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Control and treatment of type 2 diabetes in private patients in the Egyptian "DIACONTROL study"

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Abstract. – OBJECTIVE: This study aims to identify the characteristics of Egyptian patients suffering from type 2 diabetes mellitus (T2DM), determine disease control rates, and gain insights into clinical treatments.

PATIENTS AND METHODS: A total of 2,516 patients with T2DM were recruited from 244 private clinics across Egypt in a one-month period from May to June 2017. Data collected from patients included glycemic control parameters of glycosylated hemoglobin, fasting plasma glucose, and postprandial glucose. Additional information gathered included patients' weight, age, level of physical activity, smoking habits, presence of comorbidities, type of treatment received for type 2 diabetes, number and severity of hypoglycemic events, as well as treatment modification by the physician in the last visit. The type of statistics used for the analysis is descriptive statistics and regression model.

RESULTS: Only 18.4% of participating patients achieved the target level of glycosylated hemoglobin of 7% or below. The mean age of these patients was 54±11.2 years, and the mean duration since the first diagnosis was 6.6±6.4 years. A total of 33.4% of all patients had no known comorbidity, while the rest had one or more known and treated comorbidities. A total of 76% of patients received sulfonylurea either as monotherapy or in combination with other treatments. In addition, no treatment modifications or adjustments were provided for 32% of the study participants who did not reach their glycemic control target.

CONCLUSIONS: In Egypt, there is a low rate of glycemic control among private patients and a high prevalence of comorbid conditions. This is likely to cause a significant health burden to people with T2DM, the healthcare system, and the economy due to a loss in productivity. This study presented an argument for better-managed measures to improve glycemic control in the population, such as patient education to increase patient awareness and adherence to treatment protocols as well as improved adherence to guidelines by clinicians.

Key Words:
Diabetes, Epidemiology, Prevalence, Egypt, Glycemic control, Comorbidities.

Introduction

Diabetes is a highly prevalent condition that affects more than 1 person in every ten individuals between the ages of 20-79 years worldwide, according to the latest reports[1]. In 2021, the Middle East North Africa (MENA) region had the highest prevalence of diabetes worldwide, where the condition affected 16.2% of the population, roughly translating to 72.7 million cases[2] compared with a global prevalence of 10.6%. Furthermore, among the MENA region countries, Egypt had the highest rate, with 20.9% (10.9 million) of the population aged 20-79 years suffering from the condition, making the country the tenth in global rankings. In Egypt, the number of people living with the condition is expected to almost double by the year 2045[1].

Type 2 diabetes (T2DM) is associated with significant disease-related complications[3]. Poor control of diabetes over the long term results in micro-and macro-vascular complications, which may lead to organ failure and even death[4,5]. Therefore, achieving good glycemic control is essential in successfully managing the health risks of patients with T2DM.

Estimation of glycated hemoglobin A1c (HbA1c) can evaluate the mean level of glucose in the blood over a 3-month period. The risk of morbidity and mortality increases if HbA1c levels are above 7.0%. Therefore, a glycemic target of HbA1c of 7% or less in patients with T2DM is part of a multifactorial treatment approach[3,6,7].

Despite the availability of a wide range of oral antidiabetics (OADs), a high proportion of diabetic patients fail to achieve the target HbA1c of less than 7% in some countries[8]. This poor

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control may be attributed to many reasons, such as insufficient treatment intensification, lack of compliance to the prescribed regimen, or treatment failure due to a decline in the function of insulin-releasing cells (β cells)[9,10].

Although the prevalence of diabetes in Egypt is among the highest in the region and all over the world[1], there is little information regarding the level of diabetes control and the general profile of patients with T2DM. Additionally, information pertaining to current management paradigms remains obscure[11]. However, poor adherence to diabetes management is common in Egypt. Daily blood glucose testing is rarely practiced, and the omission of insulin injections is a frequent occurrence. Even educated patients commonly exhibit poor adherence to healthy eating and physical activity plans[12]. Given that diabetes care is primarily administered in the private sector, patients rarely get routine examinations or evaluations due to the high cost of private practice[13]. Routine checkups for parameters such as HbA1c or renal function are uncommon. The diagnosis and management of microvascular complications, particularly diabetic retinopathy and diabetic nephropathy, often occur too late for effective prevention[12]. All of these issues make glycemic management in Egypt a significant challenge. This study aims to explore the characteristics of Egyptian patients suffering from T2DM in private settings, determine the proportion of cases achieving HbA1c levels less than 7%, identify medications used in managing patients, and create a profile of existing and/or treated comorbidities.

