# SYNTAX MESSAGE OUTDATED? FAME, PHYSIOLOGIC GUIDANCE OF PCI, AND NEW DES: DO THEY MAKE A DIFFERENCE?

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Nico H. J. Pijls, MD, PhD Catharina Hospital, Eindhoven, The Netherlands To understand the message of SYNTAX, at first we should realize that the purpose of any kind of revacularization (whether it is CABG or PCI) is

- either to improve symptoms (quality of life)
- or to improve outcome (preventing death or MI)

#### Key Integrated information from hundreds of studies

Risk to die or experience myocardial infarction in the next 5 years related to a coronary stenosis:

- non-ischemic stenosis: < 1% per year \* (NUCLEAR studies, DEFER, FAME, PROSPECT, CCTA)
- ischemic stenosis, if left untreated: 5-10% per year (Many historical registries, ACIP, etc)
- stented stenosis: 2-3% per year (e.g DEFER, FAME, SYNTAX,many large studies and registries)

#### Circulation 2003

# Hachamovitch et al.



% Total Myocardium Ischemic

#### Circulation 2003

# Hachamovitch et al.



#### **Cardiac Death And Acute MI After 5 Years**

non-ischemic stenosis, R/x
 non-ischemic stenosis, R/x + stent
 ischemic stenosis, R/x + stent



#### Risk to die or experience myocardial infarction in the next 5 years related to a coronary stenosis:

 non-ischemic stenosis: < 1% per year \* (NUCLEAR studies, DEFER, FAME, PROSPECT, CCTA)

#### → <u>No ischemia</u>

excellent outcome with medical treatment no need for mechanical revascularization

#### Circulation 2003

# Hachamovitch et al.



#### Death & MI 5 during 5 years of follow-up after PCI vs Medical Treatment in <u>ISCHEMIC</u> stenosis



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So, at this point it will be clear that *functionally significant (= ischemic) lesions should be revascularized, .....* 

.....whereas it makes no sense to stent non-ischemic lesions

Therefore, the <u>key issue</u> is to establish if a particular stenosis is associated with reversible ischemia....

#### Fractional Flow Reserve (FFR)

# FFR is the most accurate method to indicate or exclude reversible ischemia



FFR is the *only* functional index which has ever been validated versus a true gold standard. (Prospective multi-testing Bayesian methodology)

- Exercise testing: ischemia per patient
- MIBI Spect : ischemia per artery
- FFR

: ischemia per stenosis/segment

Sensitivity : 90% Specificity : 100%

*N Engl J Med 1996; 334:1703-1708 Circulation 2010, many others* 

#### WHAT DOES THIS MEAN FOR REVASCULARIZATION IN PATIENTS WITH MVD ?



#### Intrinsic risk of death and myocardial infarction ?



Ischemic lesion → intrinsic risk 5 % per year Non-ischemic lesion → intrinsic risk 1 % per year Stented stenosis → intrinsic risk 3 % per year

"stent 'm all" (SYNTAX Strategy) "stent only the ischemic ones" (FAME)  $\rightarrow$  intrinsic risk 12  $\rightarrow$  8 %

both strategies eliminate ischemia  $\rightarrow$  similar functional class

→ intrinsic risk 12% → 12%



## SYNTAX Study: outcome in PCI Group negatively influenced in 2 ways:

Stenting of ALL stenoses > 50% by angiography, irrespective whether they were "ischemic" or not → quite a bit of non-ischemic stenoses were stented (~ 30%), increasing risk for death/MI without benefit

...and conversely some lesions which were ischemic but < 50 % by angiography, were not stented, which also mean increased risk

FAME Study: Better selection of lesions to stent, decreased death and MI rate by 25-30%

# MACCE in SYNTAX – 3VD and FAME

similar definition of MACCE, including CVA and excluding CKMB 3-5 x N



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Classification of patients in FAME study according to Syntax score (SS) or Functional Syntax Score (FSS)



Has this consequences...? → Yes!!!

Nam, JACC 2011

#### Influence of Syntax Score and Functional Syntax Score on mortality and infarction rate in FAME study



Nam et all, JACC 2011

#### **SYNTAX Message outdated ?**

**YES....!** if you believe that every stenosis > 50% should be stented

**NO....!** If you guide stenting by FFR and only stent those lesions which really matter (i.e. cause complaints and affect outcome)

*IN THAT CASE* you can select quite a number of patients with angiographic 3-vessel disease who are perfect candidates for PCI with outcome comparable to CABG

...and with better stents, this message only becomes clearer

#### **GUIDELINES ESC SEPTEMBER 2010**

## FFR UPGRADED TO LEVEL I A INDICATION

#### **10 – Procedural aspects of PCI**

 Table 28: Specific PCI devices and pharmacotherapy

	Class	Level
FFR-guided PCI is recommended for detection of ischemia-related lesion(s) when objective evidence of vessel-related ischamia is not available	I	А
DES* are recommended for reduction of restenosis/reocclusion, if no contraindication to extended DAPT	Ι	А
Distal embolic protection is recommended during PCI of SVG disease to avoid distal embolisation of debris and prevent MI	I	В
Rotablation is recommended for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting	I	С

ESC-EACTS Guidlines for Myocardial Revascularisation, August 30, 2010