

Will this trial change my practice? TASTE - a randomised registry on thrombus aspiration in primary PCI with a 30-day endpoint

Miles W. Behan¹, MD; Alexandra J. Lansky², MD; Sanjit Jolly³, MD; Andreas Baumbach^{4*}, MD

1. Edinburgh Heart Centre, Edinburgh, United Kingdom; 2. Division of Cardiovascular Medicine, Yale University School of Medicine, New Haven, CT, USA; 3. McMaster University and the Population Health Research Institute, Hamilton Health Sciences, Hamilton, Ontario, Canada; 4. Bristol Heart Institute, Bristol, United Kingdom

The Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia (TASTE) trial was a multicentre, prospective, randomised, controlled, open-label trial comparing manual thrombus aspiration followed by PCI to PCI only in patients with ST-elevation myocardial infarction (STEMI)¹. Patients were enrolled from the national Swedish Coronary Angiography and Angioplasty Registry (SCAAR) and endpoints evaluated through national registries. The primary endpoint was all-cause mortality at 30 days, and 7,244 patients with STEMI presenting within 24 hours of onset of symptoms were recruited. TASTE found no significant difference in 30-day mortality (2.8% in the aspiration group versus 3.0% in the no aspiration group, hazard ratio 0.94, 95% CI: 0.72-1.22). Rates of hospitalisation for recurrent myocardial infarction at 30 days were 0.5% and 0.9% (p=0.09), respectively. Rates for stent thrombosis were 0.2% and 0.5% (p=0.09). There were no significant differences in stroke rates (**Figure 1**).

The chair (Andreas Baumbach) opened the session by polling the audience to ask if their attitude to thrombus aspiration had changed

since the publication of TASTE. More than half the audience felt that their use of aspiration had decreased as a result.

Michael Haude presented an angiogram of an inferior STEMI in a typical patient. The actual treatment given to the patient was going to be revealed at the end of the session.

Gennaro Sardella reviewed what was known about thrombus aspiration before TASTE. Improved myocardial blush score, cardiac mortality and reduced non-fatal myocardial infarction at one year were seen with manual aspiration in the TAPAS trial². In the most recent meta-analysis of 25 trials of manual aspiration, it was associated with a 24% relative risk reduction of MACE and a 29% relative risk reduction in mortality at a median follow-up of six months³. Currently, the 2013 ACCF/AHA STEMI guidelines state that manual thrombus aspiration is reasonable for patients undergoing primary PCI (Class IIa, Level of Evidence B)⁴.

Alexandra Lansky took us through her thoughts on TASTE. In her view the trial design was innovative: recruiting via a population-based registry facilitated patient enrolment and data collection.

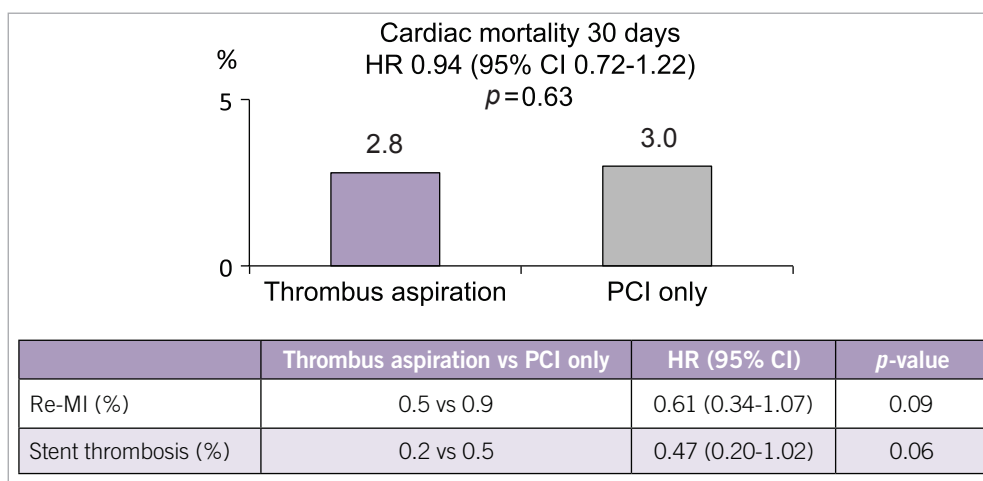


Figure 1. Summary slide taken from PCR trials book.

*Corresponding author: Bristol Heart Institute, Upper Maudlin Street, Bristol, BS2 8HW, United Kingdom. E-mail: andreas.baumbach@uhbristol.nhs.uk

Recruitment through a registry has several advantages: large numbers are generated, it is cost-effective, takes all-comers, follow-up is complete and recruitment is quick. However, because there was no independent event adjudication, stent thrombosis and myocardial infarction reporting may be unreliable. For the patient population, 7,244 of the eligible 11,709 STEMI patients were randomised, questioning the generalisability for the patient population. Patients were not randomised for a variety of reasons, including no informed consent (38%), and the operator deciding that aspiration was needed (7%). The population of patients who underwent randomisation did have significant differences from those who did not (less diabetes, younger, less previous CABG), and is therefore not entirely generalisable to all STEMI patients. Furthermore, the outcomes of randomised patients were significantly better than of those who did not undergo randomisation (a 30-day mortality rate of 2.9% versus 10.6%).

