



Przemysław W. Witek<sup>1</sup>, Paweł Wołkow<sup>3</sup>, Julita Stancel-Możwiłło<sup>1</sup>, Katarzyna Wojtyczek<sup>1</sup>, Jacek Sieradzki<sup>1, 2</sup>, Maciej Małecki<sup>1, 2</sup>

# The Polish Diabetes Registry for Adults — a pilot study

Narodowy Rejestr Chorych na Cukrzycę w Polsce — program pilotażowy

### **ABSTRACT**

Background. Over the years 2006–2009 a pilot project of the Polish Diabetes Registry for Adults financed by the Polish Ministry of Health was performed. The objective was to assess outpatient diabetes care a few years after joining the European Union.

Material and methods. Questionnaires for randomly enrolled patients were completed by diabetologists in 39 outpatient diabetes centers in different parts of Poland. Data concerning age, sex, BMI, diabetes type and duration, hypoglycemic treatment, glycated haemoglobin (HbA1c), lipids levels, blood pressure (BP), diabetes complications, concomitant diseases and their treatment, and other aspects of medical care were collected. The questionnaires were analysed centrally. Results. Data on 7606 individuals were available: 15.0% with type 1 diabetes (T1DM); 80.9% with type 2 diabetes (T2DM); 1.9% with other types of diabetes; and 2.2% with gestational diabetes. T1DM and T2DM cohorts consisted of 1134 (52.4% women) and 6119 (55.5% women) patients, mean age 40.9 and 63.8 years, mean diabetes duration 14.6 and 9.7 years, respectively. Mean HbA1c for T1DM and T2DM was 7.69 and 7.25%. Lipid parameters for T1DM and

T2DM were as followed: mean total cholesterol (TC) 4.84 and 5.06 mmol/l; mean LDL-cholesterol (LDL) 2.73 and 2.90 mmol/l; mean HDL-cholesterol (HDL) 1.58 and 1.30 mmol/l; mean triglycerides (TG) 1.26 and 1.95 mmol/l; mean blood pressure (BP) 127.4/ /77.7 and 139.8/81.8 mmHg. The following proportion of the patients within target were recorded: for HbA1c (≤ 7.0% and ≤ 6.5%): T1DM 39.4 and 22.6%, T2DM 52.1 and 32.8%; for TC levels (< 4.5 mmol/l): T1DM 40.1%, T2DM 32.6%; for TG levels (< 1.7 mmol/l): T1DM 82.1%, T2DM 53.2%; for BP (< 130/80 mm Hg): T1DM 31.9%, T2DM 12.9%, respectively. Prevalence of microvascular complications among T1DM and T2DM was as followed: retinopathy 38,4 and 23,4%; nephropathy 15,2 and 8,5%; peripheral neuropathy 25.3 and 25.4%; autonomic neuropathy 9,6 and 5,4%. Conclusions. The data show the current quality of diabetes care in Poland, which seems to show some improvement as compared to the DEPAC survey performed at the accession to EU (2004). Nevertheless, the current Registry also indicates that most patients still do not meet the criteria of diabetes control defined by the local and international guidelines. (Diabet. Klin. 2012; 1, 1: 3-11)

Key words: diabetes registry, treatment of diabetes, chronic complications of diabetes

# **STRESZCZENIE**

Wstęp. Pilotażowy projekt Rejestru Dorosłych Chorych na Cukrzycę w Polsce został przeprowadzony w latach 2006–2009. Został on sfinansowany z funduszy Ministerstwa Zdrowia. Celem projektu była

Address for correspondence: Dr Przemyslaw Witek, M.D., Ph.D. Department of Metabolic Diseases, University Hospital of Krakow ul. Kopernika 15, 31–501 Kraków, Poland

tel. +48 12 424 83 05 fax. +48 12 421 97 86

e-mail: przemyslawwitek@yahoo.co.uk Diabetologia Kliniczna 2012, tom 1, 1, 3–11

Copyright © 2012 Via Medica

Nadesłano: 21.02.2012 Przyjęto do druku: 06.03.2012

<sup>&</sup>lt;sup>1</sup>Department of metabolic diseases, University Hospital of Krakow, Poland

<sup>&</sup>lt;sup>2</sup>Department and chair of metabolic diseases, Jagellonian University of Krakow, Poland

<sup>&</sup>lt;sup>3</sup>Department of pharmacology, Jagellonian University of Krakow, Poland

ocena jakości opieki diabetologicznej w kilka lat po przystąpieniu Polski do Unii Europejskiej.

Materiał i metody. Kwestionariusze dotyczące danych pacjentów z cukrzycą były wypełniane przez lekarzy diabetologów w 39 różnych ośrodkach diabetologicznych w Polsce. Dane zawarte w kwestionariuszach zawierały pytania o: wiek, płeć, BMI, typ i czas trwania cukrzycy, rodzaj leczenia hipoglikemizującego, HbA<sub>1c</sub>, profile glikemii, lipidogram, ciśnienie tętnicze, powikłania cukrzycy, choroby towarzyszące i ich leczenie oraz inne aspekty opieki. Kwestionariusze były analizowane w centralnym ośrodku.

