Is the 2016 ESC diagnostic algorithm useful for assessing the prevalence of chronic heart failure in population-based studies?

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ABSTRACT

Background: Chronic heart failure (CHF) is a major healthcare problem. However, there are no epidemiological studies assessing the prevalence of CHF in the general population with diagnosis based on algorithms recommended for clinical practice.

Aim: The aim of the HF-Pomorskie survey was to assess the prevalence of three basic components of the 2016 ESC diagnostic algorithm for CHF (symptoms, N-terminal pro B-type natriuretic peptide [NT-proBNP], and abnormalities on echocardiography) and to determine whether this algorithm may be applicable to studies in general population samples.

Methods: The study was performed in a representative sample of 313 adults (170 women and 143 men) aged between 20 and 90 years (mean 55.2 years [15.3]) in Northern Poland. A questionnaire to determine New York Heart Association [NYHA] class, laboratory tests including NT-proBNP, as well as transthoracic echocardiography and spirometry examinations were performed in all subjects.

Results. Dyspnea (NYHA class II–IV) was reported by 13.7% of recruited participants. Dyspnea and elevated levels of NT-proBNP (>125 pg/ml) were found in 7.7% of all examined subjects, while dyspnea, elevated NT-proBNP levels accompanied by systolic or diastolic abnormalities on echocardiography occurred in 4.8%. In the group without dyspnea (86.3% of all examined subjects), every sixth subject had an elevated level of NT-proBNP. On the other hand, 5.8% of studied subjects reported a previous diagnosis of CHF, which was confirmed using the current ESC algorithm in 78% of them.

Conclusions: The prevalence of CHF assessed by the 2016 ESC diagnostic algorithm in the representative sample of adults was equal to 4.8%. The clinical algorithm for the diagnosis of CHF is fully applicable to the representative surveys in the general population. However, due to logistic and economic factors, echocardiography examination and NT-proBNP determination can be limited to patients reporting dyspnea or previous diagnosis of CHF.

Key words: epidemiology, ESC guidelines, heart failure, NT-proBNP, NYHA scale

WHAT'S NEW?

The growing incidence of chronic heart failure (CHF) has been highlighted by the World Health Organization and the European Society of Cardiology (ESC). There are only a few studies assessing the epidemiology of CHF and its symptoms in Europe, and there are no such studies in the general population in Poland, which is one of the regions of high cardiovascular risk in central and Eastern Europe. However, estimating the prevalence of CHF in the population is a challenge. The available ESC recommendations apply mainly to newly diagnosed patients, but confirming the diagnosis is difficult. Our study explored whether the ESC diagnostic algorithm (symptoms, natriuretic peptides) could be used in a population study. The conclusions of this research have very broad scientific and practical implications for prevention, which should be a priority in Poland, Europe, and around the world.

INTRODUCTION

Chronic heart failure (CHF) is a large problem not only in cardiology but also in the whole healthcare system. Along with pneumonia, it is one of the main reasons for hospital admissions among elderly patients. Nevertheless, epidemiological data on this disease are scarce and imprecise e.g., the number of patients with CHF in Poland is estimated from 600 000 to even more than a million [1, 2]. The methods of assessing the prevalence of heart failure (HF) with non-acute onset are also debatable. It seems obvious that the patient's declaration and physical examination are not enough, but should transthoracic echocardiography (TTE) or B-type natriuretic peptide (BNP) level be performed in every screened subject? According to the 2016 and 2021 guidelines of the European Society of Cardiology (ESC), diagnosis requires the presence of symptoms and confirmation of myocardial dysfunction or structural changes in TTE [3, 4]. This algorithm is relatively easy to apply in clinical settings; however, in the case of epidemiological studies, there is a question of who should be tested and what tests should be performed. Consideration should also be given to which group of subjects should be screened for CHF, e.g., should the study protocol in a population-based sample be narrowed down to symptomatic groups only?

Previous reports have pointed out that myocardial dysfunction may precede the onset of symptoms for a long time. As a result, recommendations for preventive management in asymptomatic left ventricular systolic dysfunction (LVSD) were added to the 2016 ESC guidelines [4]. Early implementation of treatment with, among others, angiotensin-converting enzyme inhibitors may slow down the development of the disease and delay the onset of symptoms [5–8]. A thorough understanding of the epidemiology of CHF and LVSD is essential in planning health policy to prevent an excessive number of disease exacerbations and hospital admissions, especially in the wake of the 2019 coronavirus pandemic.

