The use of herbal remedy Glibofit for regulating carbohydrate and lipid metabolism in patients with prediabetes and type 2 diabetes mellitus

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Summary:

The analysis of laboratory parameters of carbohydrate and lipid metabolism (fasting glucose, glycosylated hemoglobin, total cholesterol) was performed in patients with pre-diabetes and type 2 diabetes mellitus (70 people). Three clinical groups of patients (40 people with moderate type 2 diabetes mellitus, 10 people with mild type 2 diabetes mellitus and 20 people with pre-diabetes mellitus) were formed in accordance with the severity of carbohydrate metabolism. The analysis of the dynamics of certain carbohydrate and lipid metabolism parameters has shown that Glibofit had positive effect on patients with pre-diabetes and type 2 diabetes mellitus. The use of metformin at a daily dose of 1500-2000 mg in combination with Glibofit has caused a significant decrease of fasting glucose (by 17.9%), glycosylated hemoglobin (by 0.44%), and total cholesterol levels in patients of the first group. In patients of the second and third groups, the use of Glibofit has resulted in a significant decrease of fasting glycemia by 25.6% and 13% respectively. The glycosylated hemoglobin and total cholesterol parameters also tended to decrease. The obtained results confirm the rationality to use Glibofit in combination with hypoglycemic agents for the regulation of carbohydrate and lipid metabolism in patients with pre-diabetes and type 2 diabetes mellitus.

Keywords: pre-diabetes, type 2 diabetes mellitus, Glibofit, fasting blood glucose, glycosylated hemoglobin, total cholesterol.

Diabetes mellitus (diabetes mellitus) is a chronic progressive disease that has become a global epidemic of non-infectious nature in recent years. To date, according to the International Diabetic Federation (IDF), there are 415 million patients with diabetes in the world. It is suggested that another 318 million people have a glucose tolerance disorder (prediabetes), which significantly increases the risk of developing diabetes in the future. Given this information, if we do not stop the increased incidence of diabetes, by 2040, the total number of patients will increase significantly and

will make 642 million people. So today, the solution of this problem remains as a priority issue of the national health systems of all countries around the world. [1]

In Ukraine, the diabetes has the third highest incidence after cardiovascular and oncological diseases. Over the past ten years, in Ukraine the incidence of diabetes has increased by one and a half times and makes about 3% of the total population. [2]. According to the Medical Statistics Centre of the Ministry of Health of Ukraine, as of January 1, 2016, the total number of patients with diabetes mellitus in Ukraine was 1 223 607 people. Diabetic retinopathy, which causes the blindness, was registered in more than 173 thousand of these patients. And more than 76 thousand people have different complications, such as diabetic nephropathy, which causes renal failure and death. [3]

Most often, the diabetes is observed among the population of industrially developed regions, but the prevalence rate more depends on the condition of prophylactic activity (early detection of patients with type 2 diabetes mellitus). The highest prevalence rates are in Khmelnitsky (3584.1 per 100 thousand population), Cherkasy (3531.2) and Chernivtsy (3502.7) regions, the lowest are in Volyn (1836.5), Lviv (2051.4) and Chernihiv (2123.2) regions. There is also a significant increase of new registered diabetes cases (primary morbidity) in the population of Ukraine: from 194.8 per 100 thousand of population in 2005 to 249.8 in 2010, that is by 23.7% over 5 years. At the same time, the prevalence rates are higher in regions where preventive action is better. For instance, in the Kharkiv region, this rate makes 350.2 per 100 thousand of population, Khmelnytsky - 316.7, Chernivtsi - 311.8 and Cherkasy - 300.1. At the same time, a lack of active early detection of diabetes was observed in Chernihiv (183.5), Luhansk (193.7) and Kirovograd (197.8) regions. [4]

90-95% of patients with diabetes have type 2 diabetes mellitus and a lot of them are the people of working age (40-59 years). Also, a large cohort of patients consists of patients with prediabetes – it is a state of the body, when the blood glucose concentration is higher than normal, but at the same time it is lower than the critical mark, which establishes the diagnosis of "diabetes mellitus." Currently, the patients with a diagnosed prediabetic condition take a major place in the group of risk of developing diabetes mellitus because the prediabetic condition is one of the factors not only for the development of cardiovascular system diseases, but also for damage of all organs and systems of the body [5].

