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THE EFFECTS OF A 6-MONTH ADHERENCE TO A VERY LOW CARBOHYDRATE DIET PROGRAM: A CLINICAL AND METABOLIC EVALUATION

Hisham Ibrahim Khalil[1], Omar Basheer Badran[2*], Firas Husam Ali[3]

[1]MBChB, FABHS (Family Medicine), Specialist, Al-Qadisiya Family Medicine Center, Ninevah Health Directorate, Mosul, Iraq.
[2]MBChB, MSc (Community Medicine), Specialist, Department of Public Health, Ninevah, Iraq.
[3]MBChB, Al-Quds Family Medicine Training Center/ DOH, Ninevah, Iraq.

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***Corresponding Author: Omar Basheer Badran**

MBChB, MSc (Community Medicine), Specialist, Department of Public Health, Ninevah, Iraq.

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ABSTRACT

Background: Very low-carbohydrate diets (VLCDs) have emerged as an effective dietary strategy for weight loss and metabolic improvement; however, evidence regarding their medium-term safety and efficacy remains limited. **Objective:** This study evaluated the clinical and metabolic effects of a 6-month VLCD intervention in overweight and obese adults. **Methods:** A prospective cohort study was conducted with 60 participants (BMI ≥ 27 kg/m²) who adhered to a VLCD (≤50g of carbohydrates/day) over six months. Anthropometric, glycemic, and lipid parameters were assessed at baseline, 3 months, and 6 months. Data were analyzed using repeated-measures ANOVA with Bonferroni-adjusted post-hoc tests. **Results:** Significant reductions were observed in body weight (−9.3 ± 1.8 kg), BMI, waist circumference, fasting glucose, HbA1c, and triglycerides ($p < 0.001$), alongside a significant increase in HDL cholesterol ($p < 0.01$). No significant changes were detected in LDL cholesterol or markers of kidney or liver function. **Conclusion:** Six-month adherence to a VLCD resulted in clinically meaningful improvements in weight, glycemic control, and lipid profiles without adverse renal or hepatic effects, suggesting its efficacy and safety as a short- to mid-term dietary intervention for metabolic improvement.

KEYWORDS: Glycemic control; Insulin resistance; Lipid metabolism; Obesity; Very-low carbohydrate diet; Weight loss.

1. INTRODUCTION

Obesity and metabolic syndrome represent major public health challenges and are among the leading contributors to the global burden of chronic disease, including type 2 diabetes mellitus (T2DM), cardiovascular disease, and several obesity-related cancers.[1,2] The rising prevalence of excess body weight has been closely linked to adverse metabolic alterations such as insulin resistance, dyslipidemia, systemic inflammation, and impaired glucose homeostasis, all of which substantially increase morbidity, mortality, and healthcare costs worldwide. As a result, effective and sustainable strategies for weight management and metabolic risk reduction remain a clinical priority.[3]

Dietary modification continues to be a cornerstone of obesity and metabolic syndrome management. Among various dietary approaches, very low-carbohydrate diets (VLCDs)—typically defined as diets providing less than 50 g of carbohydrates per day—have gained considerable attention as an alternative strategy for promoting weight loss and improving glycemic control.[4,5] By markedly restricting carbohydrate intake, VLCDs induce a metabolic shift toward increased fat oxidation and ketone body production, which may enhance insulin sensitivity, reduce postprandial glucose excursions, and promote appetite suppression through improved satiety.[6]

Short-term clinical trials and systematic reviews have reported favorable outcomes associated with low-

carbohydrate dietary patterns, including significant reductions in body weight, fasting glucose, hemoglobin A1c (HbA1c), and triglyceride levels when compared with conventional low-fat diets.[4-6] However, much of the existing literature has focused on short-term interventions, often lasting fewer than 12 weeks, or has examined heterogeneous carbohydrate-restricted diets with variable degrees of restriction and supervision. Consequently, the long-term metabolic effects, safety, and feasibility of sustained VLCD adherence remain incompletely understood.

