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Original article

Analysis of suboptimal stent deployment using intravascular ultrasound and coronary pressure pullback measurement

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ABSTRACT

Background: There are some cases in whom a sufficient improvement in fractional flow reserve (FFR) could not be achieved even if anatomical results indicated satisfactory stent deployment. We investigated the relation of abnormal findings between intravascular ultrasound (IVUS) and coronary pressure pullback measurement (CP-PB).

Methods: IVUS and CP-PB were investigated after stent deployment in 60 vessels in 53 patients. CP-PB criterion for adequate stent deployment was defined as a ratio of coronary pressure at the stent distal edge to the proximal edge (Psd/Psp) that is greater than 0.95.

Results: Residual pressure gradient across the stent which was indicated by Psd/Psp $\leq$ 0.95 was present in 11 (18%), and four of them were caused by insufficient stent expansion (incomplete apposition and asymmetric dilation), and five of them were caused by issues with stent edge (edge dissection and incomplete coverage of the plaques). Insufficient FFR recovery which was recorded at distal part of target vessel was present in 10 (17%), and the main causes corresponded to inadequate stent deployment in half of the lesions, and presence of residual lesion at a non-stent segment in the other half. There were six lesions in whom Psd/Psp was $\leq$0.95 but FFR was $\geq$0.80. Disagreement between IVUS and CP-PB findings was seen in 12 (20%).

Conclusions: Residual pressure gradient across the stent can reflect not only an insufficient stent expansion but also issues with stent edges. The decision of optimum stent deployment as assessed by IVUS and CP-PB was mismatched in 20% of cases, therefore careful attention should be paid to decoding the CP-PB findings.

Introduction

Fractional flow reserve (FFR) guidance for the indication of stent deployment contributes to an improvement in the patients' outcome and a reduction of medical costs [1,2]. Therefore FFR-guided percutaneous coronary intervention (PCI) is recommended in the guidelines [3,4] and is widely used in the clinical setting. In addition, it has been reported that FFR guidance for the assessment of stent deployment is useful for optimization of the stent [5–7], and the FFR value just after stent deployment is one of the predictive factors of events [8,9].

However, there are some cases in whom a sufficient improvement of FFR could not be achieved even if anatomical results indicated satisfactory stent deployment. In the era of drug-eluting stents (DES), a longer stent was used to cover as much of the lesions as possible, but led to a post-stent FFR value of less than 0.80, which indicates the threshold level for ischemia, in 10–20% of lesions [10]. It was reported that insufficient FFR recovery after DES was related to the left anterior descending artery (LAD) lesion, diabetes mellitus, and chronic kidney disease (CKD) [11]. However,

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it is not clear what component of residual pressure gradient in the target coronary artery relates to the abnormality observed in intravascular ultrasound (IVUS). As it is costly and time-consuming to use both FFR and IVUS in routine practice, it might be important to clarify how the abnormal findings in both modalities are related. The purpose of this study was to compare the abnormal findings between coronary pressure pullback measurement (CP-PB) and IVUS, and to clarify what component of residual pressure gradient after stent deployment relates to the abnormality observed in IVUS.

Materials and methods

Patient population

This study was performed at Tokyo Medical University Hospital, Japan and Catharina Hospital Eindhoven, the Netherlands. The study protocol was approved by the ethics committees at both centers, and all patients provided written informed consent prior to the procedure. Fifty-three patients (60 arteries), scheduled for elective and uncomplicated coronary stent deployment, took part in this study between November 2007 and October 2008. Patients with long lesions for which it might be necessary to use more than two stents, acute coronary syndrome, and any other accepted contraindication for any of the techniques to be used were excluded from this study.

Procedures

Stent deployment was performed in accordance with normal routine. After a satisfactory result was obtained by angiography, IVUS and FFR measurements were performed. Based on the results of IVUS and FFR, high-pressure dilatation was performed in three patients and another stent was deployed in two patients. The stent procedures were angiographically successful in all patients.

