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AIR-STEMI trial Update after FAVOR 3 trial publication

At the recent TCT Congress in Washington, the results of the Functional Assessment by Virtual Online Reconstruction (FAVOR 3) Europe trial have been presented and simultaneously published on the Lancet. This is the largest randomized clinical trial (RCT) investigating the non-inferiority of quantitative flow ratio (QFR) vs. wire-based fractional flow reserve (FFR) in patients undergoing PCI, mainly for chronic coronary syndrome. The study failed to demonstrate the non-inferiority of QFR vs. FFR, for a significant increase of myocardial infarction and revascularization.

The Executive Committee of the AIR-STEMI trial internally discussed the results of the FAVOR 3 trial. Our conclusion is that the conduction of the AIR-STEMI trial is even more warranted after the FAVOR 3 trial results. In fact, some important differences should be highlighted:

- The AIR-STEMI trial is enrolling non-culprit lesions of STEMI patients, and not CCS patients
- The control arm of the AIR-STEMI trial is PCI guided by conventional angiography and not wire-based FFR
- The angiography-derived FFR analysis is centralized in the core-lab and not performed by single center
- The recruitment is near to the conclusion (enrolled more than 1400 patients with an estimated sample size of 1800 patients)
- The CEC and DSMB committees are continually monitoring the rate of adverse events and no signal of warning or concern has been reported

In addition, some important criticisms should be highlighted in the FAVOR 3 trial

- Slow rate of recruitment
- Inclusion of centers with limited experience in the conduction of RCTs
- Inclusion of centers and operators with limited experience in QFR analysis
- Unexpected low rate of adverse events in the FFR arm
- Huge variability between countries and centers in the performance of the QFR arm
- Application of a oldest version of QFR software.

Based on these important considerations, no reason emerged to stop the recruitment of the AIR-STEMI trial. We are performing a trial in a different clinical condition, with a different organization and software. We are confident that the AIR-STEMI trial will give important information for the management of STEMI patients with multivessel disease.

The Executive Committee of the AIR-STEMI trial

References

1. Quantitative flow ratio versus fractional flow reserve for coronary revascularisation guidance (FAVOR III Europe): a multicentre, randomised, non-inferiority trial. Andersen, Birgitte Krosgaard et al. The Lancet 2024 Epub Ahead of print