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*Full Length Research Paper*

# Efficiency and safety of percuSurge distal protection device in acute myocardial infarction during emergent percutaneous coronary intervention treatment

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**Acute myocardial infarction (AMI) intervention is associated with a significant incidence of slow flow or no-reflow phenomenon. PercuSurge distal protection device (DPD) has recently been approved as an effective adjunct to AMI intervention within 24 h or in the clinical settings of saphenous vein graft intervention. In this study, we evaluate the efficiency and safety of PercuSurge DPD in coronary intervention in patients with AMI during emergent percutaneous coronary intervention (PCI) treatment from 24 to 72 h. This was a prospective cohort study of patients with AMI. 174 AMI patients who received emergent coronary intervention were divided into DPD and control group according to whether Percusurge DPD was attempted during emergency PCI. The basic clinical characteristics, angiographic results, and follow up data before discharge were compared. Thrombolysis in myocardial infarction (TIMI ) grades and myocardial blush grades (MBG) were performed in all cases after emergency PCI. The device was successfully deployed in 78 of 87 patients, the visible red, white debris or red clastic thromboses were aspirated in 72 of 78 patients in DPD group. Post- PCI TIMI grades and MBG were significantly higher in DPD group than in control group. Post-PCI no-reflow, distal embolization and 30-day major adverse cardiac events were significantly higher in control group than in DPD group, whereas TIMI grades, MBG and minimal lumen diameter were significantly increased after using the export aspiration.**

**PercuSurge DPD can be used effectively and safely in coronary intervention in the thrombus laden arteries such as patients with AMI during emergent PCI treatment from 24 to 72 h.**

**Key words:** Angioplasty, coronary artery, acute myocardial infarction, PercuSurge distal protection device, clinical trials.

## INTRODUCTION

Percutaneous coronary intervention (PCI) is an effective means in acute myocardial infarction (AMI) reperfusion therapy at present. However, there are still quite a few patients who may experience postinfarct angina as a result of either failed thrombolysis or delayed presentation (arrival at hospital >12 h) after AMI, even who receive emergent PCI (Nakagawa et al., 1999), 13 - 80.9% (Morishima et al., 2000; Tanaka et al., 2002) cases of patients resulted in slow flow or no-reflow phenomenon, which impacts interventional treatment effects, increases perioperative mortality (Gibson et al., 1997), particularly in patients with failed reperfusion (Cafri et al., 1999; Saber et al., 1993). Recently, some studies confirmed the infarct-related artery (IRA) usually contain high-burden thrombus formation (Yip et al., 2002) and plaque formation

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(Cafri et al., 1999), therefore PCI operation based on such case will definitely increase the possibility of distal embolization; Besides, the embolization of distal microcirculation may be the most important cause of slow flow or no-reflow phenomenon in AMI undergoing emergent PCI treatment (Yamada and Topol, 2000). When thromboembolism and distal embolization are formed, the application of coronary thrombolytic agent, platelet glycoprotein IIb/IIIa inhibitor or direct removal of the thrombus (Angiojet) cannot significantly improve short- or long-term prognosis of the patients (Gibson et al., 2001), and further impact the effectiveness of intervention.

In recent years, PercuSurge distal protection devices (DPD) (Medtronic Incorporation, USA.) provide an effective method for the prevention of distal embolization. However, according to previous research, the use of the PercuSurge DPD has been reported in cases the time span from the onset to receiving interventional treatment was within 24 h (De Luca et al., 2007; Nakamura et al., 2004; Stone et al., 2005), or PercuSurge DPD has only been reported in the clinical settings of saphenous vein graft intervention to improve clinical outcomes (Baim et al., 2002). There are still no data available regarding large samples of patients who experienced AMI were treated with a combination of conventional PCI therapy and the PercuSurge DPD beyond 24 h. Accordingly, the purpose of this study was to test the clinical application of the PercuSurge DPD and to determine its impact on preserving reperfusion and microvascular integrity in infarct related artery (IRA) as well as the clinical outcomes with AMI during emergent percutaneous coronary intervention (PCI) treatment from 24 to 72 h.

