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IDENTIFICATION OF HEART FAILURE PATIENTS WITH HIGHEST ANXIETY LEVEL – SIMPLE SELF-INVENTED ONE-QUESTION SCALE.

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A - Koncepcja i projekt badania, B - Gromadzenie i/lub zestawianie danych, C - Analiza i interpretacja danych, D - Napisanie artykułu, E - Krytyczne zrecenzowanie artykułu, F - Zatwierdzenie ostatecznej wersji artykułu

Abstract (in English):
Aim: The aim of this work is to assess the influence of anxiety level, self-perceived disease severity, primary source of knowledge and selected socioeconomic factors on the degree of adherence to guidelines-based self-maintenance recommendations in patients with chronic heart failure.
Material and methods: 202 patients from CHF outpatient clinic and hospitalized with CHF were assessed with 5-part questionnaire, self-invented scale assessing self-perceived disease severity and with Spielberger State Trait Anxiety Inventory (STAI).

Results: Patients with highest anxiety levels (>40pts) were in more advanced stages of the disease, had lower level of education and perceived their disease as more severe than individuals with lower anxiety levels (<40pts). Primary source of knowledge was physician for majority of patients. Only 23% know and obeyed all self-maintenance recommendations. Self-perceived disease severity was the strongest determinant of anxiety level (p= 0,013; 1,041-1,418; HR=1,215). Anxiety level did not influence adherence to guidelines-based recommendations.
Conclusions: Perceived disease severity is strongly associated with anxiety level. Simple self-perceived disease severity scale can substitute for more complicated psychological tools. Physician, as the most important source of knowledge, has an immense role in educating patients on self-maintenance behaviour. Practice Implications: The use of simple, reproducible scale can significantly facilitate identification of patients with high anxiety level requiring therapeutic intervention.

Keywords: anxiety, self-perceived disease severity scale, adherence, heart failure.

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Anxiety level in patients with heart failure.

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Authors (short)
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Introduction

A growing number of heart failure patients is a challenge for healthcare systems throughout the world. Although they benefit from the immense progress in advanced CHF treatment, some psychological needs of this diverse population might still be unmet. Medical staff efforts are mainly focused on prolonging life and relieving physical symptoms with less attention paid to psychological factors influencing patients' well-being.

Numerous reports suggest that anxiety and depression are common among both ambulatory and hospitalized patients with heart failure and that they have unfavourable impact on survival, quality of life, utilization of healthcare services [1,2,3] and may also accelerate physical decline. Various definitions of anxiety usually mention a negative emotion of unease, worry or fear caused by the apprehension of future unpleasant events. The level of anxiety in heart failure is relatively high and may even exceed the intensity observed in cancer or chronic lung disease [4]. In CHF

patients anxiety (Wei Jiang) is reportedly correlated with age, presence of ischemic heart disease and heart failure severity. The impact of anxiety on adherence to medical recommendations in patients with heart failure has not been extensively studied and available data is inconsistent. De Jong at al. described the linkage between anxiety, non-adherence and worse outcome in CHF population, whereas Schweitzer did not find any relationship between anxiety and treatment adherence behaviour [5]. Some authors even suggest that degree of anxiety might in fact promote compliance [6].

Illness perception is another very important dynamic modifier of the intensity of anxiety [7]. Moreover, self-perceived disease severity was proved to significantly influence survival [8]. Whether the perception of the disease severity has an impact on adherence was not sufficiently investigated.

Adherence to guidelines itself has been extensively studied in CHF population. Wu at all using only a single-item question proved that poor medication adherence is associated with all-cause and heart failure-related hospitalization and death of CHF [9]. Song at al. reported that adherence to low-sodium diet is associated with prognosis in heart failure patients and that it may be used as a universal indicator of adherence [10].

Multidimensional evaluation of psychological factors and their relationship with adherence is difficult in patients with chronic heart failure, especially in individuals in advanced stages of the disease. Patients are often reluctant to fill multiple-choice questionnaires, as they do not regard this kind of examination as important as clinical one. Simplification of psychological risk factors evaluation could make it more available in daily clinical practice. Together with fast identification of problems with adherence it could contribute to the better management of CHF, particularly on the outpatient basis. Therefore, we designed a study protocol that utilize self-invented simple scale of patient-perceived disease severity together with 7 questions assessing familiarity and adherence to selected guidelines. Patients were also asked to indicate the main source of knowledge regarding their disease and to fill in the Spielberger State Trait Anxiety Inventory (STAI). This combination of tests was conducted in the specific setting – namely chronic heart failure outpatient clinic established by the cardiology department specializing in CHF management. The study protocol was meant to investigate the interaction between anxiety, adherence, self-assessed disease severity and selected demographic and clinical factors in this unique institution focused on CHF population.

