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Lessons from the trials

TASTE: One-year follow-up results

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INTRODUCTION

Using thrombus aspiration devices during primary percutaneous coronary intervention (PCI) in the setting of ST-segment elevation myocardial infarction (STEMI) is a highly debatable issue. In 2013, after the announcement of the Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia trial (TASTE) short term outcomes, more confusion was added to this hot topic. The main, but not only, concern about TASTE was the short-term follow-up period of just 30 days. So, can the one-year follow-up results help in solving this debate?

TASTE RESULTS AFTER ONE YEAR

TASTE is the first multicenter, randomized clinical trial that is statistically powered to evaluate the effect of thrombus aspiration on hard clinical end points in patients with STEMI.[1] The study design and short term (30 day) results, were discussed in a previous report.[2]

In September 2014, the one-year follow-up results of the TASTE trial were published in *The New England Journal of Medicine*.[3] The median duration of follow-up from enrollment of the first patient, to the completion of a 1-year follow-up for the last patient enrolled, was 858 days, (interquartile range, 597 to 1096) with a maximum of 1416 days. None of the 7244 patients enrolled in randomization were lost to follow-up for the primary end point at 1 year.

The rate of death from any cause at 1 year was 5.3% (191 of 3621 patients) in the thrombus-aspiration group, as compared with 5.6% (202 of 3623) in the PCI-only group (hazard ratio, 0.94; 95% confidence interval [CI], 0.78 to 1.15; P = 0.57). The rate of rehospitalization for myocardial infarction at 1 year was 2.7% and 2.7% in the two groups, respectively (hazard ratio, 0.97; 95% CI, 0.73 to 1.28; P = 0.81), and the rate of stent thrombosis was 0.7% and 0.9%, respectively (hazard ratio, 0.84; 95% CI, 0.50 to 1.40; P = 0.51). The incidences of target-vessel revascularization (4.4% and 4.9% respectively, P = 0.31) and target-lesion revascularization (3.2% and 3.5% respectively, P = 0.47) were similar in the two randomized groups. The incidence of the composite of death, rehospitalization for myocardial infarction, or stent thrombosis was 8.0% in the thrombus-aspiration group and 8.5% in the PCI-only group (hazard ratio, 0.94; 95% CI, 0.80 to 1.11; P = 0.48).

When the entire follow-up period (median duration is 858 days) was analyzed, the rate of death was 8.1% (295 of 3621 patients) in the thrombus-aspiration group as compared with 8.7% (316 of 3623patients) in the PCI-only group (hazard ratio, 0.93; 95% CI, 0.80 to 1.10; P = 0.40). The composite of death, rehospitalization for myocardial infarction, or stent thrombosis during the entire follow-up period occurred in 448 and 490 patients in the two groups, respectively (hazard ratio, 0.91; 95% CI, 0.80 to 1.04; P = 0.16).

The results were consistent across all pre-specified subgroups and several post hoc subgroups, including those based on hospital size and enrollment rate, and subgroups associated with high thrombotic risk, such as patients who had a TIMI flow grade of 0 or 1, a thrombus grade of G4 (large thrombus) or G5 (vessel occlusion), a proximal lesion, or a short delay from symptom onset to PCI and those who smoked.

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DISCUSSION

The main finding after 1-year follow-up of the TASTE study, is that a strategy of routine use of thrombus aspiration before PCI, as compared with PCI alone, in patients with an acute STEMI, did not result in a lower rate of death from any cause, a lower risk of the composite of death, rehospitalization for myocardial infarction, or stent thrombosis, or a lower risk of any of these end points separately. The absence of any benefit of thrombus aspiration was consistent across all patient subgroups, regardless of baseline clinical or angiographic characteristics. The authors postulated that the similarity in outcomes after 30 days and one-year of follow-up is due to the fact that thrombus aspiration is an intervention performed only in the acute phase of myocardial infarction and there is no ongoing therapy, therefore a late effect is not likely in the absence of an early benefit.[3]

Another important finding is that at 30 days, there was a trend (not statistically significant) toward reduction in the risk of hospitalization for recurrent MI and the risk of stent thrombosis in the thrombus aspiration group and PCI, compared to PCI alone. This trend disappeared over time, and at 1 year, the rates were very low and were similar in the two groups. The low rate of stent thrombosis observed in the TASTE one-year follow-up results can be explained by the frequent use of new-generation drug-eluting stents[4,5] and potent new $P2Y_{12}$-inhibitors (used in 43.7% of the patients at PCI and in 36.6% at discharge).

