ORIGINAL ARTICLE

Specialty outpatient care of diabetic patients in Poland – are we far from treatment targets?

Rationale, design, and preliminary results of the OPTIMO study

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ABSTRACT

INTRODUCTION While clinical practice guidelines reflect the best known evidence-based approach to patient care, it is individual clinicians and patients who make decisions and treatment choices, and individual patients who actually achieve (or not) the treatment goals.

OBJECTIVES The aim of the study was to describe the population of diabetic patients attending specialty outpatient clinics, to characterize the management of patients with different types of diabetes, and to assess the accordance of management with the recommendations developed by Diabetes Poland.

PATIENTS AND METHODS The OPTIMO observational study was conducted from 2006 to 2009 and included patients with diabetes diagnosed according to the 1999 World Health Organization criteria who were observed for 1 to 3 years, with control visits at least every 6 months. Participating physicians used pocket PCs equipped with specially developed software to collect patients' data and to provide educational reminders to clinicians.

RESULTS The final analysis involved 9600 patients for whom valid baseline questionnaires were available. Type 2 diabetes was observed in 92% and type 1 diabetes in 6% of the patients. Mean age was 60.5 years. Women constituted 54% of the population. Coronary heart disease was observed in 32% and arterial hypertension in 76% of the patients. At baseline, 23% of the patients had hemoglobin A_{1c} level below 6.5% and 44% below 7.0. Total cholesterol and triglycerides treatment goals were met at baseline by slightly more than half of the patients, while low-density lipoprotein cholesterol treatment goal was met only by 33% of the patients. Baseline blood pressure below 130/80 mmHg was reported for 11% of the patients.

CONCLUSIONS At the beginning of the OPTIMO study, we have observed considerable deviations from treatment targets recommended by current clinical practice guidelines for diabetic patients, which leaves significant room for improvement in the care of diabetic patients.

INTRODUCTION In recent years, we have witnessed changes in glycemic goals in international and national diabetes guidelines,[1-4] reflecting new data from randomized controlled trials.[5,6] hemoglobin A_{1c} (HbA_{1c}) goals may be now less stringent for patients with limited life expectancy, history of severe hypoglycemia, advanced microvascular or macrovascular complications, and those with extensive comorbid conditions. While guidelines reflect the best known evidence-based approach

to patient care, it is individual patients and clinicians who make decisions and treatment choices, and individual patients who actually achieve (or not) the treatment goals. Although patients' age, diabetes duration, comorbidities, and lifestyle[7] have all been linked to the level of glycemic control, much less is known of the key factors involved in the process of translation of guideline recommendations to actual patient care. While practitioners generally follow the guidelines, they may have their own preferences or limitations in their full implementation. The aim of the OPTIMO study was to prospectively observe a large population of diabetic patients in Poland and to assess whether providing additional medical information to practitioners improves compliance with the guidelines as measured by glucose, lipid, and hypertension control in diabetic patients. In this paper, we present the baseline characteristics of the study population.

The OPTIMO study consisted of 3 elements:

1 observational study aimed to collect data on the characteristics of diabetic patients treated in diabetes clinics across Poland, based on an electronic questionnaire for physicians

2 clinical decision support system (CDSS) provided to randomly selected physicians participating in the project, integrated with the electronic questionnaire

3 educational program tailored to the needs of specialists; the program was regularly updated and evaluated with a short multiple-choice test.

The aims of the entire project were as follows:

1 to characterize diabetic patient population treated in diabetes clinics in Poland

2 to describe selected methods of treatment and care of diabetes and to assess their accordance with clinical practice guidelines developed by Diabetes Poland[1]

3 to implement CDSS in the care of diabetic patients and assess suitability of different CDSS versions using randomized approach

4 to introduce educational program tailored to the needs of specialists in diabetology

5 to improve information technology system aimed to improve the quality of specialist care on the basis of the collected data and physician's opinion.

PATIENTS AND METHODS

This is the first article in the series of planned publications presenting the results of the OPTIMO study. It describes the methodology of the OPTIMO observational study and the baseline characteristics of the included patients. Data collection was scheduled to take 3 years.

The aims of the paper

This article provides data on the study protocol, the baseline characteristics of the patients and participating physicians, as well as on the baseline management of patients with different types of diabetes. It also shows to what extent management of diabetes follows the recommendations developed by Diabetes Poland.

Inclusion criteria

We included patients with diabetes diagnosed according to the 1999 World Health Organization criteria, for whom it was possible to continue a follow-up study for 1 to 3 years, with control visits at least every 6 months.

