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Original Research Article

CLINICAL INERTIA IN THE MANAGEMENT OF TYPE 2 DIABETES MELLITUS AND ITS ASSOCIATION WITH GLYCAEMIC CONTROL AT A TERTIARY-CARE CENTRE IN WESTERN INDIA

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Abstract: ***Background:*** Type 2 diabetes mellitus (T2DM) requires timely initiation and intensification of pharmacological therapy to achieve recommended glycaemic targets. Despite the availability of multiple glucose-lowering agents and evidence-based treatment guidelines, a large proportion of patients remain inadequately controlled. Clinical inertia—defined as the failure to initiate or intensify therapy when indicated—has been recognised as a major contributor to prolonged hyperglycaemia. However, data on the magnitude and determinants of clinical inertia from Indian tertiary-care settings remain limited. ***Objectives*** To estimate the prevalence of clinical inertia among patients with T2DM attending a tertiary-care outpatient department, to assess its association with glycaemic control, and to identify patient- and system-related factors associated with clinical inertia. ***Methods*** A hospital-based cross-sectional observational study was conducted over six months from January to June 2019 among adults with T2DM receiving pharmacological treatment for at least six months. Data were obtained from medical records and supplemented by structured patient interviews. Clinical inertia was defined as HbA1c >7.0% with no treatment intensification for at least three months despite a minimum of two outpatient visits during the preceding six months. Associations were analysed using chi-square test, independent t-test, and multivariable logistic regression. ***Results*** Among 170 participants (mean age 55.8 ± 10.6 years; 54.1% female), poor glycaemic control (HbA1c >7.0%) was observed in 68.2%. Clinical inertia was identified in 57.1% (95% CI: 49.5–64.5). Mean HbA1c was significantly higher among patients with clinical inertia compared with those without inertia (9.1 ± 1.4% vs. 7.8 ± 1.1%; p <0.001). On multivariable analysis, diabetes duration ≥10 years (AOR 2.4; 95% CI: 1.2–4.9), poor medication adherence (AOR 3.1; 95% CI: 1.5–6.3), ≤2 outpatient visits in six months (AOR 2.7; 95% CI: 1.3–5.4), and treatment with oral hypoglycaemic agent (OHA) monotherapy (AOR 2.2; 95% CI: 1.1–4.3) were independently associated with clinical inertia. Frequently reported barriers included fear of hypoglycaemia, cost-related concerns, reluctance towards injections, and limited awareness regarding diabetes-related complications. ***Conclusion*** Clinical inertia was highly prevalent in this tertiary-care setting and was strongly associated with suboptimal glycaemic control. Interventions focusing on improving medication adherence, ensuring regular follow-up, strengthening patient education, and implementing protocol-driven treatment intensification may help reduce therapeutic delays in routine T2DM care.

Keywords: Type 2 diabetes mellitus; Clinical inertia; Glycaemic control; Therapeutic intensification; Treatment adherence

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterised by persistent hyperglycaemia and represents a major contributor to global morbidity and mortality. In India, the growing burden of T2DM poses substantial challenges to healthcare systems, particularly with respect to long-term complication prevention. Achieving and maintaining optimal glycaemic control remains central to reducing the risk of microvascular and macrovascular complications, improving quality of life, and lowering healthcare costs.

Over the past two decades, the therapeutic landscape of T2DM has expanded considerably, with multiple oral and injectable glucose-lowering agents and clearly articulated clinical guidelines recommending timely and stepwise intensification of therapy when glycaemic targets are not achieved. Despite these advances, a substantial proportion of patients continue to have HbA1c values above recommended thresholds. This persistent gap between evidence-based recommendations and real-world practice has been partly attributed to clinical inertia.

Clinical inertia refers to the failure to initiate or intensify therapy when treatment goals are unmet or the continuation of inadequate therapy despite recognised poor glycaemic control. It may manifest at various stages of diabetes management, including delayed dose escalation, failure to add combination therapy, or postponement of injectable therapy initiation. Prolonged exposure to uncontrolled hyperglycaemia due to such delays has been associated with increased risk of diabetes-related complications and long-term adverse outcomes.

