

Utilisation of lipid-lowering therapies in outpatient settings in Poland: epidemiological survey Economedica Dyslipidaemia 2015

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Abstract

Background: Dyslipidaemia, especially elevated low-density lipoprotein cholesterol (LDL-C), is one of the most important cardiovascular risk factors. Treatment of dyslipidaemia and prevention of cardiovascular disease (CVD) with lipid-lowering drugs is one of the key issues in reducing cardiovascular mortality. Nevertheless, underutilisation of statins and lipid-lowering drugs is still a problem globally.

Aim: The present study aimed to describe the utilisation of lipid-lowering drugs in groups of patients with indications for statin treatment and elevated LDL-C.

Methods: The study included adult patients with an indication for the use of a lipid-lowering therapy, currently using or not using such therapy because of contraindications or statin intolerance, in whom LDL-C concentration was > 70 mg/dL, treated in outpatient settings. All patients were screened for CVD and had blood cholesterol concentration assessed. Patients were also divided into: (1) patients with vascular disease; (2) patients with diabetes mellitus; (3) aged ≥ 65 years; and (4) patients without the three mentioned risk factors.

Results: The study group consisted of 2812 (51.4% male) patients. Major cardiovascular risk factors including arterial hypertension, type 2 diabetes mellitus, and smoking were highly prevalent in the study population (86.2%, 44.1%, and 23.3%, respectively). Out of the prespecified risk factors (vascular disease, diabetes mellitus, age ≥ 65 years) the study population was divided into patients without any of the mentioned risk factors (n = 520), those with all the three risk factors (n = 368), two out of three risk factors (n = 934), and one risk factor (n = 990). The study showed that 89.6% of patients were treated with statins (47.8% with atorvastatin, 27.8% with rosuvastatin, and 13.8% with simvastatin). Fenofibrate was used in 5.8% of the population and ezetimibe in 2.7%. In the whole group, 7.1% of patients did not receive any type of lipid-lowering therapy. Atorvastatin was more often used in patients with all the three prespecified risk factors, while rosuvastatin was used in patients without any of the risk factors.

Conclusions: The most often-used lipid-lowering drugs in Poland are statins, with atorvastatin and rosuvastatin being used the most common of these. The present study shows that some patients with LDL-C concentration > 70 mg/dL and indications for lipid-lowering are not treated accordingly.

Key words: dyslipidaemia, statins, lipid-lowering drugs

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INTRODUCTION

Lipid-lowering drugs are currently one of the most widely used therapies in different groups of patients. Indications for the use of lipid-lowering drugs include not only treatment of lipid disorders, but also primary and secondary prevention of cardiovascular disease (CVD) [1]. Recent studies have shown that the adherence to the guideline standards for cardiovascular prevention in high-risk patients is poor [2, 3]. High prevalence of smoking, unhealthy diets, physical inactivity, obesity, and diabetes mellitus has been persistent over the years [2]. Therefore, proper introduction and assuring good adherence to cardioprotective pharmacotherapy, including lipid-lowering drugs, has become all the more important. Due to their established effectiveness and proven beneficial effect on prognosis, statins are currently the leading subgroups of lipid-lowering drugs [4, 5]. Nevertheless, there is still severe underutilisation of statins in patients with indications for their use globally [6]. Up to this day, little is known about the statin prescription habits in outpatient clinics in Poland, and the published data are limited [7, 8]. The present study aims to describe the utilisation of lipid-lowering drugs in groups of patients with indications for statin treatment and baseline low-density lipoprotein cholesterol (LDL-C) concentration over 70 mg/dL.

