Economic Evaluation of Fractional Flow Reserve–Guided Percutaneous Coronary Intervention in Patients With Multivessel Disease

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Background—The Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME) study demonstrated significantly improved health outcomes at 1 year in patients randomized to multivessel percutaneous coronary intervention guided by fractional flow reserve (FFR) compared with percutaneous coronary intervention guided by angiography alone. The economic impact of routine measurement of FFR in this setting is not known.

Methods and Results—In this study, 1005 patients were randomly assigned to FFR-guided or angiography-guided percutaneous coronary intervention and followed up for 1 year. A prospective cost-utility analysis comparing costs and quality-adjusted life-years was performed with a time horizon of 1 year. Quality-adjusted life-years were calculated with the use of utilities determined by the EuroQuol 5 dimension health survey with US weights. Direct medical costs included those of the index procedure and hospitalization and costs for major adverse cardiac events during follow-up. Confidence intervals for both quality-adjusted life-years and costs were estimated by the bootstrap percentile method. Major adverse cardiac events at 1 year occurred in 13.2% of those in the FFR-guided arm and 18.3% of those in the angiography-guided arm (P=0.02). Quality-adjusted life-years were slightly greater in the FFR-guided arm (0.853 versus 0.838; P=0.2). Mean overall costs at 1 year were significantly less in the FFR-guided arm ($14 315 versus $16 700; P<0.001). Bootstrap simulation indicated that the FFR-guided strategy was cost-saving in 90.74% and cost-effective at a threshold of US $50 000 per quality-adjusted life-years in 99.96%. Sensitivity analyses demonstrated robust results.

Conclusion—Economic evaluation of the FAME study reveals that FFR-guided percutaneous coronary intervention in patients with multivessel coronary disease is one of those rare situations in which a new technology not only improves outcomes but also saves resources.

Clinical Trial Registration—URL: http://ClinicalTrials.gov. Unique identifier: NCT00267774. (Circulation. 2010;122:2545-2550.)

Key Words: angiography ▪ coronary disease ▪ cost-benefit analysis ▪ fractional flow reserve, myocardial ▪ physiology ▪ stents

The Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME) study was a large, multicenter, international, randomized clinical trial comparing outcomes in patients with multivessel coronary artery disease (CAD) undergoing percutaneous coronary intervention (PCI) either with angiographic guidance alone or with the addition of fractional flow reserve (FFR) guidance.1 At 1 year, there was a significant decrease in the primary end point, defined as the composite of death, myocardial infarction (MI), or the need for repeat revascularization, in the group receiving FFR guidance (13.2% versus 18.3%; P=0.02). The economic ramifications of the additional costs incurred by the routine measurement of FFR in this scenario are unknown. The goal of this prospective economic evaluation is to determine the cost-effectiveness of the FFR-guided strategy in the US healthcare context.

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Methods

Study Design

The design of the FAME trial has been previously reported.1,2 In brief, the study included 1005 patients (21.9% from the United...
States) undergoing PCI for multivessel CAD, defined as 2 or 3 major epicardial arteries with $\geq 50\%$ stenosis warranting PCI. Patients with angiographically significant left main CAD, prior coronary artery bypass grafting, or extremely tortuous or calcified vessels and those within 5 days of an ST-segment elevation MI were excluded. After a baseline coronary angiogram was performed, the investigator indicated which lesions should be stented on the basis of the angiographic appearance and clinical information available. Patients were then randomized to either angiographic guidance, in which case the investigator performed PCI of the indicated lesions, or FFR guidance, in which case FFR was first measured in each diseased vessel with a coronary pressure wire and intravenous adenosine. If the FFR was $\leq 0.80$, then PCI of the respective stenosis was performed; otherwise, PCI was deferred. Patients received drug-eluting stents and clopidogrel during the first year. Major adverse cardiac events, defined as all-cause death, MI, or need for repeat coronary revascularization, were assessed at 1 year as previously described.\textsuperscript{1,2}

**Framework of the Economic Evaluation**

In the present study, an economic evaluation along the FAME trial in the context of the US healthcare system was performed. The incremental cost-effectiveness ratio (ie, the net incremental cost of the FFR-guided and angiography-guided strategies divided by the net incremental health outcomes of each strategy) was calculated.\textsuperscript{3} The time horizon was 1 year (ie, the duration of follow-up in the primary clinical study), and analyses were performed from a societal perspective using direct costs. Given the short time horizon, no discounting was performed. The primary analysis was a cost-utility analysis (ie, cost versus quality-adjusted life years [QALYs]).

