

Original Studies

Clinical Usefulness and Cost Effectiveness of Fractional Flow Reserve Among INDIan Patients (FIND Study)

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Objectives: To study the clinical usefulness, cost benefit, and medium term outcome of fractional flow reserve (FFR) based management of coronary artery disease of intermediate severity. **Background:** In spite of the advantages of FFR there is paucity of data in Indian population who have frequent diffuse, small and multivessel disease where it would probably be more beneficial in terms of cost and outcome. **Methods:** The treating cardiologist's management decision with both FFR and angiographic data was compared with that of a reviewing cardiologist decision based on a retrospective analysis of angiogram alone. **Results:** Eighty-one vessels with intermediate lesions in 59 patients required 26 stents lesser when FFR data was added to the angiogram. The concordance of management decision was about 58% which means that >40% of intermediate lesions would be misclassified as significant based on angiography alone. There were no major events at a mean follow up of 11 ± 5 months. The net cost benefit in favor of FFR based management was INR 8,57,600 (USD 15,600) in our centre. **Conclusion:** Indians with more severe form of CAD benefit from a FFR based management plan for intermediate lesions, both clinically and economically. © 2014 Wiley Periodicals, Inc.

Key words: fractional flow reserve; cost benefit; intermediate lesions; multivessel disease

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INTRODUCTION

Insights into inducible ischemia and its prognostic implications have led to a paradigm shift towards functional revascularization [1–3]. However in practice coronary angiogram forms the corner stone of decision making in spite of its inherent limitations of being a luminogram. This leads to a significant discrepancy between anatomic and functional severity of a coronary stenosis, maximally for those lesions of intermediate severity (50%–70%) [4–6]. The prevalence of such intermediate lesions in the earlier trials of DES was 6.7%, but during diagnostic angiography their frequency would be even higher. Benefits of PCI in non ACS settings are less clear. Still an evidence of objective ischemia before PCI was demonstrated in <30% of cases two decades ago which did not change much till recently (<50%) [7–10]. The non-invasive tests of inducible ischemia (exercise treadmill test, stress

nuclear myocardial perfusion imaging, and exercise stress echocardiography) are also limited by their poor sensitivity in localizing the lesions [4]. Intra coronary pressure measurements were there since the early days of PCI. Fractional flow reserve (FFR) index <0.80 as a measure of lesion severity was coined in 1995, but its routine use is hampered by many factors [11–14]. FFR has gained importance with guidelines recommending class I indication for lesions without objective evidence of ischemia [15,16]. The visual functional mismatch would be maximal in smaller vessels and where there is a disproportion between the vessel size and myocardium supplied by it [17]. Despite these there is a paucity of data on FFR from Indian patients. Our patients would probably benefit more because of their relatively smaller epicardial coronaries than Caucasians and the frequent occurrence of multi vessel, small vessel, and diffuse disease [18–20].

Aims and Objectives

Our aim was to detect and analyze the differences in the clinical management decisions taken when FFR was used in addition to angiographic interpretation of intermediate lesions. We also analyzed the differences in the number of stents used, cost savings, change in length of stents, and patient outcomes.

METHODS

Study Design

It is a retrospective study which included all consecutive patients who underwent coronary angiogram followed by FFR from May 2011 to August 2013 at our hospital. Patients with acute coronary syndrome, recent myocardial infarction, prior PCI or CABG were excluded. FFR was done on all vessels >2.5 mm and a stenosis between 50% and 70% as assessed by the treating cardiologist. All patients were managed according to the decision made by the treating cardiologist with both angiogram and FFR data. Coronary angiograms of all these patients were retrospectively analyzed independently by another interventional cardiologist (reviewing), who was blinded to the results of FFR but was provided with the clinical profile and results of other non invasive tests. The reviewing cardiologist was asked to make a management decision for all the intermediate lesions, between medical therapy versus revascularization with PCI or coronary artery bypass grafting (if appropriate). If a decision for PCI was taken he was asked to propose the number of stents needed, and their appropriate length and diameter. Differences in management decision, number of stents needed, and their average length between the original decision made by the treating cardiologist and

the decision made by the reviewing cardiologist were analyzed. We also wanted to study if FFR based revascularization could reduce the total length of the stent particularly in patients with tandem and long lesions.

