



Management and treatment goals in Polish patients with type 2 diabetes of more than ten years' duration — results of ARETAEUS2-Grupa Study

Leczenie i spełnianie celów leczenia u polskich chorych na cukrzycę typu 2 od ponad 10 lat — wyniki badania ARETAEUS2-Grupa

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Abstract

Introduction: Previous studies have shown insufficient diabetes control in patients with type 2 diabetes (T2DM). Diabetes Poland changed the target HbA1c and blood pressure (BP) values in diabetic patients in their practice guidelines in 2011, that were further sustained.

To assess the management and treatment choices in T2DM of more than ten years' duration and the degree to which diabetic control criteria recommended by the Diabetes Poland clinical practice guidelines 2012 are being met.

Material and methods: ARETAEUS2-Grupa was a cross-sectional questionnaire-based study conducted in Poland in 2012 (April–June). It involved 1,740 patients of any age and both genders, with T2DM diagnosed more than ten years before the study, and recruited by randomly selected physicians.

Results: All patients received pharmacological treatment, most of them combination therapy or insulin in monotherapy. 40% of patients met the goal for HbA1c control ($\leq 7\%$) and the median value of HbA1c was above the recommended threshold (7.2%). Only 8% of the total population met all three goals (HbA1c, BP and lipid levels), 26% — two goals, and 40% — only one goal. Over 25% of patients did not meet any of the treatment goals.

Conclusions: We observed considerable deviations from treatment targets recommended by current clinical practice guidelines for patients with T2DM of more than ten years' duration. The frequency of cardiovascular risk factors and late diabetes complications was high, while a relatively high percentage of patients was not examined for late diabetes complications. (*Endokrynol Pol* 2014; 65 (3): 158–168)

Key words: practice guideline; cross-sectional studies; diabetes mellitus type 2

Streszczenie

Wstęp: W poprzednich badaniach wykazano niewystarczającą kontrolę choroby u chorych na cukrzycę. Polskie Towarzystwo Diabetologiczne zmieniło wartości docelowe HbA1c i ciśnienia tętniczego u chorych na cukrzycę w wytycznych z 2011 roku, które zostały utrzymane w kolejnych edycjach wytycznych.

Badanie przeprowadzono w celu oceny leczenia cukrzycy i wyboru metod leczenia u chorych na cukrzycę typu 2 o czasie trwania > 10 lat oraz określenia stopnia spełniania kryteriów kontroli cukrzycy zalecanych w wytycznych Polskiego Towarzystwa Diabetologicznego z 2012 roku.

Materiał i metody: Badanie ARETAEUS2-Grupa było przekrojowym badaniem kwestionariuszowym przeprowadzonym w Polsce w 2012 roku (kwiecień–czerwiec). Badaniem objęto 1740 chorych na cukrzycę typu 2 w każdym wieku i obu płci rozpoznaną ponad 10 lat przed rozpoczęciem badania, włączonych do badania przez losowo wybranych lekarzy.

Wyniki: Wszyscy chorzy otrzymywali leczenie farmakologiczne, większość — leczenie skojarzone lub insulinę w monoterapii. 40% chorych spełniło kryterium kontroli HbA1c ($\leq 7\%$), a mediana odsetka HbA1c była powyżej zalecanej wartości (7,2%). W całej populacji jedynie 8% chorych spełniło wszystkie kryteria kontroli choroby (HbA1c, ciśnienie tętnicze i profil lipidowy), 26% — dwa z tych kryteriów, 40% — jedno z tych kryteriów. Ponad 25% chorych nie spełniło żadnego z tych kryteriów.

Wnioski: Zaobserwowano duże odstępstwa od celów leczenia zalecanych w aktualnych wytycznych postępowania u chorych na cukrzycę typu 2 o czasie trwania > 10 lat. Częstość występowania sercowo-naczyniowych czynników ryzyka i późnych powikłań cukrzycy była duża, a stosunkowo duży odsetek chorych nie był badany w kierunku późnych powikłań cukrzycy. (*Endokrynol Pol* 2014; 65 (3): 158–168)

Słowa kluczowe: wytyczne praktyki; badania przekrojowe; cukrzyca typu 2

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Abbreviations

BMI — body mass index
 BP — blood pressure
 CHD — coronary heart disease
 T2DM — type 2 diabetes
 DP — Diabetes Poland
 HbA1c — glycated haemoglobin
 HDL — high density lipoprotein
 IQR — interquartile range
 LDL — low density lipoprotein
 SD — standard deviation

Introduction

In Poland, 6.8% of the adult population has diabetes [1]. The ARETAEUS1 study, carried out in 2009, showed that a high proportion of patients with diabetes type 2 (T2DM) of short duration had cardiovascular risk factors and late diabetes complications and over half of them did not meet any of the treatment goals outlined in the Diabetes Poland clinical practice guidelines [2, 3]. The OPTIMO Study, which included patients with different diabetes durations, showed that the frequency of diabetes complications increased with diabetes duration and that glycaemic control worsened after several years of diabetes [4]. Diabetes Poland publishes practice guidelines for healthcare professionals annually, and changed its target HbA1c and blood pressure (BP) values in diabetic patients in 2011 [5–8]. Current practice guidelines recommend setting individualised treatment goals and treatment plans for patients with T2DM, which are based on age, life expectancy, comorbidities, risk of hypoglycaemia, patient education and patient preferences [7, 8]. Milder criteria ($\text{HbA1c} \leq 8\%$) are recommended for patients over 70 with long lasting T2DM, with a history of myocardial infarction or stroke [7, 8]. In the ARETAEUS2-Grupa study, we aimed to describe the characteristics of the T2DM population in Poland, including examining and diagnosing late diabetes complications, and examine diabetes control and treatment used both in patients with T2DM of short duration [9] and those with T2DM of more than ten years' duration presented here.

