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ORIGINAL ARTICLE

Living with heart failure: patient experiences and implications for physical activity and daily living

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Abstract

Aims Heart failure (HF) substantially limits the ability of patients to engage in physical activities. A detailed understanding of how patients experience these limitations is required to develop valid and sensitive measures for use in clinical research. This qualitative study was designed to provide a thorough description of how HF patients experience physical activity limitations in their daily lives.

Methods and results Semi-structured interviews were conducted with 40 HF patients. Interview transcripts were coded with the aim of identifying key aspects of physical activity. Patients were divided between HF with preserved ejection fraction (*n* = 21, 52.5%) and HF with reduced ejection fraction (*n* = 19, 47.5%); the majority of patients were New York Heart Association Class II (*n* = 22, 52.5%) or Class III (*n* = 16, 40.0%). Relevant physical activity themes, including mobility and broader daily function areas, were identified. The most frequently reported mobility limitations involved difficulty walking (up a steep incline, up steps, and long distances), limited walking speed, difficulty standing for long periods of time, and difficulty carrying and lifting objects. These limitations were principally related to three HF symptoms: dyspnoea, tiredness/fatigue, and peripheral oedema. Patients adapted to their symptoms and related mobility limitations in several ways, including taking rests during an activity, doing an activity more slowly, and avoiding/refraining from an activity altogether. The broader daily function areas most commonly impacted by the mobility limitations were housework, exercising or playing sports, and going shopping.

Conclusions Heart failure patients report numerous physical activity limitations. These specific mobility and daily function areas can be measured using clinical outcome assessments (e.g. patient-reported outcomes and performance outcomes) in clinical trials and observational research. Accelerometry can be used to contribute to a holistic picture of patient functioning by passively collecting this type of data.

Keywords Heart failure; Accelerometry; Physical function; Physical activity; Health-related quality of life; Patient experience

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Introduction

Heart failure (HF) patients experience significant physical activity limitations that impair health-related quality of life (HRQoL). Accordingly, expert and regulatory guidelines for conducting HF trials highlight the importance of measuring physical function (i.e. functional capacity and daily activity) alongside mortality and hospitalizations. For example, the US Food and Drug Administration (FDA) indicates that endpoints evaluating patient functional capacity and daily activities could provide evidence of treatment effectiveness in HF trials.[1] An international expert consensus group recommended including measures of patient functioning in clinical trials with HF with preserved ejection fraction (HFpEF) patients.[2] European Medicine Agency guidelines also indicate that improvement in functional capacity may be a relevant treatment goal in selected patients.[3] Demonstrating effects on physical activity is important in establishing the overall benefit of new treatments.

Reliable and valid clinical outcome assessment (COA) measures are needed to evaluate the effects of interventions on physical activity in HF patients. Historically, physical function

in HF patients has been measured through patient-reported outcome (PRO) measures and in-clinic performance measures. In-clinic performance assessments, particularly the 6 min walk test, aim to provide a standardized evaluation of physical capacity under controlled conditions, while PRO measures evaluate real-world physical activities from the patient's perspective. Several PROs include items evaluating physical activity limitations, such as the Kansas City Cardiomyopathy Questionnaire (KCCQ) and Minnesota Living with Heart Failure Questionnaire (MLHFQ). Both measures have been widely used in clinical trials (e.g. I-PRESERVE, PARADIGM-HF, DAPA-HF, and EMPEROR-Reduced) and are qualified by FDA to measure the patient's experience of HF.[4–7] Newer PROs designed for use in clinical trials like the Heart Failure Functional Status Assessment[8] also assess physical activity limitations.

Physical activity may also be measured through a variety of devices that passively record patient activity levels. 'Digital health technology' tools such as accelerometers and wrist-worn activity monitors including Fitbit are receiving increasing attention in HF studies.[9–12] However, the optimal use of accelerometry data in HF clinical trials requires in-depth understanding of the physical activity limitations experienced by HF patients and how they map onto the extensive list of variables that can be derived from accelerometers.

