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Title:

The paradox of self-care gender differences amongst Italian patients with Chronic Heart Failure: Findings from a real-world cross-sectional study

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Abstract

Aim. The aim of this study was to critically analyse and describe the gender differences related to the self-care amongst patients with chronic HF.

Methods and results. A monocentric real-world cohort of 367 chronic HF patients in follow-up was used for this cross-sectional study. Data related to demographic and clinical characteristics were reported, and patients' self-care was assessed before their discharge using the Self-Care of Heart Failure Index. After the bivariate analysis, logistic regression models were used to describe the relations between gender, self-care behaviours and self-care confidence. Men have more than four time the likelihood of inadequate self-care maintenance than women (OR = 4.596; 95% CI = 1.075 – 19.650), while they have approximately 60% more likelihood of adequate self-care confidence than women (OR = 0.412; 95% CI = 0.104 – 0.962). Considering that self-care confidence is described as a positive predictor of behaviours, our results seem to lead towards a paradox. It is possible that patient–caregiver relationship mediates the effect of confidence to behaviours. Overall, the adequate level of self-care behaviours are a current issue, ranging from 7.6% to 18.0%.

Conclusion. This study sketched directions for future researches where elements related to patient–caregiver relationship need to be considered to plane adequate educational interventions, which are integrating part of the treatment. We suggests to routinely measure patients' self-care to best manage their follow-up and to adjust their daily life behaviours.

Key Words. Gender differences; Heart Failure; Self-Care; Self-Confidence; Self-Management; Self-Maintenance.

Strengths and limitations of this study

- This is the first study in last five years aimed to deepen explore the gender differences in self-care amongst patient with chronic HL

- Gender differences are an important peculiarity of self-care, being also associated to the culture of people, and the possibility to adapt education intervention based on gender-specific characteristics
- Italian men have more than four time the likelihood of inadequate self-care maintenance than women, while they have approximately 60% more likelihood of adequate self-care confidence than women (This is a paradox: confidence is a positive predictor of maintenance)
- The understanding of gender difference facilitates the reduction of inequalities in healthcare delivery, giving the possibility to develop evidence-based education path
- Our findings are not generalizable abroad Italy, more cross-cultural investigations are needed

Introduction

The rate of heart failure (HF) is steadily increasing worldwide, becoming an important public health issue.[1,2] It affects more than 15 million people in Europe, and its prevalence is rising over the 25% of the worldwide population within the 2030.[3] Currently, HF prevalence ranges from 0.4 to 2.3% amongst European and American adult population.[4] The causes of HF are mostly cardiac, such as myocardial, valves, pericardium, endocardium, or heart rhythm abnormalities.[5] Both those causes and the presence of multi-comorbidities often lead towards a chronic HF, where patients have to follow the available clinical recommendations to optimize their health, monitoring their symptoms and engaging proper decision-making to manage signs and symptoms when those occur.[6,7] Recent studies show how HF patient outcomes are closely linked to their self-care, which is the ability in maintaining health through health promoting practices and managing illness.[7–10]

Self-care is currently studied awing to a widespread middle range theory of reference,[7] which allows to investigate relations between self-care and clinical outcome in HF patients. Currently, we know that adequate self-care in HF patients is associated to a better quality of life,[11,12] reduced re-hospitalizations,[13] mortality,[14] and healthcare costs.[14] Evidence shows that after 3 months of educational interventions to improve self-care levels, the HF patients emotional quality of life improved as well as their overall health status.[11,12] Other studies show how inadequate self-care is an independent risk factor for adverse clinical outcomes in HF patients and re-hospitalisations, using Cox regression analysis adjusted for clinical parameters.[13] Moreover, other recent shows the increasing of the likelihood for death in those HF patients with have inadequate self-care.[14] A typical characteristic of patients with inadequate self-care is the decline in use of HF related medications over time (i.e., low adherence). This implies a more likelihood of re-hospitalization and an increase of the healthcare cost, while HF management in patient with adequate self-care requires lower economic healthcare resources.[14]

In this scenario, gender differences are an important peculiarity of self-care, being also associated to the culture of people, and the possibility to adapt education intervention based on

gender-specific characteristics, when those will be know. At this regard, the same European Governments ask for clarity and attention in research, due to the attention in understanding gender difference facilitates the reduction of inequalities in healthcare delivery, giving the possibility to develop evidence-based education path, adjusted for gender-specific demands to treat chronic HF patients.[15] Currently, we know that there are diverse results in studies related to gender differences in chronic HF, due to some researchers show that men have better behaviours than women,[20] while other studies show that men have lower level of self-care behaviours[18]. Overall, research has not yet been assessed in depth many aspects of self-care gender differences, such as the estimation of the likelihood of inadequate/adequate self-care in relation to the gender in real-world cohorts. For the above discussed characteristics of self-care, the understanding of peculiarities related to patients' gender difference in acting their self-care behaviours is strategic to plane a correct treatment and education.[5,21]

So far, there are no recent studies on self-care gender differences amongst patients with chronic HF, and generally the evidence underpinning the understanding of those differences are weak. For this reason, the aim of this study was to critically analyse and describe the gender differences related to the self-care amongst patients with chronic HF. The results of this study could be useful to frame our understanding of those differences, providing epidemiological information useful to plane future tailored interventions.

Methods

Design and participants

This study had an observational, single-centre design, using a real-world and convenience sampling. All patients were followed in a single centre in Italy, San Donato (PSD), which is a research hospital in northern Italy. To be enrolled, all patients had to have a diagnosis of stable chronic HF and they had to have a recent craniological assessment (maximum one week before). Thus, using a real-world sampling approach, all patients with chronic HF related to a cardiac cause and assessed by their cardiologist within the week prior to our proposal were eligible to be enrolled

in this study.[22] Cardiological clinical assessment of the enrolled patients was performed in accordance to the current guidelines.[5] All the data were collected using a cross-sectional approach, between January and September 2017. For this research purpose, a specific data collection was used, and describe in the 'Measures' paragraph. The only exclusion criteria were: (a) inability to read and speak Italian, (b) diagnosis of psychiatric or cognitive problems, (c) patients aged under 18. Although this study had a real-world sampling, those exclusion criteria were needed to ensure the possibility to collect data using self-report instruments. All enrolled patients gave their written consent to participate. This study was approved by the local Ethical Committee (822/PSD/2017).

Measures

Data related to demographic and clinical characteristics were reported, and self-care was assessed before the patients' discharge using the Self-Care of Heart Failure Index (SCHFI v. 6.2).

