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The Use of Trimetazidine in Patients with Type 2 Diabetes Mellitus Who Have Suffered a Myocardial Infarction

Khusainova Munira Alisherovna
Toirov Doston Rustamovich
Uzokov Jurabek Baxtiyorovich
To'rayeva Aziza Sarvarovna
Samarkand State Medical University

Abstract: Modern achievements of world medical science and practice have made it possible to achieve tremendous success in the treatment of chronic non-infectious diseases. Improving the prognosis and quality of life of people suffering from the most common socially significant pathology of the circulatory system – coronary heart disease (CHD), contributes to progressive aging of the population economically developed countries. Thus, the number of DM patients in the world over the past 10 years has increased more than 2 times and by the end of 2015 reached 415 million people. According to the forecasts of the International Diabetes Federation, 642 million people will suffer from diabetes by 2040. According to the Federal Register, in Russia in 2016, 4 million people were registered for DM2, which amounted to almost 3% population. However, these data underestimate the real number of patients, since they only take into account you-revealed and registered cases of the disease, and the real number of patients with DM in the Russian Federation can reach 8-9 million people (about 6% of the population). It was noted that in more than 60% of cases in patients with DM2 cardiovascular diseases develop, and they are the cause of death of most patients. It is known that the risk of acute heart attack myocardium in patients with DM2 is 6-10 times higher than in the general population. The combination of coronary heart disease and diabetes is one of the most unfavorable conditions and leads to a multiple increase in cardiovascular complications and mortality of patients.
The problem of comorbidity of these two most widespread non- infectious pathologies is traditionally indicated mainly in the cohort of elderly and senile patients. However, recently the time recorded is "rejuvenation" of SD2. So, about 50% of all patients with DM2 in the world are aged 40-59 years old, i.e. people of active working age, which significantly aggravates the economic aspect of this problem.

Keywords: coronary heart disease, diabetes mellitus, myocardial infarction, trimetazidine

Introduction

Mortality from CVD in patients with diabetes mellitus (DM) is significantly higher (more than 2 times in men and more than 4 times in women) compared to the general population. The traditional approach to the treatment of angina pectoris involves the use of drugs that improve the correspondence between the myocardial oxygen demand and its flow through the atherosclerotic narrowed coronary arteries. The leading place in the pharmacotherapy of stable angina is occupied

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by the following groups of drugs: beta-blockers, angiotensin converting enzyme (ACE) inhibitors, nitrates, calcium antagonists, antiplatelet agents, statins. However, it is often not only with monotherapy, but also with a combination of these drugs complete elimination of angina attacks is not achieved. Therefore, new approaches to the treatment of coronary heart disease are currently being intensively developed. One of such directions is pharmacological correction of energy metabolism in the myocardium.

There is a point of view that in patients with DM2 after a myocardial infarction, myocardial cytoprotectors (trimetazidine) can play an important role for rehabilitation. Trimetazidine is the first widely used antianginal drug of metabolic action that improves energy metabolism in the myocardium through selective inhibition of long-chain 3-ketoacyl-CoAtiolase (3-CAT). Trimetazidine has been proven to stimulate glucose oxidation and inhibit the breakdown of fatty acids. Preductal MV has a pronounced anti-ischemic and anti-anginal effect and has already established itself as a highly effective pharmacological drug, additive in relation to traditional antianginal drugs, and has been widely recognized among doctors. The effect of trimetazidine in patients with DM2 with stable angina was demonstrated during a multicenter clinical trial. It has been shown that trimetazidine increases exercise tolerance and increases myocardial contractility by restoring the function of cardiomyocytes that were previously in a state of hibernation. Thus, to improve the results of treatment of coronary heart disease in patients with DM, including a real improvement in the prognosis after a MI, it is advisable to prescribe therapy aimed at the entire complex of hemodynamic and metabolic disorders associated with a high frequency of cardiovascular complications.

The aim of the study was to evaluate the effectiveness of the use of preductal MV against the background of basic therapy in patients with DM 2 who underwent MI.

Materials And Methods of Research

This work is a comparative, open, parallel, prospective, randomized clinical trial. 106 patients (59 men and 47 women) suffering from and undergoing DM2 were examined and treated. The age of the patients was 61.2+1.3 years. Patients were included in the study on the 18th-21st day after the development of MI (on average, 18.8 ± 1.2 days).

Criteria for inclusion of patients in the study:

a) verified primary MI of 18-21 days ago;
b) type 2 diabetes mellitus;
c) informed written consent to participate in the study.