Obtaining a detailed understanding of how HF patients experience physical limitations is a critical first step in identifying or developing 'fit for purpose' COA measures of physical activity. This type of in-depth assessment of the patient's day-to-day experience can be accomplished through qualitative research. Several qualitative interview studies have been conducted to better understand the symptoms, functional limitations, and HRQoL impacts due to HF and its treatment. For example, HF patient interview studies consistently identify dyspnoea, fatigue, and peripheral oedema as key symptoms experienced by patients.[8,13] The studies have also identified broad areas of physical activity, such as walking, climbing stairs, and lifting and carrying items, as relevant for HF patients. However, they were not designed to specifically focus on physical activity limitations and, therefore, do not provide detailed descriptions of the limitations that HF patients face in their day-to-day lives. Additionally, they do not provide insights regarding how patients cope with and adapt to their activity limitations. For example, a patient may be able to walk through their home but may need to do so more slowly, taking breaks to catch their breath. This contextual information may allow for the design of more specific measurement approaches yielding more sensitive endpoints in clinical trials.

The current patient interview study was conducted to examine physical activity limitations in HF patients. The context for these limitations was addressed by evaluating associated symptoms and how patients cope with them. This included an exploration of the core mobility limitations experienced by HF patients (e.g. bending over and walking) and how these are related to broader functional limitations in daily life (e.g. social and occupational functioning). This research was not conducted to support a particular COA measurement approach. Instead, this research aims to highlight the burden associated with physical activity limitations in HF and provide qualitative information to support multiple COA approaches and measures of physical activities that can be used in future clinical research.

Methods

Participants

Patient recruitment was conducted through clinical sites and third-party recruitment vendors. The investigation conforms with the principles outlined in the *Declaration of Helsinki*. Participants gave informed consent prior to enrolment. Adults aged >18 years were included with confirmed diagnosis of HF [HF with reduced ejection fraction (HFrEF) or HFpEF[14]] and documented diagnosis of symptomatic HF [New York Heart Association (NYHA) functional Class II–IV] present for at least 8 weeks (Supporting Information, *Table S1* for full eligibility criteria). The threshold for HFrEF or HFpEF was a left ventricular ejection fraction of <40% or ≥40%, respectively, as commonly employed.[13]

Procedure

Interviews were conducted with HF patients to capture their experience of the symptoms and functional impacts occurring as a result of HF, in accordance with regulatory best practice recommendations for conducting qualitative research in service of clinical research.[15–17] US IRB approval was obtained from the New England Institutional Review Board. An IRB-approved patient discussion guide was used in the interviews. The content of the guide was informed by published descriptions of the HF patient experience (identified through targeted literature review). Interviews included an in-depth discussion of the specific physical activity impairments experienced by this population. Patients were asked to provide details regarding their HF-related physical and mobility limitations. Patients were asked about symptoms that may be associated with their physical activity and mobility limitations and any associated impacts on daily functioning (e.g. social and occupational) that may be caused by their physical and mobility limitations.

Interviews were conducted over the telephone on a one-to-one basis and lasted for approximately 90 min, during which field notes were taken. Patients consented for

the conversations to be recorded, and recordings were used to generate transcripts.

Data coding and analysis

Interview transcripts were coded using ATLAS.ti V8 software to identify key concepts using a thematic analysis approach. Concepts were stratified according to whether they were spontaneously mentioned by the patients or were elicited following probing from the interview moderator. Pre-defined concept codes were established before coding began; coding rules were continually reviewed and updated throughout the process. Four coders independently coded transcripts and achieved acceptable inter-coder reliability of >0.7 using Krippendorf's C-alpha binary test.[18] Coder 1 (JM) was the Master Coder and reached ICA scores of >0.7 on the second attempt with Coders 2 and 3, and on the third attempt with Coder 4. Inter-rater Krippendorf's C-alpha were as follows: Coders 1 and 2 = 0.713; Coders 1 and 3 = 0.845; and Coders 1 and 4 = 0.782. ICA scores were checked at every fifth transcript to verify that a score of >0.7 was maintained throughout.

Saturation of concepts, or the point at which additional interviews did not contribute new information, was assessed by grouping the transcripts chronologically into 10 waves of 4 patients each. Saturation was considered to be achieved when new interview waves did not introduce new concepts.

Each patient was asked to rate the 'disturbance' associated with each concept noted during the interview using a scale from 0 to 10, where higher scores indicate higher levels of disturbance. The saliency of symptoms and impacts was assessed by examining the number of patients mentioning a concept and the mean disturbance rating of each concept. A concept was deemed 'salient' if at least 50% of patients mentioned the concept and it had an average disturbance rating of 5 or higher.

