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The efficacy of rosuvastatin in the treatment of coronary heart disease in elderly patients after percutaneous intervention

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Abstract. Epidemiological studies have shown that the increased levels of low-density lipoprotein (LDL-C), triglycerides (TG) and very low-density lipoproteids (VLDL-C) and the decrease in the high-density lipoproteins (HDL-C) are among the most powerful risk factors for CVD. The introduction of statins into clinical practice in the late 80s of the last century made it possible to significantly affect mortality from CVD. The meta-analysis of 10 large-scale studies, which included about 80 thousand patients, showed that this class of the drugs provides for the reduction in the frequency of cardiovascular events by 27%, stroke - by 18%, and overall mortality - by 15%.
This article is devoted to the study of the rosuvastatin efficacy in elderly patients with coronary artery disease who underwent percutaneous intervention (PCI). The data obtained indicate the effective impact of the studied drug on blood lipid composition, the decrease in mortality, coronary artery restenosis, MI, and the number of re-hospitalizations in elderly patients with coronary artery disease after PCI.
Keywords: ischemic heart disease (IHD), exertional angina, statins, percutaneous coronary intervention

Background. Based on the literature data, the prevalence of coronary heart disease in most cases depends on the age and gender. It was established that in persons aged 45-54 years, angina pectoris is observed in 2-5% among men and 0.5–1% among women. At the same time, among 65-74-year-old people it is observed in 11-20% of men and 10-14% of women, respectively. Mortality from coronary heart disease in persons under the age of 65 has decreased by 50% in recent years, which should be associated with more active tactics of acute myocardial infarction (MI) treatment with the use of thrombolysis or early revascularization. However, it should be emphasized that the overall mortality from coronary heart disease remained unchanged [1].

The main etiological factor in the development of coronary artery disease is coronary arteries atherosclerosis. The risk of developing atherosclerosis increases significantly with the risk factors such as male gender, old age, dyslipidemia, arterial hypertension, diabetes mellitus, tobacco smoking, obesity, physical inactivity, alcohol abuse [2]. Studies have shown that there is a clear positive direct correlation between the increased content of cholesterol and low-density lipoprotein cholesterol in blood

plasma and the risk of atherosclerosis, whereas this relationship is reversed with the high-density lipoprotein cholesterol [1,2].

Meta–analysis of 37 clinical studies has shown that the decrease in cholesterol levels against the background of lipid-lowering therapy is significantly associated with the reduction in the mortality from coronary heart disease [3]. So, the most important aspect of pharmacological therapy in patients with coronary heart disease is the use of medicines that reduce the level of lipids in the blood. Among the statins that have appeared in different years, rosuvastatin is the most active. In the open randomized trial MERCURI and in two open randomized trials MERCURI I and MERCURI II, the advantage of rosuvastatin at the dose of 10-20 mg/ day was shown in high-risk patients compared with equivalent doses of atorvastatin, simvastatin and pravastatin in achieving the target level of low density lipoprotein cholesterol [3].

In the ASTEROID study [4], in patients with coronary artery disease treated with rosuvastatin at the dose of 40 mg / day, the decrease in the plasma concentration of LDL cholesterol from 53.2% to 60.8 mg/ dl was achieved, which was accompanied by the significant regression of the atherosclerotic plaques volume and the increase in the coronary arteries lumen in stenopeic areas. Along with this, there was the increase in the plasma concentration of HDL cholesterol by 14.7%. In the JUPITER clinical trial, against the background of rosuvastatin, cardiovascular mortality decreased by almost 2 times (47%), MI decreased by more than 2 times (54%), the risk of stroke became almost 2 times lower (48%), and overall mortality significantly decreased (20%). Of course, these results were accompanied by the significant decrease in the level of low-density lipoproteins by 50% and the decrease in the level of C-reactive protein by 37% [3,4].

Objective: to study the effectiveness of rosuvastatin in elderly patients with coronary artery disease who underwent percutaneous intervention (PCI).

