

Characteristics of the heart failure population in Poland: ZOPAN, a multicentre national programme

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Abstract

Background: It is difficult to define the optimal management of elderly heart failure (HF) patients with complex comorbidities. Thus, comprehensive characterisation of HF patients constitutes a crucial pre-condition for the successful management of this fragile population.

Aim: To analyse the 'real life' HF patients, including the evaluation of their health conditions, management and their use of public health resources.

Methods and results: We examined 822 consecutive patients diagnosed with HF in NYHA classes II–IV in primary care practices. The mean age was 68.5 years, and 56% were male. Only 23% of the patients who were of pre-retirement age remained professionally active. Ischaemic or hypertension aetiology was found in 90% of participants. Nearly all patients had multiple comorbidities. Most patients received converting enzyme inhibitors (88%) and beta-blockers (77%), 60% of them both, although dosing was frequently inadequate. During the six months preceding the study, 31% had cardiovascular hospitalisation and 66% required unscheduled surgery visits.

Conclusions: The real life HF population differs from trial populations. Most of the real life patients who had not yet reached retirement age were professionally inactive, mainly due to a disability caused by cardiovascular conditions. Moreover, extremely few participants were free from any comorbidity. Compared to 20th century Polish data, there has been an improvement in the overall quality of HF-recommended pharmacotherapy. It must be stressed, however, that the percentage of those on optimal dosage remains unsatisfactory.

Key words: heart failure, management, general population

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INTRODUCTION

Heart failure (HF) remains one of the leading, most costly, disabling and deadly conditions encountered by a most physicians. The HF prevalence in the general population in developed countries is estimated at 0.4% to 2% [1]. Thus, it can be assumed that 600,000 to 700,000 patients in Poland may be affected. The ageing of the general population and advances in the treatment of cardiovascular disease (CVD) have led to a gradual growth in the HF population, increasing the per-

centage of patients requiring hospitalisation and intensive medical care. The HF is assumed to be responsible for about 5% of all medical and geriatric admissions and is the number one cause of hospitalisation in people aged 65 and over, consuming approximately 1–2% of the entire health care budget in developed countries.

Over the last two decades, we have gathered evidence from clinical trials showing the effectiveness of proper pharmacotherapy in reducing HF morbidity and mortality [2]. Even

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so, it is not easy to define the best management of elderly HF patients with complex comorbidities presenting in everyday practice, who differ substantially from trial populations [3]. Thus, understanding real HF patients constitutes a crucial precondition for the successful management of this fragile population.

The aim of this study was to analyse the real world of HF patients drawn from primary care physicians' (PCPs) practices, with evaluation of their health conditions, medical management and the impact they have on health system resources.

METHODS

Our data represents baseline characteristics of participants in the ZOPAN study (Randomized InterventiOnal Ambulatory Programme in Heart FAilure PatieNts), a multicentre national project (conducted as part of a national programme into the prevention and treatment of CVD known as POLKARD) coordinated by the Institute of Cardiology in Warsaw. There were a total of nine co-ordinating centres located in medium-sized and large cities in several regions of Poland, run by cardiology specialists and their assistants who were chosen by the project's main co-ordinators, in a similar manner to the EuroHeart Failure Survey (EHFS) [4]. Regional co-ordinators were responsible for recruiting clusters of PCPs (who had all volunteered to participate in this project) and supervised the recruitment of HF patients by participating PCPs over the course of six months in 2004–2005. The investigation conformed to the principles outlined in the Declaration of Helsinki. The study protocol was accepted by the Local Ethics Committees and all participants gave their informed consent.

Population

The PCPs engaged in this project were asked to register consecutive patients who had been diagnosed with HF, were over the age of 18, had sought medical care in outpatient settings (regardless of cause), and had symptoms corresponding to NYHA classes II–IV.