Transcripts were also used to quantify the frequency that patients experience their various mobility limitations, to investigate what compensatory behaviours patients used to accommodate for mobility issues, and to better understand how patients associate their symptoms with physical limitations and the impacts on their lives. A detailed qualitative conceptual model was generated for each mobility and function limitation, showing the relationship between symptoms, mobility, and impacts to patients' daily lives. The associations between individual core mobility limitations, symptoms, and functional impacts were further examined using the Excel add-on module NodeXL to perform a network analysis[19] to highlight the most frequently reported relationships among these concepts. For the network model, relationships were filtered by percentage of concept mentions ($\geq$50%) and the frequency of reported associations (top quartile).

Results

Patient demographics

From November 2019 through June 2020, 40 patients were interviewed. Baseline demographic information is shown in *Table 1*. Patients were divided between HFpEF (n = 21, 52.5%) and HFrEF (n = 19, 47.5%); the majority of patients were NYHA Class II (n = 22, 52.5%) or Class III (n = 16, 40.0%) (Supporting Information, *Table S2*). Two patients (n = 2, 5.0%) were NYHA Class IV. Average time since diagnosis was 24.7 months: the majority of patients (65%) were diagnosed <2 years prior to the interviews (median: 15 months), nine patients (22.5%) were diagnosed 2–4 years prior, and five (12.5%) were diagnosed >4 years prior. The majority of patients had hypertension (n = 31, 77.5%), seven (17.5%) patients had 'other' unspecified comorbidities, and four (10.0%) had coronary artery disease.

Signs, symptoms, and impacts

Patients described the signs, symptoms, and impacts related to physical activities (*Table 2*; for complete list, refer to Supporting Information, *Table S3*). Salient concepts were similar for ejection fraction subgroups and NYHA classes (Supporting Information, *Tables S4* and *S5*).

Dyspnoea and tiredness/fatigue were commonly referenced as limiting patients' ability to perform activities such as climbing stairs, bending over, and standing or walking for long periods of time. Patients indicated that they often had to rest or limit the intensity of such activities as walking, climbing, standing for long periods of time, manoeuvring their bodies, or lifting and carrying objects. Patients also described being unable to fall asleep or remain asleep during the night.

These basic limitations to physical activities were in turn reported by patients to have broader functional limitations; for instance, mobility problems (e.g. difficulty walking for long distances) were reported to be associated with functional limitations (e.g. being unable to go shopping). Network analysis of the associations between mobility and sleep limitation concepts and the symptoms and impacts of HF (*Figure 1*) highlighted dyspnoea (88 mentions made by the 40 patients; note that these are associations made by patients and that patients can make multiple associations between symptoms and mobility limitations) and tiredness/fatigue (45 mentions) as the HF symptoms most frequently associated with mobility limitations. In particular, limitations in walking distance, walking speed, going up and down steps, and going up a steep incline were the most commonly associated mobility limitations.

Table 1 Baseline demographics and clinical features

Demographics				
		Total	HFpEF	HFrEF
Patient ethnicity (*n*)	Black	8	4	4
	Hispanic	7	3	4
	White	25	14	11
Gender (*n*)	Male	11	5	6
	Female	29	16	13
Age, mean (years)		54.0	57.0	51.3
Age distribution (years)	33–42	4	1	3
	43–52	13	7	6
	53–62	14	8	6
	63–73	9	5	4
Time since diagnosis, mean (months)		24.7 (range = 3–88)	22.0	27.6
Ejection fraction	HFpEF	21	21	0
	HFrEF	19	0	19
NYHA class	Class II	22	12	10
	Class III	16	7	9
	Class IV	2	2	0
Comorbidities (*n*)	Hypertension	30	17	13
	Coronary artery disease	4	2	2
	Valve conditions	2	1	1
	Diabetes	3	2	1
	Pulmonary diagnosis	1	1	0
	Other	7	7	0
	None	3	1	2

HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; NYHA, New York Heart Association.

