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One-year clinical outcomes in invasive treatment strategies for acute ST-elevation myocardial infarction complicated by cardiogenic shock in elderly patients

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Abstract

Objective To investigate the clinical outcomes of an invasive strategy for elderly (aged ≥ 75 years) patients with acute ST-segment elevation myocardial infarction (STEMI) complicated by cardiogenic shock (CS). **Methods** Data on 366 of 409 elderly CS patients from a total of 6,132 acute STEMI cases enrolled in the Korea Acute Myocardial Infarction Registry between January 2008 and June 2011, were collected and analyzed. In-hospital deaths and the 1-month and 1-year survival rates free from major adverse cardiac events (MACE; defined as all cause death, myocardial infarction, and target vessel revascularization) were reported for the patients who had undergone invasive (n = 310) and conservative (n = 56) treatment strategies. **Results** The baseline clinical characteristics were not significantly different between the two groups. There were fewer in-hospital deaths in the invasive treatment strategy group (23.5% *vs*. 46.4%, $P < 0.001$). In addition, the 1-year MACE-free survival rate after invasive treatment was significantly lower compared with the conservative treatment (51% *vs*. 66%, $P = 0.001$). **Conclusions** In elderly patients with acute STEMI complicated by CS, the outcomes of invasive strategy are similar to those in younger patients at the 1-year follow-up.

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Keywords: Acute myocardial infarction; Elderly patients; Cardiogenic shock

1 Introduction

Elderly patients are considered to be at high risk for acute myocardial infarction (AMI) complicated by cardiogenic shock (CS). These events are frequently under represented in clinical trials, whereas in reality they comprise a large proportion of the cardiovascular patient population.[1] An invasive treatment strategy, such as percutaneous coronary intervention (PCI), is currently the treatment of choice for patients presenting with acute ST-segment elevation myocardial infarction (STEMI). However, the international Guidelines for managing AMI recommend primary PCI only for the CS patients who are younger than 75 years as a Class I indication.[2] Conservative strategies, such as fibrinolysis and intensive medical treatment, are a valuable alternative when mechanical reperfusion is unavailable. Data to justify PCI for elderly patients with STEMI complicated by CS have been limited to randomized clinical trials and observational studies from single centers with small sample sizes.[3-7] Hence, justifying an invasive strategy for STEMI with CS in elderly patient remains challenging. The aim of this study was to compare the clinical outcomes of invasive and conservative strategies for elderly patients with STEMI complicated by CS.

2 Methods

2.1 Patients

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Acute Myocardial Infarction Registry (KAMIR) is a prospective, multi-center observational study that investigates the mortality risk factors in patients with AMI (since November 2005) with the aim of establishing universal management guidelines to prevent AMI. The online registration of AMI cases is performed in 41 primary PCI centers that have sufficient experience and volume to perform primary PCI (www.kamir.or.kr). The study protocol was approved by the ethics committee at each participating institution. The data were registered and submitted online from individual institutions through password-protected electronic case report forms. We enrolled only those patients with STEMI complicated by CS.

From January 2008 to June 2011, data from 13,473 patients were collected in the KAMIR. Of these patients, we collected and analyzed the data from 1,565 elderly (aged ≥ 75 years) CS patients, and 6,132 acute STEMI cases were enrolled in the registry (Figure 1).

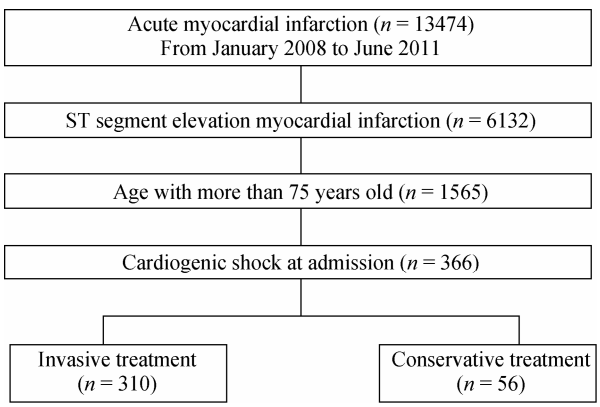

Figure 1. Flow chart of patients in the study.

2.2 Definitions

We defined STEMI as the presence of ≥ 0.1 mV ST-segment elevation in two contiguous electrocardiogram (ECG) leads with ongoing chest pain with, or without, cardiac enzyme levels above the reference range. CS was defined as a systolic blood pressure < 90 mmHg for ≥ 30 min, or the requirement of inotropic agents to maintain a systolic blood pressure > 90 mmHg associated with end-organ hypoperfusion (altered mental status, cold extremities, or a urine output of < 30 mL/h) in the emergency room.

