Cardiovascular risk factors control in Polish patients with type 2 diabetes within the first two years of diagnosis: results of the ARETAEUS1 study

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Abstract

Background: The practice guidelines of cardiological and diabetological societies emphasise that cardiovascular (CV) risk control in diabetic patients is especially important and should be stricter than in subjects without diabetes. There are little data on the frequency of meeting treatment goals in patients with newly diagnosed diabetes mellitus type 2 (DM2).

Aim: To characterise Polish patients with DM2 diagnosed within the previous two years and to assess if the treatment targets from the current (2008) guidelines of Diabetes Poland regarding control of CV risk factors are met.

Methods: ARETAEUS1 was a cross-sectional questionnaire-based study conducted in various regions of Poland in 2009 (January–April). It involved 1,714 patients of all ages and both genders, who had DM2 treated for less than 24 months. They were recruited by randomly selected physicians.

Results: Total cholesterol treatment goal (< 4.5 mmol/L) was met in 22% of all patients, triglycerides treatment goal (< 1.7 mmol/L) in 44%, LDL cholesterol treatment goal (< 2.6 mmol/L) in 20% and HDL cholesterol treatment goal (> 1.0 mmol/L in men and > 1.3 mmol/L in women) in 55%. Only 13% of the overall population met the goal of blood pressure (BP) below 130/80 mm Hg. When a less restrictive BP control threshold (< 140/90 mm Hg) was applied, 48% of patients had their BP below the threshold. In the analysis of subgroups (patients with and without previous CV events; receiving 1–5 or not receiving antihypertensive drugs; receiving and not receiving statins and fibrates) we observed from 0% to 3.3% of patients meeting three (HbA1c, BP and cholesterol) treatment goals. The percentages of patients meeting two out of three treatment goals were between 8% and 33% in different subgroups. The percentages of patients meeting only one out of three treatment goals ranged from 27.8% to 46.7% or at least one — from 39% to 69%.

Conclusions: Most patients with newly diagnosed diabetes are not meeting their treatment goals regarding control of CV risk factors, which indicates relatively low adherence to national guideline recommendations for diabetes control and primary CV prevention in DM2. Difficulties in achieving CV treatment targets in the diabetic population indicate the need for a great deal of effort on the part of clinicians and patients. Practice guidelines developers should consider what treatment targets are achievable at a reasonable expense of effort.

Key words: clinical practice guidelines, cross-sectional study, cardiovascular disease, diabetes mellitus type 2
INTRODUCTION
Type 2 diabetes (DM2) increases the cardiovascular (CV) risk [1]. Patients with diabetes have twice the risk of incident myocardial infarction (MI) and stroke as that of the general population. Large numbers of them do not survive their first event. As many as 80% of patients with DM2 will develop, and possibly die of, macrovascular disease. This is associated with a great societal cost, with major loss of life expectancy and quality of life [2, 3].

That is why the practice guidelines of cardiological and diabetological societies emphasise that CV risk factors control in diabetes is especially important and should be stricter than in people without diabetes (targets for blood pressure [BP] and lipids are more restrictive) [4–9]. There are little data on meeting treatment goals in patients with newly diagnosed DM2. The aim of the ARETAEUS1 study was to identify the Polish population in whom DM2 had been diagnosed within the previous two years, to assess if the treatment targets from the current (2008) guidelines of Diabetes Poland (DP) are being met to a satisfactory extent, and if the implementation of preventive strategies is adequate. We present results concerning the control of CV risk factors in this population. The DM2 is one of the priorities of CV disease prevention in clinical practice [6].

METHODS
The details of the ARETAEUS1 study design, protocol and patient characteristics have been described elsewhere [10]. In brief, ARETAEUS1 was a cross-sectional questionnaire-based study conducted in various regions of Poland between January and April 2009. The study aimed to identify the characteristics of patients with newly diagnosed DM2 defined as diabetes diagnosed within the previous two years according to the current criteria outlined in DP clinical practice guidelines 2008, which are consistent with those of the American Diabetes Association (ADA) and to assess if and how many treatment goals recommended by the DP clinical practice guidelines 2008 were being met [4].

The inclusion criteria for the study were: adult patients of either gender and any age, who had a diagnosis of DM2 within the previous two years (i.e. after 1 January, 2007). A random sample of clinicians stratified according to the size of the place of residence (five categories) was drawn from a database containing data of about 85% of all physicians registered in Poland. The patients were recruited over one month and each physician was asked to recruit at least five patients who fulfilled the inclusion criteria; 333 clinicians who agreed to participate and returned questionnaires (227 non-diabetologists, mainly working in primary health care institutions and 106 specialists in diabetology [specialists or physicians who completed their training in diabetology, and who worked in diabetes outpatient clinics]) recruited 1,714 patients. The study questionnaires were filled in by physicians; no data were obtained directly from the patients.

