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# The Effect of Dietary Fiber on Glycemic Control in Patients with Type 2 Diabetes Mellitus Receiving Oral Hypoglycemic Therapy

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## ABSTRACT

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Full abstract continues on the metadata continuation sheet.

Index Terms: type 2 diabetes mellitus • gut microbiota • dietary fiber • oral hypoglycemic therapy

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Nutritional recommendations for patients with T2DM from various global communities agree on the need to increase dietary fiber (DF) intake; however, there are currently no specific and unified recommendations regarding the recommended amount and type of DF. Studying the effect of DF on glycemic control in patients with T2DM may play an important role in refining intake recommendations and motivating patients to comply these recommendations.

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The study included 80 patients with T2DM, with duration not more than 5 years, with HbA1c of not more than 7.5%, and BMI of 27–35 kg/m2, without severe comorbidity. All patients were treated with a combination of metformin and a DPP-4 inhibitor or metformin and an SGLT2 inhibitor. Forty patients comprised the Main Group, where patients received Nestlé OptiFibre DF, a partially hydrolyzed guar gum (PHGG), for 3 months according to the instructions for use. The other patients, who comprised the Control Group, underwent the same examinations as the patients in the Main Group as part of routine clinical practice over a period of 3 months. Changes over time in HbA1c, fasting plasma glucose, blood glucose self-monitoring data, and ambulatory blood glucose profile based on flash glucose monitoring (FGM, FreeStyle Libre, Abbott) were evaluated. Laboratory parameters were evaluated at baseline (2–3 days from the start of the study) and at the completion of the study (84 ± 3 days from the start of the study). A FGM sensor was also applied at Days 2–3 from the start of the study; the readings were obtained and evaluated after 14 days. Repeated FGM application was performed at Day 72 ± 3, and the readings were obtained at Day 84 ± 3.

**Results:**

In the group of patients who received DF, there was a statistically significant decrease in the HbA1c level from 6.35 [5.9–7.07]% to 5.95 [5.7–6.3]%, p = 0.01, while in the Control Group almost no changes were found: at baseline, the HbA1c level was 5.85 [5.5–6.7]%, and at study completion it was 6.15 [5.5–6.78]%, p = 0.99. Fasting plasma glucose in the Main Group decreased from 7.0 [6.33–7.78] mmol/L to 6.65 [5.72–7.75] mmol/L, p = 0.18, while in the Control Group, on the contrary, an increase this parameter increased from 6.30 [5.7–7.0] mmol/L to 6.9 [5.6–7.78] mmol/L, p = 0.05. The evaluation of the ambulatory glucose profile (AGP) data showed that the Time in Range (TIR) was significantly higher by the end of the study in the Main Group vs the Control Group by 2.5%: 94.5 [92.0–97.0]% vs 92.0 [77.25–96.0]% (p = 0.01). Time Below Range (TBR) in the Main Group decreased by 0.5% while no changes were observed over time in the Control Group, and the increase in Time Above Range (TAR) in the Main Group was 0.5% lower than in the Control Group. In addition, a decrease in the mean duration of hypoglycemia was found in patients who received DF, from 144.39 ± 76.49 (95% CI 115.87; 172.91) to 118.32 ± 54.49 (95% CI 96.81; 139.84), p = 0.15, as well as a decrease in the frequency of hypoglycemic events from 6.0 [3.0–16.0] to 5.0 [3.0–9.75], p = 0.47.

**Conclusions:**

The study obtained data on the positive effect of daily intake of PHGG for 3 months on the HbA1c, fasting plasma glucose and AGP parameters, which is important not only from the point of view of managing T2DM, but also from the standpoint of the prevention of micro- and macrovascular complications and correction of risk factors. Further research is needed on the effects of DF, taking into account the duration of use, doses, and various DF types and forms.

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RESEARCH ARTICLE

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**Dr. T. Yu. Demidova*** **and A. S. Teplova**

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**Conclusions:** The study obtained data on the positive effect of daily intake of PHGG for 3 months on the HbA1c, fasting plasma glucose and AGP parameters, which is important not only from the point of view of managing T2DM, but also from the standpoint of the prevention of micro- and macrovascular complications and correction of risk factors. Further research is needed on the effects of DF, taking into account the duration of use, doses, and various DF types and forms.

**Keywords:** *type 2 diabetes mellitus, gut microbiota, dietary fiber, oral hypoglycemic therapy*

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## 1 Introduction

Despite the progressively increasing possibilities of drug therapy for T2DM, the modern diabetology gives nutrition an increasingly important role in metabolic control. The goal of T2DM therapy, including nutritional recommendations for patients with T2DM, is to reach target glycemic control values, achieve and maintain optimal body weight, manage cardiovascular risks, and select drug therapy from the point of view of cardiorenal protection [1].

Macronutrient intake standards are the basis of nutritional recommendations for patients with T2DM. Protein intake is recommended in the amount of 10–20% of the daily dietary energy value for patients under 65 years of age with a GFR of more than 60mL/min/1.73m$^2$ For patients over

65 years of age, a higher protein content in the diet 15–20%) is recommended. With regard to fat consumption, the focus of the recommendations is to limit unsaturated fatty acids to less than 10% of the daily dietary value, and trans fats to less than 1% . It is also recommended to substitute all consumed fats with mono- and polyunsaturated fatty acids. Finally, consumption of carbohydrates for patients with T2DM requires taking into account the glycemic index (GI) and glycemic load (GL) of foods, preference for low GI and GL foods, and for patients treated with insulin therapy, bread units counting is necessary. An important role is given to limiting the consumption of added sugars to 10% of the daily dietary energy value [2].

On the contrary, it is recommended to diversify the diet with dietary fiber (DF), which has a central place in modern nutritional recommendations, but the amounts recommended for daily intake vary significantly in global recommendations (Fig. 1). For example, specialists from the European Association for the Study of Diabetes (EASD) recommend daily intake of not less than 35g/day (4gper1, 000kJ) of DF [3]. At the same time, the recommendations of the American Diabetes Association (ADA) are to consume 14 g of DF per 1,000 kcal/day [4]. The Eurasian Dietary Guidelines for Cardiovascular Diseases recommend a daily intake of 20–25g/day of DF, or 10 g per 1, 000kcal , for patients with T2DM [5]. The Russian algorithms for specialized care for DM patients mention DF in the section "Lifestyle modification in DM and IHD," where patients are recommended to consume 35 –45 g of fiber daily [6]. It is also important to mention the gender differences in DF intake recommendations: for women, the recommended standard is slightly lower than for men ( 25g/ day vs 38g/day) [7].

| Association | Recommended intake of dietary fiber |
|---|---|
| ADA (American Dietetic Association) | 14 g dietary fiber per 1,000 kcal<br>or 25 g for women, 38 g for men |
| EFSA (European Food Safety Organisation) | 25 g/day |
| AHA (American Heart Association) | 25–30 g/day |
| CDA (Canadian Diabetes Association) | 25–50 g/day |

**Figure 1.** Differences in the Recommended Amounts of DF in global clinical guidelines

Thus, treatment algorithms for T2DM, obesity, cardiovascular disease, and many other conditions highlight the justified need to identify recommendations for the mandatory integration of DF into patients' diets, since the regular consumption of DF has its effect on the achievement of the above goals.

The role and place of DF in nutritional recommendations for both patients with T2DM and healthy individuals become obvious, given the variety of positive effects of DF on the human body. The influence of DF on the gastrointestinal tract (GIT) is covered in detail in modern publications. The most well-known effects of DF on digestion are the regulation of intestinal peristalsis, acceleration of intestinal transit, an increase in the amount of feces and in the frequency of bowel movements. These effects are actively used to facilitate defecation in chronic obstructive constipation. Patients with irritable bowel syndrome are a special category for whom facilitating bowel movements is of fundamental importance. The reduction of bloating, discomfort and pain represent another advantage of DF consumption. Facilitating defecation, reducing discomfort, pain and bleeding are also of special importance in the treatment of hemorrhoids [8].