## MATERIALS AND METHODS

### Patient selection

This was a prospective cohort study of patients with AMI. From December 2004 to December 2006, 174 consecutive patients who came from the hospitalized AMI patients underwent interventional treatment in Xijing Hospital affiliated to the Fourth Military Medical University, including STEMI and NSTEMI. AMI is assessed according to guideline of ACC (American College of Cardiology) and ESC (European Society of Cardiology). The time span from the onset to receiving interventional treatment was 24 h to 72 h. 7 F arterial sheath was used in patients adopted distal protection device through femoral artery or radial artery approach.

### Ethics

The study protocol was approved by the ethics committee of our institution, and patients gave written informed consent for participation.

### Enrollment criteria

Patients did not undergo thrombolytic therapy or therapy with platelet glycoprotein IIb/IIIa inhibitor; the proximal and middle vascular reference diameter of infarct-related artery ≥ 3 mm; coronary angiography showed the proximal vascular of infarct-related artery containing a high-burden thrombus formation.

### Excluded criteria

Instable hemodynamics combined with mechanical complications of acute myocardial infarction; serious calcification in infarct-related artery; Bending infarct-related artery (at least one angle lesions <100 °), significantly distorted lesions in proximal artery; A culprit lesion in the left main coronary artery; Multivessel disease needing coronary artery bypass graft.

Based on enrollment and excluded criteria, patients with AMI were selected and randomly divided into two groups. The emergent PCI cases who adopted the PercuSurge DPD belonged to DPD group while the emergent PCI cases who adopted the general guide wire belonged to control group. In the end, the DPD group included 87 patients and the control group included 96 patients.

### Coronary interventional procedures

Each patient was administered 300 mg oral aspirin (before PCI and then 100 mg daily) and clopidogrel (300 mg loading dose, 75 mg daily) and brought to the catheter laboratory. During the procedure, unfractionated heparin was given intravenously to achieve an ACT (activated coagulation time) of 300s or above; cardiac catheterization was performed by the femoral artery or radial artery approach, using a 7 F sheath and catheters. In the PCI with a distal protection device, it was first attempted to cross the lesions with the 0.014´´PercuSurge GuardWire. In unsuccessful cases, a conventional coronary guide wire was placed across the lesion, followed by another attempt of the GuardWire with the conventional wire in-situ. If IRA was right coronary artery (RCA), then the occlusion balloon was positioned distal to the right coronary artery prior to the bifurcation; If IRA was LAD (left anterior descending), then the occlusion balloon was placed at the distal part of mid LAD; If the IRA was LCX (left circumflex), then the occlusion balloon was placed at the mid portion of LCX. The distal elastomeric occlusion balloon was then inflated to 0.5 mm above the reference vessel diameter and further inflated if necessary until occlusion of flow was observed. Finally, the optimal size of the balloon was inflated up to 1.2 ~ 1.4 times of the RLD (reference luminal diameter) of the IRA or the balloon was just changed from a spherical to an elapsed shape. Then repeated dye injection was used to make sure the distal flow was already totally occluded. The export aspiration catheter was used to remove the thrombus and debris forward and backward severa1 times before lesion dilatation. Balloon predilation and stent implantation were performed in standard manner under distal protection. All lesions were predilated. Export catheter was advanced again to aspirate embolic debris, protection balloon was then deflated and final result was evaluated. PCI success criteria: postoperative residual stenosis was <20% and TIMI (thrombolysis In myocardial infarction) flow grade reached grade II or III, and without complications such as AMI, death and emergent coronary artery bypass graft.

### Assessment of TIMI flow grade and myocardial blush grade

TIMI flow grade in the IRA and myocardial blush grade (MBG) immediately were evaluated after PC1 by two experienced investigators who were otherwise blinded to all clinical data. TIMI risks score have been developed in order to risk stratify patients with coronary artery disease (Antman et al., 2000; Karounos et al., 2007; Lee et al., 1991). According to Giri et al. (2000) recommended