Wyniki. Uzyskano dane 7606 pacjentów: 15,0% z typem 1 cukrzycy (T1DM), 80,9% z typem 2 cukrzycy (T2DM), 1,9% z innymi typami cukrzycy i 2,2% z cukrzycą ciążową. Grupa chorych z T1DM i T2DM charakteryzowała się odpowiednio: liczebnością 1134 (52,4% kobiet) i 6119 (55,5% kobiet), średnim wiekiem 40,9 i 63,8 lat, średnim czasem trwania cukrzycy 14,6 i 9,7 lat. Średni poziom  $HbA_{1c}$  wynosił dla T1DM i T2DM odpowiednio 7,69 i 7,25%. Parametry gospodarki lipidowej dla T1DM i T2DM wynosiły: cholesterol całkowity 4,84 i 5,06 mmol/l; LDL-cholesterol 2,73 i 2,90 mmol/l; HDL-cholesterol 1,58 i 1,30 mmol/l; triglicerydy 1,26 i 1,95 mmol/l; ciśnienie tętnicze 127,4/77,7 i 139,8/81,8 mmHg. Odsetek pacjentów spełniających kryteria wyrównania wynosił odpowiednio dla: HbA<sub>1c</sub> ≤ 7,0% i ≤ 6,5%: T1DM 39,4 i 22,6%, T2DM 52,1 i 32,8%; cholesterol całkowity < 4,5 mmol/l: T1DM 40,1%, T2DM 32,6%; triglicerydy < 1,7 mmol/l: T1D 82,1%, T2D 53,2%; ciśnienie tetnicze < 130/80 mm Hg: T1DM 31,9%, T2DM 12,9%. Częstość występowania mikronaczyniowych powikłań cukrzycy wynosił odpowiednio dla chorych z T1DM i T2DM: retinopatia 38,4 i 23,4%; nefropatia 15,2 i 8,5%; neuropatia obwodowa 25.3 i 25.4%; neuropatia autonomiczna 9,6 i 5,4%.

Wnioski. Dane uzyskane w Rejestrze obrazują obecny stan opieki diabetologicznej w Polsce, który wykazuje tendencję do poprawy w porównaniu do badania DEPAC przeprowadzonego w krajach Europy środkowo-wschodniej, w tym w Polsce w okresie przystąpienia do Unii Europejskiej (2004). Pomimo tego trendu większość pacjentów wciąż nie spełnia kryteriów wyrównania cukrzycy rekomendowanych przez krajowe i międzynarodowe zalecenia. (Diabet. Klin. 2012; 1, 1: 3–11)

Słowa kluczowe: rejestr chorych na cukrzycę, leczenie cukrzycy, przewlekłe powikłania cukrzycy

### Introduction

Diabetes mellitus becomes an epidemic of XXI century, mainly as a result of food excess and sedentary lifestyle [1]. Chronic microvascular (retinopathy, nephropathy and neuropathy with diabetic foot syndrome) and macrovascular (coronary heart disease, brain and peripheral arteries disease) complications are major cause of disability and premature mortality in diabetic patients [2]. Diabetes generates not only medical and social but also economic problems, becoming a hard burden for health care budgets [3]. The large clinical trials, DCCT in type 1 (T1DM) [4] and UKPDS in type 2 diabetes mellitus (T2DM) [5] proved that long term glycemic control reduces frequency of chronic microvascular complications. Prolonged observation of T1DM patients in DCCT/EDIC study showed reduced frequency of macroangiopathy in previously intensively treated patients [6].

The targets for treatment have not been unequivocally determined for specific groups of patients. For example lack of improvement in cardiovascular outcomes, especially in elderly patients and even increased mortality was observed in ACCORD and VADT trials in intensively treated group [7, 8]. Possibly slower, more prolonged restoration of glucose control would have more beneficial effect [9].

Since 2005, The Polish Diabetes Association (PDA) releases the annual clinical recommendations for diabetes care in Poland. Every year they are modified according to newest evidence-based knowledge. In the years 2006-8 the HbA1c targets recommended by PDA was  $\leq$  6.1% and  $\leq$  6.5, lower in patients with low risk of hypoglycaemia. In 2009 the HbA1c targets were changed. Recommended value for T1DM patients and for T2DM patients with short duration of diabetes was  $\leq$  6.5% and for the rest of T2DM patients  $\leq$  7.0%.

Appropriate glycemic control is not sufficient to prevent chronic complications of diabetes. The full metabolic control includes treatment of hyperglycemia, lipid abnormalities, hypertension and normalization of body weight. The advantage of the multifactorial intervention has been proven in T2DM patients with microalbuminuria [10]. The effectiveness of the treatment of lipid abnormalities has well-documented beneficial impact on survival and development of chronic complications, first of all macroangiopathy [11]. It still remains controversial how low should be target blood pressure in diabetic patients.

In the years 2007–2009 the target blood pressure recommended by PDA was below 130/80 mmHg.

Valuable data about the quality of treatment in various geographical regions and countries come from Diabetic Registries (DR). DR could have local or global range. Data collected in DR are provided by primary as well as secondary medical care. Based on the stored information, it is possible to estimate the quality of diabetes care and current costs of health care system that should be provided for diabetic patients. Moreover, monitoring these parameters in time allows to predict epidemiological trends of prevalence of diabetes and its complications. It gives a prognosis of future expenditures in diabetes care.