METHODS

The present study was designed and conducted with the accordance to the Declaration of Helsinki and was approved by the Regional Ethics Committee. The study was part of the Economedica Dyslipidaemia 2015 project and included adult patients with an indication for the use of lipid-lowering therapy, currently using or not using such therapy because of contraindications or statin intolerance, in whom LDL-C concentration was > 70 mg/dL, and who were diagnosed with an intention to treat at least six months earlier. All enrolled patients were treated in outpatient settings, regardless of the frequency of visits and involvement in lipid-lowering therapy. Indications for the lipid-lowering therapy were based on the current guidelines regarding dyslipidaemia and CVD prevention [2, 9]. Data were collected from June to August 2015 by specialists (cardiologists, general practitioners, or diabetologists). Data were obtained from 2812 patients (1349 treated by general practitioners, 884 by cardiologists, and 579 by diabetologists). Data were representative for the general Polish population. Doctors were invited to participate in the study using the quota sampling technique. The sample of physicians of the above specialities were allocated proportionally between the 12 territorial layers defined by the region (six geographic regions, 2–4 voivodeships according to GUS classification) and the type of doctor's place of work (city population size). 150 doctors (75 general practitioners, 45 cardiologists, and 30 diabetologists) were invited to participate in the study. Finally, 147 physicians, including 72 general practitioners,

45 cardiologists, and 30 diabetologists, confirmed their participation. Another entry criterion for the study referred to the minimum number of patients admitted by doctors during a typical open-label week; it was defined as general practitioners — a minimum of 100 patients, cardiologists and diabetologists — a minimum of 60 patients.

The group was divided into four prespecified groups regarding major cardiovascular risk factors. The groups were: (1) patients with vascular disease, including diagnosis of peripheral vascular disease, history of myocardial infarction with and without ST-segment elevation, history of unstable angina, history of stroke or transient ischaemic attack, history of coronary artery bypass grafting or percutaneous transluminal coronary angioplasty, history of peripheral revascularisation due to peripheral artery disease, history of atherosclerosis-related amputation; (2) patients with diabetes mellitus; (3) patients at the age of 65 years or more; and (4) patients without the three abovementioned risk factors.

All patients were interviewed, screened, and had their medical records checked for prior diagnosis of the abovementioned cardiovascular risk factors. The diagnoses of the conditions were made according to the current guidelines. For example, diagnosis of diabetes mellitus was made when a random plasma glucose \geq 200 mg/dL (11.1 mmol/L) or fasting plasma glucose \geq 126 mg/dL (7.0 mmol/L), or 2-h plasma glucose \geq 200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test or taking antidiabetic drugs [10]. Additionally, patients were asked to answer questions regarding their physical activity, diet, smoking, family history of CVD, and menopause in women.

All patients had also their blood pressure values measured in out-patient settings, and data were collected regarding the last available blood lipid concentrations.

Data regarding the use of lipid-lowering therapy use was assessed based on the medical and prescription records, at the time of the enrolment into the study, regardless of the duration and intensity of treatment.

Statistical analysis

Statistical analysis was performed using the SPSS v. 21.0 (SPSS Inc., Chicago, IL, USA). Continuous data are presented as the mean \pm standard deviation (SD) and were compared using the Mann-Whitney test or Student's t-test. Categorical variables were compared using either the χ^2 or Fisher's exact tests. A p value less than 0.05 was considered statistically significant, whereas the confidence intervals (CI) were 95%. The structure of the sample of doctors divided into specialities does not reflect the proportion of specialists (cardiologists, diabetologists) to general practitioners in Poland. The sample data increased the participation of cardiologists and diabetologists in relation to general practitioners in order to obtain detailed data for these groups of specialists. At the data analysis stage, the specialisation structure was subjected to the weighing process.

