RESEARCH ARTICLE

Clinical outcomes of patients with deferred revascularisation based on fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) negative coronary artery lesions in Pakistani population

Muhammad Nasir Rahman[1], Jamshed Ali[2], Sheema Saadia[3], Ghufran Adnan[4]

Abstract

Objective: To assess long-term clinical outcomes and factors associated with target vessel revascularisation in patients with deferred revascularisation based on negative fractional flow reserve and negative instantaneous wave-free ratio.

Method: The longitudinal, retrospective study was conducted from July 1, 2020, to January 1, 2022, at the Aga Khan University Hospital, Karachi, and comprised medical records from January 2012 to January 2020 of patients with deferred revascularisation having intermediate to severe coronary lesions on coronary angiogram and had negative fractional flow reserve >0.80 or instantaneous wave-free ratio >0.89 and had not undergone immediate or planned revascularisation on the basis of negative physiological assessment. Data was collected from the institutional records, while final follow-up was taken by reviewing the medical records or telephonic interviews regarding any major adverse cardiac event after the index procedure. Data was analysed using Stata 14.2.

Results: Of the 345 patients, 245(71%) were males. The overall mean age was 62±11 years. There were 194(56%) patients who presented with stable angina and 151(44%) presented with acute coronary syndrome. Mean fractional flow reserve was 0.87±0.04 and mean instantaneous wave-free ratio was 0.93±0.03. Multivessel disease was present in 223(65%) patients. Median follow-up period was 29 months (IQR: 24-36 months). Major adverse cardiovascular events occurred in 22(6%) patients, and target vessel revascularisation was required in 11(3%). Diabetes and percentage of stenosis were found to be independent predictors of major adverse cardiovascular events ($p<0.05$).

Conclusion: Deferral of revascularisation and opting for medical treatment for coronary artery stenosis with higher fractional flow reserve or instantaneous wave-free ratio could be considered a safe and reasonable strategy.

Keywords: Fractional flow reserve, Instantaneous wave-free ratio, Deferred revascularisation, Target vessel revascularisation. (JPMA 74: 1598; 2024) **DOI: https://doi.org/10.47391/JPMA.9272**

Introduction

Physiological indices of coronary lesions are pivotal diagnostic and prognostic tools in deciding whether to do or defer revascularisation in intermediate severity coronary lesions on an angiogram.[1] In order to evaluate the significance of such lesions, functional studies, such as fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR), improve patient outcomes and procedural cost efficiencies, mainly by deferring revascularisation of haemodynamically non-significant coronary lesions.[2,3] Deferral versus Performance of Percutaneous Coronary Intervention of Functionally Non-Significant Coronary Stenosis (DEFER) trial was the first study conducted on stable ischaemic heart disease (SIHD) patients for assessing the long-term outcomes of FFR-based revascularisation. The trial demonstrated that the deferred arm, which included deferred revascularisation based on FFR negative values (>0.75), had comparable long-term outcomes to the percutaneous coronary intervention (PCI) arm. Studies have been conducted on SIHD and acute coronary syndrome (ACS) patients, and have demonstrated favourable results in lesions deferred after functional assessment with either non-ischaemic FFR or iFR.[4,5]

The applicability of these trials in clinical practice in Pakistan remains challenging for interventionists due to differences in patient demographics, younger age of presentation,[6] type of presentation, risk profile and non-compliance with medications due to financial constraints.

To the best of our knowledge, negligible data is available from Pakistan in this regard. The current study was planned to assess long-term clinical outcomes and factors associated with target vessel revascularisation (TVR) in patients with deferred revascularisation based on negative FFR and negative iFR in a tertiary care setting in Pakistan.

Materials and Methods

The longitudinal, retrospective study was conducted from

[1-3]Department of Medicine, Aga Khan University Hospital, Karachi, Pakistan; [4]Department of Cardiology, Wazirabad Institute of Cardiology, Wazirabad, Pakistan.

