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Durable versus biodegradable polymer drug-eluting stents in all-comers

Thierry Witzig, Serban Puricel, Alain Witzig, Pascal Meier, Diego Arroyo, Mario Togni, Stéphane Cook

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Cardiology, University & Hospital Fribourg, Fribourg, Switzerland

Correspondence to
Professor Stéphane Cook;
stephane.cook@unifr.ch

ABSTRACT

Background Drug-eluting stents (DESs) have become the gold standard of coronary angioplasty since their inception in 2002. Biodegradable polymer DESs (BP-DESs) have been postulated to be superior to durable polymer DESs (DP-DESs) due to their more biocompatible polymer. To date, no study has shown the superiority of one type of polymer compared with the other. We aimed to compare outcomes between a broad range of second-generation DP-DES and BP-DES in an all-comer population.

Methods We analysed data from 2824 patients who underwent percutaneous coronary intervention (PCI) with BP-DES or DP-DES in the Cardio-FR database. Of these, 2079 (1286 DP-DES and 793 BP-DES) met the inclusion and exclusion criteria and completed a 2-year follow-up: The primary outcome was the device-oriented composite endpoint (DOCE) of cardiac death, non-fatal target vessel myocardial infarction and target lesion revascularisation.

Results Mean age was 67 years, with 75% male. Despite the DP-DES group exhibiting significantly higher rates of risk factors, such as arterial hypertension (63.1% vs 57.5%, p=0.010), a greater average number of stents implanted per patient (1.72±0.92 vs 1.63±0.84, p=0.040), more acute coronary syndrome (ACS) (55.1% vs 50.2%, p=0.031) and a higher rate of post-dilatation (42.2% vs 35.2%, p<0.001), the rate of acute stent thrombosis (ST) was significantly lower than in the BP-DES group (HR 0.240, 95% CI 0.075 to 0.766; p=0.016). This difference remained significant even after adjusting for covariates using a Cox proportional hazards model and performing a win ratio analysis (4.09, 95% CI 1.28 to 13.09; p=0.018). Despite this increased rate of acute ST, there was no difference in DOCE (12.1% vs 14.5%, OR 1.218, 95% CI 0.926 to 1.600; p=0.158) between the two groups up to 2 years.

Conclusion Clinical follow-up up to 2 years shows similar outcomes between BP-DES and DP-DES. The rate of acute ST is higher in patients with BP-DES.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Biodegradable polymer drug-eluting stents (BP-DESs) were developed to improve long-term safety over durable polymer DESs (DP-DESs), but their clinical advantage remains debated.

WHAT THIS STUDY ADDS

⇒ BP-DES and DP-DES showed similar 2-year clinical outcomes, but BP-DES had a higher risk of acute stent thrombosis.

⇒ The benefits of BP-DES may be stent-specific rather than due to polymer degradation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Stent selection should be based on patient-specific factors, not polymer type alone. The increased early thrombosis risk with BP-DES warrants further research into stent design and thrombogenicity.

INTRODUCTION

Drug-eluting stents (DESs) have become the gold standard for percutaneous coronary intervention (PCI) since their inception in 2002. They have demonstrated their superiority by significantly reducing major adverse cardiac events (MACE), mainly revascularisation rates compared with bare metal stents.[1 2] However, the polymer coating on DES, which delivers growth-inhibiting drugs, may trigger hypersensitivity reactions leading to neoatherosclerosis and late stent thrombosis (ST).[3 4] Because the polymers on biodegradable polymers DES (BP-DES) are degraded in a few months, it was thought that they might outperform traditional first-generation durable polymer DES (DP-DES). However, second-generation DP-DESs have been improved by incorporating more biocompatible polymers and thinner strut design. These developments have contributed to a substantial decrease in the rates of MACEs, ST and the need for revascularisation.[2 5] Thus, while BP-DESs have shown signs of superiority to the first-generation DP-DESs, this remains to be demonstrated when compared with second-generation DP-DESs.[6 7]

This study aims to compare outcomes between a broad range of second-generation DP-DES and BP-DES in an all-comer population to assess the similarity of outcomes between the two types of devices in a real-world setting.

