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# The International Diabetes Management Practices Study (IDMPS) - Turkey's 5th Wave Results

# Uluslararası Diyabet Tedavi Pratikleri Kayıt Çalışması -Türkiye 5. Dönem Sonuçları

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The International Diabetes Management Practices Study

### **Abstract**

Purpose: The prevalence of type 2 diabetes mellitus (T2DM) is increasing in Turkey due to rising obesity rates, sedentary life styles and Turkey's aging population; up-to-date and standardized data collection is required for the global fight against diabetes. The data collected from Turkey during the 5th wave of a multinational, multi-center and observational study are evaluated in this article.

Material and Method: The International Diabetes Management Practices Study (IDMPS) which is an international, observational multicenter, cross-sectional study, evaluated demographic and clinical characteristics of diabetic patients, treatment modalities, complications, cardiovascular risk factors and also reported the results of the patient health questionnaire (PHQ-9).

Results: This study consisted of 842 T2DM and 115 Type 1 diabetes mellitus (T1DM) patients and was carried out by 94 doctors in Turkey between December 13th 2011 and January 26th 2012. Data revealed that 52% of patients were treated with oral anti-diabetic (OAD) drugs only, 29% were treated with OAD + insulin, and 18% of subjects were treated with insulin alone. 88% of T2DM patients had at least one microvascular complication and 99% had at least one cardiovascular risk factor. Only 27% of T1DM and 28% of T2DM patients reached the target hemoglobin Alc value of <7%. PHQ-9 results revealed that majority of patients did not have a depressive disorder (79% for both TIDM and T2DM).

Discussion: Attainment and maintenance of the internationally recommended optimal glycemic values is essential for effective treatment of diabetes. Almost 72% of T2DM patients in Turkey did not reach the target values. Diabetes patient education aiming to provide the knowledge necessary to make and maintain lifestyle changes is necessary.

**Keywords:** Turkey, diabetes, treatment, alycemic control, diabetes complications



Amaç: Obezite, hareketsiz yaşam tarzı ve yaşlanan popülasyon Türkiye'de tip 2 diyabeti (T2DM) arttırmaktadır ve diyabete karşı savaş için güncel ve standardize edilmiş bilgilere ihtiyaç vardır. Bu yazıda uluslarası, çok merkezli gözlemsel bir çalışmanın Türkiye'ye ait beşinci dönem sonuçları değerlendirilmiştir.

Gereç ve Yöntem: Bu çalışma diyabet hasta profili, tedavi seçenekleri, komplikasyonlar, kardiovasküler risk faktörleri, ayrıca hastaların sağlık anketi (PHQ-9) sonuçlarının değerlendirildiği kesitsel bir çalışma olarak yürütülmüştür.

Bulgular: Bu çalışma Türkiye'de 13 Aralık 2011 ve 26 Ocak 2012 tarihleri arasında 94 araştırmacı tarafından yürütülmüş ve çalışmaya 842 T2DM, 115 tip 1 diyabet (T1DM) hastası alınmıştır. Hastaların %52'si oral anti diyabetik ajan (OAD), %29'u OAD + insülin, %18'i ise sadece insülin tedavisi almıştır. Hastaların %88'inde en az bir mikrovasküler komplikasyon ve %99'unda en az bir kardiyovasküler risk faktörü tespit edilmiştir. TIDM hastaların sadece %27'si, T2DM hastaların ise sadece %28'i, <%7 olan hedef hemoglobin A1c seviyesine ulaşabilmiştir. PHQ-9 sonuçları hastaların çoğunluğunun (T1DM ve T2DM için %79) depresif olmadığını göstermiştir.

Tartışma: Önerilen optimal glisemik değerlere ulaşılması ve korunması etkili diyabet tedavisi için şarttır. Türkiye'de T2DM hastalarının neredeyse %72'si bu hedeflere ulaşamamaktadır. Hastaların diyabet eğitimine ve yaşam tarzında değişiklik yapmalarına ihtiyaç vardır.

Anahtar kelimeler: Türkiye, diyabet, tedavi, alisemik kontrol, diyabetik komplikasyon

### Introduction

Due to obesity, sedentary lifestyles and aging populations in the world, type 2 diabetes mellitus (T2DM) is becoming more prevalent thus leading to increased morbidity and mortality. In 2015, T2DM affected 415 million people in the world and in 2040, this figure is expected to rise to 642 million (1). This increase in diabetes will take place in every country, however, the amount of increase is anticipated to be higher in developing countries (2). Since this increase will bring a multitude of diabetic complications, it is one of today's biggest concerns for health service providers (3,4). The diabetic population is consuming an irrational portion of health service resources due to microvascular and macrovascular complications. Strategies related to lifestyle, such as diet and exercise as well as effective treatments for hypertension, dyslipidemia and hyperglycemia are necessary to reduce the burden on diabetic patients and health systems (5).

