# **Research Article**

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# Myocardial FFR (Fractional Flow Reserve) in patients with angiographically intermediate coronary artery stenosis - an initial institutional experience

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# **ABSTRACT**

**Background:** The clinical significance of coronary artery stenosis of intermediate severity can be difficult to determine. The management of intermediate coronary lesions, defined by a diameter stenosis of  $\geq 40\%$  to  $\leq 70\%$ , continues to be a therapeutic dilemma for cardiologists. The 2-dimensional representation of the arterial lesion provided by angiography is limited in distinguishing intermediate lesions that require stenting from those that simply need appropriate medical therapy. In the era of drug-eluting stents, some might propose that stenting all intermediate coronary lesions is an appropriate solution. However, the possibility of procedural complications such as coronary dissection, no reflow phenomenon, in-stent restenosis, and stent thrombosis requires accurate stratification of patients with intermediate coronary lesions to appropriate therapy. Myocardial fractional flow reserve (FFR) is an index of the functional severity of coronary stenosis that is calculated from pressure measurements made during coronary angiography. The objective of the study is to evaluate the usefulness of FFR in patients with angiographically intermediate coronary artery stenosis.

**Methods:** 20 patients with intermediate coronary stenosis and chest pain of uncertain origin. The Exercise Electrocardiography (TMT), Myocardial Perfusion Imaging study (MPI), Quantitative Coronary Angiography (QCA) were compared with the results of FFR measurements.

**Results:**  $\frac{1}{20}$  patients were undergone FFR measurement during the study period. With the mean age of  $\frac{57.25\pm11.2}{1.2}$  and male patients were  $\frac{16}{80\%}$ , female patients 4 (20%), in all 13 patients with an FFR of <0.75, reversible myocardial ischemia was demonstrated unequivocally on at least one noninvasive test. In contrast, 5 of 7 patients with an FFR of >0.75 tested negative for reversible myocardial ischemia on TMT and MPI study. No revascularization procedures were performed in 7 (35%) patients, and no adverse cardiovascular events were noted in all these patients during 6 months of follow-up.

**Conclusions:** In patients with coronary stenosis of intermediate severity, FFR appears to be a useful index of the functional severity of the stenosis and the need for coronary revascularization.

**Keywords:** Myocardial Fractional Flow Reserve, Intermediate stenosis, Exercise Electrocardiography Myocardial Perfusion Imaging, Quantitative Coronary Angiography

#### INTRODUCTION

An intermediate coronary lesion on angiography is defined as a luminal narrowing with a diameter stenosis  $\geq$ 40% but  $\leq$ 70%. Assessment of a coronary lesion with intermediate severity continues to be a challenge for

cardiologists. In the current era of drug-eluting stents (DES), when percutaneous coronary revascularization is achieved with high success, a low complication rate, and excellent long-term patency, 1,2 it might be tempting to treat all suspect lesions with implantation of a DES. However, there are still procedural complications

associated with angioplasty, the inherent risk of restenosis, and late stent thrombosis.

In patients with chest pain and stenosis of moderate severity as assessed by coronary angiography, evaluation and treatment are challenging. Often, many diagnostic tests are performed and no clear diagnosis of the cause of the chest pain results. In a considerable number of patients, coronary revascularization is performed without definite evidence that the coronary stenosis is causing the symptoms.<sup>3-4</sup> On the basis of pressure—flow analysis of coronary stenosis during maximal flow,<sup>5-6</sup> the concept of myocardial fractional flow reserve (FFR) has been developed as an invasively determined index of the functional severity of coronary stenosis.<sup>7-11</sup>

FFR is defined as the ratio of maximal myocardial blood flow in the presence of epicardial stenosis to maximal flow in the same vessel without stenosis. This index represents the fraction of the normal maximal myocardial flow that can be achieved despite the coronary stenosis. FFR can be derived from the ratio of the mean distal coronary-artery pressure (post stenotic-Pd) to the aortic pressure (Pa) during maximal hyperemia (FFR=Pd/Pa). 7-8 This index is independent of changes in systemic blood pressure and heart rate and is unaffected by conditions known to increase the base-line myocardial flow. 9 In addition, FFR takes into account the contribution of the collateral blood supply to maximal myocardial perfusion.<sup>7,10</sup> The normal value of the index is 1.0, regardless of the patient or the specific vessel studied.<sup>11</sup> Furthermore. in selected patients undergoing percutaneous transluminal coronary angioplasty an FFR of less than approximately 0.75 identified functionally significant stenosis -that is, stenosis associated with inducible myocardial ischemia. 11-12 The aim of the study is to evaluate the usefulness of FFR in making clinical decisions concerning patients with ambiguous clinical symptoms, contradictory or inconclusive results of noninvasive testing, and intermediate stenosis in one or more coronary artery as determined angiographically.