RESULTS

The study group consisted of 2812 (51.4% male) patients at a mean age of 64.7 years. The general population was assessed according to the prevalence of cardiovascular risk factors. Atherosclerosis was diagnosed in 39.8% of patients, 10.6% had peripheral artery disease, 46.1% had a history of myocardial infarction, and 23.2% had a history of unstable angina. Cerebral vascular disease was less prevalent, but 9.8% of patients had a history of stroke and 7.1% had a history of transient ischaemic attack. Also, major cardiovascular risk factors including arterial hypertension, type 2 diabetes mellitus, and smoking were highly prevalent in the general population of the study (86.2%, 44.1%, and 23.3%, respectively). Moreover, 60.8% of patients admitted to having an inactive lifestyle, 37.0% had a diet rich in unsaturated fatty acids, 42.3% had a family history of coronary heart disease, and 2.9% were diagnosed with familial hypercholesterolaemia.

According to the prespecified groups (1. patients with vascular disease; 2. patients with diabetes mellitus; 3. patients aged ≥ 65 years), the study population was divided into patients without any of the mentioned risk factors ($n = 520$), those with all the three risk factors ($n = 368$), those with two out of three risk factors ($n = 934$), and those in whom only one risk factor was present. Detailed characteristics of the groups according to the prevalence of cardiovascular risk factors are presented in Table 1. The most significant differences between the groups included age (lowest in patients without the specified cardiovascular risk factors and highest in patients with three risk factors), body mass index (lowest in patients without the specified cardiovascular risk factors and highest in patients with three risk factors), and systolic blood pressure (lowest in patients without the specified cardiovascular risk factors and highest in patients with three risk factors). As expected, the prevalence of other cardiovascular risk factors, including atherosclerosis, arterial hypertension, and coronary heart disease, was also the lowest in patients without any of the prespecified cardiovascular risk factors (vascular disease, diabetes mellitus, age ≥ 65 years) and highest in patients with three risk factors. Unexpectedly, patients without any of the prespecified cardiovascular risk factors had the highest concentration of total cholesterol, LDL-C, and triglycerides among the studied groups.

When we assessed the use of the lipid-lowering drugs, it was shown that 89.6% of patients with indications for this type of treatment were treated with statins. The most frequently used statins were atorvastatin (47.8% of patients), rosuvastatin (27.8%), and simvastatin (13.8%). Fenofibrate was used in 5.8% of the population and ezetimibe in 2.7%. In the whole group, 7.1% of patients did not receive any type of lipid-lowering therapy (Table 2, Fig. 1). When prescription rates between the groups were compared, there were small differences in the prescription of statins according to the number of cardiovascular risk factors, while atorvastatin was

more frequently used in patients with all the three prespecified risk factors, and rosuvastatin in patients without any of the factors (Table 3).

When we assessed the number of patients who achieved LDL-C target levels based on the European Society of Cardiology guidelines, we found that only 386 (13.7%) had target LDL levels, and among 2410 (85.7%) patients, for 16 (0.01%) cases data on the target values were not obtained. Data on patients who did and did not achieve target values are presented in detail in Table 4.

DISCUSSION

Dyslipidaemia, especially elevated levels of LDL-C are crucial risk factors for CVD and related mortality. Their role in the development of CVD is documented by genetic, pathology, observational, and intervention studies and meta-analyses. Therefore lipid-lowering agents are used not only for the treatment of lipid disorders but also for primary and secondary prevention. The most promising data have been found for statins. A large meta-analysis of trials, comprising adults without prior cardiovascular events, aimed to assess the benefits and harms of statin therapy versus placebo [11]. It showed that statin therapy is associated with reduced risk of all-cause mortality, cardiovascular mortality, stroke, myocardial infarction, and composite cardiovascular outcomes. Most importantly, benefits were consistent even in patients without marked hyperlipidaemia. No association was found between statins and an increased risk of serious adverse events, including myalgia or liver injury. Moreover, lipid-lowering treatment seems to be associated with cost-effectiveness and benefits regarding utilisation of healthcare resources [12]. In a study involving 6595 participants aged 45–54 years, who were randomised to a five-year treatment with moderate intensity statin or placebo, the treatment was associated with a saving of £710 000, including the cost of statin and lipid and safety monitoring, and it gained 136 QALYs (quality-adjusted life years) over the 15-year period. Benefits per 1000 subjects included 163 fewer admissions, with fewer admissions for myocardial infarction, stroke, heart failure, and coronary revascularisation.

