



# BMJ Open Quality of life and disease experience in patients with heart failure with reduced ejection fraction in Spain: a mixed-methods study

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## ABSTRACT

**Objectives** To gather insights on the disease experience of patients with heart failure (HF) with reduced ejection fraction (HFrEF), and assess how patients' experiences and narratives related to the disease complement data collected through standardised patient-reported outcome measures (PROMs). Also, to explore new ways of evaluating the burden experienced by patients and caregivers.

**Design** Observational, descriptive, multicentre, cross-sectional, mixed-methods study.

**Setting** Secondary care, patient's homes.

**Participants** Twenty patients with HFrEF (New York Heart Association (NYHA) classification I–III) aged 38–85 years.

**Measures** PROMs EuroQoL 5D-5L (EQ-5D-5L) and Kansas City Cardiomyopathy Questionnaire and patient interview and observation.

**Results** A total of 20 patients with HFrEF participated in the study. The patients' mean (SD) age was 72.5 (11.4) years, 65% were male and were classified in NYHA functional classes I (n=4), II (n=7) and III (n=9). The study showed a strong impact of HF in the patients' quality of life (QoL) and disease experience, as revealed by the standardised PROMs (EQ-5D-5L global index=0.64 (0.36); Kansas City Cardiomyopathy Questionnaire total symptom score=71.56 (20.55)) and the in-depth interviews.

Patients and caregivers often disagreed describing and evaluating perceived QoL, as patients downplayed their limitations and caregivers overemphasised the poor QoL of the patients. Patients related current QoL to distant life experiences or to critical moments in their disease, such as hospitalisations. Anxiety over the disease progression is apparent in both patients and caregivers, suggesting that caregiver-specific tools should be developed.

**Conclusions** PROMs are an effective way of assessing symptoms over the most recent time period. However, especially in chronic diseases such as HFrEF, PROM scores could be complemented with additional tools to gain a better understanding of the patient's status. New PROMs

## Strengths and limitations of this study

- This study followed an ethnographic approach to collect data on patient's experiences and narratives related to heart failure, a type of study not carried out before in Spain and with scarce reports worldwide.
- Both patients and caregivers could discuss freely and explain in detail the aspects of the disease that they considered under control and those where change was deemed necessary.
- The often-contrasting views of patients and caregivers highlighted the difficulties in obtaining accurate and objective evaluations of quality of life.
- Although the selection of patients aimed for inclusiveness and diversity, the limited number of patients with heart failure with reduced ejection fraction (HFrEF) selected for in-depth analysis may not be fully representative of the population of patients with HFrEF in Spain.
- The ethnographic interviews took place in the context of the COVID-19 pandemic, which transformed the daily routines of patients and caregivers and may have to a certain extent altered their perspective of living with HFrEF.

designed to evaluate and compare specific points in the life of the patient could be clinically more useful to assess changes in health status.

## INTRODUCTION

Despite advances in treatment, heart failure (HF) remains one of the leading causes of hospitalisation and readmissions, death and disability worldwide.<sup>1 2</sup> The economic burden of HF, mainly driven by recurrent hospitalisations, consumes an estimated 1%–2%

of healthcare budgets.<sup>3 4</sup> The progressive ageing of the population in some Western countries, such as Spain, and increasing HF prevalence, have positioned this disease as a major public health problem.<sup>5-7</sup>

Clinically, HF can be classified based on the left ventricular ejection fraction (LVEF) into HF with reduced ejection fraction (HFrEF), defined as an EF  $\leq 40\%$ , HF with mildly reduced ejection fraction, defined as EF  $>40\%$  and  $<50\%$ , and HF with preserved ejection fraction, defined as an ejection fraction  $\geq 50\%$ .<sup>8</sup> Patients in these subgroups often have distinct underlying etiologies, demographics, co-morbidities and response to therapies.<sup>9 10</sup> Additionally, the presence and severity of symptoms and exercise intolerance of patients with HF is usually categorised following the New York Heart Association (NYHA) classification into four functional classes (I–IV), class IV being the worst.<sup>11</sup>

