


Clinical impact of FFR-guided PCI compared to angio-guided PCI from the France PCI registry

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Abstract

Objectives: We sought to compare, in a national French registry (FrancePCI), the clinical impact of fractional flow reserve (FFR)-guided percutaneous coronary intervention (PCI) compared with angio-guided PCI at 1 year.

Background: FFR has become the invasive gold standard to quantify myocardial ischemia generated by a coronary stenosis in patients with chronic coronary syndrome, but in clinical practice it is still underutilised to guide PCI compared to angiography (angio).

Methods: We extracted from the FrancePCI database all chronic coronary syndrome patients treated with PCI for coronary stenosis <90% between 2014 and 2019. Our composite clinical endpoint was the rate of major adverse clinical events (MACE).

Results: Fourteen thousand three hundred eighty-four patients with 1-year clinical follow-up were included. Among them, 13,125 had angio-guided PCI (91%) and 1259 (9%) had FFR-guided PCI. We observed a significantly higher rate of MACE in the angio-guided group versus the FFR-guided group: 1478 (11.3%) versus 100 (7.9%) ($p < 0.0001$), respectively, with hazard ratio (HR) of 1.440, 95% confidence interval (CI) [1.211–1.713] ($p = 0.0004$). This result was driven by the higher occurrence of death in the angio-guided group versus the FFR-guided-group: 506 (3.9%) versus 17 (1.4%) ($p < 0.0001$), respectively, with HR of 2.845, 95% CI [2.099–3.856] ($p < 0.0001$). After adjustment for potential confounding factors, HRs were 1.287, 95% CI [1.028–1.613] ($p = 0.028$) for MACE and 2.527, 95% CI [1.452–4.399] ($p = 0.001$) for death. No significant differences between angio-guided PCI and FFR-guided PCI were observed for other clinical endpoints.

Conclusions: FFR-guided PCI improves outcome at 1 year compared to angio-guided PCI with a reduction of 64% of death.

KEYWORDS

chronic coronary syndrome, clinical outcome, fractional flow reserve

1 | INTRODUCTION

Fractional flow reserve (FFR) is an invasive method to assess the potential myocardial ischemia caused by a coronary stenosis and to predict improvement in terms of clinical outcome achievable by revascularization.¹ Randomized controlled trials have shown the clinical improvement achieved by guiding revascularization using FFR compared to angiography alone (angio) in patients with chronic coronary syndromes.²⁻⁴ American College of Cardiology/American Heart Association guidelines have given a Class Ia recommendation for revascularization of functionally significant stenose and to assess intermediate stenoses with the use of FFR.⁵ European guidelines have given a Ia recommendation for the use of FFR when evidence of ischemia is not available and to guide revascularization in patients with chronic coronary syndromes.⁶ Despite the level of clinical evidence and the guideline recommendations, the adoption of FFR remains low in clinical practice.⁷ With improvements made in the past decades, percutaneous coronary intervention (PCI) has become the cornerstone of revascularization in coronary artery disease (CAD).⁸ However, evidence on the clinical impact of FFR-guided PCI compared with angio-guided PCI remains limited. We sought to compare, in a large, national French registry, the clinical impact of FFR-guided PCI compared with angio-guided PCI at 1 year.

2 | MATERIALS AND METHODS

2.1 | Registry design

The prospective, multicenter France PCI registry started on January 1, 2014, by collecting data on all patients undergoing coronary angiography or coronary angioplasty at 14 interventional cardiology centers. The France PCI registry methodology has been described previously.⁹ Clinical and procedural data were collected prospectively by cardiologists at the time of the patient's admission and recorded using electronic reporting software (CardioReport; CVX Medical). The data are of high quality, with 99.6% completeness and 89% consistency.⁹ The France PCI registry is registered on clinicaltrials.org (NCT02778724).

The registry was conducted according to contemporary clinical practice guidelines and French regulations (Advisory Committee on Information Processing in Material Research in the Field of Health no. 13.245). The French Persons Protection Committee (IRB00003888) approved the study protocol (no. 15-231). Data file collection and storage were approved by the French National Commission for Data Protection and Liberties (no. 2014-073). All patients were informed of the aims of the study. All included patients gave their informed consent to participate before data collection. Follow-up was conducted at 1 year after the PCI, by phone or consultation, for all patients. Overall death, cardiovascular (CV) death, non-CV death, unknown cause of death, myocardial infarction (type 1, type 4a, type 4b),¹⁰ unplanned revascularization, stent thrombosis, target lesion revascularization (TLR), stroke, and bleeding with a Bleeding Academic Research Consortium (BARC)¹¹ type superior or equal

to three were reported with data completion greater than 99%. Major adverse clinical events (MACE) was defined as the combination of all individual endpoints, cited previously, at 1 year of follow-up.

