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CLINICAL RESEARCH
Coronary heart disease

Long-term benefit–risk balance of drug-eluting vs. bare-metal stents in daily practice: does stent diameter matter? Three-year follow-up of BASKET

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Aims To assess the long-term benefit–risk ratio of drug-eluting (DES) vs. bare-metal stents (BMS) relative to stent size.

Methods and results All 826 consecutive BASKET (BAsel Stent Kosten-Effektivitäts Trial) patients randomized 2:1 to DES vs. BMS were followed after 3 years. Data were analysed separately for patients with small stents (<3.0 mm vessel/<4.0 mm bypass grafts, $n = 268$) vs. only large stents (≥3.0 mm native vessels, $n = 558$). Clinical events were related to stent thrombosis. Three-year clinical target-vessel revascularization rates remained borderline reduced after DES [9.9 vs. 13.9% (BMS), $P = 0.07$], particularly in patients with small stents (10.7 vs. 19.8%, $P = 0.03$; large stents: 9.5 vs. 11.5%, $P = 0.44$). Cardiac death/myocardial infarction (MI) rates (12.7 vs. 10.0%, $P = 0.30$) were similar, however, death/MI beyond 6 months was higher after DES [9.1 vs. 3.8% (BMS), $P = 0.009$], mainly due to increased late death/MI in patients with large stents (9.7 vs. 3.1%, $P = 0.006$). The results paralleled findings for stent thrombosis.

Conclusion The clinical benefit of DES was maintained at no overall increased risk of death or death/MI up to 3 years. However, death/MI rates were increased in DES vs. BMS patients beyond 6 months, particularly in patients with large stents, paralleling findings for stent thrombosis. Thus, stent size seems to influence the 3-year benefit–risk ratio after DES implantation.

Keywords Drug-eluting stents • Bare-metal stents • Stent thrombosis • Outcome • Coronary artery disease

Introduction

Late stent thrombosis and its clinical consequences were first noticed in a systematic and prospective manner in the BAsel Stent Kosten-Effektivitäts LAte Thrombotic Events (BASKET-LATE) trial[1] comparing events in an unselected 'real-world' patient population randomized to bare-metal stents (BMS) or drug-eluting stents (DES). The observed increased rate of late stent thrombosis was initially surprising and questioned, however, in the meantime confirmed by many registry findings and meta-analyses, without affecting

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overall mortality.[2–9] Still, conflicting results from registries regarding longer-term mortality or cardiac death/non-fatal myocardial infarction (MI) rates were published.[2,3,7,8,10,11] A sophisticated analysis of the BASKET 18-month data defining predictors of outcome and their interaction with stent type identified a subgroup of patients with large native vessel stenting as one at particular risk for late clinical problems due to late stent thrombosis, whereas patients with small vessel or bypass graft stenting seemed to benefit most from DES implantation.[12] Since BASKET-LATE findings were restricted to an 18-month follow-up, questions arose whether these late stent thrombosis-related events were a 'chance finding' or would continue to occur virtually exclusively after DES as noted in a large restistry,[13] how this would be after BMS implantation and whether this was still particularly so in patients with large native vessel stenting which were actually those enrolled in the pivotal DES trials.[3,4]

To address these open questions we performed a clinical 3-year follow-up investigation of all patients included in BASKET.[14] Specific aims were: (i) to assess the 3-year benefit–risk ratio, i.e. the 3-year rate of clinically indicated target-vessel revascularizations (TVRs) in relation to 3-year rates of cardiac death/non-fatal MI, (ii) to differentiate early ($\leq$6 months) from late (>6 months) clinical events, (iii) to define this benefit–risk ratio in predefined subgroups of small vs. large stents (cut-off diameter 3.0 mm) and (iv) to relate these findings to stent thromboses according to the Academic Research Consortium (ARC) definition.[15]

Methods

Setting, participants, randomization and interventions

Patient selection for the BASKET trial has previously been described.[14] In short, all 952 consecutive patients treated with angioplasty and stenting between May 2002 and May 2003 at the University Hospital of Basel, Switzerland, were evaluated for study inclusion irrespective of indication for stenting. Only patients with vessels >4 mm in diameter, restenotic lesions, and those without consent were excluded ($n = 126$). Thus, the study population consisted of 826 patients, which was randomized in a 2:1 fashion to receive a DES [Cypher® Cordis, Johnson&Johnson, Miami Lakes, FL, USA ($n = 264$); TAXUS®, Boston Scientific Corporation, Natick, MA, USA ($n = 281$)], and 281 patients to receive a third generation cobalt-chromium BMS (Vision®, Guidant Corporation, Indianapolis, IN, USA). All patients gave written informed consent and later on separately for the extended follow-up. The protocol has been approved by the Ethics Committee of the University Hospital of Basel, Switzerland.