**Costs**

Costs for each strategy included the initial procedural costs and costs during the 1-year follow-up. The costs of the index procedures were calculated from the actual resource consumption by determining the amount of guiding catheters, regular wires, pressure wires, balloon dilatation catheters, stents, antiplatelet therapy, adenosine, contrast media, and hospital days used for each patient’s index procedure. These were multiplied by the cost of each resource in US dollars. On the basis of a recent publication evaluating Medicare costs for hospital days, the cost of a hospital day was estimated to be $2524 for patients initially admitted with an acute coronary syndrome before their index procedure and therefore likely to be in a cardiac care unit and a step-down or telemetry bed and $1488 for other patients on the basis of the cost for a “floor” bed.\textsuperscript{4} These costs were applied only to the index hospitalization. The costs of the other resources were obtained from a US participating site. Personnel and laboratory time costs were not included because they were similar between the 2 strategies.\textsuperscript{5} Periprocedural MI was not assigned a cost.

Costs of repeat PCI without MI, repeat PCI in the setting of a nonperiprocedural MI, coronary artery bypass grafting, and nonperiprocedural MI were based on Medicare’s reimbursement rate per diagnosis-related group.\textsuperscript{6} We obtained the national average reimbursement rate by Medicare for each of these events and added the national average Medicare physician reimbursement rate for PCI and coronary artery bypass grafting procedures. Indirect costs resulting from productivity losses were assumed to be captured by the denominator of the incremental cost-effectiveness ratio (ie, QALY) and therefore are not included in the numerator of the incremental cost-effectiveness ratio.\textsuperscript{6} All costs were converted to 2008 US dollars using the consumer price index (www.bls.gov). To evaluate whether any treatment effects exist between US and non-US patients on costs, we tested for the interaction between site effect (US versus non-US) and the treatment effect.

**Health Outcomes**

QALYs were derived from health-related quality of life and survival during the 1-year time horizon of the trial. Quality-of-life indexes (utilities) were evaluated at baseline, after 1 month, and after 1 year using the EuroQuol 5 dimension health survey with US weights.\textsuperscript{7,8}

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### Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Angiography Guided (n=496)</th>
<th>FFR Guided (n=509)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>64.2±10.2</td>
<td>64.6±10.3</td>
</tr>
<tr>
<td>Male, %</td>
<td>72.6</td>
<td>75.4</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>25.2</td>
<td>24.2</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>65.9</td>
<td>61.3</td>
</tr>
<tr>
<td>Dyslipidemia, %</td>
<td>73.0</td>
<td>71.9</td>
</tr>
<tr>
<td>Tobacco use, %</td>
<td>31.5</td>
<td>27.1</td>
</tr>
<tr>
<td>Previous MI, %</td>
<td>36.3</td>
<td>36.7</td>
</tr>
<tr>
<td>Previous PCI, %</td>
<td>26.0</td>
<td>28.7</td>
</tr>
<tr>
<td>Unstable angina, %</td>
<td>With dynamic ECG changes 18.3</td>
<td>14.3</td>
</tr>
<tr>
<td></td>
<td>Without dynamic ECG changes 17.5</td>
<td>15.1</td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>57±12</td>
<td>57±11</td>
</tr>
<tr>
<td>Indicated lesions, n</td>
<td>2.7±0.9</td>
<td>2.8±1.0</td>
</tr>
</tbody>
</table>

Values are mean±SD when appropriate. P<0.05 for all comparisons.

To correct for the difference in baseline utilities between the angiography-guided patients and the FFR-guided patients, we adjusted all utilities by adding half of the baseline difference to each utility value for the angiography-guided patients (at each time point) and subtracting the same amount from each utility value for the FFR-guided patients (at each time point).

