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New-generation drug eluting stent vs. bare metal stent in saphenous vein graft – 1 year outcomes by a propensity score ascertainment (SVG Baltic Registry)

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ABSTRACT

Background: Data regarding the efficacy of the percutaneous coronary intervention (PCI) with new-designed drug-eluting stent (new-DES) vs. bare metal stent (BMS) of saphenous vein grafts (SVG) stenosis is scarce. The primary objective was to compare one-year clinical outcomes of PCI in stenosis of SVG using new-DES vs. BMS in a real-world population.

Methods and results: We carried out a multi-center registry comparing new-DES with BMS in all consecutive patients undergoing PCI of SVG. The primary composite endpoint was major adverse cardiac and cerebrovascular events (MACCE) at 1 year. This observation included 792 consecutive patients (mean age 69 ± 8.9y), treated with either new-DES (n = 379, 47.9%) or BMS (n = 413, 52.1%). Among patients treated with new-DES compared with BMS, there was a lower risk of MACCE (21.4% vs. 28.3%, HR = 0.69, 95% CI 0.50–0.95, p = 0.025) as well as myocardial infarction (MI) (6.3% vs. 12.1%; HR 0.49, 95% CI 0.30–0.82, p = 0.005) at 1 year. After propensity score adjustment, the similar, significant reduction in MACCE and MI was observed in favor of new-DES (HR 0.66, 95% CI 0.46–0.96, p = 0.030; and HR 0.53, 95% CI 0.31–0.92, p = 0.020, respectively).

Conclusion: In patients undergoing PCI of SVG, the use of new-DES is associated with a reduced 1-year rate of MACCE and MI compared to BMS.

1. Introduction

Coronary artery bypass grafting (CABG) is the preferred treatment option for patients with complex coronary artery disease (CAD), in particular, multivessel disease coexisting with diabetes [1]. However, CABG is associated with a substantial risk of saphenous vein graft (SVG) failure, which occurs in approximately 15–35% of patients within 4–5 years and 29–68% patients over 10 years [1–3]. SVG stenosis presents different pathophysiology when compared with native vessel atherosclerosis. Notably, plaques in SVG are lipid-rich and soft, thus, are more prone to rupture than plaques in native coronary arteries [4,5]. According to the current European Society of Cardiology (ESC) guidelines, percutaneous coronary intervention (PCI) is the preferred strategy option for patients presenting with SVG failure [1,6]. Approximately 6% of all PCI are done in SVG [7,8]. In recent years, stent technology showed substantial progress, and the new generation DES (new-DES) were proven to provide better outcomes than the old generation DES (old-DES) and BMS in native coronary arteries [9–11]. New-DES gained a significant advantage over old-DES due to the application of more potent antiproliferative drugs and thinner, more biocompatible polymers as well as higher flexibility, conformability, and deliverability of cobalt chromium and platinum–chromium stent alloys [12–14].

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However, there are limited and inconsistent data regarding the impact of stent type on the outcome of PCI of SVG. Of note, patients requiring stent placement after CABG are often excluded from large, randomized clinical trials (RCT) [15,16]. As well, to date, there are no clear guidelines regarding which type of stent should be preferred during SVG PCI. Herein SVG Baltic Registry was aimed at assessing the one-year clinical outcome of new-DES vs. BMS in an all-comer population with SVG stenosis treated with PCI.

2. Methods

A flow chart of the study is presented in Fig. 1. We used data from SVG Baltic Registry for this retrospective study. This data included 792 patients after CABG with significant SVG stenosis referred for PCI. The study was conducted in three, high volume PCI centres between February 2008 and October 2014. The registry retrospectively included all consecutive patients who were treated with either new-DES or BMS.

Patients who had both types of stents implanted in the same procedure were excluded from the study. Since we aimed to investigate outcomes after PCI with new-DES vs. BMS implantation, patients with the old-DES [Cypher and Cypher Select (Cordis Corporation, Miami, FL, USA), Taxus Express and Taxus Liberté (Boston Scientific Corporation), and Endeavor (Medtronic Inc.)] implanted were also excluded from the study. Furthermore, patients who had PCI of the left or right internal mammary artery during the same procedure were also excluded. Angiographic data of patients included to the study were collected and recorded in the central cardiovascular information registry. Outcome data were obtained from the central database of the National Health Fund Service of the Ministry of Health and no patient was lost to follow-up. The patients' data were anonymized in each centre, combined into the database and statistically analyzed as a single cohort. The patient's data was protected according to the requirements of Polish law and hospital Standard Operating Procedures (SOPs).

