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CORONARY ARTERY DISEASE PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION GUIDED BY QUANTITATIVE FLOW RATIO: A CORRELATION STUDY

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Abstract: To investigate the differences in clinical baseline, imaging parameters and laboratory indicators between quantitative flow fraction (QFR)≤0.80 and QFR>0.80 in patients with coronary heart disease who make decisions on percutaneous coronary intervention (PCI) guided by QFR, and to analyze the correlation between QFR and various variables. A total of 97 patients with coronary heart disease were obtained by matching 111 patients in the QFR report database of our hospital with 111 discharge records according to patient ID. According to the preoperative target vessel QFR, the patients were divided into QFR≤0.80 group (n=37, with the indication of ischemic intervention) and QFR>0.80 group (n=60, without the indication of intervention, without PCI Treatment). Continuous variables were expressed as median [interquartile range], Mann Whitney U test was used for comparison between groups, χ^2or Fisher exact test was used for categorical variables, and Spearman rank correlation was used for correlation. The preoperative QFR of 97 patients was 0.77 ± 0.20. The clinical baseline was balanced between the two groups. At the same time, the anatomic load was heavier in the QFR≤0.80 group, while there was no difference in the reference lumen diameter (P=0.664). There was no statistically significant difference in laboratory indexes between the two groups. In the QFR≤0.80 group, the patients were grouped according to the QFR tertile (threshold p33=0.470, p67=0.670). The diameter stenosis rate and area stenosis rate in the lower tertile group were significantly higher than those in the upper tertile group (p=0.023, p=0.022). The PCI planning gainΔQFR (software simulation value) increased gradiently (p<0.001). QFR was negatively correlated with maximum diameter stenosis rate (r= − 0.800) and maximum area stenosis rate (r= − 0.799), and positively correlated with MLD (r=+0.567) (all p<0.001). In the real-world population in which QFR guides treatment decisions, the clinical background of QFR ≤0.80 and QFR>0.80 lesions is balanced and the anatomical load is significantly different. Preoperative QFR level is closely related to anatomic load and PCI planning gain, and can be used as a reference index for treatment decision-making and preoperative risk assessment.
Keywords: Quantitative blood flow fraction; Coronary angiography; Percutaneous coronary intervention; Coronary heart disease; Correlation analysis

1 INTRODUCTION

1.1 Coronary Heart Disease and Percutaneous Coronary Intervention (PCI)

Coronary heart disease is one of the main reasons threatening human health worldwide, and PCI is the key means of revascularization. For a long time, coronary angiography has been the main tool to assess the severity of stenosis, but the ability of angiography to judge the functional significance of stenosis is limited, and whether moderate stenosis lesions need to be treated is often difficult to determine by anatomic images alone.

1.2 The Clinical Value of QFR and the Definition of "Guidance"

Quantitative flow ratio (QFR) is a functional evaluation method based on conventional coronary angiography image calculation: three-dimensional reconstruction of the vascular lumen contour of two projection positions is performed, and the blood flow velocity is estimated by contrast frame counting. The favor II China study showed that the diagnostic accuracy of QFR in identifying ischemic lesions was 92.7%, significantly higher than that of QCA (59.6%) [1]; The favor III China randomized controlled study (QFR guidance vs conventional angiography guidance) confirmed that the QFR guided PCI strategy could significantly reduce 1-year major adverse cardiovascular events (5.8% vs 8.8%, relative risk reduction 35%) [2]; However, the favor III Europe Japan randomized controlled study (QFR guidance vs FFR guidance) showed that QFR guidance did not reach the pre-set threshold of non inferiority to FFR guidance in 12-month clinical outcomes (6.7% vs 4.2%, HR 1.63) [3]. Hawkeye study showed that the measured QFR≤0.89 after PCI was associated with an approximately 3-fold increase in the risk of 2-year vascular guidance composite endpoint (HR 2.91) [4], suggesting the prognostic value of functional indicators in postoperative evaluation. According to this, the guidelines recommend the functional evaluation of moderate stenosis lesions to guide revascularization decisions [5-6].

