Triple Versus Dual Antiplatelet Therapy in Patients With Acute ST-Segment Elevation Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention

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**Background**—Whether triple antiplatelet therapy is superior or similar to dual antiplatelet therapy in patients with acute ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention in the era of drug-eluting stents remains unclear.

**Methods and Results**—A total of 4203 ST-segment elevation myocardial infarction patients who underwent primary percutaneous coronary intervention with drug-eluting stents were analyzed retrospectively in the Korean Acute Myocardial Infarction Registry (KAMIR). They received either dual (aspirin plus clopidogrel; dual group; n=2569) or triple (aspirin plus clopidogrel plus cilostazol; triple group; n=1634) antiplatelet therapy. The triple group received additional cilostazol at least for 1 month. Various major adverse cardiac events at 8 months were compared between these 2 groups. Compared with the dual group, the triple group had a similar incidence of major bleeding events but a significantly lower incidence of in-hospital mortality. Clinical outcomes at 8 months showed that the triple group had significantly lower incidences of cardiac death (adjusted odds ratio, 0.52; 95% confidence interval, 0.32 to 0.84; \( P=0.007 \)), total death (adjusted odds ratio, 0.60; 95% confidence interval, 0.41 to 0.89; \( P=0.010 \)), and total major adverse cardiac events (adjusted odds ratio, 0.74; 95% confidence interval, 0.58 to 0.95; \( P=0.019 \)) than the dual group. Subgroup analysis showed that older (>65 years old), female, and diabetic patients got more benefits from triple antiplatelet therapy than their counterparts who received dual antiplatelet therapy.

**Conclusions**—Triple antiplatelet therapy seems to be superior to dual antiplatelet therapy in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention with drug-eluting stents. These results may provide the rationale for the use of triple antiplatelet therapy in these patients. (Circulation. 2009;119:3207-3214.)

**Key Words:** cilostazol ■ myocardial infarction ■ thrombosis ■ platelets

Drug-eluting stents (DES) have drastically changed the landscape of percutaneous coronary intervention (PCI), with significant reductions in the angiographic restenosis rate and need for repeated revascularization. However, several studies showed that DES is associated with a higher incidence of in-stent thrombosis compared with bare metal stents. Therefore, the latest guideline for antiplatelet therapy after PCI with DES suggests that the dual antiplatelet therapy (aspirin plus clopidogrel) be administered for at least 12 months. But is it enough for high-risk patients? Some studies showed that as many as 50% of the patients who received PCI did not react positively to aspirin or clopidogrel. Furthermore, there is increased platelet activity in acute coronary syndrome, especially in acute myocardial infarction (AMI).

Cilostazol is a potent inhibitor of type III phosphodiesterase in both platelets and vascular smooth muscle cells. The antiplatelet effect of cilostazol is 10 to 30 times more potent than that of aspirin. Antiplatelet therapy with cilostazol after PCI has similar safety and efficacy outcomes.
compared with aspirin or clopidogrel. A recent study suggested that cilostazol could ameliorate platelet responsiveness to clopidogrel in patients who underwent primary PCI. Furthermore, some other studies showed that the administration of cilostazol after PCI could significantly lower the incidence of in-stent restenosis.

Therefore, the present study was designed to evaluate the safety and efficacy of additional administration of cilostazol with aspirin and clopidogrel in a real-world cardiology practice among patients presenting with acute ST-segment elevation myocardial infarction (STEMI) who received primary PCI with DES.

