Clinical Inertia to Initiation of Insulin Therapy among Patients with Type 2 Diabetes in Moi Teaching and Referral Hospital, Kenya: A Mixed Methods Study

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Abstract

Background: The prevalence of diabetes among Kenyan adults currently stands at 4%, with Type 2 Diabetes (T2D) contributing to over 90% of cases. Clinical inertia in diabetology is defined as the lack of antidiabetic therapy escalation despite patients failing to achieve glycemic targets.

Objectives: To determine the prevalence of clinical inertia to insulin therapy among patients with T2D in Eldoret, identify associated patient factors, and to explore clinicians' view on the use of routine insulin therapy among patients with T2D.

Methods: This was a mixed methods study conducted in Moi Teaching and Referral Hospital, Eldoret in the Diabetes Out Patient Clinic (MTRH DOPC), where the quantitative stage involved a cross sectional study to determine the prevalence of clinical inertia and its associated factors with a patient sample size of 480. Questionnaires record patient biodata, HbA1c levels, patients' attitudes towards insulin using the Insulin Treatment Appraisal Scale (ITAS), clinical depression using Patient Health Questionnaire-9 (PHQ-9), and patient T2D self-care knowledge using Spoken Knowledge in Low Literacy in Diabetes (SKILLD) tool. Statistical analysis was performed using R software at a 95% confidence. The qualitative stage involved conducting key informant interviews among 15 clinicians, exploring their perceptions on routine insulin therapy among T2D patients. Qualitative data was analyzed using NVivo 12.

Results: The prevalence of clinical inertia was 54%. Single marital status increased the risk (OR 2.1; CI 95%; p=0.047), while male gender was protective (OR 0.65; CI 95%; p=0.041). Clinicians acknowledged the importance of insulin in T2D management but hesitated to prescribe it due to various patient and clinician related factors.

Conclusion and Recommendations: The study revealed a high prevalence of clinical inertia among T2D patients. Several patient and clinician related factors were identified as barriers to prescribing insulin therapy for T2D patients. Future research should include longitudinal studies to assess the evolving prevalence of clinical inertia to insulin therapy among T2D patients.

Key words: Clinical inertia, Insulin therapy, Type 2 Diabetes

Introduction

Clinical inertia to insulin therapy, defined as the delay in commencing insulin therapy in individuals with diabetes despite its clear necessity, is a critical issue in diabetes management[1]. It occurs when both healthcare providers and/or patients hesitate to initiate insulin treatment even when alternative approaches, including oral medications and lifestyle modifications are no longer effective in maintaining adequate blood glucose control. Clinical inertia's implications are substantial, as uncontrolled blood sugar levels can lead to various complications, including cardiovascular complications, neuropathies, psychological distress and overall poor quality of life.

Timely initiation of insulin therapy among T2D patients significantly improves diabetes management, allowing individuals to achieve better control over their blood glucose levels and reduce the risk of diabetes-related complications. Additionally it helps reduce healthcare costs associated with increased expenditures for treating diabetes-related complications. Current guidelines, such as those from the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE), recommend starting insulin therapy in patients with T2D and HbA1c levels of ≥9% if they exhibit symptoms of hyperglycemia or if oral therapy is inadequate[2].

Several studies have investigated clinical inertia among patients with T2D, with most of them conducted in high-income countries. These studies have identified various factors contributing to clinical inertia, including healthcare provider, patient, and healthcare system barriers[1]. Research has shown that healthcare providers may be hesitant to initiate insulin therapy due to concerns about patient adherence, fear of hypoglycemia, or the perception that insulin is a last resort for T2D management. They may also lack capacity to prescribe and educate patients on insulin therapy[3]. Patients often have misconceptions or fears about insulin therapy, such as concerns about weight gain or painful injections. These concerns can lead to resistance when healthcare providers do recommend insulin[4]. Issues related to healthcare access and healthcare costs have also been shown to create obstacles to insulin initiation[5].

This study aimed to investigate the prevalence of clinical inertia in the context of insulin initiation among patients diagnosed with T2D receiving care at the Moi Teaching and Referral Hospital Diabetes Outpatient Clinic (MTRH DOPC). The specific objectives encompassed examining potential correlations between the prevalence of clinical inertia and various patient factors. Further, the study endeavored to explore perceptions on routine insulin therapy for T2D patients among clinicians directly involved in patient care.

Materials and methods

Research design: The study employed a mixed methods design.

Study site: Moi Teaching and Referral Hospital (MTRH) is the second-largest national referral hospital within Kenya and is situated in Eldoret, Uasin Gishu County. The MTRH Diabetes Outpatient Clinic (DOPC) is a specialized healthcare clinic operating within MTRH. The primary objective of the DOPC is to provide patients highly specialized outpatient diabetes care.

