ORIGINAL ARTICLE

Incidence of Treatment Delays among Patients with Diabetes: A Clinic-based Cross-sectional Descriptive Study in India

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Received: 02 April 2025; *Accepted:* 25 April 2025

Abstract

Background: Diabetes mellitus is a global epidemic, with an increasing number of undiagnosed individuals, particularly those with type 2 diabetes mellitus (T2DM). However, there is limited data on treatment delays among drug-naïve patients in India. The present study aimed to ascertain the incidence of treatment delay among drug-naïve patients and the sequence of alternate treatments sought since diagnosis.

Materials and methods: This cross-sectional, multicentric, observational study was conducted across 10 primary and secondary care settings in Mumbai from October 2023 to April 2024. Adults of either gender, diagnosed with T2DM, who are drug-naïve, were included. Patient's demographic data, comorbidities, current medications, and medical history were recorded in an electronic case report form and analyzed.

Results: Of the 625 patients enrolled, 591 completed the study. The mean age of the patients was 46.7 years. The proportion of male patients was 54.1%. Overall, 57% of patients had no treatment delays, while 43% experienced delays of ≥3 months. Patients with treatment delays of ≥3 months used alternative/traditional medicines (56.0%), with Ayurveda being preferred by 56.7% of these patients.

Conclusion: The study indicated considerable treatment delays among drug-naïve patients in India.

Journal of The Association of Physicians of India (2025): 10.59556/japi.73.1120

Introduction

Diabetes mellitus is a global epidemic that affects individuals regardless of age, gender, or geographic location. The International Diabetes Federation (IDF) Diabetes Atlas (2021) reports that 537 million adults (20–79 years) are living with diabetes, that is, 10.5% have diabetes, with almost half unaware that they are living with the condition. This number is predicted to rise to 643 million by 2030 and 783 million by 2045. According to the Indian Council of Medical Research–India Diabetes (ICMR-INDIAB) study published in 2023, the prevalence of diabetes in India is 101 million.[1]

Another global concern is the persistently increasing proportion of individuals with undiagnosed type 2 diabetes mellitus (T2DM). The IDF estimates that worldwide, almost half are unaware that they are living with diabetes. In India, the prevalence of diabetes in India is 11.4%, and the prevalence of prediabetes is 15.3% of the population. Alarmingly, approximately 39.4 million adults with diabetes in India are estimated to be undiagnosed, accounting for about 53.1% of cases.[2] According to the National Family Health Survey (NFHS-5, 2019–2021), the prevalence of diabetes among individuals aged 15–49 years was 4.90%. Among them, 24.82% were estimated to have undiagnosed diabetes, with a higher prevalence among males (28.82%) than females (24.22%).

In developing countries like India, the increasing incidence of diabetic complications can primarily be attributed to delays in diagnosing diabetes and its complications, comorbidities, inadequate healthcare systems, and the high costs of medications, resulting in poor control of the disease.[3] This is additionally compounded by delays in treatment, which are particularly concerning as they hasten the progression of diabetes and its associated complications, such as cardiovascular disease, neuropathy, and nephropathy. Research indicates that timely interventions are crucial for preventing these complications and that failure to manage blood glucose levels effectively can significantly increase the risk of adverse outcomes, thereby impacting patients' quality of life and placing a greater burden on healthcare systems.[4,5]

In India, factors, such as limited access to healthcare, especially in rural areas, and the financial burden of diabetes management can contribute to delayed treatment.[6] Many patients delay seeking care due to the costs of medications, consultations, and follow-up appointments, leading to inadequate disease control. Furthermore, delays in initiating appropriate treatment regimens, including insulin therapy, can exacerbate complications, making them more difficult to manage over time.[7] These delays are compounded by a lack of awareness and education about the importance of early treatment among both patients and healthcare providers. A significant portion of diabetic patients, ranging from 25 to 57%, report using complementary and alternative medicine (CAM) alongside or instead of conventional treatments.[8] Social media platforms have become vital in shaping health-related decisions among patients. Many individuals turn to social media for peer support and information about diabetes management, which can sometimes lead to an increased reliance on alternate medicine. Influencers often promote alternative remedies without