Recruitment of clinicians and their patients

Physicians working in diabetes clinics were invited to participate in the study by the study sponsor. They were shown how to use data collection system and were equipped with pocket PCs (Dell Axim X30, Dell, Poland). This device was preloaded with software developed for the purposes of this study, including electronic questionnaire automatically saving patient information. In order to become a study investigator, each physician had to include at least 10 patients during months 0–6 of the study, which began in 2006, and continue their observation for 3 years or till the end of the study. Patients fulfilling the inclusion criteria were recruited in pseudorandom manner, i.e., the last 2 patients registered for the day were to be included. Patients with newly diagnosed diabetes were not eligible to enter the study according to the protocol. Patients included in the study were to attend follow-up visits at least every 6 months. All of the physicians regularly received educational content in the form of a short multimedia presentation for pocket PCs, and they were randomly assigned to receive (or not to receive) additional information appearing during visits while entering new data. Those short messages were designed to increase practitioners' awareness of certain guideline recommendations, relevant to individual patients.

At baseline, the questionnaire included questions concerning physicians (specialization and years since graduation) and patients (age, sex, height, place of residence, diabetes diagnosis [diabetes type], time from diagnosis, time from insulin initiation in those receiving insulin, participation in training for patients with diabetes, presence of diabetic complications [nephropathy, neuropathy, diabetic foot, coronary heart disease [CHD], hypertension, and stroke according to the report of an investigating physician], and smoking history). At each visit, the questionnaire contained the following items: weight, blood pressure (BP), the result of foot examination, information on newly diagnosed diabetic complications (hypertension, nephropathy, retinopathy, neuropathy, CHD, and stroke), current smoking status, information on diabetes control (current HbA_{1c}, hospitalizations due to diabetes or severe episodes of hypoglycemia), information on current treatment (diabetic drugs, antihypertensive drugs, antiplatelet drugs, and lipid lowering drugs). Periodically (as reminders were sent), the questionnaire included additional items: lipid profile, testing for diabetic nephropathy, retinopathy, testing for diabetic foot (at each visit), and information

TABLE 1 Specialties of physicians participating in the OPTIMO study (n = 369)

Specialty	% (n)
during training	10.0 (37)
internal medicine 1st degree	32.2 (119)
internal medicine 2nd degree	45.5 (168)
diabetology	21.1 (78)
endocrinology	5.4 (20)
family medicine	20.3 (75)
other	6.0 (22)

Percentages do not add to 100 because physicians could have more than 1 specialty.

TABLE 2 Time since graduation of physicians participating in the OPTIMO study (n = 366)

Time	% (n)
1–5 years	2.2 (8)
6–10 years	16.1 (59)
11–20 years	50.5 (185)
>20 years	31.1 (114)

on the follow-up of patients who completed their participation in the program.

Data entered by physicians were saved on the memory cards, which were subsequently transferred to the study data coordinating center and immediately returned with a new educational content added. Data were saved and kept in a way preventing identification of patients – only the patient's code was entered and the data from data memory card could have been read only with individual Pocket PC of the physician who took care of the patient, or in the study data coordinating center.

Statistical analysis Results are presented as mean with standard deviation (SD) or medians with interquartile range (numerical variables) or as percentage (categorical variables).

The distribution was estimated on the basis of skewness coefficient, graphical picture and the Shapiro-Wilk test. All statistical analyses were conducted using SPSS v. 17.0.

RESULTS The study involved 369 physicians. Most of them were specialized in internal medicine; 20% in diabetology (TABLE 1).

Most physicians graduated 11 to 20 years before the study onset (TABLE 2).

Median number of patients per physician was 27 (mean 26) and median number of visits per physician was 50 (mean 76). Median number of visits per patient for each physician was 1.9 (mean 2.7).

Altogether, we received 9600 valid baseline questionnaires. The majority of patients participating in the study had type 2 diabetes (over 8500), but the group of patients with type 1 diabetes was also large (over 500 patients). Only 4 patients had gestational diabetes and 5 patients were diagnosed with maturity onset diabetes of the young (MODY). Latent autoimmune diabetes in adults (LADA diabetes) was diagnosed in 80 patients and secondary diabetes due to pancreatic disorders in 94 patients. Most patients with all types of diabetes were treated by physicians specialized in internal medicine or diabetology (TABLE 3).

In overall population, the mean age of patients was 60.5 years and 54% were women. Reported lipid levels were above the values recommended in practice guidelines for diabetic patients (TABLE 4). Median HbA_{1c} was also above the level recommended in the guidelines (7.1%). Over 31% of the patients had CHD and over 76% had hypertension. Patient characteristics are presented in TABLE 4.