Criteria for excluding patients from the study:

a) ejection fraction (EF)<40%, CHF III–IV FC according to the classification of the New York Heart Association (NYHA);
b) unsatisfactory visualization of the heart;
c) valvular heart defects;
d) the heart rate (HR) at rest is more than 100 v1 min.;
e) refusal of patients to participate in research and treatment after discharge from the hospital;
f) participation in any other study.

Patients with MI by random number method were randomized into two groups.

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Group 1 patients (n=51) were prescribed preductal MV (trimetazidine MV from Servier, France) at a dose of 70 mg/day, in combination with basic therapy, which included beta-blockers, ACE inhibitors, diuretics, antiplatelet agents, nitrates, statins, hypoglycemic drugs. In the control group (n=55) only basic therapy was prescribed.

At the first stage of observation, all patients underwent a detailed collection of complaints, anamnestic data and a thorough clinical examination. Be sure to find out the presence of bad habits: smoking (with the specification of smoking dates and the number of cigarettes smoked per day), alcohol consumption.

Echocardiographic examination (ECHOCG), ECG registration, monitoring ECG, six–minute walk test and quality of life assessment were performed three times - on the day of discharge, six months later and a year later. Echocardiography was performed on an echocardiograph "Aloka-2200" in accordance with the recommendations of the ASE Nomenclature and Standardization Committee. The following parameters were determined: final systolic size (FSS), final diastolic size (FDS), final diastolic volume (FDV), final systolic volume (FSV), left atrium size (LAS), stroke volume (SV), left ventricular ejection fraction (LVEF), thickness of the posterior wall of the left ventricle (TPWLV), the thickness of the interventricular septum (TIS), the sphericity index (SI), the index of the relative thickness of the LV wall (IRTLV), myocardial stress (MS).

IRT the LV wall was determined by the ratio of the thickness of the interventricular septum and the posterior LV wall to the transverse size of the LV cavity in the diastole. SI LV was defined as the ratio of the transverse size of the LV to its long axis. SI was measured in diastole (normal – 0.55–0.65) and systole (normal – 0.40–0.45).

MS characterizes the tension force of the myocardial fibers per unit cross-section of the LV wall and is a quantitative reflection of the magnitude of pre- and post-loading. At the end of the diastole, MS reflects preload, at the end of the systole – postload. There are meridional, circumferential and regional myocardial stresses. The meridional MS in g/cm2 was calculated. MS = 0.334 = SAD = FSSLV/TPWLV = (L+(TPWLV / FDSLV)), where L is the long axis of the The Taichholz LV SV was calculated as the difference between FDS and FSS.

FSV = 7 = FSS3/ 2,4 + FSS

FDV = 7 = FDS 3 / 2,4 + FDS

The ejection fraction was determined by the formula:

SV × 100% /FDV

Monitoring ECG was performed using a computer program DiaCard (the number of patients with ST segment depression>1 mm, the number of patients with pain-free ischemia, the number of patients with pain-free and pain-free ischemia, the average number of episodes of pain-free ischemia, the average number of episodes with pain-free ischemia, the number of patients with supraventricular and ventricular extrasystole were determined).

The assessment of the quality of life of patients in points was carried out according to the adapted Minnesota questionnaire (LWHF index) of the quality of life of patients with CHF. The initial data on the quality of life were as follows: in the 1st group - 27.5 (average), in the 2nd – 26.8 points. Methods of statistical processing of research results Methods of descriptive parametric statistics were used: mean (M), standard deviation (±s) representation form [±s] or mean (M), mean error (±m) [form of representation of M±m], nonparametric statistics, as well as methods of

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comparative statistics (Chi-squared criterion, etc.), calculation of confidence intervals, median (Me) and quartiles (25%, 75%) [form of representation of Me (25%; 75%)].
Note: intergroup comparisons (comparisons with control) were carried out according to the Mann–Whitney criterion, intragroup comparisons – according to the Wilcoxon criterion. The symbol p1–2 indicates the reliability of the differences between the 1st and 2nd stages of the study, the symbol p2-3 indicates the reliability of the differences between 2nd and 3rd stages.

