REPORT

Assessment of the Clinical Efficacy of Lipomezin USA

in Patients with Elevated Levels of Blood Cholesterol

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Lipomezin USA contains dry red rice yeast extract (Monascus purpureus), dry extract of Lespedeza capitata, dry grape seed extract (Vitis vinifera), Policosanol. Lipomezin USA can be used in patients with elevated blood cholesterol levels. Lipomezin USA is a nutritional supplement with a composition of natural substances.

Hypercholesterolemia occurs in various conditions - arterial hypertension, overweight and obesity, diabetes mellitus, chronic kidney disease (CKD), family history, etc. This characteristic of etiological factors is indicative of a high number of patients with elevated cholesterol levels in the blood. These are groups of patients at high risk for cardiovascular disease, especially acute ones. This makes the treatment of hypercholesterolemia imperative. The most common therapy is the use of statins. They are synthetic products with some important side effects, among which the most important is rhabdomyolysis, especially in the patients of advanced age and the elderly people. This data gives us reason to use Lipomezin USA in patients with hypercholesterolemia.

The purpose of the clinical study is to determine the effect of Lipomezin USA in patients with elevated serum cholesterol levels.

A group of 30 male and female patients, in equal proportion, having hypercholesterolemia was monitored, but without extremely high values (over 7.5 mmol/l) and severely manifested underlying clinical conditions. The monitoring period is 90 days. Patients were initially controlled prior to initiation of treatment and at least two other controls were done, one of which - at the end of the 3rd month.

The following parameters were monitored: serum total cholesterol (<5.2 mmol/l), HDL cholesterol (>1.45 mmol/l), LDL cholesterol (<3.0 mmol/l), 3-glycerides (<1,7 mmol/l), enzyme serum creatinine, glomerular filtration, urea, uric acid, GOT, GPT, AF, GGT, LDH, bilirubin, blood glucose, blood pressure, side effects of muscle pain and rhabdomyolysis.

The main characteristics of the studied group at the start of the study are presented in the following table 1:

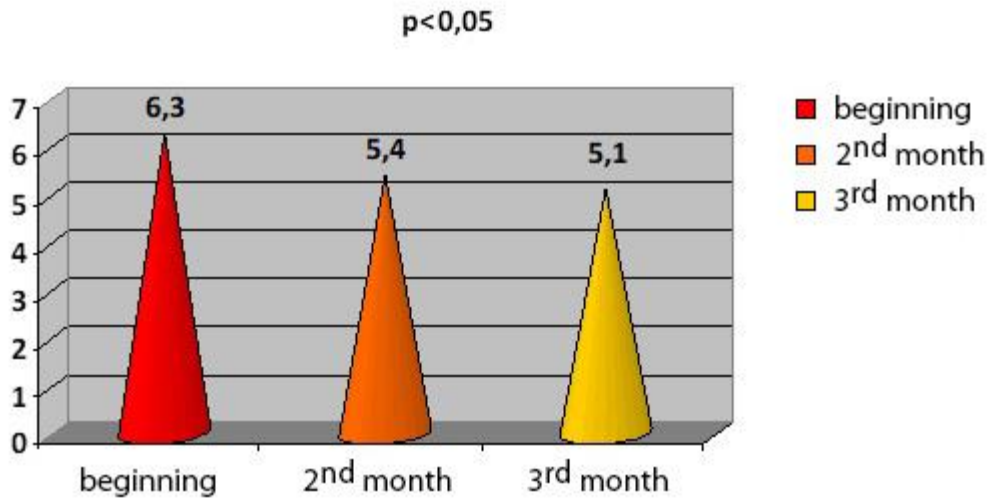
Table 1. Main characteristics of the patients studied

M: F.	Middle-aged (years)	Average cholesterol level at the beginning (mmol/l)	Average level of HDL-cholesterol at the beginning (mm/l)	Average level of LDL-cholesterol at the beginning (mmol/l)	Average level of 3-glycerides at the beginning (mmol/l)	Average GF at the beginning (ml/min/1.73 m2)
1:1	62±7	6,3±0,5	1,25±0,1	3,56±0,32	2,2±0,35	86±26