HF can severely affect the quality of life (QoL) of the patient by reducing their independence and ability to undertake daily living activities, and can also disturb their mental health and psychosocial well-being.<sup>12 13</sup> Prior studies have shown that patients with HF had an even higher incidence of limitations than patients with chronic diseases such as diabetes, cancer or Alzheimer's disease.<sup>13</sup> Several patient-reported outcome measures (PROMs) have been used to quantify health status in patients with HF, such as the generic EuroQoL 5D-5L (EQ-5D-5L) and the disease-specific Kansas City Cardiomyopathy Questionnaire (KCCQ).<sup>13-17</sup> PROMs such as the KCCQ have a good correlation with prognosis and their use has been encouraged by the American Heart Association in both routine clinical practice and clinical trials of new therapies.<sup>18 19</sup> However, although these PROMs can be useful indicators of health status and how HF impacts patients' QoL within a 2-week recall period, they have not been designed to reflect some of the patient's and caregiver's perspectives on living with HF, including aspects such as the importance of interactions with family or healthcare providers, feelings related to the course of their disease or barriers to accessing healthcare resources.<sup>20</sup> These unique aspects of culture, preferences, customs, values and attitudes could have an impact on treatment effectiveness and outcomes. Complementary to PROMs, in-depth interviews with patients and caregivers are useful to evaluate quality of patient care and the interaction between the patient and the healthcare system.<sup>21</sup> However, neglecting the limitations PROMs could hinder our understanding of the patient's attitudes and real-life disease experiences.

Ethnographic qualitative studies involve observation of the patients and caregivers in their real-world settings to determine how they behave in specific contexts. Ethnographic research collects comprehensive information from multiple sources such as interviews, caregiver perspectives, non-participant observation of healthcare visits and home tours, among others, and has previously been carried out to investigate QoL in patients with HF.<sup>12 22-27</sup> Previous ethnographic studies conducted in

patients from the UK identified barriers to interventions for HF and critical points on disease pathways which resulted in an increase in the risk of admission.<sup>28-30</sup>

Little is known about the patient's and caregiver's perspective of living with HF in Spain, and previous studies did not evaluate patients by LVEF.<sup>31</sup> The objective of this study was to gather insights on the disease experiences of patients with HFrEF and their caregivers, and the impact on their everyday life. We used a mixed-methods approach involving the parallel use of an ethnographic approach with PROMs for the assessment of health status (EQ-5D-5L and KCCQ). Rather than seeking corroboration of results from different data sources, the mixed-methods approach intended to highlight the complementarity of ethnographic data and PROMs.<sup>32 33</sup> The goal was to improve awareness of healthcare professionals, service providers, policy makers and educators on the factors that can potentially influence treatment effectiveness, and the existence of aspects of the patient's experience that are not covered by existing tools. In turn, this may encourage first, a more active participation of healthcare providers, patients and caregivers in clinical decisions considering not only the disease state, but also cultural factors and individual values and attitudes, and second, the development of instruments for the evaluation of healthcare interventions.

## METHODS

We conducted an observational, cross-sectional, descriptive, multicentre and mixed-methods study to obtain insights regarding perception and attitudes of patients with HFrEF towards their disease. The patients in the study were recruited at the Departments of Cardiology of two large tertiary-level hospitals, namely, the Puerta del Hierro University Hospital (Majadahonda, Madrid, Spain) and the Bellvitge University Hospital (Hospitalet de Llobregat, Barcelona, Spain). The patient populations attended by these hospitals were socioeconomically very distinct, as the Puerta del Hierro University Hospital is located at a high-income district of Madrid, and the Bellvitge University Hospital covers a suburban area of mostly low or very low-income patients. Due to the qualitative and observational design of the study, there was no masking or randomisation. Clinical management of the patients followed routine clinical practice, with no changes in treatment or additional clinical assessments specific for this study. All decisions related to disease management were made at the discretion of the treating physician without interference by the sponsor. Informed consent was obtained from each patient prior to study initiation. The patients authorised the interview with their main caregiver as part of the informed consent process.