Patients were subdivided into 'small-stent' and 'large-stent' patient subgroups based on an 18-month analysis, in which all predictors of cardiac death, non-fatal MI, and non-MI-related TVR were analysed and multivariable predictors tested for their interaction with the stent type implanted.[12] This analysis tested if the effects of DES vs. BMS on outcome differed significantly relative to clinical and angiographic baseline characteristics. The use of at least one small stent (<3.0 mm diameter) or bypass graft intervention showed significant interactions between stent types and outcome measures in multivariable analyses. Thus, patients with at least one small stent (<3.0 mm stents) or 'small' bypass graft stenting (<4.0 mm) were defined a priori as 'small-stent' patients and those with only large ($\geq$3.0 mm diameter stents) native vessel stenting as 'large-stent' patients for the present study.

Outcomes and follow-up

The primary endpoint of this extended follow-up investigation was the rate of cardiac death/non-fatal MI after 3 years in DES vs. BMS-treated patients. Secondary endpoints were non-MI-related TVR (and any TVR) and major cardiac events (MACE) defined as cardiac death, non-fatal MI, and non-MI-related TVR including stent thrombosis-related events as previously defined.[1,12,14] Stent thromboses were categorized into 'definite', 'probable', and 'possible' according to the ARC definitions,[15] the composite of these being total stent thrombosis.

All events were adjudicated by a Critical Events Committee blinded to stent types. For this 3-year follow-up, the same definitions were used as in the 18-month analysis of BASKET,[1] including stent thrombosis according to ARC definitions.[15]

In BASKET, all patients were followed after 6 months in the outpatient clinic for primary endpoint assessment which was cost-effectiveness.[16] All patients were treated with dual antiplatelet therapy up to that point in time and advised to stop clopidogrel then. Patients were then contacted again after 18 months in the outpatient clinic, by structured questionnaire and/or by telephone interview to assess the 18-month outcome reported in BASKET-LATE[1] and to determine 18-month cost-effectiveness.[14] For the extended 3-year follow-up, the same methods and structured questionnaires as after 18 months were used, forming the basis of the present report. No control angiography was allowed except for new relevant ischaemia-related symptoms. If intercurrent hospitalizations and/or procedures were reported, detailed hospital charts, private physician records, and death certificates were analysed. Only three patients living abroad were lost to follow-up, but 16 others, all known to be alive, gave no consent to further questioning. Thus, follow-up was complete at 3 years regarding full data in 807 (97.7%) and regarding survival in 823 patients (99.6%). For time-dependent analysis, follow-up was censored at the last contact in the other 19 patients (*Figure 1*).

Statistical analysis

All analyses were performed with the primary aim to compare patients with DES and BMS. Since this study was planned as follow-up investigation of BASKET, sample size calculations were done for the original purpose only.[14] Therefore, patients were followed in an 'observational' manner. Patients were subdivided into 'small-stent' and 'large-stent'

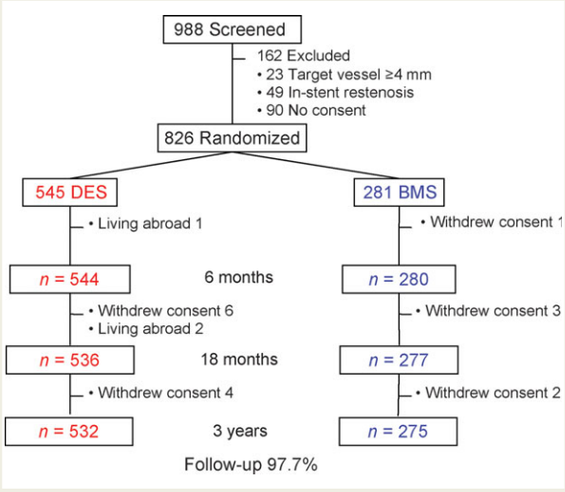

Figure 1 Patient flow diagram.

subgroups as defined earlier. Quantitative variables are presented as mean ± standard deviation. Categorical variables are described by their distribution. Two-group comparisons were done using Fisher's exact test for categorical variables and unpaired *t*-test or Mann–Whitney *U* test for quantitative variables. Cumulative incidence was used to display the proportion of patients with events over time, considering non-cardiac death as competing risk.[17] Hazards were calculated to compare DES and BMS using Cox-regression. Multivariable survival analysis using a Cox-regression model which was corrected for all variables shown in *Table 1* [for analyses in 'large-stent' and 'small-stent' subgroups all variables except bypass PCI (percutaneous coronary intervention) and use of stents <3.0 mm] was performed to test independence of the results of patient and lesion characteristics. Finally, a landmark analysis was performed dividing the entire follow-up into initial 6 months, the primary endpoint period of BASKET, and the following 30 months (months 7–36) period.[18] All calculations were performed with the use of a commercially available statistical package (SPSS 15.0), using a significance level of 0.05 and two-sided tests.

