Coronary Interventions

Revascularization Decisions in Patients With Stable Angina and Intermediate Lesions
Results of the International Survey on Interventional Strategy

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Background—Fractional flow reserve (FFR) measurement of intermediate coronary stenoses is recommended by guidelines when demonstration of ischemia by noninvasive testing is unavailable. The study aims to evaluate the penetration of this recommendation into current thinking about revascularization strategies for stable coronary artery disease.

Methods and Results—International Survey on Interventional Strategy was conducted via a web-based platform. First, participants’ experiences in interventional cardiology were queried. Second, 5 complete angiograms were provided, presenting only focal intermediate stenoses. FFR and quantitative coronary angiography values were known; however, remained undisclosed. Determination of stenosis significance was asked for each lesion. In cases of uncertainty, the most appropriate adjunctive invasive diagnostic method among quantitative coronary angiography, intravascular ultrasound, optical coherence tomography, or FFR needed to be selected. International Survey on Interventional Strategy was taken by 495 participants who provided 4421 lesion evaluations. In 3158 (71%) decisions, participants relied solely on angiographic appearance that was discordant in 47% with the known FFR, using 0.80 as cutoff value. The use of FFR and imaging modalities was requested in 21% and 8%, respectively. Comparing 4 groups of participants according to the experience in FFR, angiogram-based decisions were less frequent with increasing experience (77% versus 72% versus 69% versus 67%, respectively; \( P<0.001 \)). As a result, requests for FFR were more frequent (14% versus 19% versus 24% versus 28%, respectively; \( P<0.001 \)) and rates of discordant decisions decreased (51% versus 49% versus 47% versus 43%, respectively; \( P<0.022 \)).

Conclusions—The findings confirm that, even when all potential external constraints are virtually eliminated, visual estimation continues to dominate the treatment decisions for intermediate stenoses, indicative of a worrisome disconnect between recommendations and current practice. (Circ Cardiovasc Interv. 2014;7:751-759.)

Key Words: cardiac catheterization ■ coronary angiography ■ ischemic heart disease ■ stents ■ ultrasound, Doppler

The optimal treatment of patients with stable coronary artery disease (CAD) remains a matter of ongoing debate. Although revascularization provides an accepted symptomatic benefit, controversy lingers on its prognostic value when added to contemporary optimal medical care. Protagonists of medical therapy stress that revascularization, especially with percutaneous coronary intervention (PCI), does not reduce rates of death or myocardial infarction. Protagonists of mechanical therapy counter that most revascularization studies were based on anatomic guidance only, with visual estimation of stenosis severity from the coronary angiogram. Because \( \leq 39\% \) of angiographically obstructive coronary stenoses lack functional significance, no benefit should be expected from revascularizing nonischemic myocardium. As a result, outcome results from existing trials are confounded by the neutral or negative effects arising from unnecessary interventions.

Editorial see p 736

Based on the comparison of Deferral Versus Performance of PTCA (percutaneous transluminal coronary angioplasty) in Patients Without Documented Ischemia (DEFER) study, Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME) study, and several observational studies,}
WHAT IS KNOWN

• In stable coronary artery disease, when noninvasive functional information is missing, the use of angiographic guidance only for the evaluation of intermediate stenosis is largely imprecise in identifying functionally relevant stenoses.
• Large, randomized trials and several observational studies have shown superiority of fractional flow reserve–guided revascularization, as compared with angiographic guidance alone.
• Most recent European and American guidelines strongly recommend the use of fractional flow reserve for decision making about angiographically intermediate stenoses in stable coronary artery disease.

WHAT THE STUDY ADDS

• Treatment decisions for intermediate stenoses were examined with a web-based survey, termed International Survey on Interventional Strategy.
• Even when all potential external constraints to obtaining fractional flow reserve are virtually eliminated, the majority of operators rely solely on visual angiographic assessment.
• An important disconnect remains between the actions of the interventional community in International Survey on Interventional Strategy and the most recent recommendations.

guidelines, especially on the determination of significance of intermediate stenosis in stable CAD. Participants’ views on best clinical practice and the impact on decision making of their overall and specific experiences in interventional cardiology were targeted by a single choice questionnaire using case presentations in the survey’s virtual catheterization laboratory. We report here the main results of the ISIS investigation.

Methods

Survey

ISIS’s web-based platform was reachable continuously between October 2012 and May 2013 through PCRonline, the official site of EuroPCR/European Association of Percutaneous Cardiovascular Interventions. The survey contained specific questions and dedicated case presentations on 2 major topics. The first part queried the characteristics of the participants, including overall experience in interventional cardiology, annual volume of PCI, and duration of experience with quantitative coronary angiography (QCA), intravascular ultrasound (IVUS), optical coherence tomography (OCT), and FFR. The survey used predefined categories and single-choice questions.