Mortality at 30 days was the primary endpoint of the trial, which may present several limitations. The original power calculation suggested that a total planned enrolment of 5,000 patients (based on a one-month control mortality of 6.3% and a 30% reduction with thrombus aspiration at 30 days) would be required. When enrolment approached 5,000, the 30-day mortality was observed to be lower than expected (2.9%) in the study cohort, so the sample size had to be enlarged, now assuming a 50% reduction in 30-day mortality. A 30-day endpoint is probably too early to demonstrate a significant difference (prior trials and meta-analyses demonstrating a mortality benefit from thrombectomy showed that it was not apparent before six months; in TAPAS the mortality benefit was at one year). In addition, a 50% reduction in mortality seems ambitious (few therapies in medicine ever show such a mortality benefit). With these considerations in mind and essentially an underpowered trial for the chosen endpoint, the negative mortality finding in TASTE may not mean that thrombectomy is without clinical value. Both myocardial infarction and stent thrombosis were numerically reduced at 30 days, providing a signal of benefit with thrombectomy. Importantly, there was no increased stroke with aspiration and the procedure was safe. Ultimately, the one-year follow-up will be a critical measure to determine whether thrombectomy has a meaningful impact on mortality or other secondary endpoints.

Sanjit Jolly discussed the design of the TOTAL trial, a randomised trial of routine aspiration Thrombectomy with PCI versus PCI Alone in patients with STEMI undergoing primary PCI⁵. This randomised controlled trial aims to enrol 10,700 patients and has a composite of cardiovascular death, recurrent MI, cardiogenic shock, or new or worsening NYHA Class IV heart failure at six months.

Michael Haude then presented the conclusion to his case demonstrating successful use of thrombus aspiration. He stated that, if aspiration is performed correctly and carefully, it is a very useful technique whose benefits include removal of vasoactive substances

in addition to thrombus. He felt that, in an occluded vessel in STEMI, aspiration is better than clot disruption with a balloon.

At the end of the session, Andreas Baumbach re-pollled the audience, and this time the majority feeling was that further trial data (including TOTAL and the one-year results of TASTE) are required prior to recommending changes in clinical practice.

Conflict of interest statement

A. Baumbach has received Speakers Fees from Astra Zeneca. The other authors have no conflicts of interest to declare.

References

- Fröbert O, Lagerqvist B, Olivecrona GK, Omerovic E, Gudnason T, Maeng M, Aasa M, Angerås O, Calais F, Danielewicz M, Erlinge D, Hellsten L, Jensen U, Johansson AC, Kåregren A, Nilsson J, Robertson L, Sandhall L, Sjögren I, Ostlund O, Harenek J, James SK; TASTE Trial. Thrombus aspiration during ST-segment elevation myocardial infarction. *New Engl J Med*. 2013;369:1587-97.
- Vlaar PJ, Svilaas T, van der Horst IC, Diercks GF, Fokkema ML, de Smet BJ, van den Heuvel AF, Anthonio RL, Jessurun GA, Tan ES, Suurmeijer AJ, Zijlstra F. Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study. *Lancet*. 2008;371:1915-20.
- Kumbhani DJ, Bavry AA, Desai MY, Bangalore S, Bhatt DL. Role of aspiration and mechanical thrombectomy in patients with acute myocardial infarction undergoing primary angioplasty. An updated meta-analysis of randomized trials. *J Am Coll Cardiol*. 2013;62:1409-18.
- American College of Emergency Physicians; Society for Cardiovascular Angiography and Interventions, O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX, Anderson JL, Jacobs AK, Halperin JL, Albert NM, Brindis RG, Creager MA, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Kushner FG, Ohman EM, Stevenson WG, Yancy CW. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2013;61:e78-140.
- Jolly SS, Cairns J, Yusuf S, Meeks B, Shestakovska O, Thabane L, Niemelä K, Steg PG, Bertrand OF, Rao SV, Avezum A, Cantor WJ, Panchoy SB, Moreno R, Gershlick A, Bhindi R, Welsh RC, Cheema AN, Lavi S, Rokoss M, Džavik V. Design and rationale of the TOTAL trial: a randomized trial of routine aspiration Thrombectomy with percutaneous coronary Intervention (PCI) versus PCI Alone in patients with ST-elevation myocardial Infarction undergoing primary PCI. *Am Heart J*. 2014;167:315-321.