ORIGINAL ARTICLE

The relationship between visible thrombus aspiration material with no-reflow and in-hospital mortality ratio in patients with anterior ST-elevation myocardial infarction treated with primary percutaneous coronary intervention

Anterior miyokart enfarktüsü nedeniyle primer perkütan koroner girişim uygulanan hastalarda trombüs aspirasyonu ile görülebilir aspirat gelmesinin no reflow ve hastane içi mortalite ile ilişkisi

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ABSTRACT

Objective: The benefit of intracoronary thrombus aspiration (TA) during primary percutaneous coronary intervention (pPCI) in patients with ST-segment elevation myocardial infarction (STEMI) is not yet fully clear. The aim of this study was to investigate the clinical impact of visible thrombus aspiration (VTA) material.

Methods: A total of 295 patients with a Thrombolysis in Myocardial Infarction (TIMI) flow score of 0 or 1 after an anterior STEMI were included in the study. Manual TA devices were used before performing PCI. The patients were divided into 2 groups: (1) visible thrombus aspiration (VTA) group and (2) non-visible thrombus aspiration (non-VTA) group. No-reflow was defined as TIMI grade 0, 1, or 2 flow, or TIMI grade 3 with a myocardial blush of grade 0 or 1. The primary endpoint was the occurrence of no-reflow.

Results: VTA was retrieved in 178 (60.3%) of the patients. A no-reflow determination was significantly less frequent in the VTA group ($p<0.001$). The ejection fraction and ST-segment resolution values were higher, and the in-hospital mortality, Killip class II-IV rating, and post-pPCI TIMI frame count were lower in the VTA group ($p<0.05$ for each).

Conclusion: VTA predicted a lower rate of in-hospital mortality and no-reflow in patients with anterior STEMI who underwent pPCI.

ÖZET

Amaç: Primer perkütan girişim (PKG) sırasında uygulanan trombüs aspirasyonun faydası hala tartışmalıdır. Biz bu çalışmada görülebilir trombüs aspiratının klinik olarak etkisini araştırmayı amaçladık.

Yöntemler: Çalışmaya prospektif olarak 295 TIMI 0 veya I olan anteriyor ST segment yükselmeli miyokart enfarktüslü hasta dahil edildi. Trombüs aspirasyonu için PKG öncesinde manuel trombüs aspirasyon cihazları kullanıldı. Hastalar görülebilir aspirat elde edilenler ve görülebilir aspirat elde edilmeyenler olmak üzere iki gruba ayrıldı. No-reflow bulgusu, görülebilir aspirat elde edilen grupta anlamlı olarak düşük izlendi.

Bulgular: Görülebilir trombüs aspirasyonu tüm hastaların 178 (%60.3) inde elde edildi. No reflow belirgin anlamlı olarak görülebilir trombüas aspirasyonu grubunda düşük izlendi ($p<0.001$). Ejeksiyon fraksiyonu, ST segment rezülosyonu anlamlı olarak görülebilir trombüs aspirasyonu sağlanan grupta yüksek bulunurken hastane içi mortalite, Killip II-IV ve PKG sonrasındaki TIMI frame count belirgin olarak görülebilir trombüs aspirasyonu elde edilmeyen gruba göre düşük izlendi (hepsi için $p<0.05$).

Sonuç: Görülebilir trombüs aspirasyonu elde edilmesi anterior ST elevasyonlu miyokart enfarktüslü hastalarda kısa dönem klinik sonuçlar ve prognoz hakkında bilgi sağlayabilir.

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Primary percutaneous coronary intervention (pPCI) has become the treatment of choice for ST-segment elevation myocardial infarction (STEMI). The main goal in the treatment of STEMI is early revascularization and restoration of normal coronary flow. Nonetheless, despite restoration of epicardial infarct-related artery flow, microvascular obstruction occurs in some cases.[1] No-reflow is considered a dynamic process characterized by multiple pathogenic components, including distal atherothrombotic embolization, ischemic injury, reperfusion injury, and susceptibility of coronary microcirculation to injury, and current methods of treatment are limited.[1,2] Some studies have suggested that there may be less risk of distal embolization of atherothrombotic material during the procedure, thus better vascular perfusion and smaller infarct size.[3–5] The first meta analyses demonstrated a clinical benefit to thrombus aspiration (TA),[6–9] while later studies have failed to demonstrate a superiority of TA compared with the routinely performed pPCI.[10–12] In addition, TA does not always result in the retrieval of visible aspiration material. The hypothesis of this research was that visible atherothrombotic material collected during TA may prevent the reoccurrence of no-reflow. Therefore, this study was designed to investigate the impact of visible thrombus aspiration (VTA) material on myocardial flow in patients with anterior STEMI who underwent pPCI.