The aim of the study was to assess the influence of anxiety level, self-perceived disease severity, primary source of knowledge and selected socioeconomic factors on the degree of adherence to guidelines-based self-maintenance recommendations in the group of CHF patients treated within a clinical unit specifically dedicated to heart failure.

Methods

The study group consisted of 202 consecutive patients treated on the outpatient basis in the Heart Failure Outpatient Clinic and admitted to the IInd Clinic of Cardiology in the University Hospital no 2 in Bydgoszcz. All patients at the time of inclusion were optimally treated according to the European Society of Cardiology Guidelines on Acute and Chronic Heart Failure Management.

Inclusion criteria were: chronic heart failure diagnosed according to European Society of Cardiology Guidelines on Acute and Chronic Heart Failure Diagnosis and Treatment and left ventricular ejection fraction ≤ 45% assessed during index hospitalization or during past 6 months. Exclusion criteria consisted of: diagnosed depression and anxiety disorders or dementia, one month before planned or one month after performed surgical procedures. Written informed consent was

obtained from each study participant following a detailed explanation of the study protocol that is in compliance with the principles outlined in the Declaration of Helsinki. Bioethical Committee by the Collegium Medicum of the Nicolaus Copernicus University approval for the study was obtained.

Each study participant answered questions from a questionnaire consisting of 5 main following parts:

1. Sociodemographic data including age, gender, level of education, marital status, place of residence
2. Choice of the most important source of knowledge on the disease from the following: physician, nurse, newspapers, books, internet, family, fellow patients and other sources
3. Self-invented 10-point analogue-digital scale subjectively assessing the severity of the disease in which patients were asked to state how serious is chronic heart failure in his/her opinion. 1 point was ascribed to pharyngitis without need for an antibiotic while on the very end of the scale with 10 points was the answer: disseminated cancer *(Fig.1)*.
4. 7 questions evaluating the degree of familiarity and the level of compliance with recommendations regarding self-maintenance selected from European Society of Cardiology Guidelines on Acute and Chronic Heart Failure Diagnostics and Treatment (2016).
    1) I record my weight on a daily basis and I am able to notice an unexpected weight gain.
    2) I take my medication regularly, as prescribed, I understand the indications, dosing and side effects of drugs.
    3) I understand that depressive symptoms and cognitive dysfunction are found frequently in patients with my disease. I seek support when needed.
    4) I understand the importance of physical activity in my disease. I exercise regularly (3 times a week).
    5) I know that smoking is harmful. I do not smoke.
    6) I understand the need for fluid and salt restriction in heart failure. I avoid excessive fluid and salt intake.
    7) I understand that alcohol might be harmful. I drink no more than 250ml of beer/ 200 ml of wine/ 100 ml of vodka per day (half of this amount for women).
5. Spielberger State Trait Anxiety Inventory (STAI) consisting of two parts with 20 statements each: STAI X-1 and STAI X-2. The statements are measured on a 4-point scale with potential scores between 20 and 80 points, STAI X-1 measures self-reported anxiety level at a given moment as transitory feeling lasting from hours to days. STAI X-2 evaluates enduring feeling of anxiety experienced most of the time by the examined individual. The STAI was invented by Spieleberger, Gorsuch and Lushene and the Polish version used for testing was developed by Spielberger, Strelau, Tysarczyk and Wrześniewski.

Data from all the questionnaires was combined with clinical information and selected test results.

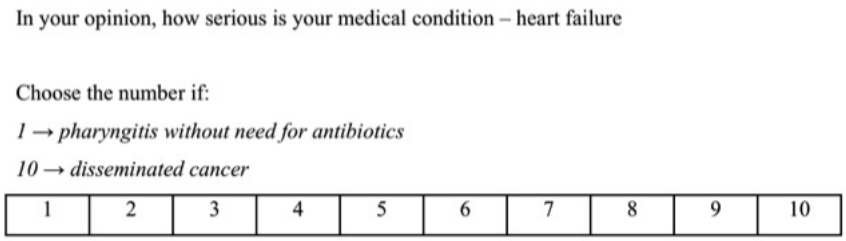

Figure 1. Digital-analogue self-perceived disease severity scale

Statistical analysis

Statistical analyses were preformed with the use of Statistica ver. 12. software. A probability less than .05 was considered statistically significant. Normality of distribution was verified with Shapiro-Wilk test.

