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IMPACT OF THE KETOGENIC DIET ON GLYCEMIC CONTROL: A SYSTEMATIC COMPARATIVE REVIEW OF THE LOW-CARBOHYDRATE DIET AND STANDARD DIABETIC DIET IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

Research Objectives: This systematic review aimed to evaluate whether the ketogenic diet (KD) offers a safe and effective pathway to clinical remission in type 2 diabetes mellitus (T2DM), compared to non-ketogenic low-carbohydrate diets and standard diabetic care. Specifically, we sought to assess the impact of KD on glycemic control, weight loss, cardiovascular risk factors, and the need for glucose-lowering medications.

Methods: Following PRISMA 2020 guidelines, we conducted a comprehensive literature search in PubMed, MEDLINE, and Embase for studies published between 2000 and 2025. Nineteen core reports from randomized controlled trials and intensive clinical programs were selected for review based on relevance and methodological quality.

Key Findings: In the short term (3 to 6 months), the KD was associated with significantly greater reductions in glycated hemoglobin (HbA1c) - typically between 0.8% and 1.5%, and more substantial weight loss than standard dietary approaches. While long-term glycemic outcomes (12 to 24 months) tended to align with other intensive interventions, the KD distinguished itself by enabling rapid deprescription of glucose-lowering medications, including insulin and sulfonylureas. Patients also showed consistent improvements in cardiovascular risk markers, such as lower triglycerides and higher HDL cholesterol. Safety data revealed no evidence of adverse effects on renal or hepatic function; on the contrary, many participants experienced improved liver enzyme profiles and stable kidney function markers.

Conclusions: The ketogenic diet appears to be a safe and effective metabolic strategy for patients with T2DM, delivering superior short-term glycemic control, weight loss, and medication reduction. These benefits suggest the KD may facilitate clinical remission in selected individuals with T2DM.

KEYWORDS

Ketogenic Diet, Type 2 Diabetes Mellitus, Glycemic Control, HbA1c, Nutritional Ketosis, Low-Carbohydrate Diet

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Introduction

The global health landscape is currently dealing with a dual epidemic of obesity and type 2 diabetes mellitus (T2DM), conditions that share a common pathophysiological foundation in insulin resistance (IR) and metabolic dysfunction.¹ T2DM has long been characterized as a chronic and progressive condition requiring lifelong pharmacological management, with therapeutic strategies focusing on managing symptoms through glucose-lowering medications rather than addressing the root cause.¹ However, recent advancements in nutritional science and clinical research have sparked interest in the potential for T2DM reversal or remission through dietary interventions.¹

The ketogenic diet (KD) is a nutritional paradigm defined by a significant restriction of carbohydrates, typically to less than 50 grams per day or less than 10% of total energy intake, which forces the body to switch its primary fuel source from glucose to fat-derived ketone bodies.⁵ This metabolic state, known as nutritional ketosis, is characterized by blood levels of beta-hydroxybutyrate (BHB) between 0.5 and 3.0 mmol/L.⁸ Historically, before the widespread availability of exogenous insulin in the early 20th century, very low-carbohydrate diets were the standard of care for diabetes management because they directly mitigated the postprandial glycemic excursions caused by carbohydrate ingestion.³

The theoretical framework supporting the KD in the context of T2DM is largely informed by the Carbohydrate-Insulin Model (CIM) of obesity. Unlike the conventional energy balance model, which posits that overeating causes adiposity, the CIM suggests that the consumption of high-glycemic-load carbohydrates produces hormonal changes - specifically hyperinsulinemia, that promote calorie deposition in adipose tissue.¹² This "internal starvation" leads to a perceived lack of fuel for metabolically active tissues, resulting in increased hunger and suppressed energy expenditure.¹² By reducing dietary carbohydrates, the KD lowers the insulin-

to-glucagon ratio, thereby suppressing the release of fatty acids from adipose tissue and promoting fat oxidation, addressing the root cause of metabolic syndrome.¹⁴

Despite the promising outcomes observed in clinical trials, the medical community remains divided on the long-term safety and sustainability of the ketogenic diet. Concerns often revolve around potential micronutrient deficiencies, deleterious effects on blood lipid profiles (specifically low-density lipoprotein cholesterol, or LDL-C), and the impact on renal and hepatic health.¹ This systematic review aims to synthesize current evidence on the impact of the ketogenic diet on glycemic control in T2DM patients, comparing it to standard diabetic diets and non-ketogenic low-carbohydrate diets, while evaluating its long-term safety and efficacy profile following the PRISMA 2020 guidelines.

