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Complications after One-Year Observation of Patients with Type 2 Diabetes Mellitus and Various Types of Coronary Heart Disease

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ABSTRACT

Aim: Evaluation of complications after one-year observation in patients with acute and chronic coronary heart disease (CHD) depending on the presence of type 2 diabetes mellitus (T2DM). **Material and methods:** This comparative clinical study included 202 men and women with acute and chronic CHD. Patients were divided into four groups, depending on the presence of type 2 diabetes mellitus: acute CHD and T2DM; acute CHD without T2DM (control group); chronic CHD and T2DM; chronic CHD without T2DM (control group). Depending on the results of clinical status and coronary angiography data, patients underwent myocardial revascularization (balloon angioplasty without stenting, stenting, coronary bypass grafting, stenting + coronary bypass grafting) followed by pharmacological treatment. One-year composite endpoints included: recurrent myocardial infarction, acute cerebrovascular accident, readmission, and death. **Results:** After admission, up to 80% of patients, regardless of CHD type and glycemic status, underwent revascularization. Patients without T2DM underwent stenting significantly more often compared with patients with T2DM. Coronary artery bypass grafting, including in combination with stenting, was more frequent in patients with T2DM with acute and chronic CHD. One year after discharge, readmissions and reoperations were more prevalent among patients with acute and chronic CHD and T2DM. The groups did not differ by the number of non-fatal and fatal complications. The total number of endpoints in patients with T2DM, regardless of the CHD type, were 2 times higher compared with the control group ($p<0.001$). **Conclusion:** Patients with acute and chronic CHD without T2DM, underwent stenting of one coronary artery more often, while patients with T2DM underwent coronary bypass surgery, including in combination with stenting. After one year of observation, the number of complications in patients with various CHD types and T2DM was higher than those without T2DM. This once again indicates the need for comprehensive secondary prevention.

Keywords: acute and chronic coronary heart disease, type 2 diabetes mellitus, revascularization, composite endpoints.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the leading health issues of the 21st century [1]. Its prevalence is increasing in both developed and developing countries. Macrovascular complications are the main cause of mortality among patients with T2DM [2]. Another valuable issue is the increasing T2DM

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prevalence among young adults. The presence of T2DM at early age is associated with higher risk of cardiovascular complications and mortality [3].

On the other hand, the number of patients with T2DM among people with acute and chronic CHD is increasing [4]. Thus, the comorbidity of these pathologies is of particular interest.

Several CHD clinical manifestations as well as cardiovascular system functional and anatomical features have been described in the literature in patients with T2DM that can be explained by the role of carbohydrate metabolism impairment in the development of atherosclerosis [5]. Angiographic studies have shown that patients with T2DM are more likely to have stenosis of the trunk of the left coronary artery (LCA) and multivessel CHD with the involvement of small blood vessels [6, 7]. In addition, patients with T2DM have higher atherosclerotic burden and increased number of lipid-rich plaques with high likelihood of rupture [8, 9]. Silent myocardial ischemia occurs more often among patients with T2DM compared with those without carbohydrate metabolism disorders [10, 11].

International clinical guidelines for the management of patients with T2DM and CHD have been developed and are regularly updated as new data from large studies accumulate. According to the latest European guidelines, myocardial revascularization by percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CBG) reduced the severity of clinical symptoms and the need for antianginal agents, and Improved exercise tolerance and quality of life compared with short- and long-term pharmacological treatment [12-14]. The predicted surgical mortality, anatomical features of coronary lesion, and the possibility of complete revascularization are important criteria for choosing between PCI and CABG. The decision on the preferred treatment method (conservative management, PCI or CABG) depends on the assessment of the risk-benefit ratio of the intervention, clarifying the risks of complications, dynamics of life quality and long-term prognosis, including the risk of myocardial infarction (MI) development [15].

It should also be emphasized that the analysis of the short-term prognosis can serve as indicator for therapy effectiveness.

This study aimed to evaluate the characteristics of myocardial revascularization and ongoing medication therapy in patients with various CHD types and different glycemic status, followed by monitoring composite endpoints during one-year follow-up.

MATERIAL AND METHODS

This clinical prospective study included 242 men and women with acute and chronic CHD, who have been admitted to the city hospital in Moscow. Acute CHD included MI without ST elevation and unstable angina. The group with chronic CHD included patients with stable CHD, including those with the history of MI. Only 202 patients completed the study. Regardless of gender, patients were divided into 4 groups:

- I group (n=50) (mean age 56.6±0.96 years, men/women 34/16) – patients with acute CHD and T2DM;
- II group (n=52) (mean age 58.7±1.01 years, men/women 37/15) – patients with acute CHD without T2DM;
- III group (n=49) (mean age 57.9±1.04 years, men/women 35/14) – patients with chronic CHD and T2DM;
- IV group (n=51) (60.2±0.9 years, men/women 34/17) – patients with chronic CHD without T2DM.

