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## VALIDATION OF MODERNIZED QUESTIONNAIRE MSAQ IN PATIENTS WITH CORONARY ARTERY DISEASE METABOLIC SYNDROME, HAVING HAD PERCUTANEOUS CORONARY INTERVENTION FOR ACUTE CORONARY SYNDROME WITHOUT PERSISTENT ELEVATION OF ST SEGMENT

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**Abstract. Aim.** To evaluate the quality of life and efficacy of the treatment of patients with coronary artery disease and metabolic syndrome after percutaneous coronary intervention for acute coronary syndrome without persistent ST segment elevation by adding modernized questionnaire "Modified Seattle Angina Questionnaire for patients with metabolic syndrome having had percutaneous coronary intervention" (MSAQ) to the diagnostic procedures.

**Materials.** 94 patients took part in the research (M 61 : F 33), all of them were referred to the hospital either in clinical routine, or in connection with disease aggravation. All of them were clinically tested especially for thrombin and cortisol levels. Patients filled in the Questionnaires EQ-5D (EuroQol -5D), PHQ-8 (Personal Health Questionnaire Depression Scale) and MSAQ.

**Results.** Patients with the results from 81 to 100% of questionnaire MSAQ (n = 26) were considered as an effective treatment group I, 61-80% (n = 49) - the group II –group of medium effectiveness of treatment and less than 60% (n = 19) – the III group –of ineffective treatment. In the group III there has been distinguished a big percent of patients independently visiting hospital on the occasion of health aggravation, 73.5% against 50.0% and 16.7% in group II and I (p <0.05), correspondingly. Veraciously big indices of thrombin were observed in group III ( $3.77 \pm 1.29$ , ng / mL) and group II ( $4.46 \pm 1.07$  ng / mL) compared with group I ( $5.96 \pm 1.89$  ng / mL), (p <0.05); cortisol blood of  $592.8 \pm 162.9$ , nmol / L,  $515.8 \pm 84.8$ , nmol / L and  $422.3 \pm 159.2$ , nmol / L (p <0.05), as well as fibrinogen:  $4.31 \pm 1.82$ , g / L,  $4.26 \pm 2.16$ , g / L,  $3.74 \pm 1.51$ , g / L, (p <0.05) for III, II and I groups, respectively. Patients of the group I demonstrated high indices of living standards according to the visual – analogous scale (VAS), EQ-5D ( $83.8 \pm 6.81$ , %) compared with the second ( $69.4 \pm 9.19$ , %) and III ( $57.8 \pm 10.69$ , %), (p <0.05) groups, respectively. There is a sustainable dynamics of increasing points on a scale PHQ-8 registered with a decrease in the effectiveness of treatment based on the results MSAQ:  $10.1 \pm 2.11$ ,  $14.0 \pm 4.63$ ,  $18.3 \pm 3.41$  in the first, second and third groups, respectively, but significant (p <0.05) difference has been registered between the first and second groups only.

**Conclusions.** MSAQ is a simple and reliable method of screening assessment of the treatment effectiveness for patients with coronary artery disease and metabolic syndrome after percutaneous coronary intervention.

**Keywords:** modified questionnaire, metabolic syndrome, percutaneous coronary intervention.

**Background.** In recent years, considerable progress has been achieved in the diagnosis and treatment of patients with coronary artery disease (CAD), but mortality and disability of these patients remains high. One of the factors contributing to the early development and compromised course of CAD is a metabolic syndrome (MS) [5].

MS is considered by specialists to be "pandemic" of the 21<sup>st</sup> century and is diagnosed in 20-25% comparatively healthy subjects and in 45% of patients with atherosclerosis [3], the

number of patients is increasing every year [4]. At the same time, atherosclerosis as a major cause of CAD has a prevalence up to 14% in different sex-age groups [7].

Assessment of the subjective condition of the patient is important for a quick solution of necessity of in-depth examination and correction of treatment strategies. With this in mind, the search for simple, reliable and affordable diagnostic approaches continues, preceded by a narrowing range of relevant laboratory and instrumental methods. Much attention is paid to filling in specialized questionnaires. A basic tool for CAD patients is evaluation of SAQ (Seattle Angina Questionnaire) [10]. However, this questionnaire does not take into consideration peculiarities of the "modern" patient (in a high percentage of cases there was PCI, a significant prevalence of MS). We have developed a modified variant of SAQ – «Modified Seattle Angina Questionnaire for Patients with MS after PCI» (MSAQ).