Patients and Methods

Study Population

The study aimed to investigate the control and management of diabetes among patients who already had the condition. Recruitment involved a comprehensive approach, and a total of 2,516 patients were recruited. These patients were already diagnosed with T2DM and aged 18 years and above. They were identified and confirmed by clinicians in 244 private clinics. These clinics were distributed across 15 Egyptian governorates, including both specialist and general practitioners' private practices. Patients were randomly assigned to the study by the physicians. Currently, Egypt has a complex and uneven system of public and private healthcare providers, with 60% of healthcare financing being out-of-pocket expenditure[14]. The prices of private healthcare providers in Egypt are quite diverse and independent. Thus, even individuals with lower incomes tend to rely heavily on private healthcare services. In Egypt's lowest income quintile, 70% of outpatient visits were at private healthcare facilities, and 15% were at government outpatient clinics[15]. Healthcare resources are concentrated in the urban centers of Cairo, Alexandria, and the Nile Valley and of lower quality in rural areas. Rural residents use private clinics, among others, due to limited healthcare options[16]. Therefore, this study assumed that private clinics provide access to patients from all socioeconomic levels. Additionally, the majority of practitioners in Egypt work in both the public and private sectors; therefore, utilizing the private sector clinics yields objective value to our research[17].

The recruiting clinics were chosen across the 5 major regions in Egypt to capture population variation, geographic, healthcare, and socio-economic differences, thus providing a representative sample for the wider population. The inclusion and exclusion criteria of the subjects were as follows:

Inclusion Criteria

- Patients with a confirmed diagnosis of T2DM.
- Patients aged 18 years and above.
- Patients identified by a specialist or a general practitioner in a private clinic.

Exclusion Criteria

- Patients diagnosed with type 1 diabetes mellitus.
- Patients receiving insulin monotherapy.
- Patients unwilling or unable to provide informed consent.
- Patients with severe cognitive impairments that prevent meaningful participation in the study.

Study Design and Data Collection

This cross-sectional study was conducted between March 2017 and June 2017, and the data collection period was from May 2017 to June 2017. Data were collected using standardized case report forms (CRF) that were distributed to participating physicians before patient enrollment. The physicians received training on how to complete the CRF, how to interview patients, how to explain the patients' roles and responsibilities, and on all aspects pertaining to the patient-signed informed consent form. Practitioners were asked to enroll five eligible patients at their sites from the patient population of the identified clinics. All patients underwent an HbA1c test during the screening visit and

were offered participation based on the results. Data entry, monitoring, and follow-up were performed by a third-party contractor, namely Accsight, a healthcare consultancy.

Data collected about patients included glycemic control (HbA1c), age, gender, weight, location, smoking habits, physical activity, presence of known and treated hypertension, dyslipidemia, renal impairment, cardiac disease, duration of diabetes, postprandial glucose (PPG), fasting plasma glucose (FPG) (when available), current diabetic medication, treatment modifications throughout the study period, the reason for treatment modifications, and number and severity of hypoglycemic events. Severe hypoglycemia was categorized into hypoglycemia, which requires hospitalization, and hypoglycemia, which requires external assistance but no hospitalization. Physical activity was classified into three categories: patients walking for 30 minutes or more per day, patients walking for less than 30 minutes per day, and patients with minimal to no physical activity. HbA1c levels were tested using the Clover A1C analyzer device. On any given screening day, an HbA1c test was administered for all type 2 diabetes patients at the respective clinic. The treating physician explained the CRF to every patient and completed it together. The services of SERVIER© Egypt were used for the collection of the CRFs.

This study received approval from the Ministry of Health and Human Population Research and Ethics Committee and was in accordance with the principles established by the Declaration of Helsinki and applicable local and international laws. The ethics approval was registered under ethics approval number IC4-05762-010-EGY. All study participants signed an informed consent form prior to entry into the study protocol.

Study Outcome Measures

The study's primary objectives were 1) to determine the proportion of patients with diabetes who were able to maintain their HbA1c at less than 7% with the study assigned management and the differences in response for each geographical area, 2) to ascertain the prevalence of known and/or treated comorbidities exhibited by the study participants, and 3) to detect the burden of risk factors associated with T2DM.

A secondary objective was to understand the proportion of hypoglycemic events and the main causes for treatment change over the study follow-up period.

Statistical Analysis

The statistical package for social science (SPSS®) version 23 -2015 (IBM Corp., Armonk, NY, USA) was used for data analysis. Results with a p-value ≤ 0.05, with a 95% confidence interval, were considered significant. A sample size of 2,516 patients was collected from 244 sites across Egypt, allowing a total margin of error of 2%. Numerical variables were summarized using means and standard deviations (SDs). Categorical variables were summarized using frequency distributions. The Student's t-test was used to compare means, and the Chi-square test was used for categorical variables using a 95% confidence level (CI). Participants with missing data were excluded from the analysis.

Multiple regression analysis (for key driver identification) was performed at 90% CI to determine which of the variables, such as brand of medication, monotherapy *vs.* combination-controlled therapy, physical activity, and others, had the highest influence on the observed HbA1c level. Squared correlation coefficient (R^2), adjusted squared correlation coefficient (adjusted R^2), and standardized regression coefficient (standardized beta) were calculated in the regression model. A per-protocol analysis method was adopted for the purposes of this investigation.

