Detection of Myocardial Ischemia in Diabetic Patients: The Limitations of Myocardial Perfusion Imaging

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A B S T R A C T

In the study of 286 patients with suspected coronary artery disease and recent exercise single photon emission computed tomography (SPECT) test, we performed coronary angiography with coronary fractional flow reserve (FFR) measurement and tested the differences between diabetic (103) and non-diabetic (183) patients in ischemia detection by this two methods. The diabetic patients had a higher prevalence of hypertension, higher BMI and cholesterol levels, as well as longer duration of hospitalization than non-diabetic patients. There was no difference found between groups according to the exercise SPECT test, but, there were significantly more negative results in the non-diabetic group than in the diabetic group according to the FFR test, also, the percentage of stenosis was higher in diabetic patients. The concordance between the two methods was found, it was fair in diabetic patients (κ=0.25, 95% C.I. 0.06–0.45) and moderate in non-diabetic patients (κ=0.49, 95 % C.I. 0.36–0.62).

***Key words**: coronary artery disease, myocardial ischemia, computed emission single photon tomography, myocardial fractional flow reserve*

Introduction

Diabetes mellitus (DM) accelerates the natural development of atherogenesis, which on its part results in structural and functional anomalies of coronary arteries and microcirculation, with a more frequent occurrence of ulcerated atherosclerotic plaques, thrombosis and microaneurysms, as well as the absence of adequate vasodilatory response[1]. In such conditions there is often a discrepancy between different non-invasive tests, which complicates the making of a clinical decision on a further treatment of the diabetic with the coronary artery disease (CAD). The ischemic heart disease in patients with diabetes shows some specificities, such as being frequently of an asymptomatic course and showing nonspecific ECG changes, while coronary atherosclerotic changes in patients with DM regularly take up a greater number of branches and spread onto longer segments that in percutaneous interventions require the implantation of a greater number of stents. This is why 20–30% of patients that undergo revascularization by percutaneous coronary intervention and the implantation of stent suffer of DM, half of whom are treated with insulin[2,3]. Due to the frequently irregular values of glucose, diabetics often suffer of endothelial dysfunction and the consequential disorder of the microvascular coronary resistance which can result in the ischemia of the heart muscle or its hibernation[4]. Silent ischemia is present in a fifth of diabetics who do not show symptoms of CAD[5]. The percentage of patients with DM who have an obvious risk of worse cardiac outcome is not clear, also whether a solution can be found for such patients[6]. Among a range of non-invasive tests available to cardiologists, myocardial perfusion imaging techniques such as Technetium-99m-labeled sestamibi single-photon emission computed tomography (exercise SPECT) are a gold standard in diagnosing CAD[7]. Exercise SPECT is based on the principle of relative flow reserve, i.e. the fact that hemodynamic

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significant coronary arteries stenoses will signal a regional perfusion deficit. The fractional flow reserve (FFR) is based on a pressure-flow analysis of the stenosed artery during the hyperemic (maximal) flow. It is an invasive index that is used to calculate the severity of the investigated lesion. FFR in normal coronary artery equals 1,0 while an FFR value of less than 0,80 identifies inadequate perfusion that causes myocardial ischemia with a predictive accuracy of more than 90%[8]. Earlier, FFR was mainly used in patients with single-vessel coronary artery disease, while its clinical benefit has nowadays been confirmed in patients with multivessel coronary artery disease, in patients with the prior myocardial infarction, with the main stem disease and in those with functionally insignificant stenoses of coronary arteries[9–12]. Yanagisawa and collaborators have confirmed that lower values of FFR (≤0.75) can dependably detect myocardial ischemia in patients with DM, if, naturally, glycaemic levels in blood are kept in normal ranges[4].

Some studies have shown that exercise SPECT can confirm CAD with the sensitivity of 90% and specificity of 70%, but the comparability and concordance of this method with the FFR values in patients with DM have not been investigated to the best of our knowledge[13].

Methods and Subjects

We enrolled 286 patients who had exercise SPECT four weeks before the coronary angiography and the FFR measurement. The patients were divided into a non-diabetic (183 patients) and a diabetic (103 patients) group. The exclusion criteria were: (1) left main stem disease; (2) chronic total occlusion of one of the coronary arteries or history of myocardial infarction; (3) acute coronary syndrome; (4) left ventricular ejection fraction less than 50%; (5) hypersensitivity to adenosine and (6) previous percutaneous coronary or surgical revascularisation within 1 month prior to the enrolment. All patients gave their written informed consent and study obtained the local ethics committee approval.

