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ORIGINAL RESEARCH

Long-Term Results After Drug-Eluting Versus Bare-Metal Stent Implantation in Saphenous Vein Grafts: Randomized Controlled Trial

Gregor Fahrni, MD; Ahmed Farah, MD; Thomas Engstrøm, MD; Søren Galatius, MD; Franz Eberli, MD; Peter Rickenbacher, MD; David Conen, MD; Christian Mueller, MD; Otmar Pfister, MD; Raphael Twerenbold, MD; Michael Coslovsky, PhD; Marco Cattaneo, PhD; Christoph Kaiser, MD; Norman Mangner, MD; Gerhard Schuler, MD; Matthias Pfisterer, MD; Sven Möbius-Winkler, MD; Raban V. Jeger, MD; for the BASKET-SAVAGE-Investigators*

BACKGROUND: Efficacy data on drug-eluting stents (DES) versus bare-metal stents (BMS) in saphenous vein grafts are controversial. We aimed to compare DES with BMS among patients undergoing saphenous vein grafts intervention regarding long-term outcome.

METHODS AND RESULTS: In this multinational trial, patients were randomized to paclitaxel-eluting or BMS. The primary end point was major adverse cardiac events (cardiac death, nonfatal myocardial infarction, and target-vessel revascularization at 1 year. Secondary end points included major adverse cardiac events and its individual components at 5-year follow-up. One hundred seventy-three patients were included in the trial (89 DES versus 84 BMS). One-year major adverse cardiac event rates were lower in DES compared with BMS (2.2% versus 16.0%, hazard ratio, 0.14; 95% CI, 0.03–0.64, P=0.01), which was mainly driven by a reduction of subsequent myocardial infarctions and need for target-vessel revascularization. Five-year major adverse cardiac event rates remained lower in the DES compared with the BMS arm (35.5% versus 56.1%, hazard ratio, 0.40; 95% CI, 0.23–0.68, P<0.001). A landmark-analysis from 1 to 5 years revealed a persistent benefit of DES over BMS (hazard ratio, 0.33; 95% CI, 0.13–0.74, P=0.007) in terms of target-vessel revascularization. More patients in the BMS group underwent multiple target-vessel revascularization procedures throughout the study period compared with the DES group (DES 1.1% [n=1] versus BMS 9.5% [n=8], P=0.013). Enrollment was stopped before the target sample size of 240 patients was reached.

CONCLUSIONS: In this randomized controlled trial with prospective long-term follow-up of up to 5 years, DES showed a better efficacy than BMS with sustained benefits over time. DES may be the preferred strategy in this patient population.

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Key Words: bare-metal stent ■ coronary artery bypass ■ drug-eluting stent ■ saphenous vein graft

Saphenous vein grafts (SVG) are commonly used during coronary bypass surgery; however, up to 15% occlude within 1 year and 50% fail by 10 years.[1] Percutaneous coronary intervention of failing aortocoronary SVG accounts for 6% of all coronary interventions.[2] While drug-eluting stents (DES) improve outcome compared with bare-metal stents (BMS) in native coronary artery lesions,[3] their efficacy and safety in SVG lesions is still unclear.

Correspondence to: Raban V. Jeger, MD, Cardiology, University Hospital, Basel, Switzerland. E-mail: raban.jeger@usb.ch

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*A complete list of the BASKET-SAVAGE-Investigators can be found in the Supplemental Material.

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CLINICAL PERSPECTIVE

What Is New?

- Implantation of drug-eluting stents in failing venous grafts revealed a sustained benefit over bare-metal stents in terms of major adverse cardiac events up to 5 years.
- More patients in the bare-metal stent group underwent multiple revascularization procedures in the target vessel throughout the study period.

What Are the Clinical Implications?

- Revascularization with implantation of drug-eluting stents may be the preferred strategy among patients undergoing saphenous vein graft interventions.

Nonstandard Abbreviations and Acronyms

BMS	bare-metal stent
DES	drug-eluting stent
MACE	major adverse cardiac events
SVG	saphenous vein graft
TVR	target-vessel revascularization

Several previous randomized trials demonstrated a beneficial effect of DES over BMS in SVG intervention on short-term outcome.[4–7] This difference in outcome was mainly driven by the need for target-vessel revascularization based on protocol-required angiographic follow-up. However, routine angiographic follow-up is known to increase the rates of repeat revascularization in favor of DES.[8]

In contrast to these concordant short-term results, existing long-term data report no difference in outcome. While the 5-year post hoc analysis of the ISAR-CABG (Is Drug-Eluting-Stenting Associated with Improved Results in Coronary Artery Bypass Grafts) trial showed loss of early advantage of DES compared with BMS,[9] the recently published DIVA (Drug Eluting Stent Versus Bare Metal Stent in Saphenous Vein Graft Angioplasty) trial reported no difference in major adverse cardiac events (MACE) between patients undergoing a SVG treatment with either new-generation DES or BMS.[10]

In view of these data, we performed a randomized controlled trial powered to assess the clinical efficacy and safety of DES among patients undergoing percutaneous coronary intervention in SVG lesions with a long-term follow-up of up to 5 years.

METHODS

The data that support the findings of this trial are available from the corresponding author upon reasonable request.