In year 2004 when Central and Eastern European countries accessed the European Union (EU) large survey DEPAC that analysed the level of diabetes care in these region was performed [12]. In year 2006 the Polish Health Ministry sponsored a grant for the Polish Diabetes Registry for Adults. Data collected in this registry comes from 2007–2009, thus comparison of these two surveys can give same information on the change in the quality of diabetes care in Poland a few years after accession to EU.

# **Materials and methods**

The pilot Polish Diabetes Registry for Adults was based on a questionnaire that concerned many aspects of diabetes care. The questionnaires were one page double sided papers that were sent to second-degree diabetological centres selected earlier by regional consultants. All biochemical measures were performed in local laboratories. The questionnaires were filled based on current records of patient's medical history and sent back to the coordinating centre that was located in Department of Metabolic Diseases in Krakow. The data from questionnaires were verified by medical specialists and stored in database by internet-based application. The questionnaires included questions on the following data:

- basic demographic data;
- type of diabetes and criterion used for diagnosis (if available);
- year of diagnosis and beginning of treatment (oral drugs, insulin);
- concomitant diseases;
- vital signs and anthropometric measurements;
- results of laboratory tests preceding the visit (HbA<sub>1c</sub>, glucose profile, lipids, C-peptide, immune markers of type 1 diabetes), frequency of hypoglycaemia;

- number of hospitalisations in the year preceding the visit;
- current diabetes treatment, number of anti-diabetic drugs and test-strips prescribed at visit;
- current treatment of concomitant diseases, number of other drugs prescribed at visit;
- history and current status of chronic complications of diabetes;
- referral to lab tests and consultations of other specialists.

In this article only partial data collected in the questionnaires were analysed.

The Polish Diabetes Registry for Adults included only patients treated in second-degree level of medical care. In late 2006 we obtained the list of 40 diabetic centres selected by regional consultants to whom in 2007 we sent 100 questionnaires per centre. We attached a detailed manual how to complete questionnaire. In each centre, all consecutive 100 patients attending from the starting point were included. Finally we obtained 3334 filled questionnaires and positively verified 3327 of them.

In 2008 4 more centres were included and 108 questionnaires were sent to each participant centre. We instructed the physicians to select patients that have not been recorded previously. Because of administrative obstacles we prolonged duration of registering to March 2009. In January 2009 we sent 800 more questionnaires to selected centres and collected them before deadline March 31-th. Eventually in 2008-9 we obtained more 4313 filled questionnaires and positively verified 4279 of them.

# Results

Overall we obtained the total number of 7647 filled questionnaires from 39 centres. 41 patients had two visits completed. Only data from the first visit were chosen for the analysis. Thus, we verified and analysed data of 7606 patients. Out of these subjects, 1134 (14.91%) had T1DM, 6119 (80.45%) had T2DM, 147 (1.93%) one of other specific types of DM, 165 (2.17%) gestational DM and in 41 (0.54%) type of DM was unspecified. Of these 4225 (55.55%) were women. The results of patients with other types of diabetes, gestational diabetes and unspecified diabetes are not discussed because of the small number of subjects.

Table 1 shows clinical characteristic of patients (age, gender, duration of diabetes, anthropometric measures) and data on glycaemic, lipid and blood pressure control. Mean  $HbA_{1c}$  for T1DM and T2DM was 7.69% and 7.25%, respectively. Only 39.4% and