The frequency of diabetic complications (on the basis of medical history) in the total population is shown in FIGURE 1; the frequency depending on duration of the disease and the type of diabetes is described in TABLE 5 and TABLE 6, respectively. The most common complication was retinopathy, followed by neuropathy. More than 20% of the patients were not examined for diabetic nephropathy, neuropathy, and retinopathy and only 5% were not examined for diabetic foot. In the analysis of meeting diabetes treatment goals in the total

TABLE 3 Type of diabetes and physician specialty (total number of patients = 9600)

Specialty	Type 1 diabetes (n = 575)	Type 2 diabetes (n = 8842)	Gestational diabetes (n = 4)	LADA (n = 80)	MODY (n = 5)	Secondary diabetes (n = 94)
during training, % (n)	5 (29)	10.1 (894)	0	7.5 (6)	0	9.6 (9)
internal medicine 1st degree, % (n)	27.8 (160)	33.5 (2959)	50 (2)	31.3 (25)	20 (1)	28.7 (27)
internal medicine 2nd degree, % (n)	56.5 (325)	44.6 (3943)	50 (2)	47.5 (38)	40 (2)	50 (47)
diabetology, % (n)	40.3 (232)	21.6 (1914)	25 (1)	30 (24)	40 (2)	26.6 (25)
endocrinology, % (n)	9.2 (53)	5.2 (458)	0	10 (8)	20 (1)	9.6 (9)
family medicine, % (n)	10.3 (59)	21.4 (1891)	25 (1)	13.8 (11)	20 (1)	19.1 (18)
other, % (n)	2.3 (13)	6.2 (547)	0	5 (4)	20 (1)	0

Abbreviations: LADA – latent autoimmune diabetes in adults, MODY – maturity onset diabetes of the young

TABLE 4 Selected baseline characteristics of patients in the OPTIMO study (n = 9600)

age, mean (SD), y			60.5 (12.15)
women, % (n)			53.9 (5175)
type of diabetes, % (n)	type 1diabetes		6.0 (575)
	type 2 diabetes		92.1 (8842)
	gestational diabetes		<1 (4)
	LADA		0.8 (80)
	MODY		<1 (5)
	secondary diabetes		1.0 (94)
time from diagnosis, % (n)	<1 year		12.8 (1232)
	1–2 years		16.7 (1607)
	3–5 years		20.0 (1923)
	6–10 years		26.2 (2519)
	11–20 years		19.7 (1895)
	>20 years		4.4 (424)
time from initiation of insulin in patients taking insulin, mean (SD), y			5.16 (5.7)
BP, mean (SD), mmHg			136 (17)/82 (9)
TC, median (IQR), mmol/l			5.4 (1.3)
LDL cholesterol, median (IQR), mmol/l			3.5 (1.2)
HDL cholesterol, median (IQR), mmol/l			1.1 (0.4)
TG, median (IQR), mmol/l			1.7 (0.8)
HbA_{1c}, median (IQR), %			7.1 (2)
education, % (n)	primary school not completed		2.3 (219)
	primary school		29.1 (2792)
	secondary school		43.6 (4185)
	higher		12.7 (1215)
	vocational		12.4 (1189)
place of residence, % (n)	town	>500,000	14.6 (1406)
		100,000–500,000	24.2 (2321)
		20,000–100,000	23.2 (2227)
		<20,000	14.3 (1369)
	village		23.7 (2277)
smoking status, % (n)	current		13.1 (1261)
	former		24.2 (2325)
	nonsmoking		62.6 (6014)
cardiovascular complications, % (n)	CHD without PTCA, CABG, and MI		21.5 (2064)
	previous CABG		2.0 (189)
	previous PTCA		3.4 (328)
	history of MI		7.9 (758)
	CHD		31.6 (3032)
	history of stroke		5.3 (511)
	hypertension		76.3 (7324)

Abbreviations: BP – blood pressure, CABG – coronary artery bypass grafting, CHD – coronary heart disease, HbA_{1c} – hemoglobin A_{1c}, HDL – high-density lipoprotein, IQR – interquartile range, LDL – low-density lipoprotein, MI – myocardial infarction, PTCA – percutaneous transluminal coronary angioplasty, SD – standard deviation, TC – total cholesterol, TG – triglycerides, others – see **TABLE 3**

population, we observed that only 23% of the patients had HbA_{1c} levels below 6.5% recommended in practice guidelines (**FIGURE 2**). When less strict goal was applied (≤7.0%), the number increased to 44%. Total cholesterol and triglyceride treatment goals (<4.5 mmol/l and <1.7 mmol/l, respectively) were met by slightly more than 50% of the patients, while low-density lipoprotein (LDL) treatment goal (<2.6 mmol/l or <1.8 mmol/l in CHD) was met only by 33% of the patients. BP below 130/80 mmHg was reported for as few as 11% of the patients. When we applied a less strict BP goal (<140/90 mmHg) the number increased to 53%. **TABLE 7** and **TABLE 8** present the proportion of patients who met treatment goals in the subgroups of patients by duration of the disease and by the type of diabetes.

The analysis of diabetic treatment and cardiovascular risk factors is currently unavailable.