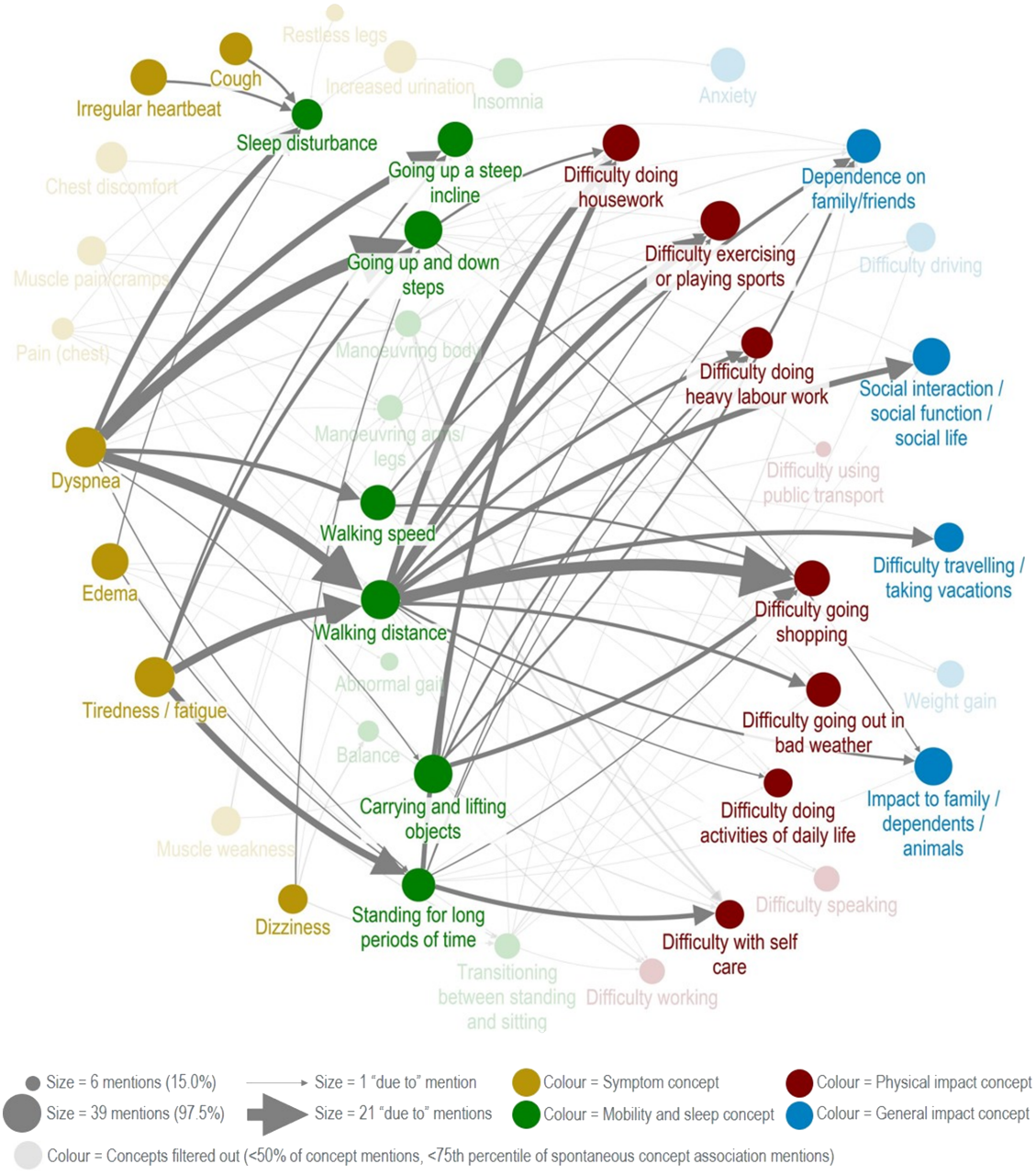
Table 2 Physical activity limitations reported by heart failure patients

