

## Should Interventional Cardiologist use Aspiration Thrombectomy?

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If there was a broken-down car on your street blocking traffic, would you rather hire a tow truck to remove it, or hire a bulldozer to smash it into smaller pieces? Asked Joshua Allen-Dicker [1]. Many randomized controlled trial examined whether removal of a coronary artery thrombus (the tow truck method) prior to stent placement improved 30 day mortality in STEMI patients as compared to placement of a stent without first removing the thrombus (the bulldozer method) [1].

In fact, this is a possible complication during primary PCI, resulting in microvascular obstruction and no-reflow phenomenon. The presence of a visible thrombus at the time of primary PCI in patients with STEMI is associated with poor procedural and clinical outcomes [2]. Physiologically, the tow truck method makes sense: removal of the thrombus prior to placing a stent should reduce distal embolization of thrombus fragments and improve overall myocardial recovery [1].

Several randomized trials have demonstrated the efficacy and safety of pretreatment with manual thrombectomy during primary percutaneous coronary intervention [3]. There are some unanswered questions about thrombus aspiration including whether there is truly a mortality benefit, which subgroups may or may not benefit from aspiration and whether patients with a large thrombus burden are better treated with mechanical thrombectomy and should an interventional cardiologist use thrombecto-my as a default strategy before primary PCI? [4].

The literature and clinical practice clearly show that the impact of thrombectomy on all outcomes is linked to multiple factors during STEMI, in particular time from symptom onset to PCI, infarct-related coronary artery and intracoronary thrombus burden [5]. Sianos, et al. have shown that both angiographic and clinical outcomes are poorer in patients with a large thrombus burden as it is associated with a greater frequency of major adverse cardiac events and is a strong independent predictor of late mortality [6].

Moreover, Napodano et al. found that patients with right coronary artery infarcts, long lesions and a high thrombus score had the highest frequency of distal embolization. We might expect these subgroups to benefit most from thrombectomy [7]. Improvement in MBG with aspiration was not better in patients with right

coronary artery (RCA) infarcts vs non-RCA infarcts, and was not better in patients with a visible thrombus compared with patients without a visible thrombus. There was a trend for greater benefit in patients with a reperfusion time of less than 3h, but there were no differential benefits in patients stratified by pre-PCI TIMI flow [8].

Overall, there are few current studies to support selective use of aspiration thrombectomy in any subgroup of STEMI patients treated with PPCI [9]. Myocardial salvage is measured and studied in trials through different parameters: angiographic (thrombolysis in myocardial infarction (TIMI) and myocardial blush grade (MBG), electrocardiographic (ST-segment resolution STR), functional (reduction of infarct size) and clinical (enhanced survival free from heart failure events) [10].

EXPIRA trial was done to evaluate the impact on myocardial perfusion and infarct size as assessed by contrast-enhanced magnetic resonance imaging of a manual thrombectomy device, Export Medtronic (EM), as adjunctive therapy in primary percutaneous coronary intervention in a subset of patients with anterior ST-segment elevation myocardial infarction [11].

The results showed that; Myocardial blush grade 2 occurred more frequently in the aspiration group (88%) vs. (60%) in the conventional PCI group and the difference was highly statistically significant ( $p = 0.001$ ) [11]. Also encouraging data for the use of manual aspiration data has been published in the recent issue of JACC 2013 Dharam K and coinvestigators carried out meta-analysis of 18 randomized trials with 3,836 patients who were randomized to aspiration device and conventional primary PCI with mean follow-up period 6 months [12].

The meta-analysis conclusively showed that: Aspiration devices showed significant reduction in MACE in aspiration group as compared to conventional primary PCI with risk ratio (RR) 0.76;  $p = 0.006$ . There was 30 days all-cause mortality benefit with aspiration group (RR 0.71;  $p = 0.049$ ). There was a trend in reduction of MI, TVR with manual aspiration devices. However the infarct size and ejection fraction were similar at 1 month, ST segment resolution and MBG 3 were seen in greater number of patients who underwent aspiration ( $p = 0.0001$ ). Thrombus aspiration catheter not only provided 30 days benefit but also

reduced all-cause mortality at 6 months [12].