Unfortunately, regardless of the proven beneficial effect of lipid-lowering, especially with the use of statins, a problem of underutilisation of these drugs is observed across Europe. One of the largest studies concerning this subject was an observational study including European Union and Norway residents over the period 1997–2003 [13]. It compared the annual utilisation data for lipid-lowering agents by class and drug. It showed that the use of statins across Europe has increased greatly over the study period, mostly due to higher prescribed daily doses, but two-thirds of this increase is due to a rise in the number of patient days of treatment, due to more patients treated. Nevertheless, large disparities exist between countries.

Table 1. Comparison of baseline characteristics according to the prevalence of cardiovascular risk factors

	Patients without the risk factors* (A)	Patients with all 3 risk factors* (B)	Patients with 2 out of the 3 risk factors* (C)	Patients with 1 out of the 3 risk factors* (D)
Male sex	262 (48.9%) ^{C D}	201 (55.2%) ^{A C D}	480 (47.7%) ^D	503 (46.3%)
Age [years]	53.9 (55)	73.2 (71) ^{A C D}	70.7 (70) ^{A D}	65.0 (65) ^A
Body mass index [kg/m ²]	27.5 (27.4)	29.1 (29.0) ^{A C D}	28.5 (28.3) ^{A D}	28.4 (28.0) ^A
Systolic BP [mmHg]	131.5 (130)	136.2 (132) ^{A C D}	132.9 (130) ^{A D}	132.3 (130) ^A
Diastolic BP [mmHg]	79.9 (80) ^{B C D}	78.9 (80) ^{C D}	78.7 (80) ^D	78.3 (80)
Lipid parameters				
Total cholesterol [mg/dL]	212.9 (205) ^{B C D}	199.9 (190) ^C	197.2 (190)	199.9 (193) ^C
LDL cholesterol [mg/dL]	129.4 (119) ^{B C D}	114.31 (106) ^C	112.66 (105)	114.25 (105) ^C
HDL cholesterol [mg/dL]	53.5 (51) ^B	50.5 (50)	53.7 (50) ^{A B}	55.8 (53) ^{A B C}
Triglycerides [mg/dL]	155.2 (142) ^{B C D}	144.9 (142) ^{C D}	137.6 (129)	139.2 (139) ^C
Cardiovascular risk factors				
Atherosclerosis	57 (9.5%)	278 (75.6%) ^{A C D}	494 (51.1%) ^{A D}	290 (28.0%) ^A
Peripheral artery disease	0 (0.0%)	109 (28.3%) ^{C D}	149 (16.3%) ^D	39 (4.0%)
Coronary artery disease	62 (8.6%)	283 (79.9%) ^{A C D}	591 (65.4%) ^{A D}	361 (33.8%) ^A
History of MI	0 (0.0%)	180 (41.7%) ^{C D}	323 (30.6%) ^D	148 (13.3%)
History of unstable angina	0 (0.0%)	85 (21.7%) ^{C D}	144 (14.9%) ^D	47 (3.3%)
History of stroke	0 (0.0%)	81 (23.8%) ^{C D}	97 (10.2%) ^D	21 (1.9%)
History of TIA	0 (0.0%)	67 (21.4%) ^{C D}	94 (8.3%) ^D	31 (3.2%)
History of CABG	0 (0.0%)	55 (12.3%) ^{C D}	93 (11.7%) ^D	28 (2.4%)
History of PTCA	0 (0.0%)	164 (37.8%) ^{C D}	294 (24.8%) ^D	135 (9.6%)
Arterial hypertension	378 (70.6%)	353 (92.9%) ^{A D}	859 (93.2%) ^{A B D}	834 (86.6%) ^A
Atrial fibrillation	43 (6.5%)	113 (34.7%) ^{A C D}	214 (23.6%) ^{A D}	125 (11.2%) ^A
Heart failure	10 (1.5%)	150 (39.3%) ^{A C D}	228 (26.5%) ^{A D}	97 (8.7%) ^A
Abdominal aorta aneurysm	2 (0.2%)	14 (3.5%) ^{A C D}	20 (2.2%) ^{A D}	9 (1.2%) ^A
Other cardiovascular disease	11 (1.0%)	14 (1.8%) ^{A C}	16 (1.1%) ^A	25 (3.0%) ^{A B C}
History of peripheral revascularisation	0 (0.0%)	28 (6.7%) ^{C D}	37 (3.0%) ^D	13 (1.2%)
History of amputation due to atherosclerosis	0 (0.0%)	7 (1.8%) ^{C D}	2 (0.2%) ^D	1 (0.1%)
Type 1 diabetes	0 (0.0%)	6 (2.0%) ^{C D}	18 (1.0%) ^D	22 (0.9%)
Type 2 diabetes	0 (0.0%)	362 (98.0%) ^{C D}	524 (52.2%) ^D	353 (24.9%)
Chronic kidney disease	13 (1.9%)	110 (30.7%) ^{A C D}	126 (9.6%) ^{A D}	53 (4.7%) ^A
Microalbuminuria	5 (1.1%)	55 (11.5%) ^{A C D}	76 (5.6%) ^{A D A D}	32 (1.1%) ^A
Hepatitis type C	2 (0.2%)	2 (1.9%) ^{A C D}	4 (0.4%) ^{A D}	6 (0.3%) ^A
Other risk factors				
Inactive lifestyle	278 (51.9%)	260 (81.4%) ^{A C D}	596 (69.9%) ^{A D}	575 (61.1%) ^A
Diet rich in saturated fatty acids	217 (41.9%) ^{B C D}	142 (38.5%) ^C	310 (35.0%)	372 (40.9%) ^{B C}
Family history of CHD	234 (42.3%)	160 (50.7%) ^{A C D}	404 (43.0%) ^A	390 (44.6%) ^{A C}
Smoking	146 (29.9%) ^{B C D}	69 (24.1%) ^C	197 (20.9%)	242 (24.1%) ^C
Women after menopause	153 (63.2%)	159 (95.5%) ^{A C D}	422 (93.3%) ^{A D}	405 (89.5%) ^A