DISCUSSION The prevalence of type 2 diabetes is increasing at an alarming rate, and the incidence of diabetes in Poland is comparable to the average values observed worldwide.[8] Despite the progress in treatment options and availability of glucose monitoring devices, the disease control remains a challenge. Median HbA_{1c} for the whole group of 9600 diabetic patients was 7.1% (interquartile range 2), and it was nearly the same as in the smaller study assessing the implementation of Diabetes Poland recommendations in patients treated in similar outpatient setting, but in 1 center only, in 2007.[9] Mean BP values (136/82 mmHg vs. 136/79 mmHg) were also quite similar, but LDL cholesterol levels were not (130.5 vs. 105.5 mg/dl). In "The Improvement of Glycemic Control" program, diabetic patients referred to specialists by general practitioners had even higher HbA_{1c} (mean 8.8%; <7% in only 18.5% of the patients) and BP (mean 140/83 mmHg), and worse lipid profile despite the same percentage of patients achieving LDL cholesterol target.[10] In the DINAMIC2 program, mean HbA_{1c} levels were slightly higher than in the present study (7.37% vs. 7.1%) and there was lower percentage of patients meeting BP goal <130/80 mmHg (5.16% vs. 10.7%).[11] Other studies in the Polish population also showed that the HbA_{1c} target values are consistently achieved only by a minority of patients,[10-15] and there are similar findings in other countries.[16,17] Current standards of care indicate the need for regular tests to diagnose and observe diabetic complications. The study revealed that more than 20% of the patients had not been examined previously for diabetic microvascular complications, including diabetic nephropathy, neuropathy, and retinopathy. There is an evident gap between the treatment goals described in the recommendations of care and the actual health care achievements, and it seems important to find new ways of translating diabetes guidelines into practice. Before we learn how to do it, we should understand the real problems of reaching and maintaining optimal control of diabetes. The initial results of the OPTIMO study presented here addressed these problems in the setting of Polish diabetes clinics, giving baseline characteristics of 9600 patients and 369 participating physicians. Considerable deviations from treatment targets that are recommended by current

TABLE 5 Diabetic complications at baseline and duration of the disease in patients participating in the OPTIMO study (n = 9600)

	<1 year (n = 1232)	1–2 years (n = 1607)	3–5 years (n = 1923)	6–10 years (n = 2519)	11–20 years (n = 1895)	>20 years (n = 424)
nephropathy, % (n)						
diagnosed	1.7 (21)	3.1 (50)	4.1 (78)	7.6 (192)	12.3 (234)	22.2 (94)
not examined	39.5 (487)	23.8 (383)	20.9 (402)	18.7 (471)	18.5 (350)	13.0 (55)
neuropathy, % (n)						
diagnosed	2.7 (33)	5.1 (82)	7.2 (138)	12.2 (307)	20.2 (383)	38 (161)
not examined	37.8 (466)	23 (369)	22 (423)	18.7 (470)	17.7 (335)	13.2 (56)
retinopathy, % (n)						
diagnosed	4.0 (49)	6.1 (98)	11 (211)	17 (427)	30.1 (570)	52.8 (224)
not examined	45.5 (561)	24.2 (389)	20.9 (401)	17.3 (436)	15.1 (286)	9.9 (42)
diabetic foot, % (n)						
diagnosed	0.7 (9)	1.4 (22)	1.7 (3)	1.6 (40)	4.6 (87)	7.1 (30)
not examined	11.1 (137)	4.6 (74)	4.3 (83)	3.3 (83)	4.2 (80)	3.8 (16)

TABLE 6 Diabetic complications at baseline and type of diabetes in patients participating in the OPTIMO study (n = 9600)

	Diabetes type 1 (n = 575)	Diabetes type 2 (n = 8842)	Gestational diabetes (n = 4)	LADA (n = 80)	MODY (n = 5)	Secondary diabetes (n = 94)
nephropathy, % (n)						
diagnosed	9.4 (54)	6.8 (597)	0	11.3 (9)	20.0 (1)	8.5 (8)
not examined	9.9 (57)	23.3 (2056)	25.0 (1)	17.5 (14)	40 (2)	19.1 (18)
neuropathy, % (n)						
diagnosed	17.2 (99)	10.9 (966)	0	22.5 (18)	40.0 (2)	20.2 (19)
not examined	8.3 (48)	23.0 (2035)	25.0 (1)	17.5 (14)	0	22.3 (21)
retinopathy, % (n)						
diagnosed	25.2 (145)	15.8 (1399)	0	20.0 (16)	20.0 (1)	19.1 (18)
not examined	7.5 (43)	23.0 (2035)	25.0 (1)	13.8 (11)	40.0 (2)	24.5 (23)
diabetic foot, % (n)						
diagnosed	3.8 (22)	2.2 (197)	0	0	0	2.1 (2)
not examined	3.1 (18)	5.1 (447)	25.0 (1)	1.3 (1)	0	4.4 (6)