METHODS

Study population

A total of 295 patients (175 male, 120 female; mean age 55.6±11.4 years) from between June 2012 and July 2013 who had an anterior STEMI Thrombolysis in Myocardial Infarction (TIMI) flow score of 0 or 1 and who underwent pPCI with thrombus aspiration within 12 hours of symptom onset and an ST elevation of >1 mV in 2 contiguous limb leads or ≥0.2 mV in 2 contiguous precordial leads were prospectively included in the study. The exclusion criteria included prior coronary artery bypass surgery or treatment with fibrinolytic therapy for index STEMI, late presentation (>12 hours), failed pPCI (inability to cross the lesion with a guidewire or inability to complete stent implantation), infectious or inflammatory disease, severe liver (history of hepatitis or alanine aminotransferase >3 times the normal value, albumin <2.5 g/dL) or renal disease (estimated glomerular filtration rate calculated using the formula of Modification of Diet in Renal Disease score <60 mL/minute/1.73 m^2), neoplasm or hematological disorder, heart failure before the index event, severe heart valve disease, or use of an antioxidant drug (such as a vitamin supplement).

Abbreviations:

MBG	*Myocardial blush grade*
pPCI	*Primary percutaneous coronary intervention*
STEMI	*ST-segment elevation myocardial infarction*
TA	*Thrombus aspiration*
TIMI	*Thrombolysis in Myocardial Infarction*
TOTAL	*Trial of Routine Aspiration Thrombectomy with PCI versus PCI Alone in Patients with STEMI*
VTA	*Visible thrombus aspiration*

Following hospital admission, a detailed medical history of all of the patients was recorded and a complete physical examination was performed. Each participant was questioned about major cardiovascular risk factors, such as age, sex, diabetes mellitus, smoking status, and hypertension. In addition, systolic and diastolic blood pressure (BP) values were recorded. All of the patients underwent a comprehensive transthoracic echocardiography during the hospitalization period. The time interval from the onset of symptoms to hospital admission and Killip classification for prognosis were also noted in each case. The left ventricle ejection fraction was measured using Simpson's method according to the guidelines of the American Society of Echocardiography.[13] The local ethics committee approved the study protocol, and each participant provided written, informed consent.

Thrombus aspiration technique

All of the study patients were medicated with 300 mg aspirin and a loading dose of 600 mg clopidogrel before performing the pPCI. After an intravenous injection of unfractionated heparin (70 U/kg), if necessary, additional boluses were administered to achieve a minimum activated clotting time of 250 seconds. The first procedural step in each case was the passing of a floppy guidewire through the culprit lesion. A thrombus aspiration catheter was advanced and positioned just before the culprit lesion, at which point aspiration was initiated before crossing the lesion. The aspiration catheter was passed through the lesion several times such that a minimum of 2 aspiration injectors were filled with aspirated blood and thrombus material (≥40 mL in total). If the aspiration catheter did not cross the target lesion, we performed predilation with a small-diameter balloon catheter to enable aspiration

to be reperformed. The PCI was performed according to current best practices. The use of glycoprotein IIb/IIIa receptor inhibitors was left at the discretion of the operating physician. A manual TA catheter (6f VMAX Astron, crossing profile, 0.068 in; Biotronik AG, Berlin, Germany) was used. The angiographic thrombus burden score was not routinely assessed before the coronary intervention. Following the procedure, the patients were divided into 2 groups according to the VTA. VTA was defined as collected visible aspiration material, including atherothrombotic debris or thrombus, such as in Fig. 1. Non-VTA was defined as no visible aspiration material and only blood. No-reflow was defined as TIMI grade 0, 1, and 2 flows, or TIMI grade 3 with a myocardial blush grade (MBG) of 0 or 1. The primary endpoints were the occurrence of no-reflow and 90-minute ST-segment resolution at a rate of >70%.[2] The patients were divided into 2 groups (VTA and non-VTA) according to the visibility of aspiration material.

Statistical analysis

The analyses were performed using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean±SD and categorical variables were expressed as percentages. Analysis of normality was performed with the Kolmogorov–Smirnov test. An independent-sample t-test was used in the analysis of continuous variables. Categorical variables were compared using a chi-square test. Univariate logistic regression analysis was performed, and the variables that were found to be statistically significant were analyzed with multivariate logistic regression analysis. A p value of <0.05 was considered statistically significant.

