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Clinical and Angiographic Predictors and Prognostic Value of Failed Thrombus Aspiration in Primary Percutaneous Coronary Intervention

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Objectives This study sought to investigate which factors are associated with failure of thrombus aspiration (TA) and if this has prognostic implications.

Background The pathophysiological mechanism and clinical benefit of TA during primary percutaneous coronary intervention for acute ST-segment elevation myocardial infarction is still in debate.

Methods Between August 2001 and October 2007, TA was attempted in 1,399 patients. Failure of TA was defined as the inability to reach and/or cross the occlusion with the aspiration catheter for effective thrombus removal. In addition, we analyzed patients in which no material could be obtained. We examined baseline clinical and angiographic variables related to failure of TA or to the lack of aspirate. Follow-up on vital status was obtained at 1 year.

Results In 144 (10.3%) patients, the aspiration catheter failed to cross the lesion. After multivariable adjustment, marked proximal tortuosity (odds ratio [OR]: 2.88, 95% confidence interval [CI]: 1.92 to 4.31, $p < 0.001$), the presence of a calcified lesion (OR: 2.70, 95% CI: 1.77 to 4.13, $p < 0.001$), and a bifurcation lesion (OR: 1.97, 95% CI: 1.15 to 3.37, $p = 0.013$) were independent predictors of failed TA. Age over 60 years and the circumflex as infarct-related artery were associated with the lack of aspirate. Mortality rates at 1 year were 6.2% in patients with failed TA and 6.4% with successful TA (hazard ratio: 0.98, 95% CI: 0.49 to 1.95, $p = 0.95$).

Conclusions The presence of marked proximal tortuosity of the infarct-related artery, a calcified lesion, and a bifurcation lesion are independent predictors of failure of thrombus aspiration. We found that unsuccessful TA did not affect 1-year mortality. (J Am Coll Cardiol Intv 2011;4:634–42)

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Reperfusion therapy by primary percutaneous coronary intervention (PPCI) with stenting has proven the optimal approach to reduce morbidity and mortality in acute ST-segment elevation myocardial infarction (STEMI). In PPCI, the presence of coronary thrombus has been linked to distal embolization and microvascular obstruction, reflected by lower post-procedure myocardial blush grade (MBG) and no-reflow, which is associated with an increased infarct size and worse outcome (1–3). Various devices designed to remove thrombus before stenting have been tested in small- to moderate-sized randomized controlled trials. Meta-analyses of adjunctive thrombectomy trials have reported an inconsistent effect of the device-based removal of thrombus from the infarct-related artery on reperfusion surrogate and clinical endpoints, with a difference between mechanical and manual devices in favor of manual aspiration (4–8).

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These previous reports on thrombectomy in the setting of PPCI did not provide information on the factors associated with failure to remove thrombus with the various manual thrombus aspiration (TA) devices and potential prognostic implications. The reported proportion of unsuccessful employment varies from 4% to 11%, mainly because of the inability to cross the lesion (9–11). Even though a retrospective study described the failure of the X-Sizer (ev3 Inc., Plymouth, Minnesota) mechanical thrombectomy device in 24% of cases (12), it is not known which factors are associated with failure of the currently used TA catheters and whether this is associated with worse outcomes. We sought to determine predictive factors as well as the prognostic value of failure of the TA catheter to reach the infarct-related lesion in PPCI in a large all-comer acute STEMI population. In addition, we evaluated which factors were associated with the inability to retrieve material after successful positioning of the TA catheter.

Methods

Procedures and medication. We analyzed data from acute STEMI patients who underwent PPCI with TA at the Academic Medical Center, University of Amsterdam between August 2001 and October 2007. Patients were eligible for PPCI when they presented with acute STEMI (≥2-mm ST-segment elevation in ≥2 contiguous leads) with symptom duration of ≤12 h. All interventions were done according to existing practice guidelines for PCI. Baseline clinical, angiographic, and procedural variables were collected prospectively in a dedicated database and included statements on possible failure of deployment of the TA device used. All patients received aspirin 300 mg and unfractionated heparin 5,000 to 10,000 IU at the start of the procedure. The use of glycoprotein IIb/IIIa inhibitors was at the discretion of the operator. Subsequently, patients were prescribed aspirin 100 mg once daily for life. Clopidogrel was administered at a loading dose of 300 or 600 mg before or immediately after the procedure, followed by 75 mg once daily for 1 month in patients treated with bare-metal stents, and 6 months in patients treated with drug-eluting stents.