Results

Study Population

Most patients (92.8%) were enrolled by a range of medical practitioners (general practitioners, cardiologists, pulmonologists, gastroenterologists, obesity specialists, cardiothoracic surgeons, hematologists, and neurologists), while specialized endocrinologists and diabetologists enrolled the remaining subjects (7.2%). Patients were enrolled from across 4 different regions in Egypt; 36.4% of patients were from Greater Cairo (Cairo and Giza regions), 13.7% were from Alexandria, 26.0% from Northern Egypt (Delta regions), and 23.9% from Southern Egypt (Upper Egypt). Baseline characteristics of the study population can be viewed in Table I.

The majority of study participants (76%) were between the ages of 40 to 65, and most subjects were females (65.3%). The mean body weight of the aggregated study population was 87.1 kilograms, 88 for males and 86.5 for females. Most smokers in the study were males (37.7% of total male subjects *vs.* 0.6% of females). Physical activity varied according to gender. More men than women (36.1% *vs.* 20.7%) walked more than 30 minutes per day.

Table I. Baseline characteristics of study participants.

Comparative Factors	Total Participants (n=2,516)	
	Mean/Count	%/±SD
Age (years)	54.0	11.2
o Male	881	34.7%
o Female	1,635	65.3%
Weight (in Kg)	87.1	19.4
Diabetes duration (years)	6.6	6.4
Smoking habits (Yes/No)	351	13.5%
Presence of associated hypertension	1,406	56.0%
Presence of associated dyslipidemia	705	28.2%
Presence of associated renal impairment	92	3.8%
Presence of associated cardiovascular disease	486	19.3%
Level of physical activity		
Not exercising at all	695	28.0%
Walking less than 30 minutes per day	1,141	45.9%
Walking more than 30 minutes per day	645	26.1%
Type of treatment		
Biguanides (Metformin)	1,672	66.5%
Sulfonylureas	1,911	76.0%
DPP-4 inhibitors	443	17.6%
Thiazolidinediones	123	4.9%
Glinide	16	0.6%
Insulin in combination with other OADs	279	11.1%
Geographical distribution		
Greater Cairo	915	36.4%
Alexandria	345	13.7%
Delta	655	26.0%
Upper Egypt	601	23.9%
Duration on current medication		
Greater Cairo	3.2	4.6
Alexandria	1.9	2.5
Delta	2.7	3.6
Upper Egypt	2.5	3.2
Total	2.7	3.8
Time since diagnosis		
Greater Cairo	7.5	7.3
Alexandria	5.7	5.4
Delta	6.4	6.0
Upper Egypt	5.9	5.5
Total	6.6	6.4

Oral antidiabetics (OADs), dipeptidyl peptidase 4 inhibitors (DPP4 inhibitors).

A total of 33.4% of patients had no known comorbidity, 36.3% of patients had one known and/or treated comorbidity, and 30.3% of patients had more than one known and/or treated comorbidity. Around 20.4% of the study population had both hypertension and dyslipidemia.

The glycemic control of enrolled patients who had been on treatment for more than two months was assessed. Figure 1 reveals that the mean fasting plasma glucose (FPG) was 156.3±58.9 mg/dl (Figure 1A), mean postprandial glucose (PPG) was 218.9±121.4 (Figure 1B), and mean HbA1c was 8.9±2.3% (Figure 1C).

Primary Outcome

Based on participants' HbA1c readings, the majority of patients had not achieved glycemic control. As we can see in Figure 2, only 18.4% of all participating patients managed to achieve the glycemic target (HbA1c less than 7%). The percentage per region was 19.2% in Greater Cairo, 12.7% in Alexandria, 18.2% in Delta, and 20.8% in Upper Egypt.

The highest percentage of patients were on sulfonylurea, followed by metformin (Table I). A total of 74.9% of the patients received sulfonylurea either as a monotherapy (29.3%) or in combination (45.6%) with other antidiabetic