Demographic and clinical characteristics. Demographic and clinical characteristics to describe the cohort were age, gender, nationality, Body Mass Index (BMI), New York Heart Association (NYHA) functional classification, ejection fraction (EF), secondary cardiac diagnosis associated to HF, and drug treatment. While the Cumulative Illness Rating Scale (CIRS) was used to control the multi-morbidity,[23] due to our real-world approach. BMI was categorized in accordance to the Centers for Disease Control and Prevention (CDC) recommendations (i.e., underweight, healthy weight, overweight, obese).[24] NYHA classification and HF were reported in line with the current guidelines.[5] CIRS was used to evaluate the multi-morbidity, considering the gravity of co-occurring medical conditions in 14 main domains. Each domain represent a physio-pathological system, using a scoring from zero to four for the assessment, where zero indicates 'no problem', and four indicates 'extremely severe problem'. The algorithm and the indication described by the CIRS authors of reference allow to consider an overall score for comorbidities from zero to four.[23] For this study, the authors used an online calculator, provided online by the Italian Society of Haematology (http://www.siematologia.it/LG/CIRS/CIRS.htm).

Self-Care of Heart Failure Index (version 6.2). SCHFI is a self-report instrument to measure self-care in HF patients, using 22 items. It allows to measure self-care within a well-defined framework, due to that instrument was developed using a situation-specific theory of reference.[25] The 22 items of the instrument are grouped in three scales to measure both the self-care behaviours (i.e., self-care maintenance and self-care management) and patients' self-efficacy in performing their behaviours (i.e., self-care confidence). According to Riegel and colleagues, patients' self-care confidence is theorized to have an effect on patients' behaviours self-care, not as an element of self-care per se.[26] The two behaviour measurements are the self-care maintenance and the self-care management. Self-care maintenance is referred to the level to which patients engage in behaviours aimed to maintain their stability, monitoring their signs and symptoms and adhering to their treatments. Conversely, self-care management is referred the patients' ability in recognizing symptoms, and in undertaking their treatment when needed (*e.g.,* consult a healthcare provider, or reduce fluid intake). Each scale of SCHFI uses a 4-point self-report response format, from one (never or rarely) to four (always or daily). To compute each scale scores, the raw scores have to be transformed in standardized scores from 0 to 100, following the procedure described in SCHFI validation studies.[27,28] Adequate self-care behaviours and self-care confidence are given by score higher than 70.[27,28]

Data analysis

All data are checked to assess possible missing, errors or outliers, using the study of the frequency distribution. Missing data are managed using pairwise approach. The study of skewness was used to preliminary assess the distribution of the variables, followed by the Kolmogorov–Smirnov test. Continuous variables are expressed as mean and standard deviation (SD) for normally distributed data, while non-normally distributed variables are expressed as median and interquartile range (IQR). Categorical variables are described by numbers and percentages. All data were preliminary tested in the univariate analysis, where categorical variables were tested by contingency table analysis (i.e., $\chi 2$ test or Fisher exact test, when appropriate), and continuous variable were

tested by Mann–Whitney U test or Student's t-test (when appropriate). Bivariate analysis to assess relations between gender and the other variables were performed using point-polyserial correlation (Rpp). Logistic regression (LR) models were used in the multivariable analysis to describe the gender differences related to the self-care maintenance, management and confidence. LR models were developed considering the univariate analysis interpretations and bivariate analysis, the theoretical rationale, the precautions to avoid model overfit,[29] the conformity with linear gradient for the included continuous variables, the control of possible collinearity amongst the independent variables, the study of statistical significance using both the Wald's $\chi 2$ and the likelihood ratio test, the assessment of the Goodness-of-fit measures through the Hosmer–Lemeshow test, and the analysis of the Pseudo-R^2 (i.e., Cox & Snell; Nagelkerke and McFadden).[29] All predictor variables selected from the univariate analysis were entered simultaneously into the equation models to control for each other. Statistics were performed using SPSS software version 22 (IBM Corp., Armonk, NY) and R Statistical Package (R Foundation for Statistical Computing, http://www.r-project.org). All tests were 2-tailored, setting a significance level of 5%.

Results

Sample

A sample of 367 chronic HF patients was enrolled in this study. The patients' characteristics are shown in Table 1. The majority of patients were males ($N = 256$; 74.0%), with an average age of 65.1 years (SD = 13.6). The mean of BMI was 26.95 Kg/m^2 (SD = 4.97). The majority of them was classified in in NYHA class II ($N = 199$, 57.5%) with a preserved EF (pEF) ($N = 163$; 47.1%). The secondary cardiac diagnosis associated to chronic HF was mainly the myocardial infarction ($N = 225$; 65.0%), followed by the hypertension ($N = 176$; 50.9%) and atrial fibrillation ($N = 111$; 30.1%). Only 66 patients had an adequate self-care maintenance (18.0%), 28 patients had an adequate self-care management (7.6%), and 131 patients had an adequate self-confidence (35.7%).

>Please add Table 1<

Gender differences

Considering the bivariate analysis, the gender (men = 1; women = 2) had a significant relationship only with CIRS (Rpp = 0.157; P-Value = 0.005), self-care maintenance (Rpp = -0.112; P-Value = 0,025) (where, Adequate self-care maintenance = 1; Inadequate self-care maintenance = 2), self-care management (Rpp = -0.101; P-Value = 0,046) (where, Adequate self-care management = 1; Inadequate self-care management = 2), self-care confidence (Rpp = +0.158; P-Value = 0.011) (where, Adequate self-care confidence = 1; Inadequate self-care confidence = 2). Thus, men reported less comorbidities, lower scores of self-care maintenance and management, but higher self-care confidence.

As shown in Table 2, the first LR model shows that the likelihood of inadequate self-care maintenance is decreased roughly by 80% when patients have adequate level of self-care confidence (OR = 0.188; 95% CI = 0.042 – 0.843) and self-care management (OR = 0.182; 95% CI = 0.037 – 0.892), while men have more than four time the likelihood of inadequate self-care maintenance than women (OR = 4.596; 95% CI = 1.075 – 19.650). The second LR model shows that the likelihood of inadequate self-care management is decreased roughly by the 83% when patients have adequate maintenance (OR = 0.171; 95% CI = 0.036 – 0.816). No associations between gender and self-care management are shown. The third LR model shows that the likelihood of inadequate self-care confidence is decreased roughly by 80% when patients have adequate level of self-care maintenance (OR = 0.211; 95% CI = 0.051 – 0.869), and men have approximately 60% more likelihood of adequate self-care confidence than women (OR = 0.412; 95% CI = 0.104 – 0.962). Moreover, every point of decreasing in CIRS total score is associated to roughly 70% likelihood of adequate levels of self-care confidence (OR = 0.297; 95% CI = 0.102 – 0.865).

