# **ORIGINAL ARTICLE**

# Detection and treatment of hypercholesterolemia in primary health care

Results of the POLKARD program of the Ministry of Health of the Republic of Poland

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# **KEY WORDS**

# ABSTRACT

cardiovascular disease, hypercholesterolemia, intervention, prevention program

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**INTRODUCTION** About 90% of Polish adults with hypercholesterolemia are not aware of their disease or are not treated.

**OBJECTIVES** The aim of the study was to evaluate hypercholesterolemia control in general practice and to assess the implications of introducing the nationwide Program of Cardiovascular Disease Prevention (PCVDP).

**PATIENTS AND METHODS** Sixty-six primary care clinics were scheduled to participate in the study. In half of them, PCVDP was implemented (active clinics), the remaining 33 constituted the control group. Study participants were selected from a group of persons aged 35–55 years with medical records established before January 1, 2005. Patients with coronary heart disease, stroke, or peripheral atherosclerosis were excluded. In a random sample of patients scheduled for the study, medical records were reviewed followed by an interview, physical examination, and blood lipid tests.

**RESULTS** The availability of data on total cholesterol (TC) levels increased from 19.2% to 40.5% in patients from the active clinics and did not change in the control group. Hypercholesterolemia treatment was reported more often in the active clinics than in the control group (4.4% and 3.3%, respectively, P < 0.01). Patients from the active clinics more often reported that a physician informed them about increased TC levels compared with the control group (29.1% and 24.1%, respectively, P < 0.01). However, the percentage of patients with increased TC or low-density lipoprotein cholesterol levels and those using statins did not differ between the study groups.

**CONCLUSIONS** PCVDP is an effective tool to identify subjects with hypercholesterolemia but has no effect on the rate of achieving the recommended treatment targets.

**INTRODUCTION** Cardiovascular disease (CVD) is the leading cause of death and one of the most common causes of disability in Europe.<sup>1</sup> Thus,

the main objective outlined by the World Health Organization (WHO) in the Cardiovascular Disease Programme and by the European Society of Cardiology in the European Guidelines on CVD Prevention in clinical practice is an effective control of CVD risk factors.<sup>2,3</sup> The WHO Health Report showed that approximately 80% of the cases of heart disease and stroke could be avoided if the most important risk factors were eliminated.<sup>4</sup> Also in Poland, there is a growing interest in effective prevention and control of the major risk factors to reduce CVD morbidity and mortality.<sup>5,6</sup>

It is known that lowering total cholesterol (TC) levels by 10% causes a reduction in the incidence of coronary heart disease by 25% in 5 years, and reducing low-density lipoprotein (LDL) cholesterol by 1 mmol/l is associated with a 20% lower incidence of exacerbations in ischemic heart disease.<sup>7,8</sup> In Poland, about 70% of men and women adults have hypercholesterolemia. According to the results of the WOBASZ Project about 90% of persons with hypercholesterolemia were not treated or were even unaware of their condition. Only 2% to 3% of patients with hypercholesterolemia were treated effectively.9 Similar proportions were found in the NATPOL 2011 Project.<sup>10,11</sup> Considering the large prevalence of hypercholesterolemia, it seems rational to address this problem to primary care physicians. They take care of the vast majority of the general population covered by the public health insurance and have the ability to identify high-risk persons, to whom no other institution of the health system has access. If primary care physicians were properly trained, they could effectively treat patients with hypercholesterolemia.

The European Guidelines on CVD Prevention provide recommendations for physicians on the detection and management of dyslipidemia in clinical practice, including: the desired goals of treatment, the recommended lifestyle modifications, medications used to treat dyslipidemia, and the recommended procedure for various groups of patients and methods to improve collaboration with patients in the modification of health behaviors.<sup>3</sup>

In 2004, the National Health Fund in Poland introduced the Program of Cardiovascular Disease Prevention (PCVDP). This program included extensive screening in primary health care clinics, which aimed to identify persons with hypercholesterolemia, and then to provide appropriate care over high-risk patients, who were referred to primary care physicians.<sup>12</sup> In 2008, the Polish Forum for Prevention of Cardiovascular Diseases published the guidelines on screening for dyslipidemia in different groups of patients and guidelines for the management of dyslipidemia based on the assessment and control of all major risk factors.<sup>13</sup> The guidelines of the Polish Forum for Prevention were available for the majority of physicians in Poland as they were published in scientific journals (organs of the scientific societies belonging to the Forum) and in the Bulletin of the Polish Forum for Prevention, which was distributed with Gazeta Lekarska - the journal of the Polish Medical Corporation.<sup>14,15</sup> However,

there was no information available on whether this activity improved the quality of medical care in the management of hypercholesterolemia.