Abbreviations: see **TABLE 3**

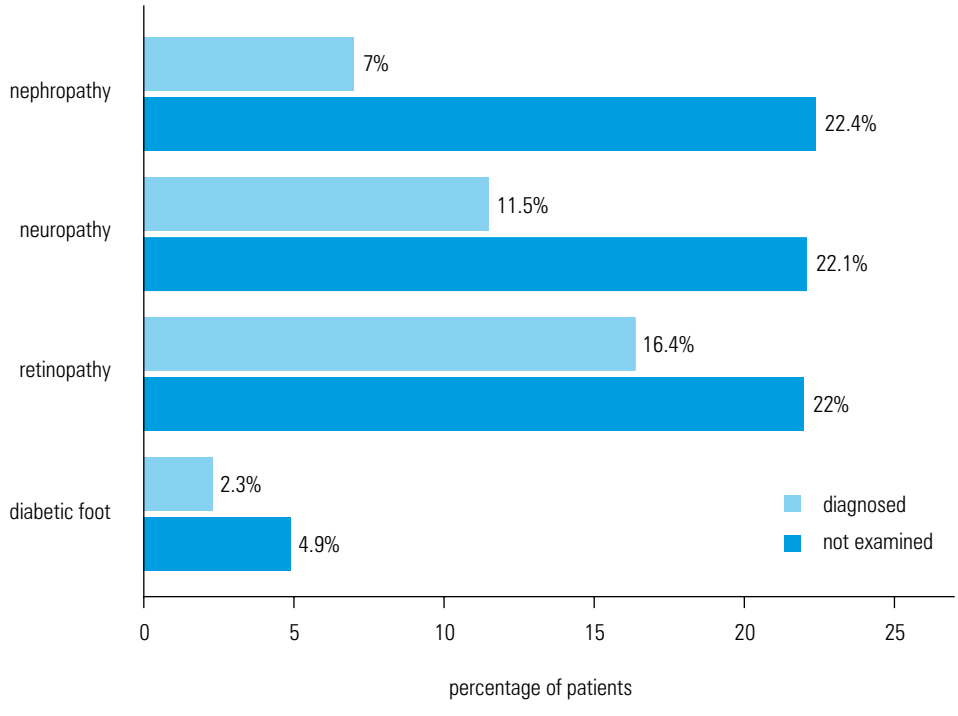

FIGURE 1 Percentage of patients in the OPTIMO study in whom complications were diagnosed and in whom complications were not examined (on the basis of medical history)

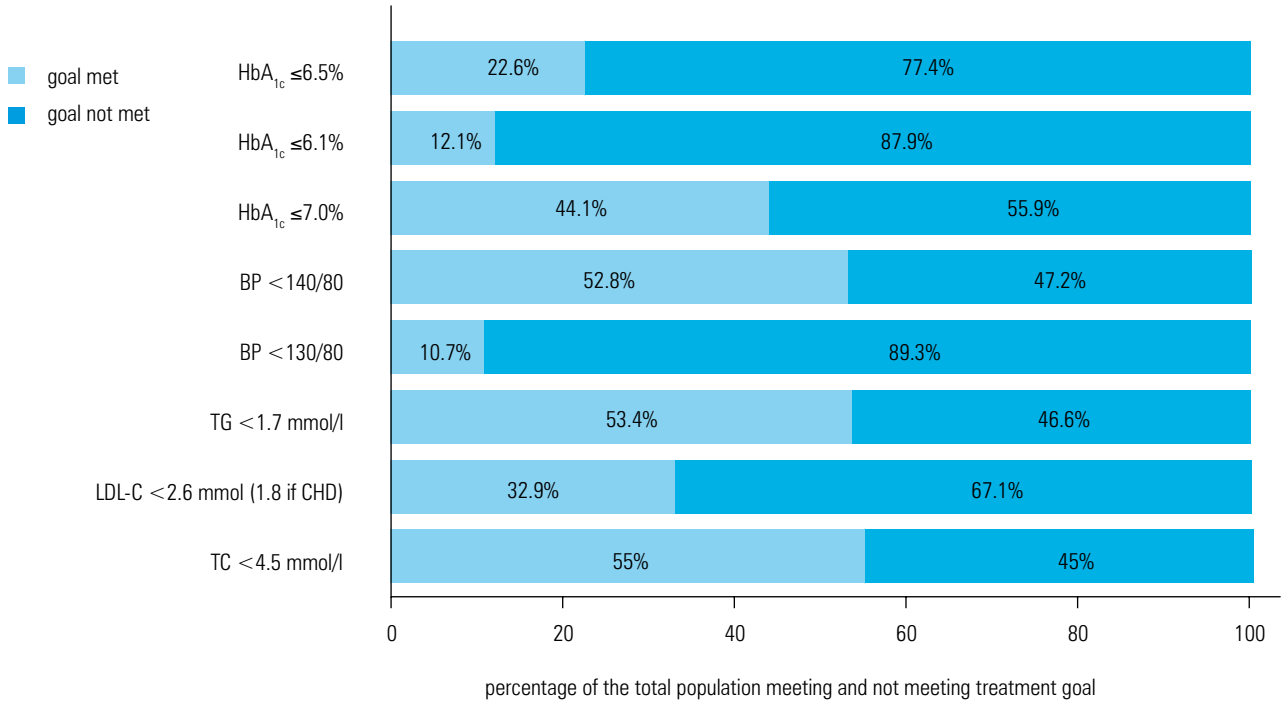

FIGURE 2 Percentage of patients in the OPTIMO study who met and who did not meet treatment goals
Abbreviations: see TABLE 4