## Patient selection

Patients were assessed for eligibility by local clinical staff according to selection criteria at each participating centre. Patients were classified by NYHA class and could

be belong to any of the four classes I–IV. The inclusion criteria were  $\geq 18$  years at the time of consent, established documented diagnosis of HF<sub>r</sub>EF (LVEF  $\leq 40\%$ ), and signed consent to participate. Patients unable to complete the PROMs because of any psychological or physical condition and patients hospitalised at inclusion were excluded.

A sample size of 20 patients was selected to have sufficient representation of the three major NYHA classes. Purposeful sampling was based on the characteristics of potential participants extracted from medical records to obtain optimal variety.

### Data collection

The patient's demographic information and medical history were collected from medical records at the selection visit. On the day of the home visit, the patients first completed two health status questionnaires and then two female senior researchers (SCC and MFE) with  $>5$  years of experience in medical sociology and medical anthropology conducted a semistructured interview following a topic guide (see online supplemental materials). There was no prior relationship between the interviewer and the patient, who was informed about the research goals prior to starting the interview. The interview conducted at the patient's home lasted approximately 90 min. In some instances, with the consent of the patient, his/her closest caregivers were interviewed at the patient's home on the same day for about 30 min. The interview with the caregivers aimed at understanding their perception of the patient's status and evaluating their social and emotional relationship with the patient.

In order to gather observational data to complement participants' accounts of their medical experience, 6 out of 20 patients (two per NYHA class) consented that the same researcher carrying out the interview would observe their first healthcare appointment after the home interview. Direct observation allowed researchers to gather information regarding patients' objective and subjective experiences during medical encounters, about how patients and caregivers conveyed concerns and needs, and provided clues about incongruent behaviour. A single appointed researcher observed the initial and main focus of conversations with healthcare providers, questions by patients and caregivers and patients' use of verbal and non-verbal communication (eg, behaviour that suggested passive, nervous, impatient, caring or expectant attitudes). Immediately after the appointment, patients and caregivers, if present, were asked to evaluate the medical visit (clinical encounters last 20 min on average). Researchers took field notes and added reflexive comments about the encounter and about participants' experience.

The in-depth interview aimed to capture the patients' experience with the disease from their own point of view, whereas the non-participant observation during the medical visits allowed to investigate the relationship with the healthcare practitioners for both patients and family members.

Data from in-depth interviews were collected by audio recording and field notes, whereas data from direct observation of medical encounters were collected by field notes only, taking into consideration all aspects of the patient's life and in all cases protecting the patient's data privacy.

### Quantitative outcomes and analyses

Secondary variables assessed included PROMs by using the EQ-5D-5L and KCCQ. The EQ-5D-5L is a self-reported questionnaire used to derive a standardised measure of health status, also referred to as a utility score.<sup>34</sup> The KCCQ is a self-administered HF-specific instrument and has shown to be a valid, reliable and responsive measure for patients with HF.<sup>14</sup> Spanish validated versions of these questionnaires were used.<sup>35 36</sup> For the EQ-5D-5L, the number and percentage of patients reporting any type of limitation for each questionnaire dimension, the number and percentage of patients reporting 'severe' or 'extreme' responses for each questionnaire dimension, as well as the index value and the visual analogue scale (VAS, where 100 equals the best health patients with HF can imagine), were assessed; for the KCCQ, the score for each domain/subdomain, and a summary score for the total symptom score, clinical symptom score and overall summary score were assessed (scores range from 0 to 100; where higher scores indicate a better health status). The PROMs were analysed descriptively.

### Qualitative outcomes and analyses

The following primary variables were assessed: the patient's profile; the patient's emotional perception (values, attitude, frustration, fear) during the HF<sub>r</sub>EF journey, including the role of the caregiver; key relationships and communication processes during the patient HF<sub>r</sub>EF journey (patient–doctor, patient–carer/family); main barriers to accessing healthcare services experienced by patients during the HF<sub>r</sub>EF journey; and the patient's unmet needs (cognitive, emotional and functional) associated with HF. Observational data, interviews and documentary materials were analysed at three levels: individual patient cases, across cases within research centres and across research centres to synthesis.