Eligibility for this study required meeting several criteria. Patients had to have clinical symptoms of HF (as described in European Society of Cardiology (ESC) HF guidelines) [2]: breathlessness, tiredness/fatigue and peripheral oedema), accompanied by either: (1) confirmed systolic dysfunction by echocardiography defined by ejection fraction (EF) < 45% (within the last 24 months) or (2) both abnormal resting ECG and chest X-ray (performed within the last 12 months). Abnormal ECG was defined as past myocardial infarction (MI), conduction abnormalities, left ventricular hypertrophy (LVH), or arrhythmias; chest X-ray was considered abnormal when cardio-thoracic ratio was > 50% or heart silhouette was enlarged with at least moderate pulmonary congestion.

All subjects were evaluated via a questionnaire (collected by PCPs), which included patients' medical history, NYHA class, laboratory tests (ECG, chest X-ray, echocardiogram,

when available), etiology of HF, pharmacotherapy and utilisation of health system resources within the six months preceding the study (surgery visits and/or hospitalisation). Causes of hospitalisation were classified by PCPs, based on the discharge summaries.

The assessment of optimal dosing of angiotensin converting enzyme inhibitor (ACEI) and beta-blocker (BB) antagonists was based on the recommendation of the ESC [2]. The same guidelines were used for classification of BB preparation accepted in HF (metoprolol, bisoprolol, carvedilol, nebivolol). Before starting the project, all PCPs underwent training in HF management, to assure a consistent level of care.

Statistical analysis

Figures from all participating centres were pooled and analysed in the central statistics centre (Office of Biostatistics in the Department of Epidemiology and CVD Prevention of the Institute of Cardiology). All statistical analyses were performed using SAS software (SAS Institute, Cary, NC, USA). Depending on the parameter analysed, they were presented either as a percentage or as a means \pm SD.

RESULTS

The total population comprised 822 subjects recruited by PCPs. For 55% of the subjects, echocardiography inclusion criteria were applied, whereas the remaining 45% were recruited using ECG and chest X-ray criteria.

Demographic and sociological data

The distribution of males and females was comparable, with slightly more men. Mean age in the study group was 68.5 years (range 33–97 years). Average body mass index (BMI) was above normal, corresponding to the 'overweight' category. One in ten patients was an active smoker. More than half of the subjects had finished their education at primary or vocational level. A minority of the study population consisted of subjects living alone (single, widowed or divorced). In the subjects of pre-retirement age, a small percentage remained professionally active. Of those who were no longer working, more than three quarters were in receipt of a disability pension, mostly due to CVDs (Table 1).

Clinical history

The mean time elapsed since HF diagnosis was 4.5 years. Our population consisted mainly of subjects in the early stages of HF (NYHA II), with only one third of the population in a more advanced stage. The predominant aetiology was ischaemic or hypertensive or both. The remainder (nearly 10%) included cases of dilated cardiomyopathy, alcoholic cardiomyopathy and valvular heart disease (Table 2).

Clinical history revealed that only 2.7% of subjects had no comorbidities, and the highest number of coexisting diseases was seven (Table 3). Of all CVDs, coronary artery disease

Table 1. Characteristics of the study population

Age [years]	68.5 ± 10.7
Male gender	56%
Body mass index [kg/m ²]	28.9 ± 5.2
Smoking	10%
Primary or vocational level of education	59%
Unmarried status*	38%
Living alone	16%
Professionally active**	23%
Disability pension (disability due to CVD)***	83% (87%)

*Unmarried status includes: single, divorced, widowed; **% of those of pre-retirement age (women < 60 years, men < 65 years); ***% of those not professionally active of pre-retirement age (women < 60 years, men < 65 years) on disability pension; CVD — cardiovascular diseases

Table 2. Clinical history

Aetiology:	
Ischaemic	32%
Hypertension	18%
Ischaemic + hypertension	38%
Others (idiopathic, alcoholic, valvular)	12%
NYHA classification:	
II	71%
III	27%
IV	2%

ase and hypertension were the most commonly found, whereas diabetes and pulmonary diseases were the most commonly-found non-CV conditions. Other comorbidities, infrequently documented by their medical history (ranging from 1–3%) included liver insufficiency, prostate disease, gastrointestinal ulcerous disease, venous disease, anaemia, and Parkinson's disease.

