Ewa Laskowska[1] , Piotr Michalski[2] , Łukasz Pietrzykowski[2], Michał Kasprzak[1], Agata Kosobucka[2], Klaudyna Grzelakowska[3], Krzysztof Buczkowski[4], Piotr Jankowski[5], Zbigniew Gąsior[6], Dariusz Kosior[7], Karol Kamiński[8], Aldona Kubica[2]

[1]Department of Cardiology and Internal Medicine, Collegium Medicum, Nicolaus Copernicus University, Bydgoszcz, Poland
[2]Department of Health Promotion, Collegium Medicum, Nicolaus Copernicus University, Bydgoszcz, Poland
[3]Faculty of Medicine, Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University, Bydgoszcz, Poland
[4]Department of Family Medicine, Nicolaus Copernicus University, Torun, Poland
[5]Department of Epidemiology and Health Promotion, School of Public Health, Centre of Postgraduate Medical Education, Warsaw, Poland
[6]Department of Cardiology, Medical University of Silesia, Katowice, Poland
[7]Department of Cardiology and Hypertension with Electrophysiological Lab, Central Research Hospital the Ministry of the Interior and Administration, Warsaw, Poland
[8]Department of Population Medicine and Civilization Diseases Prevention, Medical University of Bialystok, Poland

Implementation of therapeutic recommendations in high cardiovascular-risk patients. The Polish population of EUROASPIRE V survey

Corresponding author:

Ewa Laskowska, Department
of Cardiology and Internal Medicine,
Collegium Medicum, Nicolaus
Copernicus University, Bydgoszcz,
Poland,
e-mail: ewa.laskowska@cm.umk.pl

ABSTRACT:

Introduction: Poor medication adherence is associated with unsatisfactory health outcomes, elevated mortality, and high costs of medical care. This study aimed to assess the implementation of therapeutic recommendations in high cardiovascular-risk patients based on self-report questionnaires.

Material and methods: The study included 194 patients from the Cardiology Outpatient Clinic. Two self-reported questionnaires were used to assess medication adherence: the Medication Adherence Questionnaire (MAQ) and the Adherence in Chronic Diseases Scale (ACDS).

Results: Antihypertensive drugs were prescribed to 65.46% of the patients. According to the MAQ, 54.33% of them reported high adherence, 21.26% medium adherence, and 24.41% low adherence to the treatment. Lipid-lowering drugs were prescribed to 46.39% of the patients, all of whom were treated with statins. Among this group, 34.44% reported high adherence, 27.78% medium adherence, and 37.78% low adherence to pharmacotherapy. According to the ACDS, the majority of patients (45.55%) received a score indicating medium adherence (21–26 points), 39.27% high adherence (> 26 points), and 16.75% low adherence to treatment (< 21 points). A high level of adherence was declared by 61.54% of the patients that reached the therapeutic goal of lipid-lowering therapy, defined as LDL-C of < 2.6 mmol/L (< 100 mg/dL). On the other hand, among the patients whose LDL-C remained elevated, 23.44% declared high adherence to treatment. There were no significant differences in achieving the intended therapeutic goal of blood pressure (BP ≤ 140/90 mmHg) in the groups with high, medium and low adherence (26.53% *vs.* 23.47% *vs.* 50.00%; p = 0.1880).

Conclusion: Despite higher adherence to treatment in the patients with hypertension compared to patients with hyperlipidemia, the latter more often achieved the therapeutic goal. Declarations regarding high adherence to medication in the MAQ and in the ACDS are consistent in patients with hyperlipidemia and hypertension.