A special place in the structure of the positive effects of DF on digestion is occupied by data on the gut microbiota (GM) modulation. DF, being a nutrient substrate for the gut microbiota (GM), leads to an increase in the number and biodiversity of microorganisms, to an increase in the activity of "beneficial" microorganisms that produce metabolites important for the human body, as well as to a decrease in the activity of opportunistic and pathogenic microorganisms by modulating the physicochemical properties of the intestinal contents [9]. In addition to the GM composition modulation, DF influences the GM synthetic function by controlling the production of GM metabolites, with short-chain fatty acids (SCFAs), which mediate the interaction between the GM and the human body, being the main ones. It is due to the effects of SCFAs on the respective receptors of various organs and tissues that

the "gut-brain-periphery" axis function is ensured, which provides the relationship between the intestine, GM, brain and peripheral tissues and organs through the secretion of biologically active substances and metabolites and regulates a wide range of various metabolic processes [10].

Acetic, propionic and butyric acids, which have both local and systemic effects, are represented in the largest amounts in the body. For example, butyric acid, which has been the subject of the greatest array of research, is the main source of energy for colonocytes, as well as a substrate for the synthesis of their membranes, thus maintaining the integrity of the intestinal wall and implementing its protective potential. With regard to propionic acid, data are provided on the antiatherogenic and antibacterial effects due to the regulation of immune homeostasis in the intestine (blocking the adhesion of pathogens to the epithelium). In addition, propionic acid is a substrate for gluconeogenesis [11, 12].

Acetic and propionic acids entering the colonocyte at the level of the large intestine are involved in the regulation of its bloodstream, improving the blood supply in the mucous membrane, and thereby exhibit an anti-ischemic effect [13].

At the systemic level, these SCFAs are involved in the regulation of carbohydrate and lipid metabolism, have a protective effect on pancreatic $\beta$-cells, influence the immune system and even exhibit anticarcinogenic properties [14].

In addition to the DF digestive effects referred to as "classical" in a number of publications, there is currently a large amount of data on the metabolic effects of DF. When listing the effects of DF on carbohydrate metabolism, the decrease in glucose absorption due to the acceleration of food passage through the intestines should be mentioned first [15]. In addition, the effect of regular intake of DF on the secretion of incretin hormones by intestinal enteroendocrine cells has been demonstrated. The effects of DF on the reduction of insulin resistance and systemic inflammation [16], which are among the main pathogenetic links in T2DM, are also known.

The effect on lipid metabolism is explained by the involvement of acetic and propionic acids in the modulation of lipid synthesis processes [17], including through the regulation of the expression of human genes responsible for the regulation of lipid metabolism. DF involvement in the regulation of bile acid synthesis is an equally important component of lipid metabolism and cardioprotective properties modulation [18].

Finally, body weight regulation is an important systemic effect of DF. This effect is achieved by modulating eating behavior, due to the accelerated onset of satiety when consuming DF, as well as by prolonging the time while food contents remain in the stomach, which contributes to a longer feeling of satiety and, as a result, reduces the need for additional food intake [19].

However, an analysis of publications on the evaluation of DF consumption suggests that the recommendation for adequate DF intake is not adequately met [20]. The main reasons are the high cost of some vegetables and fruits, which are the main sources of DF, undesirable gastrointestinal manifestations in the form of flatulence and increased frequency of stools, associated in some patients with the peculiarities of DF tolerability, as well as the lack of motivation in patients to daily consume the recommended amounts of DF. In addition, the lack of consensus in global recommendations on the required amount and type of DF for daily intake is an obstacle to the unification of DF intake recommendations. It is worth mentioning that most clinical recommendations provide standards for DF intake from food [37]. However, if it is impossible to reach the recommended amount, additional DF intake in the form of food supplements (FS) is possible.

DF classification for their chemical structure implies division into starch, non-starch polysaccharides, and lignin. The largest number of options are represented by non-starch polysaccharides, which include cellulose and non-cellulose polysaccharides. The latter are subdivided into hemicellulose, pectin substances, mucus, inulin- and guar-like storage polysaccharides, and gum (Fig. 2) [21].

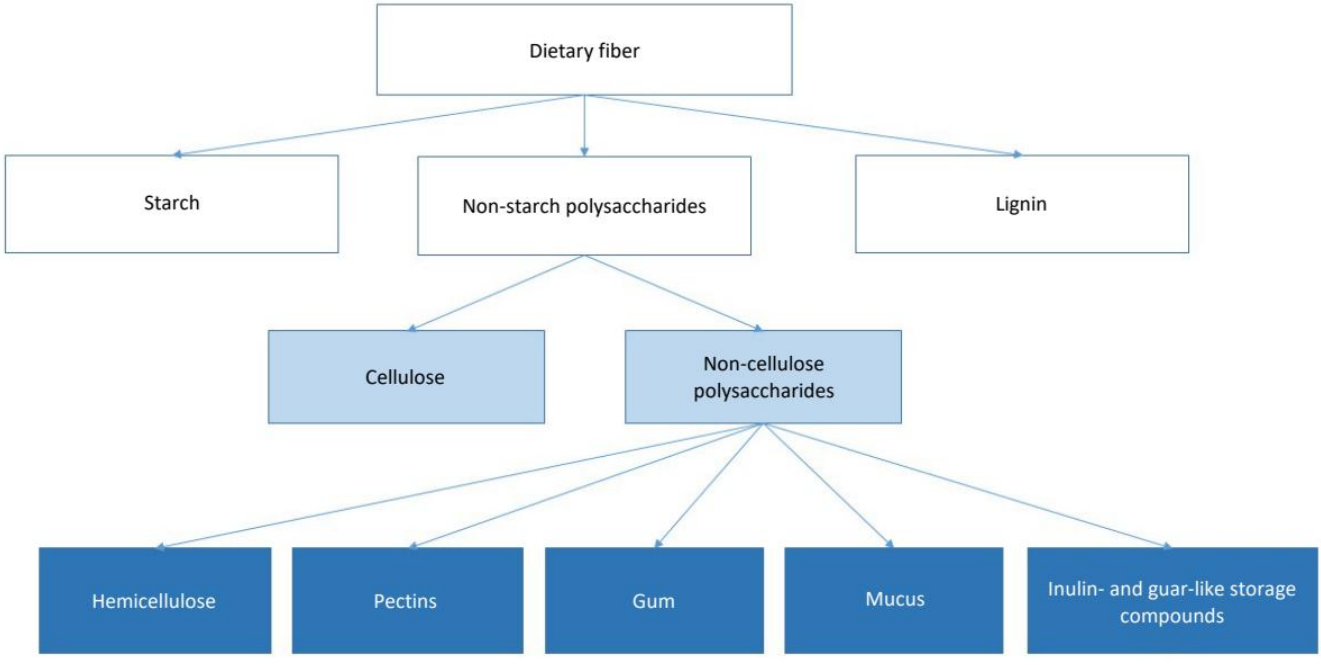


**Figure 2.** Classification of DF for their chemical structure

Gums from the stems or seeds of tropical or subtropical trees, plants, and shrubs are the most widely represented ones on the DF market. OptiFibre DF used in this study is an extract of Cyamopsis tetragonolobus seeds and is a partially hydrolyzed guar gum for its chemical structure. The partially hydrolyzed nature of DF helps improve the taste characteristics of the gum and reduce its viscosity. Thus, the studied type of DF is the most convenient and comfortable one for use by patients, and also exhibits the greatest range of positive properties among other DF options [22].

