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Original Article

Control of glycaemia and its related factors in patients with type 2 diabetes, north of Iran: generalized linear mixed models and prevalence of overdispersion in patients

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Abstract

***Background & Aims*:** Glycemic control is very important to prevent or suspend complications in patients with type 2 diabetes (PT2D). The aim of this study was to investigate the status of glycemic control and its related factors in patients with type 2 diabetes (PT2D) based on HbA1c, fasting blood glucose, and non-fasting blood glucose levels in Golestan Province, Northern Iran.

***Materials & Methods*:** The study employed a retrospective cohort design, collecting data longitudinally and retrospectively from 500 patients with type 2 diabetes (PT2D) who were referred to health centers in Golestan Province between 2013 and 2016 (every three months). The study focused on HbA1c, fasting blood glucose (FBG), and non-fasting blood glucose (NFBG) levels, which were recorded as binary data (1 = abnormal; if the value exceeded its cut point), indicating a lack of control over these markers. The Index of Glycemic Control (IGC) was calculated for each patient, with an IGC of 3 indicating inadequate glycemic control. Related factors were analyzed using a generalized linear mixed model with a beta-binomial distribution.

***Results*:** The results indicated that 93% of patients had an Index of Glycemic Control (IGC) equal to 3 in the first year, and this percentage decreased to 60.7% by the third year. The downward trend in IGC was gradual over the three years. Factors contributing to poor glycemic control included younger age, shorter duration of diabetes care, elevated blood lipid levels, high blood pressure, insulin therapy, and overweight or obesity as indicated by BMI.

***Conclusion*:** The results obtained from the samples in Golestan Province indicate inadequate blood glucose control and poor quality of care. It is essential to implement more intensive diabetes management strategies within national healthcare plans.

***Keywords*:** Blood pressure, BMI, Fasting blood glucose, Generalized Linear Mixed Models, HbA1c, Long-Term Care, Overdispersion

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Introduction

Given current epidemiological trends, global attention has shifted from acute diseases to chronic conditions. Consequently, patients' needs have evolved toward preventive and continuous care (1, 2). Diabetes is a progressive disease that affects both glycemic

control and the development of complications, serving as the primary cause of retinopathy, neuropathy, nephropathy, and 60% of foot amputations (3-7).

In managing type 2 diabetes, qualified clinical care, self-care practices, periodic follow-ups, prompt treatment interventions, and the attainment of desirable blood sugar levels are all essential. These measures not only prevent or delay complications but also significantly improve the quality of life for individuals living with diabetes while reducing healthcare costs (1, 8, 9).

The main elements of primary care include the availability of services, referrals, continuous follow-up, comprehension, and coordination (9). The success of long-term maintenance therapy and effective metabolic control for diabetes primarily depends on patients' compliance with their therapeutic plans and a fundamental change in their behaviors. Healthcare centers play a vital role in providing primary health care and assisting diabetic patients in managing their condition (10).

One aspect that guides both patients and medical staff in evaluating the status of diabetes is the monitoring of key health indicators such as HbA1c, fasting blood glucose (FBG), and non-fasting blood glucose (NFBG) (11). These blood sugar markers are routinely tested and measured in patients with diabetes. The HbA1c test indicates average blood glucose levels over the past 2 to 3 months and is considered the gold standard for long-term monitoring. In contrast, FBG and NFBG serve as short-term indicators for monitoring blood glucose levels. The American Diabetes Association recommends checking HbA1c at least twice a year (9).

Although national and international policies have aimed to improve patient care management, failures in management have been observed. Despite the significant role of self-care practices in diabetes management, specifically in controlling and preventing serious complications, there is limited information available on the self-care practices of individuals identified as diabetic through screening (12, 13).

Cross-sectional studies conducted in various populations have identified abnormal HbA1c levels as indicative of poor quality of care, with ranges reported between 56.3%, 97.4%, and 37% (14-17). Additionally, several longitudinal retrospective studies reported poor quality of care in 10% to 65% of cases (18, 19). In some studies, multiple indicators such as HbA1c, FBG, and NFBG, as well as treatment types and side effects were utilized instead of relying solely on the HbA1c index (12, 19, 20).

Recognizing that care is a continuous and ongoing process, it is also advisable for disease management and glucose monitoring to be consistent and constant.

However, checking multiple markers simultaneously for long-term disease and glycemic control is more effective than examining a single marker alone. Therefore, this study aimed to longitudinally determine the state of glycemic control in patients with type 2 diabetes by simultaneously using HbA1c, fasting blood glucose (FBG), and non-fasting blood glucose (NFBG) markers, along with their related factors.