Materials and methods of the study

105 patients were examined with coronary heart disease aged from 60 to 78 years, who were in different clinics of Tashkent city and on an outpatient basis at the Department of Cardiology and Gerontology with the course of interventional cardiology and arrhythmology of the Center for the Development of Medical Workers Professional Qualifications (CDMWPQ). Both groups were significantly dominated by men, which is consistent with the high prevalence of cardiovascular diseases among males. All examined patients had indications for myocardial revascularization (percutaneous coronary intervention).

Of 105 patients, 80 patients (the main group) took roviros (rosuvastatin, Nabiqasimpharma, Pakistan) at the dose of 20 to 40 mg per day for 4 months after PCI and 25 patients (control group) did not receive statins, due to the refusal of lipid-lowering therapy. Patients of the main group were examined three times: initially, in a month and 4 months after PCI.

Inclusion criteria: verified diagnosis of coronary heart disease based on complaints, anamnestic data, clinical picture, results of the objective study. *Exclusion criteria*: severe concomitant pathology - decompensation of diabetes mellitus, oncological diseases, fever accompanied by inflammatory changes in the blood, renal, hepatic insufficiency and severe widespread lesions of the central nervous system.

The following study methods were used: blood lipid composition, CRP, IL-6 and TNF-α, coronary angiography with subsequent stenting. The endpoints were studied; lethality, MI, re-hospitalization, coronary arteries restenosis.

In statistical processing of the study results, the Student's t-test was used, the differences were considered reliable at $p \leq 0,05$.

Study results

The results of the blood lipid spectrum study revealed that in all the examined patients, the values of total cholesterol (OHC), low-density lipoproteins (LDL), atherogenicity coefficient (CA) and triglycerides (TG) exceeded the levels recommended for the patients with very high risks of cardiovascular complications (Fig.1).

