MUNI MED

FAKULTNÍ NEMOCNICE BRNO

ČESKÁ ASOCIACE **INTERVENČNÍ KARDIOLOGIE**

FAME-3

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The NEW ENGLAND JOURNAL of MEDICINE

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ORIGINAL ARTICLE

Fractional Flow Reserve–Guided PCI as Compared with Coronary Bypass Surgery

W.F. Fearon, F.M. Zimmermann, B. De Bruyne, Z. Piroth, A.H.M. van Straten, L. Szekely, G. Davidavičius, G. Kalinauskas, S. Mansour, R. Kharbanda, N. Östlund-Papadogeorgos, A. Aminian, K.G. Oldroyd, N. Al-Attar, N. Jagic, J.-H.E. Dambrink, P. Kala, O. Angerås, P. MacCarthy, O. Wendler, F. Casselman, N. Witt, K. Mavromatis, S.E.S. Miner, J. Sarma, T. Engstrøm, E.H. Christiansen, P.A.L. Tonino, M.J. Reardon, D. Lu, V.Y. Ding, Y. Kobayashi, M.A. Hlatky, K.W. Mahaffey, M. Desai, Y.J. Woo, A.C. Yeung, and N.H.J. Pijls, for the FAME 3 Investigators*

Circulation: Cardiovascular Interventions
Volume 15, Issue 11, November 2022; Pages 884-891
https://doi.org/10.1161/CIRCINTERVENTIONS.122.012542

American Heart Association.

CORONARY PHYSIOLOGIC ASSESSMENT AND IMAGINGS

Prognostic Value of Measuring Fractional Flow Reserve After Percutaneous Coronary Intervention in Patients With Complex Coronary Artery Disease: Insights From the FAME 3 Trial

Zsolt Piroth, MD, PhD, Hisao Otsuki, MD, Frederik M. Zimmermann, MD, Tamás Ferenci, PhD, Danielle C.J. Keulards, MD, PhD, Alan C. Yeung, MD, Nico H.J. Pijls, MD, PhD, Bernard De Bruyne, MD, PhD, William F. Fearon, MD, and on behalf of the FAME 3 Investigators

