Interplay between psychosocial and heart failure related factors may partially explain limitations in self-efficacy in patients with heart failure and poor self-care behaviour: insights from a real-world cohort of 1,123 patients

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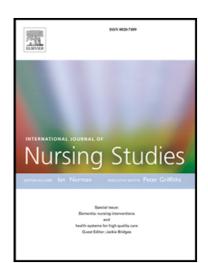
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TITLE

Interplay between psychosocial and heart failure related factors may partially explain limitations in self-efficacy in patients with heart failure and poor self-care behaviour: insights from a real-world cohort of 1,123 patients.

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What is already known

- Poor self-care is and independent predictor of adverse clinical outcomes such as hospitalization and death in patients with chronic heart failure.

- One of the most important instruments for evaluating self-care in heart failure patients is the European Heart Failure Self-Care Behavior Scale (EHFScBS).

What this paper adds

- Impaired self-care behavior is strongly determined by psychosocial factors.

- Particularly, social support, affective status and need of a caregiver are the main drivers of self-care regardless of clinical factors.

ABSTRACT

Background and aims:

Worse self-care is associated with a higher risk of readmission and mortality in patients with heart failure (HF). Little is known about how the interplay between clinical and psycho-social factors may modulate self-care behaviours in these patients. The aim of our study was to identify clinical, and particularly psycho-social factors associated with worse self-care and assess their interaction inpatients with heart failure.

Methods and results:

We conducted an observational, prospective, cohort study of 1,123 consecutive patients with chronic heart failure.. Self-care was assessed with the modified European Heart Failure Self-care Behavior Scale 9-item version (EHFSCBS-9), and both clinical and psycho-social profile of the patients included were also meticulously evaluated. A total of 484 patients (43%) were women, mean age was 72 years, and mean left ventricular ejection fraction was 44.5%. In multivariable analyses combining clinical and psychosocial factors, low social support (OR 3.53, 95% CI [2.13-5.86]; p-value <0.001), absence of caregiver support (OR 2.16, 95% CI [1.34 -3.48]; p-value 0.001) and depressive symptoms (OR 2.40, 95% CI [1.53-3.77]; p-value <0.001) were independent determinants of impaired global self-care. Advanced functional class was associated with better self-care (OR 0.43, 95%CI [0.26-0.70]; p-value 0.001). No other clinical factors remained significantly associated with self-care in these joint models. In discrimination analyses, models containing psycho-social determinants outperformed models only containing heart failure -related (clinical) variables (all p-values<0.001).

Conclusion:

Impairment in self-care behaviour is strongly determined by psycho-social factors. Specifically, low social support, the lack of caregiver support and the presence of depressive symptoms are the main drivers of the risk of impairment of self-care in_heart failure patients. Evaluation of self-care and self-care interventions should be

complemented by a comprehensive psycho-social assessment in patients with heart failure.

Key words: heart failure, self-care, heart failure nursing, psychosocial factors, scale.

Abbreviations List

- EHFScBS European Heart Failure Self-care Behaviour Scale
- DAMOCLES <u>D</u>efinition of the neuro-hormonal <u>A</u>ctivation, <u>M</u>yocardial function, gen<u>O</u>mic expression and <u>CL</u>inical outcomes in h<u>E</u>art failure patients
- NYHA: New York Heart Failure Association
- GAM: Generalized Additive Model
- BMI: Body Mass Index
- GDS Geriatric Depression Scale

INTRODUCTION

Heart failure is a syndrome with an extremely negative impact on mortality, morbidity, and health-related quality of life. Its prevalence is 1%-2% of the general adult population, and its survival barely reaches 60% at 5 years.¹ Furthermore, it represents a challenge for health systems due to its increasing prevalence and the medical resource use and costs associated with heart failure.²⁻⁵

Self-care behaviour plays a determinant role in the prognosis of these patients since recent studies demonstrate that poor self-care is and independent predictor of adverse clinical outcomes such as hospitalization and death.^{6,7} Self-care is the patients' attitude and ability to voluntarily perform activities aimed to improve their quality of life and health status.^{8,9}. The education on the management of the disease or the ability to recognize the early signs of decompensation are crucial aspects to improves self-care in heart failure patients.

There are three well-known self-care behaviour domains deemed to be particularly relevant in heart failure: autonomous-based adherence, consulting behaviour and provider-based adherence.^{7,8} One of the most important instruments for this evaluation in heart failure patients is the European Heart Failure Self-Care Behavior Scale (EHFScBS).⁷ This instrument describes global self-care, and also allow the individual assessment of the 3 domains of self-care. ⁸ A proper evaluation of self-care is crucial to gauge patient's competence and enables nurses to prompt tailored educative interventions to promote patient's behaviours directed to mitigate disease progression, worsening health status, new hospitalizations and death.

Addressing behavioural changes of patients in the setting of chronic complex conditions such as heart failure is not an easy task.¹² Self-care is a complex concept and is

influenced by modifiable and non-modifiable determinants. Identify modifiable factors as life habits, weight control, etc. that shape the level of self-care at an individual patient is important since activities directed to improve such behaviours may need specific interventions on these factors.

Previous research has partially addressed the influence of social support, gender and psychological determinants on the level of self-care.^{7,12-14} However, little is known about the importance of individual patient characteristics, including not only clinical but also psychosocial factors in patient self-care.^{8,9,15} Moreover, previous studies included a few number of patients, focused in specific heart failure phenotypes (Heart failure with reduced ejection fraction) and did not address psycho-social limitations in a comprehensive manner.^{7,12-14}

Given the limitations above mentioned, our study was designed to identify the clinical and, particularly, the psycho-social factors independently associated with self-care in a broad-spectrum cohort of real-world patients with chronic HF. Importantly, we evaluated the influence of heart failure-related clinical and psycho-social factors on self-care (globally and each of the 3 domains) to ascertain their relative contribution that may help to guide interventions in the future aimed to improve self-care behaviours.