Limitation	Patient experiences
Climbing	• Described often in the context of climbing stairs in their homes or climbing natural elevations outdoors • Commonly identified responsible symptoms include dyspnoea, tiredness/fatigue, and dizziness, while they often have to take rests or complete the climb less intensely or may avoid climbing altogether if they can
Manoeuvring	• Patients describe difficulty manoeuvring their body often in terms of bending over, for example, to pick up items, or manoeuvring their arms/legs when washing dishes • Commonly identified responsible symptoms include dyspnoea, muscle pain and cramps, and tiredness/fatigue, while they often have to take rests or require an aid to assist in their manoeuvring
Standing	• Described often in the context of difficulty standing for long periods of time in supermarket checkout lines or the shower, or difficulty getting up from their chairs • Commonly identified responsible symptoms include tiredness/fatigue, dizziness, dyspnoea, and oedema, while they often have to take rests, use an aid to help them stay standing, or seek to avoid it where they can
Lifting and carrying objects	• Described often in the context of lifting and carrying heavy shopping bags in the supermarket or their laundry around the home • Commonly identified responsible symptoms include dyspnoea, muscle weakness, and muscle cramps, while patients often require an aid to help them carry objects or they avoid the activity where they can
Walking	• Described in the context of difficulty walking long distances, at speed, or walking with an abnormal balance or gait; difficulty walking long distances causes patients the most physical and general impacts • Commonly identified symptoms responsible include dyspnoea, tiredness/fatigue, oedema, dizziness, and chest pain/discomfort, while patients often take rests, walk less intensely, refrain from walking where possible, or use an aid to help them walk
Sleeping	• Described often in the context of not being able to get to sleep or recurrent waking in the night • Commonly identified responsible symptoms include dyspnoea, irregular heartbeat, cough, oedema, and increased urination (nocturia often caused by HF medication)

HF, heart failure.

Difficulty doing housework and difficulty going shopping were the two most common physical impacts that patients related to their mobility limitations (both 44 mentions). This was followed by difficulty with self-care (e.g. needing to rest after bathing; 27 mentions), difficulty exercising or playing sports (25 mentions), and difficulty doing heavy labour work (e.g. unable to carry as much firewood; 21 mentions). Further general impacts such as dependence on family (24 mentions) were also commonly associated with mobility limitations (Supporting Information, *Table S6*).

Figure 1 Network model for heart failure physical functioning. Concepts sized by % of patient population mentioning the concept (total of spontaneous and probed), lines sized by number of patients spontaneously associating a concept to another concept, direction of arrow indicates the cause and effect relationship between the two concepts as typically described by patients. Network diagram filtered to show concepts mentioned by ≥50% of patients and concept associations in the 75th percentile of spontaneous mentions by patients.



Key aspects of mobility and sleep limitations

In an effort to accommodate and adapt to the symptoms and impacts of HF, patients reported having to apply a variety of adjustments to their behaviours. Adjustments related to walking, climbing, and standing were determined to be particularly bothersome to patients and were closely associated with HF symptoms and impacts.

Patients most often described their behaviour changes in response to mobility issues as taking rests during bouts of activity (104 mentions), doing an activity less intensely (95 mentions), or avoiding/refraining from activity altogether

Table 3 Changes in behaviour in response to mobility issues

	Behaviour					
	Take rests during bout of activity	Do bout of activity less intensely	Reduce frequency of bout of activity	Reduce amount of activity per bout	Avoid/refrain from activity	Use an aid to complete bout of activity
Going up a steep incline	8	15	0	4	16	3
Going up and down steps	16	21	6	2	15	7
Manoeuvring body	8	4	1	0	3	5
Manoeuvring arms/legs	7	1	2	1	2	3
Standing for long periods of time	19	2	2	2	4	9
Transitioning between standing and sitting	3	1	0	0	2	1
Lifting and carrying objects	11	9	4	6	17	18
Walking: Speed	7	19	4	3	14	3
Walking: Distance	22	21	4	10	17	11
Walking: Abnormal gait	1	1	0	0	1	0
Walking: Balance	2	1	1	0	1	3
Total	***104***	***95***	***24***	***28***	***92***	***63***

Data represent counts per patient per concept (i.e. patients who made repeated associations were only counted once; however, patients can display multiple behaviours, e.g. they might sometimes rest or sometimes use an aid to complete activity, so counts may total more than 40). Darker shades of red indicate higher number of association.

where possible (92 mentions) (*Table 3*). Patients discussed these as a direct consequence of HF. Behaviour changes were described particularly in association with climbing and walking speed and distance, as well as difficulties with standing for a long period of time. Patients less frequently described reducing the frequency of undertaking the activity and reducing the amount of activity undertaken. Commonly reported behaviour changes related to walking, climbing, and standing are described in more detail below.

Walking

Limitations related to walking were mentioned by all HF patients and had a mean disturbance rating of 8.0 (n = 40); see *Table 3* for changes in behaviour and Supporting Information, *Table S6* for associated physical impacts.