2.1. End-points

The composite primary efficacy endpoint was major adverse cardiac and cardiovascular events (MACCE), including all-cause death, myocardial infarction (MI), target vessel revascularization (TVR), and stroke at 1 year. Additionally, since the patient's assignments were not random, we performed the propensity score analysis to minimize selection bias. The secondary endpoints were all-cause death, MI, TVR, stroke and target lesion revascularization (TLR). TVR, TLR were defined according to the definitions of endpoints for clinical trials [17].

2.2. Statistical analysis

Continuous data were presented as mean ± standard deviation or median with interquartile range (Q1–Q3). Qualitative data were expressed as crude values and/or percentages. Normal distribution was verified by the Kolmogorov-Smirnov test. Continuous data were compared by Student *t*-test or by U-Mann Whitney test depending on the distribution. Categorical data were analyzed by Chi-square test and Fisher's exact test. Kaplan-Meier survival curves were performed to present the unadjusted time-to-event data for investigated end-points and were calculated using the log-rank test.

To limit biases, propensity score analysis was used [18]. The logistic regression was performed with new-DES as a dependent variable, including age, gender, NSTEMI on admission, hypertension, diabetes, smoking, dyslipidaemia, prior MI, prior PCI, family history of CAD, peripheral artery disease (PAD), carotid artery disease, anemia, previous neoplasms, lung disease, chronic renal failure, CCS angina class, periprocedural MI, in-stent restenosis, protection, no-reflow, dissection and length of hospitalization. The validity of logistic regression was assessed using the Hosmer–Lemeshow test. The model was well calibrated (the Hosmer-Lemeshow test x2 7.36, 8 df, $P = 0.498$). For the propensity score analysis, predicted probabilities outside 10–90% were excluded, and the remaining values were divided into quintiles. Finally, Cox-regression for 1-year event rates of MACCE, death, MI, TVR, TLR and stroke respectively as dependent variables and new-DES and propensity score (in quintiles) as independent variables were performed. *P*-value < 0.05 was considered significant. The statistical analysis was performed using Medcalc 17.9.2 (Medcalc software) and SPSS software v.21 (IBM SPSS Statistics).

3. Results

The Registry was comprised of 792 consecutive patients, that underwent PCI of SVG stenosis including 234 (29.5%) patients with stable coronary artery disease (CAD), 292 (36.8%) patients with unstable angina, 216 (27.2%) patients with non-ST elevation MI (NSTEMI) and 50 (6.3%) patients with ST elevation MI (STEMI)/left bundle branch block (LBBB). Median age was 69 (62–75) years, 602 (77.0%) patients were males. BMS were used in 413 (52.1%) patients and new-DES in 379 (47.9%) patients. The use of new-DES increased progressively throughout the study (see also Fig. 2). We observed some differences in patient's characteristics, risk factors and clinical presentation between new-DES and BMS groups. Patients who presented with stable CAD received more often new-DES while patients with the acute coronary syndrome (ACS) received more often BMS. Additionally, we observed higher rates of previous MI (74.9% vs. 66.6%, $p = 0.010$) and previous PCI (60.9% vs. 45.0%, $p < 0.001$) in the new-DES group. Also, patients with new-DES implants had more often anemia (28.0% vs. 17.7%, $p = 0.005$) and diabetes (46.4% vs. 38.5%, $p = 0.024$). However, there were no differences in CAD risk factors such as hypertension, dyslipidemia, chronic kidney disease or current smoking. The groups were comparable in the frequency of concomitant diseases such as cancer, chronic obstructive pulmonary disease, peripheral artery disease and carotid artery disease. EuroScore II and Grace Risk scores were the same in both groups (see also Table 1). After PS analysis new-DES and BMS groups ceased to differ significantly with regard to the following variables: previous MI, diabetes, length of hospitalization and number of implanted stents. Nevertheless, after PS analysis simultaneous PCI of two grafts turned out to be significantly more frequent in patients treated by BMS (5.5% vs. 2.0%, $p = 0.021$).

