Clinical research

# Can thrombectomy and catheters used increase angiographically visible distal embolization in ST elevation myocardial infarction?

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**Submitted:** 26 October 2016
**Accepted:** 28 November 2016

Arch Med Sci Atheroscler Dis 2016; 1: e139–e144
DOI: 10.5114/amsad.2016.64443


## Abstract

**Introduction:** Primary percutaneous coronary intervention (PPCI) is the preferred treatment of ST segment elevation myocardial infarction (STEMI). Manual thrombectomy catheters developed to prevent distant embolization are theoretically attractive; however, their clinical efficacy remains controversial. The effects of manual thrombectomy catheters on angiographically visible distal embolisation (AVDE) have not been studied so far. The aim of this study was to evaluate the effects of manual thrombectomy during PPCI on AVDE and to investigate whether there are differences in the incidence of AVDE according to the catheters used.

**Material and methods:** Six hundred thirty-six consecutive patients undergoing primary PCI were included in the study between January 2010 and December 2012. Patients were divided into two groups: the PCI only group (465 patients) and the PCI plus manual thrombectomy group (171 patients).

**Results:** Thrombus aspiration was associated with higher AVDE (13.55% vs. 26.9%, $p$ = 0.0001), lower thrombolysis in myocardial infarction frame rate (2.49 ±0.86 vs. 2.79 ±0.57, $p$ = 0.0001), lower myocardial blush grade (2.31 ±0.87 vs. 2.47 ±0.7, $p$ = 0.016), lower ejection fraction (EF) (49.9 ±8.5 vs. 46.1 ±9.6, $p$ = 0.0001) and higher maximal troponin release (15.7 ±16 vs. 9.4 ±11, $p$ = 0.0001). No difference was observed in terms of mortality between the groups in follow-up (5.2% vs. 9.03%, $p$ = 0.12). Angiographically visible distal embolisation was observed more frequently with Invatec catheters ($p$ = 0.0001).

**Conclusions:** Angiographically visible distal embolisation during primary PCI occurs in a significant number of patients treated with manual thrombectomy. The results indicated that the incidence of AVDE may be different depending on the thrombectomy catheters used.

**Key words:** complications, thrombectomy, primary percutaneous coronary intervention, ST segment elevation myocardial infarction, angiographically visible distal embolisation, thrombectomy catheters.

## Introduction

Primary percutaneous coronary intervention (PPCI) is the preferred treatment of ST segment elevation myocardial infarction (STEMI). Although the infarct-related artery is opened, distal movement of the thrombus resulting in impaired myocardial perfusion occurs in a large percentage of patients during PPCI [1]. This condition is named angiographically visible distal embolization (AVDE) and has been reported in 8% to 16% of patients with STEMI treated with PPCI. Angiographically visible distal embolization is associated with impaired reperfusion, larger infarct size, lower ejection fraction and lower survival rates [2–4]. Manual thrombectomy catheters developed to prevent distal embolization are theoretically attractive, but their clinical efficacy remains controversial [5–7]. The effects of manual thrombectomy catheters on AVDE have not been studied so far.

The aim of this study was to evaluate the effects of manual thrombectomy during PPCI on AVDE and to investigate whether there are differences in the incidence of AVDE according to the catheters used.

## Material and methods

### Study population

This comparative study was conducted in a tertiary heart center with a retrospective design. Patients with STEMI presenting within 12 h of symptom onset and undergoing primary PCI between January 2010 and December 2012 were recruited to the study. Exclusion criteria were defined as renal failure (creatinine $\geq$ 3 mg/dl), cardiogenic shock on admission, urgent coronary artery bypass grafting requirement on admission, history of previous coronary artery bypass grafting and/or valve replacement surgery, pretreatment with glycoprotein IIb–IIIa inhibitors before primary PCI, and previous medical therapy with clopidogrel or oral anticoagulants. Patients with unsatisfactory coronary angiograms with no clear visualization of the distal coronary vascular bed were also excluded. The clinical, demographic and laboratory data of the patients were taken from medical records. Estimated glomerular filtration rate (e-GFR) was calculated according to the Modification of Diet in Renal Disease (MDRD) formula [8]. Patients were divided into two groups: the PPCI only group and the PPCI plus manual thrombectomy group. The study was conducted in accordance with the Declaration of Helsinki, Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines. The study protocol was approved by the ethics committee of the institution, and all patients gave written informed consent for participation.

