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# Culprit-Lesion-Only Versus Multivessel Revascularization Using Drug-Eluting Stents in Patients With ST-Segment Elevation Myocardial Infarction: A Korean Acute Myocardial Infarction Registry-Based Analysis

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## ABSTRACT

**Background and Objectives:** In patients with ST-segment elevation myocardial infarction (STEMI) and multivessel disease, complete revascularization (CR) for non-culprit lesions is not routinely recommended. The aim of this study was to compare the clinical outcomes of multivessel compared with infarct-related artery (IRA)-only revascularization in patients undergoing primary percutaneous coronary intervention (PCI) for STEMI. **Subjects and Methods:** From the Korean Acute Myocardial Infarction Registry (KAMIR) database, 1,094 STEMI patients with multivessel disease who underwent primary PCI with drug-eluting stents were enrolled in this study. The patients were divided into two groups: culprit-vessel-only revascularization (COR, n=827) group; multivessel revascularization, including non-IRA (MVR, n=267) group. The primary endpoint of this study included major adverse cardiac events (MACEs), such as death, myocardial infarction, or target or nontarget lesion revascularization at one year. **Results:** There was no difference in clinical characteristics between the two groups. During the one-year follow-up, 102 (15.2%) patients in the COR group and 32 (14.2%) in the MVR group experienced at least one MACE (p=0.330). There were no differences between the two groups in terms of rates of death, myocardial infarction, or revascularization (2.1% vs. 2.0%, 0.7% vs. 0.8%, and 11.7% vs. 10.1%, respectively; p=0.822, 0.910, and 0.301, respectively). The MACE rate was higher in the incompletely revascularized patients than in the completely revascularized patients (15% vs. 9.5%, p=0.039), and the difference was attributable to a higher rate of nontarget vessel revascularization (8.6% vs. 1.8%, p=0.002). **Conclusion:** Although multivessel angioplasty during primary PCI for STEMI did not reduce the MACE rate compared with culprit-vessel-only PCI, CR was associated with a lower rate of repeat revascularization after multivessel PCI. (**Korean Circ J 2011;41:718-725**)

**KEY WORDS:** Myocardial infarction; Coronary artery disease; Angioplasty.

Received: February 22, 2011 / Revision Received: March 16, 2011 / Accepted: June 20, 2011

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• The authors have no financial conflicts of interest.

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## Introduction

The incidence of acute myocardial infarction (AMI) in South Korea increased 2.6-fold from 1997 to 2007.<sup>1)</sup> From the Korean Acute Myocardial Infarction Registry (KAMIR) data between November 2005 and December 2007, ST-segment elevation myocardial infarction (STEMI) accounted for 60% of all AMI cases,<sup>2)</sup> with 52% of the STEMI patients having significant stenosis of the noninfarct-related arteries.<sup>3)</sup> The pathophysiological process in AMI is not limited to a single coronary lesion but involves the whole coronary arterial tree.<sup>4)</sup> These patients with multivessel disease are at a higher risk of cardiogenic shock as well as in-hospital and long-term mortality than the cases of single-vessel disease.<sup>5,6)</sup> Moreover, patients with multiple complex lesions have a high incidence of recurrent acute coronary syndrome and revascularization;<sup>4)</sup> however, in multivessel coronary intervention in the context of AMI, there are concerns about procedure-related complications,<sup>7)</sup> lower success rates,<sup>8)</sup> and increased contrast use and nephropathy.<sup>9)</sup> Therefore, both the American College of Cardiology/American Heart Association (ACC/AHA) 2004 guidelines and the ACC/AHA/Society for Cardiac Angiography and Interventions 2005 guidelines have recommended that simultaneous coronary intervention for nonculprit lesions should not be performed in hemodynamically stable patients because this approach may be associated with an increased risk of adverse outcomes.<sup>10,11)</sup> Recently, due to advances in devices, antiplatelet therapy, and technology, complete revascularization (CR) can safely be accomplished,<sup>8)</sup> and a recent randomized trial has shown that in a contemporary homogeneous cohort of patients with STEMI and multivessel coronary artery disease (CAD) treated with primary percutaneous coronary intervention (PCI), culprit-lesion-only angioplasty was associated with the highest rate of cardiac events compared with multivessel treatment, with the patients scheduled for staged revascularization experiencing a similar rate of major adverse cardiac events (MACEs) as the patients undergoing complete simultaneous treatment of noninfarct-related artery (IRA).<sup>12)</sup> Therefore, the optimal management of patients with multivessel disease in this setting remains still unclear.