As per costs of diabetes in Europe-type 2 study, the total direct cost of 10 million T2DM patients in eight participating European countries in 1998 was estimated to be 29 billion Euros (27 billion US Dollars) (6). Health care resources spent for the treatment of diabetic complications are estimated to be 3 fold more than the resources spent to control diabetes before the onset of diabetic complications.

The Diabetes Control and Complications Trial conducted with type 1 diabetes mellitus (T1DM) patients and United Kingdom Prospective Diabetes Study conducted with T2DM patients, revealed that efficient control of blood glucose levels may help bring the disease under control in early stages and might reduce morbidity and mortality by reducing the chronic complications (7,8). Therefore, the optimal target for treatment is to achieve effective glycemic control (close to normal) and to prevent long-term complications.

International associations, such as the American Diabetes Association and the European Association for the Study of Diabetes suggest that attaining a global treatment goal of hemoglobin A1c (HbA1c) levels lower than 7% is imperative in order to obtain optimal glycemic control (9). Efforts were made to improve physicians compliance with these treatment guidelines, and additional diabetic treatment algorithms with clear targets were published by local and international associations.

Despite all the suggestions, effective glycemic control cannot be established in the majority of patients and the target HbA1c level (<7%) cannot be achieved. It is possible that the physicians are not initiating the insulin treatment at the right time with the right dose. Therefore, a deeper investigation of current treatment regimens and precautions to improve treatments of diabetic patients are required.

Especially in Western countries, many national or regional epidemiological studies have been conducted to evaluate treatment quality of diabetic patients and to investigate if national guidelines or programs are being followed (10). Additional international registry studies have also been conducted to have a global view of diabetes (11,12). However, the most important limitation of these international registry studies is the non-standardized data. On the other hand, in many non-Western

countries, there are insufficient data available on the quality of treatment in T2DM patients.

The International Diabetes Management Practices Study (IDMPS) was planned as an international, multi-center, prospective observational study which aimed to gather data about practices in daily care and living habits of diabetic people, in both developed and developing countries in Eastern Europe, including Turkey, and Asia and Latin America. The primary objective of this study was to assess the therapeutic management of T2DM patients in the current medical practice. Secondary objectives were to assess the therapeutic management of T1DM patients in the current medical practice and to assess the proportion of patients with HbA1c under the threshold compared to international recommendations. Here, the data that were collected from Turkey during the 5th wave of the study are analyzed and reported in this manuscript.

### **Materials and Methods**

### **Study Design**

This was an international, multi-center, non-interventional, prospective, observational study on the therapeutic strategy for patients with T1DM or T2DM. Data was collected in two week periods over five years. Each year, new patient groups were registered to the study, thus during these five years, data on treatment of diabetes and changes in the treatment regimens were collected and analyzed.

The study consisted of two phases:

a) A cross-sectional phase in which the therapeutic management of T1DM and T2DM patients in the current medical practice was assessed.

b) A longitudinal phase was conducted in the first 2 out of 5 waves. All T2DM patients' follow-up parameters were evaluated in this phase.

This cross-sectional study continued in two weeks in each period. Among the patients enrolled in the cross-sectional part of the study, those, who were treated with insulin, were included in the longitudinal part of the study if they fulfilled the inclusion and exclusion criteria. The follow-up period was nine months.

The 5<sup>th</sup> wave of the study was conducted in 21 countries and did not include a longitudinal phase. The total number of physicians in all countries, who enrolled at least one patient to the study, was 879. Globally, 12509 patients were enrolled and 12392 of them were included in the analysis population.

## Patients Enrolled to the 5th Wave of the Study From Turkey

During the 5<sup>th</sup> year of this study, between December 13<sup>th</sup> 2011 and January 26<sup>th</sup> 2012, a total of 966 adult, male or female, T1DM or T2DM patients were enrolled. Concomitant enrollment to another study, previous registration to this study, gestational diabetes and cancer of the pancreas or ongoing insulin treatment due to surgical reasons were considered as exclusion criteria. Nine hundred fifty seven patients were included in the analysis population. Among these patients, 115 were T1DM patients and 842 were T2DM patients.

### **Physician Characteristics**

The total number of physicians enrolling at least one patient to the study was 94. Among these physicians, 35 of them were endocrinology or diabetes specialists and 58 were general practitioners/family doctors/internal medicine specialists/cardiologists. The median length of duration of medical practice in endocrinology or diabetes specialists was 19 years whereas this duration was 17 years for general practitioners/family doctors/internal medicine specialists/cardiologists. The mean number of patients visiting endocrinology or diabetes specialists per month was 345, and among these patients, the mean number of ones with T2DM and receiving insulin treatment was 54. The mean number of patients visiting general practitioners/family doctors/internal medicine specialists/cardiologists per month was 258 and, among these patients, the mean number of the ones with T2DM and receiving insulin treatment was 60.