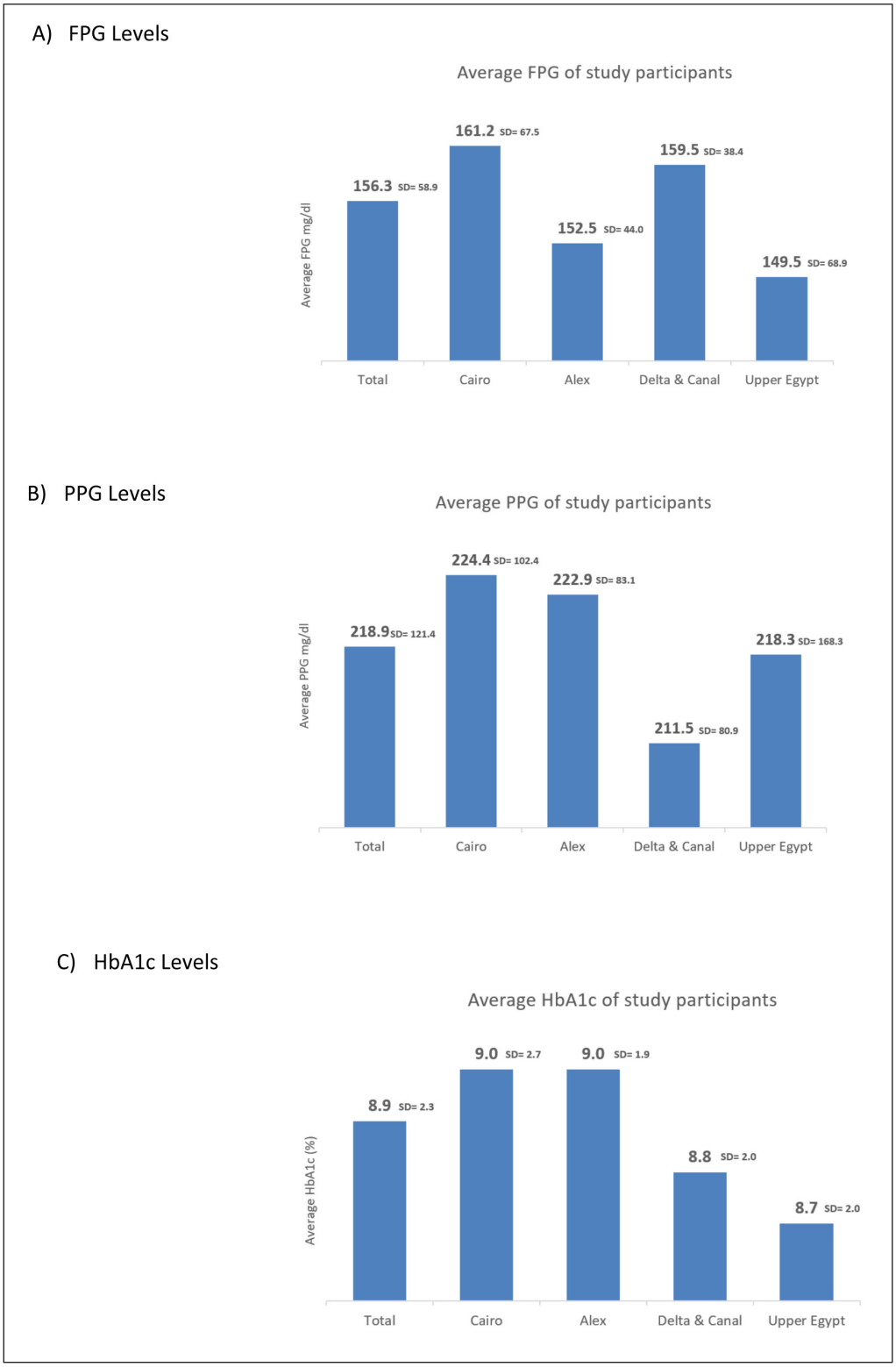

Figure 1. Various glycemic parameters across different regions in Egypt. **A**, fasting plasma glucose levels of respondents across different regions, (**B**), postprandial plasma glucose levels of respondents across different regions, (**C**), HbA1c levels of respondents across different regions.