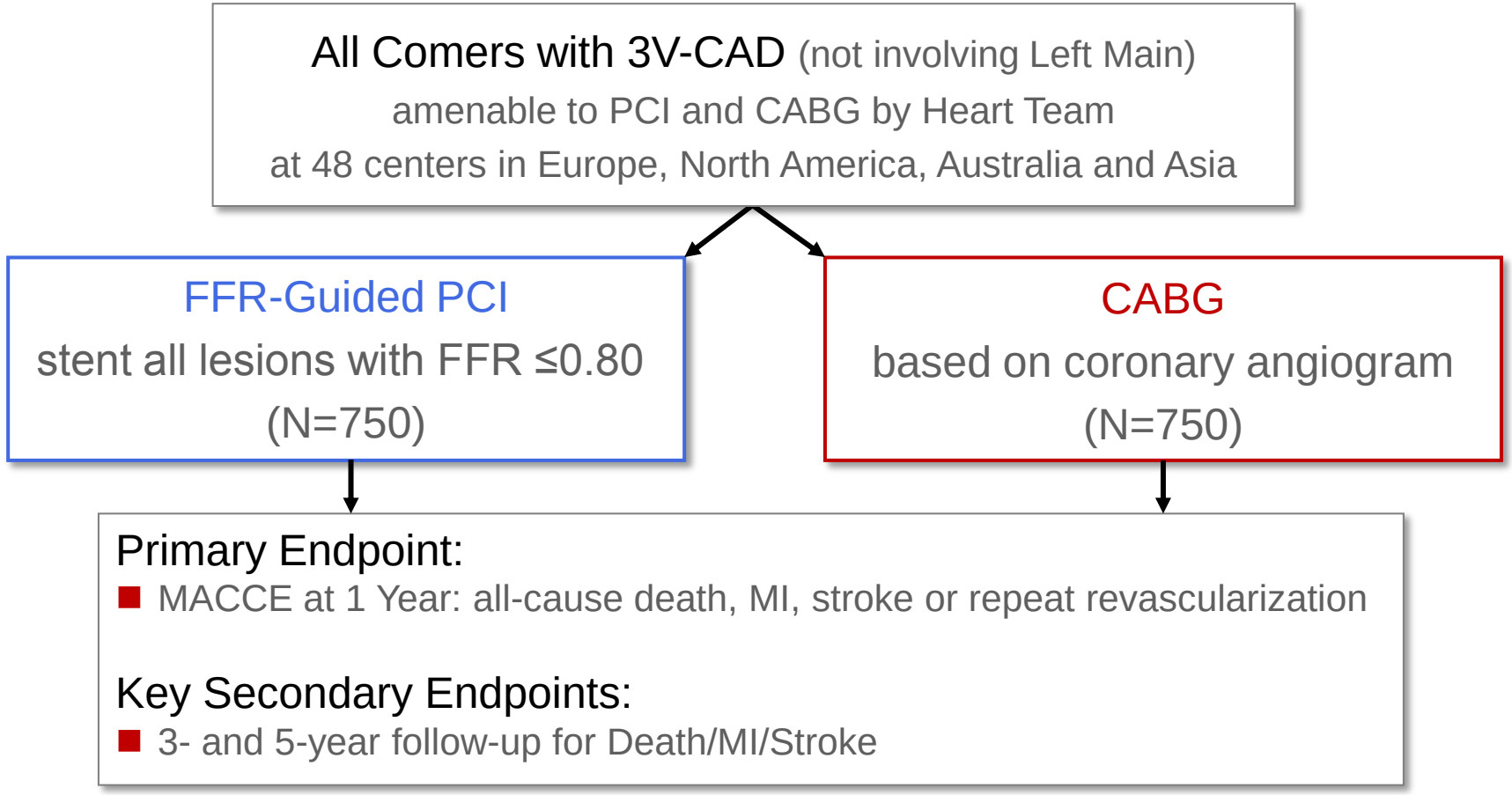
FAME 3 Trial Hypothesis

In patients with 3V-CAD, FFR-guided PCI with a current generation DES is noninferior to CABG with respect to 1-year MACCE.

Zimmermann FM, et al. *Am Heart J* 2015;170:619-626.
Zimmermann FM, et al. *Am Heart J* 2019;214:156-157

Study Design