## 2 Materials and Methods

A prospective-and-retrospective, observational, minimally interventional study was conducted, which included 80 patients with T2DM. Patients were divided into two groups of 40 subjects each: the Main and Control Groups. Patients in the Main Group were enrolled prospectively, while the Control Group included patients who, as part of routine clinical practice, underwent examination in a scope similar to that for the patients in the Main Group; their data were retrospective. In accordance with the inclusion criteria, the study included patients aged 45–60 years with a duration of T2DM of not more than 5 years, satisfactory glycemic control (HbA1c not more than 7.5% ) and BMI 27−35kg/$m^2$ , treated with combination therapy with metformin and DPP-4 inhibitors or metformin and SGLT2 inhibitors. Prior to inclusion in the study, patients were treated with the specified therapy for at least 3 months. Therapy with metformin plus SGLT2 inhibitors or plus DPP-4 inhibitors was chosen based on the optimal indications for this combination in patients with a short history of T2DM in terms of reducing both glycemic control and correction of risk factors for complications of T2DM, as well as correction of risk factors. In this case, metformin represents the “gold standard” of pathogenetic therapy for T2DM, while innovative drugs, along with a safe hypoglycemic effect, exhibit a number of additional pleiotropic properties. In addition, the tablet form of all prescribed medications, which provided the ease of use for patients, was an important aspect in favor of this combination.

Patients included in the prospective part of the study were prescribed Nestlé OptiFibre dietary fiber, which is a partially hydrolyzed guar gum (PHGG) product. In accordance with the instructions for use, in order to minimize possible adverse events during DF intake, the treatment started with a minimum dose of 5g/day , followed by titration in the increments of 5g/day every 3 days until a dose of 15g/day was reached. The DF was dissolved in liquid food or drinks. Patients in the Control Group received no DF; they were only given recommendations in accordance with the general principles of proper nutrition for patients with T2DM.

The study design provided for 7 visits, during which patients were given consultation, anthropometric data were evaluated, and blood and stool were sampled (Fig. 3).

At Visit 1, corresponding to baseline, the patient was introduced to the Investigator, a detailed medical history was taken, and anthropometric data (height, body weight, BMI, and waist circumference) were evaluated. During this visit, the patient also received detailed information about the study stages, recommendations on diet and physical activity, glucose self-monitoring, and instructions on how to prepare for blood and stool sampling. Voluntary informed consent was signed. The patient was prescribed Nestlé OptiFibre DF in accordance with the instructions for use.

The date o Visit 2 corresponded to Day 23 from the start of the study. During this Visit, venous blood was sampled, a FGM system was applied, a stool biosample was collected, and the patient’s self-monitoring diary for the previous 24 hours was evaluated. At this and all subsequent visits,

DF tolerability was evaluated and the patient was questioned about the occurrence of adverse events.

At the end of FGM system operation, the patient was invited for Visit 3 for FGM data reading and interpretation, which corresponded to Day 16 ± 2 from the start of the study. In addition, the patient’s anthropometric data and DF tolerability were evaluated.

At Visit 4 at Day 44 ± 3 from the start of the study, the patient’s anthropometric parameters and DF tolerability were evaluated, and self-monitoring data for the previous day were analyzed.

Visit 5 (Day 72±3 from the start of the study) included anthropometry, evaluation of DF tolerability, and application of a FGM system.

At Visit 6 (Day 84 ± 3 from the start of the study), anthropometric data were evaluated, the FGM sensor was removed, and the obtained data were interpreted. Venous blood was sampled and a stool biosample was collected. DF tolerability was evaluated, and self-monitoring data for the previous day were analyzed.

Visit 7 (Day 90 ± 3 from the start of the study) was the final one. At this visit, a final conversation was held with the patient, and final recommendations were given for further treatment and lifestyle changes.

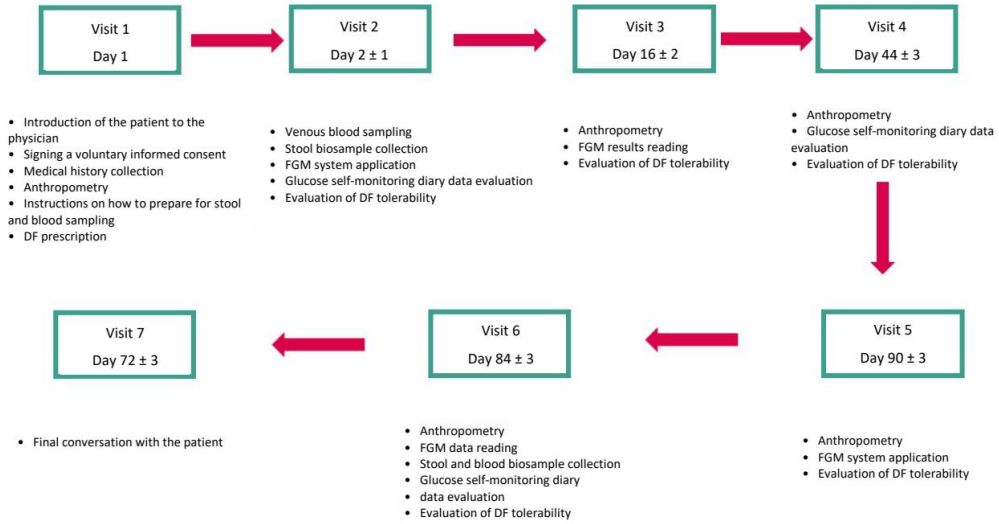


**Figure 3.** Study Design

To evaluate carbohydrate metabolism, the following parameters were studied: HbA1c (glycated hemoglobin), fasting plasma glucose, structured glucose self-monitoring using a glucose meter (measurements on an empty stomach, 2 hours after breakfast, lunch, dinner, and at night), flash glucose monitoring (FGM) (FreeStyle Libre system) parameters including an evaluation of the mean glucose level, glucose monitoring index (GMI), Time In Range (TIR), Time Above Range (TAR), Time Below Range (TBR), mean duration of hypoglycemic events, frequency of hypoglycemic events, and coefficient of variability.

The primary endpoint of the study was a statistically significant reduction in HbA1c and fasting plasma glucose compared with the Control Group at Day 84 ± 3 from the start of observation and treatment.

The secondary endpoint included statistically significant improvement in the mean glucose level, glucose monitoring index (GMI), Time In Range (TIR), Time Above Range (TAR), Time Below Range (TBR), mean duration of hypoglycemic events and determination of the frequency of hypoglycemic events based on flash glucose monitoring data (FreeStyle Libre system) vs baseline in the Study Group and the Control Group.

## 3 Results

The Main Group included 19 female and 21 male subjects, and the Control Group consisted of 21 female and 19 male subjects. In the OptiFibre Group, 50% of patients were treated with DPP-4 inhibitors $^{+}$ metformin, and 50% were treated with SGLT2 inhibitors $^{+}$ metformin. In the Control Group, the proportion of patients treated with DPP4 inhibitors $^{+}$ metformin was 45% and the proportion of patients treated with SGLT2 inhibitors $^{+}$ metformin was 55% . Table 1 summarizes a comparison of the formed groups by the anthropometric characteristics, age, and carbohydrate metabolism parameters.

**Table 1.** Comparison of the formed groups by the anthropometric characteristics, age and carbohydrate metabolism parameters

| Parameters | OptiFibre Group | Control Group | p-value |
|---|---|---|---|
| Age, years | 55 [52–57] | 54.5 [52–57] | — |
| BMI, kg/m$^2$ | 31.66 [29.42–33.77] | 31.01 [29.17–32.77] | 0.441 |
| Waist circumference at Study Day 2 ± 1, cm | 101.25 ± 9.06 (95% CI 98.32–104.18) | 97.85 ± 8.59 (95% CI 95.07–100.63) | 0.093 |
| HbA1c, % | 6.35 [5.9–7.07] | 5.85 [5.5–6.7] | 0.060 |
| Fasting glucose, mmol/L | 7.0 [6.3–7.7] | 6.3 [5.7–7.0] | 0.002 |

The formed groups were evaluated for comorbidities. The most common diseases were arterial hypertension and obesity. Arterial hypertension was observed in 20 patients from the Control Group, which constituted 50% of all patients in the group. In the OptiFibre group, the number of patients with hypertension was 25, which was equivalent to 62.5% . IHD was reported in 4 patients in the Control Group (10%) and in 8 patients in the OptiFibre Group (20%) . Obesity was observed in 28 patients in the Control Group (70%) and in 25 patients in the OptiFibre Group (62.5%) . Eye disorders were found only in one patient in the Control Group (2.5%) . Chronic kidney disease (CKD) and peripheral arterial disease were not reported in any patient. The distribution of comorbidities is shown in Fig. 4.