In particular, limited evidence exists regarding the clinical and metabolic impact of consistent VLCD adherence over 6 months in free-living adults with overweight and obesity.[7,8] Concerns have been raised about potential effects on lipid profiles, hepatic and renal function, and long-term adherence outside controlled research settings. Furthermore, data examining both objective metabolic outcomes and subjective measures, such as dietary adherence and tolerability, over extended periods are scarce.

Therefore, the present study aims to address this gap by evaluating the physiological and metabolic outcomes of a structured, supervised 6-month VLCD program in adults with overweight and obesity. By assessing changes in body weight, glycemic control, lipid profile, and markers of liver and kidney function, alongside adherence and tolerability, this study seeks to provide clinically relevant evidence regarding the effectiveness and safety of prolonged VLCD implementation in real-world settings.

2. METHODS

2.1 Study Design and Participants

This prospective, single-arm intervention study included 60 participants aged 25–65 years with a BMI ≥27 kg/m². The study was conducted between January 2025 and December 2025, and the participants were consecutive patients attending/referred to a private family medicine clinic.

Exclusion criteria included insulin-dependent diabetes, recent cardiovascular events (within 6 months), renal impairment (eGFR <60mL/min/1.73m²), liver impairment (ALT or AST >2× upper limit of normal), pregnancy or lactation, and current participation in other weight-loss programs. Participant flow through the study is depicted in Figure 1.

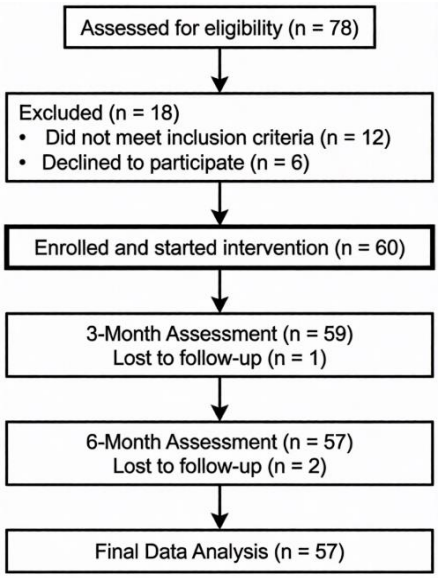

Figure 1: Study flowchart showing participant recruitment, enrollment, and retention throughout the 6-month intervention period.

2.2 Diet Intervention

Participants were enrolled in a supervised VLCD program involving ≤50 g/day of carbohydrates, moderate protein intake (1.2–1.5 g/kg body weight), and the remainder of daily energy requirements from fat. The diet emphasized whole, minimally processed foods and excluded grains, sugars, and starchy vegetables. Participants received weekly dietary counseling sessions with a registered dietitian and attended educational sessions on meal planning, food preparation, and adherence strategies.

2.3 Outcome Measures

Measurements were collected at baseline, 3 months, and 6 months by trained research staff. All participants were instructed to fast for at least 12 hours before blood collection. Primary outcomes included: body weight and BMI; fasting blood glucose and insulin; hemoglobin A1c (HbA1c); lipid profile (HDL cholesterol, LDL cholesterol, triglycerides, total cholesterol); liver enzymes (ALT, AST); and kidney function (serum creatinine, eGFR). Secondary outcomes included self-reported adherence (measured via 7-day dietary recall) and satiety levels (assessed using a validated visual analog scale).

2.4 Statistical Analysis

Data are presented as mean ± standard deviation (SD) for continuous variables and as percentages for categorical variables. Paired t-tests and repeated-measures ANOVA were used to compare outcomes across time points (baseline, 3 months, 6 months), with Bonferroni-adjusted post-hoc tests for pairwise comparisons. A p-value < 0.05 was considered statistically significant. All analyses were performed using SPSS version 28.0 (IBM Corp., Armonk, NY).

