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Original Article

Clinical Outcomes of patients with coronary artery disease who underwent FFR evaluation of intermediate coronary lesionS– COFFRS study

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ABSTRACT

Background: We undertook this study to validate the impact of FFR-guided coronary interventions among Indian patients, which is not readily available as of date. Our patients differ from their western counterparts, both in terms of risk profile (younger, more metabolic syndrome, lipid rich diet) as well as their coronary size.

Methods: We retrospectively evaluated 282 patients with intermediate stenosis in their coronary arteries, who underwent FFR to assess the functional severity of the lesion. There were 3 groups: Group 1–FFR > 0.8 and kept on medical follow-up; Group 2–FFR ≤ 0.8 and underwent revascularisation; and Group 3–FFR ≤ 0.8 and refused to undergo revascularization. 281(99.6%) patients had regular follow-up in our clinic.

Results: Median age-57 years (range = 28–78). Males = 230, 90 patients were in Group 1, 175 in group 2 (PCI in 144 & CABG in 31) and 17 in group 3. Median follow-up of patients was 17.9 months (2 to 56 months). Three patients(3.4%) in Group 1 had MACE (1 STEMI, 2 UA); 4 patients (2.3%) in Group 2 had Non-STE-ACS; 7 patients (41%) in Group 3 had MACE (3 deaths with acute LVF, 2 NSTEMI, 2 STEMI)

Conclusion: In our experience, MACE events were not higher in patients with FFR > 0.8 and kept under medical therapy and were similarly lower in patients with FFR ≤0.8 and underwent revascularisation (p = 0.73). Also MACE events were higher in patients with FFR ≤ 0.8 and did not undergo revascularisation compared to other two appropriately treated groups (p = 0.03). FFR based revascularization decision appears to be a safe strategy in Indian patients.

Invasive coronary angiography is known for its precision in delineating topographical anatomy of lumen of epicardial coronary arteries, but lacks the ability to determine the functional significance of coronary stenoses. Functional severity of coronary narrowing has been determined to be the most prominent prognostic factor among the individuals with documented coronary artery disease.[1] Hence, combined assessment of anatomy and functional information with high accuracy would help in guiding the treatment strategy for patients with known or suspected coronary artery disease, particularly those with intermediate degree of stenosis.[2]

Fractional Flow Reserve (FFR) is an invasive but 'easy and simple to measure' index of the functional significance of severity of coronary stenosis with a diagnostic precision of myocardial scintigraphy, albeit with a better spatial resolution.[2] It is derived from the ratio between coronary (distal to stenosis) and aortic pressure measurements during maximal hyperemia.[3] Hence FFR in combination with conventional angiography is rapidly emerging as an accurate approach of combining anatomy and physiology.[4]

Abbreviations: ACS, Acute Coronary Syndrome; CABG, Coronary Artery Bypass Graft; CAD, Coronary Artery Disease; COURAGE Trial, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial; DEFER Trial, measurement of fractional flow reserve to assess the functional severity of coronary-artery stenoses – DEFER Trial; DS, percent diameter stenosis; ECG, Electrocardiogram; FAME 2 Trial, fractional flow reserve versus angiography for guidance of PCI in patients with multivessel coronary artery disease (FAME); FFR, Fractional Flow Reserve; IMR, Index of Microvascular Resistance; HMR, Hyperemic Microvascular Resistance; LVF, Left Ventricular Failure; MACE, Major Adverse Cardiac Events; MLD, Minimum Luminal Diameter; Non-STE ACS, Non ST Elevated Acute Coronary Syndrome; NSTEMI, Non-ST Elevated Myocardial Infarction; PCI, Percutaneous Coronary Interventions; QCA, Quantitative Coronary Angiography; RD, Reference Diameter; STEMI, ST Elevated Myocardial Infarction; TVR, Target Vessel Revascularization; UA, Unstable Angina.

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Role of FFR in determining the need for coronary stenting has been studied in various trials and has been recommended to assess the significance of intermediate coronary lesions[2,3,5–7]. FFR has been demonstrated to be an useful index in patients referred for percutaneous revascularisation with intermediate stenosis, involving single coronary vessel,[2,3,7,8] and also in those with multivessel disease.[5,9] Additional concerns regarding the association between drug-eluting stents and late complications, continued exposure to dual anti-platelet therapy, and increased costs make appropriate use of these devices critical.[10] This leaves FFR as a better choice to assess hemodynamic significance of intermediate lesion and to guide treatment strategy.

