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Clinical Safety of Drug-Eluting Stents in the Korea Acute Myocardial Infarction Registry

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Background Percutaneous coronary intervention (PCI) with drug-eluting stents (DES) may be useful in patients with acute myocardial infarction (AMI), but safety issues still need to be solved. This study was undertaken to investigate the incidence of major adverse cardiac events (MACE) and stent thrombosis in DES-implanted AMI patients in real-life clinical practice.

Methods and Results On-line registry of AMI cases at the web site www.kamir.or.kr has been performed in 41 primary PCI centers in Korea and between November 2005 and September 2006, 1,541 surviving patients who had been implanted with either Cypher® or Taxus® stents were enrolled for analysis during a 6-month clinical follow-up. There were 2 groups: group I [834 patients, 61.9±11.9 years: sirolimus-eluting stent (Cypher®)], group II [707 patients, 62.9±12.0 years: paclitaxel-eluting stent (Taxus®)]. At both 1 and 6 months the incidence of MACE was not significantly different between the 2 groups. There were 17 cases of stent thrombosis, but the incidence of stent thrombosis was not significantly different between the 2 groups (group I:II=9(1.1%):8(1.1%), p=1.000). The stent type, length, number, lesion complexity and diabetes were not significant for the incidence of MACE or stent thrombosis after adjustment.

Conclusion MACE and stent thrombosis rates did not differ between 2 types of DES identified in Korea Acute Myocardial Infarction Registry (KAMIR). DES can be used in patients with AMI with a relatively low 6-month MACE rate. (*Circ J* 2008; **72:** 392 – 398)

Key Words: Angioplasty; Korea; Major adverse cardiac events (MACE); Myocardial infarction; Stents

Stent implantation is an effective treatment for coronary artery stenosis and is a commonly used strategy in percutaneous coronary intervention (PCI). At the present time, 2 drug-eluting stents (DES: sirolimus and paclitaxel) have made it into large clinical trials and seem to have fundamentally changed the treatment of coronary artery disease. DES are successful in most patients in preventing restenosis as compared with bare metal stents (BMS)[1–5]

There are reports of the superiority of the sirolimus-eluting stent (SES) over the paclitaxel-eluting stent (PES) in certain clinical groups such as those with diabetes or small vessels[6–8] However, in truly head-to-head comparisons, such as the REALITY trial, there were no differences in the rate of binary restenosis and major adverse cardiac events (MACE) between the 2 types[9] The importance of the angiographic endpoint of lower in-stent late luminal loss as representative of clinical events has been doubted and there are only a few published studies on the patterns of DES use in clinical practice[10,11]

Recent trials of DES in acute myocardial infarction (AMI), such as Sirolimus-Eluting Stent Versus Bare-Metal Stent in Acute Myocardial Infarction (SESAMI) trial[12] Trial to Assess the Use of the Cypher Stent in Acute Myocardial Infarction Treated with Balloon Angioplasty (TYPHOON) trial[13] and Paclitaxel Eluting Stent versus Conventional Stent in Myocardial Infarction with ST Segment Elevation (PASSION) trial[14] have shown the relative safety of DES. However, there are growing questions about the actual usefulness of DES, because of the increased incidence of thrombosis and death in DES cases compared with BMS during follow-up[15–17] Moreover, because there is more chance of a thrombotic condition in AMI, many clinicians have questioned the incidence of MACE and stent thrombosis in DES-implanted AMI patients during real-life clinical

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practice, so we investigated this issue through subgroup analysis of AMI patients who were discharged alive from hospital among those registered in the Korea Acute Myocardial Infarction Registry (KAMIR).

Methods

KAMIR

KAMIR is a Korean prospective multicenter on-line registry that has been investigating the risk factors of mortality in patients with AMI since November 2005 with the aim of establishing universal management guidelines for the prevention of AMI, with the support of the Korean Circulation Society. On-line registration of cases of AMI at the web site of www.kamir.or.kr has been carried out in 41 primary PCI centers, which are hospitals capable of primary PCI with sufficient experience and volume. The study protocol was approved by the ethics committee at each participating institution. Data were registered and submitted from individual institutions via password protected internet-based electronic case report forms. We enrolled patients if they had an AMI, including ST-segment elevation myocardial infarction (STEMI) or non STEMI (NSTEMI).