Study Design and Participants

The BASKET-SAVAGE trial is an investigator-initiated, randomized, assessor-blinded trial performed at 6 European centers in Switzerland, Germany, and Denmark between February 2008 and March 2013. Patients with previous coronary artery bypass graft operation undergoing cardiac angiography were evaluated for enrollment. Eligible patients were aged at least 18 years and presented with stable coronary artery disease or acute coronary syndrome in the presence of a significant stenosis of an SVG with a reference diameter ≤5.5 mm by visual estimation (including acute thrombotic occlusions and SVG lesions at the proximal and distal anastomosis). Exclusion criteria were previous stent implantation in the target SVG, need for concomitant intervention in a native coronary artery, SVG <6 months old, culprit lesion in an arterial graft, need for oral anticoagulation, platelet count $<100\times10^9$/L or $>700\times10^9$/L, white blood cell count <3000 cells/mm^3, coexisting conditions that limited life expectancy to <12 months, planned surgery within 1 year, a history of allergic reaction to any metal or drug included in the stent under investigation, unlikeliness to comply with the study treatment and follow-up visits, participation in another trial, and known pregnancy. All patients provided written informed consent. The local ethics committee at each participating center approved the protocol and the study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. The sponsor had no role in the design of the study, collection of the data, analysis of the result, preparation of the manuscript, or decision to submit for publication.

Randomization and Blinding

After crossing the SVG lesion with a guidewire, eligible patients were randomly assigned in a 1:1 ratio to receive either the paclitaxel-eluting TAXUS Liberté (DES group) or the bare-metal Liberté stent (BMS group; both manufactured by Boston Scientific Corporation, Natick, MA). In each participating center, the 1:1 allocation to treatment arms was made by means of an internet-based system using computer-generated simple randomization via a secure website accessible by password only. Time of randomization was defined as time zero.

Procedures and Follow-Up

The coronary intervention was performed according to standard techniques, and the use of a distal protection device was encouraged, if technically feasible.

Administration of a bolus of glycoprotein IIb/IIIa inhibitor during the intervention was recommended, depending on contraindications. In patients with multiple lesions, the same randomly assigned type of stent was implanted for all lesions whenever possible. Patients were on dual antiplatelet therapy with acetylsalicylic acid and clopidogrel at the time of the procedure. To avoid potential confounding between the treatment groups, dual antiplatelet therapy was recommended for 12 months in all patients.

All patients were followed up by a questionnaire (letter or phone) after 30 days, 6 months, 1 year, and then yearly until 5 years after randomization to assess the occurrence of clinical events. Routine follow-up angiography was discouraged.

Outcomes and Definitions

The primary end point was the incidence of MACE, defined as the composite of cardiac death, nonfatal myocardial infarction,[11] and target vessel revascularization (TVR) of the stented SVG at 1 year. Cardiac death was defined as any death not clearly attributed to a noncardiac cause. The secondary end points comprised the individual components of the primary end point, noncardiac death, the composite nonfatal myocardial infarction and cardiac death, probable or definite stent thrombosis according the Academic Research Consortium criteria,[12] and major bleeding (defined as need for surgery, need for blood transfusions, and cerebral hemorrhage) at 1 and 5 years. A landmark analysis from 1 to 5 years was performed for MACE and its components. Multiple TVR procedures were defined if >1 TVR was undertaken during the study period. All events were reviewed and adjudicated by an independent Clinical Events Committee masked to treatment allocation. Finally, quality of life was assessed using the disease-specific MacNew quality of life questionnaire for heart disease, which is built using 27 fixed questions each with a scale from 1 to 7.[13,14] Based on a summary algorithm, a global, an emotional, and a social score are calculated as the mean of a specific set of questions with higher numbers indicating better quality of life. These questionnaires were evaluated at baseline, 30 days, 6 months, and 1 year.

Sample Size and Statistical Analysis

Based on previous studies, we estimated an event rate of ≈15% for DES and 30% for BMS at 1 year.[7,15–18] Assuming a 2-sided α-level of 0.05 and a power of 80%, the trial would have required a total number of 240 patients randomized 1:1 to the 2 stent types. All analyses were performed according to the intention-to-treat principle. Baseline continuous variables are reported as means and standard deviations, and differences between study groups were tested using the nonparametric Wilcoxon rank-sum test. Counts and percentages are reported for baseline categorical variables and were compared between groups using Fisher exact test. Time-to-event analyses were carried out using the Kaplan–Meier method and Cox proportional hazards models (stratified by study center), with patients censored at their last observation. Landmark analyses, splitting follow-up time into 0 to 12 and 13 to 60 months, were performed for all end points. Hazard ratios (HR) for the primary and secondary end points, alongside their 95% CI, were estimated using Cox proportional hazard regression with numerical results stabilized by Firth's penalized-likelihood approach.[19] For the adjusted analysis, all predefined potential confounders were introduced simultaneously into the model: patient's age and age of the SVG were introduced as continuous variables, while sex, acute coronary syndrome at time of randomization, renal dysfunction, and diabetes mellitus were introduced as categorical variables. Quality of life data were analyzed using linear mixed effects models, with patient identification number as random effect. The fixed effects for the full models were treatment arm and its interaction with follow-up visit, in addition to baseline value of the respective domain. We test the effect of stent type by performing a likelihood ratio test between the full model and a model including follow-up visit as fixed effect adjusted for baseline values. The quality of life analyses were performed on the basis of available data. All analyses were performed with the statistical software system R.[20] A $P<0.05$ indicated statistical significance.