### **METHODS**

### Study patients

This study was carried out over a period of 12 months from July 2010 to Aug 2011 at Sri Jayadeva Institution of Cardiovascular sciences and research Hospital, Bangalore, India.

The study population consisted of 20 consecutive patients (16 men and 4 women) with a mean ( $\pm$ SD) age of  $57\pm11$  years (range, 36 to 74). The eligibility for this study was, each patient required to have chest pain; an angiographically detectable stenosis of intermediate severity (defined as a luminal narrowing with a diameter stenosis  $\geq$ 40% but  $\leq$ 70%) in one major coronary artery; adequate left ventricular function; and uncertainty about whether the chest pain was related to reversible ischemia

caused by the intermediate stenosis. Patients with total occlusion of target artery, STEMI (<15days) were excluded.

# Study protocol

Exercise electrocardiography (TMT), Myocardial Perfusion Imaging study (MPI), were performed in some patients. Quantitative coronary angiography (QCA) with intracoronary-pressure measurements and the calculation of FFR were performed in all patients. The clinical decision to perform myocardial revascularization (PTCA or bypass surgery) was made when the FFR was < 0.75, a value selected on the basis of the results of earlier studies. <sup>11-12</sup>

### Exercise Electrocardiography (TMT) and MPI Study

Exercise Electrocardiography (TMT) testing was performed by bruce protocol allows for 3 minutes stages. A 12-lead electro- cardiogram was recorded continuously. The test was considered positive when horizontal or down sloping ST depression of at least 0.1 mV was recorded 80msec after the J point by two adjacent leads. MPI was performed by bruce protocol rest study done first. 15mci of 99mTc-Myoview administered IV for the rest study and 15mci was administered for stress study two day protocol was followed.

# Pressure Measurements and Calculation of FFR

At the time of catheterization, 6-7 French coronary catheter was introduced into one femoral artery and advanced into the ostium of the coronary artery. A 0.014 inch sensor-tipped PCI guide wire (Pressure wire, Radi Medical, Uppsala, Sweden). The wire was set at zero, calibrated, advanced through the catheter, introduced into the coronary artery, and positioned distal to the stenosis as previously described.  $^{11-15}$  Adenosine was administered to induced maximum hyperemia, either intravenously (140µg/kg/min) or intracoronary (30µg in the RCA or 40-80µg for LCA) .When steady-state hyperemia was achieved, FFR was calculated as the ratio of the mean distal intracoronary pressure measured by the wire to the mean aortic pressure measured by the guiding catheter, as described previously.  $^{7,8,11}$ 

If the FFR was 0.75 or higher, no revascularization procedure was performed. If the FFR was below 0.75, myocardial revascularization was recommended. If the lesion was suitable for coronary angioplasty, that procedure was performed during the same session, and FFR was measured again 10 minutes after successful angioplasty. If the lesion was not considered suitable for coronary angioplasty (i.e., because of stenosis of the left main coronary artery or a long ostial stenosis of the left anterior descending coronary artery), coronary bypass surgery was adviced.

## Quantitative Coronary Angiography (QCA)

Quantitative coronary angiography was performed in all patients in two orthogonal views. Using the guiding catheter as a scaling device, reference diameter, minimal luminal diameter and percent diameter stenosis were calculated as the mean of the values obtained from the 2 projections.