Thematic content analysis was used to analyse the data gathered from interviews and direct observation of clinical encounters. The analysis was carried out by field researchers in six steps: (1) read and reread of interview and medical encounters' fieldnotes; (2) identification of main topics per interview domain; (3) text codification to identify current and new domains; (4) review of PROM scores per interviewer and NYHA class; (5) comparison of PROM scores and fieldwork data; and (6) synthesis of repetitive patterns.

Subsequently, data triangulation was used to integrate quantitative and qualitative information by the researchers, individually and in joint sessions. Three types of triangulation were used: investigator, data and methodological triangulation. Two investigators were involved in the data collection and analysis. Findings from each

**Table 1** Demographic and clinical characteristics of the patients

| Variable                                     | N=20        |
|--|-------------|
| Age, years, mean (SD)                        | 72.5 (11.4) |
| Range (minimum–maximum)                      | 38–85       |
| Gender, male, n (%)                          | 13 (65.0)   |
| Time since diagnosis, years, mean (SD)       | 2.35 (2.9)  |
| Recent diagnosis (less than 2 months), n (%) | 2 (10.0)    |
| NYHA, n (%)                                  |             |
| I  | 4 (20.0)    |
| II   | 7 (35.0)    |
| III  | 9 (45.0)    |
| LVEF, %, mean (SD)                           | 31.1 (6.0)  |
| Diabetes, type 2, n (%)                      | 9 (45.0)    |

LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.;

investigator were compared with develop a deeper understanding of how the different investigators view the issue. Preliminary conclusions were discussed with the broader team of authors in further analysis sessions. Regarding data triangulation, investigators compared the answers from patients and caregivers (information sources) separately to identify areas of agreement and disagreement over the main topics. Regarding methodological triangulation, findings from interviews, direct observations of medical appointments and PROM scores were compared with identify incongruences and disparities in patients' responses (eg, patients reporting mild limitations in PROMs but highlighting severe limitations during the interview and/or medical appointment).

The analytical process aimed to reach theoretical saturation where no new dimensions emerged during joint sessions.

## RESULTS

### Patient characteristics

A total of 20 patients with HFrEF participated in the study (table 1). The mean (SD) age of the patients was 72.5 (11.4) years (range: 38–85 years), and 13 (65.0%) were male. The study included four, seven and nine patients in NYHA functional classes I–III, respectively. Although the study protocol was designed to include class IV patients, their frailty, and the effects of the COVID-19 pandemic in the patients' self-caring strategies, hindered the participation of any patients in this class. Twelve patients were being treated at the Bellvitge University Hospital and eight patients were being treated at the Puerta del Hierro University Hospital.

### Understanding of QoL by patients with HF

During the in-depth interviews, the participants described how living with HFrEF impacted their lives, including

how they experienced the symptoms of HF and their effects on daily routines (summarised in table 2). Their responses provided relevant insights on what QoL meant to them. For many patients, QoL was 'being able to do what they did before' and missed being independent, their everyday life and maintaining an active lifestyle.

Patients tended to self-limit and isolate to limit symptomatology due to progression-related fears or even fear to a sudden death, despite a more sedentary lifestyle being detrimental to the recovery and to their own QoL.

### Impact of demographic factors in perception of QoL

Attitudes and perceptions towards HFrEF seemed to strongly depend on age and education. Young patients tend to be more informed about the disease and challenge the healthcare practitioners' opinions.

In contrast, older patients had a difficult time differentiating between HFrEF symptoms and those associated with the normal process of ageing. Often caregivers had to help them understand the information provided by healthcare workers.

The interviews also revealed that male patients showed more dependency towards caregivers than their female counterparts. Female caregivers tended to strongly challenge male patients' perception of QoL. In one case, the wife of a NYHA III patient was very critical of her husband's attitude and thought that part of his evolution strongly depended on his will, and asked him to exercise more, read, get on the computer and go out for a ride on the motorcycle. They even consulted with a psychologist friend to help them handle the situation.

