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Feasibility and safety of thrombectomy with TVAC aspiration catheter system for patients with acute myocardial infarction

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Abstract Early reperfusion with angioplasty and stenting is established as a central, effective treatment for acute myocardial infarction (AMI). The role of thrombectomy prior to angioplasty remains to be elucidated. To evaluate its feasibility, safety, and efficacy, thrombectomy using a TVAC aspiration catheter system was attempted prior to angioplasty and stenting in 40 consecutive patients with AMI. Fifty consecutive patients with AMI in whom angioplasty and stenting were performed without prior thrombectomy served as controls. Neither distribution of Killip classification nor culprit lesion was different between the two groups. In patients treated with the TVAC system, the procedure was successful in 39/40 patients (98%) and there were no procedure-related complications. In the final coronary angiogram, TIMI-3 (Thrombolysis in Myocardial Infarction) flow was obtained in 37/40 (93%) in patients treated with the TVAC system and 43/50 (86%) in control patients. Electrocardiograms before and after coronary intervention were analyzed in patients with ST elevation AMI (35 patients treated with the TVAC system and 41 control patients). ST elevation recovery >50% of the initial value was observed after coronary intervention in 26/35 (74%) in patients treated with the TVAC system and 26/41 (63%) in control patients ($P = 0.33$). In the case of anterior AMI, ST elevation recovery >50% of the initial value was observed in 13/17 (76%) in patients treated with the TVAC system and 8/20 (40%) in control patients ($P = 0.045$). Thus, thrombectomy using a TVAC system is feasible, safe, and may have the potential to enhance ST-segment resolution in patients with anterior AMI.

Key words Acute myocardial infarction · Primary angioplasty · Thrombectomy · ST resolution

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Introduction

Acute myocardial infarction (AMI) is caused by thrombotic coronary artery occlusion following plaque rupture in most patients.[1,2] Primary coronary intervention with balloon angioplasty and stenting has been established as a first-line therapy for AMI.[3–5] During this catheter-based intervention, however, thrombo- and/or atheroembolization in the coronary artery segment distal to the culprit lesion may occur, and a consequent slow flow or no-reflow phenomenon may result in adverse clinical outcomes.[6–11] Thus, not only theoretically but practically, thrombus removal from the coronary artery occlusive lesion may be advisable in order to reduce the thrombotic burden, and to improve coronary flow and procedural results. Recently, a new thrombus aspiration catheter system, TVAC (Nipro, Osaka, Japan) has been designed to remove thrombo-occlusive tissue from the coronary artery and saphenous vein graft. The present report evaluates the feasibility, safety, and efficacy of this TVAC catheter system as a primary catheter-based intervention for AMI.

Materials and methods

Aspiration system

The TVAC aspiration catheter system consists of a very flexible, 4.5-F catheter that can be advanced over a 0.014-inch guidewire through a 7-F guiding catheter using a monorail system, an extension tube, a vacuum pump, and a collection bottle. The catheter has a unique oblique tip shaped like the beak of duck's bill that provides a wide opening area and large lumen for aspiration as compared with the RESCUE PT catheter (Boston Scientific, Maple Grove, MN, USA) and the Export aspiration catheter (PercuSurge System, Medtronic AVE, Danvers, MA, USA) (Fig. 1). A marker is embedded at the distal end of the catheter so that its position can be identified under fluoroscopy. While the tip of the TVAC catheter is advanced and

