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CLINICAL RESEARCH

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Thrombus Aspiration in Patients With ST-Segment Elevation Myocardial Infarction Presenting Late After Symptom Onset

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ABSTRACT

OBJECTIVES The aim of this study was to examine whether manual thrombus aspiration reduces microvascular obstruction assessed by cardiac magnetic resonance imaging in patients with ST-segment elevation myocardial infarction (STEMI) presenting late after symptom onset.

BACKGROUND Thrombus aspiration is an established treatment option in patients with STEMI undergoing primary percutaneous coronary intervention (PCI). However, there are only limited data on the efficacy of thrombus aspiration in patients with STEMI presenting ≥12 h after symptom onset.

METHODS Patients with subacute STEMI presenting ≥12 and ≤48 h after symptom onset were randomized to primary PCI with or without manual thrombus aspiration in a 1:1 ratio. Patients underwent cardiac magnetic resonance imaging 1 to 4 days after randomization. The primary endpoint was the extent of microvascular obstruction.

RESULTS A total of 152 patients underwent randomization. The mean time between symptom onset and PCI was 28 ± 12 h. Baseline characteristics were comparable between groups. The majority of patients (60%) showed at least a moderate amount of viable myocardium in the affected region. Extent of microvascular obstruction was not significantly different between patients assigned to thrombus aspiration and the control group (2.5 ± 4.0% vs. 3.1 ± 4.4% of left ventricular mass, p = 0.47). There were also no significant differences in infarct size, myocardial salvage, left ventricular ejection fraction, and angiographic and clinical endpoints between groups.

CONCLUSIONS In this first randomized trial of thrombectomy in patients with STEMI presenting late after symptom onset, routine thrombus aspiration before PCI failed to show a benefit for markers of reperfusion success. (Effect of Thrombus Aspiration in Patients With Myocardial Infarction Presenting Late After Symptom Onset; NCT01379248) (J Am Coll Cardiol Intv 2016;9:113–22) © 2016 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CMR = cardiac magnetic resonance imaging

LV = left ventricular

%LV = percentage of left ventricular mass

MSI = myocardial salvage index

MVO = microvascular obstruction

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

TIMI = Thrombolysis In Myocardial Infarction

Thrombus aspiration is an established treatment option in patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI), although recent trials reported disappointing results, with no reduction in mortality and possibly an increase in stroke (1,2). Current evidence is restricted largely to patients presenting within the first hours after symptom onset. Nevertheless, patients presenting ≥12 h after the beginning of symptoms may display particularly high thrombus burden because of long dwelling times. Thus, thrombus aspiration might be a useful adjunct to conventional PCI in this subset of patients. A prior study suggested that thrombus aspiration may indeed be more effective in late-presenting patients (3). However, thrombectomy

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could also be detrimental in this situation because of mechanical thrombus dislodgment and distal embolization with subsequent microvascular injury and expansion of the necrotic zone. Thrombus composition may also play a role. Although in the initial stages of evolving infarction, thrombotic material is relatively soft (low fibrin content, high platelet content), it becomes more organized (high fibrin content, low platelet content) and possibly less suited for aspiration at later stages (4). However, data on the efficacy of thrombus aspiration in the subgroup of patients with STEMI presenting late after symptom onset are scarce.

In the present trial, we examined the effect of routine thrombus aspiration on microvascular obstruction (MVO) assessed by cardiac magnetic resonance imaging (CMR) in patients with subacute STEMI presenting between 12 and 48 h after symptom onset.

METHODS

DESIGN OVERVIEW. The trial's main objective was to study whether manual thrombus aspiration reduces MVO in patients with subacute STEMI. Eligible patients were randomized to primary PCI with or without manual thrombus aspiration. The main inclusion criteria were STEMI ≥12 and ≤48 h after symptom onset, irrespective of signs of ongoing ischemia, and age between 18 and 90 years. Exclusion criteria included prior thrombolysis, contraindications to CMR (known at the time of randomization), and severe comorbidities with limited life expectancy (<6 months). Patients underwent CMR 1 to 4 days after randomization. The primary efficacy endpoint was the extent of MVO on late gadolinium enhancement CMR. All patients were enrolled at a single institution (University of Leipzig-Heart Center). The study was approved by the local institutional review board and conducted in accordance with the principles of the Declaration of Helsinki. All patients provided written informed consent before randomization.

RANDOMIZATION AND BLINDING. Eligible patients willing to take part in the study were assigned in a 1:1 ratio to the treatment groups by permuted block randomization with randomly changing block sizes using an Internet-based system and a computer-generated list of random numbers. Randomization was performed before coronary angiography in the catheterization laboratory. The randomization list was generated and maintained by an information technology expert who was not involved in the clinical conduct of the study.

CMR and all other subsequent analyses were performed by readers blinded to treatment assignment. By design, physicians performing the invasive procedures were aware of randomization results. Patients were not informed about treatment allocation until completion of the study.

ENDPOINTS. The primary efficacy endpoint was the extent of MVO assessed by CMR in the modified intention-to-treat population. Secondary CMR endpoints included infarct size, myocardial salvage, and left ventricular (LV) volumes and ejection fraction. Furthermore, a central blinded analysis of angiographic markers of reperfusion success, such as the Thrombolysis In Myocardial Infarction (TIMI) flow post-PCI and myocardial blush grade, was performed. Coronary collateralization was graded according to the Rentrop classification (grade 0, no visible filling of any collateral channel; grade 1, filling of the side branches of the infarct-related artery; grade 2, partial filling of the epicardial vessel of the infarct-related artery; grade 3, complete collateral filling of the epicardial vessel) (5). For enzymatic infarct size determination, high-sensitivity troponin T after 24 and 48 h was evaluated. The clinical endpoints of all-cause and cardiovascular death, myocardial reinfarction, target vessel revascularization, stent thrombosis, and stroke were reported up to 30 days after randomization. Clinical endpoints were defined according to guidelines (6).

PCI. Thrombus aspiration had to be performed before the first balloon inflation using a 6-F manual aspiration catheter (Export AP; Medtronic, Minneapolis,