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The Ketogenic Diet and Its Effects on Patients With Type 2 Diabetes Mellitus – A Review Of Literature

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ABSTRACT

Purpose of the Study: This paper aims to analyze the impact of the ketogenic diet (keto diet) on glycemic control, weight loss, medication use, and lipid profile in patients with type 2 diabetes (T2DM), as well as to assess its long-term safety and side effects.

Research: This article is based on review of clinical trials, meta-analyses, and systematic reviews found on Pubmed, Google Scholar and other databases. After the evaluation of the articles, observational studies, experimental studies and meta-analyses, the key benefits and limitations of the keto diet in the T2DM were selected.

Results: The keto diet improves glycemic control by lowering HbA1c, fasting blood glucose, and insulin resistance in T2DM patients. It also showed positive effects on lipid metabolism. In addition keto diet has been found to lead to greater weight reduction than other diets. This weight loss, along with improved metabolic parameters, often results in a reduced need for diabetes medications. However, there is limited data on the long-term safety and effectiveness of the keto diet for managing diabetes, and it may be difficult to maintain due to its strict

carbohydrate restrictions. The diet's strict limitations may also cause challenges for certain individuals, such as pregnant women, making it less sustainable for everyone. Furthermore, concerns include potential increases in LDL cholesterol and hypoglycemia, particularly during the initial stages of the diet. Additionally, the keto diet may lead to deficiencies in vitamins, minerals, fiber, and antioxidants, which are usually obtained from carbohydrates, making supplementation necessary to mitigate these deficiencies.

Conclusions: The keto diet appears to be valuable for glycemic control, weight loss, and reducing medication use in T2DM patients. However, long-term data is lacking, and there are concerns about its sustainability and potential side effects, particularly regarding cardiovascular health and micronutrient deficiencies.

Keywords: Ketogenic diet, type 2 diabetes mellitus, glycemic control, weight loss, lipid profile, hypoglycemia, cardiovascular health

Introduction

The ketogenic diet has gained widespread attention in recent years for its potential health benefits, particularly in the management of metabolic conditions such as type 2 diabetes. While the diet has evolved from its initial use as a treatment for epilepsy nearly a century ago, modern research has highlighted its effectiveness in improving glycemic control, promoting weight loss, and enhancing lipid profiles in patients with type 2 diabetes.

Type 2 diabetes, a major global health issue, characterized by insulin resistance and impaired glucose metabolism, affects an estimated 462 million people worldwide. The disease leads to various health complications, including cardiovascular diseases and microvascular damage.

This study explores the potential benefits and limitations of the ketogenic diet in managing type 2 diabetes. Specifically, the study aims to assess the effects of the ketogenic diet on glycemic control, weight loss and lipid profile improvement in T2DM patients. Additionally, it seeks to provide a comprehensive understanding of how this diet may serve as an alternative or complementary approach to conventional diabetes management, medication use and to identify

any potential adverse effects or concerns regarding its long-term safety, sustainability, and potential negative effects.

Definition and brief history of the ketogenic diet

The ketogenic diet (also known as „keto"), is a high-fat, moderate-protein, and very low-carbohydrate eating plan. The main goal of the keto diet is to shift the body's primary energy source from carbohydrates (glucose) to fats (ketones) to a state known as ketosis.

The state of ketosis is achieved when liver converts fat into ketones, which the body then uses for energy instead of glucose. This shift is achieved by drastically reducing carbohydrate intake (usually to about 15-50 grams per day), protein remaining the widely recommended 1g protein per kilogram of body weight, and meeting most of the calorie demand by increasing fat intake.