#### **Ethics**

Ethics Committee and Turkish Ministry of Health Approvals were taken prior to the study commencing. All patients enrolled to the study signed a written informed consent form before the application of any study-related procedures.

#### **Evaluations**

Patient profiles at the end of the study, treatments prescribed for these patients, treatment profiles with insulin, frequency of the observed diabetic complications, and cardiovascular risk factors were evaluated. Cardiovascular risk factors were defined as age ( $\geq$ 45 years for men and  $\geq$ 55 years for women), blood pressure [diastolic blood pressure (DBP) ≥80 mmHg and systolic blood pressure (SBP) ≥130 mmHg], high density lipoprotein (HDL) cholesterol (HDL <40 mg/dL for men and HDL <50 mg/dL for women), and low density lipoprotein (LDL) cholesterol (LDL ≥100 mg/dL). Cardiovascular risk score was obtained with the sum of all these factors. Unlike the previous periods, a patient survey was filled up by the patients during the 5th year to provide details about their own health status in terms of depression and its frequency. The patient health questionnaire (PHQ-9) is frequently used in patients with a medical disorder to diagnose a concomitant depression and it also provides useful information for managing the therapy. It consists of nine criteria upon which the diagnosis of Diagnostic and Statistical Manual of Mental Disorders, 4th edition) depressive disorders is based (13). Patients were asked to answer the questions as per their situations in the past two weeks. The frequency and severity of the problems that the patient has been bothered by were categorized into 4 groups (frequency: Never, several days, more than one-half the days, nearly every day; severity: None, a little, a lot, excessive).

# Statistics Analysis

Analysis variables: The IDMPS consisted of 5 cross-sectional and 2 longitudinal studies. Collected variables during each study were analyzed independently each year and for each country. A statistical analysis plan was updated prior to each analysis. The latest version of the statistical analysis plan dated June 8<sup>th</sup> 2012 was used for the 5<sup>th</sup> year's analysis.

Analysis population: The analysis population was built following the cleaning up of the database. Patients eligible to be enrolled in the cross-sectional study; receiving insulin treatment (only T1DM), with known type of diabetes (T1DM or T2DM) or with no missing data about diabetes treatment (does the patient receive antidiabetic medication (yes/no) or is the patient currently receiving insulin treatment [(yes/no)] were included in the analysis population.

Statistical methods: Descriptive statistics were performed on the database. Qualitative data was summarized in frequency tables, and quantitative data was summarized in quantitative descriptive statistics [frequency, mean, standard deviation (SD), median, ranges]. Statistical analyses were conducted with SAS Software version 9.2. Tables and listings were formatted using AdClin 3.2.2 software. No interim analysis was performed for Turkey.

Justification of sample size: The sample size was determined on the country basis, according to the primary objective, which was to assess the therapeutic management of T2DM patients, and on the precision that was expected.

Based on the assumption that insulin is the least prescribed therapy in terms of proportions, the sample size was determined in order to establish the rate of insulin-treated patients. The sample size was estimated assuming 10% of patients were receiving insulin treatment, with an absolute precision of 20% and a confidence interval of 95%.

	T1DM (n=115)	T2DM (n=842
Age (years) (mean ± SD)	32.30 (±12.54)	56.85 (±11.39)
Gender/female, n (%)	56 (48.7)	467 (55.5)
BMI (kg/m $^2$ ) (mean $\pm$ SD)	24.17 (±6.16)	30.87 (±5.80)
Waist circumference (cm) (mean ± SD)	85.77 (±13.88)	104.78 (±12.87)
Time since DM diagnosis (years) (mean ± SD)	11.44 (±9.08)	8.73 (6.83)
Residence		
Metropolitan, n (%)	92 (80.0)	679 (80.6)
Rural, n (%)	16 (13.9)	122 (14.5)
Suburban, n (%)	7 (6.1)	41 (4.9)
Family history of DM, n (%)	41 (40.6)	467 (64.4)
Level of education, n (%)		
Illiterate	7 (6.4)	125 (15.4)
Primary/secondary	64 (58.2)	594 (73.0)
University/masters	39 (35. 5)	96 (11.7)
Smoking habit, n (%)		
Former smoker	10 (8.7)	217 (25.8)
Active smoker	40 (34.8)	122 (14.5)
Never smoked	65 (56.5)	503 (59.7)
Dyslipidemia, n (%)	31 (27.0)	468 (55.8)
Hypertension, n (%)	17 (14.8)	527 (62.7)

DM: Diabetes mellitus, SD: Standard deviation, T1DM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus

The number of physicians and their profile were determined in the country. The number of physicians was driven by the sample size. Since each physician was requested to enroll the first 10 adult T2DM patients visiting, to determine the number of physicians, the number of required patients was divided by 10 and rounded up to the next whole number. For example, if the sample size was 864 T2DM patients; 864/10=86.4> the number of physicians to be enrolled to the study was calculated as 87. In the cross-sectional study, a list of physicians was reviewed each year. More than one doctor from the same institution was allowed to be in the study. In Turkey, it was planned to have 100 physicians and 1000 patients, however, there were 94 doctors and 966 patients at the end of the study.