Results

Baseline characteristics of the whole patient population as well as of the two subgroups are summarized in *Table 1*. Overall, patients represent a typical 'real-world' population with high rates of acute coronary syndrome and 'off-label DES' use, cardiovascular risk factors, and multivessel disease with several high risk characteristics, such as multiple and long-vessel stenting. There were no significant differences between patients with DES and BMS at baseline except for stent length which was somewhat longer in DES patients. However, baseline characteristics differed significantly between 'small-stent' and 'large-stent' patients, as defined for this study.[12] Sixty per cent of patients stopped dual antiplatelet therapy immediately after 6 months and 83 and 80% were on monotherapy after 18 and 36 months, respectively, with no differences between the stent groups and no influence on outcome.

Three-year event rates of drug-eluting stent vs. bare-metal stent

The benefit of DES in reducing the rate of non-MI-related TVRs for clinical symptoms persisted up to 3 years ($P = 0.07$), particularly in patients with small stents ($P = 0.03$); however, this benefit was small and non-significant in patients with large stents ($P = 0.44$; *Figure 2* and *Table 2*). This result was achieved without a significant difference in total or cardiac mortality in the total study population

Table 1 Baseline characteristics

	Overall ($n = 826$)	Drug-eluting stents ($n = 545$)	Bare-metal stents ($n = 281$)	Subgroups		
				Large stents ($n = 558$)	Small stents ($n = 268$)	*P*-value (subgroups)
Male	650 (79%)	422 (79%)	223 (79%)	435 (78%)	215 (80%)	0.47
Age (years)	64 ± 11	64 (11)	64 (11)	63 ± 11	66 ± 11	<0.001
Diabetes	154 (19%)	93 (17)	61 (22)	97 (17%)	57 (22%)	0.16
Hypertension	550 (67%)	358 (66%)	192 (68%)	354 (63%)	196 (73%)	0.008
Hypercholesterol	628 (76%)	414 (76%)	214 (76%)	420 (75%)	206 (77%)	0.54
Current smoking	238 (29%)	151 (28%)	87 (31%)	184 (33%)	54 (20%)	<0.001
Previous MI	226 (27%)	151 (28%)	75 (27%)	126 (23%)	100 (37%)	<0.001
Previous PCI	133 (16%)	91 (17%)	42 (15%)	78 (14%)	55 (21%)	0.02
Previous CABG	105 (13%)	70 (13%)	35 (12%)	33 (6%)	72 (27%)	<0.001
Presentation						
STEMI	176 (21%)	115 (21%)	61 (22%)	142 (25%)	34 (13%)	<0.001
Unstable	301 (36%)	200 (37%)	101 (36%)	201 (36%)	100 (37%)	
Stable	349 (42%)	230 (42%)	119 (42%)	215 (39%)	134 (50%)	
GPIIb/IIIa blockers	212 (26%)	141 (26%)	71 (25%)	156 (28%)	56 (21%)	0.03
Multivessel disease	566 (69%)	371 (68%)	195 (69%)	347 (62%)	219 (82%)	<0.001
Bypass graft PCI	47 (6%)	34 (6%)	13 (5%)	0 (0%)	47 (18%)	<0.001
CTO	28 (3%)	14 (3%)	14 (5%)	11 (2%)	17 (6%)	0.002
Bifurcations	44 (5%)	27 (5%)	17 (6%)	20 (4%)	24 (9%)	0.002
Stented segments	1.5 ± 0.7	1–6 (0–7)	1–5 (0–7)	1.3 ± 0.6	1.8 ± 0.8	<0.001
Stents/patient	1.9 ± 1.1	1–9 (1–1)	1–9 (1–0)	1.3 ± 0.9	2.3 ± 1.1	<0.001
Total stent length (mm)	34 ± 20	34 (20)	32 (20)	30 ± 17	42 ± 24	<0.001
Stent length/lesion (mm)	28 ± 15	28 (15)	27 (16)	26 ± 14	31 ± 17	<0.001
≥1 stent(s) <3.0 mm	229 (28%)	160 (29%)	69 (25%)	0 (0%)	229 (85%)	<0.001
Off-label use[a]	548 (66%)	376 (69%)	172 (61%)	327 (59%)	221 (82%)	<0.001

Abbreviations: CABG, coronary artery bypass grafting; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation MI; GP, glycoprotein.
[a]Off-label use defined according to recent FDA guidelines.

