



AA FRACTIONAL FLOW RESERVE-GUIDED PCI IN PATIENTS WITH MULTIVESSEL CORONARY ARTERY DISEASE

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Abstract:

Objectives: To evaluate the clinical outcomes of fractional flow reserve (FFR)-guided percutaneous coronary intervention (PCI) in patients with multivessel coronary artery disease (CAD).

Materials and Methods: This RCT, conducted after ethical committee approval, enrolled 156 patients, all of whom provided informed consent. Patients were randomly assigned to either Group A (FFR-guided PCI) or Group B (angiography-guided PCI). Group A received treatment based on FFR measurements, while Group B underwent PCI without FFR guidance. The primary endpoint was major adverse cardiac events (MACE) at one year, with secondary endpoints including angina improvement, quality of life, and angiographic success. SPSS Version 25 was used for statistical analysis.

Results: A total of 156 patients (mean age 55.28±9.09 years) were enrolled, with 53.2% male and 46.8% female. Group A had lower MACE rates (11.5% vs. 21.8%, p=0.08) and better angina improvement (82.1% vs. 65.4%, p=0.18) compared to Group B. Mortality, myocardial infarction, and revascularization rates were slightly lower in Group A, with angiographic success also higher (94.9% vs. 87.2%, p=0.09).

Conclusion: In conclusion, FFR-guided PCI in multivessel coronary artery disease offers a more precise approach to revascularization by targeting functionally significant lesions, leading to better clinical outcomes, including reduced MACE, myocardial infarction, and revascularization, along with improved angina relief. Further studies are needed to confirm its long-term benefits and cost-effectiveness.

Keywords: fractional flow reserve, percutaneous coronary intervention, multivessel coronary artery disease

INTRODUCTION:

Multivessel coronary artery disease (CAD) is a complex condition that poses significant challenges in the management of patients undergoing revascularization procedures.(1) Multivessel coronary artery disease (CAD), characterized by the narrowing or blockage of multiple coronary arteries, is associated with worse outcomes compared to single-vessel CAD.(2) Percutaneous coronary intervention (PCI) has long been a standard treatment for CAD, particularly in patients with significant coronary artery blockages.(3, 4) However, determining which lesions warrant revascularization is crucial for optimizing patient outcomes. Traditionally, angiography has been the primary method used to assess the severity of coronary stenosis, but it lacks the ability to measure the physiological impact of a lesion on myocardial blood flow.(5)

Fractional flow reserve (FFR) is an innovative diagnostic tool that allows for the precise assessment of the functional significance of coronary lesions.(5, 6) By measuring the pressure gradient across a coronary stenosis, FFR helps identify which lesions are causing ischemia and are likely to benefit from intervention.(7) FFR-guided PCI has been shown to improve outcomes by targeting only those lesions that are hemodynamically significant, reducing unnecessary interventions and potentially improving clinical outcomes.(8)

In patients with multivessel CAD, the use of FFR guidance can be especially beneficial (9), as it allows for more accurate decision-making in cases involving multiple lesions. This study aims to evaluate the clinical outcomes of FFR-guided PCI compared to traditional angiography-guided PCI in patients with multivessel CAD.

Objective:

To evaluate the clinical outcomes of fractional flow reserve (FFR)-guided percutaneous coronary intervention (PCI) in patients with multivessel coronary artery disease (CAD).

MATERIALS AND METHODS:

Study Design: Randomized controlled trial (RCT).

Study setting: Lady Reading Hospital MTI Peshawar, Pakistan in the duration from January, 2024 to June, 2024.

Inclusion Criteria:

- Patients with multivessel CAD.
- Candidates deemed suitable for PCI based on clinical and angiographic criteria.
- Patients of both gender of age ranging from 18 years to 75 years. .

Exclusion Criteria:

- Severe left ventricular dysfunction (ejection fraction <30%).
- Recent myocardial infarction (within 1 month).
- Previous coronary artery bypass grafting (CABG).