The treatment of type 2 diabetes consists of a low-carbohydrate diet, a proper organization of the nutrition process and a graduated exercise against the background of self-control, as well as therapy with hypoglycaemic drugs. Considering the peculiarities of course of the disease, the importance of dietary recommendations, the role of phytopreparations is very important. Therefore, the World Health Organization (WHO) defines the integration of phytotherapy into modern medicine as one of the main tasks of medical science. According to WHO, about 25% of all modern medicinal

products, in one form or another, contain components derived from plants. [6]

In case of impaired carbohydrate tolerance (prediabetes) and type 2 diabetes, the phytotherapy may help to normalize blood sugar level against the background of traditional methods of treatment, as well as to prevent the development of complications of organs and systems occurred in type 2 diabetes. It should be considered that phytopreparations, generally, have a polyvalent, multifactorial action that allows to solve many problems at the same time with a minimal risk of toxic and allergic complications [6].

In view of the above, our attention was attracted by a herbal remedy called Glibofit ("Ananta Medicare Limited"). Glibofit contains only natural components that have long been used to improve the pancreas function, regulate blood glucose and prevent the development of diabetes and its complications. Glibofit contains 9 components such as Gymnema sylvestre leaves extract, Momordica charantia fruit extract, Azadirachta indica leaves extract, Picrorhiza kurroa rhizome extract, Ocimum sanctum leaves extract, Zingiber officinale rhizome, Commiphora mukul gum, Syzygium cumini seed extract and Asphaltum. [7]

Usually, herbal remedies have one or two mechanisms of hypoglycemic action. Advantage of Glibofit is a multifaceted mechanism of hypoglycemic action.

The plants involved into Glibofit composition (Gymnema, Momordica, Azadirachta, Syzygium) have a metformin-like effect such as reduced synthesis of glucose in the liver, reduced absorption of glucose in the intestine and improved utilization of glucose by peripheral tissues and reduced insulin resistance [8-15]

Like sulfonylurea drugs, Glibofit stimulates the release of insulin by pancreas β-cells due to the effects of gymnema, momordica, syzygium, commiphora, basil and picrorhiza [8-11,14,16-18]

The mechanism of hypoglycemic action of Momordica is similar to the inhibitors of dipeptidylpeptidase-4. Momordica contains insulin-like components (peptides) that increase glucose tolerance and promote the reduction of fasting sugar levels [10,11].

The mechanism of hypoglycemic action of Picrorhiza is similar to bean leaf. Picrorhiza inhibits the activity of alpha-amylase; it is enzyme involved in the decomposition of starch, glycogen and some other carbohydrates to glucose [19].

In addition, due to the unique composition of biologically active substances of natural origin, Glibofit:

- stimulates the regeneration of pancreas β-cells (Gymnema) [8];
- prevents the development of atherosclerosis (Gymnema, Momordica, Azadirachta, Ocimum sanctum, Commiphora) [8,10,12,16,17];

- reduces the likelihood of diabetes mellitus complications (angio-, neuro-and nephropathy), due to the presence of Zingiber and Syzygium [14,15,20];
- improves hepatic, nervous system and heart functions (Picrorhiza, Zingiber, Syzygium) [14,15,18,20];
- increases the body defences (Asphaltum) [21].

Numerous clinical studies have shown the efficacy, good tolerability and safety of medicinal plants involved in Glibofit composition. The purpose of this study was to evaluate the effect of the herbal remedy Glibofit on carbohydrate and lipid metabolism in patients with type 2 diabetes and prediabetes.

Methods and materials. The study included 70 patients with hypercholesterolemia (without statin therapy) who had prediabetes or mild to moderate type 2 diabetes mellitus, which did not reach the target glycosylated hemoglobin levels, against the background of observing dietary recommendations and metformin therapy.