Results

Patients of both groups included in the study did not significantly differ in the severity of diabetes mellitus, the ongoing hypoglycemic therapy and concomitant pathology.
Hypertension was present in 94.4% of patients in the trimetazidine MV group and in 85.7% of patients in the control group. Mild diabetes mellitus was present in 26.5% in the trimetazidine MV group and in 29.6% in the control group, moderate severity – in 58.8% and 53.5%, respectively; severe diabetes mellitus affected 14.7% and 16.9% (control) patients. Compensation of carbohydrate metabolism was achieved by using a diet inpatients with mild diabetes. Oral hypoglycemic drugs were taken by 48.6% in the trimetazidine MV group and 54.9% of patients in the control group. 22.9% and 23.9% of patients in the respective groups received insulin. The characteristics of myocardial infarction in both groups of patients were also comparable – primary in 54.3% in the trimetazidine MV group and in 49.3% of patients in the control group. Complications of a heart attack myocardium – the development of acute left ventricular failure was noted in 14.3% of patients in the trimetazidine MV group and in 15.5% of patients in the control group, the development of paroxysm atrial fibrillation was observed in 8.6% and 8.5% of patients of the corresponding groups. The therapy given to patients before the development of myocardial infarction, the treatment of acute myocardial infarction and subsequent antianginal and hypotensive therapy in both groups of patients were also comparable. Dynamics of echocardiographic parameters
To assess the effect of preductal MV in combination with basic therapy on LV myocardial remodeling using echocardiography, the following parameters of remodeling were determined in group 1 patients (n=51): myocardial stress, sphericity index and meridional myocardial stress at each stage of the study, as well as indicators of LV systolic function. With adaptive modeling, the indicators of systolic function tend to positive changes (an increase in PV, a decrease in BWR, CSR); when its maladaptive nature leads to the identification of opposite changes.
Assessment of the clinical condition of patients
To identify the features of the clinical course of the post-infarction period against the background of the treatment, patients who underwent MI underwent a 6-minute walk test with an assessment of CHF FC and an assessment of the need for nitrates in patients with post-infarction angina on the day of discharge, after 6 months and a year.
Prior to the study, postinfarction angina was observed in six patients in group 1, and in five patients in group 2. A decrease in the need for nitrates was noted in five patients of group 1, in the control group it remained the same. As can be seen from Table 4, in Group 1, after 6 months, there was an increase in exercise tolerance by 5.6%, after a year - by 17.7%; in Group 2, a slight improvement in test indicators was detected after 6 months by 0.5%, after a year – by 1.6%.

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Changes in quality of life indicators The assessment of the quality of life in the study groups was carried out according to the Minnesota questionnaire three times – on the day of discharge, six months later and a year later. In the 1st group of patients, quality of life indicators (average value in points) improved by 37.5% after 6 months, after12 months – by 55.2%; in the control group – by 2.2% in six months and by 3.7% in a year. Thus, against the background of pronounced positive dynamics in the first group, the changes in the control group were insignificant. Monitoring ECG was performed three times: on the day of discharge, after 6 months and 12 months. During this study, the frequency of rhythm and conduction disturbances and the number of episodes of pain-free myocardial ischemia were recorded. The results of CMECG in group 1 are presented: the number of episodes of pain-free myocardial ischemia decreased by 21.4% after 6 months, by 35.7% after 12 months; ventricular extrasystole decreased by 28.7% after six
months, by 31.2% after a year; supraventricular by 21.1 and 25.3%, respectively. In the control group, the number of episodes of pain-free myocardial ischemia decreased by 8.3% after six months, after 12 months – by 30.5%. Ventricular extrasystole six months later it decreased by 2%, a year later – by 6.2%; supraventricular by 11.1 and 15.5, respectively%;

Conclusions

1. The use of preductal MV in combination with multicomponent basic therapy in patients with DM2 who have undergone MI, more effectively prevents maladaptive remodeling of the heart (reduction of myocardial stress, sphericity index and increase in the index of relative thickness of the myocardium).
2. The use of a combination of preductal MV and basic therapy in patients with DM2 who have undergone MI leads to a significant reduction in the need for nitroglycerin intake in 90% of group 1 patients, episodes of ventricular extrasystole – in 31.2%; supraventricular – in 25.3%, episodes of pain–free myocardial ischemia - in 35.7% compared with patients of the control group.
3. With prolonged use of preductal MV as part of complex therapy in patients with DM2 who underwent MI, with impaired contractility, PV, FU increased ($p<0.05$), the number of episodes of pain–free myocardial ischemia decreased - according to daily ECG monitoring ($p<0.05$).
4. Complex treatment using preductal MV for 6 months after IM, then significantly improves the quality of life of patients throughout the year.

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