TA cohort. In our institution, TA has been available for use as an adjunct to PPCI since August 2001. In these first years, TA was not a proven or formally recommended therapy and its use was at the discretion of the operator. The study cohort consists of all patients for whom a TA device was used in adjunct to the standard procedure. Device selection was at the discretion of the operator. The devices used were the 7-F Rescue catheter (Boston Scientific/Scimed, Inc., Maple Grove, Minnesota), which became available in August 2001 and was mainly used until the end of 2004; the 6-F Export aspiration catheter (Medtronic Vascular Inc., Santa Rosa, California), which became available in August 2004 and currently is still in use; and the 6-/7-F Proxis embolic protection device (St. Jude Medical, St. Paul, Minnesota), which became available in February 2004 and combines aspiration with distal embolic protection. During the study period, PPCI was performed via the femoral artery only, with the standard use of 7-F guiding catheters. After 6-F–compatible Export catheters became available at the end of 2006, both 6-F and 7-F catheters were used for this device. A total of 1,399 patients were identified in which a TA device was used during PPCI. We classified patients into 2 groups based on the success of the aspiration catheter to reach and/or cross through the lesion without pre-dilation (or with device-required pre-dilation in case of the Proxis device). We compared baseline clinical and angiographic variables of both patient groups to determine factors associated with unsuccessful crossing of the TA device. In addition, we analyzed all patients in which the catheter had successfully crossed the lesion, but no thrombotic material could be obtained, and compared them with patients in which aspirate was retrieved.

We obtained information on 1-year vital status from the institutional follow-up database of PCI patients. Patients were surveyed 1 year after PCI by means of a mailed, self-administered questionnaire. Follow-up information was synchronized with computerized mortality records from the

Abbreviations and Acronyms

CI = confidence interval
HR = hazard ratio
IQR = interquartile range
MBG = myocardial blush grade
OR = odds ratio
PCI = percutaneous coronary intervention
PPCI = primary percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction
TA = thrombus aspiration
TIMI = Thrombolysis In Myocardial Infarction

National Death Index and local authorities, which were updated until August 2010.

Statistical analysis. Data are presented as mean ± SD for normally distributed, continuous variables, or median (interquartile range [IQR]), and as frequencies (percentages) for categorical variables. Differences between patient groups were tested with Student *t* test or the Mann-Whitney *U* statistic test as appropriate. Categorical variables were compared by chi-square test. All tests were 2-tailed, and a value of $p < 0.05$ was considered statistically significant. Cumulative event rates of all-cause mortality were estimated by the Kaplan-Meier method, and the timing of death is illustrated by Kaplan-Meier plots. Follow-up was censored at 1 year. The association between clinical and angiographic variables and failure to cross the lesion, or to obtain material in the case of successful passage, were assessed using logistic regression analysis in both crude models and multivariable-adjusted models for variables that showed a univariable association with failure of TA ($p \leq 0.1$). Variables were entered en bloc and the results were expressed as odds ratios (ORs) with 95% confidence intervals (CIs). Statistical analysis was performed with SPSS software (SPSS, version 18.0 for Windows, SPSS Inc., Chicago, Illinois).

Results

Failure of thrombus aspiration. The study flow chart is displayed in Figure 1. In 144 patients (10.3%) of the 1,399 patients for whom TA was attempted, the TA catheter failed to cross the lesion. Baseline clinical and angiographic characteristics are summarized in Table 1. At a mean age of 63 ± 13 years versus 60 ± 13 years, patients in the failed TA group were older than patients in the successful TA group ($p = 0.009$). In addition, these patients more often had multivessel coronary artery disease (40% vs. 27%, $p = 0.001$). As expected, some differences in the presence of certain angiographic variables were seen. A calcified lesion was more often seen in the group in which TA had failed, at 33.3% versus 14.8% in the successful TA group ($p < 0.001$). Likewise, marked proximal coronary tortuosity was significantly more frequent at 67.9% versus 32.1% in the failed TA group and successful TA group, respectively ($p < 0.001$). The circumflex artery was more often the infarct-related artery in patients with failed TA (20.1%) than it was in the patients with successful TA (10.0%), $p = 0.002$.

