

T.C.
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DEPARTMENT OF CLINICAL PHARMACY

**Exploring Glycemic Control, Self-Care Management
and COVID-19 Experience among Patients with Type
2 Diabetes Mellitus in Community Pharmacies**

MASTER THESIS

Oğuz Tanıl Çete, B.Pharm

ADVISOR

Assist. Prof. Dr. Beril Kadioğlu Yaman

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This study have approved as a Master Thesis in regard to content and quality by the Jury.

	Title, Name-Surname (Institution)
Chair of the Jury:	Prof. Dr. Mesut Sancar
Supervisor:	Assist. Prof. Dr. Beril Kadioğlu Yaman
Member/Examiner:	Assoc. Prof. Dr. Betül Okuyan
Co-advisor:	Assoc. Prof. Abdikarim Abdi

APPROVAL

This thesis has been deemed by the jury in accordance with the relevant articles of Yeditepe University Graduate Education and Examinations Regulation and has been approved by Administrative Board of Institute with decision dated and numbered

Prof. Dr. Bayram YILMAZ
Director of Institute of Health Sciences

DECLARATION

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which has been accepted for the award of any other degree except where due acknowledgment has been made in the text.

Date

Signature

Name Surname

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TABLE OF CONTENTS

THESIS APPROVAL FORM.....	ii
DECLARATION.....	iii
ACKNOWLEDGEMENTS.....	iv
TABLE OF CONTENTS.....	v
LIST OF TABLES	vii
LIST OF FIGURES	viii
LIST OF SYMBOLS AND ABBREVIATIONS	ix
ABSTRACT	x
ABSTRACT (Turkish)	xi
1. INTRODUCTION.....	1
2. LITERATURE REVIEW.....	1
2.1. Diabetes mellitus	1
2.1.1. Epidemiology	2
2.1.2. Etiology	4
2.1.3. Pathophysiology	4
2.1.4. Treatment	5
2.2. Barriers of Achieving Goals of Therapy	9
2.3. Glycemic Control Status of Diabetes Mellitus.....	10
2.4. COVID-19	10
2.4.1. COVID-19 and Restrictions	11
2.4.2. COVID-19 and Outcomes of Chronic Diseases	12
3. MATERIALS AND METHODS	15
3.1. Study Design and Population	15
3.1.1. Inclusion Criteria	15
3.1.2. Exclusion Criteria	16
3.1.3. Sample size determination.....	16
3.2. Questionnaire	16
3.3. Statistical Analysis	17
4. RESULTS	18
4.1. Demographics and Characteristic Patients Information.....	18
4.2. Comorbidities and Diabetes Care Status	20
4.3. Diabetes patients experience of COVID 19.....	24
5. DISCUSSION AND CONCLUSION.....	26

6. REFERENCES.....	30
7. APPENDICES	34
7.1. Questionnaire	34
7.2. Ethical Approval	36
8. CURRICULUM VITAE	38



LIST OF TABLES

Table 1. Characteristics of study population	19
Table 2. Patients' glycemic, creatinine clearance, and total cholesterol control	21
Table 3. Patients' Diabetes Self-Management and Medication Adherence	23
Table 4. Diabetes self-management by glycemic control of patients	24
Table 5. Patients' self-reported healthcare utilization amid COVID-19 pandemic and having probable and/or confirmed COVID-19	25



LIST OF FIGURES

Figure 1. Patients' Diabetes Self-Management and Medication Adherence.....	
22	



LIST OF SYMBOLS AND ABBREVIATIONS

DM	Diabetes Mellitus
T2DM	Type 2 diabetes mellitus
MARS	Medication Adherence Report Scale
DSMQ	Diabetes Self-Management Questionnaire
DR	Diabetic retinopathy
WHO	The World Health Organization
COVID-19	Coronavirus Disease
NIDDM	Non-insulin-dependent-diabetes mellitus
MNT	Medical nutrition therapy
CKD	Chronic kidney disease

ABSTRACT

Oğuz Tanıl (2023). Exploring Glycemic Control, Self-Care Management and COVID-19 Experience among Patients with Type 2 Diabetes Mellitus in Community Pharmacies. Yeditepe University Institute of Health Sciences, Department of Clinical Pharmacy, MSc Thesis, Istanbul.

Objective: Diabetes is a chronic disease with significant health implications, exacerbated by the challenges posed during the COVID-19 pandemic for individuals with chronic illnesses. This study evaluates self-care management, medication adherence, glycemic control, and COVID-19 experiences among T2DM patients in Türkiye during the pandemic.

Materials and Methods: A cross-sectional design involved 2772 T2DM patients approached from 67 community pharmacists, with 462 eligible patients participating in the survey using a Turkish validated MARS and DSMQ questionnaires along lab results.

Results: Nearly 51% reported experiencing COVID-19. A significant proportion (58.9%) were identified as non-adherent to their medications and scored significantly lower on all DSMQ subscales. Only a few (33.3%) achieved the target HbA1c level or total cholesterol (30.3%). Higher DSMQ general scale scores were associated with lower HbA1c levels and improved medication adherence. Poor glycemic control and multiple comorbidities were linked to hospitalization or ER admission due to COVID-19.

Conclusion: A concerning proportion of diabetic patients failing to achieve treatment targets is seen, particularly those with multiple morbidities, adding strain to the current healthcare system. Addressing medication adherence, glycemic control, and self-care activities is critical for better supporting diabetic patients and improving overall healthcare outcomes in the post-COVID-19 era.

Key words: Type 2 diabetes mellitus; adherence; self-care; glycemic control, COVID-19

ABSTRACT (Turkish)

Oğuz Tanıl (2023). Serbest Eczanelerde Tip 2 Diabetes Mellitus Hastalarında Glisemik Kontrol, Öz Bakım Yönetimi ve COVID-19 Deneyiminin Araştırılması. Yeditepe Üniversitesi Sağlık Bilimleri Enstitüsü, Klinik Eczacılık ABD., Yüksek Lisans Tezi. İstanbul

Amaç: Diyabet, kronik hastalıkları olan bireyler için COVID-19 salgını sırasında ortaya çıkan zorluklarla daha da kötüleşen, önemli sağlık etkileri olan kronik bir hastalıktır. Bu çalışma, pandemi sırasında Türkiye'deki T2DM hastalarının öz bakım yönetimi, tedaviye uyuncu, glisemik kontrolü ve COVID-19 deneyimlerinin değerlendirilmesi amaçlanmıştır.

Gereç ve Yöntem: Kesitsel tanımlayıcı nitelikte bir araştırma olan çalışmamız, 67 serbest eczaneden yaklaşık 2772 T2DM hastasına ulaşıldı. Bu hastaların uygun bulunan 462 tanesi ile laboratuvar sonuçlarının yanı sıra MARS ve DSMQ anketlerinin Türkçe geçerli versiyonları kullanılarak gerçekleştirildi.

Bulgular: Ankete katılan hastaların yaklaşık %51'i COVID-19 geçirdiğini bildirdi. Önemli sayıda hasta (%58,9) tedaviye uyumsuz olarak tanımlandı ve tüm DSMQ alt ölçeklerinde önemli ölçüde daha düşük puan aldı. Sadece bir kısım hastanın (%33,3) hedef HbA1c veya hedef total kolesterol (%30,3) düzeylerine sahip olduğu görüldü. Yüksek DSMQ genel ölçek puanları, düşük HbA1c seviyeleri ve daha iyi ilaç uyumu ile ilişkilendirildi. Kötü glisemik kontrol ve çoklu komorbiditeler, COVID-19 nedeniyle hastaneye yatış veya acil servise yatışla ilişkilendirildi.

Sonuç: Özellikle çoklu morbiditeleri olan diyabetik hastaların önemli bir oranının tedavi hedeflerine ulaşamadığı görülmektedir ve bu da mevcut sağlık sistemini zorlamaktadır. İlaç uyumunu, glisemik kontrolü ve öz bakım faaliyetlerini ele almak, diyabetik hastaları daha fazla desteklemek ve COVID-19 sonrası dönemde genel sağlık hizmeti sonuçlarını iyileştirmek için kritik öneme sahiptir.

Anahtar kelimeler: Tip 2 diabetes mellitus; uyuncu; öz bakım; glisemik kontrol, COVID-19

1. INTRODUCTION

Diabetes mellitus (DM) is a heterogeneous spectrum of metabolic diseases characterized by impaired glucose homeostasis and hyperglycemia, resulting from defects in insulin secretion, insulin action, or both. Type 1 diabetes results from autoimmune mediated destruction of the β cells of the pancreas, leading to complete or almost complete insulin deficiency. Type 2 diabetes is associated with impaired insulin secretion and action. The chronic hyperglycemia of DM is associated with long-term damage, dysfunction, and failure of various organs, especially as a result of micro and macro-vascular complications effecting the kidneys, eyes, heart, and nerves¹.

According to the reports of International Diabetes Federation (IDE), it is estimated that, with 13,4 million cases, Türkiye will become in the tenth place among the countries with the largest numbers of adults (aged 20–79 years) with diabetes in 2045².

