

Thrombosuction Utilizing an Export Aspiration Catheter during Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction

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Purpose: Effective myocardial reperfusion after primary PCI for an AMI in lesions with a thrombus is limited by distal embolization and the slow/no reflow phenomenon. We evaluated the efficacy of a thrombus reduction technique using an export aspiration catheter for thrombosuction during primary PCI. **Materials and Methods:** We analyzed 62 patients with AMIs who underwent primary PCI and had a thrombi burden during thrombosuction using an EAC (EAC group; n = 31) or without thrombosuction (control group; n = 31). **Results:** Thrombosuction with an EAC was performed safely in all the patients in EAC group without any complications. After the PCI, restoration to a TIMI flow grade 3 was significantly more frequent in the EAC group (26/31 vs. 20/31, $p < 0.05$). However, the TIMI perfusion grade did not differ between the two groups. Further, the corrected TIMI frame counts were lower in the EAC group (23.9 ± 15.1 vs. 34.8 ± 22.5 , $p < 0.05$). Although there was no statistical significance, a greater incidence of distal embolization was observed in the control group (16.1%, 5/31) as compared to the EAC group (0/31) ($p = 0.056$). However, the incidence of major adverse cardiac events at 1 and 6 months did not differ between the two groups. **Conclusion:** For AMIs, thrombosuction with an EAC before or during PCI is a safe and potentially effective method for restoration of the coronary flow.

Key Words: Acute myocardial infarction, primary percutaneous coronary intervention, thrombosuction, export aspiration catheter

INTRODUCTION

Primary percutaneous coronary intervention

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(PCI), with angioplasty or stenting of the occluded culprit artery, is effective for treating acute myocardial infarctions (AMI).^{1,2} However, the dilatation of the coronary artery stenosis invariably causes plaque disruption, which may lead to distal embolization of plaque debris or thrombus material that may play a crucial role in limiting the effectiveness of the myocardial reperfusion.^{3,4}

Recently, various new devices including the GuardWire Plus system (PercuSurge[®]) for protection against distal embolization have become widely used. The GuardWire Plus system was originally developed for embolic containment in larger vessels such as saphenous vein grafts or carotid arteries.⁵⁻⁷ Thus, the routine use of the GuardWire Plus system in coronary intervention has been limited by various technical limitations (high profile, occlusive mechanism, low trackability and maneuverability, and high time consumption). However, if the export aspiration catheter (EAC), which is one of the components of the GuardWire Plus system, is used along with a conventional steerable coronary wire, those disadvantages can be easily eliminated. Here, we report on the safety and feasibility of the adjunctive use of the EAC during primary PCI performed on native coronary arteries for AMIs.

MATERIALS AND METHODS

Patient population

This study was a single-center, non-random-

ized, retrospective trial. Between September 2002 and April 2004, 62 consecutive patients with AMIs who underwent a primary PCI were enrolled in this study. The inclusion criteria were as follows: persons who arrived at the cardiac catheterization laboratory with chest pain of < 12 hours in duration, chest pain of at least 30-min in duration and resistant to intravenous nitrates, ST segment elevation of > 1 mm in at least two standard leads or > 2 mm in at least two contiguous precordial leads, and very large thrombi noted at the lesion in the infarct-related artery with a reference lumen diameter > 2.0 mm. Patients who had cardiogenic shock on admission, or who underwent thrombolytic therapy, were excluded. The control group consisted of 31 consecutively treated patients (from September 2002 to May 2003) who underwent PCI with stents and without thrombosuction. The EAC group consisted of the next group of 31 consecutively treated patients (from June 2003 to April 2004) who underwent PCI with a stent accompanied by thrombosuction using an EAC.

Export aspiration catheter

The GuardWire Plus system consisted of two elements: the GuardWire Plus temporary occlusion wire with an inflation system and the EAC. The EAC, with a 5.4 × 3.5 Fr distal 35 cm monorail section and 4.6 Fr proximal section, was a 135 cm long catheter with a 0.040" diameter internal lumen that allowed for aspiration and removal of particulate debris. The distal monorail section could accommodate any commercial 0.014" coronary angioplasty guidewire. The catheter could be inserted through any 7Fr coronary guiding catheter over a 0.014" guidewire in a monorail fashion into coronary arteries with a luminal diameter larger than 2 mm. The catheter was connected to a syringe for manual aspiration, and the aspirated material could be retained for further examination (Fig. 1A).