The study aimed to assess the prevalence of the main components of the CHF diagnostic algorithm proposed by the ESC for clinical practice and to determine whether this algorithm may be applicable to studies in general population samples.

METHODS

The HF-Pomorskie Study is an observational study of a representative group of residents from the Pomeranian Province in Poland. The study aimed to assess the prevalence of CHF in this region. The study included people aged 20 years or older, who were also randomly selected for the WOBASZ II population study. The processes of sample drawing, data collection methodology, and blood sampling were described in detail in our previously published article [9, 10].

The HF-Pomorskie Study was carried out among the residents of the Pomeranian Province. In the first stage, 2 small communes (fewer than 8000 residents), 2 medium-sized communes (8000–40 000 residents), and 2 large communes (40 000–200 000 residents) were chosen by drawing lots. Then, 100 women and men from each commune and, additionally, 100 people from the capital of the province were randomly selected using a personal identification number (PESEL) and invited to participate. Overall, 700 individuals were invited to participate in the study. Of those, 148 addresses were incorrect, or an individual could not be contacted. The age and sex of the participants corresponded to the 2014 population structure of the Pomeranian Province. Letters of invitation to participate in the survey were sent to the randomly selected participants. In each of the 7 communes, a research center was established, where participants were invited to visit. A detailed study design was developed, taking into account the elements of the CHF diagnostic algorithm according to the ESC guidelines. Each patient completed a questionnaire and had blood laboratory tests.

To assess the premises for the use of the diagnostic algorithm, two independent experts analyzed the database to look for cases of CHF symptoms, NT-proBNP levels, and TTE findings.

Transthoracic echocardiography, spirometry, and ECG were performed on 313 participants. One of them reported that she had previously been diagnosed with HF with reduced ejection fraction (EF) and had the result of a recent echocardiography (performed 3 months before the enrolment). As the diagnosis of HF was unquestionable, this patient was included in the analysis, and the data from the echocardiography performed outside the project were entered into the database.

A MasterScreen Pneumo device (CareFusion, Germany) was used for spirometry, which was performed in accordance with the guidelines of the American Thoracic Society/European Respiratory Society [11]. Obstruction was diagnosed when the forced expiratory volume/forced vital capacity ratio, was below the lower limit of normal (i.e., below the 5th percentile) [12].

Blood samples were collected from participants, after fasting, at their homes or at the research center. The collected material was centrifuged immediately; then, the obtained plasma was frozen and transported to the central laboratory where parameters of interest, including NT-proBNP levels, were determined. The natriuretic peptide levels were measured using an Immulite 1000 analyzer (Siemens Healthcare Diagnostics, Germany) by immuno-chemiluminescence, and the elevated plasma levels of NT-proBNP were defined according to the ESC recommendations. The threshold was >125 pg/ml [3].

Data on the prevalence of symptoms, comorbidities, and exposure to tobacco smoke were obtained from the questionnaire.

Recordings and measurements were made in line with the 2016 recommendations of the European Association of Cardiovascular Imaging and the American Society of Echocardiography [13].

All examinations were performed on a Siemens Acuson S2000 device, using a vector head. The geometry of the left and right ventricles and both atria were assessed as well as the general and segmental contractility of the LV in standard projections, using the 2D, M-mode, and Doppler modes, as recommended.

To detect potential systolic dysfunction, end-diastolic and end-systolic volumes were assessed using the disk summation method according to a modified Simpson rule.

Based on left ventricular ejection fraction (LVEF), patients with HF with preserved EF, HF with mid-range EF, and HF with reduced EF were identified. Due to the increasing importance of HF with preserved systolic function (LVEF >50%), diastolic function of the LV was assessed.

The following parameters were measured to assess LV diastolic function: the ratio of mitral inflow E-wave velocity to A-wave velocity (E/A ratio), velocity of mitral annulus movement assessed by tissue Doppler (E'), E/E' ratio, left atrial volume index, and the maximum wave velocity of tricuspid regurgitation.