Selected patient quotes are as follows:

> If I'm walking with family, […] I feel I have to be at a slower pace where I have to stop and rest at times when […] I lose my breath. (Patient 06, 63 years)

> I can't go shopping. Now that everything is online, I just shop online. […] Because, I can't walk for most periods of time. (Patient 14, 64 years)

> I try to grocery shop. […] there are so many times when I actually have to go sit down, because I can't make it all the way through the shop. (Patient 26, 49 years)

Heart failure patients commonly reported difficulty walking long distances as occurring all the time (n = 17) or occasionally (n = 12); difficulty walking at speed was most commonly reported as occurring occasionally (n = 8) or all the time (n = 6).

Climbing

Limitations related to climbing were mentioned by 95% (n = 38) of HF patients and had a mean disturbance rating of 8.0; see *Table 3* and Supporting Information, *Table S6*. As reported by patients:

> I don't do hiking anymore, and that's one of the reasons why. It's just too much work on my body. […] I get very tired going up […] or going down a hill. (Patient 15, 61 years)

> I do not have stairs in my house, thankfully. I avoid stairs. […] At one doctor's appointment the elevator was broken, so there was one time that I did have to go up the stairs […] but it took me about 20 minutes […] because I had to keep sitting down and trying to catch my breath. (Patient 22, 50 years)

Difficulty going up a steep incline was most commonly reported as occurring all the time (n = 8); difficulty going up and down steps was most commonly reported as occurring all the time (n = 11) or occasionally (n = 9).

Standing

Limitations related to standing were mentioned by 54% (n = 22) of HF patients and had a mean disturbance rating of 8.6; see *Table 3* and Supporting Information, *Table S6*. Patients elaborated:

> I start feeling shortness of breath and I start feeling fatigue from standing too long. I have to sit down somehow. (Patient 23, 66 years)

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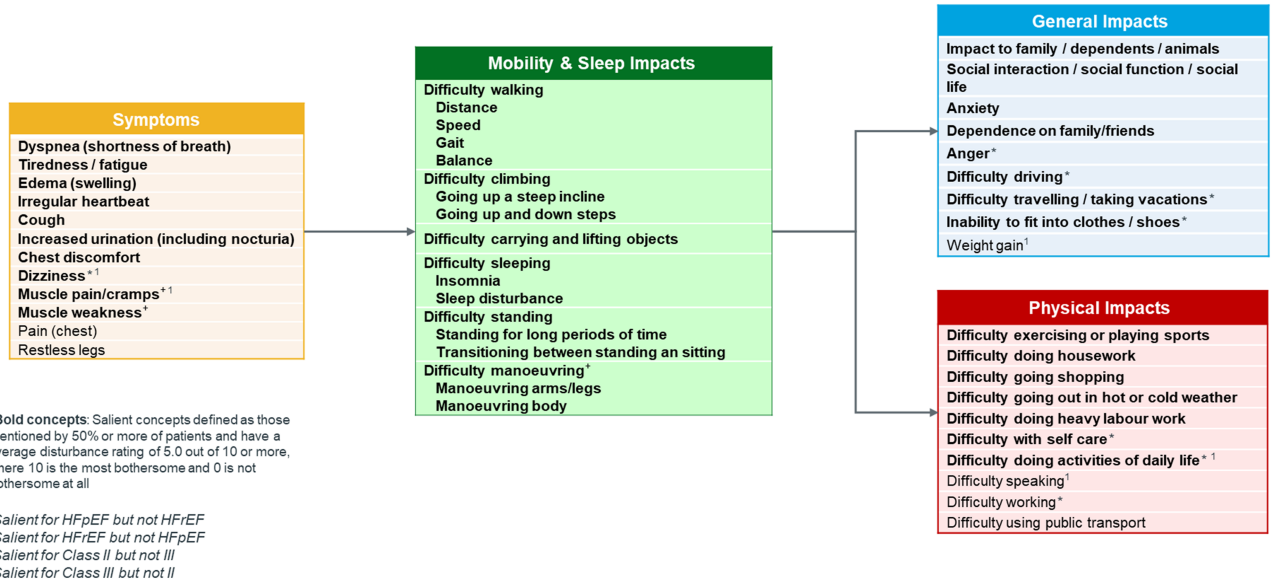
Figure 2 Heart failure (HF) physical functioning conceptual model. Conceptual model of physical functioning in HF based on patient interviews and a previously conducted literature review. Dyspnoea and tiredness/fatigue were identified as the symptoms most associated with mobility limitations, while difficulty walking was associated with the most symptoms and impacts.



