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Original article

Residual pressure gradient across the implanted stent: An important factor of post-PCI physiological results

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ABSTRACT

Background: Instantaneous wave-free ratio (iFR) has the potential to improve the accuracy of the prediction of the physiological result of percutaneous coronary intervention (PCI). The aim of this study was to evaluate the accuracy of iFR to predict the final physiological results following PCI, and investigate the factors for failed prediction.
Methods: In 73 lesions, iFR pullback recordings were measured and comparisons were made between the predicted improvement following PCI and the observed result.
Results: iFR predicted–observed difference was 0.036 ± 0.037. Multivariate analysis showed residual iFR pressure gradient across the implanted stent (odds ratio, 2.329; 95% confidence interval, 1.408–3.853; $p = 0.0010$) as an independent risk factor for error in iFR prediction.
Conclusions: iFR predicted–observed difference was 0.036 ± 0.037. Residual in-stent iFR pressure gradient following PCI is the only independent risk factor for failed prediction.
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Introduction

Fractional flow reserve (FFR) is widely used as a marker for ischemia and as guidance for percutaneous coronary intervention (PCI) [1–3]. However, the role of FFR as a tool to predict the effect of PCI is still controversial [4,5].

Instantaneous wave-free ratio (iFR) has emerged as a possible surrogate for assessment of the presence of ischemia without the necessity of hyperemia [6–9]. The validity of iFR as a marker for the application of PCI was confirmed with Functional Lesion Assessment of Intermediate Stenosis to Guide Revascularization (DEFINE-FLAIR) and iFR Swedish angiography and angioplasty registry (SWEDEHEART) [10,11].

A small study showed the possibility of iFR not only as an easy surrogate of FFR but also as an accurate predictor for the physiological effect of PCI [12,13]. However, the accuracy of iFR as an online predictor of the efficacy of PCI in real-world practice remains unknown.

The aim of this study was to assess the accuracy of iFR as a predictor of physiological outcome of PCI and explore factors that cause deviation between the predictions and the final measurements.

Materials and methods

Study population

The data from patients with a clinical indication for elective PCI of native coronary artery at Gifu Heart Center were retrospectively collected and analyzed. A total of 897 lesions from 775 patients underwent iFR measurement in Gifu Heart Center from 2013/7/31 to 2015/8/26. Among them, the number of lesions and patients with paired (pre- and post-PCI) measurements of iFR pullback was 154. After excluding patients with thrombolysis in myocardial infarction (TIMI) grade < III, difference in wire positions between

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pre- and post-procedures, and incomplete original raw data, a total of 73 lesions from 71 patients were analyzed.

Coronary catheterization

Coronary angiography and pressure wire assessments of coronary stenoses were performed using conventional approaches. Intracoronary nitrates (300 μg) were administered in all cases before pressure wires were introduced. Pressure wire normalization was performed at the coronary ostia before advancing a wire. The distal position of the pressure wire was documented angiographically. Angioplasty was performed using second-generation drug-eluting stents, which were all optimized using imaging devices such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT). Post-angioplasty physiological measurements were made at the same coronary location.

Hemodynamic recordings

Pressure wire recordings were made using 0.014-in. pressure tipped wires (Prestige pressure guide wire and Prestige guide wire PLUS, Volcano Corporation, San Diego, CA, USA). The pullback of iFR measurement was performed manually. The selection of data at each point (far distal, lesion distal, lesion proximal, and catheter tip) was identified by the operator and the value of iFR at each point was recorded manually. The drift was checked after pullback. The measurement was taken on an average of three beats and pullback was temporarily stopped at each point for more precise measurement.

The calculation of post-PCI predicted iFR

The predicted iFR values were calculated by initially identifying the area of intended stent implantation. Two positions were identified. First, a distal end position (Fig. 1a: ※:), and then a proximal end position (Fig. 1a: ※※:). The iFR values were then measured at each of these positions. The predictions were then calculated as follows:

$$iFR_{predicted} = pre - iFR + (iFR_{proximal} - iFR_{distal})$$

In all cases the predictions assume that there will be no residual pressure loss across the stented portion.

