

Fractional Flow Reserve and Quality-of-Life Improvement After Percutaneous Coronary Intervention in Patients With Stable Coronary Artery Disease

BACKGROUND: Whether the benefit in quality of life (QOL) after percutaneous coronary intervention depends on the severity of the stenosis as determined by fractional flow reserve (FFR) remains unknown. This study sought to investigate the relationship between FFR values and improvement in QOL.

METHODS: From the FAME 1 and 2 trials (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation), we identified 706 stable patients with coronary artery disease who had at least 1 lesion with an $\text{FFR} \leq 0.80$ that was treated with percutaneous coronary intervention and 185 patients with coronary artery disease who had no lesion with an $\text{FFR} \leq 0.80$ and were treated medically who served as a reference group. QOL was assessed by the European Quality of Life–5 Dimensions index at baseline, 1 month, and 1 year. We assessed the relationship between QOL improvement (defined as the change in European Quality of Life–5 Dimensions index from baseline) and FFR as a continuous value and according to abnormal FFR tertile.

RESULTS: QOL improved significantly after percutaneous coronary intervention in each abnormal FFR tertile, whereas it did not change in the reference group. The lowest abnormal FFR subgroup had the greatest improvement in QOL at 1 month ($P < 0.001$). In mixed-effects models for repeated measures, lower FFR ($P = 0.002$ for 1 month and 0.049 for 1 year), greater delta FFR ($P = 0.021$ for 1 month and 0.025 for 1 year), and higher angina class ($P = 0.001$ for 1 month and < 0.001 for 1 year) were associated with the greatest magnitude of QOL improvement at both 1 month and 1 year.

CONCLUSIONS: Among patients with stable coronary artery disease, FFR and angina severity predict QOL improvement after percutaneous coronary intervention.

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Clinical Perspective

What Is New?

- Whether the benefit in quality of life (QOL) after percutaneous coronary intervention depends on the severity of the stenosis as determined by fractional flow reserve (FFR) has not been investigated.
- A key finding from this study is that the degree of improvement in QOL was related to the degree of reduction in FFR, with patients with the lowest FFR values receiving the greatest improvement in QOL, and to the change in FFR from baseline to after percutaneous coronary intervention, with the patients with the greatest delta FFR receiving the greatest improvement in QOL.

What Are the Clinical Implications?

- These findings indicate a direct relationship between the effect of myocardial ischemia on symptoms and QOL and the relationship between the relief of ischemia and improvement in QOL.

Improving quality of life (QOL) is an important treatment goal in patients with stable coronary artery disease (CAD).¹ Previous nonblinded studies found that percutaneous coronary intervention (PCI) guided by fractional flow reserve (FFR) reduces angina and improves QOL in patients with CAD.^{2–5} A recent randomized, double-blind, sham-controlled trial found that PCI did not improve exercise capacity, angina, or QOL compared with sham PCI and medical therapy in patients with stable CAD.⁶ Unfortunately, this recent trial did not incorporate FFR into the decision process for the need for PCI. It is possible that the degree of angina relief and improvement in QOL after PCI is related to the severity of ischemia as assessed by FFR, with greater benefit occurring after the treatment of lesions with the lowest FFR. This concept, however, has not been specifically studied to date.

METHODS

Study Design and Patients

The present study is a patient-level pooled analysis from the FAME 1 and 2 trials (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation). The design and results of the FAME 1 and FAME 2 studies have been reported previously.^{2–4} Both are international, multicenter, prospective, randomized clinical trials with comparable inclusion and exclusion criteria. In brief, the FAME 1 trial enrolled patients with angiographic multivessel CAD amenable for PCI in patients presenting with stable angina, unstable angina, or

non–ST-segment-elevation myocardial infarction (<5 days after the infarction).² Patients were randomly assigned to either FFR-guided or angiography-guided PCI. In the FFR-guided arm, only lesions with an FFR ≤ 0.80 were treated with PCI, whereas in the angiography-guided arm, all narrowings with $\geq 50\%$ diameter stenosis were treated with PCI. The FAME 2 trial enrolled patients with stable angina or silent ischemia with 1-, 2-, or 3-vessel disease.^{3,4} Patients having at least 1 stenosis with an FFR ≤ 0.80 were randomized to FFR-guided PCI plus best available medical therapy or best available medical therapy alone. Patients with an FFR > 0.80 across all lesions were not randomized, and 50% of these patients were followed up in a registry.