None of the clinical variables was predictive of failure of TA (Table 2). Marked proximal tortuosity of the coronary artery, the presence of a calcified lesion, and a bifurcation

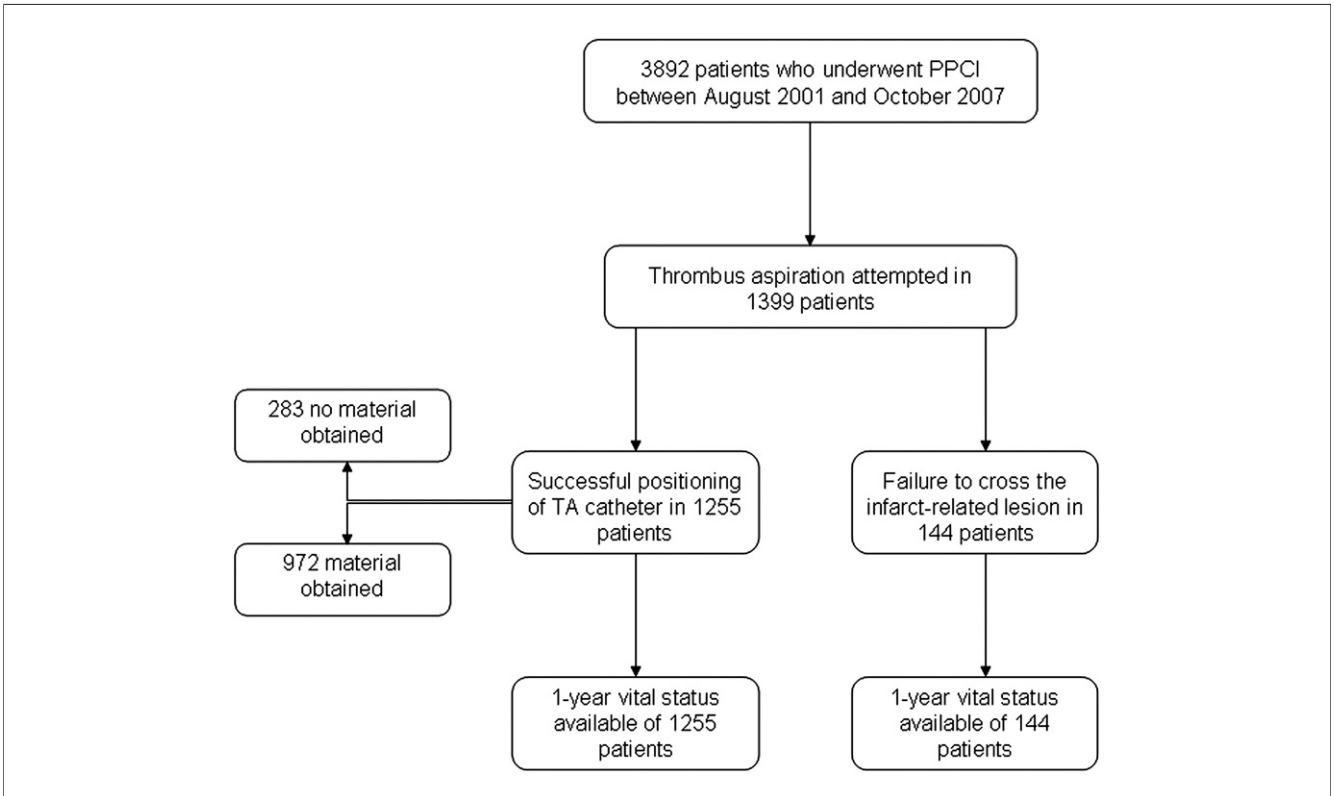

Figure 1. Study Flow Chart

All patients in whom thrombus aspiration (TA) was attempted were identified. They were divided into 2 groups (successful TA vs. failed TA). Subsequently, patients with successful TA were divided by the presence or absence of thrombotic material. PPCI = primary percutaneous coronary intervention.