**Table 1.** Balance comparison of basic clinical data between two groups (Group 1: DPD group, Group 2: control group).

| Variable | Group 1 (n = 78) | Group 2 (n = 96) | p value |
|---|---|---|---|
| Age, years | 60.6 ± 8.3 | 61.5 ± 9.2 | 0.77 |
| Male gender, % | 82.1(64) | 85.4(82) | 0.61 |
| Diabetes mellitus, % | 66.7(52) | 59.4(57) | 0.45 |
| Hypertension, % | 41.0(32) | 32.3(31) | 0.41 |
| Hypercholesterolemia, % | 16.2(36) | 40.6(39) | 0.59 |
| Current smoker, % | 43.6(34) | 48.1(45) | 0.62 |
| STEMI, % | 83.3(65) | 84.2(81) | 0.76 |
| Infarct location, % | | | 0.68 |
| Anterior | 53.8(42) | 57.3(55) | |
| Inferior | 43.6(34) | 36.5(35) | |
| lateral | 2.6(2) | 6.2(6) | |
| Systolic BP, mmHg | 138.2 ± 12.5 | 137.8 ± 13.1 | 0.53 |
| Diastolic BP, mmHg | 75.2 ± 8.2 | 74.7 ± 7.3 | 0.49 |
| Heart rate, beats/min | 79.3 ± 18.1 | 79.8 ± 17.5 | 0.78 |

criteria, the in situ occlusion undergoing interventional therapy, and the distal vascular blood flow being slowly or completely interrupted means the existence of evidence of distal vascular embolization. Myocardial blush grade (MBG) was assessed as reported (Gibson et al., 2000): MBG 0 was defined as no apparent tissue-level perfusion (no ground-glass appearance of blush or opacification of the myocardium)in the distribution of the culprit artery; MBG 1 indicates presence of myocardial blush, but no clearance from the microvasculature (blush or a stain was present on the next injection); MBG 2 indicates that blush clears slowly(blush is strongly persistent and diminishes minimally or not at all during 3 cardiac cycles of the washout phase), while MBG 3 indicates that blush begins to clear during washout (blush is minimally persistent after 3 cardiac cycles of washout). The duration of cine filming was required to exceed 3 cardiac cycles in the washout phase to assess washout of the myocardial blush. Care was taken not to mistake filling of the venous system, such as the great cardiac vein.

#### Statistical analysis

All values in the paper and tables are presented as mean ± SEM. Using SPSS 10.1 statistical software, and measurement data showed as mean ± SD. Count Data was expressed as percentage and differences were compared by Student's *t*-test and $x^2$ test. Probabilities of $p< 0.05$ were considered to be statistically significant.

## RESULTS

### Patient characteristics

Based on enrollment and excluded criteria, 87 cases were studied and randomly divided into DPD group. Nine (9) cases were unsuccessful to cross the lesions with the 0.014″ PercuSurge GuardWire, and a conventional coronary guide wire was placed across the lesion. The emergent PCI cases adopted the PercuSurge DPD were added into DPD group. When blood flow was totally occluded by the distal balloon, persistent angina took place among 3 of 78 cases, after the occluded artery recanalization, angina gradually relieved. The emergent PCI cases adopted the general guide wire were added into control group. In the end, the experimental group included 78 patients and the control group included 96 patients.

### Baseline balance comparison of clinical data

In terms of age, gender, diabetes, hypertension, high cholesterol, smoking and other clinical data, there was no significant difference in research baseline levels between control group and DPD group ($P > 0.05$) (Table 1). In addition, there was no significant difference in infarct site between the two groups, either ($P > 0.05$) (Table 1).

### Angiographic results and the 30-day adverse clinical results

The sites of target vessel, TIMI grades (≥2) before percutaneous coronary intervention (PCI), myocardial blush grades, implanted stent, the minimum lumen diameter, stenosis degree, the minimum post-PCI lumen diameter, and residue stenosis showed no significant difference between the two groups ($P > 0.05$) (Table 2). Post PCI TIMI grades ≥ 2 and myocardial blush grades were significantly higher in the DPD group than those in control group. After PCI treatment, no-reflow phenomenon, the distal vascular embolization and 30-day adverse cardiovascular events in control group were significantly higher than those in DPD group ($P < 0.05$) (Table 2).