Originally created almost 100 years ago to treat seizures, most clinical research on the ketogenic diet for managing drug-resistant epilepsy in both children and adults has taken place in the past 30 years. Additionally, ketogenic diets are emerging as a promising complementary approach in critical care for resolving acute status epilepticus, especially when conventional seizure medications and anesthetics are ineffective. (2)

Under normal conditions, the body mainly depends on carbohydrates for energy. Insulin helps to extract and store energy from glucose. When carbohydrate intake is low, insulin secretion decreases. Initially, the body uses stored glucose in the form of glycogen as fuel, but after three to four days, these stores are exhausted. At that point, the oxidation of fatty acids reaches its peak, leading to an increase in acetyl-CoA production in the mitochondria of hepatocytes. Acetyl-CoA then enters the citric acid cycle joined with oxaloacetate. When oxaloacetate is depleted and its levels do not maintain balance within the citric cycle, acetyl-CoA is redirected to produce ketone bodies, such as acetoacetate and β-hydroxybutyrate (βHB), which serve as an alternative energy source for tissues outside the liver. Ketosis occurs when blood concentrations of βHB rise to 0.5 mmol/L or higher. (21) Since the liver lacks the enzyme succinyl-CoA:3-ketoacid CoA transferase (SCOT), liver cells cannot use ketone bodies for their own energy. As a result, acetoacetate and βHB are released into the bloodstream and transported to various tissues, including the brain, via monocarboxylate transporters. Once in these tissues, ketones are used by neurons or other cells to regenerate acetyl-CoA, which then enters the citric acid cycle to produce ATP. (20, 22)

Ketones are typically produced during periods of starvation or extended exercise but can also be generated when following a very low carbohydrate diet. It's important to note that in physiological ketosis, blood pH remains normal, while in pathological ketosis, blood pH decreases. (1)

Major clinical issues associated with type 2 diabetes

Type 2 diabetes mellitus (T2DM) is a major global health concern, presenting a variety of clinical challenges. Type 2 diabetes affects an estimated 462 million people worldwide, making up 6.28% of the global population. In 2017, the condition was responsible for over 1 million deaths, positioning it as the ninth leading cause of mortality. (19)

The key issues linked to T2DM involve both microvascular and macrovascular complications, which are mainly caused by high blood sugar levels, dyslipidemia and insulin resistance. Microvascular complications, including retinopathy, nephropathy, and neuropathy, are common in individuals with T2DM, primarily due to prolonged hyperglycemia. These conditions result from the damaging effects of sustained high blood sugar levels on small blood vessels. (12) On the other hand, macrovascular complications are also prevalent, with T2DM greatly increasing the risk of cardiovascular diseases, such as atherosclerotic vascular disease and heart failure, as well as chronic kidney disease. These complications arise due to the interplay of hyperglycemia and insulin resistance, which impair the function of larger blood vessels and organs. At the heart of T2DM are insulin resistance and defects in insulin secretion, both of which disrupt glucose metabolism and contribute to the disease's progression. (13) Additionally, obesity plays a major role in the development and exacerbation of T2DM. It is a key risk factor for insulin resistance, and effective weight management through lifestyle changes is essential for controlling the disease and preventing further complications. (14)

Benefits of Ketogenic Diet in the Management of Diabetes

Glycemic Control:

The ketogenic diet has been shown to improve glycemic control in patients with type 2 diabetes mellitus. Studies indicate significant reductions in glycated hemoglobin (HbA1c) levels, fasting blood glucose, and insulin resistance, which are crucial for diabetes management.

Ketogenic and low-carb diets (LCD) have been shown to improve glycemic control in T2D patients by decreasing insulin requirements and enhancing metabolic control, with ketogenic diets potentially offering stronger effects due to ketosis. Various studies support the benefits of

these diets in both short-term and long-term glycemic management, including better weight control, reduction in HbA1c, and decreased need for diabetes medications. (3) In A 2-year randomized clinical 115 obese adults with T2D were randomly assigned to either a very-low-carbohydrate, high-unsaturated fat, low-saturated fat diet, or an isocaloric high-carbohydrate, low-fat diet for 52 weeks. Both diets resulted in weight loss and improved HbA1c, with no significant differences between the two groups. However, the low-carb diet led to greater improvements in lipid profiles, possibly due to the higher quality of fats (unsaturated vs. saturated) in the diet, as well as better blood glucose control and a reduction in the need for diabetes medication. (4)

Weight Loss:

Ketogenic diet is effective in promoting weight loss, which is beneficial for overweight or obese patients with diabetes. This weight reduction is associated with improved metabolic parameters and reduced diabetes-related complications.