RESULTS

In total, 173 patients who had previous coronary artery bypass surgery and who were undergoing cardiac angiography at a participating center were enrolled and randomly assigned to receive either a BMS (n=84) or DES (n=89, Figure 1). Because of slower than expected recruitment rates, the Steering Committee decided to terminate the study prematurely after inclusion of 72% of the anticipated sample size. All patients received the randomly assigned stent type, except for 1 patient in the BMS group, who received a DES (Figure 1). Baseline characteristics were well balanced as reported in Table 1. Mean age was 71 years and 90% were male. Forty-four percent of the patients had diabetes mellitus and the majority (63%) had a history of previous myocardial infarction. An acute coronary syndrome was diagnosed in 38% of the participants at the time of enrollment. Distal protection devices and glycoprotein IIb/IIIa inhibitors were used in 66% and 73% of all

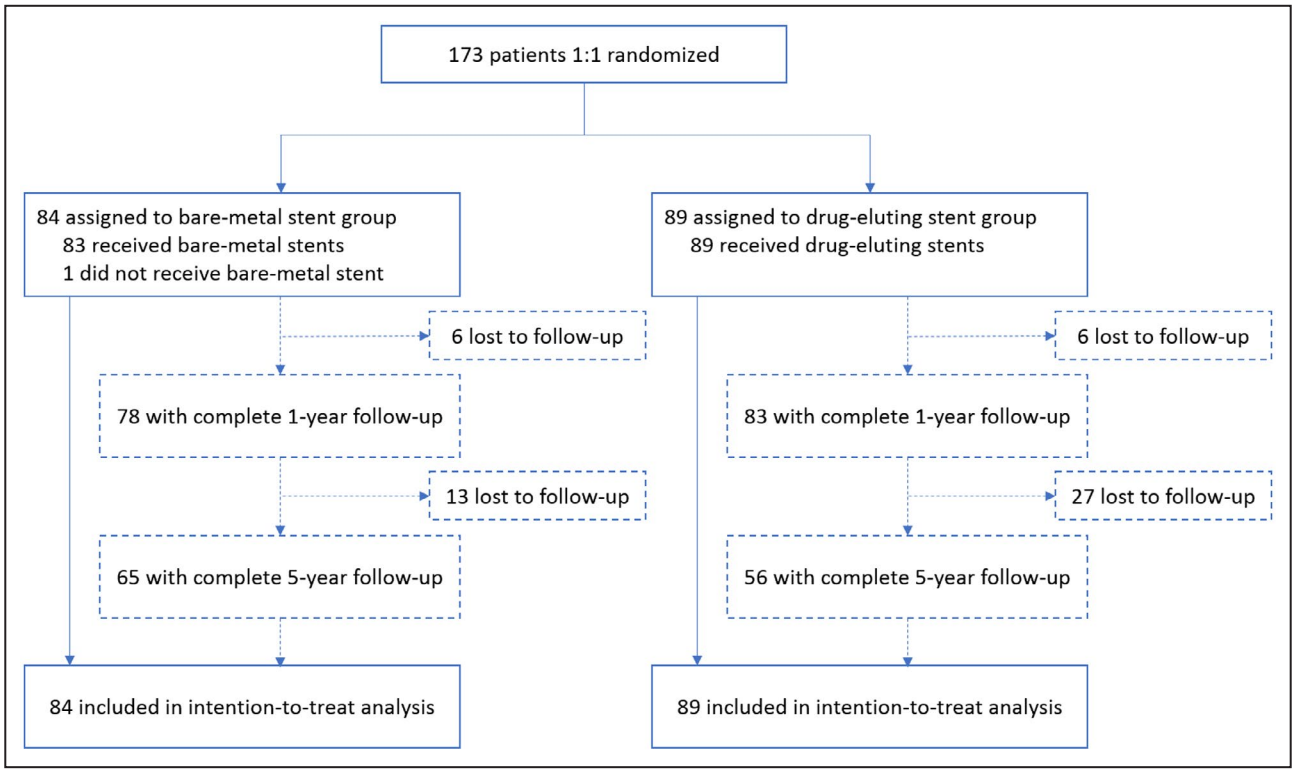

Figure 1. Patient flow-chart.

interventions, respectively. The average stent length and diameter was 31±20 and 3.7±0.6 mm. One-year follow-up was completed in all but 6 patients in each treatment group (93%, Figure 1). The 5-year results are based on a follow-up rate of 70% (121 of 173 patients). The proportional hazard assumptions of the Cox models have been checked both graphically and numerically (by testing the correlations of the scaled Schoenfeld residuals with time) and they are tenable.