After the formation of clinical groups (30 patients started receiving Glibofit after inpatient treatment at the endocrinology department of Cherkasy Regional Hospital of the Cherkasy Regional Council and 40 patients underwent outpatient treatment under the supervision of district endocrinologists at Cherkasy Third City Clinic of the Cherkasy City Council, Cherkasy Fifth City Clinic of the Cherkasy City Council, Smiliansky City Clinic for Adults). All 70 patients were divided into clinical groups according to the severity of carbohydrate metabolism:

- I group (40 patients) – moderate type 2 diabetes mellitus;
- II group (10 patients) – mild type 2 diabetes mellitus;
- III group (20 patients) – prediabetes.

Patients of I group with moderate type 2 diabetes mellitus took metformin preparations in a daily dose of 1500-2000 mg.

All patients, who were under the supervision, have trained in the school of diabetes.

The study program consisted of a laboratory diagnostic test (dynamics of parameters of fasting blood glucose, glycosylated hemoglobin, total cholesterol that were determined at the beginning and at the end of the observation period) and monthly monitoring of the clinical status of patients for 90 days. Also, during the study, the observations on the detection of side effects and changes in endocrine, cardiovascular and other organs and systems were made in order to assess the tolerability of Glibofit herbal therapy. Glibofit was prescribed 1 capsule twice a day before meals.

When processing the results, mathematical and statistical methods of analysis were used. In the study groups the arithmetic mean value of three parameters (fasting blood glucose, glycosylated

hemoglobin, total cholesterol) was determined. There were also determined the mode and median characterizing the value of variants occupying a certain position in the ranged variation series, as well as standard deviation, sample variance, excess and asymmetry of distribution. Two-sample t-test with different dispersions was used to compare data series among themselves. The significance level ($p < 0,05$) was considered as reliable [22]. The nonparametric statistical Wilcoxon signed rank test [23] was also used to check the differences between the two samples of paired measurements (before and after the preparation's intake).

Results and discussion.

A significant decrease of the main parameters of carbohydrate and lipid metabolism was observed in the examined groups of patients after 12 weeks of using the herbal remedy Glibofit (Table 1, 2; Fig. 1-3).

Effect of herbal remedy Glibofit on parameters of carbohydrate metabolism (blood glucose and glycosylated haemoglobin level).

Due to the mechanism of hypoglycaemic action (stimulation of insulin release by β-cells of the pancreas, reduction of glucose synthesis in the liver and its absorption in the intestines, reduction of insulin resistance, increase of glucose tolerance), when using Glibofit, the fasting blood glucose level decreased:

- by 17.9% – in the group of patients with moderate type 2 diabetes mellitus ($p < 0.001$);
- by 25.6% – mild type 2 diabetes mellitus ($p < 0.001$);
- by 13.0%) – in the group of patients with prediabetes ($p = 0.06$) (Table 1, Fig .1).

In all study groups, there was a decrease in the average parameters of glycosylated haemoglobin:

- by 0.44% – in the group of patients with moderate type 2 diabetes mellitus ($p=0.02$);
- by 0.54% – mild type 2 diabetes mellitus ($p<0.001$);
- by 0.28% – in the group of patients with prediabetes ($p=0,09$) (Table 1, Fig.2).

The obtained positive results are due to the complex effect of Glibofit components on the mechanism of hyperglycaemia development, and confirm their high efficiency in correcting parameters of carbohydrate metabolism.

Effect of herbal remedy Glibofit on lipid metabolism parameters (total cholesterol level).

The multicomponent composition of Glibofit provides additional benefits in terms of lowering the level of lipids in blood serum, which, in turn, has a positive effect on slowing the progression of atherosclerosis and its complications in patients with prediabetes and type 2 diabetes.