Methods
Korea Acute Myocardial Infarction Registry
The Korea Acute Myocardial Infarction Registry (KAMIR) is a Korean prospective multicenter online registry designed to reflect the “real-world” practice in Asian patients presenting with AMI in the DES era, with support from the Korean Circulation Society since November 2005. Online registry of AMI (at www.kamir.or.kr) has been performed at 41 university or community hospitals that are high-volume centers with facilities for primary PCI and onsite cardiac surgery. Before the initiation of the KAMIR study, several investigator meetings were held, and a practical steering committee from major enrolled hospitals was selected to standardize care given in clinical practice as well as the study protocol to minimize the differences in medical care among the different hospitals and across the different time periods. Data were collected at each site by a trained study coordinator using a standardized case report form. Standardized definitions of all patient-related variables and clinical diagnoses were used. 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 who were suffering from AMI, including both STEMI and non-STEMI. Patients were diagnosed with STEMI when they had new or had any other severe diseases.

Study Population
From November 2005 to December 2007, a total of 13,632 patients were diagnosed with AMI. In the present study, we retrospectively enrolled patients with acute STEMI who underwent primary PCI (PCI performed within 24 hours after the symptom onset) with DES. The criteria for exclusion included non-STEMI, STEMI undergoing primary PCI with bare metal stent or balloon angioplasty only, STEMI undergoing selective PCI or conservative treatment without PCI, Killip grade IV cardiac function, or had any other severe diseases. Patients excluded: 781 patients who received neither dual nor triple antiplatelet therapy, or had any other severe diseases.

Study Flow Chart

Figure 1. Study flow chart. BMS indicates bare metal stents.

PCI Procedure and Medical Treatment
Diagnostic angiography and PCI were performed after unfractionated heparin (50 to 70 U/kg) was administered. Coronary angiography was performed through the femoral or radial artery. During the procedure, patients received unfractionated heparin to maintain an activated clotting time of >250 seconds. Stents were deployed after prior balloon angioplasty, and the administration of platelet glycoprotein IIb/IIIa receptor blockers was left to the decision of the individual operator. A successful PCI procedure was defined as the achievement of an angiographic minimum stenosis diameter reduction to <30% in the presence of Thrombolysis in Myocardial Infarction grade III flow.

During the in-hospital period, patients received medical treatment that included β-blockers, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, calcium channel blockers, and statins. After discharge, the patients continued receiving the same kinds of medications that they received in hospital except some intravenous or temporary medications.

Study Definitions and Clinical Follow-Up
The records of cardiovascular risk factors and past history (age, sex, hypertension, dyslipidemia, smoking, diabetes mellitus, family history of coronary heart disease, prior myocardial infarction, chronic heart failure and prior cerebrovascular disease, peripheral arterial disease) were dependent mainly on the patient’s self-report, but the final records were left to the physician’s discretion after he or she comprehensively considered the patient’s self-report and the in-hospital examination results. All deaths were considered cardiac deaths if noncardiac death could be excluded. Recurrent myocardial infarction was defined as recurrent symptoms with new ST-segment elevation or re-elevation of cardiac markers to at least twice the
the propensity to receive triple rather than dual antiplatelet therapy. To adjust for potential confounders, a propensity score model by which the propensity score was estimated showed good predictive value (C statistic = 0.753). Multivariable Cox regression analysis was then performed using the propensity score, antiplatelet therapies (triple versus dual), and the aforementioned variables to determine the impact of the different antiplatelet therapies on in-hospital and 8-month clinical outcomes. In addition, the effects of the different antiplatelet therapies on 8-month clinical outcomes were further evaluated in different subgroups of patients, including old (≥65 years of age), young (<65 years of age), male, female, diabetic, and nondiabetic patients. Cox regression models adjusted for propensity score and the aforementioned variables were used to assess odds ratios for various MACEs in these different subgroups of patients. All continuous variables were described as mean±SD. All analyses were 2-tailed, with clinical significance defined as values of P<0.05. All statistical processes were done with SPSS 13.0 (Statistical Package for the Social Sciences, SPSS-PC Inc, Chicago, Ill).