METHODS

Study Design, Study Population and Ethics

The <u>D</u>efinition of the neuro-hormonal <u>A</u>ctivation, <u>Myocardial</u> function, gen<u>O</u>mic expression and <u>CL</u>inical outcomes in h<u>E</u>art failure patients (DAMOCLES) study was a single-center, observational, prospective cohort study of 1,236 consecutive patients diagnosed with chronic heart failure recruited between January 2004 and January 2013.

The methodology of the DAMOCLES study has been published previously by our group.^{5, 16-20} Briefly, for inclusion, outpatients had to be diagnosed with chronic heart failure according to the European Society of Cardiology diagnostic criteria, had at least one recent acute decompensation of chronic heart failure requiring intravenous diuretic therapy (either hospitalized or in the day care hospital), and had to be in stable condition at the time of study entry. Exclusion criteria were: significant primary valvular disease, clinical signs of fluid overload, pericardial disease, restrictive cardiomyopathy, hypertrophic cardiomyopathy, haemoglobin levels < 8.5 g/dL, active malignancy, and chronic liver disease. The study was approved by the local committee of ethics for clinical research, and was conducted in accordance with the principles of the Declaration of Helsinki. All patients gave written informed consent before study entry.

For the present analysis, all DAMOCLES participants were considered for inclusion. Of them, we excluded patients with missing baseline information on self-care. Thus, for the purposes of the present analysis, the final cohort consisted in 1123 patients.

Baseline Assessment

A detailed baseline evaluation was performed for all participants at study entry. This included collection of information about demographic characteristics, exhaustive medical history to gather clinical and disease related factors such as New York Heart Association (NYHA) functional class, co-morbidities, laboratory data, medical treatments, and the most recent left ventricular ejection fraction. Sources of information for this were the medical history and standardized questionnaires.

Evaluation of Self-Care

To assess self-care, we used the European Heart Failure Self-care Behavior Scale (EHFScBS)¹¹. The original EHFScBS consists of 12 items that can be scored with a Liker-type scale of 1 to 5 points where 5 corresponds to the worst self-care. Scores range from 12 (best possible self-care), to 60 points (worst possible self-care). This is an instrument widely used in real practice and has been validated for use in the Spanish population.²¹ In recent years, a new improved version of this scale has been developed. The new 9-item EHFScBS (EHFScBS-9) includes information from nine items of the original scale and excludes 3 individual items (items number 2, 7, and 11) of the 12-item version¹¹ The possible score of the EHFScBS-9 is 9–45, with a lower score indicating better self-care.

In order to improve the clinical interpretability of the results obtained with the EHFScBS-9, the developers of the instrument have recently introduced a standardised score from 0–100. The score is also reversed such that a higher score means better self-care.^{11,22}

Although the scale has been designed to generate a global score informing on self-care, in a recent study, the authors of the original EHFScB-9 performed a factor analysis of the EHFScB-9 and described 3 potential factors or domains of self-care that

can be individually assessed using the original EHFScBS. Items 1, 5 and 9 would inform on autonomy-based adherence, items 2, 3, 4, and 6 would inform on consulting behaviour, and items 7 and 8 would inform on provider-based adherence 6,22

Autonomous-based adherence comprises those behaviours that patients integrate in their daily life routine such as self-weighing every day, assessing the presence of ankle edema or performing water restriction correctly, among others. Consulting behaviour is the patient's ability to detect warning signs and consequently contact with the healthcare team. And finally, provider-based adherence is the level of patient's compliance with the advice given by healthcare professionals, particularly nurses.^{10,11}

In the present study, to be consistent with the methods of reporting global scores recently suggested by the original authors of the EHFScBS-9¹¹, the scores of these 3 factors or dimensions are presented after reverting and standardizing the scores from 0 to 100. Consequently, higher scores indicate better self-care at each of these domains.

Cut-off points defining impaired or preserved self-care have not been defined for the EHFScBS-9. However, for the purpose of this study we defined impaired self care when inverted and standardized individual scores were in the lowest tertile of the 9-item EHFScBS-9 (impaired global self-care [<55 points]) or in the lowest tertile of each individual domain or factor (impaired autonomy-based adherence [<42 points], impaired consulting behaviour [<62 points] and impaired provider-based adherence [<75 points]).

Psycho-Social Evaluation

To fully characterize patients in their psycho-social dimension, prospective information was collected on education and literacy, marital status, cohabitation with a

partner and the presence and need of a caregiver. Likewise, several validated instruments were administered in order to define important psycho-social aspects such as cognitive function, dependency on basic and instrumental activities of daily living, social support, family function and affective status.

Cognitive function was evaluated by means of the administration of the Short Portable Mental State Questionnaire (SPMSQ) and the Mini-Mental State Examination questionnaire (MMSE). Cognitive impairment was defined as abnormal scoring in any of the two questionnaires (MMSE<24 or 3 or more mistakes in the SPMSQ).^{6,23}

Dependency to perform basic activities of daily living was evaluated by calculating the Barthel Index²⁴. The scores of this index range from 0 (total dependence) to 100 (independence). As specified in the interpretation of this test, scoring lower than 100 points in this evaluation was considered impaired activities for daily living To assess the instrumental activities for daily living we used the Lawton and Brody scale.

