

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*

Fame 3 trial. Review y
comentarios

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Enf. 3 vasos angiográfica

**Exclusion:
TCI
STEMI
SHOCK
LVEF < 30**

PCI FFR GUIDED

CABG +/- FFR guided

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Table 1. Characteristics of the Patients at Baseline.*

Characteristic	PCI (N=757)	CABG (N=743)
Age — yr	65.2±8.6	65.1±8.3
Male sex — no. (%)	616 (81.4)	619 (83.3)
White race — no. (%) [†]	711 (93.9)	686 (92.3)
Body-mass index [‡]	28.6±4.5	28.7±4.3
Diabetes — no. (%)	214 (28.3)	214 (28.8)
Insulin-dependent	55 (7.3)	61 (8.2)
Non-insulin-dependent	159 (21.0)	153 (20.6)
Hypertension — no./total no. (%)	538/756 (71.2)	556/741 (75.0)
Dyslipidemia — no./total no. (%)	521/756 (68.9)	531/741 (71.7)
Smoking status — no./total no. (%)		
Current tobacco user	145/756 (19.2)	136/741 (18.4)
Previous tobacco user	296/756 (39.2)	296/741 (39.9)
Family history of coronary artery disease — no./total no. (%)	246/756 (32.5)	213/740 (28.8)
Previous myocardial infarction — no./total no. (%)	252/756 (33.3)	248/741 (33.5)
Previous PCI — no./total no. (%)	98/756 (13.0)	104/741 (14.0)
History of TIA or CVA — no./total no. (%)	49/756 (6.5)	56/741 (7.6)
Kidney disease — no./total no. (%) [§]	37/756 (4.9)	44/741 (5.9)
Noninvasive test for ischemia — no./total no. (%)	311/756 (41.1)	301/741 (40.6)
LVEF ≤50% — no./total no. (%)	137/753 (18.2)	130/740 (17.6)
Hospitalized with NSTEMI-ACS — no./total no. (%)	300/756 (39.7)	287/741 (38.7)

* Plus-minus values are means ± SD. CABG denotes coronary artery bypass grafting; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction.

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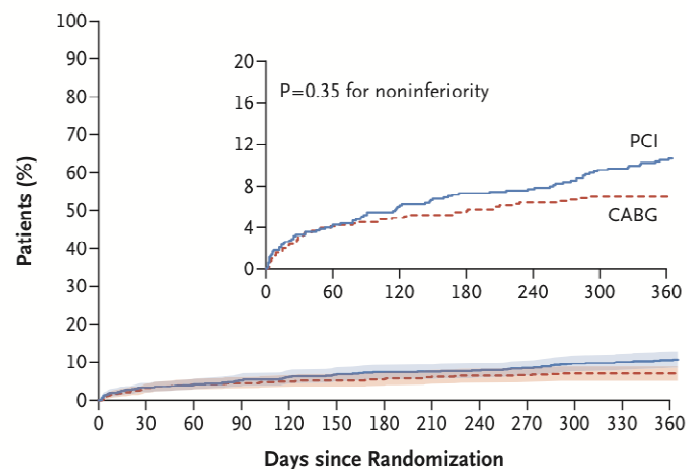
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Table 2. Angiographic and Procedural Characteristics.*