Table 1. Clinical characteristic of the examined diabetic patients

	Unit	Data type 1	Type 1	Data type 2	Type 2	Data type 1 & 2	2 Type 1 & 2
Age Years	1134	40.9	±14.5	6119	63.8 ± 10.4	7253	
Gender (males)	(%)	1134	47.66119	44.6	7253		
Duration of diabetes	Years		14.6 ± 11.2		$9.7 \pm 7.6$		
BMI total	[kg/m²]	1072	$25.00 \pm 3.92$	5838	31.28 ± 5.27	6910	$30.31 \pm 5.57$
BMI males	[kg/m²]	511	$25.50 \pm 3.67$	2599	$30.48 \pm 4.79$	3110	29.66 ± 4.98
BMI females	[kg/m²]	561	$24.54 \pm 4.09$	3239	31.92 ± 5.55	3800	$30.83 \pm 5.96$
Waist total	[cm]	813	$84.9 \pm 12.6$	4866	101.7 ± 13.2	5679	$99.3 \pm 14.3$
Waist males	[cm]	383	90.7 ± 11.2	2118	104.4 ± 12.5	2501	102.3 ± 13.3
Waist females	[cm]	430	79.8 ± 11.6	2748	99.7 ± 13.3	3178	$97.0 \pm 14.7$
WHR total		695	$0.87 \pm 0.10$	4116	$0.93 \pm 0.09$	4811	$0.92 \pm 0.09$
WHR males		327	$0.93 \pm 0.08$	1809	$0.97 \pm 0.08$	2136	$0.97 \pm 0.08$
WHR females		368	$0.81 \pm 0.08$	2307	$0.89 \pm 0.08$	2675	$0.88 \pm 0.09$
HbA <sub>1c</sub>		868	$7.69 \pm 1.64$	4043	7.25 ± 1.42	4911	$7.33 \pm 1.47$
≤ 7.0%	(%)		39.4 52.1		49.9		
≤ 6.5%	(%)		22.6 32.8		31.0		
Fasting glycemia	[mg/dl]		134.0 124.6		126.1		
Pre-prandial glycaemia	[mg/dl]		133.3 125.4		126.6		
Postprandial glycaemia	[mg/dl]		146.6 147.7		147.6		
Mean glycaemia	[mg/dl]		140.0 138.8		138.9		
Total cholesterol	[mmol/l]	559	$4.84 \pm 0.99$	3198	5.06 ± 1.16	3757	$5.03 \pm 1.14$
< 4.5 mM	(%)		40.07% 32.61%		33.72%		
HDL-cholesterol	[mmol/l]	442	$1.58 \pm 0.48$	2467	$1.30 \pm 0.51$	2909	$1.35 \pm 0.51$
> 1.0 (1.3) mM	(%)		83.26% 60.52%		63.97%		
LDL-cholesterol	[mmol/l]	410	$2.73 \pm 0.82$	2263	$2.90 \pm 0.99$	2673	$2.87 \pm 0.96$
< 2.6 mM	(%)		44.88% 40.65%		41.30%		
Triglycerides	[mmol/l]	503	$1.26 \pm 0.87$	2922	1.95 ± 1.61	3425	1.85 ± 1.55
< 1,7 mM	(%)		82.11% 53.15%		57.40%		
Systolic BP	[mm Hg]	1090	127.4 ± 16.1	5978	139.8 ± 18.7	7068	137.9 ± 18.9
< 130 mm Hg	(%)		54.50% 24.09%		28.78%		
Diastolic BP	[mm Hg]	1090	77.7 ± 9.1	5977	81.7 ± 10.4	7067	81.1 ± 10.3
< 80 mm Hg	(%)		42.11% 27.67%		29.90%		
Blood pressure	(%)	1090	31.93%5977	12.89%	706715.82%		
< 130/80 mm Hg							
Heart rate	[min <sup>-1</sup> ]	1033	$77.0 \pm 8.2$	5735	$76.2 \pm 8.9$	6768	$76.3 \pm 8.8$

<sup>\*</sup>For males > 1.0 mmol/l; for females > 1.3 mmol/l

22.6% of T1DM patients fulfilled the criteria of HbA $_{1c} \le 7.0\%$  and HbA1c  $\le 6.5\%$ , respectively. In T2DM patients these numbers were 52.1% and 32.8%, respectively. T1DM patients had better lipid parameters and blood pressure control than T2DM subjects.

Out of T2DM patients, 2.4% were without any pharmacological treatment, 42.2% were on oral antidiabetic drugs, 20.9% on insulin only and 34.6% were on combined therapy with insulin and oral drugs.

Table 2 shows the percentage of different oral anti-diabetic drugs and their combinations used in T2DM. Only metformin, sulfonylurea derivatives and

alpha-glucosidase inhibitors are shown. Other drugs like glinides, glitazones and incretin axis medications were not included because of a very small number of patients using them. The most popular model was the combination of metformin with sulfonylurea. It was used in 20.3% T2DM subjects and in 48.2% of T2DM subjects treated with oral drugs only.

Different combination of oral anti-diabetic drugs with insulin in T2DM patients were shown in Table 3. The most frequent model was a combination of insulin with metformin.

The percentage of total number of patients with T2DM treated with particular types of oral an-

Table 2. Percentage of different combination of oral antidiabetic drugs in T2DM

Oral drugs combination	Percentage of patients with T2DM		
Without treatment at all	0.3%		
Only diet	0.3%		
Diet and exercise	1.8%		
Total without pharmacotherapy	2.4%		
Monotherapy with sulfonylurea	6.9%		
Monotherapy with metformin	10.7%		
Monotherapy with alpha-	0.6%		
-glucosidase inhibitors			
Sulfonylurea + metformin	20.3%		
Sulfonylurea + alpha-glucosidase	1.4%		
inhibitors			
Metformin + alpha-glucosidase	0.6%		
inhibitors			
Sulfonylurea + metformin +	1.7%		
+ alpha-glucosidase inhibitors			
Other combinations	0.2%		
Total treated with oral drugs	42.2%		

Table 3. Combination therapy: oral anti-diabetic drugs and insulin in T2DM

	T2DM total	T2DM on insulin
Monotherapy with insulin	20.9%	37.6%
Insulin + sulfonylurea	3.0%	5.3%
Insulin + metformin	20.3%	36.6%
Insulin + alpha-glucosidase inhibitors	1.9%	3.4%
Insulin + sulfonylurea + metformin	6.9%	12.4%
Insulin + sulfonylurea + alpha-	0.7%	1.2%
-glucosidase inhibitors		
Insulin + metformin + alpha-	1.4%	2.5%
-glucosidase inhibitors		
Insulin + sulfonylurea + metformin +	0.5%	0.9%
+ alpha-glucosidase inhibitors		
Insulin + any oral hypoglycaemic drugs	34.6%	62.4%

tidiabetic drugs are presented in Table 4. The most common oral drug was metformin. There were 62,38% T2DM patients treated with metformin.

The use of different types of insulin in both types of diabetes is shown in Table 5. The most popular insulin types used in T1DM were rapid analogues and NPH insulin while in T2DM human insulin mixtures were the most frequently used.

