

Original Research Article

The effect of time restricted eating on weight in patients of type 2 diabetes mellitus

Mohit Kumar Jain*, Vishal Kumar Gupta, Kumar Satyam Rawat

Department of General Medicine, GSVM Medical College, Kanpur, Uttar Pradesh, India

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*Correspondence:

Dr. Mohit Kumar Jain,

E-mail: mohit110jain@gmail.com

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ABSTRACT

Background: The prevalence of diabetes mellitus has tripled in the past two decades, becoming a major public health concern. Time-restricted eating (TRE) shows potential in reducing weight in individuals with type 2 diabetes mellitus (T2DM). This study evaluated the efficacy of TRE for weight management in adults with T2DM.

Methods: This 14-month quasi-experimental pre-post study was conducted at LLR Hospital, Kanpur and included 50 T2DM patients aged 18-70 years. Exclusion criteria included type 1 diabetes, MODY, insulin therapy, pregnancy-related diabetes, fibro calculus pancreatitis, chronic kidney or liver disease, thyroid disorders, and HbA1c >10%. Participants underwent baseline assessments, including weight, blood sugar levels, HbA1c, kidney and liver function tests, and abdominal ultrasonography. They were instructed to follow a TRE plan, fasting from 10:00 PM to 2:00 PM, with monthly follow-ups for 12 weeks to assess adherence and weight changes.

Results: After 12 weeks, participants showed significant weight reduction, with the mean weight decreasing from 67.56 kg to 65.78 kg ($p < 0.0001$). Other metabolic parameters were monitored to ensure the intervention's safety and efficacy.

Conclusion: TRE is an effective and feasible dietary strategy for weight management in T2DM patients. Its implementation could significantly improve weight and potentially enhance overall metabolic health in this population.

Keywords: Type 2 diabetes mellitus, Time-restricted eating, Weight reduction

INTRODUCTION

Diabetes mellitus (DM) comprises a group of metabolic conditions characterized by chronic hyperglycemia and is a growing public health crisis worldwide. Over the past two decades, the number of adults with diabetes has more than tripled, driven by factors such as urbanization, sedentary lifestyles, and unhealthy dietary habits was studied Zheng et al in 2018.¹ According to the international diabetes federation (IDF) Diabetes Atlas, 537 million adults aged 20-79 are currently living with diabetes, a number projected to rise to 643 million by 2030 and 784 million by 2045 (IDF, 2021).² Similarly, the world health organization (WHO) highlights diabetes as an epidemic linked to rapid lifestyle and economic transitions. Effective diabetes management requires lifestyle

modifications, particularly in diet, alongside physical activity, medication adherence, and regular blood glucose monitoring Tuomilehto et al in 2001.³ In India, the diabetes burden is especially severe, with a prevalence rate of 8.9% among adults aged 20-79 years, affecting approximately 77 million individuals (Indian Diabetes Atlas, 2021).⁴ Urban areas show a higher prevalence (11.8%) than rural areas (5.2%), with about 44% of cases remaining undiagnosed by Anjana et al.⁵ These disparities emphasize the need for targeted public health strategies tailored to regional and demographic variations. Time-restricted eating (TRE), a dietary approach limiting food intake to specific hours while fasting for the remaining time, has gained attention for its metabolic benefits by Peterson et al.⁶ TRE aligns eating patterns with circadian rhythms, optimizing processes such as glucose metabolism and

energy expenditure by Bass et al & Takahashi et al.⁷ While TRE has shown benefits such as weight reduction, improved lipid profiles, and enhanced glucose tolerance in non-diabetic populations, its specific effects on individuals with Type 2 diabetes mellitus (T2DM) remain under-researched by Sutton et al.⁸ This study explores the efficacy of TRE in weight reduction among T2DM patients, highlighting its potential as a tailored dietary intervention to improve metabolic health.

Objective

To study the effect of time-restricted eating on weight in patients with type 2 diabetes mellitus.

METHODS

Study design

Quasi-experimental study (pre-post).

Study place

The study was conducted in LLR hospital, Kanpur.

Study duration

The study was conducted for 14 months from April 2023 to June 2024.

Study population

Diabetes patients coming in Medicine OPD & PMSSY Endocrinology OPD during the duration of the study.

Inclusion criteria

Patient with Type 2 Diabetes Mellitus between age 18 - 70 years with or without obesity.

Exclusion criteria

Patients aged below 18 or above 70 years, those diagnosed with type 1 diabetes mellitus (DM), maturity-onset diabetes of the young (MODY), gestational diabetes mellitus (GDM), or diabetes during pregnancy were excluded from the study. Additionally, patients with chronic kidney disease (CKD), chronic liver disease (CLD), congestive heart failure (CHF), thyroid disorders, or poorly controlled blood sugar levels (HbA1c >10%) were not included. Individuals on insulin therapy or those with fibro calculus pancreatitis were also excluded from participation.