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How to cite this article: Patil S, Saboo B, Bagri SA, *et al.* Incidence of Treatment Delays among Patients with Diabetes: A Clinic-based Cross-sectional Descriptive Study in India. J Assoc Physicians India 2025;73(9):e15–e20.

sufficient clinical backing, potentially swaying patients away from evidence-based treatments. This reliance on influencers can create a false sense of security, regarding the efficacy and safety of alternative therapies. Despite the widespread prevalence of T2DM in India, to our knowledge, there is no evidence of the incidence of treatment delays among drug-naïve patients.

The primary objective of this study is to ascertain the incidence of delaying treatment and profile of drug-naïve patients. Understand the alternate treatments sought since diagnosis. This evidence can highlight potential gaps in the healthcare system, including access to healthcare facilities, awareness of diabetes symptoms and management, and strategies to reduce long-term complications, ultimately improving patient's outcomes and quality of life. This study aims to bring forth new data and evidence quantifying the gap between diagnosis and treatment initiation among patients with diabetes in the Indian context.

Materials and Methods

Study Design and Population

This was a prospective, multicentric, cross-sectional study conducted at 17 study sites in India. The study was conducted over 6 months, from October 2023 to April 2024. The study participants were enrolled in primary and secondary care settings in Mumbai.

Participants eligible for inclusion are adults aged 18 years or older who have been diagnosed with T2DM, as defined by the Research Society for the Study of Diabetes in India (RSSDI) 2022 guidelines. These guidelines specify diagnosis through one or more of the following criteria: fasting plasma glucose (FPG) ≥126 mg/dL, 2-hour plasma glucose (2-h PG) ≥200 mg/dL during a 75-gm oral glucose tolerance test (OGTT), glycated hemoglobin (HbA1c) ≥6.5%, or random plasma glucose ≥200 mg/dL. Additionally, eligible participants must be drug-naïve, meaning they have received no previous pharmacological treatment for diabetes, including allopathic medicines. Participants must also provide informed consent to be included. Individuals younger than 18 years or those diagnosed with other types of diabetes, such as type 1 diabetes mellitus (T1DM), gestational diabetes mellitus (GDM), or maturity-onset diabetes of the young (MODY), are excluded from participation.

Sampling

All eligible individuals who met the inclusion criteria and visited the study site for routine care during the recruitment period, providing informed consent, were included. The recruitment phase identified 625 subjects, with 591 meeting all the inclusion criteria for the final analysis. As the study focused on a predefined patient cohort, calculations for sample size were deemed unnecessary.

Data Collection Instrument and Variables

A specialized case record form, MEDEVA eCRF (electronic Case Report Form), was created to capture demographic details, comorbidities, current medications, medical history, and attitudes. All information is captured as part of routine care. The treatment delay variable was defined as the time between the first recorded diabetes diagnosis and the initiation of medication. According to a study by Zheng et al., patients who initiated oral antidiabetic drugs (OADs) within 3 months of diagnosis experienced better clinical outcomes. This study classified medication initiation beyond 3 months as a treatment delay.[9]

Informed Consent and Ethics Approval

The study received approval from the Ethics Committee (Registration number ECR/1300/Inst/UP/2019 dated September 7, 2023). The study protocol was explained, and written informed consent was obtained from all the participants before they were recruited into the study. Physicians maintained confidentiality in accordance with their agreements, and patient data was anonymized using unique identifiers assigned to each physician. Data usage was restricted solely to this study, with any further use contingent on additional written permission to protect privacy and uphold ethical standards.

Statistical Analysis

The collected data underwent aggregate-level analysis (deidentified with respect to patient or site) using Python software. Categorical data was presented as frequencies and proportions, with statistical significance assessed using the Chi-squared test. Continuous variables were described by means and standard deviations (SDs). Analysis of variance (ANOVA) was utilized to compare mean differences among groups. Statistical analyses and visualizations were performed using Microsoft Office. Significance was determined using standard hypothesis testing with a threshold of a p-value < 0.05. All tests adhered to methodological guidelines to ensure the validity and reliability of the study's conclusion.

