Effect of Distal Protection Device on the Microvascular Integrity in Acute Myocardial Infarction During Primary Percutaneous Coronary Intervention

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Background The use of a distal protection device during primary percutaneous coronary intervention (PCI) in acute myocardial infarction (AMI) may preserve the microvascular integrity of the myocardium.
Methods and Results A total of 58 consecutive patients with AMI, who had undergone primary PCI within 24 h after onset, were enrolled (30 patients with the PercuSurge GuardWire® System, 28 without). The coronary flow velocity reserve was not different between the 2 groups. In patients with a distal protection device, the post-PCI Thrombolysis In Myocardial Infarction myocardial perfusion grades (TMP) were more favorable (TMP 0/1: 13.3%, TMP 2: 23.3%, TMP 3: 63.4% vs TMP 0/1: 35.7%, TMP 2: 35.7%, TMP 3: 28.6%, p=0.023). These patients also exhibited lower basal and hyperemic microvascular resistance index levels (4.33±2.22 vs 5.55±2.36 mmHg·cm^{-1}·s, p=0.047; 2.39±1.40 vs 3.14±1.36 mmHg·cm^{-1}·s, p=0.045, respectively), and longer basal diastolic deceleration time (679±273 vs 519±289 ms, p=0.035) after PCI.
Conclusion Distal protection with the PercuSurge GuardWire® system may effectively preserve the microvascular integrity of the myocardium during primary PCI in AMI patients. (*Circ J* 2006; **70:** 1284 – 1289)

Key Words: Acute myocardial infarction; Distal protection device; Intracoronary Doppler wire; Microvascular circulation

Acute myocardial infarction (AMI) is commonly related with thrombotic occlusion following a plaque rupture. Accordingly, early relief of the occluded coronary artery and restoration of the coronary flow to the jeopardized myocardium have been demonstrated to decrease mortality and adverse outcomes.[1,2] Primary percutaneous coronary intervention (PCI), with stent deployment in AMI, has been reported as more effective than balloon angioplasty, from the viewpoint of decreasing the rate of target vessel revascularization and restenosis.[3–5] However, as distal embolization of ruptured atherosclerotic plaque debris or thrombus is common during primary PCI with catheter-based interventions, stent deployment may also endow a greater chance of distal embolization than balloon angioplasty.[5] Evidence has accumulated that an obstruction of the distal microvasculature in the downstream bed of the infarct-related artery (IRA) is caused by distal embolization of thrombotic materials and platelets during intervention.[6–8] These are critical pathophysiologic events of myocardial infarction (MI), which is subsequently related to the slow-flow or no-reflow phenomenon and associated with additional injury to the microvasculature of the myocardium and poor clinical outcomes.[9–13] Therefore, restoration of the epicardial coronary artery will not always guarantee reperfusion of the microvasculature of the myocardium and reperfusion at the myocardial tissue level by preserving the microvasculature is crucial, as is opening of the epicardial coronary artery during primary PCI. It has been suggested that a distal embolization protection device may be a safe and effective tool in preserving the microvasculature of the myocardium during primary PCI in AMI.[14–18] The coronary angiographic Thrombolysis In Myocardial Infarction (TIMI) myocardial perfusion grade (TMP)[19,20] and phasic coronary flow velocity patterns, as assessed by an intracoronary Doppler wire after primary PCI, both of which represent the myocardial reperfusion status and microvascular integrity of the IRA, are related to functional improvement of the left ventricle and prognosis of the patient.[21,22] Thus, the aim of the present study was to determine the effectiveness of the PercuSurge GuardWire® system in preserving the microvascular integrity of the myocardium during primary PCI in AMI patients, using the intracoronary Doppler wire to measure coronary flow velocities and phasic coronary flow velocity patterns of the IRA following primary PCI.