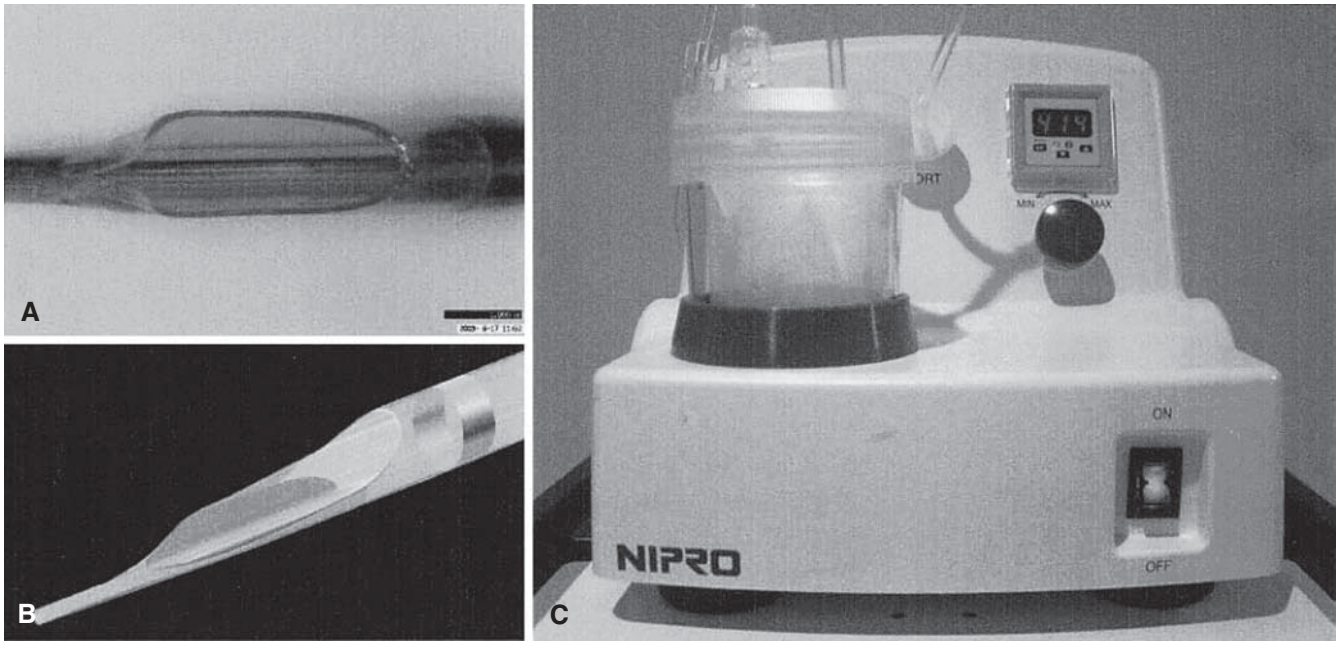

Fig. 1A–C. The TVAC system consists of a 4.5-F aspiration catheter (**A**), with the distal shaft shaped like the bill of a duck (**B**) and a vacuum pump (0.9 atm) with a connection bottle (**C**)

pulled back through the thrombus, continuous suction with a negative pressure at 0.9 atm is applied. Approximately 20–40 ml of arterial blood can be withdrawn during one attempt at thrombus removal.

Patients

The study included those patients with AMI who presented symptoms within 24 h before admission, with a total or subtotal occlusive lesion in the infarct-related coronary artery, with the lumen diameter of the coronary artery segment proximal to the occlusion site being >2 mm, and without a significant stenotic lesion in the main trunk of the left coronary artery. Those patients manifesting cardiogenic shock and with contraindications for coronary intervention were excluded. Thrombectomy with the TVAC system was initiated in May 2003, and was attempted in 40 consecutive patients with AMI, before balloon angioplasty and stenting, for a period of 8 months. Another group of 50 consecutive patients with AMI in whom angioplasty and stenting was performed without prior thrombectomy served as controls. These control AMI patients had been admitted to our hospital before the initialtion of the use of a thrombectomy device, including the TVAC system. In all patients, AMI was diagnosed by severe chest pain lasting >30 min, persistent ST segment elevation or depression on ECG, and abnormal rises of biochemical markers such as troponin T and the MB fraction of creatine kinase. Cardiac catheterization procedures including aspiration of intracoronary thrombus and primary coronary angioplasty were explained to all patients, and informed consent was obtained before the procedures. In all patients, aspirin (200 mg) was orally administered just after admission to the emergency room, and 10 000 IU heparin was administered intravenously at the beginning of the catheterization procedure. Activated coagultion time was maintained at >240 s throughout the procedure by administering additional 1 000-IU doses of heparin at an appropriate interval. None of the patients was pretreated with a thrombolytic agent and a glycoprotein IIb/IIIa inhibitor, since the latter agent was not available in Japan. Nicorandil was administered prior to primary percutaneous coronary intervention (PCI) in none of the patients in the TVAC group and in 31 patients in the control group. Angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker were administered to all patients. Statin and β-adrenergic receptor blocker were administered to 29 and 34 patients, respectively, in the group treated with the TVAC system, and 15 and 35 patients, respectively, in the control group.

