5-Year Follow-Up After Primary Percutaneous Coronary Intervention With a Paclitaxel-Eluting Stent Versus a Bare-Metal Stent in Acute ST-Segment Elevation Myocardial Infarction

A Follow-Up Study of the PASSION (Paclitaxel-Eluting Versus Conventional Stent in Myocardial Infarction With ST-Segment Elevation) Trial

Maarten A. Vink, MD,* Maurits T. Dirksen, MD, PhD,* Maarten J. Suttorp, MD, PhD,‡
Jan G. P. Tijssen, PhD,† Jeroen van Etten, MD,* Mark S. Patterson, MBBS, PhD,*
Ton Slagboom, MD,* Ferdinand Kiemeneij, MD, PhD,* Gerrit J. Laarman, MD, PhD§

Amsterdam, Nieuwegein, and Tilburg, the Netherlands

Objectives The purpose of this study was to evaluate the long-term outcomes of the PASSION (Paclitaxel-Eluting Versus Conventional Stent in Myocardial Infarction with ST-Segment Elevation) trial.

Background In primary percutaneous coronary intervention for acute ST-segment elevation myocardial infarction (STEMI), the use of drug-eluting stents (DES) is still controversial. Several randomized controlled trials of DES, compared with bare-metal stents (BMS), with short-term follow-up showed a reduction in target lesion revascularization (TLR), but no differences in rates of cardiac death or recurrent myocardial infarction. Moreover, the occurrence of (very) late stent thrombosis (ST) continues to be of major concern, and, therefore, long-term follow-up results are needed.

Methods We randomly assigned 619 patients presenting with STEMI to a paclitaxel-eluting stent (PES) or the similar BMS. The primary end point was the composite of cardiac death, recurrent myocardial infarction, or TLR. We performed clinical follow-up at 5 years.

Results At 5 years, the occurrence of the composite of cardiac death, recurrent myocardial infarction, or TLR was comparable at 18.6% versus 21.8% in PES and BMS, respectively (hazard ratio [HR]: 0.82, 95% confidence interval [CI]: 0.58 to 1.18, p = 0.28). The incidence of definite or probable ST was 12 (4.2%) in the PES group and 10 (3.4%) in the BMS group (HR: 1.19, 95% CI: 0.51 to 276, p = 0.68).

Conclusions In the present analysis of PES compared with BMS in primary percutaneous coronary intervention for STEMI, no significant difference in major adverse cardiac events was observed. In addition, no difference in the incidence of definite or probable ST was seen, although very late ST was almost exclusively seen after the use of PES. (Paclitaxel-Eluting Versus Conventional Stent in Myocardial Infarction with ST-Segment Elevation [PASSION]; ISRCTN65027270)   (J Am Coll Cardiol Intv 2011;4:24–9) © 2011 by the American College of Cardiology Foundation

In acute ST-segment elevation myocardial infarction (STEMI), primary percutaneous coronary intervention (PPCI) with stenting has proven to be the optimal treatment compared with medical therapy or angioplasty alone (1,2). After their introduction, drug-eluting stents (DES) proved to reduce neointima hyperplasia compared with bare-metal stents (BMS), when implanted in patients with stable coronary artery disease (3,4). Subsequently, several

registries and randomized controlled trials have tried to explore the possible advantage of the use of DES in STEMI (5–8). In most trials published, the implantation of either paclitaxel-eluting stents (PES) or sirolimus-eluting stents resulted in lower rates of repeat revascularization, but none of these trials showed an advantage in mortality or recurrent myocardial infarction (MI), compared with conventional BMS.

With the ongoing concern of a possible higher frequency of stent thrombosis (ST) occurring very late (beyond 1 year) after implantation of DES (9,10), routine implementation of DES in PPCI is still not widely accepted (11,12). Available data of retrospective studies suggest higher rates of ST, even several years after implantation of DES in PPCI, compared with stenting for stable angina (13,14). In the present analysis, we performed clinical follow-up 5 years after inclusion in the PASSION (Paclitaxel-Eluting Versus Conventional Stent in Myocardial Infarction with ST-Segment Elevation) trial, in which patients were randomized to a PES or a conventional BMS in PPCI. The aim was to elucidate a possible long-term benefit of DES over BMS in STEMI in terms of major adverse cardiac events (MACE) and to address the concern of (very) late ST.