The second part investigated personal strategies for evaluating angiographically intermediate stenoses in the catheterization laboratory. Here, participants evaluated 5 complete coronary angiograms presenting only focal stenoses (n=12) of intermediate severity by angiography. Cases were selected by independent interventional cardiologists (F.D.V., L.D.S.) from a database in which both QCA and FFR were known for each stenosis. Cases were ordered randomly, without any intention to make a pattern of progressive difficulty. Case order remained the same for all the participants. Of 12 lesions, 6 were functionally nonsignificant (FFR > 0.80), whereas another 6 were functionally significant (FFR ≤ 0.80). The true FFR and QCA values were never revealed to participants, not even after completion of the questionnaire. All cases were characterized as stable angina without relevant changes on resting ECG. No information about noninvasive testing was provided.

Participants were asked to (1) localize all relevant stenoses by indicating the involved segment; (2) define percent diameter stenosis (%DS) by visual estimate; and (3) determine the significance of the stenosis of interest. In cases of angiographic uncertainty, the most appropriate diagnostic tool had to be selected from the arsenal available in the catheterization laboratory, namely QCA, IVUS, OCT, or FFR. Participants were asked to make their decisions assuming ideal world conditions, without considering any financial restrictions or local regulations, but only after the best clinical practice achievable in this virtual catheterization laboratory. Figure 1 displays a screenshot from the ISIS website. For this analysis, angiogram-based decisions on significance were classified as either concordant or discordant versus the known FFR value (cutoff at ≤ 0.80) as a standard of reference.

Access to the angiograms was granted to interventional cardiologists only after verification of their identity. The ISIS website was only accessible to professionals. The coronary angiograms were anonymized and had been acquired in context of trials. Participants were informed about the surveys objectives and gave their agreement by responding positively to the invitation.

Statistical Analysis

Descriptive statistics are reported as median (interquartile range), mean±SD, or counts (%), as appropriate. Because all respondents did not answer all questions, variable numbers of responses were received for each query. As a result, tables and figures emphasize percentage of the total to focus attention on trends rather than raw counts. Variables were compared using ANOVA when continuous. A χ² goodness of fit compared categorical survey responses such as experience and PCI volume. Variances for differences between visual %DS and QCA-derived %DS were compared using a Bartlett test for unequal variances.

Multiple imputations was necessary for 5% of 6 demographic variables (age, annual PCI volume, experience in interventional cardiology, and duration of experience with FFR, IVUS, and OCT) given missing survey responses. Univariate and multivariable regression
models were used to predict treatment decisions (multinomial) or concordance with FFR (logistic). To account for correlation among survey responses from the same participant, mixed logistic models used random effects among participants. The Cochran–Armitage test assessed the association between levels of experience and decision patterns. All applicable tests were 2-tailed, and a P value of <0.05 was considered statistically significant.

Analysis was performed using Prism GraphPad 5.0 (GraphPad Software Inc, CA), SPSS 20.0 (IBM Inc, NY), and R version 3.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Characteristics of Participants

Between October 2012 and May 2013, a total of 495 unique participants filled in the questionnaire, as detailed in Table 1. More detailed analysis can be found in the supplemental material (Table I in the Data Supplement). An exploratory analysis included only the 291 participants (59%) who responded to all cases, because response fatigue may have produced discordant answers. However, no important differences were found compared with including all participants (detailed results not shown).

Analysis

Table 2 and Figure 2 are describing the 5 cases and 12 lesions, showing both the measured FFR and QCA values for %DS and the survey responses for visually estimated %DS and treatment decisions. Case 1 to 5 were evaluated by 482 (97.4%), 383 (77.4%), 342 (69.1%), 324 (65.5%), and 312 (63.0%) participants, respectively, resulting in a total of 4421 lesion-based evaluations. Because survey questions were always posed and answered consecutively, the decreasing participation rate across the 5 cases results from participants who quit before completing the entire questionnaire. Unless stated otherwise,
summary results on experience and decisions are presented on a per-lesion level.

