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Evaluating the convergent and discriminant validity of three versions of the frailty phenotype in heart failure: results from the FRAME-HF study

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Abstract

Background: Frailty is an important predictive measure of mortality and rehospitalisation in people with heart failure. To date, there are no frailty instruments validated for use in people with heart failure.

Aim: The aim of this study was to evaluate the convergent and discriminant validity of three versions of the frailty phenotype in those with heart failure.

Methods: A single site, prospective cohort study was undertaken among individuals with a confirmed diagnosis of heart failure. Frailty was assessed concurrently using three versions of the frailty phenotype: the original frailty phenotype and two modified versions; the Survey of Health, Ageing and Retirement in Europe frailty instrument (SHARE-FI) and the St Vincent's frailty instrument. Convergent and discriminant validity were assessed by reporting the correlations between each version and related heart failure subconstructs, and by evaluating the ability of each version to discriminate between normal and abnormal scores of other physical and psychosocial scales specific to heart failure-related subconstructs.

Results: The New York Heart Association classes were moderately correlated with the St Vincent's frailty instrument (r=0.47, $P \leqslant 0.001$), SHARE-FI (r=0.42, $P \leqslant 0.001$) and the frailty phenotype (r=0.42, $P \leqslant 0.001$). The SHARE-FI and the St Vincent's frailty instrument were both able to discriminate consistently between normal and abnormal scores in three out of five of the physical and psychosocial subconstructs that were assessed. The SHARE-FI was also able to discriminate between inpatients and outpatients who were classified as frail.

Conclusions: Both the SHARE-FI and the St Vincent's frailty instrument displayed good convergent and discriminant validity.

Keywords

Frailty, heart failure, frailty phenotype, frailty assessment

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Introduction

Frailty is a complex clinical syndrome associated with an increased vulnerability to acute stressors.[1,2] Frailty is strongly associated with heart failure (HF) and is a predictor of poor health outcomes including hospitalisation and mortality.[3,4] Frailty and HF share common underlying pathophysiological mechanisms. Both are associated with higher levels of circulating inflammatory cytokines, and both exhibit common symptomatology of exhaustion and decreased exercise tolerance. Cognitive impairment, depression, sarcopenia and cachexia are also common in HF and frailty.[5]

There is high variation in the prevalence of frailty in HF ranging from 15% to 79%. This large range in prevalence rate may be due to a number of factors including study population, timing of assessment in the illness trajectory as well as which instrument was used.[6] To date, there are no validated frailty assessment instruments for use in people with HF; this could explain the significant measurement heterogeneity, and hence variability in classifications of frailty. A recent systematic review identified seven frailty instruments that have been utilised in HF studies.[6] The most commonly used instrument was the frailty phenotype (FP), which defines frailty as a syndrome of increased vulnerability to acute stressors, causing age-related physical decline.[2,6] Despite being frequently used to assess frailty in people with HF, the validity and feasibility of this instrument for use in those with HF have yet to be determined. There are also many modified versions of the FP used in HF, but the validity of these modifications is also unclear.[6]

To date, there has been a focus on physical frailty in HF.[6] Therefore, we sought to focus on evaluating the validity of physical frailty instruments in this study. This study aimed to provide evidence of the convergent and discriminant validity of three different versions of the FP in adults with HF; the original FP,[2] the Survey of Health, Ageing and Retirement in Europe frailty instrument (SHARE-FI)[7] and the St Vincent's frailty instrument (SVF),[8] which are all measures of physical frailty. We hypothesised that in this cohort, those who were classified as frail would also score poorly in other physical and psychosocial subconstructs specific to HF, such as depression, poor physical performance and low quality of life.[9–11]