>Please add Table 2<

Discussion

To the best of our knowledge, this is the first study in last five years aimed to deepen explore the gender differences in self-care amongst patient with chronic HL. There is a growing interest in understanding self-care gender differences in chronic diseases,[30] especially in patients with chronic

HF, due to the enhancement of patients' self-care using adequate educational strategies is an integrating part of the treatment.[5] Gender differences are important peculiarities of self-care, owing to the fact that the same gender plays as a self-care determinant.[18] In according with current knowledge,[18] this study confirms that Italian chronic HF patients have high frequency of inadequate self-care. The added value of the current and general epidemiological description of self-care amongst Italian chronic HF patients is given by the real-world sampling and who received a recent cardiologic clinical assessment. In fact, differently from previous self-care description all the patients in this study were enrolled close to their cardiologic visit, not in a moment of their follow-up. In other words, this study gives a realistic picture of the situation of those chronic HF patients that recently received a clinical assessment and indication to adjustment their therapy. Moreover, the description of patients' self-care in our study is more alarming than the previous description.[18] In previous descriptions, adequate self-care behaviours ranges from 14.5% to 24.4%,[18] while the current adequate self-care description ranged from 7.6% to 18.0%. In this scenario, the description of gender differences was clear, starting from the bivariate analysis interpretation – where self-care behaviours and self-care confidence have a significant relationship with gender – towards the LR models analysis.

The focus of the gender differences analysis is important, due to it allows to early understand where engage endeavours in develop evidence-based educational paths. It is reasonable, that evidence arising from gender differences analysis need to be contextualized to the habits and culture of the Country. For this reasons, the literature shows diverse results, when the few evidence from different studies and Countries are compared. De facto, evidence coming from United States shows that men are more likely to undertake independent decisions about their self-care management, while women had higher self-care maintenance.[20] Conversely, considering the bivariate analysis of this study, the point-polyserial correlations show that men seem to have low level of both self-care management and maintenance, and higher level of self-care confidence, which is the task-specific

patients' self-efficacy to face this their disease. Those results are in line with previous general description amongst Italian patients. [18]

More specifically, our LR models clearly allow to interpret the gender differences using the multivariable approach, where self-care behaviours and self-care confidence are studied as dichotomous outcomes (inadequate versus adequate). Therefore, our study provides useful means to understand the associations between the included independent variables coming from the bivariate description and the binary response self-care variables. Specifically, gender is significantly associated to self-care maintenance and self-care confidence, where men have more than four time the likelihood of inadequate self-care maintenance than women, and they also have approximately 60% more likelihood of adequate self-care confidence than women. This results lead to a paradox, due to theory and evidence clearly indicate that self-care confidence positively predicts patients' behaviours.[7,31,32] This paradox is also tangible in our results, if we consider that the same self-care confidence is associated with adequate behaviours **(Table 2**), but men have more likelihood than women to act inadequate self-care maintenance, even if they have roughly 60% more likelihood than women to have adequate self-care confidence.

In other words, it is reasonable that we are currently missing some important elements to frame our understanding of gender differences in both Italian and general chronic HF patients. This paradox need to be assessed by future investigations, due to the understanding of those gender differences could guide tailored educational intervention, prior to the same patients' discharge. Considering that patients' education is an integrant part of patients' treatment,[5] it is important to frame the possible portrait underpinning the above described paradox, otherwise the same education could be undermined by gaps in knowledge in determining the right educational approach for each patient.

Very recently, some authors start to study the quality of the patient–caregiver relationship in association to patients' self-care (i.e., mutuality).[33,34] It seems that patient–caregiver good mutuality is associated to better patients' self-care. The mutuality studies shapes interdependence model

paths, thus it could explain the paradox presented in our study, due to it is reasonable that patient–caregiver mutuality mediates the relations between self-care confidence and self-care behaviours. In other words, it is reasonable to speculate that men have a poor quality relation with their caregiver than women, when men's caregiver have to contribute to help the same men to be adherent to their clinical recommendation, such as Sodium-restricted diet. If those hypothesis will be corroborate by empirical evidence, the emphasis in including patients' caregiver in the educational path from the beginning needs to grow, addressing the testing of future tailored educational interventions, and educational models for the dyads patient–caregiver.[35]

Strengths and limitations

This study has a number of limitations and strengths. Firstly, the design was cross-sectional and the sampling was not randomized, and patients were followed in a unique centre. Secondly, the major clinical implications in considering the self-care as the outcome of the study are not directly deducible in our results, but the clinical relevance is deducible acknowledging the previous solid evidence between self-care, hospitalisations, quality of life, healthcare costs, and mortality. Those aspects justify the clinical relevance of this study rationale. The monocentric sampling is a limit, but also a strength in our study, due to the topic of gender differences is closely related to the contextual culture, and this approach shows a realistic portrait of a reality of northern Italy. Another strength is the real-world sampling, which add value to the realistic sense of the investigation. Moreover, to the best of our knowledge, this is the first study that describes self-care as a dichotomous outcome, using LR models. This approach simplifies the epidemiological interpretation of self-care characteristics, owing to the likelihood interpretation coming from the adjusted OR of the independent variables of the models. In fact, self-care characteristics are usually studied using structural equation modelling approaches or path analysis, which are very useful latent multivariate approaches, but they are less intuitive under an epidemiological point of view.

Conclusion

Patients' self-care is a core element of the multidisciplinary care management programme to reduce the risk of HF hospitalization and mortality. The clinical implications of adequate self-care are currently supported by high level of evidence, as highlighted in the available guidelines.[5] So far, some gaps are still present to frame our understanding of some peculiarities to best develop tailored educational intervention to support chronic HF patients, considering that they have to lifetime cope with recommendations, follow-ups, and life style adjustments. In this scenario, the understanding of self-care gender differences helps to address researches and educational interventions in order to correctly guide the healthcare providers' clinical practice. Our study helps to frame this kind of understanding, facing with the contradictory meanings of the findings to sketch the direction of future investigation, and to give some tips for clinical healthcare providers.