Investigator-initiated, multicenter, randomized, controlled study



Patient Eligibility

Key Inclusion Criteria

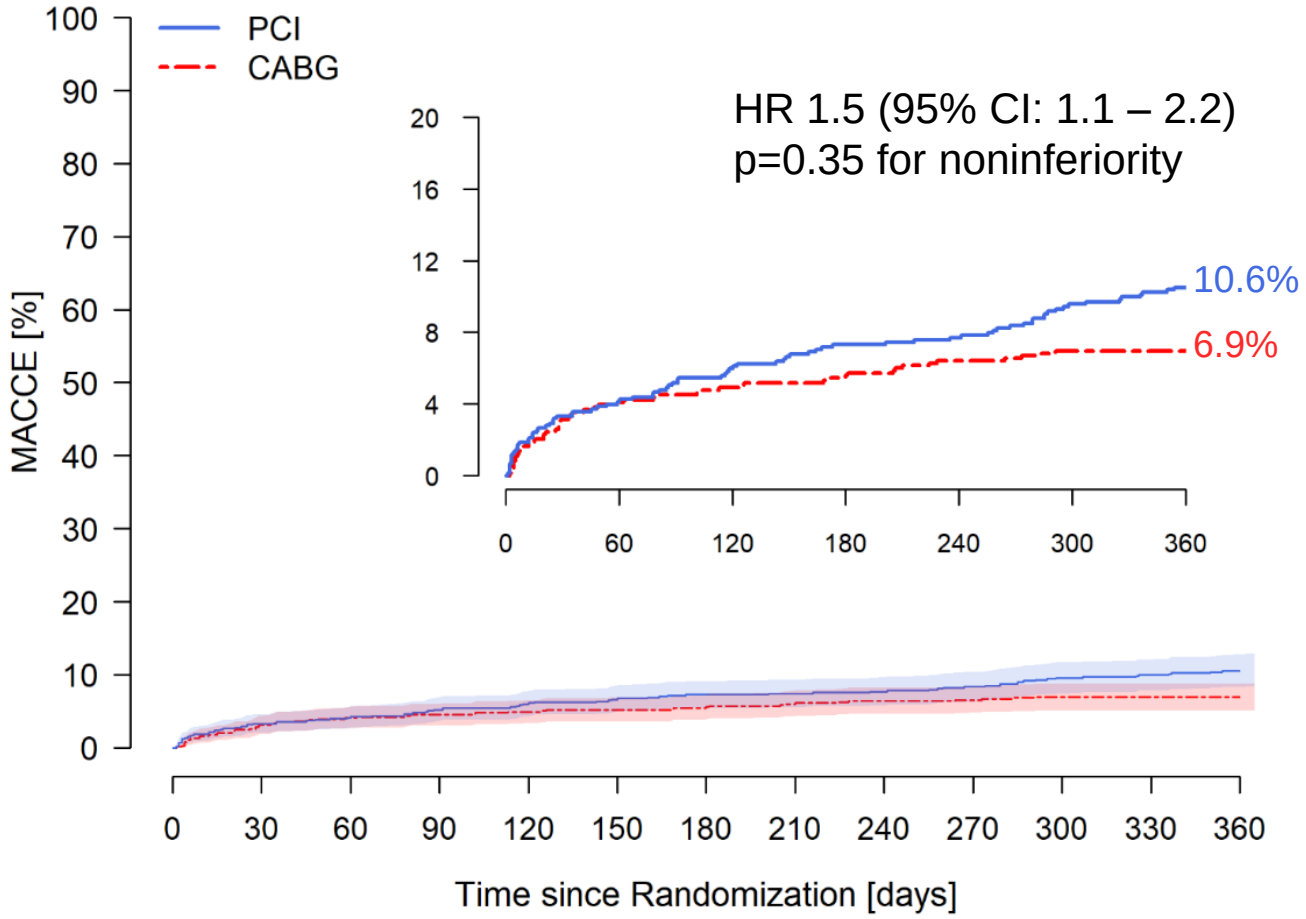
- Three vessel CAD:
  - ≥ 50% diameter stenosis in 3 major epicardial vessels (visual estimation, no Left Main involvement)
  - Amenable to revascularization by both PCI and CABG (Heart Team)