We used the version of the scale that covers scores from 8 to 30 points. Higher scores identify a higher level of dependency regarding instrumental ADLs. Dependence for instrumental activities for daily living was defined as scores on the Lawton and Brody scale higher than 8 points.^{6,25}

To assess the self-perceived social support we administered the 11-item Duke-UNC Functional Social Support Questionnaire. Scores in this questionnaire range from 11 and 55, higher scores meaning better functional social support. For the purpose of this study, impaired social support was defined when scores in the Duke-UNC questionnaire below or equal the 25th percentile (47 points).^{6,26}

Family function was evaluated using the Family APGAR test. This questionnaire captures important functional components of family function such as adaptability, partnership, growth, affection and commitment to devote time to family

members. Scores range from 0 (severe family dysfunction) to 10 (normal family functioning). For the purpose of this study, we defined impaired family function when scores were below 10 points.^{6,27}

Finally, affective status was evaluated using the 15-item geriatric depression scale (GDS-15). In this scale, scores range from 0-15. Abnormal affective status, defined by the presence of depressive symptoms, was determined using a cut-off point \geq 4 points in the gds-15 score. ^{6,28}

Statistical Analyses

Using the baseline data from the DAMOCLES cohort, a cross-sectional analysis was performed. Demographic and clinical characteristics, as well as laboratory tests results were summarized using basic descriptive statistics, both overall and categorized by level of self-care behaviour status.

For categorical variables, number and percentage were reported, and for continuous variables, mean (standard deviation) or median (inter-quartile range) were used, depending on the distribution of the variables. $\chi 2$, Student's T, and non-parametric tests were used to compare characteristics across strata.

To evaluate the association between demographic, disease-related (HF-related factors) and psychosocial factors with self-care and its 3 domains we used univariable binary logistic regressions analyses.

To define the relative contribution of disease-related (clinical) factors and psychosocial factors on self-care and on each of its domains, we constructed several multivariable models. First, we developed multivariate regressions analyses using binary logistic methods to explore the contributions of disease-related or psycho-social determinants on self-care separately (split models). Second, we developed multivariate

regressions analyses using the same method to explore the joint contributions of disease-related and psycho-social determinants on self-care (joint models). All the models were internally validated using resampling methods (bootstrapping with 1,000 iterations). Finally we evaluate the discrimination of the models using clinical factors, psychosocial factors or all of them to predict impaired self-care behaviour using ROC curves and its 95% confidence intervals.

All statistical tests and confidence intervals (CI) were constructed with a type I error alpha level of 5%, with no adjustments for multiplicity. P values below 0.05 were considered statistically significant. All analyses were performed using SPSS software (version 25.0; IBM, Armonk, NY) and R software (version 4.0.4; R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

The DAMOCLES cohort included 1,236 patients with chronic heart failure. For the present study only those patients with information available about the EHFScBS were analyzed (N=1,123). Baseline characteristics of the patients included both overall and according to self-care status are shown in **Table 1**. Of the total sample, 484 patients (43%) were women, mean age was 72 years, 419 patients (40.7%) were in advanced functional class (NYHA III or IV), mean left ventricular ejection fraction was 44.5% and comorbidities were common. Mean EHFScBS-9 scores were 69 ± 28 for global selfcare, 59 ± 33 for autonomy-based adherence, 70 ± 36 for consulting behaviour and 82 ± 23 for provider-based adherence. In our study, Cronbach's alpha coefficient of the EHFSc-9 was 0.889. For consulting behavior, autonomy-based adherence and provider-based adherence Cronbach's alpha values were 0.918, 0.709 and, 0.365 respectively.

Clinical and psycho-social characteristics of patients with impaired self-care.

Clinical characteristics of patients according to the level of self-care are presented in **Table 1**. Briefly, impaired self-care, defined as EHFScBS-9 item scores in the lower tertile, was associated with advanced NYHA functional class, heart failure admission in the preceding year, and higher use of diuretics (all p-values <0.05). Furthermore, the group of patients with lower self-care scores, had a more recent diagnosis of heart failure (p-value 0.024), chronic kidney disease was more common (p-value 0.010), they were more likely to be treated with statins (p-value 0.008) and levels of albumin were significantly lower compared to patients with better self-care (pvalue <0.001). These associations were confirmed in unadjusted binary logistic regression analyses (**Suppl table 1**).

As shown in **Table 1 and Supplementary Table 1**, several psycho-social factors were associated with impaired self-care in univariable analyses: dependency for basic activities for daily living (OR 1.3, 95% CI [1-1.7]; p-value 0.040) and instrumental activities for daily living (higher scores in the Lawton & Brody test), cognitive impairment (OR 1.7, 95% CI [1.3-2.3]; p-value <0.001), impaired family function (OR 1.8, 95% CI [1.4-2.5]; p-value <0.001) and presence of depressive symptoms (OR 2.3, 95% CI [1.7-3]; p-value<0.001). One of the strongest determinants of impaired self-care in univariable binary logistic regression analyses was impaired self-perceived social support (OR 3.4, 95% CI [2.5-4.7]; p-value <0.001). Specific analyses on other important variables such as social support or need for caregivers are depicted in the supplementary material (**Suppl Fig 1 and Suppl Fig 2**). In unadjusted logistic regression analyses, needing a caregiver and not being available was the strongest predictor of impaired global self-care (OR 3.6, 95% CI [2.4-5.5], p-value

<0.001). A similar trend was observed in each specific domain of self-care (all p-value<0.001).

On the other hand, a higher level of education (OR 0.7, 95% CI [0.5-0.9]; p-value 0.040) and living with a partner (OR 0.7, 95% CI [0.5-0.9]; p-value 0.033) were both associated with a 30% less relative risk of impaired self-care.

Clinical factors independently associated with impaired self-care.

To evaluate which heart failure-related clinical factors were independently associated with impaired self-care we performed several age-and-sex-adjusted multivariable logistic regression analyses shown in **Figure 1**. In these analyses, no single clinical factor was significantly associated with increased risk of impaired self-care. On the other hand, use of statins (OR 0 64, 95% CI [0.48-0.85]; p-value 0.002) and higher serum albumin (OR 0.73, 95% CI [0.54-0.99], p-value 0.039) were both associated with lower risk of impaired self-care.