The present analysis includes stable patients who underwent PCI with an FFR ≤ 0.80 from the FFR-guided arm of the FAME 1 trial and the PCI plus best available medical therapy arm of the FAME 2 trial (ie, does not include patients with unstable angina and non–ST-segment-elevation myocardial infarction in the FAME 1 trial). In addition, stable patients who had no lesions with an FFR ≤ 0.80 and who were treated medically (without PCI) from the FFR-guided PCI arm of the FAME 1 trial and the registry arm of the FAME 2 trial were included as a reference cohort. Patients were excluded from the present study if valid health status data and FFR data at baseline were not available. The studies were approved by an institutional review committee from each participating site, and informed consent was obtained from all patients. The data, analytical methods, and study materials will not be made available to other researchers for purposes of reproducing the results or replicating the procedure.

Measurement of Angina and Health Status

The angina status of the patient was assessed according to the Canadian Cardiovascular Society (CCS) classification, and health status was assessed by means of the European Quality of Life–5 Dimensions (EQ-5D) at baseline and 1 month, and 1 year after randomization. The EQ-5D comprises 2 components: a descriptive profile and a single-index visual analog scale (VAS). The descriptive profile assesses 5 dimensions of general health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with a 3-level scale. These scores can then be converted to utilities with an algorithm developed for the US population. Utilities are preference-weighted health status assessments with scores that range from 0 to 1, with 1 representing perfect health and 0 representing the poorest health.⁷ The minimum clinically important difference of a 1-minute increase in treadmill exercise time was shown to be associated with a 0.019 (95% CI, 0.014–0.025) increase in EQ-5D index; a 10-unit increase in the Seattle Angina Questionnaire scales was shown to be associated with increases between 0.04 and 0.07 in the EQ-5D index (95% CI, 0.03–0.05 and 0.05–0.08).⁸ The VAS records the patient's personal perspective of his/her current health status on a vertical rating scale with scores ranging from 0 to 100, with higher scores for higher QOL.⁹ The primary end point of this study was the QOL improvement, defined as the change in the EQ-5D index from baseline to 1 month and 1 year.

Statistical Analysis

Categorical variables are expressed as numbers and/or percentages and compared by use of the Fisher exact test. Continuous data are expressed as mean±SD and compared with paired or unpaired Student *t* test or Mann-Whitney *U* test. The trend in the change in EQ-5D index according to FFR subgroups was assessed with the Jonckheere-Terpstra test. Correlations between parameters were tested with the Spearman correlation coefficient. The significance of the trends in percentage was tested with the Mantel-Haenszel linear-by-linear association test. We used mixed-effects models for repeated measures (MMRM) with the EQ-5D index as a dependent variable to assess whether given variables were associated with QOL improvement. The key independent variables were the FFR value and the CCS angina classification at baseline. Because the FFR value and CCS classification have a significant correlation (correlation coefficient, -0.090 ; $P=0.007$), we put those variables into separate models (models 1 and 2). We also evaluated the association between the EQ-5D index and FFR improvement (delta FFR; defined as post-PCI FFR value minus baseline FFR value) in the MMRM (model 3). The MMRM analysis included subject as a random effect, FFR (model 1) (or CCS class [model 2] or delta FFR [model 3]), visit (baseline, 1 month, and 1 year), and FFR-by-visit interaction (for model 1) (or CCS class-by-visit interaction [model 2] or delta FFR-by-visit interaction [model 3]) as fixed effects, with adjustment for EQ-5D index at baseline, and variables with a single variable value of $P<0.05$. In addition, we put the percent delta FFR (calculated as delta FFR divided by baseline FFR value) instead of delta FFR into the MMRM to assess the relationship between QOL and FFR improvement with adjustment for baseline FFR value (model 4). Because an FFR value of 0.50 was applied for all lesions that the operator could not cross or had concerns about crossing with a pressure wire because they were chronically occluded, were subtotally occluded, had less than TIMI (Thrombolysis in Myocardial Infarction) grade 3 flow, were heavily calcified, were tortuous, or had evidence of ischemia on noninvasive testing in the territory subtended by a major epicardial vessel with an angiographically tight stenosis in the FAME and FAME 2 trials, sensitivity analyses were performed by excluding patients with a lesion of $>90\%$ stenosis or total occlusion with an FFR value of 0.50 ($n=97$). The mixed-effects model analyses were performed with SAS statistical software package version 9.4 (SAS Institute, Cary, NC). R programming language version 3.4.1 (R Foundation for Statistical Computing, Vienna, Austria) was used for creating scatterplots between the coronary physiological indexes and QOL improvement from baseline to 1 month and 1 year and for adding a locally weighted scatterplot smoothing curve for the data. All other statistical analyses were performed with IBM SPSS Statistics software version 24 (IBM, Armonk, NY). A value of $P<0.05$ was considered statistically significant.