### PROMs and health status

The results of the EQ-5D-5L and KCCQ showed a strong correspondence with the NYHA functional classes, and also between the two PROMs (table 3). We found that scores from PROMs dropped as the NYHA increased (ie, the higher the NYHA class and the HF symptoms, the worse their perceived health status was). No differences were observed in scores with respect to gender, or between the patients from the two hospitals.

Some patients with lower NYHAs, despite having visible constraints in health status, indicated high scores in the EQ-5D-5L VAS score. For example, a patient with major comorbidities (1–10) with NYHA I indicated a EQ-5D-5L VAS score of 90 and emphasised that her QoL was good. This contrasted with the views expressed by her caregiver (table 2).

Regardless of the NYHA, some patients seemed to minimise and relativise the impact of HFrEF on their QoL. Caregivers, in contrast, could emphasise the limitations imposed by HFrEF. For example, the wife and caregiver of a NYHA II patient (1–11) indicated that in the consultation with the cardiologist the patient usually underestimated his condition. In another case, the wife of a NYHA III patient commented that she must be 'present with the doctors, because when they ask him something, he



**Table 2** Domains and main perceptions among patients HFREF

| Domains  | Patients and caregivers' quotes   |
|--|---|
| <b>Domain 1: meanings related to QoL</b>                 |   |
| Attachment to previous routines                          | <p>'This has split my old age in two, having many things to do and not being able to do them because you get very tired. I miss that freedom that I had. Now I feel tied'. (patients 1–1)</p> <p>'What I have missed the most is driving, I spent 20 years as a taxi driver'. (patient 2–1)</p> <p>'For me quality of life means to go wherever you want, to do strange things'. (patient 2–4)</p> <p>'I have always solved the problems that arised, but now I feel impotence because I can't do this anymore'. (patient 2–8)</p>  |
| Fears of progression                                     | <p>'The symptoms depend on the day, they are not permanent, some days you are tired, others not'. (patient 2–2)</p> <p>'Before I went out to the country with my dog, and I liked to go out with the bike but I can't anymore, I have to depend on a cane'. (patient 2–4)</p> <p>'I was in a good, well-paid job and I liked it, but when this happened, I completely disconnected'. (patient 2–8)</p>  |
| Filling out PROM questionnaires                          | <p>'Are you sure of the answer? You barely can walk without taking a break after a few minutes...Are you sure about 'rarely'? You feel down quite often'. (caregiver of NYHA III patient 2–4)</p> <p>'Not sure how to stick to the last 15 days when I answer these questions. Some days I feel better than others and I cannot possible say how I have been doing only in the past 15 days. I notice a lot of variation'. 'It is hard to put a number here...And it is even harder because I can only think about a very a low number...I am not ok right now. It is very sad to realise how low I am, how bad is my health now (referring to the VAS score in the EQ-5D-5L questionnaire)'. (patient 2–6)</p> <p>'I will help you, mom, you must answer within the suggested scale, from mild to severe...Mild is not what you have here, you have moderate problems to get up or go for a long walk... this other one is not mild either, I've noticed that you frequently feel anxious and sadder than before...Are you sure about this number on the scale? Why do you say 80 out of 100? You are not that OK, mom; I wish you would be that OK'. (caregiver of NYHA I patient 1–10)</p> |
| <b>Domain 2: caregivers' roles</b>                       |   |
| Tracking at home   | <p>'I keep track of pressure, weight, urine. Every day. I have it written down here in the notebook and I also send it through the hospital's APP. But I really don't know if it is of much use. When I had to call the ambulance everything seemed normal, I kept a similar record in recent days'. (caregiver of NYHA III patient 1–6)</p>  |
| Medical appointments                                     | <p>'When we go to the hospital the doctors ask him if he sleeps well or if he is drowning and he always answers that he is fine, but he is not. The last time he had been sleeping on the couch because he couldn't sleep in bed even with three pillows. That's why I always go to the controls with him'. (caregiver of NYHA III patient 2–4)</p> <p>'Doctor, he says that he feels OK, but I noticed that he is more anxious, more obsessed about how many times he goes to pee per day. Most days he gets up and cannot sleep worrying about his condition'. (caregiver of NYHA III patient 1–6)</p>  |
| <b>Domain 3: relationships with healthcare providers</b> |   |
| Commitment   | <p>'I come to the very dedicated medical consultations and with the certainty that I am more closely watched than a Ferrari'. (patient 2–5)</p>   |
| Trustworthiness  | <p>'I sit in a consultation where they take their time, and they answer all my doubts. The big difference is that now I feel more secure, I know that I must deal with weight, urine, food. Having the possibility of calling them 24 hours a day gives you more peace of mind'. (patient 2–6)</p> <p>'The nurse is better than any cardiologist, everyone loves her'. (patient 2–5)</p> <p>'The nurse is very close, I think they have chosen a person with a character and attitude that is just what a patient needs'. (patient 2–6)</p>   |

