CLINICAL BRIEF SUMMARY

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Diagnostic Accuracy of Angiography-Based Quantitative Flow Ratio Measurements for Online Assessment of Coronary Stenosis

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Background

Quantitative flow ratio (QFR) is a novel angiography-based method for deriving fractional flow reserve (FFR) without pressure wire or induction of hyperemia. The accuracy of QFR when assessed online in the cath labs has not been adequately examined to date.

Objective

To assess the diagnostic performance of QFR for the diagnosis of hemodynamically significant coronary stenosis defined by FFR≤0.80.

Methods

- Prospective, multi-center trial enrolled patients who had a least 1 lesion with a diameter stenosis of 30% to 90% and a reference diameter ≥2mm according to visual estimation.
- QFR, quantitative coronary angiography (QCA), and wire-based FFR were assessed online in blinded fashion during coronary angiography and re-analyzed offline at an independent core laboratory.

Endpoints and Statistical Analysis

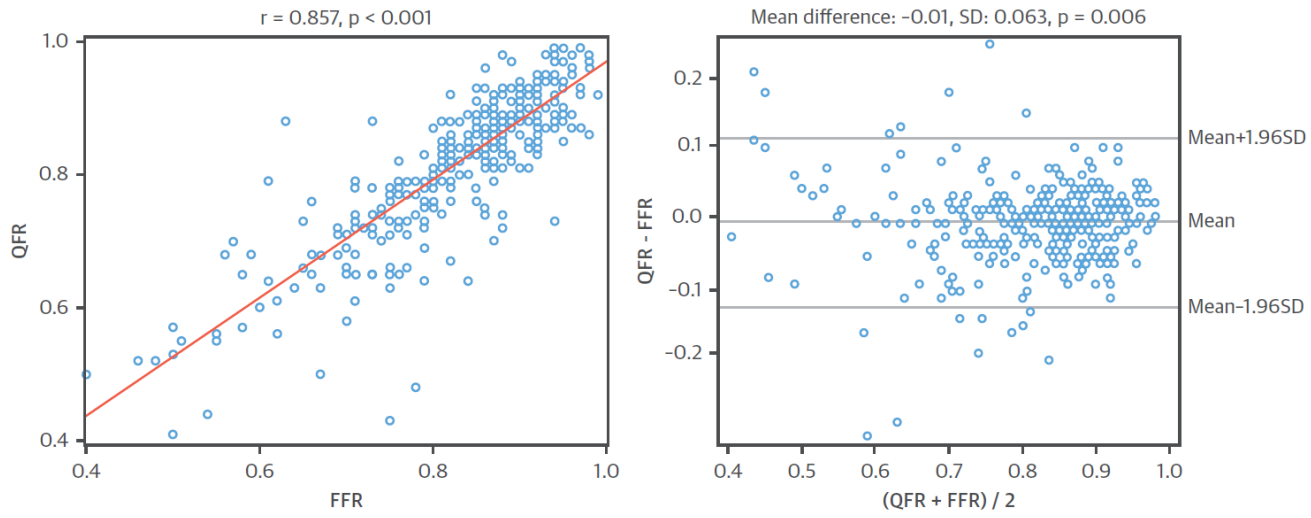
- Primary Endpoint: Diagnostic accuracy of online QFR (≤0.8 or >0.8) to identify hemodynamically significant coronary artery stenosis with FFR (≤ 0.8 or > 0.8) as the reference standard.
- Major Secondary Endpoints: Sensitivity* and Specificity** of online QFR and QCA in identifying hemodynamically significant coronary stenosis with FFR as the reference standard

*Sensitivity – proportion of QFR ≤0.8 or QCA≥50% in vessels with hemodynamically-significant stenosis as measured by FFR (FFR≤0.8)
** Specificity – proportion of QFR>0.8 or QCA<50% in vessels without hemodynamically-significant stenosis as measured by FFR (FFR≤0.8)

Results

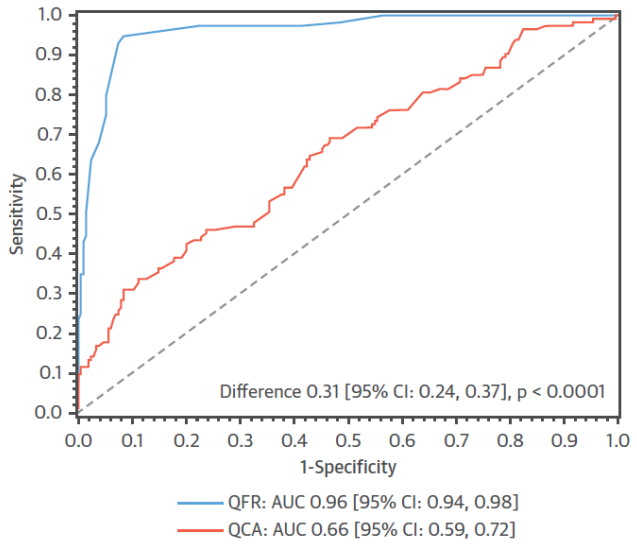
- Between June and July 2017, 308 patients were enrolled across five centers in China, and approximately 330 vessels were included in the analysis. The study met its prespecified primary performance goal for the level of diagnostic accuracy of QFR in identifying hemodynamically significant coronary stenosis.
- Patient-level diagnostic accuracy was 92.4% (95%CI: 88.9% to 95.1%) and vessel-level diagnostic accuracy of QFR was 92.7% (95%CI: 89.3% to 95.3%), both which were significantly higher than the pre-specified target value (p<0.001).
- Sensitivity and specificity in identifying hemodynamically significant stenosis were significantly higher for QFR than for QCA (sensitivity: 94.6% vs. 62.5%; difference: 32.0% [p < 0.001]; specificity: 91.7% vs. 58.1%; difference: 36.1% [p < 0.001]).
- Positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio for QFR were 85.5%,97.1%, 11.4, and 0.06.

FIGURE 3 Correlation and Agreement Between FFR and QFR



QFR demonstrated good correlation and agreements with FFR. Abbreviations as in Figure 1.

FIGURE 4 Comparison of Receiver-Operating Curves for the Discrimination of Functionally Significant Stenosis



FFR was used as the reference standard. An FFR ≤0.8, QFR ≤0.8, and QCA identified stenosis >50% as diagnostic of ischemia. AUC = area under the receiver-operating characteristic curve; CI = confidence interval; other abbreviations as in Figure 1.

Limitations

- The vessels with diameter stenosis <30% or >90% were not assessed because performing physiological assessments in such lesions was viewed as unnecessary.
- Side branches of bifurcation lesions with Medina type 1,1,1 or 1,0,1 were not assessed. Generalizability of QFR to the side branches of coronary bifurcation lesions requires further investigation.
- Because clinical decisions in the study population were based on FFR measurements, it was not possible to directly evaluate clinical outcome by using a QFR-based diagnostic strategy.
- Randomized trials comparing clinical outcomes after the use of QFR-based diagnostic strategies and standard diagnostic strategies are warranted.

Conclusions:

- The study demonstrated that QFR meets the level of diagnostic accuracy in identifying hemodynamically significant coronary stenosis, and thereby demonstrated clinical utility of QFR for use in cath labs.
- QFR bears the potential of improving angiography-based identification of functionally significant stenosis during coronary angiography.