The aim of this study was to compare the one-year clinical outcomes between the two different strategies during primary PCI with drug-eluting stents (DES) in patients with STEMI and multivessel CAD.

## Subjects and Methods

### Patient population and study design

This study is based on a database collected by KAMIR. KAMIR is a prospective, multicenter, observational registry designed to examine current epidemiology, in-hospital management, and outcome of patients with AMI in South Korea in

commemoration of the 50th anniversary of the Korean Circulation Society.<sup>13,14)</sup> Fifty hospitals with facilities for primary PCI participated in this study. Well-trained study coordinators collected data based on the standard protocol, and registered onto the web-based program. The ethics committee of each participating hospital approved the study protocol. The purpose and methods used to register patients in the KAMIR study have been previously described.<sup>15)</sup>

From the KAMIR database (14,885 patients), data of 3,791 eligible STEMI patients with multivessel CAD (defined as >70% diameter stenosis of two or more epicardial coronary arteries or their major branches by visual estimation) and who underwent primary PCI using drug-eluting stents within the period from November 2005 to November 2008 were collected.

ST-segment elevation myocardial infarction patients with prolonged (more than 30 minutes) chest pain starting less than 12 hours before hospital arrival, typical electrocardiography changes, and a door-to-balloon time of less than 120 minutes were included (Fig. 1).

Patients with cardiogenic shock at presentation (systolic blood pressure:  $\leq 90$  mm Hg), left main coronary disease ( $\geq 50\%$  diameter stenosis), and receiving bare-metal stents were excluded from the study. The eligible patients were divided into two groups and were further divided into two subgroups:

1) Culprit-vessel-only revascularization (COR) group: the IRA only was dilated, and the other arteries were left untreated during the primary procedure or index hospitalization.

2) Multivessel revascularization (MVR) group: revascularization of more than one vessel.

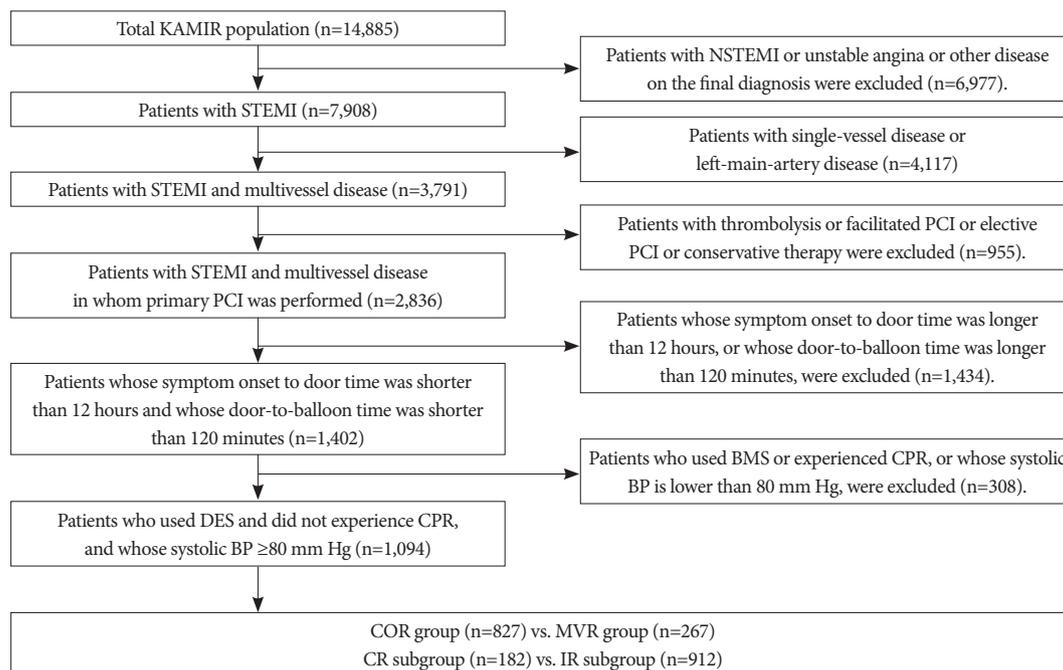
3) Complete revascularization subgroup: the IRA was opened, followed by dilatation of all other significantly narrowed arteries during the primary procedure or index hospitalization.