*Risk factors include: vascular disease, diabetes mellitus, age \geq 65 years.

Data are presented as mean (median) or number (percentage).

Statistically significant difference ($p < 0.05$) is marked with a capital letter in superscript corresponding to the column name.

BP — blood pressure; CABG — coronary artery bypass grafting; CHD — coronary heart disease; HDL — high density lipoprotein; LDL — low density lipoprotein; MI — myocardial infarction; PCI — percutaneous coronary intervention; PTCA — percutaneous transluminal coronary angioplasty; TIA — transient ischaemic attack

Table 2. The use of lipid lowering drugs in Poland

	All patients (n = 2812)	Mean daily dose
Statins	89.6%	–
Rosuvastatin	27.8%	15.9 mg
Atorvastatin	47.8%	25.7 mg
Fluvastatin	0.0%	20 mg
Lovastatin	0.1%	26.2 mg
Pravastatin	0.1%	20 mg
Simvastatin	13.8%	24.5 mg
Fenofibrate	5.8%	202.5 mg
Ciprofibrate	0.0%	100 mg
Cholestyramine	0.0%	–
Niacin	0.0%	200 mg
Ezetimibe	2.7%	10.7 mg
Other	0.2%	–
No treatment	7.1%	–

Little is known about the lipid-lowering prescription rates in Poland. One of the few studies regarding this subject has shown that only 12% of the population of patients treated with statins demonstrate a proper level of compliance and persistence [14]. One of the presumed reasons for non-adherence is a lack of proper patient education, thus all patients on statin treatment should receive sufficient attention, supervision, and better information.