Table 1. Baseline Clinical and Angiographic Characteristics

				Successful Aspiration		
	Failed Aspiration (n = 144)	Successful Aspiration (n = 1,255)	p Value	No Material (n = 283)	Material (n = 972)	p Value
Age, yrs	63 ± 13	60 ± 13	0.009	60 ± 13	61 ± 12	0.03
Male	98 (68)	919 (73)	0.20	207 (73)	712 (73)	0.97
Diabetes mellitus	17 (12)	122 (10)	0.46	25 (9)	97 (10)	0.57
Hypertension	54 (38)	359 (32)	0.16	87 (31)	308 (32)	0.76
Hypercholesterolemia	34 (24)	260 (21)	0.45	59 (21)	201 (21)	0.95
History of smoking	91 (63)	771 (61)	0.72	156 (55)	615 (63)	0.013
Family history of CAD	66 (46)	531 (42)	0.43	110 (39)	421 (43)	0.18
Previous PCI	10 (7)	83 (7)	0.86	22 (8)	61 (6)	0.37
Previous CABG	3 (2)	19 (2)	0.49	4 (1)	15 (2)	0.88
Previous MI	15 (10)	118 (9)	0.65	33 (12)	85 (9)	0.14
Symptom-to-balloon, h	3.0 (2.3–4.3)	3.0 (2.2–4.5)	0.65	3.2 (2.2–4.6)	3.0 (2.1–4.4)	0.35
Shock	4 (3)	82 (7)	0.10	22 (8)	60 (6)	0.34
Multivessel disease	58 (40)	341 (27)	0.001	79 (28)	262 (27)	0.75
Infarct-related artery			0.02			0.003
LM	0 (0)	4 (0)		3 (1)	1 (0)	
LAD	47 (33)	552 (44)		125 (44)	427 (44)	
RCA	67 (44)	558 (45)		111 (39)	447 (46)	
Cx	29 (20)	125 (10)		41 (15)	84 (9)	
SVG	1 (1)	16 (1)		3 (1)	13 (1)	
TIMI flow grade 0 or 1	114 (79)	1,063 (85)	0.09	240 (85)	823 (85)	0.96
Bifurcation lesion	21 (15)	120 (10)	0.08	29 (10)	91 (9)	0.64
Ostial lesion	9 (6)	84 (7)	1.00	16 (6)	68 (7)	0.43
Distal major branch	19 (13)	117 (9)	0.14	23 (8)	94 (10)	0.43
Side branch	11 (8)	51 (4)	0.06	16 (6)	35 (4)	0.12
Calcified lesion	48 (33)	186 (15)	<0.001	48 (17)	138 (14)	0.24
Proximal tortuosity	91 (68)	462 (40)	<0.001	107 (42)	355 (40)	0.61
>45° lesion angle	39 (29)	292 (26)	0.40	65 (25)	227 (26)	0.95
Lesion length, mm	15.6 ± 5.3	16.4 ± 5.6	0.10	15.9 ± 6.1	16.5 ± 5.5	0.47
ACC/AHA type C lesion	57 (43)	434 (37)	0.19	95 (38)	339 (37)	0.63

Values are mean ± SD, n (%), or median (interquartile range).

ACC/AHA = American College of Cardiology/American Heart Association; CAD = coronary artery disease; CABG = coronary artery bypass grafting; Cx = circumflex artery; LAD = left anterior descending artery; LM = left main; MI = myocardial infarction; PCI = percutaneous coronary intervention; RCA = right coronary artery; SVG = saphenous vein graft; TIMI = Thrombolysis In Myocardial Infarction

lesion as infarct-related lesion were independent predictors of unsuccessful passage of the catheter across the lesion at ORs of 2.88 for proximal tortuosity (95% CI: 1.92 to 4.31, $p < 0.001$), 2.70 for the presence of a calcified lesion (95% CI: 1.77 to 4.13, $p < 0.001$), and 1.97 for a bifurcation lesion (95% CI: 1.15 to 3.37, $p = 0.013$).

The procedural characteristics are stated in Table 3. Most patients received a stent (93.0% in both groups, $p = 1.00$), whereas direct stenting was performed less often after failure of TA, at 9.0% versus 30.0% ($p < 0.001$). Post-procedural TIMI (Thrombolysis In Myocardial Infarction) flow grade <3 was observed in 13.9% in the failed TA group and 9.5% in the successful TA group ($p = 0.11$). The average peak creatine kinase-myocardial band values were comparable in both groups (280 μg/l, IQR: 122 to 495 μg/l, vs. 263 μg/l, IQR: 127 to 445 μg/l; $p = 0.32$). Note that these values were available only in patients who were not transferred to the referring hospitals immediately after PPCI (81 patients with failed TA and 818 patients with successful TA).