Coronary angiography and FFR measurement

Coronarography was perfomed four weeks at most from the myocardial perfusion imaging – exercise SPECT. Through 5 or 6 Fr radial artery sheath a diagnostic/guiding catheter was introduced to the ostia of the left and right coronary arteries. The catheterization was covered with weight-adjusted dose of unfractioned heparin (100 U/kg). Coronary angiography was performed first, using standard projections in our institution. FFR measurements were performed using commercially available 0,014-inch pressure guidewires (RADI Medical, Uppsala, Sweden), which were calibrated and pressure equalised first. Passing the observed lesion the sensor tipped pressure guidewire was positioned in the distal portion of the artery. The FFR was calculated from the ratio of mean distal (distal to the lesion) and mean proximal (aortic) pressure at the maximal steady state hyperemia. Maximal vasodilatation (hyperemia) was induced with fast intracoronary boluses of 140 μg of adenosine. The FFR threshold value of 0,8 was used to recognize significant (ischemic) lesions.

Angiographic analysis

Angiograms were analyzed off-line by two independent operators. Quantitative coronary angiography analysis was performed using the special software (CAAS II system – Pie Medical Imaging, Maastricht, Netherlands) and standard parameters as minimal lumen diameter (MLD), reference diameter, diameter stenosis (DS), percentage of stenosis and lesion length were measured. If posterior descending artery originated from right coronary artery, right dominance was designated and if it originated from left circumflex artery, left dominance was designated. In patients with left dominance, four apical segments were assigned to the anterior descending artery and inferolateral segments together with inferior ones were assigned to the left circumflex artery. In patients with right dominance the apical-inferior segment was assigned to the right coronary artery and other three segments to the anterior descending artery. No co-dominant circulation was designated.

SPECT perfusion imaging and interpretation

A two day imaging protocol was performed. Stress and rest scans were obtained with a 48-hour interval. Either a multistage symptom limited exercise test or a dipyridamole test was performed (one patient underwent the adenosine test). The dipyridamole dosage was 0,56 mg/kg body weight over 4 minutes. ^{99m}Tc sestamibi was injected at peak exercise or 2 minutes after the dipyridamole infusion. All the patients were injected with a standard dose of tracer according to the EANM/ESC procedural guidelines for myocardial perfusion imaging which is 9 MBq/kg (or standard 740 MBq of ^{99m}Tc sestamibi). The gated SPECT was acquired one hour after the tracer injection with a dual head camera equipped with a low energy, all purpose, parallel – hole collimator and connected to a dedicated computer system. The acquisition protocol parameters were the following: 180° rotation arc, 32 projections, 60 s/projection, 8 frames/heart cycle and 64x64 matrices. The studies were reconstructed using filtered back projection without attenuation or scatter correction and realigned along the heart axis. The stress and rest images were divided according to the 17 standardized myocardial segments and the regional tracer uptake in each segment was semi-quantitatively determined. The defect score was determined by a 2-point scoring system: 1-no defect, 2-reversible defect.

Statistical analysis

Categorical variables are expressed as frequencies and relative frequencies; relative frequencies between the two groups were compared with the χ^2-test. Continuous variables are expressed as mean and standard deviation; differences between the two groups were compared with the unpaired t-test. Diagnostic values as sensitivity, specificity, positive and negative predictive values, posi-

tive and negative likelihood ratios were calculated for each group separately in order to compare the two methods (FFR and MPI). The inter rater agreement coefficient Kappa was calculated for each group. A p value of less than 0.05 was considered significant. Data were analyzed using the *MedCalc* statistical software, version 11.2.0.0 (MedCalc Inc., Mariakerke, Belgium).

Results

The characteristics of diabetic and non-diabetic patients are presented in Table 1. The patients with DM had a higher BMI, a longer duration of hospitalization and higher cholesterol than non-diabetic patients, and there were more diabetic patients with hypertension.

FFR data and angiographic data are presented in Table 2. The baseline FFR and FFR in hyperemia were significantly lower in diabetic patients. Also, the percentage of stenosis was higher in diabetic patients.