Methods

Study population and data collection

As part of the the FRAilty MEasurement in Heart Failure (FRAME-HF) study, participants aged 18 years and over with a confirmed diagnosis of HF were recruited from inpatient cardiology wards and the outpatient HF clinic of a quaternary referral hospital in Sydney, Australia. Non-English-speaking patients and those with diagnosed dementia or other cognitive impairment that prevented them from providing informed consent were excluded. Participants were recruited from August 2016 through to February 2018. Written informed consent was obtained at the time of enrolment for all participants. The study protocol was approved by the relevant human research ethics committees conforming to the principles outlined in the Declaration of Helsinki.[12] Sociodemographic and clinical information was collected at enrolment. Frailty was assessed concurrently at baseline using the original FP, the SHARE-FI and SVF. The items from the three versions were combined and randomly allocated to four different item orders, and each combination was randomly assigned to participants. Participants completed the self-reported questions from each version of the FP in the randomised order (16 questions in total), and the study nurse conducted the handgrip test and the 5-metre gait test. To complete both the self-reported frailty questions and the objective measures for all versions took less than 10 minutes.

Study measures

The frailty phenotype. The FP was conceptualised in 2001 from the Cardiovascular Health Study by Fried and colleagues to identify the subset of older adults at high risk of the adverse health outcomes clinically associated with 'frailty'.[2] This landmark study identified five domains of physical functioning that underpinned the syndrome of frailty: (a) unintentional weight loss (weight loss of $\geqslant$10 lb in the prior year); (b) weakness (decreased or weakened grip strength); (c) exhaustion (fatigue or declining endurance); (d) slowness (slower walking pace); and (e) low physical activity ($<$383 Kcal expended per week for men and $<$270 Kcal expended per week for women; as per the shortened Minnesota leisure time activities questionnaire.[13] Those who were positive in three or more domains are considered frail, those who are positive in one or two domains are classified as pre-frail, and those who are negative in all domains are classified as non-frail.[2]

The Survey of Health, Ageing and Retirement in Europe frailty instrument. The SHARE-FI was adapted from the FP as an alternative for use in a primary care setting and uses the same five phenotypic criteria, except for the unintentional weight loss domain; the SHARE-FI replaces the weight loss item with a question related to appetite. This study involved the assessment of 31,115 community-dwelling elderly individuals across 12 European countries.[7] Handgrip strength is collected using two consecutive measurements taken from the left and right hands. The highest of the four values is added to the algorithm. While the SHARE-FI also categorises individuals as frail, pre-frail and non-frail, these categories are determined by an algorithm rather than the simple classification mentioned above for the FP. The SHARE-FI has been used in several HF studies.[14–16]

St Vincent's frailty. The SVF is also modified from the original FP for the advanced HF population; it assesses the same five criteria as the original FP but replaces unintended weight loss with the change in appetite question from the SHARE-FI. This question also reduced the recall time from 12 months to 3 months. The shortened Minnesota leisure time activities questionnaire from the FP is replaced with the physical inactivity question from the SHARE-FI but with a shorter recall time (one week vs. one month). The SVF has been shown to be predictive of increased mortality in those undergoing heart transplantation.[8]

The Montreal cognitive assessment. The Montreal cognitive assessment (MoCA) version 7.1 was used to assess cognition.[17] The MoCA assesses cognitive functioning in the areas of visuospatial/executive thinking, naming, memory, attention, language, abstraction, delayed recall and orientation.[17] The MoCA has been shown to be sensitive for the detection of mild cognitive impairment (MCI) in heart failure patients.[18] A score of less than 26 out of 30 was considered abnormal and indicative of MCI.

Depression in medical illness-10. The depression in medical illness (DMI-10) questionnaire was used to assess depression in those with a diagnosed medical illness. The DMI-10 was chosen for this study as unlike other common depression screening instruments; it does not measure fatigue or alterations in appetite which were being assessed by the frailty instruments in this study. A score of 9 or greater was indicative of depression.[19]

EuroQoL 5D-5L. The EuroQoL 5D-5L (EQ5D-5L) is a generic self-reported, quality of life instrument, comprising five questions with five possible response levels.[20] It also includes a visual analogue scale that asks participants to rate their 'health state today' from 0 to 100. The EQ5D-5L was chosen as it is brief and non-burdensome to complete and it includes self-reported items related to physical function, self-care and mood, which are all domains regularly assessed in many frailty instruments.[5]

Australian-modified Karnofsky performance scale. The Australian-modified Karnofsky performance scale (AKPS) is a validated scale that was modified for the Australian population in those receiving palliative care treatment.[21] The AKPS is an 11-point rating scale from 0 to 100 that assesses an individual's performance status across three dimensions: activity, work and self-care. The scale is clinician rated and scores individuals from 0 (dead) to 100 (normal; no complaints; no evidence of disease). The AKPS scale has also been shown to correlate with New York Heart Association (NYHA) class.[22] For this study, we considered a score of less than 70 (cares for self, unable to carry on normal activity or active work) to be abnormal.