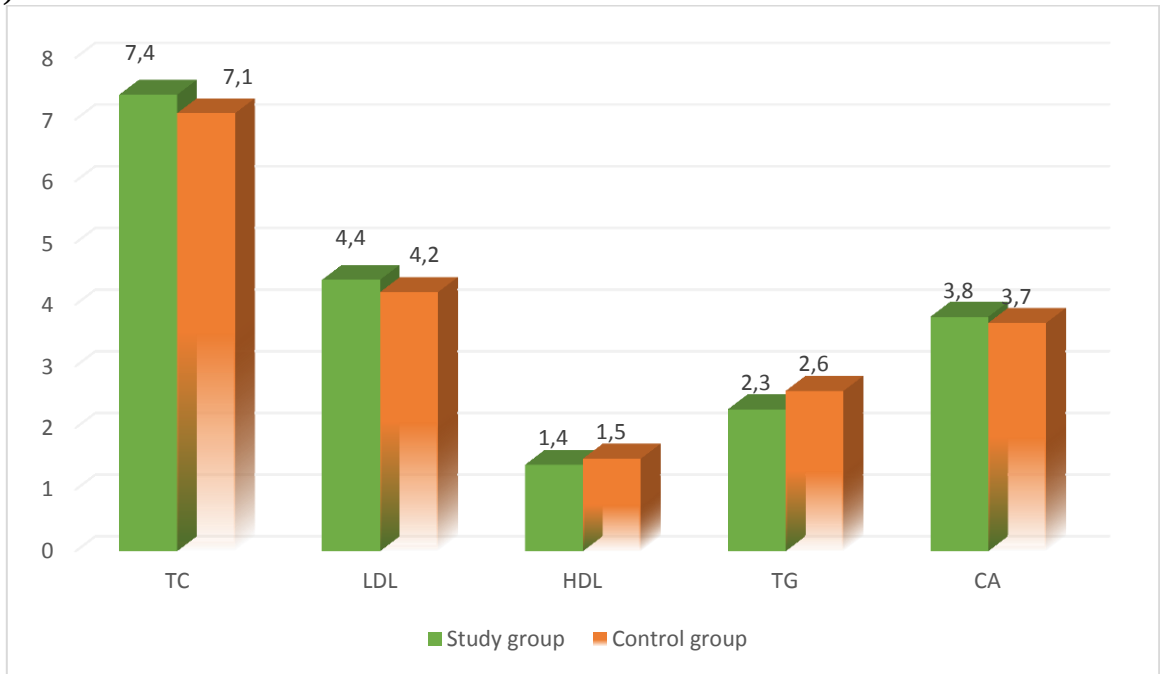


Figure 1. Indicators of lipid metabolism in the studied groups

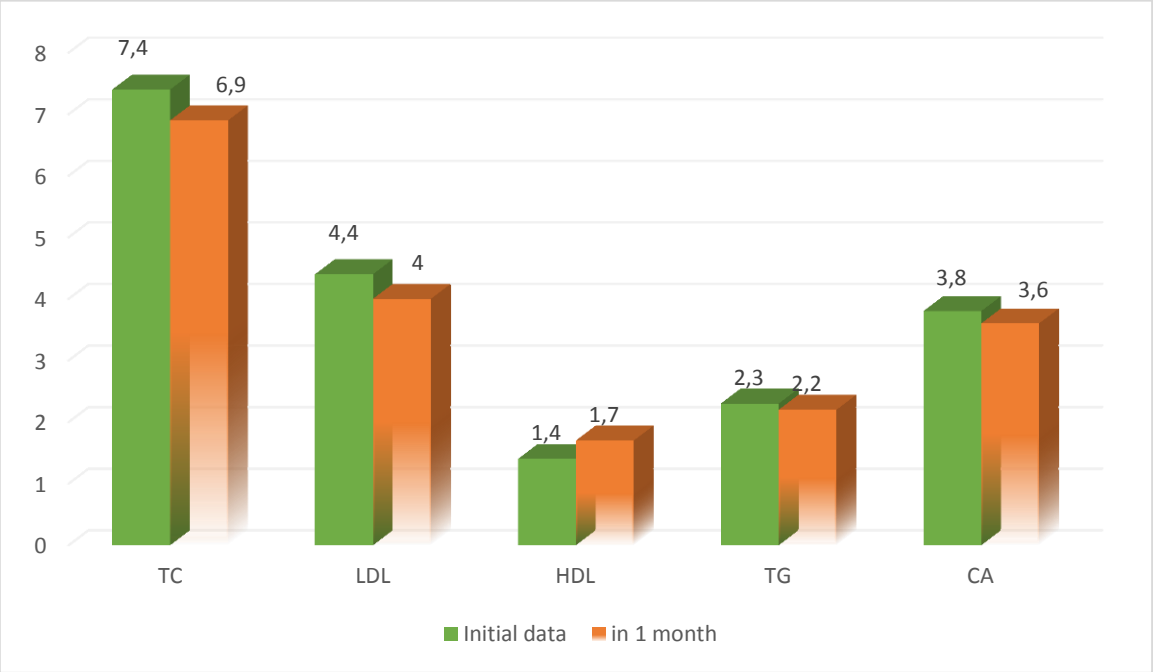
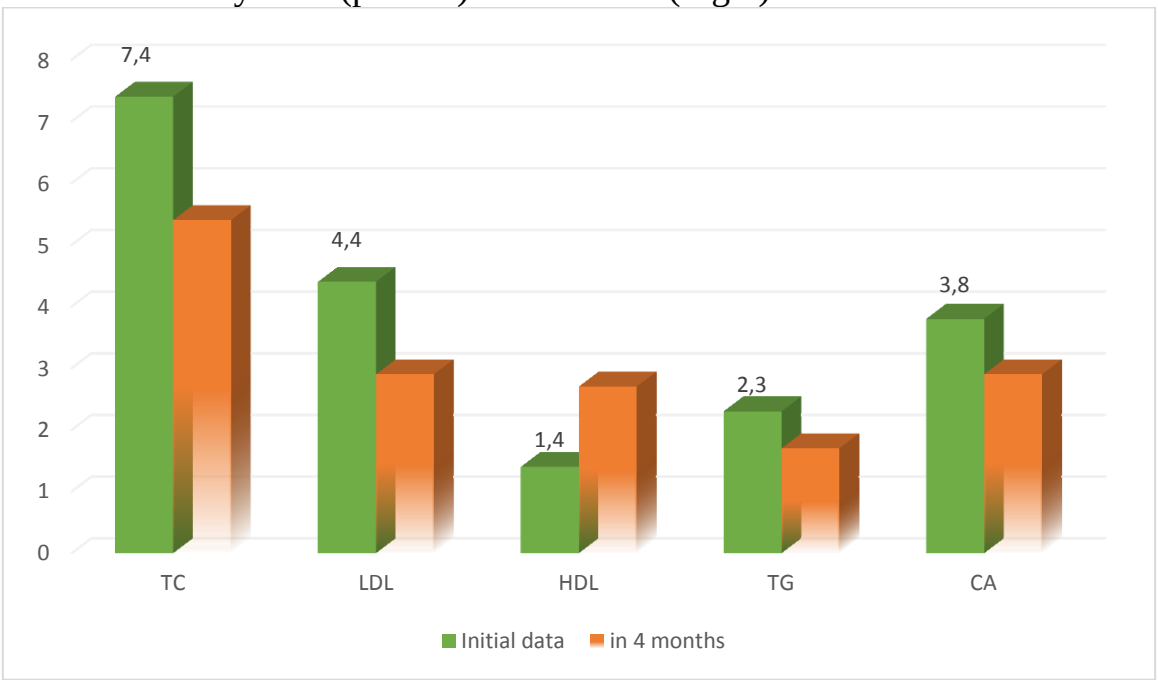


