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EVALUATION OF THE RATE OF ACHIEVING THE TREATMENT GOALS AND THE CHANGE IN THE MEDICATION THERAPY OF PATIENTS WITH TYPE2 DIABETES

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ABSTRACT

Background: The incidence of Type-2 DM continues to increase whereas new agents are involved in treatment options. No sufficient data are available on the rate changes regarding diabetic achievements in the Turkish population over the years. **Objectives:** In the study, we aimed to evaluate the 2008 and 2018 data of type-2 diabetes mellitus (T2DM) patients followed in the diabetes outpatient clinic of our hospital in terms of diabetic achievements and treatment preference. Methods: Files of T2DM patients followed in our hospital's diabetes outpatient clinic in 2008 and 2018 and hospital information processing data were evaluated retrospectively. Glycemic values, BMI, renal functions, lipid profiles, and drug use characteristics of the patients for both periods were compared. Results: A total of 449 patients, 185 male and 264 female, in 2008 and a total of 450 patients, 172 male and 278 female, in 2018 were included in the study. The mean body mass index (BMI) in 2018 was found to be higher than in 2008 (30.84±5.19 vs. 31.72±5.42; p<0.01). The average HbA1c in 2018 was higher than ten years ago (7.28% +/-1.23% vs. 7.76% +/- 1.39; p<0.01). The rate of patients with an HbA1c level below 7% was higher than the average in 2018 (7.92 +/- 1.28 vs. 8.32 +/- 1.37; p<0.001). Glomerular filtration rates (GFR) were found to be significantly higher in 2011 than in 2018 (111.5 +/- 34.5 vs. 102.1 +/- 32.3; p<0.001). Albumin/creatinine (ACR) average was found to be significantly higher in 2018 (61 +/- 174 mg vs. 105 +/- 253; p: 0.003). LDL cholesterol and non-HDL cholesterol averages were found to be significantly higher in 2018. The rate of insulin use was higher in 2018 (24% vs. 39%, p<0.001; 25% vs. 40%, p<0.001). No significant change was determined in metformin use whereas there was a significant decrease in sulphonylurea use in 2018 (34% vs. 19%, p<0.001). There was a significant increase in gliclazide use (7% vs. 12%, p: 0.018). A significant decrease was observed in the use of pioglitazone, glinide, and acarbose in 2018 whereas there was a significant increase in the use of DPP4-I (1% vs. 44%, p<0.001). No comparison could be made for the use of SGLT-2 group, which was not yet in use ten years ago. Conclusion: Diabetic targets, BMI, lipid targets, and renal functions were worsened in T2DM patients in 2018 compared to ten years ago. The rate of metformin use did not change; the use of sulphonylurea, PIO, and acarbose decreased; the use of DPP4-I increased. The increase in the rate of insulin use and doses is noteworthy.

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INTRODUCTION

Diabetes Mellitus (DM) is a serious health problem all over the world and its prevalence is increasing. According to the data of the International Diabetes Federation (IDF), the global diabetes prevalence in individuals aged 20-79 was predicted to be 10.5% (536.6 million people) in 2021 and will increase to 12.2% (783.2 million people) in 2045 (International Diabetes Federation, 2021). The largest relative increase in diabetes prevalence between 2021 and 2045 is expected to be reached in middle-income countries, including Turkey, by 21.1% (Hong,). DM is a serious cause of mortality and morbidity due to its complications, especially for cardiovascular system (Bragg, 2017; Rawshani, 2017). Numerous studies, especially the UKPDS, showed that glycemic control reduces diabetes-related complications (Diabetologia, 1991). However, glycemic targets cannot be achieved in most of the studies (Polonsky, 2016; Khattab, 2010). In recent years, many new drugs with different mechanisms of action have been included in the treatment of diabetic patients. Dipeptidyl peptidase-4 inhibitors (DPPT-I), sodium glucose co-transporter 2 inhibitors (SGLT2-I), glucagon-like peptide-1 (GLP1) analogues and new insulins with different times of action offer physicians the

opportunity to reach a better level in the treatment of diabetes. In our country, new agents approved for the treatment of diabetes generally go into use in a short time. In our study, we planned to compare the patient follow-up data of type-2 diabetes patients followed up in our diabetes outpatient clinic in 2008 and 2018 and evaluate how rates of achieving treatment goals have changed.

