Pharmacotherapy in patients with stable coronary artery disease treated on an outpatient basis in Poland. Results of the multicentre RECENT study

Waldemar Banasiak[1], Arleta Wilkins[2], Robert Pociupany[2], Piotr Ponikowski[1]

[1] Heart Diseases Center, 4th Military Clinical Hospital, Wrocław, Poland
[2] Servier Polska, Warsaw, Poland

Abstract

Background: Comprehension of therapeutic methods in patients with stable coronary artery disease (CAD) is mandatory for the introduction of successful prevention.

Aim: To gather information regarding individuals with stable coronary artery disease treated by specialists and general practitioners on an outpatient basis.

Methods: A representative group of 215 general practitioners and 67 specialists participated in this study. The analysis contains data concerning pharmacotherapy in a group of 2,593 patients with stable CAD (mean age – 65.0±9.8 years, women – 44.6%).

Results: The patients received the following treatment: acetylsalicylic acid – 75.3%, other antiplatelet drugs – 6.6% (antiplatelet drugs altogether – 81.9%), beta-blockers – 81.1%, ACE-I – 78.8%, statins – 71.9%, fibrates – 4.7%, long-acting nitrates – 53.0%, short--acting nitrates – 33.1%, molsidomine – 18.2%, calcium channel blockers – 23.8%, metabolic drugs (trimetazidine) – 13.4%, diuretics – 43.5%, and angiotensin receptor antagonists – 1.7% of patients. Drugs classified as non-cardiological were received by 36.2% of patients. The optimal pharmacotherapy including four medications, one from each therapeutic class used in order to improve the prognosis of the patient (an antiplatelet drug, a beta-blocker, an ACE-I, statin), was received by a total of 45.8% of the participants, three medications by 31.7%, two medications by 15.8%, and one medication by 5.5%; 1.2% of the participants did not receive any medication from the four groups of drugs improving prognosis. What is worth noting, however, is the use of relatively small doses of ACE-I and beta-blockers. 69.9% of patients also received at least one symptomatic drug (a long-acting nitrate, a calcium channel blocker, a metabolic drug, molsidomine), including 39.7% – 1 drug, 22.7% – 2 drugs, 6.7% – 3 drugs, and 0.8% – 4 drugs from the classes mentioned above.

Conclusions: The results of the RECENT study indicate that great progress has been made in the pharmacotherapy of CAD in Poland within the last few years. Currently, the majority of patients receive drugs that improve prognosis. The awareness of the benefits of the use of combined treatment with all the drug groups and their appropriate doses should be higher. The significant percentage of patients with persisting symptoms of angina pectoris indicates the necessity to improve the efficacy of intervention also in this respect.

Key words: stable coronary artery disease, pharmacotherapy, outpatient care

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Introduction

Stable coronary artery disease (CAD) affects dozens of millions of people in Europe and the USA, including over a million Poles alone [1]. According to a recent European registry [2] and statistical data from the American Heart Association [3], patients with stable CAD frequently undergo percutaneous coronary interventions, but pharmacotherapy constitutes the fundamental treatment and is the only method with a documented beneficial impact on survival of patients suffering from the disease [4-9]. The effectiveness of guideline-based optimised conservative treatment [10] is at least as high as of percutaneous coronary interventions [11, 12]. Meanwhile, European registry studies revealed significant discrepancies between the current guidelines and the routine management of patients in clinical practice [13-16]. Similar conclusions were drawn from the Polish screening study on Angina Treatment Pattern (ATP) in 2004 [17]. The

Address for correspondence:
Piotr Ponikowski MD, PhD, Ośrodek Chorób Serca, Klinika Kardiologii, 4. Wojskowy Szpital Kliniczny, ul. Weigla 5, 50-891 Wrocław,
tel.: +48 71 766 02 37, e-mail: piotrponikowski@4wsk.pl
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purpose of this multicentre RECENT trial, conducted under the auspices of the Polish Cardiac Society, was to gather information on individuals with stable CAD managed by specialists at the cardiology outpatient clinics and by general practitioners on an outpatient basis. General patient characteristics were published previously [18]. This paper presents data on pharmacotherapy in patients with stable CAD treated on an outpatient basis in Poland.