4) Incomplete revascularization (IR) subgroup: the IRA was successfully opened, followed by dilatation of only the significantly narrowed artery in three-vessel disease during the primary procedure or index hospitalization.

### Definitions and endpoints

The diagnosis of AMI was based on clinical presentations, increased levels of cardiac biomarkers (increase in levels of creatine kinase-MB, troponin-I, or troponin-T), and 12-lead electrocardiographic findings. Among these patients, patients with an ST-segment elevation of at least 1 mm in two or more contiguous limb electrocardiographic leads or 2 mm in precordial leads were defined as STEMI patients.

The primary endpoint of the study was the incidence of MACE defined as cardiac or noncardiac death, reinfarction, and repeat coronary revascularization (target vessel or nontarget vessel PCI) at one year. As the follow-up period was counted from the date of discharge, in-hospital events (death, reinfarction) were not defined as MACE. For repeat revascularization



**Fig. 1.** Flowchart of patients who participated in the study. KAMIR: Korean Acute Myocardial Infarction Registry, NSTEMI: non-ST-elevation myocardial infarction, STEMI: ST-elevation myocardial infarction, PCI: percutaneous coronary intervention, BMS: bare-metal stent, CPR: cardiopulmonary resuscitation, BP: blood pressure, DES: drug-eluting stent, COR: culprit-vessel-only revascularization, MVR: multivessel revascularization, CR: complete revascularization, IR: incomplete revascularization.

revascularization, all PCIs or coronary artery bypass grafts (CABGs) occurring after the baseline procedure were included. Recurrent myocardial infarction was defined as recurrent symptoms with new electrocardiographic changes reflecting MI or increased levels of cardiac biomarkers at least twice the upper normal limit.<sup>16)</sup> Target lesion revascularization (TLR) was defined as PCI for restenosis or other complications of treated lesion segment from 5 mm proximal to 5 mm distal to the stent.<sup>17)</sup> Target vessel revascularization (TVR) was defined as repeated PCI for any segment of the entire coronary artery proximal and distal to target lesion, except for TLR.

### Percutaneous coronary intervention procedures and follow-up

All patients had coronary lesions with  $\geq 50\%$  stenosis in  $\geq 2$  coronary arteries. Coronary arterial lesion type was determined according to the ACC/AHA classification. The diagnosis of the culprit vessel was based on coronary angiographic findings, 12-lead electrocardiogram, two-dimensional echocardiogram and noninvasive stress test, if possible. All patients received loading doses of aspirin 100-300 mg and clopidogrel 300-600 mg before PCI. A 50-70 U/kg dose of unfractionated heparin was used before or during PCI to maintain an activated clotting time of 250-300 seconds. After PCI, daily maintenance doses of aspirin 100 mg and clopidogrel 75 mg were prescribed. A glycoprotein IIb/IIIa inhibitor was used in patients with large thrombotic burden on angiography at the operator's discretion. Clinical follow-up was performed for 12 months.