Management: diagnostic procedures and treatment

Echocardiography was performed in 79% of patients, and the mean EF was 39% (in tests from the last 12 months). Chest X-ray was carried out on almost all participants (97%) and was described as abnormal in 89%, whereas ECG was done in 99% and was abnormal in 96%. Based on the description of ECG provided by PCPs, the following abnormalities were found: atrial fibrillation (32%), other forms of arrhythmias (19%), conduction abnormalities (21%), ischaemic changes (19%), past MI (36%) and LVH (41%). During the six months preceding the study, potassium and creatinine levels were checked at least once in approximately three quarters of subjects, and in 10% were abnormal.

Treatment pattern evaluation showed that nearly 90% of subjects were on ACEI. However the recommended doses were

Table 3. Comorbidities

Number of comorbidities:	
0	2.7%
1	13%
2	32%
3	30%
4	15%
5	5.4%
6	1.5%
7	0.2%
Type of comorbidities:	
Cardiovascular:	
Coronary artery disease (MI in the past)	77% (52%)
Hypertension	73%
Peripheral vascular disease	22%
Cerebrovascular disease**	12%
Non-cardiovascular:	
Diabetes	24%
Asthma or COPD	16%
Rheumatic disease	8%
Renal insufficiency	6%
Thyroid disease	6%

*Total does not equal 100% due to approximation; **defined as transient ischaemic attack or stroke; MI — myocardial infarction; COPD — chronic obstructive pulmonary disease

Table 4. Heart failure pharmacotherapy

ACEI/optimal dosage of ACEI	88%/52%
BB/optimal dosage of BB	77% (67%)*/22%
Combination of ACEI and BB (accepted in HF)*	60%
Angiotensin receptor antagonists	3%
Diuretics	77%
Aldosterone antagonists	48%
Digitalis	25%

*Data in brackets for beta-adrenolytic agents accepted in heart failure (HF) — see methodology; ACEI — angiotensin converting enzyme inhibitors; BB — beta-blockers

prescribed in half of them (Table 4). The main reasons for not administering ACEI included intolerance, hypotension, renal dysfunction and hyperkalemia, whereas lower than usual dosage resulted from hypotension, side effects (renal dysfunction and a tendency towards hyperkalemia) (Fig. 1). Angiotensin receptor blockers, were used in a negligible proportion of patients. The percentage of patients on BB was high (77%) but recommended BBs were administered in 67%. Similarly to ACEI, BB doses were much lower than those recommended and only a minority of patients received the optimal dosage (Table 4). The main reasons given for avoiding BB were low

blood pressure, bradycardia, pulmonary diseases and symptoms of intolerance, whereas lower dosage was mainly due to progression of HF or pulmonary symptoms and a tendency towards bradycardia or hypotension (Fig. 2). A combination therapy, with both ACEI and BB, was used in about 60% of study participants. Almost half of the population received aldosterone antagonists. Diuretics were among medications recommended most often in this population, with loop diuretics leading the group. Conversely, digoxin, was used by only one quarter of the population studied (Table 4). The HF medications constituted only a subset of the drugs used. Other most frequently administered CV drugs included aspirin (64%), statins (55%), long-acting nitrates (40%), calcium channel blockers (40%), acenocoumarol (23%), amiodarone (5%) and other antiarrhythmic medications (2%).

Utilisation of health service resources

Assessing the frequency of office visits and hospitalisations in the six months preceding the study revealed that nearly one in three subjects were hospitalised due to CV causes. Moreover, two thirds of participants claimed that they required unscheduled office visits because of HF symptoms deterioration during the time analysed (Table 5).