EQ 5D-5L, EuroQoL 5D-5L; NYHA, New York Heart Association; PROM, patient-reported outcome measure; VAS, visual analogue scale.

usually answers that he is fine and does not really say what is wrong with him'

Patients with advanced NYHAs, who experienced one or several hospital admissions, compared their current

experience with the disease to those acute periods of fear and greater uncertainty. Patients showed a limited portrait of their QoL due to the required reference to the last 2 weeks in the questionnaire. For example, a NYHA

**Table 3** Evaluation of health status by PROMs

|   | NYHA I-II (n=11) | NYHA III (n=9) | All NYHA (n=20) |
|---|------------------|----------------|-----------------|
| EQ-5D-5L, patients reporting any limitation* n (%)                |                  |                |                 |
| Mobility  | 5 (40.5)         | 9 (100)        | 14 (70.0)       |
| Self-care   | 0                | 7 (77.8)       | 7 (35.0)        |
| Usual activities  | 4 (36.4)         | 8 (88.9)       | 12 (60.0)       |
| Pain/discomfort   | 4 (36.4)         | 6 (66.7)       | 10 (50.0)       |
| Anxiety/depression  | 4 (36.4)         | 8 (88.9)       | 12 (60.0)       |
| EQ-5D-5L, patients reporting severe or extreme limitations† n (%) |                  |                |                 |
| Mobility  | 0                | 5 (55.6)       | 5 (25.0)        |
| Self-care   | 0                | 2 (22.2)       | 2 (10.0)        |
| Usual activities  | 0                | 3 (33.3)       | 3 (15.0)        |
| Pain/discomfort   | 1 (9.1)          | 2 (22.2)       | 3 (15.0)        |
| Anxiety/depression  | 0                | 2 (22.2)       | 2 (10.0)        |
| EQ-5D-5L global, mean (SD)  |                  |                |                 |
| Index value   | 0.85 (0.17)      | 0.37 (0.36)    | 0.64 (0.36)     |
| VAS score   | 74.55 (23.50)    | 45.56 (14.46)  | 61.50 (24.45)   |
| KCCQ, mean (SD)   |                  |                |                 |
| Physical limitation   | 81.06 (19.04)    | 39.72 (26.59)  | 62.46 (30.56)   |
| Symptom stability   | 59.10 (12.61)    | 66.67 (30.62)  | 62.50 (22.21)   |
| Symptom frequency   | 84.66 (17.14)    | 57.64 (27.14)  | 72.50 (25.59)   |
| Symptom burden  | 91.67 (11.18)    | 61.11 (24.30)  | 77.92 (23.61)   |
| Self-efficacy   | 94.32 (10.25)    | 85.94 (18.22)  | 90.79 (14.34)   |
| Quality of life   | 82.58 (13.15)    | 33.33 (20.83)  | 60.42 (30.09)   |
| Social limitation   | 85.61 (14.02)    | 31.94 (26.62)  | 61.46 (33.94)   |
| KCCQ global scores, mean (SD)                                     |                  |                |                 |
| Overall summary   | 82.69 (9.81)     | 41.09 (20.55)  | 63.97 (26.06)   |
| Clinical summary  | 81.30 (10.82)    | 49.55 (22.31)  | 67.01 (23.10)   |
| Total symptom   | 81.54 (10.85)    | 59.37 (23.50)  | 71.56 (20.55)   |

Scores for EQ-5D-5L and KCCQ.