Primary PCI with thrombosuction using an EAC

All patients included in the study were given

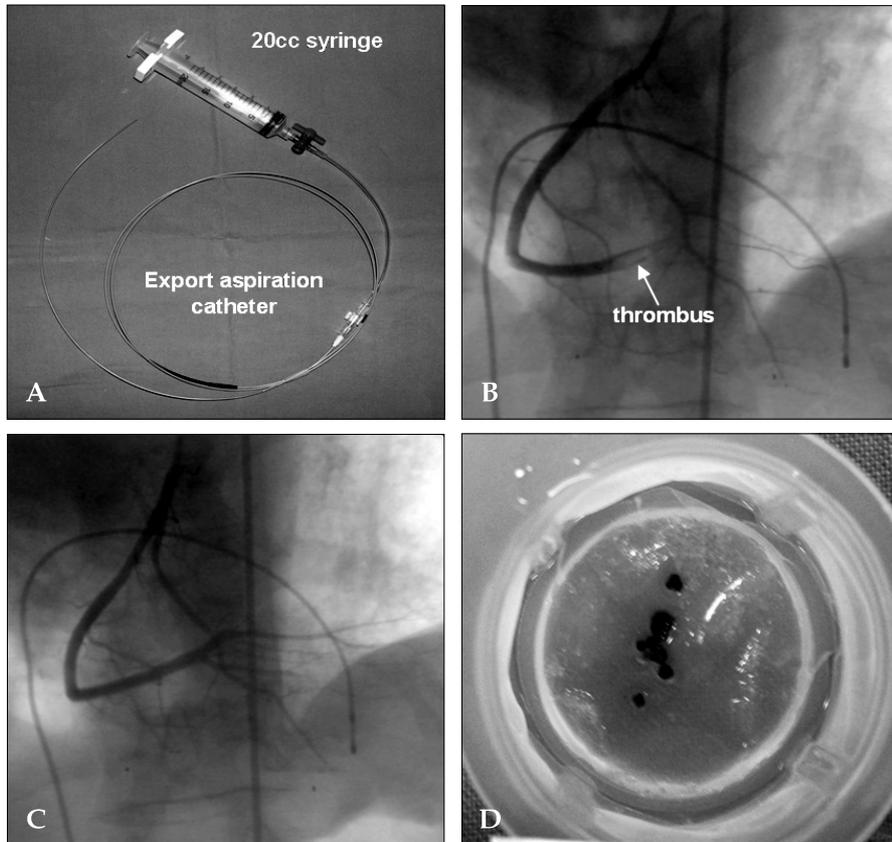


Fig. 1. (A) An export aspiration catheter connected to a 20 cc syringe. (B-D) An example of successful thrombosuction using an EAC. (B) Initial angiogram showing a total occlusion of the distal right coronary artery with thrombi. (C) After thrombosuction, the distal flow was restored to a TIMI grade 3. (D) Retrieved thrombotic material. TIMI, thrombolysis in myocardial infarction.

300 mg of oral aspirin, 300 mg of clopidogrel and a 5,000- to 10,000-U bolus of intravenous heparin in the emergency room. The patients were transferred to the cardiac catheterization laboratory and primary PCI was then performed. Before the PCI, additional heparin was given to maintain an ACT of ≥ 350 seconds. The primary PCI was performed with a 7Fr femoral access. A 7Fr guiding catheter with an appropriate curve and good backup support, usually an Amplatz or hockey stick curve for the right coronary artery and Amplatz or Extra Backup curve for the left coronary artery, was selected to engage the infarct-related artery. After passage of a coronary angioplasty guide wire, the lesion was reassessed for EAC eligibility. Contrast medium was then injected to document the TIMI flow status and assess for the existence of visible thrombi. The EAC was then placed just proximal to the lesion in a monorail fashion. Continuous negative suction was then applied while the EAC was slowly advanced across the lesion. This suction maneuver lasted around 5 seconds, and the aspirate was injected into a basket. If materials could be grossly visualized, more suction maneuvers were performed. When particles were no longer identifiable in the aspirate, and the contrast injection revealed a brisk distal flow with a TIMI flow grade 3, without residual thrombi, routine PCI was then performed. The PCI in the patients in the control group was performed using the conventional method. Procedural success was defined as a residual stenosis of $< 20\%$ with a TIMI flow grade ≥ 2 . All patients were treated with oral aspirin (300 mg/day) indefinitely and clopidogrel (75 mg daily) for at least 4 weeks. Other medications were used as clinically indicated.