2.2 | Population selection

The current analysis included all consecutive patients with chronic coronary syndrome undergoing PCI between January 2014 and October 2019. Patients with acute coronary syndromes, coronary stenosis greater than 90% as assessed by visual estimation, PCI in graft vessels, and PCI with mechanical assistance were excluded. We excluded patients from one center that did not perform clinical follow-up, and patients in whom clinical follow-up was not available (208 patients). FFR-guided PCI was defined as PCI performed immediately following FFR measurement or in a staged procedure within 30 days of the index coronary angiogram. Angio-guided PCI was defined as PCI performed without the use of FFR within 30 days. Of note, all participating centers used FFR, and no other (e.g., nonhyperemic) invasive indexes were available in the database. Data were anonymized before automatic and daily transfer to the central France PCI database. Regional data monitoring was coordinated by the France PCI clinical research associate. External independent quality control (appropriate procedures, completeness, and consistency of data) was performed periodically at each site by a multicenter research assistant.

2.3 | Statistical analysis

Descriptive statistics are reported as mean and standard deviation, median (interquartile range) or counts (%) as appropriate. Mean differences were analyzed with unpaired *t*-test and with Wilcoxon matched-unpairs signed rank test as appropriate. Means comparisons between angio-guided PCI and FFR-guided PCI were performed. Significant differences between the two groups in terms of baseline characteristics and procedural characteristics were defined as potential confounding factors and were used for adjustment in the Cox regression model if appropriate. Kaplan–Meier curves between angio-guided PCI and FFR-guided PCI were generated for MACE and all individual endpoints. Hazard ratios (HR) were calculated with a 95% confidence interval (95% CI) using log-rank tests between angio-guided PCI and FFR-guided PCI for MACE and all individual endpoints. *p* Values less than 0.05 were considered statistically significant. All analyses were performed with Prism GraphPad 8.0 (GraphPad Software Inc.) and SPSS 26.0 (IBM Inc.).

3 | RESULTS

3.1 | Patients characteristics

A total of 52,610 PCIs were reported between January 2014 and October 2019; among them, 14,384 patients with chronic coronary

syndrome were revascularized with PCI. Of these, 13,125 (91%) patients had angio-guided PCI and 1259 (9%) had FFR-guided PCI (Figure 1). Baseline characteristics are summarized in Table 1. Angio-guided PCI and FFR-guided PCI groups significantly differed in terms of age, gender, sex, diabetes, active smoker, family history of CAD, previous stroke, previous PCI, and left ventricle ejection fraction (LVEF).

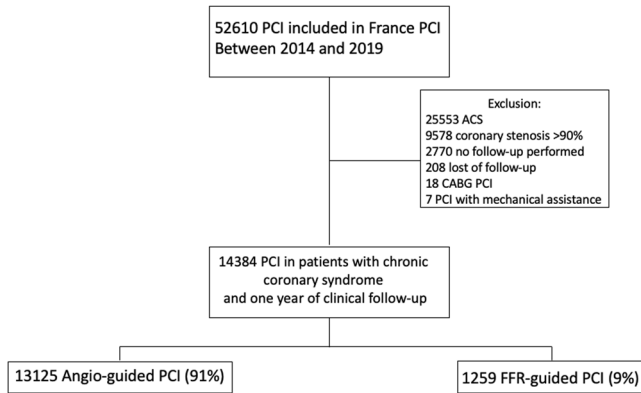


FIGURE 1 Study flow chart. PCI, percutaneous coronary intervention.

TABLE 1 Baseline characteristics between the angio-guided PCI and FFR-guided PCI populations.

	Angio-guided PCI (n = 13,125)	FFR-guided PCI (n = 1259)	p Value
Age (year)	69.6 ± 11	67.6 ± 10	<0.0001
Gender (male)	9935 (76%)	1015 (81%)	<0.0001
BMI	27.6 ± 4.8	27.7 ± 4.7	0.486
Hypertension	8159 (62%)	763 (61%)	0.056
Diabetes	3929 (30%)	402 (32%)	0.005
Dyslipidaemia	6846 (52%)	676 (54%)	0.215
Active smoker	2181 (17%)	193 (15%)	0.015
Family history of CAD	2953 (23%)	319 (25%)	<0.0001
PAD	1479 (11%)	148 (12%)	0.333
Previous stroke	697 (5%)	47 (4%)	0.003
Previous MI	2247 (17%)	213 (17%)	0.704
Previous PCI	5342 (41%)	561 (45%)	<0.0001
Previous CABG	260 (2%)	24 (2%)	0.714
Severe kidney insufficiency (creatinine level >200)	283 (2%)	21 (2%)	0.250
LVEF (%)	55.7 ± 9	56.4 ± 9	<0.0001

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; FFR, fractional flow reserve; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PAD, peripheral artery disease; PCI, percutaneous coronary intervention.