RESULTS

In the present study, 295 patients (175 male, 120 female; mean age 55.6±11.4 years) with STEMI who underwent pPCI were evaluated. There were 178 patients (109 male; mean age: 54.8±10.6 years) in the VTA group and 117 patients (66 male; mean age: 56.7±12.4 years) in the non-VTA group.

Baseline, echocardiographic, laboratory, and clinical characteristics of the study population are shown in Table 1. The baseline and laboratory characteristics were similar between groups, except for systolic blood pressure (SBP) and diastolic blood pressure (DBP), which was found to be higher in the non-VTA group (p<0.05, for both). Additionally, ejection fraction values white blood cell (WBC) and neutrophils in the VTA group were higher compared with the non-VTA group (p<0.05 for all).

Clinical characteristics of door-to-balloon time, Killip class II-IV, intra-aortic balloon pump use, and in-hospital mortality were significantly lower in the VTA group (p<0.05 for all). Furthermore, the electrocardiographic characteristic of ST segment resolution

Figure 1. Examples of visible thrombus aspiration material.

Table 1. Baseline, echocardiographic, laboratory, and clinical characteristics of study groups

Variables	Visible thrombus VTA aspiration group (n=178)	Non-Visible thrombus aspiration group (n=117)	*p*
Baseline characteristics			
Age (years)	54.8±10.6	56.7±12.4	0.157
Gender (male)	109 (61.2)	66 (56.4)	0.240
Body mass index (kg/m^2)	27.5±4.3	26.8±4.2	0.225
Systolic blood pressure (mm Hg)	131.3±24.4	138.9±32.4	0.022
Diastolic blood pressure (mm Hg)	80.1±15.3	85.5±18.1	0.006
Heart rate (b/m)	85.5±14.7	87.3±15.6	0.336
Smoking, n (%)	93 (52.2)	65 (55.6)	0.331
Diabetes, n (%)	40 (22.5)	33 (28.2)	0.164
Hypertension, n (%)	72 (40.4)	50 (42.7)	0.393
Hyperlipidemia, n (%)	40 (22.5)	18 (15.4)	0.088
Family history, n (%)	86 (48.3)	50 (42.7)	0.206
Laboratory findings			
Glucose (mg/dL)	172.8±75.5	166.8±70.6	0.493
Total cholesterol (mg/dL)	202.8±42.9	198.4±41.7	0.382
Triglyceride (mg/dL)	157.0±84.1	143.9±81.5	0.185
High density lipoprotein cholesterol (mg/dL)	40.3±11.4	40.4±11.5	0.960
Low density lipoprotein cholesterol (mg/dL)	133.4±35.0	132.1±34.8	0.756
Creatinine (mg/dL)	0.8±0.1	0.8±0.2	0.451
Uric acid (mg/dL)	5.1±1.4	5.5±1.6	0.050
Peak creatine kinase-MB (ng/mL)	168.0±113.3	145.0±112.4	0.088
Hemoglobin (mg/dL)	14.1±1.4	14.1±1.3	0.972
White blood cell	13.7±4.1	12.2±3.5	0.001
Mean platelet volume (fL)	10.1±1.0	10.0±1.2	0.659
Platelet count	240.1±74.4	229.1±80.7	0.213
Neutrophil (x10^9/L)	10.0±4.2	8.9±3.5	0.019
Lymphocyte (x10^9/L)	2.4±1.4	2.4±1.1	0.847
Neutrophil/lymphocyte ratio	5.5±3.7	4.9±3.3	0.130
Echocardiography			
Left ventricular ejection fraction (%)	45.7±6.3	43.9±6.8	0.019
Clinical findings, n (%)			
Infarction time, h	4.4±3.9	4.6±3.7	0.732
Door-balloon time, min	25.9±7.6	28.0±6.7	0.015
Killip class II–IV	23 (12.9)	26 (22.2)	0.027
Intra aortic balloon pump	0 (0)	4 (1.4)	0.024
Cardiac arrest			
In-hospital mortality	3 (1.7)	7 (6)	0.049
Re-infarct	5 (2.8)	6 (5.1)	0.235
Acute stent thrombosis	5 (2.8)	6 (5.1)	0.235
Major bleeding	0 (0)	1 (0.9)	0.397
Minor bleeding	6 (3.4)	7 (6)	0.216
Blood transfusion	0 (0)	1 (0.9)	0.397

Table 1. (cont.)

