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## Original Article

# Fractional flow reserve for all coronary lesions with intermediate stenosis, a step towards optimal PCI – Single centre experience in India



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## ABSTRACT

**Background:** Visual assessment of intermediate coronary lesions (ICL) is fraught with errors. FFR guided PCI is often advocated but runs a potential risk of disease progression and residual ischemia.

**Objectives:** To assess accuracy of visual estimation in ICL, using FFR and comparing clinical outcomes in patients with all interrogated lesions revascularized or otherwise.

**Methods:** Consecutive patients undergoing PCI between September 2010 and 2012, who had one or more of ICL, were subjected to FFR and PCI was performed if FFR was 0.80 or less. Post-revascularization patients were divided in two groups, group I consisting of patients in whom all interrogated lesion had a significant FFR value and revascularized and group II consisting of patients with one or more non-significant lesions on FFR and left non-revascularized. The clinical end points of angina, number of anti-anginal medications prescribed and repeat revascularization were assessed at 6 months.

**Results:** 74 patients had FFR done in 104 of ICL (30–80% on visual estimation) of which 37 (35.5%) lesions were considered significant (>50% diameter stenosis) by visual estimation. On confirmation with FFR visual estimation had predictive accuracy of only 57%. 87% of the patients in the group I, were free from angina, whereas 84.4% in the group II ( $P = 0.46$ ) at 6 months. Also need for repeat revascularization was similar in both groups 2.5% and 2.85% respectively ( $P = 0.82$ ).

**Conclusion:** Visual estimation has poor predictive accuracy in of ICL and FFR guided PCI gives good clinical outcomes, without any increase of events in interrogated but non-revascularized patients.

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## 1. Introduction

The increasing use of PCI to treat multivessel disease and complex anatomical subsets has created new demands for

accurate, “per stenosis” assessment. Fractional flow reserve (FFR) can be performed easily, as a surrogate of non-invasive detection of ischemia producing stenosis.<sup>1–3</sup> DEFFER study suggested that deferring PCI in non-ischemia producing stenosis as assessed by FFR is associated with an annual rate of

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death or myocardial infarction of approximately 1% in patients with single-vessel coronary artery disease, which is lower than the rate after routine stenting.<sup>4</sup> On the other hand, deferring PCI in lesions with an FFR of less than 0.75–0.80 may result in worse outcomes than those obtained with revascularization.<sup>5</sup> Previous studies suggest that in patients with multivessel coronary artery disease, FFR guided PCI is associated with a favorable outcome with respect to event-free survival.<sup>6,7</sup>

The objective of this study was to assess predictive accuracy of visual estimates of coronary stenosis for intermediate coronary lesions using FFR as gold standard and comparing clinical outcome in patients with all interrogated lesions revascularized or otherwise.

The risk associated with performance of FFR by advancing a sensor tipped guide wire across a coronary stenosis is although low but still there.<sup>8,9</sup> Also the interrogated lesion or vessel runs the risk of accelerated disease progression or residual ischemia in non-revascularized lesions. So a secondary hypothesis tested by using this study was that coronary instrumentation for pressure and flow velocity measurements could be performed without adverse clinical outcomes.

## 2. Methods

### 2.1. Study design

Consecutive patients being taken for PCI in our centre between September 2010 and 2012, who had one or more coronary lesions with stenosis severity of 30%–80% were subjected to FFR, and PCI was performed only if stenosis proved to be haemodynamically significant (FFR 0.80 or less). Post-intervention all diagnostic angiograms were analyzed by independent observer (blinded for FFR value) for degree/severity of stenosis. Lesion severity as determined by this visual estimate was compared to the FFR value of respective lesion. Post-intervention patients were divided into two groups, group I consisting of patients in whom all interrogated lesion had a significant FFR value and revascularized and group II consisting of patients with one or more intermediate lesion with FFR value of >0.80 and were left non-revascularized. Both groups were followed at 1, 3 and 6 months for clinical events.

### 2.2. Coronary pressure measurement and calculation of FFR

Coronary pressure measurement was performed with a 0.014-in pressure sensor tipped guide wire. The wire was introduced through a 6F or 7F guiding catheter, calibrated at tip of guiding catheter following this wire was advanced into the coronary artery, and sensor positioned distal to the stenosis. Adenosine infusion was administered to induce maximum hyperemia (intravenously at a rate of 140 µg per kilogram of body weight per minute).<sup>1,10</sup> FFR was calculated as the ratio of mean distal coronary pressure (measured by the pressure wire) to mean aortic pressure measured by the guiding catheter during maximal hyperemia.

### 2.3. Clinical end points and follow-up

Follow-up assessment was done on hospital visits at 1, 3 and 6 months. Clinical end points of severity of angina, graded according to the Canadian Cardiovascular Society classification system, the number of anti-anginal medications needed and need for revascularization were assessed.

### 2.4. Statistical analysis

Statistical analysis was carried on SPSS 13.0. Independent sample t test was used for comparison between FFR and Visual assessment P value less than 0.05 was considered as significant with two-tailed hypothesis. ROC was made between FFR and visual assessment methods.

## 3. Results

### 3.1. Baseline characteristics

A total of 74 patients, with 104 intermediate coronary lesions (stenosis severity of 30%–80%) were subjected to FFR. In 43 lesions stenosis was proved to be haemodynamically significant by FFR (0.80 or less) and PCI was performed in all. In 61 lesions stenosis was found to be haemodynamically non-significant on FFR (more than 0.80) and PCI was deferred. Baseline characteristics of the two groups are presented in Table 1. Baseline characteristics of the two groups were similar, as were the number of interrogated lesions, vessel and lesion dimensions as assessed by quantitative coronary angiography.

**Table 1 – Baseline characteristics.**

Characteristics	FFR > 0.80 (n = 41)(%)	FFR < 0.80 (n = 33)(%)	P value
Age	61.2 ± 10.2	60.6 ± 10.3	0.47
Sex			
Male	30 (73.2)	24 (72.8)	0.34
Female	11 (26.8)	8 (24.2)	
Clinical			
Angina class			0.17
I	4 (9.6)	2 (6.1)	
II	26 (63.4)	21 (63.6)	
III	9 (22.1)	8 (24.2)	
IV	2 (4.9)	2 (6.1)	
Unstable angina	9 (21.9)	7 (21.2)	0.31
Previous MI	18 (43.9)	13 (39.4)	0.19
Previous PCI	4 (9.6)	2 (6.1)	0.13
Diabetes	14 (34.1)	11 (33.3)	0.67
Hypertension	17 (41.5)	13 (39.4)	0.87
Hypercholesterolemia	8 (19.5)	6 (18.2)	0.36
Current smoker	13 (31.7)	10 (30.3)	0.14
Family history of CAD	4 (9.7)	3 (9.1)	0.27
LV ejection fraction (%)	52.1 ± 12.0	53.2 ± 12.0	0.92

Plus–minus values are means ± SD. FFR fractional flow reserve, and PCI percutaneous coronary intervention. \$Angina was assessed according to the Canadian Cardiovascular Society Functional Classification of Angina Pectoris.

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