Methodology

This systematic review was conducted to evaluate the comparative effectiveness of the ketogenic diet and other dietary patterns in the management of T2DM, with a specific focus on glycemic control and cardiometabolic safety. The methodology was structured to meet the reporting standards of the PRISMA 2020 statement, ensuring a comprehensive and transparent analysis of the available literature.¹

Search Strategy and Information Sources

A systematic search for relevant clinical studies was conducted across several high-impact electronic databases, including PubMed (MEDLINE), Embase (OVID), the Cochrane Library (CENTRAL), Scopus, and CINAHL.⁵ The search covered January 2000 through April 2025, encompassing more than twenty years of research on carbohydrate-restricted nutrition. Search strategy utilized a combination of Medical Subject Headings (MeSH) and text-word terms related to the population of interest and the intervention.⁶

Eligibility Criteria and Study Selection

The selection process was guided by the PICOS framework (Participants, Intervention, Comparison, Outcomes, and Study Design) to ensure high-quality evidence synthesis.⁶

1. **Participants:** The review included studies involving adults (≥ 18 years old) diagnosed with T2DM. Diagnostic criteria followed international standards, including glycated hemoglobin (HbA_{1c}) $\geq 6.5\%$ or fasting plasma glucose (FPG) ≥ 126 mg/dl.⁶ Studies involving patients with type 1 diabetes, pregnant women, or pediatric populations were excluded.²³

2. **Interventions:** The primary intervention of interest was a ketogenic diet, defined as a dietary intake restricting carbohydrates to less than 50 grams per day or less than 10% of total energy intake, specifically aiming to induce and maintain nutritional ketosis.⁵

3. **Comparators:** The ketogenic diet was compared against standard diabetic diets (typically adhering to guidelines from the American Diabetes Association or European Association for the Study of Diabetes), low-fat diets, calorie-restricted moderate-carbohydrate diets, or non-ketogenic low-carbohydrate diets (LCDs, defined as 50–130 grams of carbohydrates per day).³

4. **Outcomes:** To be included, studies had to report at least one primary glycemic outcome (HbA_{1c} , FPG, or insulin levels). Secondary outcomes included body weight, body mass index (BMI), waist circumference, lipid profile (total cholesterol, LDL-C, HDL-C, and triglycerides), blood pressure, and medication score or usage.¹

5. **Study Design:** Only randomized controlled trials (RCTs) and high-quality non-randomized controlled trials (nRCTs) with a follow-up duration of at least 12 weeks were included. The review prioritized long-term follow-up data (up to 24 months) to assess sustainability and safety.²

Data Extraction and Quality Assessment

Data from the included studies were extracted independently by two reviewers using standardized forms. Extracted information included study design, participant characteristics (age, sex, BMI, baseline HbA_{1c} , duration of T2DM), intervention details (specific macronutrient distribution, use of nutritional supplements), and quantitative results for all primary and secondary outcomes at specified intervals (3, 6, 12, and 24 months).¹⁸

The risk of bias was assessed using the Cochrane Risk-of-Bias 2.0 (RoB 2.0) tool for randomized trials.¹⁸ This tool evaluates five essential domains: (1) bias arising from the randomization process; (2) bias due to deviations from intended interventions; (3) bias due to missing outcome data; (4) bias in the measurement of the outcome; and (5) bias in the selection of the reported result.³³ For non-randomized studies, the ROBINS-I tool was applied where appropriate.³⁵ The overall certainty of evidence for each outcome was graded using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.¹⁸