Reduction of the average values of total cholesterol in the study group before and at the end of the three-month course of Glibofit herbal therapy was registered in the group with moderate type 2 diabetes mellitus –5.63 to 5.16 mmol/L ($p < 0.01$) and in the pre-diabetes group – 5.46 to 4.94 mmol/L ($p = 0.07$) (Table 2, Fig. 3). In patients with mild type 2 diabetes, total cholesterol levels tended to decrease (5.77 vs. 5.56 mmol/L, $p = 0.61$).

During the study, no metformin dose adjustment was required in the group of patients with type 2 diabetes of moderate severity.

Table 1

Averages fasting blood glucose values in the study groups before and at the end of the three-month course of Glibofit herbal therapy

Characteristics of values	Study groups					
	1		2		3	
	Before*	After**	Before	After	Before	After
Blood glucose, mmol/L	8.05±0,16	6.61±0,15	7.00±0.29	5.21±0.10	6.43±0.10	5.62±0.12
Glycosylated haemoglobin, %	7.72±0,12	7.28±0,14	6.20±0.07	5.66±0.10	6.08±0.11	5.83±0.08

Notes:

* – Value in the first visit to the physician when the patient was included in the study;

** – Value after the three-month course of Glibofit herbal therapy.

Table 2

Averages total cholesterol values in the study groups before and at the end of the three-month course of Glibofit herbal therapy

Characteristics of values	Study groups					
	1		2		3	
	Before*	After**	Before	After	Before	After
Total cholesterol, mmol/L	5.63±0.12	5.16±0.09	5.77±0.36	5.56±0.17	5.51±0.19	4.96±0.17

Notes:

* – Value in the first visit to the physician when the patient was included in the study;

** – Value after the three-month course of Glibofit herbal therapy.

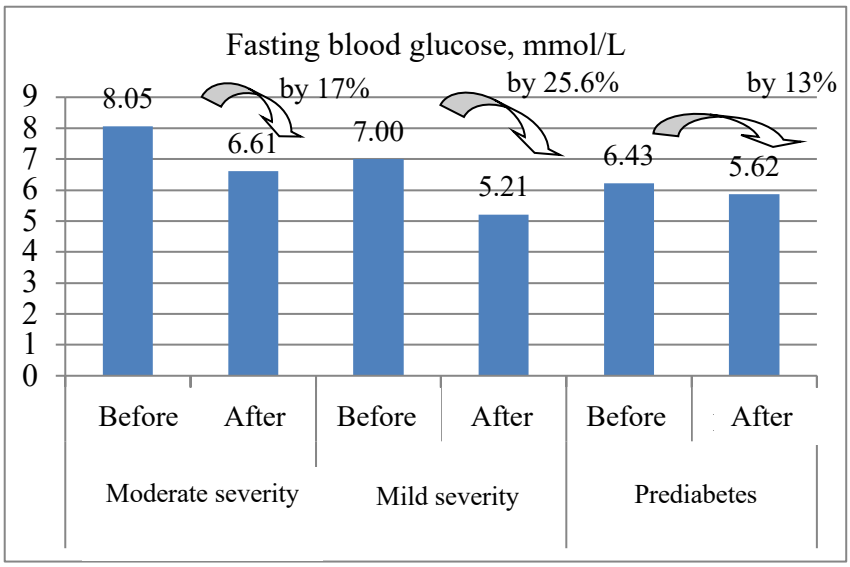

Fig. 1. Averages fasting blood glucose values in the study groups before and at the end of the three-month course of Glibofit herbal therapy, mmol/L

