One-year performance of thin-strut cobalt chromium sirolimus-eluting stent versus thicker strut stainless steel biolimus-eluting coronary stent: a propensity-matched analysis of two international all-comers registries

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Objectives **Recent improvements in coronary stent design have focussed on thinner struts, different alloys and architecture, more biocompatible polymers, and shorter drug absorption times. This study evaluates safety and efficacy of a newer generation thin-strut cobalt chromium sirolimus-eluting coronary stent (SES, Ultimaster) in comparison with a second-generation thicker strut stainless steel biolimus-eluting stent (BES, Nobori) in percutaneous coronary intervention (PCI) practice.**

Methods **A propensity score analysis was performed to adjust for differences in baseline characteristics of 8137 SES patients and 2738 BES patients of two PCI registries (e-Ultimaster and NOBORI 2). An independent clinical event committee adjudicated all endpoint-related adverse events.**

Results **The use of SES, as compared with BES was associated with a significantly lower rate of myocardial infarction (MI) (1.2% vs 2.2%; *P* = 0.0006) and target vessel-related MI (1.1% vs 1.8%; *P* = 0.002) at 1 year. One-year composite endpoints of all predefined endpoints were lower in patients undergoing SES implantation (target lesion failure: 3.2% vs 4.1%; *P* = 0.03, target vessel failure: 3.7% vs 5.0%; *P* = 0.003, patient-oriented composite endpoint 5.7% vs 6.8%; *P* = 0.03). No significant differences between SES and BES were observed in all-cause death (2.0% vs 1.6%; *P* = 0.19), cardiac death (1.2% vs 1.2%; *P* = 0.76) or stent thrombosis (0.6% vs 0.8%; *P* = 0.43).**

Conclusions **These findings suggest an improved clinical safety and efficacy of a newer generation thin-strut SES as compared with a second-generation thicker strut BES.** *Coron Artery Dis* **32: 391–396**

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Keywords: all comers, bioresorbable polymer, clinical outcomes, drug-eluting stent, percutaneous coronary intervention, strut thickness

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Introduction

Compared to bare metal stents and first-generation drug-eluting coronary stents (DES), second-generation DES have been associated with lower risks of in stent restenosis, stent thrombosis and myocardial infarction (MI) [1–3]. More recent improvements in stent design have focussed on even thinner struts, the use of different alloys and stent architecture, more biocompatible polymers, and shorter drug absorption times [4]. Integration of all these stent innovations aimed at improving deliverability, reducing vascular injury and side branch jailing, promoting faster endothelization, and decreasing neointimal proliferation and thrombogenicity [4,5]. Whether these innovations of newer generation DES actually result into better clinical outcome compared to older second-generation DES is still the focus of research. Although randomized controlled trials remain the gold

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standard to evaluate the clinical performance of devices, there is a need to conduct large, well controlled surveillance studies since randomized controlled trials are often not representative of the broad population of patients that are treated with PCI in 'the real world' of daily clinical practice [6].

The aim of this study was to evaluate the safety and efficacy of percutaneous coronary intervention (PCI) with a newer generation, thin-strut cobalt chromium sirolimus-eluting stent (SES) in comparison with an older, second-generation thicker strut stainless steel biolimus-eluting stent (BES). To that purpose, we compared data from two large registries representative of daily clinical practice (e-Ultimaster assessing the SES [NCT02188355] and NOBORI 2 investigating BES [7]).

Methods

Study design and population

The e-Ultimaster is an ongoing prospective, multicentre, single-arm registry conducted in 48 countries across Europe, Asia, South America and Africa to evaluate the safety and performance of the Ultimaster SES system in an all-comers clinical setting. The registry was started in 2014 and the current analysis includes data from patients whose index procedure occurred before 30 June 2016 (n = 10 685) and had completed a 1-year follow-up or died by 30 June 2017 (n = 8879). A detailed description of the NOBORI 2 registry has been published previously [7]. Briefly, NOBORI 2 is a finalized, prospective, open-label, single-arm, multicentre study conducted in 26 countries in Europe and Asia and designed to validate, in a real-world setting, the performance of the Nobori BES system. Between April 2008 and March 2009, 3067 patients were enrolled in the study (Fig. 1).