Statistical analysis

Statistical analysis was performed using the R version 3.6.3 R (R Foundation for Statistical Computing, Vienna, Austria). The results were presented as percentages, mean values with standard deviations or medians, and quartile/interquartile ranges. The proportions were compared through a chi-square test. The distribution of the NT-proBNP level was compared using the Kruskal-Wallis test. For all statistical analyses, the level of significance was set at 0.05. The HF-Pomorskie Study was approved by the Bioethics

Table 1. Participant characteristics in the HF-Pomorskie Study (n = 313)

	HF-Pomorskie n (%) (n 313)
Sex	
Women	170 (54.3)
Men	143 (45.7)
Age	
18–64	215 (68.7)
≥65	98 (31.2)
BMI, kg/m²	
<25	111 (35.5)
25–29.9	107 (34.2)
≥30	95 (30.4)
Comorbidities (self-reported)	
Hypertension	80 (25.1)
Diabetes	34 (10.8)
Chronic coronary syndrome (History of ischemic heart disease + prior myocardial infarction)	34 (10.8)
Hypercholesterolemia	182 (57.2)
History of chronic kidney disease and/or GFR <60 ml/min/1.73 m²	27 (8.5)
Atrial fibrillation	20 (6.3)
Chronic obstructive pulmonary disease	53 (16.6)
Current smoker	89 (28.2)
Ex-smoker	101 (31.7)
Never smoker	123 (40.1)

Abbreviations: BMI, body mass index; GFR, glomerular filtration rate

Committee at the Medical University of Gdansk (No. NKBBN/421/2013). Each participant gave their informed consent before enrolment in the study. The investigation conformed with the principles outlined in the Declaration of Helsinki.

RESULTS

The study was conducted between 2014 and 2016 and included 313 patients (170 women and 143 men) aged between 20 and 90 (mean age 55.2 [15.3]). The response rate was 56.7%. Table 1 presents the characteristics of the participants in the HF-Pomorskie Study.

Diagnostic algorithm

All participants of the study were assessed for the presence of HF symptoms according to the ESC diagnostic algorithm; the results are presented in Figure 1. The symptomatic group was composed of people who reported dyspnea (13.7%), defined as New York Heart Association (NYHA) class II–IV (Table 2). The distribution of the NT-proBNP level (between NYHA II, III, and IV) was statistically significant (P = 0.015). More than half of the patients in this group (55.8%, n = 24) had an increased level of NT-proBNP. Finally, CHF diagnosis was confirmed in every 3rd patient with dyspnea (39.5%) based on TTE. In the group without dyspnea, which was the majority of the study population, every 6th (15.9%) patient had elevated levels of NT-proBNP. For two patients in the asymptomatic group, TTE showed reduced EF (≤40%), and a diagnosis of LVSD was made.
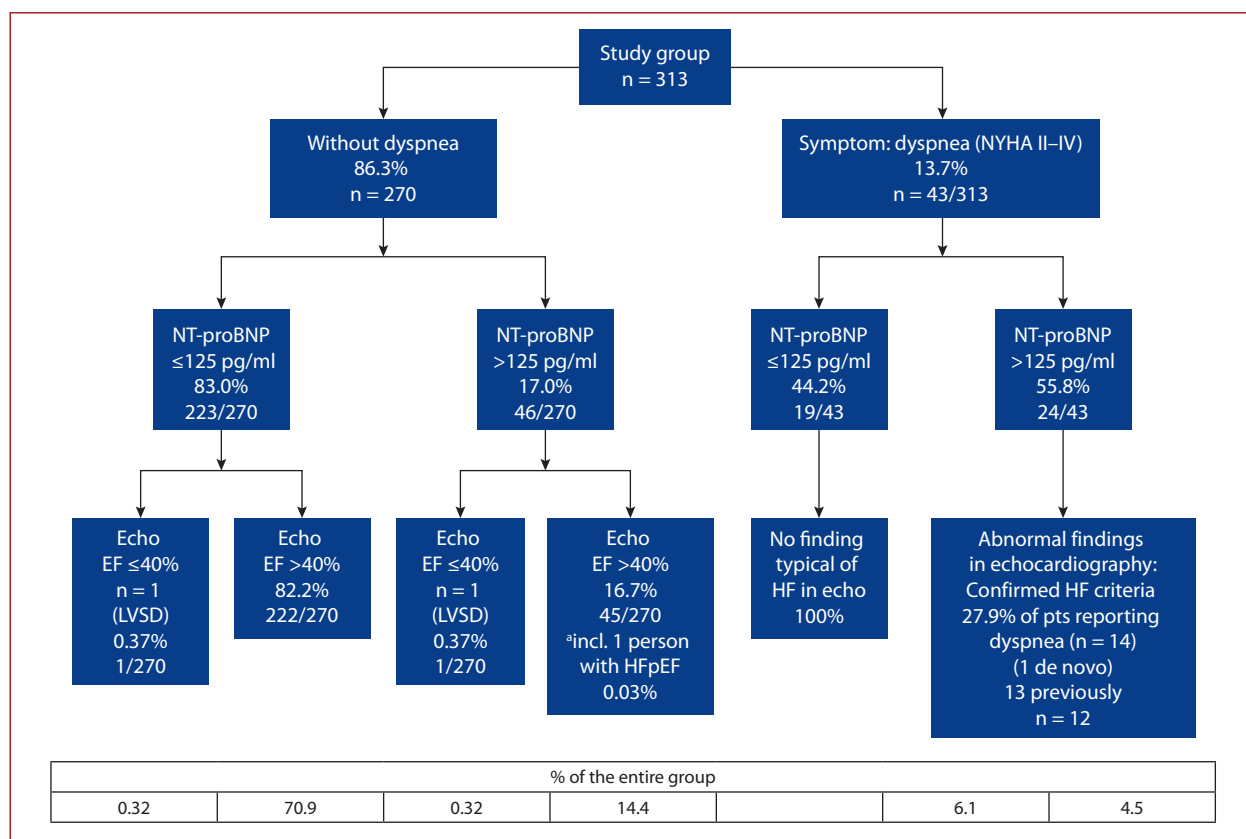
Figure 1. Components of the diagnostic algorithm (symptoms, NT-proBNP, and abnormalities in echocardiography) in the study group