Key Exclusion Criteria

- Cardiogenic shock
- Recent STEMI (within 5 days)
- LV ejection fraction < 30%

Primary Endpoint

MACCE (Death, MI, stroke or repeat revascularization) at 1 Year



No. at Risk													
PCI	757	728	721	713	707	702	697	696	693	687	678	674	670
CABG	743	709	701	698	695	693	691	686	683	682	679	679	679

Safety Endpoints

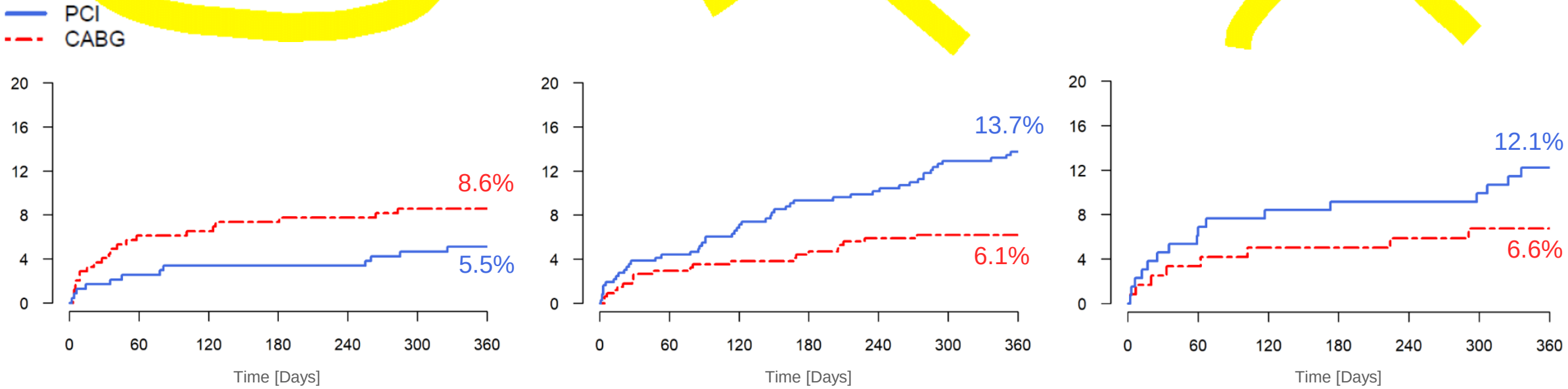
Endpoint	PCI (n=757)	CABG (n=743)	*p*-value
BARC Type 3-5 Bleeding	1.6%	3.8%	< 0.01
Acute Kidney Injury	0.1%	0.9%	< 0.04
Atrial Fibrillation/Arrhythmia	2.4%	14.1%	< 0.001
Definite Stent Thrombosis	0.8%	N/A	
Symptomatic Graft Occlusion	N/A	1.3%	
Rehospitalization w/in 30 days	5.5%	10.2%	< 0.001