Considering the sketched directions for future researches, it is paramount to consider the complexity of the management of the chronic HF. In fact, to understand how explain gender differences in those patients' self-care, future studies should consider some aspects related to the quality of the patient–caregiver relationship, due to it could play a pivotal role in determine the actual patients' behaviours. In other words, the individual confidence in one's own ability to achieve the tasks related to recommendations, such as physical exercise, dietary habits or signs and symptoms recognitions' ability, could be mediated by the role of caregiver, who have to understand the recommendations as well as the patient. Future researches are needed to corroborate this framework.

This study results also highlight an important issue related to high frequency of patients with inadequate self-care. There is an urgent need of more awareness that the education during the hospitalisation and follow-up have to be effective in changing the patients' self-care behaviours. To boost attention towards this topic, and to guide the follow-ups educational priorities, we recommend to screen patients' self-care in a longitudinal way during their follow-up. It could be also useful to assess the quality of patient-caregiver relations, when it is possible. This particular assessment

could solve problems underpinnings gender differences, even if robust evidence are strongly needed to corroborate this approach. Only validated instruments are suggested to perform those assessments.

To conclude, further cross-cultural exploration of self-care gender differences in patients with HF are needed to frame our knowledge in this field.

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Statements

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Role of Authors. FD and RC: conceived the study, supervised the collection and data analysis, and wrote the initial manuscript draft. FP, AM and GC: contributed to data collection, and analysis, revising the manuscript critically for important intellectual content. All authors: provided guidance on the analytical approach, contributed to the interpretation of results, and drafted and revised the manuscript for critical intellectual content.

Data sharing statement. We intend to make data freely available in the public domain after publication of major findings. Researchers interested in collaborations should contact the corresponding author (rosario.caruso@unimi.it)

Table 1. Sample characteristics (*N* = 346)

Demography		*N* (%)
Mean (SD),	Age (Years)	65.6 (13.6)
	Gender (male/female)	61.1%/38.9%
	Nationality (Italian)	100%
Anthropometry		
Mean (SD),	BMI (kg/m^2)	26.95 (4.97)
Clinical characteristics		
	Class II	256 (74.0%)
	Class III	82 (23.7%)
	Class IV	8 (2.3%)
	rEF (<40%)	82 (23.7%)
	MrFE (40-50%)	101 (29.2%)
	pEF (≥50%)	163 (47.1%)
	CIRS total score 0	270 (78.0%)
	CIRS total score 1	50 (14.5%)
	CIRS total score 2	26 (7.5%)
Secondary Cardiac Diagnosis		
	Myocardial Infarction	225 (65.0%)
	Hypertension	176 (50.9%)
	Atrial Fibrillation	111 (30.1%)
Drug treatment		
	ACE inhibitors	73 (21.1%)
	B-blockers	87 (25.1%)
	Diuretics	270 (78.0%)
	Cardiac glycosides	160 (46.2%)
	Aspirin or salicylates	222 (64.2%)
	Calcium channel blockers	74 (21.4%)
'Adequate' Self-care (scores ≥ 70)		
	Maintenance	66 (18.0%)
	Management	28 (7.6%)
	Confidence	131 (35.7%)

Table 2. Models of Logistic Regression analysis

Maintenance							
Predictors		**Wald's χ2**	**d.f.**	**P-Value**	**Odds Ratio**	**95% CI**	
	Constant	2.356	1	0.125	-	-	-
	Confidence (Adequate vs Inadequate)	4.767	1	0.029	0.188	0.042	0.843
	Management (Adequate vs Inadequate)	4.413	1	0.036	0.182	0.037	0.892
	CIRS	2.314	1	0.128	2.909	0.735	11.512
	Gender (Male vs Female)	4.232	1	0.04	4.596	1.075	19.650
Model		**χ2**	**d.f.**	**P-Value**	**Pseudo-R^2 (Cox & Snell)**	**Pseudo-R^2 (Nagelkerke)**	**Pseudo-R^2 (McFadden)**
	Likehood ratio test	18.69	9	0.028	0.241	0.351	0.238
	Hosmer–Lemeshow test	4.185	6	0.665	-	-	-
Management							
Predictors		**Wald's χ2**	**d.f.**	**P-Value**	**Odds Ratio**	**95% CI**	
	Constant	0.799	1	0.271	-	-	-
	Confidence (Adequate vs Inadequate)	1.992	1	0.158	0.318	0.065	1.561
	Maintenance (Adequate vs Inadequate)	4.902	1	0.027	0.171	0.036	0.816
	CIRS	0.265	1	0.607	0.729	0.219	2.429
	Gender (Male vs Female)	0.88	1	0.348	2.126	0.440	10.284
Model		**χ2**	**d.f.**	**P-Value**	**Pseudo-R^2 (Cox & Snell)**	**Pseudo-R^2 (Nagelkerke)**	**Pseudo-R^2 (McFadden)**
	Likehood ratio test	16.3	9	0.049	0.218	0.336	0.241
	Hosmer–Lemeshow test	3.404	6	0.696	-	-	-
Confidence							
Predictors		**Wald's χ2**	**d.f.**	**P-Value**	**Odds Ratio**	**95%CI**	
	Constant	2.758	1	0.097	-	-	-
	Maintenance (Adequate vs Inadequate)	4.644	1	0.031	0.211	0.051	0.869
	Management (Adequate vs Inadequate)	1.906	1	0.167	0.332	0.069	1.589
	CIRS	4.953	1	0.026	0.297	0.102	0.865
	Gender (Male vs Female)	1.474	1	0.035	0.412	0.104	0.962

Model		$\chi 2$	d.f.	P-Value	Pseudo-R^2 (Cox & Snell)	Pseudo-R^2 (Nagelkerke)	Pseudo-R^2 (McFadden)
	Likehood ratio test	17.8	9	0.044	0.221	0.314	0.221
	Hosmer–Lemeshow test	1.604	4	0.708	-	-	-

Abbreviations: CIRS, Cumulative Illness Rating Scale; d.f., degree of freedom; CI, Confidence Interval

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-7
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	7-8
		(*c*) Explain how missing data were addressed	7-8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	na
		(*e*) Describe any sensitivity analyses	7-8
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	8-9
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-9
		(*b*) Report category boundaries when continuous variables were categorized	8-9
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	8-9
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	na
Discussion			
Key results	18	Summarise key results with reference to study objectives	9-10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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The paradox of self-care gender differences amongst Italian patients with Chronic Heart Failure: Findings from a real-world cross-sectional study

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The paradox of self-care gender differences amongst Italian patients with Chronic Heart Failure: Findings from a real-world cross-sectional study

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Data sharing statement. We intend to make data freely available in the public domain after publication of major findings. Researchers interested in collaborations should contact the corresponding author (rosario.caruso@unimi.it)

Abstract

Aim. The aim of this study was to critically analyse and describe gender differences related to self-care amongst patients with chronic heart failure (HF).

