
Pre-balloon dilation	94 (91.3)	120 (89.6)	0.659
Post-balloon dilation	68 (66.0)	82 (61.2)	0.445
Debulking device	5 (4.9)	2 (1.5)	0.130
Angiographic success	96 (93.2)	126 (94.0)	0.796
Stent diameter (mm)	3.0 (2.5–3.5)	3.0 (2.75–3.5)	0.002
Stent length (mm)	26 (18–30)	28 (18–38)	0.040

Data are expressed as median (interquartile range) or number (%).
ACC/AHA, American College of Cardiology/American Heart Association; BP-SES, bioresorbable polymer sirolimus-eluting stent; DP-EES, durable polymer everolimus-eluting stents; IVUS, intravascular ultrasound; LAD, left anterior descending artery; LCX, left circumflex artery; LMT, left main trunk; OCT, optical coherence tomography; RCA, right coronary artery; SVG, saphenous vein graft.
[a] Intra-aortic balloon pumping, Impella, and extracorporeal membrane oxygenation.
[b] Per-patient analysis.

Table 3
Clinical outcomes in-hospital and at 1-year follow-up.

	BP-SES ($n = 93$)	DP-EES ($n = 120$)	p-value
In-hospital			
All-cause death	6 (6.5)	7 (5.8)	0.852
Cardiac	3 (3.2)	6 (5.0)	0.523
Non-cardiac	3 (3.2)	1 (0.8)	0.202
Acute kidney injury [a]	3 (3.2)	1 (0.8)	0.202
Cerebrovascular accident	0 (0)	2 (1.7)	0.211
Subacute stent thrombosis	0 (0)	0 (0)	1.000
Major bleeding	0 (0)	1 (0.8)	0.378
1-year follow-up			
Primary endpoint[b]	11 (11.8)	15 (12.5)	0.882
All-cause death	7 (7.5)	10 (8.3)	0.830
Cardiac	3 (3.2)	8 (6.7)	0.260
Non-cardiac	4 (4.3)	2 (1.7)	0.249
Myocardial infarction	2 (2.2)	3 (2.5)	0.867
Target vessel revascularization	2 (2.2)	1 (0.8)	0.419
Target lesion revascularization	1 (1.1)	1 (0.8)	0.856
Cerebrovascular accident	0 (0)	3 (2.5)	0.125
Hemorrhagic	0 (0)	1 (0.8)	0.378
Ischemic	0 (0)	2 (1.7)	0.211
Stent thrombosis			
Definite/probable	0 (0)	1 (0.8)	0.378
Definite	0 (0)	1 (0.8)	0.378
Probable	0 (0)	0 (0)	1.000
Bleeding events			
Major/minor	4 (4.3)	6 (5.0)	0.811
Major	2 (2.2)	2 (1.7)	0.796
Minor	2 (2.2)	4 (3.3)	0.605

Data are expressed as number (%).
BP-SES, bioresorbable polymer sirolimus-eluting stent; DP-EES, durable polymer everolimus-eluting stents.
[a] Acute kidney injury was defined as an absolute increase in serum creatinine of ≥0.5 mg/dL from baseline.
[b] Primary endpoint was defined as the composite of all-cause death, myocardial infarction, target vessel revascularization, cerebrovascular accident, and definite/probable ST at 1 year.

(Abiomed, Danvers, MA, USA), and extracorporeal membrane oxygenation, and angiographic success were similar between the two groups. Stent diameter was larger [3.0 (2.5–3.5) mm vs. 3.0 (2.75–3.5) mm, $p = 0.002$] and stent length was longer [26 (18–30) mm vs. 28 (18–38) mm, $p = 0.040$] in the lesions treated with DP-EES compared with those treated with BP-SES. The mean DAPT duration was 6.9 months in the BP-SES group and 6.1 months in the DP-EES group, with no significant difference between the two groups ($p = 0.157$).