Diabetic patients are at higher risk of developing chronic kidney disease³. Recent data from 54 countries showed that diabetes and hypertension are the underlying cause for 80% of cases with end-stage renal failure (ESRF). The Registry Report of Turkish Society of Nephrology in 2020, stated diabetes was the most common cause of ESRF, with a prevalence and incidence of 996.8 and 138.7 per million population, respectively⁴.

Diabetes was listed as one of the eight risk factors and health behaviors of having acute myocardial infarction, due to the national statistics of European Society of Cardiology (ESC) Atlas⁵. According to the results of CAPTURE study conducted across 13 countries, cardiovascular disease prevalence in people with type 2 diabetes were 34.8%. The study was conducted in 15 centers in Türkiye, with a prevalence of 31.2%, which is compatible with the global data^{6,7}.

Diabetic retinopathy (DR) is the major leading cause of preventable vision loss, with a global prevalence of 22.27%. Cases of DR is increasing in people with poor glycemic control, and by 2045, it is estimated to reach 60.50 million⁸. The prevalence of DR was reported as 30.5% in Turkish population, and it is indicated that 9.8% of patients already have DR by the time they were diagnosed with DM⁹. Results of this Turkish study emphasizes the importance of early diagnosis for the prevention of complications, and continuous follow-up is needed to improve disease outcomes.

Diabetic neuropathy is a prevalent and complex complication of DM, which includes pain, decreased quality of life and increased hospital admissions for ulcers and amputations. Although there are heterogeneous results from various studies (due to several factors like methods of assessments or different classifications of ‘neuropathy’), it is estimated that half of the diabetic patients are suffering from neuropathy¹⁰. According to the results of a study conducted in the outpatient clinics in Türkiye, the prevalence of diabetic neuropathy determined by clinical neurologic examination was 40.4%¹¹.

Hence, achieving glycemic control holds significant importance in reducing disease related long-term complications, as well as the associated costs and economic burden. The optimization of drug therapy and adherence may have a critical role in improving treatment outcomes. According to The World Health Organization (WHO), adherence to long-term therapy is defined as “The extent to which a person’s behavior taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.”¹². Ensuring patients' adherence to prescribed treatments and self-management towards achieving therapy targets is essential for managing T2DM effectively¹³.

On December 2019, the first novel pneumonia case, later diagnosed as coronavirus disease 2019 (COVID-19), was reported in Wuhan, China and within three months, the number of reported cases were increased in many countries. On March 2020, the WHO characterized the outbreak as a pandemic. In March 2023 the number of confirmed cases has reached over 274 million¹⁴.

Given the impact of the COVID-19 pandemic on individuals with chronic diseases like diabetes, studying medication adherence and glycemic control in T2DM patient’s post-COVID-19 is important. During the pandemic, communication challenges with healthcare providers arose due to social restrictions and lockdowns. Moreover, concerns about the risk of contracting the SARS-CoV-2 virus in healthcare facilities and the increased workload of healthcare providers further complicated patient care¹⁵.

In Türkiye, the Turkish Ministry of Health implemented a specific temporary regulation to facilitate patient access to chronic medications without requiring monitoring visits to primary care providers or prescription renewals. While this measure aimed to ensure medication availability, its impact on patient self-care management remains largely unexplored in this population¹⁶.

Understanding the effects of such measures on medication adherence and glycemic control in T2DM patients is essential for optimizing post-pandemic healthcare strategies. Assessing the challenges faced during the pandemic and their potential consequences on patient outcomes can help healthcare providers and policymakers develop targeted interventions to improve patient care, enhance self-management practices, and promote better glycemic control in the post-COVID-19 era. By studying these factors, we can better prepare for future health crises and improve overall health outcomes for individuals with diabetes and other chronic conditions. The aim of the study is to evaluate self-care management, medication adherence, glycemic control and COVID-19 experience in T2DM patients in Türkiye.



2. LITERATURE REVIEW

2.1. Diabetes mellitus

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels.

Several pathogenic processes are involved in the development of diabetes. These range from autoimmune destruction of the β -cells of the pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action. The basis of the abnormalities in carbohydrate, fat, and protein metabolism in diabetes is deficient action of insulin on target tissues. Deficient insulin action results from inadequate insulin secretion and/or diminished tissue responses to insulin at one or more points in the complex pathways of hormone action. Impairment of insulin secretion and defects in insulin action frequently coexist in the same patient, and it is often unclear which abnormality, if either alone, is the primary cause of the hyperglycemia¹⁷.

Type 1 diabetes is associated with β -cell destruction that leads to an absolute insulin deficiency mostly transmitted immunologically. Type 1 diabetes can be considered as a chronic autoimmune disease in which the immune system attacks and destroys the insulin-producing beta cells in the pancreas, leading to an absolute deficiency of insulin. This results in high blood sugar levels that can cause long-term complications. There are several factors that can contribute to the development of type 1 diabetes, including genetic predisposition, environmental triggers, and immune system dysfunction. Effective management of type 1 diabetes involves regular monitoring of blood sugar levels, adherence to a healthy diet and exercise plan, and insulin therapy to replace the missing hormone. It is important for individuals with type 1 diabetes to work closely with their healthcare team to develop a comprehensive management plan to reduce the risk of complications associated with the disease.

Type 2 diabetes can range from a predominant insulin resistance with a relative insulin deficiency to a largely secretory defect with insulin resistance. It is characterized by high blood sugar levels resulting from the body's inability to use insulin effectively or produce enough insulin to regulate blood sugar levels. Type 2 diabetes is often

associated with other diseases (e.g. the metabolic syndrome), which is a cluster of conditions that includes high blood pressure, high cholesterol, and abdominal obesity. The development of type 2 diabetes is influenced by a combination of genetic and environmental factors, such as poor diet, lack of exercise, and obesity.

Gestational Diabetes is a glucose tolerance disorder that occurs or is diagnosed for the first-time during pregnancy and typically goes away after delivery. It is characterized by high blood sugar levels that can pose health risks to both the mother and the baby. Gestational diabetes is diagnosed through a glucose tolerance test, which measures how the body processes glucose (sugar) after drinking a sugary solution. Women who are at higher risk for gestational diabetes, such as those with a family history of diabetes or who are overweight, may be screened earlier in their pregnancy. Treatment for gestational diabetes typically involves dietary modifications, exercise, and, in some cases, medication to help regulate blood sugar levels. Effective management of gestational diabetes is important to reduce the risk of complications for both the mother and the baby¹⁷.

Exocrine pancreatic diseases (e.g. pancreatitis, cystic fibrosis, hemochromatosis), Endocrinopathies (e.g. Cushing's syndrome, acromegaly, pheochromocytoma) can also lead to diabetes. Medically-chemically induced diabetes is a type of diabetes that is caused by certain medications or chemicals (e.g. glucocorticoids, neuroleptics, interferon-alpha, pentamidine). Genetic defects of the β -cell function, genetic defects of insulin action, other genetic syndromes (e.g., Down syndrome, Turner syndrome) which can be associated with diabetes. In addition, certain infections (e.g., Cytomegalovirus, Coxsackie virus, and Hepatitis C) can increase the risk of developing diabetes or can trigger the onset of diabetes in people who are already at risk. There are several rare forms of autoimmune diabetes that are classified as distinct subtypes of type 1 diabetes¹⁸.

2.1.1. Epidemiology

The number of people with diabetes has been increasing worldwide, with a more rapid rise in low- and middle-income countries. 537 million adults (20-79 years) are living with diabetes worldwide – 1 in 10. The total number of people with diabetes is predicted to rise to 643 million (1 in 9 adults) by 2030 and 784 million (1 in 8 adults) by

2045. 4 in 5 people with diabetes (81%) live in low income and middle-income countries.

Diabetes is a chronic disease that can lead to several complications such as blindness, kidney failure, heart attacks, stroke, and lower limb amputation. Diabetes caused 6.7 million deaths in 2021 – 1 every 5 seconds. An estimated 44% of adults living with diabetes (240 million people) are undiagnosed. Almost 90% of these people live in low income and middle-income countries. In addition, mortality rates due to diabetes have been increasing by age, and in 2019, diabetes and kidney disease due to diabetes caused an estimated 2 million deaths. However, there are several ways to prevent or delay the onset of type 2 diabetes, such as maintaining a healthy diet, regular physical activity, maintaining a normal body weight, and avoiding tobacco use. For those with diabetes, it can be treated, and its complications can be avoided or delayed with diet, physical activity, medication, and regular screening and treatment for complications¹⁹.

It is concerning to note that the prevalence of diabetes is high, with 16.5% of the population having either new or known diabetes. It is also important to address the issue of undiagnosed diabetes, as it can lead to serious complications. The higher risk profile observed in individuals diagnosed with diabetes based on HbA1c highlights the importance of considering multiple diagnostic criteria to identify those at risk. The prevalence of prediabetes is also high, which emphasizes the need for early screening and lifestyle interventions to prevent the development of diabetes²⁰. Diabetes with fasting plasma glucose (FPG) and OGTT prevalence was 16.5% (new diabetes: 7.5%, known diabetes 9%), this figure is 6.5 million in Türkiye indicates that the person has diabetes. Standardized according to TURDEP-I (1997-98) study diabetes prevalence was calculated as 13.7%. The prevalence of new diabetes by HbA1c is 3% found. In the group diagnosed with diabetes according to HbA1c, compared to those diagnosed based on FPG and OGTT phenotypic and metabolic risk profile is higher. 2/3 of known diabetics have ideal control, 1/2 far from acceptable metabolic control. Isolated impaired fasting glucose (IFG), isolated impaired glucose tolerance (IGT), and combined prediabetes prevalence; 14.7%, 7.9% and 8.2% respectively²⁰.