Methods

Study design

Criteria of doctor and patient selection as well as enrolment method were detailed in the previous publication [18]. An all-Polish, representative, randomly selected group of general practitioners and specialists working in primary health care clinics and cardiology clinics respectively participated in the study.

The study was carried out under the auspices of the Polish Cardiac Society and received financial support from a Servier Poland scientific grant. The study was performed directly by Pracownia Badań Społecznych in Sopot.

Study group

Each study doctor was obliged to complete within 14 days of enrolment a detailed questionnaire on 10 consecutive patients meeting at least one of the following CAD diagnosis criteria: a) past acute coronary syndrome with or without ST segment elevation confirmed by patient discharge cards, b) significant stenosis of the coronary artery confirmed on coronary angiography (≥70% or left main coronary artery stenosis of ≥50%), c) previous percutaneous coronary interventions, d) positive stress test (electrocardiographic, echocardiographic, scintigraphic) and/or e) typical angina in subjects >60 years old.

Questionnaire

The first part of the questionnaire aimed at collecting patients' demographic and clinical data including worsening of coronary symptoms, information confirming CAD diagnosis and the results of laboratory tests. A complete list of questions from the questionnaire was presented in the previous publication on the RECENT trial [18].

The pharmacological section was designed to acquire information on the following groups of drugs used during the study and within the previous year, their dosing and treatment duration: a) antiplatelet agents, b) beta-blockers, c) angiotensin-converting enzyme inhibitors (ACE-I), d) lipid-lowering drugs (specifying the use of statins and fibrates), e) calcium channel blockers, f) short- and long--acting nitrates, g) molsidomine, h) metabolic agents (trimetazidine), h) diuretics, i) angiotensin II receptor blockers, and j) other drugs.

Information on the primary reasons why patients were not receiving ACE-I and/or beta-blockers were collected in applicable cases as well.

As recommended by the guidelines of the European Society of Cardiology the analysis of pharmacotherapy regimens was performed [10] by dividing the drugs into agents that improve prognosis (i.e. antiplatelet agents, beta-blockers, ACE-I and statins) and those reducing symptoms only (i.e. nitrates, calcium channel blockers, molsidomine, metabolic drugs such as trimetazidine).

A range of detailed data gathered in the questionnaire regarding pharmacotherapy is presented in an attachment to this publication (Attachment 1).

Ethics

All participating patients have read and signed the written Patient Information and Consent Form. The questionnaires were completed anonymously.

Statistical analysis

The data were transferred to and analysed by Servier Polska Sp. z o.o. using SAS software rev. 8.2 (SAS Institute, Cary, NC, USA).

Descriptive statistics were used to present patients' characteristics and pharmacotherapy data. Quantitative variables with normal distribution are expressed as means and standard deviations whereas variables with a highly asymmetric distribution are expressed as medians and ranges. For qualitative variables relative rates in respective groups are given.

All analyses were performed using appropriately chosen weights taking into account the sample assignment design. This enabled us to establish estimates representative for the whole Polish population of subjects with CAD treated by specialists and general practitioners on an outpatient basis for at least 12 months.

The findings are presented for the whole study group without discrimination between patients treated by specialists and general practitioners.

Results

The study was conducted between 20 June 2005 and 01 July 2005 and involved 215 general practitioners and 67 specialists (90 and 84% of the predetermined sample, respectively). Data on 2593 patients with stable CAD were collected (81% of the predetermined sample) including 1977 patients treated by general practitioners and 616 by specialists. Mean age of the study group was 65.0±9.8 years, and females made up 44.6% of participants. CAD diagnosis was based on: previous myocardial infarction (50.1% of cases), positive electrocardiographic stress test (38.8%), typical angina in individuals over 60 years old (36.4%), history of coronary revascularisation (33.4%), and acute coronary events (29%). The majority of patients were classified as Canadian Cardiovascular Society class I or II (37.8% and 48.1%, respectively). Clinical and demographic data were detailed in the previous paper [18].