> I cannot stand a long time … just two or three minutes definitely I should hold my hand somewhere if it's a rail, or those metal things, somewhere that I can hold on. If there is nothing, I stand close to the wall, and put my weight on the wall. (Patient 32, 61 years)

The majority of patients who reported difficulty standing reported this difficulty occurring all the time (n = 8) or occasionally (n = 4).

Conceptual model of physical functioning in heart failure

A conceptual model of physical functioning in HF patients was generated based on the results of in-depth probing during interviews (*Figure 2*) and a previously conducted literature review.

The conceptual model encapsulated the most salient associations between symptoms, mobility limitations, sleep problems, and daily functional impacts for patients with HF. Specifically, dyspnoea and tiredness/fatigue—not peripheral oedema—were determined to be the key symptoms most associated with mobility limitations experienced by patients. Furthermore, difficulty walking, especially in the context of walking relatively long distances, was commonly associated with the most symptoms and impacts. These mobility limitations could be measured by the intensity of the activity, whether patients take rests during the activity, or whether they avoid the activity altogether.

Discussion

A detailed understanding of the patient's experience is required to incorporate precise, valid, and sensitive physical activity measures in HF clinical research. While many studies have previously found that HF limits physical activity in these patients, the primary focus of these interview studies has been on symptoms.[8,13] This study, however, focused on physical activity and provides an in-depth understanding of the different important aspects to physical limitations experienced by patients to a degree of detail that has not previously been reported. The current study included one-on-one interviews with patients to identify the core mobility impairments that patients experience, how these are related to symptoms, and how they impact broader limitations in day-to-day functioning.

The core mobility limitations reported by patients fell into five categories: climbing, manoeuvring, standing for long periods of time, lifting and carrying objects, and walking. Multiple problems with walking were noted, including walking long distances, walking at a fast speed, and walking with an abnormal gait. Sleep disturbance was another area that emerged in the interviews. Patient-reported mobility limitations were primarily due to three symptoms, reported as the most salient across different patient types in HF (HFpEF/HFrEF, Class II/III/IV): dyspnoea, tiredness/fatigue, and oedema. Dyspnoea was related to mobility limitations associated with movement (e.g. going up and down steps and walking speed) and sleep disturbance, tiredness/fatigue was associated primarily with

movement-related mobility limitations, and oedema was primarily associated with sleep problems and difficulty standing for long periods of time. Moreover, patients most commonly reported these symptoms when discussing the symptoms they most hope their treatments will improve (results not included). These mobility limitations were found to be described in similar ways by HF patients with different disease characteristics (ejection fraction and functional class).

Patients also described how HF impacts their lives. Symptoms and associated mobility limitations led to several broader functional limitations, including difficulties doing housework, exercising or playing sports, and going shopping. The mobility limitation of difficulty walking long distances was the most common reason for broader functional limitations. Patients had difficulty going shopping, exercising, or playing sports primarily due to their difficulties walking longer distances. Walking speed limitations were also often associated with daily function impairments. This suggests that COA measures used in HF trials should include scores related to these variables.

Patients reported using a variety of coping mechanisms and adaptations to deal with their mobility limitations. Taking rests during an activity, doing an activity more slowly, and avoiding/refraining from an activity altogether were the most commonly reported adaptive strategies. For example, patients reported taking rests when walking longer distances, standing for long periods of time, or going up and down steps or avoiding activities like lifting/carrying objects and going up steep inclines. It may be useful to include items in COA measures that capture these adaptive measures. It is common to measure the difficulty or bother associated with activities; it may also be useful to examine how often the patients need to implement compensatory behaviours. Patients may consider a treatment to be beneficial if a task is difficult but achievable without stopping, or if they are able to complete tasks they were previously unable to complete.

The results of this study can be used to evaluate the content validity of PROs for HF physical activity limitations[20] and to evaluate novel approaches to measuring physical activity in HF, such as digital health technologies.[21] For instance, the C-Path PRO Consortium Chronic Heart Failure Working Group has entered an 'activity monitor-based endpoint measure' into the FDA COA Qualification Program.[22] This measure is based on passive monitoring by a digital health technology. Additionally, the IMI Mobilise-D project is evaluating digital mobility outcomes for regulatory and clinical endorsement across five different patient groups (including HF),[23] and some industry sponsors already incorporate wearable devices in clinical trials to offer complementary activity measurements.[9,21,22,24–27] These tools offer information complementary to other COAs [e.g. PROs, performance outcomes (PerfOs), and clinician-reported outcomes (ClinROs)] and have the potential to add to a holistic picture of patient functioning, given that they can collect regular, frequent, and passive measurements of physical activity in day-to-day settings that is not currently possible using other types of COAs or in lab-based or clinical environments.

