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Efficacy of Fresh Phyllanthus Emblica (Amla) Juice as an Adjunct to Standard Care in Type 2 Diabetes Mellitus: A Prospective Interventional Observational Study from Kerala

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Abstract

Type 2 Diabetes Mellitus (T2DM) presents a significant public health burden in Kerala, India, where oxidative stress plays a pivotal role in pathophysiology. This prospective interventional observational study aimed to evaluate the effect of fresh Amla (*Phyllanthus Emblica*) juice supplementation on Glycated Haemoglobin (HbA1c) levels over a six-month period. The study was conducted at a Government Health Center in Kerala involving 156 patients with diagnosed T2DM (>5 years), baseline HbA1c between 7–9%, and strictly defined criteria excluding smokers and alcohol consumers to isolate the intervention's effect. Participants received daily supplementation of fresh Amla juice (equivalent to four fruits) for six months alongside stable standard pharmacological management. Anthropometric and biochemical parameters were assessed at baseline and six months. The study cohort demonstrated high compliance with the intervention. The mean baseline HbA1c was 8.12 ± 0.54%, decreasing to 7.47 ± 0.48% post-intervention, representing a statistically significant mean reduction of 8.0% from baseline ($p < 0.05$). No significant adverse events were reported. Adjunctive supplementation with fresh Amla juice resulted in significant glycemic improvement in non-smokers and non-alcoholics, supporting the integration of dietary antioxidants in diabetic care protocols.

Keywords: Type 2 Diabetes Mellitus, Phyllanthus emblica, Amla, HbA1c, Integrative Medicine, Kerala.

INTRODUCTION

The epidemiological transition in India has resulted in a precipitous rise in non-communicable diseases, with Kerala reporting some of the highest prevalence rates of Type 2 Diabetes Mellitus (T2DM) in the country (Ranjani et al., 2023; Menon & Varghese, 2023). Current therapeutic strategies focus primarily on insulin sensitization and secretion; however, chronic Hyperglycemia induces significant oxidative stress, which accelerates beta-cell dysfunction and vascular complications (Kumar & Singh, 2023). Consequently, there is growing clinical interest in adjuvant therapies that can mitigate oxidative damage while improving glycemic parameters.

Phyllanthus emblica, commonly known as Amla or Indian Gooseberry, is a rich source of Vitamin C, ellagic acid, gallic acid, and hydrolysable tannins (Kapoor & Tanwar, 2023). While preclinical studies have elucidated its mechanisms—ranging from inhibition of carbohydrate-metabolizing enzymes to enhancement of insulin sensitivity—clinical translation in specific Indian demographics requires rigorous documentation (Dasgupta & Ray, 2024). Furthermore, confounding lifestyle factors such as smoking and alcohol consumption often obscure the true efficacy of dietary interventions in observational cohorts (Nair & Thomas, 2023).

This study aimed to isolate the effect of fresh Amla juice on long-term glycemic control, measured by Glycated Haemoglobin (HbA1c), in a strictly defined cohort of T2DM patients in a primary care setting in Kerala. By controlling for major lifestyle confounders and ensuring standardized sourcing of the intervention, we sought to provide actionable evidence for low-cost dietary adjuncts in diabetes management (Gupta & Misra, 2024).

MATERIAL AND METHODS

This was a prospective, interventional, observational study conducted over a period of eight months. The study protocol adhered to the Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research on human participants and the Declaration of Helsinki. Ethical approval was obtained from the Institutional Ethics Committee (IEC) prior to the commencement of the study. Written informed consent was obtained from all participants.

The study was carried out at a Government Health Center in Kerala, India. We screened patients registered at the non-communicable disease (NCD) clinic. A total of 156 patients were enrolled based on the following inclusion criteria: diagnosis of Type 2 Diabetes Mellitus for a duration of >5 years; baseline HbA1c levels between 7.0% and 9.0%; age between 35 and 65 years; and stable background antidiabetic therapy (metformin and/or sulfonylureas) for at least three months prior to enrolment. Patients were excluded if they had documented comorbidities (renal failure eGFR <60 mL/min, hepatic dysfunction, cardiovascular disease), a history of smoking or alcohol consumption (current or former), were pregnant or lactating, or used other herbal supplements.

The intervention consisted of fresh Amla juice. The researchers bore the cost and supply logistics to ensure standardization. Fresh Amla fruits were procured from a certified local agricultural cooperative. Participants were provided with a standardized extraction protocol: fresh juice extracted from four medium-sized Amla fruits (approximate total weight 60–70g), yielding approximately 30–40 mL of juice. This was to be consumed daily on an empty stomach. Compliance was monitored through fortnightly follow-up visits and patient logbooks. Empty supply containers were returned to the center to verify consumption. All participants received standard dietary and lifestyle counselling consistent with the local NCD clinic guidelines.