Ethical consideration: Approval to conduct the research was obtained from the Moi University/ Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC/2018/336). Informed consent was obtained from all participants.

Study population: The study's target population comprised two groups: the quantitative segment focused on patients with T2D on follow-up at the DOPC, while the qualitative portion centered on clinicians responsible for patient care at the same clinic. Inclusion criteria for the quantitative study entailed patients attending the DOPC with a confirmed diagnosis of T2D and were not on routine insulin therapy, who could effectively communicate in English or Kiswahili. The qualitative study included clinicians involved in routine patient care at the DOPC. The exclusion criteria encompassed patients with Type 1 Diabetes (T1D), individuals diagnosed with T2D who had been on follow-up for less than three months, and patients who were severely unwell at the time of the study, rendering them unable to participate in the interview process.

Sample size determination: The required sample size for the quantitative study was determined using the Cochran formula, with the minimum required sample size found to be 376 patients. DOPC staff registers were used to identify clinician participants for the qualitative study.

Sampling procedure: Simple random sampling was used for patient participants with recruitment taking place on clinic days. All patients on follow-up for T2D attending the DOPC were shortlisted as potential participants. Eligible patients who gave written informed consent were included in the sample population. For the qualitative study, clinicians at the DOPC were recruited using purposive sampling.

Data collection: Data was collected for a duration of 3 months between April and June 2019. Patient data collection instruments were interviewer-administered and comprised of: the Insulin Treatment Appraisal Scale (ITAS) questionnaire which was used to assess patients' attitudes towards insulin therapy, the Patient Health Questionnaire-9 (PHQ-9) questionnaire which was used to screen for clinical depression, the Spoken Knowledge in Low Literacy in Diabetes (SKILLD) questionnaire which was used to assess patient diabetes self-care knowledge, and a bio demographic and clinical questionnaire. Patient HbA1C testing was performed once patients had completed filling the questionnaires and their results shared with them. Patients with high HbA1c levels were referred to clinicians for treatment optimization.

In depth, semi-structured and open-ended interview questionnaires were used to collect data among clinicians. The questionnaires contained open-ended questions with associated question probes that were conducted in English.

Data analysis: R software was used to analyze quantitative data. The dependent variable was

clinical inertia, which was defined as the failure to use exogenous insulin in T2D management for patients with glycated haemoglobin (HbA1c) levels of ≥ 9%. Independent variables included age, Body Mass Index (BMI), the duration from the time of T2D diagnosis, patients' ITAS, PHQ-9 and SKILLD scores. The significance of associations was determined using chi-square tests, while odds ratios and multiple linear regression were employed to elucidate the relationship between dependent and independent variables. All statistical analyses were conducted with a 95% confidence level and a p value of 0.05. Qualitative analysis was done using Nvivo version 12. Interview responses were summarized, and relevant excerpts were selected to illustrate the key qualitative insights derived from the study.

Results

The quantitative stage of the study targeted a sample size of 376 respondents. However, after adjusting for possible non-response at 20%, the final sample size was 480 patients with T2DM (Figure 1).

Figure 1: Sample size determination
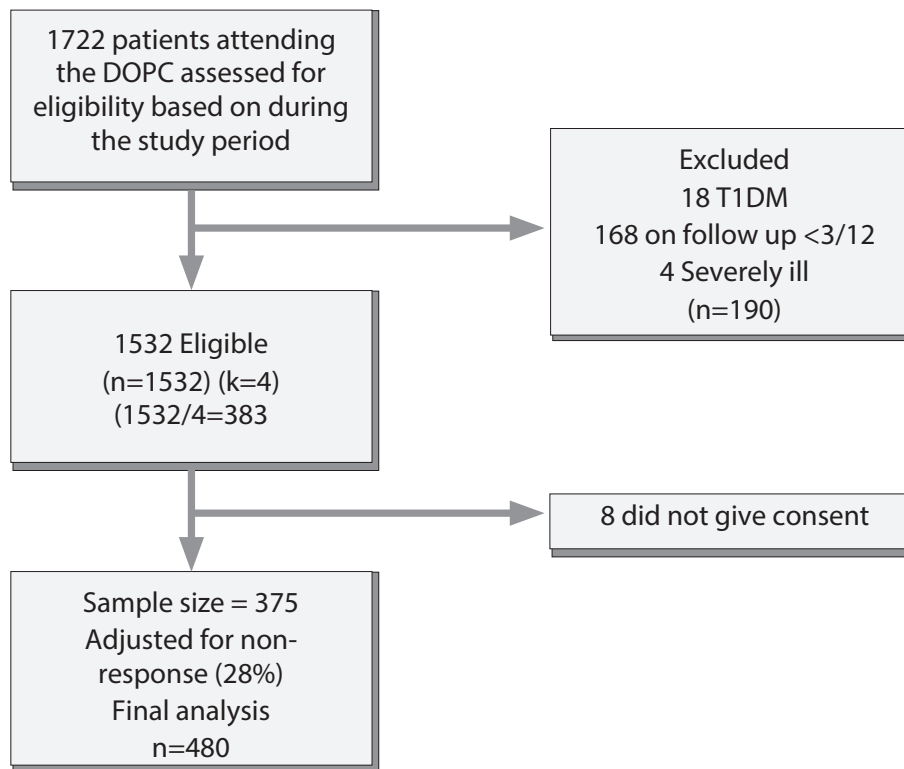
There were a total of 259 participants with an HbA1C greater than 9%. The prevalence of clinical inertia was determined to be 54% (95% CI; 49.38, 58.49) (Figure 2).