Comparison of TIMI grade, myocardial staining grade

**Table 2.** Angiographic results before and after PCI treatment (Group 1: DPD group, Group 2: control group).

| Variable | Group 1 (n = 78) | Group 2 (n = 96) | p value |
|---|---|---|---|
| Infarct-related artery, % | | | 0.56 |
| LAD | 53.8(42) | 57.3(55) | |
| RCA | 41.1(32) | 33.3(32) | |
| LCX | 5.1(4) | 9.4(9) | |
| Multivessel disease, % | 46.2(36) | 53.1(51) | 0.48 |
| Pre-PCI TIMI flow, % | | | 0.26 |
| ≤1 | 89.7(70) | 81.3(78) | |
| ≥2 | 10.3(8) | 18.7(18) | |
| Pre-intervention myocardialperfusion grades | 0.23±0.62 | 0.21±0.64 | 0.88 |
| Stenting, % | 82.1(64) | 84.4(81) | 0.77 |
| Post-PCI TIMI-3 flow, % | 94.9(74) | 79.2(76) | 0.03 |
| Post-PCI myocardial perfusion grades | 2.65±0.68 | 2.22±0.94 | 0.04 |
| Post-PCI no flow | 5.1(4) | 16.7(16) | 0.04 |
| Distal embolization, % | 5.1(4) | 18.8(18) | 0.04 |
| Lesion length, mm | 18.6±6.7 | 17.8±8.5 | 0.53 |
| Pre-PCI minimal lumen diameter, mm | 0.13±0.24 | 0.14±0.21 | 0.76 |
| Pre-PCI reference lumen diameter, mm | 3.79±0.46 | 3.73±0.45 | 0.66 |
| Pre-PCI diameter stenosis, % | 96.7±5.4 | 96.2±7.2 | 0.68 |
| Post-PCI minimal lumen diameter, mm | 3.59±0.45 | 3.48±0.61 | 0.36 |
| Post-PCI reference lumen diameter, mm | 3.98±0.57 | 3.89±0.42 | 0.48 |
| Post-PCI diameter stenosis, % | 12.3±7.8 | 11.7±6.5 | 0.67 |
| Combined 30-day MACE, % | | | 0.011 |
| Re-infarct after PCI | 2.6(2) | 7.3(7) | 0.41 |
| Repeated PCI to target vessel | 0(0) | 4.2(4) | 0.29 |
| 30-day mortality rate | 0 | 7.3(7) | 0.15 |

and the minimal lumen diameter before PCI, after thrombosis liposuction and after PCI in patients with myocardial infarction treated by the distal protection device was also made.

The minimal lumen diameter increased significantly after thrombosis liposuction. Compared to pre-PCI, TIMI grades, myocardial blush grades and the minimal lumen diameter were increased significantly after thrombosis liposuction. However, there was no significant difference between post-thrombosis liposuction and post-PCI in TIMI flow grades and myocardial blush grades (Table 3).

Various extent of material was aspirated in DPD group and pathologically examined.

In the present study, the visible red, white debris or red clastic thrombosis were aspirated in 72 of 78 patients in DPD group. Sixty four (64) cases of STEMI, the visible red debris or red clastic thrombosis were aspirated (Figure 1). Pathological examination suggested that mainly presented red thrombosis (large red stained fibrin, in which a great deal of RBC could be seen) (Figure 2). Eight (8) cases of NSTEMI were white thrombosis (Figure 3). Pathological examination suggested a great quantity of platelet (Figures 1 - 4). Crystalline cholesterol and fatty bubble were also found in these pathological slices, which further confirmed the pathological basis of acute myocardial infarction (AMI).