### Results

Eligibility is reported in Figure 1. A total of 4203 eligible STEMI patients who underwent primary PCI with DES were enrolled, and they represented 71.1% of the 5961 STEMI patients who underwent primary PCI. As shown in Table 1, the triple and dual groups had similar baseline clinical
Table 3. In-Hospital Medications

<table>
<thead>
<tr>
<th>Variables</th>
<th>Dual Therapy (n=2569), n (%)</th>
<th>Triple Therapy (n=1634), n (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycoprotein IIb/IIIa receptor blocker*</td>
<td>290 (11.3)</td>
<td>369 (22.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Low–molecular-weight heparin*</td>
<td>864 (33.6)</td>
<td>553 (33.8)</td>
<td>0.888</td>
</tr>
<tr>
<td>Unfractionated heparin*</td>
<td>1705 (66.4)</td>
<td>1081 (66.2)</td>
<td>0.888</td>
</tr>
<tr>
<td>β-Blockers</td>
<td>1970 (76.7)</td>
<td>1273 (77.9)</td>
<td>0.357</td>
</tr>
<tr>
<td>Angiotensin-converting enzyme inhibitors</td>
<td>1760 (68.5)</td>
<td>1232 (75.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Angiotensin II receptor blockers</td>
<td>336 (13.1)</td>
<td>220 (13.5)</td>
<td>0.720</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>279 (10.9)</td>
<td>129 (7.9)</td>
<td>0.002</td>
</tr>
<tr>
<td>Statins</td>
<td>2085 (81.2)</td>
<td>1335 (81.7)</td>
<td>0.660</td>
</tr>
</tbody>
</table>

*Used only during in-hospital period.

The clinical outcomes at 8 months also showed that the triple group had a significantly lower incidence of cardiac death, total death, and total MACEs than the dual group. However, the incidences of recurrent myocardial infarction, coronary artery bypass grafting, repeated PCI, and TLR were similar between the 2 groups (Table 4).

Multivariable Cox regression analysis showed that the triple group had significantly lower incidences of in-hospital cardiac death and total death than the dual group. The adjusted clinical outcomes at 8 months also showed that the triple group had significantly lower incidences of cardiac death, total death, and total MACEs (Table 5 and Figure 2).

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Subgroup analysis showed that female patients in the triple group had significantly lower incidences of cardiac death, total death, and total MACEs at 8 months compared with the women in the dual group, whereas male patients in the triple group showed only a significantly lower incidence of total death than the dual group. Among >65-year-old patients, the triple group had a significantly lower incidence of cardiac death at 8 months and had a trend toward lower incidences of total death and total MACEs than the dual group. However, among <65-year-old patients, the triple group had a trend only toward lower incidence of total death than the dual group. Among diabetics, the triple group had significantly lower incidences of repeated PCI and total MACEs and a trend toward a lower incidence of cardiac death than the dual group. However, in nondiabetic patients, although the triple group had a significantly lower incidence of total death and a trend toward lower incidence of cardiac death than the dual group, the incidences of repeated PCI and total MACE were similar between these 2 groups (Figure 3).

Discussion

The major finding of the present study is that compared with traditional dual antiplatelet therapy, triple antiplatelet therapy with additional cilostazol significantly lowered the incidences
of cardiac death, total death, and total MACEs at 8 months in patients with acute STEMI who underwent primary PCI with DES.

The recent updated guideline of post-PCI antiplatelet treatment for patients who undergo PCI with DES recommends administration of dual antiplatelet therapy with aspirin and clopidogrel for at least 12 months. But, is it enough, especially in the setting of AMI? Some previous studies suggested that as high as 20% to 50% patients did not react positively to aspirin or clopidogrel and that these patients exhibited significantly higher risks of recurrent cardiovascular events. Muller and colleagues reported that even a large loading dose (600 mg) of clopidogrel did not inhibit the aggregation and degranulation of platelets by thrombin-related activating peptides in the setting of AMI. In addition, Gawaz et al showed that platelet reactivity significantly increased in AMI patients who underwent PCI. Furthermore, Park et al suggested that primary stenting with sirolimus-eluting or paclitaxel-eluting stents in patients with AMI was an important risk factor for acute and subacute in-stent thrombosis. Therefore, it is reasonable to add a potent antiplatelet agent to aspirin and clopidogrel to strengthen the effectiveness of antiplatelet therapy in patients with acute STEMI undergoing PCI with DES.