3. RESULTS

3.1 Baseline Characteristics

Of the 60 participants enrolled, 57 (95%) completed the full 6-month intervention. Baseline demographic and clinical characteristics are presented in Table 1. The mean age was 44.3 ± 9.6 years, and 63% of participants were female. Mean baseline BMI was 33.7 ± 4.5 kg/m², indicating obesity class I.

Table 1: Baseline Characteristics of Study Participants (N=60).

Characteristic	Value
Age (years), mean ± SD	44.3 ± 9.6
Female, n (%)	38 (63%)
Weight (kg), mean ± SD	92.4 ± 13.2
BMI (kg/m²), mean ± SD	33.7 ± 4.5
Waist circumference (cm), mean ± SD	101.3 ± 11.7
Fasting glucose (mg/dL), mean ± SD	104.2 ± 9.1
HbA1c (%), mean ± SD	5.9 ± 0.4
Total cholesterol (mg/dL), mean ± SD	198.5 ± 28.3
HDL cholesterol (mg/dL), mean ± SD	47.2 ± 8.4
LDL cholesterol (mg/dL), mean ± SD	121.6 ± 24.1
Triglycerides (mg/dL), mean ± SD	156.3 ± 34.2
ALT (U/L), mean ± SD	28.4 ± 7.3
AST (U/L), mean ± SD	26.1 ± 6.8
Serum creatinine (mg/dL), mean ± SD	0.89 ± 0.14
eGFR (mL/min/1.73m²), mean ± SD	88.7 ± 12.3

BMI, body mass index; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; LDL, low-density lipoprotein; ALT, alanine aminotransferase; AST, aspartate aminotransferase; eGFR, estimated glomerular filtration rate.

3.2 Weight and Body Composition

Significant reductions in body weight, BMI, and waist circumference were observed at both 3 and 6 months compared to baseline (Table 2). Mean weight loss at 6 months was −9.3 ± 1.8 kg (p<0.001), representing approximately 10% of initial body weight. BMI decreased by −3.2 ± 0.7 kg/m², and waist circumference decreased by 8.1 ± 2.5 cm (p<0.001 for all comparisons).

Table 2: Changes in Anthropometric Measures Over 6 Months (N=57).

Parameter	Baseline	3 Months	6 Months	p-value*
Weight (kg)	92.4 ± 13.2	86.8 ± 12.6**	83.1 ± 12.4**	<0.001
BMI (kg/m²)	33.7 ± 4.5	31.6 ± 4.2**	30.5 ± 4.1**	<0.001
Waist circumference (cm)	101.3 ± 11.7	96.4 ± 10.8**	93.2 ± 10.5**	<0.001

*Data are presented as mean ± SD. *p-value from repeated-measures ANOVA. **p<0.001 vs. baseline by Bonferroni post-hoc test. BMI, body mass index.*

3.3 Glycemic Control

Markers of glycemic control showed significant improvements throughout the intervention period (Table 3 and Figure 2). Fasting glucose decreased from 104.2 ± 9.1 mg/dL at baseline to 89.7 ± 7.8 mg/dL at 6 months (p<0.001). HbA1c was reduced from 5.9% to 5.4% (p<0.001), and HOMA-IR score improved significantly, indicating enhanced insulin sensitivity.

Table 3: Changes in Glycemic Parameters Over 6 Months (N=57)

Parameter	Baseline	3 Months	6 Months	p-value*
Fasting glucose (mg/dL)	104.2 ± 9.1	95.3 ± 8.4**	89.7 ± 7.8**	<0.001
Fasting insulin (µU/mL)	14.6 ± 3.8	10.2 ± 2.9**	8.7 ± 2.4**	<0.001
HbA1c (%)	5.9 ± 0.4	5.6 ± 0.3**	5.4 ± 0.3**	<0.001
HOMA-IR	3.8 ± 1.1	2.4 ± 0.8**	1.9 ± 0.6**	<0.001

Data are presented as mean ± SD. *p-value from repeated-measures ANOVA. **p<0.001 vs. baseline by Bonferroni post-hoc test. HbA1c, hemoglobin A1c; HOMA-IR, Homeostatic Model Assessment for Insulin Resistance.