The overall QALYs were estimated as the area under the curve determined by these 3 values. Data for quality of life were missing for 9.7% of patients at baseline, for 15.4% at the 1-month follow-up examination, and for 17.5% at 1 year. All missing data were replaced with estimates using bootstrap resampling within the respective study arm.\textsuperscript{9} In particular, we generated 1000 complete data sets from the original study by resampling, and we replaced each missing value by the most likely EuroQuol 5 dimension health survey category. Observation time was used exactly from randomization to a maximum of 365 days unless death occurred before then.

**Statistical Analysis**

Categorical data are reported as frequencies, and continuous data are given as mean±SD. Categorical data were compared by use of the $\chi^2$ test. Continuous data (costs and QALYs) were compared by use of the Student $t$ test. We report 95% confidence intervals when appropriate. Confidence intervals for both differences in QALYs and costs were estimated by the bootstrap technique using the percentile method and 5000 replications. A 2-sided value of $P<0.05$ was considered to indicate statistical significance.

Sensitivity analyses were performed for a range of ±20% on all prices and for ±10% on utilities. The test for interaction was performed by testing statistical significance of the interaction term between treatment and site effect in multiple regression analysis (for costs) and logistic regression analysis (for health events). All analyses were performed with the use of SAS software, version 9.2 (SAS Institute Inc, Cary, NC).

**Results**

The baseline characteristics of the patients enrolled in the FAME trial are displayed in Table 1. At 1 year, the rate of major adverse cardiac events was 13.2% in the FFR-guided arm and 18.3% in the angiography-guided arm ($P=0.02$). The rate of death or MI was 7.3% in the FFR-guided arm versus 11.1% in the angiography-guided arm ($P=0.04$). The proportion of patients who were angina free was similar between the 2 groups (81% versus 78%, respectively; $P=0.20$). Mean utilities at baseline for patients in the angiography-guided and
were 0.808, 0.887, and 0.887 (P < 0.05 between study groups) to the angiography-guided group and 0.808, 0.895, and 0.896 at baseline, 1 month, and 1 year. The respective values in the FFR-guided group were 0.796 and 0.821, respectively. To correct for this baseline difference, we added 0.0125 (half of the 0.025 difference) to the angiography-guided group and subtracted the same amount from the FFR-guided group at each time point. The corrected mean utilities in the angiography-guided group were 0.808, 0.895, and 0.896 at baseline, 1 month, and 1 year. The respective values in the FFR-guided group were 0.808, 0.887, and 0.887 (P > 0.05 between study groups at all time points). In both groups, mean utilities increased numerically higher in the FFR-guided arm compared with the angiography-guided arm (0.853 versus 0.838; P = 0.0001) and remained stable from baseline to 1 month (P > 0.2). A sensitivity analysis of the utilities calculated from the EuroQuol 5 dimension health survey by 10% resulted in 0.748 QALYs on average for the angiography-guided arm compared with the angiography-guided arm (0.853 versus 0.838; P = 0.2).

The mean index procedural and hospitalization costs were significantly lower in the FFR-guided arm ($13 182 ± 9667 versus $14 878 ± 9509; P < 0.0001). Resources used at the index procedure for each arm and their costs are listed in Table 2. Overall costs at 1 year ranged from $2591 to $99 027 in the FFR-guided strategy and from $4445 to $108 404 in the angiography-guided strategy. At 1 year, the mean overall costs were significantly lower in the FFR-guided arm compared with the angiography-guided arm ($14 315 ± 11 109 versus $16 700 ± 11 868; P < 0.0001). A comparison of the index procedure costs between patients enrolled in the United States and those enrolled outside the United States showed no significant difference. This also held true with respect to follow-up costs. There was no statistically significant effect on costs when US and non-US centers were compared with respect to treatment (interaction term, P = 0.71). When the rates of death, nonperiprocedural MI, or repeat revascularization were compared between patients enrolled in the United States and those enrolled outside the United States, there were no significant differences. There was also no significant interaction (P = NS for all) when the rates of death, MI, or repeat revascularization were compared between US and non-US centers.