Summary results of FFR and exercise SPECT tests are presented in Table 3. There were significantly more positive results in the group with DM than in the group without DM according to the FFR test. There was no dif-

TABLE 1
CHARACTERISTICS OF DIABETIC AND NON-DIABETIC PATIENTS

Variable	DM n=103 N (%) or $\bar{X}$±SD	non-DM n=183 N (%) or $\bar{X}$±SD	Statistics p
Age	66±10	65±11	0.431[a]
gender (male)	81 (79)	147 (80)	0.403[b]
BMI	27.9±4.6	25.3±4.7	<0.001[a]
Duration of hospitalization (days)	3.1±3.6	2.1±2.7	0.007[a]
Risk factors			
Currently smoking	25 (24)	52 (28)	0.535[b]
Family cardio anamnesis	18 (17)	34 (19)	0.942[b]
Cholesterol	0.89±0.31	0.75±0.43	0.003[a]
Hypertension	91 (88)	131 (72)	0.002[b]
Medication			
Aspirin	93 (90)	152 (83)	0.134[b]
Clopidogrel	62 (60)	102 (56)	0.544[b]
In Ca 2^+	26 (25)	39 (21)	0.539[b]
ACE inhibitors	54 (52)	73 (40)	0.054[b]
Beta-blockers	77 (75)	109 (59)	0.016[b]
Nitrate	6 (6)	18 (10)	0.328[b]
Angiotensin antagonists	18 (17)	25 (14)	0.512[b]
Type of vessel			
CD	19 (18)	42 (23)	0.005
CX	11 (11)	29 (16)	0.007
IVA	73 (71)	111 (61)	0.006

DM – diabetes mellitus patients, non-DM – non-diabetes mellitus patients, [a] – t-test for independent samples, [b] – chi-square test, RCA – desna koronarna arterija, CX – zavijena grana lijeve koronarne arterije, LAD – prednja silazna grana lijeve koronarne arterije

TABLE 2
FFR DATA AND ANGIOGRAPHIC VARIABLES IN DIABETIC AND NON-DIABETIC PATIENTS

Variable	DM n=103 n (%) or $\bar{X}$±SD	non-DM n=183 n (%) or $\bar{X}$±SD	Statistics p[a]
FFR base	0.90±0.06	0.94±0.05	<0.001
FFR hyper	0.79±0.09	0.82±0.09	0.009
% stenosis	50.6±11.3	47.5±10.7	0.022
MLD (mm)	1.32±0.38	1.42±0.43	0.076
Lesion length (mm)	14.06±7.47	13.15±7.15	0.326
Reference diameter (mm)	2.74±0.56	2.77±0.59	0.794

DM – diabetes mellitus patients, non-DM – non-diabetes mellitus patients, [a] – t-test for independent samples, FFR base – basal value of FFR, FFR hyper – FFR after vasodilatation, MLD – minimal lumen diameter

TABLE 3
SUMMARY RESULTS OF FFR AND EXERCISE SPECT TEST IN DIABETIC AND NON-DIABETIC PATIENTS

Variable	DM N=103 N (%)	non-DM N=183 N (%)	Statistics p[a]
Exercise SPECT			
negative	32 (31)	74 (40)	0.057
positive	60 (58)	80 (44)	
not performed	11 (11)	29 (16)	
FFR hyper			
negative (≥0.80)	47 (46)	122 (67)	<0.001
positive (<0.80)	55 (53)	60 (33)	

DM – diabetes mellitus patients, non-DM – non-diabetes mellitus patients, [a] – chi-square test, FFR hyper – FFR after vasodilatation

ference found between groups according to the exercise SPECT test.

Concordances for detection of ischemia between FFR and exercise SPECT are presented in Tables 4. and 5. Diagnostic values of FFR and exercise SPECT are presented in Table 6. The probability of identifying patients with FFR<0.80 (sensitivity) with positive result on exercise SPECT test is 76% in diabetic and 87% in non-diabetic patients. The ability to identify patients with FFR ≥0.80 (specificity) with negative result on exercise SPECT test is 49% in diabetic and 67% in non-diabetic patients[14].

The positive predictive value was 64% for diabetic and 59% for non-diabetic patients, i.e. the ability of exercise SPECT test to recognize patients with FFR<0.80 (positive result on the exercise SPECT test) was not high, there was a large number of false positive results in both groups of patients. The negative predictive value was 63% for diabetic and 91% for non-diabetic patients, i.e.