3.1. In-hospital and discharge medications

Glycoprotein IIb/IIIa inhibitors were less often used in patients with new-DES (10.3% vs. 17.4%, $p = 0.003$). In-hospital use of oral antiplatelet and antithrombotic medications was the same in both groups. Patients with new-DES more often received statins at discharge (96.6% vs. 92.0%, $p = 0.006$). Dual antiplatelet therapy (DAPT) was given for 1 month in all patients treated with BMS in stable CAD or 12 months in ACS. In all patients treated with new-DES, the DAPT was continued up to 12 months.

3.2. Interventional treatment and reperfusion strategy

The most common native vessel territories receiving PCI-SVG implants were circumflex and right coronary artery. Patients receiving SVG-PCI in the LAD territory were more likely to receive a new-DES (29.6% vs. 20.6%, $p < 0.003$). Furthermore, the graft segment stenosis was the same in patients receiving a BMS and in those receiving a new-DES (see also Table 2). The degree of stenosis and the presence of thrombus were comparable in both groups. We observed that a distal protection embolic device was more often used in a new-DES group (29.6% vs. 18.9%, $p < 0.001$) and patients with in-stent restenosis had more often new-DES implantation (14.8% vs. 3.4%, $p < 0.001$). There were no significant differences in the use of thrombectomy (4.5% vs. 6.1%, $p = 0.237$) by stent type. Although stent diameters were larger in BMS than in a new-DES group (3.5, IQR 3.0–4.0 vs. 3.5, IQR 2.9–3.5, $p = 0.003$), stent lengths were similar. There were no differences in procedural success rate between new-DES and BMS.

3.3. Outcomes

The primary endpoint of the study was observed in 21.4% patients in new-DES group and in 28.3% patients in BMS group (HR 0.69, 95% CI 0.50–0.95, $p = 0.025$, see also Table 3 and Fig. 3). The secondary endpoint of MI was noted less frequently in new-DES vs. BMS group (6.3% vs. 12.1%, HR 0.49, 95% CI 0.30–0.82, $p = 0.005$). There were no differences between new-DES and BMS groups in secondary endpoint of death (6.9% vs. 7.0%; HR 0.98, 95% CI 0.56–1.69, $p = 0.925$), TVR (11.1% vs.12.1%, HR 0.93, 95% CI 0.60–1.44, $p = 0.718$), TLR (7.1% vs. 9.4%; HR 0.74, 95% CI 0.44–1.23, $p = 0.234$), and stroke (1.3% vs. 1.7%, HR 0.78, 95% CI 0.24–2.46), $p = 0.688$) at one year (see also Table 3 and Fig. 4). Importantly, in the subgroup of patients who experienced MI in the first 12 months after the index procedure, there was no difference between new-DES and BMS groups in terms of TVR [54.2% vs. 36.0%; HR 1.6, 95% CI 0.78–3.66, $p = 0.140$] and TLR

Table 1
Patients characteristics, risk factors and clinical presentation according to the type of stent.