Study Population

Between November 2005 and September 2006, there were 2,320 patients who underwent coronary angiography, were followed up for more than 6 month, and were discharged alive from hospital. Clinical criteria for exclusion included the administration of fibrinolytic agents for AMI, left ventricular ejection fraction <30%, infarction related to the grafted vessel, combined SES and PES implantation in the same patient and estimated life expectancy of less than 12 months. There were 1,541 patients who were implanted with a DES, 144 patients who had a BMS and 635 patients without stent implantation (Fig 1), so we enrolled these 1,541 patients for analysis and divided them into group I (SES, Cypher®, Cordis, Johnson & Johnson, n=834) and group II (PES, Taxus Express2®, Boston Scientific, n=707).

Diagnosis and PCI

The diagnosis of AMI was based on clinical presentation, ECG findings and cardiac enzyme studies (new ST-segment elevation, development of Q waves or left bundle branch block on ECG, or biochemical evidence of necrosis such as total creatinine kinase >twice the normal upper limit with an elevated creatine kinase-MB isoenzyme or a positive troponin). Diagnostic angiography and PCI were performed after premedication with aspirin (at least 100 mg) and unfractionated or low-molecular-weight heparin. Loading of clopidogrel (from 300 to 600 mg) was done before PCI. Coronary angiography was performed through the femoral or radial artery. Heparin was infused throughout the procedure to maintain an activated clotting time of at least 250 s. Stents were deployed after prior balloon angioplasty and administration of platelet glycoprotein IIb/IIIa-receptor blocker was left to the decision of each surgeon. Angiographic success was defined as the achievement of a minimum stenosis diameter reduction to less than 50% in the presence of Thrombolysis In Myocardial Infarction (TIMI) grade 2 or 3 flow without complications such as death or coronary artery bypass grafting (CABG). We prescribed 100 mg aspirin daily for life and 75 mg clopidogrel daily for at least 6 months.

The baseline clinical characteristics, coronary angiography findings (including infarct-related artery (IRA)), American College of Cardiology/American Heart Association (ACC/AHA) classification, and TIMI flow grade before and after PCI, and MACE (including death, myocardial infarction (MI), target lesion revascularization (TLR), and CABG) at both 1 and 6 months after discharge were analyzed in both groups. The primary endpoint was the composite MACE at both 1 and 6 months after survival discharge from hospital. The secondary endpoint was stent thrombosis.

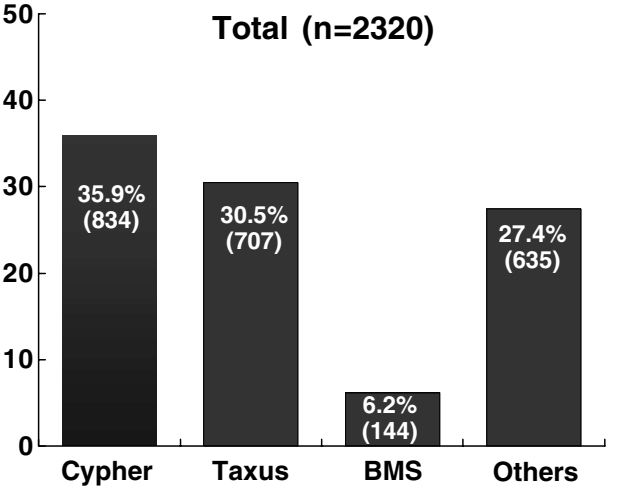

Fig 1. Overview of the study population. Of 2,320 patients who underwent coronary angiography, follow-up for more than 6 months, and who were discharged alive from hospital, there were 1,541 patients who were implanted with a drug-eluting stent, 144 with a bare metal stent (BMS) and 635 without stent implantation (others) and they were enrolled for analysis.