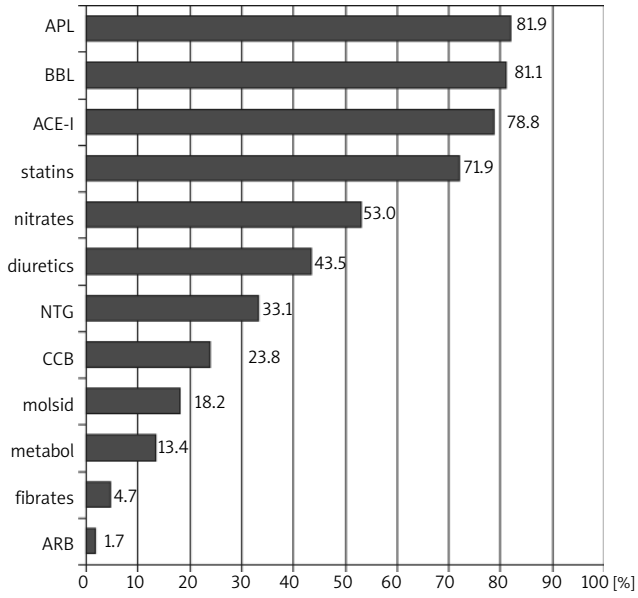

Figure 1. Medication use in patients with stable CAD in Poland (percentage of patients)

Abbreviations: APL – antiplatelet drugs, BBL – beta-blockers, ACE-I – angiotensin-converting enzyme inhibitors, nitr – long-acting nitrates, NTG – short-acting nitrates, CCB – calcium channel blockers, molsid – molsidomine, metabol – metabolic drugs (trimetazidine), ARB – angiotensin receptor blockers

Table I. Mean daily doses of the most commonly administered anti-platelet agents, beta-blockers, angiotensin-converting enzyme inhibitors and statins

International name	Frequency of use [%]	Mean daily dose [mg]
Antiplatelet drugs		
Aspirin	75.3	92.1±35.5
Ticlopidine	6.0	455.2±129.4
Clopidogrel	0.6	75.0±0.0
Beta-blockers		
Metoprolol	34.5	69.2±32.6
Bisoprolol	27.5	5.1±2.4
Carvedilol	5.4	14.8±9.7
Atenolol	5.4	61.9±37.6
Angiotensin-converting enzyme inhibitors		
Enalapril	20.6	17.2±10.9
Perindopril	19.2	4.1±1.5
Cilazapril	14.7	2.3±1.8
Quinapril	8.6	14.0±8.9
Statins		
Simvastatin	49.4	20.9±6.8
Atorvastatin	13.5	19.5± 8.2
Lovastatin	7.2	20.2±5.0
Fluvastatin	1.7	69.6± 21.7

In Figure 1 medications used by patients with stable CAD during the study are shown. So-called 'non-cardiological' drugs were taken by 36.2% of patients (most often reported were hypoglycaemic agents).

Mean daily doses of the most commonly used antiplatelet agents, beta-blockers, ACE-I and statins are presented in Table I.

Optimal pharmacotherapy consisting of 4 medications, including one of each 4 classes of survival-improving drugs, was used in 45.8% of study patients (one anti-platelet drug, one beta-blocker, one ACE-I, and one statin); 3 drugs were taken by 31.7% of surveyed patients, 2 drugs in 15.8% and 1 drug in 5.5%, whereas 1.2% of the study subjects received no drugs of the 4 groups at all.

The treatment regimen of 21.2% of study patients contained no ACE-I. The main reasons for withholding ACE-I were as follows: no indications according to the attending physician – 49.8%; known drug intolerance – 42.3%, and other contraindications – 8.0% of patients not receiving ACE-I. Low blood pressure was the most common contraindication to the use of ACE-I as reported by the doctors (25.4% of patients not taking ACE-I) (Figure 2).