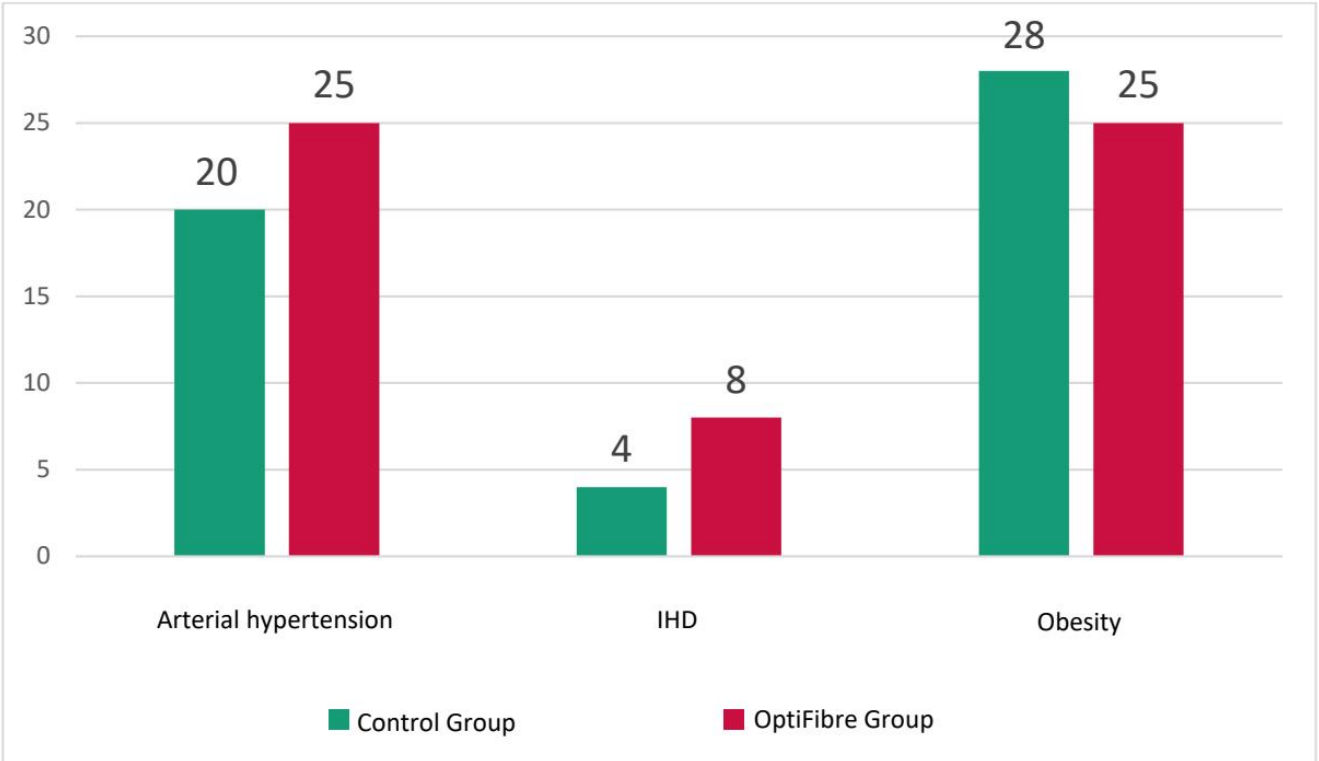


**Figure 4.** Distribution of comorbidities in patients in the formed groups

Thus, the formed groups were completely comparable for the main anthropometric characteristics, age, gender, carbohydrate metabolism parameters and treatment, as well as for the comorbidities, which made it possible to evaluate the effect of DF on the carbohydrate metabolism of patients and compare the data with the parameters in the Control Group, excluding the potential interference of extraneous factors.

During the study, at each visit, an evaluation of adverse events during treatment with Nestlé OptiFibre was performed: a detailed survey was conducted on the patients' well-being and GIT function (presence of flatulence, diarrhea, bloating and other gastrointestinal complaints). None of the patients reported any adverse events during the study.

## 4 Evaluation of changes over time in laboratory parameters of carbohydrate metabolism

Evaluation of the changes over time in HbA1c levels indicates that the primary endpoint was reached, which, in accordance with the study protocol, was a statistically significant reduction in the HbA1c level from 6.35% [5.9–7.07%] to 5.95% [5.7–6.3%], $p = 0.01$, while almost no changes were found in the Control Group: at baseline, the HbA1c level was 5.85% [5.5–6.7%] and at study completion it was 6.15% [5.5–6.78%], $p = 0.99$ (Tables 2 and 3).

**Table 2.** Laboratory parameters of carbohydrate metabolism in the Control Group

| Parameters | Baseline (Day 2 ± 1) | Completion (Day 84 ± 3) | p-value |
|---|---|---|---|
| HbA1c, % | 5.85 [5.5–6.7] | 6.15 [5.5–6.78] | 0.99 |
| Fasting plasma glucose, mmol/L | 6.30 [5.7–7.0] | 6.9 [5.6–7.78] | 0.05 |

**Table 3.** Laboratory parameters of carbohydrate metabolism in the OptiFibre Group

| Parameters | Baseline (Day 2 ± 1) | Completion (Day 84 ± 3) | p-value |
|---|---|---|---|
| HbA1c, % | 6.35 [5.9–7.07] | 5.95 [5.7–6.3] | 0.01 |
| Fasting plasma glucose, mmol/L | 7.0 [6.33–7.78] | 6.65 [5.72–7.75] | 0.18 |

A statistically significant 0.3% decrease in HbA1c in the OptiFibre Group and no changes over time in the Control Group undoubtedly represent a consequence of the positive effect of long-term DF consumption on carbohydrate metabolism. Positive changes over time were also found for the fasting blood plasma glucose: this parameter in the Main Group decreased from 7.0 [6.33–7.78] mmol/L to 6.65 [5.72–7.75] mmol/L, $p = 0.18$, while in the Control Group, on the contrary, this parameter increased from 6.30 [5.7–7.0] mmol/L to 6.9 [5.6–7.78] mmol/L, $p = 0.05$.

In the OptiFibre Group, there was a tendency towards a significant decrease in fasting blood glucose by 0.35 mmol/L, while in the Control Group, on the contrary, negative changes over time were observed: fasting blood glucose at Study Day 84 ± 3 exceeded the baseline value by 0.6 mmol/L.

## 5 Evaluation of ambulatory glucose profile based on flash glucose monitoring data

The ambulatory glucose profile (AGP) was analyzed to assess in detail the DF effect on the changes over time in glucose level and its variability during the day in the short and long term, which would not have been possible using only laboratory parameters. By assessing the AGP, it was possible to obtain data on glucose levels over time in a continuous mode, including the time spent within, above, and below the target range, on the presence and severity of hypoglycemia, glucose level variability and the glucose profile stability. The investigation of the above data is particularly relevant in the study group of patients due to the fact that these features of glucose level play an important role in the pathogenesis of micro- and macrovascular complications, including with satisfactory glycemic control based on laboratory evaluation methods; however, these parameters are not given due attention in routine laboratory examination in patients with T2DM.