Methods and results. A monocentric real-world cohort of 367 chronic HF patients in follow-up were used for this cross-sectional study. We report data related to the cohort's demographic and clinical characteristics. Self-care was assessed using the Self-Care of Heart Failure Index before patients' discharge. After bivariate analysis, logistical regression models were used to describe the relationship between gender, self-care behaviours and self-care confidence. While males were found to have more than quadruple the risk of poor self-care than women (OR=4.596; 95% CI=1.075–19.650), males were also found to be approximately 60% more likely to have adequate self-care confidence than women (OR=0.412; 95% CI=0.104–0.962). Considering that self-care confidence is described as a positive predictor of behaviours, our results suggest a paradox. It is possible that the patient–caregiver relationship mediates the effect of confidence on behaviours. Overall, adequate levels of self-care behaviours are a current issue, ranging 7.6–18.0%.

Conclusion. This study sets the stage for future research where elements of the patient–caregiver relationship ought to be considered to inform the planning of appropriate educational interventions. We recommend routinely measuring patients' self-care behaviours to guide their follow-up and as a basis for any changes in their daily life behaviours.

Key Words. Gender differences; Heart Failure; Self-Care; Self-Confidence; Self-Management; Self-Maintenance.

Strengths and limitations of this study

- This is the first study in the last 5 years aimed at exploring gender differences in self-care amongst patients with chronic heart failure (HF).
- Gender differences are an important determinant of self-care, with gender-based self-care behaviours being culturally determined. As such, gender-specific educational interventions may be effective in influencing these gender-based self-care behaviours.
- Italian men have more than quadruple the risk of poor self-care than women, while also being approximately 60% more likely to have adequate self-care confidence than women. Paradoxically, confidence is usually a positive predictor of self-care maintenance.
- Understanding gender differences in patients' responses to pathology is a necessary precursor to reducing inequalities in healthcare delivery and allows for the development of targeted evidence-based educational interventions.
- Our findings are not generalisable outside of Italy; as such, more cross-cultural investigations are needed.

Introduction

The rate of heart failure (HF) is steadily increasing worldwide, becoming an important public health issue.[1,2] HF affects more than 15 million people in Europe and its prevalence is rising, with the global prevalence of HF expected to reach 25% by 2030.[3] Currently, the prevalence of HF amongst European and American adults ranges 0.4–2.3%.[4] The most common causes of HF are related to issues with the valves, myocardium, pericardium, endocardium, or heart rhythm abnormalities.[5] These, along with multiple comorbidities, often results in chronic HF. In such cases, patients are asked to abide by list of evidence-based clinical recommendations aimed at optimising their health, monitoring their symptoms and to engage appropriate decision-making to manage their signs and symptoms.[6,7] Recent studies show how HF patient outcomes are closely linked to their self-care, which is their ability to maintain their health through health promoting practices and illness management.[7–10]

Academic interest in self-care has grown following the development of middle range theories of reference,[7] with these theories facilitating efforts to investigate the relationship between self-care and clinical outcomes in HF patients. A high standard of self-care in HF patients is associated with improved quality of life,[11,12] reduced re-hospitalisations,[13] reduced mortality,[14] and lower healthcare costs.[14] Evidence shows that HF patients who participate in educational interventions aimed at improving self-care exhibit improvements in their emotional quality of life as well as overall health status after just 3 months.[11,12] Other studies indicate that poor self-care is an independent risk factor for adverse clinical outcomes in HF patients and re-hospitalisations.[13] These adverse clinical outcomes also include the death of HF patients with poor self-care.[14] One common characteristic of patients with poor self-care is a reduction in their use of HF-related medications over time (i.e. poor adherence). This implies a greater likelihood of re-hospitalization and an increase in healthcare costs; conversely, HF management in patients with adequate levels of self-care is far less taxing in terms of healthcare economic resources.[14]

In this scenario, gender differences are an important peculiarity of self-care. These gender differences, however, may be culturally determined. With this being the case, gender-specific educational interventions may be beneficial in addressing some of these gender-specific characteristics. Understanding these gender differences can inform interventions aimed at closing the gender gap and reducing inequalities in healthcare delivery.[15] Current research suggests a range of gender differences in chronic HF; however, the findings of these studies are often contradictory. For example, while some studies indicate that men have better self-care behaviours than women,[16] other studies demonstrate poor self-care behaviours amongst men.[17] That said, there is still much about gender differences in self-care that we do not know; for example, whether it is possible to estimate the likelihood of inadequate/adequate self-care in relation to gender in real-world cohorts. Understanding the peculiarities of how gender difference influence patients' self-care behaviours is important for planning appropriate treatment and education.[5,18]

Currently, the evidence base for understanding gender differences in patients with chronic HF is weak. What evidence exists in this regard is largely inferred by way of the secondary results of studies aimed to describing self-care. For this reason, the aim of this study was to critically analyse and describe gender differences related to self-care amongst patients with chronic HF. The results of this study make a significant contribution to our understanding of these gender and behavioural differences, and can provide a wealth of epidemiological information useful for planning future tailored interventions.

Methods

Design and participants

This is an observational, single-centre design study using real-world convenience sampling. The sample includes all patients seen at a clinic in a research hospital located in San Donato (PSD), northern Italy. To be enrolled, all patients had to have a diagnosis of stable chronic HF and they had to have a recent craniological assessment (maximum 1 week before intake). Therefore, using real-world sampling, all patients with chronic HF related to a cardiac causes and assessed by their

cardiologist within 1 week prior to our study were eligible for participation.[19] Cardiological clinical assessment of the enrolled patients was performed in accordance with current guidelines.[5] All data was collected using a cross-sectional approach, between January and September 2017. The only exclusion criteria for this study were: (a) inability to read and speak Italian, (b) diagnosis of psychiatric or cognitive problems, and (c) patients aged under 18. Although this study used real-world sampling, these exclusion criteria were necessary to ensure that participants could complete all self-report instruments. All enrolled patients gave their written consent to participate. This study was approved by the local Institutional Review Board of Policlinico San Donato (822/PSD/2017).

Measures

We recorded data on participants' demographic and clinical characteristics. Self-care behaviours were assessed before the patients discharge using the Self-Care of Heart Failure Index (SCHFI v.6.2).