Angiographic analysis

Quantitative coronary angiographic analysis (QCA) was obtained with a HICOR QCA SYSTEM (Siemens). The angiograms were reviewed by two experienced interventional cardiologists who were independent of this study. A thrombus was defined as the presence of a filling defect within the lesion, surrounded by contrast material seen in multiple projections, persistence of contrast mate-

rial within the lesion, or a visible embolization of intraluminal material downstream. The quantitative coronary angiography parameters, such as the TIMI flow grade, corrected TIMI frame count (TFC), and TIMI perfusion grade (TMPG), were measured as previously described.^{8,9} Grading was done on cine film at 15 frames/second made in a Siemens digital coronary imaging catheterization laboratory. In each patient, the best projection was chosen to assess the myocardial region of the infarct-related coronary artery, preferably without superpositioning of the noninfarcted myocardium. Angiographic runs had to be long enough to allow some filling of the venous coronary system, and backflow of the contrast agent into the aorta had to be present to be certain of adequate contrast filling of the epicardial coronary artery. All angiograms were made with 7 F guiding catheters in a standardized fashion after 400 mg of nitroglycerin (intracoronary injection) had been given immediately after the primary angioplasty procedures. This procedure allowed for a quantitative coronary artery analysis. The TMPG was defined as follows: 0, no myocardial blush or contrast density; 1, minimal myocardial blush or contrast density; 2, moderate myocardial blush or contrast density, but less than that obtained during angiography of a contralateral or ipsilateral non infarct-related coronary artery; and 3, normal myocardial blush or contrast density, comparable to that obtained during angiography of a contralateral or ipsilateral non infarct-related coronary artery. With regard to the corrected TFC, the number of frames was multiplied by 30 and divided by 15 to report a cine frame count in accordance with the standard methods. The occurrence of a distal embolization was also evaluated.

Study end points

The primary end points of the present study were the safety and feasibility of thrombosuction with an EAC during primary PCI. The secondary end points were the achievement of markers of effective reperfusion (TMPG, corrected TFC and occurrence of distal embolization and incidence of MACE, including death, reinfarction, and the need for target vessel revascularization at 1 and

6 months after the PCI).

Statistical analysis

Data are expressed as mean \pm SD for continuous variables and as absolute and relative frequencies for categorical variables. The student's unpaired t test was used to compare continuous variables between groups. Categorical variables were compared by the χ^2 test or Fisher's exact test, as appropriate. Probability values < 0.05 were considered to be statistically significant.

RESULTS

Out of the 35 patients in whom we initially attempted to deliver an EAC through the lesion, successful delivery of the EAC was achieved in 31 patients (88.6%). In the remaining 4 patients, the EAC could not be delivered because of instability of the guiding catheter or a severely calcified and tortuous anatomy of the infarct-related artery. Thrombosuction with an EAC was performed safely in all the patients in whom the EAC was delivered correctly, without any complications such as coronary dissection or perforation that were attributable to the EAC delivery.

Comparison of the procedural results

Table 1 and 2 show a comparison of the baseline clinical and angiographic characteristics between the EAC and control groups, respectively. The mean age of the patients, the distribution of the risk factors and infarct-related artery, multivessel coronary disease, LV ejection fraction, systolic blood pressure and heart rate on admission, did not differ between the groups. However, as compared to the control group, in the EAC group, the lesion length was longer, and the diameter of the stenosed lesion was more severe. Further, a TIMI grade of less than 3 was more common in the EAC group.

The procedural results are shown in Table 3 and Fig. 2 and 3. Restoration of a TIMI flow grade of 3 after the primary PCI was significantly more frequent in the EAC group ($p < 0.05$), which also had lower corrected TFC values ($p < 0.05$) than the other group. Angiographic signs of distal embolization were also less common, although not significantly, in the EAC group. However, the TMPG did not differ between the two groups. In the 31 patients who underwent thrombosuction, gross thrombi were obtained from 25 patients (80.6%), and the TIMI flow improved just by performing the thrombosuction in 19 patients