3.2 | Procedure indication

Coronary angiography indications are summarized in Table 2. The angio-guided PCI and FFR-guided PCI groups differed significantly in terms of planned PCI, stable angina, asymptomatic patients with positive stress test, valvular heart disease evaluation, and other indications. Ischemic stress tests performed are

TABLE 2 Procedure indication.

	Angio-guided PCI (n = 13,125)	FFR-guided PCI (n = 1259)	p Value
Planned PCI	4205 (32%)	293 (23%)	<0.0001
Stable angina	3994 (30%)	428 (34%)	0.009
Asymptomatic with positive stress test	2373 (18%)	307 (24%)	<0.0001
Coronary evaluation	553 (4%)	66 (5%)	0.086
Heart failure	1001 (8%)	100 (8%)	0.687
Valvular heart disease evaluation	447 (3%)	22 (2%)	0.002
Coronary evaluation before surgery	83 (1%)	12 (1%)	0.170
Ventricular arrhythmia	189 (1%)	17 (1%)	0.825
Other	280 (2%)	14 (1%)	0.014

Abbreviations: FFR, fractional flow reserve; PCI, percutaneous coronary intervention.

TABLE 3 Ischemic test performed.

	Angio-guided PCI (n = 13,125)	FFR-guided PCI (n = 1259)	p Value
EKG modification	1159 (9%)	71 (6%)	<0.0001
Exercise test	1502 (11%)	169 (13%)	0.015
Stress echocardiography	886 (7%)	116 (9%)	0.001
Echocardiography abnormality	423 (3%)	35 (3%)	0.393
Cardiac CT	473 (4%)	85 (7%)	<0.0001
Cardiac MRI	72 (1%)	11 (1%)	0.146
MIBI	1994 (15%)	172 (14%)	0.662
Test negative without precision	918 (7%)	90 (7%)	0.838
Other	1866 (14%)	213 (17%)	0.009
Test not performed	3800 (29%)	296 (24%)	<0.0001

Abbreviations: CT, computerized tomography; EKG, electrocardiogram; FFR, fractional flow reserve; MRI, magnetic resonance imaging; PCI, percutaneous coronary intervention.

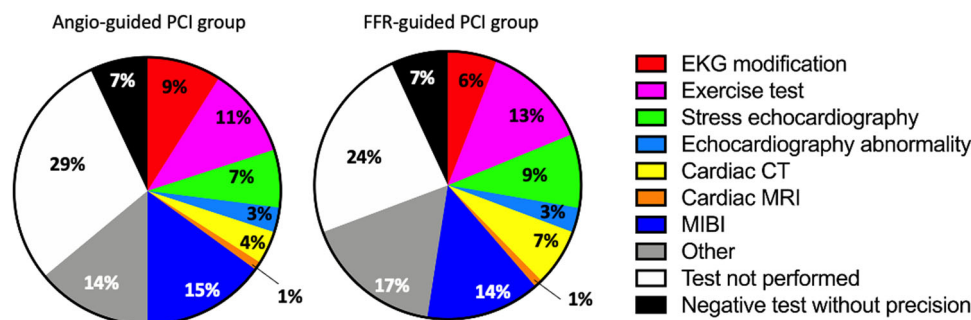


FIGURE 2 Tests performed before PCI in the angio-guided PCI group and in the FFR-guided PCI group. CT, computerized tomography; EKG, electrocardiogram; FFR, fractional flow reserve; MRI, magnetic resonance imaging; PCI, percutaneous coronary intervention. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Angiographic characteristics between the angio-guided PCI and FFR-guided PCI populations.