Table 4. Percentage of T2DM patients treated with particular non-insulin drugs with or without combination with insulin

Therapy	Percentage of patients			
Metformin	62.4%			
Sulfonylurea derivative	41.3%			
Alpha-glucosidase inhibitors	8.6%			
Tiazolidynodiones	0.02%			
Glinides	0.00%			
GLP-1 receptor agonists	0.03%			
DPP-IV inhibitors	0.16%			

Table 5. Percentage of patients treated with particular types of insulin

	Type 1 DM	Type 2 DM
Human short-acting insulin	21.4%	10.0%
Rapid-acting analogue	69.3%	9.0%
Insulin NPH	53.6%	16.7%
Long-acting analogue	24.6%	2.0%
Mixture of human insulin	10.1%	21.6%
Mixture of analogue insulin	8.8%	16.3%
Bovine or porcine insulin	0.0%	0.0%
Continuous subcutaneous insulin infusion	4.7%	0.0%
No data	1.1%	0.0%
Total insulin	100%	55.4%

Table 6 shows the prevalence of chronic complication of diabetes within analysed population. Occurrence of chronic microvascular complications of diabetes (retinopathy, nephropathy and autonomic neuropathy) was higher in T1DM than T2DM patients. Peripheral neuropathy had similar occurrence in both types of diabetes. Macrovascular complications were much more frequent in T2DM than T1DM patients.

### **Discussion**

The Polish Diabetes Registry for Adults as shown above is one of the first attempts to describe most aspects of diabetes care in Poland. The data obtained from second-degree diabetological centres are comparable with data collected in DE-PAC trial that was an international survey conducted in central and eastern European countries at accession to EU. The outcomes of this earlier trial did not find a significant difference between qua-

7

**Table 6. Chronic complications of diabetes** 

Chronic complication of diabetes	Type 1 (n)	(%)	Type 2 (n)	(%)	type 1 & 2 (n)	(%)
Microvascular						
Retinopathy	1040	41.9	5376	26.6	6416	29.1
Nephropathy	971	17.7	5053	10.3	6024	11.5
Peripheral neuropathy	1134	25.3	6119	27.1	7253	26.9
Autonomic neuropathy	1134	9.6	6119	5.4	7253	6.0
Diabetic foot	1134	4.0	6119	2.7	7253	2.9
Macrovascular						
Coronary heart disease	1005	10.7	5428	41.0	6433	36.3
Cerebral artery disease	988	3.5	5147	11.5	6135	10.3
Peripheral artery disease	983	5.3	4990	11.0	5973	10.0

lity of diabetes care between central-eastern and western Europe [12].

The Polish Diabetes Registry for Adults collected data several years after the accession to EU. The comparison with previous data obtained in the DE-PAC trial gives some answers concerning the changes in diabetes care after the geopolitical transformation in this part of Europe.

A mean  $\mathrm{HbA}_{1c}$  level in Registry was 7.33%, the values were 7.69% and 7.25% in T1DM and T2DM subjects, respectively. Values of  $\mathrm{HbA}_{1c}$  in the DEPAC trial were slightly higher in the Polish population and even worse in the population of central and eastern European (CE) countries. We were unable to perform a direct statistical comparison of these trials. Additionally, we don't have any data about methodology of  $\mathrm{HbA1c}$  assessment and its variability constitutes the shortcoming of this registry.

The percentage of T1DM patients who fulfilled the criterion of  ${\rm HbA_{1c}} < 7.0\%$  was higher in Registry than in the Polish and CE populations participating in the DEPAC trial [12]. Data shown in the Swedish National Diabetes Registry showed even less T1DM patients with  ${\rm HbA_{1c}}$  lower than 7.0% [13]. More strict criteria for  ${\rm HbA_{1c}} < 6.5\%$ , what is recommended by the Polish Diabetological Association for type 1 diabetes, met less than one-fourth of T1DM patients what is still better than in the DEPAC study [12].

After publication of results of the ACCORD study, as well as some other trials, the therapeutic goals for T2DM were reviewed. In the majority of patients, the recommended HbA $_{1c}$  target is below 7.0% however the target below 6.5% can be considered in T2DM patients with short duration of the disease. The percentage of T2DM patients achieving HbA $_{1c}$  < 7.0% and < 6.5% in Registry was 52.1%

and 32.8%, respectively. This is much better than in DEPAC's Polish and CE populations [12].

The therapeutic goals in T1DM are focused mostly on glycaemic control. Irregular daily activities related to the patient's occupation or exercise contribute to the problems with achieving targets for glucose control. Despite of constantly improving therapeutic resources targets have not been achieved in many patients. At the current state of knowledge, the most important factor influencing outcomes in T1DM is patients' compliance. This is best seen in the most motivated group of patients: pregnant women. In this population with T1DM coming from our centre the mean HbA1c was 5.8% in 3rd trimester [14].

The results of glycaemic control in the Western Europe and USA seem to be at comparable levels. Percentage of T2DM with  $HbA_{1c} < 7.0\%$  was slightly lower in Italy [15], Spain [16] and slightly better in the USA [17, 18] and Germany [19].  $HbA_{1c}$  at more strict level < 6.5 was achieved in less T2DM patients in France [20] and Sweden [21] as compared with the Polish Diabetes Registry for Adults.