From this investigation, six mobility limitations appear promising for prioritization for measurement (going up a steep incline, going up steps, walking distance, walking speed, standing for long periods of time, and lifting objects; *Table 4*). Modified patient behaviours in these domains could be mapped to endpoints that can be measured via tools such as accelerometry devices. For instance, *Amount* may be measured by number of steps climbed or flights of stairs taken. *Exertion* may be measured by the duration/time taken, heart rate during activity, or energy expenditure (i.e. time spent on non-sedentary activities, weighted by activity intensity). *Avoidance* may be measured by monitoring changes to the frequency of activities. *Taking rests* may be measured by monitoring pauses in activity, for example, number, length, or duration of rests, or amount of activity before patient requires rest.

The insights captured through the combination of complementary data sources such as passively collected data and established HF COA measures [such as 6 min walk test (6MWT), peak oxygen volume (VO_2), sit/stand test, and KCCQ] have potential to provide a picture of day-to-day functioning of patients with HF. For instance, a measure such as distance walked is only one of many potential aspects of physical functioning and mobility in HF that may be important to patients.

Table 4 Heart failure mobility limitations and associated behaviours

	Most impactful mobility limitations and their commonly associated behaviours					
Behavioural units of measure	Going up a steep incline	Going up steps	Walking distance	Walking speed	Standing for long periods of time	Lifting and carrying objects
Amount *(e.g. steps/stairs taken and time standing)*	✓	✓	✓		✓	
Exertion *(e.g. heart rate, calorie count, and speed)*	✓	✓	✓	✓		✓
Avoidance *(e.g. duration sedentary)*	✓	✓	✓	✓	✓	
Taking rests *(e.g. duration of activity)*	✓	✓	✓	✓		

These results may also provide supportive evidence when developing and validating patient-relevant accelerometry or other similar 'digital health technology tool' endpoints for use in clinical studies.

Limitations

Although saturation of concept was reached at n = 40, the sample size for HF subgroups and NYHA class is acknowledged to be small; for this reason, the main conclusions of this manuscript focus on the HF patient experience as a whole, rather than delineating between patient types. The study sample skewed towards females, especially for HFrEF population. It has been previously observed that women may be more likely than men to participate in qualitative research studies.[28] Also, the mean age of the sample was 54 years, which is slightly younger than that typically recruited for clinical trials in HF.

In addition, this study was conducted in part during the COVID-19 pandemic, which may have had confounding implications on patients' mobility, sleep, and overall HRQoL.

It should be emphasized that selection of any endpoints for clinical trials should be carefully considered as an integral part of study design. Additional evidence will be required to demonstrate meaningful effects.

Conclusions

This study details the physical activity limitations that are part of the HF patient experience. It also provides evidence establishing the relationship between physical limitations and HF symptoms and supports selection of variables associated with areas of mobility and functioning that are impaired in HF patients. Here, we have made a start at establishing promising types of variables that can be measured with accelerometry, which, when combined with other modalities of COA instruments, has the potential to reveal more about the HF patient experience. We have not investigated approaches and methods for analysis of such endpoints, which is a fundamental part of the usefulness of such endpoints. Further research can be done to build on this work to support the further development of measurements that capture the physical functioning of HF patients.

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Conflict of interest

J.M. and R.P. are paid employees of IQVIA, which received professional service fees from AstraZeneca for conducting this research. A.N., H.S., J.C., and A.R. are employees of AstraZeneca; A.N., J.C., and A.R. report stock ownership for AstraZeneca. C.G. received consulting fees for the completion of the research reported in this manuscript.

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Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Patient Eligibility Criteria.
Table S2. Diagnostic Categories of HF Patients.
Table S3. Frequency of Mentions and Mean Disturbance Ratings for HF Impacts.
Table S4. Most Salient Physical Impacts – Stratified by Ejection Fraction.
Table S5. Most Salient Physical Impacts – Stratified by Class. Physical Impacts Due to Mobility Limitations and Impact on Sleep.
Figure S1. Conceptual model based on 40 HF patient interviews with HFpEF and HFrEF patients.

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