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The definition of "QFR guidance" in this study is: preoperative target vessel QFR assessment is first used to participate in the workflow of treatment decision-making - those with QFR≤0.80 have ischemic intervention indications, and those with qfr>0.80 do not meet the intervention indications and do not receive PCI Treatment (or postpone the intervention).

2 DATA AND METHODS

2.1 Study Design and Data Sources

This study is a single center, retrospective observational study. The data came from the QFR database of our hospital: 112 QFR analysis reports (111 patients, including 1 case with 2 reports) of patients with coronary heart disease who underwent coronary angiography and were evaluated online by the QFR system (angioplus, pulse medical imaging technology, Shanghai) from January 2025 to September 2026. 111 discharge records of the same period were collected simultaneously (desensitized, excluding the patient's name). After matching according to patient ID, 97 patients with both QFR data and complete clinical data entered the analysis (Medical Ethics Review Committee of Jiangxi Provincial People's Hospital, ethics review approval No.Science and Technology Program, Health Commission, Expedited Review 2024(16))

2.2 Study Population and Grouping

Inclusion criteria: ①Age ≥ 18 years; ② Coronary angiography confirmed coronary heart disease and underwent QFR functional assessment; ③QFR report data are complete; ④It can match the clinical data of the same period, and the test results are complete. Exclusion criteria: ①key clinical data or imaging parameters were missing; ②Repeated reports of the same patient, etc.
Grouping: According to the preoperative target vessel QFR value, the patients were divided into two groups: QFR ≤0.80 group (n=37, functional ischemia positive, with intervention indications) and qfr>0.80 group (n=60, without intervention indications, without PCI). The cut-off value of 0.80 is the qfr/ffr guideline ischemic threshold; 0.80-0.90 are grey areas (n=34), which are reported separately in the subsequent sensitivity analysis.

2.3 Data

Age, gender, length of stay; Diabetes mellitus, hypertension, dyslipidemia, CKD/dialysis, atrial fibrillation, old myocardial infarction, previous PCI/cabg history, cardiac insufficiency, chronic obstructive pulmonary disease, cerebral infarction / stroke. Imaging parameters: minimum lumen diameter (MLD), reference lumen diameter, maximum diameter stenosis rate, maximum area stenosis rate, lesion length, analysis vessel segment, number of branches, and lowest branch QFR. Blood flow fraction parameters: preoperative target vessel QFR; PCI planning gainΔQFR (predicted gain obtained by virtual stent simulation, software simulation value); Predicted residual QFR (rqfr) = preoperative QFR + stent ΔQFR, which is the simulated predicted value after PCI planning, and not the measured value after surgery. Laboratory indicators: blood routine CRP、 Liver and kidney function, electrolytes, blood glucose and lipids, myocardial injury and cardiac function markers (HS cTnT, CK-MB, myo, CK, NT proBNP), coagulation and thyroid function were subject to the latest hospitalization detection value.

2.4 Statistical Methods

Continuous variables are usually described by median [interquartile range, iqr] after normality test. Mann Whitney U test (two groups) or Kruskal Wallis test (three levels) is used for comparison between groups. Categorical variables are described by examples (%) andχ^2test or Fisher exact test is used (when the expected frequency is <5); Spearman rank correlation was used for correlation, and the effect size was expressed by rank binomial correlation coefficient R. Bilateral α=0.05. Data were analyzed using R 4.3 and SPSS 26.0.

3 RESULTS

The baseline characteristics and QFR distribution of patients included in the study, the comparison between the two groups, stratification and sensitivity analysis, and correlation analysis results.