AGP was evaluated using the generally accepted algorithm, taking into account the main five steps in the FGM data interpretation: data quality analysis, Time In Range (TIR) evaluation, hypoglycemia evaluation, glucose variability evaluation, and glucose profile stability evaluation. The sensor activity time at baseline was 38.5 [81.75–94.00]% in the Main Group and 87 [77.00 94.00]% in the Control Group, and at the end of the study it was 86 ;[77.25−93.25]% in the Main Group and 91 [81.75 − 96.00]% in the Control Group. The obtained data are consistent with a satisfactory amount of information on the AGP (more than 70% ) and demonstrate a high level of patient compliance with glucose measurement when using the FGM system.

## 6 AGP characteristics in the Main Group patients

The Time In Range (TIR) at baseline was within the normal range, confirming satisfactory compensation of carbohydrate metabolism and patient eligibility in terms of the inclusion criteria for the study. A 1.5% reduction in TIR from 96.0% [92.25–98.00%] to 94.5% [92.0–97.0%] was not statistically significant but could be associated with the progression of T2DM during the study period. It is worth noting that these parameters are at the upper limit of the target range and demonstrate a high level of glycemic control and the proximity of the AGP parameters to the physiologically normal values.

To interpret the data in detail and understand the reasons for the changes over time in the Time In Range, it is also necessary to study the Time Above Range and Time Below Range. The Time Above Range in the Main Group was 0.0% [0.0–2.75%] at baseline and 2.0% [0.0–4.0%] ($p = 0.03$) at study completion. Evaluation of the Time Below Range showed a decrease from 2.0% [0.0–6.75%] to 1.0% [0.0–3.75%] ($p = 0.94$), which indicates an increase in the safety profile of hypoglycemic therapy in patients who received DF. It is also worth noting that the mentioned changes occur within the normal ranges and can only be interpreted as a variant of the physiological changes over time and natural progression of T2DM.

These findings are supported by the evaluation of hypoglycemia in the Main Group: a decrease in the mean duration of hypoglycemia in patients who received DF from 93.5 [30.0–170.75] to 80.0 [0.0–143.0], $p = 0.15$, as well as a decrease in the frequency of hypoglycemic events

from 4.0 [0.25–7.75] to 3.0 [0.0–7.0], $p = 0.36$, along with a significant decrease in the frequency of nocturnal hypoglycemic events are also arguments in favor of bringing the AGP closer to physiological values characteristic of the healthy population.

Glucose variability in this study was evaluated by the coefficient of variability, with mean value increasing from 20.34 ± 3.48 95% CI 19.1621.52) to 22.83 ± 4.99 95% CI 19.7722.55) (p = 0.37) . When interpreting this parameter, it is necessary to take into account that normal values for this parameter are considered to be values of not more than 36, which indicates that the resulting data almost reached the middle of the target range and are as close as possible to the physiologically normal values.

Due to the fact that current scientific research increasingly attaches importance to the role of TIR changes over time in the development of macro- and microvascular complications of T2DM, this parameter was evaluated over time in the group of patients who received DF. In 35% of patients, an increase in TIR was observed at Study Day 84 ± 3 compared with Study Day 16 ± 3 , while 15% reached an increase in TIR of more than 10% from baseline.

AGP parameters comparison in the Main and Control Groups

Tables 4 and 5 summarize the main AGP data of patients in the Control and Main Groups.

**Table 4.** AGP parameters in the Control Group

| Parameters | Baseline (Day 16 ± 3) | Completion (Day 84 ± 3) | p-value |
|---|---|---|---|
| Sensor activity time, % | 87 [77.0–94.0] | 91 [81.75–96.0] | 0.13 |
| TIR, % | 96.0 [92.25–98.0] | 93.0 [81.0–96.75] | 0.04 |
| TAR, % | 0.0 [0.0–1.0] | 1.0 [0.0–3.75] | 0.08 |
| TBR, % | 2.0 [0.0–5.5] | 1.0 [0.0–4.0] | 0.14 |
| Mean hypoglycemia duration, min | 114.5 [45.0–182.0] | 83.5 [30.0–142.5] | 0.21 |
| Frequency of hypoglycemia | 4.5 [1.0–9.0] | 2.0 [1.0–6.0] | 0.14 |
| Coefficient of variation, % | 21.26 ± 4.42 | 22.83 ± 4.99 | 0.16 |
| GMI, % | 5.7 [5.5–6.15] | 5.95 [5.53–6.3] | 0.13 |
| Mean glucose, mmol/L | 5.6 [5.1–6.5] | 6.15 [5.2–7.0] | 0.11 |

**Table 5.** AGP parameters in the Main Group

| Parameters | Baseline (Day 16 ± 3) | Completion (Day 84 ± 3) | p-value |
|---|---|---|---|
| Sensor activity time, % | 88.5 [81.75–94.0] | 86 [77.25–93.25] | 0.16 |
| TIR, % | 96.0 [92.25–98.0] | 94.5 [92.0–97.0] | 0.42 |
| TAR, % | 0.0 [0.0–2.75] | 2.0 [0.0–4.0] | 0.03 |
| TBR, % | 2.0 [0.0–6.75] | 1.0 [0.0–3.75] | 0.94 |
| Mean hypoglycemia duration, min | 93.5 [30.0–170.75] | 80.0 [0.0–143.0] | 0.15 |
| Frequency of hypoglycemia | 4.0 [0.25–7.75] | 3.0 [0.0–7.0] | 0.36 |
| Coefficient of variation, % | 20.34 ± 3.48 | 22.83 ± 4.99 | 0.37 |
| GMI, % | 5.7 [5.5–6.0] | 5.75 [5.5–6.07] | 0.90 |
| Mean glucose, mmol/L | 5.6 [5.03–6.57] | 6.0 [5.4–7.15] | 0.05 |

TIR evaluation found statistically significant differences in the Control Group and the group of patients who received OptiFibre at Day 84 ± 3 Visit, while in the OptiFibre Group this parameter was 1.5% higher, while a comparison of TIR at Day 84 ± 3 Visit in the Control vs the Main Group indicated a statistically significant difference (**p** = 0.01) , supposing a significantly greater effect of DF on increasing the Time In Range of patients with T2DM (Fig. 5).

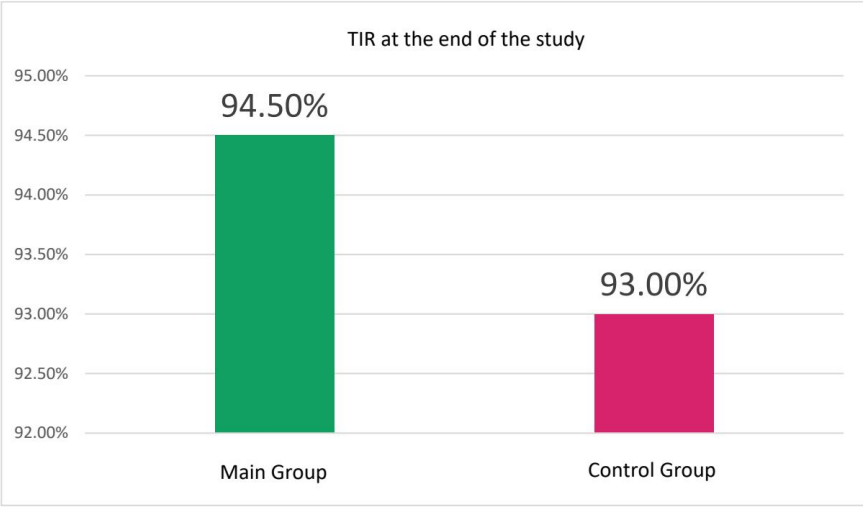


**Figure 5.** Comparison of TIR in the Main and Control Groups at Study Day 84 ± 3

TAR evaluation also found an increase in this parameter in both groups, however in the Control Group the increase in TAR was 1.0% greater than in the Main Group, indicating an increase in the glucose profile stability in patients who received DF.

Finally, TBR remained unchanged in the Control Group, while a 1.0% reduction was reached in the OptiFibre Group, which supports an improved safety profile of therapy in both cases due to a reduction in the duration of hypoglycemic events.