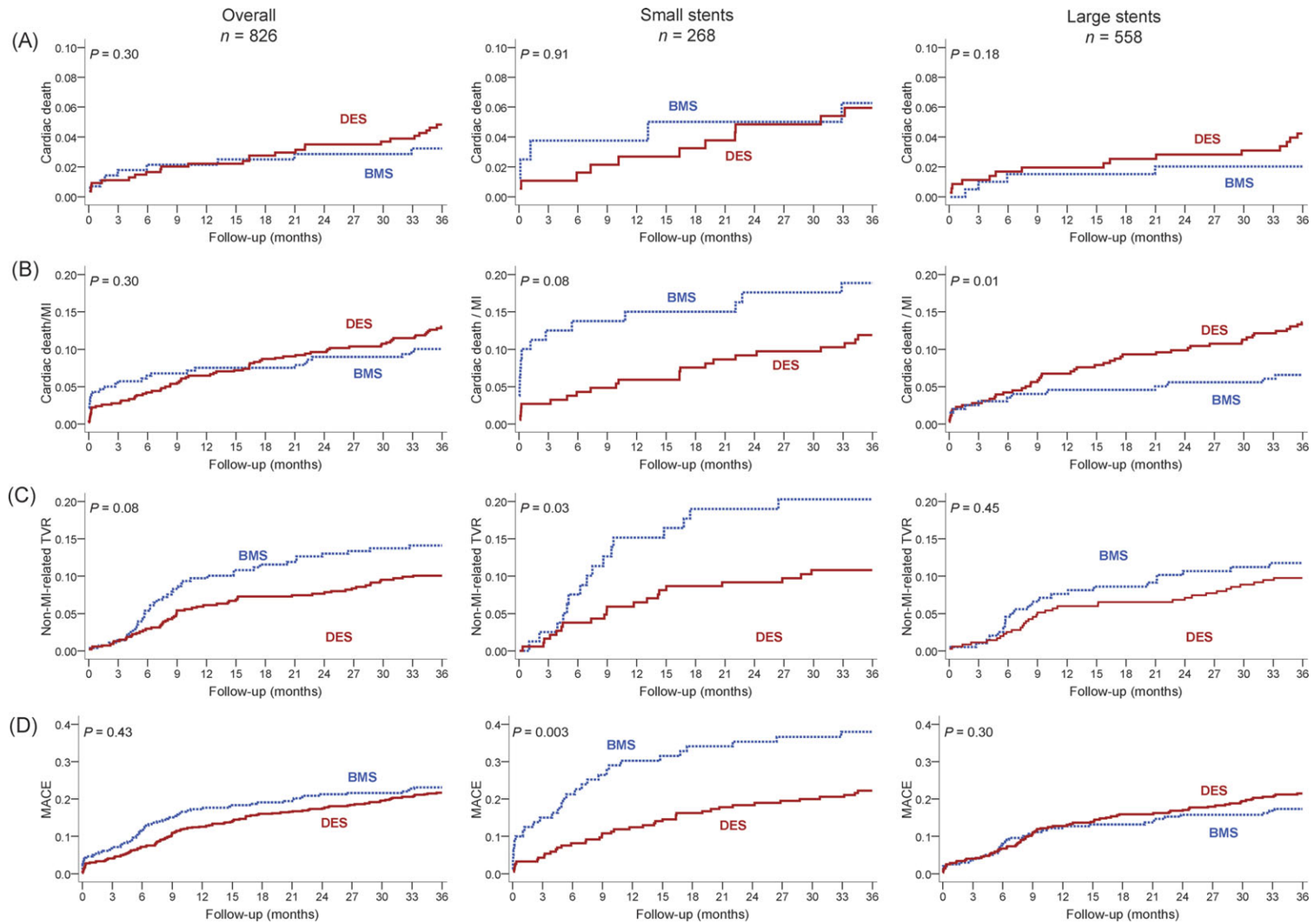

Figure 2 Cumulative incidence of events in the total study population (left) as well as in subgroups with small and large stents, respectively. Cardiac death (*A*), cardiac death/MI (myocardial infarction) (*B*), non-MI-related TVR (target-vessel revascularization) (*C*) and MACE (major cardiac events) (*D*), comparing patients treated with DES (drug-eluting stent) vs. those treated with BMS (bare-metal stent). Note that scales of cumulative incidence differ between (*A*), (*B*) and (*C*), and (*D*).

Table 2 Outcome events after 3 years

	Overall			Large stents			Small stents		
	DES ($n = 545$)	BMS ($n = 281$)	*P*-value	DES ($n = 358$)	BMS ($n = 200$)	*P*-value	DES ($n = 187$)	BMS ($n = 81$)	*P*-value
Total death	8.3%	6.8%	0.49	7.3%	5.5%	0.49	10.2%	9.9%	1.0
Cardiac death	4.8%	3.2%	0.36	4.2%	2.0%	0.23	5.9%	6.2%	1.0
Cardiac death/MI	12.7%	10.0%	0.31	13.4%	6.5%	0.02	11.2%	18.5%	0.12
Non-MI TVR	9.9%	13.9%	0.10	9.5%	11.5%	0.47	10.7%	19.8%	0.05
Any TVR	14.7%	17.5%	0.29	14.0%	14.1%	0.98	16.0%	25.9%	0.06
MACE	21.1%	22.8%	0.59	20.9%	17.0%	0.27	21.4%	37.0%	0.01