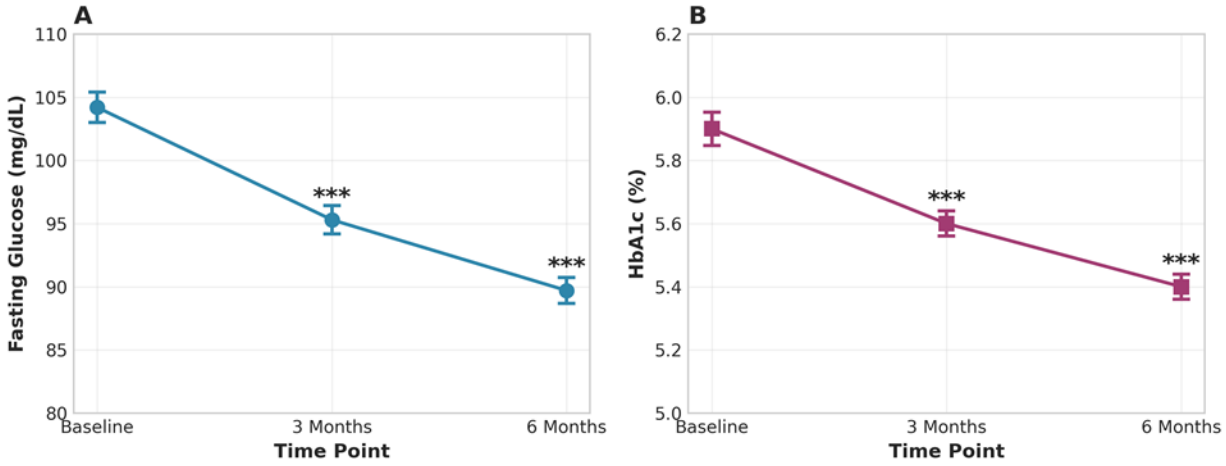

Figure 2: Changes in fasting glucose and HbA1c over the 6-month intervention period. (A) Fasting glucose decreased significantly from baseline at both 3 months and 6 months. (B) HbA1c showed progressive reduction throughout the study period. Data are presented as mean ± SEM. ***p<0.001 vs. baseline by Bonferroni post-hoc test.

3.4 Lipid Profile

The VLCD intervention resulted in favorable changes in the lipid profile (Table 4 and Figure 3). HDL cholesterol increased significantly by 9.6 ± 2.1 mg/dL (p<0.01), while triglycerides decreased substantially by 42.7 ± 10.4 mg/dL (p<0.001). Total cholesterol showed a modest but significant reduction. No significant change was observed in LDL cholesterol levels (p=0.42).

Table 4: Changes in Lipid Profile Over 6 Months (N=57).

Parameter	Baseline	3 Months	6 Months	p-value*
Total cholesterol (mg/dL)	198.5 ± 28.3	189.2 ± 26.1**	184.6 ± 25.4**	0.003
HDL cholesterol (mg/dL)	47.2 ± 8.4	52.1 ± 8.9***	56.8 ± 9.1***	<0.001
LDL cholesterol (mg/dL)	121.6 ± 24.1	119.3 ± 22.8	118.9 ± 23.5	0.42
Triglycerides (mg/dL)	156.3 ± 34.2	128.7 ± 28.6**	113.6 ± 26.3**	<0.001
TC/HDL ratio	4.3 ± 0.9	3.7 ± 0.7**	3.3 ± 0.6**	<0.001

Data are presented as mean ± SD. *p-value from repeated-measures ANOVA. **p<0.001 vs. baseline by Bonferroni post-hoc test. ***p<0.01 vs. baseline by Bonferroni post-hoc test. HDL, high-density lipoprotein; LDL, low-density lipoprotein; TC, total cholesterol.