3.1 Baseline Characteristics and QFR Distribution of Patients

The baseline characteristics of 97 patients are shown in Table 1; The preoperative QFR of the whole cohort was 0.77±0.20 (median 0.85 [0.67-0.91]). According to the cut-off value of 0.80, 37 cases (38.1%) in the QFR ≤0.80 group and 60 cases (61.9%) in the QFR>0.80 group did not accept PCI according to the database records, including 34 cases with gray area of 0.80-0.90 and 26 cases with gray area of 0.90.

Table 1 Comparison of Baseline Characteristics and Primary Parameters between the Two Groups

Parameter	QFR ≤ 0.80 group (n=37)	QFR > 0.80 group (n=60, without PCI)	P value
Age (years)	66.0 [60.0-74.0]	67.0 [60.5-73.0]	0.727
Male (n, %)	24 (64.9)	43 (71.7)	0.505
Length of hospital stay (days)	4.0 [4.0 ~ 5.0]	4.0 [3.0 ~ 5.0]	0.163
Hypertension (n, %)	26 (70.3)	40 (66.7)	0.884
Diabetes mellitus (n, %)	16 (43.2)	25 (41.7)	1.000
Dyslipidemia (n, %)	8 (21.6)	7 (11.7)	0.304
Prior PCI/CABG history (n, %)	6 (16.2)	18 (30.0)	0.199
CKD / dialysis (n, %)	2 (5.4)	7 (11.7)	0.475[a]
COPD (n, %)	3 (8.1)	5 (8.3)	1.000[a]
Cerebral infarction / stroke (n, %)	5 (13.5)	3 (5.0)	0.253[a]
Atrial fibrillation (n, %)	1 (2.7)	3 (5.0)	1.000[a]
Heart failure (n, %)	1 (2.7)	2 (3.3)	1.000[a]
Old myocardial infarction (n, %)	1 (2.7)	1 (1.7)	1.000[a]
Target vessel LM+LAD (n, %)	27 (73.0)	27 (45.0)	0.042[b]
Target vessel LM+LCX (n, %)	4 (10.8)	10 (16.7)	
Target vessel RCA (n, %)	6 (16.2)	21 (35.0)	
Target vessel LAD/LCX (single vessel), n (%)	0 (0.0)	2 (3.3)	
Preoperative QFR (grouping variable)	0.62 [0.44 - 0.70]	0.90 [0.86 - 0.93]	—
Maximum diameter stenosis (%)	56.3 [51.5 - 60.1]	39.2 [31.5 - 43.9]	<0.001
Maximum area stenosis (%)	80.9 [76.5 - 84.1]	63.1 [53.1 - 68.6]	<0.001
MLD （ mm ）	1.20 [0.94 - 1.41]	1.67 [1.39 - 1.97]	<0.001
Reference lumen diameter (mm)	2.60 [2.31 - 3.08]	2.72 [2.35 - 3.14]	0.664
Lesion length [c] (mm)	30.0 [17.8 - 42.2]	19.9 [14.8 - 27.5]	0.006
PCI planning gain ΔQFR	0.32 [0.22 - 0.46]	0.06 [0.04 ~ 0.10]	<0.001

Note: continuous variables are reported as median, and Mann Whitney U test is used for comparison between groups; Categorical variables are reported in cases (%). [a] Fisher exact test (expected frequency <5); [b] the p value of the four categories of target vessels (lm+lad / lm+lcx / RCA / lad or LCX single branch) was tested overall, and the expected frequency was <5, using Monte Carlo exact test; [c] lesion length is the target length of PCI planning stent 1 (lesion length plus the planning proxy value of the edge), and non contrast measured lesion length; Both ΔQFR and rqfr are automatically generated by QFR software (virtual stent simulation), which is the planning simulation value rather than the actual operation result. The QFR>0.80 group did not receive PCI, and its planning parameters are not the records of any actual operation.