Material and methods

The aims of the study

ARETAEUS2-Grupa was a cross-sectional questionnaire-based study conducted in Poland (April–June 2012). The study had two main aims: 1) to assess the methods of diabetes treatment used; and 2) to assess the degree to which the diabetic control criteria recommended by the Diabetes Poland clinical practice

guidelines 2012 [7] are met. An additional aim included a description of the characteristics of the T2DM population in Poland, including examining and diagnosing late diabetic complications. Diabetes was diagnosed using the widely accepted glycaemic criteria, which are consistent with the criteria of the American Diabetes Association [11], except HbA1c criteria for diagnosis of diabetes, which have not been accepted by Diabetes Poland yet [7].

The ARETAEUS2 Study had two arms: ARETAEUS2-Grupa and ARETAEUS2-Market. Physicians and patients were recruited to those two arms separately. This paper on patients with T2DM lasting > 10 years concerns only patients participating in ARETAEUS2-Grupa Study; the results for patients with T2DM of short duration have been reported elsewhere [9].

Patient inclusion criteria for the study

ARETAEUS2-Grupa Study included two groups of patients of any age and both genders:

- those diagnosed with type 2 diabetes within the previous two years (after 1 April, 2010) [9] who met the same inclusion criteria as in the ARETAEUS1 Study [2];
- those diagnosed with type 2 diabetes more than ten years before the study commencement (before 2002), in order to obtain data on treatment and disease control in intermediate to long-lasting diabetes.

Recruitment of clinicians and their patients

Two random samples of physicians were invited to participate in the study: non-diabetologists (mainly working in primary healthcare institutions) and diabetologists (specialists or physicians under training in diabetology, working in diabetes outpatient clinics).

Random samples were drawn from a database containing about 85% of all physicians practicing in Poland. Physicians were asked to recruit at least five patients with type 2 diabetes diagnosed more than ten years before the study commencement (i.e. earlier than 2002) during six weeks of the study duration. Patients were selected on a pseudorandom basis — the first two patients meeting the inclusion criteria from all the patients scheduled for a visit on that day. For a detailed description of recruitment procedures and sample size calculations, see our 2 years publication [9].

Questionnaire

The questionnaire consisted of two parts and no question allowed the identification of personal data. A detailed description of the questionnaire was published previously [9]. Briefly, the first part concerned the physician (specialisation, years since graduation, the mean number of patients with diabetes seen per week, availability of HbA1c test results on the day of

visit). The second part consisted of 24 patient-related questions including gender, age, duration of diabetes, medical history (cardiovascular events, hypertension, lipid disorders, history of cancer, diabetic complications) weight, height, test results (blood pressure, HbA1c, lipid levels), cigarette smoking status, fulfillment of treatment goals (BP, HbA1c, lipid levels), as well as details on diabetes, hypertension and hyperlipidaemia treatments used. Both parts of the questionnaire were completed by the physician.

Statistical analysis

We compared the proportions of patients achieving treatment goals in the subgroups with χ^2 test or Fischer exact test (when the expected values in any of the cells of a contingency table were below 5). For the comparison of the means, the t-test was used (for normal distribution), and the Mann-Whitney U test and Kruskal-Wallis test (for non-normal distribution of the variable). The distribution was estimated on the basis of skewness coefficient and graphical picture. The t-test for equal or nonequal variances was used depending on the result of the Levene's test. All statistical analyses were conducted using SPSS v. 18.0.

Results

We received 1,740 valid questionnaires from 331 physicians: 1,049 from 205 non-diabetologists and 691 from 126 diabetologists (for details — see our 2 years paper [9]). Seventy percent of physicians participating in the study were specialists or undergoing training for a specialisation in internal medicine, 38% were diabetologists in training or with completed training. Half of the participating physicians had graduated more than 20 years before the study commencement, and half of them reported seeing 11–30 diabetic patients per week.

Characteristics of patients

Baseline characteristics and frequency of cardiovascular risk factors (Table I.)

Glycaemic control

Eighty two percent of patients had HbA1c data available. Glycaemic control (HbA1c \leq 7%) was achieved in 40% of patients. This percentage did not change substantially after excluding patients with less restrictive glycaemic control according to the guidelines (Table II). For HbA_{1c} distribution — see Appendix Fig. 1. Most patients had their HbA1c measured 1–12 months before the study (Appendix Table I).

Median HbA1c increased with the duration of diabetes, while the percentage of patients who met the glycaemic goal decreased slightly (Table III).

Diabetes treatments used

All patients received pharmacological treatment — most of them combination therapy or insulin in monotherapy (Table IV). More patients with HbA1c \leq 7% received metformin with sulfonylurea therapy or sulfonylurea in monotherapy, while metformin with insulin or other drug and drug combinations were more commonly used in patients with HbA1c above 7% (Table IV). The use of the drugs differed in subgroups of patients defined according to BMI (Table IV). The percentage of patients using metformin in combination with insulin increased with BMI, while the percentage of patients using sulfonylurea in monotherapy decreased with BMI.

An analysis of the drug use according to the duration of the disease demonstrated that with the increasing duration of the disease, the proportions of patients receiving metformin in monotherapy or metformin with sulfonylurea decreased, while the proportion of patients receiving insulin in monotherapy increased significantly (Appendix Table II, III).

The number of diabetic drugs used by patients changed with the duration of diabetes (Appendix Fig. 2).

Meeting treatment goals

We analysed the number and type of treatment goals — BP < 140/90 mm Hg, LDL < 100 mg/dL or in case of CHD < 70 mg/dL, HbA1c \leq 7.0% — met by patients in total and in subgroups (Table V, Appendix Table IV, V, Fig. 1). The data for all treatment goals was available for 1,190 patients. In the total population, only 8% of patients met all three goals, 26% met two goals and 40% met one goal, while 25.6% did not meet any of the treatment goals (Fig. 1). In subgroups of patients (analysed by age, gender, BMI, duration of disease, types of diabetes treatment, etc. [Table V, Appendix Table IV, V]) the percentage of patients with all treatment goals met (HbA1c, LDL and BP levels goals) in different subgroups varied from 0 to 50% (in most cases it was less than 10%), while the percentage of patients with no treatment goals met was from 0 to 44.6% (in most cases between 15 and 30%).