In the present study, approximately 7% of patients were not treated with any lipid-lowering drug and 10% did not receive statins. This number is relatively low, taking into account contraindications for lipid-lowering drugs and statin intolerance. Moreover, it can be assumed that a significant fraction of the patients not treated with statins could be elderly. Cardiovascular risk prevention in this group is controversial. Evidence supporting effectiveness in the patients > 80 years of age is limited, and a recent trial suggested no harm in stopping statins in the elderly with a limited life expectancy [15, 16]. Nevertheless, the present study did not provide any data on the adherence and persistence, which are needed for full assessment of the drug's use in Poland.

Underutilisation and potential non-adherence for lipid-lowering therapy may be among the reasons for poor control of risk factors. A study that aimed to assess the achievement of treatment goals for cardiovascular risk factors among patients showed that among treated dyslipidaemia patients only 41.2% attained both the total cholesterol and LDL-C targets of < 5 mmol/L and < 3 mmol/L [17].

CONCLUSIONS

The most commonly used lipid-lowering drugs in Poland are statins, with atorvastatin and rosuvastatin being used the most often. The present study shows that some patients with LDL-C concentration > 70 mg/dL and indication for lipid-lowering are not treated accordingly. This is regardless of the treatment for primary or secondary prevention of CVD or dyslipidaemia. Cardiovascular risk factors that remain uncontrolled and lifestyle counselling are not well implemented, not only in

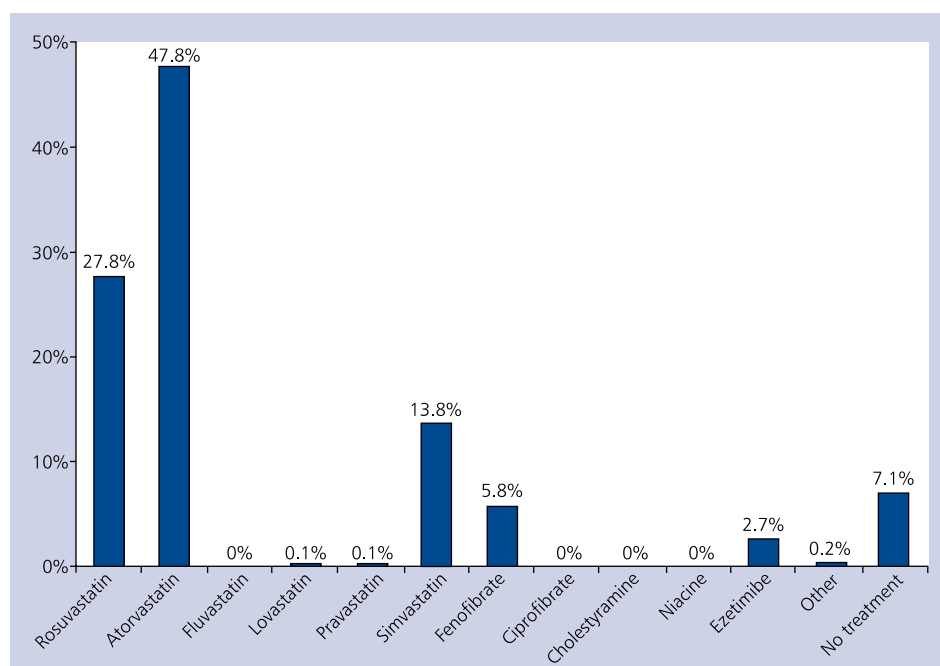
**Figure 1.** Prescription of lipid-lowering drugs in Poland

Table 3. The use of lipid lowering drugs according to cardiovascular risk factors