Cardiac catheterization and coronary intervention

In both groups of patients, after intracoronary administration of isosorbide dinitrate (2 mg), using 4-F Judkins catheters, the arteriograms of the infarct- and non-infarct-related arteries were taken from multiple projections. The 7-F guiding catheter was engaged to the orifice of the infarct-related coronary artery, and a 0.014-inch guidewire was advanced to the periphery of the infarct-related artery while penetrating the occluded lesion. In control AMI patients, conventional PCI (ballooning and stenting with either an NIR stent (Boston Scientific, Maple Grove, MN, USA), a S670/660 stent (Medtronic AVE, Danvers, MA, USA) or a BX Velocity stent (Cordis,

Miami, FL, USA) was performed. In patients treated with the TVAC system, while applying continuous aspiration the TVAC aspiration catheter was inserted into the infarct-related artery along the guidewire, and advanced until the tip of the catheter reached the occlusion site before ballooning and stenting. The aspiration catheter was further advanced to the segment distal to the occlusion site when this could be performed without any excessive pressure. The aspiration catheter was pulled back while aspirating the blood, and removed from the guiding catheter. The blood in the guiding catheter was removed for the case in which a thrombus was left in the lumen of the guiding catheter. The lumen of the aspiration catheter was washed with heparinized saline, and the same procedure was repeated until an angiographically defective shadow(s) suggesting the presence of intralumen thrombus disappeared in the infarct-related artery, or the volume of the arterial blood aspirated to the collection bottle reached 80 ml. Then, a conventional balloon angioplasty and stenting with either a multilink Penta stent (Guidant Vascular Intervention Group, Lakeside Drive, Santa Clara, CA, USA) or a S670 stent were performed when significant stenosis >75% of the lumen diameter was present at the lesion.

Evaluation of the effect of thrombectomy

Angiographic analysis was performed by two independent investigators to evaluate the procedural results and the occurrence of distal embolization for each patient. The coronary flow grade in the infarct-related artery was determined before and after coronary intervention using a Thrombolysis in Myocardial Infarction (TIMI) flow grade classification.[12] In the patients with ST elevation AMI (35 patients treated with the TVAC system and 41 control patients), 12-lead ECGs before and after coronary intervention were analyzed and a sum of the degree of ST elevation in the three ECG leads showing manifest ST elevation was measured. Persistent ST elevation >50% of the degree of ST elevation observed before the intervention was considered to represent impaired reperfusion.[13,14]

Follow-up

Aspirin (200 mg daily), ticlopidine (200 mg daily for 4 weeks), and angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker were administered to all patients. Statin and β-adrenergic receptor blocker were administered to 29 and 34 patients, respectively, in the group treated with the TVAC system, and to 15 and 35 patients, respectively, in control group. In-hospital outcomes and those within 3 months after discharge were evaluated in all patients.

Statistical analysis

All data are shown as mean ± 1 standard deviation. Difference in categorized data was analyzed using the Fisher exact probability test. $P < 0.05$ was considered to the significant.

Results

Effect of thrombectomy using the TVAC system

Clinical characteristics of the study patients are summarized in Tables 1, 2, and 4. In the patients treated with the TVAC system, the procedure of thrombectomy was successful in 39/40 patients (98%). In one patient, the TVAC system delivery was unsuccessful because of the vessel tortuosity. Of the 39 patients with successful delivery of the system, TIMI-3 flow was obtained in 29 patients and TIMI-1 or -2 flow in 10 after thrombectomy. TIMI flow grade at each stage of the procedures is shown in Fig. 2. There was no procedure-related complication. Representative cases of successful TVAC thrombecomy are shown in Fig. 3. After the procedure of coronary intervention, no patient required target vessel revascularization during their stay in hospital. Also, there was no death and stroke in any of the patients. In the 3 months following coronary intervention there was also no death, no subacute thrombosis, and no stroke in any