MATERIALS AND METHODS

Patient population and study protocol: This study was planned as a retrospective, single-center, cross-sectional study. Patients with diagnosis of Type 2 DM, who were followed up regularly in our hospital diabetes outpatient clinic and whose records were complete, were recruited. 449 patients who were suitable for the working conditions were selected from the file archive of 2008, according to the order of application. 450 of Type 2 DM patients were included in the study from the archive of files belonging to ten years later.

Exclusion criteria

- Type 1DM, gestational DM and secondary DM
- Patients with advanced cirrhosis, end-stage renal disease, stage 4 heart failure,
- oncological diseases under treatment, those using immunosuppressive drugs, and those with active infection at the last visit were excluded from the study.

For both periods ten years before and after, demographic data, BMI, duration of diabetes, HbA1c, GFR, Albuminuria, lipid profile, and medications used by the patients ,were recorded. These two periods were compared with in terms of patient characteristics, glycemic targets, lipid targets, nephropathy and treatment changes. Local ethics committee decision was taken from Kartal Dr.Lütfi Kırdar Educaitional and Research Hospital.Ethics committee no:2018/514/127/6, Date:11 April 2018

Statistical analysis: Statistical analysis were made using the computer software Statistical Package for Social Sciences (SPSS) 17. Data was expressed as "n (%)" for categorical variables. Pearson chi-square and Fisher exact tests were performed for categorical variables where appropriate. After fitness to normal distribution was analyzed with the Kolmogorov-Simirnov test, data was expressed as "median (25^{th} - 75^{th} percentiles)" for variables with abnormal distribution and mean±sd for variables with normal distribution. Mann-Whitney U test was used for comparing quantitative variables with normal distribution will estudent t test was used for variables with normal distribution. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 449 patients, 185 male and 264 female, in 2008 and a total of 450 patients, 172 male and 278 female, in 2018 were included in the study. There was no difference between the sex ratios of the patients compared to ten years ago (p:3.36). The mean age of male and female patients was significantly higher in 2018 than ten years ago (57.06±8.65 vs. 64.65±9.83; p<0.01). In terms of diabetes duration, the mean in 2018 was significantly higher (11.24±5.65 vs. 18.38±5.94; p<0.01). When compared in terms of body mass index (BMI), the mean in 2018 was significantly higher in the general population compared to 2008 (30.84±5.19 vs. 31.72±5.42; p<0.01). When the glycosylated hemoglobin (HbA1c) results were compared, the patient's average in 2018 was significantly higher than ten years ago (7.28±1.23 vs. 7.76±1.39%; p<0.01). When the rate of patients with an HbA1c level below 7% was evaluated in terms of insulin-user patients (alone and combined with oral antidiabetics), the average HbA1c in 2018 was significantly higher (7.92±1.28 vs. 8.32±1.37; p<0.001). When evaluated in terms of oral antidiabetic (OAD) use, the average HbA1c in OAD users was significantly higher in 2018 (7.22±1.21 vs. 7.76±1.39; p<0.001).