Absence of thrombotic aspirate. In 283 (27.3%) of 1,255 patients in whom the aspiration catheter successfully crossed the lesion, no material could be retrieved. The baseline clinical and angiographic characteristics are stated in Table 1. These patients were slightly older at 61 ± 12 years versus 60 ± 13 years for the patients in which thrombotic material could be obtained ($p = 0.03$). Furthermore, at 55% versus 63%, they less often had a history of smoking ($p = 0.013$). Except for the difference in the incidence of the right coronary or circumflex artery as the infarct-related artery, other baseline and angiographic characteristics were comparable in both groups. Patient age over 60 years and the circumflex

Table 2. Univariable and Multivariable-Adjusted Logistic Regression Analysis of the Association of the Presence of a Clinical or Angiographic Feature and the Likelihood of Failure of TA

			Univariable Analysis			Multivariable-Adjusted Analysis		
Variable	Present	Absent	OR	95% CI	p Value	OR	95% CI	p Value
Age >60 yrs	85/673 (12.6)	59/726 (8.1)	1.63	1.15–2.32	0.006	1.27	0.86–1.88	0.23
Male	98/1,017 (9.6)	46/382 (12.0)	0.78	0.54–1.13	0.19			
Diabetes mellitus	17/139 (12.2)	127/1,260 (10.1)	1.24	0.73–2.13	0.43			
Hypertension	54/449 (12.0)	90/950 (9.5)	1.31	0.91–1.87	0.14			
Hypercholesterolemia	34/294 (11.6)	110/1,105 (10.0)	1.18	0.79–1.78	0.42			
History of smoking	91/862 (10.6)	53/537 (9.9)	1.08	0.75–1.54	0.68			
Family history of CAD	66/597 (11.1)	78/802 (9.7)	1.15	0.82–1.63	0.42			
Previous PCI	10/93 (10.8)	134/1,306 (10.3)	1.05	0.53–2.08	0.88			
Previous CABG	3/22 (13.6)	141/1,236 (10.2)	1.38	0.41–4.74	0.61			
Previous MI	15/133 (11.3)	129/1,266 (10.2)	1.12	0.64–1.98	0.69			
Shock	4/86 (4.7)	140/1,313 (10.7)	0.41	0.15–1.13	0.09	0.47	0.17–1.34	0.16
Multivessel disease	58/399 (14.5)	86/1,000 (8.6)	1.81	1.27–2.58	<0.001	1.35	0.91–2.00	0.13
IRA Cx	29/154 (18.8)	115/1,245 (9.2)	2.28	1.46–3.57	<0.001	1.67	0.95–2.95	0.077
TIMI flow grade 0 or 1	114/1,177 (9.7)	30/222 (13.5)	0.69	0.45–1.06	0.087	0.64	0.40–1.03	0.064
Bifurcation lesion	21/141 (14.9)	123/1,257 (9.8)	1.61	0.98–2.66	0.061	1.97	1.15–3.37	0.013
Ostial lesion	9/93 (9.7)	135/1,305 (10.3)	0.93	0.46–1.89	0.84			
Distal lesion	19/136 (14.0)	125/1,263 (9.9)	1.48	0.88–2.48	0.14			
Side branch	11/62 (17.7)	133/1,337 (9.9)	1.95	0.99–3.84	0.052	1.03	0.45–2.33	0.95
Calcified lesion	48/234 (20.5)	96/1,164 (8.2)	2.87	1.96–4.20	<0.001	2.70	1.77–4.13	<0.001
Proximal tortuosity	91/553 (16.5)	43/724 (5.9)	3.12	2.13–4.57	<0.001	2.88	1.92–4.31	<0.001
>45° lesion angle	39/331 (11.8)	95/946 (10.0)	1.20	0.81–1.78	0.37			
ACC/AHA type C lesion	57/491 (11.6)	75/814 (9.2)	1.29	0.90–1.86	0.17			

Values are number of patients with failed TA/total number of patients (%).
CI = confidence interval; IRA = infarct-related artery; OR = odds ratio; TA = thrombus aspiration; other abbreviations as in Table 1.

coronary artery as infarct-related artery were independent predictors for the absence of aspirate, at ORs of 1.37 (95% CI: 1.04 to 1.80, p = 0.025) and 1.84 (95% CI: 1.23 to 1.75, p = 0.003), respectively (Table 4).

Clinical outcome. Follow-up information on all-cause mortality was available for all patients. Death rates at 1 year were 6.2% in patients with failed TA, as compared to 6.4% in patients with successful TA (hazard ratio [HR]: 0.98, 95% CI: 0.49 to 1.95, p = 0.95). In the case of successful crossing of the lesion, the mortality rate was 6.7% in patients without aspirate, as compared to 6.3% in patients with aspirated material (HR: 1.08, 95% CI: 0.64 to 1.80, p = 0.78). Figure 2 shows the Kaplan-Meier curves for all-cause mortality of the 3 different groups.