Table 1. Clinical baseline characteristics of the two groups of patients

	TVAC (n = 40)	Control (n = 50)	P
Age (years)	64 ± 10	63 ± 12	0.756
Male	34 (84%)	38 (76%)	0.604
Hypertension	20 (50%)	24 (48%)	>0.999
Hyperlipidemia	19 (48%)	21 (42%)	0.672
Diabetes mellitus	15 (38%)	20 (40%)	0.831
Current smoker	27 (67%)	35 (70%)	0.822
Culprit lesion			
Left anterior descending artery	18 (45%)	23 (46%)	>0.999
Left circumflex artery	6 (15%)	8 (16%)	>0.999
Right coronary artery	16 (40%)	19 (38%)	>0.999
Severity of CAD			
Single-vessel disease	18 (45%)	27 (54%)	0.525
Double-vessel disease	10 (25%)	17 (34%)	0.488
Triple-vessel disease	12 (30%)	6 (12%)	0.061

CAD, coronary artery disease

Table 2. Severity of myocardial infarction of in the two groups of patients

	TVAC ($n = 40$)	Control ($n = 50$)	P
Killip classification			
1	38 (95%)	43 (86%)	0.502
2	1 (3%)	7 (14%)	0.289
3	1 (3%)	0 (0%)	0.444
4	0 (0%)	0 (0%)	>0.999
Initial TIMI grade			
0	29 (73%)	30 (60%)	0.267
1	1 (3%)	6 (12%)	0.127
2	6 (15%)	12 (24%)	0.427
3	4 (10%)	2 (4%)	0.401
Time to recanalization (min)	307 ± 228	359 ± 294	0.478
Max CPK (IU/l)	2706 ± 1804	3242 ± 2242	0.254
LVEF (acute phase) (%)	50.4 ± 7.6	51.2 ± 7.7	0.199
IABP utilization	8 (20%)	10 (20%)	>0.999

TIMI, thrombolysis in myocardial infarction; LVEF, left ventricular ejection fraction; IABP, intra-aortic balloon pumping; CPK, creatine phosphokinase

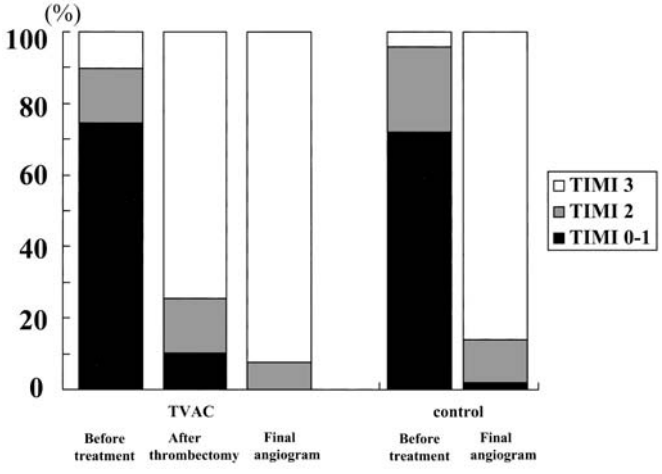

Fig. 2. Changes in Thrombolysis in Myocardial Infarction (*TIMI*) flow grade in the two groups of patients

patients. Of the 39 patients in whom thrombectomy was successfully performed, no visible thrombus or plaque segment was detected in 27 patients, while in the other 12 patients red thrombus was detected in 9, white thrombus in 3, plaque segment containing macrophages in 5, and cholesterine crystals in 4.

