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Assessment of Diffusely Diseased Coronary Artery by Instantaneous Wave-Free Ratio Co-Registration versus Quantitative Coronary Angiography

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Abstract

Purpose: Coronary physiological assessment is now routinely applied in the catheter laboratory to guide percutaneous coronary intervention (PCI). Currently most physiological assessment is performed in a binary manner to determine whether a vessel requires intervention. Although studies have reported the high diagnostic efficiency of physiological assessment in minimizing the number of vessels requiring treatment, it is widely recognized that interrogation of individual stenosis in the presence of tandem lesions or diffuse disease under hyperemic conditions makes PCI planning complex and less practical. The aim of this study was to perform assessment of severity of coronary lesions of a pressure guide wire with continuous instantaneous wave-free ratio (iFR) co-registration measurement compared coronary angiography and quantitative coronary analysis (QCA) aiming to minimize the procedure, decrease number and length of stents used.

Methodology: This non randomized controlled trial was conducted at Cardiology Department, Benha University, National Heart Institute (NHI) from February 2020 to September 2022. The study included a group of 30 patients presented with diffuse coronary artery disease and undergoing elective PCI.

Findings: The study found out that the distribution of risk factors among studied groups was HTN representing 54%, regarding DM 60%, concerning dyslipidemia 64% and smokers represented 57%. The median of expected length of stent using QCA assessment was 40.2 mm with standard deviation (SD) (8mm) higher than detected actually deployed by iFR co-registration. The mean length of stents used by IFR co-registration was 20.2 mm stents (SD: 11.2 mm) and P-value was 0.0000. Also, all patients needed stent via QCA while only 86% actually need stent application via iFR co-registration assessment, leading to a fewer stents placed per patient. The difference was statistically significant $p<0.0022$. This study demonstrates that iFR co-registration performed under resting conditions predicted the physiological outcome of PCI with a high degree of accuracy. Compared with QCA, iFR co-registration significantly decreased the number and length of hemodynamically significant lesions identified for revascularization.

Recommendation: iFR co-registration should be performed under resting conditions to predict the physiological outcome of PCI with a high degree of accuracy

Keywords: *Diffusely diseased coronary artery, instantaneous wave-free ratio co-registration, quantitative coronary angiography*

1.0 INTRODUCTION

Instantaneous wave-free ratio (iFR) is used as an index of stenosis severity that is measured at rest using conventional pressure wires. iFR is calculated as the ratio of distal coronary pressure to proximal aortic pressure over a specific period in diastole known as the wave-free period. Many studies demonstrated the efficacy of iFR in coronary revascularization like Nijjer et al. (1) (Pre-angioplasty instantaneous wave-free ratio pullback provides virtual intervention and predicts hemodynamic outcome for serial lesions and diffuse coronary artery), Kikuta et al. (2) (Pre-angioplasty instantaneous wave-free ratio pullback predicts hemodynamic outcome in humans with coronary artery disease), Younus, et al., (3) (Clinical Outcomes Data for Instantaneous Wave-Free Ratio-Guided Percutaneous Coronary Intervention), DEFINE (Functional Lesion Assessment of Intermediate Stenosis to Guide Revascularization) (4), iFR-GRADIENT (Pre-Angioplasty Instantaneous Wave-Free Ratio Pullback Predicts Hemodynamic Outcome In Humans With Coronary Artery Disease) (2)

DEFINE GPS study (global multicenter study to assess superiority of PCI procedures guided by co-registered iFR and interventional angiography) (5) and iLARDI study (Usefulness of the Use of Co-registration Strategy With iFR in Long and/or Diffuse Coronary Lesions) were started to demonstrate the value of applying iFR co-registration in coronary revascularization compared to interventional angiography, its results aren't published up till now (6)

The aim of this work was to compare data from Quantitative coronary angiography (QCA) Versus Instantaneous wave-free ratio (iFR) co-registration in diffuse coronary artery disease.

2.0 METHODS

2.1 Study Design

This is a non-randomized controlled trial conducted in the cardiology department, Benha University, and the National Heart Institute. The sample size was 30 patients. The inclusion criteria was patients undergoing elective PCI with coronary artery showing multi lesions. The exclusion criteria was patients with acute MI, simple obstructive (apparently >90%) and non-obstructive coronary artery lesion (apparently <40%), chronic total occlusion (CTO), LM lesions, small vessel disease less than 2 mm diameters, and myocardial bridge

2.2 Tools and Instruments

1) Cath. Lab

2) iFR pressure wires

2.3 Steps of Performance and Techniques used

1. Complete history taking including age, sex, and special habits, present and past medical history to determine risk factors for CAD as hypertension, Diabetes mellitus, smoking, dyslipidemia, obesity, stress, positive family history for ischemic heart disease.

2. ECG, Echocardiography

3. Coronary angiography

4. QCA and iFR co-registration study in diffuse coronary artery disease

5. Decision making and PCI if needed

2.4 Study's End Point

1. Number of stents
2. Length of stents

2.5 Statistical Analysis

Continuous variables with a normal distribution are expressed as mean ± standard deviation (SD), those with a non-normal distribution as median (inter-quartile range [IQR]). Dichotomous data are expressed as numbers and percentages. To compare numerical data between different groups paired Student's t test, analysis of variance (ANOVA), Mann—Whitney and Kruskal—Wallis tests were used as appropriate. Nominal variables were compared using either the 2 or Fisher tests.

3.0 RESULTS

The mean age of all studied patients was 55.2±10.9 years with range (29-75). Almost equal distribution between male and female was noticed. There were 17 males participating in the study representing 57%. The females were 13 representing 43% of the sample.