Intravascular ultrasound

IVUS examination was performed using a 2.9 French monorail system with a 40-MHz transducer-tipped catheter (Atlantis Pro, Boston Scientific, Natick, MA, USA). IVUS imaging was performed during an automated pullback at a speed of 1.0 mm/s. The IVUS images were stored on the hard drive of the machine (Galaxy, Boston Scientific), and quantitative IVUS analyses were performed. Minimum stent area (MSA) and the lumen for the proximal and distal stent edges that were used as the reference areas (RA) were measured. The symmetry index by IVUS was defined as the minimum stent diameter/maximum stent diameter corresponding to the most elliptic part of the stent. The presence of edge dissection, hematoma at the stent edge, and incomplete apposition of the stent over two struts length were assessed visually. Criteria for adequate stent expansion by IVUS [12–14] are described in Table 1.

Coronary pressure pullback measurement and calculation of fractional flow reserve

Coronary pressure was measured with a 0.014-inch sensor-tipped PCI guidewire (Pressure Wire, St Jude Medical, Saint Paul, MN, USA). The wire was introduced through a 6 or 7 French guiding catheter, calibrated, advanced into the coronary artery, and positioned distal to the stent. The proximal coronary pressure was recorded by the guiding catheter. Maximal hyperemia was induced by either intravenous adenosine, which was administered at a rate of 140 μg per kilogram of body weight per minute through a central vein, or intracoronary bolus injection of papaverine hydrochloride (8 mg for the right and 12 mg for the left coronary artery). FFR was calculated as the ratio of mean hyperemic distal coronary pressure to mean aortic pressure.

Coronary-pressure pullback measurement during hyperemia was performed, and pressure immediately distal to the stent (Psd) and immediately proximal to the stent (Psp) was measured. The ratio of Psd to Psp was calculated as the index of residual pressure gradient across the stent.

The definitions of adequate CP-PB results are listed in Table 1.

Table 1
Definition of adequate stent expansion.

Criteria for adequate intravascular ultrasound [12–14]
(A stent is optimally deployed if all of following criteria are fulfilled.)
1. No edge dissection, or hematoma at stent edge
2. Adequate stent expansion: minimum stent area $\geq$5.0 mm^2, if the reference vessel was $\geq$2.8 mm, minimum stent area $\geq$4.5 mm^2, if the reference vessel was $<$2.8 mm.
3. Complete apposition of the stent over its entire length against the vessel wall, i.e. no blood flow outside the stent struts.
4. Symmetric index (= minimum stent diameter/maximum stent diameter) $\geq$ 0.7
Criteria for adequate coronary pressure pullback measurement [5–8]
No or negligible residual pressure gradient across the stent during maximum hyperemia, i.e. Psd/Psp $>$ 0.95, where Psd represents hyperemic coronary pressure just distal to the stent and Psp represents hyperemic coronary pressure just proximal to the stent.

Statistical analysis

Data are presented as the mean ± standard deviation for continuous variables. An agreement of IVUS findings and Psd/Psp $>$ 0.95 was evaluated by Cohen's kappa coefficient. Linear regression analysis was used to estimate the Pearson's correlation coefficient. All statistical analyses were performed using SPSS version 11.0 (SPSS Inc., Chicago, IL, USA), and a p-value of $<$0.05 was considered statistically significant.

Results

Patient and angiographic characteristics

Sixty coronary arteries in 53 patients were studied. Patient and lesion characteristics are shown in Table 2. The average % diameter stenosis by QCA (%DS) before intervention was 61%, with an average lesion length of 12.6 mm and an average reference diameter of 2.6 mm.

Table 2
Patient and lesion characteristics.

Patients (n = 53)	
Age	63 ± 10
Gender (male, %)	43 (81%)
History of MI	13 (25%)
Diabetes	16 (30%)
Hypertension	33 (62%)
Dyslipidemia	32 (60%)
Smoking habits	25 (47%)
Lesions (n = 60)	
Target vessel (LAD/RCA/LCX)	38/16/6
Lesion type (A, B1/B2, C)	37/23
QCA	
%Diameter stenosis (%)	61 ± 14
MLD (mm)	1.0 ± 0.4
Lesion length (mm)	12.6 ± 7.4
Reference diameter (mm)	2.6 ± 0.6

Data are presented as mean ± SD or number (%). MI, previous myocardial infarction; LAD, left anterior descending artery; RCA, right coronary artery; LCX, left circumflex artery; QCA, quantitative coronary angiography; MLD, minimum lumen diameter.

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