RESULTS

A total of 716 stable patients underwent PCI of at least 1 lesion with an abnormal FFR ≤ 0.80 ; 185 stable patients had no lesions with an FFR ≤ 0.80 and served as the reference cohort (Figure 1 in the online-only Data

Supplement). The baseline characteristics of the 2 groups are summarized in Table 1. More patients were male and had hypertension in the FFR-guided PCI cohort than in the reference cohort. Patients in the reference cohort received more antianginal medications, including calcium channel blockers, β -blockers, and long-acting nitrates, than those in the PCI cohort at 1

Table 1. Patient Characteristics

	Fractional Flow Reserve–Guided Percutaneous Coronary Intervention	Reference	P Value
Patients, n	716	185	
Age, y	64±10	64±10	0.81
Body mass index, kg/m ²	28±5	28±4	0.86
Male, n (%)	570 (80)	118 (63)	<0.001
Hypertension, n (%)	508 (71)	151 (82)	0.004
Dyslipidemia, n (%)	533 (74)	133 (72)	0.51
Diabetes mellitus, n (%)	190 (27)	47 (25)	0.78
Current smoker, n (%)	162 (23)	39 (21)	0.69
Family history of coronary artery disease, n (%)	312 (44)	78 (42)	0.74
Previous percutaneous coronary intervention, n (%)	145 (20)	45 (24)	0.23
Previous myocardial infarction, n (%)	254 (35)	65 (35)	>0.99
Left ventricular ejection fraction <50%, n (%)	125 (17)	29 (16)	0.66
Antianginal medications at baseline, n	1.3±0.8	1.4±0.8	0.19
Antianginal medications at 1 mo, n	1.3±0.7	1.5±0.8	<0.001
Antianginal medications at 1 y, n	1.3±0.8	1.5±0.9	<0.001
Functionally diseased vessels, n (%)			
1	458 (64)		
2	238 (33)		
3	20 (3)		
Total stents, n	1.9±1.1		
Total stent length, mm	35±23		
Canadian Cardiovascular Society class			
Asymptomatic or 1	213 (30)	67 (36)	0.19
2	305 (43)	80 (43)	
3	156 (22)	30 (16)	
4	42 (6)	8 (4)	
European Quality of Life–5 Dimensions			
Index at baseline	0.821±0.157	0.821±0.153	0.97
Visual analog scale at baseline	68±18	67±18	0.68

Values are mean±SD or number (percent). Antianginal medications include calcium channel blockers, β -blockers, and long-acting nitrates.

month and 1 year. The mean minimum FFR value was 0.87 ± 0.04 in the reference cohort and 0.60 ± 0.14 in the FFR-guided PCI cohort (Figure II in the online-only Data Supplement). At least 1 delta FFR value could be calculated in 507 patients (71%) in the PCI cohort. The mean maximum delta FFR value was 0.28 ± 0.15 .