In 2007–2008, the Task Group for CVD Prevention of the POLKARD Program of the Polish Ministry of Health initiated a study that aimed to assess the quality of medical care in the primary prevention of CVD in primary health care clinics and to assess the impact of the PCVDP.

The aim of this paper was to evaluate the effectiveness of hypercholesterolemia control in general practices and to assess the implications of PCVDP introduction.

**PATIENTS AND METHODS** Study population and methods were described elsewhere.<sup>16</sup> Brief information necessary for this publication is given below.

In each of the 16 Polish provinces, at least 2 primary care clinics were recruited. Half of them participated in the PCVDP (active clinics). The remaining half were included in the control group (control clinics). In each clinic, persons aged from 35 to 55 years (age limit for PCVDP), without coronary heart disease, stroke, or peripheral atherosclerosis in the interview and who had medical records established before January 1, 2005, were considered for the study. All patients included in the study group obtained comprehensive information on the study and signed informed consent for participation. The study was conducted in 2 stages. In the first stage, medical records were reviewed. Data on CVD risk factors and pharmacotherapy was obtained for the period before the introduction of PCVDP (prior to January 1, 2006), during the implementation of PCVDP, and after PCVDP. In the second stage, all selected eligible patients were invited for the examination. Interviews were carried out by trained interviewers using a standard questionnaire. Data on the prevalence and knowledge of CVD risk factors, lifestyle, and also on the frequency of counseling on CVD prevention by health care professionals were collected. Knowledge of risk factors was assessed using the open question: "Can you name any factors that increase the risk of myocardial infarction?" The answers were classified by the interviewers according to a preprepared list of risk factors. Blood lipids and glucose were analyzed in the local laboratories using the local methods. However, during recruitment of the clinics only laboratories that had an internal quality control system and participated in an external quality control program were accepted. Hypercholesterolemia was defined as having TC ≥5mmol/l or LDL cholesterol  $\geq$  3mmol/l.

All data collected were coded online, added to the central computer database, and subjected to immediate quality control. Differences between studied groups (active vs. control clinics) were adjusted for age, sex, and the clustering effect of clinics. The analysis was conducted using the GLIMMIX procedure with the SAS v. 9.1 statistical software.

TABLE 1	Distribution o	t the study	groups l	by sex,	age, and	education
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			Active clinics ( $n = 3940$ )		Control clinics ( $n = 3162$ )		
			%		%		
eligible		3940		3162			
men		1794	45.5	1380	43.6	0.12	
age, y	35–45	2046	51.9	1663	52.6	- 0.58	
	46–55	1894	48.07	1499	47.4		
final examination participants		2314		2107			
men		956	41.3	847	40.2	0.48	
age, y	35–45	1152	49.8	1058	50.2	- 0.78	
	46–55	1162	50.2	1049	49.8		
education	primary or vocational	623	27.1	451	21.6	_	
	secondary	1274	55.4	1128	54.0	<0.001	
	university	404	17.6	512	24.5		

**RESULTS** The study was conducted in 66 clinics, of which 33 were in the group of active clinics. The remaining clinics were included to the control group. Of all patients registered in the clinics, 7102 persons who met the eligibility criteria were randomly selected for the study (patients of the active clinics, 55.5% [n = 3940]; patients of the control clinics, 44.5% [n = 3162]). The number of respondents differed by province. The lowest number of persons were recruited in the Pomerania Province (n = 308), and the highest number in the Małopolska Province (n = 645). Review of medical records was made in the entire group and the final examination was completed in 4421 patients (62.3%).

In the group of the active clinics, 2314 persons were examined, of whom 713 patients were offered participation in the PCVDP. Eventually, 647 persons took part in the program. In the control clinics, 2107 persons attended the final examination.

The highest number of patients were examined in the Łódź Province (n = 394) and the lowest in the Warmia-Masuria Province (n = 157). The highest participation rate was reported in the Pomerania Province (87.3%) and the lowest in the Mazovia Province (40.6%).

The characteristics of the study participants by sex and age in all those eligible for the study, and also by sex, age, and education among participants of the final examination are shown in TABLE 1. No significant differences in age and sex distribution between patients in the active and the control clinics were observed. A slightly higher level of education was found in the control group in the final examination.