### Procedure of PPCI

Routine pretreatment with 300 mg of chewable aspirin, a 600 mg loading dose of clopidogrel and intracoronary 70 U/kg of unfractionated heparin was given to all patients before PPCI. Intracoronary nitroglycerin was also given to all patients if not contraindicated. Coronary angiography and interventions were performed by experienced operators with standard methods. Once a guide wire had been passed throughout the target lesion, the next step was the advancement of the manual thrombus aspiration catheter into the target lesion according to the manufacturer's recommendations in the manual thrombectomy group. In the PPCI only group, balloon dilatation and stenting were performed conventionally. The decision of whether to use manual thrombectomy was made by the operators performing the interventions. Three thrombectomy catheters were used according to availability: the Export thrombus aspiration catheter (Medtronic Vascular, USA), the Diver C.E. Clot Extraction Aspiration Catheter (Invatec, Italy), and the Emax aspiration catheter (Tsunamed, Germany). Thrombolysis in myocardial infarction (TIMI) flow grades were assessed as previously described [9]. Myocardial blush grades were assigned as previously described by Van't Hof *et al.* [2]. Angiographic evidence of a thrombus was assessed according to the criteria summarized by Mabin *et al.* [10]. Angiographically visible distal embolization was defined as a persisting distal filling defect with an abrupt cut-off in one or more peripheral coronary branches of the infarct-related artery as a result of dislodgement of a proximal thrombus spontaneously or following wiring or catheter instrumentation. Preprocedural lesion characteristics, Syntax score, initial and postprocedural TIMI flow grades, myocardial blush grades and development of the no-reflow phenomenon were evaluated by two cardiologists blinded to the study groups at the end of diastole in at least two non-foreshortened angiographic views. Post-procedural transthoracic echocardiography examination was performed using a Vivid S6 instrument with a 3.5 MHz phased array transducer (GE Medical Systems, Horten, Norway) [11].

### Statistical analysis

Statistical analyses were performed with the Number Cruncher Statistical System software package 2007 (statistical software, Utah, USA). Data were evaluated by descriptive statistical methods as mean and standard deviation. Binary comparisons of the groups were made. The independent *t* test for normally distributed variables and the Mann-Whitney *U* test for non-normally distributed variables were used. For the qualitative compari-

sons of the data, the $\chi^2$ test was used. In identifying factors affecting the development of AVDE, logistic regression analysis was used. A *p*-value lower than 0.05 was accepted as statistically significant.