The questionnaire contained items regarding patient characteristics and medical history (demographic data, CV medical history [CV events, hypertension and lipid disorders according to the report of a participating physician based on the current criteria outlined in clinical practice guidelines], medical history concerning diabetes [11], tests results [BP, glycosylated haemoglobin — HbA1c and lipid levels] as well as diabetic drugs [11], antihypertensive drugs, lipid lowering and antiplatelet drugs) and did not include any personal data.

Statistical analysis
Results are presented as mean ± SD or numbers and percentages. We compared proportions of patients achieving treatment goals in different subgroups with $\chi^2$ test. 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). 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 Levene’s test. A p value < 0.05 was considered significant. All statistical analyses were conducted using SPSS v. 14.0.

RESULTS
Results related to diabetes control have been described elsewhere [12]. Seventy one per cent of all patients had HbA1c level above or equal to 6.5%. The current article describes the CV aspects of treatment and care of diabetic patients participating in the ARETAEUS1 study.

Mean age of patients was 60 ± 11 years, 50% were female, mean body mass index (BMI) was 30.6 ± 4.9 kg/m², 52% had BMI > 30 kg/m². Mean time from diabetes diagnosis was 9.8 ± 7.6 months, 64% were diagnosed with diabetes for less than a year. Mean waist circumference was 96.4 ± 13.4 cm in females and 103.1 ± 12.7 cm in males.

Eighty three per cent of patients fulfilled the Internatio nal Diabetes Federation criteria for the diagnosis of metabolic syndrome [13]. Cardiovascular disease risk factors were common: 77% of patients were reported to have hypertension, 73% — lipid disorders and 10.5% — previous acute coronary syndromes.

Total cholesterol treatment goal (< 4.5 mmol/L) was met in 22% of all patients, triglycerides treatment goal (< 1.7 mmol/L) in 44%, LDL cholesterol treatment goal (< 2.6 mmol/L) in 20% and HDL cholesterol treatment goal (> 1.0 mmol/L in men and > 1.3 mmol/L in women) in 53%. There were significant differences in the numbers of patients achieving these targets between patients using and not using statins, using and not using fibrates and in patients with the diagnosis of lipid disorders (or taking hypolipidaemic drugs) and without such a diagnosis (or not taking drugs) (Table 1). In each case, use of medications indicated generally worse status of risk factor control.

Eighty three per cent of patients with coronary heart disease (CHD) and 52% of patients without CHD were receiving...
Table 1. Lipid level control and lipid lowering drugs in the overall population and in the different subgroups of patients with and without cardiovascular risk factors in diabetes — the ARETAEUS study.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall Patients (n = 1,684)</th>
<th>Patients with the diagnosis of lipid disorders or taking drugs (n = 1,487)</th>
<th>Patients without lipid disorders and not taking drugs (n = 353)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol:</td>
<td>22.0 (348)</td>
<td>20.3 (314)*</td>
<td>23.1 (314)*</td>
</tr>
<tr>
<td>LDL cholesterol:</td>
<td>78.0 (1,232)</td>
<td>84.7 (188)</td>
<td>79.8 (848)</td>
</tr>
<tr>
<td>Triglycerides:</td>
<td>44.3 (660)</td>
<td>53.2 (583)</td>
<td>53.2 (583)</td>
</tr>
</tbody>
</table>

*Significant difference between patients taking and not taking drug (statin, fibrate); ^significant difference between patients with and without lipid disorders; CHD — coronary heart disease; LDL — low density lipoprotein; HDL — high density lipoprotein. Numbers in brackets — number of valid questionnaires.
all three goals, 12.5% met two goals, 35.3% met only one goal, and 50.7% met none of the treatment goals (Fig. 5, Table 5). In different subgroups, from 0% to 3.3% of patients met all three treatment goals. More patients without previous CV events met three, two or one treatment goals as compared with patients with previous CV events. In most subgroups, the percentage of patients not meeting any of the treatment goals varied between 31% and 61%. The percentages of patients meeting two out of three treatment goals were between 8% and 33% in different subgroups. The percentage of patients meeting only one out of three treatment goals ranged from about 27.8% to 46.7% and at least one of the treatment goals — from 39% to 69%.

DISCUSSION

This is the first Polish study which provides information on CV risk factors profile and lipid-lowering, antihypertensive and antiplatelet treatment in patients with newly diagnosed (i.e. within two years of diagnosis) DM2. To date, the studies addressing similar problems have been conducted in the general population, in patients with CV disease and in patients with DM1 or DM2 lasting 4–10 years.