Psycho-social factors independently associated with impaired self-care

In **Figure 2** we represent the results of age-and-sex-adjusted multivariable logistic regression models exploring the independent psycho-social determinants of global self-care and its 3 specific domains. In these analyses, impaired social support (OR 3.69, 95% CI [2.29-5.97]; p-value <0.001), depressive symptoms (OR 1.87, 95% CI [1.22-2.86]; p-value 0.004) and needing a caregiver (OR 2.09, 95% CI [1.33-3.28]; p-value 0.001) were all significant independent predictors of impaired global self-care. Similar findings were observed for autonomy-based adherence, consulting behaviour and provider-based adherence (**Figure 2**). Furthermore, impaired social support was the strongest determinant of impaired autonomy-based adherence (OR 3.6, 95% CI [2.3-

5.5]; p-value <0.001) and impaired consulting behaviour (OR 3.3, 95% CI [2.2-5.1]; p-value <0.001). On the other hand, the strongest predictor of impaired provider-based adherence was the presence of depressive symptoms (OR 1.9, 95% CI [0.40-0.99]; p-value=0.003). Interestingly, female gender tended to be associated with lower risk of impaired self-care and its dimensions although this association was only significant for impaired provider-based adherence (OR 0.63, 95% CI [1.1-2.7]; p-value 0.046),

Clinical and psycho-social factors independently associated with poor self-care: Joint analysis.

Finally, we performed age-and-sex-adjusted multivariable analyses including both clinical and psycho-social determinants (**Figure 3**).

In the models combining both clinical and psycho-social factors, NYHA functional class III-IV was the only clinical (Heart failure-related clinical) factor significantly associated with impaired self-care across global (OR 0.43, 95% CI [0.26-0.70]; p-value 0.001) and the individual dimensions of the EHFScBS-9 questionnaire. Among other heart failure-related clinical factors, a heart failure diagnosis more than 1 year before inclusion was associated with lower risk of impaired provider-based adherence.

Among psychosocial factors, impaired social support (OR 3.53, 95% CI [2.13-5.86]; p-value <0.001), needing a caregiver (OR 2.16, 95% CI [1.34 -3.48]; p-value 0.001) and depressive symptoms (OR 2.40, 95% CI [1.53-3.77]; p-value <0.001) were all independent determinants of impaired global self-care. Similar findings were observed in combined models evaluating the independent predictors of impaired autonomy-based adherence (impaired social support: OR 3.6, 95% CI [2.2-6.0], p-value <0.001; depressive symptoms; OR 2.7, 95% CI [1.7-4.1], p-value <0.001; needing a

caregiver: OR 1.9, 95% CI [1.2-2.9], p-value=0.006), impaired consulting behaviour (impaired social support: OR 3.2, 95% CI [2.0-5.4], p-value <0.001; depressive symptoms; OR 2.2, 95% CI [1.4-3.5], p-value <0.001; needing a caregiver: OR 2.1, 95% CI [1.3-3.4], p-value=0.002), and impaired provider-based adherence (impaired social support: OR 1.9, 95% CI [1.1-3.2], p-value <0.020; depressive symptoms; OR 2.4, 95% CI [1.5-3.8], p-value <0.001; needing a caregiver: OR 1.8, 95% CI [1.1-2.9], p-value=0.021).

We assessed the AUC (Area Under the Curve) for the ROC (receiver operating curve) and its 95% confidence intervals (CI) of each model along with p-values of the AUCs and p-values of comparisons between AUCs (Table 2) to assess the additive value of psycho-social determinants into the predictive models. Importantly, all models containing psycho-social determinants outperformed models only containing heart failure-related (clinical) variables (all p-values<0.01). Adding clinical-variables to the psycho-social model only significantly improved discrimination in models predicting impaired global self-care and impaired and provider-based adherence whereas models predicting impaired autonomy-based adherence or impaired consulting behaviour were not improved after adding clinical data.

DISCUSSION

In this study, we have shown that self-care is mainly determined by psychosocial factors in patients with heart failure. Specifically, low social support, needing a caregiver, and having depressive symptoms were consistently associated with impaired self-care both, globally and across individual self-care domains. This association was independent of other important psycho-social and heart failure-related clinical determinants, including important and well known prognostic factors in heart failure.

Importantly, female gender was associated with a reduced risk of impaired self-care and this association was significant for the consulting behaviour and provider-based adherence domains. We consider that the results of this study are relevant since they conclusively confirm that factors such as gender, social support, affective status and the need for caregiver are key factors to be considered when stratifying interventions aimed at improving self-care in heart failure patients.

Evidence about the potential association between gender and heart failure selfcare is scarce. Previous studies have not shown a clear relation between gender and self-care, however, in our study female sex was associated with better self-care in heart failure patients. In this case, the social and cultural environment of the Spanish population (with a strong family bond) and the age of the patients (mean age 72 years) should be taken into account. We should also highlight the historically caregiving role of women. For decades they have been caregivers of children, husbands and elderly or dependent relatives. Precisely because of this fact, they will try to get the best self-care, in order to be able to continue caring for their relatives. Furthermore, due to their habit of being caregivers, they could better understand and apply self-care advices. ^{29, 34}

In our study, the only heart failure-related clinical factor that showed a consistent association with self-care in multivariable adjusted analyses was the NYHA functional class. We found an apparently paradoxical association between advanced NYHA functional class and self-care between univariable and multivariable analyses: while NYHA III-IV was associated with poor self-care in unadjusted analyses, the sense of this association was inverted when important confounders and psycho-social covariates were introduced in the model. We hypothesize that crude associations between advanced NYHA and impaired self-care may be counterbalanced when severity of the disease, stage of the disease (previous heart failure hospitalization, recent

diagnosis), social support, affective status and need of caregiver are considered. Furthermore, patients remaining in advanced NYHA may be the more motivated to keep up with optimal self-care behaviours to attempt improvements in their functional status or to avoid new hospitalizations. All these factors may partially explain these findings.