Methods

Patient Population

A total of 58 consecutive patients (mean age: 54±15 years; 46 males, 12 females) with first episode of ST-segment-elevated AMI, who had undergone primary PCI and a coronary Doppler flow study within 24 h of symptom onset, were enrolled. The diagnosis of AMI was based on characteristic chest pain persisting for more than 30 min, significant ST segment elevation (>1 mm in limb lead and >2 mm in precordial lead) in ≥2 contiguous ECG leads, and an

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Table 1 Comparison of the Clinical and Laboratory Characteristics

	Group A (n=30)	Group B (n=28)	p value
Age (years)	51±13	56±15	0.186
Gender (male, %)	26 (87%)	20 (71%)	0.201
Anterior infarction	17 (57%)	21 (75%)	0.143
Risk factor			
Hypertension	11 (37%)	14 (56%)	0.427
Diabetes mellitus	6 (20%)	4 (14%)	0.732
Smoking	21 (70%)	19 (68%)	1.000
Lipid profile (mg/dl)			
TC	188±35	195±37	0.464
Trigylceride	140±100	148±107	0.777
HDL-C	46±12	42±7	0.138
LDL-C	111±37	124±38	0.225
Onset time to PCI (min)	373±219	413±241	0.565
Peak CK (U/L)	2,611±1,770	3,949±3,040	0.226
Peak CK-MB (μg/ml)	256±164	379±166	0.011
LVEF (%)	55±9	50±11	0.059

Group A, patients with the PercuSurge GuardWire®; Group B, without the PercuSurge GuardWire®; TC, total cholesterol; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; PCI, percutaneous coronary intervention; CK, creatine kinase; CK-MB, myocardial band of CK; LVEF, left ventricular ejection fraction.

elevation of the myocardial band of creatine kinase (CK-MB) ≥3-fold the upper normal limit. The exclusion criteria included (1) previous MI, (2) cardiogenic shock, (3) previous history of coronary intervention or coronary artery bypass graft, (4) left main trunk disease, and (5) significant arrhythmia rendering an intracoronary Doppler study inappropriate. The study population was divided into 2 groups: group A comprised 30 patients with the PercuSurge GuardWire® Temporary Occlusion and Aspiration System (Medtronic AVE, Santa Rosa, CA, USA) who were selected consecutively according to the enrolment criteria (between November, 2002 and December, 2003) and group B (control group) comprised 28 patients without such a protection device who underwent primary PCI and Doppler flow velocity measurement consecutively in the period prior to the study (between October, 2001 and October, 2002).

Procedure

On admission, all patients were pretreated with chewable aspirin (300 mg) and clopidogrel (300–600 mg). An intravenous infusion of heparin was started (1,000 U/h) after a 5,000 U intravenous bolus injection, and additional heparin was administered to attain a minimum 300 s of activated clotting time during the procedure. After a 7Fr guiding catheter was inserted to the IRA, via the femoral artery, a 0.014-inch GuardWire® was advanced directly (or, in cases where the GuardWire® could not directly pass the culprit lesion, with the use of a steerable coronary angioplasty guidewire for backup). The occlusion balloon of the GuardWire® was positioned distal to the culprit lesion. Following actuation of the MicroSeal adapter, the distal occlusion balloon of the GuardWire® was inflated using an EZ-flator with diluted contrast media (1/3 contrast media and 2/3 heparinized normal saline). The balloon size was adjusted according to the distal reference vessel size. In some patients, for the evaluation of the distal vessel diameter and side branches, a small amount of contrast was injected through the guiding catheter before inflation of the distal occlusion balloon of the GuardWire®. When protection of the distal circulation had been achieved through the system, the MicroSeal Adapter was removed, leaving the distal occlusion balloon in an inflated state. Subsequent to stent deployment, a 5Fr monorail aspiration catheter (Export® Aspiration Catheter) was loaded over the proximal end of the GuardWire®, with several aspirations performed using the plunger of aspiration syringe. At the end of the procedure, angiography was performed to document the final TIMI flow grade and TMP grade.

Table 2 Comparison of the Quantitative Coronary Angiographic Results

	Group A (n=30)	Group B (n=28)	p value
Pre-intervention			
Minimal lumen diameter (mm)	0.17±0.27	0.22±0.41	0.608
Diameter stenosis (%)	96±7	93±13	0.326
Post-stent			
Minimal lumen diameter (mm)	3.0±0.4	3.0±0.5	0.607
Diameter stenosis (%)	12±7	12±9	0.900
Reference vessel size (mm)	3.3±0.4	3.4±0.5	0.647
Infarct related artery			0.143
Left anterior descending	17 (57%)	21 (75%)	
Left circumflex	3 (10%)	0 (0%)	
Right coronary	10 (33%)	7 (25%)	

Abbreviations see in Table 1.