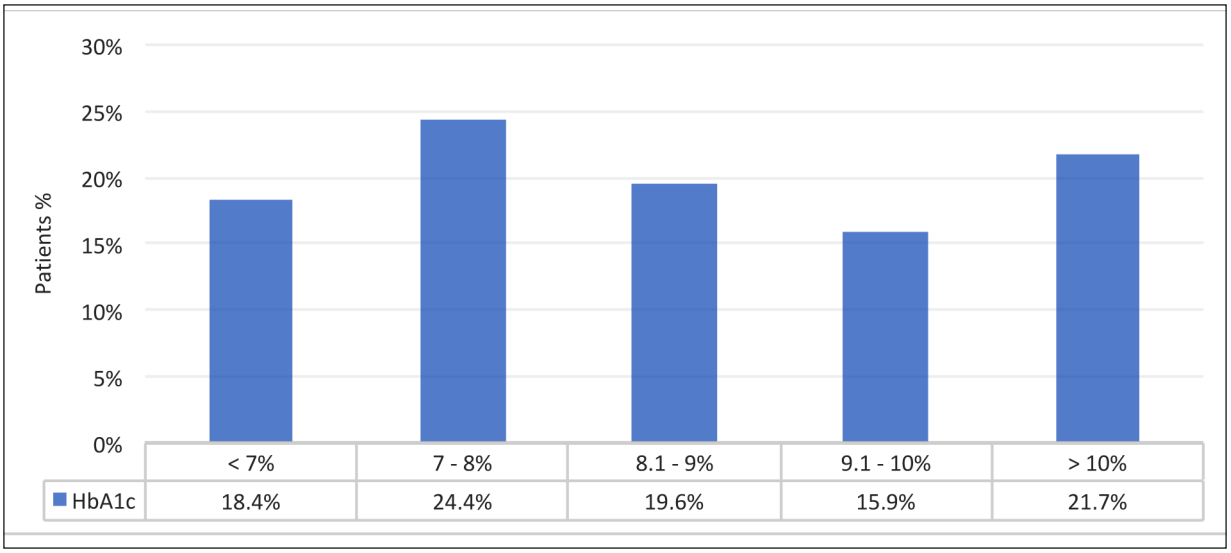

Figure 2. Proportion of patients achieving glycemic control defined as HbA1C <7%.

medications. Thirty-six percent of participants received metformin as a monotherapy, while 17% received it in combination with sulfonylurea, 13% with dipeptidyl peptidase 4 inhibitors (DPP4 inhibitors), and 1% with glitazones. Information regarding comorbidities and associated conditions is presented in Table I.

Secondary Outcome

In this study, population glycemic control was assessed in relation to current management, as we can see in Figure 3. Patients receiving gliclazide monotherapy, fixed gliclazide/metformin, and sitagliptin/metformin combinations achieved the best results in terms of reducing HbA1c to less than or equal to 7%. Results indicated that 20%, 15%, 20%, and 22% of patients in the Cairo, Alexandria, Delta, and Upper Egypt regions, respectively, achieved the target HbA1c. Additionally, the study compared the efficacy of different gliclazide doses and glimepiride as monotherapies. The percentage of patients

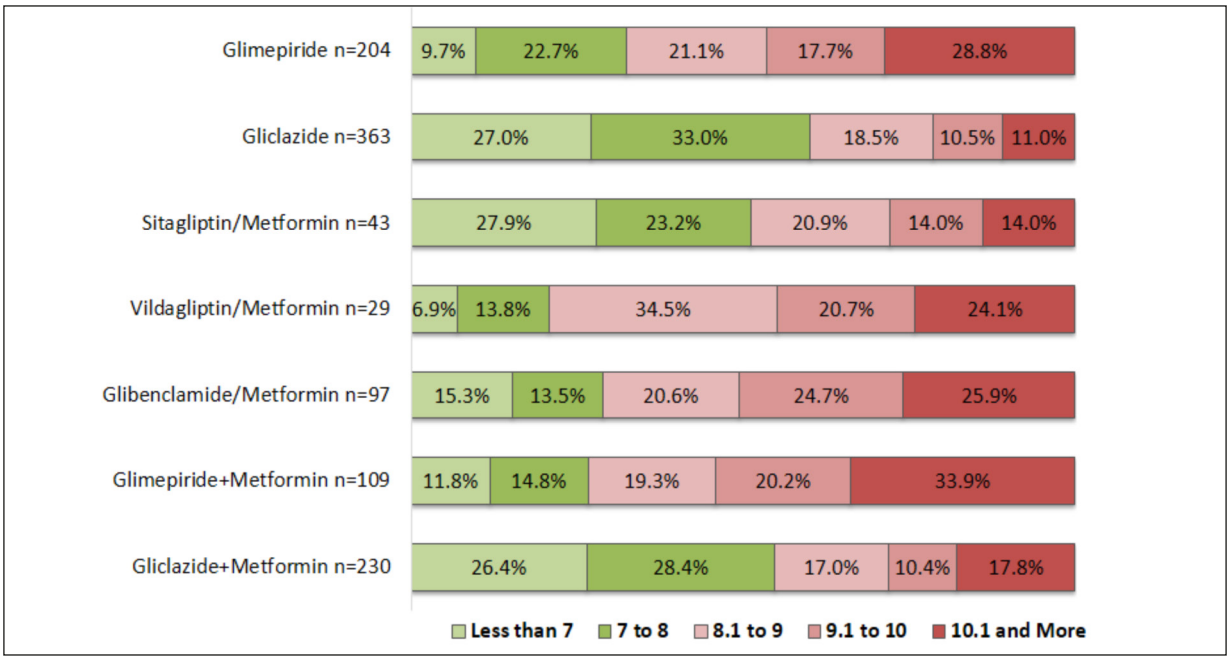

Figure 3. Glycemic control achieved with monotherapies and combination treatment.

achieving the glycemic target was 21.5% on gliclazide 60 mg and 40.3% on gliclazide 120 mg. However, only 12.3% of patients on glimepiride 2 mg, 17.0% on glimepiride 3 mg, 11.5% on glimepiride 4 mg, and 5.6% on glimepiride 6 mg achieved the HbA1c target of less than 7%.