DISCUSSION

This study looked at ambulatory HF patients recruited from PCPs’ practices. As the recruitment centres covered most regions of Poland, we can assume that the studied population mirrors the real population of ambulatory HF patients. Moreover, our data show a broader picture, as most published epidemiological projects have been limited to a single cen-

tre/region [1, 5, 6] and have mainly involved hospitalised populations [4, 7, 8]. In published studies based on subjects from general practices/population, ESC requirements of objective visualisation for HF diagnosis have not always been followed [5]. In most of them, the diagnosis of HF was based on clinical criteria and physicians’ experience, as in the EHFS [7]. Some used both objective and clinical criteria [9].

The age distribution of the study population was similar to previous findings of the age distribution of the Polish population [4, 10–13]. Likewise, observed equal gender distribution is in line with most of previous papers, constituting an obvious difference from the populations enrolled in clinical trials [6, 12–14]. Also, the trends for obesity are consistent with data regarding the Polish population, although smoking prevalence was lower [8].

Unsurprisingly, we observed that less than one quarter of the subjects of pre-retirement age remained professionally active. Disability pension (in 90% of cases due to CVDs) was the main cause of professional inactivity. This finding of a generally high impact of the disease on the patients’ work status probably contributes to the generally low quality of life with this condition. Moreover, it adds to the financial consequences of the disease.

The prevalence of ischaemic heart disease, alone or in combination with hypertension, as the commonest aetiology of HF, is in line with previous reports regarding the Polish population [8, 11]. In general, the high prevalence of coronary aetiology is a common finding in HF patients from clinical practice, in contrast to observations made in clinical trials [2].

The fact that more than half of our population had at least three coexisting diseases confirms previous findings [3].

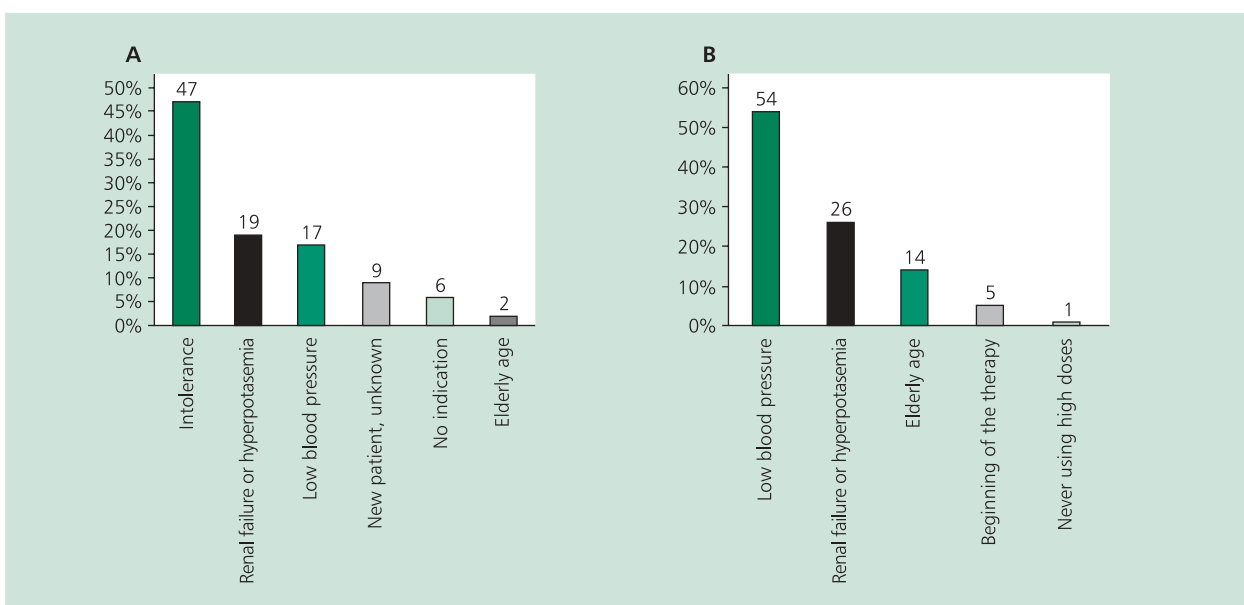


Figure 1. Reasons for not receiving angiotensin converting enzyme inhibitor (A) or for its suboptimal dosing (B)