Previous studies have explored non-clinical factors that may be associated with self-care in chronic HF.^{12,14,30,31} Heo et al. studied 122 patients and found that self-care confidence, the perceived control attitudes and the heart failure knowledge measured with specific scales were related to self-care behaviours.¹⁴ Subsequent studies have showed specifically the association of social support with self-care in patients with heart failure ^{14,30}. Also Kessing et al demonstrated in a meta-analysis that psychological factors such as depression were associated with particular self-care aspects in patients with chronic heart failure³¹. All these studies provided information about the importance of psychological, cognitive and social factors in the self-care of heart failure patients. However, all they have in common a limited psycho-social assessment in the patients included. Our study provides an exhaustive psycho-social evaluation including literacy, marital status, cohabitation with a partner, the need of a caregiver, dependency, family function and social support among others. We have analyzed the role of each clinical or psycho-social factor with global self-care but also with each of the domains of the EHFScBS-9 scale.

Furthermore, to the best of our knowledge, there are no previous studies that have jointly analyzed clinical and psycho-social factors, highlighting the leading role of the psycho-social sphere in the prediction of self-care in heart failure. Internal consistency of the complete EHFScBS-9, autonomy-based adherence, and consulting

behavior dimensions were optimal. However, this was not the case for provider-based adherence where low Cronbach's alpha values could be related to poor interrelatedness of the items and the reduced number of the items within this dimension.

Our study analyzed a cohort of 1,123 patients with HF who underwent a detailed evaluation of demographic, clinical and psycho-social parameters. In a previous study, our group demonstrated the prognostic implications of self-care in the same cohort of patients with heart failure.⁹ Higher EHFScBS-9 scores (better self-care) at baseline were associated with lower risk of all-cause death, cardiovascular death, and heart failure hospitalization.⁶ Given the prognostic influence of self-care in heart failure is crucial to identify those clinical and psycho-social characteristics associated to impaired global self-care , autonomy-based adherence, consulting behaviour or provider-based adherence. One of the main objectives in the care of patients with heart failure is gauge and subsequently improve self-care behaviours because they can eventually lead to improvements of health status and clinical outcomes.

To address the barriers imposed by poor self-care, two important aspects need to be considered: individual self-care needs to be evaluated using appropriate and validated tools; and patient's clinical and psycho-social phenotypes associated with poor self-care need to be defined and screened systematically in these patients. Regarding evaluation of self-care, we used the modified EHFScBS-9 questionnaire in our study. This is a validated tool that has demonstrated its ability to accurately measure self-care of patients with heart failure in multiple studies and meta-analysis.³³

On the other hand, a detailed evaluation of individual characteristics associated with poor self-care is a crucial step to address limitations in self-care behaviour in patients

with heart failure. In this regard, our results show that psycho-social factors are the main drivers of self-care in patients with heart failure. Models including psycho-social information of patients outperform the models that only include heart failure-related clinical and prognostic factors. Among psycho-social factors, social support, affective status and caregiver status were the most prominent predictors of self-care in multivariable models including both clinical and psycho-social variables. Particularly, poor social support, depressive symptoms and needing a caregiver were all independently associated with impaired global self-care, autonomy-based adherence, consulting behaviour and provider-based adherence. We hypothesize that self-perceived poor social support may interfere with optimal self-care by several mechanisms: a lack of an external support and social isolation may discourage the patient to maintain adequate self-care behaviour over time; in some patients with low social support, changes in self-care behaviour may not be a priority, despite the limitations imposed by heart failure; moreover, patients with depressive symptoms may represent a subset of patients with lack of interest in self-caring and in undertaking lifestyle changes once heart failure is diagnosed.

The results of our study have two important implications. First, in addition to a complete clinical evaluation of patients, a comprehensive psycho-social and socioeconomic evaluation should be routinely performed in all heart failure patients in order to gauge potential barriers that may interfere with optimal self-care. To provide this comprehensive evaluation, several psychometrically well-validated instruments can be administered in order to accurately phenotype the patients regarding their psychosocial dimension. In this important mission, the role of heart failure nurse is crucial.^{30,31,34} And second, given the results of our study, lack of social support, the presence of depressive symptoms and the need of a caregiver should prompt early self-

care evaluations of patients and allow designing specific interventions to mitigate their negative impact on self-care. The role of the nurse in the follow-up of patients with heart failure has been shown to be of paramount importance in the proper control of the evolution of the disease, helping patients to achieve a better level of self-care and detecting early warning signs of heart failure decompensation to avoid adverse outcomes. The results of this study can help to define the predictive determinants of poor self-care in patients. In this way, the heart failure nurse can address the barriers to optimal self-care, and pave the way for improvement of self-care behaviours of patients that may translate in a reduction of heart failure admissions and mortality. ^{8,35}

Limitations

Our study has some limitations that need to be commented. First, this is singlecentre study; however, the characteristics of the patients included are comparable to previous studies of patients with heart failure in real life. Second, self-care was measured at only at baseline thus information on self-care trajectories and its relationship with psycho-social factors was not available for this analysis given the cross sectional design of the study. And third, self-care was reported by patients and caregivers, thus limitations such as recall may limit accuracy of the measures of selfcare. However, evaluation of the psychometric properties of the scale suggests that reliability of these measures is optimal.

CONCLUSIONS

In patients with heart failure, psycho-social factors and particularly, social support, affective status and need of a caregiver are the main drivers of self-care. The results of this study will help to define patient's phenotypes at higher risk of poor self-

care that may benefit for earlier educational interventions aimed to improve clinical and patient-reported outcomes of patients with heart failure.