	Crude analysis			Propensity score analysis		
	BMS n = 413 (52.1%)	new-DES n = 379 (47.9%)	p	BMS *n* = 329 (52%)	new-DES *n* = 304 (48%)	p
Demographic data						
Age, median (IQR)	69(61–75)	69(63–76)	0.166	69 (62–75)	69 (62–75)	0.738
Male, n(%)	317 (76.8)	285 (75.2)	0.608	256 (77.8)	236 (77.6)	0.957
BMI [kg/m^2], median (IQR)	27.9(25.6–30.8)	28.8(25.4–30.9)	0.704	28 (25.5–30.9)	29.1 (25.7–31.8)	0.318
Discharge diagnosis						
SA, n(%)	100 (24.2)	134 (35.4)	<0.001	84 (25.5)	111 (36.5)	0.003
UA, n(%)	153 (37.0)	139 (36.7)	0.914	117 (35.6)	115 (37.8)	0.554
NSTEMI, n(%)	128 (31.0)	88 (23.2)	0.014	105 (31.9)	64 (21.1)	0.002
STEMI/LBBB, n(%)	32 (7.7)	18 (4.7)	0.052	23 (7.0)	14 (4.6)	0.201
CAD history						
Previous MI, n(%)	275 (66.6)	284 (74.9)	0.010	237 (72.0)	229 (75.3)	0.348
Previous PCI, n(%)	186 (45.0)	231 (60.9)	<0.001	160 (48.6)	178 (58.6)	0.012
CAD risk factors						
Hypertension, n(%)	366 (88.6)	338 (89.2)	0.801	290 (88.1)	273 (89.8)	0.507
Dyslipidemia, n(%)	299 (72.4)	282 (74.4)	0.523	238 (72.3)	221 (72.7)	0.920
CKD, n(%)	101 (24.5)	100 (26.4)	0.533	82 (24.9)	75 (24.7)	0.941
Anemia, n(%)	73 (17.7)	106 (28.0)	0.005	56 (17.0)	89 (29.3)	<0.001
Diabetes mellitus, n(%)	159 (38.5)	176 (46.4)	0.024	137 (41.6)	133 (43.8)	0.592
Current Smoking, n(%)	84 (20.3)	78 (20.6)	0.933	66 (20.1)	60 (19.7)	0.919
Concomitant disease						
Cancer, n(%)	21 (5.1)	16 (4.2)	0.565	17 (5.2)	13 (4.3)	0.598
COPD, n(%)	30 (7.3)	25 (6.6)	0.712	26 (7.9)	20 (6.6)	0.522
PAD, n(%)	83 (20.1)	77 (20.3)	0.938	65 (19.8)	61 (20.1)	0.923
Carotid artery disease, n(%)	48 (11.6)	50 (13.2)	0.502	40 (12.2)	39 (12.8)	0.799
Length of hospital stay (days), median (IQR)	4 (3–7)	4 (3–6)	0.022	4 (3–6.25)	4 (3–6)	0.075
LVEF, median (IQR)	50 (38–55)	47 (39–55)	0.200	50 (38–55)	47 (38–55)	0.312
GRACE score > 140, n (%)	19 (4.6)	22 (5.8)	0.213	16 (4.9)	15 (4.9)	0.454
Euroscore, median, (IQR)	4.4 (2.7–7.7)	4.6 (2.8–9.2)	0.229	4.6 (2.9–8.0)	4.5 (2.8–8.6)	0.848

BMI-body mass index; BMS = bare metal stent, CABG - coronary artery bypass graft, CAD - coronary artery disease, CKD - chronic kidney disease [CKD was defined as estimated GFR (eGFR) < 60 60 mL/min/1.73 m^2 calculated using the Modification of Diet in Renal Disease (MDRD) method], COPD - chronic obstructive pulmonary disease, DES - drug eluting stent, MI - myocardial infarction, new-DES - new generation DES, NSTEMI - non-ST-segment elevation myocardial infarction, SA - stable angina, STEMI - ST-segment elevation myocardial infarction, PAD - peripheral artery disease, PCI -percutaneous coronary intervention, UA - unstable angina.

[33.3% vs. 26.0%; HR1.3, 95% CI 0.53–3.4, $p = 0.515$]. Results regarding the 1-year-overall MACCE and MI remained significant after PS analysis (new-DES vs. BMS: HR 0.66, 95% CI 0.46–0.96, $p = 0.030$; and HR 0.53, 95% CI 0.31–0.92, $p = 0.020$, respectively, see also Table 3).