The bootstrap simulation demonstrated that the FFR-guided strategy is cost-saving in 90.74% and cost-effective (at a threshold of $50 000 per QALY gained) in 99.96% of 5000 bootstrap simulation samples (Figure 1). Similarly, the FFR-guided strategy was cost-saving with respect to clinical outcomes. Absolute and incremental QALYs and costs are presented in Table 3.

All sensitivity analyses showed robust results. Reducing the utilities calculated from the EuroQuol 5 dimension health survey by 10% resulted in 0.748 QALYs on average for the angiography-guided strategy and 0.767 for the FFR strategy. The bootstrap simulation demonstrated that the FFR-guided strategy is cost-saving in 90.74% and cost-effective (at a threshold of $50 000 per QALY gained) in 99.96% of 5000 bootstrap simulation samples (Figure 1). Similarly, the FFR-guided strategy was cost-saving with respect to clinical outcomes. Absolute and incremental QALYs and costs are presented in Table 3.

The principal finding of this study is that performing PCI guided by FFR in patients with multivessel CAD saves healthcare resources and improves health outcomes at 1 year compared with a traditional strategy of angiographic guid-

### Table 2. Resources Used and Costs

<table>
<thead>
<tr>
<th>Resource (Cost)</th>
<th>Resource Units, n</th>
<th>Mean Cost/Patient, $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guide catheter ($35)</td>
<td>2.2 (2.1–2.3)</td>
<td>77</td>
</tr>
<tr>
<td>Guidewire ($85)</td>
<td>2.2 (2.0–2.3)</td>
<td>184</td>
</tr>
<tr>
<td>Pressure wire ($650)</td>
<td>0</td>
<td>...</td>
</tr>
<tr>
<td>Balloon catheter ($150)</td>
<td>2.1 (1.9–2.2)</td>
<td>302</td>
</tr>
<tr>
<td>Contrast agent (0.5/mL)</td>
<td>302 (291–314)</td>
<td>150</td>
</tr>
<tr>
<td>DES ($2100)</td>
<td>2.7 (2.6–2.8)</td>
<td>5754</td>
</tr>
<tr>
<td>Bare metal stent ($1000)</td>
<td>0.1 (0.06–0.14)</td>
<td>101</td>
</tr>
<tr>
<td>Adenosine ($150/vial)</td>
<td>0</td>
<td>...</td>
</tr>
<tr>
<td>GPI ($500/vial)</td>
<td>0.4 (0.3–0.5)</td>
<td>157</td>
</tr>
<tr>
<td>Hospital day (floor bed, $1696/d)</td>
<td>2.1 (1.8–2.3)</td>
<td>3443</td>
</tr>
<tr>
<td>Hospital day (CCU, $2877/d)</td>
<td>1.7 (1.4–2.0)</td>
<td>4710</td>
</tr>
<tr>
<td>Hospital day (total)</td>
<td>3.7 (3.4–4.0)</td>
<td>8153</td>
</tr>
<tr>
<td>Repeat PCI ($12 780)</td>
<td>0.08 (0.05–0.11)</td>
<td>1005</td>
</tr>
<tr>
<td>CABG ($27 606)</td>
<td>0.03 (0.01–0.04)</td>
<td>696</td>
</tr>
<tr>
<td>MI ($4968)</td>
<td>0.004 (0.00)</td>
<td>20</td>
</tr>
<tr>
<td>MI with PCI ($16 544)</td>
<td>0.0006 (0–0.01)</td>
<td>100</td>
</tr>
</tbody>
</table>

| Total 1-y costs, $                  | 16 700             |
| Mean Cost/Patient, $                | 71                  |

**DISCUSSION**

The principal finding of this study is that performing PCI guided by FFR in patients with multivessel CAD saves healthcare resources and improves health outcomes at 1 year compared with a traditional strategy of angiographic guid-