In-hospital and 1-year clinical outcomes

The rates of in-hospital and 1-year clinical events are shown in Table 3. In-hospital cardiac death occurred in 3 patients with BP-SES and 6 patients with DP-EES without significant differences (3.2% vs. 5.0%, $p = 0.523$). There were also no significant differences in the incidence of all other in-hospital adverse events between the two groups. Clinical follow-up data at 1 year were available in all patients. The cumulative primary endpoint occurred in 11 patients with BP-SES and 15 patients with DP-EES (11.8% vs. 12.5%, $p = 0.882$). There were no significant differences in terms of all-cause death (7.5% vs. 8.3%, $p = 0.830$), cardiac death (3.2% vs. 6.7%, $p = 0.260$), and non-cardiac death (4.3% vs. 1.7%, $p = 0.249$) between the two groups. Furthermore, no significant differences were observed in terms of MI (2.2% vs. 2.5%, $p = 0.867$), TVR (2.2% vs. 0.8%, $p = 0.419$), TLR (1.1% vs. 0.8%, $p = 0.856$), and CVA (0% vs. 2.5%, $p = 0.125$) between the two groups. TIMI major bleeding occurred in 2 patients with BP-SES and 2 patients with DP-EES (2.2% vs. 1.7%, $p = 0.796$). TIMI minor bleeding occurred in 2 patients with BP-SES and 4 patients with DP-EES (2.2% vs. 3.3%, $p = 0.605$). During follow-up, there was only 1 definite ST at 284 days after DP-EES implantation, with no significant difference between the two groups (0% vs. 0.8%, $p = 0.378$).

Fig. 2A shows the Kaplan–Meier curve for the primary endpoint in the full cohort, comparing BP-SES and DP-EES. Event-free survival for the primary endpoint at 1 year was similar between the two groups (hazard ratio, 0.929; 95% CI, 0.427–2.024; $p = 0.854$).

Results in the propensity score-matched cohort

After propensity score matching, 146 matched patients (73 treated with BP-SES and 73 with DP-EES) were included and analyzed to identify factors associated with the 1-year primary endpoint. Baseline clinical, angiographic, and procedural characteristics of the propensity score-matched cohort are shown in Online Tables 1 and 2.

Fig. 2B shows the Kaplan–Meier curve for the primary endpoint in the propensity score-matched cohort, comparing BP-SES and DP-EES. Event-free survival for the primary endpoint at 1 year was similar between the two groups (hazard ratio, 0.893; 95% CI, 0.345–2.315; $p = 0.816$).

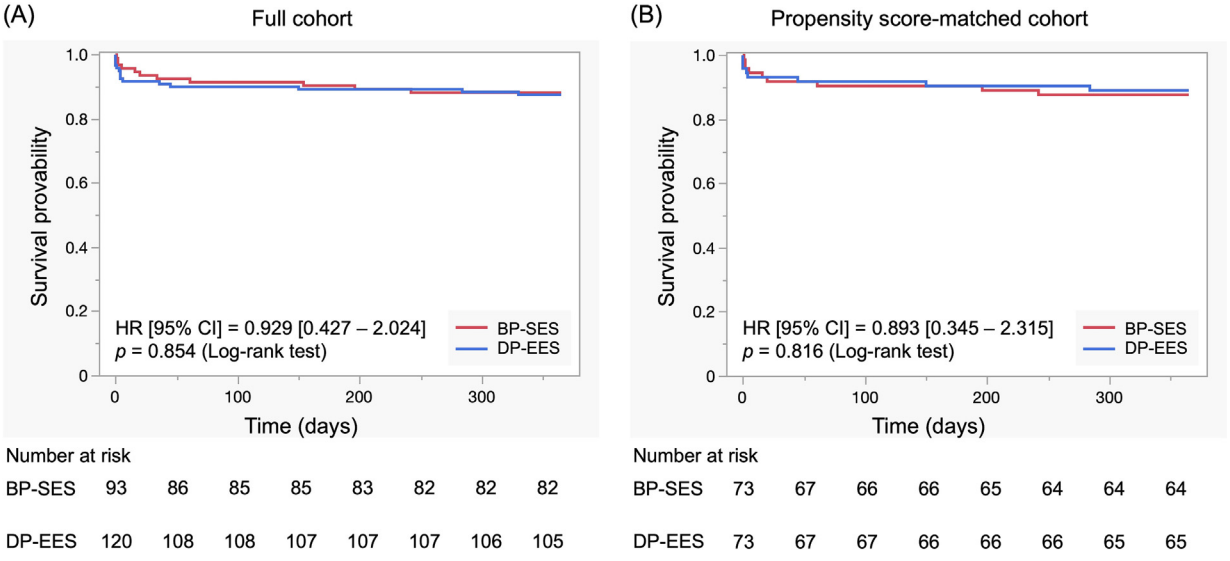

Fig. 2. (A) Kaplan–Meier curves for 1-year survival free from the primary endpoint in the BP-SES and DP-EES groups in the full cohort. (B) Kaplan–Meier curves for 1-year survival free from the primary endpoint in the BP-SES and DP-EES groups in the propensity score-matched cohort.
BP-SES, biodegradable polymer sirolimus-eluting stent; CI, confidence interval; DP-EES, durable polymer everolimus-eluting stents; HR, hazard ratio.