In addition, we assessed treatment modification in our study population at the time of the study visit; 25.7% of the patients had their medications changed, 14.6% had a new agent added to their existing drugs, 14.8% had dose adjustments to their medications, and 44.9% had no modifications done. The reasons provided for treatment modification were low efficacy in 86.6% of the cases, hypoglycemia in 8.2%, step-by-step titration in 3.1%, patient intolerability in 1.2%, and enhancing patient compliance in 1.0% of the cases.

The proportion of patients who had no change in their medications was calculated in relation to their HbA1c levels. Almost 2 in every 3 patients (66.6%) with a HbA1c level ranging from 7% to 8% had no modifications in their treatment regimens. Treatment modification rates increased in this study as HbA1c levels rose. Surprisingly, 19.7% of patients with an HbA1c level above ten still had no change in their treatment regimens (Table II and Figure 4). The mean HbA1c level of patients who had no treatment modifications was 8.7%±2.8%.

The results of the regression model were statistically significant (R^2=0.29, adjusted R^2=0.27; p=0.023). It showed that the HbA1c level is negatively related to the duration of current treatment and age at a 90% significance level. As the duration of the current treatment or age increases, the HbA1c score decreases (indicating better control). This model indicated that age made the least contribution to HbA1c level (β=-0.035) while time since diagnosis contributes the most to changes in HbA1c level (β=0.173) due to the administering of medication.

Hypoglycemic Events

A hypoglycemia side effect was recorded in patients who had been on treatment for more than two months. A total of 78.4% of the patients did not experience any hypoglycemia episodes that required external assistance during the study period, 5.5% had one episode that required external assistance but not hospitalization, and 16.1% had more than one episode. On average, the number of hypoglycemia episodes experienced by those who had one episode or more that did not require hospitalization in the year preceding the study was 5.4±7.4 episodes.

Hypoglycemic events per OAD in the year prior to study initiation were recorded. During this period, at least one hypoglycemic episode was experienced by 32.9% of patients on glimepiride, 11.2%

Table II. Treatment modification in relation to HbA1c level.

Action Taken	Less than 7 n=402	7 to 8 n=533	8.1 to 9 n=428	9.1 to 10 n=346	More than 10 n=472
Switched the Treatment	5.2%	11.3%	28.0%	43.1%	46.4%
Add on the treatment	1.5%	10.3%	24.8%	18.2%	18.6%
Adjust the doses	2.7%	11.8%	23.4%	22.3%	15.3%
No modifications done	90.5%	66.6%	23.8%	16.5%	19.7%

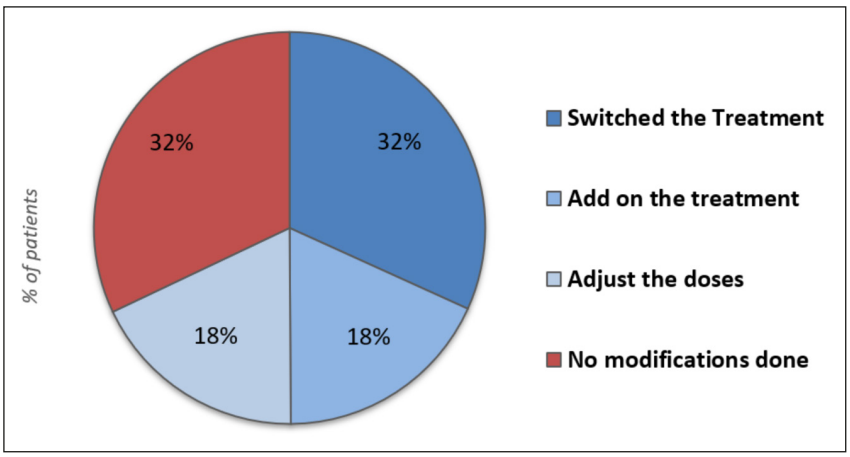

Figure 4. Action taken with patients having HbA1c ≥7%.

of cases on gliclazide, 42.3% of subjects on glibenclamide/metformin combination, 27.5% of patients on glimepiride/metformin combination, and 14.2% of patients on gliclazide/metformin combination. All previous results were significant ($p<0.05$).

The majority of patients (96.7%) experiencing hypoglycemic events did not require any hospitalization. The average number of hypoglycemic events experienced by study participants and required hospitalization was 1.7±1.7, with no significant differences between the geographical areas.

Hypoglycemic events per OAD that required hospitalization in the year before the study initiation were also recorded. During this period, hypoglycemic events requiring hospitalization occurred in 5.6% of patients on glimepiride, 0.7% of patients on gliclazide, 5.6% of patients on glibenclamide/metformin combination, 5.5% of patients on glimepiride/metformin combination, and 2.1% of patients on gliclazide/metformin combination. All the results were not statistically significant.

