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Clinical Effectiveness of Diafree Juice in Improving HbA1c and Postprandial Glucose in Type 2 Diabetes: Evidence from Real-World Use

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ABSTRACT

Background:
Polyherbal formulations are gaining clinical relevance as adjunctive therapies in the management of type 2 diabetes mellitus (T2DM), offering multi-targeted mechanisms with favorable safety profiles. Diafree Juice is an Ayurvedic proprietary blend of herbs known to modulate insulin sensitivity, secretion, and glucose metabolism. Despite supportive preclinical and ingredient-level data, real-world clinical evidence on the integrated formulation remains limited.

Aim:
To evaluate the glycemic efficacy of Diafree Juice in patients with T2DM over an 80-day observation period, focusing on changes in glycosylated haemoglobin (HbA1c) and postprandial blood glucose (PPBG) levels.

Methodology:
This was an open-label, single-arm, observational study conducted across multiple outpatient settings in India. Adults with T2DM meeting the eligibility criteria were enrolled and administered Diafree Juice (30 mL twice daily before meals) for 80 days. HbA1c and PPBG were recorded at baseline and at Day 80 to observe changes over the study period. Statistical analyses included paired t-tests and chi-squared tests for changes in the distribution of patients across HbA1c and PPBG categories.

Results:
Among 120 participants who completed the study, mean HbA1c reduced significantly from 6.3 ± 0.24% to 5.99 ± 0.47% ($p < 0.0001$), with a mean percentage improvement of 5.75%. PPBG decreased from 192.36 ± 60.36 mg/dL to 147.87 ± 19.13 mg/dL ($p < 0.0001$), reflecting a 30.34% mean reduction. A significant shift toward a normoglycemic profile was observed in both HbA1c and PPBG measurements.

Conclusion:
Diafree Juice demonstrated statistically significant improvements in glycemic parameters over a period of 80 days, supporting its role as an effective adjunct to their standard of care in T2DM management.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) has emerged as one of the most pressing global health challenges of the 21st century. As of 2023, over 529 million individuals worldwide are living with diabetes, a number projected to surpass 1.3 billion by 2050 [1]. This rapid rise, driven primarily by T2DM, has made diabetes a leading cause of death and disability, with prevalence increasing sharply in low- and middle-income countries. In India alone, an estimated 101 million people are currently affected, representing

11.4% of the population, with an additional 136 million at risk as prediabetics [2]. Urbanization, sedentary lifestyles, and dietary transitions continue to accelerate this epidemic, showcasing the urgent need for safe and effective long-term management strategies [3]. Despite the availability of multiple pharmacologic options, managing T2DM remains a complex challenge, particularly when balancing long-term efficacy, safety, and patient adherence. Conventional therapies, while effective, are often associated with adverse effects such as weight gain, hypoglycemia, gastrointestinal discomfort, or cardiovascular risk, and may lead to treatment fatigue or therapeutic inertia [4,5]. For instance, sulfonylureas and thiazolidinediones have been linked to increased cardiovascular events, while agents like sodium-glucose transport protein 2 (SGLT2) inhibitors and alpha-glucosidase inhibitors may compromise tolerability [6]. These concerns, combined with the burden of polypharmacy, highlight the need for adjunctive strategies that offer multi-pronged glycemic control with improved safety and adherence.

Given the multifactorial nature of T2DM, polyherbal formulations have emerged as a compelling adjunctive approach, leveraging the complementary pharmacological actions of multiple medicinal herbs [7]. By targeting distinct aspects of diabetes pathophysiology such as insulin resistance, impaired insulin secretion, increased intestinal glucose absorption, oxidative stress, and chronic inflammation-polyherbal combinations may offer broader metabolic regulation than single-agent therapies. Furthermore, synergistic interactions among herbal constituents allow for lower individual doses, potentially minimizing toxicity and enhancing tolerability [8]. Several clinical and preclinical studies have demonstrated that polyherbal formulations can effectively reduce fasting and postprandial glucose levels as well as HbA1c, with outcomes comparable to those of standard oral hypoglycemic agents [9,10]. However, the therapeutic potential of such combinations depends on careful selection of compatible herbs, standardization of active constituents, and rigorous evaluation in clinical settings.