Lipid abnormalities are very frequent in diabetic patients. Haffner et al. found that type 2 diabetics had risk of death similar to those who suffered from myocardial infarction [22]. This is why recommended values of the total and LDL-cholesterol are more strict than in population without diabetes. The PDA recommends LDL-cholesterol < 2.6 mmol/l for most subjects with diabetes and < 1.8 mmol/l for those with overt macroangiopathy.

In the Registry less than a half patients with T1DM reached target values for LDL-cholesterol however this value is better than in DEPAC. Patients with T2DM in this Registry had a bit worse results than T1DM but the results were much better than

presented in DEPAC [12]. This improvement in Registry may be explained by better awareness of health care professionals and dropping costs of treatment with statins what used to be a very important limiting-factor of therapy in Poland. Despite of this therapy number of patients with appropriate LDL-cholesterol level seems slightly disappointing. The trials in other countries reveal similar or worse results. In Sweden 48% of type 1 diabetics had LDL-cholesterol within target. The percentage of patients with type 2 diabetes who had satisfactory level of LDL-cholesterol < 100 mg/dl varied from 5.9% in Spain [16], 16.4% in Italy [15], 30.4% in Germany [19] to 37.2% and 46.5% in the USA [17, 18].

Arterial hypertension is another significant risk factor what contributes to the worse prognosis in diabetic population [23, 24]. The upper range of the target in the Registry was established at the level of 130/80 mmHg [25], that was recommended value in 2009 year. Recently, there is evidence that intense lowering of blood pressure in some subgroups has at least no beneficial effect [26]. Results of blood pressure control are poor as only 31.9% T1DM and barely 12.9% T2DM patients achieved recommended range. It is particularly disappointing in the light of a wide variety of antihypertensive drugs on market. Most of them are cheap and can be applied to the majority of patients. Achieving appropriate control of blood pressure seems more difficult than control of glucose and lipids levels. In the previous survey performed in Poland in 2003, only 5.2% of T2DM subjects had satisfactory blood pressure measures. The DEPAC trial showed that 42% of T1DM and barely 9% of T2DM patients had appropriate blood pressure control [12]. The results of similar surveys performed in the Western European countries are diverse. The rate of satisfactorily controlled blood pressure in type 2 diabetics was 7.8% in Spain [16], 13% in Sweden [21], 14.4% in Italy [15], 27% in Germany [19] and 29% in France [20]. Much better results were observed in the USA: 45,5% and 51.7% [17, 18].

According to the recent guidelines, metformin is recommended in every treatment paradigm: as monotherapy or in combination with other oral drugs or insulin. Data presented above suggests that even taking into account contraindications or side effects of metformin, this drug is underused in T2DM population. A very small number of patients were treated with incretin axis drugs (GLP-1 receptor agonists or DPP-IV inhibitors). This can be explained by the short presence of these drugs on market and lack of reimbursement from the National Health Care system.

In T1DM patients rapid analogues were the most frequent prandial insulins (69.3%) whereas most frequent basal insulin was the NPH insulin (53.6%). The percentage of patients treated with long-acting analogues was significantly smaller, what can be explained by lack of reimbursement by the national health system in Poland. This makes them unavailable for the majority of patients due to high price. This explains why the use of these insulins in all T2DM patients is at the level of 2.0% and 3.6% of treated with insulin. Only 4.67% of patients with T1DM were treated with personal insulin pump. High costs of devices and disposable sets that are not reimbursed for all T1DM population limit the common use of insulin pump. None of T2DM subject was treated with this method.

The most frequent microvascular complication in Registry was retinopathy. In Poland the examination of eye background in diabetic patients is performed by ophthalmologist. At least one annual examination is recommended, more frequent visits are advised in advanced stages of retinopathy. In the Registry, any form of retinopathy was found in more patients with T1DM than in T2DM and the prevalence was comparable with results of DEPAC [12]. In other surveys performed in western countries the prevalence of retinopathy was similar to the current status [27–30].

Frequency of any nephropathy defined as presence of either albuminuria or/and elevated creatinine level was lower in Registry than in the DEPAC project [12].

The frequency of neuropathy (diagnosed by the presence of symptoms or signs or abnormalities in nerve conduction studies) was slightly lower in T1DM and similar in T2DM in Registry as compared to DEPAC [12].

The prevalence of macrovascular complications was very similar in the Registry and the DEPAC. Coronary heart disease was found in 10.7% and 8.5% in T1DM and 41.0% and 43.4% in T2DM, respectively. Cerebral artery disease was found in: 3.5% and 1.1% in T1DM and 11.5% and 7.2% in T2DM, respectively. Peripheral artery disease was found in: 5.3% and 6.0% in T1DM and 11.0% and 15.6% in T2DM, respectively [12].

The natural course of chronic complications of diabetes runs in years and decades thus improvement in epidemiological indices can be expected after at least several years of significant improvement in diabetes management.

In summary treatment outcomes of Polish diabetics in 2007–9 seems to show slight improvement

9

with those presented in the DEPAC trial. It can be explained by growing awareness about diabetes, better access to medical care and improvement in welfare of society, although, one should also point out that the centres included into this registry were not randomly assigned, what could have altered the obtained results. Lack of reimbursement of some modern treatment may constitute a barrier for further improvement.

# **Acknowledgements**

The survey was supported by grant from Polish Ministry of Health. Below is the list of all participants in the survey.

