

Giselle Foureaux *

A New Diet Therapy Protocol to Manage Type 1 Diabetes Mellit us in Adults

Running title: New protocol to manage type 1 diabetes Mellitus

Amanda Aparecida Felizardo¹, Caroline de Sousa Bosco Paiva², Carlos Eduardo de Freitas Jorge³, Giselle Foureaux^{1*}

¹Department of Morphology, Federal University of Minas Gerais (UFMG), MG, Brazil.

²University of Sao Paulo (USP), SP, Brazil.

³Department of Nutrition, Angiogold: Integrative Medicine, MG, Brazil.

*Corresponding Author: Giselle Foureaux, Federal University of Minas Gerais - Department of Morphology - Av. Antônio Carlos, 6627 - Belo Horizonte, MG, 31270-901, Brazil.

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Abstract

Type 1 diabetes mellit us (T1DM) is an autoimmune disease characterized by the destruction of beta cells and absolute insulin deficiency. T1DM usually appears in childhood and adolescence, but it can also be diagnosed in adulthood. For decades, American Diabetes Association (ADA) guidelines recommended consuming 50-60% of a diabetic's daily calories as carbohydrates. With these guidelines, the average number of patients with T1DM in the therapeutic goal (less than 7%) of glycated hemoglobin (HbA1c) in the world is no more than 10-15%, that is, we are not being effective in the treatment, either due to inadequate guidance, such as poor adherence due to difficulty in following the diet proposed by the ADA. Since 2019, the ADA recognized, albeit timidly, the low-carbohydrate diet (low-carb diet) as an acceptable approach, being the most studied, safe and effective strategy for the treatment of type 2 diabetes mellit us (T2DM). We recognize these advances, but we know that much remains to be elucidated, especially with regard to the treatment of T1DM. With that in mind, we developed a protocol [1], which aim a reduction in glycemic levels, a longer time on target with less hypoglycemia, a reduction in glycated hemoglobin and insulin doses, thus promoting an improvement in the patient's health and quality of life.

Keywords: type 1 diabetes mellitus; T1DM; glycated hemoglobin; glycemic control; low-carbohydrate diet; low-carb; serum insulin

Introduction

Type 1 diabetes *Mellitus* (T1DM) is a metabolic disease characterized by the destruction of pancreatic beta cells, resulting in impaired insulin secretion, and consequently hyperglycemia [2]. People with T1DM need daily insulin injections to keep blood glucose levels within an appropriate range [2]. Despite access to multiple daily injections or insulin pumps, glucose monitoring, expert medical care and diabetes education, diabetes care remains a challenge [3, 4].

The American Diabetes Association (ADA), for decades, guided the consumption of approximately 60% of daily calories in the form of carbohydrates for patients with diabetes [2,5]. However, this recommendation is ineffective, since carbohydrate is the macronutrient that causes the greatest increase in blood glucose [6]. A recent study

showed that high carbohydrate consumption in individuals with diabetes can lead to uncontrolled glycemic control [7]. It is very clear that high glycemic indices in diabetics are due to an inability to adequately metabolize carbohydrates, either due to a deficiency in insulin production or due to peripheral resistance to its action. Therefore, stimulating the consumption of this macronutrient is, at the very least, incompatible with the best food strategy. In addition, another study showed that current guidelines were not made following the best systematic review methodology, considering that several important studies were neglected [8]. The source and amount of carbohydrate consumed affects postprandial hyperglycemia and glycemic variability more than any other dietary fator [7]. Nevertheless, carbohydrate is a non-essential macronutrient, as the body has the ability to use other sources of energy very efficiently, such as fatty acids and ketone bodies [10]. Even though advances in treatments for T1DM, the unsatisfactory results of the most prescribed diets shows an urgent need for reassessment of dietary guidelines, with more emphasis on the low-carbohydrate diet (low-carb diet).

