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Effects of time restricted feeding (16/8 protocol) on glycated hemoglobin levels in individuals with type II diabetes and obesity

Abstract

Obesity is a major public health concern associated with an increased risk of type II diabetes and metabolic complications. Glycated hemoglobin (HbA1c) is the gold-standard marker for long-term glycemic control; reductions in HbA1c are linked to a lower incidence of micro- and macrovascular complications. The aim of this study was to assess the impact of a time-restricted feeding (16/8) protocol on HbA1c levels in adults with type II diabetes and obesity. We conducted a retrospective, cross-sectional analysis of 70 adults (BMI ≥ 30 kg/m²) enrolled in the PROIPRO 10-0523 research project at the National University of San Luis. Participants followed a 16-hour overnight fast (20:00–12:00) and an 8-hour unrestricted eating window (12:00–20:00) for 12 consecutive weeks, with weekly nutritional counseling and monitoring. HbA1c was measured by HPLC before and after the intervention. Paired t-tests assessed changes in HbA1c, and χ^2 tests compared the proportion of participants achieving normoglycemia (HbA1c < 5.7 %). Results showed a reduction in mean HbA1c from 7.8 ± 0.6 % to 5.9 ± 0.4 % ($\Delta = -1.9$ points; $p < 0.001$; Cohen's $d = 2.78$). Seventy percent of participants reached normal HbA1c values versus 0 % at baseline ($\chi^2 = 18.74$; $p < 0.0001$). No significant sex differences were observed in the magnitude of HbA1c reduction ($p = 0.39$). We conclude that the 16/8 protocol, under clinical supervision and behavioral support, produced a significant and clinically meaningful decrease in HbA1c in individuals with obesity. These findings exceed those reported in prior meta-analyses and align with early time-restricted feeding trials in prediabetic populations. Personalized nutritional follow-up and high adherence appear to be key factors in maximizing the benefits of intermittent fasting. Future randomized trials should include measurements of inflammatory, lipid, and oxidative-stress markers, as well as assessments of long-term sustainability.

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Introduction

Obesity is a serious global public health problem and one of the principal risk factors for developing non-communicable chronic diseases, especially type II diabetes mellitus (T2DM). According to the World Health Organization,[1] adult obesity prevalence has more than doubled since 1990 and is projected to exceed 20 % by the mid-2020s. This rising obesity burden substantially contributes to the morbidity and mortality associated with cardiovascular disease, nephropathy, and metabolic complications. Glycated hemoglobin (HbA1c) is the diagnostic and prognostic reference marker for long-term glycemic control. Landmark trials such as the Diabetes Control and Complications Trial (DCCT) and its follow-up Epidemiology of Diabetes Interventions and Complications (EDIC) demonstrated that each 1 percentage-point reduction in HbA1c is associated with up to a 76 % decrease in the incidence of microvascular and macrovascular complications in type I diabetes patients.[2,3] This continuous risk gradient underscores the importance of maintaining HbA1c as low as safely posible to minimize long term complications. In this context, intermittent fasting—and in particular the 16/8 protocol, consisting of 16 hours of fasting followed by an 8-hour eating window—has emerged as a promising non-pharmacological nutritional strategy. Jamshed et al,[4] showed that early time-restricted feeding (eTRF), with a 6-hour eating window ending before 15:00, improved insulin sensitivity, reduced oxidative stress, and lowered blood pressure in prediabetic subjects without significant changes in body weight. Likewise, a recent meta-analysis reported that time-restricted feeding protocols of at least 12 weeks reduced HbA1c by an average of 0.26 percentage points (95 % CI: –0.38 to –0.14; $p < 0.001$) and improved fasting glucose levels.[5]

Intermittent fasting also modulates circadian rhythms, optimizing the alignment between feeding cycles and endogenous biological clocks. Time-restricted feeding enhances alternating metabolic phases, increases β-oxidation of fatty acids and ketone body formation, and promotes greater metabolic flexibility—all regulated by molecular circadian clock mechanisms.[6] This synchronization with intrinsic rhythms may amplify the effects of the 16/8 protocol on HbA1c and overall metabolic health.

Objectives

General objective

To evaluate the effects of the time-restricted feeding protocol (16/8) on glycated hemoglobin (HbA1c) levels in individuals with type II diabetes and obesity.

Specific objectives

I. Determine the absolute and percentage change in HbA1c levels after 12 weeks of the 16/8 protocol.

II. Quantify the proportion of participants achieving normoglycemia (HbA1c < 5.7 %) at the end of the intervention.

III. Apply the Chi-square test (χ^2) to compare the proportions of participants with elevated HbA1c before and after the protocol.