### Statistical analysis

Continuous variables are presented as mean  $\pm$  SD, and categorical variables as percentages. Categorical variables were compared among groups using the  $\chi^2$  test, whereas continuous variables were compared with the analysis of variance test. Kaplan-Meier curves were used to represent the survival and cumulative incidence of events to the follow-up. For the endpoint "death," the patients were censored at the time of death or at the 12-month follow-up if alive. For MACE, the patients were censored at the date of first MACE or at the 12-month follow-up. All tests were two-sided, and a *p* of less than 0.05 was considered statistically significant. All analyses were performed using the Statistical Package for the Social Sciences software, version 18.0 for Windows.

## Results

### Baseline characteristics

One thousand and ninety four patients with STEMI and multivessel CAD who met the inclusion criteria were included in the follow-up (Fig. 1). The mean age was  $63.1 \pm 12.7$  years, and 804 (73.5%) were men. The COR group included 827 (75.6%) patients, and the MVR group 267 (24.4%) patients. The CR subgroup included 182 (16.6%) patients, and the IR subgroup included 912 (83.4%) patients (Fig. 1). Table 1 and 2 show the distribution of the baseline characteristics between the two groups. The two groups were similar in terms of age, gender, risk factors, enzymatic infarct size, Thrombolysis in Myocardial Infarction (TIMI) flow grade,

**Table 1.** Baseline clinical characteristics

Variables	COR group (n=827)	MVR group (n=267)	p
Age (years)	63±13	62±12	0.152
Men, n (%)	598 (72.3)	206 (77.2)	0.068
Hypertension, n (%)	400 (49.7)	124 (48.9)	0.388
Systolic BP (mm Hg)	128±40	128±26	0.929
Diabetes mellitus, n (%)	218 (26.8)	75 (29.2)	0.250
Hyperlipidemia, n (%)	57 (8.1)	11 (4.5)	0.062
Family history of CAD, n (%)	52 (7.1)	30 (12.1)	0.016
Prior history of CAD, n (%)	86 (10.4)	23 (8.6)	0.481
Killip class	1.4±0.8	1.4±0.8	0.566
Door-to-balloon time (minutes)	73±23	71±21	0.098
CK-MB level (mg/dL)	239.9±492.7	201.8±192.8	0.469
Serum creatinine level (mg/dL)	1.2±1.2	1.1±1.0	0.577
Left ventricular EF (%)	50.1±11.6	53±10.6	0.004
Three-vessel disease, n (%)	330 (39.9)	110 (41.2)	0.380
Medications at discharge			
Aspirin	766 (99.0)	261 (99.2)	0.514
Clopidogrel	762 (98.4)	256 (97.3)	0.183
Statin	654 (84.5)	230 (87.5)	0.142
ACEI	529 (68.3)	190 (72.2)	0.134
Nitrate	348 (45.0)	141 (53.6)	0.009
Beta-blocker	585 (75.6)	202 (76.8)	0.378
In-hospital mortality	43 (5.2)	1 (0.4)	<0.001

BP: blood pressure, CAD: coronary artery disease, CK-MB: creatine kinase-myocardial band isoenzyme, EF: ejection fraction, ACEI: angiotensin-converting enzyme inhibitor, COR: culprit-vessel-only revascularization, MVR: multivessel revascularization

**Table 2.** Baseline angiographic characteristics

Variables	COR group (n=825)	MVR group (n=267)	p
Culprit artery			
LAD, n (%)	375 (45.5)	119 (44.6)	0.832
RCA, n (%)	367 (44.5)	106 (39.7)	0.178
LCX, n (%)	83 (10.1)	42 (15.7)	0.015
Type B2/C lesion, n (%)*	649 (84.9)	211 (81.8)	0.237
Preprocedural TIMI flow	0.8±1.1	0.9±1.2	0.131
Postprocedural TIMI flow	2.9±0.4	3.0±0.3	0.005
Stent size for target lesion (mm)	26.0±6.4	26.0±6.7	0.937
Total number of stents	1.3±0.6	2.4±1.0	0.001

\*Based on the American College of Cardiology/American Heart Association coronary artery lesion definition. LAD: left anterior descending artery, RCA: right coronary artery, LCX: left circumflex artery, TIMI: Thrombolysis in Myocardial Infarction, COR: culprit-vessel-only revascularization, MVR: multivessel revascularization

and creatinine level, whereas there was a difference in the mean left ventricular ejection fraction (LVEF) (higher in the MVR group). Nitrate therapy was more frequent in the MVR group, whereas the two groups had similar proportions of other therapies.