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Author Contributions:

Conceptualization, PM and JCC.; methodology, JVS and JCC; formal analysis, ECM and JCC; investigation ECM, EH, EC, NJ, MR, JMV, JVS, AG, LA, SJM, PG, SY, CG, PM, CD, LA, CE, JCC; resources, JCC; data curation, ECM and JCC; interpretations of data: JVR, ECM,JCC; writing original draft preparation, ECM; writing review and editing, PM and JCC; supervision, JVR, PM and JCC.; project administration, JCC.; funding acquisition, JCC; review for important intellectual content, ECM, EH, EC, NJ, MR, JMV, JVS, AG, LA, SJM, PG, SY, CG, PM, CD, LA, CE, JCC..Final approval of the version to be published ECM, EH, EC, NJ, MR, JMV, JVS, AG, LA, SJM, PG, SY, CG, PM, CD, LA, CE, JCC.

All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work have been appropriately investigated and resolved.

FIGURE LEGENDS:

Figure 1. Plots representing odds ratios (OR) and 95% confidence intervals obtained from multivariate regressions analyses using binary logistic methods to explore the contributions of heart failure-related determinants on self-care adjusted for age and gender.

Statin use was significantly associated with global self-care, autonomy based adherence and consulting behaviour. Serum albumin levels also show significant association with global selfcare. Hospitalization in the preceeding year and HF diagnosis >1 year were also significantly associated with provider-based adherence. The remaining associations were not significant in any of these 4 models.

Figure 2 Plots representing odds ratios (OR) and 95% confidence intervals obtained from multivariate regressions analyses using binary logistic methods to explore the contributions of psycho-social determinants on self-care adjusted for age and gender.

Poor social support, depressive symptoms and needing a caregiver were all significantly associated with impairments in global self-care, autonomy-based adherence, consulting behaviour and provider-based adherence. In addition, provider-based adherence was significantly associated with gender and dependency for basics activities for daily living. The remaining associations were not significant in any of these 4 models.

Figure 3 Plots representing odds ratios (OR) and 95% confidence intervals obtained from multivariate regressions analyses using binary logistic methods to explore the joint contributions of disease-related and psycho-social determinants on self-care .

Poor social support, depressive symptoms and needing acaregiver were all significantly associated with impairments in global self-care, autonomy-based adherence, consulting behaviour and provider-based adherence. In addition, provider-based adherence was significantly associated with dependency for basic activities for daily living. Gender was significantly associated with consulting behaviour and provider-based adherence. Among heart failure-related factors, NYHA was associated with global self-care and its 3 dimensions. Moreover, heart failure diagnosis >1 year was significantfy associated with provider-based adherence. The remaining associations were not significant in any of these 4 models.

Credit Author Statement:

Conceptualization, PM and JCC.; methodology, JVS and JCC; formal analysis, ECM and JCC; investigation ECM, EH, EC, NJ, MR, JMV, JVS, AG, LA, SJM, PG, SY, CG, PM, CD, LA, CE, JCC; resources, JCC; data curation, ECM and JCC; interpretations of data: JVR, ECM,JCC; writing original draft preparation, ECM; writing review and editing, PM and JCC; supervision, JVR, PM and JCC.; project administration, JCC.; funding acquisition, JCC; review for important intellectual content, ECM, EH, EC, NJ, MR, JMV, JVS, AG, LA, SJM, PG, SY, CG, PM, CD, LA, CE, JCC..Final approval of the version to be published ECM, EH, EC, NJ, MR, JMV, JVS, AG, LA, SJM, PG, SY, CG, PM, CD, LA, CE, JCC.

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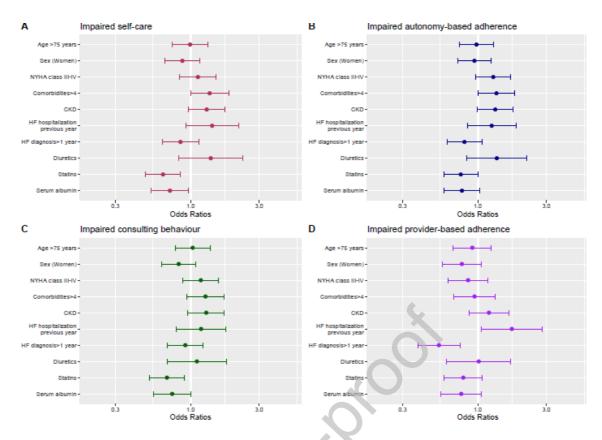


Figure 1. Plots representing odds ratios (OR) and 95% confidence intervals obtained from multivariate regressions analyses using binary logistic methods to explore the contributions of HF-related determinants on self-care adjusted for age and gender.

Statin use was significantly associated with global self-care, autonomy based adherence and consulting behaviour. Serum albumin levels also show significant association with global selfcare. Hospitalization in the preceeding year and HF diagnosis >1 year were also significantly associated with provider-based adherence. The remaining associations were not significant in any of these 4 models.

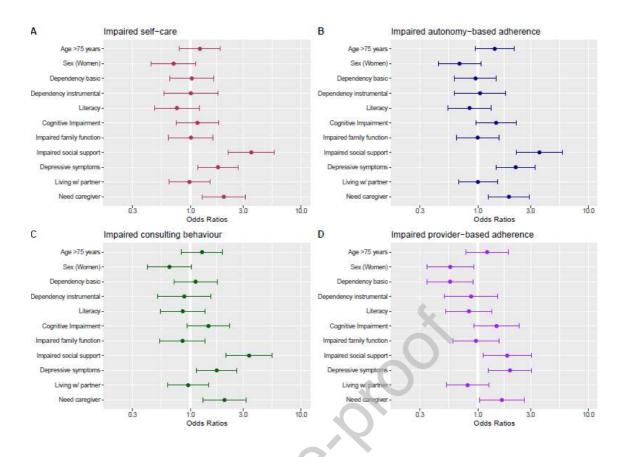


Figure 2 Plots representing odds ratios (OR) and 95% confidence intervals obtained from multivariate regressions analyses using binary logistic methods to explore the contributions of psycho-social determinants on self-care adjusted for age and gender.