The proportion of persons who had data on blood lipids and hypercholesterolemia treatment in medical records is presented in TABLE 2. Before PCVDP, data on TC was available more often than on other blood lipids. There was no significant difference between the active and control clinics in the frequency of providing information on blood lipids in medical records. After PCVDP, in the active clinics the proportion of patients with information on blood lipids increased from 19.2% to 40.5% for TC, from 8.4% to 35.9% for LDL-C, and from 9.2% to 36.8% for high-density lipoprotein

		Active clinics $(n = 3940)$		Control clinics ( $n = 3162$ )		Р	
		%ª	95% CI	%ª	95% CI		
	TC	19.2	15.5–23.5	18.1	14.5-22.3	0.25	
before PCVDP	LDL-C	8.4	7.6–9.4	8.6	7.6–9.6	0.81	
	HDL-C	9.2	7.3–11.5	8.4	6.6–10.7	0.26	
	hypercholesterolemia treatment	4.4	3.5–5.7	3.3	2.5–4.4	<0.01	
after PCVDP	TC	40.5	38.9-42.1	15.2	14.0-16.5	< 0.001	
	LDL-C	35.9	34.4–37.5	8.5	7.5–9.5	<0.001	
	HDL-C	36.8	35.3–38.3	8.9	8.0–10.0	< 0.001	
	hypercholesterolemia treatment	10.3	9.4–11.4	5.9	5.2–6.8	<0.001	

 TABLE 2
 Proportion of persons who had information on blood lipids and hypercholesterolemia treatment in medical records

a adjusted for age, sex, and design effects

Abbreviations: CI – confidence interval, HDL-C – high-density lipoprotein cholesterol, LDL-C – low-density lipoprotein cholesterol, PCVDP – Program of Cardiovascular Disease Prevention, TC – total cholesterol

**TABLE 3** Percentage of persons who indicated lipid disorders as a risk factor for cardiovascular disease according to the study group, participation in the Program of Cardiovascular Disease Prevention and in groups of exposure to elevated cholesterol levels

		%ª	95% CI	Р
active clinics (n = $2314$ )	472	19.5	16.1-23.5	0 022
control clinics (n = $2107$ )	489	23.4	19.5–28.4	- 0.023
registered in active clinics taking part in prevention program	158	21.0	16.1–26.9	0.44
registered in active clinics not taking part in prevention program	314	19.3	15.2–24.3	- 0.44
patients with hypercholesterolemia <sup>b</sup> ( $n = 489$ )	107	19.4	13.7–26.6	0.27
patients with no hypercholesterolemia <sup>b</sup> ( $n = 257$ )	46	16.1	10.6–23.8	- 0.27

a adjusted for age, sex and design effects

**b** hypercholesterolemia if TC  $\geq$ 5 mmol/l or LDL-C  $\geq$ 3 mmol/l

Abbreviations: see TABLE 2

 TABLE 4
 Participation in the Program of Cardiovascular Disease Prevention by total cholesterol in the final examination (only active clinics)

	$\text{TC} \geq \!$	TC ≥5 mmol/l (n = 1465)			TC <5 mmol/l (n = 825)		
		%ª	95% Cl		% <sup>a</sup>	95% CI	
offered to participate in the program	486	27.2	12.6–49.3	237	25.2	11.3–46.8	0.34
completed the program	352	78.4	58.7–90.3	188	81.2	61.7–92.1	0.49
refused to participate	41	8.2	3.5–17.8	15	5.7	2.2–14.1	0.26

Abbreviations: see TABLE 2

cholesterol. During the period prior to the implementation of PCVDP, data on hypercholesterolemia treatment had been recorded more often in the active clinics compared with the control group (4.4% vs. 3.3%, respectively, P < 0.01). During follow-up, this percentage increased up to 10.3% in the active clinics and only to 5.3% in the control group.

Knowledge on blood lipids as a CVD risk factor was slightly more frequent in the control clinics than in the active clinics (23.4% vs. 19.5%, respectively, P < 0.05). In the group of the active clinics, there was no significant difference in the rate of recognizing dyslipidemia as a CVD risk factor between those who participated and those who did not participate in the PCVDP. There was also no significant difference between the groups of patients with and without hypercholesterolemia (TABLE 3).

Among patients from the active clinics, 27.2% of the respondents with TC levels of 5 mmol/l or lower and 25.2% of those with cholesterol levels below the treatment target were offered to participate in the prevention program (nonsignificant difference). The PCVDP was completed approximately by 80% of all the invited participants, regardless of blood cholesterol levels, but overall it was only 16% of all patients registered in the active clinics (TABLE 4).