Demographic and clinical characteristics. We report on the following cohort demographic and clinical characteristics: age, gender, nationality, Body Mass Index (BMI), New York Heart Association (NYHA) functional classification, ejection fraction (EF), secondary cardiac diagnosis associated to HF, and drug treatment. Given the real-world approach used in this study, we used the Cumulative Illness Rating Scale (CIRS) to control for multiple forms of morbidity.[20] BMI was categorised in accordance to the Centers for Disease Control and Prevention (CDC) recommendations (i.e. underweight, healthy weight, overweight, obese).[21] Participants' NYHA classification and HF were reported in line with current guidelines.[5] CIRS was used to evaluate multi-morbidity, considering the gravity of comorbid medical conditions in 14 main domains. Each domain represents a physiopathological system, with scores ranging 0–4 for the assessment; 0=*no problem*, 4=*extremely severe problem*. The CIRS algorithm and subsequent indications result in an overall score for comorbidities that ranges 0–4.[20] For this study, the authors used an online calculator as provided by the Italian Society of Haematology.

Self-Care of Heart Failure Index (version 6.2). SCHFI is a 22-item self-report instrument used to measure self-care in HF patients. The SCHFI measures self-care within a well-defined framework, having been developed using a situation-specific theory of reference.[22] The 22 items of the instrument are grouped according to three scales used to measure both self-care behaviours (i.e. self-care maintenance and self-care management), and the self-efficacy in performing said behaviours (i.e. self-care confidence). According to Riegel and colleagues, patients' self-care confidence is theorised to have an effect on patients' self-care behaviours and is not an element of self-care per se.[23] The two behavioural measures are self-care maintenance and self-care management. Self-care maintenance describes patients' level of engagement in behaviours aimed at maintaining their stability, monitoring their signs and symptoms and adhering to their treatment. Conversely, self-care management describes patients' ability to recognise their symptoms and to take appropriate treatment-orientated actions when needed (e.g. consult a healthcare provider, or reduce fluid intake). Each scale in the SCHFI uses a 4-point self-report response format, ranging 1=*never or rarely* to 4=*always or daily*. To compute the score for each scale, raw scores must be transformed into standardised scores in the order of 0–100, following the procedure described in SCHFI validation studies.[22,24] Adequate self-care behaviours and self-care confidence are indicated by scores higher than 70.[22,24]

Data analysis

All data was checked to assess for possible missing data, erroneous entries or outliers against a frequency distribution. Missing data was managed using a pairwise approach. A study of skewness was used to provide a preliminary assessment of the distribution of variables, which was followed by a Kolmogorov–Smirnov test. Continuous variables were expressed as mean and standard deviation (SD) for normally distributed data, while non-normally distributed variables were expressed as median and interquartile range (IQR). Categorical variables have been described by numbers and percentages. All data was preliminary tested via univariate analysis, where categorical variables were tested by contingency table analysis (i.e. χ^2 test or Fisher exact test, when

appropriate), and continuous variable were tested by Mann–Whitney U test or Student's *t*-test (when appropriate). A bivariate analysis was performed to assess the relationship between gender and other variables using point-polyserial correlation (Rpp). Logistic regression (LR) models were used in the multivariable analysis to describe gender differences related to self-care maintenance, management and confidence. LR models were developed considering these univariate analysis interpretations and bivariate analysis, the theoretical rationale, precautions to avoid model overfit,[25] conformity with linear gradient for the included continuous variables, control of possible collinearity amongst the independent variables, the study of statistical significance using both Wald's χ^2 and likelihood ratio test, an assessment of goodness-of-fit measures through the Hosmer–Lemeshow test, and the analysis of pseudo-R^2 (i.e. Cox and Snell; Nagelkerke and McFadden).[25] All predictor variables selected from the univariate analysis were entered simultaneously into the equation models to control for each other. Statistics were performed using SPSS (v.22, IBM Corporation) and R Statistical Package (R Foundation for Statistical Computing). All tests were two-tailed, setting a significance level of 5%.

Patient and Public Involvement

We carefully considered patients' priorities, experience, and preferences during the process of informed consent counseling. All patients are informed about the ways to contact the principal investigation in case they wish to receive more information on the study development and findings. Patients' active involvement was related to the sole period of data collection.

Results

Sample

A sample of 367 chronic HF patients were enrolled in this study. Participant characteristics are shown in Table 1. The majority of participants were male (n = 256; 74.0%), with an average age of 65.1 years (SD = 13.6). The mean BMI was 26.95 kg/m^2 (SD = 4.97). The majority of participants were satisfied criteria for NYHA class II (n = 199, 57.5%), with a preserved EF (pEF) (n = 163;

47.1%). The most frequent secondary cardiac diagnosis associated with chronic HF was myocardial infarction (*n* = 225; 65.0%), followed by hypertension (*n* = 176; 50.9%) and atrial fibrillation (*n* = 111; 30.1%). Only 66 participants reported adequate self-care maintenance (18.0%), 28 participants had an adequate self-care management (7.6%), and 131 participants had an adequate self-confidence (35.7%).

>Insert Table 1 About Here<

Gender differences

Considering the bivariate analysis, gender (male = 1; female = 2) was significantly related to CIRS (Rpp = 0.157; *p* = 0.005) and self-care maintenance (Rpp = -0.112; *p* = 0.025) (where 1 = *adequate self-care maintenance*, 2 = *inadequate self-care maintenance*), self-care management (Rpp = -0.101; *p* = 0,046) (where 1 = *adequate self-care management*, 2 = *inadequate self-care management*), self-care confidence (Rpp = +0.158; *p* = 0.011) (where, 1 = *adequate self-care confidence*, 2 = *inadequate self-care confidence*. Therefore, male participants reported less comorbidity, as well as lower self-care maintenance and management scores, but higher self-care confidence.

As shown in Table 2, according to the first LR model, the likelihood of inadequate self-care maintenance is reduced by roughly 80% when patients have adequate levels of self-care confidence (OR = 0.188; 95% CI = 0.042–0.843) and self-care management (OR = 0.182; 95% CI = 0.037–0.892), while males were found to be more than four times as likely as females to demonstrate inadequate self-care maintenance (OR = 4.596; 95% CI = 1.075–19.650). The second LR model shows that the likelihood of inadequate self-care management decreases by approximately 83% when patients have adequate maintenance (OR = 0.171; 95% CI = 0.036–0.816). No relationship was found between gender and self-care management. The third LR model shows that the likelihood of inadequate self-care confidence decreases by roughly 80% when patients have adequate levels of self-care maintenance (OR = 0.211; 95% CI = 0.051–0.869), and that males approximately 60% more likely to possess adequate self-care confidence than women (OR = 0.412;

95% CI = 0.104–0.962). Moreover, every point reduction in the CIRS total score is associated with a 70% increase in the likelihood of the patient possessing adequate levels of self-care confidence (OR = 0.297; 95% CI = 0.102–0.865).