[a]A patient after myocardial infarction, chronic treatment with ACE-I, and beta-blocker did not report dyspnea (NYHA I), with slightly elevated NT-proBNP levels. Transthoracic echocardiography findings: segmental abnormal contractility with normal EF

Abbreviations: ACE-I, angiotensin-converting enzyme inhibitors; EF, ejection fraction; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; LVSD, left ventricular systolic dysfunction; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association

All participants underwent a spirometry test to deepen the diagnosis of dyspnea. In the whole group, obstruction was found in 15.9% (n = 50), and in the group of patients reporting dyspnea, obstruction was found in 30.2% (n = 13; $P < 0.05$ for both) (Figure 2).

Natriuretic peptides

Plasma NT-proBNP was measured in all participants. The median of NT-proBNP was 58.5 pg/ml (30.0–116.0). Values ≥125 pg/ml were found in 22.4% (n = 70) of the whole study population.

In the group of patients with dyspnea, increased levels of natriuretic peptides were demonstrated in more than half (55.8%) of patients, and HF was confirmed by TTE findings in 45.8% of patients with NT-proBNP >125 pg/ml and every fourth patient with dyspnea (25.6%).

In the group of patients with CHF, the NT-proBNP median was 539.5 pg/ml (157.3–1704.8) and 88.9% of people had NT-proBNP levels above the cut-off value (>125 pg/ml). In the group of patients with decreased EF, the NT-proBNP levels above the cut-off value were demonstrated in all patients (median 1364.0 pg/ml [1162.0–1455.0]).

In the group of patients with asymptomatic LV dysfunction, one patient did not have symptoms indicative of CHF — the NT-proBNP value was above 125 pg/ml.

CHF prevalence

In the examined group, 5.75% of patients (n = 18) had been previously diagnosed with HF. All cases were analyzed individually by two independent experts. The diagnosis reported in the interview was confirmed in 4.15% (n = 13) of cases. These were the patients whose self-reported CHF was confirmed by TTE.

In the remaining patients, previously diagnosed CHF was not confirmed. One patient was newly diagnosed with HF. Ultimately, the study found an overall prevalence of HF of 4.8%.

Additionally, 0.64% (2 patients) were diagnosed for the first time. In total, CHF was diagnosed in 4.79% of the participants, mostly in men (90.9%). The mean age in this group was 66.2 years (10.4). The mean body mass index (BMI) in this group was 28.5 kg/m² (3.8). Subgroup analysis by BMI showed that 9.1% had a BMI <25 kg/m² (normal), 54.5% had a BMI of 25–29.99 kg/m² (overweight), and 36.4% had a BMI >30 kg/m² (obese).