It is important to recognize the global impact of this disease and the need for prevention, early detection, and effective management. The increasing prevalence of diabetes, particularly in low and middle-income countries, highlights the need for greater access to healthcare resources and education on healthy lifestyle choices. Diabetes is a complex disease that requires a multi-faceted approach to combat,

including public health initiatives, advances in medical research, and individual efforts to manage the disease²¹.

2.1.2. Etiology

Diabetes mellitus is caused by derangements in the secretion of insulin, glucagon, and other hormones and results in abnormal carbohydrate and fat metabolism. This is often coupled with insulin resistance, particularly in those with type 2 DM. In many cases, the underlying etiology of the disorder is complex and involves multiple mechanisms²². Chronic exposure of β -cells to triacylglycerol or fatty acids either *in vitro* or *in vivo* decreases β -cell capacity to respond to an acute increase in glucose levels. This concept is far from new, but the observations of what happens during reversal of diabetes provide a new perspective. β -cells avidly import fatty acids through the CD36 transporter and respond to increased fatty acid supply by storing the excess as triacylglycerol. The cellular process of insulin secretion in response to an increase in glucose supply depends on ATP generation by glucose oxidation. However, in the context of an oversupply of fatty acids, such chronic nutrient surfeit prevents further increases in ATP production. Increased fatty acid availability inhibits both pyruvate cycling, which is normally increased during an acute increase in glucose availability, and pyruvate dehydrogenase activity, the major rate-limiting enzyme of glucose oxidation. Fatty acids have been shown to inhibit β -cell proliferation *in vitro* by induction of the cell cycle inhibitors p16 and p18, and this effect is magnified by increased glucose concentration. This antiproliferative effect is specifically prevented by small interfering RNA knockdown of the inhibitors. In the Zucker diabetic fatty rat, a genetic model of spontaneous type 2 diabetes, the onset of hyperglycemia is preceded by a rapid increase in pancreatic fat. It is particularly noteworthy that the onset of diabetes in this genetic model is completely preventable by restriction of food intake, illustrating the interaction between genetic susceptibility and environmental factors²³.

2.1.3. Pathophysiology

Many different paths, driven by various genetic and environmental factors, result in the progressive loss of β -cell mass and/or function that manifests clinically as hyperglycemia. Once hyperglycemia occurs, people with all forms of diabetes are at risk for developing the same complications. Though rates of progression may differ. The present challenge is to characterize the many paths to β -cell dysfunction or demise and identify therapeutic approaches that best target each path. Type 1 DM is the result of autoimmune destruction of the β -cells of the pancreas. Given that insulin therapy is required when treating type 1 diabetes, it was previously called insulin-dependent diabetes mellitus, and some references, patients, and providers continue to use this, albeit incorrect, terminology. Type 1 DM is believed to be initiated by exposure to an environmental trigger in a genetically susceptible individual. There is a link between currently known genetic markers for autoimmunity and the development of type 1 DM. However, β -cell autoimmunity develops in less than 10% of the genetically susceptible individuals and progresses to type 1 DM in less than 1%. On the other hand, β -cell autoimmunity, including ICAs, is present at the time of diagnosis in 90% of individuals. Type 1 diabetes most commonly develops in childhood or young adulthood; however, it can occur at any age²².

Hyperglycemia in Non-insulin-dependent-diabetes mellitus (NIDDM) develops due to two disorders:

- 1- Insulin resistance in liver and muscle tissue
- 2- Decreased insulin production in the pancreas

Insulin resistance, with still unknown genetic defects, influence of environmental factors develops with the most important environmental factors are obesity and lack of physical activity. In NIDDM, insulin resistance in muscle and liver tissues leads to a decrease in glucose uptake and utilization by these tissues, resulting in postprandial hyperglycemia and impaired glucose tolerance. The pancreas initially compensates by secreting more insulin to overcome insulin resistance and maintain normal blood glucose levels, but over time, the beta cells in the pancreas may become exhausted and unable to produce enough insulin to overcome insulin resistance, leading to hyperglycemia and diabetes²⁴.

2.1.4. Treatment

Diabetes mellitus is a spectrum of metabolic disorders characterized by hyperglycemia. Poorly controlled diabetes mellitus can lead to microvascular and macrovascular complications, including kidney failure, blindness, amputation, and cardiovascular disease²⁵.

The medical treatment of diabetes includes different classes of medications that are used to help manage blood sugar levels. Here is a breakdown of some common classes of antidiabetic drugs:

1- Drugs that stimulate insulin secretion: These drugs work by stimulating the pancreas to produce more insulin. Examples of such drugs include sulfonylureas (e.g. glibenclamide, glipizide) and glinides (e.g. repaglinide, nateglinide).

2- Insulin sensitizing drugs: These drugs work by improving the body's sensitivity to insulin, which helps to lower blood sugar levels. Examples of such drugs include biguanides (e.g. metformin) and thiazolidinediones (e.g. pioglitazone, rosiglitazone).

3- Alpha-glucosidase inhibitors: These drugs work by slowing down the absorption of carbohydrates from the gut, which helps to prevent spikes in blood sugar levels after meals. Examples of such drugs include acarbose and miglitol.

4- Incretin mimetic drugs: These drugs work by mimicking the effects of incretin hormones in the body, which help to stimulate insulin secretion and lower blood sugar levels. Examples of such drugs include dipeptidyl peptidase-4 (DPP-4) enzyme inhibitors (e.g. sitagliptin, saxagliptin) and glucagon-like peptide-1 receptor agonists (e.g. liraglutide, exenatide).

5- Combination therapies: Combinations of different classes of drugs may be used to target multiple aspects of diabetes pathophysiology and improve glycemic control.

The choice of medication for a person with diabetes depends on several factors, including the type and severity of diabetes, the presence of comorbidities, the individual's response to medications, and potential side effects. Treatment plans should be individualized and regularly evaluated to optimize glycemic control and minimize the risk of complications.

There are different types of insulin available that can be used to manage blood sugar levels in people with diabetes. Here is a breakdown of the main types of insulin:

Basal Insulins: These insulins work to control fasting blood sugar levels and provide a steady release of insulin throughout the day. They make up approximately

50% of the daily insulin requirement. Examples of basal insulins include intermediate-acting NPH insulin and long-acting analog insulins such as insulin glargine and insulin detemir.

Bolus Insulins: These insulins are used to control blood sugar levels after meals and make up approximately 10-20% of the daily insulin requirement. Examples of bolus insulins include short-acting regular insulin and rapid-acting analog insulins such as insulin aspart, insulin lispro, and insulin glulisine.

Ready Mixed Insulins: These insulins are a combination of basal and bolus insulins. Examples of ready mixed insulins include regular insulin mixed with NPH insulin and analog mixed insulins.

- Regular + NPH Insulin

Analog Mixed Insulins:

Analog mixed insulins are also a combination of basal and bolus insulin, but they use long-acting analog insulins instead of NPH insulin. They are typically taken once or twice daily before meals. Examples include:

- Insulin Aspart 70/30
- Insulin Lispro 75/25
- Insulin Glargine 300 U/mL

It is important for individuals with diabetes to work closely with their healthcare team to determine the most appropriate type(s) of insulin to use, as well as the dosages and timing of administration, to achieve optimal blood sugar control²⁶.

Although medical advances have increased the number of treatment options for diabetes and improved outcomes for many individuals, there remains a need to determine the appropriate therapy for each individual, since a significant number of monotherapy treatments fail within 3 years and diabetes-related morbidity and mortality continue. Currently, there is little widespread implementation of personalized medicine in diabetes mellitus treatment. Personalized medicine in diabetes mellitus treatment refers to tailoring therapy to the individual patient based on their specific genetic, environmental, and lifestyle factors. This approach has the potential to improve treatment outcomes and reduce the risk of complications. However, the implementation of personalized medicine in diabetes treatment has been limited due to several factors, such as genetic testing, lack of resources and specialized healthcare providers and also including the complexity of the disease and the lack of reliable biomarkers to predict treatment response. Further research is needed to develop and validate personalized

medicine approaches in diabetes treatment²⁵. Management of type 2 diabetes has been improved by the recent introduction of the peroxisome proliferator-activated receptor-gamma agonists and more recently by the incretins including glucagon like peptide analogues and dipeptidyl peptidase-4 inhibitors.

Great advances have been made in our exploration of the genetic architecture of diabetes and its complications, which have provided the foundations for the development of genomic medicine in diabetes. Genetic analysis can help discriminate subgroups of patients with specific molecular defects who otherwise are classified under the broad umbrella of type 1 diabetes or type 2 diabetes and provide the basis for optimal preventive or therapeutic interventions²⁷.

The management of diabetes requires a multifaceted approach that involves coordination of different components of treatment. In addition to medical treatment, other important components of diabetes management include medical nutrition therapy (MNT), physical activity and exercise, and education and information.