**Visually Estimated Diameter Stenosis**
A total of 3597 visually estimated %DS values were collected: 1321 (36.8%) for the right coronary artery, 714 (19.8%) for the left circumflex, and 1562 (43.4%) for left anterior descending. The visually estimated %DS showed an absolute overestimation of +18% (interquartile range, +4% to +28%) compared with the corresponding QCA-derived %DS values. The overestimation of stenosis severity, as compared with QCA-derived %DS was significantly more pronounced in the right coronary artery (+22% (+13% to +28%) compared with +18% (+8% to +19%) for the left circumflex and +8% (-6% to +24%) for the left anterior descending, respectively (P<0.001). Variances differed significantly among vessels, being largest for the left anterior descending (SD of 20%), intermediate for the left circumflex (SD of 15%), and smallest for the right coronary artery (SD of 12%; P<0.001 across groups and for every paired comparison; Figure 3).

**Decisions and Requested Diagnostic Tools**
Participants provided a total of 4421 decisions about stenosis significance, as summarized in Figure 4. Although the vast majority of decisions (71% of total) were made using participants’ visual assessment only, decisions that are concordant with FFR (38% of total, 53% of angiogram-based decisions) only slightly outweigh discordant decisions (34% of total, 47% of angiogram-based decisions). In the remaining cases angiographic appearance was found dubious for decision and additional diagnostic tool was requested: FFR more often than any of the imaging modalities such as QCA, IVUS, or OCT (21% versus 8%, respectively).

Figure 5 depicts how treatment decisions varied by levels of experience with FFR (Figure 5A) and IVUS (Figure 5B), as well as how angiogram-based decisions agreed with FFR. More detailed description of treatment decisions by various characteristics of the participants is summarized in Table II in the Data Supplement.

As seen in Table 3, operators selected FFR more often as PCI volume increased (20% in lowest to 25% in highest; P=0.041 for trend). Interestingly, growing experience with imaging tools also translated into a higher selection of FFR for lesion evaluation for both IVUS (19% in lowest to 24% in highest; P<0.001 for trend) and OCT (20% in lower, 24% in higher; P=0.009 for trend). As expected, increasing experience with FFR also tracks directly with more requests for FFR (14% in lowest to 28% in highest; P<0.001). However, increasing experience with IVUS or OCT did not translate into a significant trend for more imaging, whereas increasing FFR experience reduced selection of imaging for lesion evaluation (9% for lowest to 6% in highest; P<0.001).

Because of the significant, direct correlations among characteristics of the participants and the above-described multiple significant trends, a multivariable analysis by a multinomial model was performed, showing that no participant characteristic remained a significant predictor of decision pattern after adjusting for the others (details shown in Table III in the Data Supplement).

**Angiogram-Based Decisions**
When examined respondent characteristics in the subset of angiogram-based decisions by agreement with FFR, overall only a narrow majority (53%) of angiogram-based decisions was found to
agree with FFR. As seen in Table 3, regardless of operator experience, PCI volume, and experience with FFR or imaging, concordance never exceeded 57% of all angiogram-based decisions. Significantly increased agreement with FFR for angiogram-based decisions occurred only with growing experience with FFR (49% in lowest to 57% in highest; P=0.001 for trend) or IVUS (50% in lowest to 55% in highest; P=0.012 for trend).

The multinomial model also showed that no participant characteristic remained a significant predictor of concordant decisions after adjusting for the others (details shown in Table IV in the Data Supplement).

### Cutoff Value for Visual Estimation

A total of 252 participants provided the angiographic cutoff value they use when determining lesion significance. The provided values varied between 50% and 90% DS for visually assessed severity, with the vast majority at 70% DS (57.1%), followed by 75% DS (12.3%), 60% DS (9.1%), 50% DS (8.7%), and 80% DS (8.3%).

### Discussion

ISIS was designed to evaluate the interaction between guideline recommendations, the thinking process of operators when deciding about angiographically intermediate stenoses in...
patients with stable CAD, and eventual choices about diagnostic and treatment strategies. Results show a significant disconnect between evidence and the way interventional cardiologists practice.

ISIS found that despite its know inaccuracy, 21,22 interventional cardiologists are still prone to make decisions about an intermediate stenosis purely on the basis of its angiographic appearance in almost three quarter of all cases, even when noninvasive proof of ischemia is missing, and even, when the use of additional invasive diagnostic tools is not restricted by financial limitations.

By removing virtual and financial barriers, ISIS survey was intended to reveal any unaffordable desires to make more frequent use of invasive imaging in real life. The study shows that even a virtual intention to use IVUS or OCT is infrequent. This is consistent with the currently limited evidence that their use for diagnostic purposes improves outcomes in mild-to-moderate stenoses in patients with stable CAD.