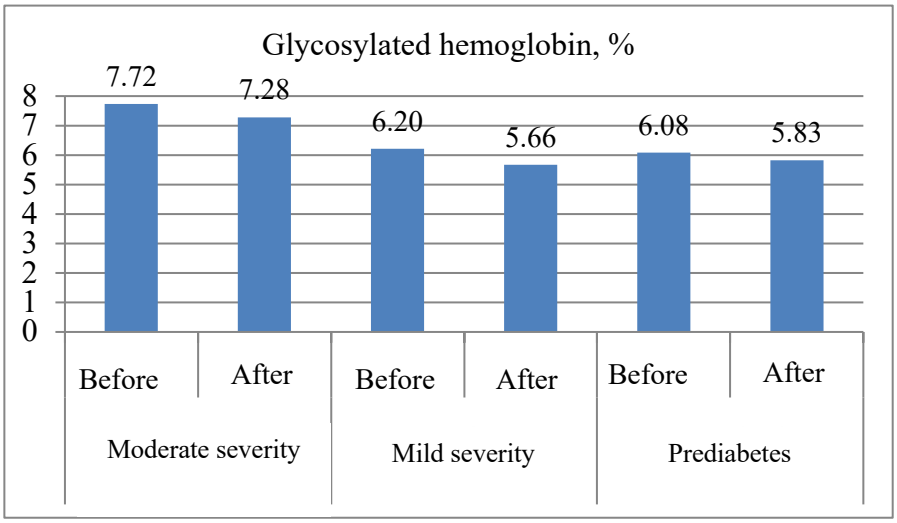

Fig. 2. Averages glycosylated haemoglobin values in the study groups before and at the end of the three-month course of Glibofit herbal therapy, %

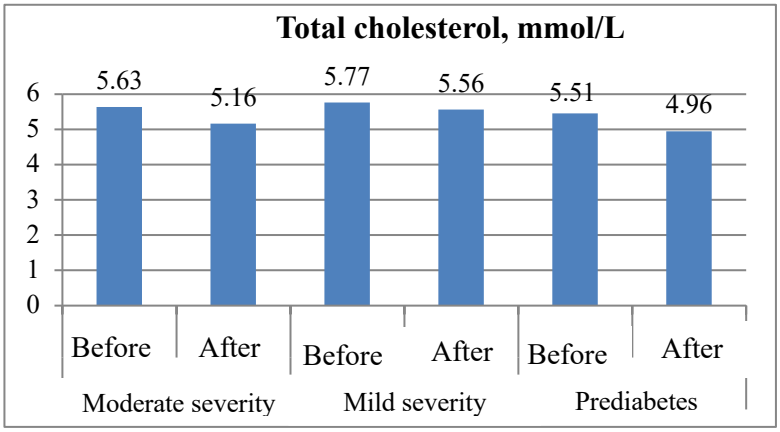

Fig. 3. Averages total cholesterol values in the study groups before and at the end of the three-month course of Glibofit herbal therapy, mmol/L

In order to assess the tolerability of Glibofit, the monitoring was carried out throughout the study period. The absence of any side effects and changes in the endocrine, cardiovascular and other body systems was confirmed.

Conclusions.

1. The assessment of the effect of Glibofit on carbohydrate metabolism, namely on the fastin blood glucose level for 90 days, has shown a significant decrease by 17.9% in the group of patients with moderate type 2 diabetes mellitus, by 25.6% in the group of patients with mild type 2 diabetes mellitus and by 13% in patients with prediabetes.
2. Glycosylated haemoglobin values have been decreased by 0.44% in the group of patients with moderate type 2 diabetes mellitus, by 0.54% in the group of patients with mild type 2 diabetes mellitus and by 0.28% in patients with prediabetes. In turn this confirms the high efficiency of Glibofit in correction of carbohydrate metabolism.
3. Reception of Glibofit during 90 days contributed to a decrease in total cholesterol level in patients with prediabetes and moderate type 2 diabetes mellitus, as well as showed positive dynamics in the group with mild type 2 diabetes mellitus. These results confirm the efficiency of Glibofit in correction of lipid metabolism.
4. During the study, the good tolerance of Glibofit was observed. Glibofit did not cause any adverse reactions or effect on the basic therapy due to this fact it is high safety of for the patient.
5. Herbal remedy Glibofit ("Ananta Medicare Limited"), at the dose of 1 capsule twice a day for 2-3 months, can be recommended for patients with mild or moderate severity of type 2 diabetes mellitus, as well as for patients with prediabetes as mono and complex treatment along with hypoglycemic agents to regulate blood glucose levels, as well as for the prevention of complications of type 2 diabetes mellitus. It is advisable to repeat the course 2-3 times a year.