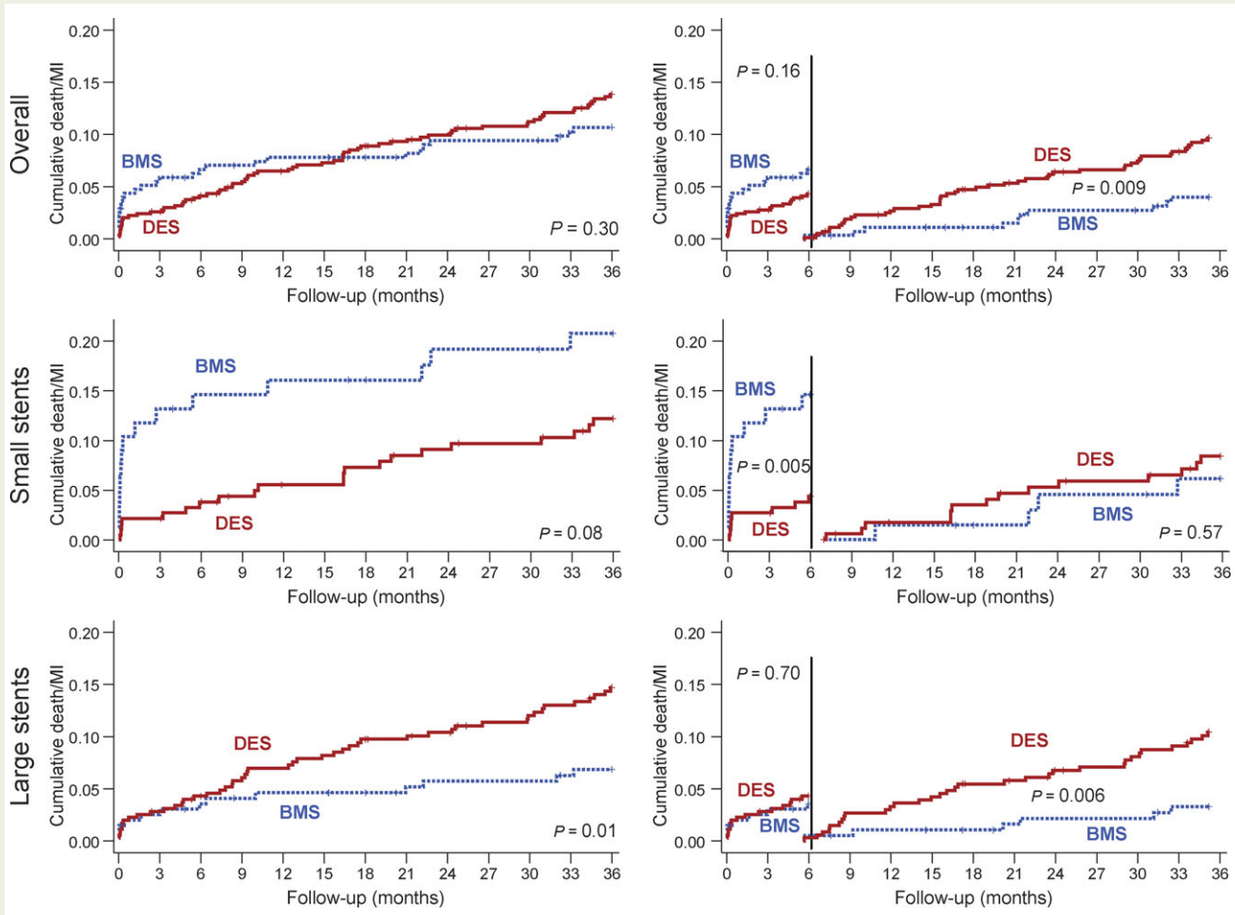

Figure 3 Three-year cumulative incidence of cardiac death/non-fatal MI (myocardial infarction) subdivided into early and late events. Cardiac death/MI over 3 years (left) and subdivided into the first 6 months and thereafter (right) for all patients (top), patients with small stents (middle) and patients with large stents (bottom).

as well as in the two subgroups. Overall, also cardiac death/MI, the primary endpoint of this study, was not different between stent types (*Figure 2*). However, the 3-year cardiac death/MI rate was significantly higher in patients with large stents treated with DES than in those treated with BMS. In contrast in patients with small stents, there was a trend favouring DES over BMS (*Table 2*, *Figure 2*). Thus, the benefit–risk ratio expressed as combination of cardiac death/MI and TVR, i.e. the 3-year MACE rate, was similar for the two stent types overall and in 'large-stent' patients, but showed a marked advantage for DES over BMS in 'small-stent' patients (*Table 2*, *Figure 3*). Multivariable analysis revealed that the effects of DES vs. BMS on the primary endpoint overall, and in the two

subgroups did not differ if other patient or lesion-specific characteristics were considered. Thus, after correction for baseline characteristics, no significant effects of DES use on cardiac death/MI was found overall (HR = 1.24, 95% CI 0.79–1.943, $P = 0.35$) nor in patients with small stents (HR = 0.69, 95% CI 0.33–1.46, $P = 0.33$). In contrast, DES use was an important risk factor for cardiac death/MI in 'large-stent' patients (HR = 2.08, 95% CI 1.11–3.89).