Sample size and sampling

A formula for quasi experimental pre-post study with a statistical confidence level (z) of 1.96 and absolute precision required on either side (d) was taken as 0.4.

Sample size was calculated by calculating the effect size by mean difference in HbA1c levels and Standard deviation of HbA1c level from the study by Dylan a et al. in 2020.

Study participants

This study was conducted among individuals with T2DM aged between 18 to 70 years who attended Medicine OPD and Endocrinology OPD of GSVM Medical College, Kanpur, Uttar Pradesh during the study duration. A total of 98 patients were screened for this study out of which 54 patients got selected based on inclusion and exclusion criteria. Out of 54 patients, 4 participants were lost to follow after 1 month of study initiation. So effective sample size came out to be 50 with a response rate of 92.6%. Those with chronic illnesses like CKD, CLD, CHF or thyroid disorder; patients with diabetes other than T2DM and HbA1c >10 or on insulin therapy were excluded from this study.

Data collection

The participants were initially contacted through the “daily clinic list.” Data were collected at the clinic premises at GSVM Medical College on Monday, and Wednesday of each week until the entire sample was obtained. The purpose of the study was discussed with all the participants and consent was obtained.

Initial investigations were done and patients were assessed for any other comorbidity, all the procedures were explained to the participants, and counselled on the diet plan to follow the same. A diet chart with initial instructions was given with counselling regarding the management and adherence to the diet was explained. Participants were followed up monthly to assess their adherence to the diet plan and weight was assessed. After 3 months, the intervention was stopped and data was analysed.

Study tool

Time restricted eating

Time-bound fasting overnight starts from 10:00 PM in the night up to 2:00 PM the next day, and limits the cooked meals. Although participants can take zero calories during the fasting period. During the meal period, patients were advised to take around 1500- 1800 Kcal according to their diet preferences.

Data analysis

Data analysis was done using licensed SPSS software version 21.0. Data is presented in the form of tables and appropriate diagrams. Qualitative data is summarized as proportions while quantitative data is as mean, median, and appropriate measures of dispersion including confidence intervals. Quantitative Data was analysed

using paired t-test and qualitative data by Chi-square/fisher exact test with a value of $p < 0.05$ is taken as significant.

Ethical consideration

Ethical clearance was obtained from the Institute Ethics Committee of GSVM Medical College, Kanpur U.P. Each eligible subject was explicitly explained about the purpose of the study by the investigator and informed written consent was obtained from all adult participants before inclusion, for participants > 12 years assent was taken.

RESULTS

Table 1 provides a comprehensive summary of the demographic and clinical characteristics of the sample population. The mean age of the participants is 53.28 years with a standard deviation of 11.28 years. Gender distribution shows 23 males (46%) and 27 females (54%). The mean baseline weight is 67.56 kg with a standard deviation of 8.60 kg.

The mean HbA1c level is 8.26% with a standard deviation of 1.30%. Fasting blood sugar levels have a mean of 165.7 mg/dl and a standard deviation of 59.7 mg/dl, while the mean post-prandial 2-hour blood sugar level is 220 mg/dl with a standard deviation of 69.7 mg/dl. Dyslipidaemia is

present in 20 individuals (60%) and absent in 30 individuals (40%). The mean serum creatinine level is 0.968 mg/dl with a standard deviation of 0.191 mg/dl. The urine albumin-to-creatinine ratio (ACR) has a mean of 28.68 and a standard deviation of 8.58. The mean AST/SGOT level is 31.66 with a standard deviation of 8.73, and the mean ALT/SGPT level is 34.3 with a standard deviation of 9.40.

Table 2 provides a comprehensive comparison of the mean weights and associated statistics at two different time points. On day 0, the mean weight of participants was 67.56 kg, with a standard error of 1.21 and a standard deviation of 8.60. The 95% confidence interval for this measurement ranged from 65.11 to 70.00 kg. After 12 weeks, the mean weight decreased to 65.78 kg, with a standard error of 1.19 and a standard deviation of 8.44. The 95% confidence interval for this time point ranged from 63.37 to 68.18 kg.

The difference in mean weights (diff) between Day 0 and 12 weeks was 1.78 kg, with a standard error of 0.25 and a standard deviation of 1.82. The 95% confidence interval for the difference was (1.26, 2.29), indicating a statistically significant change. The paired t-test yielded a t-value of 6.90 and a p value of 0.00, confirming that the observed reduction in weight over the 12 weeks was statistically significant.

Table 1: Sociodemographic characteristics of the study participants (n=50).