TABLE 7 Duration of the disease and the percentage of patients in the OPTIMO study who met and who did not meet diabetes control goals at baseline

	<1 year (n = 1232)	1–2 years (n = 1607)	3–5 years (n = 1923)	6–10 years (n = 2519)	11–20 years (n = 1895)	>20 years (n = 424)
HbA_{1c}, % (n)						
≤6.5%	16.9 (37)	33.5 (157)	26.9 (153)	20.4 (184)	17.9 (133)	18.6 (37)
>6.5%	83.1 (182)	66.5 (311)	73.1 (415)	79.6 (718)	82.1 (610)	81.4 (162)
≤7.0%	32 (70)	59.4 (278)	52.1 (296)	41.4 (373)	36.7 (273)	38.2 (76)
>7.0%	68 (149)	40.6 (190)	47.9 (272)	58.6 (529)	63.3 (470)	61.8 (123)
<6.1%	10.5 (23)	18.2 (85)	15.7 (89)	10.6 (96)	9.2 (68)	7 (14)
≥6.1%	89.5 (196)	81.8 (383)	84.3 (479)	89.4 (806)	90.8 (675)	93 (185)
TC, % (n)						
<4.5 mmol/l	50.3 (620)	53.8 (864)	56.3 (1083)	56.3 (1418)	54.7 (1036)	60.1 (255)
≥4.5 mmol/l	49.7 (612)	46.2 (743)	43.7 (840)	43.7 (1101)	45.3 (859)	39.9 (169)
LDL cholesterol, % (n)						
<2.6 mmol/l or <1.8 mmol/l if CHD	24.6 (189)	31 (317)	32.6 (403)	34.9 (595)	34.8 (470)	40.7 (127)
≥2.6 mmol/l or ≥1.8 mmol/l if CHD	75.4 (580)	69 (704)	67.4 (832)	65.1 (1112)	65.2 (879)	59.3 (185)
TG, % (n)						
<1.7 mmol/l	48.8 (583)	52.2 (810)	54.7 (1013)	54.8 (1337)	53.1 (972)	58.9 (242)
≥1.7 mmol/l	51.2 (612)	47.8 (743)	45.3 (840)	45.2 (1101)	46.9 (859)	41.1 (169)
BP, % (n)						
<140/90 mmHg	54.8 (675)	55.7 (895)	52 (1000)	52.4 (1319)	51.3 (973)	49.3 (209)
≥140/90 mmHg	45.2 (557)	44.3 (712)	48 (923)	47.6 (1200)	48.7 (922)	50.7 (215)
<130/80 mmHg	12 (148)	11.3 (182)	9.7 (187)	10.3 (260)	10.7 (202)	11.8 (50)
≥130/80 mmHg	88 (1084)	88.7 (1425)	90.3 (1736)	89.7 (2259)	89.3 (1693)	2.2 (374)

Abbreviations: see TABLE 4

clinical practice guidelines have been documented here showing room for significant improvement of diabetes control. Knowledge and awareness of the disease among patients is an important factor influencing diabetes control.[18] We hope that the OPTIMO study will provide answers as

TABLE 8 Type of diabetes and the percentage of patients in the OPTIMO study who met and who did not meet diabetes control goals at baseline