Despite the ADA not recognizing the low-carb diet in the treatment of T1DM, since 2019 it has been recognized by this entity, as the most effective, studied and safe strategy for the treatment of type 2 diabetes Mellitus (T2DM) [2]. In a 2016 study, adult patients with T1DM were randomized to either a standard (unrestricted) diet, where the patients' average carbohydrate intake was 203 ± 92g/day) or to a carbohydrate-restricted diet (75g of carbohydrates/day). After 12 weeks, the group receiving a carbohydrate-restricted diet demonstrated significant reductions in daily doses of insulin and HbA1c [11]. In the same study, it was also observed that a low-carb diet is also directly linked to weight loss and fat mass reduction, in addition to an improvement in the lipid profile, such as an increase in HDL, decrease in triglycerides and glycemic control, also influencing parameters cardiovascular diseases [11]. In another study, with 221 type 1 diabetics in a Brazilian public referral center for the treatment of T1DM, it was shown that 96.8% of patients had at least 1 symptomatic hypoglycemia in the last three months; 68% of patients had frequent nocturnal hypoglycemia and 34.8% had severe hypoglycemia [6]. Furthermore, it was concluded that a very small rate of only 6.8% of patients follow the ADA recommendation and an interesting fact is that both patients with T1DM who follow the ADA recommendations and patients who do not follow, they have poor control of diabetes, prevailing with a glycated hemoglobin index > 9.0% [6]. A systematic review was conducted to examine the effect of a low-carb diet in the treatment of T1DM. In this review nine studies were considered for eligibility, of these eight studies reported a mean change in HbA1c with a low-carb diet. Four reported a non-significant change, three reported statistically significant reductions and two studies reported severe hypoglycemia [12]. Overall, reductions in insulin dose, hypoglycemic episodes and HbA1c are visible. However, it is worth mentioning that the existing evidence so far presents a heterogeneity of information, reinforcing the need for short- and long-term studies that evaluate the control of T1DM using the low-carb diet to achieve the safety of its use in practice [12].

Given the scenario found, it is necessary to seek promising treatments, both to provide a better quality of life for individuals with T1DM, and to reduce complications arising from inadequate control. For this reason, our research group, in a previous work [1], showed a welldefined protocol to achieve reliable and effective results to evaluate the benefits of a low carb diet in the treatment of T1DM [1]. In the mentioned study, we defined an protocol lasts for six months, consisting of 3 phases of treatment: in the first phase the patient with T1DM consumes 130g of carbohydrates for 15 days, followed by the consumption of 90g of the carbohydrates for 7 days, and finally, 50g of carbohydrates until the sixth month of treatment. Why do we start the protocol with 130g of carbohydrate per day? According to the American Diabetes Association (ADA), low-carb diets are defined by the consumption of less than 130 g of carbohydrates per day [12]. So, our intention was to start from this cutoff point and gradually reduce the intake of carbohydrates, in order to mitigate possible discomforts resulting from the adaptation process.

A very important aspect addressed by our research group is to provide diabetes education to all patients, in order to equalize their knowledge, aiming at better glycemic control. The patient is monitored throughout the treatment by a multidisciplinary team, composed of endocrinologists, nutritionists, and nurses renowned in the area of T1DM. In order to obtain reliable and accurate data, the patient should consider capillary blood glucose and blood glucose sensors, such as the FreeStyle Libre glucose meter, glycemic range from 70 mg/dL to 180 mg/dL and the glycemic target of 100 mg/dL. Starting from an initial parameter, the sensitivity factor, the insulin-carbohydrate ratio and the waiting time for insulin action before meals are adjusted daily by the doctor and nurse, within the individuality of each patient. Hypoglycemic episodes were considered at 3 levels: level 1, low blood glucose levels (ranges from 70 to 55 mg/dL); Level 2, very low blood glucose levels (below 55 mg/dL); and level 3, characterized by cognitive impairment with need for help. For each level there is an orientation, being the gold standard for the treatment of hypoglycemia, the use of sugar diluted in water, according to the individual need of the patient. Patients with T1DM need basal insulin to suppress hepatic gluconeogenesis and maintain controlled fasting and 24-hour blood glucose. Basal insulin should be divided into 2 doses in order to better cover the 24 hours. In addition to basal insulin, regular and ultrarapid insulin are also needed. Ultra-fast insulin to cover carbohydrates and correct hyperglycemia and regular insulin to cover proteins and fats. As the primary standard for evaluating the low-carb diet, we considered glycated hemoglobin [1].

Finally, we belive that this protocol will become a gold standard for the treatment of T1DM, since it has great potential to reduce direct complications resulting from its inadequate control, such as: amputations, hemodialysis, blindness; and also other indirect complications, due to the fact that diabetes is a complicating condition in several acute and chronic comorbidities.

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