All deaths were considered as cardiac death unless non-cardiac death could be excluded. MI was defined as the development of either pathologic Q wave in at least 2 contiguous leads or an increase in the creatine kinase level to more than twice the upper limit of normal with an elevation of creatine kinase-MB isoenzyme. TLR was defined as repeat PCI of the target lesion because of restenosis or re-occlusion within the stent or in the adjacent 5 mm of the distal or proximal segment. Stent thrombosis was classified as early if it occurred within 30 days and late if it occurred after 30 days. Stent thrombosis was defined as angiographic proof of vessel occlusion, any recurrent Q-wave MI in the territory of the stented vessel, or any death from cardiac cause.

Statistical Analysis

For continuous variables, comparison between groups was done by Student's t-test. Fischer's exact test was used to evaluate the categorical variables. To test whether initial differences between 2 groups influenced the different results, multiple logistic regression analysis was performed after controlling the variables that were significantly different at baseline. All continuous variables are described as mean ± standard deviation. All analyses were 2-tailed, with clinical significance defined as a $p<0.05$. All statistical processing was done using SPSS-PC 13.0 (SPSS-PC Inc, Chicago, IL, USA).

Results

Baseline Clinical and Laboratory Characteristics

There was no significant difference between the 2 groups

Table 1 Baseline Clinical Characteristics of the 2 DES Groups

	Group I (n=834)	Group II (n=707)	p value
Age (years)	61.9±11.9	62.9±12.0	0.990
Male sex (%)	626 (75.1%)	497 (70.3%)	0.039
BMI (kg/m²)	24.4±9.5	24.2±5.2	0.635
Hip circumference (cm)	92.6±7.6	92.3±8.1	0.412
Waist circumference (cm)	87.2±8.4	87.0±8.4	0.633
Waist to hip ratio	0.9±0.1	0.9±0.1	0.567
Risk factor			
HTN	367 (44.0%)	337 (47.7%)	0.151
Diabetes	223 (26.7%)	157 (22.2%)	0.044
Dyslipidemia	52 (6.2%)	43 (6.1%)	0.916
Smoking	523 (62.7%)	441 (62.4%)	0.916
Family history of CAD	76 (9.1%)	48 (6.8%)	0.110
Diagnosis			
STEMI	565 (67.7%)	469 (66.3%)	0.586
NSTEMI	269 (32.3%)	238 (33.7%)	0.414

Group I, sirolimus-eluting stent; group II, paclitaxel-eluting stent.
DES, drug-eluting stents; BMI, body mass index; HTN, hypertension; CAD, coronary artery disease; STEMI, acute ST-segment elevation myocardial infarction; NSTEMI, acute non ST-segment elevation myocardial infarction.

Table 2 Baseline Laboratory Variables of the 2 DES Groups

	Group I (n=834)	Group II (n=707)	p value
Killip classification			
I	650 (77.9%)	551 (77.9%)	1.000
II	110 (13.2%)	105 (14.9%)	0.458
III	44 (5.3%)	38 (5.4%)	0.818
IV	30 (3.6%)	13 (1.8%)	0.059
SBP (mmHg)	129.7±28.0	132.2±27.3	0.081
DBP (mmHg)	79.3±16.4	80.6±16.5	0.127
Laboratory findings			
Maximal troponin I (mg/dl)	36.7±76.2	43.3±74.9	0.084
Maximal CK (unit/L)	1,515.8±2,016.7	1,618.4±2,068.3	0.236
Maximal CK-MB (unit/L)	172.2±344.9	160.7±242.9	0.323
Glucose (mg/dl)	165.0±72.5	161.8±66.4	0.368
Creatinine (mg/dl)	1.1±1.0	1.0±0.4	0.007
Total cholesterol (mg/dl)	187.6±41.4	185.9±43.1	0.419
Triglyceride (mg/dl)	128.4±90.6	133.5±101.5	0.304
HDL-C (mg/dl)	44.7±11.8	44.2±10.6	0.396
LDL-C (mg/dl)	121.8±34.3	121.6±36.4	0.889
Triglyceride/HDL-C	3.2±2.5	3.3±2.8	0.390