Beta-blockers were not taken by 18.9% of patients. In this case the primary reasons for not prescribing beta-blockers were: contraindications – 53.5% of patients not on beta-blockers, no indications according to the doctor's discretion – 27.9%, and known intolerance to the drug – 18.1%. The participating doctors most commonly reported the following contraindications to beta-blockers: asthma or chronic obstructive pulmonary disease (COPD) – 19.4%, bradycardia (<50 beats/min) – 18.0%, age >65 years – 17.4%, and diabetes – 13.1% of patients not receiving

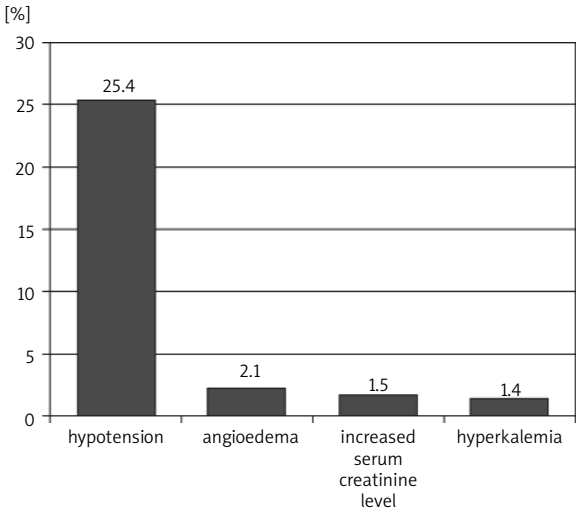

Figure 2. Contraindications to the use of angiotensin-converting enzyme inhibitors most commonly reported by attending physicians (results are presented as percentage of all patients not taking ACE-I)

beta-blockers (Figure 3). At least one symptom-relieving agent (long-acting nitrates, calcium channel blockers, molsidomine or metabolic drugs) was taken by 69.9% of patients. Symptom-relieving medications with haemodynamic effects, i.e. aiming to reduce angina by improving the myocardial oxygen supply to demand ratio (long-acting nitrates, calcium channel blockers, and molsidomine) were used by 66.6% of subjects, while metabolic drugs were taken by 13.4% of patients.

Among patients receiving symptom-relieving medications with haemodynamic effects (long-acting nitrates, calcium channel blockers, and molsidomine), 42.2% were taking one, 20.3% two, and 4.0% three drugs. The effectiveness of the symptomatic treatment was found to be low – 70.4% of patients being treated with three symptom-relieving drugs with haemodynamic effect reported angina within the last 3 months (Table II).

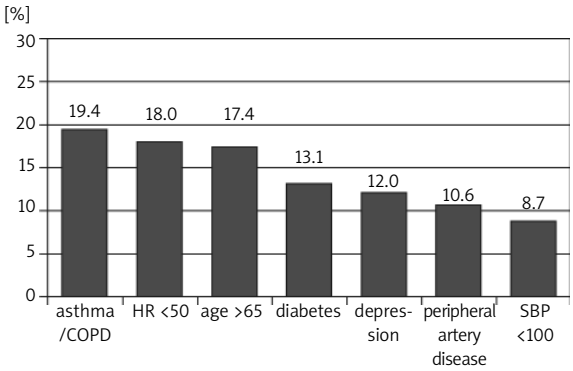

Figure 3. Contraindications to the use of beta-blockers most commonly reported by attending physicians (results are presented as percentages of all patients not taking beta-blockers)

Abbreviations: COPD – chronic obstructive pulmonary disease, HR – heart rate, SBP – systolic blood pressure

Discussion

The RECENT trial provides the latest data on pharmacotherapy of stable CAD in patients treated on an outpatient basis in Poland. The trial documented widespread use of survival-improving medications – 82% of patients received antiplatelet agent(s), 81% beta-blockers, 79% ACE-I, and 72% statins. It should be emphasised that relatively low doses of these drugs are administered to patients and less than half of them (46%) receive an optimised therapy, consisting of a combination of all four drug classes. A great majority of patients (70%) additionally take symptom-relieving medications (apart from beta-blockers).

Managing stable CAD remains a great challenge. Already in 1972, based on the observations from the Framingham study, attention was paid to the poor prognosis of patients presenting with stable CAD, which was similar to the prognosis of patients with a history of myocardial infarction. Ten-year mortality in males aged >50 years and females >60 years was as high as 40% [19]. Importantly, an 'update' published 20 years later showed no significant changes in the prognosis [20]. Although the latest large clinical trials demonstrated better survival of subjects with stable CAD (e.g. the rate of cardiovascular deaths in the PEACE trial in the placebo group over about 5-year follow-up was only 3.7%) [21], in the Finish study published in 2006, the estimated incidence of fatal and nonfatal myocardial infarctions during 10-year follow-up exceeded 10% and was higher than observed in clinical trials [22]. Such differences may result from great discrepancies between real-life patient populations followed under population studies and those recruited for contemporary clinical trials, which enrol selected groups managed usually in large tertiary care centres and not by general practitioners or even by specialists on an outpatient basis.