Materials & Methods

This study was a retrospective cohort analysis involving 500 patients with type 2 diabetes (PT2D) who were continuously referred to health centers affiliated with Golestan University of Medical Sciences in Iran and were covered by the National Diabetic Prevention and Care Plan (NDPCP) from 2013 to 2016. The data were collected from patients' records. Inclusion criteria included being over 18 years of age and having a complete patient history. The first five health centers were randomly selected, and 100 patient records were systematically chosen from each center.

The National Diabetic Prevention and Care Plan (NDPCP) has been implemented in Golestan Province since 2004. Patients were monitored by physicians based at the health centers. Each patient's treatment was individualized. For each patient, tasks performed included providing general and essential information about diabetes; offering advice on nutrition, exercise, and self-care; diagnosing complications; performing

foot care; administering pharmaceutical treatments; and, if necessary, initiating insulin therapy (20). The criteria for entering the study were that individuals must be over 18 years of age, participants had to be covered by health centers in Kordkuy City and diagnosed with type 2 diabetes to be eligible for the study.

Data Collection

In this research, a random cluster sample was taken, such that five health centers in this city were randomly selected from eight centers. Then 100 patient files were randomly selected from each center.

Patient information was extracted from individual files at each visit. The data included demographic details, baseline values at the initial referral, and subsequent values from later referrals. Fixed variables included gender and family history of diabetes (yes/no). Variables at the initial referral included age, blood fat levels (high/low), smoking status (yes/no), and the duration of diabetes (in years). Longitudinal variables collected every three months included systolic blood pressure, body mass index (BMI), insulin therapy (yes/no), HbA1c, (FBG), and (NFBG).

BMI was categorized into two groups: thin-normal (BMI < 24.9) and overweight-obese (BMI ≥ 25). The three glycemic markers studied were HbA1c, FBG, and NFBG, with abnormal glycemia being determined based on the following cut points: HbA1c > 6.5%, FBG > 126 mg/dL, and NFBG > 200 mg/dL (21). These three binary variables were summed for each patient, resulting in a new variable named the Index of Glycemic Control (IGC). An IGC score of 3 indicated very poor blood sugar control and quality of care, while a score of 0 indicated very good glycemic control.

Statistical analysis

The longitudinal data were obtained by continuously examining the HbA1c, PPG, and FPG indicators in the patients and assessing whether their levels were normal or abnormal. In addition, the possibility of overdispersion in the data due to the categorical response should be considered in the model.

Generalized Linear Mixed Models (GLMM): These models are used to analyze the structure of inter-individual or cluster correlation in data with repeated measurements and an abnormal response (often binomial and numerical). In fact, the main and primary assumption in the models of random effects for longitudinal data is that there is natural heterogeneity among the individuals in the study population. This heterogeneity can be accounted for by including random effects in the model.

The Index of Glycemic Control (IGC) dependent variable was described in terms of frequency and percentage, presented in tables and plots. In fitting the model, the presence of overdispersion in the response variable was tested first. A generalized linear mixed model was employed to assess the factors related to IGC. Data analysis was conducted using R version 3.5.3.

Results

A total of 500 patients were followed up (with a range of 1 to 12 visits, mean = 4.6, SD = 3.6). The results indicated that 81.4% of the patients had been affected for less than 5 years, and 77.2% were under the age of 50. Among the participants, 294 (58.8%) were women. At the start of the follow-up period, only 7% of the patients had a history of insulin injection (Table 1).

Table 1. Characteristics of patients with type 2 diabetes at baseline

Variables	n (%)	Variables	Mean (SD)
Sex (female)	294 (58.8)	Age	45.2 (8.2)
Smoking (yes)	101 (20.2)	BMI	28.9 (4.4)
Diabetes family history (yes)	320 (64.0)	Duration of diabetes	2.5 (2.4)
High fat blood history (yes)	361 (60.2)	Systolic blood pressure	138.8 (17.6)
Insulin therapy (yes)	35 (7.0)		

At the beginning of the study, only three patients had an IGC of 1 or 2, while the remaining 99.4% had an IGC of 3. After one year, 93% of patients had an IGC of 3; after 2 years, this figure dropped to 81%, and after 3 years, it was 61%. The percentage of patients with good glycemic control was negligible. The changes in HbA1c, FBG, NFBG, and IGC during each follow-up period are presented in Table 2 and Figure 1.