Characteristic	PCI (N=757)	CABG (N=743)
Median time to procedure (IQR) — days	4 (1–13)	13 (6–26)
Median procedure duration (IQR) — min	87 (67–113)	197 (155–239)
Median length of hospital stay (IQR) — days	3 (1–7)	11 (7–16)
No. of lesions	4.3±1.3	4.2±1.2
At least one chronic total occlusion — no./total no. (%)	157/755 (20.8)	171/739 (23.1)
At least one bifurcation lesion — no./total no. (%)	522/755 (69.1)	491/739 (66.4)
SYNTAX score [†]	26.0±7.1	25.8±7.1
SYNTAX score category — no./total no. (%)[†]		
Low, 0 to 22	237/734 (32.3)	245/710 (34.5)
Intermediate, 23 to 32	365/734 (49.7)	343/710 (48.3)
High, >32	132/734 (18.0)	122/710 (17.2)
PCI characteristics		
Staged procedure — no./total no. (%)	166/750 (22.1)	NA
No. of stents	3.7±1.9	NA
Median total length of stents placed (IQR) — mm	80 (52–116)	NA
Intravascular imaging used — no./total no. (%)	87/744 (11.7)	NA
CABG characteristics		
Multiple arterial grafts — no./total no. (%)	NA	173/705 (24.5)
No. of distal anastomoses	NA	3.4±1.0
LITA used as graft — no./total no. (%)	NA	684/705 (97.0)
Off-pump surgery — no./total no. (%)	NA	168/698 (24.1)
FFR used before CABG — no./total no. (%)	NA	72/718 (10.0)

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No. at Risk

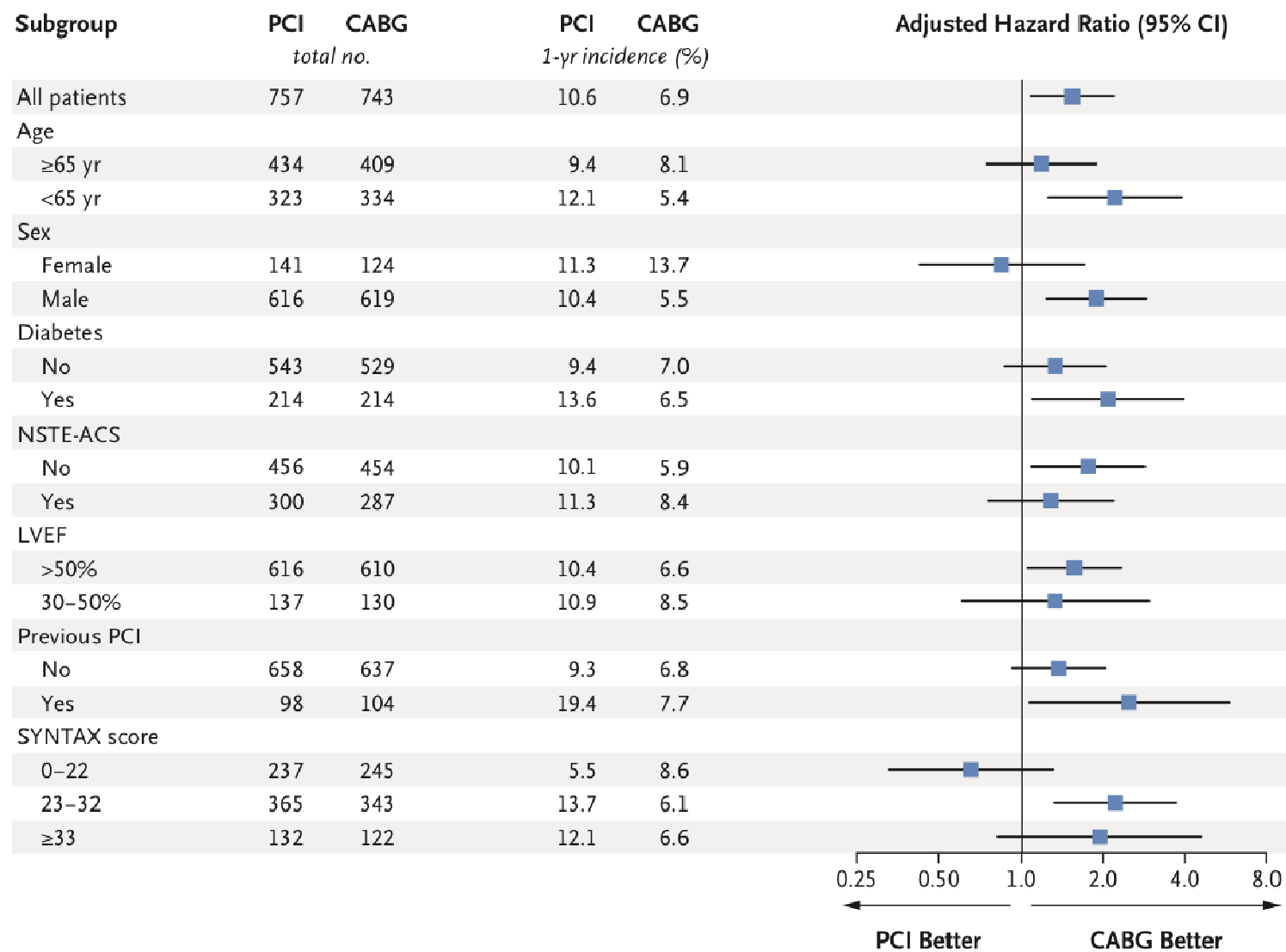
PCI	757	728	721	713	707	702	697	696	693	687	678	674	670
CABG	743	709	701	698	695	693	691	686	683	682	679	679	679