Key words: adherence, self-report questionnaires, hyperlipidemia, hypertension

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Introduction

Poor medication adherence is associated with unsatisfactory health outcomes, elevated mortality, and high costs of medical care [1, 2]. According to various studies, 30% to 50% of patients do not adhere to medical recommendations [3–8]. In secondary prevention of myocardial infarction, the adherence to pharmacotherapy decreases over time, for nearly all classes of drugs [3, 13]. The pharmacotherapy of hypertension, dyslipidemia, and diabetes reduces the risk of cardiovascular events [9]; yet, adherence to preventive pharmacotherapy is even lower compared to secondary prevention [9–12]. In a meta-analysis comparing adherence to pharmacotherapy of coronary heart disease in primary *vs.* secondary prevention, Naderi et al. [12] reported an adherence rate of 50% (CI, 45–56) and 66% (CI, 56–75), respectively (p = 0.012). Overall, the adherence in the study was 57% during a median treatment of 24 months [12].

A number of validated medication-adherence scales have been described in the literature [8, 13–15]. These scales, based on self-reported questionnaires, are low-cost and easy to use in routine clinical practice [8].

This study aimed to assess the implementation of therapeutic recommendations in a group of patients treated for hypertension, hyperlipidemia, and/or diabetes with the use of two self-report questionnaires.

Material and methods

The data were collected as a part of the EUROASPIRE V survey, a prospective observational study conducted between 2016 and 2017 in European countries. The study included 200 patients (66.50% women and 33.50% men), with a mean age of 51.49 years, from the Cardiology Outpatient Clinic of the Department of Cardiology and Internal Medicine of the University Hospital No. 1 in Bydgoszcz, Poland. The following inclusion criteria were applied: adult (18–80 years old), diagnosed with hypertension, hyperlipidemia or diabetes, without documented cardiovascular diseases. All the patients provided written informed consent. Baseline characteristics of the patient population are presented in Tables 1 and 2.

The final analysis comprised 194 patients treated with one or more medications for a period of 6–24 months (lipid-lowering drugs, antihypertensive drugs, oral antidiabetic medicines, and/or insulin). Six of the patients were treated with a diet for diabetes, and therefore were excluded from the analysis.

Questionnaires

Two self-reported questionnaires were used to assess medication adherence: the Medication Adherence Questionnaire (MAQ) and the Adherence in Chronic Diseases Scale (ACDS) [13–15].

In the MAQ, the patients were asked to answer the question "How often do you take your medications as

Table 1. Characteristics of the study population

Parametr	Mean	SD	Median	Q1	Q3	Min	Max
Age [years]	51.49	13.63	52.00	43.00	60.00	20.00	81.00
SBP [mmHg]	127.23	14.47	125.00	118.00	135.00	97.00	183.00
DBP [mmHg]	76.52	9.32	77.50	70.00	82.00	54.00	100.00
Waist circumference [cm]	88.01	12.20	87.00	80.00	95.50	54.00	126.00
Height [cm]	169.47	9.62	169.50	162.00	176.00	147.00	200.00
Weight [kg]	75.77	14.79	74.00	64.75	86.00	44.00	118.00
BMI [kg/m2]	26.35	4.06	26.00	23.90	28.73	17.10	42.20
T-CH [mg/dL]	217.42	41.78	214.85	190.84	241.69	105.60	344.50
LDL-CH [mg/dL]	129.09	38.13	127.10	103.80	154.55	42.20	253.00
TG [mg/dL]	121.04	71.32	106.80	79.96	137.50	40.20	630.90
Glucose [mg/dL]	100.60	19.74	97.60	90.75	106.35	52.20	207.70
ACDS — score	24.35	3.67	25.00	22.00	28.00	12.00	28.00

ACDS — Adherence in Chronic Diseases Scale; BMI — body mass index; DBP — diastolic blood pressure; LDL-CH — low-density lipoprotein cholesterol; SBP — systolic blood pressure; SD — standard deviation; T-CH — total cholesterol; TG — triglyceride

Table 2. Qualitative variables in the study population

Parameter	Count	Percent
Gender (female/male)	133/67	66.5/33.5
Hypertension	127	63.5
Hyperlipidemia	90	45
Diabetes	41	20.5
Smoking	76	38
Any pharmacotherapy	194	97
Antihypertensive drugs	127	63.5
Lipid-lowering drugs	90	45
Hypoglycemic drugs	34	17