The second and fourth groups without T2DM were control groups.

Exclusion criteria:

- age < 35 and > 75 years;

- type 1 diabetes mellitus;

- asthma and stages I-III of chronic obstructive pulmonary disease with respiratory failure;

- diseases of the hematopoietic system and collagenoses;

- oncology;

- endogenous mental disorders;

- participation in any other study no later than 30 days before selection.

According to the protocol, all patients underwent health records assessment, clinical examination, hemodynamic, and anthropometric parameters analysis. To verify the diagnosis, patients underwent the following instrumental studies:

- 12-lead electrocardiogram (ECG) (Schiller AT-10 plus, Switzerland).

- 24-hour ECG monitoring to assess cardiac rhythm, conduction disturbances, and ST segment abnormalities (Schiller MT - 101, Switzerland).

- transthoracic echocardiogram (Samsung HM70A, South Korea) according to the protocol of the American Society of Echocardiography in M- and B-modes.

In order to visualize coronary arteries (CA), determine the severity of atherosclerotic lesions and select the optimal treatment strategy, all patients underwent selective coronary angiography using the Allura Xper FD20 angiographic unit (Phillips, the Netherlands) using infiltration anesthesia (0.5% novocaine solution) according to the M. Judkins method with S. Seldinger's percutaneous femoral artery or right radial artery puncture.

Subsequently, patients underwent the following types of revascularization: balloon angioplasty (BAP) without stenting, stenting (drug-eluting stent - DES), coronary artery bypass grafting + stenting.

The type of revascularization depended on the clinical condition and the results of coronary angiography. Patients with acute CHD underwent emergency revascularization, while those with chronic CHD underwent planned procedure.

To assess complications and endpoints one year after the hospitalization, the following incidents were evaluated:

• recurrent MI;

• acute cerebrovascular accident (ACA)

• death;

• re-admission for cardiovascular events;

• repeat revascularization.

The assessment of the total number of endpoints was carried out.

All patients signed written informed consent to participate in this study. The protocol was approved by the Local Ethics Committee.

Statistical analysis

Data entry was carried out with the ACCESS MS OFFICE system. Statistical analysis was performed using the SAS (Statistical Analysis System) software and the R statistical environment. The distribution was considered close to normal as there was no asymmetry and multimodality of the histogram. To assess the significance of differences between the two groups, in case when the parameter was normally distributed, we used Student's t-test, otherwise, the Mann–Whitney U test was performed. The differences between qualitative data were determined using the $\chi 2$ test and Fisher's exact test. Data are presented as means (M) with standard errors (m). For pairwise comparisons between groups, Bonferroni-Holm correction for multiple comparisons was applied. The chosen significance level for all tests was set as $p = 0.05$.

RESULTS

Patients with acute coronary syndrome (ACS) and T2DM had non-ST elevation MI in 42% of cases, and those without T2DM in 19% of cases. The differences were statistically significant (p=0.018). Unstable angina was detected in 58% of patients with T2DM, and in 81% of patients without T2DM (p=0.046). Up to 20% of participants from both groups had the history of MI (Table 1).

Table 1: CHD types among study participants, n (%)

	Acute CHD and T2DM n=50	Chronic CHD and T2DM n=49	Acute CHD without T2DM n=52	Chronic CHD without T2DM n=51	p		
					group1 vs. group 3	group2 vs. group 4	group 1 vs. group2
MI without ST elevation	21 (42%)		10 (19%)		0,018		
Unstable angina	29 (58%)		42 (81%)		0,046		
Stable angina		16 (33%)		26 (51%)		0,072	
History of MI	12 (24%)	22 (45%)	10 (19%)	20 (39%)	0,634	0,686	0,035

Stable angina was the reason for admission in 33% of patients with chronic CHD and T2DM, and was diagnosed in every second patient without T2DM. The history of MI was seen in 45% of patients with T2DM and in 38% of those without T2DM. In general, patients with chronic CHD and T2DM had 2 times higher incidence of MI compared with acute CHD (p=0.03).