	Angio-guided PCI (n = 13,125)	FFR-guided PCI (n = 1259)	p Value
Vascular access			
Radial	12,022 (92%)	1200 (95%)	<0.0001
Femoral	1069 (9%)	55 (4%)	<0.0001
Humeral	34 (0.3%)	4 (0.3%)	0.699
Sheath size (French)			
5	1593 (12%)	153 (12%)	0.987
6	10,968 (84%)	1058 (84%)	0.668
7	306 (2%)	25 (2%)	0.435
8	12 (0.1%)	0	0.283
Left main stenosis	642 (5%)	42 (4%)	0.012
Global syntax score	7 ± 6	8 ± 6	0.201
Number of vessels treated	1.16 ± 0.43	1.14 ± 0.42	0.104
Number of coronary segments treated	1.44 ± 0.73	1.43 ± 0.70	0.671
Number of stents implanted	1.48 ± 0.81	1.47 ± 0.85	0.208
Contrast medium administered (ml)	132 ± 60	154 ± 64	0.002
Fluoroscopy time (min)	10 ± 8	11 ± 7	0.103
X-rays performed (cGY.cm)	3228 ± 3229	3895 ± 3420	0.082

Abbreviations: FFR, Fractional flow reserve; PCI, percutaneous coronary intervention.

summarized in Table 3. The angio-guided PCI and FFR-guided PCI groups differed significantly in terms of baseline electrocardiogram modification, exercise test, stress echocardiography, cardiac computed tomography, and other tests, respectively. No tests were performed in 3800 (29%) in the angio-guided PCI group compared to 296 (24%) in the FFR-guided PCI group ($p < 0.0001$) (Table 3 and Figure 2).

3.3 | Procedural characteristics

Characteristics of the procedure are summarized in Table 4. The angio-guided PCI and FFR-guided PCI groups differed significantly in terms of radial access, femoral access, left main stenosis, and volume of contrast medium administered. Antithrombotic and antiplatelet therapies at baseline are summarized in Table 5.

TABLE 5 Antithrombotic and antiplatelet therapy at baseline (a) and at 1 year (b) between the angio-guided PCI and FFR-guided PCI populations.

	Angio-guided PCI (n = 13,125)	FFR-guided PCI (n = 1259)	p Value
<i>(a) Baseline</i>			
Aspirin	11,454 (87%)	1205 (96%)	<0.0001
Clopidogrel	8574 (65%)	921 (73%)	<0.0001
Ticagrelor	2970 (23%)	280 (22%)	0.093
Prasugrel	300 (2%)	28 (2%)	0.494
Ticlopidine	3 (0.1%)	1 (0.1%)	0.250
VKA	804 (6%)	52 (4%)	0.004
DOA	1145 (9%)	129 (10%)	0.069
<i>(b) At 1 year of follow-up</i>			
Aspirin	10,937 (83%)	1067 (85%)	0.048
Clopidogrel	4789 (44%)	605 (48%)	0.007
Ticagrelor	1785 (14%)	122 (10%)	<0.0001
Prasugrel	215 (2%)	13 (1%)	0.322
Ticlopidine	5 (0.1%)	1 (0.1%)	0.493
VKA	728 (6%)	54 (4%)	0.060
DOA	1269 (10%)	129 (10%)	0.509
DAPT duration (months)	11 ± 3	11 ± 3	0.475

Abbreviations: DAPT, double antiplatelet therapy; DOA, direct oral anticoagulation; FFR, fractional flow reserve; PCI, percutaneous coronary intervention; VKA, vitamin K antagonist.

3.4 | Clinical outcomes at 1 year

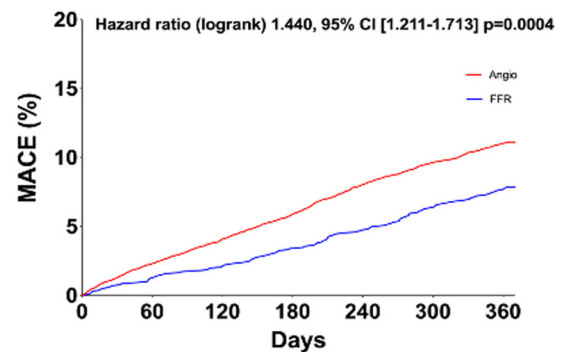
Antithrombotic and antiplatelet therapies at 1 year of follow-up are summarized in Table 5. Clinical outcomes are summarized in Table 6. The angio-guided PCI and FFR-guided PCI groups differed significantly in terms of MACE: 1478 (11.3%) versus 100 (7.9%) ($p < 0.0001$), overall deaths: 506 (3.9%) versus 17 (1.4%) ($p < 0.0001$), CV death: 177 (1.3%) versus 6 (0.5%) ($p = 0.008$), non-CV death: 231 (1.8%) versus 8 (0.6%) ($p = 0.003$), unknown cause of death: 98 (0.7%) versus 3 (0.2%) ($p = 0.039$), TLR: 222 (1.7%) versus 14 (1.1%) ($p = 0.002$), stroke: 82 (0.6%) versus 4 (0.3%) ($p = 0.006$), and major bleeding: 309 (2.4%) versus 24 (1.9%) ($p = 0.036$), respectively. We observed a lower rate of MACE of 30% and a lower rate of death of 64% in the FFR-guided PCI group compared to angio-guided PCI.