Another challenging finding in ISIS was the underuse of FFR despite existing outcome trials3,5–13,23 and guideline recommendations14,16. Even in a virtual, utopian environment with unrestricted access to all technologies, this worldwide survey of interventional behavior shows that anatomy mostly suffices to decide about the fate of intermediate lesions, even without availability of prior functional data. Although the European Society of Cardiology class I recommendation for FFR would apply to all 12 lesions in our survey, given their intermediate nature and absence of prior functional testing, no respondent selected FFR for 100% of the cases. A single respondent of 495 (0.2%) selected FFR in 10 of the 12 cases (the highest FFR user among all), whereas 133 of the 495 participants (27%) never selected FFR at all.

When using visual estimation, as expected,21 marked interobserver variability and notable overestimation of visual %DS were found as compared with QCA. Surprisingly, different cutoff values for angiographic significance were applied among participants, further contributing to inconsistencies of angiogram-guided strategies.

The most striking and worrisome finding was that, aligned with previous data in literature,22,23 when angiogram-based decisions were taken, half of them were discordant with the FFR value that had been obtained in all cases but was not disclosed to the participants: using FFR as an independent standard of functional significance of a lesion, angiogram-based decisions were
discordant in 47%, namely falsely significant in 30% and falsely nonsignificant in 17% of all cases. These results underline the profound diagnostic instability of decisions merely based on visual estimates of stenosis severity, meaning that inadequate treatment might follow in a large proportion of cases.

The decision patterns of the participants were independent of overall or specific experience. More experienced interventionalists, and those who had more experience with FFR or IVUS, requested additional functional information more often than others. Consequently, the decisions of participants who do not rely exclusively on visual angiographic assessment were more often consistent with FFR values.

This survey concurs with other studies showing that failure to adhere to guidelines goes beyond just cost or evidence base, although it is possible that a positive financial incentive would result in further adoption. Prior work has proposed seven general barriers to guideline adherence: lack of awareness, lack of familiarity, lack of agreement with guideline, lack of self-efficacy (belief that one can perform the guideline behavior), lack of outcome expectancy (expectation that guideline behavior will produce outcome), inertia of previous practice, and external barriers.\textsuperscript{24} ISIS suggests that external barriers play only a marginal role while there is an important human barrier that prevents adherence to guideline recommendations on evaluation and treatment of stable CAD.

**Limitations**

ISIS carries the limitations of anonymous surveys, which need to be considered during interpretation. Although operators had to provide a visual estimate of stenosis severity and their own personal cutoff value for angiographic significance, the survey did not probe other potentially relevant factors such as lesion location (a surrogate for downstream myocardial mass), lesion length, or multivessel disease. Such additional questions might have identified specific factors that significantly entered into decision making. Missing data in the survey might have affected our results. To examine the sensitivity of our findings to this criticism, we have used multiple imputations as detailed above.

**Conclusions**

ISIS offers a novel summary of how interventional cardiologists think about invasive evaluation strategies in stable CAD.
The findings confirm that, in spite the virtual elimination of all potential external constraints, a significant disconnect remains between action and current guideline recommendations. The use of FFR as an invasive evaluation strategy of intermediate stenoses in stable CAD was markedly under-represented, even in this utopian virtual setting. Clearly, participants prefer to rely solely on eye-balling in the vast majority of cases, which resulted in high rate of discordant decisions with respect to true functional importance of the stenoses to be evaluated. When translated in real life, these practice habits might lead to unnecessary stenting or inappropriate deferral in about a third of all cases.

**Acknowledgments**

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**Table 3. Interaction Between Decision Patterns and Participant Characteristics**

<table>
<thead>
<tr>
<th>Decision</th>
<th>Level of Experience*</th>
<th>Age, y†</th>
<th>Overall PCI Volume</th>
<th>IVUS</th>
<th>FFR</th>
<th>OCT</th>
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<td>38%</td>
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<td>38%</td>
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<tr>
<td></td>
<td>P value (test for trend)</td>
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<td></td>
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<td>50%</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>52%</td>
<td>52%</td>
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<td></td>
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<td></td>
<td>P value (test for trend)</td>
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<td>P value (test for trend)</td>
<td>0.84</td>
<td>0.72</td>
<td>0.65</td>
<td>0.25</td>
<td>&lt;0.001</td>
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*As per Tables I, III, and IV in the Data Supplement, the levels no. 1 to no. 4 categorize overall experience (<2 year/between 2 and 5 years/between 5 and 10 years/>10 years); PCI volume (<75/y/between 75 and 150/y/between 151 and 250/y/>250/y); experience with IVUS (no experience/<1 year of experience/between 1 and 3 years of experience/>3 years of experience); and experience with OCT (no experience/any experience), respectively.
†Grouped according to quartiles of participants’ age.
References


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