Diafree Juice is a proprietary Ayurvedic polyherbal formulation composed of different botanicals, including *Gymnema sylvestre*, *Momordica charantia*, *Trigonella foenum-graecum*, *Aegle marmelos*, *Phyllanthus emblica*, *Azadirachta indica*, and *Tinospora cordifolia*, among others. Each of these ingredients has demonstrated independent antidiabetic potential through mechanisms such as pancreatic β-cell regeneration, insulin-mimetic action, enhanced insulin sensitivity, α-glucosidase inhibition, and modulation of oxidative and inflammatory pathways. The formulation is designed to offer a multi-targeted intervention for glycemic control by combining herbs that act at different stages of glucose metabolism [11–13]. While the individual components have been studied extensively, there is limited real-world evidence evaluating the integrated effect of Diafree Juice on key clinical outcomes. This study was therefore undertaken to assess the glycemic efficacy of Diafree Juice in patients with type 2 diabetes under routine clinical conditions, focusing on changes in HbA1c and postprandial blood glucose levels over an 80-day period.

Methodology:

Study Design and Setting

This was an open-label, single-arm, observational study conducted across real-world outpatient settings in India. Participants were enrolled by qualified Ayurvedic physicians with clinical evaluations performed at baseline and at the end of study (Day 80).

Study Objectives

The primary objective of this study was to evaluate the glycemic control efficacy of Diafree Juice, an Ayurvedic proprietary formulation, in patients with T2DM as measured by the change in HbA1c levels from baseline to end of study. The secondary objective was to assess changes in PPBG levels from baseline to end of study.

Sample Size Calculation

Based on a statistical power of 80%, an effect size of 0.46 for HbA1c, and a standard deviation of 1.00, the calculated sample size for this study was 82 subjects to detect a statistically significant change at a 5% significance level ($\alpha = 0.05$). Considering a potential dropout rate of 10%, the final target enrolment was set at 82 participants. This estimation was informed by data from a systematic meta-analysis evaluating the effectiveness of herbal formulations in type 2 diabetes management [10].

Study Participants

The study enrolled 82 adult participants diagnosed with T2DM who were either initiating Diafree Juice for the first time or using it as an adjunct to their existing standard of care (SOC) for diabetes management. Eligible participants were those with a documented diagnosis of type 2 diabetes as per ICD-11 diagnostic criteria (5A11) and MadhuMeha classification (EF-2.4.4) according to the NAMASTE portal [14,15]. Participants were required to have an HbA1c value between 5.5% and 7.0% (both inclusive) and be able to provide this value at the time

of interview. All participants were required to provide informed consent and commit to a 90-day follow-up. Patients were excluded if diagnosed with type 1 diabetes mellitus, those currently on insulin therapy, individuals with recent dose fluctuations in oral antihyperglycemic agents within the past three months, and those with known contraindications to any herbal ingredient in the Diafree Juice formulation.

Product Composition and Dosage

Diafree Juice is a proprietary Ayurvedic formulation comprising a blend of herbal ingredients traditionally used in the management of type 2 diabetes mellitus. The formulation includes extracts of *Phyllanthus emblica* (Amla), *Momordica charantia* (Karela), *Syzygium cumini* (Jamun), *Tinospora cordifolia* (Giloy), *Ocimum tenuiflorum* (Tulsi), *Azadirachta indica* (Neem), *Aegle marmelos* (Belpatra), *Trigonella foenum-graecum* (Methi), *Picrorhiza kurroa* (Kutki), *Pterocarpus marsupium* (Vijayasar), and *Gymnema sylvestre* (Gudmar). Participants were instructed to consume 30 mL of Diafree Juice diluted in 200 mL of water twice daily, approximately one hour before meals, for a total duration of 80 days.