Kaplan–Meier curves with log-rank HR calculations were performed for MACE and individual endpoints between the angio-guided PCI and FFR-guided PCI groups (Figures 3–6). MACE was significantly higher at 1 year in the angio-guided PCI group compared to the FFR-guided PCI group: HR 1.440, 95% CI [1.211–1.713] ($p = 0.0004$). Overall death was significantly higher at 1 year in the angio-guided PCI group compared to the FFR-guided PCI group: HR

TABLE 6 Outcomes at 1 year between the angio-guided PCI and FFR-guided PCI populations.

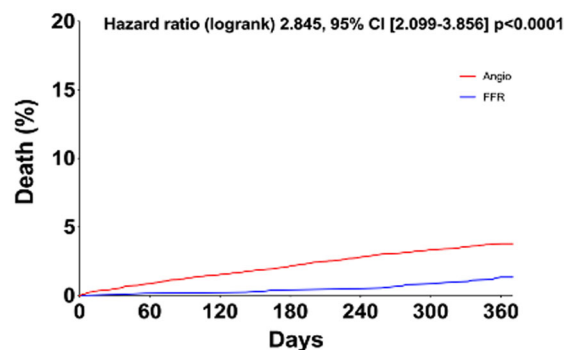
	Angio-guided PCI	FFR-guided PCI	p Value
MACE	1478 (11.3%)	100 (7.9%)	<0.0001
Overall death	506 (3.9%)	17 (1.4%)	<0.0001
Cardiovascular death	177 (1.3%)	6 (0.5%)	0.008
Non-cardiovascular death	231 (1.8%)	8 (0.6%)	0.003
Unknown cause of death	98 (0.7%)	3 (0.2%)	0.039
MI	145 (1.1%)	12 (1.0%)	0.302
Any revascularization	692 (5.3%)	60 (4.8%)	0.101
Target lesion revascularization	222 (1.7%)	14 (1.1%)	0.002
Stent thrombosis	49 (0.4%)	3 (0.2%)	0.121
Stroke	82 (0.6%)	4 (0.3%)	0.006
Major bleeding	309 (2.4%)	24 (1.9%)	0.036

Abbreviations: FFR, fractional flow reserve; MACE, major adverse clinical events; MI, myocardial infarction; PCI, percutaneous coronary intervention.



Numbers At risk

Angio	13112	12814	12581	12343	12061	11850	11667
FFR	1259	1244	1233	1217	1200	1181	1163



Numbers At risk

Angio	13115	13003	12917	12860	12740	12682	12620
FFR	1259	1258	1258	1255	1254	1250	1243

FIGURE 3 Upper panel: Kaplan–Meier curves reporting MACE in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. Lower panel: Kaplan–Meier curves reporting overall death in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. CI, confidence interval; FFR, fractional flow reserve; MACE, major adverse clinical events; PCI, percutaneous coronary intervention. [Color figure can be viewed at wileyonlinelibrary.com]