4. Discussion

The most salient finding of the SVG-Baltic multicenter registry is that MACCE and MI rates were significantly lower in the patients treated with new-DES implantation compared to BMS at one year. However, no significant difference in the secondary endpoint of mortality, TVR, TLR, and stroke was observed in the crude- and propensity score analysis. With 792 patients, herein, we provide a comprehensive overview of the safety and efficacy of the new-DES vs. BMS in the setting of SVG disease. The current registry expands one-year follow-up data from previous studies, which showed favorable results of new-DES implantation in native coronary arteries [10,19]. So far there were many studies comparing DES and BMS in SVG disease, however, importantly, the majority of them included old-DES providing truly inconsistent results [15–17]. For instance, DIVA randomized trial [20] and meta-analysis by Elgendy et al. [21] reported no significant differences in outcomes between DES and BMS at 12 months. Notably, the lack of advantage of PCI with DES in comparison to BMS and a relatively high incidence of target vessel failure (TVF) could be caused by the inclusion of patient subset treated with old-DES. Indeed, the old and new-DES in SVG disease have been compared in the subgroup analysis of retrospective study prepared by Aggarwal et al. [22]. At two years, they observed a lower mortality rate in patients receiving new-DES. Although this particular result was statistically non-significant, generally, the advantage of new-DES over BMS in SVG disease should be driven by the lower restenosis rate and TVF, especially since stent thrombosis is not an issue with the new-DES [23]. Of note, the lower rate of TLR and TVR at one year was observed in patients with DES compared to BMS in ISAR-CABG randomized study. In that study, there was no significant difference in death, MI or stent thrombosis [24]. Similar trends were also observed by Lupi et al. [25] in their meta-analysis, where DES significantly reduced TVR but did not provide clear benefits on mortality and MI. On the other hand, in our study, the lack of difference between groups regarding TLR and TVR might indicate, that the higher rate of MI in BMS treated patients might have been caused by either non-target vessel related coronary events or non-diagnosed target vessel related coronary events in patient treated conservatively. There was also a hypothesis that the size of the stent could play a role in the outcomes. Notwithstanding, this hypothesis has been challenged by Jeger et al. [26], who in a small study on PCI in large vessel grafts (>3 mm) reported lower MACE and TVR rates in DES group vs. BMS group, with no significant differences between groups regarding cardiac death and MI rates at 18-months. In our registry, we compared BMS and new-DES in a wide range of graft diameters, from small (2.0 mm) to large (3.5 mm). Nevertheless, we did not observe any differences in all components of MACCE between groups. More recently, a large retrospective analysis by Iqbal et al. [27] showed the advantage of new-DES over BMS as well as old-DES with regard to in-hospital major adverse cardiac events (MACE), 30-day and 1-year mortality. However, the authors speculated that the difference in outcomes might have resulted from the fact that BMS was being used in older or

Table 2
Angiographic and procedural data according to the type of stent.

	Crude analysis			Propensity score analysis		
	BMS n = 413 (52.1%)	new-DES n = 379(47.9%)	p	BMS n = 329 (52%)	new-DES n = 304 (48%)	p
Access, n (%)						
Radial	37 (9.0)	78 (20.6)	<0.001	29 (8.8)	61 (20.1)	<0.001
Femoral	376 (91.0)	301 (79.4)		298 (90.6)	243 (79.9)	
Degree of stenosis, (%), median (IQR)	90 (80–95)	90 (80–95)	0.283	90 (80–95)	80 (80–95)	0.241
Thrombus, n(%)	39 (9.4)	27 (7.1)	0.238	33 (10.0)	20 (6.6)	0.117
Restenosis in previously implanted stent, n(%)	14 (3.4)	56 (14.8)	<0.001	12 (3.6)	40 (13.2)	<0.001
PCI, n (%)						
Ao-LAD	85 (20.6)	112 (29.6)	0.003	70 (21.3)	88 (28.9)	0.026
Ao-LCx	198 (47.9)	160 (42.2)	0.106	155 (47.1)	123 (40.5)	0.092
Ao-RCA	140 (33.9)	111 (29.3)	0.163	112 (34.0)	91 (29.9)	0.269
Ao-Y	18 (4.4)	20 (5.3)	0.545	15 (4.6)	15 (4.9)	0.824
Segment, n (%)						
Ostium	128 (31.0)	119 (31.4)	0.902	97 (29.5)	96 (31.6)	0.567
Medial	63 (15.3)	67 (17.7)	0.357	53 (16.1)	54 (17.8)	0.579
Distal	81 (19.6)	84 (22.2)	0.485	63 (19.1)	69 (22.7)	0.272
Other	149 (36.1)	117 (30.9)	0.121	123 (37.4)	92 (30.3)	0.059
Simultaneous PCI of two SVG, n (%)	21 (5.1)	13 (3.4)	0.251	18 (5.5)	6 (2.0)	0.021
Predilatation, n (%)	90 (21.8)	138 (36.4)	<0.001	75 (22.8)	106 (34.9)	0.001
Thrombectomy, n (%)	25 (6.1)	17 (4.5)	0.237	19 (5.8)	14 (4.6)	0.397
Device distal protection, n (%)	78 (18.9)	112 (29.6)	<0.001	56 (17.0)	92 (30.3)	<0.001
Total stent length (mm), median (IQR)	20.0 (15–30)	18.5 (15–28)	0.965	20 (15–30)	19 (15–28)	0.212
Length of stent > 28 mm, n (%)	123 (29.8)	118 (31.1)	0.797	97 (29.5)	94 (30.9)	0.809
Average stent diameter (mm), median (IQR)	3.5 (3.0–4.0)	3.5 (2.9–3.5)	0.003	3.5 (3.0–3.8)	3.25 (2.8–3.5)	0.005
Diameter of stent > 3.5 mm, n (%)	234 (56.7)	190 (50.1)	0.060	180 (54.7)	151 (49.7)	0.177
Number of stents, median (IQR)	1(1–2)	1(1–1)	<0.001	1 (1–1)	1 (1–1)	0.212
Residual stenosis, n (%)	12 (2.9)	11 (2.9)	0.945	10 (3.0)	8 (2.6)	0.748
TIMI 3 post-PCI, n (%)	406 (98.3)	373 (98.4)	0.901	323 (98.2)	298 (98.0)	0.890
Vessel perforation, n (%)	2 (0.5)	–	–	2 (0.6)	0 (0.0)	–
Dissection, n (%)	7 (1.7)	4 (1.1)	0.442	4 (1.2)	3 (1.0)	0.783
No reflow during PCI, n (%)	7 (1.7)	6 (1.6)	0.901	6 (1.8)	3 (1.0)	0.374