Correspondence: M. Nasir Rahman. e-mail: nasir.rahman@aku.edu

ORCID ID: 0000-0002-5988-8708

Submission complete: 15-05-2023 **Review began:** 01-07-2023

Acceptance: 20-07-2024 **Review end:** 08-05-2024

July 1, 2020, to January 1, 2022, at the Aga Khan University Hospital (AKUH), Karachi, and comprised medical records from January 2012 to January 2020 of patients with deferred revascularisation. Data was retrieved after approval from the institutional ethics review committee. Data included was related to patients of either gender aged >18 years having intermediate to severe coronary lesions on coronary angiogram, had negative FFR >0.80 or iFR >0.89 and had not undergone immediate or planned revascularisation on the basis of negative physiological assessment. Patients with severe valvular heart disease, patients on haemodialysis, patients with bronchial asthma, and patients to whom aspirin was contraindicated were excluded. Also, patients who had coronary artery bypass graft (CABG) and prior PCI to the target vessel were excluded.

Data was collected on a predesigned proforma from patient medical record using Health Information Management Service. Data was collected on age, gender, co-morbidities at presentation, mode of hospital presentation, prior history of atrial fibrillation, stroke, myocardial infarction (MI), prior PCI or CABG, coronary angiographic details of the target artery, FFR and iFR details, discharge medications and follow-up. The final follow-up was taken by a review of medical records/telephonic interviews regarding any a major adverse cardiac event (MACE) which occurred after the index procedure i.e. cardiac death, non-fatal myocardial infarction, and target vessel revascularisation (TVR) were noted. Data of patients having positive FFR/iFR values irrespective of revascularisation status was excluded. Similarly, those who were lost to follow-up and could not be traced via telephone were also excluded.

The coronary angiogram had been performed via radial or femoral approach using French sheath.[5-7] After angiographic images, target vessel physiological measurements were performed using 0.014-inch coronary pressure guidewire (Verrata, Philips Volcano, United States). To achieve hyperaemia during FFR measurement, continuous intravenous adenosine 140/mcg/kg/min through large-bore cannula had been administered for 3-4 minutes. The iFR was calculated using an automatic algorithm within the same console. Pre-specified treatment thresholds were 0.89 for iFR and 0.80 for FFR.

Follow-up was performed by reviewing hospital medical charts, hospital admission data, clinic visits and e-mail or telephonic interview with the patient, or, in case of deceased patients, the next of kin. For establishing the cause of death in deceased patients, death certificates were obtained. The clinical events recorded were cardiac death, non-fatal MI and TVR. MI was defined as having typical cardiac symptoms with elevated cardiac enzymes and/or ischaemic electrocardiogram (ECG) changes. TVR was defined as PCI or application of bypass grafts for the lesions with prior negative FFR/iFR.

Data was analysed using Stata version 14.2. For descriptive analysis, mean and standard deviation were calculated for quantitative variables, while frequencies and percentages were computed for qualitative variables. For quantitative variables, an independent t-test was used to compute the difference between the two groups after assessing normality. For inferential analysis, the groups of patients were compared for all their characteristics using the Pearson Chi-square test and Fisher's exact test for qualitative variables. Cox proportional hazard model building was done using a stepwise approach by assessing all the plausible interactions and considering $p<0.05$ statistically significant. MACE, TVR, non-fatal MI and cardiovascular death were analysed with the association of negative and positive iFR, adjusted for other variables. Kaplan-Meier curves of MACE, TVR, non-fatal MI and cardiovascular death with negative and positive FFR or iFR were compared using the log-rank test.

Results

Of the 515 patients who underwent physiological assessment, 345(%) met the inclusion criteria. Of them, 245(71%) were males. The overall mean age was 62±11 years. There were 263(76%) patients with hypertension (HTN), while diabetes mellitus (DM) and dyslipidaemia were present in 169(49%) and 185(53%) patients, respectively. History of myocardial infarction (MI) was present in 43(12%)67(19%) had history of PCI and 12(3%) had undergone CABG. Mean ejection fraction (EF) was 52±10.39% and 31(9%) patients had EF <30%. Overall, 151(44%) patients presented with ACS and 194(56%) with angina pectoris. In the ACS group, 101(67%) presented with non-ST-elevation myocardial infarction (NSTEMI), 41(27%) with unstable angina and 9(6%) with ST elevation MI (STEMI) (Table 1).