However, this relationship was not observed between individual oral drug groups and HbA1c. When compared in terms of glomerular filtration rate (GFR), values in 2011 were significantly higher than that in 2018 (111.5±34.5 vs. 102.1±32.3; p<0.001). When evaluated in terms of albumin/creatinine (ACR), the average in 2018 was significantly higher (61±174 mg vs. 105±253; p: 0.003). When compared according to the LDL cholesterol averages, the average in 2018 was significantly higher (109.9±33.0 vs. 118.3±35.8; p<0.001). Non-HDL cholesterol level was significantly higher in 2018 (142.6±39.3 vs. 150.7±44; p: 0.003) (Table 1). In terms of antihypertensive drug use, the use of angiotensin converting enzyme inhibitor (ACE-I) and angiotensin receptor blocker (ARB) groups was higher in 2008 (60-34% vs. 33%-25%, respectively; p:0.006). The use of calcium channel blocker (CCB) group drugs was higher in 2018 (14% vs. 21%; p: 0.007). Beta blocker (BB) use was also significantly higher in 2018 (%9 vs. %19;p<0.001). There was an increase in statin use in 2018 (46% vs 54%, p: 0.025) whereas the use of fibrate significantly decreased (%15 vs. %8, p<0.001). The rate of patients who received only basal insulin or basal bolus insulin therapy was significantly higher in 2018 (24% vs. 39%, p<0.001; 25% vs. 40%, p<0.001). The total doses of basal insulin used in treatment (7.9±16.8 vs. 14.5±21.7 U/day, p<0.001) and basal-bolus insulin (12.3±26.7 vs. 21.2±32.9 U/day, p<0.001) were also significantly higher in 2018. When evaluated in terms of OAD use, there was no significant change in the rate of metformin use between the years (82% vs. 82%, p: 0.850). There was a significant decrease in general sulphonylurea use in 2018 (34% vs. 19%, p<0.001) whereas there was a significant increase in gliclazide use in the same period (7% vs. 12%, p:0.018). A significant decrease was observed in the use of pioglitazone (17% vs. 0.6%, p <0.001)glinide (6% vs. 2%, p:0.006), and acarbose (11% vs. 4%, p:0.004) in 2018 whereas the use of DPP4-I significantly increased (1% vs. 44%, p<0.001). No comparison could be made for the SGLT-2 group, which was not yet in use ten years ago.(Table 2).

DISCUSSION

Our study evaluates the data of diabetic patients followed in the same hospital in Istanbul Kartal Region in 2008 and 2018. As the most obvious result of our study, the rate of reaching the glycemic target of A1c 7% decreased significantly within ten years and reduced from 56% to 44%. Compared to ten years ago, the average HbA1c of diabetic patients was found to be higher (7.76 vs. 7.28) in 2018. A similar picture was determined in terms of reaching the target in the geriatric group. In terms of drug use, the average HbA1c in 2018 were found to be higher in both the patient group using insulin and those using oral antidiabetic drugs compared to ten years ago (8.32 vs. 7.92). Another important result of our study was that the BMI of the patients increased after ten years (31.72 vs. 30.84). When evaluated in terms of reaching lipid targets, it was seen that this rate decreased significantly in 2018 in terms of the rate of reaching LDL level of 100mg and below (P=0.012). LDL C averages of the patients were also determined to be significantly higher in 2018 (109.9 \pm 33.0 vs. 118.3 ± 35.8 , p: 0.001). Although there is no such comprehensive study comparing ten years ago and today in our country, the data of TURDEP and PURE studies provide insight (8,9,10). The PURE Turkey study is a prospective cohort study including 4056 participants from different geographic regions. The primary aim of the study was to determine the frequency and risk factors of CVD. The study was conducted in 2008, the year which corresponds to the first period of our study. In the study, in which the prevalence of diabetes was found to be 13.7%, the rate of reaching the glycemic target was 25%, which is quite low compared to our study. Moreover, the rate of reaching the LDL cholesterol value of 100 mg and below was 22.2% in diabetic patients. In our study, this rate was determined to be 59%. This difference, which is in favor of our study according the data of the same year, can be attributed to the regular follow-up of the patient group in our diabetes outpatient clinic of a tertiary hospital and the irregular follow-up of different patient groups in different centers in TURDEP study. Compared to TURDEP-I, the TURDEP-2 study reported an increased rate of 90% for diabetes, 106% for IGT, 40% for obesity, and 35% for central obesity over 12 years.

