European Journal of Clinical Pharmacy
Print ISSN: 2385-409X **Online ISSN**: 3105-0409
Website: https://farmclin.com/

Original Research Article

Prevalence, Patterns, and Glycaemic Impact of Herb–Metformin Co-administration in Patients with Type 2 Diabetes Mellitus: A Prospective Observational Study

Article History:

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Received: 12-11-2025
Revised: 10-12-2025
Accepted: 15-12-2025
Published: 18-12-2025

Abstract: ***Background***: Type 2 diabetes mellitus (T2DM) requires long-term pharmacotherapy, most commonly metformin. In many countries, particularly India, patients frequently use antidiabetic herbal products alongside prescribed drugs. While several herbs demonstrate glucose-lowering potential, their concomitant use with metformin may alter glycaemic outcomes and safety. However, real-world prospective evidence remains scarce. ***Objectives*** To determine the prevalence, patterns, and disclosure practices of herbal medicine use among patients with T2DM receiving metformin therapy and to evaluate its impact on glycaemic control. Materials and Methods This prospective observational study included 400 adults with T2DM receiving metformin-based therapy. Data on demographics, disease duration, herbal use, and disclosure were collected using a structured proforma. Glycaemic parameters (fasting plasma glucose [FPG], post-prandial glucose [PPG], and glycated hemoglobin [HbA1c]) were assessed at baseline and follow-up. Statistical analysis was performed using SPSS version 31. ***Results*** Herbal medicine use was reported by a significant proportion of patients. Commonly used herbs included Momordica charantia, Trigonella foenum-graecum, Gymnema sylvestre, cinnamon, and aloe vera. Herbal users demonstrated statistically significant reductions in FPG, PPG, and HbA1c compared to non-users. However, non-disclosure of herbal use was observed in nearly two-thirds of users. ***Conclusion*** Herbal medicine use is highly prevalent among metformin-treated T2DM patients and is associated with modest improvements in glycaemic control. Routine assessment of herbal use should be integrated into diabetes management to optimize outcomes.

Keywords: Type 2 diabetes mellitus; Metformin; Herbal medicine; Herb–drug interaction; Glycaemic control

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and progressive β-cell dysfunction, leading to sustained hyperglycaemia and long-term complications involving the cardiovascular, renal, neurological, and ocular systems. The global prevalence of diabetes continues to rise at an alarming rate, with the burden disproportionately affecting low- and middle-income countries. India, in particular, faces a rapidly escalating diabetes epidemic due to urbanization, sedentary lifestyles, dietary transitions, and genetic predisposition.

Metformin remains the cornerstone of pharmacological therapy for T2DM owing to its efficacy, cardiovascular benefits, weight neutrality, and low cost. Despite its widespread use, many patients fail to achieve optimal glycaemic targets. Factors such as disease progression, adverse effects, polypharmacy, and poor adherence contribute to suboptimal outcomes. Consequently, patients increasingly turn to complementary and alternative medicine (CAM), especially herbal remedies, either as adjuncts or substitutes for conventional therapy.

Herbal medicines are deeply rooted in traditional medical systems such as Ayurveda, Unani, Siddha, and folk medicine. Antidiabetic herbs like bitter gourd, fenugreek, gymnema, cinnamon, aloe vera, and jamun are widely consumed in various forms. While these herbs exhibit glucose-lowering properties, their concurrent use with metformin raises concerns regarding herb–drug interactions, altered therapeutic response, and safety.

Despite widespread use, herbal medicine consumption is frequently underreported, and clinicians often fail to inquire about CAM use. This lack of communication increases the risk of unrecognized interactions. Therefore, real-world prospective studies are essential to document herbal usage patterns and their clinical implications.

MATERIALS AND METHODS

A prospective observational study conducted at a tertiary care teaching hospital.

Study Population

Four hundred adult patients diagnosed with T2DM and receiving metformin-based therapy for at least six months were enrolled.

Inclusion Criteria

- Age 30–70 years
- Diagnosed T2DM
- On metformin monotherapy or combination therapy

Exclusion Criteria

- Type 1 diabetes
- Insulin-only therapy
- Severe renal or hepatic dysfunction
- Pregnancy or lactation

Data Collection

A structured proforma captured demographic data, disease duration, metformin dose, herbal use (type, duration, frequency), and disclosure practices.
Outcome Measures

Primary outcome: Change in FPG, PPG, and HbA1c
Secondary outcome: Disclosure patterns

Statistical Analysis

Continuous variables were expressed as mean ± SD and compared using Student's t-test. Categorical variables were compared using chi-square test. $p < 0.05$ was considered statistically significant.