All patients underwent complex pharmacological treatment. Oral hypoglycemic medications were prescribed in 2/3 of patients with acute CHD and T2DM. Every fourth patient received insulin therapy, including combination therapy. Among those with chronic CHD and T2DM, oral hypoglycemic therapy was received by every second patient, while insulin therapy, including combination therapy was seen in 37% of cases. All patients were prescribed with antiplatelet therapy. All patients with acute CHD received dual antiplatelet therapy. Up to 61% of patients with chronic CHD received dual antiplatelet therapy, the rest were prescribed with monotherapy. Beta-blockers and angiotensin-converting enzyme inhibitors (or sartans) were prescribed in 95% of cases among all groups, diuretics – in 60% of patients with acute CHD without T2DM and 94% of those with acute CHD and T2DM, calcium channel antagonists were seen in 30% of all cases. Patients from all four groups received statins.

The data of coronary angiography indicate that the groups with acute CHD with or without T2DM were comparable by the frequency of lesions of the main coronary arteries. Stenosis of the distal third of the coronary artery in patients with T2DM occurred 2 times more often than in the group with T2DM (78% of cases), and in patients without T2DM (42%), these differences were statistically significant (p<0.001).

Patients with chronic CHD did not differ significantly by the frequency of lesions of the main coronary arteries. Patients with CHD and T2DM significantly more often had diffuse multivessel CA lesions compared with those without T2DM – 73% and 45%, respectively (p<0.005).

Stenting, the combination of stenting and CABG, as well as angioplasty without stenting prevailed among patients with acute and chronic CHD (Table 2).

Table 2: Type of revascularization in patients with acute and chronic CHD with and without T2DM

	Acute CHD and T2DM n=50	Chronic CHD and T2DM n=49	Acute CHD without T2DM n=52	Chronic CHD without T2DM n=51	p		
					group 1 vs. group 3	group 2 vs. group 4	group 1 vs. group2
Stenting	21 (42%)	17 (35%)	34 (65%)	31 (61%)	0,028	0,01	0,537
Coronary artery bypass surgery	6 (12%)	9 (18%)	4 (7,7%)	3 (5,9%)	0,521	0,069	0,414
Stenting + CABG	8 (16%)	9 (18,4%)	3 (5,8%)	4 (7,8%)	0,119	0,144	0,795
Balloon angioplasty without stenting	3(6%)	2 (4%)	0 (0%)	0 (0%)	0,114	0,238	1
Number of procedures	38(76%)	37(75%)	41(79%)	38(74%)	0,815	1	1
No revascularization	12(24%)	12(25%)	11(21%)	13(26%)	0,815	1	1

The number of stents was by 50% higher among patients with acute CHD without T2DM compared with those with T2DM, – 65 vs 42% (p=0.028). Patients with chronic CHD showed similar pattern. Stenting was performed in 61% of patients without T2DM, and in 35% of patients without T2DM (p=0.01). CABG frequency ranged from 6 to 18% among patients with acute and chronic forms of CHD. The frequency of this procedure did not differ significantly between the groups. The frequency of the combination of interventions (CABG followed by PCI) was comparable between those with and without T2DM. Angioplasty without stenting was performed among 4-6% of patients with T2DM. No patients from the control group underwent this procedure. Myocardial revascularization was not performed in 25% of cases, for various reasons, including subjective ones.

The aim of this study was to analyze endpoints in patients with acute and chronic CHD and T2DM (Table 3).

Table 3: The frequency of endpoints after one-year follow-up in patients with acute and chronic CHD with various glycemic status, n (%)

	Acute CHD and T2DM n=50	Chronic CHD and T2DM n=49	Acute CHD without T2DM n=52	Chronic CHD without T2DM n=51	p		
					group 1 vs. group 3	group 2 vs. group 4	group 1 vs. group2
Repeated MI	5 (10%)	3(6,1%)	2 (3,8%)	1 (1,9%)	0,265	0,357	0,715
Cerebral stroke	2 (4%)	1 (2%)	1 (1,9%)	2 (3,8%)	0,614	1	1
Death	3 (6%)	3 (6,1%)	1 (1,9%)	1 (1,9%)	0,358	0,357	1
Readmission	15 (30%)	10 (20,4%)	8 (15,3%)	5 (9,8%)	0,099	0,168	0,356
Repeated revascularization	10 (20%)	14 (28,6%)	4 (7,7%)	4 (7,8%)	0,088	0,009	0,356
Total number of endpoints	35 (70%)	31 (63,3%)	16 (30,1%)	13 (25,5%)	<0,001	<0,001	0,527

In both groups, recurrent MI was detected 2 times more often among patients with T2DM compared with those without T2DM. The frequency of stroke was up to 5%. One-year mortality in patients with acute and chronic CHD was 6%, and about 2% in patients without T2DM. Readmission was observed 2 times more often in patients with T2DM compared with the control groups. It is noteworthy that patients with acute and chronic CHD required repeated revascularization 3 times more often than patients without T2DM. This difference in patients with chronic CHD was statistically significant. The total number of endpoints in patients with acute and chronic CHD and T2DM2 was 2.5 times higher compared with those without T2DM that was statistically significant in both cases (p<0.001).