Statistical analyses

All statistical analyses were computed using IBM SPSS Statistics version 25 (IBM Corp., Armonk, NY, USA). Demographic and clinical characteristics were summarised using descriptive statistics; continuous data were summarised using means ± standard deviation for normally distributed data or median (interquartile range) for non-parametric data. Categorical variables were summarised using frequencies and percentages. For the group comparisons, the one-sample Kolmogorov–Smirnov test indicated that none of the continuous variables were normally distributed, these variables were dichotomised at the median.[23] Pearson's correlation coefficient was used to examine convergent validity and the chi-square test for discriminant validity. The threshold for statistical significance was a P value of less than 0.05.

Results

Study participants

A total of 131 participants was recruited and included in the analyses. Seventy-six per cent were men, with a mean age of 54 ± 14 years. Two-thirds were inpatients (65%) with the majority of those admitted for HF-related causes (93%). The majority reported English as their first language (94%) and three-quarters (76%) were of Caucasian background (Table 1).

Frailty prevalence

The frailty prevalence rates varied across the three versions, ranging from 33% to 54% being classified as frail, 31% to 54% being classified as pre-frail and 1% to 19% being classified as non-frail (Figure 1). There was no statistically significant difference between the prevalence of frailty between inpatients and outpatients (Figure 2). Of the five frailty domains measured according to the three versions, the weight loss/poor appetite domain was the most consistent across the FP, SVF and SHARE-FI instruments, with 41%, 53% and 49% of the cohort positive in this domain, respectively. The slowness domain was the least consistent, with the FP and SVF reporting that 15% and 27% were positive and the SHARE-FI reporting 77% positive in this domain. In the physical inactivity domain according to the SHARE-FI and SVF 34% were positive, while 86% were positive in this domain according to the FP (Figure 3).

Analysis of the five frailty domains according to inpatient or outpatient status revealed there was a statistically significant difference between those positive in the physical inactivity domain of the FP (90% inpatients, 78% outpatients; P=0.041) and between inpatients and outpatients who were positive in the slowness domain of the SVF (34% inpatients, 13% outpatients; P=0.012) (Table 2).

Table 1. Baseline characteristics.

Baseline characteristics, *N*=131	*N* (%), mean ±SD, median (IQR)
Age (years)	54 ± 14
Sex (male)	99 (76)
Inpatient	83 (65)
Length of stay days of inpatients	20 (12–35)
Caucasian background	100 (76)
English language	123 (94)
Heart failure-related hospitalisation	77 (93)
Medical history and clinical characteristics	
LVEF	31 ± 16
Myocardial infarction	32 (24)
Atrial fibrillation	70 (53)
Stoke	14 (11)
Hemiplegia	3 (2)
Chronic respiratory disease	18 (14)
Biochemistry	
Haemoglobin (g/L)	129 ± 25
Estimated glomerular filtration rate (mL/min/1.73 m^2)	62 ± 21
Creatinine (µmol/L)	108 (88–136)
Medications	
Beta-blockers	78 (66)
RAAS inhibition	97 (74)
Loop diuretics	103 (77)
Anticoagulants	76 (59)
Antiarrhythmics	48 (38)
Vitamin D	20 (16)
Physical and psychosocial characteristics	
Kcal expended per week (*n*=131)	0.00 (0.00–129)
Left hand grip strength (kg) (*n*=128)	30 ± 29
Right hand grip strength (kg) (*n*=129)	30 ± 12
5-Metre walk speed (s) (*n*=116)	5.1 ± 4.5
MoCA score (*n*=114)	26 ± 3
DMI-10 (*n*=123)	3 (1–12)

IQR: interquartile range; LVEF: left ventricular ejection fraction; RAAS: renin–angiotensin–aldosterone system; MoCA: Montreal cognitive assessment; DMI-10: depression in medical illness-10.