When the patients in the PCI cohort were grouped according to tertile of abnormal FFR value (upper [0.80–0.70], middle [0.69–0.51], and lowest [≤ 0.50] tertile) (Table I in the online-only Data Supplement), there was a higher percentage of patients with CCS class 2 or higher angina in the lowest FFR tertile at baseline (Figure 1). This difference was not observed at 1 month and 1 year after PCI.

There was no statistically significant difference in the EQ-5D index at baseline between the reference and the abnormal FFR subgroups (upper, middle, and lowest tertiles) (reference, 0.821 ± 0.153 ; upper, 0.817 ± 0.158 ; middle, 0.839 ± 0.146 ; lowest, 0.807 ± 0.167 ; $P=0.36$; Table II in the online-only Data Supplement). The EQ-5D index improved significantly after PCI in all of the FFR subgroups ($P<0.001$ for all), whereas it did not change in the reference group ($P=0.85$). There was a significant progressive improvement in EQ-5D index from baseline to 1 month based on baseline FFR value and delta FFR value. The reference group with nonischemic FFR values treated medically had no change, whereas the PCI subgroup with the lowest FFR at baseline had the greatest improvement (Figure 2). This same significant and progressive improvement in the EQ-5D index also was found from baseline to 1 year (Figure 3). Likewise, when the patients in the PCI cohort were grouped according to tertile of delta FFR value (upper [≥ 0.33], middle [0.32–0.19], and lowest [≤ 0.18] tertile), the greatest delta FFR subgroup had the greatest improvement in the EQ-5D index (Figures 4 and 5). When FFR and delta

FFR were treated as continuous values, the correlation was significant between FFR (baseline value and delta) and change in EQ-5D index at 1 month and 1 year (Figures III and IV in the online-only Data Supplement).

There was also significant progressive improvement in the EQ-5D VAS at 1 month and 1 year based on baseline FFR ($P<0.001$ for trend both at 1 month and 1 year; Tables III and IV in the online-only Data Supplement). The correlation between FFR and EQ-5D VAS was significant at 1 month and 1 year (Figure V in the online-only Data Supplement).

We explored the QOL improvement in patients with abnormal FFR who were treated medically from the medical therapy arm of the FAME 2 trial (432 patients who had a baseline EQ-5D index). Patient characteristics and medications are listed in Tables V and VI in the online-only Data Supplement. The EQ-5D index did not significantly improve in the medical therapy cohort. The EQ-5D VAS improved slightly at 1 month, but the improvement was small and less than that in the PCI cohort (Table VII and Figures VI and VII in the online-only Data Supplement). Note that there were many crossovers to PCI in the medical therapy cohort. We performed a sensitivity analysis excluding crossover patients (ie, patients who underwent PCI within 1 month and 1 year). The results were consistent with that from the overall medical therapy cohort (Table VIII in the online-only Data Supplement).

The MMRMs found that lower FFR, greater delta FFR, greater percent delta FFR, and higher CCS angina class were associated with significantly greater improvement in the EQ-5D index at both 1 month and 1 year (Table 2).

Sensitivity analyses excluding patients with a lesion of $>90\%$ stenosis or total occlusion with an FFR value of 0.50 consistently showed a significant progressive improvement in the EQ-5D index at 1 month and 1 year