Aksamit-Białoszewski Ewa (Olsztyn), Banasik--Paczyńska Grażyna (Wrocław), Bartos Tadeusz (Końskie), Bąbol Irena (Gdańsk), Borucińska Ewa (Szczecin), Bresler Maria (Zabrze), Broma-Kondrat Anna (Katowice), Bromirska Marzena (Rzeszów), Bronisz Agata (Bydgoszcz), Cylkowska Barbara (Elbląg), Dąbrowska-Milczarek Małgorzata (Końskie), Dzienis--Strączkowska Stella (Białystok), Galicka-Stankowska Dorota (Tarnów), Gorczyca-Pluta Marta (Jasło), Jakubczyk Jolanta (Białystok), Jakuszewska Romana (Opole), Janiak Elżbieta (Sobótka), Jaromczyk-Ślisz Janina (Gdańsk), Jaromin Bogumiła (Skarżysko-Kamienna), Jaskulska-Gorzelewska Barbara (Gdańsk), Kaczmarek-Kusznierewicz Przybysława (Gdańsk), Kałużny Józef (Wadowice), Karczewicz-Janowska Jadwiga (Wrocław), Kaźmierska Dorota (Elbląg), Kąkol Zofia (Szczecin), Kędzierska Joanna (Rzeszów), Kepa Danuta (Bochnia), Kłysiak Anna (Lublin), Kocięcki Marek (Hajnówka), Kolcowa Olga (Gdańsk), Kowalski Aleksander (Wałbrzych), Kozioł Małgorzata (Zabrze), Kramarczuk Elżbieta (Zamość), Laskus Hanna (Słupsk), Laszewska Grażyna (Białystok), Limont Alfreda (Toruń), Madziarska Katarzyna (Wrocław), Majcher-Witczak Grażyna (Kielce), Majchrzak Anna (Poznań), Malinowska-Maciejewska Maria (Szczecin), Matysiak Elżbieta (Kielce), Michniowski Grzegorz (Sanok), Miszczyszyn Zofia (Przemyśl), Mykietyn Agnieszka (Kędzierzyn Koźle), Nowak-Bieńkowska Małgorzata (Jasło), Ołdakowska Mieczysława (Łomża), Olejniczak Henryka (Bydgoszcz), Pasek Urszula (Krapkowice), Pietraszek Felicja (Zabrze), Pisarczyk-Wiza Dorota (Poznań), Polaszewska-Muszyńska Mirosława (Władysławowo), Popławska Elżbieta (Białystok), Puch Urszula (Białystok), Rogacewicz Klaudia (Elblag), Ruprecht Zofia (Bydgoszcz), Rutkowska Joanna (Olsztyn), Ryś Ryszard (Koszalin), Semetkowska-Jurkiewicz Ewa (Gdańsk), Siegel Anna (Katowice), Smolec-Talaga Jadwiga (Wadowice),

Sobel-Maruniak Anna (Rzeszów), Sobiś-Żmudzińska Małgorzata (Bydgoszcz), Sołkiewicz-Hammer Halina (Tarnów), Sowiński Dariusz (Wrocław), Starzewska Beata (Kielce), Sumper Rafał (Andrychów), Szadok Ewa (Wałbrzych), Szcześniak Grzegorz (Lublin), Szopa Magdalena (Kraków), Tarasiewicz Urszula (Olsztyn), Towpik Iwona (Zielona Góra), Urbańska Wanda (Opole), Wańczyk Anna (Olsztyn), Wilejto-Cierpisz Elżbieta (Katowice), Wiśniewska Krystyna (Warszawa), Witek Robert (Tarnów), Wolnik Bogumił (Gdańsk), Zarzycka Barbara (Białystok), Zarzycka-Lindner Grażyna (Bydgoszcz)

### **REFERENCES**

- Wild S., Roglic G., Green A., Sicree R., King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care 2004. 27:1047–1053.
- Gu K., Cowie C.C., Harris M.I. Mortality in adults with and without diabetes in a national cohort of the U.S. population, 1971–1993. Diabetes Care 1998; 21: 1138–1145.
- American Diabetes Association. Economic costs of diabetes in the U.S. in 2007. Diabetes Care 2008; 31: 596–615.
- 4. The Diabetes Control and Complications Trial Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The New England Journal Of Medicine 1993; 329: 977–986.
- United Kingdom Prospective Diabetes Study Group: Intensive blood-glucose control with sulfonylureas or insulin compared with conventional treatment and risk of complication in patients with type 2 diabetes. Lancet 1998; 352: 837–848.
- Nathan D.M., Cleary P.A., Backlund J.Y. i wsp.; Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. N. Engl. J. Med. 2005; 353: 2643–2653.
- Duckworth W., Abraira C., Moritz T. i wsp.; VADT Investigators. Glucose control and vascular complications in veterans with type 2 diabetes. N. Engl. J. Med. 2009; 360: 129–139.
- Action to Control Cardiovascular Risk in Diabetes Study Group, Gerstein H.C., Miller M.E., Byington R.P. i wsp. Effects of intensive glucose lowering in type 2 diabetes. N. Engl. J. Med. 2008; 358: 2545–2559.
- ADVANCE Collaborative Group, Patel A., MacMahon S., Chalmers J. i wsp. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. N. Engl. J. Med. 2008; 358: 2560–2572.
- Gaede P., Lund-Andersen H., Parving H.H., Pedersen O. Effect of a multifactorial intervention on mortality in type 2 diabetes. N. Engl. J. Med. 2008; 358: 580–591.
- Colhoun H.M., Betteridge D.J., Durrington P.N. i wsp.; CARDS investigators. Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. Lancet 2004; 364: 685–696.
- Andel M., Grzeszczak W., Michalek J. i wsp.; DEPAC Group. A multinational, multi-centre, observational, cross-sectional survey assessing diabetes secondary care in Central and Eastern Europe (DEPAC Survey). Diabet. Med. 2008; 25: 1195–1203.
- Eeg-Olofsson K., Cederholm J., Nilsson P.M., Gudbjörnsdóttir S., Eliasson B.; Steering Committee of the Swedish National Diabe-