Data Collection and Follow-up

Data were collected at two time points: Day 1 (baseline) and Day 80 (end of study duration). At each point, values for HbA1c and PPBG were recorded based on standard-of-care laboratory investigations. Follow-up was conducted by the prescribing Ayurvedic physicians through routine outpatient visits, telephonic consultations, or electronic communication. Data from patients with both baseline and end-of-study HbA1c and PPBG values available were included in the final analysis.

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. This study is registered with the International Standard Randomised Controlled Trial Number (ISRCTN) registry with registration no. ISRCTN16382675.

Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics and outcome measures. Changes in continuous variables such as HbA1c and postprandial blood glucose (PPBG) from baseline to Day 80 were assessed using paired t-tests. Shifts in the distribution of patients across predefined HbA1c and PPBG categories were evaluated using the chi-squared test. A p-value of <0.05 was considered statistically significant. Results are presented as mean ± standard deviation unless otherwise specified.

Results

A total of 120 participants with type 2 diabetes mellitus who completed both baseline and Day 80 assessments were included in the final analysis.

HbA1c:

The mean HbA1c reduced significantly from 6.30 ± 0.24 % at baseline to 5.99 ± 0.47 % at Day 80 ($p < 0.0001$) (Figure 1). This corresponds to a mean percentage reduction of 5.75%. Categorical analysis of HbA1c values revealed a significant redistribution of participants from higher to lower glycemic brackets. At baseline, 85.8% of patients had HbA1c >6.4%, which reduced to 35.0% at Day 80. Concurrently, the proportion of patients with HbA1c <5.7% increased from 2.5% to 10.8% ($\chi^2 = 26.26$, $p < 0.0001$) (Table 1).

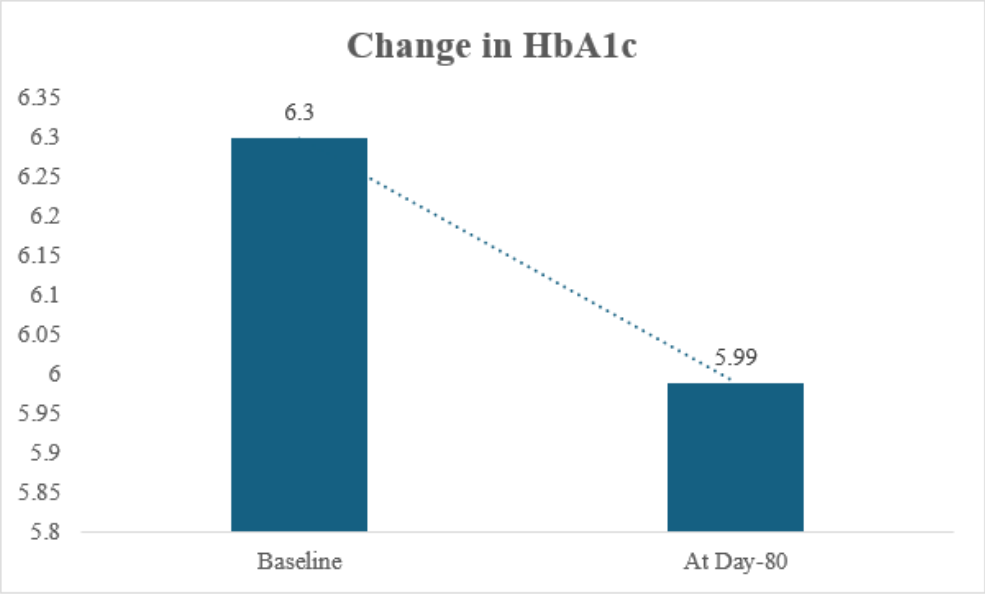

Figure 1: Change in mean HbA1c levels from baseline to Day 80 ($p < 0.0001$, paired t-test.)