Data Synthesis and Statistical Analysis

A quantitative synthesis was performed where study homogeneity allowed. Effect sizes were reported as standardized mean differences (SMDs) or mean differences (MDs) with 95% confidence intervals (CIs).¹⁸ Heterogeneity between studies was assessed using the I^2 statistic, with values greater than 50% indicating significant heterogeneity.¹⁸ Subgroup analyses were conducted based on the duration of the intervention (short-term: ≤ 6 months; long-term: > 6 months) and the type of comparator diet.¹⁸

Results

The systematic search and screening process identified a strong body of evidence evaluating the role of the ketogenic diet (KD) in the treatment of type 2 diabetes mellitus (T2DM). After the initial screening of 124 identified studies, a selection of 19 reports derived from 11 core randomized controlled trials and large-scale intensive lifestyle programs were included in the final synthesis.¹ These studies provided an overview of the metabolic impact of carbohydrate restriction over follow-up periods ranging from three months to eight years.¹

Study Characteristics and Participant Profiles

The participants across the included trials were primarily adults with overweight or obesity, typically presenting with a baseline BMI exceeding 30 kg/m².⁶ Baseline HbA_{1c} levels varied from 6.0% (pre-diabetes threshold) to over 9.0%, representing a broad spectrum of glycemic severity.³⁰ Several studies focused specifically on populations requiring intensive management, including those prescribed insulin or sulfonylureas at the start of the intervention.⁹

The interventions were generally categorized as very-low-carbohydrate ketogenic diets (VLCKDs), restricting intake to < 20 to 50 grams of carbohydrates per day.⁵ Comparison diets included moderate-carbohydrate calorie-restricted diets (MCCR), low-glycemic index diets (LGID), and standard-of-care diets following ADA guidelines.³

Glycemic Control: Impact on HbA_{1c} and Fasting Glucose

The most significant finding across the systematic review was the rapid and substantial reduction in HbA_{1c} levels among participants adhering to a ketogenic diet [Table 1.]. Short-term studies (3 to 6 months) consistently reported HbA_{1c} reductions ranging from 0.8% to 1.5%, significantly outperforming standard low-fat and moderate-carbohydrate diets.³⁸

Table 1. Comparison of glycemic control outcomes (HbA_{1c}) and statistical significance between ketogenic and standard dietary interventions across selected longitudinal studies.

Study	Population (n)	Duration	KD HbA _{1c} Change	Control HbA _{1c} Change	Statistical Significance
Westman et al. (2008)	84	24 weeks	-1.5%	-0.5%	p = 0.03
Saslow et al. (2017)	34	12 months	-0.5%	-0.2%	p = 0.007
Tay et al. (2015)	115	52 weeks	-1.0%	-1.0%	p = NS
Hallberg et al. (2018)	349	12 months	-1.3%	0.0%	p < 0.0001
Goday et al. (2016)	89	4 months	-0.9%	-0.5%	p < 0.05

The data indicates that while the KD is universally effective, its relative advantage over the control group depends on the intensity of the comparator.³⁷ In the trial by Tay et al., both the VLCKD and the high-carbohydrate control group received intensive exercise training and caloric restriction, leading to similar HbA_{1c} reductions in both arms.³⁷ However, the KD group achieved these results with significantly less medication.³⁷

In the long term (1 to 2 years), the Continuous Care Intervention (CCI) conducted by Hallberg and the Virta Health team demonstrated sustained glycemic improvements. At two years, CCI participants maintained an average HbA_{1c} of 6.3%, compared to a baseline of 7.6%, while the usual care group showed no improvement.⁹ Despite a slight "drift" or regression in HbA_{1c} between year one and year two, the clinical outcomes remained significantly superior to standard care.³²

Anthropometric Changes and Body Composition

Weight loss was a primary secondary outcome in all included studies, serving as both a driver of improved insulin sensitivity and a key motivator for patient adherence.⁸ The KD resulted in significant reductions in body weight, BMI, and waist circumference [Table 2].²

Meta-analysis results for body weight indicated a standardized mean difference (SMD) of -1.91 kg in favor of the KD compared to control diets in short-to-medium term studies.²⁸ In the Westman trial, the KD group lost an average of 11.1 kg, compared to 6.9 kg in the low-glycemic index group.⁴⁰ Long-term studies, such as the CCI, showed that 75% of participants maintained a weight loss of at least 5% of their body weight at the two-year mark.³²

Table 2. Comparison of mean changes in body weight, BMI, and body composition between ketogenic and standard dietary groups with evidence grading.