### Cardiovascular events

Forty-four (4.0%) patients died during index hospitaliza-

tion, 31 (2.8%) from cardiac causes. Of them, 43 (5.2%) patients were in the COR group and in the IR subgroup, and 1 (0.4%) patient was in the MVR group and in the CR subgroup. The in-hospital mortality was higher in the COR group than in the MVR group ( $p<0.001$ ). However, the multivariate analysis after adjusting for age, sex, Killip class, post-MI TIMI flow, systolic blood pressure, LVEF, existence or nonexistence of complications, and serum creatinine, did not show that

**Table 3.** One-year MACE in the COR and MVR groups

Variables	COR group (n=701)	MVR group (n=247)	p
Total MACEs (%)	102 (14.6)	32 (13.0)	0.330
Death (%)	15 (2.1)	5 (2.0)	0.822
Cardiac	9 (1.3)	2 (0.8)	0.519
Noncardiac	6 (0.9)	3 (1.2)	0.682
MI (%)	4 (0.7)	2 (0.8)	0.910
STEMI	3 (0.4)	0 (0)	0.293
NSTEMI	1 (0.1)	2 (0.8)	0.116
Revascularization events (%)	82 (11.7)	25 (10.1)	0.301
TVR	21 (3.0)	13 (5.3)	0.190
Nontarget vessel PCI	58 (8.3)	12 (4.9)	0.053
CABG	3 (0.4)	0 (0)	0.194

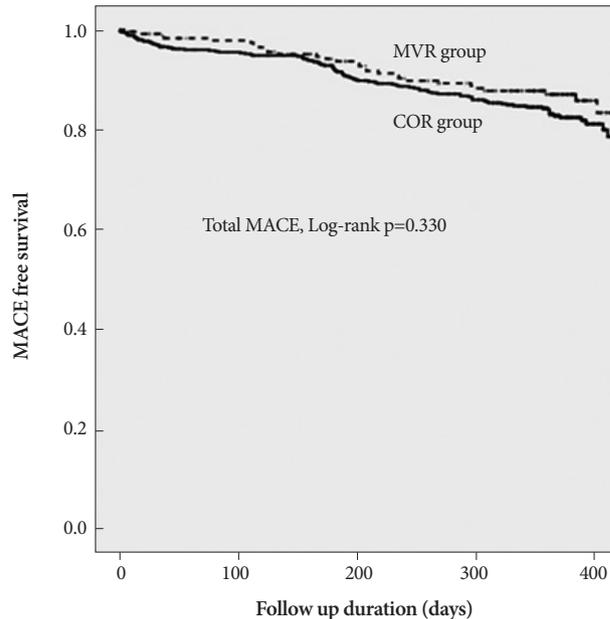
MACEs: major adverse cardiac events, MI: myocardial infarction, STEMI: ST-segment elevation myocardial infarction, NSTEMI: non-ST-segment elevation myocardial infarction, TVR: target vessel revascularization, PCI: percutaneous coronary intervention, CABG: coronary artery bypass graft, COR: culprit-vessel-only revascularization, MVR: multivessel revascularization

the culprit-only PCI was significantly associated with higher in-hospital mortality ( $p=0.995$ ) which had a significant  $p$  in the univariate analysis. Low post-TIMI flow (odds ratio: 0.191; 95% confidence interval: 0.044-0.834;  $p=0.028$ ) and the existence of complications during index hospitalization (odds ratio: 21.916; 95% confidence interval: 1.145-419.361;  $p=0.028$ ) were significantly associated with higher in-hospital mortality. The in-hospital mortality was also higher in the IR subgroup than in the CR subgroup ( $p=0.002$ ).