The use of particular components of PCVDP, i.e., information materials (leaflets), the lifestyle intervention and check-up did not differ by the TC level. However, compared with patients with TC below treatment target, patients with high TC had blood lipids measured more frequently (87.4% and 91.7%, respectively, P < 0.01).

Patients of the active clinics had medical consultations for increased TC more frequently as compared with the control group (90.9% and 86.3%, respectively, P < 0.01). There were no significant differences in the frequency of counseling by a nurse or by a dietician between the active and control clinics. In both clinics, most consultations were provided by doctors and only about 20% of the patients received advice from other professional groups (TABLE 5).

TABLE 6 shows the prevalence of elevated TC, LDL cholesterol, frequency of statin use, and the frequency of information on increased TC levels received from physicians. In both groups, approximately 65% of the patients had increased TC and about 60% had increased LDL cholesterol levels. There were no significant differences in the proportion of patients with elevated TC and proportion of statin use between the active and the control clinics. However, patients from the active clinics reported that the doctor had told them about increased blood cholesterol more frequently, compared with patients from the control clinics (29.1% and 24.1%, respectively, *P* <0.001).

**DISCUSSION** The results of the present paper indicate that the standard primary health care is ineffective in controlling hypercholesterolemia. Information on TC and hypercholesterolemia treatment is rarely included in medical records by physicians. The introduction of PCVDP contributed to a significant increase in the availability of data on blood lipids and treatment, but had no impact on

TABLE 5 Medical staff who provided information on how to deal with elevated cholesterol levels

	Active clinics ( $n = 1061$ )			Control	Control clinics ( $n = 627$ )		
		%ª	95% CI		% <sup>a</sup>	95% CI	
physician	939	90.9	87.1–93.7	519	86.3	80.5–90.6	<0.01
nurse or dietician	347	20.4	10.8–35.2	222	21.9	11.6–37.6	0.50

a adjusted for age, sex, and design effects

Abbreviations: see TABLE 2

TABLE 6 Prevalence of elevated cholesterol, statin use, and the information provision about high cholesterol

	Active clinics ( $n = 2314$ )			Control c	= 2107)	Р	
		%ª	95% CI		%a	95% CI	
TC ≥5 mmol/l	1465	64.5	62.5–66.5	1360	66.0	63.9–68.1	0.23
LDL-C ≥3 mmol/l	1323	58.0	55.9–60.0	1285	62.2	60.0–64.3	0.07
use of statins	107	3.1	2.3–4.2	96	2.9	2.1–4.0	0.76
information from a doctor about high cholesterol	688	29.1	24.9–33.6	541	24.1	20.4–28.4	< 0.001

a adjusted for age, sex, and design effects

Abbreviations: see TABLE 2

the effectiveness of treatment in the active clinics. Doctors took the main burden of the intervention, while involvement of other professional groups was rather limited. In the active clinics, few people were invited for PCVDP. Patients of the active clinics were more often informed by their physician about increased TC. However, still about 80% of the respondents did not indicate lipid disorders as a CVD risk factor. It is likely that even when patients are informed about increased TC levels, they do not pay enough attention to the implications for CVD and to the need of treatment.

There are some limitations in the interpretation of the presented results, mainly related to the method of sample selection. The study was nationwide and typical clinics were included to the studied groups, but recruitment of primary care clinics depended first on the applicability of the procedures related to the research and second on the consent of the head of the clinic. This selection did not meet the criteria of a random selection and therefore these results should not be generalized to the whole country. It is possible that clinics having difficulties with the implementation of PCVDP did not agree to be included in the study. Therefore, it is likely that the effectiveness of hypercholesterolemia control in the whole country may be even worse than the results indicate. The age of the study group was limited according to PCVDP requirements so using conclusions from this study to other age groups is not legitimate. Moreover, the major part of the presented analysis was conducted using the data from the final examination, in which the participation rate was low (62%). It should be noticed, however, that the percentage of persons with high TC in the final examination (65%) corresponded to the results obtained in the nationwide WOBASZ

Project and NATPOL 2011 Project, which examined a representative sample of the Polish population with higher participation rates.<sup>9,10</sup>

The low percentage of participants who indicated lipid disorders as a CVD risk factor could be partially explained by the way the question was asked. The open question was used to verify more profound knowledge. It is likely that if participants could choose the correct answer from the preprepared list in a closed question the proportion would be higher.