A cut-off value of 40 for STAI X1 and X2 score was set to dichotomize patients into low- or high-anxiety groups. The good level of adherence was defined as 75% followed recommendations. 6 points or more on the self-invented digital-analogue scale was considered as high patient-perceived disease severity. U-Mann Whitney test was used to compare nonparametric independent variables. χ^2 test and χ^2 with Yates correction were used to test association between the following variables: NYHA class, aetiology of heart failure, educational level, place of residence and STAI X1/X2 score or enrolment place (outpatient/inpatient). Association between the familiarity with the recommendation and compliance was assessed with χ^2 test and χ^2 with Yates correction and Pearson correlation coefficient. Linear regression model was used to test the relationship between STAI X1/X2 score, the level of familiarity and compliance with recommendations, and selected parameters. Logistic regression models were employed to test the influence of selected parameters on the level of compliance. χ^2 and χ^2 with Yatesa correction was used to test the association between STAI and the level of familiarity and compliance with guidelines.

Results

202 patients with chronic heart failure with reduced ejection fraction were included in the study. Mean age was 59 ± 12 years, 84,16% of them were males. Mean score in STAI X1 was 41,73 ± 9,68 points, while in STAI X2 43,78 ± 9,34 points. In concordance with previous publications we adopted 40 points as a cut-off value to divide patients into those with low and high anxiety level. Patients with higher both STAI scores had lower educational level, perceived their disease as significantly more severe and were in higher NYHA class compared to individuals with STAI scores <40 points.

Table 1. Overall clinical characteristics of the study group and comparison between patients with high and low anxiety level according to STAI X1 and STAI X2 score.

Parameter	All (n=202)	STAI1<40 (n=73/36,14%)	STAI1≥40 (n=129/ 63,76%)	p	STAI2<40 (n=70/ 34,65%)	STAI2≥40 (n=132/ 65,35%)	p
Age (years)	58,74±11,99	58,14±12.39	59,1±11,78	0,059	57,97±13,52	59,15±11,12	0,507
STAI X1	41,73 ± 9,68 pkt.	31,65+ / -5,07	47,43+ / -6,47	0,000	32,92+ / -6,31	46,40+ / -7,69	0,00
STAI X2	43,78 ± 9,34 pkt.	36,3+ / -6,78	48,01+ / -7,8	0,000	33,72+ / -3,91	49,11+ / -6,57	0,00
Hospital/ outpatient	42 / 160 20% / 80%	24,66% / 75,44%	18,6% / 81,40%	0,308	17,14% / 82,86%	22,73 / 77,27%	0,352
Self perceived disease severity (points)	7,8 ± 2,02	7,30±2,40	8,11±1,71	0,006	7,41±2,30	7,03±1,83	0,039
Males	84,16%	82,19%	85,27%	0,662	81,43%	85,61%	0,745
In relationship	77,72%	73,97%	79,84%	0,335	75,71%	78,79%	0,617
Education level (primary, vocational, college, university)	13,37% / 43,07% / 31,68% / 11,88%	6,84% / 38,36 / 38,36 / 16,44	17,05 / 45,74 / 27,91 / 9,3	0,0497	8,57 / 38,57 / 32,86 / 20%	15,91 / 45,45 / 31,06 / 7,58%	0,039
Residence (rural/ town<10.000/ town >10.000)	32,18% / 14,37% / 53,47%	30,14 / 13,7 / 56,16%	33,33% / 14,73% / 51,94%	0,844	31,29 / 12,86 / 52,86%	31,06 / 15,15 / 53,79%	0,850
Ischaemic aetiology	53,47%	54,79%	52,71%	0,878	48,57%	56,06%	0,310
Physician as primary source of knowledge	84,65%	82,19%	86,05%	0,809	78,57%	87,88%	0,753
NYHA functional class II/III/IV	76% / 22% / 2%	31,44+ / -5,15 32,66+ / -5,21 32+ / -0 (2 pts)	46,72+ / -5,71 49,57+ / -8,1 45,5+ / -3,53 (2 pts)	0,029	33,75+ / -3,84 34+ / -5,16 32+ / -0,0 (2 pts)	48,64+ / -6,15 50,21+ / -7,6 50+ / -1,4 (2 pts)	0,008
Diabetes	24,26%	23,29%	24,8%	0,234	18,57%	27,27%	0,170
LVEF (%)	32,57 ± 9,09	32,81±8,66	32,44±9,36	0,784	33,86±876	31,89±9,23	0,145
Arterial Hypertension	42,08%	50,68%	37,21%	0,062	45,71%	40,15%	0,446

Patients perceiving CHF as severe disease (≥6 pkt.) had more advanced heart failure as assessed by NYHA classification (Figure 1).