The rates of complications during the procedure were similar between the two groups. All four acute CVA patients were in the COR group. One patient with acute thrombosis was in the MVR group and in the CR subgroup. Of the three reinfarction patients, two were in the COR group, and one was in the MVR group and in the CR subgroup. One case of acute renal failure was in the MVR group and in the IR subgroup. The other complications were ventricular tachycardia, ventricular fibrillation, atrial fibrillation, cardiogenic shock, multi-organ failure, bleeding, and atrioventricular block.

After a mean follow-up of  $9.0\pm 4.2$  months from the date of discharge, 23 (2.4%) patients died, 14 (1.5%) from cardiac causes. Throughout the follow-up, 134 (14.4%) patients experienced at least one MACE, 102 (14.9%) in the COR group and 32 (13.0%) in the MVR group ( $p=0.379$ ). Seven patients (five in the COR group and two in the MVR group) experienced reinfarction (MI) while 107 patients (82 in the COR group and 25 in the MVR group) underwent re-PCI or CABG (Table 3). The Kaplan-Meier analysis showed no significant difference between the two groups for survival free of total MACE and of all kinds of MACE (Fig. 2).

However, the Kaplan-Meier analysis showed significant differences between the two subgroups (the CR and IR subgroups) for survival free of total MACE and nontarget vessel PCI (Table 4). The survival free of total MACE and nontarget vessel PCI was lower in the IR subgroup ( $p=0.039$  and



**Fig. 2.** One-year MACE-free survival in the COR and MVR groups. MACE: major adverse cardiac event, COR: culprit-vessel-only revascularization, MVR: multivessel revascularization.

0.002, respectively) (Fig. 3). Fifteen of 85 patients in the MVR group and in the IR subgroup experienced at least one MACE. Of them, nine patients underwent nontarget vessel PCI.