Figure 2. Indicators of lipid metabolism in the studied groups in a month

Analysis of the lipid composition in a month gave little significant positive dynamics in patients with coronary heart disease after PCI (Fig.2).

More significant hypolipidemic effect on the background of roviros therapy can be traced in 4 months, where the significant decrease in total cholesterol by 37% ($p< 0.01$), LDL by 52% (($p<0.05$), TG by 35% ($p<0.01$), CA by 31% ($p<0.05$) and the increase in HDL by 51% ($p<0.05$) are detected (Fig.3).



Note: *p<0,05, ** p<0,01 reliability of differences between groups

Figure 3. Indicators of lipid metabolism in the studied groups in 4 months

The decrease in lipids after PCI in patients is explained not only by the main effect of statins, but also by the increase in their compliance from among those who had not previously received statins. The proven relationship between the level of LDL and mortality from coronary heart disease, the frequency of acute coronary events dictates the need for the significant reduction in the content of LDL in the blood [3].

Numerous studies have proven the "pleiotropic effects" of statins, which are realized in improving endothelial function, suppressing inflammation in the vascular wall, reducing platelet aggregation and proliferative activity of smooth muscle cells [4].

In 1994, Luiza G. et al. has been proven that the high level of CRP is the predictor of coronary heart disease unfavorable prognosis. In our patients at the first visit, the CRP index in both groups had a high value (Fig.4). We observed the significant decrease in its level against the background of regular therapy with roviros in 4 months ($p<0.01$) (Fig.5).