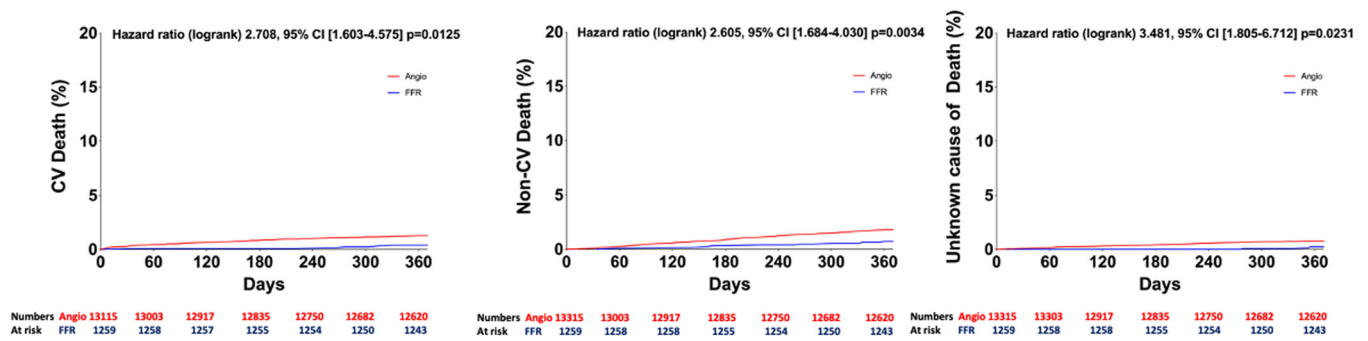


FIGURE 4 Left panel: Kaplan–Meier curves reporting cardiovascular death in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. Middle panel: Kaplan–Meier curves reporting non-cardiovascular death in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. Right panel: Kaplan–Meier curves reporting unknown cause of death in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. FFR, fractional flow reserve; PCI, percutaneous coronary intervention. [Color figure can be viewed at wileyonlinelibrary.com]

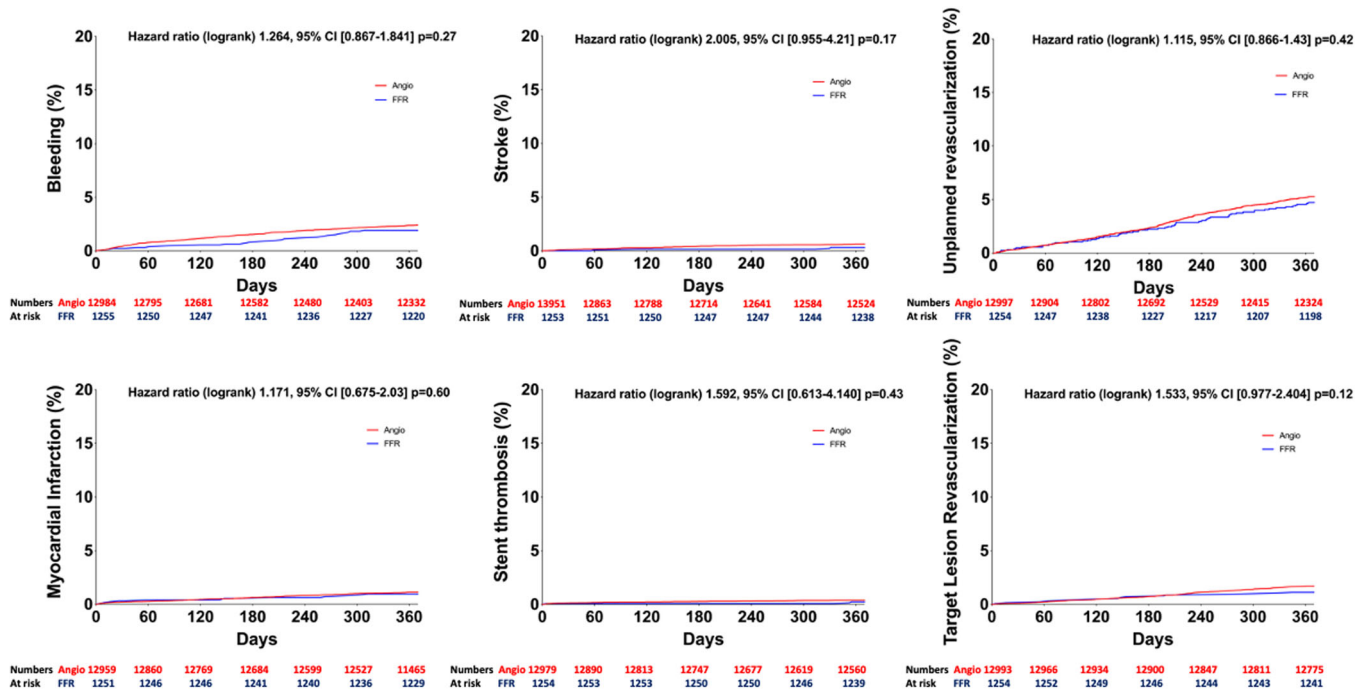


FIGURE 5 Upper left panel: Kaplan–Meier curves reporting bleeding in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. Upper middle panel: Kaplan–Meier curves reporting stroke in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. Upper right panel: Kaplan–Meier curves reporting unplanned revascularization in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. Lower left panel: Kaplan–Meier curves reporting myocardial infarction in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. Lower middle panel: Kaplan–Meier curves reporting stent thrombosis in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. Lower right panel: Kaplan–Meier curves reporting target lesion revascularization in the angio-guided PCI group and in the FFR-guided PCI group with log-rank hazard ratio. FFR, fractional flow reserve; PCI, percutaneous coronary intervention. [Color figure can be viewed at wileyonlinelibrary.com]