The present study showed that compared with dual antiplatelet therapy, triple antiplatelet therapy had a similar

Figure 2. Adjusted cumulative incidence of cardiac death (A), total death (B), and total MACEs (C) at 8 months in patients who received triple or dual antiplatelet therapy. Variables in the multivariable Cox regression analysis included propensity scores, antiplatelet therapy (triple versus dual), age, sex, Killip class on admission, cardiovascular risk factors (hypertension, dyslipidemia, smoking, diabetes mellitus, family history of coronary heart disease), prior myocardial infarction, chronic heart failure and prior cerebrovascular disease, peripheral arterial disease, stent type, number of diseased vessels, and cardiovascular medications (glycoprotein IIb/IIIa receptor blockers, heparins, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, β-blockers, calcium channel blockers, and statins). Cum. Prob. indicates cumulative probability; OR, odds ratio.
incidence of in-hospital major bleeding events but significantly decreased the incidences of cardiac death, total death, and total MACEs up to 8 months. In addition, it is noted that the event curves including cardiac death and total death separate primarily in the first 30 days and then gradually become linear (Figure 2), suggesting that the mortality benefits of triple antiplatelet therapy were obtained mainly within 30 days after AMI. However, the MACE curve showed that the beneficial effects of triple antiplatelet therapy appeared continuously throughout the 8 months of follow-up (Figure 2), suggesting that the composite beneficial effects of triple antiplatelet therapy were not limited to 30 days but persisted up to 8 months. This result might be attributed to the antirestenotic property of cilostazol and different pharmacological actions with aspirin and clopidogrel as demonstrated in other studies.14–17 Our results were consistent with a previous study from Lee et al.23 That study compared the effects of triple antiplatelet and dual antiplatelet strategy on stent thrombosis up to 30 days after the index procedure in all patients who received PCI with both bare metal stents and DES. Their results showed that compared with the dual antiplatelet regimen, triple antiplatelet therapy seemed to be more effective in preventing thrombotic complications after stenting without an increased risk of side effects. However, that study included only a relatively small number of AMI cases (total, 573 AMI cases). Furthermore, they did not provide a subgroup analysis in the patients with AMI. In contrast, we evaluated in a larger scale the safety and efficacy of triple antiplatelet therapy in STEMI patients who underwent primary PCI with DES.

Some previous studies suggested that the administration of cilostazol after PCI significantly lowered the incidence of in-stent restenosis.15–17 Tsuchikane et al15 reported that cilostazol significantly reduced the incidences of in-stent restenosis and TLR after successful PCI. Douglas et al16 also reported that treatment with cilostazol resulted in a significantly larger minimal luminal diameter and a significantly lower binary restenosis rate compared with placebo-treated
patients and that these favorable effects were apparent in patients at high risk for restenosis.

However, in the present study, although we found that the treatment of cilostazol significantly improved clinical outcomes at 8 months, we did not find the extra beneficial effects of cilostazol on the TLR and repeated PCI in overall study population. Recently, Lee et al.18 reported a randomized study comparing triple and dual antiplatelet therapy in angina patients with diabetes mellitus who received DES. Their results showed that triple antiplatelet therapy after DES implantation decreased the extent of late loss and the incidence of 9-month TLR. In the present study, the subgroup analysis performed in diabetic patients showed that although the incidence of TLR was similar between the triple and dual groups, the incidence of repeated PCI was significantly reduced in diabetic patients. We speculate that the difference between our study and that of Lee et al.18 might be due to the different study populations and follow-up regimens. In the present study, we routinely performed only clinical follow-up. Some patients with angiographic in-stent restenosis might be asymptomatic and would not be found in routine clinical follow-up. This may be an important reason for the similar incidences of TLR between the triple and dual groups in our study. Cilostazol has pleiotropic effects on preventing the progression of atherosclerosis.24,25 Nakamura et al.24 reported that treatment with cilostazol in type 2 diabetic patients with peripheral arterial disease could induce some beneficial changes in serum lipid profile and plasma fatty acid composition. These mechanisms might be associated with the reduction in repeated PCI observed in diabetic patients in the present study.