Table 3. Procedural Characteristics

				Successful Aspiration		
	Failed Aspiration (n = 144)	Successful Aspiration (n = 1,255)	p Value	No Material (n = 283)	Material (n = 972)	p Value
Stenting	131 (93)	1,157 (93)	1.00	251 (92)	906 (93)	0.23
Direct stenting	13 (9)	376 (30)	<0.001	63 (22)	313 (32)	0.001
Stent length	19.3 ± 5.8	19.0 ± 5.0	0.96	18.4 ± 4.6	19.1 ± 5.1	0.06
Stent diameter	3.4 ± 0.6	3.5 ± 0.5	0.004	3.5 ± 0.5	3.6 ± 0.5	0.001
GP IIb/IIIa inhibitor	65 (45)	499 (40)	0.24	110 (39)	389 (40)	0.73
Distal embolization	18 (13)	163 (13)	1.00	27 (10)	136 (14)	0.05
Post-procedural TIMI flow grade <3	29 (14)	119 (10)	0.11	27 (10)	92 (10)	0.96
IABP inserted	7 (5)	106 (8)	0.15	30 (11)	76 (8)	0.14
Peak CK-MB	280 (144–495)	263 (127–445)	0.32	224 (95–384)	268 (136–462)	0.007

Values are n (%), mean ± SD, or median (interquartile range).
CK-MB = creatine kinase-myocardial band; GP = glycoprotein; IABP = intra-aortic balloon pump; TIMI = Thrombolysis In Myocardial Infarction.

Table 4. Univariable and Multivariable-Adjusted Logistic Regression Analysis for the Association of Clinical and Angiographic Variables and the Lack of Aspirate

			Univariable Analysis			Multivariable-Adjusted Analysis		
Variable	Present	Absent	OR	95% CI	p Value	OR	95% CI	p Value
Age >60 yrs	152/588 (25.9)	131/667 (19.6)	1.43	1.09–1.86	0.009	1.37	1.04–1.80	0.025
Male	207/919 (22.5)	76/336 (22.6)	1.00	0.74–1.34	0.97			
Diabetes mellitus	25/122 (20.5)	258/1,133 (22.8)	0.87	0.55–1.39	0.57			
Hypertension	87/395 (22.0)	296/860 (22.8)	0.96	0.72–1.27	0.76			
Hypercholesterolemia	59/260 (22.7)	224/995 (22.5)	1.01	0.73–1.40	0.95			
History of smoking	156/771 (20.2)	127/484 (26.2)	0.71	0.55–0.93	0.013	0.76	0.58–1.01	0.054
Family history of CAD	110/531 (20.7)	173/724 (23.9)	0.83	0.64–1.09	0.18			
Previous PCI	22/83 (26.5)	261/1,172 (22.3)	1.26	0.76–2.09	0.37			
Previous CABG	4/19 (21.1)	279/1,236 (22.6)	0.92	0.30–2.78	0.88			
Previous MI	33/118 (28.0)	250/1,137 (22.0)	1.38	0.90–2.11	0.14			
Shock	22/82 (26.8)	261/1,173 (22.3)	1.28	0.77–2.13	0.34			
Multivessel disease	79/341 (23.2)	204/914 (22.3)	1.05	0.78–1.41	0.75			
IRA Cx	42/125 (32.8)	242/1,130 (21.4)	1.79	1.20–2.67	0.004	1.84	1.23–2.75	0.003
TIMI flow grade 0 or 1	240/1,063 (22.6)	43/192 (22.4)	1.01	0.70–1.46	0.96			
Bifurcation lesion	29/120 (24.2)	253/1,134 (22.3)	1.11	0.71–1.72	0.64			
Ostial lesion	16/84 (19.0)	266/1,170 (22.7)	0.80	0.46–1.40	0.44			
Distal lesion	23/117 (19.7)	260/1,138 (22.8)	0.83	0.51–1.33	0.43			
Side branch	16/51 (31.4)	267/1,204 (22.4)	1.60	0.87–2.94	0.13			
Calcified lesion	48/186 (25.8)	234/1,068 (21.9)	1.24	0.87–1.78	0.24			
Proximal tortuosity	107/462 (23.2)	149/681 (21.9)	1.08	0.81–1.43	0.61			
>45° lesion angle	55/292 (22.3)	191/851 (22.4)	0.99	0.72–1.36	0.95			
ACC/AHA type C lesion	95/434 (21.9)	153/734 (20.7)	1.07	0.80–1.43	0.63			

Values are number of patients without aspirate/total number of patients with successful TA (%).
Abbreviations as in Tables 1 and 2.