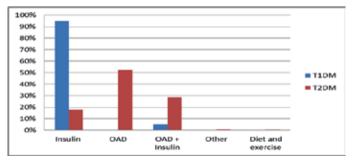
### Profiles of Patients with T1DM and T2DM

A total of 966 patients were recruited to this study, however, 957 patients were found to be eligible according to the inclusion/exclusion criteria and included in the statistical analysis.

The mean ( $\pm$ SD) age of 115 T1DM patients who were registered was 32 ( $\pm$ 12.6) years and almost half of these patients (49%) were female. The mean duration from the first diagnosis of diabetes to enrollment to the study for T1DM patients was 11 ( $\pm$ 9.1) years. On the other hand 842 T2DM patients, who were enrolled to the study, had a mean age of 57 ( $\pm$ 11.4) years and 56% of those patients were female. The mean duration from the first diagnosis of diabetes to enrollment to the study for T2DM patients was 9 ( $\pm$ 6.8) years. The mean body mass index (BMI) in T1DM and T2DM patients was 24 kg/m² 31 kg/m², respectively. The average waist circumference was higher in T2DM patients compared to that in T1DM patients (105 cm vs. 86 cm). A history of diabetes was present in 41% of T1DM patients and 64% of T2DM patients.

The majority (80%) of patients was living in metropolitan cities and 73% had graduated from primary/secondary schools. Almost all the patients (97%) had some sort of health insurance coverage. On the other hand, 15% of T1DM patients and 63% of T2DM patients were evaluated as hypertensive and 94% of T1DM patients and 63% of T2DM patients were receiving anti-hypertensive treatment. 27% of T1DM patients and 56% of T2DM patients were considered dyslipidemic and 74% and 86% of these patients were receiving dyslipidemia treatment, respectively (Table 1).

The duration since the diagnosis was categorized as <1 year, 1-5 years, 5-10 years, 10-20 years and  $\geq$ 20 years and percentage of T1DM and T2DM patients diagnosed during those time periods were 11% and 12%, 23% and 28%, 21% and 25%, 28% and 27% and 18% and 8%, respectively.



**Figure 1.** General treatment patterns of diabetic patients *TIDM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus* 

# Basic Characteristics of Treatment Regimens in Patients with Diabetes Mellitus

Data on treatment practices in the management of patients with T2DM showed that 52% of patients (n=441) were treated with oral anti-diabetic (OAD) drugs only, 29% (n=241) of patients were treated with a combination of OAD with insulin and 18% of the patient population (n=148) was treated with insulin only. The remaining 1% of patients (n=12) received other types of treatments (Figure 1).

Among T2DM patients who were receiving OADs, 47% of patients were on treatment with only one OAD, 36% with a combination of two OADs and 16% with more than two OADs. 95% of T1DM patients were treated with insulin only and 5% were receiving insulin + OAD.

Overall, 19% of T2DM patients were not receiving any OAD treatment. In the patient group who were treated by diabetologists endocrinologists and receiving only OAD treatment, the majority (47%) was receiving two OADs and among the ones receiving OAD + insulin, the majority (78%) was receiving one OAD. The results revealed that in the patient group that was treated by general practitioners/primary care practitioners/internists/cardiologists, similar treatment patterns were followed.

### **Preferred Insulin Treatment Regimens**

Among TIDM patients receiving insulin, basal prandial insulin was the most frequently used (83%) insulin in the registered diabetic population; premix alone (8%) and prandial alone (6%) were the second and third most frequently used insulin treatment options, respectively. Insulin treatment was on-going for an average of 11 years. For T2DM patients receiving insulin, basal prandial combination was the most frequently (36%) used insulin treatment regimen. Premix alone (34%) and basal alone (25%) treatment regimens were the following most preferred regimens respectively. Insulin treatment was ongoing for an average of 4 years (Figure 2).

The mean age of T2DM patients receiving insulin treatment alone was higher ( $60\pm12.8$ ) than patients receiving OAD + insulin treatment ( $56\pm9.9$ ). Among these patients, 69% had diabetic complications, and among patients who developed complications, 94% had microvascular complications. The macrovascular complication percentage was found to be 52%. For the T1DM patient group (n=115), the mean total daily dose of insulin was 46 ( $\pm20.0$ ) IU and the majority (75%) of patients had 4 injections per day. Among patients who were administering insulin injections to themselves, 87% adjusted their own insulin dose.