MACCE According to SYNTAX Score

LOW (<23)
SYNTAX SCORE

INTERMEDIATE (23-32)
SYNTAX SCORE

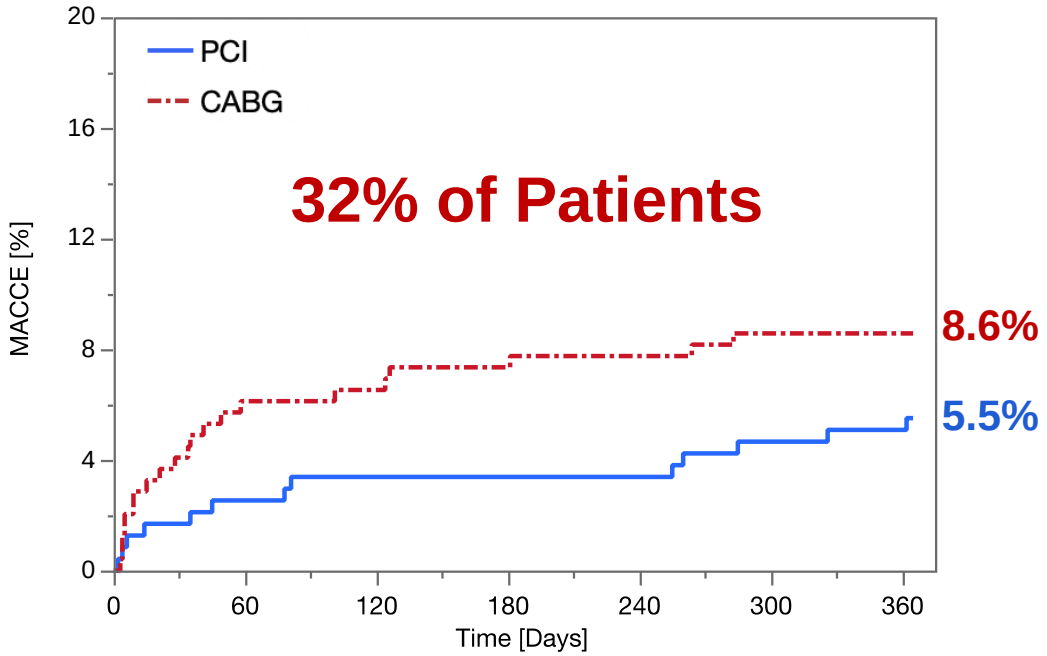
HIGH (>32)
SYNTAX SCORE



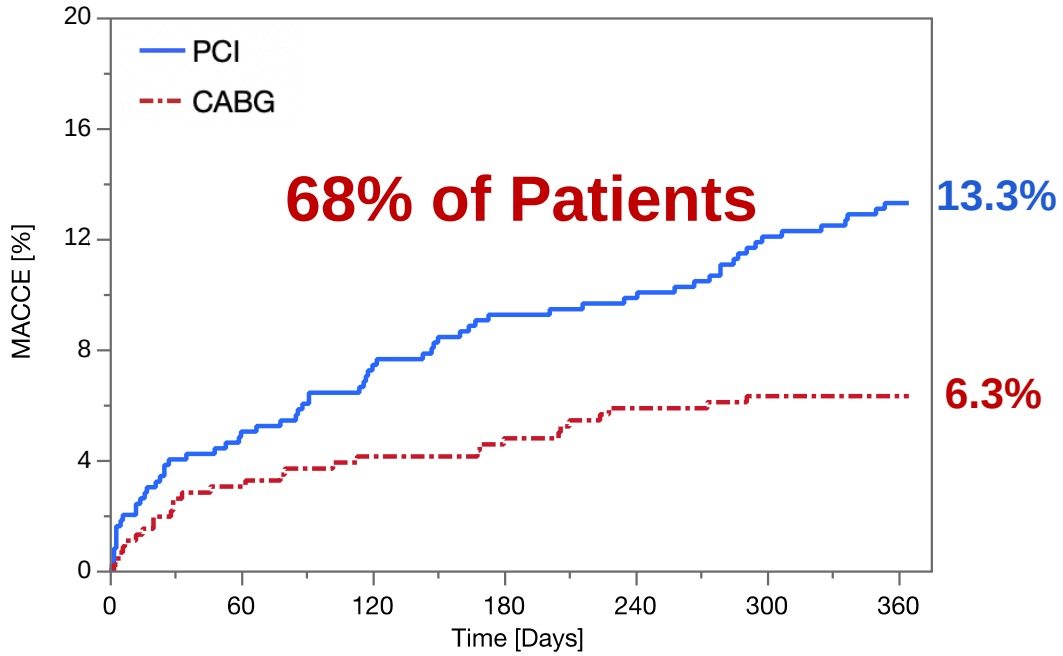
FAME 3