Table 4
Univariate and multivariable analyses of the 1-year primary endpoint in the propensity score-matched cohort.

	Univariate analysis OR (95% CI)	*p*-value	Multivariate analysis OR (95% CI)	*p*-value
Male gender	0.572 (0.197–1.581)	0.282	–	–
Hypertension	0.806 (0.235–3.731)	0.756	–	–
Dyslipidemia	0.904 (0.326–2.634)	0.848	–	–
Diabetes mellitus	1.275 (0.452–3.543)	0.640	–	–
Smoking	0.998 (0.300–2.894)	0.997	–	–
ACEI/ARB at discharge	0.298 (0.104–0.861)	0.026	0.229 (0.057–0.858)	0.029
Statin at discharge	0.377 (0.129–1.191)	0.094	0.480 (0.130–1.880)	0.282
CKD[a]	1.645 (0.589–5.021)	0.347		
ACS	3.623 (1.209–13.399)	0.021	3.478 (1.019–14.190)	0.047
Stent diameter (mm)	1.283 (0.106–14.184)	0.841	–	–
Stent length (mm)	0.701 (0.073–5.745)	0.746	–	–
Bifurcation lesion	1.450 (0.496–4.045)	0.485	–	–
Angiographic calcification	1.659 (0.586–4.632)	0.333	–	–
Angiographic success	0.159 (0.040–0.685)	0.016	0.058 (0.008–0.347)	0.002
RA approach	0.292 (0.092–1.025)	0.054	0.486 (0.119–2.239)	0.340
Type of stent (BP-SES or DP-EES)	0.875 (0.310–2.427)	0.796	–	–

ACEI, angiotensin-converting enzyme inhibitor; ACS, acute coronary syndrome, ARB, angiotensin II type 1 receptor blocker; BP-SES, bioresorbable polymer sirolimus-eluting stent; CI, confidence interval; CKD, chronic kidney disease; DP-EES, durable polymer everolimus-eluting stents; OR, odds ratio; RA, radial artery.
[a] Estimated glomerular filtration rate < 60 mL/min/1.73 m^2.

Univariate logistic regression analysis showed that ACEI/ARB and statin use at discharge, ACS, and angiographic success were associated with the 1-year primary endpoint (Table 4 shows ORs and 95% CIs). In the multivariable logistic regression analysis, ACS (OR, 3.478; 95% CI, 1.019–14.190; $p = 0.047$) was independently associated with a higher incidence of the 1-year primary endpoint, whereas angiographic success (OR, 0.058; 95% CI, 0.008–0.347; $p = 0.002$) and ACEI/ARB use at discharge (OR, 0.229; 95% CI, 0.057–0.858; $p = 0.029$) were independently associated with a lower incidence (Table 4).

Discussion

In the present study, clinical outcomes after PCI with BP-SES were generally consistent with those after DP-EES in patients aged ≥80 years, without a clinically meaningful increase in bleeding complications. In addition, the incidence of ST was low and similar in both groups. These results suggest that PCI with BP-SES may be a safe and feasible option for patients aged ≥80 years with coronary artery disease.