The average daily insulin dose among T2DM patients receiving insulin treatment alone was 43 ( $\pm 26.3$ ) IU and 40% of them received 4 injections/day; 62% were adjusting their own insulin dose. On the other hand, in 241 patients receiving OAD + insulin treatment, the mean daily insulin dose was 39 ( $\pm 23.0$ ) IU and this dose was taken in 2 daily injections in 32% of patients. In this group, most of the patients were adjusting their insulin dose on their own (70%). The insulin dose and daily insulin injection regimens for T2DM patients are provided in Table 2.

Patients receiving insulin alone or insulin + OAD had received better diabetes training and visited a diabetologist more frequently when compared to the remaining T2DM patients.

### **Reaching the Glycemic Control Target**

There were no previous HbA1c measurements in 1% of T1DM patients and 3% of T2DM patients. The mean (±SD) value of the

Table 2. Insulin dose and daily diabetes mellitus patients	insulin injectio	on regimen for	type 2
	Insulin treatment alone (n=148)	OAD + insulin treatment (n=241)	Total (n=389)
Basal insulin alone	n=18	n=81	n=99
Mean daily insulin dose, IU	21.28	23.99	23.49
(±SD)	(±12.98)	(±10.74)	(±11.6)
Insulin injection/day (%)			
1	88.9	84.8	85.6
2	11.1	15.2	14.4
Prandial insulin alone	n=8	n=4	n=12
Mean daily insulin dose, IU	30.00	29.00	29.67
(±SD)	(±11.82)	(±16.45)	(±12.77)
Insulin injection/day (%)			
1	12.5	0	8.3
2	62.5	75.0	66.7
3	25.0	25.0	25.0
Basal + prandial insulin	n=70	n=71	n=141
Mean daily insulin dose, IU	52.03	54.83	53.44
(±SD)	(±30.97)	(±23.09)	(±27.23)
Mean daily basal insulin	27.16	29.52	28.35
dose, IU (±SD)	(±14.24)	(±14.44)	(±14.34)
Mean daily prandial insulin	24.87	25.31	25.09
dose IU (±SD)	(±20.06)	(±18.42)	(±19.18)
Basal insulin injection/day (%)			
1	85.5	85.9	85.7
2	13.0	14.1	13.6
Prandial insulin injection/day (%)			
1	1.4	4.2	2.8
2	2.9	2.8	2.8
3	94.3	93.0	93.6
Premix insulin	n=51	n=82	n=133
Mean daily insulin dose, IU	38.86	40.74	40.02
(±SD)	(±17.30)	(±21.74)	(±20.01)
Insulin injection/day (%)			
1	6.0	6.2	6.1
2	82.0	72.8	76.3
3	12.0	21.0	17.6
SD: Standard deviation, OAD: Oral	anti-diabetic		

last HbA1c measurements that were available was found to be 8.8% ( $\pm 2.5$ ) for T1DM patients and 8.6% ( $\pm 2.2$ ) for T2DM patients. When compared to the international guidelines, only a small portion of T1DM and T2DM patients had reached the target HbA1c level of <7%, however, the majority had HbA1c values higher than the laboratory normal values (73.5% of T1DM and 71.9% of T2DM patients). Mean ( $\pm$ SD) last laboratory fasting blood glucose (FBG) levels for T1DM and T2DM patients were 200 ( $\pm$ 110.7) and 183 ( $\pm$ 78.9) mg/dL, respectively. It was recorded that 86% of T1DM and 92% of T2DM patients had not reached the target FBG levels of <100 mg/dL as suggested in the guidelines. The distribution of T1DM and T2DM patients reaching the target glycemic control levels per treatment regimen are presented in Figure 3.

In T2DM patients, the frequency of laboratory testing of HbA1c was approximately 2 times per year. 80% of the enrolled patients had their own blood glucose monitoring device and almost all of these patients (93%) were able to measure their own glucose levels. However, the rate of patients performing glucose monitoring every day was only 35% and the mean number of self-monitoring blood glucose tests per day was 1.7 ( $\pm 1.0$ ). The data revealed that among T2DM patients, the ones being treated with a diet and exercise program had best glycemic control. The majority of T2DM patients could not reach the target FBG and HbA1c values and the

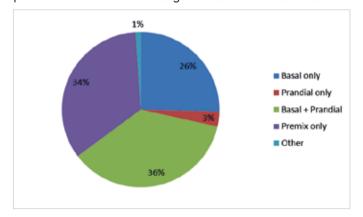
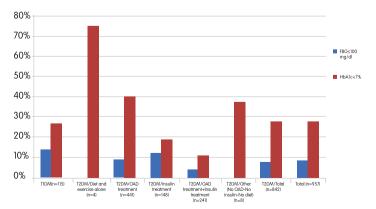


Figure 2. Distribution of insulin treatments in type 2 diabetes patients



**Figure 3.** Type 1 diabetes and type 2 diabetes patients reaching the target glycemic levels

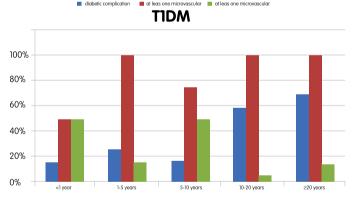
T1DM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus, OAD: Oral antidiabetic rate of patients above the determined limit was 72% for HbA1c and 92% for FBG.