Medical nutrition therapy involves working with a registered dietitian or nutritionist to develop a personalized meal plan that takes into account the individual's dietary preferences, cultural background, and lifestyle. This can help individuals with diabetes achieve better blood sugar control and improve overall health outcomes.

Physical activity and exercise are also important components of diabetes management. Regular physical activity can help improve blood sugar control, reduce the risk of complications, and improve overall fitness and well-being. Healthcare providers can work with individuals with diabetes to develop a safe and effective exercise program that takes into account their individual health status and preferences.

Education and information are also critical components of diabetes management. Individuals with diabetes need to understand the importance of blood sugar monitoring, medication adherence, and lifestyle changes, as well as how to recognize and manage symptoms of hypoglycemia and hyperglycemia. Healthcare providers can provide education and support to help individuals with diabetes make informed decisions about their health and manage their condition effectively.

By coordinating these different components of treatment, individuals with diabetes can achieve optimal glycemic control and improve their long-term health outcomes. It is important for healthcare providers to take a holistic approach to diabetes management and work with individuals with diabetes to develop individualized care plans that address their unique needs and preferences²⁸⁻³⁰.

2.2. Barriers of Achieving Goals of Therapy

The availability of information at different healthcare system levels that affects several processes in the healthcare provision; insufficient financial resources; and insufficient human resources trained in diabetes management³¹.

Lower neighborhood income quintile, history of substance abuse, mood disorder, cardiovascular disease, albuminuria, and high LDL cholesterol were also associated with poor glycemic control³².

Overall themes for the barriers included lack of knowledge and misperceptions as well as lack of cultural adaptation to diabetes management. Language and communication discordance with the healthcare provider was a significant barrier to receiving and understanding diabetes education. Patients reported a lack of understanding about diabetes medication management, preference for folk and phytotherapy, and concerns about the long-term safety of diabetes medications³³.

In multivariate analyses, lower neighborhood socioeconomic status, older age, fewer HbA1c tests, and fewer physician visits were associated with lower rates of self-monitoring. Obesity and fewer comorbidities were also associated with lower rates of self-monitoring among insulin-managed patients, while black race and high glycemic level ($\text{HbA1c} > 10$) were associated with less frequent monitoring. For patients taking oral sulfonylureas, higher dose of diabetes medications was associated with initiation of self-monitoring and HbA1c lab testing was associated with more frequent testing³⁴. geriatric conditions, including dementia, depression, and falls, as well as hypoglycemia, may be especially important in older adults because of the potential barrier posed by these conditions on diabetes self-management³⁵.

The availability of information at different healthcare system levels is a critical factor that affects the processes involved in healthcare provision, including diabetes management. Inadequate information can lead to misdiagnosis, improper treatment, and poor patient outcomes. It is important that healthcare providers have access to accurate and up-to-date information on diabetes, including its causes, symptoms, and treatment options.

Insufficient human resources trained in diabetes management is another significant challenge in diabetes care. Many healthcare providers lack the necessary training and expertise to effectively manage diabetes. This can lead to inadequate care,

mismanagement of the condition, and poor patient outcomes. It is crucial that healthcare providers receive adequate training in diabetes management, including how to diagnose and treat the condition, how to monitor blood sugar levels, and how to provide ongoing support and education to patients.

Overall, addressing these challenges requires a multi-faceted approach that involves increasing access to information, improving financial resources for diabetes care, and investing in training and education for healthcare providers. By doing so, we can improve diabetes management and ultimately improve the health outcomes of patients with diabetes^{31,32}.

2.3. Glycemic Control Status of Diabetes Mellitus

The perceptions of personal control were positively associated with better glycemic control, indicating that individuals who felt they had more control over their diabetes management were more likely to have better blood sugar control. On the other hand, regimen-related distress was negatively associated with glycemic control, suggesting that individuals who experienced more distress related to their diabetes treatment were more likely to have higher blood sugar levels.

Socioeconomic status and insulin use were also significant contributors in predicting HbA1c, which is a measure of blood sugar control over the past several months. It's possible that individuals with lower socioeconomic status may face additional challenges in managing their diabetes, such as limited access to healthcare or healthy food options, which could contribute to poorer glycemic control. Insulin use may also affect glycemic control, as individuals who require insulin may have more advanced or difficult-to-manage diabetes.

The illness perceptions, socioeconomic status, and insulin use are important factors to consider when working with individuals with diabetes to improve glycemic control. Addressing regimen-related distress and promoting a sense of personal control may be helpful strategies to support diabetes self-management and improve blood sugar control³⁶.

2.4. COVID-19

SARS-CoV-2 is a novel coronavirus that emerged in late 2019 and causes the respiratory illness known as COVID-19. SARS-CoV-2 is a highly transmissible and pathogenic coronavirus that emerged in late 2019. The virus primarily spreads through respiratory droplets when an infected person talks, coughs, or sneezes. It can also be transmitted by touching a surface contaminated with the virus and then touching one's mouth, nose, or eyes. COVID-19 is the disease caused by SARS-CoV-2 and primarily affects the respiratory system. The symptoms can range from mild to severe, and some people may not have any symptoms at all. However, the disease can be life-threatening, especially for older adults and those with underlying health conditions.

COVID-19 has rapidly spread around the world, causing a pandemic of acute respiratory disease that threatens human health and public safety. The pandemic has had significant social and economic impacts, and efforts to control the spread of the virus have included measures such as social distancing, wearing masks, and vaccination.

SARS-CoV-2 and COVID-19 are significant global health concerns, and ongoing efforts are needed to control the spread of the virus, treat those who are infected, and develop effective prevention and treatment strategies³⁷.

While many people with COVID-19 experience mild to moderate symptoms and recover without needing special treatment, certain individuals are at higher risk for developing severe illness and complications. This includes older adults and those with underlying medical conditions such as cardiovascular disease, diabetes, chronic respiratory disease, or cancer. However, it's important to note that anyone can become infected with COVID-19 and potentially develop serious illness or even die, regardless of their age or health status. It's important to take precautions such as vaccination, wearing masks, and practicing good hygiene to protect oneself and others from the virus³⁸.

According to the data, since the beginning of the pandemic, over 656 million confirmed cases and over 6.6 million deaths have been reported globally as of 1 January 2023.

These statistics highlight the ongoing global impact of the COVID-19 pandemic, underscoring the need for continued efforts to control the spread of the virus and minimize its impact on public health³⁹.

2.4.1. COVID-19 and Restrictions

10.05.2020 The city entry/exit restrictions introduced for 24 provinces and the restrictions on our citizens aged 65 and older with chronic diseases and our children/young people under the age of 20 going out on the streets throughout the country (with exceptions) continue in the same way.

10.11.2020 Within the scope of Kovid-19 measures in Ankara, restrictions were imposed on people aged 65 and over to go out, except between 10.00-16.00. After this decision in Ankara, a regulation was made regarding the curfews of people aged 65 and over in Istanbul.

10.11.2020 65 Age Restriction Has Been Introduced in Istanbul and Ankara.

02.03.2021 In our provinces in low and medium risk groups; The curfew will be lifted for our citizens aged 65 and over, as well as young people and children under the age of 20. In our provinces that are in high and very high risk groups; The curfew times for our citizens aged 65 and over and under the age of 20 will be increased from 3 hours to 4 hours, Our citizens aged 65 and over, between 10:00 and 14:00, Our children and young people under the age of 20 will be able to go out on the street between 14.00-18.00.

16.05.2021 Apart from the curfew restriction applied for everyone for our citizens aged 65 and older who have received two doses of vaccine using the right to vaccination, as well as for young people under the age of 18 and our children, there will also be no curfew restriction applied.

16.05.2021 Our citizens aged 65 and over who are not vaccinated despite having the right to be vaccinated will only be able to go out between 10.00-14.00 on weekdays and will be subject to a full-time curfew on weekends⁴⁰.

2.4.2. COVID-19 and Outcomes of Chronic Diseases

The World Health Organization (WHO) has identified elderly individuals and those with underlying medical conditions as being at higher risk of developing severe COVID-19 disease. While there have been numerous studies investigating the epidemiological and clinical characteristics of patients infected with COVID-19, there is still a need to better understand the risk factors for severity and mortality associated with the disease.

Comorbidities such as hypertension, diabetes mellitus, stroke, cancer, kidney issues, and high cholesterol have been identified as high-risk factors for severe COVID-19 disease.

Identifying major risk factors and taking corresponding clinical measures could significantly contribute to saving lives, particularly among vulnerable populations. It is important to note that ongoing research into the risk factors and treatment options for COVID-19 is critical for effectively managing the disease and minimizing its impact on global health⁴¹.

Several studies have reported changes in lipid profiles in patients with SARS-CoV-2 infection. For example, a study published in the Journal of Lipid Research found that COVID-19 patients had significantly lower levels of high-density lipoprotein (HDL) cholesterol and apolipoprotein A1 (apoA1), which are associated with cardiovascular disease risk. Another study published in the Journal of Clinical Lipidology found that COVID-19 patients had higher levels of triglycerides and lower levels of HDL cholesterol. These changes in lipid profiles may be useful as biomarkers for diagnosing and managing COVID-19 and may also have implications for the increased risk of cardiovascular complications in COVID-19 patients.