The assessment of total vessel disease burden and the amount of myocardium supplied by the targeted vessel

The total vessel disease burden was calculated using the SYNergy between PCI with TAXus and cardiac surgery (SYNTAX) score online calculator [14]. Alberta Provincial PRoject for Outcome Assessment in Coronary Heart disease (APPROACH) score calculated the amount of supplied myocardium by targeted vessel [15].

Anatomic lesion measurement

Lesion length and severity were measured using quantitative coronary angiography (QCA) (CCPI-310/W GADELIUS MEDICAL K.K, Tokyo, Japan) using the contrast-filled catheter for calibration. Trained single QCA operator measured each parameter in a blinded fashion. Calcification was defined as multiple persisting opacifications of the coronary wall visible in more than one projection, surrounding the complete lumen of the coronary artery at the site of the lesion.

Statistical analysis

The frequencies and descriptive statistics of the demographic and clinical variables are summarized in Tables 1a and 1b. The correlation coefficients in terms of $iFR_{predicted}$ and $iFR_{observed}$ were calculated and correlation coefficients were compared using a *z*-test. The difference between predicted and observed values was then assessed using a Bland–Altman plot. The failure of the prediction of $iFR_{observed}$ was defined as the absolute difference between $iFR_{observed}$ and $iFR_{predicted}$ was more than the cut-off value of 0.036 which was the mean difference between $iFR_{observed}$ and $iFR_{predicted}$. To evaluate the risk factors for the failure of the prediction of $iFR_{observed}$, we used the univariate and multivariate logistic regression analyses that provide the odds ratio (OR) and 95% confidence interval (CI). We used the SAS version 9.3 (SAS Institute Inc., Cary, NC, USA).

Results

Study demographics

A total of 73 coronary arteries in 71 patients (57% male, 69 ± 9 years of age) undergoing elective coronary intervention

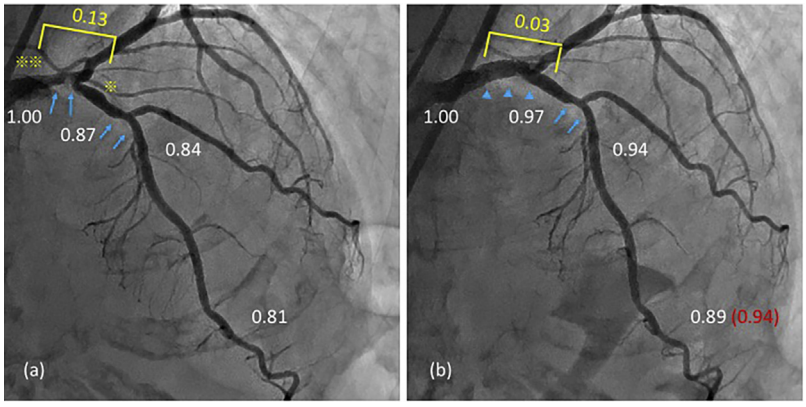

Fig. 1. Representative case of failed prediction by the residual iFR pressure gradient across the implanted stent. (a) Pre-percutaneous coronary intervention: blue arrows, lesion; white number, iFR value at each point; yellow number, iFR pressure gradient across the lesion. ※: Estimated stent distal end position. ※※: Estimated stent proximal end position. (b) Post-percutaneous coronary intervention: blue arrows, lesion; blue arrowheads, implanted stent; white number, iFR value at each point; yellow number, residual iFR pressure gradient across the implanted stent; parenthetic red number, $iFR_{predicted}$. $iFR_{predicted}$ was 0.94. However, actual iFR post-PCI was 0.89. Subtracting 0.03 (residual iFR pressure gradient across the implanted stent) from $iFR_{predicted}$ improve the agreement between $iFR_{predicted}$ 0.03 (0.91) and $iFR_{observed}$ (0.89). iFR, instantaneous wave-free ratio.

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