**REFERENCES**


[2] Adenosine ($150/vial) 0.000 (0–0.01) 222

[3] Bare metal stent ($1000) 0.06 (0.03–0.09) 59

[4] DES ($2100) 1.9 (1.8–2.0) 4043

[5] Guide catheter ($35) 2.0 (2.0–2.1) 71

[6] Guide wire ($85) 1.2 (1.1–1.3) 95

[7] Pressure wire ($650) 1.3 (1.2–1.3) 819

[8] Balloon catheter ($150) 1.7 (1.5–1.8) 245

[9] Contrast agent ($0.5/mL) 0.01 (0.002–0.02) 313

[10] Balloon catheter ($150) 3.5 (3.2–3.7) 7356

[11] Pressure wire ($650) 0.06 (0.04–0.09) 778

[12] Guide wire ($85) 1.5 (1.4–1.6) 222

[13] Guide catheter ($35) 0.002 (0–0.006) 33

[14] Contrast agent ($0.5/mL) 1.5 (1.4–1.6) 222

[15] Bare metal stent ($1000) 0.06 (0.03–0.09) 59
The cost savings occur both at the index procedure, primarily owing to a decrease in drug-eluting stent use being a major cost driver, which more than offsets the increased cost of the pressure wire and adenosine, and during follow-up as a result of a decrease in rehospitalization and fewer major adverse cardiac events. About 90% of the total cost occurred at the index hospitalization. However, 30% of the overall cost difference between the 2 strategies is generated during follow-up, indicating increasing cost savings even after the initial procedure.

For both groups, the utility improvement compared with baseline occurs by 1 month after the index procedure and persists at 1 year. These results appear to be robust because the bootstrap simulation demonstrated that an FFR-guided strategy was dominant (cost-saving, ie, costs less and provides better health outcomes) in 90.7% of the samples. In addition, sensitivity analyses varying costs and utilities did not change these results.

The presumed explanation for these results lies in the fact that the coronary angiogram, although our reference standard for diagnosing CAD, is a poor predictor of ischemia-producing lesions. For example, in the FAME trial, 65% of lesions with 50% to 70% diameter stenosis based on visual estimation were not responsible for an abnormal FFR (<0.80), and 20% of lesions with a 71% to 90% diameter stenosis were not responsible for an abnormal FFR. Yet, the angiographic appearance of lesions causing ischemia is identical to that of lesions not responsible for ischemia, particularly when in the moderate range of stenosis. Prior studies have demonstrated the importance of identifying ischemia and suggest improved outcomes with the relief of ischemia. Likewise, the lack of benefit of PCI on non–ischemia-producing lesions also has been clearly documented.

In the present study, the angiography-guided arm likely received a number of stents for lesions not responsible for ischemia. This increased the costs without improving the health outcome. In fact, the additional stents may have resulted in harm, ie, more major adverse cardiac events resulting from both procedural complications and late complications. Conversely, it is possible that relief of ischemia was not complete in some patients in the angiography-guided arm because mild ischemia-producing lesions were not recognized, translating into a higher adverse event rate. In contrast, the FFR-guided arm, presumably only those lesions responsible for ischemia and hence at a higher likelihood for causing adverse events were treated with PCI. This approach resulted in fewer stents being placed and hence lower costs, despite the costs of the pressure wire and adenosine.

Table 3. Overall Health Outcomes and Costs

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Angiography Guided</th>
<th>FFR Guided</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACEs, %</td>
<td>18.3</td>
<td>13.2</td>
<td>5.2 (0.7–9.7)</td>
</tr>
<tr>
<td>MI, %</td>
<td>8.7</td>
<td>5.7</td>
<td>3.0 (−0.2–6.2)</td>
</tr>
<tr>
<td>Death, %</td>
<td>3.0</td>
<td>1.8</td>
<td>1.3 (−0.6–3.2)</td>
</tr>
<tr>
<td>MI or death, %</td>
<td>11.1</td>
<td>7.3</td>
<td>3.8 (0.3–7.4)</td>
</tr>
<tr>
<td>QALY</td>
<td>0.838</td>
<td>0.853</td>
<td>0.015 (−0.008–0.037)</td>
</tr>
<tr>
<td>Costs of initial procedure, $</td>
<td>6007</td>
<td>5332</td>
<td></td>
</tr>
<tr>
<td>Costs of initial hospitalization, $</td>
<td>14 878</td>
<td>13 182</td>
<td>−1 697 (−2 893–−510)</td>
</tr>
<tr>
<td>Cost of events during 12-mo follow-up</td>
<td>1 821</td>
<td>1 134</td>
<td>−666 (−1 383–−25)</td>
</tr>
<tr>
<td>Overall costs, $</td>
<td>16 700</td>
<td>14 315</td>
<td>−2 384 (−3 826–−1 011)</td>
</tr>
</tbody>
</table>