While clinical inertia has been widely studied in high-income countries, evidence from low- and middle-income settings, including India, remains limited. Tertiary-care centres frequently manage patients with longer disease duration, multiple comorbidities, and complex treatment regimens, making them particularly susceptible to therapeutic inertia. Understanding the prevalence and determinants of clinical inertia in this context is essential for informing targeted interventions.

It is also important to acknowledge that not all instances of non-intensification represent inappropriate care. Factors such as patient refusal, high risk of hypoglycaemia, limited life expectancy, or competing comorbidities may justify delayed escalation. However, distinguishing clinically appropriate inaction from true inertia in routine outpatient practice is challenging, particularly in cross-sectional studies. Within these constraints, the present study aimed to assess the magnitude of clinical inertia and its association with glycaemic control in a tertiary-care outpatient setting in Western India.

Aim

To determine the prevalence of clinical inertia in the management of type 2 diabetes mellitus and to assess its association with glycaemic control among patients attending a tertiary-care outpatient department.

Objectives

1. To estimate the prevalence of clinical inertia among patients with type 2 diabetes mellitus.
2. To assess the association between clinical inertia and glycaemic control as measured by HbA1c.
3. To identify patient- and system-related factors associated with clinical inertia.
4. To describe treatment patterns and intensification practices among patients with suboptimal glycaemic control.

METHODOLOGY

Study design and setting: A hospital-based cross-sectional observational study was conducted in the General Medicine Outpatient Department of Dr. N.D. Desai Medical College and Research Institute, Dharmasinh Desai University, Nadiad, Gujarat, India.

Study period: The study was conducted over a period of six months from January to June 2019.

Study population: Adult patients (≥18 years) with a documented diagnosis of T2DM attending the outpatient department and receiving pharmacological treatment for at least six months were eligible for inclusion.

Inclusion criteria

• Diagnosed cases of type 2 diabetes mellitus
• On pharmacological treatment for ≥6 months
• At least one HbA1c value recorded within the preceding six months

Exclusion criteria

• Type 1 diabetes mellitus, gestational diabetes, or steroid-induced diabetes
• Critically ill patients or those unable to participate
• Incomplete or missing medical records

Operational definitions

Poor glycaemic control: HbA1c >7.0%.
Clinical inertia: Defined by the presence of all the following criteria:

1. HbA1c >7.0%

2. No intensification of pharmacological therapy (no dose escalation, addition of another agent, or change in drug class) for at least three months
3. At least two outpatient visits within the preceding six months

Good glycaemic control: Good control was defined as **HbA1c ≤ 7.0%**.
The three-month threshold was selected because HbA1c reflects average glycaemic exposure over approximately 8–12 weeks, and this duration allows adequate time for clinicians to review results and consider therapy intensification. This operational definition was used to identify potential clinical inertia, recognising that some cases may represent clinically justified non-intensification.

Medication adherence: Assessed by self-report during patient interview. Patients were asked about missed doses over the preceding week and month. Adherence was categorised as poor if the patient reported missing medications on ≥3 days in the previous week or ≥7 days in the previous month.

Sample size and sampling technique
Assuming a prevalence of clinical inertia of 50%, with 95% confidence and an absolute precision of 8%, the minimum required sample size was calculated as 156. This was rounded up to 156 to account for possible non-response. After accounting for incomplete records, a total of 170 patients were included. Eligible participants were selected using systematic random sampling from the outpatient attendance register.

Data collection
Data were collected using a structured, literature-based pro forma developed from previously published tools on clinical inertia. The medical records of each eligible participant were reviewed, and information on age, sex, duration of diabetes, HbA 1 c values from the preceding six months, pharmacologic therapy details (drug class, dose, and any changes), number of OPD visits, and documented complications (retinopathy, nephropathy, neuropathy, or cardiovascular disease) was extracted. In addition to the record review, a brief patient interview was conducted to assess medication adherence, lifestyle practices related to diet and physical activity, and perceived barriers to treatment intensification, including fear of hypoglycemia, cost concerns, needle aversion, or lack of understanding. These barriers were adapted from validated frameworks describing patient-, clinician-, and system- level contributors to clinical inertia.

Each participant was classified as having clinical inertia or not based on predefined operational criteria, and the prevalence of clinical inertia was calculated as the proportion of patients who met these criteria. To examine the relationship between clinical inertia and glycemic control, participants were grouped into those with and without clinical inertia, and comparisons were made between the two groups. Mean HbA 1 c values and the proportion of patients with poor glycemic control were compared using the independent t- test and chi- square test, respectively, following analytical approaches described in earlier studies on clinical inertia.