	2008 n=449	% VALUE	2018 n=450	% VALUE				
MALE PATIENT	185	42%	172	38%	0.361			
FEMALE PATIENT	264	58%	278	62%	0.361			
AGE (year)	57.06 ± 8.65		64.65 ± 9.83		0.001			
DURATION OF DIABETES (year)	11.24 ± 5.65		18.38 ± 5.94		0.001			
BMI : (kg / m2)	30.82 ± 5.19		31.72 ± 5.42		0.011			
BMI; aged over 65	29.78 ± 4.04		31.60 ± 5.34		0.002			
BMI: aged under 65	31.02 ± 5.37		31.84 ± 5.50		0.077			
HbA1c %	7.28 ± 1.23		7.76 ± 1.39		0.001			
HbA1c %: 65 aged over 65	6.88 ± 1.01		7.59 ± 1.23		0.001			
HbA1c %: 65 aged under 65(adult)	7.35 ± 1.25		7.95 ± 1.51		0.001			
HbA1c %: insulin users	7.92 ± 1.28		8.32 ± 1.37		0.001			
HbA1c %: insulin + OAD users	7.69 ± 1.27		8.37 ± 1.36		0.003			
HbA1c %: OAD users	7.22 ± 1.21		7.76 ± 1.39		0.001			
HbA1c (7% andbelow)	252	56%	199	44%	0.001			
GFR (ml/min/1.73m2)	111.5 ± 34.5		102.1 ± 32.3		0.001			
Albuminuria mg/day	61 ± 174		105 ± 253		0.003			
Albuminuria(30- 300mg/day)	$92.6 \pm 65,5$		98.6 ± 73.2		0.651			
MAC (30-300) Number of patients	62		51		0.263			
LDL (mg/dl)	$109.9 \pm 33,0$		118.3 ± 35.8		0.001			
LDL below 100mg/dl	270	60%	180	%40	0.014			
Triglyseride (mg/dl)	164.3 ± 92	50%	162 ± 104	50%	0.742			
Non HDL (mg/dl)	142.6 ± 39.3		150.7 ± 44		0.003			
Non HDL below 130mg/dl	113	24%	104	22%	0.090			
BMI:Body mass index.HbA1c:glycosylated hemoglobin.GFR:glomerular filtration rate. MAC:albuminuria/								

Table 1. Baseline demographic and clinical variables of study population

creatinine, LDL: Low density lipoprotein,NonHDL:Non high density lipoprotein, kg/ m2:kilogram/square meters,ml/min:mililiter/minute, mg/day:miligram/day,mg/dl:miligram

Table 2. Drugs used by the study population

	2008(n=449)		2018(n=450)					
	NUMBER	%	NUMBER	%	P sig			
	ORAL ANTIDIABETIC DRUG USE							
METFORMIN	369	82%	372	82%	0.850			
GLICLAZIDE	33	76%	54	12%	0.018			
DPP-4I	4	0%	198	44%	< 0.001			
PIOGLITAZONE	78	17%	3	0.6%	< 0.001			
GILINID	28	6%	12	2%	0.009			
SGLT-2 I	0	0%	29	6%	< 0.001			
ACARBOSE	48	11%	19	4%	< 0.001			
SULPHONILUREA	151	34%	85	19%	< 0.001			
	INSULIN USE							
BASAL INSULIN ONLY	106	24%	176	39%	< 0.001			
MIX INSULIN ONLY	84	19%	87	19%	0.810			
BASAL+BOLUS INSULIN	111	25%	182	40%	< 0.001			
	ANTIHYPERTENSIVE DRUG USE							
ACE INH.	271	60%	148	33%	< 0.001			
ARB	151	34%	114	25%	0.006			
CCB	63	14%	94	21%	0.007			
ALPHA BLOCKER	5	1%	10	2%	0.194			
BB	42	9%	86	19%	< 0.001			
HTZ	2	0%	0	100%	0.156			
	ANTILIPIDEMIC DRUG USE							
STATINS	209	46%	243	54%	0.025			
FENOFIBRATE	66	15%	35	8%	0.001			

SGLT-2 I: Sodium Glucose Co-Transporter-2 Inhibitor, ACE INH.: Angiotensin converting enzyme inhibitor, ARB: Angiotensin receptor blocker, CCB: Calcium channel blocker, BB: Beta blocker, HTZ: Hydrochlorthiazide, DPP-4I: Dipeptidyl peptidase 4 inhibitor

In our study, we observed that BMI significantly increased in diabetic patients compared to ten years ago. Both studies reveal that the prevalence of diabetes and obesity has increased much more in Turkey compared to other European countries. The increase in obesity rate reported in TURDEP-I and II supports the findings of our study. Globally, the increase in the prevalence of diabetes and obesity is almost at the level of a pandemic. Consistent with the results of our study, many studies reported an increase in obesity in diabetic patients (Barnes, 2011; Hossain, 2007; Wang, 2021; Damian, 2017; Ampofo, 2020; Pagidipati, 2020) Fang M carried out a study using NHANES(19) data with a methodology similar to ours. In the aformentioned study conducted in the USA, the data of 6653 non-pregnant diabetic patients aged over 20 between 2009 and 2018 were evaluated.