Anthropometric Outcome	KD Mean Change	Control Mean Change	Evidence Quality
Body Weight (kg)	-10.0 to -12.7	-3.0 to -10.1	Moderate ³⁷
BMI (kg/m ²)	-1.56 (SE 0.39)	NS	Low ⁴⁵
Waist circumference (cm)	-0.10 (SMD)	Ref	Low ¹⁸
Visceral Fat Reduction	Significant	Minimal	Moderate ⁴³

The reduction in visceral adiposity was specifically highlighted in the Goday and Hallberg trials.⁴³ The KD was associated with a dramatic decrease in suspected liver steatosis (from 96% to 68%) and an improvement in liver fibrosis markers, which are critical contributors to the metabolic dysfunction seen in T2DM.⁴³

Cardiovascular Risk Factors and the Lipid Profile

The impact of the KD on the lipid profile is multifaceted and represents a shift toward a less atherogenic phenotype, despite occasional increases in absolute LDL cholesterol (LDL-C) levels.⁹

1. **Triglycerides:** The most consistent lipid improvement observed was a significant reduction in serum triglycerides (TG), with meta-analyses reporting an SMD of -0.41.¹⁸ This reduction is attributed to decreased carbohydrate availability for hepatic de novo lipogenesis.¹⁴

2. **HDL Cholesterol:** A significant increase in high-density lipoprotein (HDL) cholesterol was recorded across studies, with an SMD of 0.19.¹⁸ Westman et al. reported a +5.6 mg/dl increase in the KD group compared to 0 mg/dL in the control.⁴⁰

3. LDL Cholesterol and Particle Size: Several studies reported a rise in LDL-C (e.g., +10% in the Hallberg 1-year analysis).⁹ However, detailed subfraction analysis using ion mobility revealed that this increase was driven by larger, cholesterol-enriched LDL particles (Pattern A), while the more dangerous small, dense LDL particles (Pattern B) decreased by 23%.⁹ This shift resulted in the reversal of the atherogenic lipoprotein phenotype (ALP) in 48.1% of CCI participants.⁴⁷

4. Blood Pressure: Reductions in both systolic (SBP) and diastolic blood pressure (DBP) were observed, with the KD often proving more effective for lowering blood pressure than standard low-fat diets.²

Medication Deprescription and Disease Remission

A unique and arguably the most clinically relevant outcome of the ketogenic diet is the reduction in pharmacological burden [Table 3.]. The rapid decrease in dietary glucose input requires a concomitant decrease in medication to prevent iatrogenic hypoglycemia.³

In the Westman (2008) trial, 95.2% of KD participants reduced or eliminated their diabetes medications, compared to 62% in the low-glycemic index group.³ Over 2 years in the Virta Health CCI, the use of any glycemic control medication (excluding metformin) declined from 55.7% to 26.8%.³² Specifically, insulin use was reduced by 62%, and sulfonylureas were eliminated in 100% of the participants.⁹

Table 3. Two-year clinical outcomes of ketogenic diet therapy versus usual care: A summary of medication reduction and disease reversal rates.

Clinical Outcome (2 Years)	CCI KD Group	Usual Care Group	Significance
Insulin elimination/reduction	62% decrease	No change	p < 0.0001
Sulfonylurea elimination	100%	No change	p < 0.0001
T2DM Remission (HbA _{1c} < 6.5%)	17.6%	0%	p < 0.0001
T2DM Reversal (incl. Metformin)	53.5%	0%	p < 0.0001

T2DM remission, defined as an HbA_{1c} < 6.5% for at least three months without medications, was achieved by 17.6% of participants in the CCI at 2 years.³² When including those who remained only on metformin, the "reversal" rate was as high as 53.5%. [Table 3.].³² While these rates are known to decline as adherence wanes over long periods (5 years), they represent a level of disease control rarely seen in standard primary care.¹

Safety and Tolerability: Renal, Hepatic, and General Health

Safety markers were closely monitored across the included systematic reviews to address clinical concerns regarding high-fat, high-protein intake.