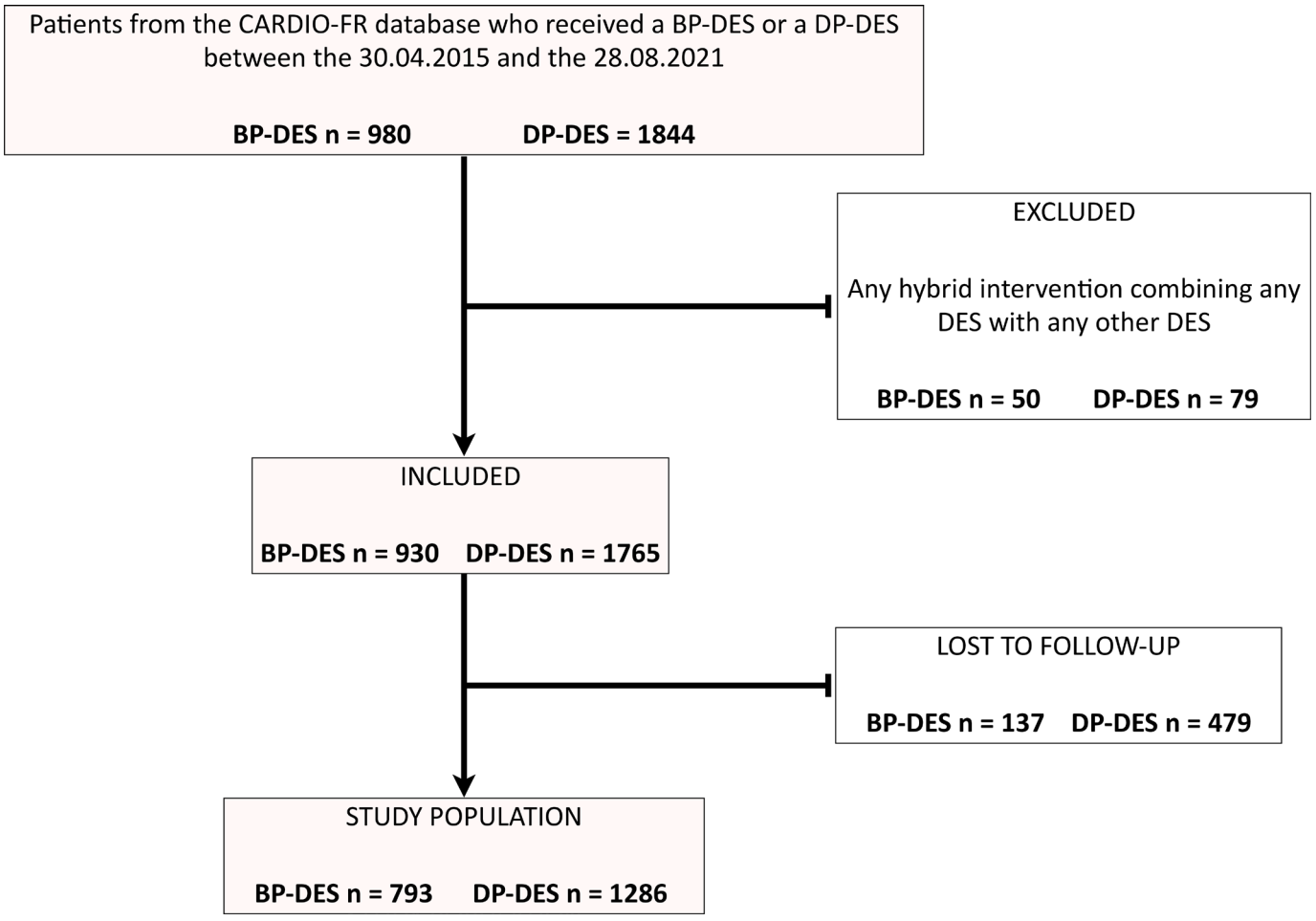

Figure 1 Flowchart presenting the selection process. BP-DES, biodegradable polymer drug-eluting stent; DES, drug-eluting stent; DP-DES, durable polymer drug-eluting stent.

METHODS

Study population

The Cardio-FR registry at the University and Hospital Fribourg includes all patients aged 18+ admitted for PCI who provided written informed consent. It collects data on baseline characteristics, procedural details, in-hospital outcomes and annual clinical follow-ups via phone. The registry has been previously described.[8 9] Briefly, stent allocation is randomised using a preset distribution key based on the annual calendar. We included all patients undergoing PCI with second-generation DP-DES or BP-DES from May 2015 to August 2021, with a completed 2-year follow-up. Exclusion criteria were lack of consent, loss to follow-up or hybrid procedures involving different DES types.

The registry complies with the Helsinki Declaration and was approved by the local ethics committee (003-REP-CER-FR) and registered in ClinicalTrials.gov (NCT04185285).