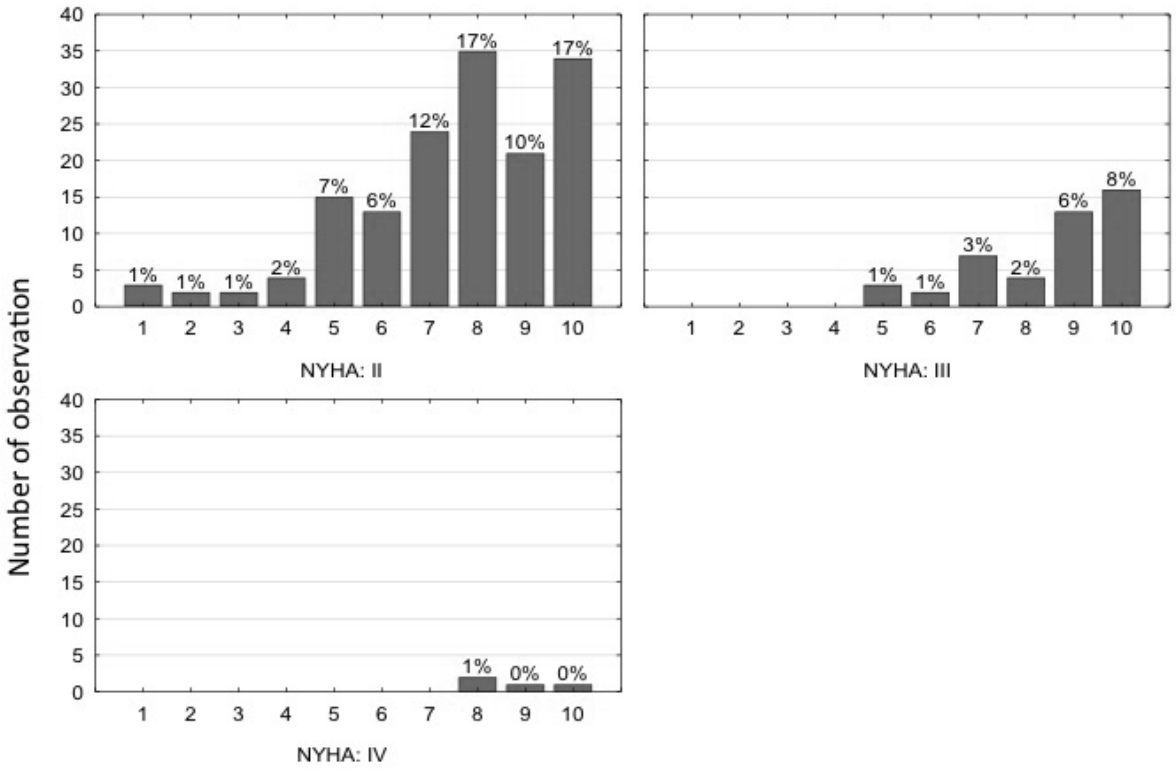

Figure 2. Self-perceived CHF severity across NYHA functional classes.

Only 23% of the studied group knew and obeyed all 7 recommendations (Table 2). The most widely known and applied guideline was that on taking medications. Patients were least familiar with recommendation on regular weight control and relatively few participants knew about the higher risk of depressive disorders associated with CHF. Moderate physical exercise was a guideline with the lowest level of adherence (Table 3).

Table 2. Number and percentage of patients adhering to the guidelines.

Number of recommendations obeyed	Patients adhering to recommendations (n/%)
0 (none)	4 /1,98
1	2 / 0,99
2	13 / 6,44
3	21 / 10,40
4	29 / 14,36
5	43 / 21,29
6	44 / 21,78
7 (all)	46 / 22,77

Table 3. Number and percentage of patients familiar with and adhering to 7 selected guidelines.