When we analysed how the treatment goals were met in different BMI subgroups, we noted significant differences between subgroups: more patients met all treatment goals in the low BMI subgroup, while more patients did not meet any treatment goals in the highest BMI subgroup.

Diabetic complications

Seventy six to 86% of patients were examined for diabetic complications and the most commonly reported complication was retinopathy. The frequency of diabetes complications is shown in Figure 2.

Table I. Characteristics of the patient population with T2DM for more than ten years

Tabela I. Charakterystyka populacji chorych na cukrzycę typu 2 od ponad 10 lat

	Total (n = 1,740) ^a
Gender (%) (n) (n = 1,682)	
Female	53.9 (907)
Male	46.1 (775)
Age (n = 1,723), mean (SD) (years)	68 (9.8)
Time from diabetes diagnosis, median (IQR), months (n = 1,740)	156 (65)
Diabetes duration (%) (n)	
> 10–15 years	68.6 (1,193)
≥ 15–20 years	17.5 (305)
> 20 years	13.9 (242)
BMI, mean (SD) [kg/m ²] (n = 1,710)	30.4 (5.2)
HbA1c, median (IQR) (%) (n = 1431)	7.2 (1)
Total cholesterol, mean (SD) [mg/dL] (n = 1,668)	194 (45)
LDL cholesterol mean (SD) [mg/dL]	
Patients with no CHD (n = 683)	111 (38)
Patients with CHD (n = 744)	110 (39)
HDL cholesterol, median (IQR) [mg/dL]	
Female (n = 766)	50 (18)
Male (n = 668)	46 (15) ^b
Triglycerides, median (IQR) [mg/dL] (n = 1,629)	142 (74)
Lipid disorders ^c (%) (n) (n = 1,721)	83.1 (1,431)
Hypertension ^c (%) (n) (n = 1,737)	91.7 (1,592)
BP systolic/diastolic, mean (SD) [mm Hg] (n = 1,723)	138 (15)/81 (10)
Current smokers (%) (n)	14.6 (244)
History of ACS ^c (%) (n) (n = 1,702)	18.1 (308)
History of stable CHD ^c (%) (n) (n = 1,702)	48.5 (825)
History of stroke ^c (%) (n) (n = 1,708)	8.9 (152)
History of TIA ^c (%) (n) (n = 1,707)	10.7 (183)
History of cancer ^c (%) (n) (n = 1,700)	6.5 (110)

Items in bold type were assessed as treatment goals. ^atotal number of valid responses; ^bsignificant difference between subgroups (p = 0.000);

^caccording to the physician report

ACS — acute coronary syndrome; BMI — body mass index; BP — blood pressure; CHD — coronary heart disease; HbA1c — glycated haemoglobin; HDL — high-density lipoprotein; IQR — interquartile range; LDL — low-density lipoprotein; SD — standard deviation; TIA — transient ischaemic attack

Table II. Glycaemic control in patients with T2DM for more than ten years

Tabela II. Kontrola glikemii u chorych na cukrzycę typu 2 od ponad 10 lat

	Total ^a (n = 1,431)	After excluding patients with a history of cancer (n = 1,305)	After excluding patients with a history of cancer or over 80 years (n = 1,188)	Patients > 70 years old with ACS, stroke, TIA or with diabetes for > 20 years (n = 304)	After excluding patients > 70 years old with ACS, stroke, TIA or with diabetes for > 20 years (n = 534)
HbA1c ≤ 7%	39.8 (570)	40.0 (522)	39.2 (466)	39.5 (120)	37.3 (199)
HbA1c > 7%	60.2 (861)	60.0 (783)	60.8 (722)	60.5 (184)	62.7 (335)
HbA1c ≤ 8%	–	–	–	77.3 (235)	72.7 (388)
HbA1c > 8%	–	–	–	22.7 (69)	27.3 (146)

^atotal number of valid responses

Table III. Glycaemic control according to the duration of the disease in patients with T2DM for more than ten years

Tabela III. Kontrola glikemii w zależności od czasu trwania cukrzycy u chorych na cukrzycę typu 2 od ponad 10 lat

Total (n = 1,431) ^a	Diabetes > 10–15 years	Diabetes > 15–20 years	Diabetes > 20 years
HbA1c, median (IQR)	7.2 (1)	7.3 (2)	7.38 (2)
HbA1c ≤ 7%	40.3 (386)	39.7 (104)	37.9 (80)
HbA1c > 7%	59.7 (572)	60.3 (158)	62.1 (131)

^atotal number of valid responses

Table IV. Current diabetes treatment according to HbA1c levels and BMI in patients with T2DM for more than ten years

Tabela IV. Obecne leczenie cukrzycy w zależności od wartości HbA1c i BMI u chorych na cukrzycę typu 2 od ponad 10 lat

Exclusive drug categories n (%)	Overall	HbA1c (n = 1,331)		BMI (n = 1,593)		
	(n = 1,620) ^a	≤ 7.0%	> 7.0%	< 25 (n = 193)	25–30 (n = 639)	> 30 (n = 761)
No antidiabetic drugs	0	0	0	0	0	0
Metformin in monotherapy	6.6 (107)	9.7 (51)	3.0 (24) ^b	8.3 (16)	6.4 (41)	6.2 (47)
Metformin and SU	22.9 (371)	28.2 (148)	15.5 (125) ^b	22.8 (44)	26.8 (171)	20.0 (152) ^c
Metformin and insulin	29.1 (472)	25.6 (134)	35.9 (290) ^b	19.7 (38)	23.5 (150)	36.5 (278) ^b
Metformin and other drug (not SU or insulin)	1.0 (16)	1.0 (5)	0.7 (6)	0	0.8 (5)	1.3 (10)
SU in monotherapy	4.1 (66)	6.1 (32)	1.1 (9) ^b	9.3 (18)	4.2 (27)	2.6 (20) ^b
SU and insulin	1.9 (31)	1.9 (10)	2.0 (16)	1.0 (2)	1.6 (10)	2.1 (16)
SU and other drug (not metformin or insulin)	1.0 (17)	1.1 (6)	0.9 (7)	3.1 (6)	1.1 (7)	0.4 (3) ^d
Insulin in monotherapy	17.5 (283)	16.4 (86)	20.4 (165)	25.9 (50)	18.8 (120)	14.5 (110) ^e
Other drug or drug combinations ^g	15.9 (257)	9.9 (52)	20.4 (165) ^b	9.8 (19)	16.9 (108)	16.4 (125)