Figure 2: The prevalence of clinical inertia was 54% (95% CI: 49.38, 58.49).

□ Absent ■ Present
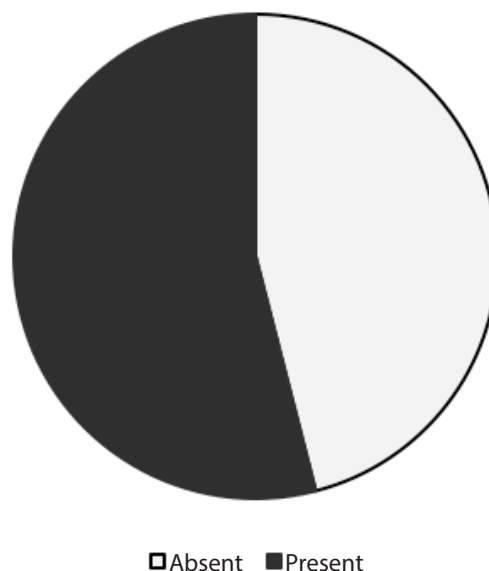
Table 1: Factors associated with clinical inertia

Characteristic	OR	95% CI	P-value
Age categories (years)			
25-35	1		
35-44	0.73	0.24, 2.22	0.600
45-54	1.71	0.57, 5.03	0.300
55-64	0.98	0.33, 2.84	>0.900
65-74	1.25	0.42, 3.67	0.700
>=75	1.41	0.44, 4.51	0.600
Gender			
Female	1		
Male	0.65	0.43, 0.98	**0.041**
Education level			
None at all	1		
Primary School	2.03	0.90, 4.73	0.093
High School	2.06	0.88, 4.95	0.100
College	2.09	0.79, 5.61	0.140
Marital status			
Married	1		
Single	2.10	1.03, 4.48	**0.047**
Widowed/Separated/Divorced	1.14	0.67, 1.96	0.600
Health insurance			
Yes	1		
No	1.28	0.76, 2.17	0.400
BMI			
Extreme obese	1		
Obese 2	0.28	0.06, 1.29	0.110
Obese 1	0.60	0.13, 2.41	0.500
Overweight	0.64	0.15, 2.48	0.500
Normal	0.94	0.22, 3.65	>0.900
Underweight	1.43	0.27, 7.27	0.700
Years DM diagnosis			
>=5	1		
Less than 5	0.83	0.56, 1.23	0.400
PHQ-9			
Mild	1		
Moderate	0.87	0.48, 1.59	0.700
Moderately severe	0.91	0.19, 4.95	>0.900
ITAS	0.98	0.95, 1.01	0.130
SKILLD			
Knowledgeable	1		
Not knowledgeable	1.06	0.71, 1.58	0.800

Qualitative study

Fifteen clinicians were interviewed. The group represented a diverse range of healthcare cadres, including nursing, clinical medicine, general medicine, internal medicine registrars, and qualified physicians. Findings from the key informant interviews shed light on several key aspects:

1. Clinicians generally held a positive view of insulin therapy, recognizing its significance in managing T2D.

   • "I think insulin has a big role in management of type two diabetes." IDI_001

2. Patient-related factors identified as barriers to insulin prescription among clinicians included concern about challenges in patients' self-administration of insulin, patients' preference for oral medications, concern for non-adherence to insulin therapy, patients' financial constraints and lack of proper facilities for insulin storage at home. Clinicians generally felt that insulin therapy had a negative impact on patients' quality of life because of the stigma associated with its use.

   • "Insulin therapy is significantly more expensive than oral hypoglycaemic agents" IDI_009

   • "Patients may be unable to store that insulin in a way that they preserve its effectiveness." IDI_008

   • "There is stigma with using insulin especially in public places where they might need to inject before they feed and so on." IDI_007

3. Clinician-related factors emerging as barriers to insulin therapy included fear of hypoglycaemia, and lack of confidence to prescribe routine insulin therapy due to inadequate training. Additionally, clinicians did not feel that they had enough time with patients during clinic consultations to effectively prescribe and titrate insulin.