Variables	Frequency	%	Mean±SD
Age			53.28±11.28 years
Gender			
Male	23	46	
Female	27	54	
Baseline weight	--	--	67.56±8.60 kg
Hba1c	--	--	8.26±1.30 %
Fasting blood sugar (FBS)	--	--	165.7±59.7 mg/dl
Post prandial 2 hr (PP)	--	--	220±69.7 mg/dl
Dyslipidaemia			
Yes	20	60	
No	30	40	
Serum creatinine	--	--	0.968± 0.191
Urine ACR	--	--	28.68±8.58
AST/SGOT	--	--	31.66±8.73
ALT/SGPT	--	--	34.3±9.40

Table 2: Paired t-test to measure the difference of mean weight at 0 and 12 weeks of study (n=50).

Statistic	Day 0	After 12 weeks	Difference (diff)
Observations (N)	50	50	50
Mean	67.56	65.78	1.78
Standard error (SE)	1.21	1.19	0.25
Standard deviation (SD)	8.6	8.44	1.82
95% confidence interval (CI)	(65.11, 70.00)	(63.37, 68.18)	(1.26, 2.29)
T value	-	-	6.9
Degrees of freedom (df)	-	-	49
P value	-	-	0

DISCUSSION

The primary objective of this study was to evaluate the effect of time-restricted eating (TRE) on weight in patients with type 2 diabetes mellitus (T2DM). We collected and analysed data from 50 patients who met the inclusion criteria. This discussion aims to interpret our findings in the context of existing literature and compare our results with those from other significant studies.

Baseline characteristics

Our study sample consisted of 46% males (n=23) and 54% females (n=27), with an average age of 53.28 years (SD=11.28). This gender distribution aligns closely with Carter et al. (2018), who studied a sample of 56% women (n=77) and 44% men (n=60).¹⁰ However, it contrasts with the male predominance reported by Lowe et al, who found a 60.3% male sample (n=70).¹¹ The age distribution in our study (30 to 70 years, with the highest frequency around 50 years) is somewhat younger than Zhao et al who reported an average age of 63 years (SD=4), and Carter et al, with a mean age of 61.0 years (SD=9.1).^{9,10} These differences in demographic composition could be attributed to the specific population our hospital serves, reflecting regional and healthcare access disparities.

Weight reduction

In our study, the mean weight decreased from 67.56 kg (SD=8.60) at baseline to 65.78 kg (SD=8.45) after 12 weeks, representing a significant mean difference of 1.78 kg (p=0.00). This reduction is similar to Pavlou et al, where weight decreased by -4.28% or -4.52 kg (p=0.004) over 6 months of TRE.¹² Other studies showed varied effects: Andriessen et al noted a -0.7 kg (p=0.003) reduction over 3 weeks of 10 hour TRE.¹³ Che et al. reported -2.98±0.43 kg (p<0.05) over 12 weeks of TRE.¹⁴ Arnason et al, found a -1.395 kg (p=0.009) reduction over 6 weeks of TRE.¹⁵ Lowe et al. showed a -0.94 kg (95% CI, -1.68 to -0.20; p=0.01) reduction over 12 weeks in overweight and obese individuals.¹²

The slightly greater weight loss in Pavlou et al (4.3%) compared to our study is likely due to their longer 6-month intervention.¹² Variations with other studies may stem from differences in diet, culture, lifestyle, and individual responses to energy deficits influenced by genetics, neurohormonal responses, metabolic efficiency, tissue capacity, non-exercise activity thermogenesis, and gut microbiome composition, as noted by Dent et al.¹⁶

The clinical implications of our findings are significant. TRE offers a simple, non-pharmacological intervention that can be easily incorporated into patients' lifestyles. It provides a flexible approach to managing T2DM, potentially reducing the need for medication and its associated costs and side effects. Healthcare providers can consider recommending TRE as part of a comprehensive

diabetes management plan, tailored to individual patient needs and preferences.

Our study shows promising results but has limitations. The sample size of 50 participants limits generalizability, and larger, more diverse populations are needed for validation. The 12-week duration provides insights into short-term effects, but long-term studies are necessary to assess the sustainability and long-term benefits of TRE. Conducted as a single-centre trial, its generalizability is further limited. Additionally, we did not control for other lifestyle factors like physical activity and diet, which could influence outcomes. Future research should include these variables, explore different TRE schedules, and compare TRE with other dietary interventions such as continuous caloric restriction or intermittent fasting.

CONCLUSION

Our study shows that time-restricted eating (TRE) significantly reduces weight in patients with type 2 diabetes mellitus (T2DM), consistent with existing literature. This highlights TRE's potential as an effective intervention for managing T2DM. Personalized approaches are crucial due to individual variability in response to TRE, but overall, they prove valuable in diabetes care.

Recommendations

Future research should prioritize larger, long-term studies to validate these findings and explore TRE's underlying mechanisms. Investigating TRE's interaction with other lifestyle factors and diets will enhance our understanding of its role in T2DM management. As evidence accumulates, TRE could become a mainstream recommendation for improving metabolic health and managing diabetes.

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