Ahmed et al., Int J Cardiovasc Res 2018, 7:4
DOI: 10.4172/2324-8602.1000388

International Journal of Cardiovascular Research

Research Article

A SCITECHNOL JOURNAL

Quantitative Coronary Angiography for Assessment of Non-Obstructive Coronary Artery Disease: Comparison to Fractional Flow Reserve

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Abstract

Objective: To assess intermediate coronary artery lesions by 2D and 3D Quantitative Coronary Angiography (QCA) and compare the results with standard fractional flow reserve (FFR).

Background: FFR is the standard for assessment of physiological significance of an intermediate coronary stenosis, but it expensive, sometimes it is unavailable, or limited use by contraindications to adenosine, QCA especially three-dimensional (3D-QCA) can be used as another method to help in assessment of the intermediate coronary lesions.

Patients and methods: Thirty two vessels in 30 patients with intermediate coronary lesions were scheduled for FFR, 2D and 3D QCA measurement and the results of QCA were compared and correlated to the obtained from FFR. Results: The studied group included 32 vessels, 24 diabetic patients (75%). 18 hypertensive (56.3%). 20 smokers (62.5%). Mean FFR value was 0.80 ± 0.13. FFR? 0.80 was observed in 18 lesions (56.25%). Lesions severity obtained by 3D-QCA was better correlated to FFR than 2D-QCA. Both 3D area stenosis percent and 3D diameter stenosis percent have comparable correlation in term of accuracy but with better sensitivity for the percent diameter stenosis. 2D-QCA measurements were less correlated to FFR.

Conclusion: 3D QCA is better than 2D QCA in assessment of intermediate coronary lesions and it is better correlated with FFR so it may be used in assessment of intermediate coronary lesions, when FFR is unavailable or contraindicated. Key words: Quantitative Coronary Angiography (QCA), Fractional Flow Reserve (FFR), Intermediate coronary lesions, Functional severity of coronary stenosis.

Keywords

Quantitative coronary angiography (QCA); Fractional flow reserve (FFR); Intermediate coronary lesions; Functional severity of coronary stenosis

Introduction

The presence of ischemic myocardium is a significant risk factor for unfavorable clinical outcome. Revascularization of obstructive coronary lesions that induce ischemia can improve a patient's functional condition and outcome [1]. For lesions with stenosis that do not induce ischemia, however, the beneficial result of revascularization is less clear, and pharmacological therapy alone is likely to be effective [2]. With the invention of drug-eluting stents (DES), the number of patients with multi-vessel coronary artery disease in whom invasive percutaneous coronary intervention (PCI) is performed has progressively increased [3]. However, in patients with multi-vessel coronary artery disease (MVD), determining which lesions cause ischemia and deserve stenting can be challenging 9 (Table 1).

Noninvasive stress imaging studies has limited ability to accurately confine ischemia-producing lesions in these patients [4]. Although coronary angiography may underestimates/overestimates a lesion's functional severity, it is still the standard technique to guide PCI in patients with MVD [5]. Fractional flow reserve (FFR) is a guide of the physiological significance of a coronary stenosis and is defined as the ratio of maximal blood flow in a stenotic artery to normal maximal flow [6]. It can be assessed during coronary angiography by calculating the ratio of distal coronary pressure measured with a coronary pressure guide wire to aortic pressure measured simultaneously with the guiding catheter. FFR in a normal coronary artery equals 1.0. An FFR value of 0.80 or less identifies ischemia-causing coronary stenosis with an accuracy of more than 90% [6,7] (Table 2). The data provided by FFR is similar to that gained with myocardial perfusion studies, but it is more specific and has a better spatial resolution, because each artery or segment is separately analyzed [4,8] Deferring PCI in non-significant stenotic lesions as assessed by FFR is associated with an annual rate of death or myocardial infarction of approximately 1% in patients with single-vessel coronary artery disease, which is lower

Table 1: Personal and clinical data of the studied group.

Personal data	Total studied group N=32	
Age mean ± SD	60.8 ± 6.9	
Sex	NO	%
Male/Female	24/8	75%/25%
DM	24	75%
HTN	18	56.3%
Smoker	20	62.5%
HDL	32.8 ± 6.3	
LDL	128.6 ± 35.2	

Table 2: Coronary stenosis assessment by FFR vs. area stenosis% and diameter stenosis% seen by 2D angiography.