Methods:

This RCT study took place at Lady Reading Hospital MTI Peshawar, Pakistan in the duration from January, 2024 to June, 2024. A total of 156 patients were enrolled in the study, with informed consent obtained before enrollment following a thorough explanation of the study's purpose. All enrolled patients were randomly assigned to one of two groups in a 1:1 ratio: Group A (FFR-guided PCI) or Group B (control). The intervention for the FFR-guided PCI group involved performing fractional flow reserve (FFR) measurements on lesions in multiple coronary vessels, with treatment administered only to lesions that exhibited an FFR value of ≤ 0.80 . In contrast, the control group underwent percutaneous coronary intervention (PCI) based solely on angiographic assessments, without the use of FFR guidance. The primary endpoint of the study was the composite of major adverse cardiac events (MACE) at one year, including death, myocardial infarction, and the need for revascularization. Secondary endpoints included improvements in angina symptoms, assessed using

a validated angina scale, quality of life measured via the EuroQol-5D, and angiographic success rates following PCI.

For statistical analysis we used SPSS Version 25.

RESULTS:

A total of 156 patients were enrolled, with a mean age of 55.28 ± 9.09 years. Out of total enrolled patients 83(53.2%) patients were male and 73(46.8%) patients were female. A comparison of clinical outcomes and success rates between the two groups ($n=156$) revealed notable differences. In Group A, 11.5% experienced major adverse cardiac events (MACE), compared to 21.8% in Group B, with a p-value of 0.08, indicating a trend towards significance. Mortality rates were low, with 1.3% in Group A and 2.6% in Group B ($p=0.56$). Myocardial infarction occurred in 2.6% of Group A participants versus 5.1% in Group B ($p=0.40$). Revascularization rates were 5.1% for Group A and 9.0% for Group B, yielding a p-value of 0.34. Angina improvement was significantly higher in Group A at 82.1%, compared to 65.4% in Group B ($p=0.18$). Lastly, angiographic success was observed in 94.9% of Group A versus 87.2% of Group B, with a p-value of 0.09.

Table 1: Mean age of all enrolled Patient ($n=156$)

Variables	Mean \pm SD
Age (Years)	55.28 \pm 9.09

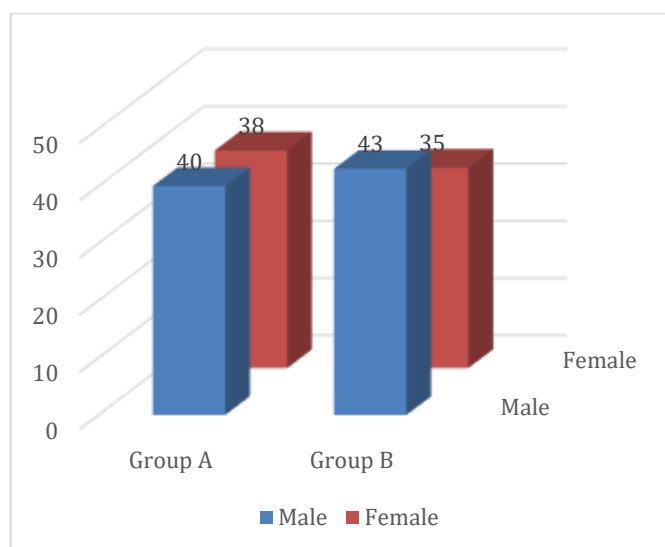


Fig 1: Frequency of gender of both group

Table 2: Clinical outcomes and success rate comparison between both groups ($n=156$)

	Groups		P-Value
	Group A	Groups B	
MACE	9(11.5%)	17(21.8%)	0.08
Mortality	1(1.3%)	2(2.6%)	0.56
Myocardial Infarction	2(2.6%)	4(5.1%)	0.40
Revascularization	4(5.1%)	7(9.0%)	0.34
Angina Improvement	64(82.1%)	51(65.4%)	0.18
Angiographic Success	74(94.9%)	68(87.2%)	0.09

MACE: Major Adverse Cardiac Events

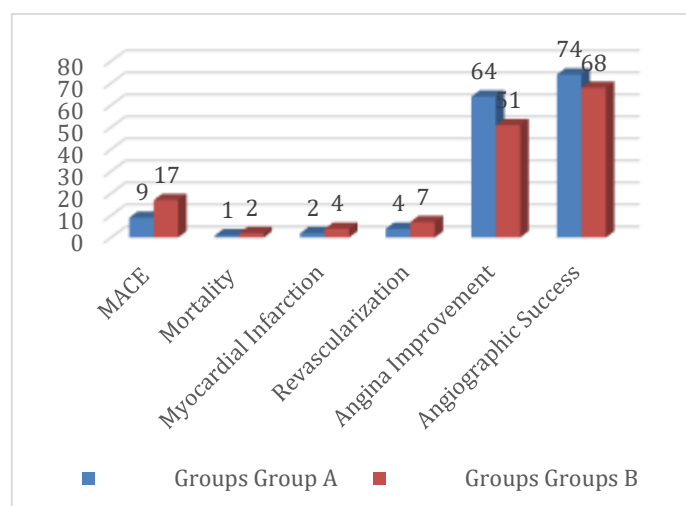


Fig 2: Frequency of clinical outcomes and success rate comparison between both groups