DISCUSSION

High cardiovascular mortality in patients with T2DM remains one of the main medical and social issues worldwide. According to the Gulf COAST registry, every second patient with ACS was diagnosed with T2DM (1906 patients out of 3576). One-year mortality was 13.7%, inpatient and 30-day mortality was 4.8% and 6.75%, respectively, that was higher compared with patients without T2DM [16].

The long-term prognosis of patients with ACS and T2DM was studied in another prospective study that included 2000 patients. At the same time, every fifth patient had previously established T2DM. It was demonstrated that 17% of patients died at the medium-term follow-up period that was 3.7 years. The significance of T2DM did not depend on such factors as smoking, age, thrombolysis, and hypoglycemic therapy. The risk of death associated with T2DM was significantly higher in females [17].

According to the literature data, T2DM was diagnosed in 25-30% of patients admitted with ACS, and in 40% of patients who underwent CABG [18].

Myocardial revascularization plays a pivotal role in the

reduction of absolute risk in patients with T2DM compared with those without T2DM [19]. International guidelines recommend CABG as revascularization method for patients with T2DM and multivessel CHD. However, the presence of severe comorbidity, older age, and a SYNTAX score of 0-22 are indications for PCI. [20].

In the present study, up to 80% of patients with acute and chronic CHD, regardless of the presence of T2DM, underwent myocardial revascularization, primarily stenting. It should be noted that the frequency of stenting among patients without T2DM with acute and chronic CHD was significantly higher compared with those without T2DM. At the same time, absolute number of patients with CABG and combination of CABG with stenting was higher in patients with T2DM.

According to the meta-analysis of 11 randomized trials involving 11518 patients who underwent PCI (n=5753) or CABG (n=5765) with mean follow-up of 3.8 years, mortality was higher in those who underwent CABG compared with PCI in patients with multivessel CHD (11.5% after PCI vs 8.9% after CABG, p=0.0019) and T2DM (15.5% vs 10.0%, p=0.0004) [21]. It is suggested that longer follow-up is needed to determine the difference in mortality between various revascularization strategies.

According to the Finnish National Registry (2000-2015) on day 28, the mortality risk after PCI was lower than after CABG among patients without T2DM, while no difference was observed among patients with T2DM. The situation was reversed during the long-term follow-up: PCI showed higher risk than CABG for most outcomes. In particular, during 3-year follow-up, all-cause mortality was higher among patients with T2DM (risk ratio (RR) - 1.30) than among patients without T2DM (RR - 1.09) when comparing PCI with CABG. Similar pattern has been shown for cardiovascular mortality (RR - 1.29) among patients with and without T2DM (RR - 1.03) [22].

In the present study, the majority of patients with T2DM underwent myocardial revascularization, however the number of refusals to procedure occurred 2 times more often than in patients without carbohydrate metabolism disorders - 15 vs 7%, respectively.

The present study assessed the effect of treatment on the number endpoints during one-year follow-up. A greater number of readmissions and repeated revascularization procedures was registered among patients with acute and chronic CHD and T2DM. The groups of patients with and without T2DM did not differ by the number of non-fatal and fatal complications. However, the frequency of total endpoints in patients with T2DM, regardless of the CHD type, was 2 times higher compared with the control groups. It is obvious that more pronounced coronary atherosclerosis and multivessel and distal coronary lesions worsens the prognosis in patients with T2DM.

Experts argue that after successful myocardial revascularization, the incidence of cardiovascular events in patients with T2DM remains high, regardless of the revascularization method, which emphasizes the need for secondary prevention [10]. According to the Swedish national registry SWEDEHEART (the Swedish Web-system for enhancement and development of evidence-based care in heart disease evaluated according to recommended therapies), long-term use of secondary prevention agents after myocardial revascularization (statins, β-blockers, renin-angiotensin system blockers and antiplatelet agents) is associated with a lower mortality risk that once again underlines the importance of long-term secondary prevention using pharmacological agents with various mechanisms of action [23].

CONCLUSION

The majority of patients with acute and chronic CHD without T2DM underwent stenting of one coronary artery, while patients with T2DM underwent CABG or the combination of two procedures along with stenting. After one-year observation, the number of cardiovascular complications in patients with T2DM was 2 times higher than in patients without T2DM, which emphasizes the importance of secondary prevention, including complex pharmacological treatment.

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