All patients were followed up at 1, 3, 6, 12 months, and then yearly till August 2013. The primary end point was a composite of all cause death, cardiovascular death, non fatal myocardial infarction, or the need for urgent revascularization. Data regarding the recurrence of angina and the need for elective revascularization was also collected.

Pressure Measurements and Calculation of FFR

Coronary angiogram was done with a 5/6 French coronary diagnostic catheters and lesions was assessed after intra coronary nitro-glycerine. A 0.014 inch sensor-tipped PCI guide wire (Pressure wire Certus, SJM, Westford, MA) was used for pressure measurement. The wire was set at zero, calibrated, advanced through the catheter, introduced into the coronary artery, equalized, and positioned distal to the stenosis. Adenosine was administered to induce maximum hyperemia, either intravenously (140 $\mu\text{g}/\text{kg}/\text{min}$) or intracoronary (75–100 μg in the RCA or 100–200 μg for LCA) or intracoronary Papaverine (10–12 mg). FFR was measured at steady state hyperemia as the ratio of the mean distal intracoronary pressure measured by the wire to the mean aortic pressure measured by the guiding catheter. If the FFR was ≥ 0.80 , revascularization was deferred. If the FFR was below <0.80 , revascularization was done. In patients with serial or multiple lesions in one vessel, intravenous adenosine infusion was used and FFR pressure wire was pulled back slowly during hyperemia, precisely indicating at which particular locations hemodynamically significant abnormalities were present. Thus FFR at various segments over the length of the artery were obtained [21].

Statistical Analysis

Continuous variables were expressed as mean and standard deviation whereas categorical variables are expressed as frequency and percentage. Normality of the data was assessed by Shapiros–Wilk’s test. Categorical variables between groups are analyzed using chi-square test or Fisher’s exact test based on number of observations. A two sided *P* value <0.05 was taken as statistically significant.

RESULTS

Demography

Sixty-five patients had undergone angiogram followed by FFR during the study period of which six

TABLE I. Baseline Characters

S. No	Character	N = 59
1	Age (mean \pm SD, years)	59.9 \pm 10.5
2	Males, n(%)	47(79.7)
3	Diabetes, n(%)	39(66%)
4	Hypertension, n(%)	36(61%)
5	Dyslipidemia, n(%)	11(18.6%)
6	Smoking, n(%)	11(18.6%)
7	Typical angina, n(%)	34(58.6%)
8	Positive treadmill test, n(%)	10(17.2%)
9	Ejection fraction (mean \pm SD)	54% \pm 7%

patients were excluded. Three had a recent ACS, two had undergone prior PCI and one had a prior CABG. Of the 59 patients included, 80% were males and 66% were having diabetes. Rest of the baseline characters were tabulated in Table I. Eighty-one vessels were considered to be >2.5 mm with a lesion between 50% and 70% by the treating cardiologist and FFR was done. These 81 vessels included single vessel in 41 patients, two vessels in 14, and all three vessels in 4 patients. About 67 out of these 81 vessels was also considered to have an intermediate lesion by the reviewing cardiologist, whereas 9 were considered to have $>70\%$ and 5 was considered to have $<50\%$. Adenosine was the hyperemic agent used in all except one, in whom papaverine was used because of bronchial asthma. Adenosine was used through the intracoronary route in 51 patients and through intravenous route in 7 patients (those with serial lesion or diffuse disease). The overall reference diameter was 2.8 ± 0.09 mm for all of these intermediate lesions. Eighteen of our patients had multivessel disease (14 double vessel disease and 4 triple vessel disease), 7 patients had diffuse or serial lesions, and 3 had left main disease. The mean and standard deviation of FFR of all the 81 intermediate lesions assessed were 0.84 ± 0.10 .