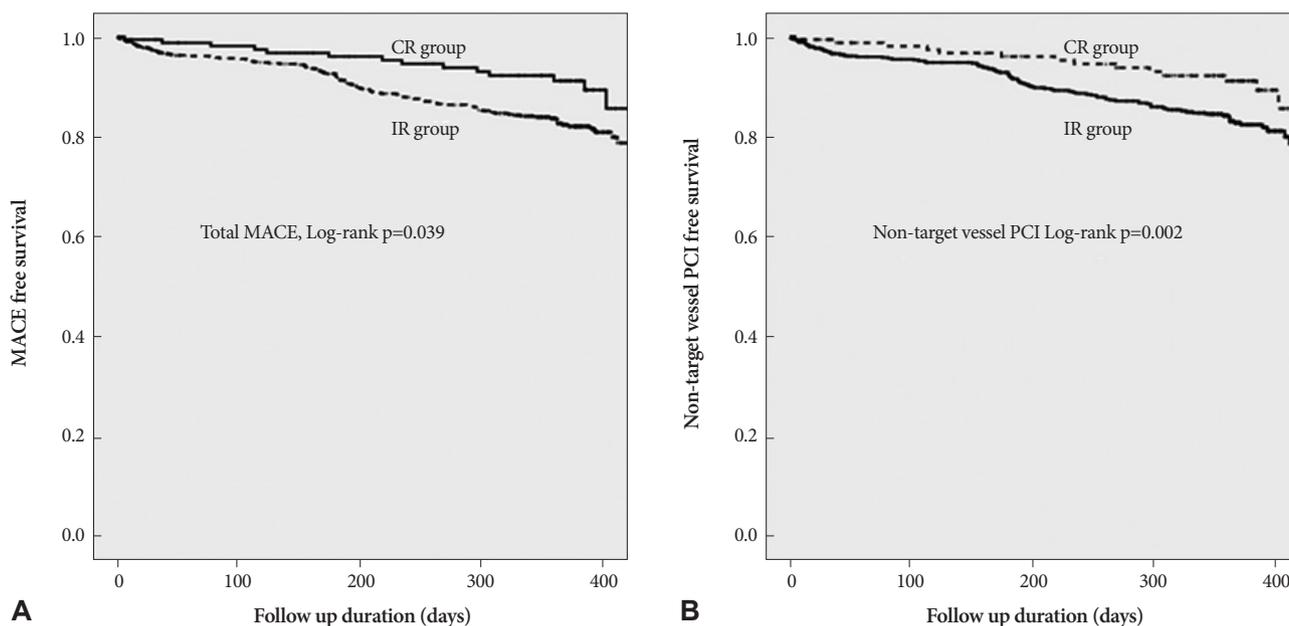
## Discussion

This study was designed to compare MVR with COR in patients with STEMI and multivessel CAD; it is the first study to compare MVR with COR in patients with STEMI in Asia. The main finding of the present study was that in hemodynamically stable patients with multiple coronary lesions treated by primary PCI using DES, MVR had a lower rate of in-hospital mortality and, after a mean follow-up of  $9.0\pm 4.2$  months, it had better clinical outcomes in non-target vessel PCI-relat-

**Table 4.** One-year MACE rate in the CR and IR subgroups

Variables	CR subgroup (n=182)	IR subgroup (n=779)	p
Total MACE (%)	16 (9.5)	117 (15.0)	0.039
Death (%)	2 (1.2)	18 (2.3)	0.321
Cardiac	2 (1.2)	9 (1.2)	0.995
Noncardiac	0 (0)	9 (1.2)	0.157
MI (%)	1 (0.6)	5 (0.6)	0.798
STEMI	0 (0)	3 (0.4)	0.414
NSTEMI	1 (0.6)	2 (0.3)	0.485
Revascularization events (%)	13 (7.7)	94 (12.1)	0.068
TVR	10 (6.0)	24 (3.1)	0.156
Nontarget vessel PCI	3 (1.8)	67 (8.6)	0.002
CABG	0 (0)	3 (0.4)	0.407

MACEs: major adverse cardiac events, MI: myocardial infarction, STEMI: ST-segment elevation myocardial infarction, NSTEMI: non-ST-segment elevation myocardial infarction, TVR: target vessel revascularization, PCI: percutaneous coronary intervention, CABG: coronary artery bypass graft, CR: complete revascularization, IR: Incomplete revascularization



**Fig. 3.** A: one-year MACE-free survival in the CR and IR subgroups. B: one-year nontarget vessel percutaneous coronary intervention-free survival in the CR and IR subgroups. MACE: major adverse cardiac event, CR: complete revascularization, IR: Incomplete revascularization.

ed events than with the treatment of IRA alone. However, the additional treatment of non-IRA during primary PCI or index hospitalization, resulted in a similar risk of death, MI, TVR, and CABG compared with the culprit-vessel-only procedure. Revascularization of the nonIRA probably prevented myocardial ischemia, and these differences were associated with better clinical outcomes in the multivessel PCI group of the present study.

Due to the increased numbers of implanted coronary stents, multivessel PCI was prone to higher in-stent restenosis rates.<sup>18)</sup> However in the present study, the TLR and TVR rates were statistically similar between the two groups. The reason for the higher in-hospital mortality rates in the culprit-vessel-only group despite the absence of differences in the baseline clinical

characteristics and complications is not clear. It might be associated with other factors, such as indications for PCI (elective, urgent, and emergent), presence of chronic total obstruction, and duration of procedure.

According to the current guidelines, PCI should be performed only in IRA, at least in patients without cardiogenic shock.<sup>10,11)</sup> However, data from the National Cardiovascular Data Registry showed that multivessel PCI should not be performed in even hemodynamically unstable patients.<sup>19)</sup> This is based on the hypothesis that single-vessel PCI has a more favorable benefit-to-risk ratio and better financial implications. Some studies suggest that the more conservative strategy of treating only the IRA could avoid the complications arising from longer procedures, such as the larger use of

a contrast medium with a potentially increased risk of contrast-induced nephropathy (CIN), increased administration or radiation, as well as the danger of ischemia in noninfarcted myocardial regions.<sup>20,21)</sup>