1-Year MACCE Based on SYNTAX Score

Low (≤22) SYNTAX SCORE



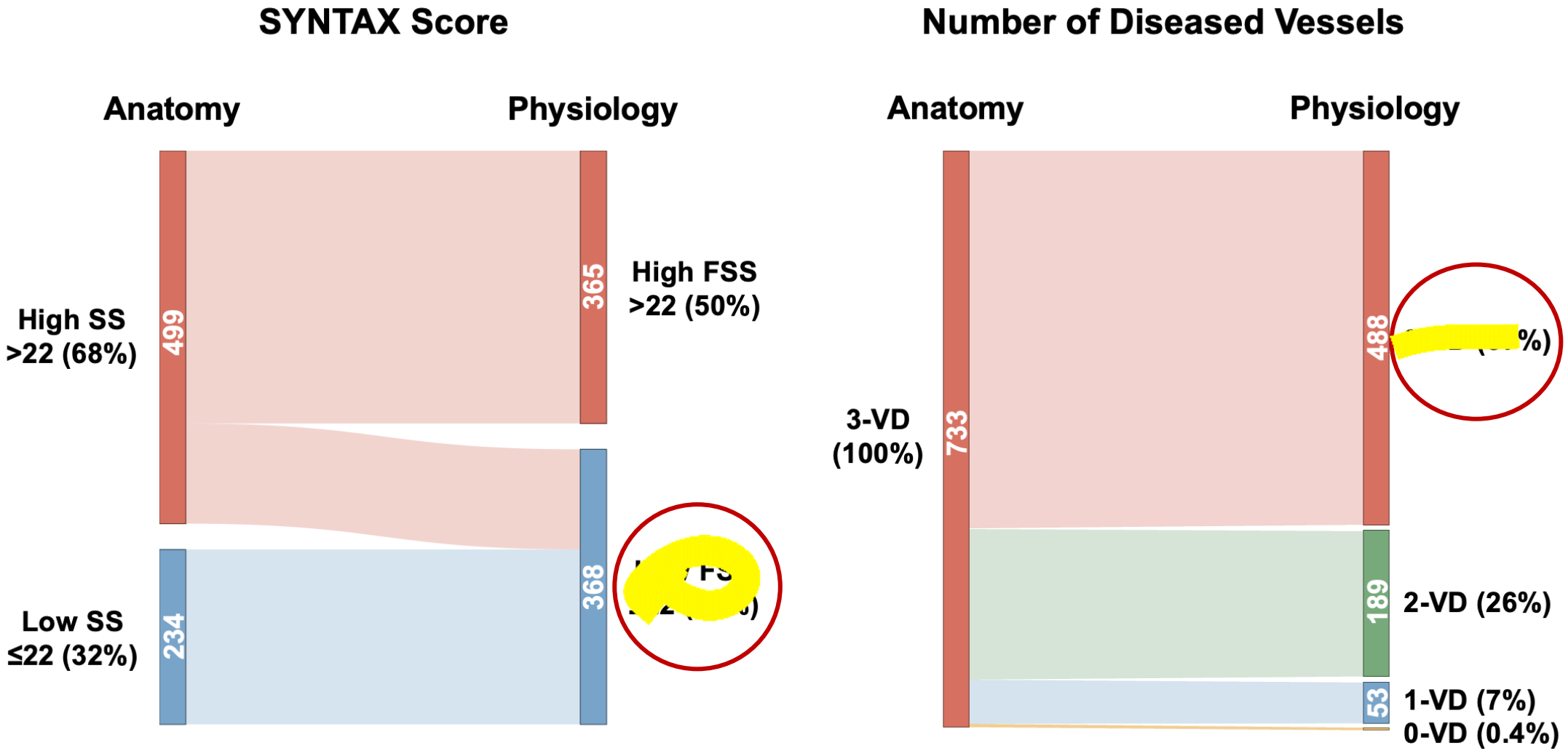
High (>22) SYNTAX SCORE



Can the functional SYNTAX score identify which high SYNTAX score patients have a good outcome with PCI?