Drugs in monotherapy or combined (%) (n)	Overall	HbA1c (n = 1,405)		BMI (n = 1,676)		
	(n = 1,705)	≤ 7.0%	> 7.0%	< 25 (n = 206)	25–30 (n = 672)	> 30 (n = 798)
Metformin	74.2 (1,265)	81.6 (525)	83.3 (334)	59.2 (122)	73.8 (496)	78.6 (627) ^b
SU	42.8 (726)	36.1 (231)	46.6 (183) ^b	44.4 (92)	47.7 (319)	38.1 (302) ^e
Acarbose	11.0 (184)	5.5 (35)	7.0 (27) ^f	10.3 (21)	11.5 (75)	10.5 (82)
Insulin	61.4 (1,046)	11.2 (71)	30.1 (118) ^b	53.4 (110)	57.2 (383)	67.0 (535) ^b
GLP-1 agonist	0.4 (7)	0.2 (1)	0.6 (5)	0	0.3 (2)	0.6 (5)
DPP-4 inhibitor	0.7 (12)	1.9 (12)	2.4 (9)	0.5 (1)	0.9 (6)	0.6 (5)

^atotal number of valid responses; ^bstatistically significant differences between the subgroups, χ^2 , $p = 0.000$; ^c $p = 0.11$; ^d $p = 0.003$; ^e $p = 0.001$; ^f $p = 0.027$;^galso included three or more drug combinations including metformin; GLP-1 — glucagon-like peptide-1; DPP-4 — dipeptidyl peptidase-4; SU — sulfonylurea

Discussion

The ARETAEUS2-Grupa Study provided information on risk factors, presence of diabetes complications and management of patients with T2DM of more than ten years' duration.

The current clinical practice guidelines [7, 8, 11, 12] recommend setting individualised treatment plans and treatment goals for patients with T2DM. We assessed the efficacy of diabetes treatment using the degree to which the criteria of diabetes control recommended by the Diabetes Poland clinical practice guidelines are met [7] in a population of patients with T2DM lasting for

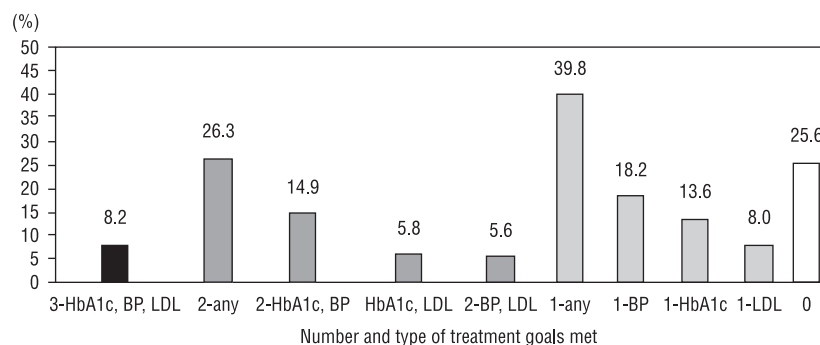
more than ten years, and we observed changes in the pattern of drugs used.

Median HbA1c increased with the duration of the disease and the percentage of patients meeting this goal slightly decreased with longer duration of the disease and compared to T2DM of short duration (40% vs. 62%) [9]. Also, the percentage of patients meeting all treatment goals was slightly lower in this study compared to T2DM of short duration (8% vs. 11%) [9]. The results remain valid as the current 2013 recommendations are consistent with those published in 2012 in terms of treatment goals criteria [8]. On the other hand, current practice guidelines recommend milder criteria (HbA1c

Table V. Meeting treatment goals in patients with T2DM for more than ten years: subgroup analysis by treatment type, %(n); treatment goals: B < 140/90 mm Hg, C < 100 mg/dL or if CHD < 70 mg/dL, A ≤ 7.0%**Tabela V. Spełnianie celów leczenia u chorych na cukrzycę typu 2 od ponad 10 lat: analiza w podgrupach w zależności od rodzaju leczenia, %(n); cele leczenia: B < 140/90 mm Hg; C < 100 mg/dl lub jeśli choroba wieńcowa < 70 mg/dl, A ≤ 7%**

Subgroup	Number of patients in subgroup ^a	Percentage of patients with goals met (A, B, C)			
		3 goals met	Only 2 goals met ^b	Only 1 goal met ^c	0 goals met (all not met)
No antidiabetic drugs	Yes (n = 0)	0	0	0	0
	No (n = 1,101)	8.4 (93)	26.2 (288)	40.0 (440)	25.4 (280)
Metformin in monotherapy ^d	Yes (n = 67)	19.4 (13)	35.8 (24)	34.3 (23)	10.4 (7)
	No (n = 1,034)	7.7 (80)	25.5 (264)	40.3 (417)	26.4 (273)
Metformin and SU ^d	Yes (n = 233)	10.7 (25)	36.1 (84)	34.3 (80)	18.9 (44)
	No (n = 868)	7.8 (68)	23.5 (204)	41.5 (360)	27.2 (236)
Metformin and insulin ^e	Yes (n = 345)	7.2 (25)	20.6 (71)	41.7 (144)	30.4 (105)
	No (n = 756)	9.0 (68)	28.7 (217)	39.2 (296)	23.1 (175)
Metformin and a drug other than SU and insulin	Yes (n = 9)	11.1 (1)	11.1 (1)	33.3 (3)	44.4 (4)
	No (n = 1,092)	8.4 (92)	26.3 (287)	40.0 (437)	25.3 (276)
Insulin in monotherapy	Yes (n = 203)	5.9 (12)	26.1 (53)	44.8 (91)	23.2 (47)
	No (n = 898)	9.0 (81)	26.2 (235)	38.9 (349)	25.9 (233)
Insulin and other drug ^d	Yes (n = 500)	6.4 (32)	18.8 (94)	43.0 (215)	31.8 (159)
	No (n = 601)	10.1 (61)	32.3 (194)	37.4 (225)	20.1 (121)