Comparison of the TIR, TAR and TBR data in the Main and Control Groups is shown in Figures 6 and 7.

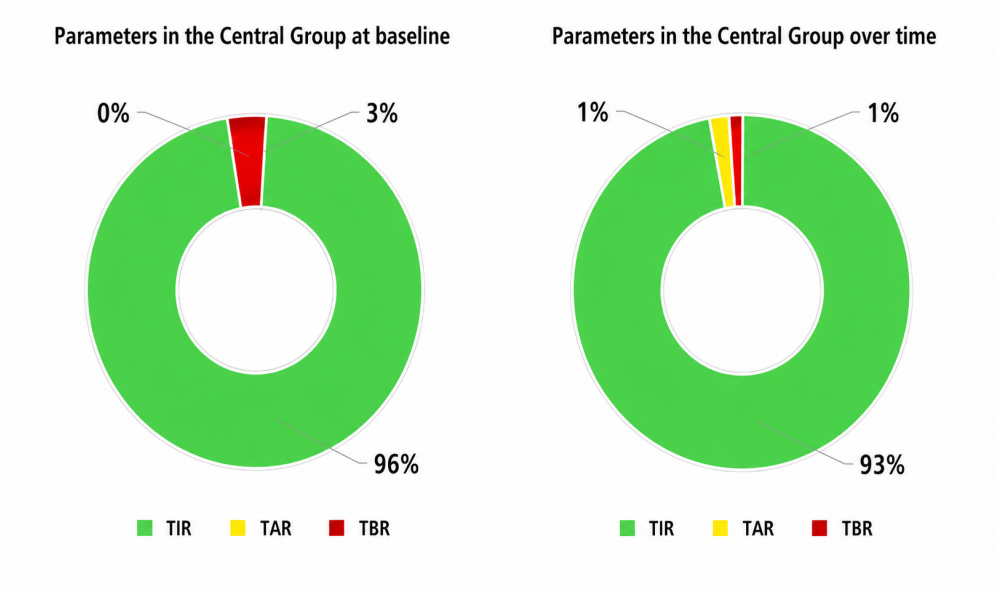


**Figure 6.** TIR, TAR, and TBR in the Control Group

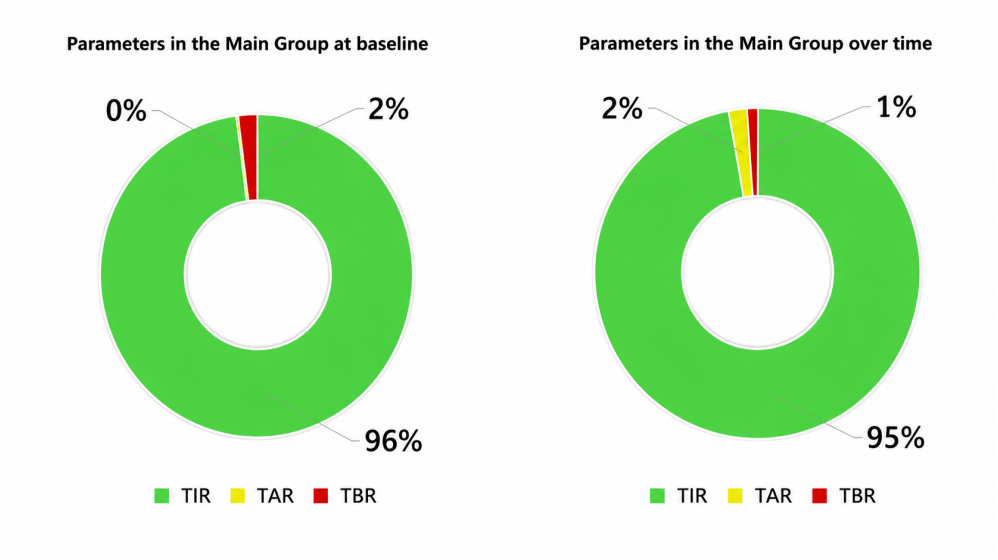


**Figure 7.** TIR, TAR, and TBR in the Main Group

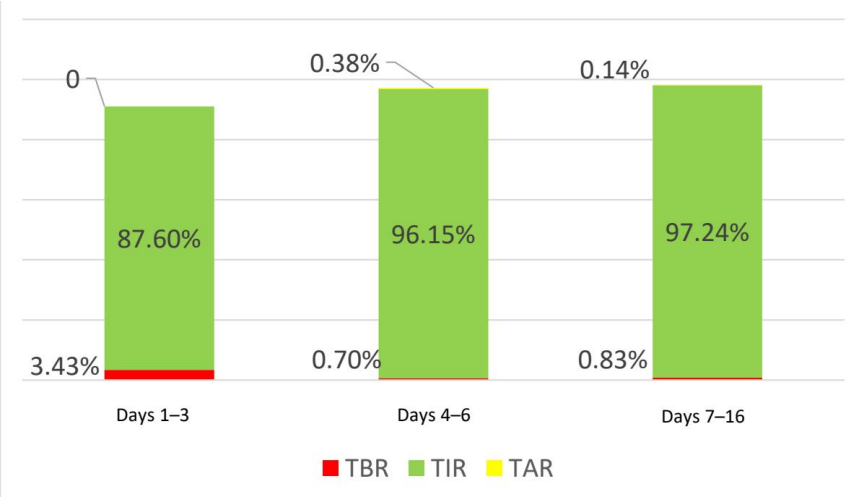


**Figure 8.** Changes in AGP parameters over time depending on the DF dose at baseline

For patients of the Main and Control Groups, the parameters of glucose level in, above and below target range, were compared. In both patient groups, reduction in the frequency and in the mean duration of hypoglycemic events was observed.

No statistically significant differences were found among the compared parameters; however, an increase in the coefficient of variability was observed in both groups, which may also be associated with the changes in TIR and TBR over time. Moreover, in the OptiFibre Group, the increase in this parameter was not as significant as in the Control Group, allowing to conclude that the glucose level stability was more marked in the group of patients who received DF.

The evaluation of AGP parameters showed a decrease in Time In Range, while in the Control Group it was more marked and statistically significant. In terms of Time Below Range, a reduction was also observed in both groups, but it was more marked and statistically significant in the OptiFibre Group. Finally, Time Above Range increased in the Control Group but remained unchanged in the OptiFibre Group.

The found changes indicate a positive effect of OptiFibre intake on the AGP. A statistically significant reduction in Time Below Range is a criterion for increased safety of therapy with respect to hypoglycemia, which allows considering DF as an additional component of hypoglycemic therapy, including in patients with a high risk of hypoglycemia.

A clinical example of changes over time in the AGP in a patient receiving DF

Figure 9 shows an example of the AGP data of patient V., evaluated in accordance with the “5- step” algorithm. Data quality was satisfactory (84%) . At baseline, the AGP was characterized by TIR, TAR and TBR alignment within the normal limits ( 89% , 5% and 6% , respectively), but at the same time, attention was drawn to the relatively high frequency and duration of hypoglycemia, mainly in the early morning hours, as well as occasionally during the day. Ten glycemic events of varying severity were observed, with a total duration of 144 minutes, including two severe hypoglycemic events, down to 2.2mmol/L . The coefficient of variability in this case was 26% which corresponded to almost the middle of the target range. The median and interdecile intervals are mostly within the target range, but the plot is neither narrow nor flat, indicating relatively high variability during the day.