One-Year Outcome

The primary end point of MACE at 1 year occurred in 2 patients (2.2%) in the DES group compared with 13 patients (16.0%) in the BMS group (HR, 0.14; 95% CI, 0.03–0.64, *P*=0.01) as shown in Table 2 and Figure 2. There was a numerically higher rate of subsequent myocardial infarction (2.2% versus 9.8%, HR, 0.27; 95% CI, 0.06–1.28) and a significantly higher need for TVR (0% versus 10.1%, HR, 0.05; 95% CI, 0.00–0.44) in the BMS compared with the DES group. There was only 1 cardiac death in the BMS and none in the DES group. Rates of stent thrombosis were higher in the BMS group (DES 0% versus BMS 6.2%, HR, 0.10; 95% CI, 0.00–0.92, *P*=0.04), whereas major bleeding (2.3% versus 2.4%, HR, 0.89; 95% CI, 0.13–6.35, *P*=0.91) and noncardiac death (1.2% versus 4.9%, HR, 0.30; 95% CI, 0.03–2.79; *P*=0.29) were similar in both arms. After adjusting for potential confounders such as the age of patients and of SVGs, sex, initial presentation with an acute coronary syndrome, renal dysfunction, and diabetes mellitus, the multivariable analysis showed that the advantage of DES treatment in terms of MACE remained significant (HR, 0.16; 95% CI, 0.03–0.71; *P*=0.01). This result was confirmed by bivariable analyses and in particular we found no interaction of the randomly allocated treatment with the above potential confounders: age (*P*=0.63), SVG age (*P*=0.89), sex (*P*=0.66), acute coronary syndrome (*P*=0.29), renal dysfunction (*P*=0.53), or diabetes mellitus (*P*=0.49).

Five-Year Outcome and Landmark Analysis

At the long-term follow-up of 5 years, the primary end point of MACE remained significantly in favor of DES compared with BMS (DES 35.5% versus BMS 56.1%, HR, 0.40; 95% CI, 0.23–0.68; *P*<0.001, Table 2 and Figure 2). A focused analysis on TVR again showed a significant advantage for patients treated with a DES (DES 13.9% versus BMS 37.5%, HR, 0.23; 95% CI, 0.10–0.51, *P*<0.001).

The Landmark analysis from 1 to 5 years revealed a maintained benefit of DES over BMS (1–5 years, HR,

Table 1. Baseline Characteristics According to Treatment Group

	DES Group (n=89)	BMS Group (n=84)	*P* Value
Patient characteristics			
Male sex	80 (89.9)	75 (89.3)	1.00
Age, y	70.5±7.9	71.4±8.7	0.74
Height, cm	171.4±8.0	171.1±7.5	0.54
Weight, kg	82.2±13.5	85.0±13.9	0.26
Diabetes mellitus	41 (46.1)	34 (41.0)	0.54
Hypertension	81 (91.0)	75 (89.3)	0.80
Dyslipidemia	76 (85.4)	73 (86.9)	0.83
Family history of CAD	35 (39.3)	37 (44.0)	0.54
Smoker			0.71
Former	37 (41.6)	32 (38.1)	
Current	10 (11.2)	13 (15.5)	
History of myocardial infarction	57 (65.5)	47 (60.3)	0.52
History of PCI	32 (36.0)	36 (42.9)	0.44
History of stroke	7 (8.2)	4 (4.8)	0.54
Renal failure	2 (2.2)	5 (6.2)	0.26
Indication for PCI			
Chronic angina	45 (50.6)	46 (54.8)	0.65
Acute coronary syndrome	33 (37.1)	33 (39.3)	0.88
Silent ischemia	18 (20.2)	16 (19.0)	1.00
Medications (periprocedural)			
Aspirin	88 (98.9)	83 (98.8)	1.00
Clopidogrel	88 (98.9)	84 (100)	1.00
Glycoprotein IIb/IIIa inhibitors	67 (76.1)	60 (72.3)	0.60
Lesion characteristics			
Grafts per patient	3.0±1.0	3.1±1.0	0.50
Saphenous vein graft age, y	11.9±4.7	13.5±5.6	0.07
Target graft recipient vessel			0.77
Left anterior descending artery	13 (14.6)	14 (16.7)	
Left circumflex artery	36 (40.4)	39 (46.4)	
Right coronary artery	36 (40.4)	28 (33.3)	
Ramus intermedius	4 (4.5)	3 (3.6)	
Diameter stenosis, %	89.7±9.3	88.9±12.1	0.95
Procedure characteristics			
Stent diameter, mm	3.7±0.6	3.7±0.6	0.61
Inflation pressure, atm	15.7±3.1	15.7±3.4	0.97
Stent length, mm	31.4±19.2	29.9±20.2	0.37
Postinterventional TIMI flow	2.8±0.6	2.9±0.4	0.15
Embolic protection device used	61 (68.5)	53 (63.1)	0.52

Values are mean (±SD) or n (%). *P* values for comparisons between BMS and DES from Wilcoxon rank-sum test for continuous variables and from Fisher exact test for categorical variables. atm indicates atmosphere; BMS, bare-metal stent; CAD, coronary artery disease; DES, drug-eluting stent; PCI, percutaneous coronary intervention; and TIMI, thrombolysis in myocardial infarction.

0.33; 95% CI, 0.13–0.74; *P*=0.007) in terms of TVR as shown in Figure 3.

Of note, patients treated with a BMS presented more often for multiple TVR procedures throughout the study period compared with patients treated with a DES (DES 1.1% [n=1] versus BMS 9.5% [n=8] versus, *P*=0.013).

Quality of Life

Quality of life was assessed in a global, an emotional, and a social domain. In all 3 domains, postoperative values were slightly higher than preoperative ones. Stent type had no noticeable effect on baseline adjusted quality of life measurements (likelihood ratio tests: p-global=0.842; p-emotional=0.675; p-social=0.748).