Methods

Study design. Between March 2003 and December 2004, 619 patients were included in the PASSION trial. The PASSION trial was a prospective, single-blind, randomized study, performed at 2 centers in the Netherlands (Onze Lieve Vrouwe Gasthuis, Amsterdam, and Sint Antonius Ziekenhuis, Nieuwegein). The study has been registered as an International Randomized Controlled Trial.

Both details of study design and the results of clinical follow-up have been published previously (5,15).

Procedures. After arrival at the hospital, we first administered a loading dose of aspirin (100 to 500 mg) and clopidogrel (300 mg), followed by aspirin 80 to 100 mg once daily for life and clopidogrel 75 mg once daily for at least 6 months. A bolus of 10,000 IU of unfractionated heparin was administered before the procedure. The use of glycoprotein IIb/IIIa receptor inhibitors was at the discretion of the operator, as were the use of pre-dilation balloons and thrombus aspiration devices. After coronary angiography patients were randomized in a 1:1 ratio using permuted blocks of 50, to receive either a PES (Taxus Express2, Boston Scientific, Natick, Massachusetts) or a BMS with the same platform (Express2 or Liberté, Boston Scientific).

Follow-up. After the initial hospital discharge, patients were contacted by phone or mail at pre-defined intervals. All adverse cardiac events were recorded during each patient's hospital stay, as well as during follow-up visits at 30 days, 6 months, 1 year, 2 years, and 5 years after randomization. In the case of an event, information was obtained from hospital records or from the treating cardiologist. If the patient could not be reached, vital status and date of death (if applicable) was obtained from local authorities.

End points. G.J.L. and M.J.S. adjudicated all end points in a blinded fashion. The primary end point was the first occurrence of MACE, defined as the composite of cardiac death, recurrent MI, or target-lesion revascularization (TLR), either by PCI or coronary artery bypass grafting. A secondary end point was the occurrence of ST, as determined by the Academic Research Consortium (16). Definite ST was defined as angiographic confirmation of vessel occlusion or proven ST either by angiography or at autopsy within, or adjacent to, the stented segment. Probable ST was defined as unexplained death within 30 days, or target-vessel recurrent MI without angiographic confirmation. When unexplained death occurred beyond 30 days, it was classified as possible ST. Stent thrombosis was categorized according to timing of the event after stent implantation and divided into acute ST ($<$24 h), subacute ST (between 24 h and 30 days), late ST (30 days to 1 year), and very late ST (beyond 1 year).

Statistical analysis. Baseline data are presented as proportions or mean ($\pm$SD) values and were compared using Student t test or Wilcoxon rank-sum test for continuous variables and Fisher exact test for categorical variables. A 2-sided p value $<$0.05 was considered to indicate statistical significance. We estimated the cumulative incidence rates of the primary and secondary end points at 5 years with the Kaplan-Meier method. Hazard ratios (HRs) with 95% confidence intervals (CIs) were calculated with Cox proportional-hazards models with treatment allocation as the only variable. The significance of differences in event rates between treatment groups was assessed by the log-rank

Abbreviations and Acronyms

BMS = bare-metal stent(s)

DES = drug-eluting stent(s)

MACE = major adverse cardiac event(s)

MI = myocardial infarction

PES = paclitaxel-eluting stent(s)

PPCI = primary percutaneous coronary intervention

SES = sirolimus-eluting stent(s)

ST = stent thrombosis

STEMI = ST-elevation myocardial infarction

TLR = target-lesion revascularization

test. Statistical analysis was done with SPSS (version 16.0 for Windows, SPSS, Inc., Chicago, Illinois).