Group I, sirolimus-eluting stent; group II, paclitaxel-eluting stent.
SBP, systolic blood pressure; DBP, diastolic blood pressure; CK, creatine kinase; HDL-C, high-density lipoprotein-cholesterol; LDL-C, low-density lipoprotein-cholesterol. Other abbreviation see in Table 1.

in age, but the proportion of males was higher in group I (group I: 626 (75.1%), group II: 497 (70.3%), p=0.039). The rates of hypertension, hyperlipidemia and smoking were not significantly different between the 2 groups, but diabetes was more common in group I (group I: 223 (26.7%), group II: 157 (22.2%), p=0.044). Family history of coronary artery disease, clinical diagnosis of STEMI or NSTEMI, distribution of Killip class, and waist circumference, hip circumference, body mass index and initial blood pressure were not significantly different between the 2 groups (Table 1). Laboratory findings, including the level of maximal troponin I, maximal creatine kinase, maximal creatine kinase-MB, total cholesterol, triglyceride, high-density lipoprotein-cholesterol, and low-density lipoprotein-cholesterol were not different between the 2 groups, but the level of serum creatinine was higher in group I (group I: 1.1±1.0, group II: 1.0±0.4, p=0.007) (Table 2).

Baseline Angiographic Variables

Distribution of 1-, 2- and 3-vessel coronary artery disease did not significantly differ between the 2 groups. The order of the most common IRA was left anterior descending artery (LAD), right coronary artery (RCA), left circumflex artery (LCX) and left main stem (LM) in both 2 groups [group I–LM:LAD:LCX: CA=17(2.0%):461(55.3%):116 (13.9%):240(28.8%), group II–LM:LAD:LCX:RCA= 10(1.4%):322(45.5%):120(17.0%):255(36.1%)]. However, the distribution of LAD as the IRA was higher in group I (group I: 461(55.3%), group II: 322(45.5%), p=0.000) and the RCA was higher in group II (group I: 240(28.8%), group II: 255(36.1%), p=0.003). Type B2 according to the ACC/AHA classification was more common in group II (group I: 203(24.3%), group II: 210(29.7%), p=0.018), and complex lesions (type B2 or C) were higher in group II (group I: 634 (76.0%), group II: 572(80.9%), p=0.022) (Table 3).

Table 3 Baseline Angiographic Variables of the 2 DES Groups

	Group I (n=834)	Group II (n=707)	p value
Distribution of CAD			
1-vessel	*380 (45.6%)*	*309 (43.7%)*	*0.472*
2-vessel	*261 (31.3%)*	*231 (32.7%)*	*0.953*
3-vessel	*193 (23.1%)*	*167 (23.6%)*	*0.856*
Infarct-related artery			
Left main	*17 (2.0%)*	*10 (1.4%)*	*0.437*
Left anterior descending	*461 (55.3%)*	*322 (45.5%)*	*<0.001*
Left circumflex	*116 (13.9%)*	*120 (17.0%)*	*0.103*
Right coronary artery	*240 (28.8%)*	*255 (36.1%)*	*0.003*
ACC/AHA classification			
A	*29 (3.5%)*	*16 (2.3%)*	*0.174*
B_1	*171 (20.5%)*	*119 (16.8%)*	*0.067*
B_2	*203 (24.3%)*	*210 (29.7%)*	*0.018*
C	*431 (51.7%)*	*362 (51.2%)*	*0.878*
Complex (B_2+C)	*634 (76.0%)*	*572 (80.9%)*	*0.022*

Group I, sirolimus-eluting stent; group II, paclitaxel-eluting stent.
ACC/AHA, American College of Cardiology/American Heart Association. Other abbreviations see in Table 1.

