

that the patient profile of both studies bears little resemblance to that seen in everyday practice and consequently the results should be interpreted with caution.

Iñigo Lozano,* Juan Rondán, José M. Vegas, and Eduardo Segovia

Servicio de Cardiología, Hospital de Cabueñes, Gijón, Asturias, Spain

*Corresponding author:

E-mail address: inigo.lozano@gmail.com (I. Lozano).

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Thrombectomy in Primary Angioplasty: Do the Latest Large Studies Address the Doubts About Its Usefulness? Response



Trombectomía en angioplastia primaria: ¿aclaran los últimos grandes estudios las dudas sobre su utilidad? Respuesta

To the Editor,

We would like to thank Dr. Lozano et al. for their interest in our meta-analysis, which investigated clinical and procedural outcomes of aspiration thrombectomy-assisted primary percutaneous coronary intervention compared with conventional primary percutaneous coronary intervention in patients with ST-segment elevation myocardial infarction.¹ Among unselected patients with ST-segment elevation myocardial infarction, aspiration thrombectomy-assisted primary percutaneous coronary intervention did not improve clinical outcomes at a weighted mean follow-up time of 10.4 months, despite improved epicardial and myocardial parameters of reperfusion.

Out of 26 randomized trials, only the TASTE trial (Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia) was powered for clinical outcomes.² Its primary endpoint was all-cause mortality at 30 days; and, based on Swedish registry data, the steering committee assumed an event rate of 6.3%. To show a 30% higher mortality without thrombectomy with 80% statistical power, the trial required the occurrence of 456 events and planned to include 5000 patients. The sample size of the trial was extended due to a lower than expected rate of death (ie, 2.9% in the first 5000 patients). Final results included 7244 patients with no differences between treatment arms.

Given the innovative trial design (ie, registry-based randomized trial), the authors simultaneously published outcomes in patients who were not randomized—more than one third—and showed that event rates were much higher than those in patients included in the randomized trial. The most frequent reason for not having been randomized was inability to provide informed consent, which generally applies to patients in critical condition (eg, intubated, cardiogenic shock). Thus, the use of thrombectomy in an unrestricted ST-segment elevation myocardial infarction population did not show a benefit in the randomized

trial, findings which were confirmed in the nonrandomized population at higher risk, attesting to the external validity of the TASTE trial results.

The results of the TOTAL trial³ were presented after our meta-analysis and were consistent with our findings regarding clinical endpoints, except for stroke.

CONFLICTS OF INTEREST

S. Windecker has received research contracts for his institution from Abbott Vascular, Biotronik, Boston Scientific, Medtronic, Edwards Lifesciences and St. Jude Medical.

Ernest Spitzer^{a,b} and Stephan Windecker^{a,*}

^aDepartment of Cardiology, Bern University Hospital, Bern, Switzerland

^bCardialysis B.V., Rotterdam, The Netherlands

*Corresponding author:

E-mail address: stephan.windecker@insel.ch (S. Windecker).

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