Results

A total of 310 patients were randomized to receive a PES and 309 to a BMS. Baseline clinical characteristics were well matched (Table 1). In addition, angiographic and procedural characteristics were similar between both groups (Table 2). Approximately 50% of patients underwent thrombus aspiration before stenting, and the use of a glycoprotein IIb/IIIa receptor inhibitor was comparable in the PES and BMS groups, with rates of 73.2% and 74.4%, respectively.

Clinical follow-up at 5 years. At 5-year follow-up, complete data on vital status was available for 98.7% of patients. Complete datasets on all clinical events were available for 97.6% of patients. The results are stated in Table 3. The composite end point of cardiac death, recurrent MI, or TLR was reached in 56 (18.6%) versus 66 (21.8%) patients in the PES and the BMS groups, respectively (HR: 0.82, 95% CI: 0.58 to 1.18; p = 0.28). Figure 1 shows the Kaplan-Meier curve for the incidence of the primary end point. With 7.7% in the PES group and 10.5% in the BMS group, a slight trend toward a lower incidence of TLR was observed in favor of PES (HR: 0.71, 95% CI: 0.41 to 1.23; p = 0.21). The occurrence of cardiac death or MI was comparable between both groups (15.0% vs. 14.6%; HR: 1.02, 95% CI: 0.67 to 1.55; p = 0.92). Cardiac death rates at 5 years were relatively low, at 8.9% in the PES group versus 11.5% in the BMS group (HR: 0.76, 95% CI: 0.46 to 1.25, p = 0.28). We performed a landmark analysis of the occurrence of the primary end point between 1 and 5 years (Fig. 2). At a rate of 10.8% in the PES group, and 10.2% in the BMS group

Table 2. Baseline Angiographic and Procedural Characteristics

Variable	PES (n = 310)	BMS (n = 309)	p Value
Symptom to balloon, min	180 ± 102	178 ± 108	0.86
Sum of ST-segment elevation, mm	11 ± 8	11 ± 9	0.76
Infarct-related artery			
Left anterior descending artery	156 (50.3)	154 (49.8)	0.94
Left main stem	2 (0.6)	0	0.50
Right coronary artery	129 (41.6)	118 (38.2)	0.41
Left circumflex artery	18 (5.8)	32 (10.4)	0.04
Intermediate branch	3 (1.0)	4 (1.3)	0.72
Saphenous-vein graft	2 (0.6)	1 (0.3)	1.00
Pre-procedural TIMI flow grade			
0	193 (62.3)	196 (63.4)	0.80
1	26 (8.4)	25 (8.1)	1.00
2	41 (13.2)	48 (15.5)	0.42
3	50 (16.1)	40 (12.9)	0.30
Reference diameter, mm	3.13 ± 0.43	3.20 ± 0.47	0.04
Visible thrombus	213 (68.7)	204 (66.0)	0.49
Thrombus aspiration	156 (50.3)	155 (50.2)	0.97
Number of stents implanted	1.26 ± 0.55	1.33 ± 0.63	0.14
Stent size, mm	3.21 ± 0.30	3.26 ± 0.38	0.08
Stent length, mm	19 ± 5.6	19 ± 5.5	0.71
Final TIMI flow grade			
0	2 (0.6)	3 (1.0)	0.69
1	2 (0.6)	2 (0.6)	1.00
2	17 (5.5)	7 (2.3)	0.06
3	289 (93.2)	297 (96.1)	0.15
GP IIb/IIIa receptor antagonist	227 (73.2)	230 (74.4)	0.78
Procedural success	289 (93.2)	297 (96.1)	0.15

Values are expressed as mean ± SD or n (%).

GP = glycoprotein; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.

(HR: 1.07, 95% CI: 0.63 to 1.82; p = 0.80), no difference in the occurrence of late events was seen.

Stent thrombosis. The occurrence of definite or probable ST up to 5 years was comparable between both groups, with 12 (4.2%) in the PES group and 10 (3.4%) in the BMS group (HR: 1.19, 95% CI: 0.51 to 2.76; p = 0.68) (Fig. 3). Definite ST occurred in 11 (3.9%) and 5 (1.7%) patients in the PES and BMS groups, respectively (HR: 2.19, 95% CI: 0.76 to 6.29; p = 0.14). The incidence of (very) late definite or probable ST was higher in the PES group than the BMS group, at 10 (3.5%) versus 3 (1.1%), p = 0.06. Similarly, (very) late definite ST occurred in 9 (3.3%) patients in the PES group versus 2 (0.7%) in the BMS group, p = 0.04 (Table 4).