It was shown that there has been no improvement in glycemic regulation in 9 years. The rate of adult diabetic participants with glycemic control decreased from 57.4% to 50.5% between 2007 and 2010. The most important feature of this study is that the HbA1c level decreased (from 7.43 to 7.08) between 1999 and 2004, but then started to increase (7.08-7.22). The negative trend in glycemic regulation is consistent with the results of our study. When our data in terms of OAD use were compared with this study, there was no change in the use of metformin, similar to this study. In the following periods, sulphonylurea was preferred less in this study and a very high increase was observed in the use of new groups, especially DPP4-I. In our study, apart from the increase in the use of gliclazide, the tendency to use drugs was determined to be similar to this study.

In a study that included 406,344 type-2 diabetic patients belonging to primary care applications in England, the use of oral antidiabetic drugs was evaluated between 2000 and 2013 (20). The rate of metformin use, which was 55.8% in 2000, peaked at 83.6% in 2013, whereas the rate of sulphonylurea prescription dropped from 64.8% to 41.4%. Although there was an increase in the use of TZD, glinide, and acarbose for a period, the rate of use of these drugs decreased in 2013. No significant difference was found in the use of insulin (20-24%). In our study, the rate of metformin use did not change in both periods, while the use of glinide and thiazolidine decreased in 2018. Unlike other sulphonylureas, the use of gliclazide increased in 2018. There was a significant increase in the use of DPP4 and SGLT2 in 2018. When evaluated in terms of insulin use, there was a significant increase in the use of insulin types other than ready-mixed insulin in 2018 compared to 10 years ago. In the International Diabetes Management Practices Study (IDMPS) of Pablo Ashner et al., 66088 patients with type-2 diabetes from 49 developing countries were followed between 2005 and 2017. In this study, in which the data of the years in this period were compared, it was determined that 80% of the patients used oral antidiabetic drugs, that the use of sulphonylurea decreased, and that the use and dose of insulin increased in the process. In the IDMPS study, the rate of patients with HbA1c (<7%) was 36% in 2005 and decreased to 30.1% in 2017 (p<0.0001). The primary aim of the study was to evaluate the change in the characteristics of drug use, especially the negativity in the glycemic course over the years and the findings are pretty consistent with the results of our study (Aschner, 2020). The Turkish data of the fifth wave results of IDMPS were published by Ilkova et al. (2016). 842 T2DM and 115 type-1 diabetes (T1DM) patients were included in the study conducted with 94 researchers between 2011 and 2012. It was stated that 52% of Type-2 DM patients were treated with OAD alone, that 29% were treated with OAD+ insulin, and that 18% were treated with insulin only. In the 2011 data of our study, the rate of insulin use was determined as 43%, which is higher than this study. In the study, the rate of reaching the target HbA1c 7% level was 28%. In our study, when evaluated with an interval of ten years, the rate of reaching the target A1c level was observed to be higher in both periods compared to this study. In the fifth wave study, the BMI of patients with type-2 diabetes was as 30.87 (±5.80).

In our study, the the mean BMI in 2010 was found to be very close to this value (30.82±5.19). The fact that our patients were regularly followed-up in the same clinic explains these better results in terms of reaching glycemic targets. Despite all the efforts and developments in the treatment of diabetes, the treatment goals are not achieved. Wang et al. (88) evaluated the data of 28143 diabetic patients between 1999-2000 and 2017-2018 using the data of National Health and Nutrition Examination Survey (NHANES) and revealed that only 22% of the patients were able to reach their glycemic, blood pressure, and lipid targets (Li wang). Considering the use of antihypertensive drugs in this study, in which the trend of drug use is similar, contrary to this study, the use of ACE and ARB was higher in the first period of our study but decreased in 2018 whereas the use of CCB and BB increased. This result can be attributed to patient characteristics; however, why RAS blockers, whose positive effects are well-known, are less prescribed for diabetic patients should be investigated in detail. In the US study, it was stated that a better level has been reached in terms of lipid treatment and achievements, although the pace has slowed down recently. In terms of reaching lipid targets, the average LDL and non-HDL levels were significantly higher in 2018. In the PURE study, which is one of the most important studies regarding the data of Turkey, 79.8% of the diabetic patients seen in 2015 had LDL cholesterol levels of $\geq 100 \text{ mg/dL}$ (Oğuz, 2018). Diabetes prevalence was reported as 21% in 4056 patients included in this study. Adequate glycemic control was achieved in only 25% of patients. Although there are no data on diabetic patients, it was observed that 52% of the patients were obese according to their BMI. In the Third National Health and Nutrition Examination Survey (NHANES III), and the studies for 1988-1994 and 1999-2002 study, it was stated that the rate of overweight and obesity was 85.5% in diabetic patients in the American adult population. The National Diabetes Audit (NDA) reported that 90% of adults with type-2