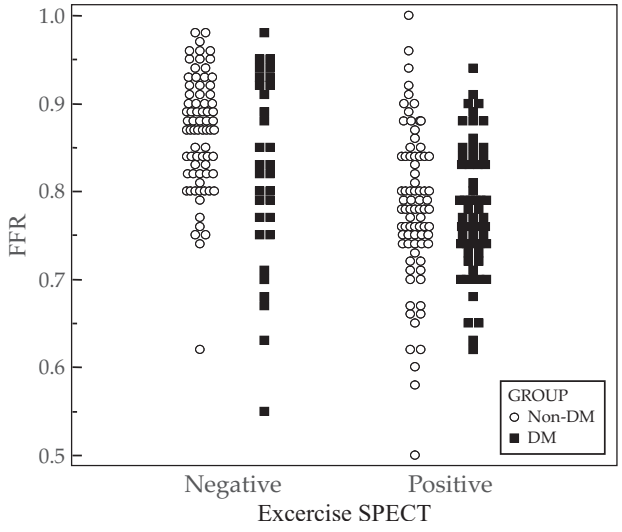

Fig. 1. Results of excercise SPECT and FFR tests in groups of diabetes and non-diabetes patients.

TABLE 4
CONCORDANCE FOR DETECTION OF ISCHEMIA BETWEEN FFR AND EXERCISE SPECT FOR DIABETES MELLITUS PATIENTS

		FFR	
		<0.80 N (%)	≥0.8 N (%)
Exercise SPECT	Positive	38 (37)	21 (20)
	Negative	12 (12)	20 (19)

TABLE 5
CONCORDANCE FOR DETECTION OF ISCHEMIA BETWEEN FFR AND EXERCISE SPECT FOR NON-DIABETES MELLITUS PATIENTS

		FFR	
		<0.80 N (%)	≥0.8 N (%)
Exercise SPECT	Positive	47 (26)	33 (18)
	Negative	7 (4)	67 (37)

TABLE 6
DIAGNOSTIC VALUES FOR EXERCISE SPECT

Diagnostic value	DM N=103 % (95% C.I.)	non-DM N=183 % (95% C.I.)
Sensitivity	76 (61–87)	87 (75–95)
Specificity	49 (32–65)	67 (57–76)
Positive predictive value	64 (51–76)	59 (47–70)
Negative predictive value	63 (44–79)	91 (81–96)
Positive likelihood ratio	1.48 (1.06–2.08)	2.64 (1.96–3.55)
Negative likelihood ratio	0.49 (0.27–0.88)	0.19 (0.10–0.39)
Kappa coefficient of concordance	0.25 (0.06–0.45)	0.49 (0.36–0.62)

DM – diabetes mellitus patients, non-DM – non-diabetes mellitus patients

the ability of exercise SPECT test to recognize the patients with FFR≥0.80 (negative results on exercise SPECT test) was lower for the diabetic patients than for the non-diabetic patients, i.e. truly negative results were identified in most cases of non-diabetic patients, but not in diabetic patients.

The positive likelihood ratio is small in both groups; the odds of having FFR<0.80 are 10% for diabetics and 20% for non-diabetics with a positive exercise SPECT result than in the group that has a negative exercise SPECT result (2.64 *vs.* 1.48)[15]. Negative likelihood results are lower than 0.50, the odds of having FFR≥0.80 are 15% for diabetics and 30% for non-diabetics greater in the group of patients that have a negative exercise SPECT test result,(0.49 *vs.*0.19). The concordance between the two methods was found, it was fair in diabetic patients (κ=0.25, 95% C.I. 0.06–0.45) and moderate in non-diabetic patients (κ=0.49, 95 % C.I. 0.36–0.62)[16].