**Objective.** To evaluate the quality of life and efficacy of the treatment of patients with CAD and MS who underwent PCI – coronaroangioplasty for ACS without ST segment elevation, by adding modernized questionnaire – MSAQ to the diagnostic procedures.

**Materials and methods.** The study included 94 patients (61 M : 33 F), referred to the clinic in a planned way, or due to the deterioration of their condition. Inclusion criteria were a history of stenting for ACS without ST segment elevation, concomitant MS. Exclusion criteria were age over 80, type 1 diabetes, anemia less than 100 g/l, presence of absolute and relative contraindications for exercise testing.

The causes for reference to the clinic were: recommended planned examination and/or carrying out loading tests (n = 53) in order to control early (1 month) and late (6 or more months) complications after PCI [9, 14], or self-reference (n = 41) for reduction of exercise tolerance, shortness of breath, pain in the heart, not enough effective control of blood pressure (BP), arrhythmia.

There was made general clinical diagnostics as well as determination of the thrombin and cortisol levels. Exercise stress test (EST) was carried out by cycle ergometry [13]. The EST result was assessed by the categories: positive, equivocal, negative, and uninformative. During the evaluation test, the first two categories have been considered as "unfavorable". When conducting echocardiography there was additionally calculated a left ventricular ejection fraction (LVEF) by segment method [8]. The thrombin level was measured by «ELISA» («Assay Max Human Thrombin Complexes», USA); reference levels are 1.18 – 3.41 ng/ml. The presence of MS was assessed by the criteria of the recommendation NCEP ATP-III 2001, the modification of 2005 [4, 9].

The patients were asked to complete questionnaires of the subjective determination of the life quality (EQ-5D with a visual analogue scale (VAS), the level of anxiety (PHQ-8) and angina (MSAQ) at the time of reference. The first two questionnaires are presented in conventional variants [2, 6, 12].

The developed MSAQ consists of 5 sections: DP (Disease Perception), TS (Treatment Satisfaction), AF (Angina Frequency), AS (Angina Stability), PL (Physical Limitation); 2-5 questions in each; the patient chooses one of the four proposed answers; the doctor calculates the results as a percentage of each group of questions and determines the level of effectiveness of treatment (ET) by the formula:  $ET = (DP + TS + AF + AS + PL)/5$  at the end.

Compliance with ethical standards. The study conducted in accordance with the directives of the State Ethics Committee and local ethical committee, recommendations of "Good Clinical Practice".

During randomization all study participants signed in an informed consent. The authors have taken all measures to ensure the anonymity of patients.

Statistical analysis of the data presented was conducted with the help of Statistica (version 8.0) with the expectation of the arithmetic average, standard deviation, based on detection methods for quality differences ( $\chi^2$ ) and quantitative variability (t). The difference was considered reliable when the result was  $p < 0.05$  for each of the parameters.

**Results.** By completing a questionnaire, the patients with indices of 81-100% MSAQ ( $n = 26$ ) were regarded as a group of effective treatment (group I), 61-80% ( $n = 49$ ) – insufficiently effective (group- II) and 60% and less ( $n = 19$ ) – inefficient treatment (group III).

Average time after PCI was  $15.9 \pm 1.52$  for all patients and did not differ significantly between groups (Table 1).

**Table 1. Characteristics of the subjective condition and clinical – instrumental indices of the patients.**

Index <sup>1</sup> Group I (n=26)	Group II (n=49)	Group III (n=19)	
Time after PCI, month	16.1 ± 1.7	15.4 ± 1.1	16.9 ± 1.3
LVEF (segment method), %	50.1 ± 5.9	49.2 ± 5.24	49.1 ± 4.86
VAS EQ-5D, %	83.8 ± 6.81	69.4 ± 9.19 *	57.8 ± 10.69***
PHQ-8, points	10.1 ± 2.11 14.0 ± 4.63*	18.3 ± 3.41	

Notes: <sup>1</sup> – the value is represented in the form: mean ± standard deviation, \* –  $p < 0.05$  when compared with the corresponding index of the first group, \*\* –  $p < 0.05$  when compared with the corresponding index of the second group.