Results

Sample Profile

A total of 625 subjects were enrolled, of whom 34 were excluded due to missing data. The final sample size of the study was 591 patients. Detailed demographic characteristics of all the subjects are presented in Table 1. The mean age of the subjects is 46.7 years. The proportion of males is 54.1%, while females comprise 45.9% of the study population. Grade III obesity is prevalent among 38.3% of patients, and grade IV among 14.7%. Hypertension was the highest reported comorbidity, with a prevalence of 28.8%. Overall, 33% of subjects have at least one comorbidity (Table 1).

Incidence of Delay

Figure 1 illustrates the incidence of treatment delays following the diagnosis of T2DM. A delay in treatment has been defined as a gap of ≥3 months between the diagnosis and treatment for T2DM. Overall, 57.4% of patients sought treatment within 3 months of diagnosis, and 42.6% delayed the treatment by ≥3 months (17.1% delayed by 3–6 months, 12.4% by 6–11 months, and 13.2% by ≥12 months).

The incidence of delay has been analyzed by cohorts and is presented in Table 2. No differences were observed among age-groups, gender, body mass index (BMI), or blood pressure groups.

Delay Period—What Did They Do in the Interim Period and Impact of Delay on Glycemic Levels?

During the period between diagnosis and the initiation of therapy, 56.0% of participants sought alternative or traditional medicine as a remedy, while 32.9% adopted only lifestyle and dietary modifications, and 11.1% did not pursue any interventions. Among those who utilized alternative

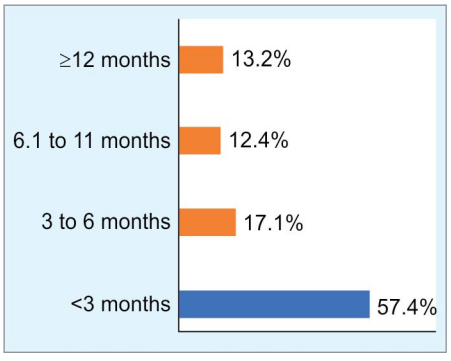

Fig. 1: Gap in months between diagnosis and start of treatment

Table 1: Demographic characteristics of patients

Parameters	*No. of patients*
Age (years), mean (SD)	46.7 (12.4)
Age-group (years), *n* (%)	*N* = 591
18–40	214 (36.2)
41–50	164 (27.7)
Above 50	213 (36.0)
Gender	*N* = 591
Male	320 (54.1)
Female	271 (45.9)
BMI (kg/m^2), mean (SD)	28.7 (10.6)
BMI (kg/m^2), *n* (%)	*N* = 551
Underweight (<18.5)	7 (1.3)
Normal weight (18.5–24.9)	133 (24.1)
Overweight (25–29.9)	258 (46.8)
Obesity (≥30)	153 (27.8)
Blood pressure (mm Hg) *n* (%)	*N* = 590
Optimal (SBP <130 and DBP <85)	230 (39.0)
High normal (SBP: 130–139 or DBP: 85–89)	139 (23.6)
Grade I hypertension (SBP: 140–159 or DBP: 90–99)	164 (27.8)
Grade II hypertension (SBP ≥160 and DBP ≥100)	57 (9.7)
Comorbidities, *n* (%)	*N* = 503
At least one comorbid condition	198 (39.4)
Hypertension	145 (28.8)
Hypothyroidism	35 (7.0)
History of stroke	12 (2.4)
CVD/IHD	11 (2.2)