diabetes aged 16-54 in the UK were overweight or obese and that only 10% of the patients in 2009-10 were at a healthy weight or underweight (Holman, 2021). All these results are consistent with the results of our study. Despite the increase in the rate of patients using statin in our study, insufficient dose or regular drug use may play a role in inability to reach lipid targets. Fang and Elvin (2021) evaluated the data of the last 30 years of patients with type-2 diabetes between ten-year periods and reported a better trend in terms of nephropathy (Fang, 2021). No difference was found in terms of other micro- and macrovascular complications. Although our study is not similar in terms of design, it suggests that there has been an improvement in the awareness of hypertension, hyperlipidemia which play a role in the development of diabetic nephropathy. When our study was evaluated in terms of diabetic renal functions, the finding that GFR was significantly lower in 2018 data (111.5 vs. 102, p 0.001) differs from this study. In a recent study conducted in the Thai population, 186,010 type-2 DM patients were evaluated between 2011 and 2018 (25). The rate of patients achieving adequate glycemic decreased by 34.5% (95% CI 33.8-35.2%) for 2011, 33.0% for 2012 (95% CI 32.4-33.6%), 34.7% (95% CI 34.1-35.4%) for 2013, 35.5 (95%CI 34.9-36.1%) for 2014, 35.6 (95%CI 35.0-36.2%) for 2015, and 35.6% (95%CI 35.0-36.2%) for 2018, respectively (p < 0.001) and these rates support our study results.

Research Limitations: Our study had some limitations. Primarily, our study was designed retrospectively for a single center. Some of the data were based on patient statements. The results may not reflect the results of the general population, since the patients in our study were followed up more regularly than diabetes outpatient clinics and other health institutions. No detailed comparison could be made as there were missing information in the files in terms of micro and macro complications. On the other hand, since the study was conducted in the same center, a population with high patient loyalty was included. Since the patient data were recorded in special files, the data were easily accessed. Since the patients came to the clinic every 3 months for follow-up, laboratory findings were completely available. Our study is important in terms of showing the success/failure of treatment in diabetic patients within ten years since no such scaled comparative study has been conducted in Turkey. It is remarkable that our results are generally better in terms of glycemic regulation since no study has been conducted with the same methodology at a diabetes center in our country.

The fact that glycemic success is much lower in other cross-sectional studies, both in Turkey and other countries, indicates the positive effect of diabetes centers on treatment. However, the decrease in the rate of glycemic control, failure in weight control, and inability to reach lipid targets are the important results of our study. In terms of drug use, it was seen that the tendency to use higher doses of insulin more frequently is not successful. We think that the increase in sulphonylurea use despite weight-neutral or positive agents is one of the causes of weight gain. Likewise, the fact that ACE-I and ARB group drugs have been less preferred over the years is one of the negative changes in the treatment trend. The first period examined in our study should be considered as a period when SGLT-2 I and GLP1 analogs could not be adequately used. Given that gliflozins and GLP1 analogs have become very popular in recent years and guidelines have changed drastically, the latest situation necessitates an evaluation with a new study.

CONCLUSION

Compared to ten years ago, glycemic achievement could not be improved in type-2 diabetes patients. In terms of obesity and reaching lipid targets, we are similarly at a worse point than we were ten years ago. We use higher doses of insulin more frequently. We attribute our better condition in terms of reaching glycemic targets compared to studies in Turkey and other countries to the fact that the patients in our study were followed up regularly at the same diabetes center.

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