^aonly the patients for whom data on all treatment goals was available; ^bexcludes patients from the previous column who met all three goals; ^cexcludes patients from the previous columns who met more than one goal; ^dsignificant difference between the groups, $p = 0.000$; ^e $p = 0.007$. A — HbA1c; B — blood pressure; C — LDL-cholesterol; CHD — coronary heart disease; other — see Table I

**Figure 1. Proportions of patients (total population) with T2DM for more than ten years meeting treatment goals according to the Diabetes Poland 2012 guidelines****Rycina 1. Odsetek chorych na cukrzycę typu 2 od ponad 10 lat (cała populacja) spełniających cele leczenia zgodnie z wytycznymi Polskiego Towarzystwa Diabetologicznego z 2012 roku**

≤ 8%) for patients over 70 with long lasting T2DM, with a history of myocardial infarction or stroke [7,8]. In such patients included in our study, the percentage of those meeting the general goal ≤ 7% was similar to the total population; excluding such patients also did not change the results.

Compared to patients with T2DM of short duration [9], those with longer lasting and more advanced disease received oral drugs in monotherapy less frequently (metformin 6.6% vs. 42.3%, sulfonylurea 4.1% vs. 9.4%) and more frequently were treated with

insulin in monotherapy (17.5% vs. 5.8%) or both with metformin and insulin (29.1% vs. 5.7%), and the latter scheme was the most common drug combination used in those patients, particularly in a subgroup with BMI > 30 kg/m² (36.5% vs. 6.3% in patients with T2DM of short duration).

It is interesting to note that after ten years of diabetes duration, 13% of patients were still treated with only one oral antidiabetic drug. This finding is similar to the one in The Polish Diabetes Registry for Adults project [13], where 17.6% of patients were treated with

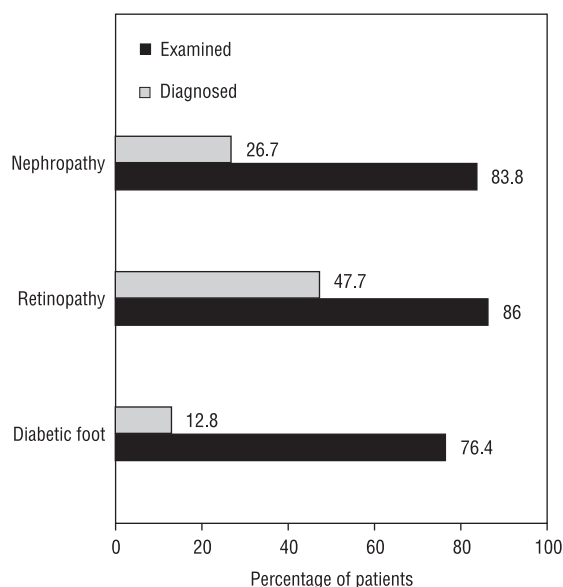


Figure 2. Proportion of patients examined for and diagnosed with diabetic complications

Rycina 2. Odsetek chorych badanych w kierunku powikłań cukrzycy i z rozpoznanymi powikłaniami cukrzycy

a single oral drug (metformin or sulfonylurea), however their diabetes duration was shorter (mean 9.7 years).

This single drug treatment despite ten years of diabetes duration may be explained by meeting the goal because of natural history of the disease, proper dosing of an oral drug or good patient adherence to physician recommendations and not meeting the goal and clinical inertia — failure of healthcare provider to intensify treatment when indicated [14].

In our study, the possible explanation may be meeting the goal with a single oral drug — when each of the diabetes duration categories and drug treatments were split by HbA1c value, it was noted that many patients with a single oral drug had $HbA1c \leq 7\%$. However, the cross sectional nature of the study calls for cautious interpretation of the results.

When analysing meeting treatment goals in subgroups divided by treatment type, we noted significant differences between them. In subgroup of metformin in monotherapy *vs.* other treatments and combinations (also including metformin combined with other drugs) and metformin combined with sulfonylurea *vs.* other treatments or combinations, more patients had three or two treatment goals met and fewer patients did not meet any of the goals. On the other hand, in a subgroup of metformin with insulin *vs.* other treatments and combinations and insulin with other drugs *vs.* other treatments or combinations, more patients had one or none of the goals met and fewer patients had three or two goals met. However this data should be interpreted cautiously due to the cross-sectional nature

of the study — these patients may have begun insulin treatment due to not meeting HbA1c goal.

In our patient population, only mean BP values were below the threshold recommended in the Diabetes Poland guidelines ($< 140/90$ mm Hg), while median HbA1c value and mean values of total cholesterol and LDL-cholesterol were above recommended thresholds ($HbA1c \leq 7\%$, and for total cholesterol < 175 mg/dL for LDL cholesterol < 100 mg/dL or < 70 mg/dL in patients with CHD). In patients with T2DM of short duration, not only mean BP but also the median values of HbA1c were below the general thresholds recommended in the guidelines [9].

Several epidemiological studies have documented the treatment and control of type 2 diabetes in Poland [2–4, 13, 15–19], but none of them has specifically addressed patients with T2DM of more than ten years' duration. Only two of those previous studies provided some data on diabetes control by the duration of the disease which enables comparisons with the current study. The OPTIMO study showed that 37% of patients with diabetes lasting for more than ten years had $HbA1c \leq 7\%$, which is similar to the percentage reported in the current study (40%) [4] and the DINAMIC study [17, 18].