## Results

In the whole study group, AVDE was observed in 109 (17%) of 636 patients. Angiographically visible distal embolization was observed in 46 (26.9%) of 171 patients treated with manual thrombectomy and 63 (13.5%) of 465 patients treated with PPCI only ($p$ = 0.0001). Demographic, clinical and laboratory characteristics of the groups are given in Table I. The patients in the thrombectomy group were younger (53.85 ±12.25 vs. 56.6 ±11.91, $p$ = 0.01). There was no difference between the two groups in terms of gender, history of previous myocardial infarction, hypertension, diabetes mellitus, smoking and e-GFR. Left ventriculat ejection fraction (LVEF) measurements before hospital discharge were lower in the thrombectomy group than the PCI only group (46.1 ±9.6% vs. 49.9 ±8.5%, $p$ = 0.0001). While there was no difference between groups with regard to initial troponin levels, post-PCI peak troponin levels were higher in patients treated with thrombectomy (15.73 ±16.28 vs. 9.48 ±11.6, $p$ = 0.0001). However, there was no mortality difference in mid-term follow-up between groups (9.03% vs. 5.26%, $p$ = 0.12) (Table I). In view of the procedural parameters, balloon utilization, balloon length and stent length were similar between groups (Table II). Syntax score was lower in patients treated with thrombectomy than without (14.74 ±8.61 vs. 17.32 ±10.57, $p$ = 0.018) (Table II). Thrombectomy was performed more frequently in LAD lesions ($p$ = 0.0001). Stent-implanted patients were higher in the PPCI only group (88.3% vs. 77.5%, $p$ = 0.001) (Table II). However, balloon and stent diameters were significantly larger in the thrombectomy group (2.8 ±2.8 vs. 2.3 ±0.6, and 3.4 ±0.4 vs. 3.2 ±0.5, $p$ = 0.0001, respectively). Myocardial blush grade and post-PCI TIMI flow grade were also lower in the thrombectomy group than the PPCI only group (2.31 ±0.8 vs. 2.47 ±0.7, $p$ = 0.016 and 2.49 ±0.8 vs. 2.79 ±0.5, $p$ = 0.0001, respectively) (Table II).

Longer stent length, higher balloon diameter, lower Syntax score, lower LVEF and chronic renal failure were found to be associated with AVDE in univariate analysis, and these variables were entered into multivariate stepwise logistic regression analysis. In the multivariate analysis, stent length, EF and Syntax score were found to be predictors of AVDE (OR = 1.11, 95% CI: 1.06–1.16, $p$ = 0.0001 and OR = 0.85, 95% CI: 0.80–0.91, $p$ = 0.0001 and OR = 0.85, 95% CI: 0.79–0.91, $p$ = 0.0001, respectively) (Table III). There was an association between AVDE frequency and the types of thrombectomy catheters used. Angiographically visible distal embolization was observed more frequently with Invatec catheters ($p$ = 0.0001) (Table IV).

**Table I.** Demographic, clinical and laboratory characteristics of the groups

| Parameter | Thrombectomy (–) ($n$ = 465) | | Thrombectomy (+) ($n$ = 171) | | *P*-value |
|---|---|---|---|---|---|
| Age [years] | 56.6 ±11.91 | | 53.85 ±12.25 | | 0.01 |
| Sex: | | | | | |
| Female | 93 | 20.00% | 26 | 15.20% | 0.169 |
| Male | 372 | 80.00% | 145 | 84.80% | |
| AVDE (+) | 63 | 13.55% | 46 | 26.90% | 0.0001 |
| Hypertension | 172 | 36.99% | 67 | 39.18% | 0.613 |
| Diabetes | 117 | 25.16% | 37 | 21.64% | 0.358 |
| Smoking | 332 | 71.40% | 128 | 74.85% | 0.388 |
| Previous MI | 76 | 16.34% | 22 | 12.87% | 0.281 |
| Follow-up [days] | 677.64 ±260.12 | | 734.33 ±353.23 | | 0.028 |
| EF (%) | 49.92 ±8.53 | | 46.14 ±9.67 | | 0.0001 |
| e-GFR [ml/min] | 94.09 ±30.24 | | 98.85 ±29.3 | | 0.083 |
| Troponin (initial) [ng/ml] | 3.51 ±7 | | 5.08 ±11.02 | | 0.046 |
| Troponin (max) [ng/ml] | 9.48 ±11.6 | | 15.73 ±16.28 | | 0.0001 |
| Mortality | 42 | 9.03% | 9 | 5.26% | 0.121 |

*AVDE – angiographically visible distal embolization, EF – ejection fraction, e-GFR – estimated glomerular filtration rate.*