- tes Register. Glycemic and risk factor control in type 1 diabetes: results from 13,612 patients in a national diabetes register. Diabetes Care 2007; 30: 496–502.
- 14. Cyganek K., Hebda-Szydlo A., Katra B. i wsp. Glycemic control and selected pregnancy outcomes in type 1 diabetes women on continuous subcutaneous insulin infusion and multiple daily injections: the significance of pregnancy planning. Diabetes. Technol. Ther. 2010; 12: 41–47.
- De Berardis G., Pellegrini F., Franciosi M. i wsp.; QuED Study. Quality of care and outcomes in type 2 diabetic patients: a comparison between general practice and diabetes clinics. Diabetes Care 2004; 27: 398–406.
- Orozco-Beltrán D., Gil-Guillen V.F., Quirce F. i wsp.; Collaborative Diabetes Study Investigators. Control of diabetes and cardiovascular risk factors in patients with type 2 diabetes in primary care. The gap between guidelines and reality in Spain. Int. J. Clin. Pract. 2007; 61: 909–915.
- Cheung B.M., Ong K.L., Cherny S.S., Sham P.C., Tso A.W., Lam K.S. Diabetes prevalence and therapeutic target achievement in the United States, 1999 to 2006. Am. J. Med. 2009; 122: 443–453.
- Bertoni A.G., Clark J.M., Feeney P. i wsp.; Look AHEAD Research Group. Suboptimal control of glycemia, blood pressure, and LDL cholesterol in overweight adults with diabetes: the Look AHEAD Study. J. Diabetes Complications 2008; 22: 1–9.
- Ott P., Benke I., Stelzer J., Köhler C., Hanefeld M. Diabetes in Germany (DIG) study. A prospective 4-year-follow-up study on the quality of treatment for type 2 diabetes in daily practice. Dtsch Med. Wochenschr. 2009; 134: 291–297.
- Charpentier G., Genès N., Vaur L. i wsp.; ESPOIR Diabetes Study Investigators. Control of diabetes and cardiovascular risk factors in patients with type 2 diabetes: a nationwide French survey. Diabetes Metab. 2003; 29: 152–158.
- Eliasson B., Cederholm J., Nilsson P., Gudbjörnsdóttir S.; Steering Committee of the Swedish National Diabetes Register.
   The gap between guidelines and reality: type 2 diabetes in

- a National Diabetes Register 1996-2003. Diabet. Med. 2005; 22: 1420–1426.
- Haffner S.M., Lehto S., Rönnemaa T., Pyörälä K., Laakso M. Mortality from Coronary Heart Disease in Subjects with Type 2 Diabetes and in Nondiabetic Subjects with and without Prior Myocardial Infarction. N. Engl. J. Med. 1998; 339: 229–234.
- United Kingdom Prospective Diabetes Study Group: High blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. Br. Med. J. 1998: 7160: 703–712.
- 24. Patel A; ADVANCE Collaborative Group, MacMahon S., Chalmers J., Neal B. i wsp. Effects of a fixed combination of perindopril and indapamide on macrovascular and microvascular outcomes in patients with type 2 diabetes mellitus (the ADVANCE trial): a randomised controlled trial. Lancet 2007; 370: 829–840.
- Clinical Practice Recommendations. Diabetes Care 2010; 33, supl. 1.
- ACCORD Study Group, Cushman W.C., Evans G.W., Byington R.P. i wsp. Effects of intensive blood-pressure control in type 2 diabetes mellitus. N. Engl. J. Med. 2010; 362: 1575–1585.
- Pedro R.A., Ramon S.A., Marc B.B., Juan F.B., Isabel M.M. Prevalence and relationship between diabetic retinopathy and nephropathy, and its risk factors in the North-East of Spain, a population-based study. Ophthalmic Epidemiol. 2010; 17: 251–265.
- Heintz E., Wiréhn A.B., Peebo B.B., Rosenqvist U., Levin L.A. Prevalence and healthcare costs of diabetic retinopathy: a population-based register study in Sweden. Diabetologia 2010; 53: 2147–2154.
- Delcourt C., Massin P., Rosilio M. Epidemiology of diabetic retinopathy: expected vs reported prevalence of cases in the French population. Diabetes Metab. 2009; 35: 431–438.
- Zhang X., Saaddine J.B., Chou C.F. i wsp. Prevalence of diabetic retinopathy in the United States, 2005–2008. JAMA 2010; 304: 649–656.

www.dk.viamedica.pl