

RESULTS OF ADVISE II Final Analysis¹

ADVISE II: Adenosine Vasodilator Independent Stenosis Evaluation II (NCT01740895)

PRINCIPAL INVESTIGATORS

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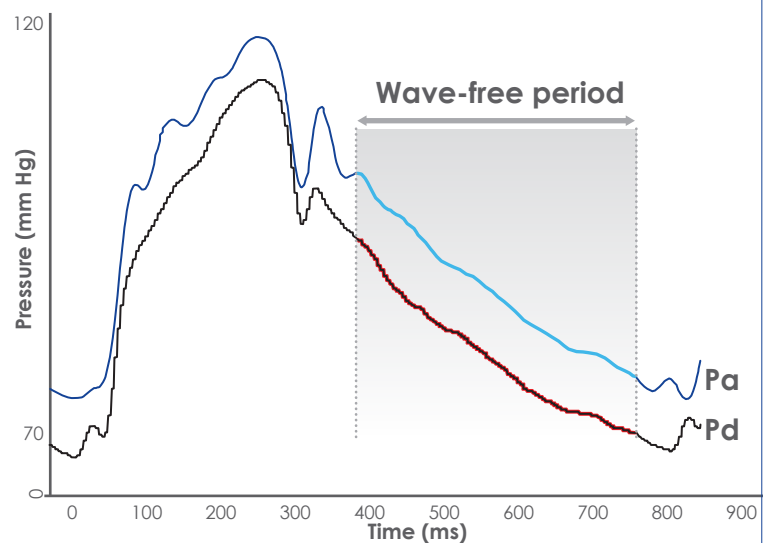
40 centers (27 United States, 12 Europe, 1 Africa)

BACKGROUND

- ▶ The purpose of the study was to prospectively assess the clinical value of iFR[®] modality to characterize, without concomitant administration of hyperemic agents and outside a specified range of iFR values, coronary stenosis severity as determined with fractional flow reserve (FFR).
- ▶ This study was a prospective, observational, non-randomized, double blind, global, multi-center registry investigating the diagnostic utility of iFR in assessing coronary stenosis relevance.

WHAT IS iFR[®]?

- ▶ The iFR[®] modality is a pressure-derived, hyperemia-free index for assessment of coronary stenosis relevance.
- ▶ > 4,000 iFR comparisons with fractional flow reserve (FFR) have been made since its introduction at TCT 2011.
- ▶ Numerous prospective iFR studies have been published in peer-reviewed journals.

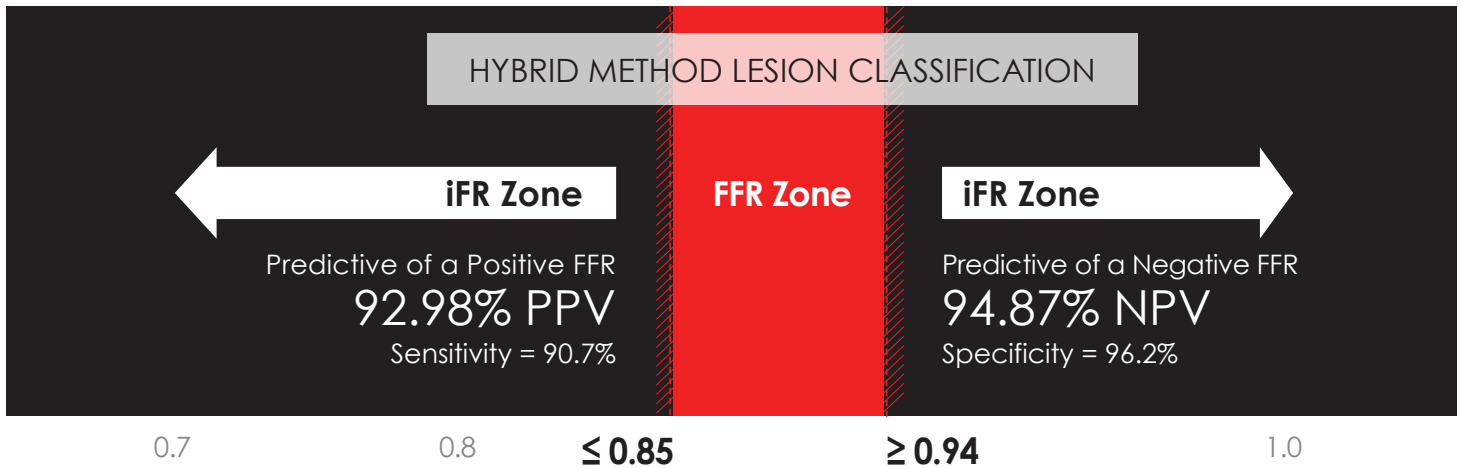


WHAT IS the Hybrid Method?¹

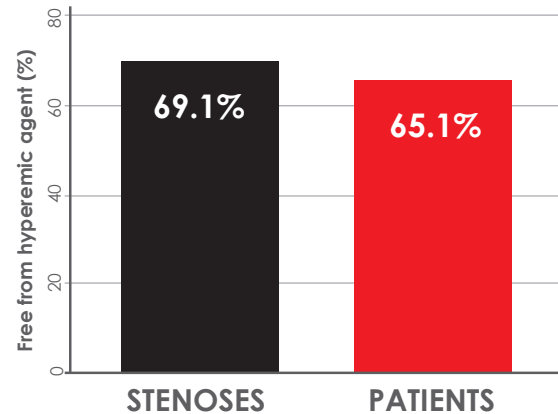
Hybrid iFR[®]/FFR Approach



PERCENTAGE OF LESIONS Properly Classified Using the Hybrid Approach² **94.0%**



PATIENTS MAY BE FREE FROM Hyperemia Using the Hybrid Approach³ **65.1%**



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1. Escaned J, on behalf of the ADVISE II investigators. ADVISE II: A Prospective, Registry Evaluation of iFR vs. FFR. Late Breaking Clinical Trial, TCT 2013. Available online at: <http://www.tctmd.com/show.aspx?id=122086>
 2. Using the iFR cut points of 0.85 and 0.94 matches best with an FFR ischemic cut-point of 0.80 with a specificity of 90.7% and sensitivity of 96.2%. (iFR Operator's Manual 505-0101.23)
 3. The ADVISE II study illustrated a 5.8%, i.e. (17+23)/690, classification discordance between the iFR Hybrid Approach and FFR. Among 477 lesions that would be assessed without hyperemia by the iFR Hybrid Approach, 40 (17+23) were due to classification discordance.

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