In the ATTEMPT trial a meta-analysis of 11 prospective randomized trials suggested that the use of thrombectomy devices is associated with a significant reduction of angiographically evident distal embolization and no-reflow (as assessed by post-procedural myocardial blush grade (MBG) and ST-segment resolution) [13]. But data from multicentric trial Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia (TASTE) which included 7,244 patients randomized to conventional primary PCI and manual thrombus aspiration failed to show benefit of routine aspiration before primary PCI as compared to conventional primary PCI. The 30 days mortality was similar in both the arms (2.8% in thrombus aspiration and 3.8% in conventional primary PCI). However the data was for 30 days outcome only [9].

Also Intracoronary Abciximab and Aspiration Thrombectomy in Patients with Large Anterior Myocardial Infarction (INFUSE-AMI) trial failed to show difference in the 30 days outcome between aspiration thrombectomy and conventional primary PCI. There was no difference in the ST segment resolution, TIMI count, 30 days infarct size and MACE [14]. (TAPAS) trial was a single center, prospective, randomized, open trial which involved the blinded evaluation of patients. It enrolled 1,071 patients who were randomized either to thrombus aspiration group with 6F Export catheter or to the conventional primary PCI group [14]. Randomization was done before performing coronary angiography. After passing a guide wire, thrombus aspiration was done followed by the usual PCI procedure. The primary end point of the study was MBG 0/1 which was defined as absent/minimal reperfusion. Secondary end points were the post procedural frequency of TIMI flow grade 3, complete resolution of ST elevation, target vessel revascularization (TVR), reinfarction, death and the combination of MACE after 30 days [15].

Myocardial blush grade 0/1 occurred in 17.1% with thrombus aspiration group and 26.3% in the conventional primary PCI group ( $p = 0.001$ ). Complete resolution of ST elevation was observed in 56.6% in the aspiration group and 44.2% in the conventional PCI group ( $p < 0.001$ ). At 30 days patients who had MBG 3 had 1% mortality as compared to 5.2% in patients who had MBG 0/1. The rates of adverse events were significantly higher in patients with MBG 0/1 as compared to the patients with MBG 3 [15].

We go back to the question should an interventional cardiologist use thrombectomy as a default strategy before primary PCI? It is not easy to decide. ACC/AHA guidelines give a recommendation of class IIa to the manual aspiration before PPCI [16]. Also Gennaro S and Rocco E recommended the use of manual thrombectomy as first approach during PPCI to prevent distal embolization in case of culprit vessel diameter  $> 2.5$  mm with a TIMI flow 0-1 and a visible thrombus (score  $> 3$ ) [17].

Interventionists were waiting for the results from (TOTAL) trial and recommended to perform manual aspiration as default strategy especially in patients with large thrombus burden [17]. Total trial

included 10,000 patients concluded that Routine thrombectomy compared to PCI alone did not reduce CV death, MI, shock or heart failure within 180 days But was associated with increased risk of stroke within 30 days [18]. The findings argue against “up-front” thrombectomy as a routine part of a PCI procedure in patients with acute STEMI.

But guidelines have changed and On the basis of the results of these studies, the prior Class IIa recommendation for aspiration thrombectomy has been changed. Routine aspiration thrombectomy before primary PCI is now not recommended (Class III: No Benefit, LOE A). There are insufficient data to assess the potential benefit of a strategy of selective or bailout aspiration thrombectomy (Class IIb, LOE C-LD). “Bailout” aspiration thrombectomy is defined as thrombectomy that was initially unplanned but was later used during the procedure because of unsatisfactory initial result or procedural complication [19].

Let’s answer our question; there is no clinical benefit for routine rheolytic thrombectomy has been demonstrated in patients with STEMI undergoing primary PCI [19].

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