Table 3. Distribution of adherence levels according to the MAQ in the study population

MAQ levels	Count	Percent
MAQ hypertension (n = 127)		
Low level	31	24.41
Medium level	27	21.26
High level	69	54.33
MAQ hyperlipidemia (n = 90)		
Low level	34	37.78
Medium level	25	27.78
High level	31	34.44
MAQ diabetes mellitus (n = 34)		
Low level	18	52.94
Medium level	3	8.82
High level	13	38.24

prescribed by the doctor. Based on their response, they were then classified into one of three groups depending on the level of adherence: high (taking medication 100% of the time as prescribed), medium (90% of the time), low (75% of the time or less).

Another tool used to evaluate adherence to pharmacotherapy was the ACDS. This scale consists of 7 questions relating to behaviors influencing adherence, either directly (questions 1–5) or indirectly (questions 6 and 7). The maximum score in the ACDS is 32 points. A score above 26 points indicates high adherence, while a score under 21 points indicates low adherence; the remaining score range of 21–26 points is classified as medium adherence [13–15].

Statistics

The statistical analysis was carried out using the Statistica 13.0 package (TIBCO SoftwareInc, California, USA). Continuous variables were presented as means with standard deviations, medians with interquartile range, minimum and maximum value. The Shapiro-Wilk test demonstrated the non-normal distribution of the investigated continuous variables.

Therefore, non-parametric tests were used for statistical analysis. For comparisons of ACDS scores and MAQ levels, the Kruskal-Wallis one-way analysis of variance and a multiple comparison test was used. Categorical variables were expressed as counts and percentages. Categorical variables were compared using the χ^2 test. Results were considered significant at $p < 0.05$.

Results

Among 200 patients included in the study, there were 127 cases of hypertension, 90 of dyslipidemia, and 41 of diabetes. The clinical and anthropometric data of the study population are shown in Tables 1 and 2.

Antihypertensive drugs were prescribed to 65.46% of patients. The most common medications were angiotensin-converting enzyme inhibitors (ACEI; 45.50%), followed by beta-adrenolytics (20%), calcium channel blockers (7%), angiotensin receptor blockers (ARBs; 7%), and diuretics (4.5%). According to the MAQ, 54.33% of the patients on antihypertensive drugs reported high adherence, 21.26% medium adherence, and 24.41% low adherence to the treatment. Lipid-lowering drugs were prescribed to 46.39% of the patients, all of whom were treated with statins. Among this group, 34.44% reported high adherence, 27.78% medium adherence, and 37.78 % low adherence to pharmacotherapy. Antihyperglycemic drugs were prescribed to 17.53% of the patients. Based on the MAQ, 38.24% of them reported high adherence, 8.82% medium adherence, and 52.94% low adherence. Due to the low number of patients on glucose-lowering drugs, the results were not analyzed statistically. The distribution of adherence levels according to the MAQ is presented in Table 3.

According to the ACDS, the majority of patients (45.55%) received a score indicating medium adherence, 39.27% high adherence, and 16.75% low adherence to the treatment (Tab. 4).

Among the hypertensive patients who achieved blood pressure of ≤ 140/90 mmHg, only half declared high adherence to treatment while in the patients with elevated blood pressure (> 140/90 mmHg) as many as 68.97% declared taking medication 100% of the time as prescribed. The high level of adherence was declared by 61.54% of the patients who reached the

therapeutic goal of lipid-lowering therapy defined as LDL-C of < 2.6 mmol/L (< 100 mg/dL). On the other hand, among the patients whose LDL-C remained elevated, 23.44% declared high adherence to treatment. In patients with diabetes, who achieved fasting blood glucose concentration of < 100 mg/dL, only 8.33% declared high adherence to medication while 83.33% declared low adherence. Due to the low number of patients on glucose-lowering drugs, the results were not analyzed statistically. The distribution of adherence levels according to the MAQ in relation to the treatment goal achievement is presented in Table 5.