Discussion

Previously, we published the 1-year clinical outcomes of the PASSION trial (5). This report did not show a difference in TLR and MACE rate after the use of PES compared with

Table 1. Baseline Clinical Characteristics

Variable	PES (n = 310)	BMS (n = 309)	p Value
Age, yrs	61 ± 12	61 ± 13	0.91
Male	229 (73.9)	241 (78.0)	0.26
Diabetes mellitus	31 (10.0)	37 (12.0)	0.44
Hypertension	95 (30.6)	98 (31.7)	0.80
Hypercholesterolemia	72 (23.2)	86 (27.8)	0.20
Family history of CAD	125 (40.3)	110 (35.6)	0.25
Smoking	165 (53.2)	154 (49.8)	0.42
Previous PCI	14 (4.5)	13 (4.2)	1.00
Previous stent	5 (1.6)	6 (1.9)	0.77
Previous CABG	2 (0.6)	2 (0.6)	1.00
Previous MI	14 (4.5)	18 (5.8)	0.48
Anterior infarction	158 (51.0)	158 (51.1)	0.97

Values are expressed as mean ± SD or n (%).

BMS = bare-metal stent(s); CABG = coronary artery bypass grafting; CAD = coronary artery disease; MI = myocardial infarction; PCI = percutaneous coronary intervention; PES = paclitaxel-eluting stent(s).

Table 3. Clinical Outcome at 5 Years

Adverse Cardiac Events	PES (n = 310)	BMS (n = 309)	HR	95% CI	p Value
Cardiac death, recurrent MI, or TLR	56 (18.6)	66 (21.8)	0.82	0.58–1.18	0.28
Cardiac death	27 (8.9)	35 (11.5)	0.76	0.46–1.25	0.28
Recurrent MI	19 (6.8)	2 (4.3)	1.58	0.77–3.26	0.21
Cardiac death or MI	45 (15.0)	44 (14.6)	1.02	0.67–1.55	0.92
TLR	22 (7.7)	30 (10.5)	0.71	0.41–1.23	0.21

Values are expressed as n (%).
Percentages were estimated using the Kaplan-Meier method.
CI = confidence interval; HR = hazard ratio; TLR = target lesion revascularization; other abbreviations as in Table 1.

BMS. The present analysis shows there is still no significant difference observed through 5 years of follow-up. The hazard ratio for TLR at 5 years (HR: 0.71, p = 0.21) was identical to that observed at 1 year (HR: 0.68, p = 0.23). Although the hazard ratio for MACE (the composite end point of cardiac death, recurrent MI, or TLR) at 5 years still was in favor of PES, it had somewhat attenuated relative to that at 1 year (HR: 0.82, p = 0.28 at 5 years vs. HR: 0.69, p = 0.12 at 1 year). The attenuation was mainly due to a slightly higher incidence of ST-related MI in the PES group beyond 1 year. Moreover, no difference was seen in the occurrence of cardiac death or recurrent MI, neither early nor late after implantation.

Only short-term results have been published of the other randomized trials comparing DES with BMS for STEMI. Our study design was best comparable to that of the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) trial, in particular with regard to stent usage and the absence of angiographic follow-up (6). The HORIZONS-AMI trial, the largest trial so far, reported a 1-year TLR incidence of 4.5% in PES-treated patients versus 7.5% in BMS-treated patients (p = 0.002). The HORIZONS-AMI 1-year results (HR: 0.59 for TLR in favor of PES) were similar to those observed in PASSION. The larger number of patients included in the HORIZONS-AMI trial explains its statistical significance, which our study lacked.