In addition to an inverse correlation between HDL levels and the severity of COVID-19, multiple studies have also reported that low HDL levels are associated with increased levels of the inflammatory marker C-reactive protein (CRP) in COVID-19 patients. This suggests that the anti-inflammatory properties of HDL may play a role in mitigating the inflammatory response associated with COVID-19.

The cytokine storm is a potentially fatal immune response in which the body releases a large amount of cytokines, small proteins that play a crucial role in immune response, causing widespread inflammation and tissue damage. In COVID-19 patients, the cytokine storm is thought to be triggered by an excessive immune response to the virus, which can lead to severe respiratory distress and multi-organ failure. Low levels of HDL-C have been suggested as a possible contributor to the development of the cytokine storm in some COVID-19 patients, although further research is needed to fully understand the mechanisms involved. While the observed associations between low HDL levels and severity of COVID-19 suggest a potential protective role of HDL, it is also possible that low HDL levels are simply a consequence of the disease and not a causal factor. Further research is needed to establish the exact relationship between HDL and COVID-19⁴².

Chronic obstructive pulmonary disease (COPD) patients have a higher risk of worse outcomes with COVID-19 due to various mechanisms. One of the mechanisms is hypoxic pulmonary vasoconstriction, which occurs in COPD patients due to reduced

ventilation, leading to a higher risk of in-situ thrombus formation. This mechanism can be further worsened by COVID-19. Other important mechanisms include an increased risk for micro-thrombosis, the effects of intrapulmonary shunting, and the potential for secondary bacterial infection. These mechanisms can lead to severe respiratory failure and mortality in COPD patients infected with COVID-19⁴³.

Chronic kidney disease (CKD) is a risk factor for more severe COVID-19 disease outcomes, including increased in-hospital mortality. The fact that COVID-19 can cause acute kidney injury (AKI) in some patients, which can be particularly harmful for those with preexisting kidney disease. The underlying mechanisms include the effects of systemic inflammation and hypercoagulability caused by the overproduction of inflammatory cytokines. Patients with CKD may also have underlying comorbidities that further increase their risk of severe COVID-19 disease⁴⁴.

Diabetes is associated with poorer outcomes in COVID-19 due to several specific factors that increase the risk and severity of infection with SARS-CoV-2. These factors include increased ACE-2 expression, increased furin, impaired T-cell function, increased Interleukin-6 (IL-6), hyperglycemia, co-morbidities, delayed diagnosis, and medications used to manage diabetes. All these factors contribute to an increased risk of severe illness and poorer outcomes in people with diabetes who contract COVID-19. Therefore, it is important for people with diabetes to take extra precautions to prevent COVID-19 infection and seek prompt medical attention if they develop symptoms^{26,45}.

In this study, we aimed to conduct a questionnaire that evaluates self-care management, medication adherence, glycemic control, and COVID-19 experiences among T2DM patients in Türkiye during the pandemic. By studies like this we can better prepare for future health crises and improve overall health outcomes for individuals with diabetes and other chronic conditions.

3. MATERIALS AND METHODS

3.1. Study Design and Population

This cross-sectional study was carried in community pharmacies in different districts of Istanbul, Türkiye during January and March 2022. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statements are adopted as a guide for reporting this study⁴⁶. Data collection was performed in person at community pharmacy.

Adult patients who diagnosed with T2DM before June 2021, currently using at least 1 oral glucose-lowering agent or medication, refilling their medications in person and signed informed consent were included in this study.

Demographic and clinical data (including patient age, sex, educational level, number of medications, working status, marital status, smoking and alcohol consumption, physical activity, comorbidities, body mass index, and duration of T2DM) was collected. Clinical values including HbA1c levels, fasting plasma blood glucose levels, creatinine levels and total cholesterol were collected from medical records (e-nabız, Turkish Ministry of Health - health record system). Patients with HbA1c levels (%) more than 7 were considered uncontrolled. HbA1c levels higher than 8.5 were considered poor glycemic control. Creatinine clearance was calculated using CKD-EPI formula with values less than 45ml/min considered advanced CKD stage (Stage 3B, 4 and 5). Total Cholesterol values higher than 200 mg/dl were as well considered uncontrolled cholesterol levels.

Ethical approval was obtained from the Non-Interventional Clinical Research Ethical Committee of the Yeditepe University (202202182/14) and the Ministry of Health Scientific Research Platform. Patients were informed about the scope of the study. Both verbal and written consent was obtained from the participants.

3.1.1. Inclusion Criteria

Adult patients who diagnosed with T2DM before June 2021, currently using at least 1 oral glucose-lowering agent or medication, refilling their medications in person and received informed consent were included in this study.

3.1.2. Exclusion Criteria

Patients who did not have any laboratory results or could not fully answer the questions in the questionnaire for any reason were excluded from the study.

3.1.3. Sample size determination

The minimum required sample size was estimated (n=385) using the following equation:

$SS = Z^2 \times p \times (1 - p) / c^2$, where Z represents the confidence level (1.96 confidence level for 95%), p is the choice of estimated percentage (assigned 50%) and c is the desired level of precision, i.e. 0.05⁴⁹.

3.2. Questionnaire

Demographic and clinical data, patients' self-reported healthcare utilization due to COVID-19, medication adherence and diabetes self-management were evaluated with the questionnaire (appendix 01).

Patients' self-reported healthcare utilization (hospitalization and emergency room visits) amid COVID-19 pandemic and having probable and/or confirmed COVID-19 were collected.

To assess medication adherence among participants, the Turkish language-validated version of the 5-item Medication Adherence Report Scale (MARS-5) was used⁴⁷. The MARS-5 questionnaire is a widely recognized tool used to evaluate patients' adherence to medication regimens. It consists of five items that assess various aspects of medication adherence, such as forgetfulness, timing, and dosage accuracy. Participants were re-requested to provide their responses to each item on a 5-point Likert scale, allowing for a detailed evaluation of their adherence behavior. A higher total score (up to 25) indicated greater adherence to their prescribed medication regimen. Based on the scoring criteria, only patients with a high score of 25 were considered adherent to their medication.

In order to evaluate patients' self-care management activities related to diabetes, the Turkish version of the Diabetes Self-Management Questionnaire (DSMQ) was utilized. The DSMQ is a comprehensive questionnaire designed to measure various aspects of self-care behaviors among individuals with diabetes. It includes items that assess dietary control, physical activity, glucose management, and healthcare use. The Turkish version of the DSMQ has been culturally adapted and validated for use in Turkish-speaking patients with diabetes⁴⁸. Participants were asked to provide their responses to each item on a 4-point Likert scale. The questionnaire allows the summation to a 'Sum Scale' score as well as estimation of four subscale scores. The four subscales were 'Glucose Management' (2 items), 'Dietary Control' (2 items), 'Physical Activity' (1 item), and 'Health-Care Use' (5 items). To calculate the scale scores, we summed the item scores and then transformed them to a scale ranging from 0 to 10. This transformation was achieved by dividing the raw score by the theoretical maximum score and then multiplying by 10.

3.3. Statistical Analysis

Data was analyzed by using the Statistical Package for the Social Sciences (SPSS) V21.0 Software. Variables were assessed for normality. The non-parametric hypothesis adopted following Kolmogorov Smirnov test results. Variables are expressed as median (interquartile range). Descriptive statistics were used to express the data; the Chi-square test was used to analyze the association between categories of variables; Mann-Whitney test was used to evaluate associations between categorical and continuous variables. The MARS scale and DSMQ questionnaire showed good reliability in the current study population (Cronbach α =0.89 and 0.72 respectively). Statistical significance will be considered at $p<0.05$.

4. RESULTS

4.1. Demographics and Characteristic Patients Information

From the 31 districts of Istanbul, 2772 T2DM patients from 67 community pharmacists were approached to participate in this study. Out of these 462 patients were eligible and accepted to participate in the study. Male patients formed 52.3% of responders, only 38.6% are secondary or university graduates while around 6% reported not to be able to read or write. The median age of responders is 62 (IQR=17, range 23-90). Majority of patients had a BMI>24.9 (79.4%) of these 40.9% were obese. Only 18.8% patients were of normal BMI. Table 1 shows demographic characteristics of responders.