Meta-analysis indicated that patients on a ketogenic diet experienced greater weight reduction compared to those on other diets (standardized mean difference (SMD), −0.46; 95% confidence interval (CI), −0.90 to −0.03; I^2= 78%; moderate to low quality evidence), with a mean weight loss difference of −7.78 kg in diabetic patients and −3.81 kg in overall patients. Although the ketogenic diet showed a trend toward significant reductions in BMI and waist circumference, these results were not statistically significant ($p = 0.08$ and $p = 0.09$, respectively). (5) Webster et al. proclaimed that participants self-reported a weight loss of 16 kg (range 7–31) from Start-LCHF (low-carb hig-fat diet) to First-Assessment ($p < 0.001$), with no significant change in weight from First-Assessment to Follow-Up ($p = 0.64$). All 28 participants experienced weight loss between Start-LCHF and First-Assessment, with a median loss of 17% (range 7–25) of their initial weight at Start-LCHF. At Follow-Up, 10 participants had maintained weight losses greater than 25 kg for an average of 3.5 ± 1.3 years, including 4 individuals who had lost over 50 kg. Participants who had Type 2 Diabetes (T2D) for a longer period before starting the LCHF diet experienced greater weight loss compared to those who began the diet soon after their T2D diagnosis. (7)

Reduction in medication use:

A reduction in the use of glucose-lowering medications in patients with type 2 diabetes on ketogenic diet has been observed by numerous studies. In a study by Hallberg et al. a notable decrease in the use of all diabetes medications among participants in the keto diet group was recorded compared to those in the usual intervention group. Medication prescription other than

metformin declined from 56.9 ± 3.1% to 29.7 ± 3.0% ($P < 1.0 \times 10^{-16}$). Insulin therapy was reduced or eliminated in 94% of users; sulfonylureas were entirely eliminated in the CCI (continuous care intervention). GLP-1 prescriptions were statistically unchanged (13.4% at baseline to 14.4% at 1 year, $P = 0.67$), and metformin decreased slightly (71.4–65.0%, $P = 0.04$) for CCI participants (6) Webster et al. reported a decrease in glucose-lowering medications. At Start-LCHF, 24 participants reported taking a median of 1850 mg/d of metformin, compared with 16 participants taking 1000 mg/d at First-Assessment. 8 out of 11 participants discontinued and 2 reduced doses of insulin after 15 months. There were 2 participants using sulphonylureas at Start-LCHF and by First-Assessment, 1 had discontinued and the other had reduced their dose. The only other diabetes medication reported at Start-LCHF was a DPP-4 inhibitor used by one participant, which was discontinued by First-Assessment. In terms of cholesterol-lowering medications (statins), 14 participants reported that they were taking statins at Start-LCHF (among which 1 participant reported a prior cardiovascular disease event). By First-Assessment, 7 participants had discontinued statins. (7) Lipid Profile Improvement:

Studies show that ketogenic diet has a possibility to positively affect lipid metabolism. A study by Chong Zhouet al. revealed that the ketogenic diet was associated with a significantly higher reduction in triglyceride levels (TG) and an increase in high-density lipoprotein (HDL) levels with no significant differences with regard to changes in total cholesterol and low-density lipoprotein (LDL) levels between the ketogenic and non-ketogenic diet groups of overweight patients with type 2 diabetes mellitus (8) Another study by Mohamed Rafiullah et al. concludes that ketogenic diet was superior in decreasing triglyceride levels and increasing high-density lipoprotein cholesterol levels (11) Another metaanalysis by Yuan X. et al. shows that multiple studies support the positive effect of ketogenic diet on lipid levels in diabetic patients. Specifically, ketogenic diet consumption led to a mean reduction in triglycerides by 0.72 mmol/L, total cholesterol (TC) by 0.33 mmol/L, and low-density lipoprotein by 0.05 mmol/L, while high-density lipoprotein increased by 0.14 mmol/L. (9) The Dashti et al. study (10) reported even more significant improvements, with TG decreasing by 3.67 mmol/L, TC by 1.88 mmol/L, and LDL by 1.78 mmol/L, while HDL increased by 0.14 mmol/L. This larger effect was likely due to the study's participants, who were obese with hyperglycemia and dyslipidemia, and had higher baseline lipid levels compared to typical T2DM patients. The improvement in lipid metabolism is especially beneficial for individuals with insulin resistance, as dyslipidemia exacerbates insulin resistance and increases the risk of cardiovascular diseases.