Table 3 Comparison of the Pre-Intervention and Post-Stent Angiographic Results of TIMI and TMP Grades

	Group A (n=30)	Group B (n=28)	p value
Pre-PCI			0.699
TIMI 0/1	20 (66.7%)	20 (71.4%)	
TIMI 2	7 (23.3%)	4 (14.3%)	
TIMI 3	3 (10.0%)	4 (14.3%)	
Post-stent TIMI flow			0.040
0/1	1 (3.3%)	0 (0.0%)	
2	1 (3.3%)	7 (25.0%)	
3	28 (93.4%)	21 (75.0%)	
TMP grade			0.023
0/1	4 (13.3%)	10 (35.7%)	
2	7 (23.3%)	10 (35.7%)	
3	19 (63.4%)	8 (28.6%)	

TIMI, Thrombolysis In Myocardial Infarction; TMP, TIMI myocardial perfusion grade. Other abbreviations see in Table 1.

Measurement of Coronary Flow Velocity Parameters and Assessment of Phasic Coronary Flow Velocity Patterns With an Intracoronary Doppler Guidewire

After stenting and aspiration of the embolized materials, 100–300 μg nitroglycerin was administrated into the coronary artery, and a 0.014-inch Doppler guidewire (FloWire™, Cardiometrics, Mountain View, CA, USA) was introduced just distal to the culprit lesion. Maximal hyperemia was induced by a bolus of intracoronary adenosine administration (24 μg for the right coronary artery, 48 μg for the left coronary artery). The coronary flow velocity reserve (CFR) was defined as the ratio of the hyperemic averaged peak velocity (hAPV) to the baseline APV (bAPV). After removing significant stenosis of the coronary artery, the microvascular resistance index (MVRI) was calculated from the mean aortic blood pressure divided by the APV at the baseline (bMVRI) and during hyperemia (hMVRI), respectively. In 3 consecutive cardiac cycles, the deceleration times of the diastolic flow velocity (DDT) at baseline were measured and averaged for the mean value.

Table 4 Comparison of the Hemodynamics, Coronary Flow Velocity and Phasic Coronary Flow Velocity Patterns

	Group A (n=30)	*Group B (n=28)*	*p value*
Heart rate (beats/min)	*76±16*	*79±14*	*0.701*
Baseline mean blood pressure (mmHg)	*75±11*	*82±17*	*0.069*
Hyperemic mean blood pressure (mmHg)	*74±12*	*83±17*	*0.024*
Flow velocity parameters			
bAPV (cm/s)	*21.6±9.6*	*17.2±7.0*	*0.050*
hAPV (cm/s)	*38.4±16.8*	*29.9±11.0*	*0.027*
CFR	*1.87±0.66*	*1.84±0.61*	*0.867*
bMVRI ($mmHg \cdot cm^{-1} \cdot s$)	*4.33±2.22*	*5.55±2.36*	*0.047*
hMVRI ($mmHg \cdot cm^{-1} \cdot s$)	*2.40±1.40*	*3.14±1.37*	*0.045*
Coronary phasic flow patterns			
SAPV (cm/s)	*12.5±7.9*	*11.8±8.8*	*0.152*
DDT (ms)	*679±274*	*520±289*	*0.035*

bAPV, baseline average peak velocity (APV); hAPV, hyperemic APV; CFR, coronary flow velocity reserve; bMVRI, baseline microvascular resistance index (MVRI); hMVRI, hyperemic MVRI; SAPV, baseline systolic average peak velocity; DDT, baseline diastolic deceleration time. Other abbreviations see in Table 1.

Statistical Analysis

Data are expressed as percentages for discrete variables and as the mean ± standard deviation for continuous variables. The continuous variables of the clinical, angiographic and intracoronary Doppler flow data were compared between the 2 groups using Student's t-test. The categorical variables of clinical characteristics, angiographic TIMI and TMP grades were compared by chi-square analysis or Fishers exact test. A value of $p<0.05$ was considered to indicate statistical significance.