BMS - bare metal stent, DES- drug eluting stent, new-DES - new generation DES, PCI-percutaneous coronary intervention, LAD - left anterior descending artery, LCx - left circumflex artery, RCA - right coronary artery, SVG - saphenous vein graft.

high-risk patients or in patients with other morbidities that were not collected in the registry. In our study, no mortality benefit of new-DES over BMS was noted in a one-year observation.

4.1. Study limitations

There are several limitations of this study. First, although the sample size was large, it was not a randomized trial, but a retrospective registry with all its inherent limitations. However, in our opinion, this limitation is offset to a certain extent by the "all-comer" inclusion criteria, 100% follow-up rate and confirmation of the end-points by National Health Service database as well as robust statistical analyses including propensity score analysis to adjust for known confounders. Furthermore, patients treated with new-DES more often than those treated with BMS had previous MI, previous PCI, anemia and diabetes. On the other hand, in the study population, patients treated with BMS were more frequently diagnosed with ACS than those treated with new-DES, that might have also impacted the results. Finally, data regarding pharmacotherapy before patient's admission and data about the adherence to dual antiplatelet therapy after PCI were unavailable.

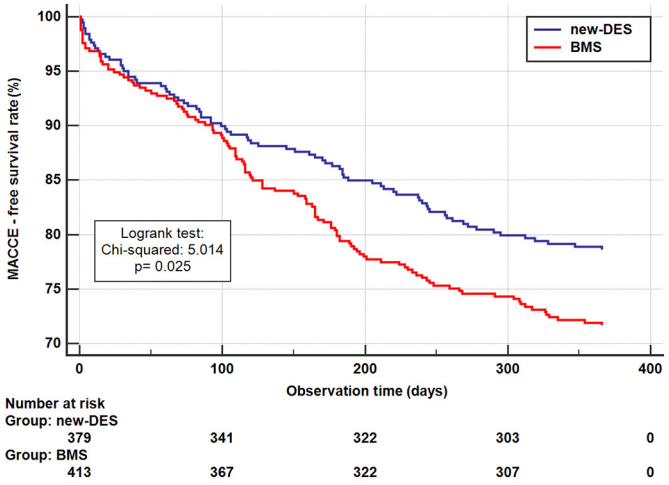

Fig. 3. Kaplan-Meier Curves for MACCE (myocardial infarction, stroke, death, TVR) according to the type of stent. BMS- bare metal stent, DES- drug eluting stent, new-DES- new generation DES.

5. Conclusion

The outcomes of PCI in SVG at one year were more favorable with the use of new-DES regarding MACCE and MI, in comparison to BMS. There were no significant differences in secondary endpoints of death, TVR, and TLR at one year.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2019.04.022.

Acknowledgments

None.