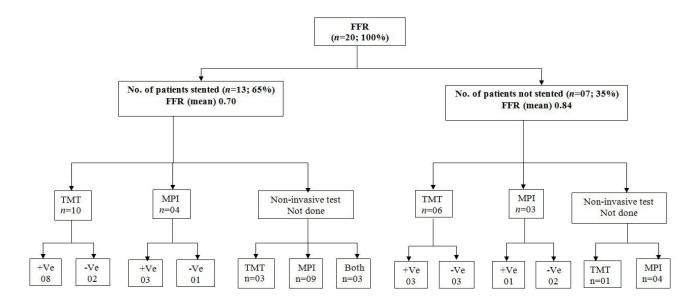
# Definition of Inducible Ischemia Based on the Results of the Noninvasive Tests

Despite the excellent sensitivity and specificity of MPI testing in patients with angiographically significant coronary stenosis, these tests are known to be less accurate in patients with atypical chest pain or only intermediate coronary stenosis on angiography. 16,21 It is thus difficult to establish the value of any new method to assess the functional severity of coronary artery disease, because there is no single unequivocal or gold standard. This is especially true of this study population with intermediate stenosis. To overcome this problem, Study compared the value of the invasive index, FFR, with that of the information derived from a combination of noninvasive indexes. It is postulated that functionally significant stenosis (indicative of potentially inducible myocardial ischemia) were present if and only if at least one of the noninvasive tests had a clearly positive result and reverted to normal after successful coronary angioplasty or bypass surgery.

It is further postulated that there was no functionally significant stenosis (and therefore no inducible ischemia) if and only if all the noninvasive tests were negative. Patients with one or more positive results of noninvasive testing but in whom the FFR exceeded 0.75 were considered to have false negative results with respect to FFR.

# **RESULTS**

The characteristics of the patients, the results of noninvasive testing, and the angiographic data are shown in flow chart & table 1. All the patients had normal electrocardiograms in resting and FFR done in all 20 patients. There was no difference in the reference diameter and the minimal luminal diameter between the patients with an FFR below 0.75 and those with higher values. The diameter of stenosis between FFR <0.75 and FFR >0.75 were 65% and 54% respectively. Figure 1 shows representative coronary angiograms and coronarypressure tracings typical of those used to calculate FFR. The FFR was  $\geq 0.75$  in 7 patients, and in these patients revascularization was not performed. The FFR was < 0.75 in 13 patients, who underwent coronary angioplasty; FFR was measured again 10 minutes after the procedure. Post procedure FFR was increase to mean of 0.95.



Flow chart of Non invasive test
TMT - Treadmill test, FFR - Fractional flow reserve, MPI - Myocardial Perfusion Imaging

# Comparison of FFR with the Results of Noninvasive Tests

The relation between FFR and the results of the noninvasive tests is shown in table 2 and flow chart. In all 13 patients with an FFR <0.75, signs of myocardial

ischemia could be induced by at least one noninvasive test and coronary angioplasty was performed in all patients table 3. Among 13 patients with FFR < 0.75, TMT was done in 10 patients, out of which 8 were positive, 2 were negative for inducible ischemia and in 3 patients TMT was not done, MPI was done in 4 patients

out of which 3 patients were positive for reversible ischemia and 1 patients was negative for reversible ischemia, in 9 patients MPI was not done.

In seven patients with an FFR of >0.75 TMT was done in 6 patients, of which 3 were positive, 3 were negative for inducible ischemia and in one patient TMT was not done,

MPI was done in 3 patients, of which one patient was positive for reversible ischemia and 2 patients were negative for reversible ischemia and in 4 patients MPI was not done. Among positive non invasive test (3 TMT, 1 MPI) FFR yielded false negative results, because evidence of inducible ischemia was present despite an FFR of >0.75.

Table-1: Baseline characteristics of study patients.