Table 1. Characteristics of study population (n = 462)

Characteristic		n (%)
Sex	Male	241 (52.3)
	Female	220 (47.7)
Age Median [IQR]		62 (53-70)
Older patients	< 65 y	244 (52.8)
	≥ 65 y	218 (47.2)
Educational level	<12	286 (61.4)
	≥ 12 y*	176 (38.6)
Active worker	Yes	112 (24.2)
	No	350 (75.8)
Presence of Comorbidities	Yes	357 (77.4)
	No	104 (22.6)
Most common comorbidities (ICD code)	Hypertension (I15)	286 (61.9)
	Hyperlipidemia (E78.2)	160 (34.6)
	Cardiac disease (I51.9)	195 (42.2)
Total number of medications Median [IQR]		4.0 [3.0-6.0]
Smoking	Yes	116 (25.8)
	No	316 (70.2)
Alcohol consumption	Yes	53 (12)
	No	397 (88.2)
Having physical activity***	Yes	131 (28.7)
	No	326 (71.1)
Body mass index Median [IQR]		
Obese		189 (40.9)
Overweight		178 (38.5)
Normal		87 (18.8)
Duration of T2DM (y) [IQR]		10 [5-15]

* including secondary education and bachelor degree; **polypharmacy: using 5 or more medications concurrently;

***30 min walking or equivalent more than 3days.

4.2. Comorbidities and Diabetes Care Status

More than 77% of the patients suffered at least 1 comorbidity with DM, while more than 51% had multiple comorbidities. Hypertension and Coronary artery disease (CAD) were the most common comorbidities among sampled patients (61.9% and 42.2%). Dyslipidemia (34.6%), thyroid disorder (35, 7.6%), asthma (5.6%) depression (5, 3.9%), cancer (9, 1.9%) and chronic heart failure (12, 2.6%) were as well reported.

HbA1c level were monitored in only 312 patients (67.5%)(Table 2). In those evaluated only 49.4% had HbA1c <7.0. More than 50% of the patient's fasting blood sugar was higher than 140% ranging between 140 - 425 mg/dl as reported by the patients (mean±SD 148.99±56.22). Average total cholesterol for those who checked during quarantine (n=259, 56%) was reported to be 194±69.8 where 45.9% of these reported total cholesterol levels higher than 200 mg/dl.

Table 2. Patients' glycemic, creatinine clearance, and total cholesterol control (*n* = 462)

Outcome		n (%)
Fasting Blood Glucose Check	Yes	365 (79.0)
	No/Missing	97 (21.0)
Fasting Blood Glucose within normal range (n=365)	Yes	180 (49.3)
	No	185 (50.7)
HbA1C Check	Yes	312 (67.5)
	No/Missing	150 (32.5)
HbA1C >7.0% (n=312)	Yes	158 (50.6)
	No	154 (49.4)
HbA1C >8.5% (n=312)	Yes	91 (29.2)
	No	221 (70.8)
Creatinine clearance	Yes	212 (45.9)
	No/Missing	250 (54.1)
CKD Stage (n=212)	1/2/3A	180 (84.9)
	3B/4/5	32 (15.1)
Total Cholesterol Check	Yes	259 (56.1)
	No/Missing	203 (43.9)
Total Cholesterol > 200 mg/dL (n=259)	Yes	119 (45.9)
	No	140 (54.1)

Figure 1 shows self-management and medication adherence of patients. Most patients (58.9%) were identified to be non-adherent when evaluated using the MARS self-reporting scale. On the Diabetes self-care activities questionnaire patients report low physical activity (3.3 (IQR=0.0-6.7)), moderate Diet Control (4.3(3.0-6.11)), higher Glucose Management (8.0(6.3-8.0)) and higher Medical Services Utilization (7.3(5.3-8.7)) (Table 3).

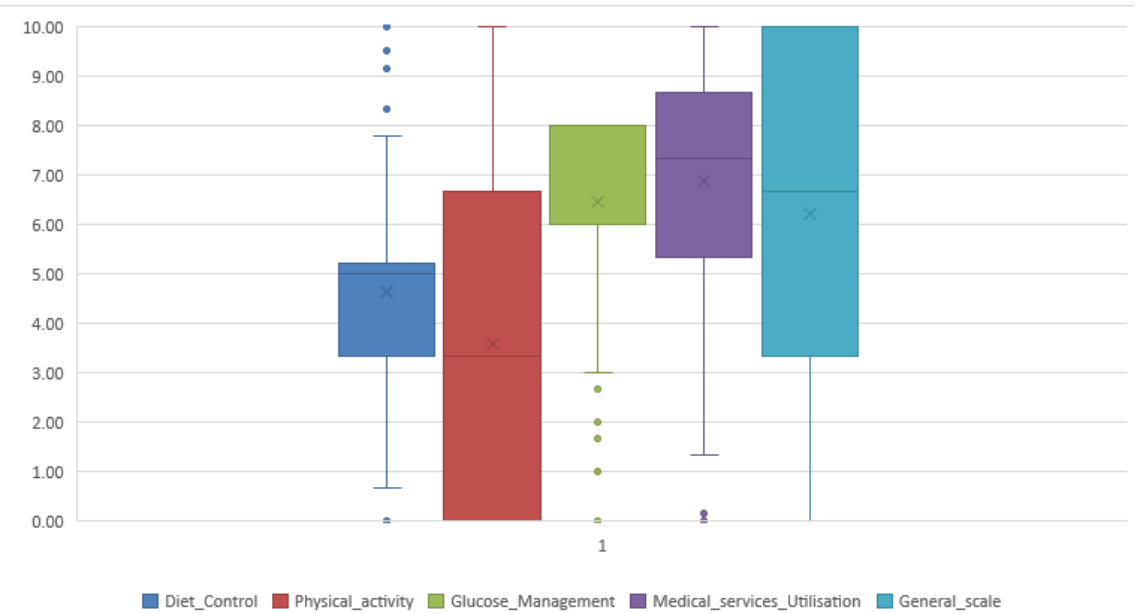


Figure 1. Patients’ Diabetes Self-Management and Medication Adherence

		Yes (n=190 [41.1%])	No (n=272 [58.9%])	
Diet control				
Median [IQR]	4.3 [3.0-6.1]	5.3 [3.7-7.0]	4.3 [2.7-5.3]	<0.001
Physical activity				
Median [IQR]	3.3 [0.0-6.7]	3.3 [0.0-6.7]	3.3 [0.0-6.7]	0.008
Glucose management				
Median [IQR]	8.0 [6.3-8.0]	8.0 [8.0-8.0]	7.0 [5.3-8.0]	<0.001
Medical services utilization				
Median [IQR]	7.3 [5.3-8.7]	8.0 [6.2-8.7]	6.7 [5.3-8.0]	<0.001
General scale				
Median [IQR]	6.7 [3.3-10.0]	10.0 [6.7-10.0]	6.7 [3.3-10.0]	<0.001

Table 3. Patients' Diabetes Self-Management and Medication Adherence

Adherent patients had significantly higher diabetes self-management scores compared to non-adherents in terms of Diet Control, Physical Activity, Glucose Management and Medical Services Utilization ($p<0.001$). The median General Scale Scores was 6.7 (3.3-10). Patients' non-adherent to medication or with poor glycemic control had significantly less General Scale Scores ($p<0.05$) (Table 4).

Male patients were also less achieving HbA1c target (28.2 vs 39.1% $p<0.05$), as well patients with comorbidities (29% vs 34%, $p<0.05$), patients with less educational level attainment (28.7 vs 40.9%, $p<0.05$) and patients with polypharmacy (32% vs 38%, $p<0.05$). These patient groups had as well more proportion of patients with HbA1c level higher than 8.5% ($p<0.05$).

HbA1C >7.0% (n=312)	<i>p</i> value	HbA1C >8.5% (n=312)	<i>p</i> value
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	Yes (n=158)	No (n=154)		Yes (n=91)	No (n=221)	
General scale	6.7 [3.3-10.0]	6.7 [3.3-10.0]	0.013	6.7 [3.3-10.0]	6.7 [3.3-10.0]	0.030
Median [IQR]						
Diet control	4.3 [2.7-6.0]	4.3 [3.3-6.3]	0.146	4.3 [2.7-6.3]	4.3 [3.0-6.3]	0.587
Median [IQR]						
Physical activity	3.3 [0.0-6.7]	3.3 [0.0-6.7]	0.682	3.3 [0.0-6.7]	3.3 [0.0-6.7]	0.670
Median [IQR]						
Glucose management	8.0 [6.3-8.0]	8.0 [6.3-8.0]	0.676	8.0 [6.3-8.0]	8.0 [6.3-8.0]	0.623
Median [IQR]						
Medical services utilization	7.3 [6.0-8.7]	7.3 [6.0-8.7]	0.560	7.6 [6.0-8.7]	7.3 [6.0-8.7]	0.371
Median [IQR]						

Table 4. Diabetes self-management by glycemic control of patients

4.3. Diabetes patients experience of COVID 19

Based on patient response, almost half of the patients (51%) reported to experience COVID-19 at least once either confirmed with PCR (49%) and or without a confirming PCR (29%). 10.2 % (n=47) of patients reported to be hospitalized or admitted to emergency department due to COVID-19 (Table 5). No significant differences were seen in the incidence of COVID19, and frequency of hospitalization or ER admission due to COVID19 in different patients' groups based on the status of gender, diabetes lasting for 10 years or not, body mass index, educational level, smoking or alcohol use, living with comorbidities, fasting blood sugar, Creatinine clearance, polypharmacy and medication adherence ($p > 0.05$, supplement 1).

Age younger than 65, active working status, and non-compliance with routine exercise was significantly associated with higher incidence of COVID19 in diabetic patients ($p < 0.01$). High HbA1C levels (> 8.5), and presence of comorbidity or multiple morbidities were associated with more hospitalization or ER admission due to COVID19 ($p < 0.05$).