Table 1. Clinical Characteristics on Admission of the Patients in the EAC and Control Groups

| | EAC (n = 31) | Control (n = 31) |
|----------------------------------|------------------|------------------|
| Age (yrs) | 54.7 \pm 11.8 | 55.5 \pm 12.2 |
| M (%) | 24 (77.4) | 20 (64.5) |
| Risk factors | | |
| Smoking (%) | 12 (38.7) | 14 (45.2) |
| Diabetes (%) | 11 (35.5) | 10 (32.3) |
| Hypertension (%) | 13 (41.9) | 10 (32.3) |
| Dyslipidemia (%) | 5 (16.1) | 3 (9.7) |
| Prior MI (%) | 1 (3.2) | 0 |
| Multivessel coronary disease (%) | 19 (61.3) | 16 (51.6) |
| LVEF (%) | 50.3 \pm 10.9 | 53.2 \pm 11.8 |
| Systolic blood pressure (mmHg) | 119.2 \pm 18.0 | 112.7 \pm 23.8 |
| Heart rate (bpm) | 68.1 \pm 19.6 | 73.3 \pm 20.8 |

EAC, export aspiration catheter; MI, myocardial infarction; LVEF, left ventricular ejection fraction.

Table 2. Angiographic Characteristics of the Patients on Admission

| | EAC (n = 31) | Control (n = 31) |
|-------------------------------------|--------------|------------------|
| Infarct-related coronary artery (%) | | |
| Lt main | 0 | 1 (3.2) |
| Left anterior descending | 12 (38.7) | 14 (45.2) |
| Left circumflex | 1 (3.2) | 2 (6.4) |
| Right coronary artery | 18 (58.1) | 14 (45.2) |
| Reference vessel diameter (mm) | 3.28 ± 0.55 | 2.96 ± 0.43 |
| Minimal lumen diameter (mm) | 0.08 ± 0.14 | 0.38 ± 0.45* |
| Diameter stenosis (%) | 97.9 ± 3.7 | 87.3 ± 13.5* |
| Lesion length (mm) | 24.9 ± 12.9 | 16.1 ± 6.5* |
| TIMI flow grade < 3 (%) | 30 (96.8) | 24 (77.4)* |

**p* < 0.05.

EAC, export aspiration catheter; TIMI, thrombolysis in myocardial infarction.

Table 3. Procedural Results

| | EAC (n = 31) | Control (n = 31) |
|-------------------------------------|-----------------|------------------|
| Procedural success (%) | 31 (100) | 29 (93.5) |
| Angiographic success (%) | 31 (100) | 27 (87.1) |
| ER-to-1 st balloon (min) | 122.0 ± 41.5 | 116.0 ± 35.9 |
| Total procedure time (min) | 50.6 ± 24.8 | 45.2 ± 19.4 |
| Stenting (%) | 23 (74.2) | 24 (77.4) |
| Reference vessel diameter (mm) | 3.13 ± 0.48 | 2.91 ± 0.52 |
| Minimal lumen diameter (mm) | 2.98 ± 0.42 | 2.76 ± 0.43 |
| Diameter stenosis (%) | 7.9 ± 0.3 | 6.6 ± 0.4 |
| Stent length, mm | 26.8 ± 8.3 | 18.6 ± 4.1* |
| Distal embolization, n (%) | 0 | 5 (16.1) |
| Retrieved thrombus, n (%) | 25 (80.6) | |
| EAC related complications | | |
| Dissection | 0 | |
| Perforation | 0 | |
| Peak CK (U/L) | 2713.5 ± 1540.5 | 2550.6 ± 1734.9 |

**p* < 0.05.

EAC, export aspiration catheter.

(61.3%) without any additional intervention. Of interest, in one patient, after the thrombosuction with an EAC, the coronary blood flow was com-

pletely restored without any distal embolization or residual stenosis. Thus, the procedure was completed without any additional intervention

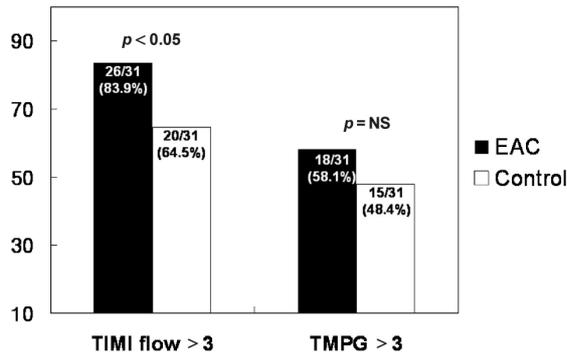


Fig. 2. After the PCI, the recovery rate to a TIMI grade 3 flow was higher in the EAC group than the control group. However, there was no difference between the two groups for the TIMI perfusion grade. PCI, percutaneous coronary intervention; EAC, export aspiration catheter; TIMI, thrombolysis in myocardial infarction; TMPG, TIMI perfusion grade.