In patients undergoing PCI, age is an important predictor of adverse cardiac events [20]. A previous study has demonstrated that the beneficial effect of DP-EES over BMS in terms of MI and TVR, can be applied to patients aged ≥80 years, without increased risk of bleeding or ST [11]. It has also been reported that the 1-year safety and efficacy outcomes of DP-EES in patients aged ≥80 years were comparable to younger populations [12]. In the BIOFLOW trials, BP-SES provided similar clinical outcomes and was non-inferior to DP-EES [13,14]. However, data on safety and efficacy of BP-SES compared with DP-EES in patients aged ≥80 years are limited. In this study, although most baseline characteristics were similar between the two groups, there were some clinical differences, including a higher prevalence of smoking and ACS in the DP-EES group. To minimize the influence of these confounders, we performed propensity score matching. In the propensity score-matched cohort, clinical outcomes after BP-SES were generally consistent with those after DP-EES in our study population aged ≥80 years. There was a trend towards in-hospital all-cause death in both groups compared with younger generations. This may be because the present study was conducted in patients older than 80 years, and heart failure treatment was often unsuccessful in ACS. Another possible explanation is that several deaths from non-cardiac causes, including aspiration pneumonia, were observed. Patients aged ≥80 years generally have a higher burden of comorbidities than younger patients, which may have contributed to these events. In the XIMA trial [11], which enrolled patients aged ≥80 years, the incidence of all-cause death within 1 month was 1.2–1.5% and cardiac death was 0.5–0.7%. This discrepancy might be explained by the patients with STEMI being included (more than 30% of all) in this study and resulting in higher in-hospital mortality. Furthermore, the higher proportion of ACS patients in the DP-EES group than in the BP-SES group may have contributed to the higher rates of ACEI/ARB and statin use at discharge. In addition, when these variables were included in the multivariable analysis after propensity score matching, ACEI/ARB use was associated with the 1-year primary endpoint. This may be partly attributable to the prognostic benefit of ACEI/ARB therapy in patients with hypertension [21], which was highly prevalent in our cohort.

CKD is strongly associated with cardiovascular risk factors such as hypertension and diabetes mellitus, and these cause and contribute to CKD [22]. CKD has been reported to predict major adverse cardiac events after MI [23]. Consequently, even in the contemporary era in which PCI and optimal medical therapy are widely implemented, CKD remains an important predictor of major cardiovascular events after acute MI. In the present elderly cohort, however, CKD was not a statistically significant predictor of the 1-year primary endpoint. Whereas the previous report consisted exclusively of patients with acute MI, our study included patients with stable angina as well as ACS aged ≥80 years. Moreover, in this elderly cohort, more than half of the patients in both groups had CKD, and most had moderate CKD. These factors may explain why CKD was not associated with the primary endpoint in this study. The trans radial approach for patients undergoing PCI is usually adopted in clinical practice. It has been reported that patients aged ≥80 years undergoing transradial intervention are less likely to have major post-PCI bleeding than those undergoing transfemoral intervention, without an increased incidence of major adverse cardiac events (a composite of cardiac death, MI, and TVR) at both hospitalization and 1 year [24]. In this study, bleeding events occurred in approximately 5% of patients in each group, and the RA approach tended to be associated with a lower incidence of the primary endpoint at 1 year. These findings suggest that, particularly in elderly patients, an RA-based PCI approach may be preferable whenever feasible. And pre-PCI upper arm prolonged occlusion should be considered, as it could be a feasible procedure for patients with a narrow RA or weak RA pulsation [25].

Recent comparative studies have shown the superiority of the ultra-thin strut DES over other DES of conventional design [15]. One of the advantages of BP-SES is that it has a higher strut coverage rate and thinner neointima than DP-EES, as reported in a previous study using optical coherence tomography [26]. This may explain why BP-SES can shorten the DAPT duration and be easier to use in elderly patients at high bleeding risk. However, whether the benefits observed with this specific BP-SES are isolated to a specific design feature or are multifactorial remains uncertain. In other words, not only ultra-thin struts but also biodegradable

polymers could be a factor; however, further large investigations are required in the future. Furthermore, beyond ultra-thin struts and biodegradable polymers, magnesium-based bioresorbable metal scaffolds—which are almost fully resorbed within 12 months [27]—may offer potential advantages for elderly patients at high bleeding risk. However, clinical evidence in humans remains limited, and current materials do not fully meet ideal requirements. Therefore, future research is warranted to focus on developing bioresorbable metallic stents with improved performance characteristics to better address clinical needs [28].

Study limitations

Several potential limitations of this study should be noted. First, since this is a retrospective study involving a small number of patients aged ≥80 years treated with BP-SES or DP-EES, there is a potential selection bias for this study. Second, the follow-up period was 1 year, and long-term outcomes beyond 1 year remain unknown; thus, further studies should be conducted in the future. However, because the target population comprises patients aged ≥80 years, careful consideration should be given to appropriate long-term prognostic endpoints (e.g. healthy life expectancy). Third, because there were only 26 primary events in total and few secondary outcome events, the validity of the statistical comparisons was limited. Finally, DP-EES was used more frequently in patients with ACS, which may reflect operator-driven stent selection and could have introduced potential selection bias. Therefore, large-scale randomized trials are needed in the future to achieve definitive conclusions.