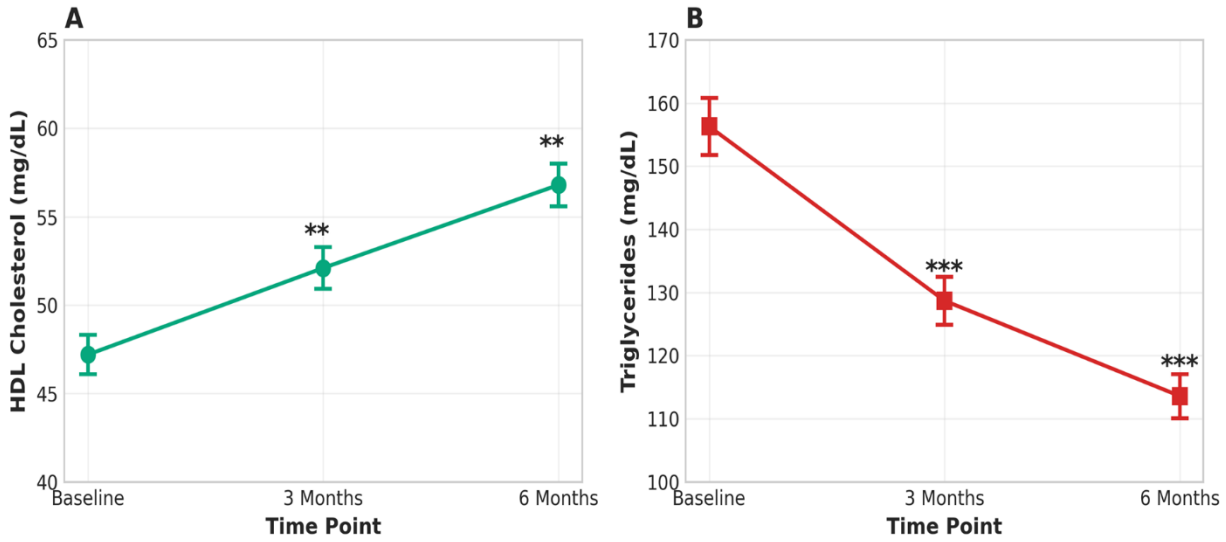

Figure 3: Changes in HDL cholesterol and triglycerides over the 6-month intervention period. (A) HDL cholesterol increased progressively throughout the study. (B) Triglycerides showed a significant reduction at both assessment time points. Data are presented as mean ± SEM. **p<0.01, ***p<0.001 vs. baseline by Bonferroni post-hoc test.

3.5 Liver and Kidney Function

Safety monitoring revealed no significant changes in markers of hepatic or renal function throughout the study period (Table 5). Mean values for ALT, AST, serum creatinine, and eGFR remained within normal reference ranges at all time points, indicating no hepatic or renal dysfunction attributable to the VLCD intervention.

Table 5: Changes in Hepatic and Renal Function Markers Over 6 Months (N=57)

Parameter	Baseline	3 Months	6 Months	p-value*
ALT (U/L)	28.4 ± 7.3	27.1 ± 6.9	26.8 ± 7.1	0.28
AST (U/L)	26.1 ± 6.8	25.4 ± 6.3	24.9 ± 6.5	0.35
Serum creatinine (mg/dL)	0.89 ± 0.14	0.88 ± 0.13	0.87 ± 0.14	0.52
eGFR (mL/min/1.73m²)	88.7 ± 12.3	89.3 ± 11.8	89.8 ± 12.1	0.61

Data are presented as mean ± SD. *p-value from repeated-measures ANOVA. ALT, alanine aminotransferase; AST, aspartate aminotransferase; eGFR, estimated glomerular filtration rate.