Of the coronary lesions studied, 184(53%) were in the left anterior descending (LAD) coronary artery, followed by right coronary artery (RCA) 81(23%) and left circumflex (LCX) artery 54(16%). Mean FFR value was 0.87±0.04 and mean iFR was 0.93±0.03. Multivessel disease (MVD) was present in 223(65%) patients. Mean percentage vessel stenosis was 61±6.45% and moderate and severe stenotic lesions were found in 260(75%) and 85(25%) patients, respectively. Post-physiological coronary assessment revascularisation of other arteries was done by PCI in 140(41%) patients and by CABG in 4(1%). Revascularisation of the similar artery but different lesion was done in 11(3%)

Table-1: Baseline characteristics of the study sample.

Baseline characteristics	**Total** Cohort (n=345) n (%)	**FFR** (n=276) n (%)	**iFR** (n=34) n (%)	**FFR + iFR** (n=35)n (%)	***p*-value**
Mean Age (years)	62±10.79	62±11.05	63±10.23		0.582
Gender Male	245 (71)	191 (69)	28 (82)	26 (74)	0.251
HTN	263 (76)	214 (78)	20 (59)	29 (83)	0.030
Diabetes	169 (49)	131 (47)	17 (50)	21 (60)	0.371
Dyslipidaemia	185 (53)	160 (58)	13 (38)	12 (34)	<0.01
Smoker	60 (17)	45 (16)	10 (29)	5 (14)	0.141
COPD	19 (6)	15 (5)	2 (6)	2 (6)	0.990
CKD	23 (7)	20 (7)	1 (3)	2 (6)	0.610
Prior MI	43 (12)	41 (15)	2 (6)	0	0.021
Prior CABG	12 (3)	9 (3)	1 (3)	2 (6)	0.742
Prior Stroke	12 (3)	9 (3)	1 (3)	2 (6)	0.742
Prior PCI	67 (19)	52 (19)	7 (21)	8 (23)	0.831
History of Atrial fibrillation	12 (3)	9 (3)	2 (6)	1 (3)	0.712
Indication for procedure					
ACS	151 (44)	124 (45)	13 (38)	14 (40)	0.670
CCS I	3(2)	2 (1)	0	0	
CCS II	58 (29)	43 (27)	9 (43)	6 (27)	0.111
CCS III	135 (68)	110 (70)	12 (57)	13 (59)	
CCS IV	4 (2)	2 (1)	0	2 (9)	
Discharge Medications					
Aspirin	338(98)	272(99)	33(97)	33(94)	0.222
Clopidogrel	223(68)	195(71)	14(41)	24(69)	<0.01
Statin	340(99)	272(99)	33(97)	35(100)	0.594
Beta blocker	273(79)	226(82)	25(74)	22(63)	0.020
Calcium channel blocker	74(21)	55(20)	12(35)	7(20%)	0.110
ACE inhibitors/ARBs	137(40)	114(41)	14(41)	9(26)	0.201
Ejection fraction					
EF<30%	31 (9)	24 (9)	6 (17)	1 (3)	0.161
EF<45%	41 (12)	36 (12)	2 (6)	3 (9)	

HTN: Hypertension, COPD: Chronic obstructive pulmonary disorder, CKD: Chronic kidney disease, MI: Myocardial infarction, CABG: Coronary artery bypass graft, ACS: Acute coronary syndrome, CCS: Chronic coronary syndrome, FFR: Fractional flow reserve, iFR: Instantaneous wave-free ratio, ACE: Angiotensin-converting enzyme, ABR: Angiotensin 2 receptor blocker.

patients. The most prescribed medication on discharge were statins 340(99%).

Median follow-up period was 29 months (IQR: 24-36 months). MACE occurred in 22(6%) patients and TVR was required in 11(3%). The predominant MACE was non-fatal MI 20(6%) (Table 3).