Study Strengths and Limitations
The strengths of the KAMIR study include its prospective design and large multicenter population base. The registry provides a comprehensive view of the contemporary treatments and outcomes in the Asian patients with AMI in the era of DES.

The present study has some limitations. First, although there is a large number of subjects in the present study, because of the nonrandomized nature of the registry study, there were baseline differences in several important prognostic factors between our primary comparison groups. Although we included most confounders in the multivariable Cox regression model, including propensity score to control the baseline biases, it is possible that some potential confounders might have crept in. However, this multicenter registry may help complete the picture gained from randomized trials, which usually have highly selected patients treated in a nonroutine setting. Second, in the present study, we divided patients into different antiplatelet therapies on the basis of their in-hospital, discharge, and follow-up medical records, but we did not collect information on adverse reactions to cilostazol during the follow-up period. However, we have detailed information on the major and minor bleeding events, mortality, and recurrent myocardial infarction, which also are very important components of safety profiles and can help us understand the main safety profiles of cilostazol.26 Fortunately, a recent study showed that the adverse reactions in patients who received triple antiplatelet therapy were similar to those who received dual therapy.18 Third, because we did not collect data on cardioactive medications, including β-blockers, statins, angiotensin-converting enzyme inhibitors, and angiotensin II receptor blockers, during the follow-up period, this also might be a confounding factor.

Conclusions
The present study showed that aggressive antiplatelet treatment with aspirin, clopidogrel, and cilostazol not only had a good safety profile but also improved midterm clinical outcomes in acute STEMI patients who underwent primary PCI in the era of DES. Notably, female patients, old patients, and diabetic patients seemed to get more benefits from the triple antiplatelet therapy. Therefore, these results might provide the rationale for the use of triple antiplatelet therapy in these patients. Because of the limitations of the registry study, a randomized trial designed to compare triple and dual antiplatelet therapy in these patients is needed.

Appendix
KAMIR Investigators
The complete list of KAMIR Investigators follows: Myung Ho Jeong, MD; Young Jo Kim, MD; Chong Jin Kim, MD; Myeong Chan Cho, MD; Young Keun Ahn, MD; Jong Hyun Kim, MD; Shung Chull Chae, MD; Seung Ho Hur, MD; In Whan Seong, MD; Taek Jong Hong, MD; Dong Hoon Choi, MD; Jei Keon Chae, MD; Jae Young Rhew, MD; Doo Il Kim, MD; In Ho Chae, MD; Jung Han Yoon, MD; Bon Kwon Koo, MD; Byung Ok Kim, MD; Myoung Yong Lee, MD; Kee Sik Kim, MD; Jinyong Hwang, MD; Seok Kyu Oh, MD; Nae Hee Lee, MD; Kyoung Tae Jeong, MD; Seung Jea Tahk, MD; Jung Ho Bae, MD; Seung Woon Rha, MD; Keum Soo Park, MD; Kyoo Rok Han, MD; Tae Hoon Ahn, MD; Moo Hyun Kim, MD; Ju Young Yang, MD; Chong Yun Rhiim, MD; Hyeon Cheol Gwon, MD; Seong Wook Park, MD; Young Youp Koh, MD; Seung Jae Joo, MD; Soo Joong Kim, MD; Dong Kyu Jin, MD; Jin Man Cho, MD; Jeong Gwan Cho, MD; Wook Sung Chung, MD; Yang Soo Jang, MD; Ki Bae Seung, MD; and Seung Jung Park, MD.