If possible, STEMI complicated by CS was confirmed by cardiac catheterization. Additionally, bilateral pulmonary congestion using chest X-ray and predominant systolic dysfunction with regional wall motion abnormalities using echocardiography were clinically considered to be a CS diagnosis in the emergency room.

An invasive treatment strategy was defined as primary PCI; a conservative treatment strategy comprised non-invasive treatments, including successful thrombolysis, or intensive medical treatment.

2.3 Conservative strategy including thrombolysis

All conservative treatments, including thrombolysis treatment, were performed because of the refusal of an invasive procedure by patients or proxies. The recommended thrombolysis protocol was triggered by the following signs and symptoms: symptoms of STEMI that persisted for more than 30 min and were accompanied by an elevation > 1 mm (0.1 mV) in the ST segment in ≥ 2 contiguous electrocardiographic leads and presentation within 6 h after the onset of symptoms (or between 6 h and 24 h if there was evidence of continuing ischemia). A conservative strategy that included the use of antithrombotic agents, but excluded thrombolysis was used in patients with previous strokes or with other known intracranial diseases, recent trauma or surgery, active bleeding, or prolonged cardiopulmonary resuscitation.

In the fibrinolysis, a weight-adjusted single intravenous dose of tenecteplase was administered, ranging from 30 mg in patients weighing 60 kg; to 50 mg in patients weighing ≥ 90 kg. Simultaneously, a 60 unit/kg bolus of unfractionated heparin was administered (to a maximum of 4,000 units), followed by an infusion of 12 units/kg per hour (to a maximum of 1,000 units/h) with an initial adjustment to maintain an activated partial thromboplastin time 1.5–2 times the upper normal limit. This treatment regimen is based on the results of the COMMIT trial.[8]

Unsuccessful thrombolysis was defined by a 12-lead ECG obtained 60 min after the onset of fibrinolytic therapy that demonstrated a failure of the ST-segment elevation to resolve by at least 50% in the worst lead compared with the baseline ECG and the absence of chest pain relief. Invasive treatment strategies, such as rescue PCI, were also recommended and chosen depending on the decisions of patients or proxies regarding the conservative treatment.

2.4 Invasive strategy

All patients who planned to have primary or rescue PCIs (the invasive strategy) were pretreated with 200 mg of aspirin and 300 mg of clopidogrel. Abciximab was administered at the discretion of the operator: an intravenous preprocedural bolus of 0.25 mg/kg body weight followed by a continuous infusion of 0.125 μg/kg per minute for 12 h (up to a maximum dose of 10 μg/min). During the PCI, an intravenous bolus of unfractionated heparin was administered to maintain an activated clotting time of more than 200 s. A successful invasive strategy was defined as an infarct-re-

lated artery stenosis < 30%, associated with a thrombolysis in myocardial infarction flow grade of 2 or 3, without the requirement for emergent coronary artery bypass (CABG). Multivessel disease was defined as ≥ 70% stenoses in one other major vessel in addition to another segment of the culprit vessel.

2.5 Clinical follow-up

All patients were discharged on aspirin (100 mg) indefinitely and clopidogrel (75 mg) daily for 6–12 months. The follow-up protocol included an evaluation at hospital discharge and at 1-, 3-, 6-, and 12-month follow-ups.

2.6 Study endpoint

The 1-month and 1-year clinical outcomes included all-cause death, MI, and target vessel revascularization (TVR, defined as repeat revascularization within 5 mm of the treated segment and repeat revascularization of the treated vessel). Major adverse cardiac events (MACE) were a composite of all-cause death, MI, and TVR during a 1 year follow-up. The primary endpoint of the study was the 1-year rates of MACE-free survival. These rates were reported for the patients who underwent invasive (n = 310) and conservative (n = 56) treatment strategies during the 1-year follow-up.

3 Results

The basic patient characteristics are shown in Table 1. The mean age was 80 years. There was no significant difference between the two groups regarding age, hypertension, previous MI, diabetes mellitus, dyslipidemia, and current smoking. Regarding the ECG localization, most of the ST segment elevations were located in the anterior and inferior regions, but this difference was not significant. However, the door-to-needle time for thrombolysis in the conservative strategy group was significantly shorter than the door-to-balloon time in the invasive strategy group (39 min *vs*. 63 min, P < 0.001; Table 2). In 33% (4/12) of the patients in the conservative group, revascularization was achieved through successful thrombolysis. When rescue PCI was performed in the conservative strategy group (67%), the infarct-related artery was mostly the right coronary artery. Fifty-three patients (17%) were treated with an intra-aortic balloon pump (IABP), and 67 patients (21%) were treated with temporary pacemaker insertion in the invasive strategy group (Table 3). Anti-platelet agents, beta-blockers, and angiotensin converting enzyme inhibitors were more frequently taken in the invasive strategy group than in the conservative strategy group.