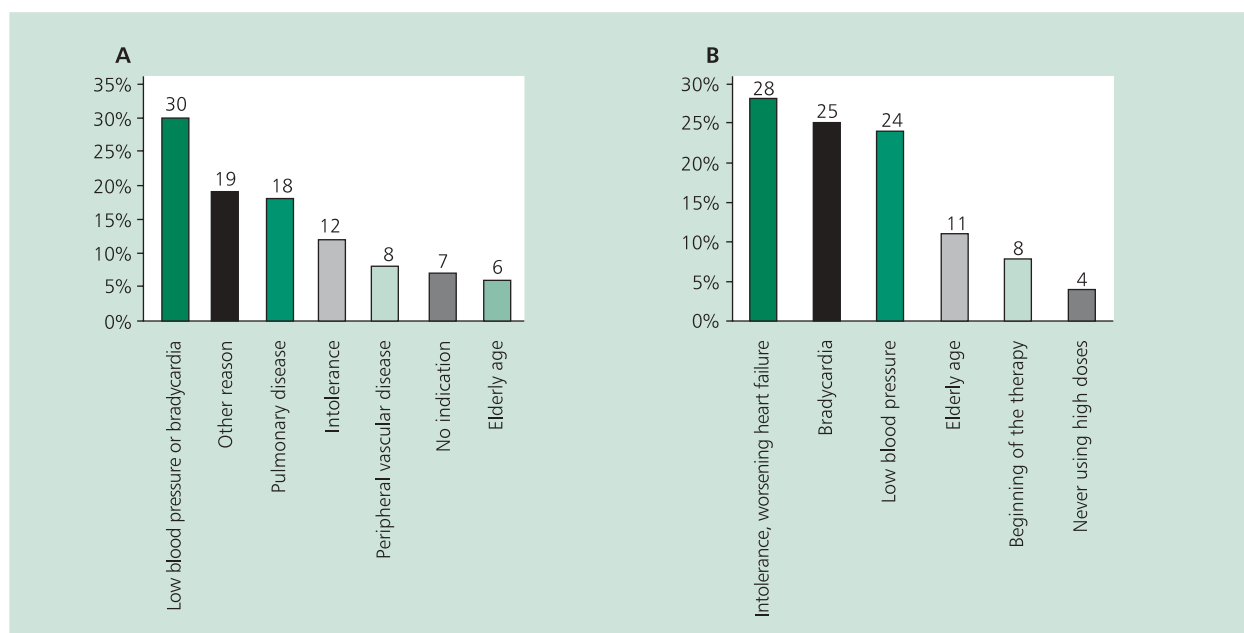


Figure 2. Reasons for not receiving beta-blocker (A) or for its suboptimal dosing (B)

Table 5. Hospitalisation and unscheduled office visits within the six months preceding the study

CV hospitalisation	31%
Number of CV hospitalisations per patient	1.3 ± 0.6
Number of HF hospitalisations per patient	1.2 ± 0.6
Unscheduled office visits caused by HF	61%
Number of unscheduled office visits caused by HF per patient	2.8 ± 2.3

Continuous data presented as means ± SD; CV — cardiovascular; HF — heart failure; CV hospitalisation defined as hospitalisation due to CV reasons; HF hospitalisations defined as hospitalisation due to HF reasons

On the other hand, a Dutch study showed a much lower proportion (25%) of multiple comorbidities [6].