Overall, ketogenic diet shows significant potential in managing both glucose metabolism and lipid disorders in T2DM patients, improving insulin sensitivity and reducing diabetic complications. (9)

Limitations of ketogenic diet in the management of Diabetes:

There is concern about the long-term safety and adherence to such diets, as well as their suitability for certain groups, such as pregnant women, individuals with eating disorders, or those on SGLT-2 inhibitors due to the risk of diabetic ketoacidosis (DKA).

Insufficient Long-term Data:

Although short-term benefits in glycemic control and weight loss have been reported, there is limited evidence regarding the long-term safety and effectiveness of the ketogenic diet for managing diabetes. Most studies are conducted for less than a year, and the long-term effects on liver health and cardiovascular outcomes are not yet well understood. A study by Shivam Joshi et al. suggests that the ketogenic diet has shown temporary improvements in glycemic control regarding type 2 diabetes management, but long-term randomized studies suggest no significant differences in blood sugar levels compared to low-fat diets. Though weight loss from any diet can improve insulin resistance, there is little evidence that the ketogenic diet improves carbohydrate intolerance independently of weight loss. (15)

Sustainability and Compliance:

The strict limitation on carbohydrates in the ketogenic diet can be difficult for many people to maintain in the long run. This often results in low adherence, reducing its effectiveness as a lasting approach to managing diabetes. (15) (16)

Possible Negative Effects:

The ketogenic diet may cause various side effects, such as dyslipidemia, nutrient deficiencies, and digestive problems. Additionally, there are concerns that elevated LDL cholesterol levels could counteract any potential cardiovascular benefits.

Evidence suggests that the ketogenic diet may not lead to improvements in low-density lipoprotein (LDL) cholesterol or apo-B-containing lipoproteins, and in some cases, these levels may even increase despite weight loss. Although the ketogenic diet may raise high-density lipoprotein (HDL) cholesterol levels, this increase has not been shown to translate into reduced cardiovascular events. Therefore, while the ketogenic diet is often associated with

improvements in weight loss, its effects on dyslipidemia and overall cardiovascular health remain unclear and may not be as beneficial as some hope. (15, 23)

Sumei Li et al. reported that the ketogenic diet group experienced higher rates of hypoglycemia during the initial four weeks compared to the control group. Specifically, there were 10 instances of hypoglycemic symptoms and two cases of severe hypoglycemia (blood glucose <3.9 mmol/L) in the keto group, while the control group had 10 instances of hypoglycemic symptoms but no severe hypoglycemia. Both groups had no hypoglycemic events in the following weeks. Additionally, uric acid levels increased in the ketogenic diet group, but not in the control group, although this difference was not statistically significant. (17) Some studies reported cases of euglycaemic diabetic ketoacidosis. Medication adjustments (like reducing insulin) can help prevent hypoglycemia, but reports of ketoacidosis in patients on SGLT2 inhibitors indicate that VLCKD (Very Low Carbohydrate Ketogenic Diet) should be avoided in these cases. (18, 24)

Common side effects reported by participants following ketogenic diet include gastrointestinal issues such as constipation and diarrhea, as well as short-term symptoms like headaches, muscle cramps, and weakness -often referred to as "keto flu". (18) The onset of "keto flu" varies among individuals, appearing anywhere from a few days to up to two weeks after starting the ketogenic diet. Factors like metabolism, hydration, electrolyte balance, and overall health influence the timing and severity of symptoms. Staying hydrated, maintaining electrolyte balance, and ensuring adequate nutrition can help ease symptoms. (18)

Ketogenic diet may also cause micronutrient deficiencies, particularly in vitamins, minerals, fiber, and antioxidants found in unprocessed carbohydrates like whole grains, fruits, and vegetables. Few studies have reported on these deficiencies, but some suggest that supplementation may be necessary. (18)

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