All patients with at least one SES from the e-Ultimaster registry or BES from the NOBORI 2 registry implanted were included in the analysis. In both registries, patients >18 years of age and with an indication for PCI were included. The inclusion criteria were broad and representative of real-life clinical practice. No limit was set on the number of treated lesions or vessels, lesion characteristics, comorbid conditions or age. The only exclusion criterion was patient's refusal or inability to provide written informed consent. Both registries were conducted in accordance with the Declaration of Helsinki and country-specific regulatory requirements. All patients signed informed consent as reviewed and approved by the Institutional Review Board or Ethics Committee of each participating centre.

Study stents

The SES (Ultimaster, Terumo Corporation, Tokyo, Japan) consists of the cobalt chromium (Co-Cr) coronary stent platform, a polymer coating (poly (D,L) lactic acid-polycaprolactone) and an antiproliferative agent, sirolimus. The stent strut thickness is 80 μm, with an abluminal gradient coating drug polymer matrix and the polymer degradation time of 3–4 months [7]. The BES (Nobori, Terumo Corporation, Tokyo, Japan) consists of a stainless steel stent platform, a bioresorbable polymer (polylactic acid) coating and an antiproliferative agent, Biolimus A9 (Biosensors International Ltd, Singapore) drug. The stent strut thickness is 120 μm, with an abluminal drug polymer matrix and a polymer degradation time of 9–12 months [9]. In the e-Ultimaster registry, the SES was available in six diameters (2.25, 2.5, 2.75, 3.0, 3.5 and 4.0 mm) and eight lengths (9, 12, 15, 18, 24, 28, 33 and 38 mm). In the NOBORI 2 registry, the BES was available in three diameters (2.5, 3.0 and 3.5 mm) and five lengths (8, 14, 18, 24 and 28 mm) (Fig. 1).

Clinical follow-up

Baseline and procedural characteristics were recorded prospectively in an electronic database in both registries. Adverse events were assessed in-hospital. Clinical follow-up was performed in the e-Ultimaster registry at 3 months and 1 year. Clinical follow-up in the NOBORI 2 registry was performed at 1 month, 6 months, 1 year, and annually until 5 years after the baseline procedure. Clinical evaluation included angina status, medication use and occurrence of adverse events. In both registries, two independent clinical event committees reviewed and adjudicated all deaths, MI, revascularizations and stent thrombosis.