Declaration of interest statement

No conflicts of interest.

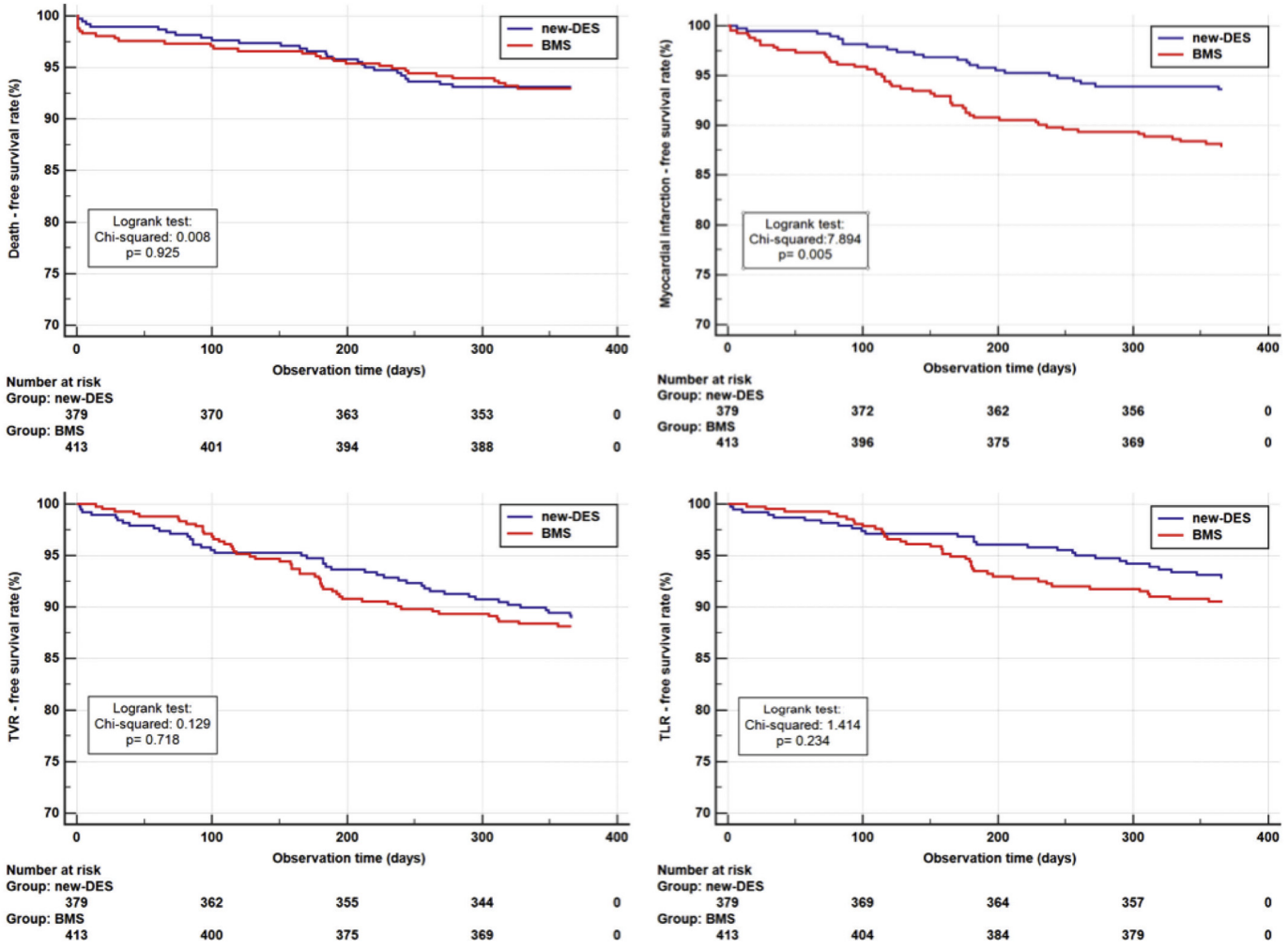

Fig. 4. Kaplan-Meier Curves for myocardial infarction, death, TLR, TVR, according to the type of stent. BMS- bare metal stent, DES- drug-eluting stent, new-DES- new generation DES, TLR-target lesion revascularization, TVR-target vessel revascularization.

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