Safety of negative FrActional flow reserve in patients with ChallEnging lesions: the FACE, a prospective multicenter study.

ABSTRACT.

The new ESC guidelines have stressed the pivotal role of a fractional flow reserve for patients with stable angina and challenging lesions, like unprotected left main or multivessel disease in patients with reduced ejection fraction. The present study aims to systematically validate this approach.

INTRODUCTION.

Fractional Flow Reserve (FFR) has recently emerged and has been largely validated as a safe and efficacious way of ischemia testing for patients with stable angina.[1,2].

The new recently ESC guidelines have strongly suggested a FFR based approach for patients with stable angina, also for those with challenging lesions like left main disease, severe multivessel stenosis for heart failure patients and those with single remaining vessels [3] although left main disease and an ejection fraction less than 30% are exclusion criteria of the randomized controlled trials on this topic [2,4].

Consequently we performed a prospective multicenter study to understand the safety and efficacy of a FFR based approach for these patients.

METHODS.

The present is a multicenter prospective study enrolling all patients with stable angina and/or documented ischemia presenting with:

- An angiographic stenosis of more than 50% and less than 90% of the left main
- Any proximal descending anterior with a stenosis of more than 50% and less than 90%
- Two or three vessel disease with a stenosis of more than 50% and less than 90% and a left ventricle ejection fraction less than 40%
- Single remaining patent coronary artery with stenosis >50% and less than 90%

In all of these patients FFR (Fractional Flow Reserve) or will be performed according to guidelines and stenting will be performed or deferred according to the result of this test.

Other techniques, like iFR, IVUS and OCT will be left at the operators' choice and will be recorded.

MACE (a composite end point of death, myocardial infarction and target vessel revascularization and stent thrombosis) will be the primary end point, while its single components will be the secondary ones.

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