Smaller randomized controlled trials of DES in STEMI with short-term follow-up showed a similar pattern as HORIZONS-AMI, with no differences in the incidence of cardiac death or recurrent MI, although with differences in the need for TLR favoring DES. In the TYHPOON (Trial
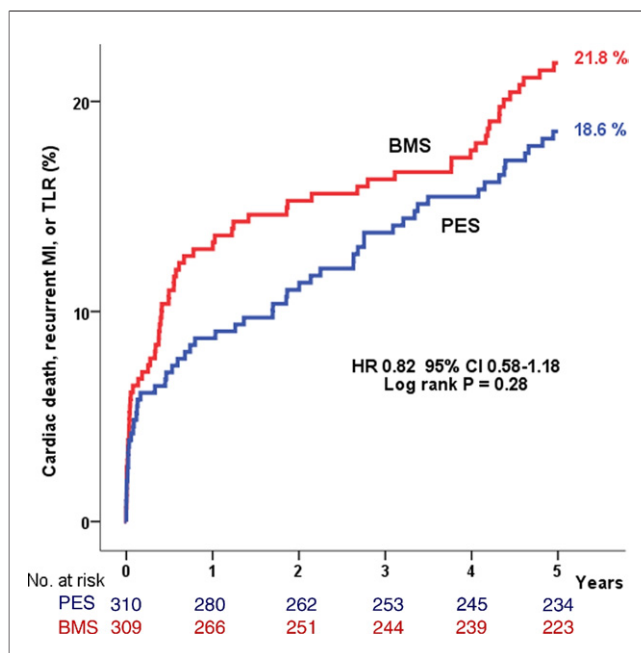
Figure 1. Kaplan-Meier Time-to-Event Curve for the Primary End Point of the Composite of Cardiac Death, Recurrent MI, or TLR
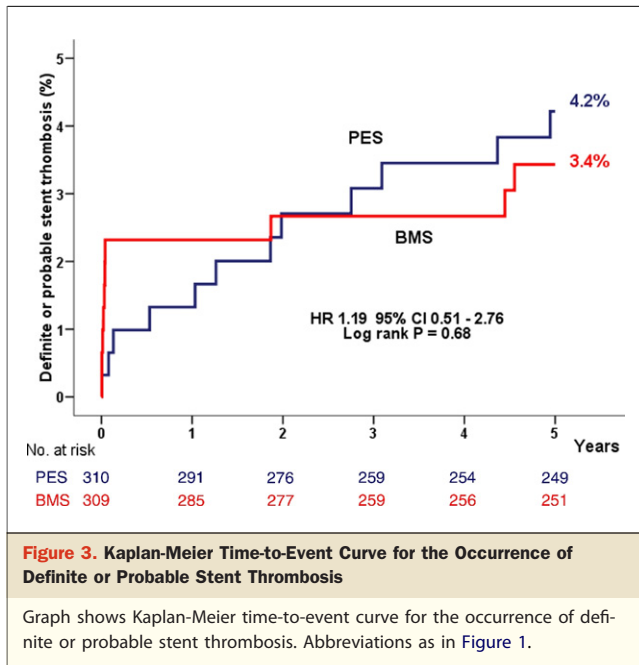
Graph shows the Kaplan-Meier time-to-event curve for the primary end point of the composite of cardiac death, recurrent myocardial infarction, or target lesion revascularization. BMS = bare-metal stent(s); CI = confidence interval; HR = hazard ratio; MI = myocardial infarction; PES = paclitaxel-eluting stent(s); TLR = target lesion revascularization.
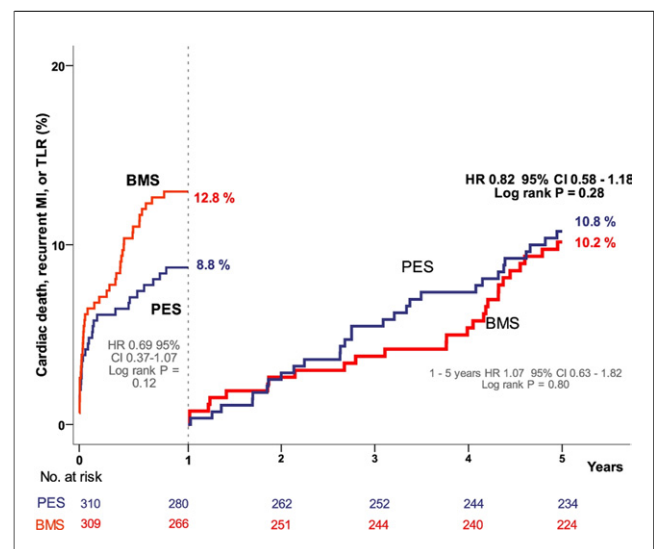
Figure 2. Kaplan-Meier Time-to-Event Curve of the Primary End Point of the Composite of Cardiac Death, Recurrent MI, or TLR