Difference between early and late events

The landmark analysis separating early from late clinical events is shown in *Figure 3* for cardiac death/MI. Overall, there was an early non-significant benefit of DES, which contrasted to a significantly higher rate of cardiac death/MI beyond 6 months (DES 9.1%, BMS 3.8%, $P = 0.009$). This was mainly due to an increased rate of such late events in patients with large stents (9.7 vs. 3.1%, $P = 0.006$), whereas this difference was smaller and not significant in patients with small stents (7.9 vs. 5.8%, $P = 0.57$). This resulted in overall yearly cardiac death/MI rates after 6 months at 3.6% per year in DES (95% CI 2.6–4.6%) and 1.5% per year (95% CI 0.6–2.5%) in BMS-treated patients. These yearly event rates after 6 months were 3.9% (95% CI 2.6–5.2%) vs. 1.3% (95% CI 0.3–2.3%) for 'large-stent' and 3.1% (95% CI 1.5–4.7%) vs. 2.3% (95% CI 0.1–4.6%) for 'small-stent' patients, respectively.

Stent thrombosis-related clinical events

Overall, stent thrombosis-related clinical events were noted in 9.0% of DES and 7.5% of BMS-treated patients ($P = 0.51$) without significant differences in any of the ARC stent thrombosis categories (*Figure 4*). However, there was a higher rate of total stent thrombosis-related events in patients with large stents treated with DES, whereas an opposite trend was seen in 'small-stent' patients. The latter trend was related to a higher rate of target-vessel MIs within the first 6 months in this group and no relevant difference thereafter. In 'large-stent' patients, however, there was no significant difference in the rate of early stent thrombosis between stents, but, after 6 months, stent thromboses occurred more frequently after DES vs. BMS implantation.

Stent thrombosis-related events were noted more often in both stent groups after a first follow-up TVR, which was always performed using a DES irrespective of the initial stent. Overall, rates were 5.2% after a first TVR vs. 2.7% with no previous reintervention in patients initially treated with DES and 8.8 vs. 2.8% in patients initially treated with BMS.

Discussion

The present findings of the first 3-year-follow-up study of an unselected patient population randomized to DES or BMS irrespective of indication for stenting provides new important insights into the late benefit–risk relation of DES vs. BMS; results confirm that overall benefits of DES, i.e. the reduced need for repeat revascularization due to restenotic events, are maintained long-term, and that overall safety, i.e. the rate of cardiac death or non-fatal MI, is similar to that seen after BMS. New are observations that the safety problems discussed after first generation DES implantation in fact increase with time and become clinically relevant late after stenting, particularly in patients treated with large native vessel stenting. This is markedly different from what was found after BMS implantation in this randomized study; late thrombotic events after BMS were a rare event, ~2.5 times less frequent than after DES, and this rate was lower in 'large-stent' patients, adding to the different risk–benefit ratio between small and large-stent patients. These results were paralleled by findings of stent thromboses suggesting a clear association between late stent thrombosis and late clinical events. Thus, hypotheses formulated in an earlier analysis[12] are substantiated by hard clinical findings of the present study and call for caution in the unrestricted use of first generation DES.

In the present clinical study, the reduced need for TVRs due to new symptoms was numerically smaller compared with previous observations resulting in a *P*-value of only 0.07 for the difference. This may be due to the fact that repeat angiography was only allowed for clinical symptoms. A scintigraphic substudy of BASKET[19] showed an additional significant reduction in target vessel ischaemia by DES in absence of relevant symptoms (10.4% after BMS, 5.4% after DES, $P = 0.05$). Thus, the present findings are in agreement with TVR results of previous long-term studies.[5,8,9] Importantly, the benefit of DES in reducing TVR rates was mainly found in patients with small stents and was very small in patients with large stents. The notion that the benefit of DES is larger in small stents has been shown[19] and led to the summary recommendation by the National Institutes of Clinical Excellence in England to restrict the use of DES to small stents.