Variables	Visible thrombus VTA aspiration group (n=178)	Non-Visible thrombus aspiration group (n=117)	*p*
Electrocardiography			
ST segment resolution ≥70%	117 (65.7)	50 (42.7)	<0.001
30<ST segment resolution <70%	55 (30.9)	59 (50.4)	0.001
ST segment resolution <30%	6 (3.4)	6 (5.1)	0.323
Previous drug use, n (%)			
Angiotensin converting enzyme inhibitor	40 (22.5)	24 (20.5	0.402
Angiotensin receptor blocker	14 (7.9)	6 (5.1)	0.252
Statin	22 (12.4)	13 (11.1)	0.448
Beta blocker	16 (9)	7 (6)	0.238
Oral anti-diabetic	31 (17.4)	25 (21.4)	0.243

Table 2. Comparison of the procedural characteristics of study groups

Variables	Visible thrombus VTA aspiration group (n=178)	Non-Visible thrombus aspiration group (n=117)	*p*
Procedural characteristics			
Initial SYNTAX score	17.6±6.2	17.1±6.3	0.527
Post-pPCI SYNTAX score	12.6±5.4	12.7±5.1	0.935
LMCA lesion, n (%)	3 (1.7)	0 (0)	0.218
Total stent length (mm)	20.1±5.7	21.6±5.8	0.128
Stent diameter (mm)	3.3±0.4	3.2±0.3	0.001
Glycoprotein IIb/IIIa inhibitors, n (%)	54 (30.3)	44 (37.6)	0.121
Mean stent count (n)	1.3±0.5	1.4±0.6	0.222
Bifurcation intervention, n (%)	6 (3.4)	4 (3.4)	0.612
Post-pPCI TIMI frame count	36.2±15.4	42.6±22.6	0.004
Intervention time, min	8.4±4.9	9.2±6.4	0.248
Side branch loss, n (%)	4 (2.2)	6 (5.1)	0.157
No-reflow, n (%)	28 (15.7)	47 (40.2)	<0.001
Pre-dilatation, n (%)	8 (4)	6 (5)	0.457

ETA: Effective thrombus aspiration; SYNTAX: SYNergy between percutaneous coronary intervention with TAXus and cardiac surgery; pPCI: Primery percutaneous coronary intervention; LMCA: Left main coronary artery.

was significantly higher in the VTA group (p<0.05).

Procedural characteristics

Procedural characteristics of total stent length (mm), initial SYNTAX score, post-primary PCI SYNTAX score, predilatation, and the use of IIb/IIIa glycoprotein inhibitors were similar in the 2 groups (p>0.05 for all). However, the no-reflow frequency and post-pPCI TIMI frame count were higher in the non-VTA group (p<0.05 for all). A comparison of the procedural characteristics is shown in Table 2.

Multivariate logistic regression analysis demonstrated an independent negative relationship between VTA and no-reflow (beta=3.597, 95% confidence interval= 2.081–6.217; p<0.001), which can be seen in Table 3.

Table 3. Multivariate logistic regression analysis between visible thrombus aspiration and no-reflow

VTA	Odds ratio	95% CI (lower-upper)	*p*
No reflow	3.597	2.081–6.217	<0.001

VTA: Visible thrombus aspiration; CI: Confidence interval.

DISCUSSION

The results of the present study demonstrated a lower rate of no-reflow and in-hospital mortality in VTA patients with STEMI undergoing pPPC.

No-reflow is one of the undesirable complications of PCI in patients with STEMI and is defined as failure to restore myocardial perfusion after elimination of the epicardial coronary occlusion. The main mechanism of no-reflow is microembolization of atherothrombotic debris during PCI[14] and no-reflow is associated with a poor short-term and long-term prognosis in patients with STEMI. Therefore, the prediction, prevention, and treatment of no-reflow are likely to have an important impact on the outcome of pPCI. The prevention strategy may be pharmacological or device-based. Decreasing the thrombus burden in the culprit artery is very important to prevent distal embolization, which is one of the mechanisms of no-reflow, and it improves myocardial perfusion.[15,16] Thus, a lower no-reflow ratio was observed in the patients in the VTA group.