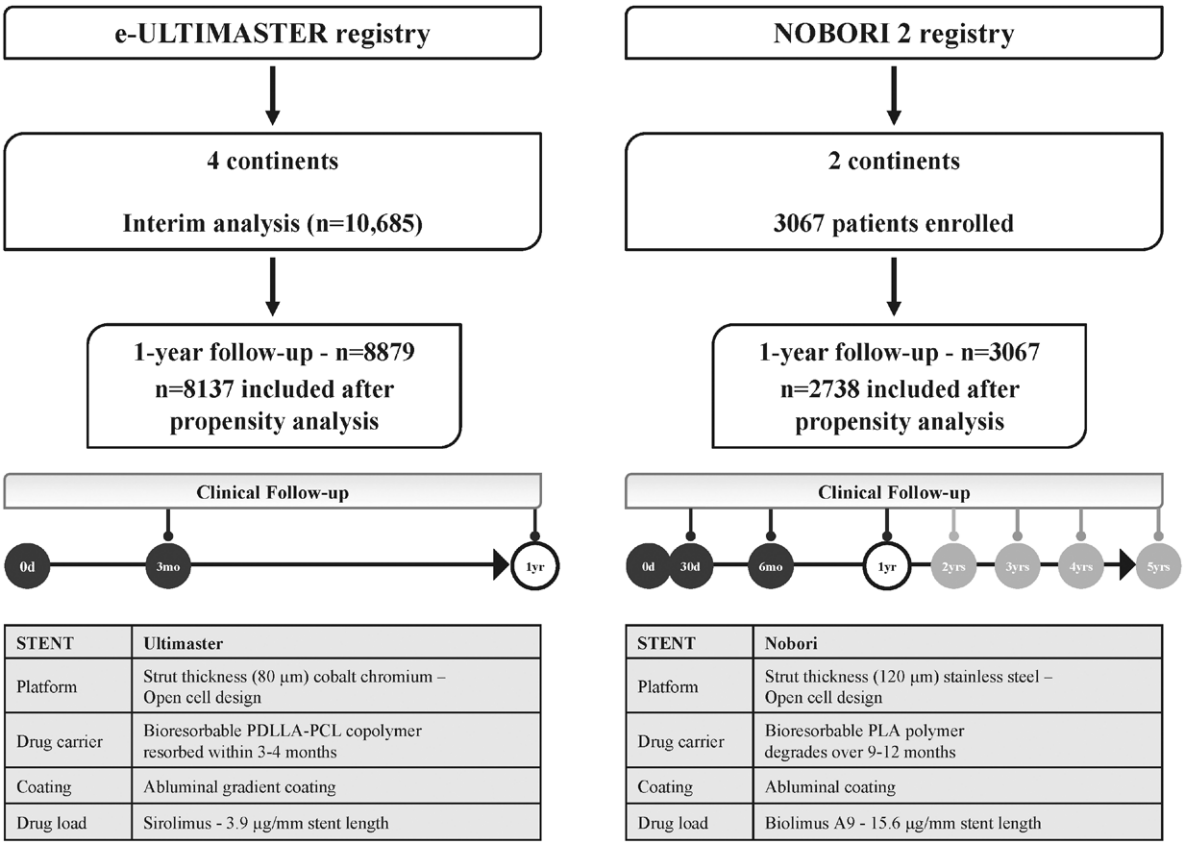
Endpoints

The primary outcome measure was target lesion failure (TLF) defined as a composite of cardiac death, target vessel-MI and clinically driven target lesion revascularization (TLR). Cardiac death was defined as any death due to cardiac cause (e.g., MI, low-output failure and fatal arrhythmia), unwitnessed death, death of unknown cause as well as all procedure-related deaths. MI occurring any time beyond the baseline procedure and end of study was defined as the elevation of troponin or CK-MB above the upper reference limit, and ischaemic symptoms or ECG changes. TLR was defined as clinically driven repeat PCI or surgical bypass of any treated segment. Safety endpoints included cardiac death, MI and stent thrombosis. Stent thrombosis was classified as definite, probable and possible according to the Academic Research Consortium definitions [10]. Efficacy endpoints were TLR and target vessel revascularization (TVR). Composite endpoints include TLF, target vessel failure (TVF) and patient-oriented composite endpoint (POCE). TVF was defined as a composite of cardiac death, target vessel-related MI and clinically driven TVR. POCE was defined as any death, MI or any coronary revascularization.

Statistical analyses

Propensity scores were calculated using a logistic regression model, with the group (e-Ultimaster or NOBORI 2) as outcome and the variables that needed to be matched

Fig. 1



STENT	Ultimaster
Platform	Strut thickness (80 μm) cobalt chromium – Open cell design
Drug carrier	Bioresorbable PDLLA-PCL copolymer resorbed within 3-4 months
Coating	Abluminal gradient coating
Drug load	Sirolimus - 3.9 μg/mm stent length

STENT	Nobori
Platform	Strut thickness (120 μm) stainless steel – Open cell design
Drug carrier	Bioresorbable PLA polymer degrades over 9-12 months
Coating	Abluminal coating
Drug load	Biolimus A9 - 15.6 μg/mm stent length

Study flowchart.