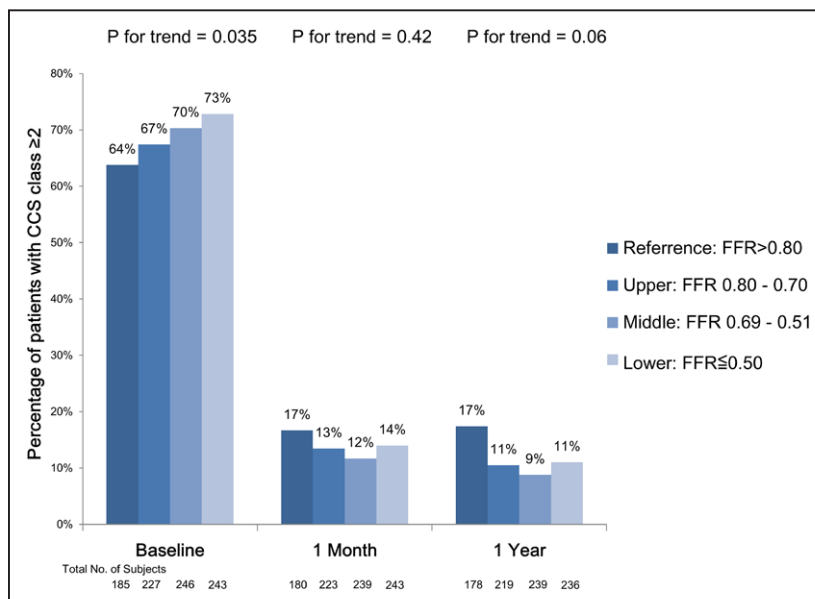


Figure 1. Differences in angina according to fractional flow reserve (FFR) subgroups.

Presented are percentages of patients with Canadian Cardiovascular Society (CCS) class II to IV angina between the reference group (FFR >0.80) and FFR tertile subgroup (upper [0.80–0.70], middle [0.69–0.51], and lowest [≤ 0.50]).

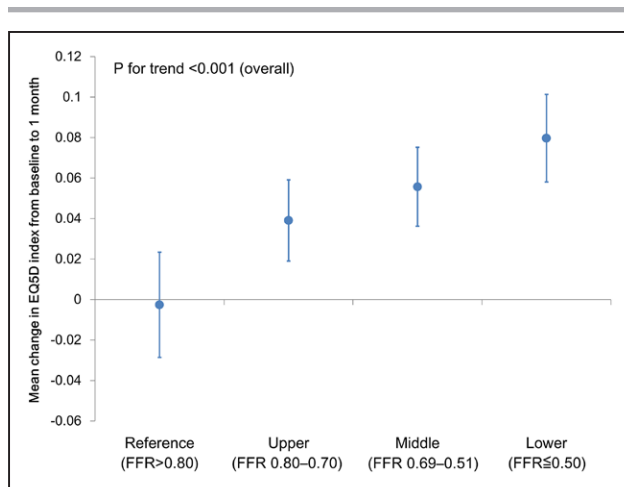


Figure 2. Change in European Quality of Life-5 Dimensions (EQ-5D) index from baseline to 1 month.

Mean change in EQ-5D index from baseline to 1 month between the reference group (fractional flow reserve [FFR] >0.80) and FFR tertile subgroups (upper [0.80–0.70], middle [0.69–0.51], and lowest [≤ 0.50] tertiles) (–0.003 [95% CI, –0.029 to 0.024], 0.039 [95% CI, 0.019–0.059], 0.056 [95% CI, 0.036–0.075], and 0.080 [95% CI, 0.058–0.101], respectively). Error bars indicate 95% CIs.

based on baseline FFR and delta FFR (Figures VIII–XIII in the online-only Data Supplement). The MMRM analyses confirmed that lower FFR, greater delta FFR, and greater percent delta FFR were associated with greater improvement in the EQ5D index at 1 month and 1 year (Table IX in the online-only Data Supplement).