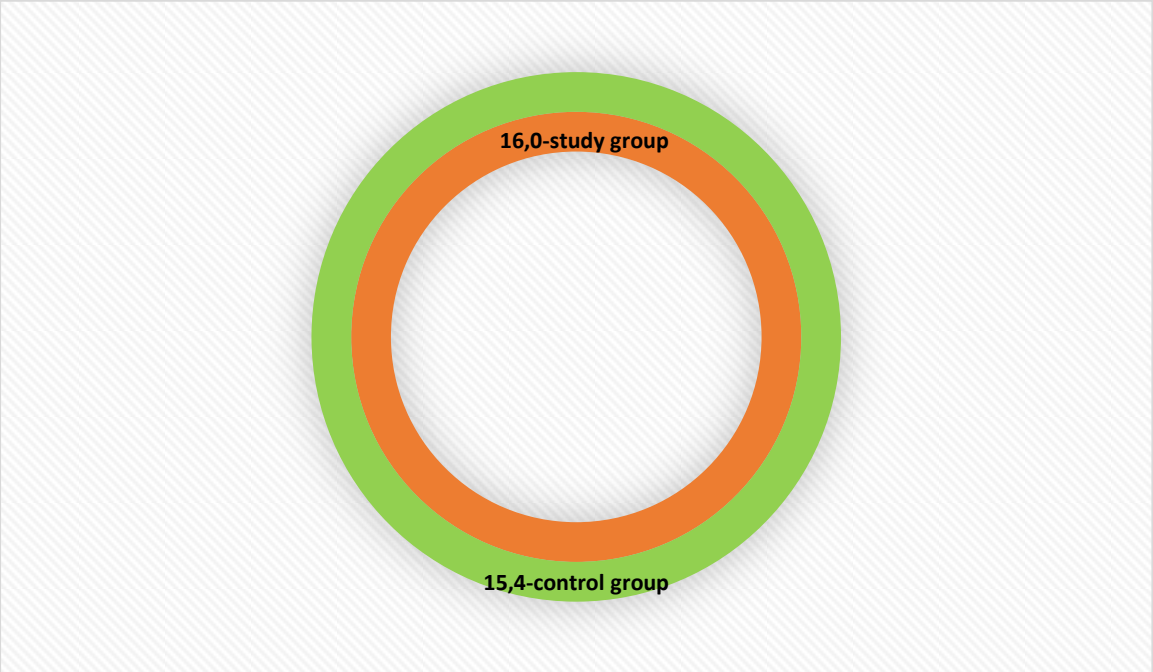
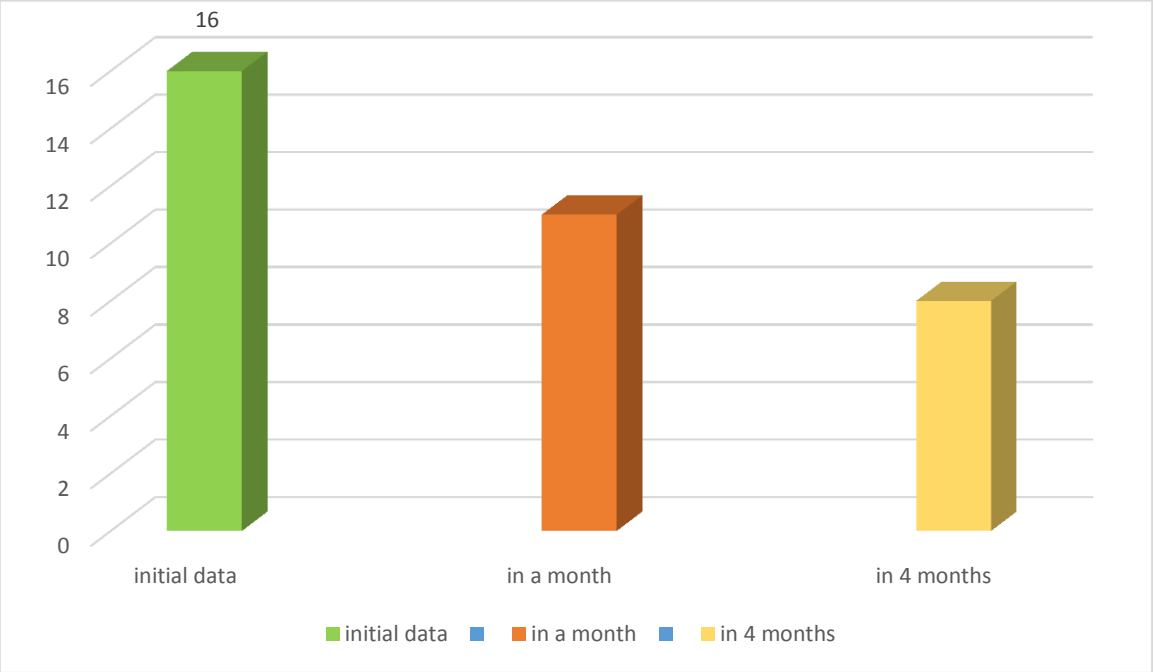