Clinical outcome of the decision to intervene based on FFR has been addressed in various trials, conducted in controlled environment.[7,11–14] Availability of such data from routine clinical practice is limited.[15] In India, clinical use of FFR is more or less limited to tertiary care centres and its utilization is probably confined to a small group of patients with coronary artery disease (CAD). Demographic, risk profile and natural history of coronary artery disease among Indian/Asian patients are affected by some unique factors such as younger age group, predominant metabolic syndrome, exposure to lipid-rich diet and increasingly common sedentary life style[16–18] and there is data which discuss about smaller coronary artery diameters in Indian patients undergoing angiography.[19] Thus it is speculative that many Indian patients with borderline lesions undergo unwarranted revascularization without much clinical improvement. FFR, by assessing the ischemic profile, could benefit by helping to select a better revascularization strategy. There is no data regarding the utility of FFR from India.

In this study, we intended to assess the clinical outcome of FFR-based management strategies in Indian patients, the results of which could serve to validate and re-emphasize the utility of this investigation in our setting.

1. Objectives

1. To study the clinical outcomes among the patients who underwent FFR as part of the evaluation of their coronary stenosis
2. To compare the outcomes between patients who underwent revascularisation and those kept under medical follow up based on FFR assessment.

2. Methods

2.1. Study design

This is a retrospective study (approved by the Institutional Ethics Committee, No: – SCT/IEC/778/JUNE 2015) conducted between June 2010 and June 2015 at Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum, a tertiary care hospital in India.

2.2. Study patients

Medical records of all patients who underwent FFR during the period between June 2010 to June 2015 were reviewed.

2.3. Inclusion criteria

- All patients with stable ischemic heart disease with denovo intermediate lesions or
- those patients who had acute coronary event a week or more prior to the procedure with denovo borderline lesions.

Study population were grouped into 3 groups:

Group 1–FFR > 0.8 and kept on medical follow-up;

Group 2–FFR ≤ 0.8 and underwent revascularization by PCI or CABG; and

Group 3–FFR ≤ 0.8 and did not undergo revascularisation as per patient preference.

2.4. Exclusion criteria

1) Culprit coronary vessel responsible for acute coronary syndrome within 7 days. (However if the FFR was studied in non-culprit coronary arteries in the same patient it was included)
2) Left Main Coronary artery lesion
3) Previous CABG/ prior PCI
4) Contraindication to adenosine,
5) Conditions for which FFR has not been validated (tortuous coronary arteries, left ventricular hypertrophy)
6) Life-threatening comorbidity.
7) FFR assessment of a stenosis in a coronary artery supplying collaterals to the vascular bed subtended by a totally occluded artery.

A total of 8263 patients had undergone coronary angiography during the study period for evaluation of their coronary ischemic symptoms, of whom, 471 (5.7%) patients had undergone FFR for physiological severity assessment of coronary lesions. After reviewing these 471 patient medical records, 189 patients were excluded from the analysis (86 had associated valvular heart disease, 74 had significant left main disease, 9 had significant tortous coronary anatomy, 4 had prior CABG, 12 had significant renal dysfunction, 2 had intracranial neoplasm, and 2 had incomplete data)

2.5. Coronary pressure measurement and calculation of FFR

FFR was measured in all intermediate stenoses for assessment of hemodynamic significance. Intracoronary pressure measurements were performed with a 0.014-inch pressure guidewire (Pressure Wire Aeris from St. Jude Medical or Prime wire PRESTIGE from Volcano Inc, Rancho Cordova, California, USA) introduced through a guide catheter. Hyperemia was induced by intravenous adenosine (140 μg/kg/min until a steady state was obtained or for at least 6 min) after a bolus dose of intracoronary nitroglycerin of 200 micrograms. The FFR was calculated from the ratio of mean hyperemic distal coronary pressure measured by the pressure-wire and the mean aortic pressure obtained by the coronary guide catheter. (RADIANALYZER, St Jude Medical OR VOLCANO, Volcano Corporation). As per the hospital protocol, FFR value of >0.80 was considered as a criteria to defer revascularisation at the time of procedure and the decision to revascularise was based on the cut-off value of FFR ≤ 0.80. If there were serial stenotic lesions, pressure gradient drop of >10 was considered significant. All patients had received antiplatelets, statins and beta blockers. Those who underwent revascularization received aspirin and clopidogrel for at least 12 months after the procedure.

2.6. Quantitative coronary arteriography

Angiograms were reviewed by two independent investigators to determine the severity. Quantitative assessment of lesions (QCA – Quantitative Coronary Angiography) was done using a validated software employing Siemens/Philips algorithm. Reference diameter(RD), minimum luminal diameter (MLD), and percent diameter stenosis (DS) were assessed in two orthogonal views.

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