PIE MEDICAL IMAGING

Clinical evidence for CAAS vFFR

FAST Study series

Pre-stent scenario

- The **initial FAST I**[1] study evaluated 100 patients and assessed the diagnostic accuracy of vFFR to predict invasive FFR $\leq$ 0.8. The diagnostic accuracy was 0.93 and a high reproducibility was shown with a correlation coefficient of 0.95

- In the **FAST Extend**[2] study 303 were evaluated confirming the high diagnostic accuracy (0.94) of vFFR to predict FFR $\leq$ 0.8.

- The **FAST Left Main**[3] study investigated the correlation between vFFR and IVUS for left main coronary stenosis.

- The **FAST II**[4] study was an *international multi-center prospective trial* in 6 countries (Netherlands, Germany, Italy, France, Unites States and Japan) evaluating the diagnostic accuracy and reproducibility of vFFR in an in-hospital and off-line core laboratory setting. The diagnostic accuracy to predict FFR $\leq$ 0.8 for both corelab and in-hospital were very high 0.93 and 0.91, respectively. Reproducibility between in-hospital and corelab also demonstrated to be very high at 0.87.

- The **FAST III**[5] trial is an ongoing *international multi-center prospective trial* in 7 European countries at 35 sites enrolling 2228 patients investigating a vFFR vs FFR guided stenting strategy. The principal investigator is Dr. Joost Daemen and the study is led by the European Cardiovascular Research Institute: https://www.ecri-trials.com/studies/fast-iii/

Post-stent scenario

- The **FAST Post**[6] study evaluated 100 patients and assessed the diagnostic accuracy of vFFR to predict invasive FFR $\leq$ 0.9 after stent implantation. The diagnostic accuracy was 0.98 and high reproducibility was shown with a correlation coefficient of 0.95.

- In the **FAST Outcome**[7] study vFFR was carried out post-stenting in 800 patients and related to 1-year clinical outcome in these patients. The study demonstrated that patients with a

[1] Masdjedi et al. Validation of 3-Dimensional Quantitative Coronary Angiography based software to calculate Fractional Flow Reserve: Fast Assessment of STenosis severity (FAST)-study. EuroIntervention 2019
[2] Neleman et al. Extended Validation of Novel 3D Quantitative Coronary Angiography-Based Software to Calculate vFFR: The FAST EXTEND Study. JACC Cardiovasc Imaging. 2021
[3] Tomaniak M et al. Correlation between 3D-QCA based FFR and quantitative lumen assessment by IVUS for left main coronary artery stenoses. Catheter Cardiovasc Interv. 2020
[4] Daemen et al. Presented as Late Breaking Clinical Trial at EuroPCR 2021.
[5] Clinicaltrials.gov identifier: NCT04931771
[6] Masdjedi et al. Validation of novel 3-dimensional quantitative coronary angiography-based software to calculate fractional flow reserve post stenting. Catheter Cardiovasc Interv. 2020
[7] Masdjedi et al. The Prognostic Value of Angiography-Based Vessel-FFR After Successful Percutaneous Coronary Intervention: The FAST Outcome Study. Presented at TCT 2019.

post-stent vFFR < 0.9 showed a significantly higher rate of target vessel revascularization at 1 year.

Various scenarios

- The **FAST Residual vFFR** study evaluated the correlation of residual vFFR as calculated on the pre-stent angiogram with the post-stent invasive FFR. The results will be presented at TCT 2021.

- The **FAST dPR** study evaluated the correlation of vFFR with a non-hyperaemic pressure ratio dPR. The results will be presented at TCT 2021.

- The **FAST OCT**[8] trial is an ongoing *international multi-center prospective trial* associating vFFR with OCT.

LIPSIA STRATEGY

Pre-stent scenario

- The **LIPSIA STRATEGY**[9] study is an ongoing *German multi-center prospective trial* at 7 sites enrolling 2000 patients investigating a vFFR vs FFR guided stenting strategy. The study is led by Prof. Holger Thiele (principal investigator) from Herzzentrum Leipzig

[8] Clinicaltrials.gov identifier: NCT04683133
[9] Clinicaltrials.gov identifier: NCT03497637