Studies conducted in other countries also showed that most diabetic patients do not meet their HbA1c, BP and lipid treatment goals [20–26]. The most recent survey in U.S. patients [26] showed improvements in diabetes control over 12 years, but only 14% of patients met all their treatment goals ($HbA1c \leq 7\%$ and individualised goals, BP $< 130/80$ mm Hg and LDL-cholesterol < 100 mg/dL and < 70 mg/dL in those with CHD) and achieved non-smoking status, which is slightly better than in our study (8%). Over 70% of U.S. patients had annual eye and foot examinations, while in our study the percentages were higher. However the U.S. survey's population included all diabetics independent of disease duration, with only 34% of patients with T2DM lasting for five to 15 years.

Diabetes Poland guidelines recommend regularly examining patients with T2DM for late diabetes complications since diagnosis (every year for nephropathy and retinopathy). However, as we observed in our study — during ten or more years since T2DM diagnosis, 17% of patients were not examined for nephropathy, 14% were not examined for retinopathy and 24% were not examined for diabetic foot, which must be worrying. One possible explanation for this situation could be restricted access to recommended examinations — a recent study has shown that specialised care provided by diabetes outpatient clinics in Poland is not used by more than half of the people suffering from diabetes (60.3%), which may be caused by limited access to those services [27]. Another explanation could be poor

communication between different diabetes healthcare providers, mainly primary care and diabetes specialists, or not adhering to the practice guidelines. This can also be attributed to clinical inertia, the previously explained failure of the healthcare provider to intensify treatment when indicated. Clinical inertia is ascribed mainly to three factors: overestimation of care provided (i.e. physicians tend to overestimate the frequency of practices such as foot examinations, dilated-eye examinations, haemoglobin A1c measurement, and urine protein screening compared to analyses of large claims databases [14, 28]); the use of 'soft' reasons to avoid intensification of therapy (i.e. lack of time at office visits, previous patient nonadherence [14, 29]); and lack of education, tools, training to support active care for people with chronic diseases [14, 29].

However, due to the cross-sectional nature of our study, we are unable to recognise the reason for this situation.

There are some limitations of our study. First is the cross-sectional design of the study, which does not provide us with long-term data. Since the study included patients with different diabetes durations, the median or mean values of the parameters may not be informative due to recommended individualisation of the therapy. To provide more information, we also analysed treatment goals by T2DM duration. In addition, to ensure the representative nature of our study population and to adequately reflect an average T2DM patient, we randomly selected physicians participating in our study separately for diabetologists and non-diabetologists (stratified by size of the place of residence) and we introduced patient selection on a pseudo-random basis.

The study lacked the verification of data collected from the physicians, which is also a limitation. Since the reliability of the data was dependent on the physicians, this may be associated with bias toward better results, although in fact the degree of diabetes control might even be less satisfactory than shown in the current study.

The number of patients for whom HbA1c values were available, although higher than in patients with T2DM of short duration [9], is also a limitation of our study. Eighty two percent of patients had HbA1c values recorded, with only 44% having HbA1c measured one to six months before the study. Many physicians do not follow recommended HbA1c measurement frequency and many patients do not know how important this marker of diabetes control is [13]. These facts may affect the reliability of the assessment of diabetes care quality in Poland.

We can only speculate why the control of diabetes is so suboptimal. It could be explained by poor access to education, low number of nurses or diabetes educators,

restricted access to recommended examinations, diabetes specialists or drugs (due to lack of reimbursement of new drugs, such as incretins), poor communication between different diabetes healthcare providers, and/or lack of understanding of the nature of disease by both physicians and patients. Moreover, suboptimal cooperation of specialists from many fields of medicine in the management of this complex disease makes treating it very demanding.

Conclusions

We have observed considerable deviations from treatment targets recommended by current clinical practice guidelines and poorer disease control in patients with T2DM of more than ten years' duration compared to those with T2DM of short duration. The frequency of cardiovascular risk factors and late diabetes complications was high, while there was a relatively high percentage of patients who were never examined for late diabetes complications. A large body of evidence exists that supports a variety of interventions to improve diabetes outcomes, and patients may need to have better access to care where many issues, beyond glycaemic control, could be addressed.

Contributors

All of the authors contributed to the study concept, design, and implementation, and to the content and development of this report.

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Appendix Table I. Time of last HbA1c measurement and diabetes duration (n = 1,528)

Dodatek. Tabela I. Ostatni wynik HbA1c a czas trwania cukrzycy (n = 1528)

Last HbA1c measurement before the study	% (n)	Median diabetes duration, months (IQR)
< week	9.0 (137)	171 (77)
< 1 month	8.8 (135)	148 (74)
1–3 months	23.0 (352)	156 (65)
4–6 months	20.7 (317)	157 (67)
7–12 months	18.8 (287)	157 (63)
> 12 months	11.1 (169)	160 (64)
Not known	8.6 (131)	156 (55)

Appendix Table II. Current diabetes treatment according to diabetes duration in patients with T2DM for more than ten years
Dodatek. Tabela II. Obecne leczenie cukrzycy w zależności od czasu trwania choroby u chorych na cukrzycę typu 2 od ponad 10 lat