Data presented as *n* (%) unless otherwise specified; BMI, body mass index; BP, blood pressure; CKD, chronic kidney disease; CVD, cardiovascular disease; DBP, diastolic blood pressure; IHD, ischemic heart disease; SBP, systolic blood pressure; SD, standard deviation; T2DM, type 2 diabetes mellitus; BMI World Health Organization (WHO) classification underweight (chronic energy deficiency): BMI <18.5, normal weight: BMI 18.5–24.9, overweight: BMI 25–29.9, obesity: BMI ≥ 30; The Indian Society of Hypertension (InSH) consensus guidelines 2023 classification: Optimal BP: SBP <130 mm Hg and DBP <85 mm Hg; high normal BP: SBP 130–139 mm Hg/DBP 85–89 mm Hg; grade I hypertension: SBP 140–159 mm Hg/DBP 90–99 mm Hg; grade II hypertension: SBP ≥160 mm Hg, and DBP ≥100 mm Hg

medicine, Ayurveda was the preferred modality (56.7%), followed by homeopathy (24.1%). Notably, more than half of the individuals who tried alternative medicine (47.5%) did not consult a certified medical practitioner. Instead, the majority (80.5%) relied on advice from family or friends, while the remainder conducted independent research, primarily through internet sources (Table 3).

The average HbA1c at the start of treatment is 9.3% (SD 2.3%). There is no significant difference between the group that delayed treatment by >3 months and the group that did not delay the start of treatment. There is a significant difference in HbA1c levels among subjects who "did nothing" (HbA1c 9.1%), those who tried only lifestyle and diet changes/interventions (HbA1c 8.3%), and those who tried alternative/traditional medicine (HbA1c 10.0%) ($p < 0.001$) (Fig. 2).

Reasons for the Delay in Seeking Allopathic Treatment and Reasons for Nondelay

The reasons cited for not wanting to start allopathy are the perception that it needs to be taken lifelong (58.7%), has side effects (40.1%), and that it is not effective (24%). Among subjects who did not try alternative or traditional medicine, the main reasons cited are that allopathy is more effective (35.2%) and that family and friends advised it is better (35.2%). A total of 73.1% of subjects are unwilling to use Ayurvedic/other traditional medications alongside allopathy treatment for diabetes management (Table 4).

Discussion

The timely initiation of diabetes treatment during the early stages of the disease is crucial for preventing disease progression and preserving pancreatic β-cell function. Improved glycemic control, evidenced by reductions in HbA1c, is critical in minimizing the risk of complications. Each 1% reduction in HbA1c is associated with significantly better long-term outcomes for patients, demonstrating a continuous benefit without a discernible threshold effect.[10] Treatment delay hastens disease progression, increases the risk of complications (both microvascular and macrovascular), worsens symptoms, hinders patients from achieving glycemic control, increases the risk of hospitalization, and can lead to early mortality.[11] The concept of metabolic memory emphasizes the importance of early and adequate blood glucose control, as studies have demonstrated that microcirculatory changes induced by hyperglycemia can be partially reversed with prompt intervention.[12] Given the increasing burden of diabetes, addressing delays in treatment initiation should be a priority for improving outcomes.

In the present study, 42.6% of the individuals have delayed the treatment by ≥3 months. People with comorbidities (hypertension, obesity, etc.) were more likely to experience treatment delays. This may suggest that managing multiple comorbidities along with diabetes may require multiple hospital visits, extensive care, and monitoring, along with financial burdens, which may have contributed to the delay. Among those who delayed treatment, 56% opted for alternative or traditional medicine, specifically Ayurveda (58.4%) and homeopathy (24.8%), while 32.9% chose diet and lifestyle modifications. The reliance on nonallopathic treatments may have contributed to further delay in initiating diabetes management.

The average HbA1c at baseline was 9.3% in individuals who delayed treatment for ≥3 months and in whom treatment was started early. Both groups experienced poor glycemic control prior to starting therapy, underscoring the importance of early screening, timely intervention, and enhanced patient education. Among individuals who delayed treatment, people who relied on lifestyle and dietary modifications had an HbA1c of 8.5%, and those on alternative medicine had 9.9%. This suggests some degree of benefit from nonpharmacological interventions for glycemic control. High HbA1c in individuals on alternative medicine might be due to the use of unverified local remedies that lack evidence and reliance on unqualified and uncertified practitioners.

