EDITORIALS

Choosing a Method for Guiding PCI

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In contemporary clinical practice, interventional cardiologists use both fractional flow reserve (FFR) and intravascular ultrasonography (IVUS) to guide percutaneous coronary intervention (PCI) for intermediate coronary stenosis (i.e., a narrowing of the coronary-artery lumen by 40 to 70%). FFR, a physiological test, is used to evaluate the ischemic potential of a stenosis and decide whether PCI is needed. IVUS, a high-resolution intracoronary imaging method, is used to select the appropriate stent size and to determine whether the stent is correctly placed and sized after implantation. These tools are necessary because the severity of a stenosis on a coronary angiogram does not always correlate with its ischemic potential. In addition, once a stent has been implanted, angiography does not provide direct evidence that it is in good contact with the vessel wall.

The use of FFR to guide the decision to proceed with PCI has been shown to result in a lower frequency of urgent revascularization in patients treated with drug-eluting stents than the use of medical therapy alone, but FFR guidance has not been useful in improving stent sizing, implantation, and expansion.[1,2] The use of IVUS to determine whether a stenosis requires PCI (with the exception of the left main coronary artery) has been controversial; attempts to identify a minimal luminal area that correlates well with ischemia have resulted in a wide range of threshold values, and the positive predictive value has remained low.[3,4] However, IVUS does have a role in improving stent implantation that has been associated with lower mortality and a lower frequency of target-vessel revascularization.[4] Thus, the use of both FFR and IVUS is considered to be the best current practice, even though recent estimates suggest that FFR and IVUS are used in only 18.5% and 13.9% of procedures, respectively.[5,6] Since many cardiac catheterization laboratories have either FFR or IVUS but not both, a frequently asked question is whether one device can be used both to make the decision to proceed with PCI and to improve stent implantation.

In this issue of the *Journal*, Koo and colleagues report the results of a randomized trial that tested whether FFR guidance was noninferior to IVUS guidance in evaluating patients for PCI.[7] At 18 sites in Korea and China, 1682 patients with an intermediate coronary stenosis were randomly assigned to either FFR guidance or IVUS guidance to make the decision whether to proceed with PCI and, if so, to improve the stenting procedure. Revascularization was performed if the FFR was 0.80 or less or if IVUS identified a minimal luminal area of 3 mm^2 or less or a luminal area of 3 to 4 mm^2 with a plaque burden of more than 70%. On the basis of these criteria, stents were implanted in 44.4% of the patients in the FFR group and in 65.3% of those in the IVUS group. At 24 months, the composite outcome of death from any cause, myocardial infarction, or revascularization occurred in 8.1% of the patients in the FFR group and in 8.5% of those in the IVUS group, an absolute difference of 0.4 percentage points, which met the criteria for the noninferiority of FFR guidance.

In this trial, the proportion of patients who did not undergo PCI was higher in the FFR group than in the IVUS group (66.8% vs. 41.6%). This difference occurred even though patients in the two groups had similar low-risk clinical characteristics and coronary anatomies. The high frequency of PCI in the IVUS group suggests that the criteria regarding the minimal luminal area that were used to perform PCI were not stringent enough, despite the fact that lower thresholds were selected for the Asian population in this trial.[3] The finding of no appreciable difference in the composite outcome at 24 months also merits consideration, since the composite outcome of cardiac death and acute myocardial infarction is worse when stents are implanted in patients without a flow-limiting stenosis.[8] Because the measurement of FFR was not performed in the IVUS group, the true number of stenoses that were not flow-limiting but that were still treated with stents is not known. The mandated use of FFR or IVUS for improving stent placement may also have minimized the frequency of stent thrombosis or restenosis and related revascularization, myocardial infarction, or death, thereby leading to the lack of between-group difference in clinical outcomes.

In this head-to-head comparison between FFR guidance and IVUS guidance for evaluating the need for PCI, investigators reexamined whether IVUS is useful in deciding whether an intermediate stenosis should be revascularized. They also reassessed the suitability of FFR in determining whether a stent has been successfully implanted. Since there were no apparent differences in the frequency of revascularization (driven either by ischemia or target lesion) during the follow-up period, these questions appear to be answered affirmatively and suggest that it is feasible to use only one of these tools to guide PCI. However, the trial design did not include a group that reflected the use of FFR to decide whether to proceed with PCI and the use of IVUS to improve stent implantation. Thus, we await results from future studies that will test whether either FFR or IVUS alone is noninferior to using both tools for their currently defined roles. Since the current trial enrolled only Asian patients, future studies will need to include patients of other races and ethnic backgrounds as well as higher-risk patient populations and coronary anatomical features to show the generalizability of the findings. Nonetheless, the results from this trial have immediate real-world implications for interventional cardiologists and cardiac catheterization laboratories that only have access to either FFR or IVUS.

Disclosure forms provided by the author are available with the full text of this editorial at NEJM.org.

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