Comparison of the results of coronary intervention with and without prior TVAC system

In the final coronary angiogram after coronary intervention, TIMI-3 flow was obtained in 37/40 (93%) patients treated with the TVAC system and in 43/50 (86%) control patients ($P = 0.502$) (Table 3). Electrocardiograms before and after coronary intervention were analyzed in patients with ST elevation AMI. Resolution of ST elevation after intervention was 62% ± 24% of the baseline value of ST elevation in patients treated with the TVAC system ($n = 35$) and 53% ± 34% in control patients treated with conventional PCI ($n = 41$) ($P = 0.241$) (Table 3). ST elevation recovery >50% of the initial degree of ST elevation was observed after coronary intervention in 26/35 (74%) patients treated with the TVAC system and in 26/41 (63%) control patients ($P = 0.33$). In the cases of anterior AMI, resolution of ST elevation was 60% ± 26% in patients treated with the TVAC system ($n = 17$) and 40% ± 24% in control patients ($n = 20$) ($P = 0.017$). ST elevation recovery >50% of the initial degree of ST elevation was observed after coronary intervention in 13/17 (76%) patients treated with the TVAC system and in 8/20 (40%) control patients ($P = 0.045$) (Table 5).

Discussion

Feasibility and safety of thrombectomy with the TVAC system in AMI

Clinical evidence obtained from previous coronary angioplasty trials showed that the presence of angiographic thrombus is associated with increased incidences of abrupt closure and early and late post-procedure occlusion of the infarct-related artery.[7,10] Although new treatments for acute coronary syndrome and high-risk angioplasty have been under development, a new device that can easily, rapidly, and safely remove occlusive tissue, thrombus, and friable materials from the coronary arteries remains necessary. With the use of a TVAC system, a new thrombectomy catheter system developed in Japan, in patients with AMI, we demonstrated that the thrombectomy system improved coronary flow in the infarct-related artery, assessed by TIMI flow grade. TIMI-3 flow was obtained in 29/40 (75%) patients treated with the TVAC system immediately after thrombectomy (Fig. 2). There were no procedure-related complications. After thrombectomy, a standard angioplasty including stent implantation was successfully accomplished in all patients. Further, there was no death, no stroke, and no revascularization therapy required while the patients were in hospital. In the 3 months following coronary inter-