Groups were comparable by indices of LVEF and glycosylated hemoglobin levels (Table 2). Despite a high compliance and quite a long time after the intervention, the majority of the examined patients failed to achieve the target data of the lipidogram, although figures differed significantly only by the level of very low density lipoproteins in the patients of group II ( $0.78 \pm 0.34$ , mmol / L) versus group III ( $1.01 \pm 0.54$  mmol / L), ( $p < 0.05$ ), which indicated the severity of atherosclerosis course in the patients with MS against the background of insulin resistance [3, 9].

A higher percentage of the patients was recorded in the group III who referred to the hospital due to deterioration of the health state – 73.5 % versus 50.0 % and 16.7 % in the group I and group II, ( $p < 0.05$ ), respectively. The maximum percentage of the patients with "unfavorable" EST result was also identified in the group III – 78.9 % versus 22.4 % (in the group II) and 20.4 % (in the group I), respectively. These data are comparable with the quality of life by the visual analog scale (VAS) EQ-5D: ( $83.8 \pm 6.81$  %) in the group I compared with group II ( $69.4 \pm 9.19$  %) and group III ( $57.8 \pm 10.69$  %), ( $p < 0.05$ ) groups, respectively.

**Table 2. Clinical and laboratory characteristics of the patients.**

Index <sup>1</sup>	Group II (n=49)	Group III (n=19)	
Group I (n=26)			
Thrombin, ng/mL	3.77±1.29	4.46±1.07*	5.96±1.89***
Blood cortisol, nmol/L	422.3 ± 159.2	515.8 ± 84.8*	592.8 ± 162.9*
Fibrinogen, g/L	3.74 ± 1.51	4.26 ± 2.16*	4.31±1.82***
HbA1C, %	7.04±2.24	5.91±2.64 6.87±1.15	

Notes: <sup>1</sup> – the value is represented in the form: mean ± standard deviation, \* –  $p < 0.05$  when compared with the corresponding index of the first group, \*\* –  $p < 0.05$  when compared with the corresponding index of the second group.

There were obtained reliably high indices of the plasma thrombin between group III ( $3.77 \pm 1.29$ , ng / mL), group II ( $4.46 \pm 1.07$  ng / mL) and group I ( $5.96 \pm 1.89$  ng / mL), ( $p < 0.05$ ) (Table 2), as well as fibrinogen:  $4.31 \pm 1.82$  g / L,  $4.26 \pm 2.16$  g / L,  $3.74 \pm 1.51$  g / L, ( $p < 0.05$ ) for the III, II and I groups, accordingly. These data are evidence of the marked metabolic imbalance with the phenomena of coagulation disorders of homeostasis, severe endothelial dysfunction, and as a result, the progression of atherosclerotic affection of the coronary arteries in the patients of the group III [1, 4].

Assessment of the level of blood cortisol showed a significant increase in group II ( $515.8 \pm 84.8$  nmol / L) and group III ( $592.8 \pm 162.9$  nmol / L) compared with group I ( $422.3 \pm 159.2$  nmol / L), ( $p < 0.05$ ). By the PHQ-8 scale the result was  $10.1 \pm 2.11$ ,  $14.0 \pm 4.63$  and  $18.3 \pm 3.41$ , for I, II and III groups, respectively, with ( $p < 0.05$ ) between I and II groups. These figures reflect the appearance of a direct correlation between chronic hypercortisolemic and nervous-mental disorders in worsening of CAD course against the background of MS [3, 5, 11].

**Conclusions.** MSAQ is a simple and reliable method of screening assessment of the treatment effectiveness. The data calculated by MSAQ allow to decide on further tactics of management of patients with CAD and MS after PCI for ACS without ST segment elevation. Factors leading to a decrease in the treatment effectiveness of patients with MS after PCI and the possibility of prevention and early correction require further study.

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