PCIs and medications

Procedures were performed via femoral or radial artery with a 6 French guiding catheter using standard techniques per guidelines. Intravascular imaging was at the operator's discretion. Preprocedural antithrombotic therapy included aspirin (250–500 mg IV bolus if not pretreated, 100 mg/day thereafter) and unfractionated heparin (70 UI/kg); cangrelor and tirofiban were used at operator discretion. All patients received a loading dose of 600 mg clopidogrel, 180 mg ticagrelor or 60 mg prasugrel preprocedure or postprocedure. Long-term antiplatelet therapy included aspirin ≥100 mg/day plus either clopidogrel 75 mg, ticagrelor 90 mg two times per day or prasugrel 10 mg for at least 3 months. In patients on oral anticoagulation, aspirin 100 mg was given for at least a week and clopidogrel 75 mg daily for 6 months. Other medications followed standard care. Patients were monitored for 4–12 hours in intermediate care and underwent biomarker and ECG assessments preprocedure and postprocedure.

Study endpoints

The primary endpoint was device-oriented composite endpoint (DOCE), including cardiac death, non-fatal target vessel myocardial infarction (TVMI) and target lesion revascularisation (TLR). Secondary endpoints included patient-oriented composite endpoint (POCE), individual primary endpoints, all-cause mortality and ST incidence. Endpoints followed the Academic Research Consortium-2 (ARC-2) criteria.[10] Death was cardiac if

Table 1 Baseline patient, lesion and procedural characteristics

Patient characteristics	BP-DES n=793	DP-DES n=1286	P value
Age, mean±SD	67.7±11.7	67.3±11.7	0.441
Male, n (%)	597 (75.3)	963 (74.9)	0.838
Body mass index, mean±SD	27.3±4.9	27.4±4.6	0.625
Diabetes mellitus, n (%)	182 (23.0)	289 (22.5)	0.800
Non-insulin dependent, n (%)	135 (17.0)	197 (15.3)	0.303
Insulin dependent, n (%)	47 (5.9)	92 (7.2)	0.277
Arterial hypertension, n (%)	456 (57.5)	812 (63.1)	0.010
Current smoker, n (%)	198 (25.0)	349 (27.1)	0.275
Family history, n (%)	171 (21.6)	241 (18.7)	0.117
Renal insufficiency, n (%)	257 (32.4)	384 (29.9)	0.345
Previous MI, n (%)	115 (14.5)	174 (13.5)	0.534
Previous PCI, n (%)	237 (29.9)	336 (26.1)	0.062
Previous CABG, n (%)	75 (9.5)	114 (8.9)	0.648
Multivessel PCI, n (%)	86 (10.8)	140 (10.9)	0.976
ACS, n (%)	398 (50.2)	708 (55.1)	0.031
CCS, n (%)	376 (47.4)	549 (42.7)	0.035
Staged PCI, n (%)	19 (2.4)	29 (2.3)	0.835
Number of vessels treated per patient, mean±SD	1.13±0.36	1.13±0.35	0.463
Number of lesions treated per patient, mean±SD	1.39±0.69	1.43±0.68	0.062
One lesion, n (%)	558 (70.4)	849 (66.0)	0.040
Two lesions, n (%)	175 (22.1)	341 (26.5)	0.023
Three lesions, n (%)	50 (6.3)	79 (6.1)	0.882
Four and more lesions, n (%)	10 (1.3)	17 (1.3)	0.905
Lesion and procedural characteristics	n=1102	n=1838	
Target vessel			
Left main, n (%)	21 (2.6)	43 (3.3)	0.372
Left anterior descending artery, n (%)	488 (61.5)	783 (60.9)	0.767
Left circumflex, n (%)	225 (28.4)	378 (29.4)	0.619
Right coronary artery, n (%)	349 (44.0)	600 (46.7)	0.239
Saphenous vein graft, n (%)	18 (2.2)	32 (2.5)	0.752
Internal mammary artery, n (%)	1 (0.1)	2 (0.2)	0.863
Number of stents per patient, mean±SD	1.63±0.84	1.72±0.92	0.040
Maximum stent diameter per lesion, mm±SD	2.97±0.49	3.00±0.54	0.495
Total stent length per lesion, mm±SD	22.27±11.51	23.10±12.70	0.501
Maximal inflation pressure, atm±SD	14.74±3.51	14.30±3.20	0.003
Bifurcation treatment, n (%)	179 (16.2)	341 (18.6)	0.112
Predilatation, n (%)	883 (80.1)	1408 (76.6)	0.026
Post dilatation, n (%)	388 (35.2)	775 (42.2)	<0.001
Shockwave, n (%)	1 (0.1)	9 (0.5)	0.072