>Please add Table 2<

Discussion

To the best of our knowledge, this was the first study in last 5 years to have explored the issues of gender differences in the self-care of patients with chronic HF. Understanding these gender differences is important for informing evidence-based educational interventions aimed at improving self-care behaviours within this patient population. Our results indicate that gender is strongly correlated with self-care behaviours. Our LR models allow for the investigation of gender differences using multivariable approaches, where self-care behaviours and self-care confidence are treated as dichotomous outcomes (i.e. inadequate versus adequate). Specifically, gender is significantly associated with self-care maintenance and self-care confidence, where males are more than four time as likely to exhibit inadequate self-care maintenance than females. Males are also approximately 60% more likely to describe having adequate self-care confidence than females. These results present somewhat of a paradox, with current theories and evidence indicate that self-care confidence should positively predict self-care behaviours.[7,26,27] Nonetheless, this paradox is tangible in our results, considering the relationship between self-care confidence and adequate self-care behaviours (Table 2). For example, we can see that men are significantly less likely than women to demonstrate adequate levels of self-care maintenance, despite being roughly 60% more likely than women to have adequate levels of self-care confidence.

In short, our understanding of gender differences in both Italian chronic HF patients and the wider chronic HF population may be missing some important elements. Future investigations are needed to better understand this paradox. Having a better understanding of these gender differences

might allow for the development of tailored educational intervention, specific to the needs of each gender, prior to the patient's discharge. Patient education is an integral part of treatment and rehabilitation;[5] therefore, understanding the nature of this paradox is important to ensure that the efficacy of educational interventions is not undermined by gaps in knowledge concerning educational best practice. To improve our understanding of this phenomenon, future investigations should take into account the potential role of comorbidities related to mental disorders by measuring depression and anxiety,[28–30] and by the determining the potential influence of self-delusion with respect to self-care.[31] Literature suggests that patients with even minor depression exhibit lower levels of self-care than patients with major depression, and women are more likely to present with anxiety; however, there is currently no evidence of gender differences in terms of the self-care–depression relationship.[28] Moreover, the greater self-care confidence of males should predict greater self-care knowledge; however, there are no evidence that males have a deeper understanding of their chronic HF than females. This could imply that the greater self-care confidence seen in males is simply the product of a form of self-delusion.[31] Moreover, the effect of this self-delusion might be enhanced when male patients are threatened by a perceived loss of autonomy and control, thus providing one possible explanation for the aforementioned paradox.

Notwithstanding, any evidence arising out of the study of gender differences needs to be contextualised to the patients' cultural norms. Consequently, the literature describes a broad range of conflicting results when the evidence of multisite international studies are compared. De facto, evidence coming from United States shows that men are more likely to undertake independent decisions about their self-care management, while women have higher self-care maintenance.[16] Conversely, in our study, men seem to exhibit low levels of both self-care management and maintenance, and higher levels of self-care confidence, which is what these patients bring to bear in terms of self-efficacy to overcome their disease. These results are consistent with previous general descriptions of Italian patients.[17] In recent years, there has been a growing interest in understanding self-care gender differences in chronic diseases,[32] especially in patients with chronic HF, given

evidence indicating that patients' self-care is improved considerably following the integration of educational strategies into their overall treatment plans.[5] Gender differences, however, are an important issue in self-care, especially given the evidence that gender is often a determinant of self-care.[17]

Consistent with current knowledge, the findings of this study confirm that Italian chronic HF patients have a high frequency of poor self-care.[33] These findings, with regard to the self-care of Italian chronic HF patients, are particularly valuable given the real-world sampling used in this study and the fact that participants had only recently completed their cardiological assessment. In fact, unlike previous self-care studies, all the patients in this study were enrolled close to their primary cardiology visit and not simply during follow-up. In other words, this study paints a realistic picture of chronic HF patients who have only recently received their clinical assessment and have been prescribed lifestyle adjustment therapies. Moreover, the description of patients' self-care deficits in our study is more disconcerting than in previous studies.[17] Previous studies have reported self-care behaviours in the range of 14.5–24.4%,[17] while the current study describes adequate self-care in the range of 7.6–18.0%. In this scenario, gender differences become readily apparent, starting from the bivariate analysis interpretation—where self-care behaviours and self-care confidence have a significant relationship with gender—towards the LR models analysis.

Several recent studies have undertaken to explore the quality of the patient–caregiver relationship in relation to patients' self-care (i.e. mutuality).[34,35] It seems that positive patient–caregiver mutuality is associated with better patient self-care. These mutuality studies shape interdependence model paths and might also explain the paradoxical findings in our study, with patient–caregiver mutuality mediating the relationship between self-care confidence and self-care behaviours. In other words, it is reasonable to speculate that men might have a poorer quality relationship with their caregivers than women, where the males' caregivers play an important role helping their male partners to adhere to their clinical recommendation (e.g. sodium-restricted diet).

If this hypothesis can be corroborated with empirical evidence, then it is logical to include the caregivers of male patients in any educational interventions.[36]

Strengths and limitations

This study has a number of limitations and strengths. Firstly, the design was cross-sectional and sampling was not randomised. Moreover, this study was a single centre in Italy. Secondly, the monocentric sampling used in this study was both a limitation and a strength given that the topic of gender difference is so closely related to the contextual culture; as such, this approach depicts a realistic image of the northern Italian reality. Another strength of this study is the real-world sampling, which adds value to the realistic sense of the investigation. Moreover, to the best of our knowledge, this was the first study of its kind to describe self-care as a dichotomous outcome, using LR models. This approach simplifies the epidemiological interpretation of self-care characteristics, owing to the likelihood interpretation coming from the adjusted OR of the independent variables of the models. In fact, self-care characteristics are usually studied using structural equation modelling approaches or path analysis, which are very useful latent multivariate approaches, but are less intuitive from an epidemiological point of view.

