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Short commentary

Is FFR Precise Enough as a "Gold Standard"?

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There has been controversy as to which of coronary function and intravascular imaging is more effective in guiding PCI treatment. After the evidence provided by several decisive clinical trials, FFR was recommended to determine the indication for intervention in intermediate lesions. However, in practice, even if the FFR result of a lesion is higher than 0.80, we still have doubts about the need of intervention for that lesion. We have previously reported a case of an LCX lesion with an FFR of 0.81 and therefore a significant exacerbation after 3 years of deferral to PCI [1]. This lesion is very representative and demonstrates a bottleneck in our understanding of FFR, i.e., do we need to strictly adhere to a precise cut-off value of 0.75 or 0.80?

Defects in the measurement methodology may be the main reason for this doubt. Due to the anatomical position relationship, there is a height difference of +(4.9±1.6) cm and -(3.9±0.9) cm between the position of the distal LAD and LCX reached by the pressure guidewire and the position of the LCA ostium, respectively. Distal PDA and distal PL have a height difference of +(3.8±1.0) cm and -(2.6±1.6) cm with the RCA opening, respectively. The relative heights of the aforementioned vessels to the coronary artery ostium are also changing from proximal to distal [2]. This results in differences in the FFR values obtained from different vessels and different position of the same vessel, which are derived from methodological standardization. A more precise method would be to use a tiltable examination bed during FFR measurements or to correct for the height relationship between the end of the guidewire and the coronary ostium as determined by imaging, operations that were not performed in the earlier clinical trials on FFR.

This status quo has resulted in a failure to standardize the screening criteria each patient receives, at least across vessels. In the few landmark clinical studies that provided evidence for FFR, FFR cut-off values for LAD, LCX, and RCA were not analyzed separately. Therefore, the current criteria may be high for LAD and low for LCX and RCA. Such results may give rise to many subsequent problems. The first is in guiding PCI treatment, leading to the possibility that some LAD lesions may have received unnecessary PCI, while non-LAD lesions were missed. In particular, for non-LAD lesions, the degree of ischemia caused by the lesion can be underestimated, leaving the patient in a state of persistent myocardial ischemia; also, the degree of stenosis of the lesion can be indirectly underestimated, missing some high-risk lesions that may progress in the short term, since plaque loading is an important feature of unstable plaques.

For this problem, we may need to do some remedial work. On the one hand, the data from completed large-scale clinical trials should be re-analyzed, requiring some degree of numerical correction according to different vessels or designing new clinical trials to find more precise diagnostic criteria; on the other hand, for lesions in the critical range, such as LCX or RCA with an FFR between 0.80 and 0.85 and LAD with an FFR between 0.75 and 0.80, more intra-vascular imaging assessment such as OCT and IVUS should be performed in order to compensate for the accuracy of the evaluation from multiple latitudes.

Second, this methodological error can also have a detrimental effect on subsequent studies, especially with some imaging-based coronary functional testing methods such as QFR and CT-FFR. Since these new techniques are based on imaging analysis to obtain coronary functional data through computer simulation, deep learning, and other techniques, using the actual FFR as a reference. In principle, the functional science assessment method based on imaging analysis should be able to circumvent the influence caused by relative height. However, if the FFR is used as a reference for technology development, it can lead to flaws in the obtained model. In addition, the use of FFR as the "gold standard" in the clinical validation of new technologies may also have a negative impact. In fact, as more factors are taken into account during the development of new technologies, imaging-derived coronary function assessment may have the potential to perform even better!

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