Table 1: Demographic data

Variables	Studied group (n=40)
Age per year	55.2±10.9
Mean ±SD	29 -75
Range	
Sex	
Females	17(57%)
Males	13(43%)

The studied group have showed the following risk profile. Hypertension was evident in 16 patients representing 54% of the study population. Out of the total studied group, 19 patients representing 60% admitted to be diabetics. Dyslipidemia was declared by 20 patients representing around 64% of the sample. Additionally, 57% of the sample (18 patients) were smokers.

Table 2: Risk factors

Risk factors	Yes		No	
	N	%	N	%
DM	18	60	12	40
Dyslipidemia	19	64	11	36
HTN	16	54	14	46
Smoking	17	57	13	43

The study was done at national heart institute cath lab, only the patients recruited were presented on elective bases. Patients with ACS were excluded from the study. Phillips equipped cath lab AUZurion 7, using QCA and IFR co-regestration were used in all the patients. There were no complications among the studied group regarding variables as myocardial infarction

coronary dissection, arrhythmia, bleeding, stent thrombosis. There was a highly statistically significant difference regarding the total length of stents by the QCA and IFR co-registration. The mean length of stents deployed based on QCA was 40.2 mm stents (SD: 8 mm). The mean length of stents used by IFR co-registration was 20.2 mm stents (SD: 11.2 mm). P value was 0.0000 as shown in table 3.

Table 3: Length of stent by QCA compared by iFR co-registration by t test

Variable	Sample	Mean	SD	95% confidence interval	
Stent length by QCA	30	40.2	8.0	37.2	43.1
Stent length by IFR co registration	30	30.2	11.2	16.07	24.4
P value	0.000001				

The number of stents deployed based on IFR co-registration were significantly less than the number of stents expected to be used by QCA. The mean number of stents deployed by IFR co-registration was 0.8 per patient (SD: 0.34). The mean number of stents expected by QCA was 1.1 stent per patient (SD: 0.37), p-Value: 0.0022 as shown in table 4.

Table (4): number of stent by QCA compared by iFR co-registration

Variable	Sample	Mean	SD	95% confidence interval	
Number by QCA	30	1.16	0.37	1.02	1.3
Number by IFR co-registration	30	0.86	0.34	0.737	t\0.995
P value	0.0022				

4.0 DISCUSSION

In the present study, the mean age of all studied patients was 55.2±10.9 years with range (29-75), 17of them males (57%). This came in agreement with Nijjer et al. (1) who found that from a total of 32 coronary arteries in 29 patients (69% male, 64 years of age) undergoing elective coronary intervention were prospectively assessed. Matching with results from this study, Kikuta et al. (2) found that a total of 159 patients (81% male, 67 years of age) with 168 coronary vessels eligible for PCI were prospectively enrolled. In the current study, the distribution of risk factors among studied groups; HTN representing 54%, regarding DM 60%, concerning dyslipidemia 64% and smokers represented 57%.

Nijjer et al. (1) found that 76% of the patients had HTN, 28% had diabetes, 83% had dyslipidemia, and 38% were smokers. Kikuta et al. (2) found that 76% of patients had HTN, 40% had diabetes, 75% had dyslipidemia and 23% were smokers. In the current study, the median of expected length of stent using QCA assessment was 40.2 mm with standard deviation (SD) (8mm). This was higher than the total length of stents actually deployed by iFR co-registration. The mean length of stents used by IFR co-registration was 20.2 mm stents (SD: 11.2 mm, P value: 0.0000). In agreement with this study, Kikuta et al. (2) found that the

availability of iFR pullback data decreased the total lesion length identified for revascularization from 31.3±1.3 mm after angiography alone to 26.9±1.3 mm after iFR pullback ($p < 0.0001$ for difference). Disagreement between total lesion length identified by angiography alone and iFR pullback occurred in 118 patients (74%) in 121 vessels (72%).

Also, all patients needed stent via QCA while only 86% actually need stent application via iFR co-registration assessment, leading to a fewer stents placed per patient. The difference was statistically significant $p<0.0022$. This came in agreement with Younus, et al., (3), who found that there were significantly fewer hemodynamically significant lesions as assessed by iFR, leading to a fewer stents placed per patient. DEFINE-REAL study, confirmed in a clinical observational study, that the ease of iFR measurement facilitates and encourages the measurement of multiple vessels. And also, iFR-GRADIENT showed there was a significant decrease in the number and length of hemodynamically significant lesions planned for revascularization (2).

Also, Kikuta et al. (2) demonstrates in their multicenter registry study that online iFR performed under resting conditions predicted the physiological outcome of PCI with a high degree of accuracy. They found that compared with angiography alone, availability of iFR pullback data significantly decreased the number and length of hemodynamically significant lesions identified for revascularization. Overall, revascularization procedural planning was altered in nearly one-third of patients. Park et al. (7) and Kim et al. (8) found that before physical PCI is commenced, iFR pullback data can inform the clinician whether their proposed strategy will improve coronary physiology sufficiently to achieve a physiologically favorable outcome.

The authors expand their observations to potential future applications; a manual pressure wire pullback with angiographic coregistration technology that allows physiological intensity of coronary artery disease to be displayed, potentially simplifying interpretation of pullback data and, hence, clinical decision making. The study confirmed that the use of iFR co-registration modality in revascularization especially in diffusely disease vessel will significantly reduce number and length of stents

5.0 CONCLUSION

iFR co-registration is a feasible technique that can provide a physiological map of the entire coronary vessel, measure physiological stenosis length, and predict The outcome of stenting in tandem or sequential stenosis. This study demonstrates that iFR co-registration performed under resting conditions predicted the physiological outcome of PCI with a high degree of accuracy. Compared with QCA, iFR co-registration significantly Decreased the number and length of hemodynamically significant lesions identified for revascularization.

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