Results

Clinical Characteristics

The study population consisted of 58 patients (46 men, 12 women) with a mean age of 54±15 years. The clinical and laboratory data of both groups are summarized in Table 1. Of the 58 patients, 38, 17 and 3 had anterior, inferior and lateral wall infarctions, respectively. All patients underwent echocardiography immediately after primary PCI. The mean ejection fraction was 52.5±10.3%. The mean time elapsed from symptom onset to reperfusion with primary PCI was 392±228 min. There were no significant differences in the clinical characteristics of the 2 groups,

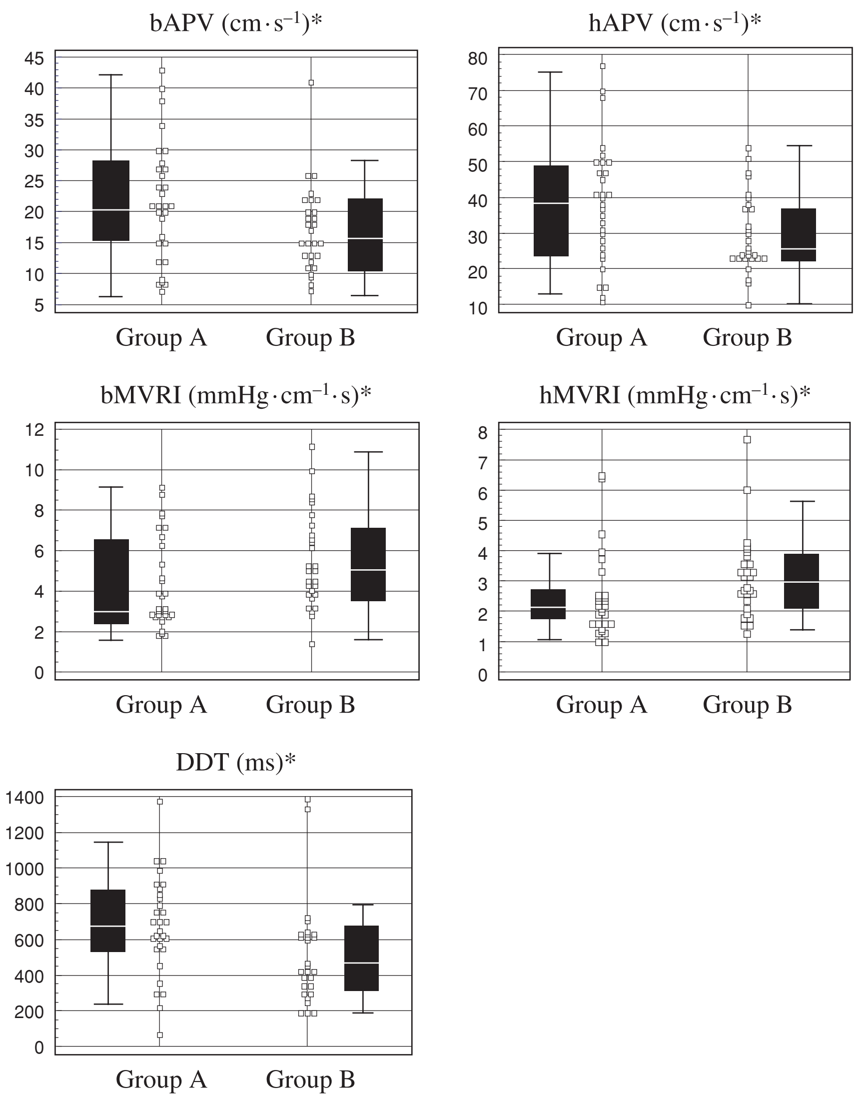

Fig 1. Comparison of the coronary flow velocity, MVRI and DDT between patients with and without a distal protection device. Group A, patients with the PercuSurge GuardWire®; Group B, patients without the PercuSurge GuardWire®; b, baseline; h, hyperemic; APV, average peak velocity; MVRI, microvascular resistance index; DDT, baseline diastolic deceleration time. *$p<0.05$ between 2 groups.

with the exception of the peak cardiac enzymes. The peak creatine kinase had a significant correlation with TMP grade and DDT (r=–0.314, p=0.020; r=–0.306, p=0.023, respectively) and peak CK-MB also had a significant correlation with TMP grade(r=–0.435, p=0.001). The peak CK-MB was lower in the group A than in the group B (256±165 vs 379±166 μg/ml, p=0.011). No patient received glycoprotein IIb/IIIa inhibitor before or during PCI.