3.2 Stratified Analysis and Sensitivity Analysis

The group with QFR≤0.80 was grouped according to the QFR tertile (Table 2): the tertile of the measured QFR value in the group with QFR≤0.80 (n=37) was taken as the grouping boundary value (the boundary value was automatically generated by the data distribution: QFR ≤0.47 in the lower tertile group (n=14), 0.47 - 0.67 in the middle tertile group (n=11), and >0.67 in the upper tertile group (n=12)). There was no significant difference in the distribution of clinical characteristics and comorbidities among the three groups. The imaging parameters increased gradiently with the decrease of QFR, and there was a significant difference in the PCI planning gainΔQFR (software simulation value) (p<0.001). The overall difference of MLD was not significant (P = 0.057), but there was a difference between middle vs upper (P = 0.045) and lower *vs* upper (P = 0.040) in pairwise comparison (before post hoc correction); There was no significant difference in lesion length (P = 0.164).

Table 2 QFR Tertiles in the Group with QFR ≤ 0.80

Parameter	Lower tertile ≤0.47 (n=14)	Middle tertile 0.47–0.67 (n=11)	Upper tertile >0.67 (n=12)	P value (Kruskal-Wallis)	P Lower vs Middle	P Lower vs Upper	P Middle vs Upper
Maximum diameter stenosis (%)	62.0 ± 10.1	56.7 ± 7.3	51.6 ± 6.5	0.023	0.155	0.009	0.166
Maximum area stenosis (%)	84.6 ± 7.1	80.7 ± 6.1	76.2 ± 6.6	0.022	0.154	0.009	0.157
MLD(mm)	1.04 ± 0.37	1.10 ± 0.25	1.34 ± 0.32	0.057	0.742	0.040	0.045
Lesion length (mm)	40.4 ± 23.3	29.6 ± 11.2	25.7 ± 16.8	0.164	0.366	0.095	0.207
PCI planning gain ΔQFR	0.53 ± 0.21	0.31 ± 0.08	0.20 ± 0.06	<0.001	0.006	<0.001	0.004
Predicted residual QFR (rQFR)	0.88 ± 0.17	0.93 ± 0.08	0.94 ± 0.05	0.703	0.822	0.377	0.733
Age (years)	62.2 ± 11.9	65.6 ± 10.3	68.0 ± 10.4	0.552	0.493	0.279	1.000
Preoperative QFR	0.36 ± 0.10	0.62 ± 0.05	0.73 ± 0.03	<0.001	<0.001	<0.001	<0.001

Parameter	Lower tertile ≤0.47 (n=14)	Middle tertile 0.47–0.67 (n=11)	Upper tertile >0.67 (n=12)	P value (Kruskal-Wallis)	P Lower vs Middle	P Lower vs Upper	P Middle vs Upper
Male (cases, %)	6 (43%)	10 (91%)	8 (67%)	—	0.033	0.267	0.317
Dyslipidemia (cases,%)	1(7%)	2(18%)	5(42%)	—	0.565	0.065	0.371

Note: Kruskal Wallis test was used for comparison between groups. [a] lesion length is the proxy value of PCI planning stent 1 target length; [b] PCI planning gain is the simulated value of QFR software virtual stent, which is not the measured benefit. Part a age, length of stay hs-cTnT、NT-proBNP、 There was no significant difference in serum potassium (P = 0.190-0.830); In part B, the three-level boundary value is automatically generated by the data distribution (p33=0.470, p67=0.670). No fixed cutoff is set in advance, and the same value of the boundary is treated as "≤ the boundary value belongs to the lower group"; The clinical characteristics of the three groups were balanced (P >0.05), and serum potassium (p=0.066) and HS cTnT (p=0.104) were not significant.