Conclusion

Self-care is an important issue in multidisciplinary care management programmes aimed at reducing the risk of HF hospitalisation and mortality. There is strong evidence attesting to the clinical benefits of appropriate levels of self-care, as highlighted in the available guidelines.[5] Notwithstanding, these interventions are far from foolproof and it is not clear what should constitute best practice with respect to the development of tailored educational intervention to support chronic HF patients. Nonetheless, more needs to be done to chronic HF patients successfully adjust to cope with their self-care recommendations, follow-ups and lifestyle adjustments. In this scenario, understanding gender differences in self-care can help to promote further research, the outcomes of which can correctly guide healthcare providers in the provision of educational interventions targeting the needs of this patient group. Our study helps to establish the foundations for such future

investigations and mat provide some insights for healthcare providers looking to understand gender differences in patients' presentation of self-care behaviours.

Considering these proposals for future research, it is of paramount importance that some consideration be afforded in relation to the complexity of the management of chronic HF. In fact, no understanding of how gender differences impact patients' self-care can be complete without factoring in the quality of the patient–caregiver relationship, which plays a pivotal role in determining actual patient self-care behaviours. In other words, an individual's confidence in their ability to achieve their clinical recommendations (e.g. physical exercise, dietary habits, the recognition of signs and symptoms) may be mediated by their caregiver. As such, it is imperative that this caregiver has an understanding of the recommendations on par with the patient. Future research, however, is needed to corroborate this framework.

The results of this study also highlight an important issue related to the frequency of patients with inadequate self-care. There is an urgent need of more awareness regarding the importance of education during hospitalisation and follow-up. Timely educational interventions may be effective in altering patients' self-care behaviours. To call attention to this important topic and to guide follow-up educational priorities, we recommend the longitudinal screening of patients' self-care behaviours during follow-up visits. This approach can also be useful for assessing the quality of the patient–caregiver relationship, and could help to resolve some of the problems underpinning the gender differences described here. Notwithstanding, we suggest that only validated instruments be used to perform these assessments. In conclusion, further cross-cultural exploration of gender differences in the self-care of patients with HF is needed to frame our knowledge in this field.

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Table 1. Sample characteristics (*N* = 346)

Demography		*N* (%)
Mean (SD),	Age (Years)	65.6 (13.6)
	Gender (male/female)	61.1%/38.9%
	Nationality (Italian)	100%
Anthropometry		
Mean (SD),	BMI (kg/m^2)	26.95 (4.97)
Clinical characteristics		
	Class II	256 (74.0%)
	Class III	82 (23.7%)
	Class IV	8 (2.3%)
	rEF (<40%)	82 (23.7%)
	MrFE (40-50%)	101 (29.2%)
	pEF (≥50%)	163 (47.1%)
	CIRS total score 0	270 (78.0%)
	CIRS total score 1	50 (14.5%)
	CIRS total score 2	26 (7.5%)
Secondary Cardiac Diagnosis		
	Myocardial Infarction	225 (65.0%)
	Hypertension	176 (50.9%)
	Atrial Fibrillation	111 (30.1%)
Drug treatment		
	ACE inhibitors	73 (21.1%)
	B-blockers	87 (25.1%)
	Diuretics	270 (78.0%)
	Cardiac glycosides	160 (46.2%)
	Aspirin or salicylates	222 (64.2%)
	Calcium channel blockers	74 (21.4%)
'Adequate' Self-care (scores ≥ 70)		
	Maintenance	66 (18.0%)
	Management	28 (7.6%)
	Confidence	131 (35.7%)

Table 2. Models of Logistic Regression analysis

Maintenance							
Predictors		**Wald's χ2**	**d.f.**	**P-Value**	**Odds Ratio**	**95% CI**	
	Constant	2.356	1	0.125	-	-	-
	Confidence (Adequate vs Inadequate)	4.767	1	0.029	0.188	0.042	0.843
	Management (Adequate vs Inadequate)	4.413	1	0.036	0.182	0.037	0.892
	CIRS	2.314	1	0.128	2.909	0.735	11.512
	Gender (Male vs Female)	4.232	1	0.04	4.596	1.075	19.650
Model		**χ2**	**d.f.**	**P-Value**	**Pseudo-R^2 (Cox & Snell)**	**Pseudo-R^2 (Nagelkerke)**	**Pseudo-R^2 (McFadden)**
	Likehood ratio test	18.69	9	0.028	0.241	0.351	0.238
	Hosmer–Lemeshow test	4.185	6	0.665	-	-	-
Management							
Predictors		**Wald's χ2**	**d.f.**	**P-Value**	**Odds Ratio**	**95% CI**	
	Constant	0.799	1	0.271	-	-	-
	Confidence (Adequate vs Inadequate)	1.992	1	0.158	0.318	0.065	1.561
	Maintenance (Adequate vs Inadequate)	4.902	1	0.027	0.171	0.036	0.816
	CIRS	0.265	1	0.607	0.729	0.219	2.429
	Gender (Male vs Female)	0.88	1	0.348	2.126	0.440	10.284
Model		**χ2**	**d.f.**	**P-Value**	**Pseudo-R^2 (Cox & Snell)**	**Pseudo-R^2 (Nagelkerke)**	**Pseudo-R^2 (McFadden)**
	Likehood ratio test	16.3	9	0.049	0.218	0.336	0.241
	Hosmer–Lemeshow test	3.404	6	0.696	-	-	-
Confidence							
Predictors		**Wald's χ2**	**d.f.**	**P-Value**	**Odds Ratio**	**95%CI**	
	Constant	2.758	1	0.097	-	-	-
	Maintenance (Adequate vs Inadequate)	4.644	1	0.031	0.211	0.051	0.869
	Management (Adequate vs Inadequate)	1.906	1	0.167	0.332	0.069	1.589
	CIRS	4.953	1	0.026	0.297	0.102	0.865
	Gender (Male vs Female)	1.474	1	0.035	0.412	0.104	0.962

Model	$\chi 2$	d.f.	P-Value	Pseudo-R^2 (Cox & Snell)	Pseudo-R^2 (Nagelkerke)	Pseudo-R^2 (McFadden)
Likehood ratio test	17.8	9	0.044	0.221	0.314	0.221
Hosmer–Lemeshow test	1.604	4	0.708	-	-	-

Abbreviations: CIRS, Cumulative Illness Rating Scale; d.f., degree of freedom; CI, Confidence Interval

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-7
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	7-8
		(*c*) Explain how missing data were addressed	7-8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	na
		(*e*) Describe any sensitivity analyses	7-8
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	8-9
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-9
		(*b*) Report category boundaries when continuous variables were categorized	8-9
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	8-9
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	na
Discussion			
Key results	18	Summarise key results with reference to study objectives	9-10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.