Table 4 Procedural Characteristics of the 2 DES Groups

	Group I (n=834)	Group II (n=707)	p value
Success of PCI			
Yes	*809 (97.0%)*	*696 (98.4%)*	*0.065*
No	*25 (3.0%)*	*11 (1.6%)*	*0.065*
TIMI flow grade before PCI			
0	*339 (40.7%)*	*299 (42.2%)*	*0.403*
1	*101 (12.1%)*	*101 (14.3%)*	*0.322*
2	*128 (15.3%)*	*122 (17.3%)*	*0.403*
3	*266 (31.9%)*	*185 (26.2%)*	*0.017*
TIMI flow grade after PCI			
0	*7 (0.8%)*	*3 (0.4%)*	*0.357*
1	*4 (0.5%)*	*1 (0.1%)*	*0.629*
2	*30 (3.6%)*	*23 (3.3%)*	*0.434*
3	*793 (95.1%)*	*680 (96.2%)*	*0.373*
Stent			
Diameter (cm)	*3.11±0.33*	*3.10±0.31*	*0.808*
Length (cm)	*26.40±5.52*	*25.72±5.51*	*0.015*
No. of implanted stents	*1.52±0.78*	*1.65±0.96*	*0.003*

Group I, sirolimus-eluting stent; group II, paclitaxel-eluting stent.
PCI, percutaneous coronary intervention; TIMI, Thrombolysis In Myocardial Infarction. Other abbreviation see in Table 1.

Table 5 MACE at 1 and 6 Months in the 2 DES Groups

	Group I (n=834)	Group II (n=707)	p value
1 month			
Death	*0 (0.0%)*	*2 (0.3%)*	*0.210*
MI	*6 (0.7%)*	*2 (0.3%)*	*0.301*
TLR	*1 (0.1%)*	*3 (0.4%)*	*0.339*
MACE	*7 (0.8%)*	*7 (1.0%)*	*0.793*
6 months			
Death	*4 (0.5%)*	*6 (0.8%)*	*0.527*
MI	*7 (0.5%)*	*5 (0.7%)*	*1.000*
TLR	*21 (2.5%)*	*26 (3.7%)*	*0.234*
MACE	*32 (3.8%)*	*37 (5.2%)*	*0.177*
Stent thrombosis			
Total	*9 (1.1%)*	*8 (1.1%)*	*1.000*
Early	*2 (0.2%)*	*1 (0.2%)*	*1.000*
Late	*7 (0.8%)*	*7 (1.0%)*	*0.793*

Group I, sirolimus-eluting stent; group II, paclitaxel-eluting stent.
MI, myocardial infarction; TLR, target lesion revascularization; MACE, major adverse cardiac events. Other abbreviation see in Table 1.

Table 6 Multivariate Logistic Regression Analysis for Total MACE

	aOR (95%CI)	p value
Male	*1.174 (0.658, 2.093)*	*0.587*
Diabetes	*1.167 (0.680, 2.004)*	*0.576*
LAD	*1.027 (0.780, 1.352)*	*0.848*
RCA	*1.130 (0.946, 1.349)*	*0.177*
Preprocedural TIMI	*0.897 (0.634, 1.269)*	*0.540*
STEMI	*1.129 (0.666, 1.914)*	*0.653*
Complex lesion	*1.223 (0.924, 1.618)*	*0.160*
Cypher	*0.658 (0.404, 1.072)*	*0.093*
Stent length	*0.987 (0.944, 1.033)*	*0.575*
Stent diameter	*1.647 (0.756, 3.589)*	*0.209*
Stent number	*1.021 (0.769, 1.356)*	*0.887*
Creatinine	*0.995 (0.720, 1.375)*	*0.975*

aOR, adjusted odds ratio; CI, confidence interval; LAD, left coronary artery; RCA, right coronary artery. Other abbreviations see in Tables 1,4,5.