Taking into consideration only moderate improvement of prognosis in patients with stable CAD within the last 35 years, the use of life-saving medications is of growing importance in this patient population. European guidelines on the management of stable CAD [10] distinguish two basic medication types – survival-improving drugs (antiplatelet drugs, ACE-I, beta-blockers and statins) and symptom-relieving agents, preserving the quality of life (beta-blockers, nitrates, calcium channel blockers, molsidomine, and metabolic drugs).

Table II. Percentage of patients with angina within the last three months in relation to the number of symptom-relieving drugs with haemodynamic mechanism of action taken (long-acting nitrate, calcium channel blocker, and molsidomine)

Symptom-relieving drugs with haemodynamic mechanism of action	Percentage of patients with angina within the last three months [%]
Not receiving any agent	50.2
1 agent	60.3
2 agents	67.9
3 agents	70.4

These guidelines [10, 23] stress the importance of extensive use of survival-improving agents. However, review studies conducted among others in France [24], Spain [25], the UK [26], the international EUROASPIRE II study [13] and the Euro Heart Survey [14-16] as well as the Polish ATP studies [17] and POLKARD-SPOK [27] documented a gap between the recommendations and real-life clinical practice.

As far as the RECENT trial is concerned survival-improving drugs were taken by the majority of subjects: antiplatelets – 82% of patients, statins – 72%, ACE-I – 79%, beta-blockers – 81% (including 86% of patients with a history of myocardial infarction and 77% with heart failure). In the EUROASPIRE II study [13] at hospital

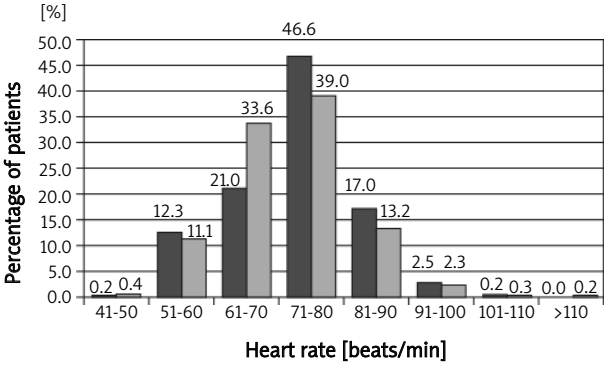

Figure 4. Heart rate distribution in patients with stable ischaemic heart disease in Poland with respect to the use of beta-blockers (patients not receiving beta-blockers – dark bars, patients on beta-blockers – grey bars)

discharge these values ranged from 42.5% (lipid-lowering drugs) to 91.5% (antiplatelets), while in the Euro Heart Survey [14], in patients managed by cardiologists on an outpatient basis the range was from 62% (for ACE-I) to 90% (for aspirin). Polish data for primary care physicians participating in the ATP study [17] reveal that the rate of patients receiving these agents varies from 9.9% (statins) to 65% (aspirin). In the more recent POLKARD-SPOK study [27] these values range from 67.4% (for beta-blockers) to 81.9% (for aspirin).

One reason for the variability observed between the studies may be the differences in methods of data acquisition. In the EUROASPIRE II study [13] medical records of hospitalised patients were analysed, whereas the Euro Heart Survey [14] included data of patients reporting to cardiologists on an outpatient basis. The Polish ATP [17] and POLKARD-SPOK [27] studies assessed only patients managed by general practitioners. The RECENT study involved both specialists and general practitioners who take care of patients with ischaemic heart disease in Poland. In the RECENT [18] and POLKARD-SPOK studies [27] stratified and multi-stage physician selection was employed to ensure sample representativeness. Differences in patients' clinical characteristics may also partially explain the variability of pharmacotherapy. For example, a history of myocardial infarction was found in only 4% of patients in the Euro Heart Survey [14], in 29% in EUROASPIRE II [13], 37% in the ATP study [17], 36.4% in POLKARD-SPOK [27] and 50.1% in the RECENT study. Detailed data on the population of the RECENT study and its comparison with populations from the Euro Heart Survey, EUROASPIRE II and ATP studies are presented in the previously published report of the RECENT study results [18].