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Disclosures
None.

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4. Snoep JD, Hovens MM, Eikenboom JC, van der Bom JG, Huisman MV. Association of laboratory-defined aspirin resistance with a higher risk of
Drug-eluting stent implantation in acute myocardial infarction is associated with an increased risk for acute and subacute in-stent thrombosis. Increased platelet activity also has been observed in acute myocardial infarction. Therefore, more aggressive antiplatelet therapy rather than conventional dual antiplatelet therapy may offer extra benefits for acute myocardial infarction patients undergoing primary percutaneous coronary intervention with drug-eluting stents. This article retrospectively evaluates the safety and efficacy of triple antiplatelet therapy (aspirin plus clopidogrel plus cilostazol; n=1634) and dual antiplatelet therapy (aspirin plus clopidogrel; n=2569) in 4203 ST-segment elevation myocardial infarction patients who underwent primary percutaneous coronary intervention with drug-eluting stents. Selection of patients for treatment with triple antiplatelet therapy was left to the physician’s discretion. Compared with dual antiplatelet therapy, triple antiplatelet therapy had a similar incidence of major bleeding events but a significantly lower incidence of in-hospital mortality. After adjustment for known confounders, triple antiplatelet therapy had significantly lower incidences of cardiac death (adjusted odds ratio, 0.52; 95% confidence interval, 0.32 to 0.84; P=0.007), total death (adjusted odds ratio, 0.60; 95% confidence interval, 0.41 to 0.89; P=0.010), and total major adverse cardiac events (adjusted odds ratio, 0.74; 95% confidence interval, 0.58 to 0.95; P=0.019) at 8 months than dual antiplatelet therapy. In this large, real-world clinical study in patients with ST-segment elevation myocardial infarction who underwent primary percutaneous coronary intervention with drug-eluting stents, triple antiplatelet therapy not only had a good safety profile but also improved midterm clinical outcomes. Randomized trials are needed to compare the safety and efficacy of the triple and dual antiplatelet therapies in these patients.

**CLINICAL PERSPECTIVE**

Drug-eluting stent implantation in acute myocardial infarction is associated with an increased risk for acute and subacute in-stent thrombosis. Increased platelet activity also has been observed in acute myocardial infarction. Therefore, more aggressive antiplatelet therapy rather than conventional dual antiplatelet therapy may offer extra benefits for acute myocardial infarction patients undergoing primary percutaneous coronary intervention with drug-eluting stents. This article retrospectively evaluates the safety and efficacy of triple antiplatelet therapy (aspirin plus clopidogrel plus cilostazol; n=1634) and dual antiplatelet therapy (aspirin plus clopidogrel; n=2569) in 4203 ST-segment elevation myocardial infarction patients who underwent primary percutaneous coronary intervention with drug-eluting stents. Selection of patients for treatment with triple antiplatelet therapy was left to the physician’s discretion. Compared with dual antiplatelet therapy, triple antiplatelet therapy had a similar incidence of major bleeding events but a significantly lower incidence of in-hospital mortality. After adjustment for known confounders, triple antiplatelet therapy had significantly lower incidences of cardiac death (adjusted odds ratio, 0.52; 95% confidence interval, 0.32 to 0.84; P=0.007), total death (adjusted odds ratio, 0.60; 95% confidence interval, 0.41 to 0.89; P=0.010), and total major adverse cardiac events (adjusted odds ratio, 0.74; 95% confidence interval, 0.58 to 0.95; P=0.019) at 8 months than dual antiplatelet therapy. In this large, real-world clinical study in patients with ST-segment elevation myocardial infarction who underwent primary percutaneous coronary intervention with drug-eluting stents, triple antiplatelet therapy not only had a good safety profile but also improved midterm clinical outcomes. Randomized trials are needed to compare the safety and efficacy of the triple and dual antiplatelet therapies in these patients.
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