Table 2. Index of glycemic control (IGC) over time (months), and the mean (SD) of glycemic markers

Time (month)	n	IGC, N (%)				Mean of glycemic indicators (SD)		
		0	1	2	3	NFBG	FBG	HbA1c
Baseline	500	-	2 (0.4)	1 (0.2)	497 (99.4)	359.1 (58.9)	307.9 (58.7)	9.8 (4.4)
3	500	-	1 (0.2)	10 (2.0)	489 (97.8)			
6	500	1 (0.2)	2 (0.4)	8 (1.6)	489 (97.8)			
9	500	1 (0.2)	2 (0.4)	11 (2.2)	488 (97.2)			
12	488	1 (0.2)	2 (0.4)	31 (6.4)	454 (93.0)	289.2 (54.1)	239.4 (50.1)	8.3 (0.9)
15	471	3 (0.6)	7 (1.5)	27 (5.7)	434 (92.1)			
18	414	4 (1.0)	9 (2.2)	29 (7)	372 (89.9)			
21	411	5 (1.2)	13 (3.2)	29 (7.1)	364 (88.6)			
24	367	14 (3.8)	19 (5.2)	36 (9.8)	298 (81.2)	263.9 (65.3)	215.5 (60.8)	7.9 (3.2)
27	364	11 (3)	30 (8.2)	46 (12.6)	277 (76.1)			
30	247	16 (6.5)	13 (5.3)	28 (11.3)	190 (76.9)			
33	234	18 (7.7)	27 (11.5)	26 (11.1)	163 (69.7)			
36	215	21 (9.8)	36 (16.7)	28 (13)	130 (60.5)	229.3 (65.2)	178.3 (59.0)	7.3 (0.9)

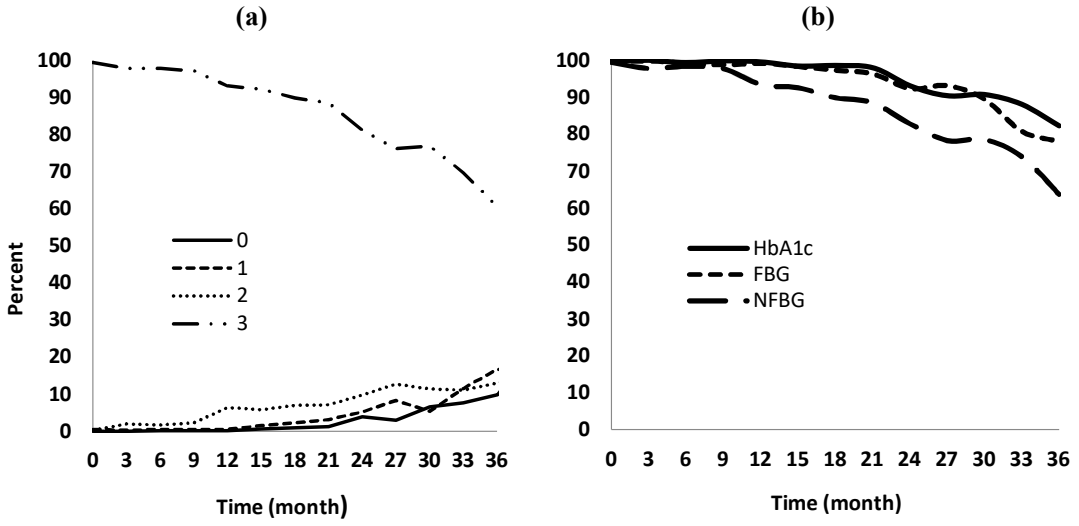

Fig. 1. Percentage of patients with abnormal indicators over time. (1-a): percentage of patients for index of glycemic control (IGC) over time (3: all glycemic indicators are abnormal, 2: two glycemic indicators are abnormal, 1: one glycemic indicator is abnormal, 0: no abnormal glycemic indicators abnormal). (1-b): percentage of patients with abnormal HbA1c, FPG, and PPG.

Figure 1-a represents the percentage of patients with different IGC scores (IGC = 0, 1, 2, and 3) at various referral times. When the IGC score is 3, the slope remains almost flat until month 9, after which a slight downtrend is observed from months 9 to 21, followed by a steeper decline from month 21 onward. The diagram for IGC scores of 0-2 shows increasing trends, with an upward trend for IGC = 2 beginning at the 9th month, while trends for IGC = 1 and 0 start at months 18 and 24, respectively. Overall, patients' conditions appear to improve after 24 months, although only 61% of patients had an IGC score less than 3 after 36 months, indicating that good recovery was noted in fewer than 40% of patients.