3.3 Correlation Analysis

In the whole cohort (n=97) (Table 3), QFR was strongly negatively correlated with maximum diameter stenosis rate (r=−0.800, p<0.001), maximum area stenosis rate (r=−0.799, p<0.001), moderately positively correlated with MLD (r=+0.567, p<0.001), moderately negatively correlated with lesion length (r=−0.479, p<0.001), and not correlated with age (r=+0.132, p=0.197). In the QFR≤0.80 group (n = 37), the correlation between QFR and maximum diameter stenosis rate (r = − 0.488, P = 0.002), maximum area stenosis rate (r = − 0.489, P = 0.002), MLD (r = +0.387, P = 0.018), lesion length (r = − 0.357, P = 0.030) remained the same, but the intensity was weakened; It was strongly negatively correlated with the PCI planning gain Δ QFR (r= − 0.763, p<0.001), suggesting that the lower the baseline QFR, the greater the PCI planning gain simulated by the software.

Among the laboratory indexes, QFR ≤ 0.80 hs-cTnT（r=−0.450，P=0.016，n=28）、NT-proBNP（r=−0.505，P=0.023，n=20）、CK（r=−0.685，P=0.029，n=10） Serum potassium was positively correlated with QFR (r = + 0.429, P = 0.041, n = 23).

Table 3 Spearman Correlation Analysis of QFR and Major Parameters

Parameter	Whole cohort (n=97) r (P)	QFR ≤ 0.80 group (n=37) r (P)
Maximum diameter stenosis (%)	−0.800（<0.001）	−0.488（0.002）
Maximum area stenosis (%)	−0.799（<0.001）	−0.489（0.002）
MLD（mm）	+0.567（<0.001）	+0.387（0.018）
Lesion length [a] (mm)	−0.479（<0.001）	−0.357（0.030）
Age (years)	+0.132（0.197）	—
PCI planning gain ΔQFR	—	−0.763 （ <0.001 ） [b]
hs-cTnT（ng/L）	—	−0.450(0.016)[c]
NT-proBNP(pg/mL)	—	−0.505(0.023)[c]
CK(U/L)	—	−0.685(0.029)[c]
Serum potassium (mmol/L)	—	+0.429(0.041)[c]

Note: Spearman rank correlation. [a] lesion length is the proxy value of PCI planning stent 1 target length; [b] contains mathematical coupling components (rqfr= the defined structure of preoperative qfr+ Δ QFR) and is a software simulated value, which should be interpreted with caution; The number of available cases was small (n=10-28) without multiple comparison correction, and HS cTnT / CK was affected by the phase of acute coronary events. It was only an exploratory finding and could not infer causality or gradient relationship.

4 DISCUSSION

4.1 Main Findings around the QFR Guided PCI Decision-Making Process

This study reported the functional distribution characteristics of 97 patients with coronary heart disease. The main findings are as follows: ① the QFR of the whole cohort was 0.77±0.20, 38.1% of lesions had QFR ≤ 0.80 (with the indication of ischemic intervention), and 61.9% had qfr>0.80 (without PCI); ②The clinical baseline of the two groups was balanced (age, gender, 11 complications and hospital stay were not different; the target vessel distribution difference was not corrected for multiple comparisons, see Table 1), while the imaging load was significantly different (diameter stenosis rate, area stenosis rate, MLD, lesion length P ≤ 0.006, effect dose R 0.33-0.90); ③ There was no difference in 66 laboratory indexes between the two groups; ④ In the QFR ≤ 0.80 group, the lower the QFR, the heavier the anatomic load and the greater the gain of PCI planning simulated by software; ⑤ The correlation between QFR and anatomic load is the same in the whole cohort and QFR ≤ 0.80 group, but the two are homologous contrast data, and the correlation intensity includes the intrinsic mathematical correlation of the algorithm.