Figure 4. CRP indicator in the analyzed groups (initial data) mg/l



Note: *p<0,05, ** p<0,01 reliability of differences in relation to the initial data

Figure 5. CRP indicator in the analyzed groups (one month and 4 months after PCI) mg/l

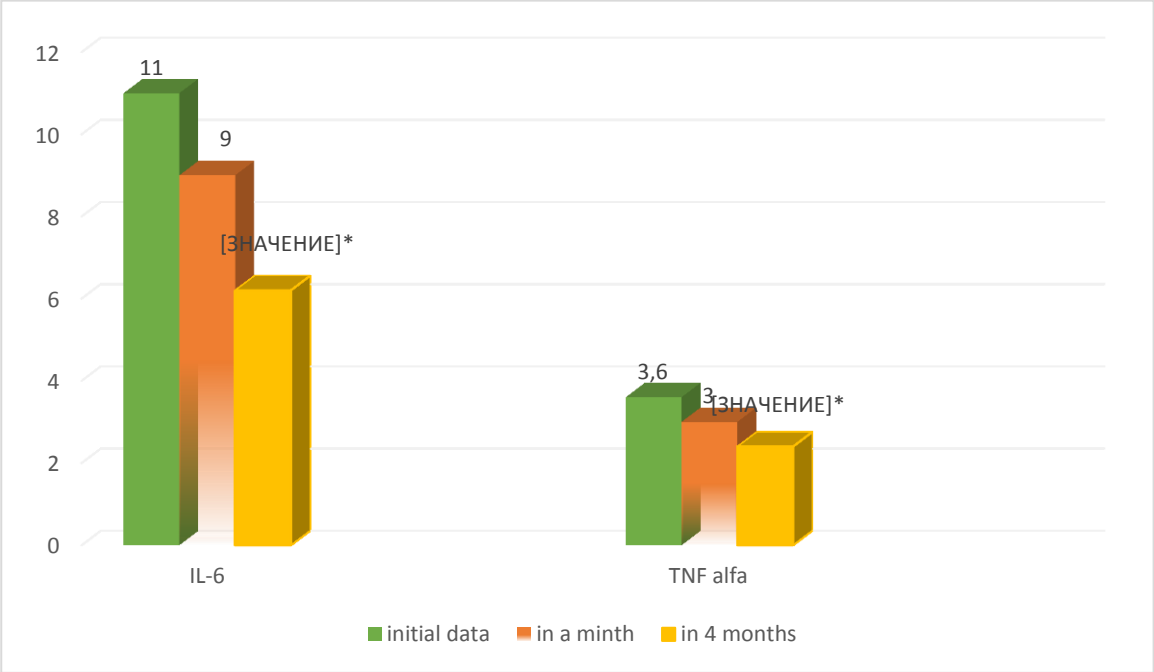
In patients who did not receive roviros after PCI, the mean values of CRP remained at the significantly higher level for 4 months (17.6±1.3 mg/l).

Table 1.