Table 3. End Points at 1 Year.

End Point	PCI (N=757)	CABG (N=743)	Hazard Ratio (95% CI)	P Value
<i>no. of patients (%)*</i>				
Primary end point				
Death from any cause, myocardial infarction, stroke, or repeat revascularization	80 (10.6)	51 (6.9)	1.5 (1.1–2.2)	0.35†
Secondary end points‡				
Death	12 (1.6)	7 (0.9)	1.7 (0.7–4.3)	
Death from cardiac causes	6 (0.8)	4 (0.5)		
Myocardial infarction	39 (5.2)	26 (3.5)	1.5 (0.9–2.5)	
Spontaneous	25 (3.3)	17 (2.3)		
Procedural	13 (1.7)	9 (1.2)		
Stroke	7 (0.9)	8 (1.1)	0.9 (0.3–2.4)	
Death, myocardial infarction, or stroke	55 (7.3)	39 (5.2)	1.4 (0.9–2.1)	
Repeat revascularization	45 (5.9)	29 (3.9)	1.5 (0.9–2.3)	
PCI	39 (5.2)	26 (3.5)		
CABG	6 (0.8)	3 (0.4)		
Safety end points§				
BARC type 3–5 bleeding¶	12 (1.6)	28 (3.8)		<0.01
Acute kidney injury	1 (0.1)	7 (0.9)		<0.04
Atrial fibrillation or clinically significant arrhythmia	18 (2.4)	105 (14.1)		<0.001
Definite stent thrombosis	6 (0.8)	NA		
Definite symptomatic graft occlusion	NA	10 (1.3)		
Rehospitalization within 30 days	42 (5.5)	76 (10.2)		<0.001

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2/7: Issue 1) We all know the controversy of peri-procedural MI. FAME-3 used the UDMI type 5 CABG defn. Rates 3.3% PCI, 2.3% CABG. Had the SCAI defn been used (which is more prognostically relevant), the rates were 10.3% PCI, 14.5% CABG and non-inferiority would have been met.

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4/7: Issue 3) Absolute differences are more important than relative differences. The absolute magnitude of differences in the 2 most important major events were small: Death (0.7% favoring CABG) and stroke (0.2% favoring PCI).

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7/7: Implications for future trials: Pts care about living longer and (feeling) better. We need to start selecting endpoints that more strongly emphasize not only longevity but also quality of life, the latter encompassing the spectrum of low frequency individual adverse events.

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- Stop estudios que buscan enterrar la cirugía
- Estudio con diseño que favorece a cirugía
- ICP no gold standard
- CCV sin FFR
- Mortalidad quirúrgica muy baja
- DEFINIR EXACTAMENTE LO QUE LE IMPORTA AL PACIENTE

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- ***Desgraciadamente, un trial con muchas red flags al que se le ha dado un hype absurdo y que no resuelve ninguna duda en la vida real***