Achieving all of the treatment goals (HbA1c, BP and lipid values) was very uncommon in this population (1.4% of patients), and the proportion achieving some of these goals was also unsatisfactory. The results clearly indicate either inadequate adherence to national clinical practice guideline recommendations, or that those guidelines are too rigorous in their treatment goals. The fact that the BP treatment goal (< 130/90) was fulfilled in 13% of patients, while a less restrictive goal (140/90) was fulfilled in 48% makes the second possibility more probable. The percentage of patients reaching treatment goals is similar to that observed in other European studies [14, 15], which also supports the hypothesis that the treatment goals are rela-
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...tively too strict and not easily enough reached in clinical practice. In some guidelines this problem has also been noticed. The most recent position statement of the European Society of Hypertension [16, 17] contains a less strong recommendation to achieve BP below 130/80 mm Hg in diabetic patients than those featured in the previous guidelines of this society [18]. Moreover, in one study [19], tight control of systolic BP (< 130 mm Hg) in patients with diabetes and CHD was not associated with improved CV outcomes compared to usual control (systolic BP < 140 mm Hg).

The new DP guidelines (2011) also recommend less stringent target BP of < 140/90 mm Hg in all diabetic patients except those with newly diagnosed hypertension and those with diabetic nephropathy (who should aim at < 130/80 mm Hg values) [20].

We cannot exclude the possibility that physicians do not put enough attention into prevention and do not find time to explain to patients the importance of prevention, and that results in low compliance of patients (especially with newly diagnosed DM2).

Another possibility is illustrated by the fact that in an observational study (POLKARD Study Group) over 60% of subjects without the diagnosis of hyperlipidaemia and not receiving hypolipaemic drugs had total cholesterol and LDL-cholesterol levels above the treatment goals [21]. It shows that risk factors are not only managed inadequately but are also under-diagnosed.

Hypertension was better diagnosed in our population of patients. Only 15% of patients without the diagnosis of...
hypertension and not taking antihypertensive drugs had BP > 140/90 mm Hg.

In our study, in the subgroup of patients with diagnosed hypertension, only 2% of those with BP above 130/80 mm Hg did not receive any antihypertensive drug. So the problem is not with deciding on initiation of the pharmacological treatment for patients with diagnosed hypertension, but rather with inadequate drug use — too often only one drug is used, and we can also assume that the doses are too low. In a study assessing the competence of Polish general practitioners in terms of their compliance with hypertension treatment guidelines, poor compliance with guidelines was noted for patients with diabetes mellitus [22].

The adherence to clinical practice guidelines is better when the recommendations are clear, simple and easy to follow (e.g. using specific drugs in specific clinical situations — ASA in CHD [83% of study participants with CHD received it] or beta-blocker in patients with previous MI [85% of this population received this drug]). Similar proportions were observed in the Polish parts of the EUROASPIRE (European Action on Secondary Prevention through Intervention to Reduce Events) III survey conducted among hospitalised patients with CHD [23].

The results of the ARETAEUS1 study provide valuable information for doctors and nurses delivering care to patients with diabetes and those teaching medical students, but also for experts developing practice guidelines. The information is directed mostly to a Polish audience, but issues are likely to be general. Clinicians can find out how their colleagues manage newly diagnosed diabetes. Clinicians who teach students and diabetic patients should, on the basis of these results, point out to their audiences that as CV prevention is important in diabetes, there are major difficulties in achieving treatment targets, so much effort is required on the part of clinicians and patients. Authors of practice guidelines sho-
uld pay attention to what is achievable at a reasonable expense of effort and should consider direct proven benefits and costs (money, time and effort) required to achieve treatment targets.

CONCLUSIONS

1. Most patients with newly diagnosed diabetes are not meeting their treatment goals regarding control of CV risk factors, which indicates relatively low adherence to national guideline recommendations for diabetes control and primary CV prevention in DM2.

2. Clinicians who teach students and diabetic patients should point out that there are difficulties in achieving treatment targets in the diabetic population, meaning that a great deal of effort is required on the part of clinicians and patients to meet these goals.

3. Practice guidelines developers should consider which treatment targets are achievable at a reasonable expense of effort.

CONTRIBUTORS

All of the authors contributed to the study concept, design, and implementation of this report.
Maciej Malecki, MD, PhD, Bogna Wierusz-Wysocka, MD, PhD. We would like to thank the physicians participating in the study.

Conflicts of interest: Dr Małgorzata M. Bala: nothing to declare; Dr Ewa Placzkiewicz-Jankowska: nothing to declare; Dr Roman Topór-Madry: nothing to declare; Dr Wiktoria Leśniak: nothing to declare; Prof. Roman Jaeschke: a deputy editor of a medical journal which draws part of its revenue from pharmaceutical advertisements including drugs for diabetes; Prof. Jacek Sieradzki: nothing to declare; Prof. Władysław Grzeszczak and Prof. Waldemar Banasiak: received honoraria from Teva Pharmaceuticals Polska Sp. z o.o. for presenting the study results at the conference of Diabetes Poland.

References

Słowo kluczowe: badanie przekrojowe, choroba sercowo-naczyniowa, cukrzyca typu 2, wytyczne praktyki klinicznej
Kardiol Pol 2011; 69, 12: 1249–1257