3.6 Adherence and Tolerability

Overall adherence to the VLCD protocol was high, with 88% of participants reporting adherence ≥85% of days based on 7-day dietary recall assessments. The dropout rate was low (5%), and no serious adverse events were reported. Common positive experiences reported by participants included improvements in satiety, reduced hunger between meals, increased energy levels, and improved mental clarity. Minor transient side effects during the first 2-4 weeks included mild headache (n=12, 20%), fatigue (n=9, 15%), and constipation (n=7, 12%), which typically resolved with continued adherence and adequate hydration.

4. DISCUSSION

This prospective study demonstrates that a 6-month VLCD program leads to significant and clinically meaningful improvements in body weight, glycemic control, and lipid metabolism in overweight and obese adults. The magnitude of weight loss (mean 9.3 kg, representing ~10% of initial body weight) exceeds that reported in many standard calorie-restricted diet interventions[9,10] and aligns with prior literature suggesting that carbohydrate restriction may reduce insulin levels and promote lipolysis.[11,12]

The observed reduction in HbA1c (from 5.9% to 5.4%) and improvement in insulin resistance (as measured by HOMA-IR) underscore the potential of VLCDs in prediabetic or insulin-resistant populations. These findings are consistent with mechanistic studies showing that carbohydrate restriction reduces postprandial glucose excursions and insulin demand, thereby improving pancreatic β-cell function and peripheral insulin sensitivity.[13,14]

Lipid profile improvements were particularly notable, with significant increases in HDL cholesterol and substantial decreases in triglycerides. The 27% reduction in triglycerides and 20% increase in HDL cholesterol support VLCDs as cardiometabolically favorable interventions.[15,16] The lack of significant change in LDL cholesterol is consistent with previous reports showing variable individual responses, likely related to genetic factors such as APOE (Apolipoprotein E) genotype.[17,18] The improved TC/HDL ratio (from 4.3 to 3.3) suggests overall cardiovascular risk reduction.

Importantly, our safety monitoring revealed no adverse changes in liver enzymes or kidney function markers, contradicting common concerns about potential hepatic or renal stress associated with higher protein and fat intake. These findings suggest short-to-medium term safety among individuals without pre-existing organ dysfunction, consistent with other controlled studies of similar duration.[19,20]

The high adherence rate (88%) and low dropout rate (5%) in our study suggest that VLCDs, when properly supervised with regular counseling and education, are feasible and well-tolerated. Participants' reports of improved satiety and energy levels may contribute to sustained adherence, as ketogenic diets have been shown to reduce appetite through multiple mechanisms, including stable blood glucose, increased satiety hormones, and the appetite-suppressing effects of ketone bodies.[21,22]

STUDY LIMITATIONS

Limitations of this study include the single-arm design without a control group, which limits causal inference. The relatively short 6-month duration does not provide information on long-term sustainability or outcomes beyond this timeframe. Additionally, the study population was predominantly female and from a single geographic region, which may limit generalizability. Future research should include randomized controlled trials with longer follow-up periods, diverse populations, and comparison with other dietary interventions.

5. CONCLUSION

A 6-month adherence to a very low-carbohydrate diet results in substantial weight loss, improved glycemic control, and favorable lipid profile changes, without compromising liver or kidney function. These findings support the use of VLCDs as an effective and safe dietary intervention for individuals with overweight or obesity when properly supervised. The improvements in metabolic markers suggest potential benefits for preventing or managing type 2 diabetes and cardiovascular disease. Further long-term studies are

warranted to evaluate the sustainability and durability of these metabolic improvements.

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ETHICAL APPROVAL
The study was conducted in compliance with the Declaration of Helsinki and applicable national regulations. All participants were fully informed about the study objectives and procedures and provided written informed consent prior to participation. Participant anonymity and data confidentiality were ensured throughout the study.

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