Continued

Table 1 Continued

Patient characteristics	BP-DES n=793	DP-DES n=1286	P value

ACS, acute coronary syndrome; CABG, coronary artery bypass graft; CCS, chronic coronary syndrome; MI, myocardial infarction; PCI, percutaneous coronary intervention.

the cause was evident, unwitnessed or unknown. TLR was defined as repeat revascularisation within the stent or 5 mm proximal/distal. Target-vessel revascularisation was any revascularisation in the stented vessel, considered ischaemia-driven if associated with a positive functional study, stenosis ≥50% with ischaemic symptoms or stenosis ≥70% regardless of symptoms. Myocardial infarction (MI) was defined as new pathological Q waves (≥0.04 s in ≥2 contiguous leads) or creatine phosphokinase elevation >2× normal with specific elevation of myocardial enzymes, such as the CK-MB isoenzyme or troponin I.

ST was definite with angiographic thrombus confirmation and ischaemic signs or creatine kinase elevation >2× normal within 48 hours. Probable ST included unexplained death within 30 days or MI in the target vessel area without angiographic confirmation. Possible ST included unexplained death beyond 30 days. ST was classified as acute (<24 hours), subacute (24 hours–30 days), late (30 days–1 year) and very late (>1 year).

Statistical analysis

Categorical variables are reported as counts and percentages while continuous variables are reported as mean and SD. Normality was assessed by the computation of Q-Q plots and the Shapiro-Wilk test. Continuous variables were analysed using the Student's t-test or the Wilcoxon rank-sum test per distribution. Categorical variables were compared using the χ^2 or Fisher exact test as appropriate. Survival data were analysed with the log-rank test. The proportional hazard condition was assessed with Kaplan Meier plots as well as ln/ln curves. Primary outcomes were also analysed using win ratio and Cox regression or binary logistic regression as appropriate. All statistical analyses except win ratios were performed using SPSS version 29 (SPSS, Chicago, Illinois, USA) at a 2-tailed significance level of alpha=0.05. Win ratios were performed with R V.4.4.1 (R Core Team, Vienna, Austria) using the WinRatio package[11] at a 2-tailed significance level of alpha=0.05.

RESULTS

Population

During the inclusion period, 2824 patients were registered in the Cardio-FR registry. Of these, 2695 met the inclusion and exclusion criteria, but 616 patients were lost to follow-up. Consequently, the study population comprised 2079 patients, divided into two groups: 793 patients in the BP-DES group and 1286 patients in the DP-DES group. The flowchart is shown in figure 1.

Table 2 Studied stent characteristics and patient distribution across groups

Stent name	Polymer type	Coating	Alloy	Strut size (µm)	Drug	Number of patients, per cent of study group
Synergy II	Biodegradable	Abluminal	PtCr	74	Everolimus	561 (70.1)
Orsiro	Biodegradable	Conformal	CoCr	60	Sirolimus	158 (19.9)
Biomatrix Alpha	Biodegradable	Abluminal	CoCr	84	Biolimus	62 (7.8)
Firehawk	Biodegradable	Abluminal	CoCr	86	Sirolimus	6 (0.8)
Supraflex Cruz	Biodegradable	Conformal	CoCr	60	Sirolimus	5 (0.6)
Ultimaster	Biodegradable	Abluminal	CoCr	80	Sirolimus	1 (0.1)
Resolute Onyx	Durable	Conformal	Pt-Ir, Co	81	Zotarolimus	856 (66.2)
Xience Alpine	Durable	Conformal	CoCr	81	Everolimus	265 (20.6)
Xience Sierra	Durable	Conformal	CoCr	81	Everolimus	156 (12.1)
Xience Xpedition	Durable	Conformal	CoCr	81	Everolimus	9 (0.7)

Alloy composition: CoCr is for Cobalt-Chromium; PtCr, for Platinum-Chromium and Pt-Ir/Co, for Platinum-Iridium-Cobalt.

The presentation in terms of acute or chronic coronary syndromes is summarised in online supplemental table S1.

Baseline patient, lesion and procedural characteristics

The DP-DES group exhibited significantly higher rates of arterial hypertension (63.1% vs 57.5%, p=0.010), a greater average number of stents implanted per patient (1.72±0.92 vs 1.63±0.84, p=0.040), a higher proportion of patients with dual lesions (26.5% vs 22.1%, p=0.023) and more frequent use of postdilatation (42.2% vs 35.2%, p<0.001). Conversely, the BP-DES group demonstrated a significantly higher maximal inflation pressure (14.7±3.5 vs 14.3±3.2 ATM, p=0.003), higher rates of predilatation (80.1% vs 76.6%, p=0.026) and a numerical, though not statistically significant, difference in the number of patients who had undergone a previous PCI (29.9% vs 26.1%, p=0.062). The two groups also differed significantly in presentation, with more acute coronary syndrome (ACS) cases (55.1% vs 50.2%, p=0.031) in the DP-DES group and more chronic coronary syndrome cases (47.4% vs 42.7%, p=0.035) in the BP-DES group (table 1).