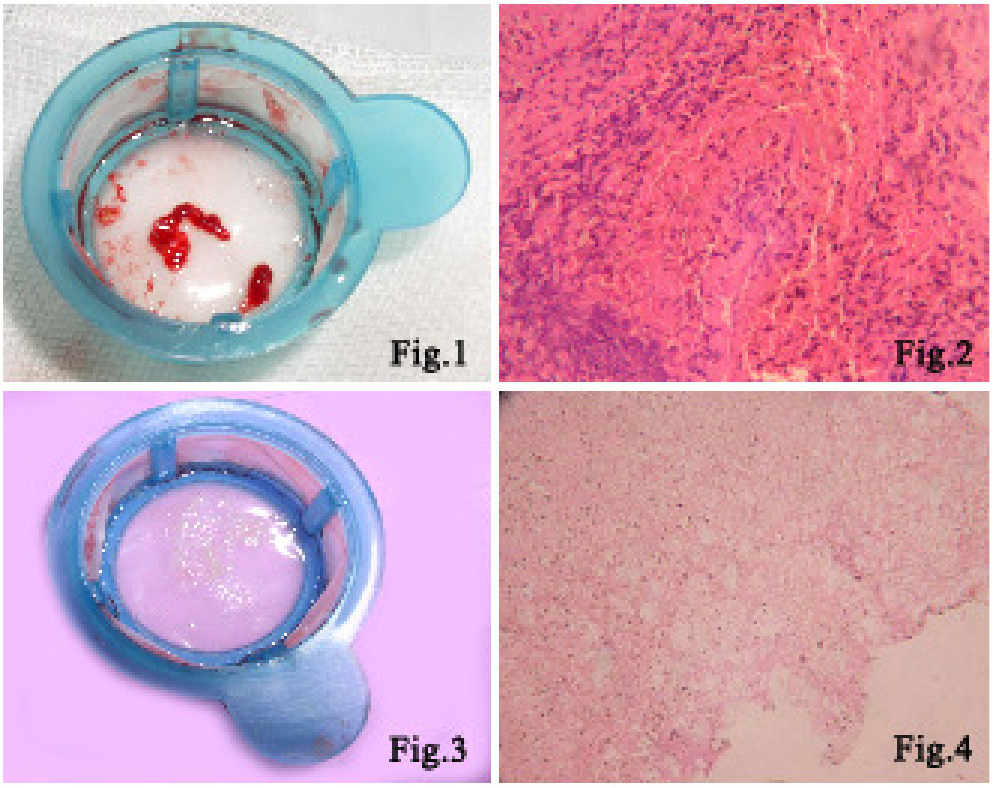
## DISCUSSION

Large scale trials provide evidence that early reperfusion therapy is extremely effective after AMI (Johnston et al., 2006). PCI therapy is one of the major means in AMI reperfusion therapy. It is of great significance to reduce the infarct size, protect cardiac function and improve the long-term prognosis. But intervention has often leads to the breakdown and shedding of fresh thrombus and causes obstruction of distal vascular, which further induces slow flow or no-reflow phenomena, seriously affecting the effectiveness of intervention therapy and

**Table 3**. Comparison of TIMI grade, myocardial staining grade and the minimal lumen diameter before PCI, after thrombosis liposuction and after PCI in patients with acute myocardial infarction in DPD group.

| Variable | Pre-intervention | Post-aspiration | Post-PCI | p value |
|---|---|---|---|---|
| TIMI flow grades | 0.42±0.79[a] | 2.93±0.27[b] | 2.96±0.21[b] | <0.0001[#] |
| myocardial perfusion grades | 0.23±0.62[a] | 2.28±0.74[b] | 2.64±0.65[b] | <0.0001[#] |
| minimal lumen Diameter | 0.13±0.22[a] | 1.99±0.67[b] | 3.63±0.46[c] | <0.0001[*] |

[#]: *P* < 0.0001 indicates a vs. b; *: *P* < 0.0001 indicates c vs. a and b versus a.
*[#]: P < 0.0001 indicates a vs. b; *: P < 0.0001 indicates c vs. a, and b* versus *a.*




**Figures 1 - 4**. Pathological slices of white and red thrombosis. (1) The red thrombosis and red or white clastic sucked out by DPD during PCI treatment; (2) Pathological slice of red thrombosis; (3) The white thrombosis sucked out by DPD during PCI treatment; (4) Pathological slice of white thrombosis. DPD, Distal protection device; PCI, percutaneous coronary intervention.

increasing perioperative mortality. Its complex causes and mechanisms include reperfusion injury, microvascular spasm, platelet activation and aggregation, endothelial cell swelling, edema of the vascular wall and distal microvascular embolization caused by thrombosis, and debris of plaque rupture, while the latter is frequently encountered in the process of PCI (Baim et al., 2002; Michaels et al., 2000). The distal embolization is usually involved in the treatment of intervention and caused by shedding of plaque thrombosis and lipid debris or spontaneous rupture of vulnerable plaque, therefore embolic particles is mainly thrombosis and atherosclerotic plaque debris. As the "cheese rolling" effect, distal embolization is more easily formed by stenting (stent implantation) than by simply percutaneous transluminal coronary angioplasty. The small particles which cause microvascular obstruction are often only 15-100 μm. A large number of small particles can cause various micro-infarction, which in turn leads to left ventricular dysfunction or even leads to re-infarction (Henriques et al., 2002). Once distal embolization formed, the application of calcium channel blockers, nitroglycerin, sodium nitroprusside, adenosine and nicardipine in coronary artery, or directly removal of thrombus such as Angiojet cannot satisfactorily improve the patients with the short- or long-term prognosis. However, the distal protection device can effectively reduce the distal embolization to improve distal myocardial perfusion, improve cardiac function, reduce or elimi

nate the distal emboli and improve the reperfusion in tissue level. In recent years, this technology has been used in AMI interventional treatment to prevent distal vascular embolization (Taghizadeh et al., 2002).