Demographics	All patients	FFR < 0.75	FFR ≥ 0.75			
Demographics	(n=20; 100%)	(n=13; 65%)	(n=7; 35%)			
AGE (yrs)	57.25±11.2	57.69±9.3	56.42±14.9			
MALE	16(80%)	11(84.6%)	05(71.4%)			
FEMALE	04(20%)	02(15.3%)	02(28.5%)			
RISK FACTOR						
a) DM	13(72.2%)	10(76.9%)	03(42.8%)			
b) HTN	12(66.6%)	08(61.5%)	05(71.4%)			
c) Hyperlipidemia	4(22.2%)	02(15.3%)	02(28.5%)			
d) Smoker	08(44.4%)	05(38.4%)	03(42.8%)			
e) FHx of CAD	01(5.6%)	01(7.6%)	00			
PREVIOUS H/o						
a) MI	05(33.4%)	04(30.7%)	01(14.2%)			
b) PCI	04(22.4%)	03(23%)	01(14.2%)			
c) CABG	01(5.6%)	01(7.6%)	00			
d) Angina	02(11.1%)	01(7.6%)	01(14.2%)			
LVEF (%)	54.78±5.4	55.2±5.2	53±4.3			
ANGINA (CCS Class)						
a) I	02(10%)	00	02(28.4%)			
b) II	17(85%)	12(92.3%)	05(71.4%)			
c) III	01(5%)	01(7.6%)	00			
d) IV	00	00	00			
MEDICATIONS						
a) BB	08(44.4%)	04(30.7%)	04(57.1%)			
b) CCB	00	00	00			
c) Nitrates	00	00	00			
d) ACEI/ARB	17(94.4%)	12(92.3%)	05(71.4%)			
e) Statins	16(88.9%)	12(92.3%)	04(57.1%)			
f) Antiplatelets	11(61.1%)	09(62.2%)	2(28.5%)			
ANGIOGRAPHY (QCA)						
a) Reference diameter (mm)	3.1±0.3	3.0±0.2	3.14±0.2			
b) Diameter Stenosis (%)	57.6±6.5	$65.07 \pm 8.4$	54.01±4.3			
c) MLD (mm)	1.3±0.2	1.21±0.2	1.40±0.3			
FFR (max hyperemia)	$0.75\pm0.07$	0.70±0.01	$0.84 \pm 0.03$			
FFR-Post PTCA		0.95±0.02				
TREATMENT						
a) Medical	07(35%)	00	07(100%)			
b) PTCA	13(65%)	13(100%)	00			
c) CABG	00	00	00			

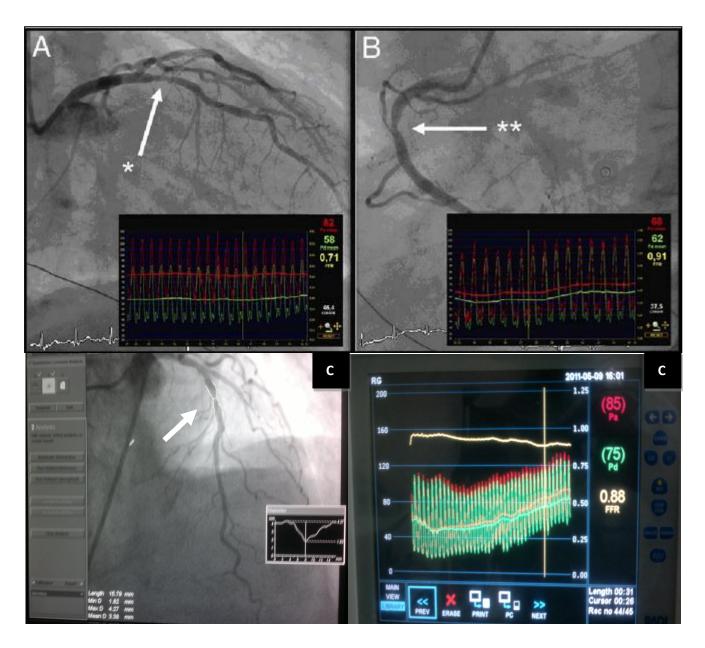


Figure 1: Three patients with intermediate stenosis by angiography but completely different functional importance as assessed by the FFR. A stenosis in the left anterior descending artery (A, arrow with asterisk), a stenosis in the right coronary artery (B, arrow with double asterisks) of a patient in the study and stenosis in the left anterior descending artery (C, arrow) all three lesions were categorized as 50% to 70% stenosis severity by angiographic assessment. After the FFR was measured in arteries. The FFR was below the ischemic threshold of 0.80 in the left anterior descending artery (A) (0.71; functionally significant). Subsequently, the left anterior descending artery was stented study protocol. The FFR of the RCA was 0.91(B) and LAD was 0.88 (C), indicating a functionally nonsignificant stenosis, and therefore was not stented.