Landmark analysis with the incidence up to 1 year and from 1 to 5 years of follow-up. Abbreviations as in Figure 1.

Figure 3. Kaplan-Meier Time-to-Event Curve for the Occurrence of Definite or Probable Stent Thrombosis

Graph shows Kaplan-Meier time-to-event curve for the occurrence of definite or probable stent thrombosis. Abbreviations as in Figure 1.

to Assess the Use of the Cypher Stent in Acute Myocardial Infarction Treated With Angioplasty) trial, which compared sirolimus-eluting stents (SES) with BMS, there was a significant difference in the occurrence of target-vessel revascularization at 1 year, at 5.6% versus 13.4% (HR: 0.41, $p < 0.001$) in SES and BMS, respectively (7). Likewise, the 1-year report of the SESAMI (Sirolimus-Eluting Stent Versus Bare-Metal Stent in Acute Myocardial Infarction) trial showed a large absolute difference in TLR in favor of SES, at 4.3% versus 11.2% ($p = 0.02$) in SES and BMS, respectively (17). These differences, however, were larger than those observed in PASSION and HORIZONS-AMI. The larger differences in repeat revascularization between the 2 stent groups in both TYPHOON and SESAMI were mainly due to a much higher incidence in the BMS groups. Variations in study design may well explain this disparity. First, this difference could have been influenced by routine angiographic follow-up within the first year after implantation (18). Our protocol did not include planned angiography during follow-up, which might explain the smaller absolute difference in TLR between both groups. Furthermore, the stent platform of the DES used in our study was the exact same stent platform with which it was compared. This is an important difference with TYPHOON and SESAMI, in which a DES was compared with a range of types BMS, possibly resulting in less favorable outcome after the use of BMS. Except from the 3-year data of the SESAMI trial, which showed maintenance of the early benefit in TLR (19), no long-term clinical outcomes of both trials have been published.

Stent thrombosis. At 1 year, no difference in the occurrence of ST was seen in our study, with a rate of 1.0% in both

groups. These comparable results between DES and BMS were in line with those of the HORIZONS-AMI, TYPHOON, and SESAMI trials, although HORIZONS-AMI and TYPHOON showed a higher incidence in both stent groups, at 2.6% versus 3.0% and 3.4% versus 3.6%, respectively. This could be explained by a difference in the definition of ST and/or, given the low number of events, by chance. In the meantime, the definitions of ST established by the Academic Research Consortium provide the opportunity of an unambiguous comparison (16). At 5 years, we observed a similar incidence of definite or probable ST, with 12 patients (4.2%) in the PES group and 10 (3.4%) in the BMS group, at a hazard ratio of 1.19 ($p = 0.68$). This indicates the safety of both PES and BMS throughout follow-up. Worth mentioning, very late ST was almost exclusively seen after implantation of PES ($p = 0.06$ for definite or probable ST, $p = 0.04$ for definite ST). The present analysis suggests there might be a small but continuously present risk of ST in the PES group several years after cessation of dual-antiplatelet therapy. Our observation accords with observations from retrospective studies, showing that ST is associated with DES, with the emphasis on the risk of very late ST related to implantation in acute coronary syndromes (13,14,20). Noteworthy, in current daily practice, PES have been supplanted by newer generations of DES as subsequently conducted trials showed superiority in both efficacy and safety of everolimus-eluting stents compared with PES (21,22). Nevertheless, long-term follow-up of larger trials evaluating the efficacy and safety of DES in STEMI is necessary to substantiate our findings.