	Type 1 diabetes (n = 575)	Type 2 diabetes (n = 8842)	Gestational diabetes (n = 4)	LADA (n = 80)	MODY (n = 5)	Secondary diabetes (n = 94)
HbA_{1c}, % (n)						
≤6.5%	18.8 (67)	22.8 (605)	0	25.6 (11)	50.0 (1)	41.5 (17)
>6.5%	81.2 (290)	77.2 (2050)	100 (1)	74.4 (32)	50.0 (1)	58.5 (24)
≤7.0%	34.5 (123)	45.3 (1203)	0	37.2 (16)	100 (2)	53.7 (22)
>7.0%	65.5 (234)	54.7 (1452)	100 (1)	62.8 (27)	0	46.3 (19)
<6.1%	9.0 (32)	12.3 (326)	0	16.3 (7)	0	24.4 (10)
≥6.1%	91.0 (325)	87.7 (2329)	100 (1)	83.7 (36)	100 (2)	75.6 (31)
TC, % (n)						
<4.5 mmol/l	65.0 (374)	54.1 (4787)	100 (4)	52.5 (42)	80.0 (4)	69.1 (65)
≥4.5 mmol/l	35.0 (201)	45.9 (4055)	0	47.5 (38)	20.0 (1)	30.9 (29)
LDL cholesterol, % (n)						
<2.6 mmol/l or <1.8 mmol/l if CHD	31.5 (90)	33.0 (1980)	100 (1)	19.2 (10)	50.0 (1)	36.5 (19)
≥2.6 mmol/l or ≥1.8 mmol/l if CHD	68.5 (196)	67.0 (4020)	0	80.8 (42)	50.0 (2)	63.5 (33)
TG, % (n)						
<1.7 mmol/l	64.3 (362)	52.5 (4490)	100 (4)	49.3 (37)	80.0 (4)	67.4 (60)
≥1.7 mmol/l	35.7 (201)	47.5 (4055)	0	50.7 (38)	20.0 (1)	32.6 (29)
BP, % (n)						
<140/90 mmHg	78.4 (451)	50.9 (4500)	100 (4)	70.0 (56)	40.0 (2)	61.7 (58)
≥140/90 mmHg	21.6 (124)	49.1 (4342)	0	30.0 (24)	60.0 (3)	38.3 (36)
<130/80 mmHg	20.3 (117)	9.9 (875)	50.0 (2)	18.8 (15)	0	21.3 (20)
≥130/80 mmHg	79.7 (458)	90.1 (7967)	50.0 (2)	81.3 (65)	100 (5)	78.7 (74)

Abbreviations: see TABLES 3 and 4

to whether the clinical decision support system and educational program tailored to the needs of specialists proves helpful for clinicians and enables them to meet therapeutic goals and improve diabetes care.

Study limitations The system of data collection might have been troublesome for some doctors; therefore, only those who agreed to collect data using pocket PC could participate in the study. The only way of reducing bias in patient selection was a pseudorandom manner of patient recruitment described above, and we consider this a limitation to obtain reliable data. Another shortcoming is that both HbA_{1c} and BP target values of Diabetes Poland practice guidelines have changed since the study was performed, becoming less stringent and more dependent on individual patients' characteristics. Although we calculated not only the proportions of patients meeting the previous goals (HbA_{1c} ≤6.5 and BP <130/80 mmHg) but also the new ones for the majority of patients (HbA_{1c} ≤7.0% and BP <140/90 mmHg), we did not show data for all HbA_{1c} treatment goals (≤6.1%; ≤6.5%, ≤7.0%, <8.0%) currently recommended by Diabetes Poland in the subgroups.[2] Although HbA_{1c} <8.0% is now accepted in patients over 70 years of age with a long diabetes duration (>20 years) and a history of cardiovascular events, we did not use this treatment goal because at the time of the study there was no higher target HbA_{1c} than that of 6.5%.

Of note, the study was not designed to collect data on laboratory methods used in HbA_{1c} assays, so there is uncertainty as to the accuracy of all HbA_{1c} results from different centers in Poland. Diabetes Poland recommends that the methods used in HbA_{1c} assays should be certified by the National Glycohemoglobin Standardization Program, and this is what we have assumed.

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REFERENCES

1 Diabetes Poland. [Clinical recommendations for the management of patients with diabetes 2006. Statement of Diabetes Poland]. Diabetol Prakt. 2006; 8 (suppl A). Polish.

2 Diabetes Poland. Clinical recommendations for the management of patients with diabetes 2011. Statement of Diabetes Poland. [Diabetol Prakt]. 2011; 12 (suppl A). Polish.

3 American Diabetes Association. Standards of medical care in diabetes – 2006. Diabetes Care. 2006; 29 (Suppl 1): 4-42.

4 American Diabetes Association. Standards of medical care in diabetes – 2011. Diabetes Care. 2011; 34 (Suppl 1): 11-61.

5 Action to Control Cardiovascular Risk in Diabetes Study Group. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med. 2008; 358: 2545-2559.

6 The ADVANCE Collaborative Group. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. N Engl J Med. 2008; 358: 2560-2572.

7 Fchiu CJ, Wray LA. Factors predicting glycemic control in middle-aged and older adults with type 2 diabetes. Prev Chronic Dis. 2010; 7: A08. http://www.cdc.gov/pcd/issues/2010/jan/08_0250.htm. Accessed September 20, 2011.

8 Polakowska M, Piotrowski W. Results of the Multicenter Polish Population Health Status Study – WOBASZ. Pol Arch Med Wewn. 2011; 121: 156-163.

9 Kamińska A, Bronisz A, Bronisz M, et al. [The assessment of the implementation of the Polish Diabetes Association recommendations in the scope of metabolic control in patients with diabetes treated in endocrinological-diabetological outpatient clinic]. Diabetol Prakt. 2010; 11: 160-166. Polish.

10 Szymborska-Kajanek A, Koblik T, Bandurska-Stankiewicz E, et al. [Metabolic control in type 2 diabetic patients treated by general practitioners and referred to the specialists -preliminary results of the Project "The Improvement of Glycaemic Control"]. Diabetol Prakt. 2009; 10: 228-233. Polish.