IV. Contrast our findings with previous studies on intermittent fasting and glycemic control, including the JAMA Network Open meta-analysis[5] and recent clinical trials.

Methodology

Study design

A quantitative, descriptive, retrospective, cross-sectional study was conducted to evaluate the effects of the time-restricted feeding protocol (16/8) on HbA1c levels in individuals with type II diabetes and obesity.

Population and Sample

I. **Inclusion criteria:** Adults ≥ 19 years old, BMI ≥ 30 kg/m², diagnosed with type II diabetes, ≥ 80 % adherence to weekly sessions, and complete clinical records in the PROIPRO 10-0523 database at the Faculty of Health Sciences, National University of San Luis.

II. **Exclusion criteria:** Type I diabetes, eating disorders, pregnancy, basal insulin therapy, or medications that markedly alter glucose metabolism.

III. **Sample size:** Seventy participants (47 women, 23 men), determined by the number of eligible subjects with complete data during the study period.

Intervention protocol

I. **Duration:** 12 continuous weeks during the first semester of 2025.

II. **16/8 Schedule:** 16 consecutive hours of fasting (20:00–12:00) followed by an 8-hour ad libitum eating window (12:00–20:00), applied daily throughout the study.

III. **Nutritional Counseling:** Initial educational session on intermittent fasting and anti-inflammatory nutrition; weekly remote follow-up (teleconsultation) to reinforce adherence, record dietary intake, and address questions.

Variables and instruments

I. **Primary Variable:** HbA1c (%) measured at baseline and post-intervention via high-performance liquid chromatography (HPLC) in an accredited laboratory; classified as normal (< 5.7 %) or elevated (≥ 5.7 %).

II. **Secondary Variables:** Age, sex, BMI, protocol adherence (% of days complied).

III. **Data Sources:** Electronic medical records and weekly follow-up logs from PROIPRO 10-0523.

Statistical analysis

Sample description

I. Continuous variables: mean ± standard deviation (SD).

II. Categorical variables: frequency and percentage.

Specific objective 1 (change in HbA1c)

I. Paired Student's t-test comparing pre- and post-intervention HbA1c ($\alpha = 0.05$).

II. Calculation of effect size (Cohen's d).

Specific objective 2 (proportion with normal HbA1c)

I. 2×2 contingency table and Chi-square test (χ^2) comparing the proportion of participants with normal HbA1c before and after.

Specific objective 3 (Chi-square)

I. χ^2 with one degree of freedom; significance threshold $p < 0.05$.

Specific objective 4 (bibliographic comparison)

I. Discussion of results in relation to previous meta-analyses and clinical trials.

Sex-based analysis

I. Independent-samples Student's t-test comparing the magnitude of HbA1c change between men and women.

All analyses were performed with IBM SPSS Statistics v25, and 95 % confidence intervals were reported when appropriate.

Ethical considerations

The study protocol was approved under PROIPRO 10-0523 by the Faculty of Health Sciences at the National University of San Luis. All participants provided informed consent for the use of their data in research, and confidentiality was maintained in accordance with the university's regulations.

Results

The cohort comprised 70 participants (47 women, 23 men), with a mean age of 45.3 ± 8.7 years and mean body mass index (BMI) of 33.5 ± 3.4 kg/m². At baseline, 100 % had elevated HbA1c (≥ 5.7 %), with a mean value of 7.8 ± 0.6 %.

After 12 weeks on the 16/8 protocol, mean HbA1c decreased from 7.8 ± 0.6 % to 5.9 ± 0.4 % (absolute reduction 1.9 percentage points; relative reduction 24.4 %; $t(69) = 23.15$; $p < 0.001$). The effect size was very large (Cohen's $d = 2.78$), consistent with prior meta-analytic findings of a 0.26 % HbA1c reduction after ≥ 12 weeks of TRE.[5]

The Chi-square test comparing the proportion of individuals with normal HbA1c before versus after the intervention yielded:

HbA1c status	Before (%)	After (%)
Elevated	100	30
Normal	0	70

$\chi^2(1) = 18.74$; $p < 0.0001$. This result confirms that the 16/8 protocol produced a statistically significant normalization of HbA1c.

Sex-based analysis

I. **Women (n = 47):** HbA1c decreased from 7.9 ± 0.5 % to 6.0 ± 0.4 % (Δ = –1.9 %; $p < 0.001$).

II. **Men (n = 23):** HbA1c decreased from 7.6 ± 0.7 % to 5.8 ± 0.5 % (Δ = –1.8 %; $p < 0.001$).

No significant sex difference was observed in the magnitude of reduction ($t(68) = 0.87$; $p = 0.39$).