Table 5. Patients’ self-reported healthcare utilization amid COVID-19 pandemic and having probable and/or confirmed COVID-19

	n (%)
Hospitalization due to diabetes during the COVID-19 pandemic	16 (3.5)
Emergency room visits due to diabetes during the COVID-19 pandemic	42 (9.1)
COVID-19 PCR confirmed cases during the pandemic	227 (49.1)
COVID-19 symptomatic cases without PCR, but with exposure or typical symptoms	135 (29.2)

5. DISCUSSION AND CONCLUSION

The present study aimed to evaluate glycemic control and self-care of type 2 diabetes mellitus (T2DM) patients during the COVID-19 pandemic in Türkiye, along their experiences with COVID-19. Assessment of glycemic control revealed that only one third of patients achieve the recommended HbA1c targets while the remaining patients either did not meet the target (34.2%) or had not checked their HbA1c levels during the quarantine period (32.5%). Lipid targets were as well rarely achieved and hyperglycemia and presence of comorbidities were associated with hospitalization and ER admission due to COVID-19 in diabetic patients.

Several studies have reported that cases of COVID-19 with diabetes mellitus and hypertension require more hospitalization and possible ICU admission^{50,51}. A recent systemic review has reported cardiovascular risk factors such as hypertension, diabetes mellitus, and obesity to be associated with severe COVID-19 disease and intensive care unit admission along poor prognosis⁵². A meta-analysis involving 45 studies and 18300 patients investigated the effect of cardiovascular risk factors on in-hospital COVID-19 mortality. Any type of diabetes with COVID-19 infection, compared to patients without diabetes mellitus was associated with a higher risk for in-hospital mortality⁵³. Comparably in the current study comorbidities with DM mainly hypertension and dyslipidemia and high HbA1c levels (>8.5%) were associated with more hospitalization independent of other demographic variables.

Hyperglycemia, hypertension and hyperlipidemia (traditional CVD risk factors) are thought to significantly contribute to the morbidity and mortality from SARS-CoV-2 infection. Yue Zhou et al summarized the literature on the underlying mechanisms and relationships between diabetes and COVID-19 to involve a lung injury associated with diabetes, aggravated inflammatory storm, immune system dysfunction, increased infectivity and virulence of the virus, diabetes-related comorbidities, altered lung mechanics and physiology, and complement system over activation⁵⁴.

The study involved a sample of 462 eligible T2DM patients. Demographic characteristics such as younger age, active working status and less compliance with exercise recommendations were associated with higher incidence of COVID-19 both PCR confirmed or patient reported incidence. Studies elsewhere report health disparities

across age, race, ethnicity, language, income, and living conditions to be associated with higher incidence of COVID-19 infection⁵⁵.

Regarding diabetes care status, a significant proportion of T2DM patients in this study had at least one comorbidity in addition to diabetes (77%), and more than half had multiple comorbidities (51%). The most prevalent comorbidities among the sampled patients were hypertension (61.9%) and coronary artery disease (CAD) (42.2%) and dyslipidemia (34.6%), similar to other studies⁵⁶. These findings highlight the high burden of comorbidities in T2DM patients, which can further complicate disease management and contribute to poorer health outcomes⁵⁶. Assessment of glycemic control revealed suboptimal glycemic control among the study participants. Additionally, the average total cholesterol level among those who checked during quarantine was 194 ± 69.8 mg/dl, with 45.9% reporting levels higher than 200 mg/dl. Furthermore, the study assessed self-care activities and medication adherence using validated scales and suboptimal self-management behaviors and medication adherence among T2DM patients during the pandemic was reported. The majority of patients were found to be non-adherent (58.8%) when evaluated using the Medication Adherence Report Scale (MARS). Moreover, patients reported low levels of physical activity, moderate diet control, minimal glucose management, and higher utilization of medical services.

Male patients were found to have a lower rate of achieving the target compared to female patients. This finding suggests that there may be gender-specific factors influencing glycemic control in diabetes, which warrant further investigation. Potential explanations could include differences in adherence to treatment regimens, lifestyle factors, or hormonal influences on glucose metabolism⁵⁷.

The presence of comorbidities was associated with a decreased likelihood of achieving the HbA1c target. Patients with comorbidities had a lower rate of achieving target HbA1c levels compared to those without comorbid conditions. This finding underscores the complexity of managing diabetes in the presence of other health conditions as seen elsewhere⁵⁸. Comorbidities can pose additional challenges to glycemic control, necessitating a comprehensive and integrated approach to treatment that takes into account the management of multiple conditions simultaneously⁵⁹. Additionally, complex medication regimens associated with polypharmacy may pose challenges to

achieving glycemic control⁵⁸. In our study patients with polypharmacy (the use of 5 or more multiple chronic medications), had a lower rate of achieving the HbA1c target compared to those without polypharmacy. Polypharmacy can complicate diabetes management by increasing the risk of medication interactions, non-adherence, and treatment burden. A recent systemic review and meta-analysis of 74 studies, involving 21,133 participants has reported younger and older age, gender, low level of education, longer duration of diabetes, use of statins or antihypertensives, and the presence of comorbidities among others to be associated with poor glycemic control⁶⁰.

Furthermore, educational attainment among the respondents was relatively low, with only 38.6% reporting secondary or university education, while approximately 6% reported being unable to read or write. Our study identified a significant association between educational level attainment and HbA1c target achievement. Studies in Türkiye had previously associated patients with lower educational levels with poor glycemic control compared to those with higher educational levels. This finding suggests that educational disparities play a role in diabetes management and glycemic control. Limited health literacy, inadequate understanding of self-care practices, and reduced access to healthcare resources could contribute to the lower rates of achieving the HbA1c target among patients with lower educational levels⁶¹.

These factors should be addressed as they take a crucial role in achieving optimal glycemic control and reducing the risk of complications. These findings emphasize the need for targeted interventions and intensified efforts to improve outcomes in T2DM patients, especially during challenging times such as the COVID-19 pandemic where a substantial proportion of patients did not carry routine follow-up during the quarantine period (32.5%). Strategies adopted elsewhere included use of telemedicine and telepharmacy⁶² and beside other pharmaceutical care services that greatly improved outcomes in these patients⁶³.

The current study highlights the state of control in T2DM patients during the COVID-19 pandemic and the vulnerability of patients not meeting treatment goals as they are more susceptible to severe illness and complications. Age, occupational status, exercise habits, glycemic control, and the presence of comorbidities were identified as important factors influencing directly or indirectly the risk of COVID-19 and related hospitalization or emergency department admission. Yet the study's cross-sectional

design limits our ability to establish causal relationships between the identified factors and the risk of COVID-19 and related hospitalization or emergency department admission. The reliance on self-reporting and medical records introduces potential biases and inaccuracies in the data. The study's population characteristics and study setting may restrict generalizability, and confounding factors were not fully accounted for. Additionally, the cross-sectional design hinders the ability to capture changes over time. Factors influencing glycemic control and the achievement of the HbA1c target may vary at different stages of the disease or in response to treatment modifications as well COVID-19 out-comes. The current study lacked the evaluation or comparison of impact of different diabetes pharmacotherapies on COVID-19 incidence therapy outcomes and complications that could be addressed in future studies. Despite these limitations, the study provides valuable preliminary insights into the factors associated with lower rates of achieving the HbA1c target. Further research employing robust study designs and addressing these limitations is necessary to confirm the findings and develop evidence-based interventions for improving glycemic control in these patient groups.

In conclusion, this study provides valuable insights into the self-management, glycemic control, and experiences of T2DM patients during the COVID-19 pandemic in Türkiye. The findings underscore the importance of improving self-care activities, medication adherence, and glycemic control among T2DM patients. Furthermore, the study highlights the increased vulnerability of T2DM patients to COVID-19 and the need for tailored interventions to reduce the risk of infection and severe outcomes in this population. The results of this study can inform public health strategies and healthcare practices to optimize the care and outcomes of T2DM patients during the ongoing COVID-19 pandemic.