Table 2. Clinical Outcomes According to Treatment Group at 1 and 5 Years

	1-y Follow-Up				5-y Follow-Up			
	DES	BMS	Hazard Ratio (95% CI)	*P* Value	DES	BMS	Hazard Ratio (95% CI)	*P* Value
MACE	2 (2.2)	13 (16.0)	0.14 (0.03–0.64)	0.01	22 (35.5)	39 (56.1)	0.40 (0.23–0.68)	<0.001
Cardiac death	0 (0.0)	1 (1.3)	0.30 (0.00–5.67)	0.43	9 (14.8)	12 (19.0)	0.69 (0.29–1.64)	0.40
Nonfatal myocardial infarction	2 (2.2)	8 (9.8)	0.27 (0.06–1.28)	0.10	12 (19.9)	16 (23.6)	0.63 (0.29–1.34)	0.23
Target-vessel revascularization	0 (0.0)	8 (10.1)	0.05 (0.00–0.44)	0.003	8 (13.9)	24 (37.5)	0.23 (0.10–0.51)	<0.001
Nonfatal myocardial infarction or cardiac death	2 (2.2)	9 (11.0)	0.23 (0.05–1.09)	0.06	20 (32.9)	26 (38.1)	0.67 (0.37–1.20)	0.18
Stent thrombosis	0 (0.0)	5 (6.2)	0.10 (0.00–0.92)	0.04	7 (11.1)	8 (11.6)	0.78 (0.28–2.19)	0.63
Noncardiac death	1 (1.2)	4 (4.9)	0.30 (0.03–2.79)	0.29	3 (4.3)	6 (8.2)	0.57 (0.14–2.32)	0.43
Major bleeding	2 (2.3)	2 (2.4)	0.89 (0.13–6.35)	0.91	3 (4.2)	2 (2.4)	1.37 (0.23–8.21)	0.73

Values are n (%). Hazard ratio and *P* values for comparisons between BMS and DES from Cox proportional hazards models. BMS indicates bare-metal stent; DES, drug-eluting stent; and MACE, major adverse cardiac events.

The marginal difference of the baseline adjusted quality of life domain values between the DES and the BMS arms, averaged on all time-points, were estimated at (estimate [95% CI]) 0.11 [–0.22, 0.44], 0.06 [–0.2, 0.33], and 0.21 [–0.18, 0.60] for the global, emotional, and social domains, respectively.

DISCUSSION

The BASKET-SAVAGE trial is the only randomized clinical trial among patients undergoing stenting of SVG lesions with a prespecified long-term follow-up of 5 years. The results show a lower rate of the primary composite end point MACE after DES implantation at 1 year with a sustained benefit throughout the study period compared with BMS. This benefit is mainly driven by a reduction of subsequent myocardial infarctions and TVR at 1-year follow-up and a need for TVR procedures up to 5 years. Moreover, following initial BMS implantation, more patients required multiple TVR interventions during the whole study period compared with patients randomized into the DES group.

Previous randomized trials on percutaneous vein graft interventions have shown that DES are associated with a lower risk of restenosis as compared with BMS, when focusing on the short-term outcome. In summary, the RRISC (Reduction of Restenosis in Saphenous Vein Grafts With Cypher Sirolimus-eluting Stent) trial revealed a significant reduction in late in-stent lumen loss and TVR with sirolimus-eluting stents compared with BMS at 6 months, without an increase in death or myocardial infarction.[7] Paclitaxel-eluting stents were studied in the SOS (Stenting of Saphenous Vein Grafts) trial, which reported a reduction in restenosis rate and target-lesion revascularization in the DES group compared with the BMS group through 1-year follow-up.[6] The ISAR-CABG trial, which randomized 610 patients with failing SVG to first-generation DES or BMS, demonstrated that DES were associated with lower rates of target-lesion revascularization and met the primary end point 1-year MACE.[5] However, these trials had protocol-required angiographic lesion reassessment, which is known to increase the rates of repeat revascularization in favor of the DES.[8] The BASKET-SAVAGE trial was the first study to assess for clinical end points without routine angiographic follow-up. Our findings provide an important addition to the literature, namely, that DES reduces "robust" clinical end points, without being influenced by routine angiography-triggered revascularization.

Conflicting results were reported among the few studies investigating outcome beyond 1 year. The recently published 5-year results of the large ISAR-CABG trial mentioned earlier, which showed a loss of early advantage of DES in reducing revascularization after SVG lesion interventions compared with BMS.[9] This late catch-up phenomenon was found 2 to 3 years after the index procedure and launched a debate about the efficacy and safety of DES in SVG-treated lesions. However, the long-term results from the ISAR-CABG trial were a nonprespecified post hoc analysis of a randomized study, and therefore these findings should be viewed as hypothesis-generating. The same limitation applies to the post hoc analysis of the long-term results from the RRISC (excessive all-cause mortality with no difference in myocardial infarction or TVR with DES) and SOS (sustained benefit regarding MACE with DES) trials; moreover, these results were even more limited by a rather short follow-up duration of <3 years and a small sample size.[21,22] In contrast to the long-term results from the ISAR-CABG and RRISC trials and in line with the SOS data, our long-term analysis showed a sustained benefit of DES over BMS in terms of MACE throughout the study period of 5 years. In addition,