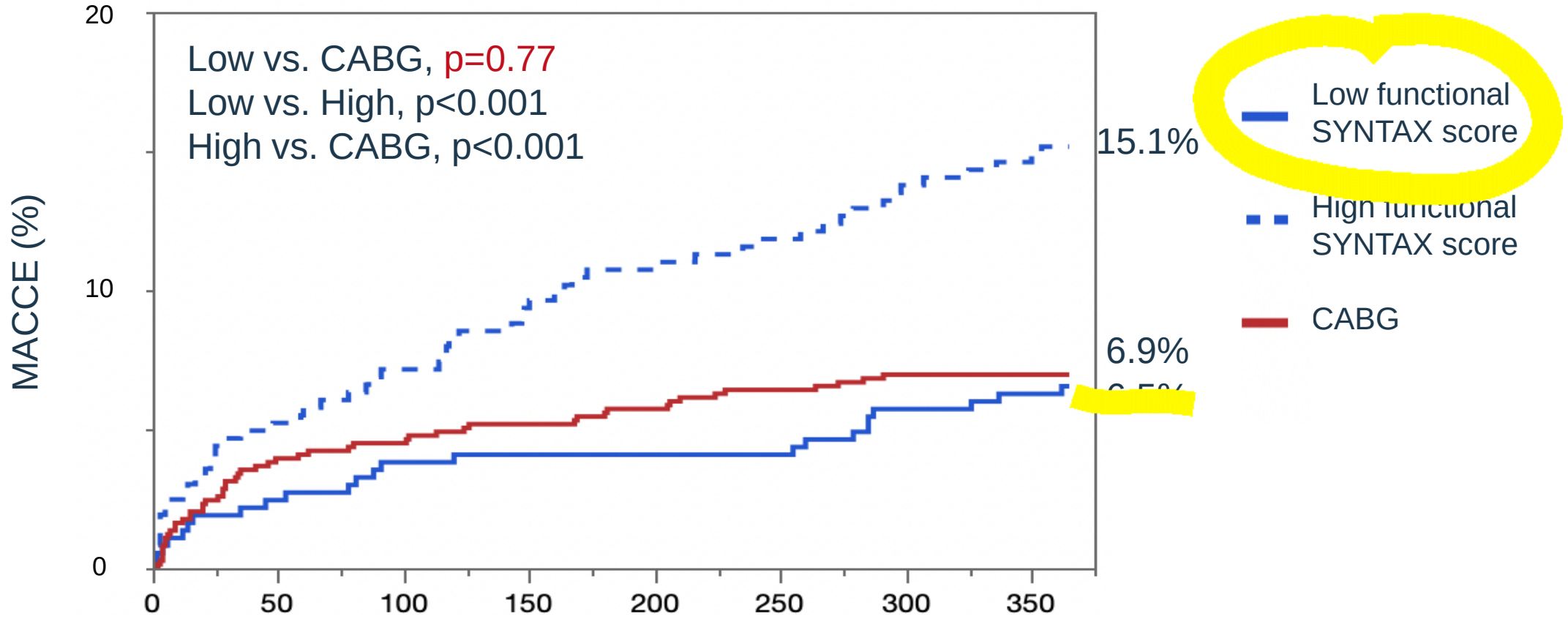
Fearon et al. *NEJM* 2022

Reclassification with FFR Information



FSS = functional SYNTAX score; VD = vessel disease

MACCE According to Functional SYNTAX Score



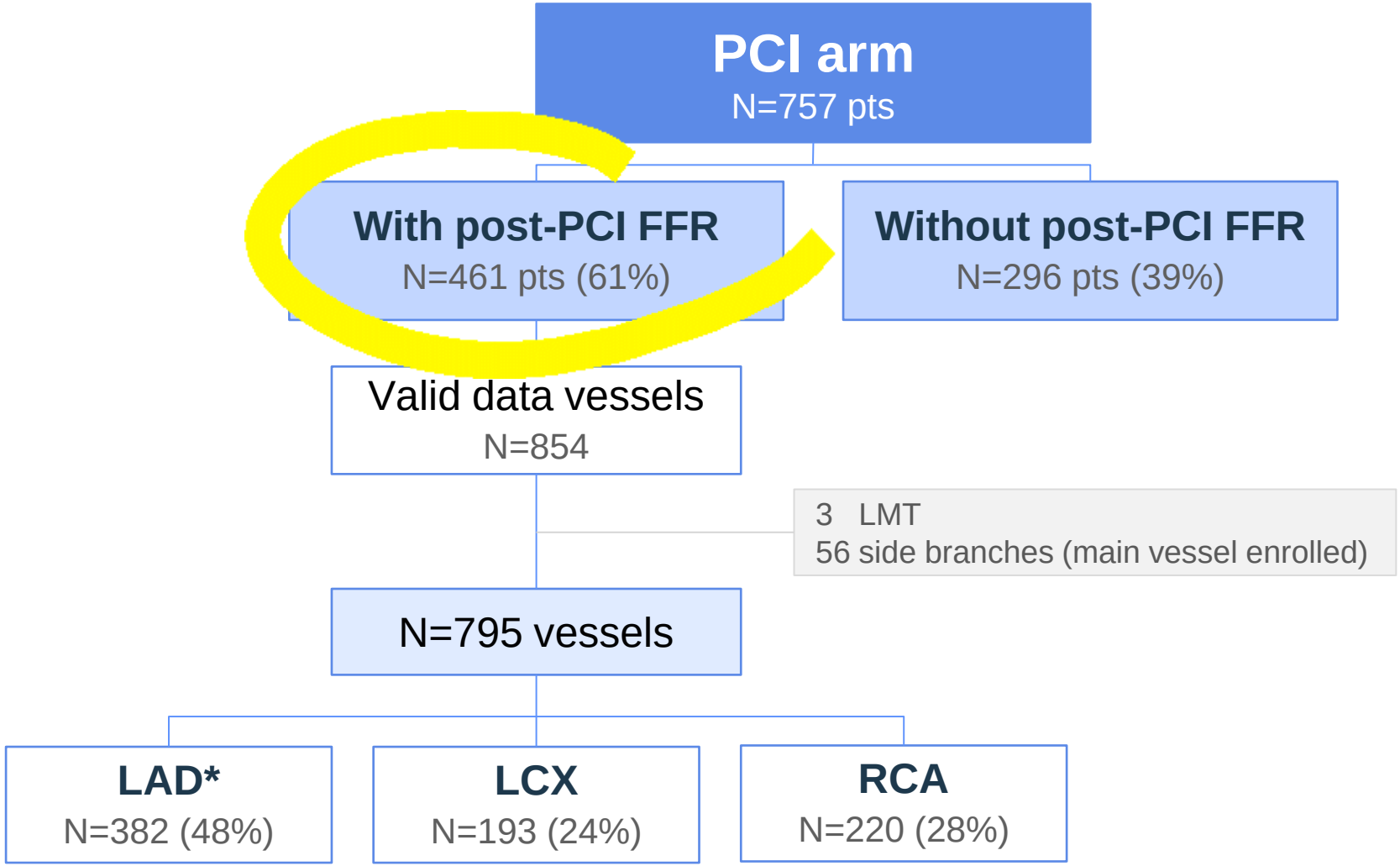
Low	368	354	353	346	342
High	365	338	325	313	306
CABG	743	699	689	680	678

MACCE (Death, MI, CVA or repeat Revascularization)

Outcome of Deferred Lesions at 1 Year

- Among all deferred lesions (n=597):
  - MI rate = 0.5% (n=3)
  - Revascularization rate = 3.2% (n=19)
- Related to stented lesions or de novo lesions:
  - [illegible]
  - [illegible]