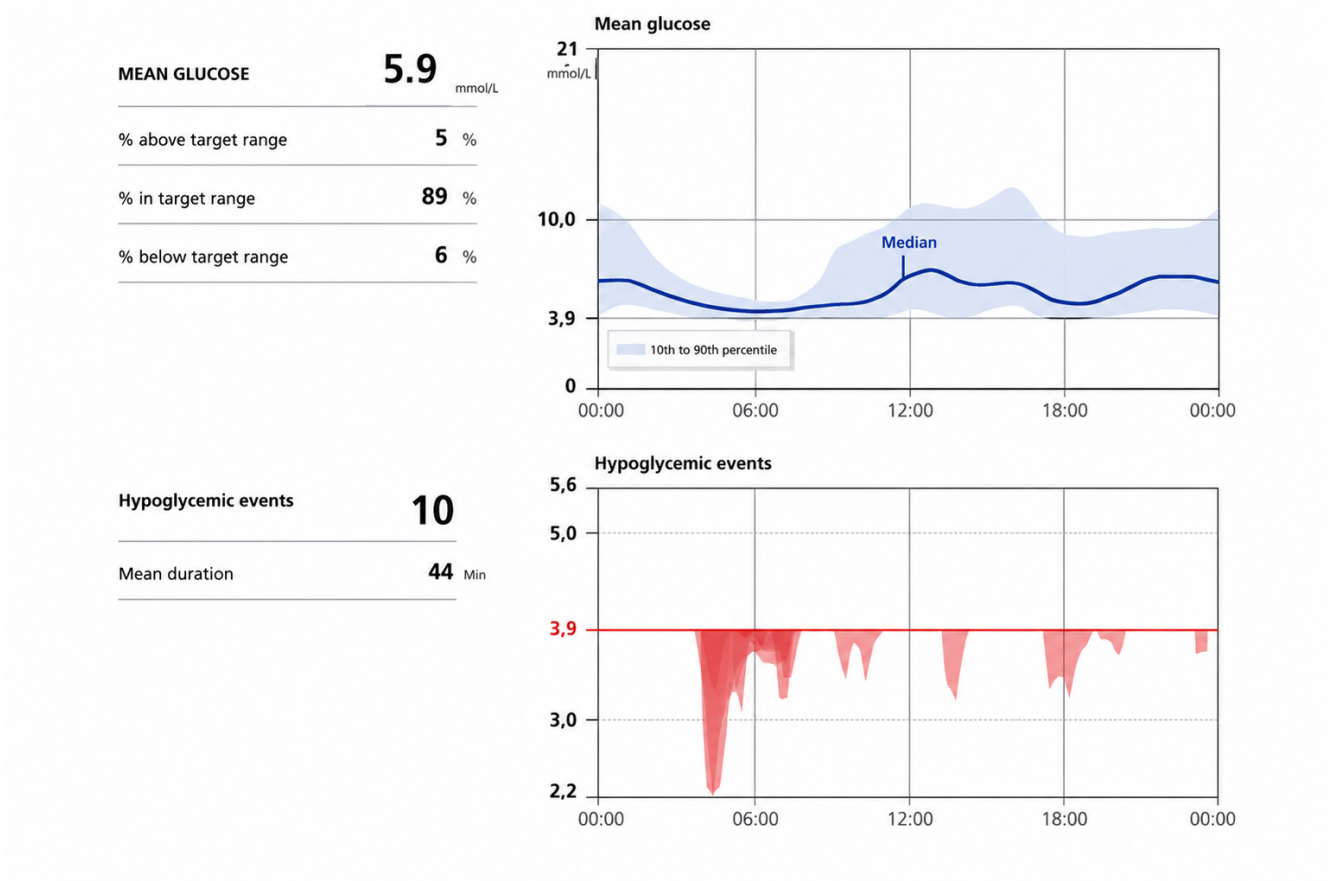


**Figure 9.** AGP of Patient V. at Study Day 16 ± 2 Visit

By the end of the study (Fig. 10), the quality of the AGP data was still satisfactory (the sensor activity percentage was 90). As compared with the previous AGP, TIR increased by 8% and amounted to 97% , TAR decreased by 2% , and TBR was found to decrease to 0% , which indicates almost complete absence of hypoglycemia.

This observation is further illustrated by a marked reduction in the number and duration of hypoglycemic events: only a single mild hypoglycemic event was reported in the early morning hours, lasting 59 minutes. The patient reached a more than twofold reduction in the duration of hypoglycemia. No significant changes over time were observed for the coefficient of variability: it was 27% , which is fully consistent with the physiologically normal value. Compared with the AGP at baseline, in this case a large area of the plot corresponds to the limits of the target range, and the plot is also narrower, especially during the daytime.

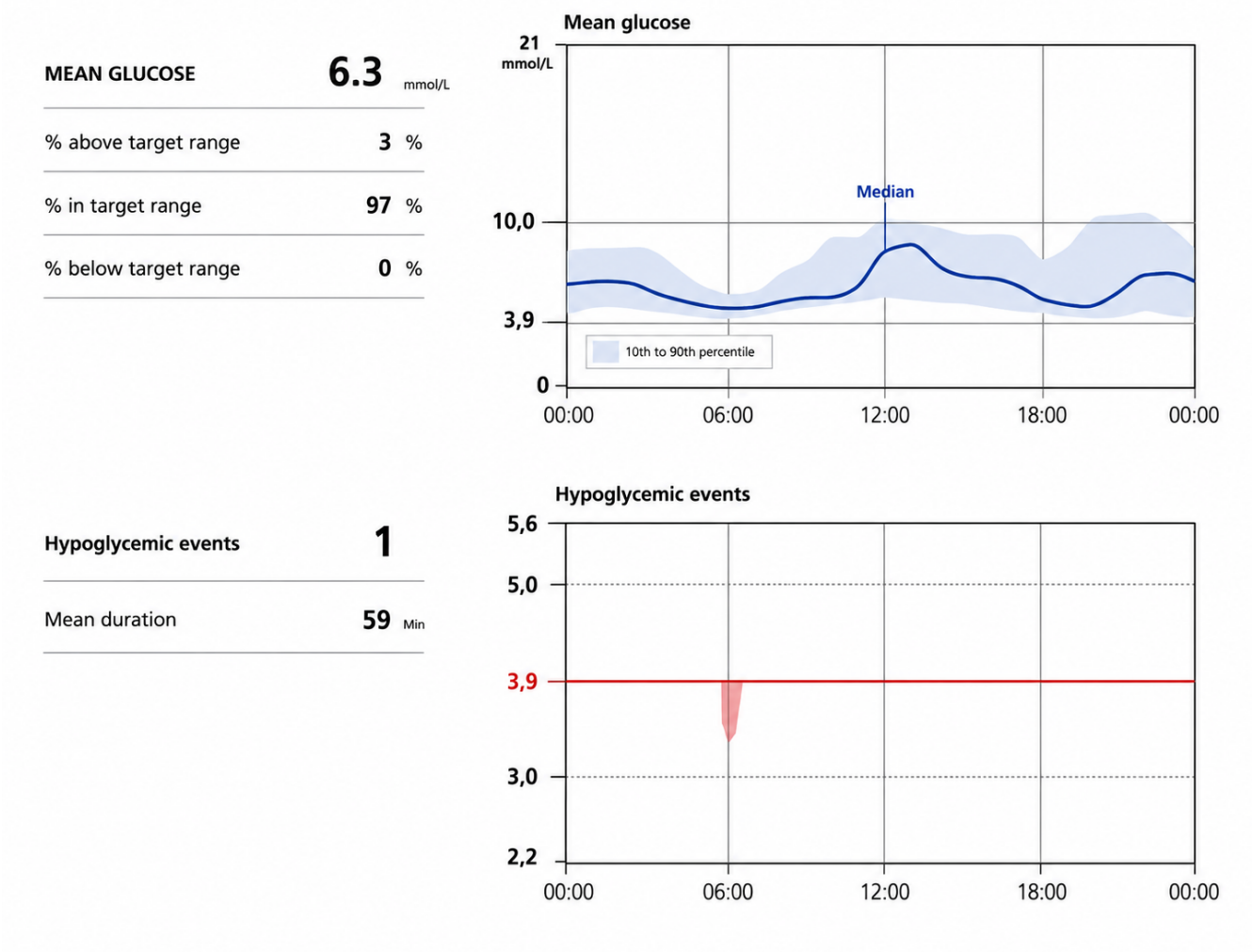


**Figure 10.** AGP of patient V. at Study Day 84 ± 3 Visit

## 7 Discussion

The study findings clearly indicate a justified positive effect of daily consumption of PHGG on carbohydrate metabolism parameters. This assumption is confirmed by a statistically significant ($p = 0.01$) decrease in HbA1c in the Main Group by 0.49% at Study Day 84 ± 3 compared with Study Day 16 ± 3 against a complete absence of changes over time in the Control Group, as well as by a decrease in fasting plasma glucose at Study Day 84 ± 3 compared with Study Day 2 ± 3 by 0.35 mmol/L ($p = 0.18$) against negative changes over time in the Control Group. It is likely that the increase in blood glucose levels in the Control Group is associated with the natural progression of T2DM, while in the OptiFibre Group not only was there no evidence of progression, but, on the contrary, evidence of a statistically significant improvement in glycemic control was found.