Table 1. Distribution of Patients by HbA1c Categories at Baseline and Day 80

HbA1c Category	Baseline n (%)	Day 80 n (%)	Statistical Test
< 5.7%	3 (2.5%)	13 (10.8%)	$\chi^2 = 26.26$, $p < 0.0001$
5.7% – 6.4%	14 (11.7%)	42 (54.2%)	
> 6.4%	103 (85.8%)	65 (35.0%)	

Postprandial Blood Glucose (PPBG):

The mean PPBG decreased significantly from 192.36 ± 60.36 mg/dL at baseline to 147.87 ± 19.13 mg/dL at the end of study ($p < 0.0001$) (Figure 2). This represents a mean reduction of 30.34%, with a median improvement of 24.22%. Categorical analysis showed that patients with PPBG <140 mg/dL increased from 8.2% to 17.2%. The proportion in the 140–200 mg/dL range rose from 38.2% to 71.7%. Meanwhile, those in higher glycemic brackets (200–300 mg/dL and >300 mg/dL) decreased markedly from 33.5% to 6.0% and from 20.2% to 5.2%, respectively ($\chi^2 = 71.07$, $p < 0.0001$) (Table 2).

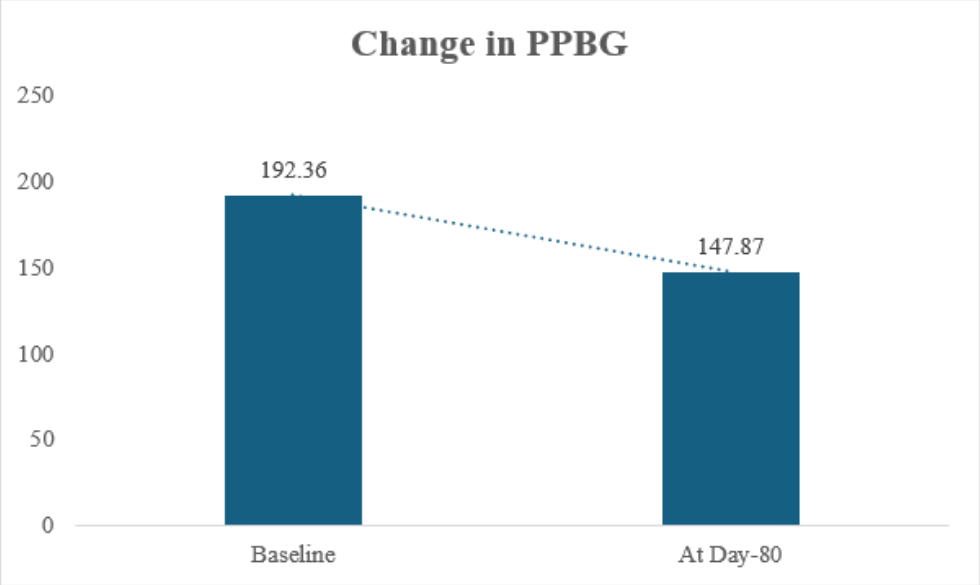

Figure 2: Change in mean PPBG levels from baseline to Day 80 ($p < 0.0001$, paired t-test.)

Table 2. Distribution of Patients by Postprandial Blood Glucose (PPBG) Categories at Baseline and Day 80

PPBG Category (mg/dL)	Baseline n (%)	Day 80 n (%)	Statistical Test
< 140	19 (8.2%)	40 (17.2%)	$\chi^2 = 71.07$, $p < 0.0001$
140 – 200	89 (38.2%)	167 (71.7%)	
200 – 300	78 (33.5%)	14 (6.0%)	
> 300	47 (20.2%)	12 (5.2%)	

Discussion

T2DM is a progressive condition that often requires long-term pharmacological management, which can be limited by adverse effects and treatment fatigue. This has led to growing interest in adjunctive herbal therapies that offer multi-targeted mechanisms with better tolerability. The present study aimed to evaluate the glycemic impact of Diafree Juice, a polyherbal Ayurvedic formulation, in routine clinical practice with standard of care. The significant reduction in HbA1c and PPBG values observed in this study suggests a robust glycemic response to Diafree Juice. The formulation's effectiveness can be attributed to the synergistic effects of its multiple herbal constituents, each acting on distinct but complementary metabolic pathways.