Exclusive drug categories (%) (n); n = 1,620^a			
	10–15 years (n = 1,108)	> 15–20 years (n = 287)	> 20 years (n = 225)
No antidiabetic drugs	0	0	0
Metformin in monotherapy ^b	8.3 (92)	3.8 (11)	1.8 (4)
Metformin and SU ^b	26.1 (289)	22.6 (65)	7.6 (17)
Metformin and insulin	27.9 (309)	32.4 (93)	31.3 (70)
Metformin and other drug (not SU or insulin)	1.3 (14)	0.3 (1)	0.4 (1)
SU in monotherapy	4.7 (52)	2.4 (7)	3.1 (7)
SU and insulin	1.4 (16)	3.1 (9)	2.7 (6)
SU and other drug (not metformin or insulin)	0.9 (10)	1.4 (4)	1.3 (3)
Insulin in monotherapy ^b	13.3 (147)	19.2 (55)	36.0 (81)
Other drug or drug combinations	16.2 (179)	14.6 (42)	16.0 (36)
Drugs in monotherapy or combined (%) (n)			
	10–15 years (n = 1,166)	> 15–20 years (n = 302)	> 20 years (n = 237)
Metformin ^b	78.8 (919)	72.2 (218)	54.0 (128)
SU ^b	47.3 (549)	40.7 (122)	23.4 (55)
Acarbose	10.5 (120)	11.1 (33)	13.3 (31)
Insulin ^b	55.9 (651)	65.1 (196)	83.6 (199)
GLP-1 agonist	0.6 (7)	0	0
DPP-4 inhibitor	0.7 (8)	0.7 (2)	0.9 (2)

^atotal number of valid questionnaires; ^bstatistically significant differences between the subgroups, $p = 0.000$

Appendix Table III. Current diabetes treatment according to diabetes duration and HbA1c in patients with T2DM for more than ten years (n = 1,331)

Dodatek. Tabela III. Obecne leczenie cukrzycy w zależności od czasu trwania choroby i wartości HbA1c u chorych na cukrzycę typu 2 od ponad 10 lat

Exclusive drug categories (%) (n)						
	10–15 years (n = 890)		> 15–20 years (n = 245)		> 20 years (n = 196)	
	HbA1c ≤ 7.0% (n = 356)	HbA1c > 7.0% (n = 534)	HbA1c ≤ 7.0% (n = 97)	HbA1c > 7.0% (n = 148)	HbA1c ≤ 7.0% (n = 71)	HbA1c > 7.0% (n = 125)
No antidiabetic drugs	0	0	0	0	0	0
Metformin in monotherapy	11.5 (41)	4.3 (23) ^a	7.2 (7)	0 ^a	4.2 (3)	0.8 (1) ^a
Metformin and SU	31.5 (112) ^b	17.2 (92) ^c	27.8 (27) ^b	19.6 (29) ^c	12.7 (9) ^b	3.2 (4) ^c
Metformin and insulin	21.9 (78) ^d	37.3 (199)	32.0 (31)	35.1 (52)	35.2 (25)	31.2 (39)
Metformin and other drug (not SU or insulin)	1.1 (4)	1.1 (6)	1.0 (1)	0	0	0
SU in monotherapy	7.9 (28) ^e	0.9 (5)	2.1 (2)	1.4 (2)	2.8 (2)	1.6 (2)
SU and insulin	1.7 (6)	1.3 (7)	3.1 (3)	3.4 (5)	1.4 (1)	3.2 (4)
SU and other drug (not metformin or insulin)	0.8 (3) ^f	0.9 (5)	0 ^f	1.4 (2)	4.2 (3) ^f	0
Insulin in monotherapy ^b	13.8 (49) ^g	14.6 (78) ^c	16.5 (16) ^g	23.0 (34) ^c	29.6 (21) ^g	42.4 (53) ^c
Other drug or drug combinations	9.8 (35)	22.3 (119)	10.3 (10)	16.2 (24)	9.9 (7)	17.6 (22)
Drugs in monotherapy or combined (%) (n); n = 1405						
	10–15 years (n = 939)		> 15–20 years (n = 259)		> 20 years (n = 207)	
	HbA1c ≤ 7.0% (n = 379)	HbA1c > 7.0% (n = 560)	HbA1c ≤ 7.0% (n = 103)	HbA1c > 7.0% (n = 156)	HbA1c ≤ 7.0% (n = 78)	HbA1c > 7.0% (n = 129)
Metformin	76.0 (288) ^e	81.1 (454) ^c	75.7 (78) ^e	69.9 (109) ^c	62.8 (49) ^e	50.4 (65) ^c
SU	50.9 (191) ^h	39.4 (218) ^c	41.2 (42) ^h	36.8 (57) ^c	28.2 (22) ^h	16.5 (21) ^c
Acarbose	8.2 (30)	12.4 (68)	8.0 (8)	11.8 (18)	11.7 (9)	14.3 (18)
Insulin	45.2 (168) ^c	71.8 (405) ^c	58.8 (60) ^c	73.7 (115) ^c	75.3 (58)	91.6 (120) ^c
GLP-1 agonist	0.3 (1)	0.9 (5)	0	0	0	0
DPP-4 inhibitor	0.3 (1)	1.3 (7)	0	1.3 (2)	0	0.8 (1)

^astatistically significant differences between the age subgroups within HbA1c category, $p = 0.007$; ^b $p = 0.006$; ^c $p = 0.000$; ^d $p = 0.018$; ^e $p = 0.049$; ^f $p = 0.025$; ^g $p = 0.005$; ^h $p = 0.001$

Appendix Table IV. Meeting treatment goals in patients with T2DM for more than ten years: subgroup analysis by patient characteristics, %(n); treatment goals: B < 140/90 mm Hg, C < 100 mg/dL or if CHD < 70 mg/dL, A ≤ 7.0% (total = 1,190)^a

Dodatek. Tabela IV. Spełnianie celów leczenia u chorych na cukrzycę typu 2 od ponad 10 lat: analiza w podgrupach w zależności od charakterystyki chorych, %(n); cele leczenia: B < 140/90 mm Hg; C < 100 mg/dl lub jeśli choroba wieńcowa < 70 mg/dl, A ≤ 7% (łącznie = 1190)