CRITIQUE

The study design of the TASTE trial has never been tested before and failed to solve the problem of selection bias in large clinical trials. This is clearly documented by 40% rate of STEMI patients excluded from randomization and by the 3.5-fold higher 30-day mortality rate observed in excluded patients (10.6%; vs 2.9% of randomized patients). Indeed, despite all the efforts in the study design and conduction, the enrollment of such a "selected" study population composed of low-risk STEMI patients was unanticipated and created a drop in the statistical power of the study.

In the setting of primary PCI for STEMI, neither the Thrombus Aspiration during Percutaneous Coronary Intervention in Acute Myocardial Infarction Study (TAPAS),[6] nor the TASTE trial, showed a significant reduction in mortality or in the incidence of other clinical events at 30 days of follow-up for patients treated with thrombus aspiration and PCI compared to those treated with PCI alone. But after one year of follow-up the outcomes from the two trials are not coherent. The TAPAS results showed a 40% relative reduction in all-cause mortality in patients treated with thrombus aspiration and PCI, whereas the one-year follow-up results of the TASTE declared the absence of any benefits from the routine use of thrombus aspiration device during primary PCI in STEMI. However we must take into consideration the fact that TAPAS enrolled only 1071 patients and is a single center trial that was not designed for the evaluation of clinical outcomes.[3,6]

An important missing variable in the TASTE follow-up results after one year is the left ventricular (LV) systolic and diastolic functions and rate of rehospitalization for heart failure. Although the results for TASTE one-year clinical outcomes negate any benefits from thrombus aspiration, the coronary artery thrombus aspiration before PCI still reduces the thrombus burden and improves ST-segment resolution and coronary flow[7,8]. This may have an important impact on microvascular resistance, myocardial perfusion, and subsequently on the LV function, in both the short and long term.

Significant differences in the LV function and/or rehospitalization for heart failure after one year of follow-up between the two randomized groups, is important in comparing the outcomes of the two strategies (thrombus aspiration and PCI vs PCI alone) in the setting of primary PCI for acute STEMI. In concordance with this concept; is the results from INFUSE-AMI (Intracoronary Abciximab and Aspiration Thrombectomy in Patients with Large Anterior Myocardial Infarction) trial that showed significant reduction in rehospitalization for heart failure after 1-year follow-up in 452 high-risk patients presenting with proximal or mid-occlusion of the left anterior descending coronary artery treated with thrombus aspiration prior to PCI.[9,10]

WHAT HAVE WE LEARNT?

The TASTE one-year follow-up results do not recommend the routine use of thrombus aspiration device in primary PCI in the setting of STEMI. However this advice should be taken cautiously in practice. As high-risk patients with STEMI were excluded from the randomization and despite the suspected

underreporting of the excluded patients, a 3.5-fold higher 30-day mortality rate was observed in this group.

The trial was statistically powered for evaluation of clinical outcomes, however data related to the rehospitalization for heart failure and/or evaluation of LV function after 30 days and one year is not available.

Finally, given the one-year results and limitations of the TASTE trial, and taking into consideration the multifactorial etio-pathogenesis of no-reflow during primary PCI for STEMI, and the possible relevance of an interplay between thrombus-aspiration devices and adjunctive pharmacology, the decision of using manual aspiration devices cannot be all or none, but should be tailored during every procedure depending on the clinical, anatomical and angiographic data.

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