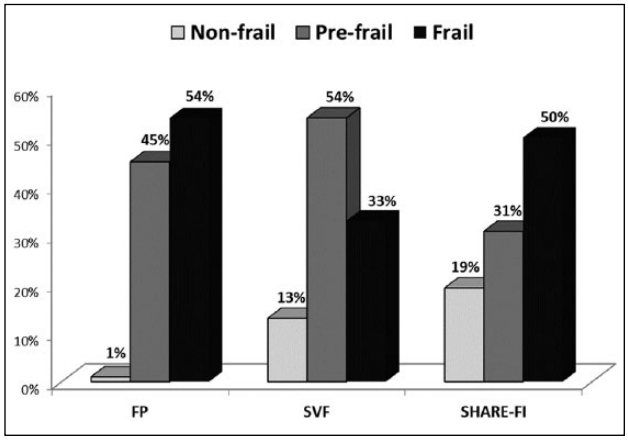

Figure 1. Frailty classifications according to instrument version.

Convergent validity

The correlations between the versions were highest between the SHARE-FI and SVF (r=0.64, $P\leqslant$0.001), followed by between the SVF and FP (r=0.51, $P\leqslant$0.001) and finally between the SHARE-FI and FP (r=0.45, $P\leqslant$0.001). The NYHA classes were moderately correlated with the SVF (r=0.47, $P\leqslant$0.001), SHARE-FI (r=0.42, $P\leqslant$0.001) and FP (r=0.42, $P\leqslant$0.001). Similarly, the AKPS scores were also moderately correlated with all three versions; SVF (r=0.43, $P\leqslant$0.001), SHARE-FI (r=0.39, $P\leqslant$0.001) and FP (r=0.24, $P\leqslant$0.001). All EQ-5D-5L dimensions were low to moderately correlated with each of the versions except for the anxiety and depression dimension, which was only correlated with the SVF. The DMI-10 and the MoCA score were also only correlated with the SVF.

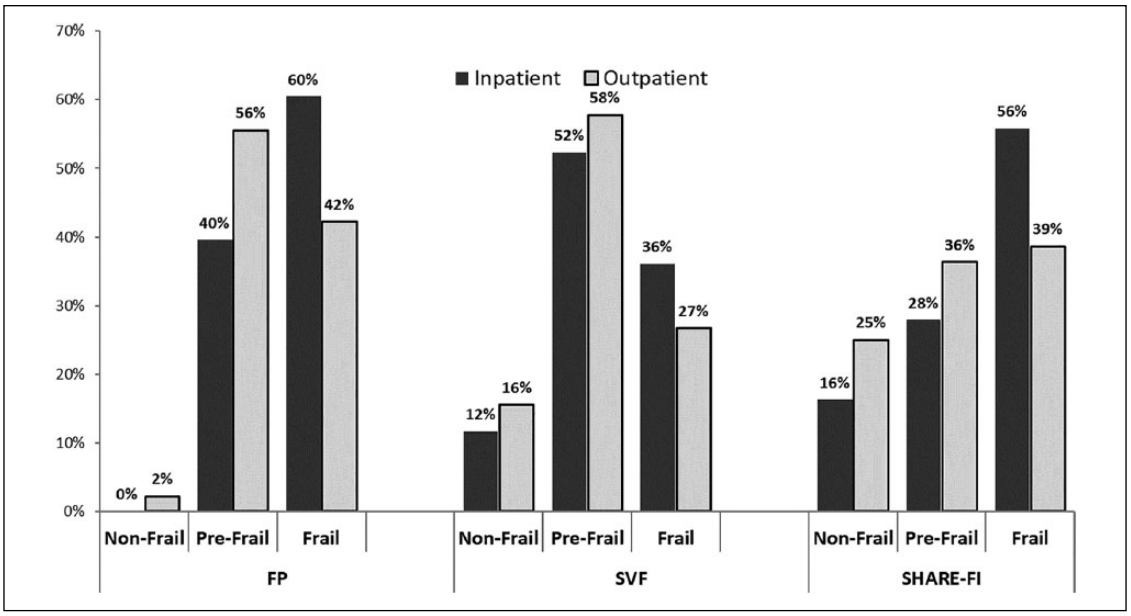

Figure 2. Frailty classifications of inpatients and outpatients according to instrument version.