Studied stent characteristics

Table 2 presents the stents included in this study along with their key characteristics. The BP-DES group primarily comprised the Synergy II BP-DES (70.1%), whereas the DP-DES group mainly consisted of the Resolute Onyx DP-DES (66.2%).

Clinical outcomes

Table 3 and figure 2 illustrate clinical outcomes at 1-month, 1-year, and 2-year follow-up. At 1 month, treatment with BP-DES was associated with significantly higher rates of MI (7.6% vs 5.0%, p=0.015), a greater need for ischaemia-driven revascularisation (3.7% vs 2.0%, p=0.024) and a higher incidence of definite/probable ST (1.8% vs 0.8%, p=0.040). However, these differences were no longer observed at longer follow-up, and the occurrence of all events was similar between the two groups up to 2 years: the overall DOCE rate was comparable between the BP-DES and DP-DES groups (12.1% vs 14.5%, p=0.132), as was the incidence of TLR (6.3% vs 7.7%, p=0.238).

A subanalysis of the timing of ST revealed a notably higher incidence of acute ST in the BP-DES group (1.3% vs 0.3%, p=0.010) online supplemental table S2. The antiplatelet status, lesion and patient characteristics, as well as the use of intravascular imaging were similar between groups.

Multivariate analyses to adjust for potential confounders were also conducted. A Cox regression confirmed the significantly higher rate of acute ST (HR 0.240, 95% CI 0.075 to 0.766; p=0.016) in the BP-DES group but a similar rate of ST (HR 0.520, 95% CI 0.259 to 1.043; p=0.065) between the two groups at 2-year follow-up. Similarly, a binary logistic regression corroborated the comparable incidence of DOCE (OR 1.218, 95% CI 0.926 to 1.600; p=0.158) and POCE (OR 1.043, 95% CI 0.855 to 1.274; p=0.677) between the two groups at 2-year follow-up(online supplemental table S3).

Finally, an exploratory win ratio analysis was performed, further supporting the higher rate of acute ST (win ratio 4.09, 95% CI 1.28 to 13.09; p=0.018) in the BP-DES group, while showing a similar incidence of ST (win ratio 1.86, 95% CI 0.93 to 3.73; p=0.081) between the two groups at 2-year follow-up.

DISCUSSION

In this registry-based study, we observed no significant differences in clinical outcomes between the two groups after 2 years. There was, however, an increased rate of acute ST in the BP-DES group.

The overall event rates reported in this study were comparable to those of similar studies that included an all-comer population and a real-world setting approach, such as those by Zanchin *et al*[12] or the BIOSCIENCE (A

Table 3 Clinical outcomes

1-month follow-up	BP-DES n=793	DP-DES n=1286	P value
DOCE, n (%)	31 (3.9)	50 (3.9)	0.981
Cardiac death, n (%)	13 (1.6)	31 (2.4)	0.235
TVMI, n (%)	13 (1.6)	17 (1.3)	0.555
TLR, n (%)	15 (1.9)	16 (1.2)	0.237
POCE, n (%)	92 (11.6)	118 (9.2)	0.073
Death, n (%)	16 (2.0)	38 (3.0)	0.191
MI, n (%)	60 (7.6)	64 (5.0)	0.015
Ischaemia-driven revascularisation, n (%)	29 (3.7)	26 (2.0)	0.024
Stroke, n (%)	4 (0.5)	11 (0.9)	0.359
Definite/probable ST, n (%)	14 (1.8)	10 (0.8)	0.040
1-year follow-up			
DOCE, n (%)	64 (8.1)	119 (9.3)	0.357
Cardiac death, n (%)	28 (3.5)	55 (4.3)	0.394
TVMI, n (%)	18 (2.3)	32 (2.5)	0.756
TLR, n (%)	32 (4.0)	59 (4.6)	0.554
POCE, n (%)	163 (20.6)	265 (20.6)	0.938
Death, n (%)	36 (4.5)	80 (6.2)	0.103
MI, n (%)	75 (9.5)	101 (7.9)	0.191
Ischaemia-driven revascularisation, n (%)	73 (9.2)	125 (9.7)	0.729
Stroke, n (%)	17 (2.1)	17 (1.3)	0.153
Definite/probable ST, n (%)	15 (1.9)	12 (0.9)	0.060
2-year follow-up			
DOCE, n (%)	96 (12.1)	186 (14.5)	0.132
Cardiac death, n (%)	42 (5.3)	79 (6.1)	0.416
TVMI, n (%)	22 (2.8)	47 (3.7)	0.282
TLR, n (%)	50 (6.3)	99 (7.7)	0.238
POCE, n (%)	235 (29.6)	389 (30.2)	0.832
Death, n (%)	61 (7.7)	127 (9.9)	0.088
MI, n (%)	87 (11.0)	130 (10.1)	0.500
Ischaemia-driven revascularisation, n (%)	113 (14.2)	200 (15.6)	0.446
Stroke, n (%)	28 (3.5)	30 (2.3)	0.107
Definite/probable ST, n (%)	17 (2.1)	15 (1.2)	0.078