   • "We are not very well trained to prescribe insulin." IDI_010

   • "Things that will cause me to withhold on insulin would be side effects of it, especially hypoglycaemic episodes." IDI_007

   • "I sometimes have to see like thirty patients on my own and so I don't get enough time with each patient." IDI _004

Discussion

The prevalence of clinical inertia in our study was 54%. Comparable studies conducted in Spain[7] and the UK[8] reported rates of 77.8% and 46.4%, respectively. A Brazilian study by Alvarenga *et al*[9] showed prevalence rates of 78.5%, 56.2%, and 62.2% at initiation, one-year, and two-year follow-ups. Varying HbA1c thresholds, ranging from 7-9%, in defining clinical inertia may contribute to differing prevalence rates across studies.

Our study identified that single individuals were twice as likely to experience clinical inertia compared to their married counterparts. This discrepancy may be attributed to the lack of adequate social support for single individuals in managing T2D. In contrast, male patients were less likely to exhibit inertia than females. This was in keeping with other studies which showed similar gender distributions. A UK study on clinical inertia conducted in 2013 showed that 56% of the study participants were female with an average patient age of 66.5 years[8]. Males may experience lower levels of clinical inertia due to perceived tolerance for more aggressive therapy. Notably, our findings differed from Alvarenga's study in Brazil[9], which associated male gender with inertia, and from a study in Sudan where gender showed no significant link to clinical inertia[10]. These variations could be attributed to different study sites and patient clinical characteristics.

In our study, clinical depression was infrequent, with only 1.4% of T2D patients scoring 10 or higher on the PHQ-9 assessment. This aligned with a study in the United States reporting an age-adjusted clinical depression prevalence of only 8.3%[11]. In contrast, a study in Webuye County, Kenya, depicted a significantly higher clinical depression rate of 20.9% among T2D patients using the PHQ-2 tool[12]. Analysis regarding the association between clinical inertia and clinical depression in T2D patients showed no statistically significant correlations. This contradicts findings by a study conducted in 2014[13] that showed a higher prevalence of clinical inertia among patients with clinical depression.

In our study, patients exhibited positive attitudes to exogenous insulin therapy with an average ITAS score of 22.39, with no statistically significant correlation made with clinical inertia. This contrasts with a study conducted at Kenyatta

National Hospital (KNH)[14], where patients with poor glycaemic control showed high ITAS scores, and an Australian study reporting high ITAS scores of 60.7[15] among T2D patients.

Only 38.5% of patients had SKILLD scores of 50% and above, with no significant associations between SKILLD scores and clinical inertia. This compares to a U.S. study indicating majority of T2DM patients had scores below 50%[16]. In contrast, a 2013 study conducted in KNH reported good self-care knowledge with 77.2% scoring above 50%[17]. An Iranian study found better self-care in T2DM patients with HbA1C <7% compared to those with HbA1c ≥9%[18].

Clinician interviews indicated the importance of insulin use in T2D management, similar to qualitative studies conducted in the Middle East[19] and USA[20]. In contrast, a study in the UK found that clinicians preferred delaying insulin therapy until absolutely necessary[21]. Patient factors that emerged as barriers to insulin prescription by clinicians included concerns regarding patients' ability to self-administer insulin, patents' preference for OHAs, concern for non-adherence, patients' financial constraints and lack of proper facilities for insulin storage at home. Clinicians also expressed that insulin therapy had a negative impact on patients' quality of life because of the stigma associated with its use. These findings were consistent with studies conducted in the Middle East[19] and USA[20]. Clinician-related factors emerging as barriers to insulin therapy included fear of hypoglycaemia, lack of confidence to prescribe routine insulin therapy and short consultation times. In a US study, inadequate time with patients also contributed to delays in insulin initiation[21].

Study limitations

This study adopted a cross-sectional design. Future longitudinal studies may offer better perspective on the evolving prevalence of clinical inertia in response to ongoing clinic care.

Conclusion and recommendations

The study revealed a high prevalence of clinical inertia among patients with T2D in Moi Teaching and Referral Hospital, and an association with patient marital status and gender. Clinicians recognized the importance of insulin therapy but demonstrated predominantly unfavorable attitudes concerning exogenous insulin therapy for T2D patients, with various patient and clinician related factors contributing to their reluctance to prescribe insulin. Future research should include longitudinal studies to assess the evolving prevalence of clinical inertia and should extend to intervention development targeting clinician education and capacity building on T2D management using routine insulin therapy.

Conflicts of interest

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