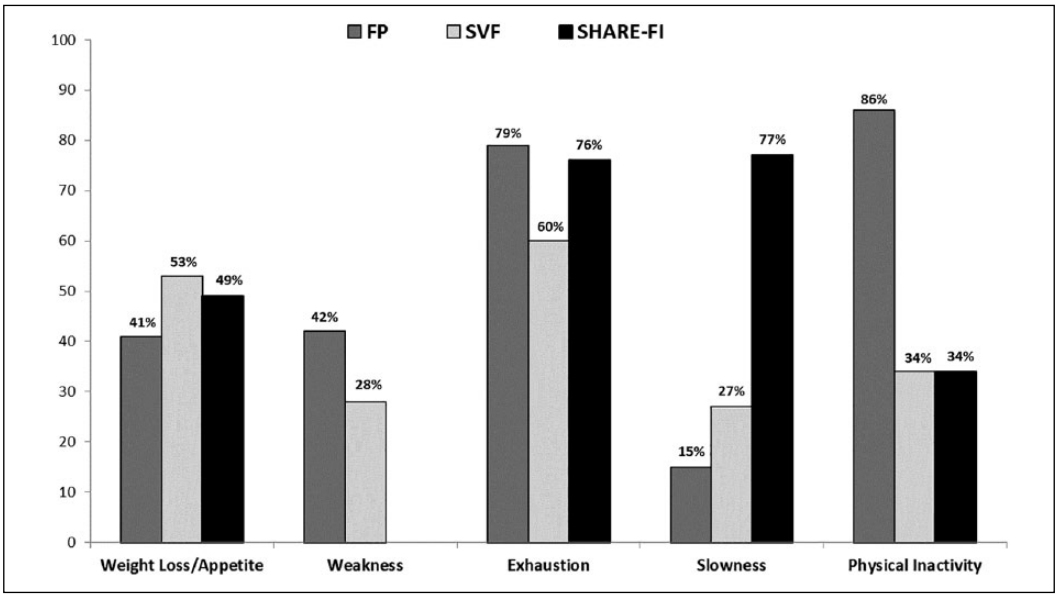

Figure 3. Proportion of those classified as positive in the five frailty domains according to frailty instruments.

Discriminant validity

Statistically significant group differences were detected between normal and abnormal AKPS, EQ5D-5L and DMI-10 scores within the three frailty categories (not-frail, pre-frail and frail) according to the SVF and SHARE-FI. The FP was only able to detect statistically significant group differences between normal and abnormal AKPS scores (Table 3). Both the FP (60% vs. 42%; P=0.067) and SHARE-FI (56% vs. 39%; P=0.170) were able to discriminate between inpatients and outpatients who were classified as frail (Figure 2).

Discussion

This study of three versions of the FP in people with HF showed that measurement heterogeneity exists within the same cohort, even when measuring the same frailty

Table 2. Proportion of inpatients and outpatients classified as positive in the five frailty domains according to three versions of the frailty phenotype.

	Weight loss/appetite			Weakness			Exhaustion			Slowness			Physical inactivity		
	n (%)	χ^2 (df=1)	*P* value	*n* (%)	χ^2 (df=1)	*P* value	*n* (%)	χ^2 (df=1)	*P* value	*n* (%)	χ^2 (df=1)	*P* value	*n* (%)	χ^2 (df=1)	*P* value
FP	37 (43)	0.470	0.465	38 (44)	0.158	0.691	67 (80)	0.271	0.603	15 (17)	1.400	0.237	78 (90)	4.161	0.041*
	16 (36)			17 (42)			36 (82)			4 (10)			35 (78)		
SVF	48 (56)	0.569	0.451	25 (29)	0.317	0.573	51 (59)	0.006	0.938	29 (34)	6.272	0.012*	28 (33)	0.119	0.730
	22 (49)			11 (24)			27 (60)			6 (13)			16 (36)		
SHARE-FI	44 (51)	0.379	0.538				70 (81)	2.863	0.091	69 (80)	0.946	0.331	28 (33)	0.119	0.730
	20 (46)						30 (67)			32 (73)			16 (36)		

df: degrees of freedom.
*Indicates statistical significance.
^Unable to calculate as variable is kept continuous.