Angiographic Data

Tables 2 and 3 summarize the angiographic data obtained before and after primary PCI. Before and after primary PCI with stenting, the mean of minimal lumen diameter, percentage of diameter stenosis and reference vessel diameter were not significantly different between the 2 groups. Also, there was no significant difference in the respective TIMI flow grades before intervention (p=0.699) (Table 3). After primary PCI, the TIMI flow grades were more improved in patients with the distal protection device (group A) compared with those without (group B) (93.4% had TIMI grade 3, 3.3% grade 2 and 3.3% grade 0 or 1 in the group A vs 75.0%, 25.0%, and 0.0%, respectively, in the group B, p=0.040) (Table 3). A significant difference was found in the respective TMP grades between the 2 groups after primary PCI (63.4% had TMP grade 3, 23.3% grade 2 and 13.3% grade 0 or 1 in group A vs 28.6%, 35.7%, and 35.7%, respectively, in group B, p=0.023) (Table 3). Furthermore, TMP grade 3 was more common in group A (63.4 vs 28.6%, p=0.010). In 49 patients who achieved TIMI 3 flow after stenting, TMP grade 3 was also more common in group A (67.9 vs 38.1%, p=0.048).

Coronary Flow Velocity Parameters and Phasic Coronary Flow Velocity Patterns

Heart rate and baseline mean aortic blood pressure were no different between the 2 groups. The hyperemic mean aortic pressure was lower in group A than in group B (74±12 vs 83±17 mmHg, p=0.026). After primary PCI, the CFR demonstrated no difference between the 2 groups. However, the bAPV and hAPV were higher in group A (21.6±9.6 vs 17.2±7.0 cm/s, p=0.050; and 38.4±16.8 vs 29.9±11.0 cm/s, p=0.027, respectively), and the bMVRI and hMVRI were lower in group A (4.33±2.22 vs 5.55±2.36 mmHg·cm^{-1}·s, p=0.047; and 2.40±1.40 vs 3.14±1.37 mmHg·cm^{-1}·s, p=0.045, respectively). Early systolic reversal flow was documented in 1 patient with the distal protection device, compared with 2 without. The baseline DDT was significantly longer in group A (679±274 vs 520±289 ms, p=0.035) (Table 4, Fig 1).

Of the 38 anterior AMI patients, 17 with the distal protection device and 21 without were analyzed for TMP grade, CFR, MVRI and DDT. In patients with a distal protection device, the post-PCI TMP grades were more favorable (TMP 0/1: 11.8%, TMP 2: 17.6%, TMP 3: 70.6% vs TMP 0/1: 33.3%, TMP 2: 38.1%, TMP 3: 28.6%, p=0.035). The patients achieving TMP grade 3 was more significantly common among the patients with a distal protection device (70.6% vs 28.6%, p=0.021). The bMVRI and hMVRI levels were lower in group A than in group B (3.64±1.79 vs 5.50±2.53 mmHg·cm^{-1}·s, p=0.015; 1.97±0.90 vs 2.91±0.94 mmHg·cm^{-1}·s, p=0.003, respectively). The DDT was longer in group A than in group B after PCI (727±289 vs 518±244 ms, p=0.021) (Table 5). Of the 17 inferior AMI patients, the patients achieving TMP 3 was also more significantly common in group A than in group B (70.0% vs 14.3%, p=0.050), and the TMP grades tended to be more favorable among the patients with the distal protection device (p=0.051) (Table 5).

Table 5 Comparison of the TMP Grade, CFR, MVRI and DDT in Anterior and Inferior AMI Patients

	Group A	Group B	p value
Anterior AMI (n)	17	21	
TMP grade			0.035
0/1	2 (11.8%)	7 (33.3%)	
2	3 (17.6%)	8 (38.1%)	
3	12 (70.6%)	6 (28.6%)	
CFR	1.88±0.71	1.89±0.62	0.961
bAPV (cm/s)	24.4±8.0	18.1±7.5	0.017
hAPV (cm/s)	43.8±16.9	31.3±9.7	0.007
bMVRI (mmHg·cm^{-1}·s)	3.64±1.79	5.50±2.53	0.015
hMVRI (mmHg·cm^{-1}·s)	1.97±0.90	2.91±0.94	0.003
bDDT (ms)	727±289	519±244	0.021
Inferior AMI (n)	10	7	
TMP grade			0.051
0/1	1 (10.0%)	4 (57.1%)	
2	2 (20.0%)	2 (28.6%)	
3	7 (70.0%)	1 (14.3%)	
CFR	1.87±0.65	1.70±0.58	0.585
bAPV (cm/s)	19.8±11.6	14.5±4.7	0.267
hAPV (cm/s)	33.7±13.9	25.4±14.1	0.249
bMVRI (mmHg·cm^{-1}·s)	4.80±2.63	5.71±1.91	0.446
hMVRI (mmHg·cm^{-1}·s)	2.58±1.53	3.84±2.17	0.117
bDDT (ms)	657±263	523±421	0.333

MVRI, microvascular resistance index; AMI, acute myocardial infarction. Other abbreviations see in Tables 1,3,4.