\*Any score but 1 (no problems).

†Only patients scoring 4 or 5 in each domain.

EQ-5D-5L, EuroQoL 5D-5L questionnaire; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Heart Association; PROMs, patient-reported outcome measures; VAS, visual analogue scale.

III patient (2–8) had doubts when filling out the questionnaires since he related his mobility limitations to a problem with his legs (a consequence of an aortic dissection) but he did not relate it to HF. Also, he mentioned that his physical and emotional situation was much better now compared with the initial moments where he was more affected. He had a hard time taking the prior 2 weeks as a reference point, therefore his responses showed a feeling of improvement compared with the most critical moments.

Another NYHA III patient (2–6) had doubts when filling the questionnaires, since his symptoms varied from day-to-day and between morning, afternoon and night. He also had moments of crises where he considered his symptoms to be worse, so limiting to the last 2 weeks seemed difficult. Likewise, he stated that shortness of breath or

air was something he thought he got from lying down for a long time and not that it was a symptom of HFrEF.

Caregivers could overestimate and present a dramatic view of the patient's day-to-day life with HFrEF. Family caregivers showed more distress when discussing their relatives with HFrEF compared with that showed by remunerated caregivers:

She is concerned about his low spirits and his anguish. She says that the symptoms she develops from anxiety can “mask” the symptoms of HF, such as pressure and pain in the chest, agitation, a feeling of suffocation. (caregiver of patient 1–8, NYHA III)

As cardiologists told us that little can be done to improve his condition, we live these years ‘as a gift’. (caregiver of patient 1–6)

### Caregivers' roles and needs

In this study, only five patients were able to live without a caregiver. Generally, strong family bonds were apparent and important for the patient. Caregivers were often in charge of organising visits to the healthcare providers, keeping track of parameters such as weight and blood pressure, and administering medication (table 2). Caregivers acted also as interpreters of the disease status on behalf of their patients.

### Relationships with healthcare providers

The interactions between patients and caregivers with healthcare workers at hospitals were investigated by the social scientists by accompanying them to a medical appointment. The study showed that patients are usually highly positive about their experience with cardiologists and nurses (table 2). A patient (1–9) explained that the nurse called him weekly to ask about how he was coping, and to discuss data such as weight and blood pressure changes. He generally felt very accompanied by the hospital staff, both cardiologists and nurses. Other patients also expressed a high opinion of the healthcare personnel. Often patients highly value their relationship with the nurse, as they probably feel more confident to express their experiences to his/her.

## DISCUSSION

In this study, we used ethnographic methods with patients with HF<sub>rEF</sub> and their caregivers, complemented with general and disease-specific health status assessments, to obtain insights regarding patients' disease perception and attitudes towards their disease. Ethnographic methods adopt a phenomenological perspective, aiming to understand individuals' life experiences to acquire relevant knowledge. The results of this study suggest that the patient's perspectives of their QoL were dependent on their memories of what they could do before, and often were better than reality. Caregivers, in contrast, offered a distinct view of the patient's status and QoL, often substantially worse and emphasising the severity of their life-limiting condition.

As healthcare systems aim to become more 'patient-centred', there is a recognised need to capture accurately the patient's experience of the disease, in an effort to improve it. The use of PROMs have therefore become common in assessing current treatments and new therapies and medical interventions, although their application in clinical practice is still very limited. Despite their widespread use by cardiologists, an awareness of the limitations of PROMs when evaluating the experience of the patient with HF is critical for their interpretation. For example, the effects of comorbid conditions could add confounding factors to the evaluation of HF through a single PROM instrument. Likewise, patients often relate their overall QoL experience to the moments of crisis, such as

hospitalisations, 'anchoring' all subsequent experiences to those events and distorting their responses in the questionnaires.