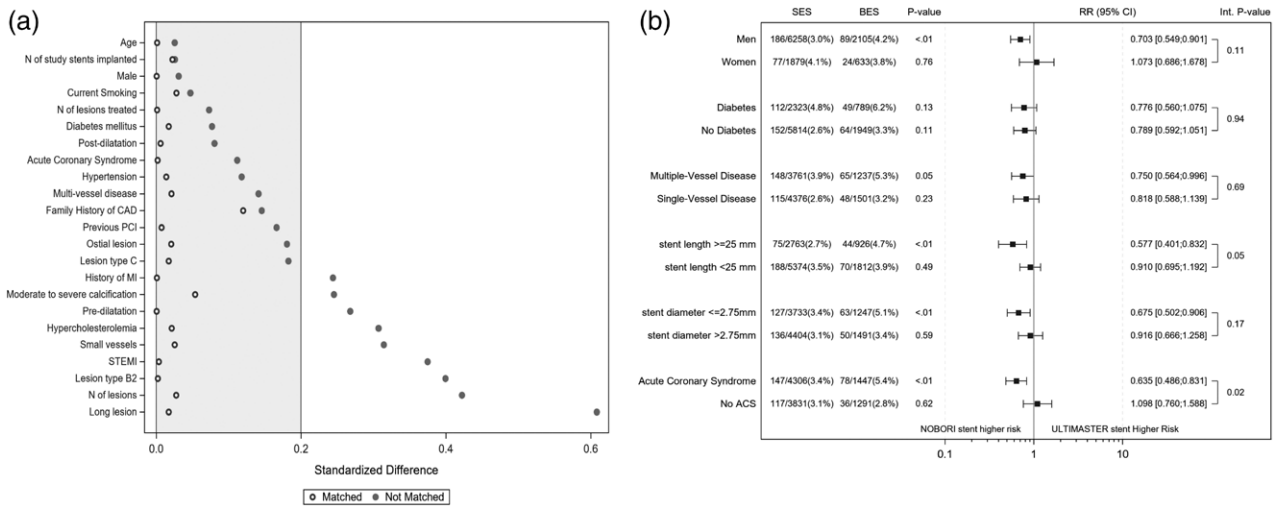
as independent variables. Variables to be entered into the model were predefined based on any possible impact on the outcomes. No variable model selection was performed: all predefined variables were entered into the logistic regression model to accommodate for any possible differences in all covariates between the subgroups studied. The probability of belonging to one of the two subgroups was used as propensity score. The inverse probability of treatment weights (IPTW) methodology was used to perform a matched analysis. This methodology uses the inverse of the propensity score of its own subgroup, that is, the probability of the subject of belonging to the subgroup the person is in, as a weight that can be used in the analyses. The balance after matching can be tested by calculating the weighted standardized difference for the IPTW analysis using the calculated weights. Generally, a standardized difference for all variables below 0.20 is considered well balanced, while standardized difference for all variables below 0.10 can be considered extremely well balanced (Fig. 2). For the matched analyses using the IPTW methodology, all analyses are performed using the weights as calculated. Weighted Chi-square tests were used for binary or categorical data and weighted Wilcoxon rank sum tests were used for continuous data. For subgroup analyses, weighted relative risks were calculated using logistic regression. A P value of less than 0.05 was considered statistically significant. Statistical analyses were performed using SAS software, version 9.4 (SAS Institute, Inc., Cary, North Carolina, USA).

Results

The e-Ultimaster registry population included 8879 patients treated with SES, while the NOBORI 2 registry cohort included 3067 patients treated with the BES (Fig. 1). NOBORI 2 had a low attrition rate of only 3%. The e-Ultimaster registry was an interim analysis of all patients with a completed 1-year follow-up or death before 30 June 2017. After IPTW propensity analysis to obtain a similar distribution of baseline patient and lesion characteristics in both registries, 8137 patients from e-Ultimaster and 2738 patients from NOBORI 2 were selected.

Between the SES and BES groups, there was no difference in baseline clinical characteristics except for a higher prevalence of family history of coronary artery disease in the SES group (36.1% vs 30.4%, $P < 0.001$). Ostial

Fig. 2



(a) The weighted standardized difference for the IPTW analysis. x axis: Variables included in the propensity score. y axis: The standardized difference before (blue) and after (red) weighting. (b) Subgroup analysis showing propensity-adjusted relative risk (RR) with 95% confidence interval (CI) of TLF at 1-year follow-up. CAD, coronary artery disease; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; TLF, target lesion failure. Lesion type B2 and C according to American College of Cardiology/American Heart Association classification system.

lesions and type C lesions were treated in 10 and 40% of the groups, respectively. Radial access was used more commonly in the e-Ultimaster registry than in NOBORI 2 (82.8% vs 38.8%). BARC 3 and 5 bleeding rates were 0.66 and 0.81%, respectively, in the e-Ultimaster and NOBORI 2 registries. The total stent length was longer in the SES group (38.8 vs 31.7 mm, $P < 0.001$). Baseline patient and lesion characteristics after IPTW propensity analysis are listed in Table 1, Supplemental digital content 1, *http://links.lww.com/MCA/A396*.