	Patients without the risk factors* (A)	Patients with all 3 risk factors* (B)	Patients with 2 out of the 3 risk factors* (C)	Patients with 1 out of the 3 risk factors* (D)
Statins	434 (92.6%)	344 (93.7%) ^{A C}	856 (93.4%) ^A	886 (94.7%) ^{A C}
Rosuvastatin	173 (33.3%) ^{B C D}	89 (24.2%) ^{C D}	247 (26.4%) ^D	273 (27.6%)
Atorvastatin	211 (40.3%)	201 (57.1%) ^{A C D}	483 (56.0%) ^{A D}	450 (49.3%) ^A
Fluvastatin	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lovastatin	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)
Pravastatin	1 (0.1%) ^D	1 (0.1%) ^{A D}	0 (0.0%)	1 (0.1%)
Simvastatin	49 (9.6%)	53 (13.3%) ^{A C}	124 (12.7%) ^A	161 (20.1%) ^{A B C}
Fenofibrate	38 (9.1%) ^{B C D}	17 (4.6%) ^D	47 (6.0%) ^{B D}	62 (3.9%)
Ciprofibrate	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Cholestyramine	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Niacin	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Ezetimibe	25 (1.3%) ^{B C D}	12 (1.3%) ^{C D}	20 (0.6%)	19 (0.9%) ^C
Other	3 (0.6%) ^{C D}	0 (0.0%)	3 (0.1%) ^D	1 (0.1%)
No treatment	47 (7.4%) ^{B C D}	17 (6.3%) ^D	61 (6.6%) ^{B D}	76 (5.3%)

*Risk factors include: vascular disease, diabetes mellitus, age \geq 65 years. Data are presented as numbers (percentages). Statistically significant difference ($p < 0.05$) is marked with a capital letter in superscript corresponding to the column name.

Table 4. Comparison of patients who did or did not achieve target low-density lipoprotein (LDL) cholesterol levels

	Patients who achieved target LDL levels	Patients who did not achieve target LDL levels
Atherosclerosis	76 (19.7%)	1039 (43.1%)
Peripheral artery disease	17 (4.4%)	279 (11.6%)
Coronary artery disease	76 (19.7%)	1219 (50.6%)
History of myocardial infarction	13 (3.4%)	638 (26.5%)
History of unstable angina	12 (3.1%)	264 (11.0%)
History of stroke	11 (2.8%)	188 (7.8%)
History of TIA	21 (5.4%)	170 (7.1%)
History of CABG	3 (0.8%)	173 (7.2%)
History of PTCA	17 (4.4%)	576 (23.9%)
Arterial hypertension	319 (82.6%)	2093 (86.8%)
Atrial fibrillation	55 (14.2%)	440 (18.3%)
Heart failure	40 (10.4%)	444 (18.4%)
Abdominal aorta aneurysm	3 (0.8%)	42 (1.7%)
Other cardiovascular disease	9 (2.3%)	55 (2.3%)
History of peripheral revascularisation	5 (1.3%)	72 (3.0%)
History of amputation due to atherosclerosis	2 (0.5%)	8 (0.3%)
Type 1 diabetes	3 (0.8%)	43 (1.8%)
Type 2 diabetes	105 (27.2%)	1125 (46.7%)
Chronic kidney disease	16 (4.1%)	286 (11.9%)
Microalbuminuria	7 (1.8%)	161 (6.7%)
Hepatitis type C	1 (0.3%)	12 (0.5%)
Risk factors:		
Inactive lifestyle	212 (54.9%)	1487 (61.7%)
Diet rich in saturated fatty acids	129 (33.4%)	906 (37.6%)
Family history of CHD	130 (33.7%)	1054 (43.7%)
Smoking	75 (19.4%)	575 (23.9%)
Women after menopause	73 (18.9%)	446 (18.5%)

Data are presented as number (percentage). CABG — coronary artery bypass grafting; CHD — coronary heart disease; PTCA — percutaneous transluminal coronary angioplasty; TIA — transient ischaemic attack

Poland but also across Europe. Therefore, more effort should be made regarding the education of patients and improvement of prescription rates.

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