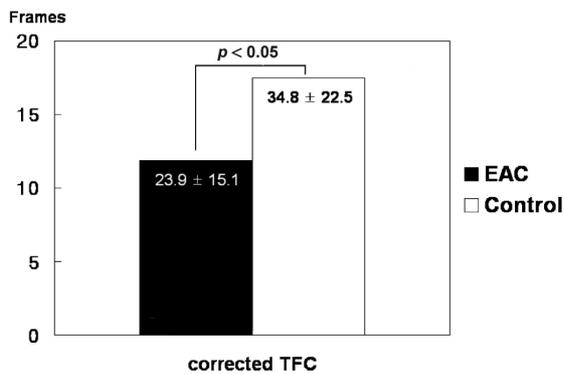


Fig. 3. After the PCI, the corrected TIMI frame count was less in the EAC group than in the control group. PCI, percutaneous coronary intervention; EAC, export aspiration catheter; corrected TFC, corrected TIMI frame count.

(Fig. 1. B-D).

Clinical outcome at 1 and 6 months

Three patients died from refractory heart failure and one patient underwent a repeat PCI in the control group within 1 month after the primary PCI. However, the incidence of MACE at 1 month did not significantly differ between the EAC and control groups. In the EAC group, one patient died from refractory heart failure and another patient underwent a repeat PCI during the 6-month follow-up. Further, in the control group, one additional patient underwent a repeat PCI procedure during the same follow-up period. The incidence of MACE at 6 months also did not significantly differ between the two groups. The adverse clinical events are summarized in Tables 4 and 5.

DISCUSSION

In this preliminary study, the thrombosuction with an EAC in AMI patients who had very large thrombi in infarct-related arteries revealed the following: (1) It may be used during primary PCI in selected cases with a high delivery rate and without any significant complications. (2) After the PCI, in comparison to the control group, the TIMI flow grade improved, and the corrected TFC values decreased. (3) Further, although it was not significant, the incidence of a distal embolization decreased in the EAC group. (4) However, the incidence of MACE during the follow up period

Table 4. Cumulative MACE (Major Adverse Cardiac Events) at 1 Month

| | EAC | Control |
|--------------|-----|-----------|
| Death | 0 | 3 (9.7%) |
| MI | 0 | 0 |
| TLR | 0 | 1 (3.2%) |
| Repeated PCI | 0 | 0 |
| CABG | 0 | 1 |
| MACE | 0 | 4 (12.9%) |

EAC, export aspiration catheter; MI, myocardial infarction; TLR, target lesion revascularization; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

Table 5. Cumulative MACE (Major Adverse Cardiac Events) at 6 Month

| | EAC | Control |
|--------------|----------|-----------|
| Death | 1 (3.2%) | 3 (9.7%) |
| MI | 0 | 0 |
| TLR | 1 (3.2%) | 2 (6.5%) |
| Repeated PCI | 1 | 1 |
| CABG | 0 | 1 |
| MACE | 2 (6.4%) | 5 (16.2%) |

EAC, export aspiration catheter; MI, myocardial infarction; TLR, target lesion revascularization; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

did not significantly differ between the two groups.

An AMI is usually caused by a sudden thrombotic occlusion of a coronary artery at the site of a fissured atherosclerotic plaque. To restore the occluded coronary blood flow, primary PCI has shown preferable results as compared to thrombolytic therapy.^{1,2} However, the increased risk of distal embolization during balloon dilatation or stenting is a challenging problem for primary PCI in AMI. Distal embolization is related to a reduced myocardial perfusion resulting in more extensive myocardial damage and a poor prognosis,^{3,4} so distal protection during primary PCI may limit the embolization of thrombi and atherosclerotic debris potentially able to wedge into small vessels and to cause myocardial injury. Recently, various additional pharmacological interventions and/or mechanical devices have been studied to prevent and/or treat distal embolizations. In acute coronary syndrome, the adjunctive use of an intracoronary thrombectomy system during the primary PCI significantly improves the myocardial reperfusion.¹⁰⁻¹² Although these data strongly suggest that a substantial benefit can be expected by preventing embolization during the primary PCI, the use of distal protection systems, including the GuardWire Plus system in this clinical setting, has not been encouraging because of the technical limitations of the available devices, such as the high profile, low trackability and maneuverability, and excessive time consumption.