The use of SES was associated with a lower rate of MI (1.2 vs. 2.2%, $P = 0.0006$) as well as target vessel-related MI (1.1% vs 1.8%, $P = 0.002$) at 1 year compared with BES. In addition, the use of SES was associated with a lower rate of TLF, TVF and POCE (TLF 3.2% vs 4.1%, $P = 0.03$, TVF 3.7% vs 5.0%, $P = 0.003$ and POCE 5.7% vs 6.8%, $P = 0.03$) (Table 2, Supplemental digital content 1, *http://links.lww.com/MCA/A396*.

No significant differences were observed in all-cause death (2.0% vs 1.6%, $P = 0.19$) or cardiac death (1.2% in both groups). Rates of definite or probable stent thrombosis (0.6% vs 0.8%, $P = 0.43$) at 1-year follow-up were low and similar for both study stents in this analysis despite SES-treated patients having longer implanted stent length (38.8 vs 31.7 mm, $P < 0.0001$) and less likely to be on dual antiplatelet therapy (DAPT) at 1 year (26.9% vs 35.0%; $P < 0.0001$).

Figure 2 illustrates the propensity-adjusted relative risk and 95% confidence interval (CI) for TLF at 1 year according to subgroups including gender, diabetes mellitus, multivessel disease, long lesions (stent length ≥ 25 mm), small vessels (stent diameter ≤ 2.75 mm) and acute coronary syndrome (ACS). A significant interaction ($P = 0.02$) between clinical presentation (ACS vs no ACS) and treatment group (SES vs BES) was observed, showing a lower risk of 1-year TLF in ACS patients if treated with SES as compared with BES (3.4% for SES vs 5.4% for BES; relative risk 0.64; 95% CI 0.49–0.83, $P = 0.02$).

Discussion

The aim of this study was to evaluate the safety and efficacy of PCI with a newer generation, thin-strut cobalt chromium SES in comparison with an older second-generation, thicker strut stainless steel BES. Results are obtained from two large-scale prospective registries with broad inclusion criteria, and considered to be representative of daily clinical practice. The results of this propensity-matched analysis suggest an improved clinical safety and efficacy profile of the thin-strut cobalt chromium SES. Accordingly, significantly lower rates of the primary endpoint of TLF at 1 year were observed after treatment with SES compared with BES.

According to contemporary production trends, Ultimaster SES, as the third-generation DES, has thin-struts (80 μm on a cobalt chromium platform) as compared to the second-generation BES with a strut thickness of 120 μm (on a stainless steel platform). Whether even thinner struts, the use of different alloys and stent architecture, more

biocompatible polymers, and shorter drug absorption times will result in better outcomes is still subject of ongoing research. The majority of newer generation DES have been evaluated against the second-generation DES in order to demonstrate noninferiority [5]. In the SORT OUT VII trial, in which 2525 patients were randomized to either the Nobori BES or an ultrathin strut (60 μm) bioresorbable polymer Orsiro SES, no differences were found in the primary endpoint of TLF at 2-year follow-up (7.0% vs 6.7%, $P = 0.71$) [11].

Our findings of significantly lower event rates of the thinner Ultimaster SES compared to the Nobori BES are in line with recent meta-analysis of 11 658 patients comparing newer generation ultrathin strut DES vs second-generation DES, which demonstrated a 16% reduction in TLF, primarily driven by less MI in favour of the ultrathin strut DES [5]. The BIOFLOW V trial randomized 1334 patients in a 2:1 fashion the 60-μm Orsiro SES vs a 81-μm strut durable polymer everolimus-eluting stent (EES). The 2-year TLF rate was 7.5% for the ultrathin SES and 11.9% for the EES (95% CI −8.16 to −0.91%, $P = 0.015$), driven by differences in target vessel-MI (5.3% vs 9.5%, $P = 0.01$) and ischaemia-driven TLR (2.6 vs 4.9%, $P = 0.04$) [12]. Within the ACS subgroup in the BIOFLOW V trial, TLF at 1-year follow-up occurred in 5.6% (24/426) of ultrathin SES patients vs 11.0% (23/209) in the EES patients ($P = 0.02$) [13]. Within our analysis, a similar conclusion was drawn in the ACS subgroup analysis with the observation of a lower risk of TLF in the SES group compared to BES. Apart from the reintervention rate, we also observed a significant reduction in target vessel-MI after treatment with thin-strut SES.