RESULTS

In the process of patients monitoring, the total cholesterol values monitoring was the most important. We have seen a downward trend with available statistical proof of change at the end of the third month. The results are illustrated in the following graph 1:

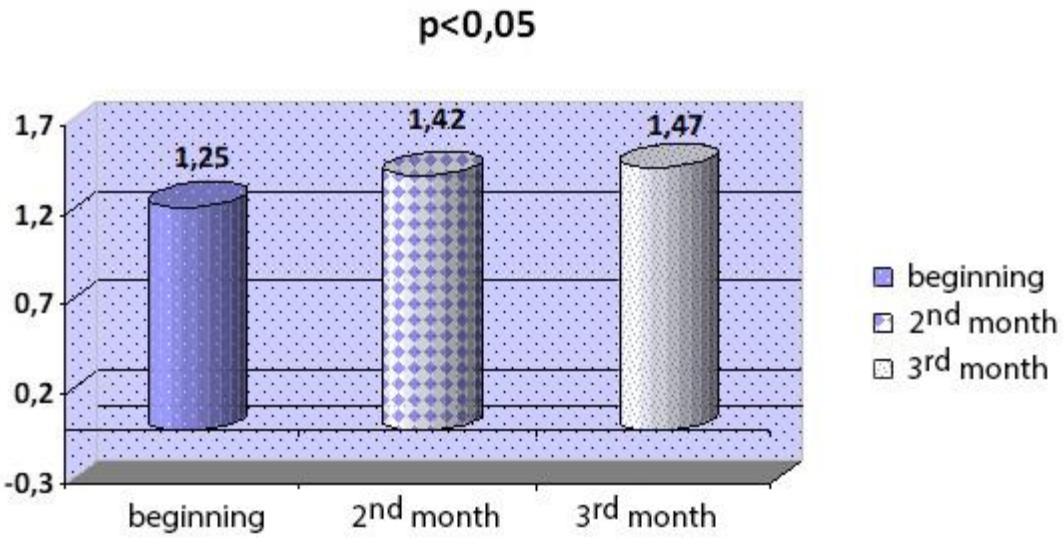
Graph. 1. Change in cholesterol levels at the beginning and on the 90th day of study.



The change in total cholesterol level is from a baseline of 6.3 mmol/l at the beginning to 5.4 mmol/l at the second month, and to 5.1 mmol/l at the end of the study. The reduction is greater in the first half of the study but at the end the cholesterol levels are normal. The conclusion is that the administration of Lipomezin USA for treatment of patients with elevated serum total cholesterol levels leads to a reduction of the elevated serum cholesterol levels, and achievement of normal levels.

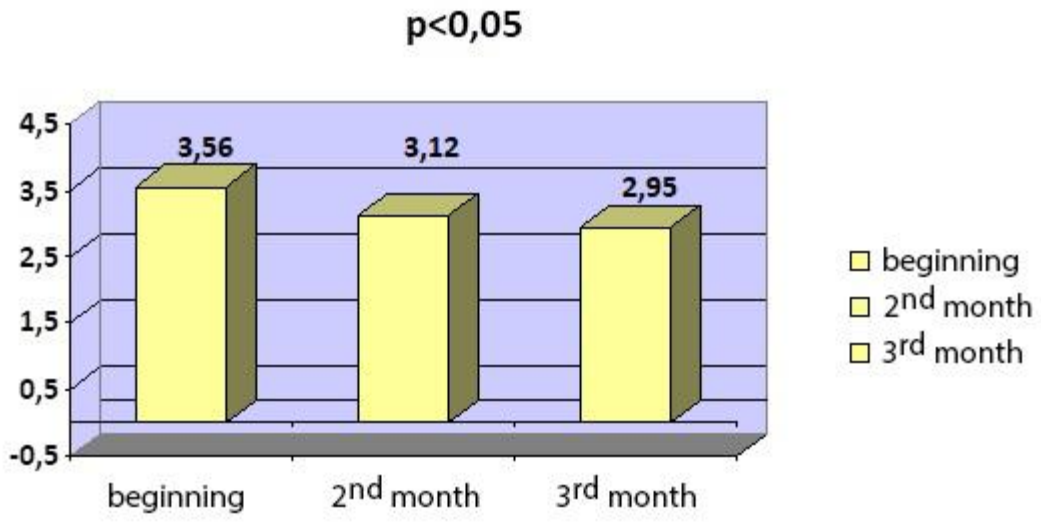
In monitoring the changes in the individual total cholesterol fractions statistically reliable results were achieved. The change in HDL-cholesterol levels is respectively 1.25 mmol/l initially, 1.42 mmol/l at the second month, and 1.47 mmol/l at 90th day, or in fact reaching normal HDL cholesterol values. These changes are presented on Graph 2:

Graph. 2. Changes in HDL-cholesterol levels.



Changes in LDL-cholesterol levels are similar to those in HDL-cholesterol. They are respectively 3.56 mmol/l at the beginning, 3.12 mmol/l at the second month and 2.95 mmol/l at 90th day, with statistically significant proof p <0.05. This is presented in the following graph 3:

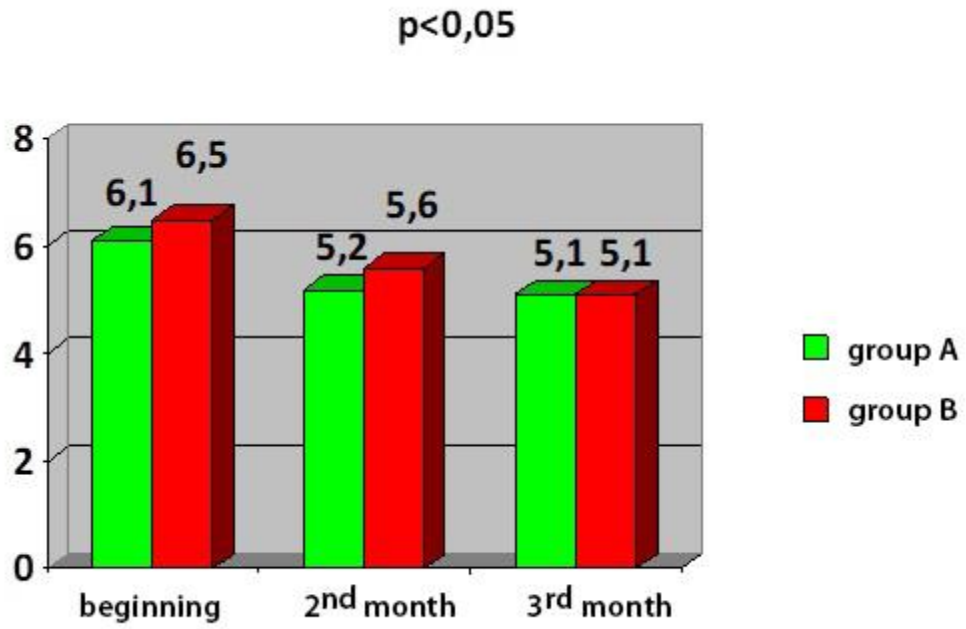
Graph. 3. Changes in LDL-cholesterol in the studied group.



Changes in HDL- and LDL-cholesterol levels are a logical feature of the credible reduction in total serum cholesterol.