Table 2: Incidence of patients with treatment delays of ≥3 months

Parameters	*Overall*	*Patients with treatment delays of ≥3 months*	*Incidence (%)*	*p-value*
N	591	252	43	
Age (years), mean (SD)	46.7 (12.4)	47.3 (12.2)	–	0.334
Age-group (years)				
18–40	214	81	38	0.104
41–50	164	80	49	
Above 50	213	91	43	
Gender				
Male	320	137	43	0.993
Female	271	115	42	
BMI (kg/m^2)				
Underweight (<18.5)**	7	3	43	0.14
Normal weight (18.5–24.9)	133	68	51	
Overweight (25–29.9)	258	107	42	
Obesity (≥30)	153	58	38	
Blood pressure				
Optimal (SBP <130 and DBP <85)	230	98	43	0.417
High normal (SBP: 130–139 or DBP 85–89)	139	53	38	
Grade I hypertension (SBP: 140–159 or DBP: 90–99)	164	72	44	
Grade II hypertension (SBP ≥160 and DBP ≥100)	57	29	51	
Comorbidities				
Anyone comorbid condition	198	109	55	<0.001
None	305	100	33	
HbA1c groupings				
<7%	84	24	29	
7–9%	223	105	47	<.001
>9%	277	122	44	

**Small sample size; Data presented as *n*, unless otherwise specified; BMI, body mass index; BP, blood pressure; CVD, cardiovascular disease; DBP, diastolic blood pressure; IHD, ischemic heart disease; SBP, systolic blood pressure; SD, standard deviation; T2DM, type 2 diabetes mellitus; BMI WHO classification underweight (chronic energy deficiency): BMI <18.5, normal weight: BMI 18.5–24.9, overweight: BMI 25–29.9, obesity: BMI ≥ 30; The InSH consensus guidelines 2023 classification: Optimal BP: SBP <130 mm Hg and DBP <85 mm Hg; high normal BP: SBP 130–139 mm Hg/DBP 85–89 mm Hg; grade I hypertension: SBP 140–159 mm Hg/DBP 90–99 mm Hg; grade II hypertension: SBP ≥160 mm Hg and DBP ≥100 mm Hg

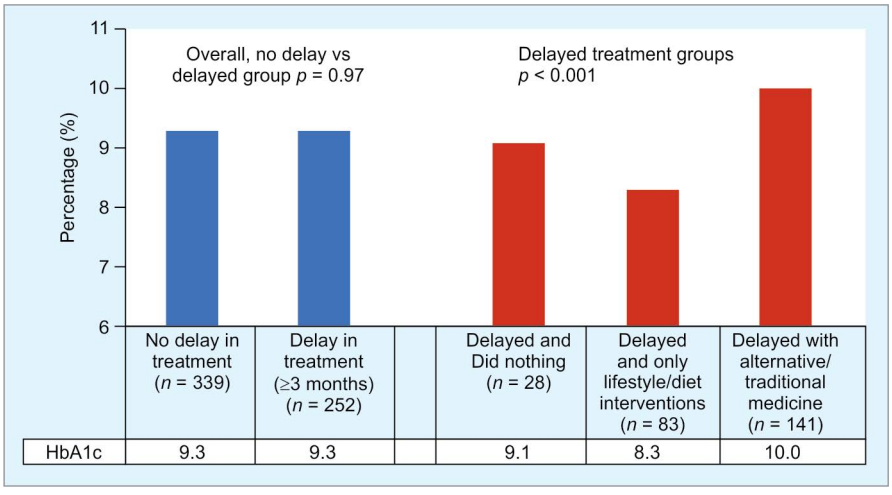

Fig. 2: HbA1c at the start of treatment

Individuals delayed management of diabetes due to misconceptions and concerns about its long-term implications. The belief that allopathy requires lifelong medication (58.7%), fears of side effects (40.1%), and doubts about its effectiveness (24%) indicate a lack of awareness and misinformation about evidence-based diabetes management. According to a study by Patil et al., the most common misconceptions include "diabetes can be cured by herbal treatment" and "the treatment should be stopped if the diabetes is controlled for a few months.[13] Another study conducted in five cities across India reported that 87.4% of individuals believed that management with allopathic medication should be initiated within 3 months of diagnosis, 69.6% believed that medication should be continued lifelong, and 67.3% believed that Ayurvedic medicine does not cure diabetes.[14]