In pharmacologically treated patients with hypertension and hyperlipidemia, as well as in the entire study population, the results of the MAQ were consistent with those of the ACDS (Tab. 6). The patients who declared high adherence in the MAQ obtained the highest mean ACDS scores, while the patients with low adherence, according to the MAQ, were characterized by the lowest mean ACDS scores.

Discussion

Poor adherence to recommended medication is a well-documented problem in the pharmacological treatment of chronic conditions, such as coronary artery disease, diabetes, hyperlipidemia, hypertension [2–8, 15, 16]. It is hard to define medication adherence with a clear quantitative threshold below which a patient is classified as effectively non-adherent [17]. In the literature, the level of actual adherence $\geq$ 80% is typically considered relevant for the effectiveness of long-term pharmacotherapy [3, 17–19]. In this study, the patients with indications for chronic pharmacotherapy due to hypertension, diabetes, and/or hyperlipidemia, were classified as having low, medium, or high declared adherence. It is extremely important to differentiate between the actual adherence and the declared adherence, as the latter is usually higher than the former [16, 34–37]. Insufficient or low adherence was defined as taking drugs 75% of the time or less according to the MAQ or as a score of < 21 points in the ACDS [13–15]. In our study, 24.41% of the hypertensive patients and 37.78% of the patients with hyperlipidemia declared a low level of adherence in self-reported MAQ. Among the patients that were treated for hypertension and achieved the intended therapeutic goal of blood pressure $\leq$ 140/90 mmHg, only 50% declared high adherence in the MAQ. A slightly higher percentage was observed in the patients with hyperlipidemia; in this group, 61.54% of patients who reached the LDL-C of < 2.6 mmol/L (< 100 mg/dL) declared high adherence to the lipid-lowering treatment. The patients with high adherence reached their therapeutic goals significantly more often than those who were considered non-adherent to statin therapy ($p = 0.0005$).

Adherence to medications is a long process consisting of initiation, implementation, and persistence. The problem of non-initiation is estimated at 4-5% in clinical trials [19, 20]. In routine clinical practice, over 20% of patients with hypertension, as well as those with dyslipidemia, never start their treatment [20–23]. However,

Table 4. Distribution of adherence levels according to the ACDS in the study population

ACDS	N = 194	Percent
Low (score < 21)	32	16.50
Medium (score 21–26)	87	44.85
High (score > 26)	75	38.65

Table 5. Distribution of adherence levels according to the MAQ in relation to treatment goal achievement in the study population

	MAQ			P-value
	Low	**Medium**	**High**	
Hypertension (n = 127)				
BP > 140/90 mmHg	17.24%	13.79%	68.97%	0.1880
BP $\leq$ 140/90 mmHg	26.53%	23.47%	50%	
Hyperlipidemia (n = 90)				
LDL > 2.6 mmol/L (> 100 mg/dL)	48.44%	28.13%	23.44%	0.0005
LDL < 2.6 mmol/L (< 100 mg/dL)	11.54%	26.92%	61.54%	
Diabetes (n = 34)				
Glucose > 100 mg/dL	36.36%	9.09%	54.55%	na*
Glucose < 100 mg/dL	83.33%	8.33%	8.33%	

*Due to the small number of patients on glucose-lowering drugs, the results were not analyzed statistically

Table 6. Comparison of adherence levels with the score in the ACDS

	ACDS			P-value
	N	Mean	SD	
Hypertension (n = 127)				
MAQ Low level	31	21.29	3.95	< 0.0001
MAQ Medium level	27	23.93	3.01	
MAQ High level	69	26.01	2.34	
Hyperlipidemia (n = 90)				
MAQ Low level	34	22.74	4.63	0.0024
MAQ Medium level	25	24.76	3.05	
MAQ High level	31	26.19	2.50	
Diabetes (n = 34)				
MAQ Low level	18	24.80	2.93	na*
MAQ Medium level	3	20.00	1.73	
MAQ High level	13	26.38	3.55	
Overall (n = 191)				
MAQ Low level	64	22.25	4.09	< 0.0001
MAQ Medium level	47	24.62	3.01	
MAQ High level	80	25.97	2.61	

*Due to the small number of patients on glucose-lowering drugs, the results were not analyzed statistically

it is the discontinuation of treatment that seems to be a greater issue [13, 22–26].