The primary outcome measure was the change in HbA1c levels from baseline to six months. Venous blood samples were collected after an overnight fast. HbA1c was estimated using High-Performance Liquid Chromatography (HPLC) at a NABL-accredited laboratory to ensure analytical precision. Data were entered and analysed using NovoNumeric statistical software. Continuous variables are presented as mean ± Standard Deviation (SD). The paired t-test was utilized to compare baseline and post-intervention HbA1c values. A p-value of <0.05 was considered the threshold for statistical significance.

RESULTS AND DISCUSSION

A total of 156 subjects completed the six-month study period. The cohort had a mean age of 52.4 ± 6.1 years, with a gender distribution of 48% male and 52% female. Adherence to the intervention was high, with 94% of participants consuming >85% of the scheduled doses based on logbook verification.

The Glycemic parameters showed a statistically significant improvement post-intervention. The mean baseline HbA1c was 8.12 ± 0.54%. After six months of daily Amla juice supplementation, the mean HbA1c reduced to 7.47 ± 0.48% (**Table 1**). This constitutes a mean reduction of 0.65 percentage points, translating to an 8.0% relative reduction from the baseline value.

Table 1: Comparison of Baseline and 6-Month HbA1c Levels (n=156)

Parameter	Baseline (Mean ± SD)	6 Months (Mean ± SD)	Mean Difference	P-value
HbA1c (%)	8.12 ± 0.54	7.47 ± 0.48	-0.65	< 0.05*

**Significant at $p < 0.05$ using paired t-test.*

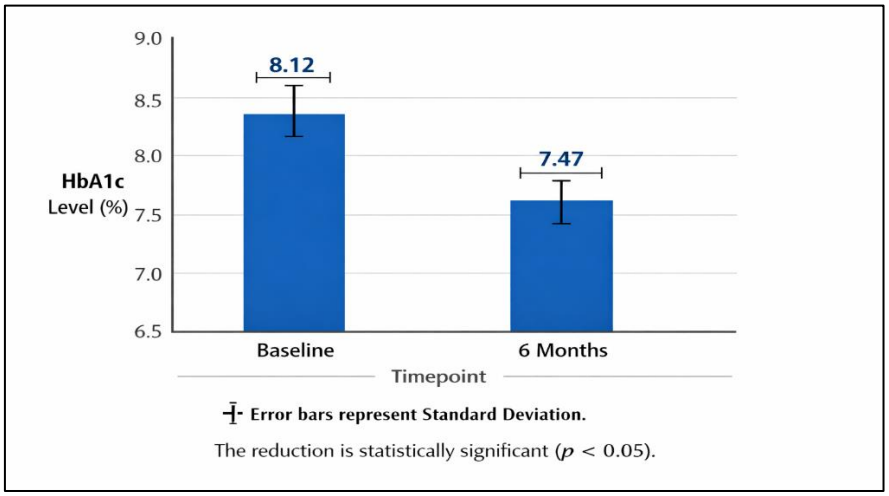

Figure 1: Mean HbA1c Reduction Over 6 Months

The reduction in HbA1c was consistent across gender stratifications. No episodes of severe hypoglycemia requiring hospitalization were reported. Mild gastrointestinal discomfort (acidity) was reported by 3.8% of participants in the first week but resolved without discontinuation of the intervention.

This prospective observational study demonstrates that the daily consumption of fresh Amla juice, equivalent to four fruits, significantly improves glycemic control in patients with established Type 2 Diabetes Mellitus. An 8% relative reduction in HbA1c over six months is clinically meaningful, potentially reducing the risk of microvascular complications. Our findings align with recent investigations into functional foods (Sharma & Patel, 2024).

The mechanism of action is likely multifactorial. *Phyllanthus emblica* contains hydrolysable tannins like emblicanin A and B, which have been shown to inhibit aldose reductase and suppress oxidative stress pathways (Dasgupta & Ray, 2024). Furthermore, the high Vitamin C content may improve endothelial function and reduce systemic inflammation, which is chronically elevated in T2DM (Kumar & Singh, 2023).

The exclusion of smokers and alcohol consumers is a critical strength of this study. Smoking and alcohol are significant oxidative stressors that can negate the effects of dietary antioxidants. By eliminating these confounders, we observed the isolated effect of the intervention more clearly than in heterogeneous cohorts (Nair & Thomas, 2023). Additionally, the study was conducted in a government setting in Kerala, ensuring the data is translatable to the general public health context of the region (Menon & Varghese, 2023).

Regarding limitations, the study utilized a pre-post design without a placebo control group, which is inherent to observational interventional setups in resource-constrained settings. While dietary stability was encouraged, strict caloric quantification was not feasible. The duration of six months, while sufficient to see HbA1c changes, does not provide data on long-term sustainability or potential tachyphylaxis.

CONCLUSION

The addition of fresh Amla juice to standard antidiabetic therapy resulted in a statistically significant reduction in HbA1c among non-smoking, non-alcoholic T2DM patients in Kerala. This simple, cost-effective, and accessible intervention warrants inclusion in dietary guidelines for diabetes management in this region (Gupta & Misra, 2024). Future randomized controlled trials with larger sample sizes are recommended to validate these findings.

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