Poor social support, depressive symptoms and needing acaregiver were all significantly associated with impairments in global self-care, autonomy-based adherence, consulting behaviour and provider-based adherence. In addition, provider-based adherence was significantly associated with gender and dependency for baisc ADLs. The remaining associations were not significant in any of these 4 models.

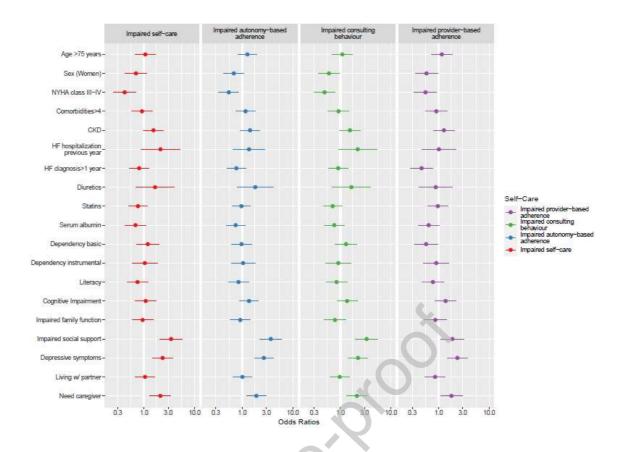


Figure 3 Plots representing odds ratios (OR) and 95% confidence intervals obtained from multivariate regressions analyses using binary logistic methods to explore the joint contributions of disease-related and psycho-social determinants on self-care .

Poor social support, depressive symptoms and needing acaregiver were all significantly associated with impairments in global self-care, autonomy-based adherence, consulting behaviour and provider-based adherence. In addition, provider-based adherence was significantly associated with dependency for basic ADLs. Gender was significantly associated with consulting behaviour and provider-based adherence. Among HF-related factors, NYHA was associated with global self-care and its 3 dimensions. Moreover, HF diagnosis >1 year was significantñy associated with provider-based adherence. The remaining associations were not significant in any of these 4 models.

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TABLES

Table 1. Baseline characteristics of the study population (N=1,123), overall and according self-care behaviour status

	n	Whole Cohort (n=1,123)	Impaired Self- Care (n=349)	Preserved Self-Care (n=774)	P- value
Demographic and Clinical Factors			<u> </u>		
Age, years	1123	72 (11.3)	73 (10.78)	72 (11.6)	0.101
Gender (female)	1123	484(43.1)	154 (44.1)	330 (42.6)	0.649
Systolic blood pressure, mmHg	1121	124 (21.7)	123 (21.57)	124 (21.87)	0.940
Heart rate, bpm	1120	74 (14.4)	75 (14.1)	73 (14.6)	0.017
NYHA Functional Class, n (%)	1115	2			<0.001
Ι	145	145 (13.0)	21 (6.1)	124 (16.1)	
Π	516	516 (46.3)	162 (47.0)	354 (46.0)	
111	370	370 (33.2)	137 (39.7)	233 (30.3)	
IV	84	84 (7.5)	25 (7.2)	59 (7.7)	
Heart Failure Hospitalisation previous year, n (%)	1121	929 (82.9)	310 (88.8)	619 (80.2)	<0.001
Heart Failure diagnosis>1 year, n (%)	1121	425 (37.9)	115 (33)	310 (40.1)	0.028
Left ventricular ejection fraction, %	1120	44 (16.7)	44 (17.4)	44 (16.5)	0.799
Ischaemic aetiology of heart failure, n (%)	1123	429 (38.1)	129 (37.0)	300 (38.8)	0.596
Comorbidities					

Hypertension, n (%)	1123	902 (80.3)	279 (79.9)	623 (80.5)	0.871
Diabetes Mellitus, n (%)	1122	517 (46.1)	171 (49)	346 (44.8)	0.196
Previous Myocardial Infarction, n(%)	1122	517 (46.1)	89 (25.5)	199 (25.7)	1
Dyslipidaemia, n (%)	1123	624 (55.6)	197 (56.4)	427 (55.7)	0.698
Chronic kidney disease (CKD), n (%)	1118	619 (55.4)	213 (61)	406 (52.8)	0.011
Anaemia, n (%)	1122	545 (48.6)	164 (47.0)	381 (49.3)	0.479
Iron Deficiency, n (%)	1103	751(66.9)	230 (68.5)	521 (67.9)	0.889
Chronic obstructive pulmonary disease, n (%)	1123	245 (21.8)	84 (24.1)	161 (20.8)	0.242
Cerebrovascular accident, n (%)	1117		73 (9.5)	40 (11.5)	0.335
Osteoarthritis, n (%)	1114	143 (12.8)	56 (16)	87 (11.4)	0.034
Chronic Liver Disease, n (%)	1117	57 (5.1)	38 (4.9)	19 (5.4)	0.770
Major Psychiatric Disorder, n (%)	1118	366 (38)	45 (5.8)	14 (4.0)	0.248
Treatments (%)					
ACEI or ARBs	1119	824 (73.6)	262 (75.3)	562 (72.9)	0.421
Beta-blockers	1122	984 (87.6)	303 (86.8)	681 (88.1)	0.557
MRA	1120	422 (37.7)	128 (36.8)	294 (38.1)	0.690
Diuretics	1123	1021 (95)	327 (93.7)	694 (89.8)	0.042
Statins	1122	669 (59.6)	188 (53.9)	481 (62.2)	0.009
Antiplatelet or anticoagulant therapy	1122	502 (44.7)	153 (43.8)	345 (45.1)	0.698
Laboratory					
Haemoglobin, g/dL	1123	12.6 (2.27)	12.6 (2.01)	12.6 (2.38)	0.624
Creatinine	1121	1.3 (0.59)	1.3 (0.56)	1.3 (0.60	0.082