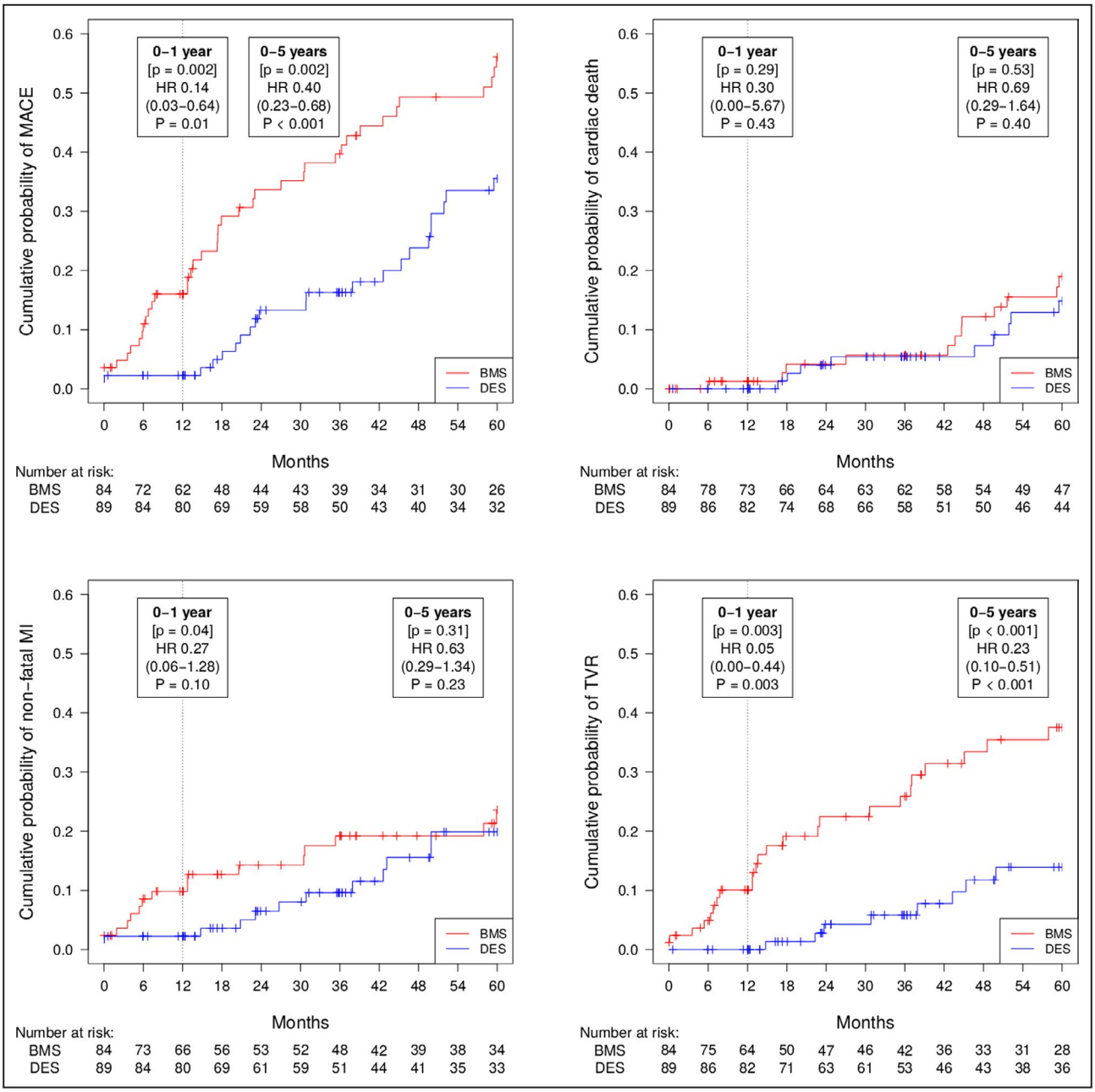

Figure 2. Kaplan–Meier estimates for MACE (composite of cardiac death, nonfatal MI, and TVR) and its individual components stratified by randomized treatment assignment.
P values without brackets are derived from a center-stratified Wald test. *P* values in brackets report the results from an unstratified log-rank test. BMS indicates bare-metal stent; DES, drug-eluting stent; HR, hazard ratio; MACE, major adverse cardiac events; MI, myocardial infarction; and TVR, target-vessel revascularization.

more patients underwent multiple TVR procedures in the BMS group compared with the DES group, which further supports the superiority of DES in treating SVG lesions.

Early-generation DES and BMS are associated with more adverse events.[23,24] Newer DES were designed to improve upon the limitations of first-generation stents by modifying the eluting drug, improving the biocompatibility of polymers, and reducing the stent strut thickness. The DIVA trial was designed to compare the efficacy of DES with BMS for the treatment of de novo SVG lesions in a contemporary setting.[10] In this multicenter trial, 597 (17%) of the 3482 screened patients were randomized to either treatment arm. With the more generous use of newer-generation stents, the DIVA trial showed no difference in MACE or TVR. Of note, this is the only study that failed to demonstrate the superiority of DES over