The GuardWire Plus system has been proven to be effective in embolization containment. How-

ever, its original design was intended for saphenous vein grafts and large peripheral vessels. Several studies demonstrated its efficacy during elective interventions, mainly on saphenous vein grafts. Yet, in native coronary lesions,⁵⁻⁷ because the unique design of the GuardWire makes it less trackable and maneuverable, only proximal coronary lesions with a favorable anatomy can be treated. Belli et al. used it in eight attempted primary native coronary interventions, but they could not treat a large left circumflex coronary lesion with an angled takeoff in the left posterior direction. The successful lesions were limited to six proximal right coronary arteries and one proximal left anterior descending artery.¹³ Thus, attempts have been made to use the EAC with a conventional steerable coronary wire to overcome this problem. Wang et al. reported its utilization in 12 patients undergoing primary PCI in native coronary lesions.¹⁴ The three coronary vessels could be reached easily and treated successfully regardless of the site of the lesion. Further, another advantage of this technique is that in AMI cases with potential hemodynamic instability, this relatively simple thrombosuction is easy to perform without much time consumption. In the present study, we could perform thrombosuction without complications with this technique except in four cases. Two cases had a tortuous anatomy of the proximal coronary artery, and in another two cases, we could not pass the EAC through the lesion due to instability of the guiding catheter.

The present study was not designed to demonstrate the benefits of the procedure in terms

of the clinical outcome. Instead, it evaluated the surrogate markers known to be associated with improved LV function and survival. After the PCI, in comparison to the control group, the corrected TFC values decreased in the EAC group. A corrected TFC cutoff value of 23 has been demonstrated to be highly predictive of the clinical and functional outcome;¹⁵ in the present study, a corrected TFC > 23 was observed in 35.5% of the patients that underwent thrombosuction with an EAC and in 67.7% of the control patients ($p < 0.05$). Further, although it was not significant, the incidence of distal embolization decreased in the EAC group. However, the TMPG, which is another surrogate marker of effective myocardial reperfusion and a predictor of the clinical outcome, did not significantly differ between the two groups. There is the possibility that, although the gross thrombi could be removed by an EAC, microembolization by atherosclerotic debris or remnants of thrombi generated after the balloon angioplasty or stenting may not be completely prevented by the EAC. Glycoprotein IIb/IIIa inhibitors are effective in decreasing the periprocedural ischemic complications during PCI and stenting. The benefit may be partly related to the prevention of microembolization. Thus, the combined use of an EAC and glycoprotein IIb/IIIa inhibitors may improve the myocardial perfusion, resulting in improved clinical outcomes. Further, it is possible that, in conjunction with a distal protection device, the effect of the EAC would increase. Taguchi et al. reported that the distal embolic protection method is superior to the aspiration method for prevention of embolization after PCI with stenting for AMIs.¹⁶ However, the distal embolic protection method could be limited for some lesions due to the reasons described above. Several studies have shown that the distal protection during primary PCI did not offer any benefit when using the GuardWire system in the EMERALD trial¹⁷ or with the FilterWire in the PROMISE trial.¹⁸ Compared to these study populations, because the population in our study consisted of highly selective cases who had very large thrombi in the infarct-related artery, our study showed encouraging results. Stone GW et al. also reported that thrombectomy with the X-SIZER device prior to the stent implantation in

high-risk diseased saphenous vein grafts and thrombus-containing native coronary arteries may reduce the extent of myonecrosis.¹⁹ In conclusion, our preliminary study showed thrombosuction with an EAC is a simple, safe method for the removal of the thrombi burden and is effective for restoration of the coronary flow during the primary PCI in highly selective AMI patients (very large thrombi in infarct-related arteries). However, these preliminary data should be verified by a large scale, randomized, long term follow-up study.

Study limitations

The ST-segment resolution, biomarker measurements and echocardiographic analyses (LVEF, and LV wall motion score index), which are other surrogate markers of effective myocardial reperfusion, were not evaluated during the pre and post-intervention stages. This study was performed in a relatively small group of highly selective patients (very large thrombi in infarct-related arteries), therefore, the clinical role of the thrombosuction with an EAC must be confirmed with further controlled studies enrolling larger patient cohorts.

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