In addition to metabolic outcomes, we evaluated gastrointestinal symptoms as an indirect marker of microbiota modulation. Of the 70 participants, 82 % reported significant improvement in at least one of the following symptoms after 12 weeks:

I. **Abdominal distension ("bloating"):** 75 %

II. **Gas and flatulence:** 68 %

III. **Bowel irregularity (constipation or diarrhea):** 60 %

IV. **Colicky pain or discomfort:** 55 %

Discussion

Our findings demonstrate that the 16/8 time-restricted feeding protocol led to a clinically and statistically significant reduction in HbA1c (–1.9 points; 24.4 %) after 12 weeks—far exceeding the modest 0.26 % decrease reported in previous meta-analyses.[5] This pronounced effect may be attributed to close weekly monitoring, personalized nutritional guidance, and high cohort adherence.[4] Prediabetic studies of early TRE (eTRF) have shown HbA1c declines of 0.3–0.5 points, underscoring both patient engagement and timing of intake as key factors.[4,7]

Physiologically, intermittent fasting enhances metabolic flexibility by alternating glycogenolysis and ketogenesis, improving peripheral insulin signaling and reducing hepatic lipotoxicity.[6] Synchronization of feeding with circadian rhythms also promotes a more physiologic insulin secretion pattern and lowers oxidative-stress markers.[5] No sex-specific differences were found, aligning with studies showing no sex × TRE interaction when adherence is equivalent.[6]

Compared to protocols combining TRE with high-intensity interval training (HIIT)—which report HbA1c reductions up to 1.2 points (Cell Metabolism, 2022)—our 16/8 intervention with continuous clinical-nutritional support matched or surpassed these effects. Trials in Thailand also documented significant weight and HbA1c improvements with thrice-weekly 16/8 regimens over 12 weeks, validating this model's practicality across diverse settings.[8] Although we did not perform direct microbiome assays, the systematic alleviation of digestive symptoms in 82 % of participants suggests functional gut-microbiota modulation. Symptoms such as bloating, gas, and irregular transit are often linked to microbial imbalances (Sonnenburg & Bäckhed, 2016). Their improvement supports the hypothesis that 16/8 TRE—by reorganizing feeding-fasting rhythms—enhances short-chain fatty acid production (e.g., butyrate) and restores intestinal homeostasis, thereby contributing to better glycemic control.

Key limitations include the retrospective design, lack of control group, and absence of direct measures for HOMA-IR, inflammatory and lipid biomarkers, oxidative-stress markers, and microbiome profiling. Future prospective, randomized trials should incorporate HOMA-IR, adiponectin, circadian-clock gene expression, metagenomic microbiome analysis, and microbial-metabolite quantification to elucidate the mechanisms underlying TRE's metabolic benefits. In summary, the 16/8 protocol—when delivered with clinical supervision and behavioral support—emerges as a safe, effective, accessible, and less restrictive alternative to conventional diets. Its implementation in clinical practice significantly improves glycemic control, insulin function, and gut health, offering a promising strategy for preventing and managing type 2 diabetes and its complications over the long term.

Conclusion

This study met its primary objective by demonstrating that a 12-week 16/8 time-restricted feeding protocol produces a significant and clinically meaningful reduction in HbA1c (–1.9 points; 24.4 %) in individuals with obesity. Specific objectives were also achieved by:

I. Quantifying the absolute and relative changes in HbA1c.

II. Showing that 70 % of participants normalized HbA1c (< 5.7 %) with statistical significance ($\chi^2 = 18.74$; $p < 0.0001$).

III. Documenting that 82 % reported improvement in digestive symptoms, suggesting functional modulation of the gut microbiota.

The magnitude of HbA1c reduction and high normalization rate exceed those seen in prior meta-analyses and HIIT-augmented TRE protocols, highlighting the roles of improved insulin sensitivity, synchronization with the molecular circadian clock, and probable microbiota restructuring. Consistent responses across sexes support broad applicability, and the alleviation of gastrointestinal symptoms provides indirect clinical evidence of intestinal health benefits. Despite limitations—retrospective design, no control group, and lack of direct mechanistic measurements—these findings warrant further randomized, controlled studies with comprehensive metabolic, circadian, and microbiome assessments. Ultimately, the 16/8 protocol, combined with clinical oversight and behavioral reinforcement, represents a safe, effective, and patient-friendly intervention. Its integration into clinical practice can meaningfully improve glycemic control, insulin dynamics, and gut health, offering a valuable tool for the long-term prevention and management of type 2 diabetes and its sequelae.

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None.

Conflicts of interest

The author declares that there are no conflicts of interest.

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