Figure 1-b displays the percentage of patients with abnormal HbA1c, FBG, and NFBG separately at different referral times. All three indicators show a decreasing trend. The diagrams for HbA1c and FBG are similar, remaining flat with a zero slope until the 21st month, after which they begin to decline with a negative slope. For NFBG, the slope is zero until the 9th month, at which point the downtrend begins. As observed, it takes approximately 21 to 24 months to achieve better glycemic control and quality care. Comparing Figures 1-a and 1-b, it is clear that the decreasing trend for IGC = 3 at the 9th month is primarily due to the downtrend in NFBG, rather than changes in HbA1c and FBG.

As time passes, the means of the three indicators have decreased; however, they still remain above the cut points (Table 2). First, the existence of over-dispersion was confirmed by the quality control chart test (*P-value* < 0.05). Subsequently, a univariate generalized linear mixed model was fitted for each independent variable. Those variables with a *P-value* > 0.2 were simultaneously included in the multivariate generalized linear mixed model (Table 3).

Table 3. Generalized linear mixed model with a beta-binomial distribution on the index of glycemic control (IGC)

Independent var (ref.)	Coefficient	SE	Value	*P-value*
Time (month)	-0.17	0.01	-20.90	< 0.001
Age	-0.04	0.02	-2.059	0.009
Diabetes family history (no)	-1.26	0.28	-4.49	0.001
High fat blood history (no)	0.53	0.28	1.88	0.059
BMI (thin-normal)	0.41	0.24	1.75	0.079
Systolic blood pressure	0.04	0.01	6.09	< 0.001
Insulin therapy (no)	0.71	0.37	1.92	0.054

The model results indicated that less time in care, lack of a family history of diabetes, high blood fat levels, overweight and obese BMI, elevated blood pressure, and insulin therapy have significant relationships with IGC, resulting in a lower quality of care for patients (*P-value* < 0.05). These factors directly affect the IGC, leading to levels of 3, which fail to control glycemia. The coefficients indicated that the mean IGC decreased by 0.17. For each additional year of age, the mean IGC decreased by 0.04. Patients with high blood fat levels had a mean IGC that was 0.53 higher than those without. Conversely, patients with a family history of diabetes had a mean IGC that was 1.26 lower than others. The mean IGC in overweight or obese patients was 0.41 higher than that of their peers. Additionally, an increase in blood pressure was associated with a mean IGC increase of 0.04. Lastly, the mean IGC in patients undergoing insulin therapy was 0.71 higher than those not undergoing therapy.

Discussion

Achieving the desired blood sugar levels while reducing side effects and mortality are key objectives in diabetes care. This study aims to assess blood sugar

control and the factors related to abnormalities in the HbA1c, FBG, and NFBG indicators simultaneously.

Based on the IGC, the improvement in patients' status was quite limited. After 3 years, 61% of the patients still had all three markers abnormal. The decreasing trend in IGC over 3 years of care was neither significant nor impressive among diabetic patients.

No studies have simultaneously investigated these markers as this study does; therefore, discussions can focus on each marker individually or address them collectively in the relevant sections.

The percentages of abnormal HbA1c in this study were 99.6%, 93.2%, and 82.3% after 1, 2, and 3 years of care, respectively. These figures are significantly higher than those reported in other countries. The levels of abnormal and uncontrolled HbA1c were 50.3% in China (2018), 73% in Malaysia (2003), 75% in Venezuela (2010), 49% and 42% in developed countries such as Canada and the Netherlands, 64% in some European countries (2011), 64% in Brazil (2017), 67.5% in Turkey (2017), and 78% in Libya (2016) (10, 22-26). Most of these studies were cross-sectional and did not consider the duration of treatment.

Furthermore, the indicators remained stable until the 24th month, after which they began to decrease from the second year. The mean values of these indicators remained above the standard cut-off points after 2 and 3 years. A clinical trial conducted in the UK compared standard and intensive care methods. It found that the HbA1c level in the intensive care group reached 6.7% after 4 months and stabilized after 1 year, while in the standard care group, it reached 7.5% after 4 months and then stabilized (27) In the present study, the HbA1c level was 7.9% after 24 months. Comparing the results of the current study with those from the standard care group in the UK study (excluding the intensive group), it appears that the reduction in HbA1c in our cohort was delayed by approximately 20 months.

Despite ongoing efforts, glycemic control has still failed in some cases. This study found several variables associated with poor glycemic control, including shorter treatment duration, high blood lipid levels, insulin therapy, overweight and obesity (BMI), lack of a family history of diabetes, and hypertension.

Insulin therapy was a significant factor. Patients undergoing insulin therapy often do not have adequate glycemic control, which aligns with findings from other studies (10, 23, 27-30). This may be related to resistance to regular injections and non-adherence to doctors' orders due to fear of side effects (23, 28). Additionally, patients receiving insulin are typically in more advanced stages of the disease (25).