In the present study, there were no overall increased rates of the safety endpoints, cardiac or total death nor of cardiac death/MI, in DES compared with BMS-treated patients, although this study was not powered to prove this definitively. This reassuring finding was not confirmed, however, in the larger subgroup of patients with large stents in which cardiac death/MI occurred more frequently after DES compared with that after BMS implantation. In fact in multivariable analysis, DES use was the most important risk factor for cardiac death/MI in this subgroup independent of all other patient and lesion-related characteristics. In contrast, there was a trend towards a benefit in this primary endpoint in patients with small stents after 3 years similar to earlier randomized observations with small DES within the initial year of stenting.[20] In the benefit–risk balance expressed as MACE, this resulted in no significant difference in DES vs. BMS-treated patients overall, nor in 'large-stent' patients, but a persistent and marked advantage of DES in 'small-stent' patients.

The present analysis supports the notion of a different benefit–risk relation early and late after DES implantation.[1,6] Whereas early thrombotic events seem to be influenced strongly by procedural factors[21] and are heavily dependent on the continuation of dual antiplatelet therapy,[22,23] late events are mainly related to incomplete or inhomogeneous healing[24] and may occur despite continued dual antiplatelet therapy.[1,13,22] It has been noted that the rate of 'definite' late stent thrombosis increases ~0.6% per year[13] and that this figure increases up to 2.2%[25] or 2.75% per year[26] for definite, possible and probable stent thrombosis events according to the ARC definition, not much different from the present 'real-world' findings. In addition, the present study

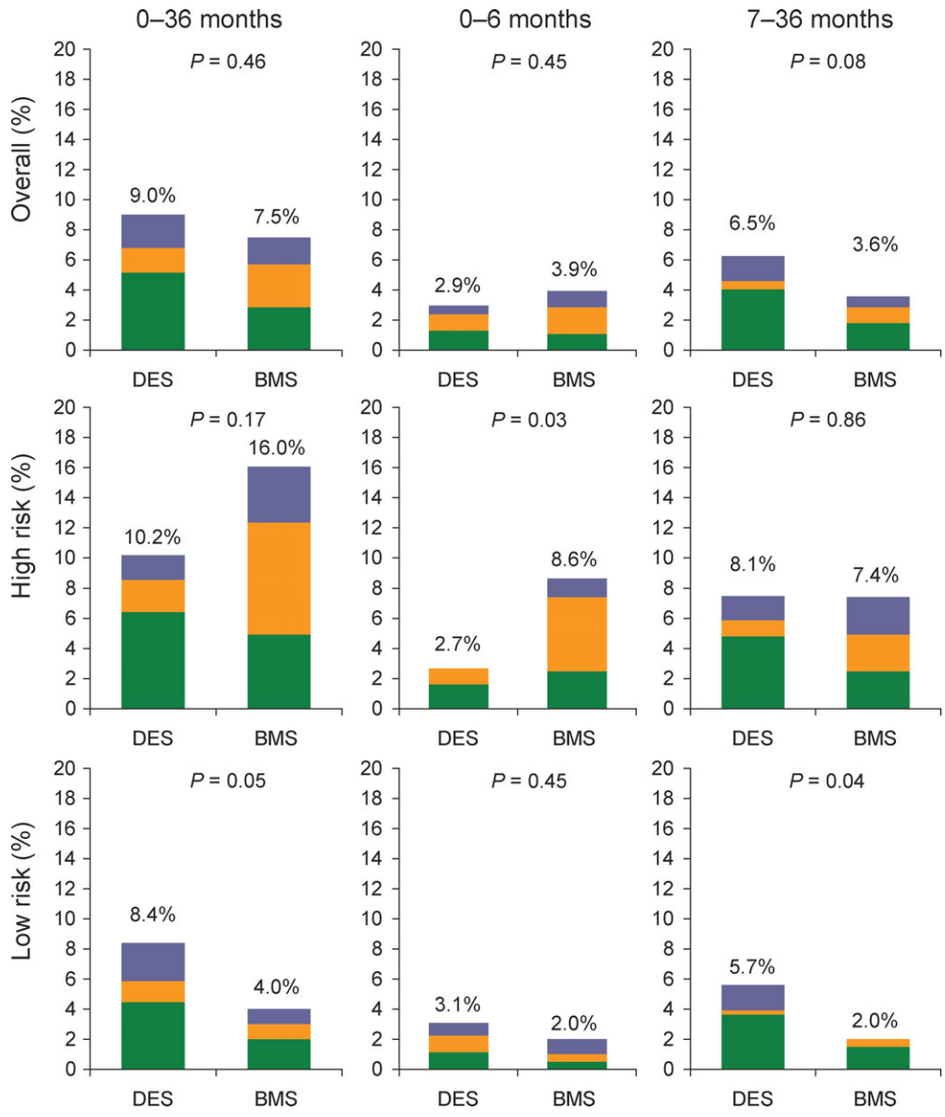

Figure 4 Three-year stent thrombosis rates subdivided into early and late events. Stent thrombosis rates for all patients (top), subgroups with small stents (middle) and large stents (bottom) for the entire 3-year observation period (left panels), the initial 6 months (middle panels) and months 7–36 (right panels). ARC (Academic Research Consortium) 'definite' thromboses in green, 'probable' orange and 'possible' in blue: *P*-values for total stent thrombosis.