Personal data	FFR assessment	
2D assessment of area stenosis%	Diseased	Not diseased
Positive	(a) 10	(b) 10
Negative	(c) 8	(d) 4
2D assessment of diameter stenosis%	(a) 10	(b) 6
Positive Negative	(c) 8	(d) 8
a=True positive cases b=False positive c=False negative d=True negative		

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Received: August 24, 2018 **Accepted:** September 13, 2018 **Published:** September 18, 2018

in comparison to the rate after routine stenting [2] On the other hand, the deferring PCI in lesions with an FFR of less than 0.75 to 0.80 may lead to worse outcomes than those who do revascularization [9] Retrospective studies suggest that in patients with multi-vessel coronary artery disease, FFR-guided PCI is associated with a favorable outcome with respect to event-free survival [10] QCA can be used as another method to help assessment of the intermediate coronary lesions.

Three-dimensional quantitative coronary angiography (3D-QCA) uses standard images acquired during routine coronary angiography to reconstruct a 3D model of a coronary artery by fusing two or more orthogonal angiographic images. 3D-QCA reportedly allows a more accurate representation of true vessel geometry when compared with standard two-dimensional (2D) QCA in phantom models [11] and has been tested against intravascular ultrasound (IVUS) [12] Although IVUS currently provided the most accurate measurements of vessel geometry and lesion severity [13] 3D-QCA measurements can be obtained by using the existing standard coronary angiography images without the need for additional time or equipment during the procedure [14].

The aim of this study is to compare the result of QCA with the results of FFR in assessment of intermediate coronary lesion (Table 3).

Patients and Methods

The study prospectively included 34 patients performing percutaneous coronary angiography with/without revascularization due to known or suspected coronary artery disease in International Medical Center (IMC, Cairo) during the period between May 2015 and December 2016. All patients had intermediate coronary artery disease that can be managed both medically and by revascularization, so the ischemic objective evidence is needed to justify treatment method and help decision making for either PCI or medical treatment [15].

Exclusion criteria

Patient were excluded if they have any of the following: Serial stenosis that may complicate the measurement of FFR, as in diffusely diseased vessels or successive nearby stenosis, to the extent that no adequate healthy area where the pressure wire sensor can be advanced to it, lesions with known infarction in the target vessel territory (because microvascular perturbations from myocardial infarction cause discordance between the FFR and angiographic stenosis severity), left main coronary stenosis (due to differences between the severity left main stenosis and functional significance).

Some mild insignificant lesions in coronaries may be functionally significant if it occurs with the same percentage of stenosis in left main and myocardial bridge, as this not a true atherosclerotic lesion and medical treatment is the treatment of option. All patients had provided informed consent and all were subjected to full history taken, thorough clinical examination, ECG and routine laboratory testing (CBC, renal function and lipid profile).

Coronary angiography

Diagnostic coronary angiography using the routine angiographic projections, in addition to dedicated projections if needed. Assessment of non-obstructive coronary lesions by 2D-QCA. An image that shows the specified coronary vessel with least lesion foreshortening is chosen. After calibration of the used catheter, drawing a line into the vessel, starting from before the lesion and ending after it including the lesion itself (from healthy to healthy).

Assessment of non-obstructive coronary lesions by 3D quantitative coronary angiography

The machine is set to 3D mode and the patient position adjusted midway between the C-arm ends with insuring that the C-arm has a clear filed of moving with no obstacles. 20 ml of contrast agent in the lower lock syringe should be ready for injection (Table 4).

For both 2D and 3D the reference vessel diameter, minimal luminal diameter, percent of diameter stenosis, minimal luminal area, and percent of area stenosis, and lesion length are calculated automatically. Assessment of the same lesions by fractional flow reserve: The pressure wire (PW) is opened in a sterile technique and its distal end (two types of pressure wires are commercially available; Volcano Corporation (San Diego, Calif) and St Jude Medical, Inc (St.

Paul, Minn) is connected to a set/analyzer that displays the intracoronary pressure, aortic pressure and can measure the pressure distal to the lesion (Pd)/pressure proximal to the lesion (which is same the aortic pressure) (Pa). Once the sensor of the PW is distal to the stenosis, a hyperemic stimulus is administered by injection through the guide catheter, and the FFR is monitored for a significant change. To achieve maximum hyperemia, adenosine is typically used: a 100 µg bolus in the right coronary artery, a 200 µg bolus in the left coronary artery.

Table 3: Validity of 2D angiography to diagnose coronary stenosis according to percent of area stenosis.

	AUC	P value	Sensitivity	Specificity	Accuracy	PPV	NPP
Area by 2D angiography	0.421	0.597	56%	29%	44%	55%	33%

Table 4: Validity of 2D angiography to diagnose coronary stenosis according to percent of diameter stenosis.

	AUC	P value	Sensitivity	Specificity	Accuracy	PPV	NPP
Diameter by 2D angiography	0.492	0.958	56%	57%	56%	63%	50%

Table 5: Coronary stenosis assessment by FFR vs. area stenosis% and diameter stenosis% seen by 3D angiography.