BP-DES, biodegradable polymer drug-eluting stent; DOCE, device-oriented composite endpoint; DP-DES, durable polymer drug-eluting stent; MI, myocardial infarction; POCE, patient-oriented composite endpoint; ST, stent thrombosis; TLR, target lesion revascularisation; TVMI, target vessel myocardial infarction.

Randomized Comparison of a Sirolimus-eluting Stent With Biodegradable Polymer Versus an Everolimus-eluting Stent With a Durable Polymer for Percutaneous Coronary Revascularization)[13] randomised controlled trial (RCT). However, they remained higher than in the registry-based study by De Araujo and colleagues,[14] which applied propensity score matching to select a population with more favourable risk factors.

No net clinical benefit of BP-DES over DP-DES

This study found no significant difference in cumulative endpoints between the two groups. The BP-DES cohort consisted of 70% Synergy II, 20% Orsiro and 8% Biomatrix Alpha. This distribution may have influenced the results, as the most favourable studies supporting BP-DES over DP-DES were conducted with Orsiro.

Indeed, large-scale RCTs with 5-year follow-ups, such as BIOSCIENCE (A Randomized Comparison of a Sirolimus-eluting Stent With Biodegradable Polymer Versus an Everolimus-eluting Stent With a Durable Polymer for Percutaneous Coronary Revascularization),[13] BIO-RESORT (Comparison of Biodegradable Polymer and Durable Polymer Drug-Eluting Stents in an All Comers Population),[15] and COMPARE II (Abluminal biodegradable polymer biolimus-eluting stent versus durable polymer everolimus-eluting stent),[16] have shown no significant differences between BP-DES and DP-DES. Similarly, the HOST REDUCE POLYTECH ACS RCT (Harmonizing Optimal Strategy for Treatment of coronary artery diseases–comparison of REDUCtion of prasugrEl dose or POLYmer TECHnology in ACS patients)[17] reported comparable patient-oriented outcomes between DP-DES and BP-DES after 3 years in an ACS population. However, treatment with BP-DES was associated with a higher risk of device-oriented endpoints (HR 0.73, 95% CI 0.57 to 0.95; p=0.020), primarily due to an increased rate of TLR. This heightened risk was attributed to polymer degradation, as the higher incidence of device-oriented endpoints was only observed during the polymer degradation phase (8–16 months).

Conversely, BIOFLOW V (Ultrathin, bioresorbable polymer sirolimus-eluting stents versus thin, durable polymer everolimus-eluting stents in patients undergoing coronary revascularisation)[18] reported significantly lower rates of TVMI (6.6% vs 10.3%, p=0.015) and late/very late ST (0.3% vs 1.6%, p=0.021) in the BP-DES group compared with the Xience DP-DES. Similarly, the BIOSTEMI (Biodegradable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents in patients with ST-segment elevation myocardial infarction)[19] trial also noted a significant reduction in target lesion failure (TLF) in favour of BP-DES versus DP-DES (Δ−3%; RR 0.70, 95% CI 0.51 to 0.95) in patients with acute ST-segment elevation myocardial infarction. Both studies were conducted with the Orsiro BP-DES.