The AGP data showed statistically significant intergroup differences for TIR and TAR: patients in the Main Group had a statistically significantly higher TIR value and a lower TBR value. Of particular interest is the evaluation of the number of patients who experienced an increase in TIR: an increase in TIR was observed in 35% of patients, while in 15% it exceeded 10% of the baseline TIR. The findings may be associated with the fact that the partially hydrolyzed nature of the PHGGs enhanced their absorption and, as a consequence, caused a certain increase in blood glucose. The latest data are particularly relevant given the increasing attention paid to TIR in modern scientific research. Data are provided on a 64% increase in the risk of retinopathy, a 40% increase in the risk of microalbuminuria and on the risk of a 6.4% increase in the abnormal thickness of the carotid artery intima-media complex as TIR decreases by every 10% [2325]. Only 12.5% of patients had a decrease in TIR of more than 10% , indicating that the number of patients who reached positive changes over time was significantly higher compared with the number of patients with a decrease in TIR.

On the other hand, the number and total duration of hypoglycemic events decreased in both groups of patients, with the reduction being more significant in the OptiFibre Group. The obtained data can also be considered as an advantage of daily consumption of DF, which allowed patients in the Main Group to make the glucose level profile safer and to bring the parameters closer to those of healthy people relative to the Control Group.

The effect of DF on the glucose profile can be explained by a number of mechanisms, some of which have not yet been fully studied. The most obvious mechanisms include changes in gastrointestinal tract (GIT) motility when consuming DF, which results in an increase in the rate of transit of food contents and, as a consequence, a decrease in the absorption of macronutrients, including carbohydrates.

The modulation of GM with a change in its metabolic activity, a decrease in the formation of metabolites with a negative effect and an increase in the production of SCFAs, which have a beneficial effect on a number of metabolic processes, including carbohydrate metabolism, can be considered another key mechanism. In addition, due to GM correction, systemic inflammation may be reduced in general, which may be manifested in a decrease in insulin resistance and, as a consequence, in an improvement in glycemic control [26].

Another important aspect of the interpretation of the obtained data comprises the partially hydrolyzed form of Nestlé OptiFibre DF: gums are known to be highly viscous, but due to the partially hydrolyzed form, their viscosity is significantly reduced, which makes using this form of DF more comfortable for patients [27]. Presumably, DF hydrolysis has a certain effect on increasing the amount of carbohydrates absorbed in the intestine, which would explain the effect of daily DF intake on Time Below Range reduction and bringing the AGP parameters of patients who received DF closer to the parameters characteristic of people who have no carbohydrate metabolism disorders.

To date, there are no similar Russian or foreign studies examining the long-term effect of PHGG on the glucose profile of patients with T2DM. The study closest in design to this one is that by Dall'Alba et al., which examined the effect of PHGG on key metabolic parameters in patients with T2DM over 6 weeks. A total of 44 patients were included in the study. Patients in the Main Group received 10 g of PHGG daily in addition to a standard diet, while patients in the Control Group followed a standard diet. At study completion, the Main Group showed a decrease in HbA1c from 6.88 ± 0.99% at baseline to 6.44 ± 0.94% at Study Week 4 and 6.57 ± 0.84% at Study Week 6 [28]. The main data of studies examining the effect of DF on metabolic parameters are summarized in Table 6.

**Table 6.** Findings of studies investigating the effect of DF on metabolic (adapted from [29])

| Authors | Sample characteristics | Duration | DF type and amount | Key findings |
|---|---|---|---|---|
| Su et al [30], 2021 (China) | 16 patients with T2DM, aged 41–76 years | 90 days | Combination of probiotics, prebiotics and whole grains (44 g/day) + standard diet | Reduction of HbA1c from 6.9 ± 1.1% to 5.9 ± 1.0% ($p < 0.01$) |
| Pedersen et al [31], 2016 | 32 male subjects with T2DM aged 42–65 years | 12 weeks | Oligosaccharide mix 5.5 g/day or maltodextrin 5.5 g/day (control) | No statistically significant changes in fasting glucose or HbA1c |
| Farhangi et al., 2016 [32] | 46 female patients with T2DM | 8 weeks | Chicory (10 g/day), placebo (control) | Statistically significant reduction in fasting plasma glucose and HbA1c |
| Gargari et al. [33] | 60 female patients with T2DM aged 30–60 years, BMI ≥ 30 kg/m$^2$ | 8 weeks | Resistant starch (10 g/day), placebo (control) | Statistically significant decrease in HbA1c (−0.3%) ($p < 0.05$) |

Of no less interest are studies whose design involves the evaluation of the effect of DF on glucose levels using LMWH or FGM. For example, a study by Arias-Cordova et al. examined data from 10 patients with T2DM aged 2865 years with a BMI ≥ 25kg/m$^2$. Patients received natural banana starch, high-amylose corn starch, or easily digestible corn starch in addition to their main diet for 4 days. During the administration of DF, the FGM characteristics and variability indices were studied in patients. Patients receiving natural banana starch had the most significant increase in Time Above Range (TAR): from 11.63 [4.42, 99.57]% at Day 2 to 9.37[2.60, 94.10]% at Day 3 and 48.09 [3.12, 100.4]% at Day 4. The same parameter in the group of patients who received high-amylose corn starch increased from 100.4]% at Day 4, while in the group receiving easily digestible corn starch, on the contrary, it decreased from 14.24 [0.0, 59.20]% at Day 2 to 7.98 [0.00, 61.02]% at Day 4; however, no statistically significant changes in glycemic variability (GV) were reported in the study [34]. Studies investigating the effect of DF on the ambulatory glucose profile of T2DM patients are poorly represented in modern foreign and domestic publications. A large number of studies primarily investigated the effects of various types of nutrition and DF intake on glycemic control in patients with T1DM, which may be explained by the fact that in routine clinical practice, the use of LMWH is more common among patients with T1DM. However, given the differences in the pathogenesis of T1DM and T2DM, a comparison of the data from this study with the data from studies conducted in a population of T1DM patients is not advisable.

## 8 Conclusion

Therefore, this study showed a positive effect of DF on glycemic control in patients with T2DM, as demonstrated by a statistically significant reduction in HbA1c, a significant reduction in fasting plasma glucose, and a significant improvement in AGP parameters. The study data provide the basis for increasing the efficacy of T2DM therapy for both glycemic control and minimizing the risk factors for T2DM complications. The listed changes have been repeatedly substantiated from the point of view of the mechanism of action of DF and are consistent with the available data in the international publications. This study is unique in that strict inclusion criteria made it possible to create a sample of patients in whom the effect of DF on glycemic control was studied against a "clean" background, which allowed to exclude the influence of extraneous factors, and also in that the modern Russian and international literature currently presents single studies investigating the effect of DF on glycemic control in patients with T2DM using a comparable sample size and similar duration of patient follow-up. However, to achieve the goal of introducing DF into clinical guidelines for the management of patients with T2DM, further research is required to examine the effects of different types, regimens, and durations of administration, as well as the daily DF dose.

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