4.2 Compared with Previous Studies

the favor II China study took FFR as the reference standard and confirmed that the diagnostic accuracy of QFR (92.7%) was significantly higher than that of QCA (59.6%) [1]; The favor III Europe Japan randomized controlled study further confirmed that QFR guidance strategy did not reach the pre-set threshold of non inferiority to FFR guidance. The composition of the study population is consistent with the decision-making logic of the above trials: Taking 0.80 as the boundary, 38.1% of lesions with QFR ≤ 0.80 have intervention indications, and 61.9% do not reach the indications to postpone intervention. It should be emphasized that the above study is a prospective multicenter design and reports the clinical outcomes, while this study is a single center retrospective description with no follow-up endpoint. It can neither make any inferences about the long-term safety of "delayed intervention", nor constitute a re validation or evidence supplement to the random control conclusions such as favor III. Hawkeye study found that the measured QFR ≤ 0.89 after PCI was associated with an approximately 3-fold increase in the risk of vascular guidance composite endpoint. In this study, the median predicted residual QFR (rqfr, software virtual simulation value) after PCI planning in the QFR ≤ 0.80 group was 0.96, and 75.7% (28 / 37) simulated planning value ≥ 0.90; For patients with multivessel coronary artery disease treated with drug-eluting stent PCI, routine detection of fractional flow reserve can significantly reduce the incidence of the composite endpoint of death, nonfatal myocardial infarction and revascularization at 1 year [7]. According to the QFR results, the TCM doctors in this cohort made the decision of whether to intervene or not, which was consistent with the recommendation logic; However, this study is a single center retrospective description, which cannot supplement the efficacy evidence for this recommendation. Compared with coronary angiography guided percutaneous coronary intervention (angio-pci), fractional flow reserve guided percutaneous coronary intervention (ffr-pci) has a lower incidence of myocardial infarction (MI) and major adverse cardiovascular events (MACE) in-hospital and during follow-up [8]. If the simulation planning value is measured by the literature threshold, the planning results of most lesions can reach this interval [9]. However, rqfr is not the measured postoperative value and is not comparable with Hawkeye's measured postoperative QFR. This comparison is only an indirect reference at the planning level and cannot be interpreted as actual functional benefit. The favor II Europe Japan study also showed that the sensitivity (86.5% vs 44.2%) and specificity (86.9% vs 76.5%) of QFR in identifying ischemic lesions were significantly better than those of two-dimensional qca [10]. The meta-analysis of individual patient data from four prospective studies showed that the diagnostic sensitivity, specificity and negative predictive value of QFR were 84%, 88% and 95%, respectively [11].

4.3 Clinical Significance

first, this data fully reflects the decision-making consequences of QFR guidance: 60 of 97 cases (61.9%) did not receive PCI after functional evaluation, and QFR classification directly determines the decision-making shunt of whether to intervene or not. The value of QFR in such decisions has been established by diagnostic accuracy and randomized controlled outcome evidence. This study only provides a single center real-world executive portrait, which cannot be used to demonstrate the efficacy of QFR guidance in reverse. Secondly, the clinical background of the two groups was balanced while the imaging separation was significant, indicating that the QFR classification in this cohort reflects the functional anatomic load of the lesion, rather than the difference in the clinical composition of patients, which enhances the internal validity of this functional index as a basis for stratification. Third, in the QFR ≤ 0.80 group, the lower the QFR, the heavier the anatomic load, and the greater the gain of PCI planning simulated by the software, suggesting that the functional severity changes in the same direction as the gain space at the level of simulation planning, which has reference significance for preoperative expected evaluation; However, the gain is the predicted value of virtual simulation and is mathematically coupled with QFR, which cannot be equivalent to the actual clinical benefit.

5 CONCLUSION

In real-world CHD patients with QFR guided treatment decisions, compared with QFR>0.80 lesions, the anatomic load of QFR ≤0.80 lesions was significantly heavier (diameter stenosis rate 56.3% vs. 39.2%, MLD 1.20 vs. 1.67 mm, P <0.001), while the clinical baseline and laboratory indexes of the two groups were balanced; Preoperative QFR level was closely related to anatomic load and PCI planning gain (software simulation value) (QFR and diameter stenosis rate of the whole cohort r= − 0.800, p<0.001; And MLD r=+0.567, p<0.001), which can be used as a reference index for QFR to guide the treatment decision-making and preoperative risk assessment in the PCI decision-making process.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose.

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