To describe this group, participants were divided according to the LVEF value. In the HF group, there were 6 patients (1.92%) with reduced EF, 3 (0.96%) with intermediate EF, and 6 (1.92%) with a preserved EF. In the CHF group, 35.7% had hypertension, 21.4% had previously diagnosed diabetes, 35.7% had chronic obstructive pul-

Table 2. Distribution of patients reporting dyspnea in the study group

Dyspnea	Total NYHA II–IV	NYHA II (n)	NYHA III (n)	NYHA IV (n)
Percentage of people with dyspnea in the study group n = 313	43 (13.7%)	28 (8.9%)	12 (3.8%)	3 (1.0%)
NT-proBNP level, pg/ml, median (Q1–Q3)	143.0 (70.25–296.0)	98.0[a] (63.0–168.0)	220.0[a] (120.25–1235.25)	1364.0[a] (795.5–2433.0)
Percentage of patients with NT-proBNP >125 pg/mL, n = 44	24 (54.5%)	13 (44.8%)	8 (66.7%)	3 (100%)

[a]$P = 0.015$

Abbreviations: see Figure 1
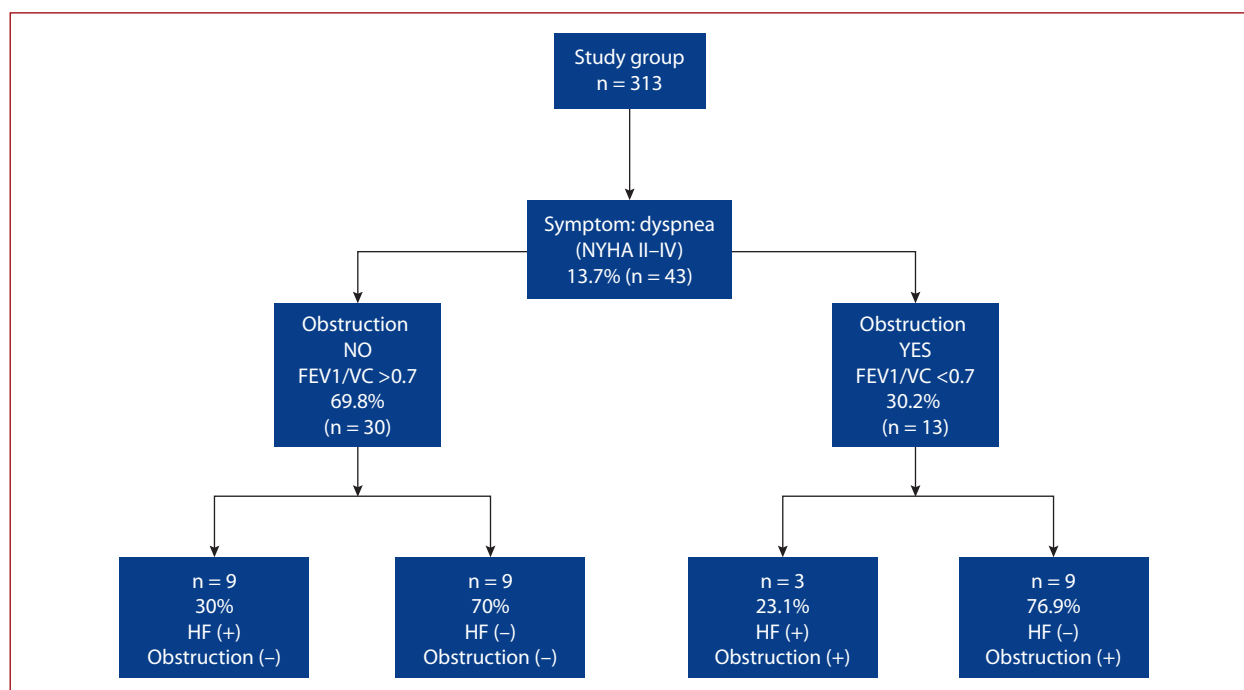
Figure 2. Obstruction in spirometry and heart failure in patients reporting dyspnea (NYHA II–IV)

Abbreviations: FEV1, Forced Expiratory Volume during the first second of expiration; VC, vital capacity; other — see Figure 1

monary disease (COPD) or obstruction in spirometry, and 35.7% had previously diagnosed chronic kidney disease or eGFR ≤60.

There were 3 participants in the study group without prior diagnosis of HF, whose TTE test showed a reduction in LVEF of more than 50%. One person who complained of dyspnea was diagnosed with HF. In the other two patients, asymptomatic LV dysfunction (LVSD) was diagnosed due to the lack of symptoms.