In many European countries, lipid control remains poor and most patients with dyslipidemia do not achieve the treatment goals recommended by the ESC guidelines [27]. This could be attributed to a high percentage of discontinuation of lipid-lowering treatment. Among patients with coronary heart disease in the EUROASPIRE IV survey, 90.4% were on statins, and only 19.3% achieved values of LDL-C < 1.8 mmol/L; statin was discontinued in 11.6% of cases [28]. Statins were also the most common medication class to be discontinued one year after myocardial infarction [24]. Only 50% of patients after myocardial infarction continued the therapy with statins in one-year follow-up [27–29].

Adherence to pharmacotherapy of hypertension is necessary to achieve optimal levels of blood pressure control. Discontinuation of antihypertensive therapy is a common problem as more than 50% of patients stop their treatment after one year [16, 20]. In addition, the rate of omitted doses is reported to be 10% per day [20]. A much higher adherence rate was observed in clinical trials with frequent clinical visits and where pill count was used to assess adherence [19]. In our study, there were no significant differences in achieving the therapeutic goal of blood pressure (BP ≤ 140/90 mmHg) in the groups with high (100%), medium (90%), and low adherence (≤ 75%) (26.53% *vs.* 23.47% *vs.* 50.00%;

p = 0.1880). Apart from low adherence, failure to achieve therapeutic goals might be related to inadequate therapy, as well as suboptimal dosage of prescribed medications.

As there are multiple reasons for non-adherence, efficient and simple tools are needed to determine patients' adherence in clinical practice [16, 26, 30–33]. Questionnaires are subjective methods and generally tend to overestimate true adherence when compared with more objective measures [34–37, 40]. The relatively low specificity and sensitivity may occur due to incorrect data reporting by patients. However, the simplicity, practicality, low cost, and real-time feedback have caused a widespread use of self-report questionnaires in clinical practice [16, 38, 40, 41]. Yet, adherence determined by questionnaires correlates with objective adherence measures and clinical outcomes, such as lipid levels, blood pressure, and blood glucose control [17]. Moreover, questionnaires can be useful tools to complement more objective methods of measurement as they may identify patients' concerns and reasons for non-adherence. Declarations regarding high and medium adherence in the MAQ and the ACDS were consistent; the patients with hyperlipidemia and hypertension with high adherence in the MAQ received an average of > 26 points in the ACDS. The higher the adherence level declared in the MAQ, the higher was the score in the ACDS. The ACDS is designed to reflect various aspects of patient adherence [14, 15, 34–36].

This information can help implement an appropriate therapeutic plan, including additional personalized education and motivation methods [26, 39, 40].

Limitations of the study

The presented study had some limitations. The patients included in the study were not representative of all high cardiovascular-risk patients. Due to the small number of diabetic patients on glucose-lowering drugs, the results were not analyzed statistically. For evaluating medication adherence, only subjective methods in the form of self-report questionnaires were used. Patients' self-reported drug intake is often overestimated [34, 35]. Since there is no single method of choice in evaluating adherence, selecting at least two different methods (objective and subjective) can yield more reliable results. Finally, other factors that could have affected the therapeutic goals were not analyzed. In some cases, insufficient control of risk factors might have resulted from suboptimal doses of prescribed drugs.

Conclusion

Despite higher adherence to treatment in the patients with arterial hypertension compared to the patients with hyperlipidemia, the latter more often achieved the therapeutic goal. Declarations regarding high adherence to medication in the MAQ and in the ACDS are consistent in patients with hyperlipidemia and hypertension.

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