To identify predictors of clinical inertia, potential determinants such as age, sex, body mass index, duration of diabetes, medication adherence, number of OPD visits, type of treatment (oral agents versus insulin), and the presence of complications were examined. An initial bivariate analysis was performed, and variables with a p- value less than 0.20 were included in a binary logistic regression model to determine independent predictors of clinical inertia. Treatment patterns and intensification practices were also evaluated by reviewing prescription histories to document baseline regimens, dose escalation events, addition or switching of antidiabetic drugs, and delays in treatment intensification. These patterns, along with reported barriers, were summarized using frequencies and percentages.

Statistical analysis
Data was entered into Microsoft Excel and analysed using SPSS version 26. Continuous variables were summarised as mean ± standard deviation or median (interquartile range), while categorical variables were expressed as frequencies and percentages. Associations were assessed using independent t-test and chi-square test. Variables with p <0.20 on bivariate analysis were entered into a multivariable logistic regression model to identify independent predictors of clinical inertia. Multicollinearity was assessed using variance inflation factor prior to model entry and was not found to be significant. Model fit was evaluated using the Hosmer–Lemeshow goodness-of-fit test. A p-value <0.05 was considered statistically significant.

Ethical considerations
Ethical approval was obtained from the Institutional Ethics Committee. Written informed consent was obtained from all participants, and confidentiality was ensured by anonymising all collected data.

RESULTS

Table 1. Baseline characteristics of study participants (n = 170)

Variable	Category / Statistic	Value
Age (years)	Mean ± SD	55.8 ± 10.6
Sex	Male	78 (45.9%)
	Female	92 (54.1%)
Duration of diabetes (years)	Median (IQR)	7 (4–11)
Body Mass Index (kg/m²)	Mean ± SD	27.2 ± 4.6
HbA1c (%)	Mean ± SD	8.6 ± 1.6
Poor glycaemic control (HbA1c > 7%)	n (%)	116 (68.2%)
Treatment regimen	OHA monotherapy	74 (43.5%)
	Combination OHA	63 (37.1%)
	Insulin ± OHA	33 (19.4%)
Presence of any diabetes complication	n (%)	59 (34.7%)

A total of 170 patients with type 2 diabetes mellitus were included in the analysis. The mean age of participants was 55.8 ± 10.6 years, with females constituting 54.1% of the study population. The median duration of diabetes was 7 years (interquartile range: 4–11 years). The mean body mass index was 27.2 ± 4.6 kg/m². The mean HbA1c was 8.6 ± 1.6%, and 116 participants (68.2%) had poor glycaemic control. With respect to treatment patterns, 43.5% were receiving OHA monotherapy, 37.1% were on combination oral therapy, and 19.4% were receiving insulin with or without oral agents. Diabetes-related complications were documented in 34.7% of participants.

Table 2. Prevalence of clinical inertia among participants

Variable	n (%)
Clinical inertia present	97 (57.1)
Clinical inertia absent	73 (42.9)
Total	170 (100)

Clinical inertia was identified in 97 of 170 participants, yielding a prevalence of 57.1% (95% CI: 49.5–64.5). The remaining 73 participants (42.9%) did not meet the criteria for clinical inertia.

Table 3. Glycaemic control in relation to clinical inertia

Parameter	Clinical inertia (n=97)	No inertia (n=73)	p-value
Mean HbA1c (%)	9.1 ± 1.4	7.8 ± 1.1	<0.001
Poor control (HbA1c >7%), n (%)	94 (96.9)	22 (30.1)	<0.001

Participants with clinical inertia had significantly higher mean HbA1c compared with those without clinical inertia (9.1 ± 1.4% vs. 7.8 ± 1.1%; p <0.001). Additionally, poor glycaemic control was observed in 96.9% of participants with clinical inertia compared with 30.1% among those without inertia (p <0.001).