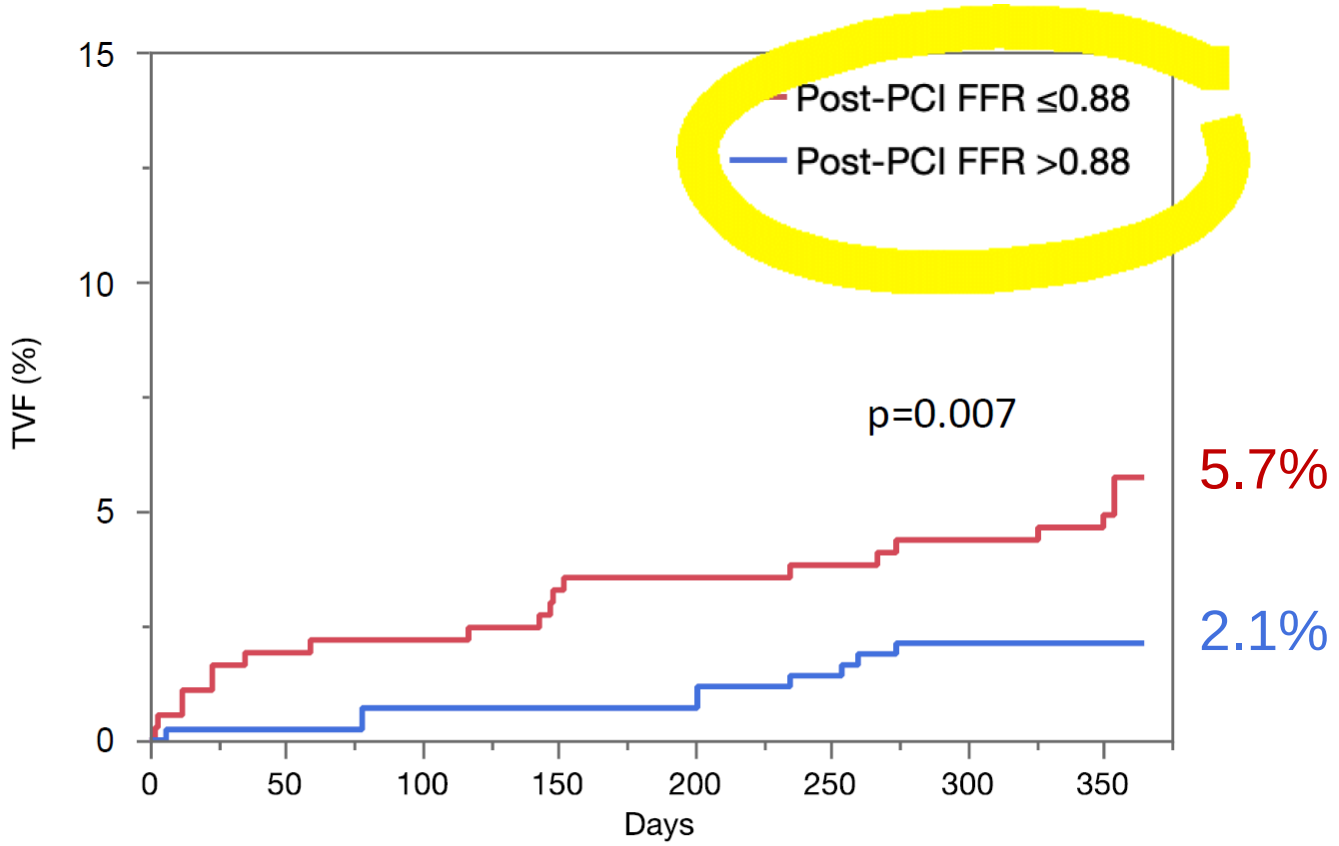
Post-PCI FFR Flowchart



*N=12 (1.5%) were diagonal branches included as LAD

Primary Endpoint: TVF at 1 Year

(Vessel-Level Analysis)



Post-PCI FFR ≤0.88	367	360	355	351	345
Post-PCI FFR >0.88	428	427	427	415	414

TVF = Target Vessel Failure, defined as cardiac death, target vessel MI, or target vessel revascularization (vessel-level)

FAME 3 - Shrnutí

- FFR-guided PCI s moderním typem DES je u pacientů s 3VD spojena s horšími výsledky oproti anatomicky vedené CABG v 1 roce.
- CABG je spojena s vyšším rizikem krvácení, FISI, AKI a krátkodobých rehospitalizací.
- PCI má stejné výsledky jako CABG u pacientů s nízkým Syntax skóre (anatomicky u 32% a funkčně u 50% pacientů).
- Post-PCI FFR s hodnotou >0,88 (event. >0,85) je spojeno s významně lepšími klinickými výsledky.
- FFR >0,80 značí velmi dobrou prognózu u lézí bez revaskularizace.