Table 3. Group comparison analysis of the instrument version and abnormal scores of physical and psychosocial scales.

Clinical characteristics	Frailty category	FP (%)	χ^2 (df=2)	*P* value	SVF (%)	χ^2 (df=2)	*P* value	SHARE-FI (%)	χ^2 (df=2)	*P* value
Charlson index score (>2)	Frail	60	3.151	0.207	40	2.374	0.305	60	5.379	0.068
	Pre-frail	38			50			28		
	Non-frail	2			10			12		
MoCA score (up to 26)	Frail	57	1.535	0.464	33	0.976	0.614	48	0.214	0.899
	Pre-frail	42			58			31		
	Non-frail	2			9			21		
AKPS score (up to 70)	Frail	61	10.094	0.006*	40	11.066	0.004*	57	9.249	0.010*
	Pre-frail	40			50			28		
	Non-frail	1			11			16		
DMI-10 score (⩾9)	Frail	60	1.296	0.523	37	7.327	0.026*	50	7.871	0.020*
	Pre-frail	40			63			44		
	Non-frail	0			0			6		
EQ5D-5L VAS (up to 60)	Frail	60	3.415	0.181	48	17.910	<0.001*	60	7.322	0.026*
	Pre-frail	40			40			28		
	Non-frail	0			12			13		

Pearson chi squared indicates statistically significant.*
MoCA: Montreal cognitive assessment; AKPS: Australia-modified Karnofsky performance scale; DMI-10: depression in medical illness-10; EQ5D-5L: EuroQoL5D-5L visual analogue score.

domains. Previous reviews of frailty in HF have reported large variance in the prevalence rate, and this difference is likely to be due not just to study design and population but to the frailty instrument chosen.[24,25] As this study has demonstrated, when using different versions of the same instrument, even minor modifications provide very different results. It is therefore important that studies identify not only the instrument used but also if a modified version has been used and any validation work of the modified instrument that was undertaken.

This study revealed that most of the frailty domains across the three versions were highly variable. The weight loss/appetite domain was the most consistent across the three versions. The FP uses a question related to weight loss of 'more than 5 kg of unintended weight loss in the previous 12 months', the SVF and SHARE-FI both use a question related to appetite. In this study, replacing the weight loss question with a question regarding appetite did not significantly alter the outcome in this domain and so would seem to be appropriate, particularly given the challenges of accurately assessing self-reported, unintended weight loss in HF. The slowness and physical inactivity domains displayed a floor and ceiling effect in each version, and therefore may not be appropriate for capturing those with HF who are positive in these frailty domains.

The slowness domain was the least consistent across the five frailty domains, with 15%, 27% and 77% positive in this domain according to the FP, SVF and SHARE-FI, respectively. The 5-metre walk test is used to measure slowness in the FP and SVF, but the result is calculated differently for both. There was 11% of the cohort who were unable to complete the 5-metre walk test. The majority of these were due to the patient being too unwell, and therefore unable to mobilise to perform the test. For analysis, those unable to complete the 5-metre walk test were given a point and assessed as positive in this domain. While walking speed as a measure of physical function has been used clinically across many health conditions, there is no advice guiding when it is clinically advisable for a person with HF to mobilise or refrain from attempting this test.[8,26,27] The clinical boundaries around performing the 5-metre walk test in HF need to be established. There were also significant differences detected between inpatients and outpatients who were positive in this domain according to the SVF (34% vs. 13%; P=0.012) but not with the FP (17% vs. 10%; P=0.237). The SHARE-FI replaces the 5-metre walk speed test with two questions related to an individual's ability to walk 100 metres or climb a flight of stairs without resting. This replacement question, while less burdensome for a participant to complete, is subjective and the ambiguous time frame may cause individuals to over or underestimate their abilities. The SHARE-FI slowness questions are also closely related to exercise capacity, which may be problematic in those with HF. With decreased exercise tolerance and shortness of breath intrinsic to HF,[28] asking someone with symptomatic HF if they have difficulty walking 100 metres or climbing a flight of stairs they are likely to respond 'yes', which could explain why 77% were positive in this domain according to the SHARE-FI. The benefit of the 5-metre walk speed test is that it allows the assessment of walking speed over a short distance. Those with HF will be likely to start a walking speed test at their normal pace but have to slow down or stop before they reach 100 metres. Therefore, the 5-metre walk speed test may provide better discrimination between slowness caused by frailty and slowness caused by HF.