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7. APPENDICES

7.1. Questionnaire

Serbest Eczanelerde Tip 2 Diabetes Mellitus Hastalarında Glisemik Kontrol, Öz Bakım Yönetimi ve COVID-19 Deneyiminin Araştırılması (Anket)

1-Katılımcının Demografik Özellikleri

Cinsiyet	Kadın			Erkek		
Doğum yılı						
Eğitim durumu	Okuma yazma bilmeyen	Okur yazar	İlkokul mezunu	Orta okul mezunu	Lise mezunu	Üniversite mezunu
Sosyal alışkanlıklar	Sigara	Alkol	Sigara ve alkol	Diğer		Hiçbiri
Dişabet süresi	ay/yıl			Vücut kitle : indeksi	Boy: ---	Kilo: ---
Varsa eşlik eden kronik hastalık (tansiyon, kolesterol vb.)						
Çalışma durumu	ÇALIŞAN		İŞSİZ		EMEKLİ	

2- Patient Experiences associated with COVID19

- COVID-19 pandemisinde kaç kere COVID hastalığını geçirdiniz? (PCR test ile)
- COVID-19 pandemisinde kaç kere COVID hastalığını geçirdiniz? (PCR yaptırmadan temaslı veya temazsızsymptomları geçirdiniz)
- COVID-19 pandemisinde dişabet hastalığınız nedenli hastaneye yattınız mı?
3.2 Varsa süre belirtiniz
- COVID-19 pandemisinde diyabethastalığınız nedenli acil servise başvurdunuz mu?
4.2 Varsa süre belirtiniz
- COVID-19 hastalığını önlemek için gıdatakviyesi/bitkisel ürün kullandınız mı?
5.2 Varsa ürünü belirtiniz

3- UYUNÇ:

Lütfen her bir ifade için size en çok uyan kutucuğışaretleyiniz. İlaç kullanımınıza dair kendi tarzınız;	Her zaman	Sık sık	Bazen	Nadiren	Asla
M1. Almayı unuturum.					
M2. Dozunu değıştiririm.					
M3. Bir süreliğine almayı bırakırım.					
M4. Bir dozu atlamaya karar veririm.					
M5. Söylenenden daha az alırım					

4- Diyabet Öz Yönetim Anketi (DSMQ)

Aşağıdaki ifadeler diyabetinizle ilgili öz bakım aktivitelerini tanımlamaktadır. Son 8 haftadaki öz bakımınızı düşünerek, lütfen her bir ifadenin sizin için ne derece geçerli olduğunu belirtiniz.	Benim için çok geçerli	Benim için önemli ölçüde geçerli	Benim için bir dereceye kadar geçerli	Benim için geçerli değil
M1: Kan şekeri seviyemi özenle ve dikkatle kontrol ediyorum.				
M2: Yemek için seçtiğim yiyecekler doğru kan şekeri seviyesine ulaşmamı kolaylaştırıyor.				
M3: Diyabet hastalığımın tedavisi için doktor randevularıma uyuyorum.				
M4: Reçetede verilen diyabet ilaçlarımı alıyorum.				
M5: Bazen bol miktarda tatlı ya da karbonhidrat açısından zengin olan besinlerden tüketiyorum.				
M6: Düzenli olarak kan şekeri seviyemi kaydediyorum.				
M7: Diyabetle ilgili doktorların randevularından kaçınma eğilimindeyim.				
M8: En uygun kan şekeri seviyesine ulaşabilmek için düzenli fiziksel aktiviteler yapıyorum.				
M9: Doktorum ya da diyabet uzmanı tarafından verilen diyet önerilerine sıkı bir şekilde uyuyorum.				
M10: Kan şekeri seviyemi iyi bir kan şekeri kontrolü sağlamak için yeteri kadar sık kontrol etmiyorum.				
M11: Diyabetime faydalı olduğunu bildiğim halde fiziksel aktiviteden kaçınıyorum.				
M12: Diyabet ilaçlarımı almayı unutmaya ya da atlamaya meyilliyim.				
M13: Bazen aşırı yemek yeme krizlerim oluyor.				
M14: Diyabet bakımım ile ilgili olarak doktorumu (doktorlarımı) daha sık görmeliyim				
M15: Planlı fiziksel aktiviteleri geçiştirme eğilimindeyim.				
M16: Benim diyabet öz bakımım zayıftır.				

5- Lab Ölçümleri (Son 6 ay için)

Açlık Kan şekeri	
HbA1c	
Kreatinin	
Trigliserid	
Total Kolesterol	

6- İlaç listesi:

İlaç listesi	Doz	Sıklık	Başlama tarihi

7.2. Ethical Approval



YEDİTEPE ÜNİVERSİTESİ
GİRİŞİMSEL OLMAYAN KLİNİK ARAŞTIRMALAR
ETİK KURULU

Versiyon No 2.0
13.02.2022
Sayfa 1 / 2

KARAR FORMU

18.03.2022

ETİK KURUL BİLGİLERİ	Etik Kurulun Adı	Yeditepe Üniversitesi Girişimsel Olmayan Klinik Araştırmalar Etik Kurulu
	Açık Adres	Yeditepe Üniversitesi Kayışdağı Kampüsü, Tıp-Mühendislik Binası, Sağlık Bilimleri Enstitüsü, İnönü Mah. Kayışdağı Cad. 326A, 26 Ağustos Yerleşimi 34755 Ataşehir, İstanbul
	İnternet Sayfası	http://goetik.yeditepe.edu.tr/
	Telefon	0216 578 00 00
	E-posta	goetik@yeditepe.edu.tr

DEĞERLENDİRİLEN BELGELER	Islak imzalı başvuru dosyası, CD'si ve elektronik başvuru	☒
	Araştırma başlığı ve araştırmacıların isimleri	☒
	Başvuru dilekçesi	☒
	Başvuru Formu- Araştırmanın;	☒
	• Niteliği	☒
	• Önemi ve özgün değeri	☒
	• Amaç ve hedefleri	☒
	• Yöntemi	☒
	• Yönetimi	☒
	• Yaygın etkisi	☒
	• Araştırma bütçesi (Mevcutsa)	☒
	• Süresi ve uygunluğu (Zaman cetveli)	☒
	• Kaynakları	☒
	Bilgilendirilmiş Gönüllü Olur Formu (yapılan araştırmaya özel olarak hazırlanmış)	☒
	Taahhütname-1	☒
	Araştırmanın yapılacağı kurumdan izin alma sorumluluğunun araştırmacılara ait olduğuna dair taahhüt	☒
	Taahhütname-2	☒
	Dünya Tıp Birliği Helsinki Bildirgesinin son versiyonunun ve Sağlık Bakanlığı'nın ilgili tüm kılavuzlarının okunmasına dair taahhüt	☒
	Taahhütname-3	☒
	Daha önce yapılmış etik kurul başvuruları mevcut olup olmadığına dair taahhüt	☒
	Taahhütname-4	☒
	Araştırma sırasında araştırma bütçesinde yer almayan ve gönüllünün kendisine veya Sosyal Güvenlik Kurumuna ek yük getirecek hiçbir işlem uygulanmayacağına dair taahhüt	☒
	Taahhütname-5	☒
	COVID-19 hastalarında tedavi yaklaşımları ve bilimsel araştırmalar genelgesi okunmasına dair taahhüt	☒
	Taahhütname-6	☒
	Milli Eğitim Bakanlığı Araştırma Uygulama İzinleri konulu yazının okunmasına dair taahhüt	☒
	Araştırmacıların her birisine ait özgeçmiş formu	☒
	Ek belgeler (Varsa kullanılan ölçek izinleri vb.)	☒

KARAR BİLGİLERİ	Başvuru Numarası	202202182
	Toplantı Tarihi	11.03.2022
	Toplantı Yeri	Çevirim içi (Google Meet)
	Karar No	14

Araştırmanın Başlığı COVID-19 pandemi sürecinde Tip 2 diyabetin tedavi sonuçları ve tedaviye uyuncu etkileyen faktörler: kesitsel bir çalışma

Araştırmacılar Ecz. Onur Tanıl Çete, Doç. Dr. Abdikarim Abdi, Araş. Gör. Kübra Yalman



YEDİTEPE ÜNİVERSİTESİ
GİRİŞİMSEL OLMAYAN KLİNİK ARAŞTIRMALAR
ETİK KURULU

Versiyon No 2.0
13.02.2022
Sayfa 2 / 2

BAŞVURU NUMARASI: 202202182

KARAR

18.03.2022

☒ KABUL	☐ RET ☐ KAPSAM DIŞI (GİRİŞİMSEL) ☐ BİLİMSEL VE/VEYA ETİK KURALLARA AYKIRI ☐ BİR SORUMLU ARAŞTIRMACININ (TEZ İŞE TEZ DANIŞMANI), BİR TOPLANTIYA İKİ (2) ADETTE FAZLA ÇALIŞMA BAŞVURUSUNDA BULUNMASI ☐ KURUM İÇİ BAŞVURULARINDA KURUMSAL E-POSTA HESABI İLE GİRİŞ YAPILMAMIŞ OLMASI ☐ ŞARTLI KABULDE BELİRTİLEN REVİZYONLARIN ZAMANINDA VE/VEYA İSTENİLDİĞİ ŞEKİLDE YAPILMAMIŞ OLMASI
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Yeditepe Üniversitesi Girişimsel Olmayan Klinik Araştırmalar Etik Kurulu adına
Prof. Dr. Didem Özdemir ÖZENEN
Başkan

Araştırmanın Başlığı	COVID-19 pandemi sürecinde Tip 2 diyabetin tedavi sonuçları ve tedaviye uyuncu etkileyen faktörler: kesitsel bir çalışma
Araştırmacılar	Ecz. Onur Tanıl Çete, Doç. Dr. Abdikarim Abdi, Araş. Gör. Kübra Yalman

8. CURRICULUM VITAE

Personal Informations

Name		Surname	
Place of Birth		Date of Birth	
Nationality		TR ID Number	
E-mail		Phone number	

Education

Degree	Department	The name of the Institution Graduated From	Graduation year
Master			
University			
High school			

Languages	Grades (#)
English	YÖKDİL:

All the grades must be listed if there is more than one (KPDS, ÜDS, TOEFL; EELTS vs),

Work Experience

Position	Institute	Duration (Year - Year)

Computer Skills

Program	Level
Microsoft Office Programs (Word, Excel, PowerPoint)	

*Excellent , good, average or basic

Scientific works

Journals in the proceedings book of the refereed conference / symposium