Discussion and Conclusion

A high prevalence of DM in general population, a significant risk of developing CAD in these patients and the need of dependable identification of significant coronary lesions in routine practice, all emphasise the potential significance of presented results. Exercise SPECT is a non-invasive method suitable for extensive use with well known limitations that are defined by its sensitivity and specificity[17]. Our finding, according to which SPECT shows a significantly lower concordance with FFR in patients with DM than in patients without DM, additionally identifies the limitations of this method. It also confirms previous results obtained by the comparison with coronary angiography without the hemodynamic evaluation. Namely, it is known that the diagnostic value of exercise SPECT in patients with DM is worse than in patients without DM. The sensitivity of this test varied in different studies from 80–90%, while the specificity from 75–90% with the positive predictive value of 57–87%, and the negative one of 85–95%[17]. The fact that according to the available literature the testing of concordance of results of exercise SPECT and coronary angiography with FFR measurements has not been conducted so far additionally emphasises the significance of our results. Differences in the diagnostic value of exercise SPECT between patients without and those with DM, besides the anatomical specificities of CAD, definitely depend on its specific functional determinants. Namely, besides the morphological presentation covered by the classic coronary angiography, the FFR test also comprises the sensitive functional test of the capability of vasodilatation of the tested coronary branch. As CAD in patients with DM involves a heavy impact of endothelial dysfunction, microcirculatory disorder and myocardial hypertrophy, the heart muscle perfusion disorder in these patients can also be present without a significant coronary stenosis[18]. As scintigraphy is a functional diagnostic test, unlike the coronary angiography without FFR, being exclusively a morphologic method of presentation, the coronary angiography with FFR, used in our research, is the method that combines the advantages of both tests. With regard to the specificities of CAD in patients with DM, the confirmation of the above mentioned limitations of scintigraphy in these patients, which we carried out with the FFR test, seem to be highly significant. Chamuleau et al. have compared the specificity of myocardial SPECT perfusion with FFR and therewith showed that the incidence of coronary events was significantly higher in the group that on the basis of normal findings of perfusion test did not undergo PCI despite significant values of FFR (<0.75)[19]. The above mentioned emphasised the superiority of the FFR method in the identification of significant coronary lesions and additionally confirms the value of our results in their clinical interpretation. In our research we did not use methods such as the exercise ECG testing and stress echocardiography, which we do not consider to be a significant limiting factor as their sensitivity and specificity in detecting ischemic lesions in patients with DM is defined as a low one, i.e. significantly lower than that of the exercise SPECT that we used. Our results obtained using combined morphological and functional method with the confirmed high sensitivity and specificity in detecting myocardial ischemia can thus be transposed to confirmed limitations of the use of exercise ECG testing and stress echocardiography in patients with DM[20]. Furthermore, the conclusions of our research confirm these limitations, as well as the frequent inconclusiveness and inappropriateness of noninvasive methods in patients with DM and suspected CAD.

The prospective DEFER study has shown that untreated lesions with FFR value of <0.75 are predictable for higher incidence of adverse events during the five-year follow up[21]. With the aim to improve the sensitivity of FFR and its better correlation with the scintigraphic findings, we used the upper limit of FFR of 0.80 in our research, so that what remains open is the issue of correlation of methods in diabetics and non-diabetics at other levels of defined limit values. The issue of defining different limit values of the FFR measurement of the significance of coronary lesions in groups with or without DM is one of the theories that still needs to be tested.

Dominguez – Franco and collaborators tried to evaluate the prognostic value of FFR in diabetics, following 40 patients during 30 months[22]. This number of patients was too small for the observed differences to reach the level of statistical significance, while the analysed coronary lesions cannot represent typical changes in patients with DM. Namely, the average diameter of analysed coronary lesions measured 3 mm, which means that these were only the changes in large epicardial coronary arteries, while the rigorously selected patients regularly had lesions of the focal character, i.e. it was not the case of diffuse atherosclerotic disease typical of patients with DM.

Although the presented results need a further confirmation in future research studies, they convincingly point to a high limitation of exercise SPECT and emphasise the need for a wider application of FFR testing in routine coronary angiography in patients with DM.

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ISHEMIJA MIOKARDA U BOLESNIKA SA ŠEĆERNOM BOLEŠĆU: OGRANIČENJA PERFUZIJSKIH PRIKAZA

S A Ž E T A K

U istraživanju koje je obuhvatilo 286 pacijenata s utemeljenom sumnjom na koronarnu bolest i nedavno učinjenom kompjutoriziranom jednostrukom emisionom fotonskom tomografijom (SPECT) u opterećenju, izveli smo koronarnu angiografiju s izmjerom pričuve frakcijskog protoka (FFR) kako bismo testirali postojanje razlike u detekciji miokardne ishemije SPECT-om u bolesnika sa šećernom bolešću (103) i bez nje (183). Dijabetičari su imali višu prevalenciju arterijske hipertenzije, viši indeks tjelesne mase (ITM) i razine kolesterola, kao i dužu prosječnu hospitalizaciju od nedijabetičara. Rezultati SPECT-testa nisu pokazali značajnih razlika između skupina, dok su rezultati FFR-testa ukazali na postojanje značajno više negativnih nalaza u nedijabetičara. Također, FFR-test je u skupini dijabetičara iskazao značajno više stupnjeve koronarnih stenoza. Sukladnost uspoređivanih metoda definirana je niskom u dijabetičara (κ= 0,25, 95% C.I. 0,06–0,45) i umjerenom u nedijabetičara (κ=0,49, 95% C.I. 0,36–0,62).