- **Renal Function:** Meta-analyses of markers such as serum creatinine and eGFR showed no evidence of renal harm.¹⁸ In fact, the CCI study reported a significant increase in eGFR over two years, particularly in patients with baseline impairment, suggesting that the reduction in glycemic and inflammatory stress may be renoprotective.⁴²

- **Hepatic Health:** Liver enzymes (ALT, AST, and ALP) showed significant and sustained declines in participants on a ketogenic diet.¹ These results are highly correlated with the reduction in visceral fat and the resolution of NAFLD.³²

- **Bone Health:** Spine bone mineral density (BMD) remained unchanged in KD participants over two years, alleviating concerns about potential bone loss during ketosis.³²

- **Adverse Events:** The most common adverse effects were mild, transient symptoms occurring during the first 2-4 weeks (e.g., headache, constipation, insomnia), often resolving as the body adapted to fat-burning.⁴⁶ No serious adverse events related to the diet, such as diabetic ketoacidosis or symptomatic micronutrient deficiency, were reported.¹

Discussion

This review synthesizes current evidence and underscores the ketogenic diet (KD) as a promising metabolic intervention that can bring about rapid, meaningful improvements in glycemic control for type 2 diabetes mellitus (T2DM) patients. The underlying mechanisms, comparative efficacy, and long-term implications of these findings warrant a detailed examination to inform clinical practice.

Pathophysiological Mechanisms of Ketosis in T2DM

The efficacy of the KD is mainly driven by its ability to resolve hyperinsulinemia and improve tissue-specific insulin sensitivity. In the context of T2DM, obesity and stationary lifestyle lead to "metabolic overload," where the capacity for skeletal muscle and liver to oxidize fuels is exceeded.¹⁴ This results in the accumulation of ectopic fat and lipotoxic intermediates such as ceramides and diacylglycerols (DAGs) in these tissues.¹⁶ These molecules interfere with the Akt signaling pathway, essential for GLUT4 translocation and glucose uptake.¹⁶

By restricting dietary carbohydrates, the KD considerably lowers the stimulus for insulin secretion.¹² This shift in the insulin-to-glucagon ratio activates lipolysis in adipose tissue and facilitates the oxidation of ectopic fat in the liver and muscle.¹¹ Research has shown that a 3-week KD can increase insulin-stimulated glucose disposal in skeletal muscle even before significant weight loss occurs, suggesting that nutritional ketosis per se exerts a direct metabolic benefit.¹⁶ Furthermore, the appetite-suppressing effects of ketone bodies and the high-protein nature of the diet allow for spontaneous caloric reduction without the psychological burden of hunger associated with traditional calorie-restricted diets.⁵

The Carbohydrate-Insulin Model and Metabolic Flexibility

The success of the KD provides empirical support for the Carbohydrate-Insulin Model (CIM) of obesity. According to this model, the chronic consumption of high-glycemic-load carbohydrates promotes an anabolic state where calories are partitioned into fat cells, leaving fewer fuels available in the circulation for lean tissues.¹² This creates a state of "internal starvation" that drives the patient to consume more calories and reduces their basal metabolic rate.¹²

The transition to a ketogenic state restores "metabolic flexibility" - the ability of the body to switch efficiently between carbohydrate and lipid oxidation.¹⁶ While standard low-fat diets may exacerbate the metabolic problem by keeping insulin levels high and restricting fuel availability, the KD provides a stable supply of fat-derived fuels (fatty acids and ketones), effectively reversing the "starvation response" and improving markers of cardiovascular health.¹²

Comparative Efficacy: KD vs. LCD vs. Standard Diabetic Diet

A critical nuance in the literature is the comparison between very-low-carbohydrate ketogenic diets (<50 g/day) and non-ketogenic low-carbohydrate diets (LCDs, 50–130 g/day). Meta-analyses consistently show that while both approaches are superior to high-carbohydrate, low-fat diets for glycemic control and weight loss, the KD generally yields more significant HbA_{1c} reductions and higher rates of medication discontinuation.²⁴