Table 1. Baseline clinical characteristics.

	Conservative strategy (n = 56)	Invasive strategy (n = 310)	P value
Age (yrs)	80 ± 6	80 ± 6	0.929
Male	24 (42.9)	141 (45.5)	0.716
Body mass index (kg/m^2)	21.3 ± 3.7	22.3 ± 3.1	0.055
Risk Factor			
Hypertension	39 (69.6)	177 (57.0)	0.244
Previous MI	10 (17.9)	33 (10.6)	0.123
Diabetic mellitus	15 (26.7)	78 (25.1)	0.472
Dyslipidemia	6 (7.5)	21 (6.4)	0.821
Current smoker	13 (16.25)	57 (17.33)	0.930
Physical findings			
Systolic BP (mmHg)	67 ± 20	67 ± 23	0.961
Diastolic BP (mmHg)	39 ± 30	42 ± 27	0.493
Heart rate (beats/min)	69 ± 46	60 ± 36	0.083
LVEF (%)	42 ± 16	45 ± 13	0.482
ECG localization			0.102
Anterior	31 (55.4)	129 (41.6)	
Lateral	4 (7.1)	11 (3.5)	
Inferior	6 (10.7)	133 (42.9)	
Antero-inferior	8 (14.3)	20 (6.5)	
Antero-lateral	3 (5.4)	9 (2.9)	
Lateral-inferior	1 (1.8)	6 (1.9)	

The data are mean ± SD or n (%). BP: blood pressure; ECG: electrocardiogram; IHD: ischemic heart disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction.

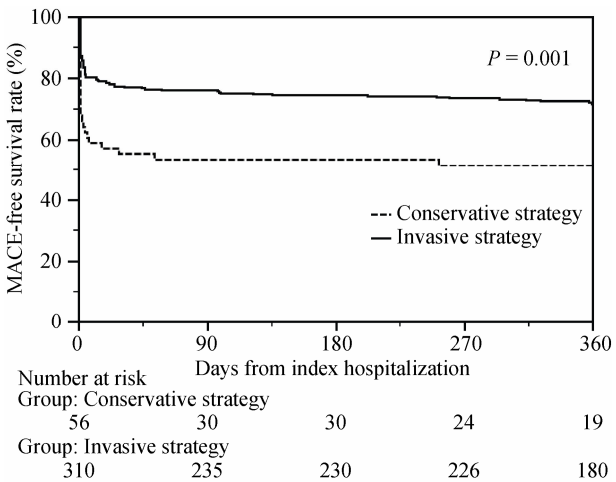

Figure 2. One-year Kaplan-Meier estimates of MACE-free survival. MACE: Major adverse cardiac events.

No patient was lost to follow-up, and the in-hospital mortality for patients receiving the conservative treatment strategy was higher than that for patients receiving the inva-

sive treatment strategy (46.4% *vs*. 23.5%, $P < 0.001$; Table 4). In addition, the 1-year MACE-free survival rates were significantly different between the invasive and conservative treatment groups (48.2% *vs*. 33.8%, $P = 0.001$). The Kaplan-Meier survival curves showed that the invasive treatment was superior to the conservative treatment (Figure 2). The multivariate predictors of the 1-year MACE were age ($P = 0.018$) and low ejection fraction ($P < 0.001$) in the clinical baseline parameters as well as ß blockers ($P = 0.004$) and ACEI ($P = 0.005$), as shown in Table 5.

Table 2. Reperfusion-related angiographic characteristics.

	Conservative strategy ($n = 56$)	Invasive strategy ($n = 310$)	*P* value
Door-to-balloon or needle time (min)	39 ± 38*	63 ± 28	< 0.0001*
Successful reperfusion	4 (33.0)*	286 (92.2)	< 0.001*
Infarct-related artery			
Left main		13 (4.1)	
Left anterior descending artery		122 (39.3)	
Left circumflex artery		33 (10.6)	
Right coronary artery		159 (51.2)	
Number of stenotic coronary artery			
coronary one vessel		150 (48.3)	
coronary two vessel		81 (26.1)	
coronary three vessel		95 (30.6)	
Lesion type			
A/B1		48 (15.4)	
B2/C		262 (84.5)	
Infarct-related artery TIMI flow			
0		238 (76.7)	
1		29 (9.3)	
2		22 (7.0)	
3		21 (6.7)	
Post-procedure TIMI flow			
0		22 (7.0)	
1		2 (0.6)	
2		22 (7.7)	
3		264 (85.1)	
Stent implantation			
Bare metal stent		48 (15.4)	
Drug eluting stent		225 (72.5)	

The data are mean ± SD or *n* (%). *Statically significant.