High blood pressure (SBP  $\geq$ 130 and DBP  $\geq$ 80 mmHg) was detected in 43% of T1DM and 80% of T2DM patients, constituting 75% of all enrolled patients. High LDL levels ( $\geq$ 100 mg/dL) were observed in 43% of T1DM and 65% of T2DM patients. A HDL level of  $\geq$ 40 mg/dL was observed in the majority of T1DM (76%) and T2DM (64%) patients. One third of T1DM patients (30%) had high triglyceride levels ( $\geq$ 150 mg/dL), however this rate was higher (51%) in T2DM patients.

## **Diabetic Complications and Cardiovascular Risk Factors**

39% of all T1DM patients and 49% of all T2DM patients had diabetes complications. In patients with at least one late-term complication of diabetes, microvascular complications were present in 96% of T1DM patients and 88% of T2DM patients and macrovascular complications were present in 16% of T1DM and 43% of T2DM patients.

Almost all the T2DM patients (98%) were screened at least once in the past year for any diabetes-related complications and almost half (49%) had diabetes complications. The number of patients with complications increased proportionally with the increase in time since diagnosis, and reached the highest level (87%) in the group of patients with time period of  $\geq$ 20 years since diagnosis. In the patient groups with time since diagnosis <1, 1-5, 5-10, 10-20 and >20 years, the percentage of patients with at least one



**Figure 4.** Percentage of diabetes complications by diabetes duration for type 1 diabetes patients

T1DM: Type 1 diabetes mellitus

Table 3. Cardiovascular risk factors and risk score				
Cardiovascular risk score	TIDM	T2DM		
0	15.5%	0.7%		
1	29.1%	7.3%		
2	27.2%	25.8%		
3	24.3%	41.8%		
4	3.9%	22.1%		
5	0%	2.3%		

Cardiovascular risk factors: Age  $\geq$ 45 (males), age  $\geq$ 55 (females), systolic blood pressure  $\geq$ 130 and diastolic blood pressure  $\geq$ 80 mmHg, high density lipoprotein <40 mg/dL (males), high density lipoprotein <50 mg/dL (females), low density lipoprotein  $\geq$ 100 mg/dL cardiovascular risk score, sum of these factors T1DM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus

microvascular complication in T1DM group was 50,100, 75,100 and 100% respectively (Figure 4) and in T2DM group was 85, 83, 90, 91 and 87% respectively (Figure 5).

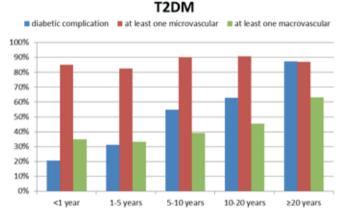
Cardiovascular risk factors were evaluated and the data revealed that 15% of patients were smokers; the mean SBP and DBP were 133 ( $\pm$ 17.7) mmHg and 80 ( $\pm$ 10.6) mmHg, respectively. Mean LDL and HDL values were calculated as 119 ( $\pm$ 40.2) mg/dL and 46 ( $\pm$ 18.3) mg/dL, respectively. Almost all T2DM patients (99%) had at least one cardiovascular risk factor and among all T2DM patients, 42% had 3 risk factors out of 5. No cardiovascular risk factor was detected (risk score=0) in 15% of T1DM patients (Table 3).

#### **PHQ-9 General Health Questionnaire**

In this study, 75 TIDM and 522 T2DM patients completed the PHQ-9. Major depression was observed in 13% of TIDM and 11% of T2DM patients. Approximately 79% of patients (TIDM: 79% and T2DM: 79%) did not have depression. Severity of the depression was evaluated and it was found that 44% of TIDM patients and 48% of T2DM patients did not have severe depression. Severe depression was observed in 2% of patients (TIDM: 3% and T2DM: 2%) (Figure 6).

### **Discussion**

In the 5<sup>th</sup> period of the IDMPS, the majority of 842 patients with T2DM, who were enrolled to this study by 94 doctors, were living in cities (85%), they were hypertensive (63%) and dyslipidemic



**Figure 5.** Percentage of diabetes complications by diabetes duration for type 2 diabetes patients

TIDM: Type 2 diabetes mellitus

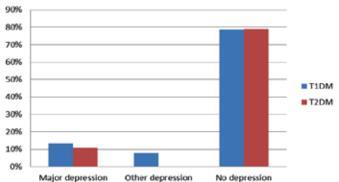


Figure 6. Patient health questionnaire-9 questionnaire results TIDM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus

(56%), and they had a family history of diabetes (64%) high BMI (mean: 31 kg/m²) and high waist circumference values (mean: 105 cm). 56% of the 842 patients were female. 98% of hypertensive patients and 86% of dyslipidemic patients were being treated. In the majority of patients (88%), at least one microvascular complication, and in almost all patients (99%) cardiovascular risk factors were detected.