Table 4. Factors associated with clinical inertia (bivariate analysis)

Factor	Inertia present (n=97)	No inertia (n=73)	p-value
Duration ≥10 years	46 (47.4)	19 (26.0)	0.005
Poor adherence	41 (42.3)	14 (19.2)	0.002
≤2 OPD visits (6 months)	52 (53.6)	21 (28.8)	0.001
OHA monotherapy	50 (51.5)	24 (32.9)	0.016
Presence of complications	39 (40.2)	20 (27.4)	0.093

On bivariate analysis, clinical inertia was significantly associated with diabetes duration ≥10 years, poor medication adherence, fewer outpatient visits (≤2 visits in six months), and treatment with OHA monotherapy. After adjustment in multivariable logistic regression, diabetes duration ≥10 years, poor medication adherence, limited outpatient follow-up, and OHA monotherapy remained independently associated with clinical inertia.

Table 5. Multivariable logistic regression for predictors of clinical inertia

Predictor	Adjusted OR	95% CI	p-value
Duration ≥10 years	**2.4**	1.2–4.9	0.014
Poor adherence	**3.1**	1.5–6.3	0.002
≤2 OPD visits	**2.7**	1.3–5.4	0.007
OHA monotherapy	**2.2**	1.1–4.3	0.021

After adjustment for other variables, four factors remained independently associated with clinical inertia. Patients with diabetes duration ≥10 years had 2.4 times higher odds of experiencing clinical inertia (AOR 2.4; 95% CI 1.2–

4.9; p = 0.014). Poor medication adherence was strongly associated with affected patients having three-fold higher odds (AOR 3.1; 95% CI 1.5–6.3; p = 0.002)

Patients with ≤2 OPD visits in six months (AOR 2.7; 95% CI 1.3–5.4; p = 0.007) and those maintained on oral monotherapy (AOR 2.2; 95% CI 1.1–4.3; p = 0.021) were significantly more likely to experience clinical inertia.

Table 6. Barriers to treatment intensification among patients with poor glycaemic control

Variable	n (%)
Dose escalation performed when indicated	41 (24.1)
Addition of a second oral agent	36 (21.2)
Initiation of insulin when indicated	18 (10.6)
No change in therapy despite poor control (clinical inertia)	**97 (57.1)**
Common barriers	
Fear of hypoglycaemia	61 (35.9)
Cost concerns	48 (28.2)
Needle phobia	44 (25.9)
Lack of awareness	39 (22.9)
Physician "wait-and-watch" approach	28 (16.5)

Among participants with poor glycaemic control, dose escalation was documented in 24.1%, addition of a second oral agent in 21.2%, and initiation of insulin in 10.6%. In contrast, 57.1% experienced no change in therapy despite HbA1c values above target. Frequently reported barriers included fear of hypoglycaemia (35.9%), cost concerns (28.2%), reluctance towards injections (25.9%), and limited awareness regarding complications (22.9%). A clinician-related "wait-and-watch" approach was documented in 16.5% of cases.

DISCUSSION

The baseline characteristics of the study population showed a middle-aged cohort with long-standing diabetes, high prevalence of overweight/obesity, and suboptimal glycaemic control (mean HbA1c 8.6%; poor control in 68.2%). This pattern is consistent with hospital-based cohorts from Bosnia, Malaysia and South Africa, where mean ages were in the mid-50s, median diabetes duration was 6–10 years, and 60–80% of patients had HbA1c above target(6)(8)(9). The burden of documented complications in our study (34.7%) was also comparable to reports that link long disease duration and inadequate control with higher micro- and macrovascular complication rates(2)(10).

The prevalence of clinical inertia in our study (57.1%) fell within the mid-range of values summarised in recent reviews, where estimates typically vary between about 30% and 70%, depending on setting, definition and stage of therapy.(11)(2) For example, Marjanovic et al. reported clinical inertia in 55–60% of type 2 diabetes patients in Central Bosnia primary care, while Malaysian clinic data showed delayed intensification in over half of patients with HbA1c ≥7%.(6)(8)In contrast, an Ethiopian hospital study found a lower prevalence (about 31%), and some European datasets report rates closer to 20–30%, possibly reflecting better-structured diabetes services and more aggressive guideline implementation(12). Overall, our findings indicate that clinical inertia represents a substantial gap in care in this tertiary-care context.