A 2017 meta-analysis by El-Hayek *et al*,[7] including 20 000 patients over 26 months, as well as longer 5-year follow-up meta-analyses by Kobayashi *et al*[20] and Lou *et al*,[21] found no significant differences between BP-DES and DP-DES. However, Zhu *et al*[22] and Monjur *et al*[23] reported a significant reduction in MI risk (RR 0.78, 95% CI 0.62 to 0.98) and TLF risk (OR 0.82, 95% CI 0.69 to 0.98; p=0.037) in the Orsiro BP-DES group. Furthermore, a network meta-analysis by Taglieri *et al*[24] involving 99 039 patients identified the Orsiro BP-DES as potentially the DES with the lowest DOCE after 5 years, while

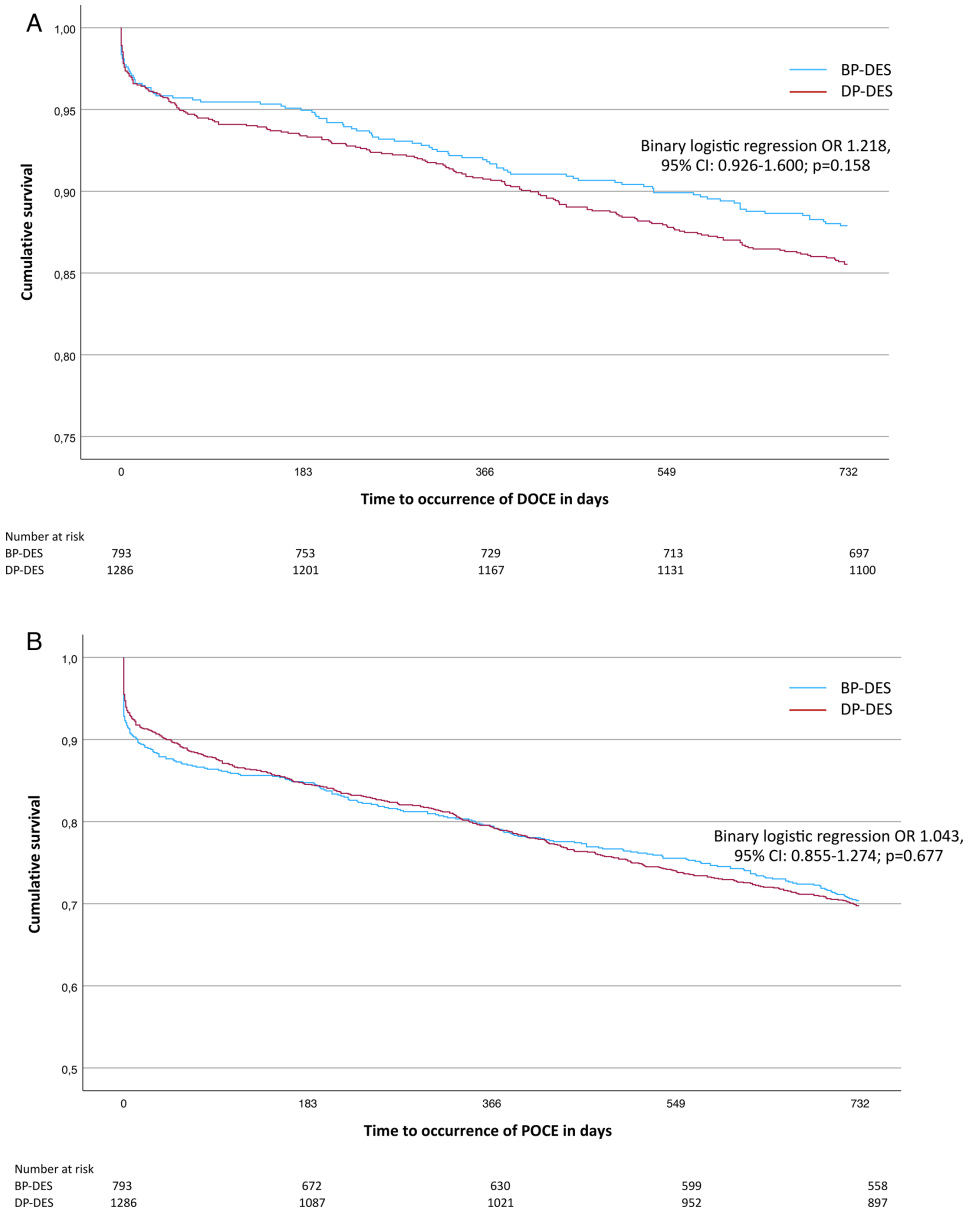

Figure 2 Kaplan-Meier survival free from DOCE (panel A) and POCE (panel B) at 2-year follow-up. BP-DES, biodegradable polymer drug-eluting stent; DOCE, device-oriented composite endpoint; DP-DES, durable polymer drug-eluting stent; POCE, patient-oriented composite endpoint.

reporting no significant differences between other BP-DES and DP-DES.