Discussion

Primary PCI with stent deployment in AMI is regarded as the optimal therapeutic strategy for reperfusion of the IRA, lowering the rate of target vessel revascularization and restenosis during the first 30 day and in long-term follow-up.[3–5] However, primary stenting has not shown greater improvement in TIMI flow grade than primary balloon angioplasty, because of the higher likelihood of distal embolization of thrombotic materials during PCI with stent deployment.[5] Angiographic evidence of distal embolization during primary PCI occurs in approximately 15% of cases, and can be associated with the no-reflow phenomenon.[11] The no-reflow phenomenon contributes to more extensive myocardial damage, poor left ventricular functional improvement and negative clinical prognosis than when it does not occur.[12,13] Increasing evidence suggests that the no-reflow phenomenon might be related to embolization of athero and/or thrombotic debris, plugging with platelets and inflammatory cells, endothelial and myocardial edema, and the shedding of vasoactive proteins and cytokines from the plaque.[6–8] A distal protection device is expected to protect the microvascular integrity of the myocardium by preventing embolization of thrombotic materials during primary PCI in AMI patients. Recently, thrombosuction with an export aspiration catheter before angioplasty during primary PCI has achieved excellent angiographic results, with all target vessels achieving TIMI grade 3 flow.[15] In the present study, there was no difference in the pre-PCI TIMI grades between the 2 groups; however, the post-PCI TIMI grades significantly improved in patients with the distal protection device (group A) compared with patients without (group B). TIMI grade 3 flow was significantly more common in group A. These results show that the use of the distal protection device was desirable in restoring epicardial coronary blood flow in AMI patients during primary PCI. However, the TIMI grade 3 flow had inhomogeneous hemodynamic characteristics, with a wide range of coronary flow velocity values, and some patients had less optimal reperfusion at the myocardial tissue level, which may be related to different clinical outcomes.[20]

The TMP grading system, using coronary angiography in the catheterization laboratory, facilitates the detection of microvascular obstruction as a cause of impaired myocardial perfusion, and implicates distal embolization as the most likely explanation for microvascular plugging. The TMP grading system provides independent risk stratification after reperfusion therapy in AMI.[19] Yip et al showed the PercuSurge device during primary PCI is superior to adjunctive tirofiban therapy in terms of epicardial flow, TMP grade and 30-day clinical outcomes.[16] Recently, Taguchi et al also reported that using a distal protection device is superior to the aspiration method for distal embolization after PCI with stenting for AMI.[17] In our study, the post-PCI TMP grades were more favorable in group A than in B. TMP grade 3 was more common in group A, and in 49 selected patients with TIMI grade 3 flow, TMP grade 3 was also more common in group A. These results suggest that a distal protection device is effective in the recovery of reperfusion at the myocardial tissue level, which may be effective in preserving the microvascular integrity of the myocardium during primary PCI.

The CFR and phasic coronary flow velocity patterns are known to be prognostic factors for left ventricular functional improvement and for the clinical prognosis in AMI.[21–24] We directly evaluated microvascular function by assessing the coronary flow velocities and coronary flow velocity patterns using an intracoronary Doppler wire after primary PCI. In severely damaged myocardium, with diffuse obstruction of the microvasculature caused by cell necrosis or multiple microvascular emboli, the microvascular resistance of the myocardium and distal coronary pressure may be increased and the diastolic coronary flow velocity rapidly decreased. This may impact on the coronary flow velocity patterns. In the presenty patients, the coronary flow velocity showed rapid deceleration of the diastolic flow. During the systolic phase, the coronary flow resulted in an early systolic retrograde flow or a decreased systolic flow.[13] The unfavorable coronary flow velocity patterns, such as decreased DDT and baseline systolic average peak velocity or early systolic reversal flow after primary PCI, were related to severe damage of the myocardium and poor functional recovery of the left ventricle.[21,22]