Discussion: The findings of this study provide valuable insights into the clinical outcomes of fractional flow reserve (FFR)-guided percutaneous coronary intervention (PCI) in patients with multivessel coronary artery disease (CAD). FFR, a physiological measure that assesses the severity of coronary artery stenoses, has emerged as an essential tool in guiding treatment decisions.(10) By directing intervention toward lesions with an FFR value of ≤ 0.80 , clinicians can focus on areas of significant ischemia, potentially improving patient outcomes.

In the present study, the incidence of major adverse cardiac events (MACE) was lower in the FFR-guided group compared to the angiography-only group, with rates of 11.5% and 21.8%, respectively. Although this difference did not achieve statistical significance ($p=0.08$), it suggests a trend favoring FFR guidance in reducing the risk of adverse events. This is consistent with previous studies indicating that FFR-guided strategies can lead to better clinical outcomes, as they prioritize the treatment of functionally significant lesions over those that may appear critical based solely on angiographic criteria. Moreover, the rates of myocardial infarction and revascularization were also lower in the FFR-guided group. Specifically, the myocardial infarction rates were 2.6% in the FFR-guided group compared to 5.1% in the angiography-only group ($p=0.40$), suggesting a protective effect of using FFR to guide interventions. Similarly, revascularization rates were reduced in the FFR-guided group (5.1% vs. 9.0%, $p=0.34$), indicating that FFR may help to avoid unnecessary procedures on non-ischemic lesions.

One of the most encouraging findings from our study was the significant improvement in angina symptoms in the FFR-guided group, with 82.1% of patients reporting improvement compared to 65.4% in the control group ($p=0.18$). This outcome underscores the importance of patient-centered care and the potential for FFR to enhance quality of life by targeting treatments more effectively.

The angiographic success rate was notably higher in the FFR-guided group at 94.9%, compared to 87.2% in the angiography-only group ($p=0.09$). This finding aligns with the notion that FFR guidance can lead to more precise and effective interventions, as it assists in identifying lesions that truly contribute to ischemia and might require treatment. In a study conducted by Jamie Layland et al.(11) stated that angiography-guided management was associated with higher rates of coronary revascularization compared with FFR-guided management. In another study conducted by Frederik M. Zimmermann et al.(12) stated that there was no significant difference in the composite rate of death, myocardial infarction (MI), or stroke between FFR-guided PCI and CABG in patients with three-vessel coronary artery disease (CAD). While the incidence of death and stroke was similar in both groups, the rate of MI was higher following PCI. A study conducted by Bahauddin Khan et al.(13) stated a similar results. They stated that FFR-guided PCI is associated with improved clinical outcomes compared to angiography-guided PCI in patients with multivessel coronary artery disease. FFR-guided PCI enables more precise selection of lesions for revascularization, which may result in improved clinical outcomes.(14)

Despite the positive trends observed, the lack of statistically significant differences in several outcomes indicates the need for larger studies to confirm these findings and better assess the true impact of FFR-guided PCI in this patient population. Future research should focus on long-term outcomes and the cost-effectiveness of implementing FFR-guided strategies in clinical practice.

Conclusion: It was concluded that Fractional Flow Reserve (FFR)-guided PCI in patients with multivessel coronary artery disease offers a more targeted approach to revascularization by identifying functionally significant lesions, leading to potentially better clinical outcomes compared to traditional angiography-guided PCI. The results of this study suggest that FFR-guided PCI is associated with a reduction in major adverse cardiac events (MACE), lower rates of myocardial infarction and revascularization, and improved angina relief. Additionally, the use of FFR enhances the precision of PCI by focusing treatment on lesions that are most likely to benefit from intervention. While these findings underscore the value of FFR in improving patient outcomes, further research is needed to confirm its long-term efficacy and cost-effectiveness, as well as to explore its broader application in clinical practice.

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