

mechanical support measures comprises two devices: Impella® and ECMO plus VA. Percutaneous Impella® produces an increase in cardiac output of 2.5-4.0-5.0 liters and, although its cost is approximately 3-fold higher than that of VA-ECMO, the device appears to be effective for the performance of angioplasty in high-risk patients.<sup>2</sup> However, in patients in whom femoral access is not possible or those having severe aortic stenosis, which were the cases in our patients nos. 1 and 4, respectively, its use is not possible.

The implantation of VA-ECMO is considered to be an aggressive technique because of the vascular complications derived from the size of the cannulas and the hematologic complications inherent in an extracorporeal circuit. In our experience, these complications are minimized by limiting the use of VA-ECMO to the duration of the procedure, ensuring safety and hemodynamic stability when they are technically difficult, in unstable and very high-risk patients. Moreover, the possibility of providing partial circulatory support enables the use of smaller cannulas, reducing the rate of vascular complications.

Finally, we subscribe to the initiative proposed by Ariza-Solé et al concerning the creation of a high-quality, prospective, multicenter registry to gather all the available experience with the use of VA-ECMO in the different clinical scenarios associated with the cardiology patient. Once again, the idea is to extend the utilization of this strategy for circulatory support in cardiac critical care units.

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



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

#### To the Editor,

We read the study by Spitzer et al<sup>1</sup> and the editorial by Moreno<sup>2</sup> about the usefulness of manual thrombectomy in primary coronary thrombectomy. There is discordance in the literature, with the TAPAS study (Thrombus Aspiration during Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) and 3 meta-analyses<sup>3-5</sup> finding it advantageous, but 2 more recent large trials, TASTE (Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia) and TOTAL (A Randomized Trial of Routine Aspiration Thrombectomy With PCI Versus PCI Alone in Patients With STEMI Undergoing Primary PCI), suggesting otherwise. Due to its results and sample size, the TASTE trial had a decisive influence on the meta-analysis of 26 trials by Spitzer et al,<sup>1</sup> comprising 60.6% of the patients included in the meta-analysis. With the addition of the 10 732 patients from the TOTAL trial, future meta-analyses will take a similar course. However, we believe that there are important aspects that must be taken into account when evaluating the influence of these trials. The TASTE trial was a multicenter, prospective, randomized trial, with patients from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR), and included patients who were candidates for primary percutaneous coronary intervention. Patients gave initial verbal consent and subsequent written consent and were then randomized in a 1:1 ratio to receive primary percutaneous coronary intervention either with or without thrombus aspiration. The primary endpoint was all-cause mortality in the first month

and annually thereafter. A total of 11 709 patients attended the centers but, as Moreno pointed out,<sup>2</sup> only 7244 (60%) were randomized; the remaining 4580 were included in a parallel registry, 1138 (24.8%) of them undergoing aspiration. The reasons for exclusion were inability to give consent (38%); thrombus aspiration not possible (16%), inappropriate (11%), indicated (7%); and other reasons (28%). The 30-day mortality of the study patients was 2.8% in the thrombus aspiration group vs 3.0% in the control group and was 10.9% vs 10.5% in the 2 registry arms. Finally, although the results were concordant according to Sianos classification of thrombus burden, the study appendix provided the percentages of each study patient group, but not those of the registry. Therefore, we believe that while the TASTE trial has the strengths of being multicenter and prospective, with a very large sample, and based on a positive initiative such as the SCAAR, it also has some limitations. These include not providing the percentage of direct stent implants in each treatment arm, not having a central angiography assessment laboratory, and 2 more aspects that we judge to be of vital relevance: not providing the percentage of types of thrombus for registry patients and, equally important, having a mortality 3 times higher in the parallel registry patients than in the randomized patients.

Similarly, the TOTAL trial included 10 732 patients from 87 hospitals over 4 years of recruitment, with a mean 30.8 cases per year per center. In this study there was no parallel registry of excluded patients. The percentage of patients classified as Killip I was 95.6% in the thrombectomy group and 95.8% in the percutaneous coronary intervention group, and mortality at 180 days was only 3.1% in the thrombectomy group and 3.4% in the percutaneous coronary intervention group without thrombectomy. This information could indicate a significant selection bias.

In our opinion, it is surprising that the analysis of these studies does not mention the low mortality rates.<sup>6</sup> Therefore, we believe

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.

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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.<sup>1</sup> 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.<sup>2</sup> 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 trial<sup>3</sup> were presented after our meta-analysis and were consistent with our findings regarding clinical endpoints, except for stroke.

## CONFLICTS OF INTEREST

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