Recommendation	Familiarity with recommendation n=202	Compliance	P (χ^2)	Percentage of familiarity and compliance
Weight	N=144 (71,29%)	N=113/144 (78,5%)	P<0,0001	55,94%
Drugs	N= 198 (98,02%)	N= 192/198 (96,97%)	P<0,0001	95,05%
Depression	N=135 (66,83%)	N= 109/135 (80,74%)	P<0,0001	53,96%
Physical activity	N= 174 (86,14%)	N= 138/174 (79,31%)	P<0,0001	68,32%
Smoking	N= 174 (86,14%)	N= 151/174 (86,78%)	P<0,0001	74,75%
Fluid balance	N= 185 (91,58%)	N=149/185 (80,54%)	P<0,0001	73,76%
Alcohol	N= 179 (88,61%)	N= 156/179 (87,15%)	P<0,0001	77,23%

The only difference between patients recruited from the outpatient clinic and those hospitalized were in NYHA class and left ventricular ejection fraction. Logistic regression models revealed statistically significant association between the STAI X1 but not STAI X2 score and self-perceived disease severity. Individuals with high anxiety level perceived their disease as more severe than patients with lower STAI X1. None of the studied clinical and demographic parameters had the significant influence on the adherence to the selected recommendations. (Table 4)

Table 4. Logistic regression model assessing the relationship between STAI X1 and X2 score and selected parameters.

Parameter	STAI X1	STAI X2
Disease Severity	**p= 0,013 (1,041;1,418) HR=1,215**	p= 0,126 (0,965;1,330) HR=1,133
Compliance	p= 0,721 (0,977;1,016) HR=0,991	p=0,520 (0,980;1,010) HR=0,995
The most important source of knowledge	p= 0,782 (0,800;1,206) HR=0,970	p= 0,392 (0,736;1,129) HR=0,911
EF	p=0,957 (0,966;1,037) HR=1,001	p=0,837 (0,856;1,054) HR=1,005
NYHA	p= 0,692 (0,586;2,233) HR=1,144	p= 0,106 (0,873;3,976) HR=1,863
Etiology	p=0,671 (0,596;2,230) HR=1,153	p= 0,401 (0,347;1,532) HR=0,729
DM	p=0,757 (0,434;1,837) HR=0,893	p=0,506 (0,604;2,766) HR=1,290
Marital status	p=0,489 (0,372;1,610) HR=0,774	p=0,795 (0,401;2,014) HR=0,900
Age	p=0,731 (0,997;1,103) HR=1,005	p=0,797 (0,962;1,030) HR=1,000
Gender	p=0,492 (0,588;3,004) HR=1,329	p=0,500 (0,566;3,200) HR=1,345
ICD	p=0,575 (0,432;1,799) HR=0,889	p=0,542 (0,655;3,301) HR=1,382

Discussion

Anxiety, often with accompanying depression, is a feeling commonly associated with severe somatic disorders including chronic heart failure with reduced ejection fraction. Factors influencing anxiety level and the impact of anxiety itself on prognosis in CHF are not well recognized. Tsuchihashi-Makaya et al. described the relation between anxiety and heart failure related re-admissions [11] whereas Suzuki et al. found the association between worse outcome and clustered

anxiety and depression but not anxiety alone [12]. Apart from its plausible impact on prognosis, anxiety is still a problem influencing quality of life in this group of patients [13]. In our study STAI score was used to assess anxiety level and attempt has been made to define factors associated with higher STAI results. Patients with STAI 1/STAI 2 scores >40 were considered as having high anxiety level. Simple self-invented scale used in this research to assess perception of the disease severity showed that this population perceived their disease as more severe than those with STAI scores below 40 points. This assessment seems to be accurate, as these patients were indeed in more advanced stages of CHF as evaluated by NYHA functional classification. Interestingly, place of inclusion – outpatient clinic or hospital – did not have any influence on anxiety level although admittance was caused by exacerbation. Another difference between groups with high and low anxiety level was in an educational status – patients better educated had significantly lower intensity of anxiety. The association between low education level and anxiety was previously described in general population [14]. However, De Jong at al. and Schweitzer et al. did not observe this kind of relationship in CHF population [15,5]. Insufficient communication with healthcare providers as a source of anxiety has recently been described in palliative care [16]. For vast majority of our patients the main source of knowledge on the disease was their cardiologist, therefore we hypothesized that the form of communication between them may not be adequate for individuals with lower educational level leading to higher anxiety level. However, another interpretation of this phenomenon might also exist. The actual relationship between communication quality, anxiety and demographic or socioeconomic indices remains to be investigated.