MVD was an independent predictor of adverse outcomes (p=0.008) (Table 4). DM and percentage of stenosis were found to be independent predictors (Table 5).

Discussion

The current study investigated the clinical outcomes after deferral of coronary revascularisation (deferred lesions) in patients with negative FFR (>0.80) and iFR (>0.89) in actual patients. The results showed that MACE on follow-up occurred in 6% of the total sample. The independent predictors of MACE on multivariable analysis were DM and percentage of stenosis on visual estimation of coronary angiogram.

The number of MACE patients was higher than a an earlier pooled analysis at one year.[7] Similarly a lower rate of MACE (3.41%) was also reported by S. Prasad et al. at 1.5 years of follow-up.[8] The dominant factor in primary endpoint in the current study was non-fatal MI that in 6% patients. This was unlike a study[7] in which unplanned revascularisation was the biggest contributing factor to MACE. The higher percentage of MACE in the current study was probably due to significant differences in co-morbid conditions as the study had a higher proportion of patients with risk factors, such as HTN, DM, dyslipidaemia and ACS. A higher percentage of MACE in the shape of deferred target lesion failure (DTLF) (7.3%, 18% and 9.5%) similar to the current study has also been reported,[9-11] this could be explained by similar long-term follow-up ranging from 3 years to 4.5 years.

In Asian studies, two-year incidence of TVR was 5.5% in a registry which enrolled patients from 28 centres in Japan. A considerably higher 5-year Kaplan Meir-estimated revascularisation rate of 16% was reported in China.[12] In the current study, this was reported in 3% which was an observation similar to a study in Japan.[13]

Studies done previously did not report significant differences in event rate based on clinical presentation with ACS or stable coronary artery disease (CAD)[9,10,14] which was consistent with the current findings, and could be explained by higher population in the non-ACS group in the current study. On the contrary, several other recent studies reported a higher DTLF or MACE rate for patients presenting with ACS.[7,11,15] Differences in event rate between FFR or iFR based deferral were reported by a study, with patients in whom iFR-guided deferral was performed having had significantly lower event rates than those with FFR-guided deferral in LAD lesions,[16] whereas no such discrepancy was reported by Escaned et al.[7] which was in line with the current findings.

In a South Korean registry,[17] univariate analysis found previous PCI, ACS, left ventricular ejection fraction (LVEF), LAD and DM to be independent predictors of MACE at 3 years, while on multivariate analysis, only previous PCI and ACS were statistically significant. In comparison, DM, MVD and severity of stenosis on angiographic visualisation were predictors of MACE on univariate analysis, while DM and severity of stenosis were significant with multivariate

analysis. These findings are similar to an earlier study[18] which reported FFR, thrombus-containing lesion, multivessel coronary artery and diameter stenosis being independent predictors of MACE.

Table-2: Angiographic and procedural characteristics of the patients.

Angiographic findings and revascularisation	Total	FFR	iFR	FFR+iFR	*p*-value
Percentage stenosis:					
Moderate stenosis	260 (75)	209 (76)	26 (76)	15 (71)	0.622
(50-69%)			7.53	4.34	
Severe stenosis (>70%)	85 (25)	67 (24)	8 (24)	10 (29)	
Target artery					
LM	6(2)	4(1)	0	2(6)	0.080
LAD	184(53)	152(55)	12(35)	20(57)	
LCX	54(16)	42(15)	8(24)	4(11)	
RCA	81(23)	62(22)	13(38)	6(17)	
Diagonal	3(1)	2(0.7)	0	1(3)	
OM	7(2)	7(8)	0	0	
Ramus	8(2)	6(2)	0	2(6)	
RPDA	2(1)	1(0.3)	1(3)	0	
Multivessel disease	223 (65)	180 (65)	22 (65)	21 (60)	0.831
Post physiological assessment intervention					
PCI of different lesion in FFR measured artery	11(3)	9(3)	1(3)	1(3%)	0.231
PCI only to FFR non-measured lesion	140(41)	119(43)	10(29)	9(26)	
CABG	4(1)	3(1)	0	1(3)	
PCI of different lesion in FFR measured artery and non-measured artery	10(3)	6(2)	3(9)	0	

FFR: Fractional flow reserve, iFR: Instantaneous wave-free ratio, LM: Left main, LAD: Left anterior descending, LCX: Left circumflex artery, RCA: Right coronary artery, OM: Obtuse marginal, RPDA: Right posterior descending artery, PCI: Percutaneous coronary intervention, CABG: Coronary artery bypass graft.