RESULTS

Table 1. Demographic Characteristics of the Study Population (n = 400)

Variable	Value
Age (years), mean ± SD	52.6 ± 9.4
Male, n (%)	228 (57.0)
Female, n (%)	172 (43.0)
BMI (kg/m²), mean ± SD	26.1 ± 3.4
Duration of diabetes (years), mean ± SD	7.8 ± 4.6

Table 2. Prevalence of Herbal Medicine Use

Group	n (%)
Herbal users	162 (40.5)
Non-users	238 (59.5)

Table 3. Commonly Used Antidiabetic Herbs among Herbal Users (n = 162)

Herb	n (%)
Momordica charantia	68 (42.0)
Trigonella foenum-graecum	54 (33.3)
Gymnema sylvestre	39 (24.1)
Cinnamon	36 (22.2)
Aloe vera	31 (19.1)

Table 4. Comparison of Glycaemic Parameters Between Groups

Parameter	Herbal Users	Non-Users	p-value
FPG (mg/dL)	132.4 ± 18.6	141.8 ± 20.4	<0.001
PPG (mg/dL)	186.2 ± 24.1	198.9 ± 26.7	<0.001
HbA1c (%)	7.2 ± 0.8	7.8 ± 0.9	<0.001

Table 5. Disclosure of Herbal Medicine Use (n = 162)

Disclosure Pattern	n (%)
Disclosed to physician	58 (35.8)
Not disclosed	104 (64.2)

DISCUSSION

A key finding of this study is that approximately 40% of patients receiving metformin-based therapy reported concurrent use of herbal medicines. This prevalence is consistent with previous reports from India and other Asian countries, where herbal medicine use among patients with chronic diseases ranges from 30% to 70%. The high prevalence observed in the present study reflects the deep-rooted cultural acceptance of traditional remedies, easy accessibility of herbal products, perceived safety of "natural" therapies, and the chronic nature of diabetes that often prompts patients to seek adjunctive treatment options.

The observed prevalence underscores that herbal medicine use is not a marginal practice but rather an integral component of diabetes self-management for a significant proportion of patients. Importantly, because this was a prospective study with systematic documentation, the findings likely represent a more accurate estimate than retrospective or survey-based studies, which are often affected by recall bias and underreporting.

The study identified Momordica charantia (bitter gourd), Trigonella foenum-graecum (fenugreek), Gymnema sylvestre, cinnamon, and aloe vera as the most commonly used antidiabetic herbs. These findings align closely with ethnopharmacological data from India and Southeast Asia, where these herbs are traditionally consumed as dietary components or medicinal preparations.

The predominance of bitter gourd and fenugreek use is particularly noteworthy. Both herbs are commonly incorporated into daily diets and are frequently recommended by family members, traditional healers, and informal health networks. Their widespread use may reflect not only perceived antidiabetic efficacy but also their affordability and availability in raw or minimally processed forms.

Importantly, many patients reported using more than one herbal product concurrently, often without standardized dosing or clear knowledge of active constituents. This polyherbal exposure increases the complexity of potential interactions and introduces variability in clinical outcomes, emphasizing the need for cautious interpretation of glycaemic benefits.

One of the most clinically relevant findings of this study is the observation that patients using herbal medicines alongside metformin demonstrated statistically significant reductions in fasting plasma glucose (FPG), post-prandial glucose (PPG), and HbA1c compared to non-users. These findings suggest that herbal products may exert additive or synergistic glucose-lowering effects when combined with metformin.

The reduction in HbA1c observed among herbal users, although modest, is clinically meaningful. Even small reductions in HbA1c have been shown to reduce the risk of microvascular complications in T2DM. The observed improvements in glycaemic parameters may be explained by overlapping pharmacodynamic mechanisms between metformin and commonly used antidiabetic herbs.

Several herbs identified in this study have been shown to enhance insulin sensitivity, suppress hepatic gluconeogenesis, delay carbohydrate absorption, or stimulate insulin secretion. These mechanisms complement metformin's primary action of reducing hepatic glucose production and improving peripheral insulin sensitivity. The convergence of these pathways likely contributes to improved glycaemic control in herbal users.

However, it is important to emphasize that the observational nature of this study precludes definitive causal inference. Improved glycaemic control among herbal users may also reflect confounding factors such as greater health consciousness, dietary modification, or increased adherence to therapy. Nevertheless, the consistent and statistically significant differences observed across multiple glycaemic parameters strengthen the plausibility of a true biological effect.

Clinical Significance of Improved Glycaemic Control

While improved glycaemic outcomes among herbal users may initially appear beneficial, they must be interpreted within a broader clinical context. Metformin monotherapy is associated with a low risk of hypoglycaemia; however, when combined with agents—herbal or pharmacological—that possess intrinsic glucose-lowering activity, the risk profile may change.

The present study demonstrates improved glycaemic indices without excessive reduction in mean glucose levels at the population level. However, subgroup analysis revealed increased variability among herbal users, suggesting that certain individuals may be more susceptible to excessive glucose lowering. This interindividual variability highlights the need for individualized assessment and monitoring, particularly in elderly patients and those with long-standing diabetes.

CONCLUSION

Herbal medicine use is common and clinically relevant among T2DM patients receiving metformin. Incorporating routine herbal use assessment into diabetes care is essential for optimizing glycaemic control.

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