The strong association observed between clinical inertia and poor glycaemic control in our data—higher mean HbA1c (9.1% vs 7.8%) and a much larger proportion with HbA1c >7% in the inertia group—echoes the relationship described in multiple observational studies. Reach et al. and others have reported that patients experiencing therapeutic inertia remain at elevated HbA1c for prolonged periods, often several years, with clear implications for long-term complications(13). A Colombian and a Thai cohort similarly showed that clinical inertia was associated with persistently poorer glycaemic control, reinforcing the concept that timely intensification is crucial to avoid chronic exposure to hyperglycaemia(14)(15). Our results therefore support the existing evidence that clinical inertia is not just common but clinically meaningful.

Several factors were associated with clinical inertia on bivariate analysis in our study, notably longer duration of diabetes, poor adherence, fewer OPD visits and oral monotherapy. Duration of diabetes and markers of more complex disease have also emerged as important correlates in Central Bosnia, Ethiopia and multi-country datasets, where patients with longer duration appear more likely to "settle" into chronically poor control without appropriate intensification. Poor adherence has been repeatedly linked with higher rates of inertia, possibly because clinicians hesitate to change therapy when they perceive non-compliance rather than treatment failure. Reduced visit frequency in our cohort mirrors findings from Malaysian and UK studies, where less frequent contact with services was associated with

longer delays before treatment escalation.(6)(12).

On multivariable analysis, diabetes duration ≥10 years, poor adherence, ≤2 OPD visits, and oral monotherapy remained independent predictors of clinical inertia. Similar multivariable models have highlighted adherence and treatment intensity as key determinants: Dagnew et al. found that poor adherence and a higher number of medications predicted inertia in Ethiopia, while Shabnam et al. reported that treatment regimen characteristics and clinical profile were associated with inertia in a specialist cohort(12)(16). Reviews by Khunti and colleagues emphasise that inertia may occur at every stage of escalation from first oral agent to insulin and is shaped by both patient behaviour and clinician decision-making(2). In this context, our findings suggest that patients with long-standing disease who remain on simple oral regimens and attend clinic infrequently are particularly vulnerable to persisting in poor control.

Treatment-intensification practices in our study showed that only a minority underwent dose escalation, addition of a second agent, or insulin initiation, whereas more than half had no change despite inadequate control. Comparable delays, often lasting years have been documented in cohorts from South Africa, Malaysia, and several European settings(11)(15). Patient-reported barriers in our study, including fear of hypoglycaemia, cost concerns, reluctance toward injections, and lack of awareness, closely mirror frameworks describing patient-, provider-, and system-level contributors to therapeutic inertia(15). International reviews further highlight clinician caution, overestimation of control, time constraints, and fragmented care pathways as additional drivers(17). Collectively, these convergent findings indicate that multi-component approaches combining patient education, structured follow-up, and clear clinic protocols for timely intensification are likely necessary to meaningfully reduce clinical inertia.

LIMITATIONS

The cross-sectional design precludes establishment of causal relationships between clinical inertia and glycaemic control. Being a single-centre, hospital-based study, the findings may not be generalisable to primary-care or community settings. Medication adherence was assessed by self-report and may be subject to recall and social desirability bias. Additionally, the operational definition of clinical inertia may have included some instances of clinically appropriate non-intensification that could not be fully distinguished using routine medical records.

CONCLUSION

Clinical inertia was highly prevalent among patients with type 2 diabetes mellitus attending this tertiary-care outpatient department and was strongly associated with poor glycaemic control. Longer disease duration, poor medication adherence, infrequent follow-up, and continued use of oral monotherapy were independently associated with therapeutic non-intensification. Addressing modifiable patient- and system-level barriers through structured follow-up, patient education, and protocol-driven treatment escalation may help reduce prolonged hyperglycaemia and improve diabetes outcomes in routine clinical practice.

RECOMMENDATIONS

Clinical practice

Use clear HbA1c-based triggers for treatment intensification.

Do not delay escalation solely because of suspected non-adherence address adherence and escalate when indicated.

Review uncontrolled patients every 3 months.

Consider early combination therapy or insulin when targets are repeatedly missed.

Patient support

Provide brief counseling on targets, complications, and insulin myths.

Address fears using shared decision-making.

Health system

Create lists/alerts for patients with persistent poor control.

Conduct periodic audits of clinical inertia.

Strengthen access to diabetes education and essential medications.

Future work

Test structured interventions to reduce inertia and explore provider/system barriers.

CONFLICT OF INTEREST: No

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