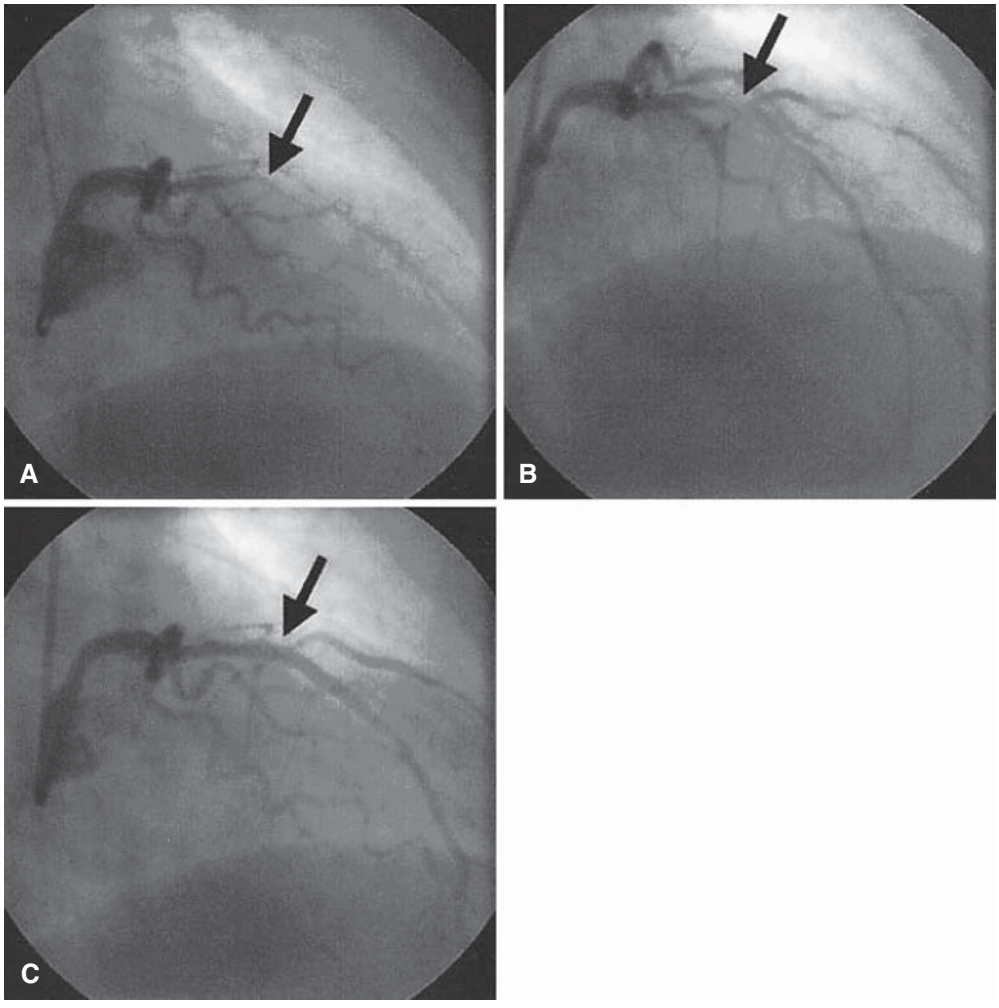

Fig. 3. **A** Thrombotic occlusion in the middle of the left anterior descending coronary artery (indicated by an *arrow*). **B** Initial recanalization with the TVAC system. An *arrow* indicates the occlusion site before treatment. **C** Final left coronary angiogram after treatment with the TVAC system. An *arrow* indicates the occlusion site before treatment

Table 3. Clinical outcomes of the two groups of patients

	TVAC ($n = 40$)	Control ($n = 50$)	P
Clinical success	40 (100%)	50 (100%)	>0.999
Rate of TIMI-3 at the final angiogram	93%	86%	0.502
ST resolution from the initial value	62% ± 24%	53% ± 34%	0.241
Rate of recovery of ST elevation >50% of the initial value	74%	63%	0.33

Clinical success: successful angioplasty without cardiac death, reinfarction, emergency bypass surgery, and stroke in hospital

vention there was also no death, no subacute thrombosis, and no stroke in any of the patients. Thus, thrombectomy with the present TVAC system was found to be feasible and safe.

The TVAC system used in this study is a specially designed monorail catheter which is as flexible as a balloon catheter and can be advanced distally to the lesion with thrombus. Furthermore, the unique oblique tip with a shape like the beak of duck's bill allows a passage through a stenotic lesion and increases trackability in tortuous trajectories. Compared with other aspiration catheters, the TVAC has a wide opening area (5.59 mm^2 in TVAC vs 1.37 mm^2 in RESCUE PT and 3.90 mm^2 in Export) and large lumen (0.90 mm^2 in TVAC vs 0.60 mm^2 in RESCUE PT and 0.82 mm^2 in Export) for aspiration. The system is simple, and extensive experience or a long learning period is not necessary, as may be the case with the other aspiration catheters.[15,16]

Efficacy of thrombectomy with the TVAC system in AMI

This study showed that, in the final arteriogram of the infarct-related artery, TIMI-3 grade flow was obtained in 37/40

Table 4. Clinical baseline of the two groups of patients (anterior AMI)

	TVAC (n = 18)	Control (n = 23)	P
Age (years)	62 ± 11	60 ± 13	0.689
Male	13 (72%)	17 (74%)	>0.999
Hypertension	9 (50%)	13 (57%)	0.758
Hyperlipidemia	10 (56%)	11 (48%)	0.756
Diabetes mellitus	7 (39%)	8 (35%)	>0.999
Current smoker	11 (61%)	15 (65%)	>0.999
Severity of CAD			
Single-vessel disease	8 (44%)	17 (74%)	0.106
Double-vessel disease	5 (28%)	5 (22%)	0.725
Triple-vessel disease	5 (28%)	1 (4%)	0.07
Killip classfication			
1	18 (100%)	20 (87%)	0.243
2	0 (0%)	3 (13%)	0.243
3	0 (0%)	0 (0%)	>0.999
4	0 (0%)	0 (0%)	>0.999
Initial TIMI grade			
0	12 (67%)	13 (57%)	0.54
1	1 (6%)	4 (17%)	0.363
2	4 (22%)	6 (26%)	>0.999
3	1 (6%)	0 (0%)	0.439
Time to recanalization (min)	297 ± 209	451 ± 341	0.11
Max CPK (IU/l)	3351 ± 2241	3007 ± 2213	0.626
LVEF (acute phase) (%)	48.0 ± 10.3	47.1 ± 8.7	0.805
IABP utilization	6 (33%)	7 (30%)	>0.999