The present study emphasizes upon the importance of early detection and timely intervention in diabetes management to reduce complications. Identifying high-risk individuals and addressing treatment delays can significantly improve health outcomes. Community-based initiatives and targeted awareness programs can play

Table 3: Understanding behavior—among those who delayed treatment

Question with response	*Overall*
Can you remember the most recent alternative treatment you took before coming to me?	*N* = 252
Only lifestyle and diet changes/ interventions	83 (32.9)
Alternative/traditional medicine	141 (56.0)
None	28 (11.1)
What type of medicine was it?	*N* = 141
Ayurvedic	80 (56.7)
Unani	6 (4.3)
Homeopathy	34 (24.1)
Home made	17 (12.1)
No response	4 (2.8)
Have you consulted a certified doctor about this medication?	*N* = 141
Yes	50 (35.5)
No	67 (47.5)
Not aware/no response	24 (17.0)
Source of recommendation/advice (among those who did not consult a certified doctor)?	*N* = 67
Family	28 (41.7)
Friends	26 (38.8)
Self-search from internet	10 (14.9)

Table 4: Reasons for the delay in seeking allopathic treatment and reasons for not delaying

Question with response	*Overall*
What were your reasons for not wanting to start allopathy/modern medicine?	*N* = 242
Needs to take lifelong	142 (58.7)
Has serious side effects	97 (40.1)
Does not cure/not effective	58 (24.0)
Is expensive	45 (18.6)
My family members/friends tell me not to trust	40 (16.5)
My doctor told me no need for medicines	28 (11.6)
Took for some time and stopped	5 (2%)
None	36 (14.9)
What was your reason for starting with allopathy/modern medicine and not trying traditional medicines?	*N* = 250
My family members/friends advised that it is better	88 (35.2)
Allopathy is more effective	88 (35.2)
I know people who have tried traditional medicines and it was ineffective	35 (14.0)
Sugars did not get controlled	10 (4.0)
None	45 (18.0)
Would you also take Ayurvedic/other traditional medications along with allopathy medicines?	*N* = 249
No	182 (73.1)
Yes, maybe	57 (22.9)
Yes, definitely	10 (4.0)

a crucial role in educating individuals about the benefits of initiating early treatment. Implementing structured screening and intervention strategies can help bridge the gap between diagnosis and treatment, improving long-term diabetes control. The primary strength of the study lies in presenting new evidence on the incidence of treatment delays among individuals with T2DM in India. The study's exclusive focus on healthcare settings within Mumbai may limit its generalizability to the broader Indian population, as extending the research to tier 2 and tier 3 cities, as well as rural areas, could reveal even more concerning figures regarding treatment delays and diabetes management. Reliance on patient-reported data introduces the possibility of bias or inaccuracies, further emphasizing the need for larger, more diverse studies to validate these findings.

Conclusion

Delayed treatment not only affects individual health outcomes but also places an additional strain on healthcare infrastructure, consuming resources that could be better utilized with timely interventions. To address this, large-scale mass media education campaigns should be prioritized, focusing not only on diabetes detection but also on the importance of early intervention postdiagnosis. Strengthening community-based programs, enhancing accessibility to evidence-based treatments, and dispelling misconceptions about allopathic medicine are crucial steps toward reducing treatment delays and improving long-term diabetes management.

Acknowledgment

The authors acknowledge Rama Regulla, Raghunath Dantu, Insha Nissar, Karthikayan Visvanathan, and Naveen Kumar Thattepalli from MEDEVA (www.medeva.io) for their support with data management, analysis, and manuscript editorial assistance.

Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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