MACEs indicates major adverse cardiac events. Values are means with 95% confidence intervals (CIs).
adenosine, and better outcomes because the benefit of the stents was maximized and the risk minimized. It is unusual in modern medicine to find a new technology or treatment strategy that not only improves the intended health benefit and reduces risk and unintended effects but also saves costs. A strategy of providing free medications to patients after MI to improve compliance may be cost-saving. Radiofrequency ablation for Wolff-Parkinson-White syndrome compared with surgical ablation, statins after MI, and angiotensin-converting enzyme inhibitors in congestive heart failure are other examples. A unique finding from the present analysis is the fact that an FFR-guided strategy to PCI in multivessel CAD not only was cost-saving but also achieved these results in just 1 year, a remarkably short period of time.

The cost-effectiveness of FFR has previously been evaluated in other settings. With a decision-tree model, measuring FFR in patients with single-vessel intermediate lesions and no prior noninvasive stress test was found to be cost-effective compared with deferring the decision to perform PCI to obtain a nuclear perfusion study and compared with a routine strategy of performing PCI on all intermediate lesions. Similar results have been reported by a recent European health technology assessment report. A small, single-center, randomized study compared an FFR-guided strategy with a nuclear perfusion imaging strategy in patients presenting with non–ST-elevation acute coronary syndromes with single-vessel intermediate disease and found equivalent outcomes and lower costs with the FFR-guided strategy. In a nonrandomized, single-arm study of 137 patients with multivessel CAD, costs were lower and outcomes were better in the 57 patients who had FFR-guided PCI compared with the 80 patients with angiography-guided PCI. Based on its large size, multicenter nature, and randomized prospective design, the present study further strengthens the evidence supporting the health economic advantage to measuring FFR to guide PCI.

Limitations

This analysis is limited by its relatively short time horizon; the durability of these findings need to be confirmed after longer follow-up. Such data are currently not yet available. However, given that most of the difference in expenditure is expected during the first year, a short time horizon may be sufficient. Further research may apply decision analytic modeling techniques if the long-term health and budget impacts are of interest. With respect to our assessment of quality of life, there were missing values and relatively large time intervals. We addressed this issue by performing extensive sensitivity analyses. None of the 1-way sensitivity analyses (ie, numeric variation of utility or cost parameters) had the potential to change the result of the FFR-guided strategy as being cost-saving.

We did not account for other hospitalizations, outpatient services, or medication costs. We also did not explicitly account for indirect costs such as loss of productivity or for nonmedical costs; this likely biased the results in favor of the angiography-guided arm given that there was a higher event rate in this group, which would have increased indirect costs. These results apply to the US healthcare system and cannot be directly generalized to other healthcare systems, although based on the significant differences between the 2 strategies, it is unlikely that the direction of the overall results will be very different. A final limitation of this study is the fact that the majority of the patients were enrolled outside the United States, yet we applied United States–specific costs. The index procedure costs, follow-up costs, and rates of adverse events were similar between the US and non-US patients without any significant interaction with treatment.

Conclusion

FFR-guided PCI with drug-eluting stents in patients with multivessel CAD compared with standard angiographic guidance improves outcomes and saves costs at 1 year and hence is a dominant strategy in this setting.

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Disclosures

None.

References


**CLINICAL PERSPECTIVE**

The Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME) study demonstrated that performing percutaneous coronary intervention guided by fractional flow reserve measurement in patients with multivessel coronary artery disease leads to improved outcomes at 1 year compared with the traditional approach of using angiography alone to guide percutaneous coronary intervention. In this economic evaluation of the FAME study, we find that a fractional flow reserve–guided strategy not only improves outcomes but also saves money at 1 year. This finding provides further support for the routine measurement of fractional flow reserve in patients with multivessel coronary artery disease undergoing percutaneous coronary intervention.

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