In group A, the bAPV and hAPV were significantly higher, and the bMVRI and hMVRI significantly lower, than in group B. The higher APV and lower MVRI strongly suggested that patients with the distal protection device, compared with those without, had less damage, and preserved microvascular circulation of the infarct-related myocardium. In this present study, the CFR showed no difference between the 2 groups because the bAPV was significantly higher in group A, which may have been related to the compensatory hyperemic response of resting coronary blood flow due to the relatively small amount of distal embolization[25] in patients with the distal protection device than those in without. Therefore, by definition, the CFR in this study might have been underestimated after primary PCI in the patients with the device. Lepper et al studied the CFR, as assessed immediately after the primary PCI within 24 h of MI onset, and showed no difference between the recovery and non-recovery group, although the non-recovery group showed a larger region of no-reflow compared with recovery group as assessed by myocardial contrast echocardiography.[26]

Our study showed that patients with the distal protection device had more favorable coronary flow velocity patterns. The DDT was significantly longer in patients with the device. These results indicate a preserved microvascular pool and less damage to the myocardium in patients with the device.

The present study demonstrates that the distal protection device was effective not only in anterior AMI but also in inferior AMI patients during primary PCI. Of 17 inferior AMI patients, the patients achieving TMP grade 3 was more common in group A. However, other indexes of microvascular integrities were not significantly different between group A and B in inferior AMI patients, which might be related to the small number of studied patients. The number of inferior AMI patients might be too small to show the effectiveness of the distal protection device. However, despite the small study population, statistically significant differences in the TMP grade strongly suggest the effectiveness of the distal protection device in the preservation of myocardial integrity during primary PCI in inferior AMI patients. Further study is required to evaluate the effectiveness of the distal protection device in inferior AMI patients.

This study is the first to show the effectiveness of the PercuSurge GuardWire® system as a distal protection device for preserving the microvascular integrity, according to angiographic index of TMP grade, even in patients with similar CFR and MVRIs and phasic coronary flow velocity patterns.

However, the EMERALD trial, a randomized multicenter trial, did not show any efficacy of distal protection devices during primary or rescue PCI in AMI.[27] They showed that the use of the distal protection device was not associated with reduced infarct size or improved clinical outcomes. However, there are some difference in the characteristics of enrolled patients between their report and our study. One is that we included patients who were within 24 h of the onset of AMI, whereas the EMERALD trial included those within 6 h of the onset of AMI. Nakamua et al reported the benefit of distal protection during PCI for AMI patients within 24 h of the onset of AMI.[18] Furthermore, in the EMERALD trial, 83% of enrolled patients received Gp IIb/IIIa inhibitor periprocedurally, which is known to be related to the preservation of microvascular integrity during PCI in AMI.[28] Using glycoprotein IIb/IIIa receptor blockade might have reduced the chances of additional improvement[28] through distal protection in the EMERALD trial. In our study, none of the patients received glycoprotein IIb/IIIa receptor blockade during the procedure, which might affect microvascular integrity and clinical prognosis and therefore we could evaluate the effect of the distal protection device more clearly. Distal protection with the PercuSurge GuardWire® Temporary Occlusion and Aspiration System may be effective in preserving microvascular integrity which is known as a predictor of clinical outcomes in patients with first AMI undergoing PCI with 24 h of the onset of chest pain. The effectiveness of a distal protection device in preserving the microvascular integrity was also shown in selected anterior and inferior AMI patients.

Study Limitations

First, this study was non-randomized and studied only a relatively small number of patients. However, we believe it can still evaluate the effect of the distal protection device, because baseline characteristics were similar between the 2 groups. And, despite the small study population, statistically significant differences in the TIMI grade, TMP grade, MVRI, and phasic coronary flow patterns were observed between the 2 groups. These results strongly suggest the effectiveness of the distal protection device in preserving myocardial integrity during primary PCI in AMI patients. Another limitation is that there are no results of the clinical outcomes, again because the number of studied patients was too small. Further well-designed randomized clinical trials are required to fully evaluate the effectiveness of distal protection devices in AMI patients.

Conclusion

The PercuSurge GuardWire® Temporary Occlusion and Aspiration System may be effective in preserving microvascular integrity by preventing atherothrombotic microembolization or large particle embolization during primary PCI in AMI patients.

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