To assess physical inactivity, the FP uses a 12-item shortened version of the Minnesota leisure time activity questionnaire, which asks the participant to recall the amount of time spent performing physical activities over the past 2 weeks, such as walking for exercise, jogging and tennis.[13] As more than two-thirds of our cohort were inpatients, many of whom were in hospital for more than 2 weeks at the time of assessment, it was difficult for participants to answer the questions, as most pertain to physical activities performed outside, making it impossible for people to complete these activities while hospitalised. We had responses from all participants, but only 45% of the cohort was able to answer that they had completed any of the physical activities listed on the questionnaire. Therefore, we were unable to calculate a mean Kcals expenditure per week result greater than 0. Consequently, 86% were positive in the physical inactivity domain according to the FP (90% inpatient vs. 78% outpatient; P=0.041). These results suggest that the Minnesota leisure time activity questionnaire has poor utility in HF, particularly in those who are hospitalised. There may be scope in future research to explore if modifying the activities listed may be more appropriate in HF or if wearable physical activity trackers could be more useful.[29]

This study showed that the two modified versions of the FP, the SVF and the SHARE-FI, displayed the strongest validity over the original FP. The SVF instrument correlated most highly with the other relevant HF subconstructs, displaying good convergent validity. The SHARE-FI also displayed good convergent validity with low to moderate correlation with the subconstructs assessed.

The SHARE-FI and SVF both displayed discriminant validity, with both versions able to detect significant group differences between the three frailty classifications (not-frail, pre-frail and frail) and abnormal scores in three out of five of the HF-related subconstructs. The FP was only able to detect significant group differences in one out of five of the subconstructs. The SHARE-FI was also able to discriminate between the inpatients and outpatients who were classified as frail; it was able to recognise that (as expected) those who were admitted to hospital at the time of frailty assessment had higher rates of frailty than those who were outpatients.

Strengths and limitations

The strengths of this study include the pragmatic design, which aims to improve the clinical applicability of these results, in the hope of standardising methods of assessment and interpretation. Some limitations also need to be considered. First, the sample we used is unique compared to other HF studies and may limit the generalisability of results; it was a younger cohort, reflecting the population of the study site, and the length of stay for those who were inpatients was considerably higher compared to other HF studies.[16, 30] The high prevalence of frailty in those with HF, despite the low mean age, is further evidence of the strong association between frailty and HF.

Conclusions

The SVF and SHARE-FI both displayed good convergent and discriminant validity, suggesting both versions are valid measures of frailty in those with HF. To the authors' knowledge, this is the first study to compare the validity of different versions of the FP in HF. These results need to be confirmed in a larger and more diverse HF cohort.

Implications for practice

- This study provides evidence of the convergent and discriminant validity of three versions of the fraily phenotype in those with heart failure.
- Frailty prevalence is highly variable even when using different versions of the same frailty instrument.
- When assessing frailty it is important to not only identify the instrument used, but if any modifications have been made, as even minor modifications can cause wide variations in prevalence rates.

Author contributions

All authors contributed to this current manuscript. All authors met the criteria for authorship and have given their final approval of the submitted manuscript.

Declaration of conflicting interests

The authors declare that there is no conflict of interest.

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