In recent years, with the development of new advanced devices and the use of platelet glycoprotein IIb/IIIa inhibitors, the outcome of multivessel PCI has markedly improved.<sup>22,23)</sup>

Some reports have indicated that the multivessel approach is safe and cost-effective. Brener et al.<sup>24)</sup> retrospectively examined more than 100,000 patients with acute coronary syndromes, and demonstrated a similar incidence of in-hospital events between patients receiving single and multivessel treatment. Ijsselmuiden et al.<sup>8)</sup> randomly assigned 219 patients with acute coronary syndromes to culprit-only versus MVR, and they found that the multivessel approach had better outcomes by decreasing the need for further interventions. A recent randomized trial by Politi et al.<sup>12)</sup> has shown that in 214 patients with STEMI and multivessel CAD treated with primary PCI, COR angioplasty was associated with the highest rate of MACE compared with multivessel treatment, and that the patients scheduled for staged revascularization experienced a similar rate of MACE as the patients undergoing complete simultaneous treatment of non-IRA during the mean 2.5-year follow-up period. The findings in the present study were similar to those of the randomized trial by Politi et al. in which the incidence of repeat revascularization and in-hospital mortality were higher in the single-vessel strategy. As the definition of MACE and the follow-up duration in the present study were different from those in the trial discussed above, the total MACE results were different. Although the study by Kim et al.<sup>25)</sup> using the same KAMIR data focused on NSTEMI patients, the findings in the present study were also similar to those of the said study, in which the incidence of in-hospital mortality was higher in the culprit-only group, MVR reduced nonTVR, and there were no significant differences in the TLR.

Only one case of CIN was observed in the MVR group and in the IR subgroup. The rates of the other procedure-related or procedure-unrelated complications were not different between the COR and MVR groups. Therefore, it was found that compared with the single-vessel approach, MVR is safe and is associated with a lower risk of nontarget PCI at a mean follow-up of  $9.0 \pm 4.2$  months. Moreover, CR is associated with a low risk of MACE. This result is attributable mainly to the lower incidence of nontarget vessel PCI in the CR subgroup compared with the COR group, and the result is mainly attributable to the nine added events of nontarget vessel PCI in 85 patients of the MVR group but of the IR subgroup. A possible explanation for the protective effect of multivessel PCI is that it allows a more complete treatment of other potentially unstable plaques. Indeed, the inflammatory reaction arising during acute coronary syndromes, and responsible for plaque

instability is not limited to the culprit lesion, but involves the entire coronary tree.<sup>4)</sup>

Although simultaneous revascularization was not distinguished from staged revascularization, the results suggest that the multivessel and complete approach during primary PCI or index hospitalization is safe and is possibly less expensive than an incomplete approach, through a reduction in the probability of further unplanned procedures.

### Limitations

The possible limitations of the present study were the imbalance in the number of patients in the two groups and the difference in the LVEF. The lack of data on stent thrombosis and CIN during the follow-up period also limits the comparison of safety between MVR and culprit-only revascularization. The present study was not a randomized controlled trial, and a selection bias may have existed. However, due to the absence of significant differences in the baseline characteristics in this study, propensity score matching was not needed in the present study.

Since protocol on selection did not exist, the selection of the culprit vessel under similar conditions varied among operators. In patients with multivessel PCI, simultaneous PCI could not be distinguished from staged PCI during index hospitalization. The registry has no information on this distinction. Although, the analysis was conducted by adjusting all the possible confounding factors, other factors could be associated with the clinical outcomes.

### Conclusions

In-hospital mortality was higher in the culprit-vessel-only PCI group than in the multivessel angioplasty group, and was also higher in the IR subgroup than in the CR subgroup.

Although multivessel angioplasty during primary PCI with DES for STEMI did not reduce the rates of death, reinfarction, TLR, TVR, and CABG compared with culprit-vessel-only PCI at one year, CR was associated with reduced nonTVR events. This finding of the present study should be further corroborated in a randomized controlled trial, and if confirmed, it may eventually lead to the recommendation of multivessel and CR for patients with STEMI and multivessel CAD.

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