These findings suggest that the overall benefits of BP-DES may be primarily driven by Orsiro and that the predominance of Synergy II in the BP-DES cohort analysed in this study may have influenced the observed results. However, overall, the differences between the two DES classes remain marginal.

Increased early ST with BP-DES compared with DP-DES

Early ST is influenced by multiple factors, including patient characteristics (eg, diabetes mellitus), clinical setting (eg, ACS), procedural factors (eg, malapposition, malexpansion, stent length) and stent-related properties.[25] The use of BP-DES has been theoretically associated with an increased prothrombotic risk during the polymer resorption phase, due to its proinflammatory properties. Indeed, experimental models have shown that conformal permanent polymer stents exhibit lower platelet accumulation under single antiplatelet therapy compared with abluminal bioabsorbable polymer-coated stents such as Synergy, which was the most commonly used BP-DES in this study.[26 27]

Consistently, despite the DP-DES group having a higher proportion of ACS cases and more stents per patient, the rate of acute ST was lower in the DP-DES group than in the BP-DES group in our study. The literature remains divided on this matter, with some studies reporting higher acute ST rates with BP-DES like the one by Zanchin *et al*[12] (1.2% vs 0.3%; p=0.03) and others reporting higher unspecified ST rates with BP-DES like the MAUDE

registry[28] (10.0% vs 2.6%, p<0.001), while others, like the BIOFLOW V[18] study reported lower late/very late ST rates (0.3% vs 1.6%, p=0.021) with BP-DES or the study from de Araujo and colleagues[14] which reported equal unspecified ST rates between DP-DES and BP-DES (1.4% vs 1.4% p=1.000).

A possible explanation for this discrepancy is the specific stent used. In this registry, the most frequently implanted BP-DES was Synergy II, which may exhibit prothrombotic characteristics compared with other BP-DES, such as Orsiro[18] or Inspiron.[14] Supporting this hypothesis, an analysis of Synergy stent data from the POEM (Performance of Bioresorbable Polymer-Coated Everolimus-Eluting Synergy Stent in Patients at HBR Undergoing Percutaneous Coronary Revascularization Followed by 1-Month Dual Antiplatelet Therapy) trial,[29] which evaluated 1-month dual antiplatelet therapy discontinuation, reported a higher ST rate (0.94%) (14) than comparable DP-DES cohorts (eg, 0.3% in Xience 28).[30] This may be attributable to the proinflammatory degradation of Synergy's polymer or from the more thrombogenic abluminal coating design.[31]

Finally, there is no reason to assume there was any difference in the implantation technique between the two groups in this study, and the statistical analysis revealed comparable antiaggregation status and lesion and patient characteristics in ST patients. It should be noted that STs are not systematically confirmed by intravascular imaging and that this significant difference in acute ST rates could be a chance finding resulting from the number of analyses from this current study. In any case, these findings should be interpreted with caution, as neither the other trials reporting ST rates[12 14 18 28] nor this study were sufficiently powered to detect such rare events effectively.

STUDY LIMITATIONS

This open-label single centre study is based on a registry that uses a non-randomised population. However, stent allocation was determined randomly and prospectively, which helped mitigate methodological biases. Nevertheless, differences in baseline characteristics between the groups persist, and this issue has been rigorously addressed in our analyses to minimise the impact on internal validity.

Moreover, the broad range of DES included in this study may also influence results due to other stent factors than polymer, such as differences in strut thickness, polymer degradation kinetics or antiproliferative drugs. The lack of an independent event adjudication committee also threatens internal validity.

Finally, while the study size is sufficient for the analysis of composite endpoints, it remains limited for detecting rare events, such as ST. Low rates of events also severely restrain multivariate analyses by restricting the number of covariables of the model. As such, the differences observed in the analysis of ST may still reflect a type II error, even if a similar study arrives at the same conclusions. Only meta-analyses and large registries (over 15 000 patients) could specifically address this question.

CONCLUSION

Clinical follow-up up to 2 years for patients treated with BP-DES or DP-DES shows similar outcomes. While the rate of acute ST remains low across both groups, it appears to be slightly higher in patients with BP-DES.

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Ethics approval This study involves human participants and was approved by the Cardio-FR registry complied with the Helsinki Declaration and was approved by the local ethics committee (003-REP-CER-FR). The registry is registered in ClinicalTrials.gov, number NCT04185285. Participants gave informed consent to participate in the study before taking part.

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ORCID iD

Stéphane Cook http://orcid.org/0000-0003-1221-2978

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