With regard to CV conditions, our results are comparable with EHFS results, showing similar proportions for ischemic heart disease and MI [15]. Hypertension was more prevalent, but comparable to recent observations made of the Polish population [8, 13].

In the HF population, non-CV conditions are a significant challenge, as they influence treatment options and add to the burden of polytherapy. In fact, Braunstein et al. [3] documented that some patients had as many as ten non-CV comorbidities. Diabetes and pulmonary disease are among the most frequently reported (usually 20–30%) [3, 6, 10, 15], with renal failure reaching at most 20% [16]. The difference with regard to frequency of renal failure might be due to imprecise descriptive criteria of renal dysfunction in our study.

Populations with more comorbidities are at a greater risk of adverse events and preventable hospitalisation, producing higher costs for health systems.

Atrial fibrillation is one of the arrhythmias reported most often in HF, reaching as much as 40–50% [13, 16, 17]. Nevertheless, in EHFS and IMPROVEMENT it was overall slightly above 20% [4, 10]. So, our results, showing a prevalence of 32%, lie in the middle. Other findings from ECG are not often reported in publications, despite the fact that previous infarction, LVH and bundle branch block are well known risk factors for an adverse prognosis [2].

Availability of echocardiography remains a weak point in the management of the HF population, despite an improvement in comparison to previous studies [11]. Based on the recent data, echocardiography was not performed in more than 50% of patients cared for by non-cardiologists (both out- and in-patients). Results were better for specialist care (both out- and in-patients, 24% and 18–27%, respectively) [8, 13]. Considering these reports, our finding confirms a substantial improvement, although the situation remains unsatisfactory.

At present, a combination of ACEI and BB is regarded as a cornerstone of treating HF with reduced systolic function [2]. Our data, showing 88% of subjects on ACEI and 77% on BB, is an impressive improvement compared with the studies conducted at the turn of this century, where ACEI was used in 60–62%, and BB in 34–37% [10, 14]. In subsequent reports from the Polish population, ACEIs were administered in 80–95% [7, 13], consistent with our current findings. Only a few other reports [17] have been similar, whereas in others the numbers remained lower [9, 15]. Only

a limited number of studies have analysed not only prescription patterns, but also optimal dosage. The current data, implicating target dosing in 50% for ACEI and 22% for BB, must be considered a remarkable improvement in relation to previous Polish data [8, 14, 17]. Similarly to previous reports [8, 14], our population received a broader range of BB preparations than recommended by ESC [2]. The commonest reasons for not prescribing ACEI or BB (intolerance, renal failure and hyperpotasemia, low blood pressure, pulmonary disease) were similar to a previous report regarding a hospital population [8]. Aldosterone antagonists, conversely to ACEI and BB, are recommended in patients in advanced HF. Nevertheless, in our study only 29% of participants were in NYHA classes III and IV, suggesting their overuse. Identical findings in this regard were presented in two previous studies of a Polish population [8, 14], although they have been contradicted by other authors [10, 14, 17]. These findings suggest that there may be insufficient concern about the safety of these agents, something which has been brought up recently by Jensen et al. [17] who showed that aldosterone antagonists in elderly HF patients modifies prognosis unfavourably. As recent clinical trials did not confirm the advantage of statins in HF [2], their use along with aspirin is justified by a history of ischaemic heart disease, and in fact indicates a higher level of secondary prevention than previously reported [8, 10, 14].

Most papers, based on patients with index HF hospitalisation, have analysed the number of readmissions, showing the risk for subsequent all-cause hospitalisation within 30 days to be 13.8% [18], and for 6–12 months ranging from 40% [18] up to 65%. Therefore, the highest risk is likely to be observed within a short time after the initial event. In this study, we saw CV hospitalisation in 31% of subjects within six months. In addition to hospitalisations, which are the main problems in regular care of HF patients, as many as 61% of them reported attending unscheduled surgery visits due to HF-related problems (an average of one visit every second month), a high usage of health services resources.