Discussion

Diabetes is a disease of pandemic proportion and a significant contributor to morbidity and mortality[18,19]. The MENA region is among the areas with the highest prevalence of the disease, where it exceeds the global prevalence by more than 50%. In Egypt, the situation is even more dire, as the number of individuals affected by diabetes reaches up to 1 in every five people between the ages of 20-79 years, according to the latest reports[1,2]. Type 2 diabetes constitutes the majority of these cases (>90%) despite being a preventable condition[2].

Diabetes is a significant burden to the Egyptian economy. The results presented by Assaad-Khalil et al[20] highlighted that the total cost of diabetes in Egypt amounts up to $3.5 billion (equivalent to ~55 billion EGP during the article's writing)[20]. The majority (~85%) of expenses were attributed to direct medical costs, while the remaining fell under the category of indirect costs. Of the direct medical costs, 65% were allocated towards managing diabetes complications. They included the costs associated with the medications, hospitalization, and amputation, while laboratory investigation and monitoring accounted for over 30% of the total diabetes cost in Egypt. With regard to indirect costs, absenteeism accounted for more than 72% of the total indirect expenses[20]. This highlights the significant economic burden associated with the condition, especially the complication that arises from it.

The results from our study revealed that the majority of patients (81.6%) failed to achieve a target HbA1c of <7%. This outcome was consistent across different geographical regions (Figure 1C) despite the unequal distribution of healthcare facilities. The results obtained in our study are lower than data reported by some literature[21], where the proportion of patients with poor glycemic control mounted up to 93%. However, the results of our study align with data reported by the International Diabetes Management Practices (IDMP)[22], where 82.7% of patients affected by T2DM in Egypt had poor control in terms of HbA1c >7%. In our study, the mean HbA1c of the study population was found to be 8.9±2.3, which is similar to results obtained from other earlier studies[23,24] suggesting little improvement over time. This weak control is translated into poor patient outcomes and increased financial cost that is otherwise avoidable[25]. Additionally, poor glycemic control in the long term leads to the development of micro- and macro-vascular complications[5]. It is important to note that characteristics of T2DM control in the Egyptian population are similar to regional and international patient profiles, where poor glycemic control prevails[26-28].

Among patients who did not reach their glycemic control target, 32% had no treatment modifications, and no data was captured on circumstances surrounding this and whether this was their choice or a decision made by the physician (Figure 4). Understanding the reasons behind such a phenomenon was not a part of the study objectives; however, we sought to gain more insight into the situation in Egypt. We assume that the reason behind the said phenomenon is the patient's reluctance to accept therapy modifications or the treating physician's judgment. These reasons have also been highlighted in literature elsewhere[26]. Within the same context, physicians may fail to intensify treatment by overestimating the efficacy of medications or patients' adherence to the treatment regimen[29]. These points have been identified in the literature, and tested responses like a short message service (SMS) and educational programs in Egypt have proven to be effective in helping patients improve adherence[30,31]. In addition, providing guidance to physicians about glycemic control and providing them with the tools necessary to monitor progress has also been shown[32] to be effective tools for improving glycemic control.

Regarding our study population, the majority were females (the ratio to males is about 2:1). This could indicate that women are more likely to seek medical help in private clinic settings than their

male counterparts, a trait that women are proven to exhibit across most clinical areas[33]. This could also be attributed to higher disease prevalence among females, as highlighted in a study that took place in Alexandria, Egypt, where the proportion of females suffering from T2DM was found to be 19.1% compared to 12.7% in males[34].

Generally, guidelines[35] highlight that metformin is usually included as first-line treatment in the therapeutic regimen of most adults suffering from T2DM. In addition, these guidelines acknowledge that therapeutic regimens need to be adjusted to fit the patient's requirements and treatment targets. For the past 60 years, sulfonylureas, both conventional and new, have been a cornerstone in the treatment of T2DM, especially in the MENA region in general and Egypt specifically[36]. In our study, more than 3 in every 4 participants received sulfonylurea, either as monotherapy or as a combination treatment. This result is consistent with those of other studies and literature[22,37], where sulfonylurea was among the most widely prescribed therapeutic agents.

In our study, gliclazide, a medication belonging to the sulfonylurea family, produced the best results in terms of overall glycemic control when compared to other therapeutic agents (Figure 3). In addition, the proportion of patients achieving glycemic control using gliclazide 120 mg was almost double that of those using gliclazide 60 mg (40.3% *vs.* 21.5%, respectively). This effect was achieved without increasing the risk of hypoglycemia. The efficacy of gliclazide was compared to medications belonging to the same class or different ones and consistently demonstrated better efficacy. In another study[38], gliclazide was compared to metformin and rosiglitazone; results highlighted that all three molecules had similar efficacy as monotherapies, and the combination of gliclazide with metformin achieved the best results in terms of glycemic control and lipid profile. This highlights the importance of gliclazide in treating T2DM in the Egyptian population, which is aligned with literature[39] that recommends its early incorporation in the treatment paradigm to achieve the best possible outcomes for patients.