# **DISCUSSION**

Angiography is inaccurate in assessing the functional significance of a coronary stenosis when compared with the FFR, not only in the 50% to 70% category but also in the 70% to 90% angiographic severity category. Our study supports the concept that FFR reliably indicates functionally significant coronary stenosis. This index

performed well as compared with standard noninvasive tests for myocardial ischemia. Decisions made on the basis of the FFR resulted in excellent clinical outcomes in the patients in whom unnecessary revascularization was prevented. Such decisions are often difficult in patients with coronary stenosis of intermediate severity. In most patients with coronary artery disease, the decision to perform revascularization procedures should be based not

only on the coronary anatomy but also on the functional severity of a lesion. <sup>23-25</sup> This is especially true in patients with narrowings of intermediate severity demonstrated on coronary angiograms. If, when such a lesion is present, myocardial ischemia can be clearly demonstrated by exercise or pharmacologic stress testing, revascularization is appropriate when medical therapy fails to control symptoms. <sup>24-25</sup> In some patients, however, noninvasive tests are inconclusive. Moreover, both TMT,

MPI and stress echocardiography have limited sensitivity in such patients. When chest pain persists despite repeatedly negative tests, confusion often arises about the clinical importance of the lesions.<sup>3-4</sup> Therefore; it would be useful to have a measurement that is easily obtainable at the time of diagnostic coronary angiography that would indicate clearly whether the coronary stenosis is responsible for reversible ischemia.

Table 2: Non invasive test with FFR comparison.

		FFR <0.75(<0.80) n=13	FFR >0.75(>0.80) n=07			
TM'	TMT (n=16)					
a)	Positive	08	03			
b)	Negative	02	03			
c)	Not Done	03	01			
MP	I (n=07)					
a)	Positive for reversible ischemia	03	01			
b)	Normal/No e/o reversible ischemia	01	02			
c)	Not done	09	04			

Table 3: Outcome of FFR studied arteries.

	Numbers n= 20	Not Stented ( <i>n</i> =7; 35%)	Stented	(n=13; 65%)
FFR Artery				
a) LAD	14 5 09	09	DES-09	
a) LAD	14	3	09	BMS-00
b) LCX	02 00 02	02	DES-01	
b) LCA	02	02 00 02	BMS-01	
a) DCA	03	01	02	DES-02
c) RCA	03	01		BMS-00
a) IMCA	01	01	00	DES-00
d) LMCA	01	01		BMS-00
FFR value (mean)	0.75	0.84	0.70	
Post procedure			0.95	

Myocardial FFR is such an index of the effect of an epicardial coronary artery stenosis on maximal myocardial perfusion. In previous studies of selected patients undergoing percutaneous transluminal coronary angioplasty, a cutoff FFR value of approximately 0.75 distinguished lesions associated with inducible ischemia from other lesions, and there was minimal overlap

between the two groups. 11,12 This study extends previous observations by assessing the clinical application of FFR. The results indicate that FFR performed well in assessing the functional severity of coronary stenosis.

As previously demonstrated, the risk associated with advancing a sensor-tipped guide wire across a coronary

stenosis is extremely low and is offset by the important clinical information gained, especially in the case of a moderate stenosis in the proximal portion of a large coronary artery. With such a stenosis, omitting an intervention that is indicated and performing one that is not indicated can both be harmful.

The calculation of FFR from measurements of pressure is limited by the presence of small-vessel disease, diffuse disease. left coronary artery and ventricular hypertrophy. 12,26 These conditions restrict the increase in blood flow after pharmacologic vasodilatation and the corresponding decrease in distal coronary pressure. Under these conditions, therefore, the severity of the stenosis may be underestimated because of the limited increase in flow and the associated limitation in the pressure gradient. Also, in some patients exerciseinduced vasospasm may occur during physical exercise.<sup>27</sup> In those patients, the hyperemia induced by adenosine in the catheterization laboratory is not necessarily equivalent to exercise-induced maximal hyperemia in daily life. This mechanism could have played a part in the patients with positive exercise tests but FFR values of 0.75 or higher.

#### **CONCLUSION**

Measuring FFR during coronary angiography is useful in determining whether an angiographically intermediate stenosis is functionally important and may therefore be responsible for reversible myocardial ischemia. In this study, the accuracy of FFR for this purpose was equivalent to that of the information provided by a combination of the noninvasive tests currently used. Therefore it is believed that myocardial FFR may be useful in making clinical decisions about revascularization procedures in patients with intermediate coronary stenosis when other objective evidence of reversible ischemia is lacking.

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