Comparative analysis of cytokine status indicators

Index	Study group		Control group	
	M	m	M	M
IL-6 pg/ml	11,0	0,32	11,7	0,46
TNF-α pg/ml	3,6	0,04	4,0	0,08

The results of the TNF-α and IL-6 determination in the blood serum of patients with coronary heart disease indicate its increase in both groups of patients on the day of hospitalization.



Note: *p<0,05- reliability of differences in relation to the original data

Figure 6. Comparative analysis of cytokine status indicators one month and 4 months after PCI (pg/ml)

Comparative analysis of the indicators in patients with respect to the baseline values also showed the substantial and significant decrease in the level of proinflammatory cytokines after 4 months and that once again proves the pleiotropic effects of statins.

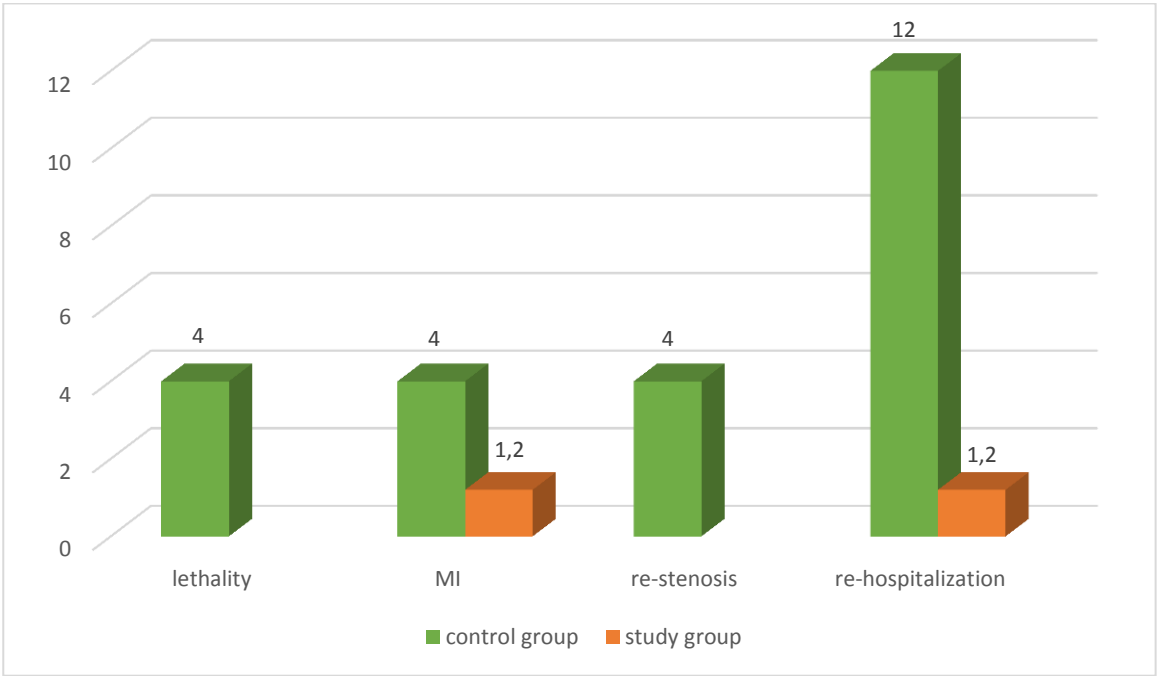


Figure 7. Analysis of endpoints in the examined patients (%)

By the 4th month of observation, the groups differed in the frequency of large CVD. The frequency of MI was 4.0% in patients of the control group (n=1). No deaths were observed in the study group, but one (1.2%) patient had MI. Lethality in the control group within 4 months was detected in one patient (4%).

Conclusions:

1. In the course of the study, it was shown that taking roviros in the complex treatment after myocardial PCI improves the course of coronary artery disease, which is confirmed by the improvement in lipid metabolism and proinflammatory cytokines.
2. Roviros effectively affect the reduction of mortality, coronary artery restenosis, MI and the number of repeated hospitalizations in elderly patients with coronary heart disease after PCI.

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