Table 5. Clinical outcomes in patients with anterior AMI

	TVAC (n = 17)	Control (n = 20)	P
Rate of TIMI-3 at the final angiogram	83%	87%	0.502
ST resolution from the initial value	60% ± 26%	40% ± 24%	0.017
Rate of recovery of ST elevation >50% of the initial value	76%	40%	0.045

(93%) patients treated with the TVAC system followed by angioplasty and stenting, compared with 43/50 (86%) in control patients treated with angioplasty and stenting without prior thrombectomy. Although not significant, primary angioplasty with prior thrombectomy with the TVAC system was found to be of use in the treatment of AMI. It should be pointed out that this study was not done in a prospective, randomized fashion. Thus, thrombectomy using the TVAC system was attempted in 40 consecutive AMI patients. Another group of 50 consecutive patients with AMI in whom angioplasty and stenting were performed without prior thrombectomy served as a control group, since at that time no thrombectomy device was available. There was no difference in the clinical characteristics between the two groups, including the distribution of the infarct-related artery and the degree of coronary flow before coronary intervention.

Although epicardial coronary flow has been identified as an important predictor for clinical outcomes, it is well known that patency of the epicardial vessel does not necessarily indicate adequate reperfusion at the level of coronary microcirculation.[17] Impairment of microvascular function may occur particularly during mechanical reperfusion procedures. Thus, primary angioplasty for AMI may induce dislodgment of thrombi, causing distal macroembolization and microembolization. Further, mechanical dilation results in plaque disruption and may induce distal embolization with atheromatous gruel and plaque components.[18] Distal embolization and subsequent slow flow or no-reflow have been reported to occur in up to 30% of patients treated with primary angioplasty.[19–22]

An analysis of ST-segment resolution has been validated as a surrogate marker for restoration of microvascular functiohn. In patients with ST elevation AMI, early resolution of ST elevation >50% of the initial degree of ST elevation has been shown to be associated with greater myocardial salvage and improved clinical outcome.[13,14,23] In the present study, the degree of resolution of ST elevation after primary coronary intervention and the number of patients with ST elevation recovery more than 50% of the initial degree of ST elevation after primary coronary intervention were both greater in the patient group treated with the TVAC system than in the group without prior thrombectomy, although the difference did not reach statistical significance. When the same analysis was made in the patients with anterior AMI, both parameters were significantly greater in the group treated with the TVAC system than in the group without prior thrombectomy. Thus,

though not done in a prospective, randomized fashion, this study suggested that thrombectomy with the TVAC system prior to primary coronary intervention may enhance ST-segment resolution in the infarct-related artery in patients with AMI. It may be pointed out that the TVAC system was more effective in patients with anterior AMI that in those with nonanterior AMI. In fact, in nonanterior AMI the results of ST resolution were similar between the patient groups with and without treatment with the TVAC system. The present study could not clarify the reason for the difference in the effect between anterior and nonanterior AMI. Anterior AMI may be at a higher risk of microvascular dysfunction than nonanterior AMI because of the differences in the number of side branches and the size of the perfusion territory. Further studies in this respect are required.

Study limitations

This study was not done in a prospective, randomized fashion, and a comparison of the clinical outcomes between the patient groups treated with and without prior thrombectomy may be inappropriate in reaching some conclusions. Further prospective studies are necessary to establish the effectiveness of the TVAC thrombectomy system. Also, the present study did not show the long-term effect of the TVAC system. Since the prognosis of the patients with AMI is influenced by many factors including the size of infarction, left ventricular function, ventricular arrhythmias, and residual myocardial ischemia, the long-term effect of the TVAC system on the prognosis should be evaluated cautiously.

Conclusions

Thrombectomy with the TVAC system before balloon angioplasty and stent implantation in patients with AMI is feasible and safe, and may have the potential to minimize thrombus dislodgment and distal embolization. Further prospective studies are required to establish the efficacy of the TVAC system in the treatment of patients with AMI.

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