In the general population the understanding of HF and its outcome is low, contributing to anxiety about the evolution of the disease in both patients and caregivers. In contrast, other life-limiting diseases, such as cancer, often have better-defined pathways of care and psychosocial support.<sup>30</sup> In this regard, patient associations and support groups could play a role by helping the patient understand the disease, the treatments and the expectations. Patient associations promote social integration and help patients share their experiences, providing the necessary encouragement to cope with their disease and go on with daily activities. Also, as reflected in some of the interviews described in this study, it is important for the patient to feel that he/she can have rapid access to medical services. In this regard, the study reflected that while some patients were reluctant to discuss aspects of daily life or to express their feelings and fears to the cardiologist, they were more open and felt closer to the nurse, a relationship that was highly valued by many patients. Generally, an efficient and fluid communication with all the healthcare providers involved in the treatment is essential.<sup>12 29</sup>

The study revealed that the fear to losing independence and the uncertainty about the progress of their disease could be factors that motivate some patients with HF to downplay their limitations. Conversely, caregivers could overemphasise the poor QoL of the patients, also motivated by concerns of the progress of the disease, its unpredictable trajectory and lack of proper knowledge and training. Also, it is possible that, since these caregivers were very often family members, their views could be overstated due to emotional attachment to the patient. In any case, these results suggest that instruments should be developed to help caregivers in their daily work with patients with HF, so that they are better informed on the course of the disease and expectations.<sup>25</sup> In this regard, numerous recent studies have highlighted challenges experienced by caregivers of patients with HF.<sup>37–40</sup> Some initiatives along these lines, such as caregiver-specific QoL questionnaires,<sup>41</sup> and video coaching,<sup>42 43</sup> are currently being developed and tested.

The results of our study suggest recommendations for future PROM design or questionnaire selection. In patients with HF the PROM instruments should aim to truly mirror patients' experience, using language that the patient associates with their cultural views of QoL. To provide insights on relevant changes in QoL, the PROMs should be constructed to capture specific timepoints related to the patient experience (eg, healthcare status before the diagnosis, and before and after hospitalisations). In this way, reference points in the patient's lives could be established that favoured meaningful QoL before/

after comparisons. Instruments should allow an alternative stratification based on these clinical events and patients' perceived QoL along them. Also, as self-care behaviours can greatly affect symptoms in patients with HF,<sup>44</sup> the patient's self-caring strategies, perception of autonomy, level of empowerment and the perception of past and present experiences with the disease should be taken into consideration when developing and introducing future PROM instruments.<sup>45</sup> Finally, additional instruments should be developed to evaluate the key aspects of the patient's support system, and explore caregivers' needs.

Given the lack of studies assessing the patient's and caregiver's perspective on the HFrEF pathway in Spain, this study aimed to fill this gap to better understand possible cultural differences. The ethnographic approach, which involved in-depth interviews with patients at their homes and with their caregivers, made it possible to collect relevant data not normally discussed or shared in healthcare facilities. Both patients and caregivers could talk freely and explain the aspects of the disease that they considered under control and those where change was deemed necessary. However, a limitation of this study is that the small sample size, although not unusual in qualitative research that requires extensive and detailed analysis of each patient, may not fully represent the diversity of people with HFrEF in Spain. Also, as it is the case in other ethnographic studies, interviewing patients and caregivers together may have resulted in individual perspectives being altered or withheld. Finally, since this study was carried out during the COVID-19 pandemic, it is possible that the disruption imposed by the social restrictions could have some effect in the results described here.

In conclusion, this study analysed, by the use of PROMs and in-depth interviews, the complexity of the actual experiences of the patients with HFrEF. The lack of knowledge about the disease generates confusion and anxiety about symptoms, and patients could tend to minimise the impact of HF in QoL. Patients tend to maintain a closer relationship with their nurses, compared with the cardiologist, favouring a more open discussion of feelings and experiences related to the disease with them. In order to provide personalised care to patients with HFrEF, QoL could be assessed by comparing two points in time, thus helping the healthcare practitioner understand the patient's point of view of specific interventions. Since QoL is a multidimensional, subjective concept that is affected by a variety of factors, its evaluation should be carefully designed to capture specific moments and changes in the trajectory of the disease. The study suggests that tools and training should be made available to caregivers to alleviate the burden of care and anxiety derived from uncertainty in the progression of the disease. Further work is needed to fully integrate the use of well-designed and useful PROMs into clinical practice.

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