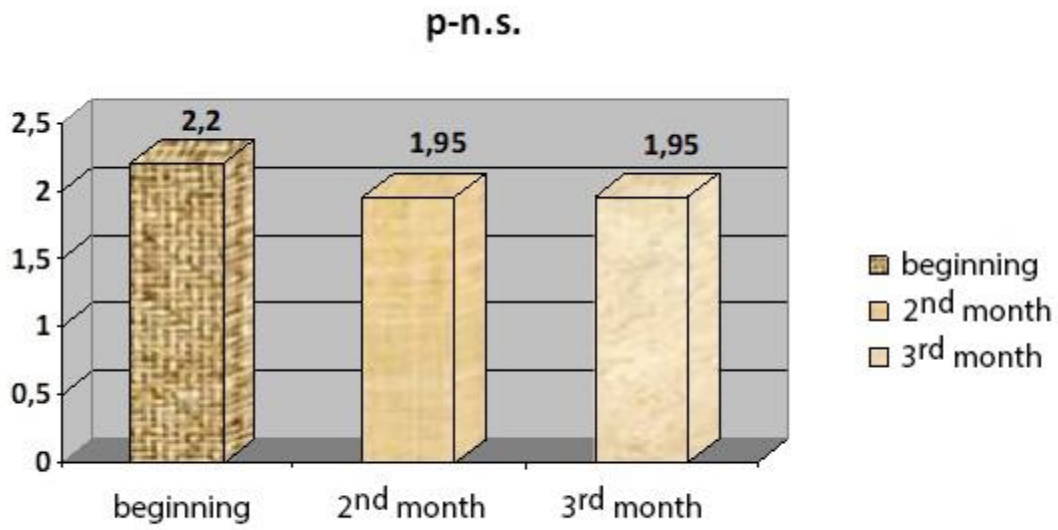
The studied group of patients with hypercholesterolemia was divided into two subgroups according to glomerular filtration (GF) - group A with normal GF ≥ 90 ml/min/1.73 m2 (mean creatinine 89+7 μmol/l); Group B with slightly or moderately reduced GF - 76-30 ml/min/1.73 m2 (mean creatinine 182±18 μmol/l), respectively 18 patients in group A and 12 in group B. The changes in the two subgroups are respectively: with reduced GF - 6.5-5.6-5.1 mmol/l, respectively; with normal GF - 6.1-5.2-5.1 mmol/l, respectively. The decrease in serum cholesterol in both subgroups has statistical reliability, respectively, there is no statistical difference between the two subgroups. The conclusion on the application of Lipomezin USA in patients with hypercholesterolemia with both normal and slightly and moderately reduced GF (CKD - 3 degree) is that it leads to normalization of cholesterolemia irrespective of the renal function. This is illustrated on Graph 4:

Graph. 4. Changes in serum cholesterol levels in groups A and B.



The monitoring of the changes in triglyceride levels show a decrease in their levels at the third month and are presented on Graph 5:

Graph. 5. Changes in serum triglyceride levels.



The change from 2.2 mmol/l to 1.95 mmol/l at the second month, and to 1.95 mmol/l at the third month of triglyceride monitoring is without statistical significance, but shows a clear downward trend.

During the monitoring process of the entire group of patients studied, the other parameters mentioned above were also regularly monitored. There was no statistically significant change in these parameters.

It is important to note that in patients with impaired renal function the application of Lipomezin USA does not lead to its worsening.

Patients were closely monitored and questioned for side effects - pain or weakness in the muscles as a sign of rhabdomyolysis, gastrointestinal symptoms - appetite decline, nausea, burning, upset, allergic manifestations, etc. have not been established. This proves optimal tolerability when taking Lipomezin USA, making it safe for patients.

CONCLUSION

On the basis of the study and the results obtained, we can draw the following conclusions:

Administration of Lipomezin USA results in a significant decrease and normalization of serum total cholesterol.

Administration of Lipomezin USA in patients with hypercholesterolemia leads to normalization of HDL- and LDL-cholesterol levels.

The effect of Lipomezin USA on triglycerides tends to reduction, but no normal serum levels are achieved.

The administration of Lipomezin USA does not cause unnecessary side effects, making it optimally tolerable by patients.

The application of Lipomezin USA in patients with impaired renal function does not cause its deterioration.