DISCUSSION

We evaluated the relationship among the FFR value, angina, and improvement in health status after PCI in

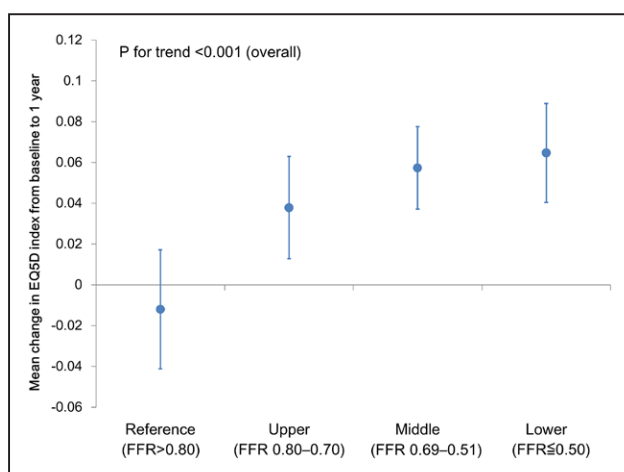


Figure 3. Change in European Quality of Life-5 Dimensions (EQ-5D) index from baseline to 1 year.

Mean change in EQ-5D index from baseline to 1 year between the reference cohort (fractional flow reserve [FFR] >0.80) and FFR tertile subgroups (upper [0.80–0.70], middle [0.69–0.51], and lowest [≤ 0.50] tertiles) (–0.012 [95% CI, –0.041 to 0.018], 0.038 [95% CI, 0.013–0.063], 0.057 [95% CI, 0.037–0.078], and 0.065 [95% CI, 0.040–0.089], respectively). Error bars indicate 95% CIs.

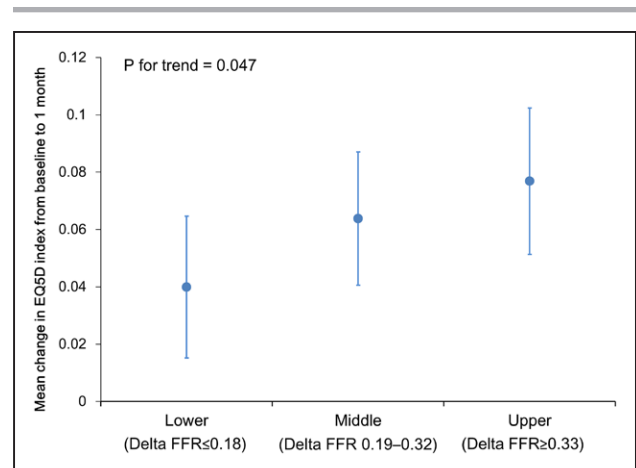


Figure 4. Change in European Quality of Life-5 Dimensions (EQ-5D) index from baseline to 1 month.

Mean change in EQ-5D index from baseline to 1 month between delta fractional flow reserve (FFR) tertile subgroups (lowest [≤ 0.18], middle [0.32–0.19], and upper [≥ 0.33] tertiles) (0.040 [95% CI, 0.015–0.065], 0.064 [95% CI, 0.040–0.087], and 0.077 [95% CI, 0.051–0.103], respectively). Error bars indicate 95% CIs.

patients with stable CAD. The primary finding was that a lower baseline FFR value and a higher angina class were associated with greater improvements in health status at 1 month and at 1 year after PCI.

Previous randomized studies have shown a QOL benefit and angina improvement with revascularization for the treatment of stable CAD.^{10–13} The COURAGE trial (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) compared PCI with medical therapy in patients with stable CAD. On the basis of the Seattle Angina Questionnaire analyses, patients had an incremental benefit from PCI for the first 12 to 24 months in the key domains of physical limitations, frequency of angina, and QOL, although there was

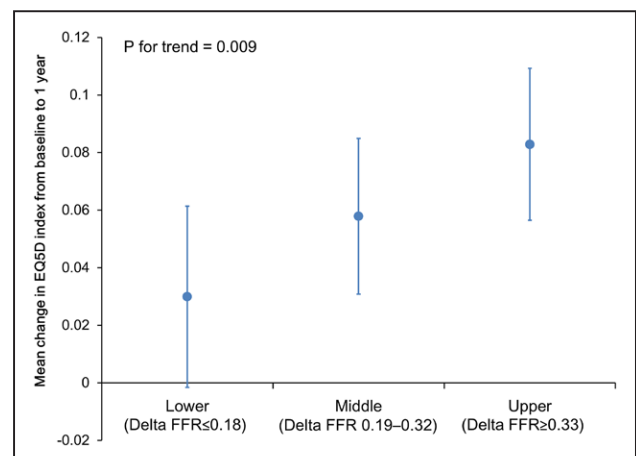


Figure 5. Change in European Quality of Life-5 Dimensions (EQ-5D) index from baseline to 1 year.