	1100	1502 5005	1 (11 1710	1551(277	1 1
NT-proBNP, pg/mL	1120	1582 [685- 3723]	1611 [712- 4422]	1551{677- 3517.50}	0.573
Serum proteins, g/dL	993	6.7 (0.66)	6.7 (0.66)	6.7 (0.66	0.404
Serum albumin, g/dL	1111	3.84 (0.48)	3.7(0.51)	3.8 (0.47)	< 0.001
Total cholesterol, mg/dL	1116	152 (38.63)	150 (38.77)	153 (38.57)	0.272
Psycho-social Factors					
Barthel index, points	979	94 (41.5)	92 (23.36)	95 (47.09)	0.278
Dependency for activities for daily living, n (%)*	979	387 (39.5)	129 (44.5)	258 (37.4)	0.045
Lawton test, points	1036	12 (6.08)	13 (7.28)	12 (5.41)	0.002
Dependency instrumental activities, n(%)	1036	775 (74.8)	245(76.1)	530(74.2)	0.537
Literacy		.0			0.045
primary school	1004	701 (69.8)	231 (74.3)	470 (67.8)	
higher than primary school	1004	303 (30.3)	80 (25.7)	223 (32.2)	
Cognitive impairment, yes vs. no	963	366 (38)	137 (47.4)	229 (34.0)	< 0.001
Poor Family Function, n (%)	> 996	308 (30.9)	181 (26.8)	121 (40.7)	<0.001
Self-perceived social support (Duke Scale), points	993	49 (9.62)	44 (10.82)	51 (8.43)	<0.001
Poor Social Support, n (%)	993	245 (24.7)	125 (42.1)	120 (17.2)	< 0.001
Score in the Geriatric Depression Scale (GDS), points	980	5 (3.36)	4.92 (5.47)	3.61 (5.27)	0.788
Depressive symptoms, n (%)	980	433 (44.2)	170 (58.6)	263 (38.1)	< 0.001
Living with a partner,	1078	580 (53.8)	163 (28.1)	417 (71.9)	0.034

yes vs. no					
Caregiver status, n (%)					< 0.001
Caregiver not needed	798	416 (521)	83 (35.6)	333(58.9)	
Caregiver needed and available	798	242 (30.3)	83 (35.6)	159 (28.1)	
Caregiver needed and not available	798	140 (17.5)	67 (28.8)	73 (12.9)	

NYHA: New York heart Association. CKD: Chronic kidney disease, defined as estimated glomerular filtration (eGFR) date <60 mL/min/ $1.73m^2$. Anaemia was defined according to the WHO Criteria. ACEi: angiotensin-converting enzyme inhibitors. ARBs: angiotensin receptor blockers. MRA: mineral-corticoid receptor antagonists. Dependency, defined as Barthel Index \leq 99 points. Cognitive impairment was defined as abnormal Mini Mental State Examination or Pfeiffer Tests adjusted for age and literacy. Poor social support was defined as Duke Scale <47 points (corresponding to scores below to Q1). Poor Family Function was defined as Apgar Test<10 points. Depressive symptoms were defined as Geriatric Depression Scale (GDS) \geq 4 points.

*Impaired self-care was defined as the first tertile of the global self-care score.

*Preserved self-care was defined as the second and third tertiles of the global self-care score.

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		Model 1 elated fa		Model 2 Psycho-Social Factors			P- valu e	valu Joint Model			P- valu e	P- valu e
	AUC	95 CI %	P- valu e	OR	95 CI %	P- valu e	Mod el 2 vs. Mod el 1	AUC	95% CI	P- valu e	Mod el 3 vs. Mod el 1	Mod el 3 vs. Mod el 2
Self- Care Behavi our					24	Ś						
Impaire d global self- care	0.6	0.570-	<0.0 01	0.71 5	0.674- 0.756	<0.0 01	0.00 2	0.73 9	0.699- 0.779	<0.0 01	<0.0 01	0.0 39
Impaire d autono my- based adheren ce	0.5	0.55 5- 0.62 4	<0.0 01	0.7 31	0.69 2- 0.77 1	0.00	<0.0 01	0.7 32	0.69 4- 0.77 1	<0.0 01	<0.0 01	0.2 26

 Table 2. Evaluation of the discrimination of the models predicting impaired self-care

 behaviour.

Impaire												
d		0.55			0.66				0.68			
consulti	0.5	6-	< 0.0	0.7	6-	< 0.0	0.0	0.7	2-	< 0.0	< 0.0	0.2
ng	92	0.62	01	07	0.74	01	01	22	0.76	01	01	12
behavio		7			8				2			
ur												
Impaire												
d		0.51			0.60				0.68			
provide	0.5	4-	0.0	0.6	9-	< 0.0	0.0	0.7	2-	< 0.0	< 0.0	0.0
r-based	52	0.59	08	56	0.70	01	11	22	0.76	01	01	39
adheren		1			4		.(2			
ce							5					

The table present the data of the AUC (Area Under the Curve) for the ROC (receiver operating curve) and its 95% confidence intervals (Cl) of each model along with p-values of the AUCs and p-values of comparisons between AUCs. Model 1 corresponds to disease-related (clinical) factors, Model 2 corresponds to psycho-social factors and model 3 is the joint model combining both, model 1 and 2. Dependent variables of the models evaluated were: 1)impaired global self-care behaviour (scores in the lowest tertile [<55 points]of the 9-item EHFScBS (inverted and standardized)), 2) autonomy-based adherence (scores in the lowest tertile [<42 points]of the 9-item EHFScBS (inverted and standardized)), 3)impaired consulting behaviour (defined as scores in the lowest tertile [<75 points] of the 9-item EScBS (inverted and standardized)).