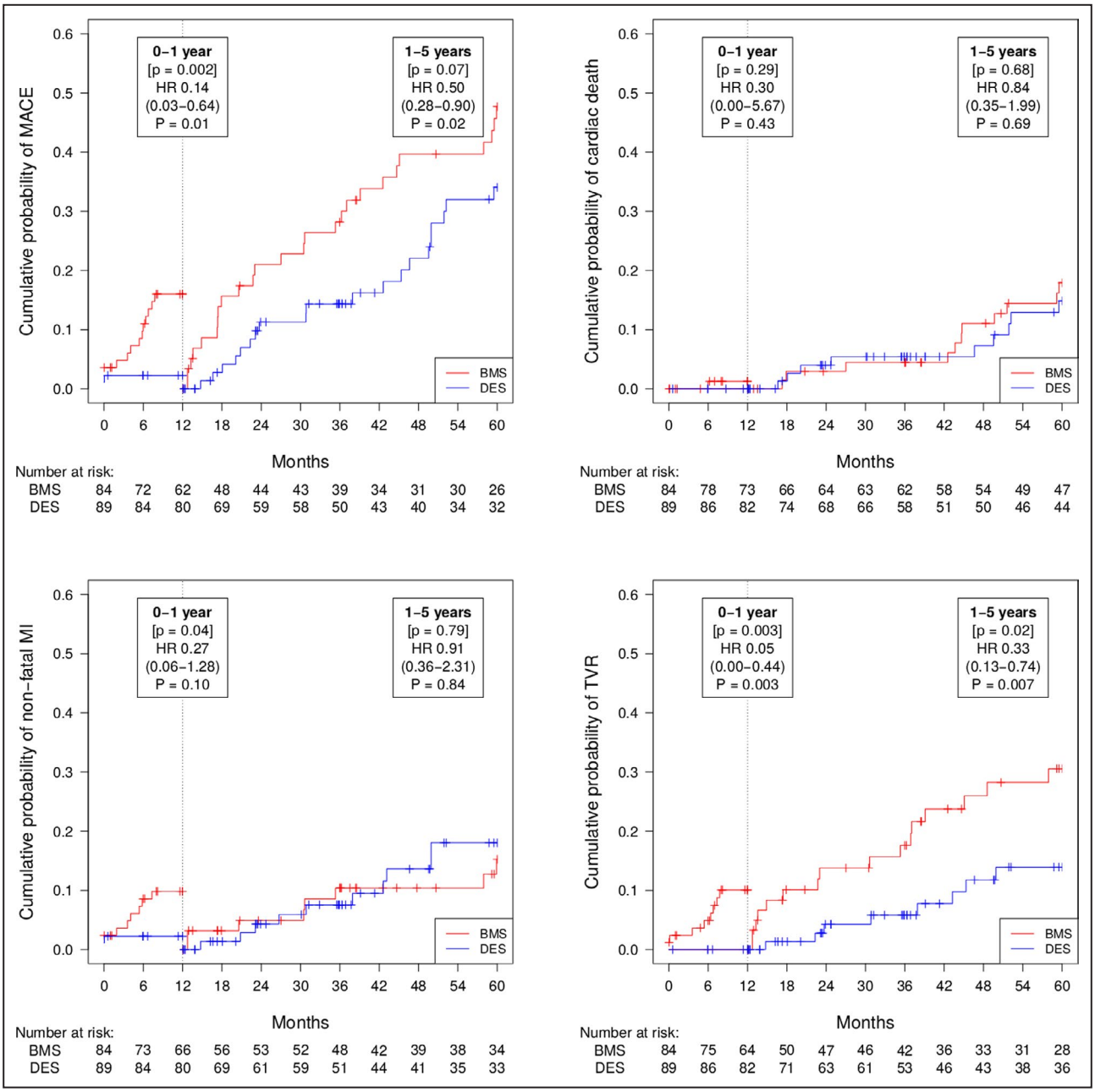

Figure 3. Land-mark analyses at 1 to 5 years for MACE, cardiac death, nonfatal MI, and TVR stratified by randomized treatment assignment.

P values with and without brackets as in Figure 2. BMS indicates bare-metal stent; DES, drug-eluting stent; HR, hazard ratio; MACE, major adverse cardiac events; MI, myocardial infarction; and TVR, target-vessel revascularization.

BMS in SVG lesions at 1-year follow-up. The absence of benefit with DES in DIVA is unclear but could be related to the double-blinded study design, different stenting technique (as indicated by the numerically greater stent diameter of 3.7 mm in BASKET-SAVAGE versus 3.4 mm in DIVA), or the use of different antiproliferative drug content as previously discussed.[25] However, these differences in study design cannot solely explain the lack of differences between the results of the DIVA as compared with the other randomized trials. First, the premature termination of the study after enrollment of 76% of the anticipated recruitment goal, second, the systematic use of thin-strut stent platforms that have a lower risk of adverse events as compared with thicker strut stents used in previous SVG intervention studies,[24,26] and finally, the use of more powerful and prolonged dual antiplatelet therapy as well as more aggressive secondary prevention of atherosclerotic disease progression in the past decade might have mitigated the differences

between the DES- and BMS-treated arms.[27] These factors may have resulted in insufficient power to find a difference in outcome. Moreover, because of the rather short follow-up duration of the DIVA trial of only 2.7 years, it is possible that a divergence in outcome may occur at a later point in time (given the sustained benefit of DES over BMS found in the BASKET-SAVAGE trial).