Personal data	FFR assessment	
3D assessment of area stenosis% Positive Negative	**Diseased**	**Not diseased**
	(a) 14	(b) 4
	(c) 4	(d) 10
3D assessment of diameter stenosis% Positive Negative	1. (a) 16	2. (b) 6
	(c) 2	(d) 8

Pd/Pa is displayed on the analyzer; if it <0.8 this means that the lesion is functionally significant and justifies revascularization. PCI can be done, if needed, through the same PW by disconnecting it from the analyzer and using it directly as a usual PTCA guide wire.

Intra- and Inter-observer variation analysis

For intra-observer variability, a single operator repeats analysis of QCA image (2D&3D) in 10 patients (one month apart). For inter-observer variation analysis, two independent operators did the same procedure for QCA measurement separately in 20 patients.

Results

The study included 34 studied patients, 4 were excluded because of the poor image quality and difficult obtaining the data and two patients have two vessels lesions studied, so the total number of studied vessels is 32 vessels.

Of the 32 studied vessels there were 24 vessels in male patients (75%), 8 vessels in female patients (25%) with mean age 60.8 ± 6.9. Of the studied vessels, left anterior descending (LAD) constitute 50% of the affected vessels, while left circumflex (LCX) and right coronary artery (RCA) constitute the reaming vessels equally (25% for each). For statistical purposes; each vessel will be represented as single case.

The studied group included 24 diabetic patients (75%). 18 hypertensive (56.3%). 20 smokers (62.5%). The mean HDL level was 32.8 ± 6.3 mg/L and the LDL level was 128.6 ± 35.2 mg/L. Mean FFR value was 0.80 ± 0.13. FFR 0.80 was observed in 18 lesions (56.25%). Lesions severity obtained by 3D-QCA was better correlated to FFR than 2D-QCA.

Both 3D area stenosis percent and 3D diameter stenosis percent have comparable correlation in term of accuracy but with better sensitivity for the percent diameter stenosis. 2D-QCA measurements were less correlated to FFR. Overall, 3D-QCA showed a non-significant trend towards more accurate prediction of FFR than 2D-QCA. Both 3D- and 2D-QCA were less accurate in predicting FFR? 0.80 than in predicting FFR, 0.75 (Table 5).

Intra-observer and inter-observer variation analysis for QCA were assessed and the difference between two measurements was found to be located within 95% confidence interval so that P value had more than 0.05.

Two dimensional stenosis percent (area stenosis % and diameter stenosis %)

I-Area stenosis percent: The number of truly diagnosed cases by 2D area % is 14 cases (10 true positive, 4 true negative) which represent 43.75% of total cases (Table 6).

While the number of falsely diagnosed cases by 2D area % is 18 (10 false positive, 8 false negative) which represent 56.25% of total cases. The best cut off point to diagnose coronary artery stenosis by 2D area % is 69.3% with 56% sensitivity and 29% specificity, 55% PPV and 33% NPV.

II- Diameter stenosis percent: The number of truly diagnosed cases by 2D diameter stenosis % is 18 cases (10 true positive, 8 true negative) which represent 56.25% of total cases. While the number of falsely diagnosed cases by 2D diameter stenosis% is 14 (6 false positive, 8 false negative) which represent 43.75% of total cases (Table 7). The cutoff point to diagnose coronary artery stenosis by 2D diameter stenosis % is 51.8% with 56% sensitivity and 57% specificity, 63% PPV and 50%.

Three dimensional area stenosis percent (area stenosis % and diameter stenosis %)

Area stenosis percent: The number of truly diagnosed cases by 3D area stenosis % is 24 cases (14 true positive, 10 true negative) which represent 75% of total cases. While the number of falsely diagnosed cases by 2D diameter stenosis% is 8 (4 false positive, 4 false negative) which represent 25% of total cases with 66.4% as a cutoff point to diagnose coronary artery with 78% sensitivity and 71% specificity.

Diameter stenosis percent: The number of truly diagnosed cases by 3D diameter stenosis % is 24 cases (16 true positive, 8 true negative) which represent 75% of total cases. While the number of falsely diagnosed cases by 3D diameter stenosis% is 8 (6 false positive, 2 false negative) which represent 25% of total cases. With 47.4% cut off point to diagnose coronary artery stenosis by 3D diameter stenosis % is 47.4% with 89% sensitivity and 57% specificity.

Table 6: Validity of 3D angiography to diagnose coronary stenosis according to percent of area stenosis.