Besides strut downsizing, polymer and drug properties are also known to influence safety and efficacy of DES devices. Other iterations of devices, as alternatives to durable polymer-based first- and second-generation DES, have been introduced, including bioresorbable polymer-based DES and polymer-free DES. However, the clinical outcomes with these newer systems have at the best been noninferior to their durable polymer counterparts. For instance, bioresorbable polymer-based but non ultrathin stents are at best noninferior to the second-generation durable polymer stents, without evidence of any superiority [14–16]. Both study stents included in this analysis were new generation DES with abluminal-only drug release and gradient (lack of drug polymer on the stent areas experiencing the highest physical stress to reduce the risk of polymer cracking and delamination). Furthermore, the bioresorbable polymer of the SES was intentionally designed to have a shorter degradation time (3–4 months) compared to BES (9–12 months) in order to help reduce the inflammatory response and translate into lower rates of (very) late stent thrombosis, a critical flaw of earlier generations of DES [3,17,18]. In our report, no significant difference in the overall low rate of stent thrombosis was observed between the two stents (definite or probable stent thrombosis 0.6% vs 0.8%, $P = 0.43$). A recent study showed almost complete strut coverage (95.2%) assessed by optical frequency domain imaging (OFDI) at 3 months after implantation of Ultimaster SES, with an already high rate of strut coverage at 1 month (84.9%) [18]. Also, a recent randomized clinical trial comparing strut coverage of Xience durable polymer EES (Abbott) with Nobori BES showed a similar strut coverage (assessed by optical coherence tomography) of both stents at 3 months (91.8% strut coverage of the Nobori BES versus 91.2% of Xience EES; $P = 0.69$) [20]. We observed a very low and similar stent thrombosis rate of both study stents in this analysis despite SES-treated patients having longer implanted stent length (38.8 vs 31.7 mm, $P < 0.0001$) and shorter DAPT duration (DAPT at 1 year 65.2% vs 73.4%; $P < 0.0001$). The optimal duration of DAPT in high bleeding risk patients will be evaluated in an ongoing randomized trial (MASTER DAPT; www.clinicaltrials.gov/ct2/show/NCT03023020).

Strengths and limitations

Our study has several strengths such as the high quality of the individual patient data in these large-scale phase 4 registries that reflect everyday clinical practice. Furthermore, all endpoint-related events were adjudicated by an independent clinical event committee, through comprehensive online and on-site monitoring. However, the following limitations need to be addressed. First, this is a patient-level combined analysis of two independent studies. Second, the clinical follow-up is limited to 1 year. Third, the two registries differed in time of enrolment (the ongoing e-Ultimaster registry was started in 2014, while NOBORI 2 registry enrolled patients between 2008 and 2009). Therefore, we cannot exclude that changes in clinical practice not tracked in the baseline or procedural characteristics may have influenced outcomes. In general, in recent years, an increase in the percentage of complex PCIs has been seen [21], as for instance reflected by the longer stent length in the SES population. Therefore, it may be assumed that confounding due to changes in clinical practice over time, most probably would have led to and underestimation of the performance of the SES compared to the BES. A fourth limitation relates to the fact that stent strut thickness is not the only difference between the Ultimaster SES and the Nobori BES. These stents also differ in the alloy, architectural design, polymer and drug release kinetics. On the basis of our analysis, it is not possible to solitarily evaluate the effect of strut thickness on the improved clinical outcome as observed for SES.

Conclusion

Significantly lower rates of MI, TLR, TVR and POCE at 1-year follow-up were observed after treatment with SES Ultimaster as compared with BES Nobori. TLF in

ACS patients was less frequent in those treated with SES. The rate of stent thrombosis and overall and cardiac mortality were similar. These findings suggest an improved clinical safety and efficacy profile of the new generation thin-strut cobalt chromium SES as compared with the thick-strut stainless steel BES

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Conflicts of interest

M.R. reports institutional research grants from Terumo, Medtronic, Abbott Vascular, Biotronik and Boston Scientific, outside the submitted work. There are no conflicts of interest for the remaining authors.

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