Table-3: Clinical events on follow-up [n (%)].

Clinical events	Total	FFR	iFR	FFR and iFR	*p*-value
MACE	22 (6)	20 (7)	1 (3)	1 (3)	0.411
Cardiac death	1 (0.3)	1 (0.4)	0	0	0.882
Non-fatal MI	20 (6)	18 (7)	1 (3)	1 (3)	0.513
Target lesion revascularisation	11 (3)	11 (4)	0	0	0.242

FFR: Fractional flow reserve, iFR: Instantaneous wave-free ratio, MACE: Major adverse cardiovascular events, MI: myocardial infarction.

Table-4: Univariate analysis of major adverse cardiac events (MACE).

	MACE- [n (%)]	**MACE+** [n (%)]	*p*-value
ACS	142/151(94.04)	9/151(5.96)	0.780
Non-ACS	181/194(93.3)	13/194(6.70)	
DM+	153/169(90.53)	16/169(9.47)	0.021
DM-	170/176(96.59)	6/176(3.41)	
MVD+	203/223(91.03)	20/223(8.97)	0.008
MVD-	120/122(98.36)	2/122(1.64)	

ACS: Acute coronary syndrome, DM: Diabetes mellitus, MVD: Multivessel disease.

Table-5: Multivariate analysis of major cardiac events (MACE).-

Variable	Hazard Ratio	*p*-value	95% CI Interval
Diabetes	2.98	0.002	1.42-6.24
Percentage stenosis	1.07	0.018	1.01-1.13

CI: Confidence interval.

The current study had limitations. First, this was a retrospective observational single-centre study. Therefore, the decision of whether or not to measure FFR was based on operator preference, and selection bias may have been present. Second, follow-up angiography was not performed except when clinically indicated. Therefore, clinically silent lesion progression could not be evaluated. Also it was difficult to do indexed case tracing and response from patients enrolled in earlier years of study. This, along with comparatively smaller sample, reduced the statistical power and strength of the findings. A number of studies have demonstrated the importance of location of the lesion. Revascularisation deferred based on FFR and iFR in proximal lesion is associated with more adverse outcomes than the distal lesions.[3-5,7] This was not assessed in the current study. Besides, FFR pull-back data was not available in the study which had to rely solely on absolute FFR for analysis. Another limitation was that clinical outcomes in cases of discordant results between FFR and iFR were not evaluated. Lee et al.[19] reported that discrepancy was not associated with increases risk of MACE.

Prospective comparative studies with large sample size are required to validate the current findings and investigate the predictors of future coronary events in deferred versus revascularised lesions.

Conclusion

In routine cardiac catheterisation lab practice, physiological assessment of the lesion by FFR and iFR was found to have paramount importance, particularly when stratifying for clinical outcomes. Deferral of revascularisation and opting for medical treatment for coronary artery stenosis with higher FFR and iFR values can be considered a safe and reasonable strategy. Therefore, in addition to a visual estimate, FFR and/or iFR should be considered a clinical prognostic index to identify flow-limiting stenosis. However, whether or not intermediate coronary lesions can be safely deferred based on FFR or iFR requires further evaluation in Pakistani population.

Acknowledgements: We are grateful to Dr Ihsanullah Dawlat, Dr Awais Farhad and Maria Khan for facilitating the study.

Disclaimer: The text was presented as an Abstract at the 11th Annual Emirates Cardiac Society Conference.

Conflict of Interest: None.

Source of Funding: None.

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Author Contribution:

MNR: Study concept, design, data analysis and drafting.
JA: Literature search, data collection, analysis, interpretation and drafting.
SS: Data analysis, interpretation and drafting.
GA: Data collection, analysis and drafting.