Table 7 Multivariate Logistic Regression Analysis for Stent Thrombosis

	aOR (95%CI)	p value
Male	*1.22 (0.943, 1.134)*	*0.914*
Diabetes	*1.862 (0.659, 5.264)*	*0.241*
LAD	*1.087 (0.994, 1.189)*	*0.066*
RCA	*1.183 (0.849, 1.648)*	*0.322*
Preprocedural TIMI	*0.525 (0.267, 1.035)*	*0.063*
STEMI	*1.232 (0.418, 3.632)*	*0.705*
Complex lesion	*0.565 (0.274, 1.165)*	*0.122*
Cypher	*0.765 (0.321, 2.303)*	*0.765*
Stent length	*1.083 (0.989, 1.187)*	*0.086*
Stent diameter	*2.731 (0.555, 13.438)*	*0.217*
Stent number	*2.076 (0.866, 4.975)*	*0.102*
Creatinine	*1.105 (0.583, 1.766)*	*0.959*

Abbreviations see in Tables 1,4,6.

Results of PCI

The proportion of successful PCI cases did not significantly differ between the 2 groups. However, the proportion of initial TIMI 3 flow grade was higher in group I (group I: 266 (31.9%), group II: 185 (26.2%), p=0.017). The diameter of the implanted stent was not different between the 2 groups, but the length and number of implanted stents were significantly different between the 2 groups (length of stent (mm): group I:II=26.40±5.52:25.72±5.51, p=0.015; number of stents: group I:II=1.52±0.78:1.65±0.96, p=0.003) (Table 4).

The 1-Month and 6-Month Outcomes

The 1- and 6-month outcomes, including MACE, were not significantly different between the 2 groups (Table 5) nor was the rate of stent thrombosis (group I:II=9(1.1%): 8(1.1%), p=1.000).

Multivariate Logistic Regression Analysis for MACE and Stent Thrombosis

Because the baseline laboratory, angiographic, and procedural characteristics were different, we conducted our analysis after adjustment of the variables. Male gender, diabetes, LAD, RCA, preprocedural TIMI, STEMI, lesion complexity, stent type, length, diameter or number, and serum creatinine were not significant for the incidence of MACE or stent thrombosis after adjustment (Tables 6,7).

Discussion

There are large-scale, nationwide or worldwide AMI registration programs, such as A National Registry of Myocardial Infarction in the US in 1998, A national Survey of Acute Myocardial Infarction and Ischaemia (SAMII) in the UK in 2000, The Maximal Individual TheRapy of Acute myocardial infarction (MITRA) in Germany in 2002 and the Monitoring of Trends and Determinants in Cardiovascular Disease (MONICA) project. The World Health Organization (WHO) now suggests efficient AMI management systems beyond providing detailed information. KAMIR is also expected to make a contribution to the establishment of better AMI management and preventive systems, as well as investigating the risk factors for mortality in AMI patients.

DES have rapidly and profoundly affected the field of interventional cardiology, being now used in the majority of intracoronary stenting procedures. As a result of many "trial-and-error" endeavors, DES have emerged as a potential solution for solving the problem of restenosis. The SES (Cypher stent®) and PES (Taxus stent®) are the 2 most widely used DES, both with well-known usefulness for the prevention of restenosis and short-term safety[18–22] Moreover, patients with small vessels or bypass grafts seem to benefit from the use of DES, as far as long-term outcome is concerned, in contrast to patients with large native vessel stenting in whom there can be late harm[23,24] Emerging evidence of stent thrombosis that is fatal is a major limitation to the use of DES and so far there is consensus for the discontinuation of clopidogrel, because although the benefit of DES in reducing TLR is maintained, there is an increase in late cardiac death or nonfatal MI, possibly related to late stent thrombosis.

Although there are cautions for routine DES use in AMI, there is already widespread use of DES for AMI treatment in daily practice. Most early DES trials did not include patients undergoing primary PCI because of their relatively lower incidence of restenosis than other patient groups and slightly higher thrombosis risk than with BMS. However, the TYPHOON trial, funded by the manufacturer and enrolling 712 patients, showed that the use of the SES was safe and reduced the rate of restenosis at 1 year[13] The PASSION trial, also funded by the manufacturer and enrolling 619 patients, showed a relatively reduced incidence of adverse cardiac events as compared with BMS[14] However, there were no direct comparisons of the 2 DES in either of those clinical trials.