4 Discussion

In our chosen cohort of elderly patients with acute STEMI complicated by CS, the MACE-free survival rates were significantly different between the conservative and invasive strategy groups during the 1-year follow-up.

Previous randomized studies demonstrated a difference in the clinical outcomes between the conservative and invasive treatment strategies in elderly patients with AMI.[8-11] The SHOCK trial also demonstrated the superiority of the invasive strategy over the conservative strategy in patients with STEMI complicated by CS, with a lower 6-month mortality rate in the invasive strategy group (50.3% *vs*. 63.1%, $P = 0.027$). However, with a small number of elderly patients, further subgroup analysis showed that this beneficial effect did not extend to elderly patients (> 75 years), who experienced a difference in the 1-month mortality between the invasive and conservative strategy groups (70.0% *vs*. 53.1%, $P = 0.16$). [9] In the elderly patients (> 75 years) with STEMI, the TRIANA trial reported that the 1-month and 1-year mortality rates of the invasive and conservative strategy groups were not significantly different (13.6% *vs*. 17.2%, $P = 0.43$ and 21.1% *vs*. 23.1%, $P = 0.71$, respectively),[10] and the yet-unpublished senior PAMI trial also failed to document a differences between the invasive and conservative strategies in the 1-month mortality rates of 481 randomized elderly patients.[11] However, in the Zwolle study, the 46 patients assigned to the invasive strategy group showed a lower 2-year mortality rate compared with those treated with thrombolysis (15% *vs*. 32%, $P = 0.04$).[12] In addition, a conservative strategy that includes fibrinolysis could be harmful in elderly patients with STEMI, whereas the patients who underwent invasive treatment strategies showed a lower 1-month mortality rate than those who underwent conservative strategies.[13]

Recently, in the Polish Registry of Acute Coronary Syndromes (with a large population), Gasior *et al*.[14] concluded that an invasive strategy is better after 6 months of follow up. Compared with previous results, we demonstrated that the 1-year MACE-free survival rates in the invasive strategy group were significantly different from those in the conservative strategy group (66% *vs*. 51%, $P = 0.001$), despite similar baseline clinical characteristics (Table 1, Figure 2). Antiplatelet and beta-blocker treatments, which both affect the clinical outcome, appeared to be more frequently used in the invasive group than in the conservative group (Table 3). In reality, mechanical supports were applied to adjust the hemodynamic status and beta-blockers were frequently used in the invasive group, whereas only vasopressors were used in the conservative group during hospitalization. After hos-

Table 3. In-hospital management.

	Conservative strategy (*n* = 56)	Invasive strategy (*n* = 310)	*P* value
CABG		7 (2.2)	
IABP		53 (17.0)	
Temporary pacemaker		67 (21.6)	
Intubation		11 (3.5)	
Medical treatment			
Aspirin	48 (85.7)	296 (95.5)	0.005*
Clopidogrel	43 (76.8)	295 (95.2)	< 0.001*
Unfractional heparin	44 (78.6)	254 (81.9)	0.551
Glycoprotein IIb/IIIa inhibitor	0 (0.0)	38 (12.8)	0.006*
β blocker	23 (41.1)	200 (64.5)	0.001*
Angiotensin-converting enzyme inhibitor	21 (37.5)	165 (53.2)	0.030*
Angiotensin II receptor blocker	8 (14.3)	45 (14.5)	0.964
Statin	42 (52.5)	184 (55.9)	0.712
Vasopressor	30 (53.5)	110 (35.4)	0.009*

The data are *n* (%). *Statically significant. CABG: coronary artery bypass surgery; IABP: intraaortic balloon pump.

Table 4. Clinical outcomes.