For example, in a network meta-analysis of 42 RCTs, the ketogenic diet was ranked as one of the most effective options for controlling HbA_{1c} and fasting glucose.³¹ The "dose-response" relationship of carbohydrate restriction appears particularly relevant for the elimination of insulin. While a moderate LCD may allow for the reduction of oral hypoglycemics, the profound suppression of insulin requirement afforded by the KD is often necessary to facilitate the total deprescription of insulin in long-standing cases.⁹

The Lipid Paradox and Cardiovascular Safety

The potential for a rise in LDL cholesterol (LDL-C) remains a point of clinical caution. However, the systematic review reveals that the KD leads to a significant reduction in the most atherogenic markers: triglycerides and small, dense LDL particles.⁹ The increase in LDL-C often observed is typically due to an increase in large, buoyant LDL particles, which have a lower affinity for the arterial wall and are less prone to oxidation.⁹

Furthermore, markers of systemic inflammation, such as high-sensitivity C-reactive protein (hsCRP) and white blood cell count, show significant declines in participants on a KD, suggesting a net reduction in cardiovascular risk despite changes in absolute cholesterol numbers.⁹ The stabilization of carotid intima-media thickness (CIMT) over two years further corroborates the safety of this nutritional approach in patients with T2DM.⁴⁷

Long-Term Sustainability and the Role of Continuous Care

A significant barrier to the widespread adoption of the KD is the perceived difficulty in long-term adherence. Indeed, some studies show a "re-gain" of HbA_{1c} and weight after the initial 12-month period as patients potentially drift toward higher carbohydrate intakes.¹ However, intensive support models, such as the digitally-delivered continuous care intervention (CCI), have shown remarkably high retention rates (83% at 1 year and 60% at 2 years).³²

The success of these models highlights that the KD is most effective when combined with behavioral support, nutritional education, and frequent medical monitoring.⁹ For patients who cannot maintain a strict ketogenic state, the evidence suggests that even a transition to a more flexible low-carbohydrate diet still offers metabolic benefits compared to standard high-carbohydrate care.³

Limitations of the Current Evidence

Despite the strength of the findings, several limitations must be acknowledged. First, there is considerable heterogeneity in the definitions of "ketogenic" and "low-carbohydrate" across studies, which can complicate the synthesis of data.² Second, long-term randomized controlled trials (exceeding 2 years) are still scarce, and much of the multi-year evidence comes from non-randomized, though well-controlled, clinical programs.¹ Finally, the majority of the research has been conducted in Western populations, and further study is needed to evaluate the cultural and genetic generalizability of the ketogenic diet to other global populations.²

Conclusions

This systematic review provides convincing evidence that the ketogenic diet is an effective nutritional intervention for the management and potential remission of type 2 diabetes mellitus. By targeting the underlying pathophysiology of carbohydrate intolerance and insulin resistance, the KD achieves rapid and sustainable improvements in glycemic control, body weight, and cardiovascular risk factors.

The primary clinical advantages of the ketogenic diet over standard diabetic care include:

1. **Superior HbA_{1c} Reduction:** KD consistently results in HbA_{1c} lowering that is often double the effect of standard low-fat diets, particularly in the short-to-medium term.
2. **Effective Medication Deprescription:** The KD uniquely facilitates the rapid reduction or elimination of high-risk medications such as insulin and sulfonylureas, significantly reducing the pharmacological burden and the risk of iatrogenic hypoglycemia.
3. **Comprehensive Metabolic Improvement:** Beyond glucose control, the KD promotes significant weight loss, reduces visceral adiposity, resolves NAFLD markers, and improves the atherogenic lipoprotein profile.
4. **Demonstrated Safety:** When monitored clinically, the KD does not adversely affect renal or hepatic function and may provide renoprotective and hepatoprotective benefits in T2DM patients.

While long-term adherence remains a challenge for some, the emergence of digital health models and intensive support systems has demonstrated that sustained nutritional ketosis is achievable and safe for a significant proportion of the population. For clinicians, the ketogenic diet should be viewed not merely as a "weight-loss diet" but as a potent metabolic tool for disease management. Future clinical guidelines should continue to integrate carbohydrate restriction as a frontline therapeutic option, emphasizing the importance of individualized clinical support to maximize the potential for long-term T2DM remission.

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