Importance of the study

One of the major benefits of the presented data is the significant number of subjects included from several centres and different regions of Poland. It should be stressed that our study looks at HF patients at population level, cared for by PCPs, not cardiology specialists. Thus, our results provide information about the management of ambulatory HF patients in everyday practice, who differ significantly from participants in clinical trials (who tend to be mostly young men free of any serious comorbidities).

Limitations of the study

This study has some limitations which must be addressed.

1. Participating PCPs were not chosen randomly. This might influence the data, and we cannot guarantee that this

HF group is 100% representative of the adult HF population in Poland. However, there was some random selection of participants, because we included subsequent patients with HF showing up at PCPs' settings.

2. Although we assume that all consecutive patients with HF diagnosis had been registered, we were not able to verify if the participating PCPs fully complied with this requirement.
3. We were unable to verify the diagnosis of HF, or to distinguish between systolic and diastolic HF objectively in all subjects, as the echocardiography testing was limited. However, in those in whom echocardiography was performed, the EF was low, which reassures us that the diagnoses were correct.

CONCLUSIONS

The real life HF population differs from trial populations. Most of the real life patients who had not yet reached retirement age were professionally inactive, mainly due to a disability caused by cardiovascular conditions. Moreover, extremely few participants were free from any comorbidity. Compared to 20th century Polish data, there has been an improvement in the overall quality of HF-recommended pharmacotherapy. It must be stressed, however, that the percentage of those on optimal dosage remains unsatisfactory.

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Charakterystyka populacji chorych z niewydolnością serca w Polsce: ZOPAN — badanie wieloośrodkowe

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Streszczenie

Wstęp: Ustalenie optymalnego leczenia pacjentów w podeszłym wieku z niewydolnością serca (HF), którzy są obciążeni wieloma chorobami współistniejącymi, jest zagadnieniem szczególnie trudnym. Dlatego też podstawą skutecznego postępowania w tej grupie osób jest dokładna charakterystyka populacji.

Cel: Celem pracy była analiza charakterystyki chorych z HF na podstawie codziennej praktyki lekarskiej, z oceną ich stanu zdrowia, jakości opieki oraz stopnia obciążenia dla systemu opieki zdrowotnej.

Metody i wyniki: Do badania włączono 822 kolejnych pacjentów ambulatoryjnych z HF w II–IV klasie NYHA z ośrodków podstawowej opieki zdrowotnej. Średni wiek badanej grupy wynosił 68,5 roku, 56% stanowili mężczyźni, a 23% pacjentów w okresie przedemerytalnym pozostawała aktywna zawodowo. Etiologia niedokrwienne lub nadciśnienie tętnicze było wskazywane jako przyczyna HF w 90% przypadków. Choroby współistniejące stwierdzano u prawie wszystkich badanych osób. Większość pacjentów otrzymywała inhibitory enzymu konwertującego angiotensynę (88%), a 77% — beta-adrenolityki, z czego 60% chorych przyjmowało połączenie tych dwóch leków, przy czym ich dawkowanie było niższe od zalecanego. W okresie 6 miesięcy poprzedzających badanie 31% osób było hospitalizowanych z przyczyn sercowo-naczyniowych, a 66% wymagało dodatkowych, nieplanowanych wizyt lekarskich.

Wnioski: Rzeczywisty obraz populacji chorych z HF różni się od opisywanego w badaniach klinicznych. Większość pacjentów w okresie przedemerytalnym była nieaktywna zawodowo, przede wszystkim z powodu chorób sercowo-naczyniowych. Dodatkowo brak chorób współistniejących stwierdzano jedynie u niewielkiego odsetka osób. W porównaniu z poprzednimi danymi w przypadku populacji polskiej poprawiła się jakość opieki nad chorymi z HF w odniesieniu do stosowanej farmakoterapii, nadal jednak dawkowanie leków odbiega od standardów.

Słowa kluczowe: niewydolność serca, postępowanie, populacja ogólna

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