Hypoglycemia is among the most commonly reported side effects of OADs that usually arise due to treatment intensification and lead to outcomes like reduced compliance[40]. Many patients fail to report hypoglycemia due to a lack of awareness[41,42]. In our study, a total of 21.6% of enrolled patients reported having hypoglycemic events requiring external assistance but not hospitalization, with 16.5% reporting one event and 5.5% reporting more than one. In addition, 3.3% of the study population reported one (2%) or more (1%) hypoglycemic events requiring hospitalization. Our results align with those reported in the literature, where a meta-analysis[43] of over 530,000 participants highlighted that the prevalence of severe hypoglycemia was 5% for those on sulfonylurea and non-sulfonylurea treatment regimens. Additionally, it was reported that the prevalence of mild/moderate hypoglycemic events in sulfonylurea treatment was 33%. Moreover, other reports[44,45] have highlighted that gliclazide has a lower risk of hypoglycemia compared to other sulfonylureas like glibenclamide, glimepiride, and glipizide and similar risk compared to dipeptidyl peptidase-4 (DPP-4) inhibitors.

There was a high health burden among participants. More than 1 in two patients reported suffering from hypertension, about 1 in every three from dyslipidemia, almost 1 in every five from an associated cardiovascular disease, and 3.8% from renal impairment. Most of these numbers were significantly lower when compared to results obtained from a recent study[46] of 1.9 million subjects, in which hypertension, hyperlipidemia, cardiovascular disease (CVD), and chronic kidney disorder affected 82.1%, 77.2%, 21.6%, and 24.1%, respectively.

Limitations

Our study has some limitations. Since it aimed to measure the HbA1c of diabetic patients, we purposively recruited physicians who treated these patients and could collect relevant data from them. Although we did not seek a generalizable population sample, we sought to obtain a population range by recruiting across regions, and different types of healthcare practitioners and by including a mix of gender and age among the patients. Another limitation is the inability to thoroughly extrapolate these outcomes to patients being treated in public settings. However, as we have already noted, most patients in Egypt pay for their own care due to the long waiting time associated with the availability of subsidized care, suggesting that this study includes people from all income quintiles. Another limitation is that physicians may introduce bias into the study by completing case forms on their patients. It is becoming an accepted practice as physicians are frequently called on to manage trials and other research. Potential financial conflicts generate the most concern[47]. However, in this study, there were no financial incentives involved, and it is

unclear how the physicians would benefit financially. Furthermore, the treating physicians were trained on the use of the Case Reporting form and on ethical requirements.

Some data was not calculated for enrolled patients. For example, this study did not measure the patients' body mass index and central obesity, which are important predictors of T2DM in young adults[48]. The participants as a group had high weights for their age categories on average, which is associated with diabetes. However, patient characteristics were not used in the calculation of key study outcomes. In addition, our study did not recruit people of younger age (school-age children and teenagers) due to ethical complications and their low attendance in the recruiting practices. It is likely that the prevalence of T2DM will increase in this population48 if interventions are not made. Therefore, future studies that address these points are strongly warranted. Finally, while there has been some debate in the literature about whether HbA1c >7% is an appropriate measure of uncontrolled diabetes, evidence in the literature suggests that this is a widely accepted measure of uncontrolled diabetes.

Conclusions

This cross-sectional, observational study demonstrated that there is low glycemic control among Egyptian patients affected by T2DM. This could be attributed to poor patient adherence to medications or reluctance to switch therapies when glycemic profiles were not satisfactory upon follow-up testing. Such results suggest that measures and guidelines should be implemented to improve the care provided to those patients, such as early detection, patient education, continuous monitoring, and treatment modifications and adjustments. Sulfonylurea was the most prescribed medication class in the investigated cohort, with gliclazide demonstrating the highest effectiveness in terms of efficacy and safety, even in relation to other molecules. The patient profile in our study reveals that T2DM patients in Egypt have low levels of exercise, are obese, and suffer from several associated comorbidities, which are associated with high glucose levels[49]. Therefore, improving health practices and addressing these comorbidities earlier could improve patients' prognoses and enhance their quality of life. The recommended interventions are best delivered as government-regulated guidelines and applied in public as well as private practice to ensure better outcomes and improved quality of life for T2DM patients. While deduced under some limitations, it is likely that these findings and recommendations can be useful if implemented for the care and management of middle- and older-aged Egyptians generally and especially those diagnosed or at risk of being diagnosed with T2DM.

Ethics Approval

This study received approval from the Ministry of Health and Human Population Research and Ethics Committee and was in accordance with the principles established by the Declaration of Helsinki and applicable local and international laws. The ethics approval was registered under the number IC4-05762-010-EGY.

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Authors' Contributions

The authors would like to highlight that they all contributed equally to this research.

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Conflicts of Interest

Authors report no conflict of interest.

Data Availability

Study data is available upon request from the corresponding author.

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All subjects provided written informed consent for inclusion before they participated in the study.

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