One of the key mechanisms likely responsible for the observed glycemic improvement is enhanced insulin secretion and β-cell preservation. Herbs such as *Gymnema sylvestre* and *Trigonella foenum-graecum*, present in the formulation, have been shown to stimulate pancreatic function and improve insulin output [16,17]. In particular, *Gymnema sylvestre* is known for its gymnemic acids, which not only suppress intestinal glucose absorption but also promote regeneration of pancreatic β-cells—supporting endogenous insulin availability. This could explain the downward trend in HbA1c over the 80-day period, reflecting improved long-term glycemic control. The reduction in PPBG may be partly due to delayed carbohydrate absorption and enhanced peripheral glucose uptake [10,18].

Ingredients such as *Aegle marmelos* (bael patra) have demonstrated insulin-mimetic actions. Bael patra, shown in earlier clinical studies to significantly lower both fasting and postprandial glucose, likely acts through its alkaloid content, which may enhance insulin sensitivity or stimulate insulin secretion in response to elevated blood glucose levels [19,20]. The relatively rapid response in PPBG categories seen in our study corroborates these findings, especially the marked shift of patients from higher PPBG brackets (>200 mg/dL) to lower glycemic ranges(<200 mg/dL).

The improvement in glycemic control may also involve modulation of inflammatory and oxidative stress pathways. Several herbs in Diafree Juice, including *Neem*, and *Fenugreek*, have known antioxidant and anti-inflammatory properties, which contribute to improved insulin signaling. Inflammatory cytokines such as TNF-α and IL-6 have been implicated in insulin resistance; thus, their suppression could enhance insulin sensitivity [12]. Prior randomized trials of polyherbal formulations with similar ingredients have noted reductions in inflammatory markers alongside glycemic improvements, suggesting that Diafree Juice may exert metabolic benefits beyond glucose lowering [10].Another plausible explanation for the observed effects is the inhibition of carbohydrate-digesting enzymes. Herbs such as *Methi* (fenugreek) are known to inhibit α-glucosidase activity, thereby slowing the breakdown of complex carbohydrates and blunting postprandial glucose spikes. Fenugreek's 4-hydroxyisoleucine has also been shown to directly stimulate insulin release in response to glucose, supporting the dual benefit seen in both HbA1c and PPBG outcomes [13,16]. These findings are consistent with previous clinical trials and systematic reviews that have demonstrated the glycemic benefits of polyherbal combinations containing ingredients like fenugreek, bitter melon, and Gymnema sylvestre, which act on insulin secretion, glucose absorption, and peripheral sensitivity [9,10].

The findings from this study highlight the potential of Diafree Juice as an effective adjunctive therapy for improving glycemic control in patients with type 2 diabetes. However, the study has certain limitations, including the absence of a control group and relatively short follow-up duration. Despite these constraints, the magnitude and consistency of the glycemic improvements observed provide a strong rationale for further investigation. Future studies with randomized, controlled designs and additional metabolic assessments will be critical to validate these results and explore the long-term impact of Diafree Juice on insulin resistance, disease progression, and the potential to reduce reliance on conventional antidiabetic medications.

Conclusion:

Diafree Juice, a polyherbal Ayurvedic formulation, demonstrated significant improvements in glycemic control over an 80-day period in patients with type 2 diabetes. Reductions in HbA1c and postprandial blood glucose suggest its potential as an effective adjunct to conventional therapy.

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