Discussion

Success of thrombus aspiration. The present analysis of a large dataset of unselected acute STEMI patients demonstrates that manual TA failed in a considerable number of procedures where TA was attempted. Our data show that the presence of a calcified lesion, marked tortuosity of the infarct-related artery, and a bifurcation lesion are independent predictors of failure of the aspiration catheter to reach and/or cross through the infarct-related lesion. In addition, when the segment could successfully be engaged and crossed with the thrombectomy catheter, no thrombotic material was obtained in a substantial part of procedures. Our analyses show that restoration of coronary flow was not influenced by failure of TA or whether thrombotic aspirate was retrieved and, importantly, no difference in 1-year mortality was observed.

In the past years, several randomized controlled trials examining the potential benefit of adjunctive TA during PPCI have been published (9–11,13–15). Information on the occurrence of failure of successful application of the different TA devices is lacking in most of these reports. The largest trial comparing the Rescue catheter with conventional PPCI did report failure to cross the lesion in 11% of cases despite pre-dilation (9). The TAPAS (Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction) trial is the largest trial comparing the adjunctive use of the Medtronic aspiration catheter with conventional PPCI (13). In this study, patients with lesions that were judged by the operator to be too tortuous or too small for delivery of the aspiration catheter were crossed over to the conventional treatment group. No details are available for the treatment success rates of the actual patients in which TA was attempted. Likewise, the authors of the EXPIRA (Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) trial, which is a smaller trial investigating the use of the Medtronic aspiration catheter compared with conventional PPCI, did not describe in what proportion TA had failed (14). The recently published PREPARE (Proximal Embolic Protection in Acute MI and Resolution of ST-Elevation) trial is the only randomized controlled trial in which the Proxis system was investigated (15). In 6% of patients, the system could not be satisfactorily positioned, although only patients with lesions presumably suitable for

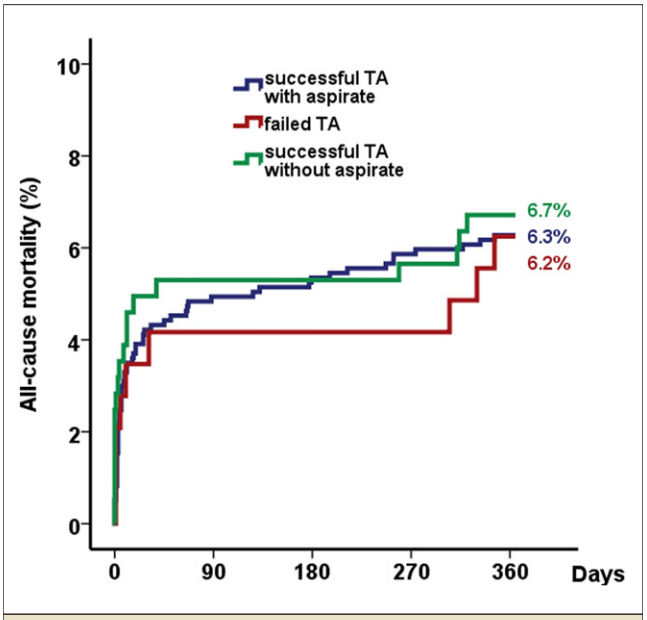

Figure 2. Kaplan-Meier Curves

Cumulative incidence of all-cause mortality in patients with successful thrombus aspiration (TA) with aspirate, patients with failed TA, and patients with successful TA without aspirate.

treatment with the device were included. At an incidence of 10.3%, the proportion of failure observed in our analysis is comparable to that described by Kaltoft et al. (9).