Regression analysis revealed the most prominent determinant of high anxiety level – after adjustment for age, sex, aetiology, NYHA class, LVEF, main source of knowledge, level of adherence to guidelines, marital status, presence of diabetes and ICD – only self-perceived disease severity turned out to be independently associated with higher STAI 1 but not STAI 2 anxiety score. It points toward the conclusion that such a simple instrument as our self-designed digital-analogue scale of disease perception can help to single out patients experiencing more severe anxiety. This kind of fast assessment may be valuable especially in an outpatient setting, where efficient risk stratification and delivering psychological support to most endangered patients would reduce unnecessary interventions and minimize costs.

Our results regarding adherence to selected self-care guidelines are in concordance with other authors [5]. Similarly, to Schweitzer et al. we did not find any relationship between adherence and anxiety assessed with STAI scores nor with the self-perceived disease severity. Interestingly, no apparent influence of educational status on adherence to guidelines was observed. Only about 20% of study participants know and obeyed all seven selected guidelines. Taking the medictions was the most widely known and obeyed recommendation, whereas adherence to non-pharmacologic guidelines was significantly lower. Low compliance with non-pharmacologic guidelines such as daily weighing and regular exercise has been described in previous studies [17,18]. Nieuwenhuis et al. reported transient increase in compliance with daily weight recording in patients shortly after hospitalisation with subsequent decrease over time. Authors also recorded a positive impact of education on daily weighting adherence, while exercise compliance was not increased by this kind of intervention [17]. We did not observe significant difference in compliance with any recommendation between patients recruited during outpatient visit or at a time of hospitalization. Moreover no demographic or clinical variable significantly influenced the level of knowledge on guidelines or adherence. Relatively high adherence to moderate exercise training recorded in our population comparing to that observed by

other authors [19,20] may be explained by a high proportion of patients with only moderate symptoms (NYHA class II) in the study group. Relatively young mean age of observed population may also be of some importance. Surprisingly, only less than three quarters of patients were aware of the need for daily weight recording and 78% of them obeyed this recommendation. This observation is quite disturbing, considering the fact that body mass monitoring guideline is aimed at fast recognition of CHF worsening. Delay in seeking medical care for heart failure exacerbation is reported to reach 14 days in extreme cases [21], Johansson et al. reported that patients with heart failure worsening and prehospital delay exceeding one day had longer hospital stay [22]. Limited knowledge on symptoms heralding exacerbation of the disease is one of the most frequent causes of such a delay [23]. In this context our observation should prompt more efficient education on self-care behaviour associated with fast recognition of warning signs, especially in high-risk individuals in most advanced stages of the disease. Relatively low percentage of the study group realized that CHF place them at risk for depressive disorders. The lack of knowledge in this area is even more disturbing considering that over 60% of patients suffers from considerable anxiety. These two comorbidities put patients in emotional distress and may have unfavourable influence on prognosis.

Consistently with previous reports [24], main source of knowledge on the disease for CHF patients was their physician. This observation may also be associated with specific situation in Poland, where the nurse's role in actual management of ambulatory patients is limited. This distinct reliance upon information provided by physicians highlights their immense responsibility for efficient, precise communication and patients' education.

Conclusions and practice implications

Anxiety in patients with chronic heart failure with reduced ejection fraction is associated with self-perceived disease severity. Simple one-question scale assessing self-perceived disease severity helps to single out patients with potentially highest anxiety level and address this comorbidity with appropriate psychological intervention. Identifying such patients is even more important considering the fact that only a small proportion of this population is aware of the risk of depression associated with chronic heart failure. Adherence to self-care guidelines seems to be independent of the anxiety intensity, other socio-demographic indices and disease severity. In this specific population compliance with non-pharmacologic recommendations is relatively low and should be addressed with tailored interventions aimed specifically at educating patients about symptoms of imminent CHF exacerbation. The use of simple, reproducible scale of self-perceived disease severity can significantly facilitate identification of patients with high anxiety level requiring therapeutic intervention. Patients with chronic heart failure, especially those in advanced stages of the disease, due to their poor clinical condition are frequently reluctant to participate in elaborate questionnaire-based evaluations. At the same time this population is at greatest risk of depression and anxiety. The scale we propose will make the identification of patients requiring more extensive psychological approach much easier and faster.

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

Ackonowledgements: None

Conflict of interest: None

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