Almost 4% (3.83%) of the studied population had asymptomatic diastolic dysfunction.

DISCUSSION

The HF-Pomorskie Study was designed to analyze the prevalence of specific CHF symptoms and CHF itself in a selected province in Poland and to assess the usefulness of a diagnostic algorithm recommended by cardiology societies. The above analysis focused not only on the assessment of CHF prevalence but also on establishing recommendations for the most favorable screening design for a population-based study.

It should be noted that the ESC diagnostic algorithm applies only to newly diagnosed CHF. It is much more difficult to confirm the diagnosis in people who are already undergoing treatment. This is largely due to the reduction in the severity of symptoms and the levels of natriuretic peptides in patients who are optimally treated. However, this problem arises only in the case of screening, whereas in clinical practice it is a desired effect.

CHF prevalence

In the HF-Pomorskie Study, the prevalence of self-reported CHF was 5.75%. All patients underwent TTE, and this diagnosis was confirmed in 4.5% (n = 14) of them, and *de novo* diagnosis was made in 0.3% (1 patient). Finally, CHF was diagnosed in 4.8% of the study group.

These findings seem to be consistent with the results of the European studies that form the basis of the epidemiological data. So far, the most frequently cited data were published in the Rotterdam Heart Study (CHF prevalence 3.9%) and the EPICA study (CHF prevalence 4.36%) [14, 15]. These studies are considered to have the strongest methodologies.

The Hamburg City Health Study published in 2022 seems to be the best-planned screening study reported in the literature at the moment. Among the 7000 participants (45–78 years old), the prevalence of CHF was 4.83% and LVSD 1.12%. In that study, like in HF-Pomorskie, a detailed medical history was taken, the level of natriuretic peptides was assessed, and echocardiographic examinations were performed [16].

It should be noted that there is a pilot HF registry project conducted in 12 countries. It includes both outpatients and hospitalized patients. Although not a population-based study, still it provides useful details about this group of patients [17, 18].

The NATPOL 2011 study was the only attempt to analyze the prevalence of HF in a representative sample of adults in Poland. Based on interviews with patients, the self-reported prevalence of CHF was 4.3%. TTE was not performed, which certainly reduced the value of the data obtained. To verify the reported percentage of diagnoses, the authors analyzed the public medical insurer's database (National Health Fund) for the ICD10 code I50 (corresponds to CHF), and the percentage of confirmed diagnoses was 3.0%. The data obtained in the above studies should be treated with caution, as they do not reflect the actual situation in Poland [19]. However, it can be assumed that the number of CHF patients reported recently (600 000–700 000) is certainly underestimated [1, 2].

Correale et al. [20] presented an overview of comorbidities in HF patients. In their study, the proportion of patients with diabetes and chronic kidney disease was similar to HF-Pomorskie. The exception was COPD – in the HF Pomorskie study it was 35.7%, whereas Correale et al. reported 15.0% [20]. In our study, we included patients with self-reported COPD and additionally obstruction in spirometry. Thanks to performing echocardiography in all participants, it was possible to estimate the number of patients with LVSD, which was 0.64% of the study group. We had expected that the clinical problem of LVSD was more widespread. It seems, however, that population-based testing to detect LVSD is not cost-effective and does not meet the criteria for screening even though estimating the prevalence of this disease seems to be important for health policy planning. It may be worth considering searching for LVSD in a narrower group of patients with other CVD risk factors, e.g., diabetes or hypertension. However, due to the small number of participants, further analyses were not possible in this study.

Assessment of symptom severity

Dyspnea, which is often reported as a decrease in exercise tolerance and increased weakness is a nonspecific symptom and patients often do not associate it with HF. In our study, dyspnea was reported by 13.7% of the participants. In this group, HF was diagnosed in every 4th person (27.8%). At the same time, when analyzing the group reporting dyspnea, every 3rd patient was diagnosed with airway obstruction in spirometry, but only 25% of participants with such obstruction suffered from HF. This indicates the need for performing spirometry in patients with dyspnea because most of these cases do not have a cardiac cause. At the same time, this group requires further pulmonary function tests. It is also worth noting that for almost one-third of participants reporting dyspnea (29.3%), its underlying cause was not found. Similar results were obtained in the NATPOL 2011 study by Undrunas et al. [21] who analyzed the frequency of self-reported dyspnea in a representative group of 2413 people. The dyspnea equivalent (NYHA II–IV) was reported by 10.1% of participants, and in this group, the diagnosis of CHF was reported only by every 9th patient (13.1%) [21]. Dyspnea, as a symptom, is subjective and non-specific. There is probably a group in which this symptom can be associated with obesity or a low level of physical activity.