The history of high blood fats was significantly associated with glycemic control. The results were consistent with previous studies (2, 10, 23, 31). High cholesterol can reduce β-cell function, while elevated triglycerides can impair insulin absorption (32). Consequently, poor control of fat levels can lead to insufficient glycemic control.

The model illustrated that the quality of care improved over time as the number of abnormal indicators decreased. However, this reduction occurred relatively late, becoming more evident during the second year. Few studies have discussed the effect of time on glycemia. In developed countries, a decrease in blood glucose levels was observed before the end of the first year (27).

The quality of care and glycemic control were poorer in young patients compared to older ones. These results align with findings from previous studies (10, 17, 24, 33). Younger individuals tend to pay less attention to their treatment (10), resulting in lower self-management behaviors compared to older adults (34). In contrast, older adults are generally more compliant with their doctors' prescriptions (35).

Family history of diabetes is recognized as a factor in glycemic control; however, in a previous study, it was identified as a deterrent factor (10). This discrepancy may be related to individuals' awareness of the disease's side effects and their self-care methods. Nevertheless, this issue warrants further investigation with more comprehensive data on diabetes.

According to the results of previous studies, being overweight is an important factor in treatment resistance (10, 34, 36). In this study, overweight and

obese individuals exhibited a higher number of abnormal glycemic readings compared to those who were of normal weight or thin. It is important to note that in this study BMI was measured longitudinally, indicating that a patient's BMI may change from overweight to normal or vice versa over the course of treatment. Overweight diabetic patients can better control their blood sugar levels through weight loss (37).

Patients with higher systolic blood pressure demonstrated lower quality of care and poorer glycemic control in the study. Generally, managing diabetes becomes more challenging in individuals with long-term hypertension (38-40).

No significant relationship was found between gender and glycemic control, which is consistent with the findings of other studies (17, 25, 29). However, some studies have indicated poorer glycemic control in women due to hormonal differences between men and women (26, 27).

This study has both strengths and weaknesses. One strength is that HbA1c, FBG, and NFBG were considered simultaneously. Since HbA1c reflects average blood sugar over the past 3 months, while FBG and NFBG represent short-term blood sugar levels, combining these measures provides a more comprehensive view of glycemic control, making the results more reliable and generalizable. Participants were followed up every 3 months for 3 years, resulting in more comprehensive data than that obtained from cross-sectional studies.

However, the study had some limitations, including a lack of information on education, adherence to doctor prescriptions, and accurate blood cholesterol/triglyceride levels during the follow-up period, which could bias the results. Additionally, some self-reported information, such as the duration of the disease, may be subject to recall bias and was therefore not included in the analysis. Furthermore, the side effects of the disease were not assessed in this study.

Disease management aims to reduce blood glucose levels. Numerous studies have reported that global barriers to achieving controlled glycemia include non-adherence to the recommended diet, irregular use of medications, lack of exercise, infrequent blood sugar monitoring, and, more generally, failure to make lifestyle changes (10, 26, 34). The healthcare team associated with these patients also plays a crucial role in this regard (13).

The results of the study indicated that patients are in poor condition regarding care quality and glycemic control, as the mean indicators remain higher than the recommended limits after 3 years. This issue may be related to the regional diet, which primarily consists of rice. Considering the important role of healthcare providers, the NDPCP team needs to emphasize and enhance the care process by raising awareness about illnesses and the risk of serious complications. This includes promoting lifestyle changes such as smoking cessation, managing blood lipids and pressure, encouraging a balanced diet and regular exercise, facilitating weight loss, and ensuring treatment adherence. Ultimately, the balance between the healthcare team and the patient's self-care should be prioritized.

It is recommended that similar longitudinal and prospective studies be conducted using more accurate data collection methods, such as adherence to prescriptions and the training methods provided to patients under treatment, in order to assess the performance of the NDPCP. Additionally, applying the HEDIS checklist is suggested to evaluate the quality of care for diabetic patients.

Conclusions

The results obtained from the samples in Golestan province indicate inadequate blood glucose control and care quality. It is necessary to implement more intensive care for diabetes patients in national health plans.

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Authors' Contributions

None declared.

Data Availability

The data that support the findings of this study are available on request from the corresponding author.

Conflict of Interest

The authors declared no conflict of interest.

Ethical Statement

This study was conducted in accordance with the ethical standards set by the ethics committee of the University of Social Welfare and Rehabilitation Sciences, with ID code IR.USWR.REC.1397.166.

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