Conclusion

Based on our results, in patients aged ≥80 years, 1-year clinical outcomes after PCI with BP-SES were generally consistent with those with DP-EES. However, larger, well-designed studies in elderly populations are warranted to compare the safety and efficacy outcomes.

Funding

None.

Declaration of competing interest

All authors have no conflict of interest to declare.

Acknowledgments

This research was supported in part by the Japan Society for the Promotion of Science KAKENHI Grant Number 22K08163 (Grant-in-Aid for Scientific Research C).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jjcc.2026.03.015.

References

[1] Johnman C, Oldroyd KG, Mackay DF, Slack R, Pell AC, Flapan AD, et al. Percutaneous coronary intervention in the elderly: changes in case-mix and periprocedural outcomes in 31,758 patients treated between 2000 and 2007. Circ Cardiovasc Interv 2010;3:341–5.
[2] Ohira T, Eguchi E, Hayashi F, Kinuta M, Imano H. Epidemiology of cardiovascular disease in Japan: an overview study. J Cardiol 2024;83:191–200.
[3] Stefanini GG, Kalesan B, Serruys PW, Heg D, Buszman P, Linke A, et al. Long-term clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with coronary artery disease (LEADERS): 4 year follow-up of a randomised non-inferiority trial. Lancet 2011; 378:1940–8.
[4] Raber L, Magro M, Stefanini GG, Kalesan B, van Domburg RT, Onuma Y, et al. Very late coronary stent thrombosis of a newer-generation everolimus-eluting stent compared with early-generation drug-eluting stents: a prospective cohort study. Circulation 2012;125:1110–21.
[5] Palmerini T, Biondi-Zoccai G, Della Riva D, Stettler C, Sangiorgi D, D'Ascenzo F, et al. Stent thrombosis with drug-eluting and bare-metal stents: evidence from a comprehensive network meta-analysis. Lancet 2012;379:1393–402.
[6] Stefanini GG, Holmes Jr DR. Drug-eluting coronary-artery stents. N Engl J Med 2013; 368:254–65.
[7] Palmerini T, Biondi-Zoccai G, Della Riva D, Mariani A, Sabate M, Valgimigli M, et al. Clinical outcomes with drug-eluting and bare-metal stents in patients with ST-segment elevation myocardial infarction: evidence from a comprehensive network meta-analysis. J Am Coll Cardiol 2013;62:496–504.
[8] Valgimigli M, Sabate M, Kaiser C, Brugaletta S, de la Torre Hernandez JM, Galatius S, et al. Effects of cobalt-chromium everolimus eluting stents or bare metal stent on fatal and non-fatal cardiovascular events: patient level meta-analysis. BMJ 2014; 349:g6427.
[9] Palmerini T, Benedetto U, Biondi-Zoccai G, Della Riva D, Bacchi-Reggiani L, Smits PC, et al. Long-term safety of drug-eluting and bare-metal stents: evidence from a comprehensive network meta-analysis. J Am Coll Cardiol 2015;65:2496–507.
[10] Brugaletta S, Gomez-Lara J, Ortega-Paz L, Jimenez-Diaz V, Jimenez M, Jimenez-Quevedo P, et al. 10-Year follow-up of patients with everolimus-eluting versus bare-metal stents after ST-segment elevation myocardial infarction. J Am Coll Cardiol 2021;77:1165–78.
[11] de Belder A, de la Torre Hernandez JM, Lopez-Palop R, O'Kane P, Hernandez Hernandez F, Strange J, et al. A prospective randomized trial of everolimus-eluting stents versus bare-metal stents in octogenarians: the XIMA Trial (Xience or Vision Stents for the Management of Angina in the Elderly). J Am Coll Cardiol 2014;63: 1371–5.
[12] Kitabata H, Kubo T, Mori K, Yamamoto Y, Kashiwagi M, Arita Y, et al. Safety and efficacy outcomes of second-generation everolimus-eluting stents in octogenarians compared to non-octogenarians. Cardiovasc Revasc Med 2018;19:12–6.
[13] Windecker S, Haude M, Neumann FJ, Stangl K, Witzenbichler B, Slagboom T, et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: results of the randomized BIOFLOW-II trial. Circ Cardiovasc Interv 2015;8:e001441.