2.845, 95% CI [2.099–3.856] ($p < 0.0001$) (Figure 3). CV death was significantly higher at 1 year in the angio-guided PCI group compared to the FFR-guided PCI group: HR 2.708, 95% CI [1.603–4.575] ($p = 0.0125$). Non-CV death was significantly higher at 1 year in the angio-guided PCI group compared to the FFR-guided PCI group: HR 2.605, 95% CI [1.684–4.030] ($p = 0.0034$). Unknown cause of death

was significantly higher at 1 year in the angio-guided PCI group compared to the FFR-guided PCI group: HR 3.481, 95% CI [1.805–6.712] ($p = 0.0231$) (Figure 4). No significant HR differences were observed between angio-guided PCI and FFR-guided PCI in terms of bleeding, stroke, unplanned revascularization, myocardial infarction, stent thrombosis, or TLR (Figure 5). All HR are summarized

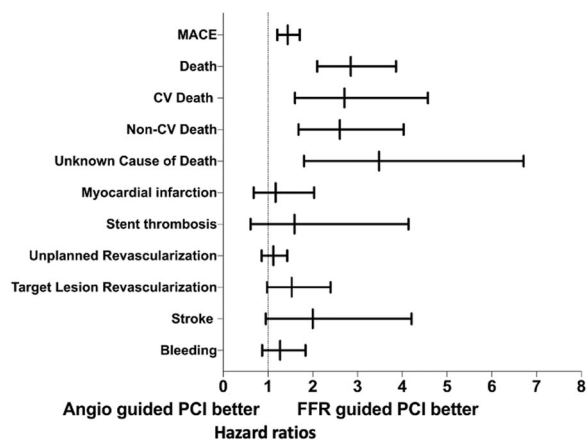


FIGURE 6 Forrest plot of clinical outcomes. CV, cardiovascular; FFR, fractional flow reserve; MACE, major adverse clinical events; PCI, percutaneous coronary intervention.

TABLE 7 Cox regression for MACE.

	aHR	95% CI	p Value
Age	1.034	1.027–1.040	<0.0001
Gender	1.099	0.957–1.262	0.183
Smoking status	1.131	0.943–1.358	0.185
Diabetes	1.347	1.193–1.521	<0.0001
Family history of CAD	0.943	0.812–1.096	0.447
LVEF	0.993	0.987–0.999	0.016
Vascular access	1.860	1.579–2.190	<0.0001
Previous PCI	1.037	0.921–1.168	0.550
Previous stroke	1.166	0.918–1.482	0.208
Volume of contrast medium	1.001	1.000–1.002	0.210
Left main stenosis	1.298	1.035–1.627	0.024
FFR	1.289	1.030–1.614	0.027

Abbreviations: aHR, adjusted hazard ratio; CI, confidence interval; CAD, coronary artery disease; FFR, fractional flow reserve; LVEF, left ventricle ejection fraction; MACE, major adverse clinical events; PCI, percutaneous coronary intervention.

in Figure 6. We performed adjustment of HR (aHR) in significant endpoints for potential confounding factors defined as significant mean differences, in Tables 1 and 4. Confounding factors were age, gender, smoking status, diabetes, family history of CAD, LVEF, vascular access, previous PCI, previous stroke, volume of contrast medium administered, left main stenosis, and FFR. FFR remained a significant predictor of MACE: aHR 1.289, 95% CI [1.030–1.614] ($p = 0.027$) (Table 7). FFR was the most important predictor of overall death: aHR 2.524, 95% CI [1.421–4.312] ($p = 0.001$) (Table 8). FFR aHRs for CV death, non-CV death, and unknown cause of death were 1.878 95% CI [0.764–4.616] ($p = 0.169$), 2.193 95% CI [1.028–4.678]

TABLE 8 Cox regression for death.

	aHR	95% CI	p Value
Age	1.074	1.061–1.086	<0.0001
Gender	1.223	0.967–1.546	0.201
Smoking status	2.077	1.550–2.784	<0.0001
Diabetes	1.520	1.240–1.863	<0.0001
Family history of CAD	0.636	0.464–0.872	0.005
LVEF	0.970	0.962–0.978	<0.0001
Vascular access	2.153	1.684–2.752	<0.0001
Previous PCI	0.877	0.713–1.080	0.216
Previous stroke	1.126	0.761–1.667	0.551
Volume of contrast medium	0.999	0.997–1.001	0.284
Left main stenosis	1.524	1.092–2.127	0.013
FFR	2.524	1.421–4.312	0.001

Abbreviations: aHR, adjusted hazard ratio; CI, confidence interval; CAD, coronary artery disease; FFR, Fractional flow reserve; LVEF, left ventricle ejection fraction; PCI, percutaneous coronary intervention.