Subgroup	Number of patients in the group A	Percentage of patients with goals met									
		3 goals met	Only 2 goals met (excludes patients from the previous column who met all 3 goals)			Only 1 goal met (excludes patients from the previous columns who met more than 1 goal)			0 goals met		
		A, B, C	any two	B and C	A and C	A and B	anyone	B	C	A	A, B, C, all not met
Male											
Age	< 40 yrs (n = 2)	50.0 (1)	50.0 (1)	50.0 (1)	0	0	0	0	0	0	0
	≥ 40 yrs (n = 538)	7.8 (42)	26.2 (141)	6.7 (36)	4.5 (24)	15.1 (81)	40.3 (217)	17.8 (96)	7.6 (41)	14.9 (80)	25.7 (138)
BMI ^b	< 25 (n = 65)	13.8 (9)	32.3 (21)	9.2 (6)	1.5 (1)	21.5 (14)	38.5 (25)	23.1 (15)	4.6 (3)	10.8 (7)	15.4 (10)
	25–30 (n = 237)	8.9 (21)	28.7 (68)	6.3 (15)	5.9 (14)	16.5 (39)	40.1(95)	21.1 (50)	5.5 (13)	13.5 (32)	22.4 (53)
	> 30 (n = 242)	5.4 (13)	20.7 (50)	5.8 (14)	3.7 (9)	11.2 (27)	41.3 (100)	13.6 (33)	10.3 (25)	17.4 (42)	32.6 (79)
Female											
Age	< 40 yrs (n = 7)	28.6 (2)	0	0	0	0	71.4 (5)	28.6 (2)	14.3 (1)	28.6 (2)	0
	> 40 yrs (n = 589)	8.8 (52)	27.0 (159)	4.6 (27)	6.8 (40)	15.6 (92)	38.7 (228)	18.7 (110)	7.6 (45)	12.4 (73)	25.5 (150)
BMI ^c	< 25 (n = 77)	16.9 (13)	40.0 (30)	7.8 (6)	3.9 (3)	27.3 (21)	31.2 (24)	19.5 (15)	3.9 (3)	7.8 (6)	13.0 (10)
	25–30 (n = 206)	8.7 (18)	24.8 (51)	2.9 (6)	6.8 (14)	15.0 (31)	44.2 (91)	19.4 (40)	9.2 (19)	15.5 (32)	22.3 (46)
	> 30 (n = 307)	7.5 (23)	24.8 (76)	4.9 (15)	6.8 (21)	13.0 (40)	37.8 (116)	18.2 (56)	7.8 (24)	11.7 (36)	30.0 (92)

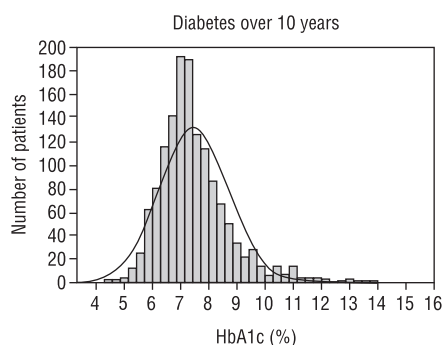
^aonly the patients for whom data on all treatment goals was available; ^bsignificant difference between the groups, p = 0.003; ^cp = 0.005; differences in any and specific percentages are the result of rounding up. A — HbA1c; B — blood pressure; C — LDL-cholesterol; CHD — coronary heart disease; other — see Table I

Appendix Table V. Meeting treatment goals in patients with T2DM for more than ten years: subgroup analysis by HbA1c goal and diabetes duration, %(n); treatment goals: B < 140/90 mm Hg, C < 100 mg/dL or if CHD < 70 mg/dL, A ≤ 7.0%

Dodatek. Tabela V. Spełnianie celów leczenia u chorych na cukrzycę typu 2 od ponad 10 lat: analiza w podgrupach w zależności od celu HbA1c i czasu trwania cukrzycy, %(n); cele leczenia: B < 140/90 mm Hg; C < 100 mg/dl lub jeśli choroba wieńcowa < 70 mg/dl, A ≤ 7%

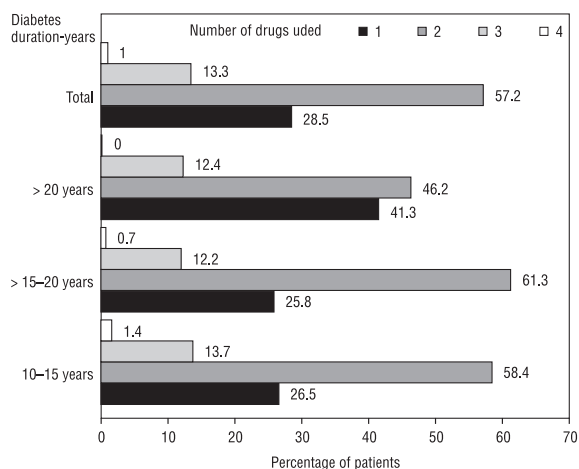
Subgroup	Number of patients ^a	3 goals met	Only 2 goals met ^b	Only 1 goal met ^c	0 goals met
A ≤ 7%	506	19.4 (98)	48.6 (246)	32.0 (162)	0
A > 7%	684	0	9.8 (67)	45.6 (312)	44.6 (305)
Diabetes 10–15 years	804	7.8 (63)	26.5 (213)	38.8 (312)	26.9 (216)
Diabetes 16–20 years	210	9.5 (20)	24.8 (52)	41.4 (87)	24.3 (51)
Diabetes > 20 years	176	8.5 (15)	27.3 (48)	42.6 (75)	21.6 (38)

^aonly the patients for whom data on all treatment goals was available; ^bexcludes patients from the previous column who met all three goals; ^cexcludes patients from the previous columns who met more than one goal. A — HbA1c; B — blood pressure; C — LDL-cholesterol; CHD — coronary heart disease; other — see Table I



Appendix Figure 1. Distribution of HbA1c values in patients with T2DM for more than ten years

Dodatek. Rycina 1. Rozkład wartości HbA1c u chorych na cukrzycę typu 2 od ponad 10 lat



Appendix Figure 2. Number of antidiabetic drugs used by patients with T2DM for more than ten years by the duration of the disease

Dodatek do ryciny 2. Liczba leków przeciwcukrzycowych stosowanych przez chorych na cukrzycę typu 2 od ponad 10 lat w zależności od czasu trwania choroby