One fifth of the RECENT trial patients did not use ACE-I. These agents were not given due to a lack of indications according to attending physicians (half of cases), despite obvious recommendations of ESC (class IIa, in each case of confirmed CAD – evidence level B). In addition, ACE-I doses were at the most moderate (for example, mean daily doses of perindopril and ramipril were 4 mg and 6 mg, respectively, while in the EUROPA and HOPE studies the doses were twice as high) [4, 5]. In reference to other sources, a frequent reason for physicians not to increase ACE-I dose was a fear of potential adverse effects such as hypotension or renal failure [28]. These data indicate the need for further education and implementation of recommendations into daily clinical practice.

Nearly 20% of patients did not receive beta-blockers, including 14% with a history of myocardial infarction and almost 23% with heart failure symptoms, which according to respective guidelines represent class IA indications. There were slightly different reasons for not administering beta-blockers as compared to ACE-I. The main cause turned out to be the presence of contraindications as assessed by attending physicians (in more than half of patients not receiving this drug), including asthma or COPD, bradycardia <50 beats/min, age >65 years, and diabetes.

As in the case of ACE-I, administration of inappropriately low doses of beta-blockers is a crucial problem. This phenomenon is not exclusively observed in Poland. The literature highlights potential (relative) contraindications and drug intolerance as the main determinants of not administering higher beta-blocker doses [29-31]. It is worth emphasising that the mean heart rate in the whole analysed population was 73.1 beats/min (72.8 beats/min in the group treated with beta-blockers and 74.3 beats/min in the group not taking these drugs) and in 88.5% and 87.4% of patients treated and not treated with beta blockers, respectively, the mean heart rate exceeded 60 beats/min (Figure 4). In the light of these findings the suggestions included in the guidelines of the American Heart Association are gaining significance [23]; they recommend reduction of the heart rate to 55-60 beats/min or even below 50 beats/min in patients with more severe angina (unless there are bradycardia-associated symptoms).

Moreover, attention must be paid to the extensive use and relatively low effectiveness of symptom-relieving medications – not less than 70% of patients were given such therapy, but over two thirds (70%) of patients receiving three agents of this type with haemodynamic effects experienced angina within the last three months (Table II).

Conclusions

Findings from the RECENT study demonstrate substantial improvement in pharmacotherapy of CAD in Poland in recent years. The vast majority of patients are currently receiving survival-prolonging medications. Further improvement needs to be made with respect to awareness of combined therapy involving all relevant drug classes

(less than half of patients receive optimised treatment) and the requirement of dosing titration to appropriately high doses. The high percentage of patients with persistent angina despite treatment emphasises the need for improvement of medical interventions in this field as well. Undoubtedly, great progress has been made especially in comparison with data from the EUROASPIRE II study (conducted in 2001) regarding the use of lipid-lowering drugs [13]. Nevertheless, pharmacotherapy of patients with CAD remains suboptimal in Poland.

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Attachment 1

Data on pharmacotherapy obtained from RECENT study questionnaire

CLINICAL SECTION

1. Current pharmacological treatment of the patient (drug name, single dose, number of doses per day, administration time): long-acting nitrates, molsidomine, beta-blockers, calcium channel blockers, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, statins, fibrates, metabolic drugs (trimetazidine), antiplatelet drugs, diuretics and short-acting nitrates used as 'rescue' medication during the last three months.

2. The main reasons for not administering beta-blockers (in the case of patients not currently on beta-blockers) were as follows: arrhythmias, bradycardia, hypotension, asthma/COPD, peripheral arterial disease, unstable heart failure, pregnancy or lactation, other reasons (elderly, severe heart failure, decreased exercise capacity, erectile dysfunction, decreased mood or depression, intolerance of glucose, diabetes, and renal failure).

3. The main reasons for not administering angiotensin-converting enzyme inhibitors (in the case of patients not currently on ACE-I): pregnancy or lactation, history of angioedema, bilateral renal artery stenosis or artery of the only functional kidney, other (low blood pressure, increased creatinine levels, hyperkalemia).