Mean change in EQ-5D index from baseline to 1 year between delta fractional flow reserve (FFR) tertile subgroups (lowest [≤ 0.18], middle [0.32–0.19], and upper [≥ 0.33] tertiles) (–0.030 [95% CI, –0.002 to 0.062], 0.058 [0.031–0.085], and 0.083 [0.056–0.110], respectively). Error bars indicate 95% CIs.

Table 2. Results of Mixed-Effects Models for Repeated Measures to Predict Quality of Life at Follow-Up After Percutaneous Coronary Intervention

	β Value	Lower 95% CI	Upper 95% CI	P Value
At 1 mo				
FFR value at baseline	-0.142	-0.231	-0.053	0.002
Canadian Cardiovascular Society angina class	0.024	0.010	0.038	0.001
Delta FFR	0.120	0.018	0.222	0.021
Percent delta FFR	0.038	0.010	0.066	0.009
At 1 y				
FFR value at baseline	-0.090	-0.180	-0.0003	0.049
Canadian Cardiovascular Society angina class	0.030	0.016	0.045	<0.001
Delta FFR	0.116	0.015	0.218	0.025
Percent delta FFR	0.031	0.004	0.059	0.026

FFR indicates fractional flow reserve.

The mixed model for repeated measures analysis included subject as a random effect, FFR (model 1) (or Canadian Cardiovascular Society class [model 2]), delta FFR [model 3], or percent delta FFR [model 4]), visit (baseline, 1 month, and 1 year), and FFR-by-visit (or Canadian Cardiovascular Society class-by-visit [model 2], delta FFR-by-visit [model 3], or percent delta FFR-by-visit [model 4]) interaction as fixed effects, with adjustment for European Quality of Life-5 Dimensions index at baseline, and variables with a single variable value of $P < 0.05$ as follows: sex, reduced left ventricular ejection fraction ($< 50\%$), number of antianginal medications, history of diabetes mellitus, and enrolling sites. The number of subjects is 716 in models 1 and 2 and 507 in models 3 and 4.

no significant difference in health status between the treatment groups by 36 months.¹⁰ In the FAME 2 trial, in patients with at least 1 lesion with an FFR ≤ 0.80 , angina relief was significantly greater at 3 years with PCI compared with medical therapy, and the EQ-5D index was significantly increased after PCI at 1 month and remained significantly higher during 2-year follow-up compared with baseline, whereas it did not improve significantly from baseline to any time point during follow-up in patients with functionally significant disease treated medically.⁵

In the present study, we found that patients with greater angina had a greater QOL benefit from PCI, in line with previous studies.^{10,14} The important new finding from this analysis is that patients with the lowest FFR at baseline and the greatest FFR improvement received the greatest QOL improvement after PCI. This is biologically plausible in that myocardial ischemia with angina caused by obstructive CAD reduces functional capacity, leading to a decreased activity level and QOL impairment. Treating obstructive CAD, which is responsible for ischemia, should relieve angina, restore functional capacity, and improve QOL. The present study demonstrates that measuring FFR can identify patients whose QOL will improve the greatest with PCI.

The ORBITA trial (Objective Randomised Blinded Investigation With Optimal Medical Therapy of Angioplasty in Stable Angina), which was a randomized, double-blind study comparing PCI with sham PCI in patients with stable, single-vessel CAD, raised questions about this paradigm by showing no significant difference in angina or QOL after PCI at the 6-week follow-up.⁶ However, the main limitation of ORBITA, which likely explains the discrepant findings, is that FFR was not used to guide PCI, although it was measured. Approximately one-third of the lesions treated with PCI in ORBITA had FFR values > 0.80 , which we know from previous studies do not benefit from PCI; patients with functionally nonsignificant CAD do just as well, if not better, when treated medically.^{15,16} Treating these nonsignificant lesions with PCI only dilutes the benefit of PCI.