Our study showed relative widespread use of DES in clinical practice, implanted in approximately two-thirds of AMI patients. The SES was more commonly used in LAD territory infarction, and the PES was more commonly used in both RCA territory infarction and more complex lesions. The length of the implanted stent was longer cases with the SES and the number of implanted stents was higher with PES.

We chose a 6-month cutoff because the recommended duration of clopidogrel treatment after stent implantation in most centers in South Korea is more than 6 months. We excluded patients who could not take survival discharge from hospital because of relative high rates of events in the early period after AMI. However, there was no significant difference in the rates of MACE and stent thrombosis between the 2 DES after adjustment for baseline characteristics. The cumulative incidence of the primary endpoint (ie, composite MACE at 1 and 6 months) was 3.8% in the SES group and

5.2% in the PES group. The adjunctived risk ratio for the SES was 0.66, which was not statistically significant. The cumulative incidence of the secondary end point (ie, stent thrombosis during the 6 months) was 1.1% in both groups without statistical significance. Moreover, according to the multivariate logistic regression analysis, diabetes, TIMI flow grade, STEMI, lesion complexity, stent type, length and diameter, and the number of implanted stents were not significant factors for the development of MACE or stent thrombosis. In contrast, previous trials comparing these 2 types of DES in elective PCI have showed a superiority of the SES in certain clinical groups such as those with diabetes or small vessels[6–8]

The possible explanations for these differences between our registry and other trials are as follows. First, we did not include the angiographic follow-up results. Because restenosis during angiographic follow-up could have led to reintervention without symptoms, there was the possibility of excluding this type of TLR, which would produce a different TLR rate compared with the previous trials. Second, our study was only for AMI patients. Even though there is some debate, a different restenois rate after PCI in the setting of AMI compared with the more stable coronary artery disease would be possible[25,26]

In the present study the rates of stent thrombosis were similar between the SES and PES (1.1%). There is a variable rate of stent thrombosis according to clinical presentation and definition. Recent trials reported cumulative rates of stent thrombosis between 0 and 1.1% in elective cases;[1,2,9] however, the Sirolimus-Eluting Stent Compared with Paclitaxel-Eluting Stent for Coronary Revascularization (SIRTAX) trial, which included AMI cases, showed a higher rate of stent thrombosis (2.0%)[27] In our study the lack of angiographic follow-up and exclusion of in-hospital death might have produced an underestimation of the real rate of stent thrombosis. Moreover, a recent report using analysis from the Swedish Coronary Angiography and Angiography Registry showed an increased incidence of death (0.5% higher per year) in DES recipients compared with BMS after 6 months![15] So we have to await the final results of KAMIR before knowing the exact rate of stent thrombosis in Korean patients.

Study Limitations

First, our study was of low-risk patients. Because of the exclusion of high-risk patients such as those who died in hospital, our results cannot be generalized to routine DES implantation in all patients. Furthermore we could not confimr the long-term safety of DES because there is an increased incidence of stent thrombosis after 6 months. We are attempting to follow-up our registered patients for at least 2 years, after which a definitive conclusion about the use of DES in Korean patients will be possible in a large cohort. Second, we did not analyze the use of glycoprotein IIb/IIIa receptor blocker and other important medications such as β-blockers and angiotensin converting enzyme inhibitors. Moreover, because our registry did not include the medical record for clopidogrel medication, we did not know the exact compliance with clopidogrel. Analysis for these variables after protocol modification could produce a more accurate interpretation. Third, because our registry did not include angiographic follow-up, there might be an underestimation of the incidence of MACE and stent thrombosis.

In conclusion, based on data from KAMIR we have demonstrated that the rates for MACE and stent thrombosis within 6 months of discharge were not different between 2 types of DES. DES can be used safely, but long-term clinical follow-up is needed to clarify this in AMI patients.

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