11 Sieradzki J, Kasperska-Czyżyk T, Grzeszczak W, et al. [National results of the DYNAMIC2 (II) study]. Diabetol Prakt. 2003; 4: 103-111. Polish.

12 Bała MM, Płaczkiewicz-Jankowska E, Topór-Mądry R, et al. Characteristics of patients with type 2 diabetes of short duration in Poland. Rationale, design and preliminary results of the ARETAEUS1 study. Pol Arch Med Wewn. 2009; 119: 533-540.

13 Bała MM, Płaczkiewicz-Jankowska E, Topór-Mądry R, et al. Do patients with recently diagnosed type 2 diabetes reach recommended treatment targets? Results of Polish ARETAEUS1 Study. Pol Arch Med Wewn. 2011; 121: 7-17.

14 Grzeszczak W, Sieradzki J, Kasperska-Czyżyk T, et al. [DINAMIC 2 study: comparison of results in various regions of Poland (III)]. Diabetol Prakt. 2003; 4: 111-124. Polish.

15 Sieradzki J, Grzeszczak W, Karnafel W, et al. [The PolDiab Study. Part I. Analysis of diabetes treatment in Poland]. Diabetol Prakt. 2006; 7: 8-15. Polish.

16 Dodd AH, Colby MS, Boye KS, et al. Treatment approach and HbA1c control among US adults with type 2 diabetes: NHANES 1999-2004. Curr Med Res Opin. 2009; 25:1605-1613.

17 Raum E, Lietzau S, Stegmaier C, et al. For the majority of patients with diabetes blood pressure and lipid management is not in line with recommendations. Results from a large population-based cohort in Germany. Pharmacoepidemiol Drug Saf. 2008; 17: 485-494.

18 Ozcelik F, Yiginer O, Arslan E, et al. Association between glycemic control and the level of knowledge and disease awareness in type 2 diabetic patients. Pol Arch Med Wewn. 2010; 120: 399-406.

ARTYKUŁ ORYGINALNY

Specjalistyczna opieka ambulatoryjna nad chorymi na cukrzycę w Polsce – czy jesteśmy daleko od osiągnięcia celów leczenia?

Przesłanki, metody i wstępne wyniki badania OPTIMO

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SŁOWA KLUCZOWE

cukrzyca, system wspomagania decyzji klinicznych, wytyczne

STRESZCZENIE

WPROWADZENIE Wytyczne praktyki klinicznej opisują najlepszy oparty na danych z badań klinicznych sposób postępowania z pacjentami, jednak lekarze i pacjenci każdorazowo podejmują indywidualne decyzje dotyczące zarówno celów, jak i środków leczenia, a poszczególni pacjenci osiągają (lub nie) cele leczenia.

CELE Celem badania był opis populacji chorych na cukrzycę leczonych przez lekarzy pracujących w specjalistycznej opiece ambulatoryjnej, opis postępowania z pacjentami z różnymi typami cukrzycy i ocena, do jakiego stopnia spełnione są kryteria kontroli cukrzycy zalecane w wytycznych Polskiego Towarzystwa Diabetologicznego.

PACJENCI I METODY Badanie obserwacyjne OPTIMO przeprowadzono w latach 2006–2009. Obejmowało ono chorych na cukrzycę rozpoznaną zgodnie z kryteriami Światowej Organizacji Zdrowia z 1999 roku, którzy uczestniczyli w badaniu przez 1–3 lata i zgłaszali się na wizyty kontrolne przynajmniej co 6 miesięcy. Do zbierania danych i odbierania edukacyjnych przypomnień uczestniczący lekarze używali palmtopów wyposażonych w specjalne oprogramowanie.

WYNIKI Ostatecznej analizie poddano 9600 pacjentów, u których uzyskano prawidłowo wypełnione kwestionariusze wyjściowe. U 92% chorych rozpoznano cukrzycę typu 2, u 6% – cukrzycę typu 1. Średni wiek chorych wynosił 60,5 roku. Kobiety stanowiły 54% badanych. U 32% chorych stwierdzono chorobę wieńcową, a u 76% – nadciśnienie tętnicze. Podczas wizyty kwalifikującej u 23% pacjentów stężenie hemoglobiny glikowanej wynosiło $<6,5\%$, a u 44% – $<7\%$. Stężenie cholesterolu całkowitego i triglicerydów na początku badania mieściło się w zalecanym zakresie u nieco ponad połowy chorych, a stężenie cholesterolu LDL – u 33%. Ciśnienie tętnicze $<130/80$ mmn Hg odnotowano na początku badania u 11% chorych.

WNIOSKI Na początku badania OPTIMO zaobserwowano znaczne odstępstwa od celów leczenia zalecanych w aktualnych wytycznych postępowania klinicznego u chorych na cukrzycę, co stwarza konieczność znacznej poprawy kontroli cukrzycy.

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