Some have argued that the results of the FAME 2 trial are caused by a placebo effect resulting from the patient's and physician's knowledge of the abnormal FFR. However, if that were the only reason for benefit, one would expect a dichotomous result, with all patients with an abnormal FFR value who had PCI improving to a similar degree with respect to angina relief and QOL. A key finding from this study is that the degree of improvement in QOL after PCI was related to the degree of reduction in FFR, with patients with the lowest FFR values receiving the greatest improvement in QOL, and to the change in FFR from baseline to after PCI, with the patients with the greatest delta FFR receiving the greatest improvement in QOL. This argues against a placebo effect and for a direct relationship between the effect of myocardial ischemia on symptoms and QOL and the relationship between the relief of ischemia and improvement in QOL.

The recently published physiology-stratified subanalysis of ORBITA found that the lower the FFR, the greater the magnitude of stress echocardiographic improvement caused by PCI.¹⁷ This finding supports the concept that the degree of benefit of PCI is greatest in those patients with the highest degree of ischemia measured by invasive physiology. However, in the subanalysis of ORBITA, PCI did not improve patient-reported QOL scores, including Seattle Angina Questionnaire QOL and EQ-5D scores, more than placebo, as with the ORBITA main report, and in contrast to the present study, there was no detectable evidence of interaction between FFR and the effect of PCI on the QOL scores. The clear differences between the ORBITA subanalysis and the present study are the blinding of the investigators and the presence of a sham control as a comparator. In addition, the discordant findings between the studies may be a result of the fact that only patients with single-vessel disease were included in the ORBITA trial, whereas patients with multivessel disease, who may more likely benefit from PCI, were also included in the FAME 1 and FAME 2 trials. In addition, the sample size was much larger

in the present study than in the ORBITA subanalysis. In particular, only 76 patients with baseline FFR ≤ 0.80 underwent PCI in the ORBITA physiology-stratified subanalysis, and a significant minority of the PCI group did not have angina at the time of randomization. Because QOL has a wide between-individual variability and multifactorial nature, a larger sample size might be required to identify the relationship between QOL improvement and the degree of ischemia measured by invasive physiology.

Limitations

The key limitation of this study is that PCI was performed in an unblinded fashion. Therefore, the blinded impact of FFR and PCI on angina and QOL improvement is unknown. We did not have a sham-controlled PCI cohort; therefore, we were not able to evaluate the relationship between baseline FFR value and QOL improvement after a sham procedure. Some other limitations of this study include that we were not able to demonstrate a lack of QOL improvement after PCI in patients with lesions with FFR >0.80 because these patients did not receive PCI. We did not use a disease-specific measure for QOL assessment such as Seattle Angina Questionnaire, which might be more sensitive to the intervention than the more generic EQ-5D index.¹⁸ In patients with multivessel CAD, the delta FFR was not always available for all treated lesions because some lesions may not have had a post-PCI FFR measured. However, the post-PCI FFR value was measured in the most severe lesion in 449 of 507 patients (89%) who had a post-PCI FFR value. Although baseline FFR was significantly associated with the change in EQ-5D index, baseline EQ-5D index was not significantly different in the reference and abnormal FFR subgroups. The subjective experience of QOL can vary between individuals, and factors unrelated to severity of CAD may influence QOL at baseline. Assessing the change in QOL from baseline to follow-up could reduce the influence of such factors on QOL, consequently allowing the significant relationship between FFR and the QOL benefit from PCI to be demonstrated.

Conclusions

In the present study, we found that in patients with stable CAD, the degree of QOL improvement after PCI is directly related to the degree of ischemia as assessed by the measurement of FFR.

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