Predictors of failure of thrombus aspiration. In the current study, predictors of failure of TA were generally lesion-specific rather than patient-dependent. Previously, the presence of marked tortuosity and coronary calcification have been identified to be predictors of failure of intravascular ultrasound imaging, at a rate of 23% failed procedures described in a prospective cohort of patients with stable or unstable angina (16). The difference in flexibility of the catheters used for intravascular ultrasound with those currently used for TA and the dissimilar patient characteristics may explain the lower failure rate we observed. Additionally, the presence of a type C lesion was not an independent predictor of failure of TA. The American College of Cardiology/American Heart Association lesion morphology was originally introduced to provide a tool for estimation of the difficulty of a procedure and its probability of angiographic success (17). This concept of lesion morphology classification is not well defined for STEMI patients presenting with an acutely occluded vessel, which may explain the lack of correlation with TA failure in our observation.

After successful passage of the aspiration catheter through the lesion, no material could be identified in 27.3% of the patients in our cohort. This proportion is comparable with that reported in the TAPAS trial, in which no material was obtained in 27.1% of the procedures where TA was performed. The potency of endogenous fibrinolysis, enhanced by pharmacological therapy administered promptly after diagnosis before arrival at the catheterization laboratory, probably is a major contributor to this finding (18). The diversity in the morphology of the vulnerable plaque in acute myocardial infarction implies the possibility of a nonthrombotic lesion (19), whereas distal embolization could have occurred before treatment, either spontaneously or because of manipulation by the guidewire. Furthermore, the aspiration capacity of the devices used at our institution may not be sufficient to remove large thrombus load, as opposed to mechanical thrombectomy (20). During the study period, we did not use mechanical devices in the absence of beneficiary evidence in literature.

Survival. Interestingly, we found that survival at 1 year was not influenced by failure of the TA catheter to reach and/or cross the infarct-related lesion or, in the case of successful catheter passage, if thrombotic material could be retrieved. In previous reported investigations, removal of thrombus from the infarct-related artery reduced no-reflow by limiting the embolization of thrombotic material and was associated with improved TIMI flow and MBG, with an inconsistent effect on clinical outcome (4–7). It proved to be difficult to translate the benefit in surrogate endpoints in better clinical outcome. The TAPAS trial was the first trial to report better clinical outcome after routine manual TA compared with conventional PPCI (21). The occurrence of distal embolization, however, was not influenced by TA (22). The deterioration in coronary perfusion, as seen frequently in PPCI, is a complex condition related to multiple factors as endothelial dysfunction, microvascular obstruction, and reperfusion injury (23). These are unlikely to be affected simultaneously by TA alone. Thus, in the case of prompt restoration of coronary flow after wiring the coronary artery, the additional effect of TA on prognosis probably is modest. However, TA commonly allows for direct stenting, which was reported to be associated with reduced microvascular injury (24). In the present analysis, the final TIMI flow grade was not affected by failure of TA, which could explain, to some extent, the lack of a prognostic association of successful TA on 1-year mortality (25). In addition, the prognosis of these unselected acute STEMI patients may have been influenced by unidentified confounders or comorbidities associated with worse outcomes (26).

Study limitations. First, in our institution, TA is executed on the judgment of the interventional cardiologist, which could have resulted in selection bias. However, we studied patients in whom TA was attempted, where the operator considered the infarct-related lesion as suitable for TA. Second, the available data on surrogate outcomes are limited. The effect of TA on MBG could not be determined because the appropriate images to assess MBG were not collected routinely as part of daily practice. In addition, because patients were transferred to the referring hospitals

within hours after the procedure, infarct size could not be determined accurately as information on serial serum markers or left ventricular function was not available. Still, peak creatine kinase-myocardial band values were available in a considerable proportion of patients and were comparable in both groups. Furthermore, follow-up information was limited to vital status alone; therefore, a possible cardiac cause of death could not be identified.

Conclusions

Our findings demonstrate that in a considerable proportion of patients presenting with STEMI, the successful completion of TA during PPCI is limited either by the inability to reach and/or cross the infarct-related lesion, or by the lack of aspirate retrieved from the lesion. Marked proximal tortuosity of the infarct-related artery, the presence of a calcified lesion, and the presence of a bifurcation lesion are independent predictors of unsuccessful catheter passage through the lesion. Failure of TA limits the ability of direct stenting but has no influence on restoration of coronary flow as compared to successful TA. Age above 60 years and the circumflex artery as infarct-related artery were independently associated with the absence of aspirated material after successful passage of the infarct-related lesion. In our analysis of 1,399 unselected acute STEMI patients in whom TA was attempted in adjunct to PPCI, compared with successful TA, the failure to reach and/or cross the lesion and the absence of aspirate did not affect 1-year all-cause mortality.

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