shows that late stent thrombosis-related clinical events occur also after BMS implantation, but ~2.5× less frequently than that after DES use. The fact that late clinical events paralleled findings of stent thrombosis suggests a distinct relation between them. However, the occurrence of stent thrombosis shows a different pattern after BMS implantation; it is a rare event if large stents are used, but not if small stents are used. Thus, in patients with small stents the difference in stent thrombosis rates after DES vs. BMS implantation is so low relative to the large benefit of DES that the overall clinical outcome up to 3 years favours DES use in these patients. In contrast, this balance is much worse for patients with large stents mainly due to the small clinical TVR benefit noted previously,[27] arguing against a general DES use in these patients. The increased rate of late stent thrombosis in large DES may be explained by the complexity of patients and lesions treated (mainly more acute coronary syndromes/acute MIs) compared with earlier studies, the higher chance of a clinically apparent event if a large vs. a small vessel is occluded and is in agreement with recent autopsy findings where stent thrombosis was found in 44% of stents $\geq$3.5 mm vs. 9% of stents $\leq$2.5 mm ($P < 0.01$; R. Virmani, personal communication, Local Drug Delivery Meeting, Geneva, January 2007).

The present study is limited by the fact that BASKET was not initially planned to detect late clinical events related to late stent

thrombosis. This is particularly true for the subgroup comparison relating to stent size which would need a much larger sample size for definite answers. However, the present data are supported by the fact that the findings up to 18 months are enhanced in the present 3-year-follow-up study with cardiac death/MI curves separating significantly up to 3 years (*Figure 3* top, bottom). If 18-month results would have been a chance finding, the opposite would be anticipated. In addition, the study was not powered to assess the magnitude of late stent thromboses definitively, however, it is the first randomized investigation presenting detailed data collected prospectively. Finally, since all findings relating to subgroup analyses (i.e. stent size) are only hypothesis generating, they may not be interpreted as stipulating that DES should not be used in 'label' indications, particularly since stent size and 'on-' vs. 'off-label' indications are not at all congruent.

Conclusions

Taken together, the findings of this long-term study suggest, based on randomized data, that baseline stent size seems to determine the long-term benefit–risk balance in a relevant way: patients with at least one small stent have a large benefit of DES in all clinical endpoints, which is not significantly reduced by late stent thrombosis-related events up to 3 years. In contrast, patients with large stents have a small clinical benefit on restenosis-related events only and, therefore, late stent thrombosis-related problems become relevant after 3 years. It remains uncertain how this will translate into an even longer-term outcome balance which, however, will also be affected by the natural progression of underlying coronary disease. This uncertainty and the possible impact of newer DES on this benefit–risk balance, particularly regarding the large group of patients in need of large stents in daily practice, is addressed prospectively in the ongoing European multicentre BASKET-PROVE (BASKET-PROspective Validation Examination), in which 2323 consecutive patients with large vessel stenting were randomized to a first vs. a second generation DES vs. a BMS[28] (results expected in 2010).

Conflict of interest: none declared.

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CARDIOVASCULAR FLASHLIGHTS

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A thrombus stuck in the ostium of the coronary artery

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A 55-year-old male ex-smoker was admitted to our hospital with a 2-h history of anterior chest and back pain. His vital signs and serum biomarkers including troponin I were normal. An electrocardiogram showed atrial fibrillation without an ST-elevation. Plain computed tomography (CT) imaging revealed the high density in the proximal segment of the right coronary artery (RCA), which suggests a thrombus in this vessel (*Panel A*), and axial view and curved planar reconstruction (CPR) in contrast-enhanced CT visualized a large thrombus of 20 × 12 mm stuck at the orifice of RCA (*Panels B* and *C*). Thus, acute coronary syndrome caused by emboli was most likely diagnosis. Thrombolysis was chosen instead of percutaneous coronary intervention to avoid systemic embolization. We used pamiteplase, a recombinant tissue plasminogen activator, as fibrinoytic agent for intravenous therapy and warfarin as anticoagulant. The magnitude of ST-elevation was gradually increased. Atrial fibrillation was converted to normal sinus rhythm but an ST-segment remained elevated in II, III, and aVF for 18 h after thrombolysis therapy. The serum creatine phosphokinase was increased, and reached a peak of 2119 IU/L at 27 h after the onset. On the 15th day, the CPR image showed disappearance of the thrombus at the orifice, and there was no evidence of atherosclerotic plaques in the entire RCA (*Panel D*). These findings allowed us to diagnose that ACS was caused by a thrombus stuck in the ostium of RCA. Cardiac CT may have advantages to detect coronary thrombo-embolism in the patients with atrial fibrillation.