[14] Saito S, Toelg R, Witzenbichler B, Haude M, Masotti M, Salmeron R, et al. BIOFLOW-IV, a randomised, intercontinental, multicentre study to assess the safety and effectiveness of the Orsiro sirolimus-eluting stent in the treatment of subjects with de novo coronary artery lesions: primary outcome target vessel failure at 12 months. EuroIntervention 2019;15:e1006–13.
[15] Kandzari DE, Koolen JJ, Doros G, Garcia-Garcia HM, Bennett J, Roguin A, et al. Ultra-thin bioresorbable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents: BIOFLOW V final 5-year outcomes. JACC Cardiovasc Interv 2022; 15:1852–60.
[16] Nakamura M, Kimura K, Kimura T, Ishihara M, Otsuka F, Kozuma K, et al. JCS 2020 guideline focused update on antithrombotic therapy in patients with coronary artery disease. Circ J 2020;84:831–65.
[17] Thygesen K, Alpert JS, Jaffe AS, Chaitman BR, Bax JJ, Morrow DA, et al. Fourth universal definition of myocardial infarction (2018). J Am Coll Cardiol 2018;72:2231–64.
[18] Cutlip DE, Windecker S, Mehran R, Boam A, Cohen DJ, van Es GA, et al. Clinical end points in coronary stent trials: a case for standardized definitions. Circulation 2007;115:2344–51.
[19] Mehran R, Rao SV, Bhatt DL, Gibson CM, Caixeta A, Eikelboom J, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. Circulation 2011;123:2736–47.
[20] Floyd KC, Jayne JE, Kaplan AV, Friedman BJ, Niles NW, Hettleman BD, et al. Age-based differences of percutaneous coronary intervention in the drug-eluting stent era. J Interv Cardiol 2006;19:381–7.
[21] van Vark LC, Bertrand M, Akkerhuis KM, Brugts JJ, Fox K, Mourad JJ, et al. Angiotensin-converting enzyme inhibitors reduce mortality in hypertension: a meta-analysis of randomized clinical trials of renin-angiotensin-aldosterone system inhibitors involving 158,998 patients. Eur Heart J 2012;33:2088–97.
[22] Sarnak MJ, Amann K, Bangalore S, Cavalcante JL, Charytan DM, Craig JC, et al. Chronic kidney disease and coronary artery disease: JACC state-of-the-art review. J Am Coll Cardiol 2019;74:1823–38.
[23] Hashimoto Y, Ozaki Y, Kan S, Nakao K, Kimura K, Ako J, et al. Impact of chronic kidney disease on in-hospital and 3-year clinical outcomes in patients with acute myocardial infarction treated by contemporary percutaneous coronary intervention and optimal medical therapy - insights from the J-MINUET study. Circ J 2021;85:1710–8.
[24] Xu Y, Jin C, Qiao S, Wu Y, Yan H, Dou K, et al. A propensity score matching analysis of transradial versus transfemoral approaches in octogenarians undergoing percutaneous coronary intervention. Acta Cardiol Sin 2019;35:301–7.
[25] Taniguchi M, Ozaki Y, Katayama Y, Satogami K, Ino Y, Tanaka A. Impact of upper arm prolonged occlusion on radial artery diameter before coronary angiography in patients with coronary artery disease. Cardiovasc Revasc Med 2023;51:38–42.
[26] Kawamura A, Egami Y, Kawanami S, Sugae H, Ukita K, Nakamura H, et al. Preferable vascular healing of ultrathin strut biodegradable-polymer sirolimus-eluting stents in patients with acute coronary syndrome. Cardiovasc Interv Ther 2022;37:681–90.
[27] Ozaki Y, Garcia-Garcia HM, Hideo-Kajita A, Kuku KO, Haude M, Ince H, et al. Impact of procedural characteristics on coronary vessel wall healing following implantation of second-generation drug-eluting absorbable metal scaffold in patients with de novo coronary artery lesions: an optical coherence tomography analysis. Eur Heart J Cardiovasc Imaging 2019;20:916–24.
[28] Zhang J, Chen Z, Rao L, He Y. Coronary bioresorbable metallic stents: advancements and future perspectives. J Cardiol 2025;85:69–78.