Study limitations. This study has some limitations. The event rates in both groups were lower than anticipated in our power calculations. As a result, the estimated relative risk reduction of 15% in the occurrence of MACE, using PES compared with BMS, lacked statistical significance. In addition, with 619 patients included, the PASSION trial was not powered to detect differences in the occurrence of

Table 4. Incidence of ST According to Definition of the Academic Research Consortium, Classified by Timing of Event

ST	PES (n = 310)	BMS (n = 309)	HR	95% CI	p Value
Definite or probable ST, n (%)	12 (4.2)	10 (3.4)	1.19	0.51–2.76	0.68
Acute	1	0			
Subacute	1	7			
Late	2	0			
Very late	8	3			
Definite ST, n (%)	11 (3.9)	5 (1.7)	2.19	0.76–6.29	0.14
Acute	1	0			
Subacute	1	3			
Late	1	0			
Very late	8	2			

Percentages were estimated using the Kaplan-Meier method.

ST = stent thrombosis; other abbreviations as in Tables 1 and 3.

the safety end point ST. Although we did find a notable difference in rates of very late ST between the 2 stent groups, our findings should be interpreted with caution. A much larger trial would have been needed to demonstrate statistical significance. Another limitation of this long-term follow-up study is the lack of autopsy data in patients who died suddenly, which may well have resulted in underestimation of the real incidence of ST.

Conclusions

Our present report is the first 5-year clinical follow-up of a prospective, randomized trial of DES in STEMI. We observed no significant difference in the occurrence of MACE and TLR in PES compared with BMS. Up to 5-years follow-up, no difference in the occurrence of definite or probable ST was seen, although there might be a higher incidence of (very) late ST using PES.

In current clinical practice guidelines, the use of DES in acute STEMI is mentioned only as a method to reduce restenosis. Because there is no evidence for a reduction in the occurrence of death, recurrent MI, or ST, the guidelines of the European Society of Cardiology or the American College of Cardiology/American Heart Association do not make a general recommendation for the use of DES in the setting of STEMI. Our present analysis is the first to provide long-term efficacy and safety data on DES in PPCI. The possibility of a higher risk of very late ST in PES supports the ambivalence of the guidelines on this matter, which needs to be substantiated in further clinical research.

Reprint requests and correspondence: Dr. Maarten A. Vink, Amsterdam Department of Interventional Cardiology, Onze Lieve Vrouwe Gasthuis, Oosterpark 9, 1091 AC Amsterdam, the Netherlands. E-mail: m.a.vink@olvg.nl.