**Table II.** Procedural features of the patient groups

| Variable | Thrombectomy (–) (*n* = 465) | | Thrombectomy (+) (*n* = 171) | | *P*-value |
|---|---|---|---|---|---|
| Infarct-related artery: | | | | | |
| LAD | 112 | 24.09% | 81 | 47.37% | 0.0001 |
| Cx | 102 | 21.94% | 15 | 8.77% | |
| RCA | 251 | 53.98% | 75 | 43.86% | |
| Syntax score | 17.32 ±10.57 | | 14.74 ±8.61 | | 0.018 |
| NRF | 55 | 11.83% | 25 | 14.62% | 0.346 |
| Balloon | 348 | 75.32% | 119 | 69.59% | 0.145 |
| Balloon diameter | 2.3 ±0.65 | | 2.85 ±2.87 | | 0.001 |
| Balloon length | 15.48 ±6.45 | | 15.87 ±3.57 | | 0.531 |
| Stent implantation | 410 | 88.37% | 131 | 77.51% | 0.001 |
| Stent diameter | 3.21 ±0.53 | | 3.4 ±0.42 | | 0.0001 |
| Stent length | 24.4 ±10.15 | | 25.68 ±11.32 | | 0.221 |
| Pre-PCI TIMI score | 0.65 ±1.03 | | 0.11 ±0.4 | | 0.0001 |
| Post-PCI TIMI score | 2.79 ±0.57 | | 2.49 ±0.86 | | 0.0001 |
| MBG | 2.47 ±0.7 | | 2.31 ±0.87 | | 0.016 |

*LAD – left anterior descending artery, Cx – circumflex artery, RCA – right coronary artery, NRF – no re-flow phenomenon, PCI – percutaneous coronary intervention, MBG – myocardial blush grade.*

**Table III.** Logistic regression analysis of factors that can predict AVDE

| Variable | B | *P*-value | OR | 95% CI |
|---|---|---|---|---|
| Balloon diameter | 0.64 | 0.129 | 1.90 | 0.83 |
| Stent length | 0.10 | 0.0001 | 1.11 | 1.06 |
| EF% | –0.16 | 0.0001 | 0.85 | 0.80 |
| Syntax score | –0.17 | 0.0001 | 0.85 | 0.79 |

*AVDE – angiographically visible distal embolization, EF – ejection fraction.*

## Discussion

The major finding of the present study is that manual thrombus aspiration in patients with STEMI did not reduce the frequency of AVDE although thrombectomy was performed according to the manufacturer's advice. On the contrary, thrombus aspiration was found to be associated with increased frequency of AVDE. The results also indicated that the incidence of AVDE may be different depending on the thrombectomy catheters used. According to our results, stent length, low EF and low Syntax score may also predict the development of AVDE.

In previous studies, the incidence of AVDE in patients with STEMI undergoing primary PCI varied between 8 and 16% [2–4]. The incidence of AVDE was 17% in our study. A reasonable explanation of the higher incidence of AVDE in our study may be the exclusion of patients administered upstream GpIIb/IIIa inhibitors. An angiographically visible distal embolization is associated with the no-reflow phenomenon, microvascular obstruction and impaired myocardial perfusion after PPCI [12–17]. It is associated with larger myocardial infarction size, lower LVEF and a higher mortali-

**Table IV.** Catheter type used in patients with and without AVDE

| Catheter type | AVDE (–) (*n* = 527) | | AVDE (+) (*n* = 109) | | *P*-value |
|---|---|---|---|---|---|
| None | 402 | 76.28% | 63 | 57.80% | 0.0001 |
| Export | 24 | 4.55% | 8 | 7.34% | |
| Emax | 92 | 17.46% | 29 | 26.61% | |
| Invatec | 9 | 1.71% | 9 | 8.26% | |

*AVDE – angiographically visible distal embolization.*

ty rate in patients with STEMI [12–17]. Recently, Yunoki *et al.* reported that thrombus composition is also associated with the development of AVDE and AVDE is more often observed in thrombi with an erythrocyte-rich component [14].