	Conservative strategy (*n* = 56)	Invasive strategy (*n* = 310)	*P* value
CCU stay (days)	5.6 ± 5.6	4.5 ± 3.4	0.290
In-hospital death	26 (46.4)	73 (23.5)	< 0.001*
Complications		70 (22.5)	
Periprocedureal MI		6 (1.9)	
Bleeding		9 (2.9)	
Renal failure		51 (16.1)	
Stroke		4 (1.2)	
Out-of-hospital outcome			
1-month MACE	26 (46.4)	91(29.3)	< 0.001*
Death	26 (46.4)	87 (28.0)	< 0.001*
MI	0 (0)	2 (0.6)	0.818
TVR	0 (0)	4 (1.2)	0.321
1-year MACE	27 (48.2)	105 (33.8)	0.001*
Death	26 (46.4)	89 (28.7)	< 0.001*
MI	1 (1.7)	4 (1.2)	0.921
TVR	0 (0)	16 (5.1)	< 0.001*

The data are *n* (%). *Statically significant. CCU: coronary care unit; MACE: major adverse cardiac event; MI: myocardial infarction; TVR: target vessel revascularization.

pital discharge, there was no significant difference in the prescription of anti-platelet agents, beta-blockers, and statins between the conservative and invasive treatment groups. A few possible explanations were mentioned in our study. First, a previous report showed that the reperfusion time is an important factor for survival in CS patients.[15] In our results, although the time from door to needle in the conservative group was shorter than the time from door to balloon in the invasive treatment group, the early reperfusion time in the conservative group may not influence the survival benefit in elderly STEMI patients with CS compared with the invasive group. Second, a successful invasive procedure is another important determinant for the clinical outcome. These temporal and procedural determinants may also influence the clinical outcomes, as in the previous study.[9]

Until now, determining the treatment strategy for STEMI with CS in elderly patients has remained challenging. Despite controversies among previous studies, in elderly patients with acute STEMI complicated by CS, the survival benefit of an invasive treatment strategy appears to be superior to a conservative strategy during the 1-year follow-up.

4.1 Study limitation

This non-randomized, observational study may have resulted in a selection bias with respect to the baseline characteristics. The number of elderly patients who underwent a conservative treatment strategy was limited, and a larger sample size would improve the likelihood of determining whether significant differences in the clinical outcomes exist between the invasive and conservative strategies. Primary care could affect the differences among the types of shock complicated by acute STEMI (shock caused by left ventricular dysfunction, shock caused by right ventricular dysfunction, or shock caused by fatal arrhythmia). The infarct-related artery in the conservative group was not known exactly, and favorable outcomes in the elderly patients with STEMI complicated by CS may have been influenced by physician bias for patients deemed the most likely to benefit from intensive adjunctive medical treatment.

4.2 Conclusion

In our study, elderly patients with acute STEMI compli-

Table 5. Cox proportional hazard regression for the predictors of the occurrence of MACE in the invasive group.

	Univariate analysis			Multivariate analysis		
	HR	**95% CI**	***P*-value**	**HR**	**95% CI**	***P*-value**
Clinical parameters						
Age	1.03	1.00–1.05	0.017	1.03	1.00–1.05	0.018*
Sex	0.62	0.41–0.95	0.030			
Body mass index	0.95	0.89–1.02	0.178			
Hypertension	1.07	0.71–1.62	0.719			
Previous MI	0.55	0.24–1.27	0.168			
Diabetes mellitus	1.53	0.97–2.41	0.066			
Dyslipidemia	0.38	0.12–1.19	0.099			
Smoking	0.26	0.108–0.652	0.004	0.28	0.11–0.71	0.008*
Systolic blood pressure	1.01	0.98–1.04	0.340			
Heart rate	1.00	0.99–1.01	0.102			
Ejection fraction < 40%	2.34	1.55–3.53	0.001	2.32	1.53–3.50	< 0.001*
ST segment location at ECG	0.87	0.74–1.02	0.104			
In-hospital management						
CABG	1.19	0.168–8.54	0.857			
IABP	1.32	0.90–1.94	0.153			
Temporary pacemaker	1.42	0.92–1.81	0.201			
Intubation	1.28	0.89–1.65	0.261			
Aspirin	0.14	0.08–0.27	< 0.001			
Clopidogrel	0.18	0.09–0.33	< 0.001			
Unfractionated heparin	0.81	0.49–1.34	0.422			
β blocker	0.24	0.15–0.37	< 0.001	0.49	0.30–0.80	0.004*
ACEI	0.21	0.13–0.35	< 0.001	0.48	0.29–0.80	0.005*
Statin	0.39	0.25–0.60	< 0.001			
Vasopressor	2.51	1.63–3.85	< 0.001			

*Statically significant. ACEI: angiotensin converting enzyme inhibitor; ARB: angiotensin receptor blocker; CABG: coronary artery bypass graft; CI: confidence interval; HR: hazard ratio; IABP: intra-arterial balloon pump; MACE: Major adverse cardiac events; MI: myocardial infarction.

cated by CS may be suitable candidates for an invasive strategy, similar to young patients. However, our conclusion should be confirmed through a multi-center, randomized, prospective study.

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