	AUC	P value	Sensitivity	Specificity	Accuracy	PPV	NPP
Area seen by 3D angiography	0.730	0.125	78%	71%	75%	78%	71%

Table 7: Validity of 3D angiography to diagnose coronary stenosis according to percent of diameter stenosis.

	AUC	P value	Sensitivity	Specificity	Accuracy	PPV	NPP
Diameter seen by 3D angiography	0.611	0.459	89%	57%	75%	73%	80%

Table 8: Correlation between FFR and QCA.

		FFR
3D area stenosis%	r (Spearman)	-0.320
	p	0.074 (NS)
3D diameter stenosis%	r (Spearman)	-0.358
	p	0.044 (S)
2D area stenosis%	r (Pearson)	-0.032
	p	0.861 (NS)
2D diameter stenosis%	r (Pearson)	0.013
	p	0.943 (NS)

Discussion

In patients with stable coronary artery disease, it was unclear whether an initial management strategy by percutaneous coronary intervention (PCI) with intensive medical therapy is superior to optimal medical therapy alone in reducing the cardiovascular risk events [15]. A meta-analysis of randomized clinical trials that studied PCI versus OMT in stable CAD showed that PCI, as compared with OMT, did not reduce the mortality risk, cardiovascular death, nonfatal myocardial infarction, or revascularization. PCI, however, provided a greater ischemic pain relief compared with OMT alone [16]. Considering the lack of clear clinical benefit, in addition to cost implication these findings continue to support existing clinical practice guidelines that medical therapy be considered the most appropriate initial clinical management for patients with stable angina [16].

The assessment of lesion severity was firstly depending on visual estimation of the operator, which may be inaccurate with marked difference between assumed lesion severity and physiological significance. Angiographic-physiological mismatch is frequent in patients with moderate coronary stenosis, which suggests the clinical importance of using physiological assessment to guide PCI [17]. A meta-analysis [18] showed that SPECT, CMR, and PET all have a high sensitivity, while a broad range of specificity was observed.

SPECT is widely available also it is extensively validated; PET achieved the highest diagnostic performance; CMR may provide another tool without ionizing radiation and with a similar diagnostic accuracy as PET [19,20]. The FAME study assessed the FFR-guided PCI and concluded the lack of accuracy of angiography in assessing the functional significance of a coronary stenosis when compared with the FFR, not only in the 50% to 70% category but also in the 70% to 90% of angiographic severity category [21], 2 years [22] and 5 years [23] follow up of the study results confirm the long-term safety of FFR-guided PCI in patients with multi-vessel disease. However, despite its accuracy and being helpful in intermediate lesion physiological significance assessment, the use of both techniques is limited by its relatively high cost.

In a study by Naganuma et al. [19] showed that the accuracy of QCA in predicting functionally significant FFR is dependent on FFR cut-off used and lesion severity. It suggested that where FFR is not available or contraindicated; 3D-QCA may help in the evaluation of coronary lesions of intermediate severity. Saad et al. [24] showed 3-D QCA showed a significant correlation with FFR values. A cross-sectional stenosis>57% obtained by 3-D QCA has a high degree of sensitivity and specificity to detect a hemodynamically significant intermediate coronary stenosis [25]. Recently Nishi et al. [26], found that that 3D-QCA is more useful than 2D-QCA and possibly comparable to IVUS in the assessment of functional stenosis severity. The study suggested that when FFR is not available, 3D-QCA MLA and MLD may assist in the assessment of functional severity of intermediate lesions. Another prospective, head-to-head study (ATLANTA I and II) [27] comparing QCA, quantitative CTA, and IVUS for the prediction of hemodynamic significance in intermediate and severe lesions, using fractional flow reserve as reference standard showed in intermediate-to-severe lesions, QCA-, CTA-, and IVUS-derived quantitative anatomic measurements correlated with FFR (Table 8). CTA-derived cut-points were similar to respective measurements on QCA and IVUS and had similar or better diagnostic performance compared with IVUS. In our study we found that the best cut off point to diagnose coronary artery stenosis is 66.4%, as assessed by 3D-QCA, above which or equal to it there is significant stenosis.

Conclusion

2D and 3D QCA can be used for assessment of intermediate coronary lesions, when FFR is unavailable or contraindicated to assess the need for revascularization. Study limitations: Patients with suboptimal image quality were excluded, who, in practice, constitute a proportion of patients with CAD. Also, the unavailability or relatively expensiveness of the pressure wires and finally the small sample size were the main limitations in our study.

Study Limitations

Patients with suboptimal image quality were excluded, whom, in practice, constitute a proportion of patients with CAD. Also, the unavailability or relatively expensiveness of the pressure wires and finally the small sample size were the main limitations in our study.

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