These findings are compatible with the most important studies on the prevalence of diabetes performed in Turkey in recent years, i.e. the Turkish Diabetes Epidemiology Study I, (1997-1998) (TURDEP-I) (14) and the Turkish Diabetes, Hypertension, Obesity and Endocrine Diseases Prevalence Study, (2010) (15). Global IDMPS included almost 50% of 24.788 patients included in the TURDEP-I, and both of these studies, which were conducted simultaneously, had similar findings. When compared with the TURDEP-I findings, the prevalence of diabetes increased by 90% and climbed to 14% (14,15). This fact shows that the population in the productive age will struggle with complications at an earlier time in the future and this will increase both treatment and labor costs due to loss of productivity.

In this study, the PHQ-9, scientifically proven for sensitivity and specificity (16) for the detection of concomitant depression in patients with long-term medical disorders, was used and depression symptoms were detected in approximately 10% of patients. The prevalence of depression in diabetic populations varies between geographical regions. Our results were similar to the results (12%) of a study conducted in London with 182 patients (17). A higher prevalence rate (18%) was reported in Hong Kong (18). On the other hand, a North American study conducted in Canada with 1388 T2DM patients declared that 33% of patients had depression (19).

Half of the patients with T2DM (52%) were treated with OAD only, 18% were treated with insulin only and 29% were treated with OAD + insulin. The mean duration of treatment in insulin-treated T2DM patients was 4 years and the preferred treatment regimens were basal + prandial (36%); premixes (34%) and only basal (25%) insulin. Preferred treatment patterns did not vary according to whether the physicians were specialist or practitioner/family physician. T2DM patients treated with insulin only had a high average age (60±12.8) and 69% had diabetic complications. 40% of patients were receiving 4 injections per day and were able to give their own injections; 62% adjusted their own insulin dose. 32% of OAD + insulin-treated patients were able to give their 2 injections per day and 70% adjusted their own insulin dose. Only insulin or insulin + OAD-treated patients with T2DM received more diabetes education and visited specialists more often comparing to the patients receiving other types of treatments. It seems specialists show more courage in the initiation of insulin therapy in patients over 60 years of age, with advanced diabetes and developed complications. Since patients receiving insulin treatment need to get more training (giving their own injections, measuring their own blood sugar and adjusting their own insulin dose) in order to maintain insulin treatment, T2DM patients in this group received more diabetes education comparing to the patients who do not receive insulin treatment.

The majority of patients with T2DM could not reach the target value for optimal glycemic control as defined by the international diabetes authority; 92% of patients could not reach the target value for FBG and 72% of patients could not reach the target value for HbA1c. According to the overall results of IDMPS, regardless of region and used insulin regimens, 18-35% of patients had a HbA1c level of <7% (20).

Despite the fact that most of the patients (80%) enrolled to the study in Turkey had glucose measuring devices and almost all of them (93%) were capable of measuring their own blood sugar levels, glycemic control was poor in the majority of the patients. The reason for this was the fact that only 35% of patients performed daily blood glucose measurement and HbA1c measurements were done in the laboratory twice a year.

Almost all patients with T2DM in Turkey (98%) were screened for diabetic complications at least once in the past year and approximately half of the patients (42%) were diagnosed with a diabetic complication. The rate of complications, which increases proportionately to elapsed time after the diagnosis of diabetes, reached 87% in 20 years and over. At least one microvascular complication in the majority of patients (88%), and cardiovascular risk factors in almost all patients (99%) were detected. 15% of patients smoked cigarettes, the average SBP and DBP, HDL and LDL levels were above the normal range.

These findings indicate that current metabolic control in patients with T2DM in Turkey is not sufficient to prevent complications of diabetes.

In diabetes treatment, hyperglycemia should be taken under control appropriately and hence, new strategies should be developed for preventing or delaying macro- and microvascular complications. The results showed that there was a conflict between recommendations in the international guidelines and real life applications.

The Clinical Practice Guidelines for Diagnosis, Treatment and Follow-up of Patients with Diabetes Mellitus and its Complications is prepared by the Study Group of the Society of Endocrinology and Metabolism of Turkey Education and Study Group in 2006, updated biennially and distributed to all physicians in Turkey. In this guideline, target HbA1c level was indicated as  $\leq$ 7% (21). Apparently, there is a need for serious improvements about diabetes care according to the guidelines in our country.