The results indicate that in the majority of patients physician counseling was the only tool used to intervene in blood lipids although doctors were free to apply other methods of intervention. Numerous studies reported that more effective achievement of hypercholesterolemia treatment targets was observed when the patient was under the care of a multidisciplinary team.<sup>17-19</sup> For example, the international EuroAction program showed that the intervention carried out by specialized nurses contributed to an increase in the proportion of persons achieving the hypercholesterolemia treatment target after 1 year.<sup>20</sup> Also the literature review published in 2011 provided evidence that the nurses coordinating systematic, multidisciplinary programs were effective in reducing CVD risk factors.<sup>21</sup>

Medical consultation is important but insufficient to induce a permanent lifestyle change and only a long-term lifestyle change can contribute to the effective treatment of dyslipidemia. The process of lifestyle change should not only deliver knowledge but also shape attitudes, increase motivation, and develop practical skills.<sup>22</sup> Information about the need to change one's behavior, for example to reduce the consumption of animal fat, must be supported by teaching practical skills, for example, how to cook without using such fat, and reinforcing beliefs, for example, that it is worth trying new cuisine. Considering time limitations in clinical practice, it seems obvious that visiting a general practitioner is not the best way to achieve a change in lifestyle. The recommendation to address the problem to interdisciplinary groups seems to be rational.

In conclusion, it should be strongly emphasized that the PCVDP was an effective tool in identifying persons with hypercholesterolemia. On the other hand, the effectiveness of treatment of high-risk individuals identified in the PCVDP was unsatisfactory. The methods of intervention in the PCVDP should be improved or replaced by the practices that would contribute to a reduction in the proportion of persons with dyslipidemia.

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**APPENDIX** Study group of the project "Organization of the regional reference centers for cardiovascular disease prevention within the high-risk strategy; introduction of methods of assessment of quality control and effectiveness of prevention programs" counducted within the framework of the POLKARD Program of the Ministry of Health of the Republic of Poland.

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# Wykrywanie i postępowanie w hipercholesterolemii w podstawowej opiece zdrowotnej

Wyniki badania zrealizowanego w ramach Programu Ministerstwa Zdrowia POLKARD

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### SŁOWA KLUCZOWE STRESZCZENIE

choroby układu krążenia, hipercholesterolemia, interwencja, program prewencji

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**WPROWADZENIE** Około 90% dorosłych Polaków z hipercholesterolemią nie jest świadomych występowania u nich tego stanu lub nie podejmuje leczenia.

**CELE** Celem badania była ocena skuteczności postępowania w hipercholesterolemii w podstawowej opiece zdrowotnej oraz ocena skutków wdrożenia Programu Profilaktyki Chorób Układu Krążenia (PPChUK).

**PACJENCI I METODY** Do badania zakwalifikowano 66 przychodni podstawowej opieki zdrowotnej. W połowie z nich wdrożono PPChUK, pozostałe 33 stanowiły grupę kontrolną. Uczestników badania wylosowano z grupy osób w wieku 35–55 lat, z dokumentacją medyczną założoną przed 1 stycznia 2005 r. Wykluczono osoby z chorobą wieńcową, udarem mózgu i miażdżycą tętnic obwodowych w wywiadzie. W losowej próbie chorych zakwalifikowanych do badania dokonano przeglądu dokumentacji medycznej, a następnie przeprowadzono wywiad, badanie przedmiotowe i pomiar stężenia lipidów w surowicy.

WYNIKI Dostępność informacji o stężeniu cholesterolu całkowitego (*total cholesterol* – TC) wzrosła z 19,2 do 40,5% u pacjentów przychodni realizujących PPChUK i nie zmieniła się w grupie kontrolnej. Leczenie hipercholesterolemii częściej odnotowywano w przychodniach realizujących PPChUK niż w przychodniach z grupy kontrolnej (odpowiednio 4,4% i 3,3%; p <0,01). Pacjenci z przychodni realizujących PPChUK częściej niż chorzy z grupy kontrolnej zgłaszali, że lekarz poinformował ich o zwiększonym stężeniu cholesterolu (odpowiednio 29,1% i 24,1%; p <0,01). Odsetki osób ze zwiększonym stężeniem TC lub cholesterolu frakcji lipoprotein o małej gęstości oraz osób stosujących statyny nie różniły się w badanych grupach. WNIOSKI PPChUK jest skutecznym narzędziem służącym do identyfikacji osób z hipercholesterolemią, nie wpływa jednak na częstość osiągania zalecanych celów leczenia.

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