Many reports indicated PercuSurge DPD could improve the patients' prognosis by increasing distal myocardial reperfusion, reducing infarct size and improving heart function. And the use of DPD could reduce the mortality in patients with AMI (Silva et al., 2001; Taghizadeh et al., 2002). However, according to previous research, the use of the PercuSurge DPD has only been reported in cases with STEMI (De Luca et al., 2007), and the time span from the onset to receiving interventional treatment was within 24 hours (De Luca et al., 2007; Nakamura et al., 2004; Stone et al., 2005). There are still no data available regarding large samples of patients who experienced NSTEMI were treated with a combination of conventional PCI therapy and the PercuSurge DPD beyond 24 h. In the present study, we found that both in STEMI and NSTEMI cases beyond 24 h and within 72 h, the combined use of conventional percutaneous coronary intervention (PCI) and adjunctive PercuSurge device was superior to use of conventional PCI in terms of final TIMI-3 grades flow and myocardial blush grades, and a reduction of distal embolization in patients in the clinical setting of AMI with high-burden thrombus formation in their IRA. Furthermore, our results also indicated that this mechanical device appeared to be more effective on reduction of 30-day major adverse cardiac events than conventional PCI.

Our results also showed that in the DPD group, 92.3% (72/78) cases were aspirated visible red, white clast or red thromboses. DPD group has better blood flow and tissue reperfusion than control group. The use of PercuSurge DPD can effectively protect the distal vascular with siphon out coronary thrombosis to avoid distal blood clots. Without serious complications, this device has good therapeutic effect in direct intervention treatment to the coronary with heavy thrombosis load such as acute myocardial infarction.

The long-term effects of the distal protection device are still in controversy. The enhanced myocardial efficacy and recovery by aspiration of liberated debris (EMERALD) trial failed to show the effectiveness of the distal protection device in patients with AMI (Yamada and Topol, 2000). 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 differences in the characteristics of enrolled patients between their reports and our study. One of them is that we included patients who were within 72h of the onset of AMI, whereas the EMERALD trial included those within 6 h of the onset of AMI. Nakamura et al. (Nakamura et al., 2004) reported the benefit of distal protection during PCI for anterior MI patients within 72h of the onset of AMI. Furthermore, in the EMERALD tria1, 83% of enrolled patients received platelet glycoprotein IIb/IIIa inhibitor per procedurally. Using platelet glycoprotein IIb/IIIa inhibitor might have reduced the chances of additional improvement through PercuSurge DPD in the EMERALD tria1. In our study, the time span from the onset to receiving interventional treatment was from 24 to 72 h, patients did not undergo thrombolytic therapy or therapy with platelet glycoprotein IIb/IIIa inhibitor, coronary angiography showed the proximal vascular of infarct-related artery contains a high-burden thrombus formation, all this as enrollment criteria, so we have good therapeutic effect.

There were several limitations in this study. First, the number of patients reported in our study was small, thus our conclusions should be viewed as preliminary and await confirmation using results of a larger series or controlled clinical trials. Second, as our study was not designed to determine the long-term clinical outcomes in patients with these clinical characteristics, Third, although the combination therapy of conventional PCI and PercuSurge DPD provided additional benefits for successful reperfusion in the IRA with high-burden thrombus formation, this mechanical device still has limitations when applied to heavily calcified, very tortuous, or distally occluded or small-sized IRA. So, it requires further randomized and large scale studies to see if successful prevention of distal embolization with this device would translate into better long-term clinical outcomes when compared with traditional unprotected angioplasty.

## Conclusion

The application of PercuSurge DPD provides an effective and safe method for patients with AMI through PCI treatment and the system has a broad prospect in application. A high rate of successful reperfusion, without death within 30 days, and low cardiovascular or bleeding complications show encouraging findings in this first clinical study.

## Abbreviations

**AMI,** Acute myocardial infarction; **DPD,** distal protection device; **PCI,** percutaneous coronary intervention; **TIMI,** thrombolysis in myocardial infarction; **MBG,** myocardial blush grade; **IRA,** infarct-related artery; **RCA,** right coronary artery; **LAD,** left anterior descending; **LCX,** left circumflex; **RLD,** reference luminal diameter; **MBG,** myocardial blush grade; **STEMI =ST,** segment elevation acute myocardial infarction

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