Management Decisions

The reviewing cardiologist advised for PCI in 45 patients based on angiogram alone. Of these, only 29 patients had actually required PCI after FFR. Thus there was a reduction in unnecessary PCI in 35.5%

(16 out of 45) of patients. Similarly out of 6 patients advised for CABG based on angiogram alone, only 3 actually required CABG and two were managed by PCI and the other with medical management. Thus the need for CABG was reduced in 50% of patients at the same time increasing the PCI in this patient group requiring CABG. (Table II; Fig. 1). Overall the addition of FFR data to angiogram led to a change in decision in 42% (25/59) of patients with intermediate lesions and majority them were in favor of medical management. This implies that majority of the angiographically appearing borderline lesions are in fact not flow limiting, and stenting would be inappropriate. The reviewing cardiologist was not able to arrive at a management plan in seven patients (12.5%) with angiogram alone and wanted further non invasive tests. Six out of these seven (85.6%) patients actually had a definite management plan after FFR thereby increasing the overall diagnostic clarity to 98.3%, when FFR was added to angiogram.

The reviewing cardiologist with angiographic data alone proposed for 66 stents which is significantly higher than the number of stents ($n = 40$) actually used to treat these patients. Though the reviewing cardiologist considered 67/81 vessels in 59 patients as intermediate lesions, when forced to make a management decision, revascularization was advised in majority of these patients ($n = 51$). The mean length and diameter of the stents for lesions, for which both the treating and the reviewing cardiologist advised for PCI was 30.3 ± 17.3 mm/ 2.83 ± 0.11 mm and $34.03 \pm 14.5/2.81 \pm 0.14$, respectively. Though there was a small decrease in length and increase in diameter after FFR, it was not statistically significant. So a total of 26 stents were avoided on adding the FFR data to the angiogram in these 59 patients with intermediate lesions in 81 vessels. In other words for every 2 patients or 3 vessels with intermediate lesions the addition of FFR to angiogram avoids one stent.

Outcomes

The mean duration of follow up was 11 ± 5 months. There were no procedure related complications and

TABLE II. Patient Management by Angiographic Assessment Versus with Angiographic + FFR Assessment

		ANGIOGRAM + FFR				
		Medical	PCI	CABG	Inconclusive	Total
ANGIOGRAM	Medical	1 (5.3%)	0	0	0	1
	PCI	15 (79%)	29 (83%)	1 (25%)	0	45
	CABG	1 (5.3%)	2 (5.7%)	3 (75%)	0	6
	Inconclusive	2 (10.5%)	4 (11.4%)	0	1 (100%)	7
	Total	19	35	4	1	59

* $P < 0.01$ Fisher's Exact test

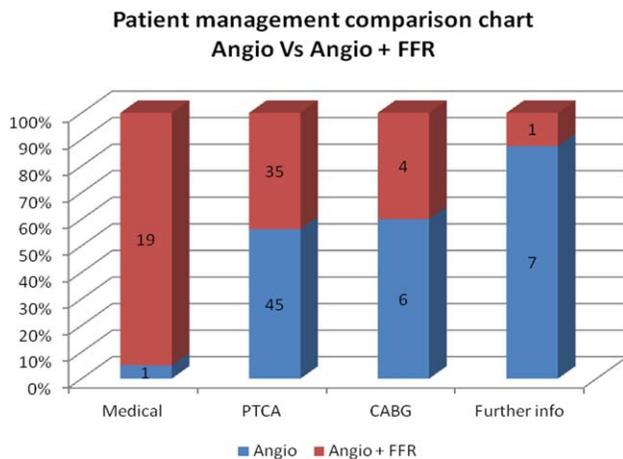


Fig. 1. Pictorial representation of the management decisions between the treating and reviewing cardiologist. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

none of these patients had a primary end point till the time of compiling this data and this is comparable to FFR plus medical therapy arm and the registry arm of the FAME II trial.