PHARMACOECONOMIC SECTION

1. Pharmacotherapy used within the last year (365 days prior to the visit): name of the agents, daily dose, number of tablets per day, administration time.

Farmakoterapia stabilnej choroby niedokrwiennej serca w lecznictwie otwartym w populacji polskiej. Wyniki wieloośrodkowego badania RECENT

Waldemar Banasiak[1], Arleta Wilkins[2], Robert Pociupany[2], Piotr Ponikowski[1]

[1] Ośrodek Chorób Serca, 4. Wojskowy Szpital Kliniczny, Wrocław

[2] Servier Polska, Warszawa

Streszczenie

Wstęp: Znajomość sposobów leczenia osób ze stabilną chorobą niedokrwienną serca (CAD) jest konieczna do prowadzenia skutecznej prewencji.

Cel: Uzyskanie informacji na temat chorych ze stabilną CAD będących pod opieką lekarzy specjalistów i lekarzy pierwszego kontaktu w ramach lecznictwa otwartego.

Metodyka: W badaniu wzięła udział reprezentatywna próba 215 lekarzy pierwszego kontaktu oraz 67 lekarzy specjalistów. W opracowaniu przedstawiono dane dotyczące farmakoterapii w grupie 2593 chorych ze stabilną CAD (średni wiek 65,0±9,8 roku, 44,6% kobiet).

Wyniki: Chorzy przyjmowali następujące leczenie: kwas acetylosalicylowy – 75,3%, inne leki przeciwpłytkowe – 6,6% (łącznie leki przeciwpłytkowe – 81,9%), beta-blokery – 81,1%, inhibitory enzymu konwertującego angiotensynę (ACE-I) – 78,8%, statyny – 71,9%, fibraty – 4,7%, nitraty długo działające – 53,0%, nitraty krótko działające – 33,1%, molsidominę – 18,2%, blokery kanału wapniowego – 23,8%, leki metaboliczne (trimetazydyna) – 13,4%, diuretyki – 43,5%, blokery receptora angiotensyny II – 1,7% chorych. Leki zaklasyfikowane jako niekardiologiczne przyjmowało 36,2% chorych. Optymalną farmakoterapię obejmującą 4 preparaty, po jednym ze wszystkich czterech klas leków stosowanych w celu poprawy rokowania (lek przeciwpłytkowy, beta-bloker, ACE-I, statyna), przyjmowało łącznie 45,8% ankietowanych; 3 preparaty – 31,7%, 2 – 15,8%, a jeden preparat – 5,5%; 1,2% ankietowanych nie otrzymywało ani jednego preparatu z czterech grup leków poprawiających rokowanie. Uwagę zwraca jednak powszechne stosowanie stosunkowo małych dawek ACE-I i beta-blokerów. Wśród badanych 69,9% chorych otrzymywało także co najmniej jeden lek o działaniu objawowym (nitrat długo działający, bloker kanału wapniowego, lek o mechanizmie metabolicznym, molsidomina), w tym 39,7% – jeden lek, 22,7% – 2 leki, 6,7% – 3 leki, 0,8% – 4 leki z wymienionych klas.

Wnioski: Wyniki badania RECENT wskazują, iż w Polsce dokonał się na przestrzeni ostatnich lat duży postęp w leczeniu farmakologicznym CAD. Obecnie znaczna większość chorych otrzymuje leki poprawiające rokowanie. Nadal należy zwiększać wiedzę na temat stosowania leczenia skojarzonego lekami z wszystkich tych grup oraz ich dawkowania. Wysoki odsetek chorych z utrzymującymi się dolegliwościami dławicowymi świadczy o konieczności poprawy skuteczności interwencji także w tym zakresie.

Słowa kluczowe: stabilna choroba niedokrwienna serca, farmakoterapia, lecznictwo otwarte

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Adres do korespondencji:

prof. dr hab. n. med. Piotr Ponikowski, Ośrodek Chorób Serca, Klinika Kardiologii, 4. Wojskowy Szpital Kliniczny, ul. Weigla 5, 50-891 Wrocław, tel.: +48 71 766 02 37, e-mail: piotrponikowski@4wsk.pl

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