Limitations

Several limitations must be considered when interpreting the results of this study. First, the study reached only 72% of the projected sample size. In view of a growing number of patients presenting with multivessel disease, it proved difficult to recruit patients with pure SVG disease during the course of recruitment. Despite this limitation, the beneficial effect of DES therapy in our study is obvious and the initially calculated sample size might have been exaggerated based on the lack of randomized data at the time the study was designed. This notion is supported by the fact that based on data from the SOS trial (revascularization rate paclitaxel-eluting stent 20% versus BMS 41% at 1 year, α=0.05, power 80%[6]), 148 patients would have been sufficient to achieve an adequate sample size for this end point. Second, the DES under investigation was a paclitaxel-eluting stent, which is less used for native coronary lesion treatment at present. The aim of the study was to compare the same stent platform with and without antiproliferative drug. At the time of study development, the Liberté stent platform was the only commercially available devices that allowed treatment of lesions with a diameter up to 5.5 mm, which might be found in SVG lesions. Third, the overall follow-up rate at 5 years was only 70% with numerically more patients lost in the DES group, which may have influenced the result. Fourth, the use of glycoprotein IIb/IIIa inhibitor during the intervention was recommended according to the study protocol, whereas its use is discouraged in the current cardiology guidelines. However, the use of glycoprotein IIb/IIIa inhibitor was balanced in the 2 groups and is therefore unlikely to influence our findings. Finally, the study was open-label, though adjudication of the clinical events was performed blinded to stent allocation.

CONCLUSIONS

The randomized BASKET-SAVAGE trial with a long-term analysis of 5 years revealed a sustained benefit of DES over BMS implantation in terms of MACE reduction when treating failing venous grafts, despite lower than targeted sample size. More patients in the BMS group underwent multiple revascularization procedures in the target vessel throughout the study period. This trial provides evidence that DES may be preferred in patients undergoing SVG intervention.

ARTICLE INFORMATION

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Affiliations

From the University Hospital, Basel, Switzerland (G.F., P.R., D.C., C.M., O.P., R.T., M.C., M.C., C.K., M.P., R.V.J.); Klinikum Westfalen, Dortmund, Germany (A.F.); Central Clinic, Bad Berka, Germany (A.F.); Rigshospitalet, Copenhagen, Denmark (T.E.); Bispebjerg University Hospital, Copenhagen, Denmark (S.G.); Gentofte Hospital, Hellerup, Denmark (S.G.); Triemli Hospital, Zürich, Switzerland (F.E.); Population Health Research Institute, McMaster University, Hamilton, Canada (D.C.); Herzzentrum Dresden, Technische Universität Dresden, Dresden, Germany (N.M.); Heart Center, University of Leipzig, Germany (N.M., G.S., S.M.-W.); and University of Jena, Germany (S.M.-W.).

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Disclosures

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Supplemental Material

Appendix S1

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SUPPLEMENTAL MATERIAL

BASKET SAVAGE - List of Investigators			
Center	**Title**	**Name**	**Role**
Basel	MD	Jeger, Raban	principal investigator
	MD	Buser, Peter	sub investigator
	MD	Kaiser, Christoph	sub investigator
	MD	Zellweger, Michael	sub investigator
	MD	Sticherling, Christian	sub investigator
Triemli	MD	Eberli, Franz	principal investigator
	MD	Kurz, David	sub investigator
	MD	Tüller, David	sub investigator
	MD	Zbinden, Rainer	sub investigator
	MD	Reho, Ivano	sub investigator
Gentofte Sygehus	MD	Galatius, Søren	principal investigator
	MD	Abildgaard, Ulrik	sub investigator
	MD	Galløe, Anders	sub investigator
	MD	Jensen, Jan Skov	sub investigator
	MD	Madsen, Jan Kyst	sub investigator
Rigshospitalet	MD	Engstrøm, Thomas	principal investigator
	MD	Kelbæk, Henning	sub investigator
	MD	Jørgensen, Erik	sub investigator
	MD	Saunamäki, Kari	sub investigator
	MD	Holmvang, Lene	sub investigator
	MD	Helqvist, Steffen	sub investigator
Leipzig	MD	Möbius-Winkler, Sven	principal investigator
	MD	Thiele, Holger	sub investigator
	MD	Erbs, Sandra	sub investigator
	MD	Lenk, Karsten	sub investigator
	MD	Boudriot, Enno	sub investigator
	MD	Fürnau, Georg	sub investigator
	MD	Halfwassen, Uwe	sub investigator
	MD	Beutner, Frank	sub investigator
	MD	Woinke, Michael	sub investigator
	MD	Pittl, Undine	sub investigator
	MD	de Waha, Suzanne	sub investigator
	MD	Mangner, Norman	sub investigator
	MD	Woitek, Felix	sub investigator
	MD	Höllriegel, Robert	sub investigator
	MD	Winzer, Ute	sub investigator
	MD	Teren, Andrej	sub investigator
	MD	Haussig, Stephan	sub investigator
	MD	Tasca, Manuela	sub investigator
Bad Berka	MD	Farah, Ahmed	principal investigator
	MD	Buchter,Björn	sub investigator
	MD	Lauer, Bernward	sub investigator
	MD	Daralammouri, Yunis	sub investigator
	MD	Ohlow, Marc-Alexander	sub investigator
	MD	Schreiber, Matthias	sub investigator
	MD	Fuhrmann, Jörg	sub investigator
	MD	Wagner, Andreas	sub investigator