For many decades, the NYHA classification has been used to assess the severity of symptoms of HF. Its main disadvantages are subjectivity and lack of precision. The study by Raphael et al., which analyzed the reproducibility of the NYHA symptom classification, showed only 54% agreement between cardiologists assessing the same patient [22]. In a similar study, Goldman et al. found that the repeatability of symptom assessment using the NYHA classification by two independent cardiologists was only 56% [23].

Natriuretic peptides

The next step according to the ESC diagnostic algorithm was the analysis of natriuretic peptides. Since 1993, their role has been increasing in successive editions of the ESC recommendations for CHF management. Currently, it is recommended that this parameter should be initially measured in every patient with suspected CHF. This test appears to be widely available and easy to perform. However, in Poland, there are healthcare facilities where it is easier to perform TTE than to assess the natriuretic peptide concentration [23]. Although the measurement of this parameter could significantly facilitate initial differential diagnosis of dyspnea in the outpatient setting, primary care physicians working in Poland's public healthcare system are not able to order it.

In the group of patients who did not report dyspnea, increased levels of NT-proBNP were found in 15.9%, and a previous diagnosis of CHF was confirmed in one patient. These results indicate that elevated levels of natriuretic peptides are common in that population and may be related to non-cardiac causes, e.g. chronic kidney disease or COPD. Nonetheless, it is certainly a useful screening tool.

Limitations

The main limitation of our study is its sample size. The cost of a study designed according to the ESC guidelines and analyzing the prevalence of LVSD in a representative group is enormous; therefore, our study group was limited to approximately 300 people. A thorough analysis of

our research question would require inclusion of several thousand people in the study. However, the use of three-stage randomization allowed for effective analysis of the distribution of variables even in that small group.

We did not analyze ECG in this group. ECG abnormalities are widespread in CHF patients [25]. It can be used in the CHF diagnostic algorithm, similar to chest X-rays. In the guidelines, both examinations have a class I C recommendation [3, 4]. Nevertheless, natriuretic peptides and echocardiography had a decisive role when CHF was suspected.

Another limitation is that spirometry was performed without assessing bronchodilator reversibility; therefore, it allowed us to identify a group of people with obstructive disorders but did not allow us to diagnose COPD.

Summary of findings

A diagnostic algorithm designed for clinical practice (according to the ESC criteria) is useful for assessing the prevalence of CHF in the population-based survey. However, such a study requires significant financial resources and extensive involvement of specialized equipment and qualified personnel. Moreover, imaging diagnostics should be limited to selected participants (those reporting symptoms and those with elevated NT-proBNP levels).

The prevalence of CHF among the residents of the Pomeranian Province was 4.8%, including newly diagnosed cases (0.3%).

Almost all CHF patients, both treated and newly diagnosed, had elevated levels of natriuretic peptides.

The percentage of people who self-reported CHF was 5.75%. It should be noted, however, that after careful evaluation of their medical history and current state, in 1% of cases, the CHF diagnosis could be considered doubtful, and in another 2.0% it was disputable.

In the general population, dyspnea, defined as NYHA class II–IV, was reported by 13.7% of participants. Every third patient with dyspnea had features of obstruction in spirometry, and every fourth patient had an elevated level of NT-proBNP

CONCLUSIONS

The use of the clinical algorithm for the diagnosis of CHF in population-based studies is possible; however, imaging tests and NT-proBNP should be limited to patients reporting dyspnea or with prior diagnosis of CHF for its verification. The extensive use of TTE and the determination of NT-proBNP levels to identify patients with asymptomatic LVSD or LV relaxation disorders do not seem justified.

It is sometimes difficult to assess the validity of a prior diagnosis of CHF, especially in pharmacologically treated patients with acute coronary syndrome.

The inclusion of spirometry in the screening for CHF in the population seems to be justified not only to differentiate CHF from lung diseases but also because of the coexistence of CHF with lung diseases.

We must still remember that in the clinical management of suspected HF, we should follow the ESC recommendations. If possible, we should measure natriuretic peptides in each patient, and in the next step, we perform an imaging test, e.g., echocardiography.

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