In the present study, we investigated whether manual thrombus aspiration is associated with AVDE. According to our knowledge, the present study is unique in reporting increased incidence of AVDE in patients with STEMI treated with manual thrombectomy during primary PCI. The AVDE incidence was 26.9% in STEMI patients treated with manual thrombectomy in our study. Manual thrombectomy was associated with worse TIMI flow grade and myocardial blush grade, lower predischarge LVEF and higher troponin release. In a recent meta-analysis of 14 randomized trials on thrombectomy involving a total of 20 285 patients, it was found that despite the benefits of thrombectomy in terms of post-procedural TIMI-3 flow, myocardial blush grade, the occurrence of distal embolization and ST segment resolution, no benefit was observed in terms of mortality, and it increased the incidence of ischemic stroke [18]. The initial enthusiasm for manual thrombectomy emerged after the apparent mortality benefit observed in the TAPAS trial [19]. Recently published larger trials on routine manual thrombectomy as compared with PPCI alone showed that routine manual thrombectomy did not reduce the risk of death, recurrent MI, shock or class 4 heart failure [17, 20]. Although thrombectomy devices aim to remove the thrombus from the culprit lesion and to prevent distal embolization during PCI, distal embolization may additionally occur as a result of mechanical manipulation of the culprit lesion during thrombectomy. Our results suggest that manual thrombectomy may have deleterious effects rather than beneficial ones. The negative result of this trial testing thrombectomy catheters during primary PCI has questioned not only the effects of thrombectomy on AVDE but also the impact of catheters on AVDE incidence. A possible explanation for our results may be the harmful effects of the thrombectomy catheters on the infarct-related artery. This study using indirect measures of reperfusion such as TIMI flow and myocardial blush grade indicates that reperfusion may not be improved after thrombectomy and distal embolization may worsen the prognosis. However, whether the higher incidence of AVDE associated with thrombectomy would transform into a worse prognosis is not known exactly. The results also showed that AVDE was observed more frequently with Invatec catheters than Export and Imax catheters in our study. However, in our opinion, these results are not sufficient to make a judgment about a catheter, because of the relatively small sample size of the study.

This study does have some limitations to take into consideration. This is a single-center retrospective study. Glycoprotein IIb-IIIa inhibitors were not used, and their potential effects on AVDE could not be studied. The use of thrombectomy catheters was not equal due to the availability, which should be considered in the interpretation of the results. The pre-PCI TIMI score and SYNTAX score were lower in the thrombectomy group; this may cause a patient selection bias, but thrombectomy catheters were used in patients who would benefit most. In other words, thrombectomy catheters were used in patients with a low atherosclerotic burden and high thrombus load. Since we did not perform an evaluation of infarct size using advanced imaging technology such as magnetic resonance imaging and nuclear scanning, we probably underestimated the impact of AVDE on the extent of necrosis. However, the troponin I serum level has been recognized as a good surrogate of infarct size estimation because of its proven correlation with the extent of necrosis as evaluated by magnetic resonance imaging study [21]. Despite the limitations above, this study supports the opinion that manual thrombus aspiration should be reserved for carefully selected cases because of the high risk of distal embolization and the lack of clinical benefit associated with its routine upfront use [18]. In the light of two large randomized studies, the TOTAL trial (a trial of routine aspiration ThrOmbecTomy with PCI versus PCI ALone in Patients with STEMI) ($n$ = 10.732) [20] and the TASTE study (Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia) ($n$ = 7244) [22, 23], in the latest ACC/AHA/SCAI guideline update on PPCI for patients with STEMI, routine upfront use of manual thrombectomy in PPCI is not recommended (class III: no benefit, level of evidence A) [24].

In conclusion, according to our study, AVDE during primary PCI occurs in a significant number of patients treated with upfront manual thrombectomy. The results also indicated that the incidence of AVDE may be different depending on the thrombectomy catheters used in the thrombectomy group, but large scale studies with different catheters are needed to reveal their effects on the incidence of AVDE.

## Conflict of interest

The authors declare no conflict of interest.

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