TA, like embolic protection devices, is one method of preventing a distal microembolism. But the role of coronary TA in pPCI for STEMI has been controversial. There are insufficient data on the potential benefits of selective aspiration. A recent meta-analysis of randomized trials suggested that TA is associated with a reduction of distal embolization and improvement of myocardial reperfusion, compared with routine primary or rescue PCI.[17] Evidence of a beneficial effect of manual TA on myocardial perfusion and mortality has been reported.[18–22] Nevertheless, recent studies have showed no advantage to TA over routine PCI and current European Society of Cardiology Myocardial Revascularization guidelines recommend the routine use of TA with a Class III indication.[23–27] A meta-analysis of 16 randomized trials (not including the Trial of Routine Aspiration Thrombectomy with PCI versus PCI Alone in Patients with STEMI [TOTAL] trial) indicated that TA did not reduce the rate of all-cause mortality.[28] In these studies, TA was performed routinely, it was not assessed whether or not thrombus material was retrieved, and they included all types of STEMI. Keskin et al.[29] reported no benefit from TA in patients with STEMI and a large native coronary artery thrombus burden. As far as we know, ours is the first TA study designed using visible aspiration material and including only anterior STEMI patients.

Manolis et al.[30] found that selective thromboaspiration for angiographically visible thrombi in myocardial infarction patients undergoing PCI may prevent the no-reflow phenomenon in acute coronary syndromes. Boghdady et al.[31] also reported higher MBG levels and fewer instances of no-reflow during rescue PCI with TA.

The results of the Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction (TAPAS) study indicated that the improvement in myocardial perfusion obtained with manual TA compared with conventional PCI and TA before stenting of the culprit artery seemed to improve the 1-year clinical outcome after PCI for STEMI patients.[18,19] Consistent with our study, similar findings have also been observed in terms of myocardial reperfusion and mortality.

TOTAL is the largest randomized trial so far to compare routine manual TA with PCI alone during STEMI PCI. TA in the TOTAL study resulted in improved ST-segment resolution and reduced the occurrence of angiographic distal embolization.[12] In the TOTAL angiographic substudy, routine TA during pPCI did not result in improved MBG or post-PCI TIMI flow grade.[29] Also, the TOTAL and the Tenecteplase versus Alteplase for Stroke Thrombolysis Evaluation (TASTE) trials demonstrated no difference in cardiovascular death at 30 days.[26,32] However, in the subgroup with a high thrombus burden (TIMI thrombus grade ≥3), TA was associated with fewer cardiovascular deaths in the TOTAL study.[15] One possible explanation for this is that aspiration may be more effective with a high thrombus burden, preventing distal microembolism and reducing no-reflow, which affects mortality. This may be why we found a lower in-hospital mortality rate in the VTA group. The lower in-hospital mortality of patients with VTA in our study may also be associated with a shorter door-to-balloon time, lower Killip class, and better TIMI flow after TA.

Mahmoud et al.[33] demonstrated better myocardial reperfusion in patients with STEMI treated with TA with pPCI compared with conventional pPCI.[33] Additionally, 2 small, randomized studies reported that TA was associated with better left-ventricular remodeling compared with routine PCI.[34] In this study, the benefit of TA on myocardial reperfusion was mainly based on the subset of patients with a large thrombus burden and total occlusion of the culprit coronary artery.[34]

Similarly, we found a lower post-pPCI TIMI frame count that supported better myocardial reperfusion in the VTA group irrespective of thrombus burden.

As a result of the present study, although large randomized studies have shown no benefit to the routine use of TA in patients with STEMI, we may speculate that VTA retrieved with TA may predict the occurrence of no-reflow after stent deployment and reduce in-hospital mortality.

Limitations

First, we did not use intravascular ultrasound to quantitatively evaluate thrombus burden and plaque content. Another limitation of this study is that it was not based on the thrombus burden. We assessed the TA material only by aspirate visibility, and while there is no accepted single method of quantification, this is a subjective criterion. Also, intracoronary imaging predictors of the no-reflow phenomenon, such as an attenuated plaque, diffuse coronary atherosclerosis, or severe vascular calcification, were not considered in the analysis. One further limitation of our study is that we did not perform routine postdilatation. Our results cannot be generalized beyond this group of patients.

Conclusion

The most important way to prevent no-reflow is to reduce embolization of thrombotic debris to the microvascular area. From this point of view, we can expect that improved epicardial and myocardial perfusion following TA may positively affect clinical outcomes, such as no-reflow and in-hospital mortality. The main target of the present study was to the demonstrate the impact of retrieving VTA material rather than to investigate the indications for TA. Our results suggest that obtaining macro TA material may predict short-term clinical outcomes and prognosis in patients with anterior STEMI.

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