Cost Saving

This is calculated according to the market value during the mid-part of the study (June 2012) at our center. The cost for FFR is calculated at the patient level as the same pressure wire can be used for multiple vessels in the same patient. With an average cost of a DES at INR 1 lakh (USD 1800) avoiding 26 stents saved a total amount of INR 26 lakhs (USD 47,300). FFR procedure costs Rs 30,000 (USD 550) incurring an additional cost of INR 17.7 lakhs (USD 32,200) for 59 patients amounting to a benefit of INR 8.3 lakhs (USD 15,000). This is the cost saved at the time of the management decision. As a stent avoided is equivalent to avoiding DAPT in non ACS setting INR 1200 (USD 22) is saved for each patient not receiving a stent at the end of 1 year. In our study 26 stents were avoided in 23 patients amounting to a net benefit of INR 8,57,600 (USD 15,600) at the end of 1 year.

DISCUSSION

In this retrospective analysis of 59 patients with 81 vessels having intermediate lesions, we found that concordance of management plan assessed by angiography alone and by angiography with FFR is about 58% which means that >40% of intermediate lesions would be classified wrongly using angiography alone. Majority of this change is in favor of medical management

and avoiding unnecessary stenting implying the fact that most of these lesions of borderline severity are actually non-ischemic. At the same time by converting CABG surgery to PCI, FFR also increases the PCI procedures by small numbers and avoids unnecessary CABG surgery. Avoiding a stent has many implications like immediate cost benefit (a net of Rs 70,000 for each stent avoided after using FFR at our centre), avoidance of procedure related complications, avoidance of long term DAPT (its cost and complications), avoidance of ISR and the most dreaded stent thrombosis.

Based on FAME I trial, lack of mortality benefit for percutaneous coronary intervention over medical therapy in chronic stable angina patients has been hypothesized to be due to lack of ischemia in a significant proportion of these intervened lesions [22]. Subsequently the result of the FAME II trial has shown that there are physiologically significant lesions in patients with chronic stable angina as identified by FFR which when intervened selectively reduces the need for urgent revascularization procedures. Although a mortality benefit was not demonstrated due to early termination of the FAME II study a mortality benefit was proposed if it would have been continued [23]. Therefore, a FFR based strategy for managing intermediate lesions has definite advantages but with an additional cost. This holds true for any new technology that has been added to the armamentarium of the interventional cardiologist. Also indispensable is the learning curve and the radiation exposure. In our study we have shown that the addition of FFR for intermediate lesions to be cost effective by avoiding a significant number of stents (initially proposed for a DES). If there was a proposal of BMS for all these lesions the net cost benefit would be minimal in favor of FFR as the cost of BMS and the FFR procedure would nullify each other. Randomization to DES before FFR data has been argued to be the reason for the huge cost benefit shown in the FAME I trial in favor of FFR [24,25]. Cost-wise, patients with multivessel disease would be benefited most as the FFR cost remains same and even avoidance of single stent tilts the cost benefit in favor of FFR.

In the RIPCORD study the protocol allowed the second cardiologist to perform FFR according to his assessment of the vessels, also FFR was allowed in all lesions including those >70%. The discordance between the two management decisions in this trial was 28% which is lower than our study where FFR was done only on vessels with intermediate lesions [26]. This is plausible as it is the intermediate lesions which are prone for wrong management plan based on angiographic data alone.

Limitations and Future Directions

It's a retrospective study and we did not have a control arm managed according to angiographic data alone for outcome analysis. But our outcomes are comparable to the event rates of major FFR trials. The sample size is smaller but this is the largest data on FFR from this part of the sub continent. The reviewing cardiologist had only the angiographic views taken by the treating cardiologist and did not have an opportunity to perform additional views of his choice for intermediate lesions. Future randomized studies with long term clinical follow up are suggested. Also including functional SYNTAX score would be beneficial in determining optimal revascularization strategy.

CONCLUSION

Indians with lesions of intermediate severity on conventional coronary angiogram benefit both economically and clinically when FFR is added to angiography. The benefit would be most for those with multi vessel disease.

Conflicts of Interest: None.

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