In their study, Ringborg et al. (22) suggested that micro- and macrovascular complications and inadequate glycemic control in people with T2DM were strong predictors of resource use in developing countries. In a study conducted by Degli Esposti et al. (23) it has been suggested that poor glycemic control (HbA1c) is not only associated with diabetes-related complications, but it is also a significant indicator of their associated healthcare costs. Shetty et al. (24) determined that the diabetes-related cost for T2DM patients exceeding the recommended limit value of HbA1c (7%) was 32% higher than that for patients whose HbA1c levels were within the normal limits (p<0.001). The positive effect of improved glycemic control on overall costs has been shown in many studies (25,26).

### **Study Limitation**

The results of the IDMPS are based on the descriptive analysis of interviews made with the patients and answers of the patients to the questionnaire. No corrective measure was implemented for preventing bias since there was no control group in the study and statistical analysis of the data is limited to descriptive statistics only. Non-standardized laboratory tests and non-standardized evaluation of complications are among the limitations of this study. A standard method was applied to all regions in this study in terms of diabetic treatment applications and this can be counted as a strength of this study allowing comparisons between regions. Even though this was a cross-sectional study, it shows that the most important determinants of alycemic control are early diagnosis, early treatment and capability of patients to manage the treatment on their own. This study is making it possible to observe the change in the performance indicators within the study period of 5 years giving us the opportunity to have a global view that patients, doctors and factors related to the heath-care system, as most important components for determining treatment quality, may lead the treatment to be incompatible with the ideal one.

### **Conclusion**

Lifestyle modification and diabetes patient education may lead to significant improvements in good metabolic control. Therefore, the basic target lies in providing efficient training, and at the end of the training, the aim should be obtaining optimal glycemic levels. In diabetic populations, increasing complications drain a large portion of healthcare resources. Almost all T2DM patients have at least one cardiovascular risk factor. Microvascular complications increasing the risk of death due to cardiovascular reasons and the complications can be prevented only with efficient and continuous diabetes treatment. Therefore, early diagnosis, periodic check-ups and good metabolic control as well as significant improvements in life style may reduce morbidity and mortality due to microvascular complications.

To reach this target, close monitoring of the treatments, efficient diabetes education and, most importantly, increasing awareness of the disease including long-term effects of the complications are the most important conclusion of this study.

While designing programs to control diabetes, as well as feasibility and the cost, continuing surveillance and periodic validation mechanisms should be established in order to ensure that all steps of the program are being followed efficiently and measures are being taken on time. For realization of these programs, governmental and private institutions and also civilian (non-governmental) organizations should work together in unison (27).

## **Ethics**

Ethics Committee Approval: The study was approved by Istanbul University Cerrahpaşa Faculty of Medicine Local Ethics Committee. Informed Consent: A written consent form was completed and signed by all participants.

Peer-review: Externally peer-reviewed.

# Authorship Contributions

Surgical and Medical Practices: Hasan İlkova, Kubilay Karşıdağ, Abdurrahman Çömlekçi, Taner Damcı, Concept: Practices: Hasan İlkova, Data Collection or Processing: MapiNaxis, France, Analysis or Interpretation: Practices: Hasan İlkova, Taner Damcı, Kubilay Karşıdağ, Abdurrahman Çömlekçi, Göksun Ayvaz, Literature Search: Taner Damcı, Writing: Abdurrahman Çömlekçi.

Conflict of Interest: Hasan İlkova is a member of the IDMPS Steering Committee and has received honoraria and traveling sponsorships in relation to the IDMPS. Hasan İlkova has also received consulting fees from Novo Nordisk, Astra Zeneca, Servier, Eli Lilly, Sanofi, Bristol Myers Squibb, MSD, Takeda, Novartis, Medtronic, Bayer, Abbot and Bilim İlaç AŞ. T. Damcı has received consulting fees from Astra Zeneca, Bristol Myers Squibb, Merck, Novo Nordisk, Bilim İlaç, Takeda, Pfizer, Eli Lilly and Sanofi. Kubilay Karşıdağ has no conflict of interest to declare. Abdurrahman Çömlekçi has received consultancy fees from Novo Nordisk, Sanofi, Eli Lilly, Boehringer Ingelheim, MSD, Novartis, lecture fees from Pfizer, Sanofi, Novo Nordisk, Eli Lilly, Abdi İbrahim, Bilim İlaç AŞ, MEDA Pharma, Takeda, MSD, Novartis. Göksun Ayvaz has disclosed that he has received sponsorship from Novartis; research grants from Novartis, Novo Nordisk and Sanofi; he is on Astra Zeneca's and Sanofi's Advisory Board and is a consultant to Eli Lilly; he is on the Speakers' Bureau of Astra Zeneca, Bristol Myers, Squibb, Merck and Sanofi.

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