REFERENCES

1. Grines CL, Cox DA, Stone GW, et al. Coronary angioplasty with or without stent implantation for acute myocardial infarction. Stent Primary Angioplasty in Myocardial Infarction Study Group. N Engl J Med 1999;341:1949–56.
2. De Luca G, Suryapranata H, Stone GW, et al. Coronary stenting versus balloon angioplasty for acute myocardial infarction: a meta-regression analysis of randomized trials. Int J Cardiol 2008;126:37–44.
3. Stone GW, Ellis SG, Cox DA, et al., for the TAXUS-IV Investigators. A polymer-based, paclitaxel-eluting stent in patients with coronary artery disease. N Engl J Med 2004;350:221–31.
4. Stone GW, Moses JW, Ellis SG, et al. Safety and efficacy of sirolimus- and paclitaxel-eluting coronary stents. N Engl J Med 2007;356:998–1008.
5. Laarman GJ, Suttorp MJ, Dirksen MT, et al. Paclitaxel-eluting versus uncoated stents in primary percutaneous coronary intervention. N Engl J Med 2006;355:1105–13.
6. Spaulding C, Henry P, Teiger E, et al., for the TYPHOON Investigators. Sirolimus-eluting versus uncoated stents in acute myocardial infarction. N Engl J Med 2006;355:1093–104.
7. Stone GW, Lansky AJ, Pocock SJ, et al., for the HORIZONS-AMI Trial Investigators. Paclitaxel-eluting stents versus bare-metal stents in acute myocardial infarction. N Engl J Med 2009;360:1946–59.
8. De Luca G, Stone GW, Suryapranata H, et al. Efficacy and safety of drug-eluting stents in ST-segment elevation myocardial infarction: a meta-analysis of randomized trials. Int J Cardiol 2009;133:213–22.
9. Pfisterer M, Brunner-La Rocca HP, Buser PT, et al., for the BASKET-LATE Investigators. Late clinical events after clopidogrel discontinuation may limit the benefit of drug-eluting stents: an observational study of drug-eluting versus bare-metal stents. J Am Coll Cardiol 2006;48:2584–91.
10. Daemen J, Wenaweser P, Tsuchida K, et al. Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study. Lancet 2007;369:667–78.
11. Van de Werf F, Bax J, Betriu A, et al. Management of acute myocardial infarction in patients presenting with persistent ST-segment elevation: the Task Force on the Management of ST-Segment Elevation Acute Myocardial Infarction of the European Society of Cardiology. Eur Heart J 2008;29:2909–45.
12. Kushner FG, Hand M, Smith SC Jr., et al. 2009 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2009;54:2205–41.
13. Kukreja N, Onuma Y, Garcia-Garcia HM, et al., for the Interventional Cardiologists of the Thoraxcenter (2000 to 2005). The risk of stent thrombosis in patients with acute coronary syndromes treated with bare-metal and drug-eluting stents. J Am Coll Cardiol Intv 2009;2:534–41.
14. Leibundgut G, Nietlispach F, Pittl U, et al. Stent thrombosis up to 3 years after stenting for ST-segment elevation myocardial infarction versus for stable angina—comparison of the effects of drug-eluting versus bare-metal stents. Am Heart J 2009;158:71–6.
15. Dirksen MT, Vink MA, Suttorp MJ, et al., for the PASSION Investigators. Two year follow-up after primary PCI with a paclitaxel-eluting stent versus a bare-metal stent for acute ST-elevation myocardial infarction (the PASSION trial): a follow-up study. EuroIntervention 2008;4:64–70.
16. Cutlip DE, Windecker S, Mehran R, et al., for the Academic Research Consortium. Clinical endpoints in coronary stent trials: a case for standardized definitions. Circulation 2007;115:2344–51.
17. Menichelli M, Parma A, Pucci E, et al. Randomized trial of sirolimus-eluting stent versus bare-metal stent in acute myocardial infarction (SESAMI). J Am Coll Cardiol 2007;49:1924–30.
18. Uchida T, Popma J, Stone GW, et al. The clinical impact of routine angiographic follow-up in randomized trials of drug-eluting stents: a critical assessment of "oculostenotic" reintervention in patients with intermediate lesions. J Am Coll Cardiol Intv 2010;3:403–11.
19. Violini R, Musto C, De Felice F, et al. Maintenance of long-term clinical benefit with sirolimus-eluting stents in patients with ST-segment elevation myocardial infarction 3-year results of the SESAMI (Sirolimus-Eluting Stent versus Bare-Metal Stent in Acute Myocardial Infarction) trial. J Am Coll Cardiol 2010;55:810–4.
20. Nakazawa G, Finn AV, Joner M, et al. Delayed arterial healing and increased late stent thrombosis at culprit sites after drug-eluting stent placement for acute myocardial infarction patients: an autopsy study. Circulation 2008;118:1138–45.
21. Stone GW, Rizvi A, Newman W, et al., for the SPIRIT IV Investigators. Everolimus-eluting versus paclitaxel-eluting stents in coronary artery disease. N Engl J Med 2010;362:1663–74.
22. Kedhi E, Joesoef KS, McFadden E, et al. Second-generation everolimus-eluting and paclitaxel-eluting stents in real-life practice (COMPARE): a randomised trial. Lancet 2010;375:201–9.

Key Words: drug-eluting stent ■ primary percutaneous coronary intervention ■ ST-segment elevation myocardial infarction.