($p = 0.042$), and 4.075 95% CI [1.000–16.598], respectively ($p = 0.050$).

4 | DISCUSSION

This study was designed to evaluate the clinical impact of angio-guided PCI versus FFR-guided PCI after revascularization. Therefore, all patients had complete revascularization at the time of inclusion. The key findings of our study are as follows¹: FFR-guided PCI was performed in 9% of the entire study population²; FFR-guided PCI was performed more often in patients with noninvasive stress tests before the procedure compared to angio-guided PCI³; no significant differences were observed between the FFR-guided PCI group compared to the angio-guided PCI group in terms of global Syntax score, number of lesions treated, or number of stents implanted⁴; we observed a significant reduction in MACE driven by death in the FFR-guided PCI group compared to the angio-guided PCI group at 1 year⁵; FFR was the most important predictor of death after adjustment for confounding factors⁶; the death rate was 64% lower in the FFR-guided PCI group compared to the angio-guided PCI group.

In contrast to these study results, we note that the randomized controlled trial FAME (fractional flow reserve vs. angiography for multivessel evaluation) study did not report a clinically significant survival benefit with FFR-guided revascularization at 1 year, although the study did show a relative risk reduction of 58% for death.³ It would appear that no randomized control trial comparing FFR-guided PCI to angio-guided PCI has been powered to detect a significant difference in mortality rate. Angio-guided PCI and FFR-guided PCI registries have shown a mortality reduction with use of FFR to guide revascularization compared to angio.^{12,13} Parikh et al.¹² analyzed the VA CART registry to determine the clinical

impact of angiographically intermediate coronary stenosis in patients with chronic coronary syndrome. This study included patients with FFR-guided revascularization compared to angio-guided revascularization including surgery, PCI, and medical therapy. The authors observed a 43% reduction in death in the FFR-guided revascularization group compared to the angio-guided revascularization group at 1 year. Our study focused on the clinical impact of FFR-guided PCI compared to angio-guided PCI, with all patients treated with PCI. It is interesting to notice that we observed a significant reduction in death at 1 year of clinical follow-up in a group which benefitted only from revascularization with PCI. Data from the SCAAR registry evaluated the clinical impact of FFR-guided PCI compared to angio-guided PCI in patients with stable angina at 10 years.¹³ This study showed a significant mortality reduction of 42% in the FFR-guided PCI group compared to the angio-guided PCI group, with a significant reduction in stent restenosis at 10 years. Patients in the FFR-guided PCI group received fewer stents per target segment compared to the angio-guided PCI group.¹³ Our study design differs in that we excluded all patients with coronary stenosis greater than 90% by visual estimation. According to guidelines and clinical practice, these coronary stenoses do not benefit from FFR interrogation, although this might cause some imbalance between groups in a registry. Our study evaluated the rates of myocardial infarction, stent thrombosis, unplanned revascularization, TLR, bleeding, and stroke without significant differences observed between the angio-guided PCI and FFR-guided PCI groups. It is noteworthy that dual antiplatelet therapy duration was similar between the angio-guided PCI and FFR-guided PCI groups, and that long-term follow-up could therefore be of interest.

4.1 | Limitations

There are several limitations inherent to our study. First, this large registry of routine clinical practice was conducted, by definition, according to local practice in terms of angiographic evaluation of a coronary stenosis, and FFR and PCI performance. However, this reflects real-world clinical practice and the clinical indication to guide revascularization with FFR. Second, a number of interesting data were not collected in the registry, such as the FFR value, and the type of coronary lesion,¹⁴ and only the global Syntax score was available. Third, we reported only 1 year of clinical outcome due to the registry design and we therefore had to exclude patients without follow-up available. Due to the observational nature of this study we cannot exclude selection bias. For these reasons, our results should be considered associative and not causative.

5 | CONCLUSION

In a large, national registry of routine clinical practice, FFR-guided PCI was associated with a significant reduction in MACE driven by death at 1 year compared to angio-guided PCI. Our results

support the current guidelines and pave the way for increased FFR utilization in clinical practice.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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