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EDITORIAL

# Thrombus Aspiration: Is It the Art or the Science?

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Restoring adequate myocardial perfusion is fundamental in the management of patients with acute ST-segment–elevation myocardial infarction. In a significant number of patients, the distal macro- and microembolization of atheromatous and thrombotic debris, detected on angiography, lead to incomplete myocardial salvage.[1] Distal embolization occurs predominantly at the time of the first balloon inflation or stent deployment. Thrombus burden is a predictor of no-reflow phenomenon and an independent predictor of adverse outcomes.[2] Routine manual thrombus aspiration (TA) is a technique to help remove the thrombus from the culprit vessel before angioplasty and stent deployment. Early small studies of TA showed improvement in surrogate primary end points suggesting better microvascular perfusion.[3,4] Among the early trials, The TAPAS (Thrombus Aspiration during Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) trial showed improvements in myocardial perfusion as well as 1-year mortality. However, the TAPAS trial was conducted at a single high-volume center with experienced operators, with short reperfusion times, and more important, was underpowered for hard clinical end point.[5] Two larger trials, TASTE (The Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia) and TOTAL (The Trial of Routine Aspiration Thrombectomy with PCI [percutaneous coronary intervention] versus PCI Alone in Patients with STEMI [ST-segment–elevation myocardial infarction]), challenged the results of the TAPAS trial by showing no significant difference in clinical outcomes with routine TA[6,7] but rather a higher periprocedural stroke risk in the TOTAL trial.[6] A patient-level meta-analysis of these 3 trials confirmed the lack of benefit with routine TA; however, it suggested that the subgroup of patients with high thrombus burden might derive a benefit.[8] Accordingly, societal guidelines recommend against routine TA (class III).[1,2] Yet, among patients with heavy thrombus burden, TA is considered a class IIB indication, indicating potential room for using selective TA in primary PCI (ie, with careful patient and lesion selection), keeping in mind the risk of periprocedural stroke.[1,9]

See Article by Sotomi et al.

In the current issue of the *Journal of the American Heart Association (JAHA)*, Sotomi et al report the results of a large prospective multicenter analysis evaluating the periprocedural stroke with TA among all comers with acute ST-segment–elevation myocardial infarction.[10] The authors are to be commended for providing another angle on the stroke risk with TA in the real world. The authors used the OACIS (Osaka Acute Coronary Insufficiency Study) database from 1998 to 2014. Treatment strategy including TA was left to the operator's discretion. Stroke events were clinically adjudicated at each site. Among 9147 eligible patients from the OACIS database, TA was performed in 4448 patients (48.6%). Patients in the TA group were more likely to be male, had history of cancer, and shorter time from symptoms onset to PCI. Although patients

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in the TA group had higher baseline atrial fibrillation, anticoagulation use was less common in TA group at discharge. TA group also had higher use of statins and beta blockers at discharge. In addition, patients in the TA group had lower Thrombolysis in Myocardial Infarction grade pre PCI, more distal protection performed (TA versus non-TA group 12.7% versus 2.9%, $P<0.001$), more stenting performed (TA versus non-TA group 86.5% versus 53.2%, $P<0.001$) and higher peak creatine kinase-MB, suggesting larger myocardial infarction size. There was an increase in the use of TA for primary PCI during the study period. The rate of stroke within 7 days of admission (periprocedural stroke) was significantly higher in the TA group (1.19% versus 0.70%), and TA was significantly associated with risk of stroke on the unilevel logistic regression model. Interestingly, the multilevel logistic model, which factored the treating hospitals, did not show such an association between TA and periprocedural risk of stroke. On subgroup analysis, there was no significant relationship between TA performance rate, case numbers enrolled, and periprocedural stroke.

There are a few limitations to keep in consideration when interpreting the analysis by Sotomi et al First, the study time frame (1998–2014) does not reflect contemporary PCI techniques, which included introduction of new aspiration devices (eg, Penumbra aspiration catheter) or contemporary pharmacological therapeutics after primary PCI. Second, there was a relatively high proportion of distal protection performed during PCI (12.7%) in the TA group. It is unclear if these were performed in a setting of saphenous vein graft interventions or native vessel disease. It is well known that saphenous vein graft PCIs have higher risk of stroke and periprocedural myocardial infarction. Third, the stroke risk in both the TA and non-TA groups (1.2% and 0.7%) was higher than that reported in pooled data from randomized trials (0.8% and 0.5%).[8] Such difference could be related to lack of independent adjudication of the primary end point in the current study and could also be a reflection that patients in randomized trials often might not be representative of the real world. Fourth, although there was a lack of significant association between TA and periprocedural stroke in the multilevel logistic model, this model included >20 covariates to evaluate an outcome with only 86 events; which might have resulted in an overfitted model. This represents an important limitation that should be taken into consideration when interpreting the study findings. Notwithstanding these issues, the analysis by Sotomi et al has several strengths; including the relatively large sample size, the long time span of the study period, and the robust statistical analyses. Additionally, they performed clinical adjudication for acute stroke events and did not rely on discharge diagnosis or administrative codes. These findings are hypothesis provoking and help improve our understanding of the debatable topic of selective use of TA.

The higher use of TA in this study (48.6%) is probably a reflection of the practice before the publication of the TOTAL trial. An analysis of the NCDR CathPCI registry (National Cardiovascular Data Registry) has demonstrated a reduction in use in TA after the publication of the TOTAL trial (ie, 2014 and later).[11] Nevertheless, the use of TA was considerably higher in the study by Sotomi et al as compared with the NCDR analysis (<15%), which suggests a potential difference in operators/practice in Japan as opposed to the United States. The analysis by Sotomi et al also suggests that the stroke risk after TA might be mediated by institution specific variation rather than patient-specific factors. Data on institutional variation in stroke risk after TA have not been previously illustrated in previous multicenter studies, including the TOTAL trial.[6] Additionally, Sotomi et al further demonstrated that the increased stroke risk is only limited to the periprocedural period (ie, within 7 days of PCI), with no increased stroke risk beyond that point. This finding comes in accordance with results of a post hoc analysis from the TOTAL trial, which demonstrated that the increased stroke risk with TA was driven by a higher number of events within first 48 hours after PCI.[6] Another meta-analysis of clinical trials demonstrated that TA might be associated with stroke, but this risk was mainly driven by higher events in the periprocedural period.[12] The findings from this study suggest that periprocedural stroke risk after TA could be mitigated by prudent PCI procedure and appropriate periprocedural management. From a technical standpoint, the increased risk of stroke after TA might be attenuated with careful procedural techniques (ie, proper guide engagement into the coronary ostia, maintaining aspiration until the catheter is removed from the guide, adequate guide flushing etc). Recently, a study suggested that hospitals with a high volume of TA use were not associated with increased stroke risk as opposed to lower volume hospitals.[13]

In summary, the study by Sotomi et al is a welcome contribution to the literature, confirming prior studies that TA is associated with higher risk of stroke, but highlights that institutional and operator factors contribute to this risk-"art of TA." Until this is addressed in further studies, we should continue to believe in the science and avoid routine use of TA.

## ARTICLE INFORMATION

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