



Research Paper

Development and validation of heart failure-specific quality-of-life measurement tool in India

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ABSTRACT

Objective: To develop and validate a sensitive tool for assessment of quality of life (QoL) in heart failure (HF) patients in Indian settings.

Methods: The authors conducted literature review, in depth interviews, clinical observations and designed the first draft of the QoL tool. The tool was validated using content and face validity by a panel of experts. For internal consistency reliability, the questionnaire was administered among 270 HF patients. Test-retest reliability was assessed in 20 HF patients. Principal component factor analysis with varimax rotation was employed to assess the dimensionality and to reduce the number of items. Cronbach's alpha, and Intra-class correlation coefficients (ICCs) were employed to investigate reliability of questionnaire. The responsiveness data were collected 6 months after the baseline data collection from 30 HF patients. IBM® SPSS® Statistics Version 21 was used for statistical analysis.

Results: The principal component factor analysis revealed mainly 5 domains. The final tool included 25 items. Cronbach's alpha (α) for the overall tool was 0.915. Intra-class correlation coefficients (ICCs) based on test-retest was 0.734. The final tool showed good responsiveness to changes with a mean \pm SD of the change in response of 46 ± 12.4 and a standardized mean response of 3.7 within six-months.

Conclusion: The HF specific QoL tool developed for Indian patients is a valid and reliable instrument and it can be applied in daily clinical practice, and research.

Short summary: We had developed and validated a quality-of-life tool for heart failure patients in India. This is the first ever attempt to develop a measure for heart failure patients in India. We had used a mixed methodology approach to identify all the domains in the tool. The newly developed tool is a valid, reliable, sensitive and responsive tool to measure quality of life in HF patients in India. This tool can be applied in daily clinical practice, research and health system for patients with HF in India.

1. Introduction

Heart failure (HF), a disabling multimorbid chronic condition with high mortality, is estimated to be prevalent in 1.3 million to 4.6 million adults in India [1]. Further, the annual incidence of heart failure in India is estimated to be around 0.5 to 1.8 million [3]. Only four of ten patients survive past five years after the first diagnosis of HF [4] in India. The mortality in HF is even worse than the rate observed in some of the common types of cancers in India.

Quality of life (QoL) has been recognised as an essential patient-

oriented outcome in HF patients along with mortality [5]. The standard emotional and physical symptoms associated with HF, such as fatigue, depression, anxiety, dyspnoea, and sleeping difficulty, have severe and negative impact on the QoL [6]. Given the debilitating nature and high mortality, the clinical management recommends prioritising strategies to improve QoL in HF patients. Further, QoL often predicts future adverse clinical outcomes and progression of HF. For example, a low QoL score in HF is associated with frequent rehospitalisation and poor survival [7].

Assessment of QoL in HF often involves the measurement of multiple

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domains of physical, mental, and social well-being. Proper evaluation of QoL helps to improve the understanding of the disease process, identify the critical areas of concern of the patient, and facilitate the provision of comprehensive health care in HF management. A valid and reliable method to assess QoL is also essential to evaluate the relative merits of various treatment options. Additionally, it is an important indicator to assess quality improvement programs or health system's performance in managing HF. Invariably, QoL is recognised as an essential patient-reported outcome in clinical trials, quality assessment, and clinical care [5].

Instruments such as Short-Form 36 [8,9], Euroqol [10,11], Minnesota Living with Heart Failure [12,13], and Kansas City Cardiomyopathy questionnaires [14,15] have been employed to measure the QoL in HF patients in clinical settings. The Minnesota Living with Heart Failure Questionnaire and Kansas City Cardiomyopathy Questionnaire (KCCQ) are currently used as the standard QoL assessment tools and are utilised in most clinical studies in HF. The HF-specific QoL measurement tools allow the measurement of significant clinical domains and are sensitive to identify clinical changes over time with the progression of disease severity. However, cross-cultural adaptations of these tools are often difficult due to differences in the patient's cultural and social background across different regions. Further, disease-specific QoL instruments sometimes miss essential aspects on the general impact of the illness in activities of daily living and the general well-being of the patient [16]. Generating a standardized, culturally sensitive, contextually relevant, inexpensive, and regionally acceptable tool that measures both disease-specific and general QoL is crucial in supporting their use in serial monitoring of HF patients. Such assessments might help identify those who warrant additional testing with biomarkers or treatment intensification. We aimed to develop a valid and sensitive tool for the assessment of the quality of life in HF patients in Indian settings.

2. Methods

We conducted a multi-phase, mixed-method design (Fig. 1) to develop and validate an Indian HF-specific QoL questionnaire (IHFQoL). The study was approved by the institutional ethics committee of Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala, India (SCT/IEC/1313.7/February 2019).

2.1. Generation of the item pool

Initially, we conducted a scoping review to identify the existing literature on health-related QoL questionnaires validated in the adult population (supplementary documents: Table S1). The literature review did not identify the existence of a contextually relevant and culturally adapted questionnaire for the assessment of QoL in HF patients in India. A pool of items was generated ($n = 250$) from the existing tools for QoL measurement. All duplicate and unrelated items were removed ($n = 116$). The item pool was reviewed by experts (cardiologist = 2, public health expert = 2), and additional duplicates were removed ($n = 14$). The remaining 120 items were grouped under various domains (Fig. 2), such as physical symptoms, psychological environment, coping with illness, social interaction, social support, and cognitive domain.

Secondly, we conducted in-depth interviews with stakeholders (patients and experts such as senior residents in cardiology, nurses, and public health professionals) to identify potential additional domains of QoL for inclusion in the assessment tool. Eligible patients were identified from the HF clinic of a tertiary care hospital in Trivandrum. We included HF patients who were at least 18 years old. Potential patient participants were contacted during routine visits to the HF clinic in the outpatient settings. Other stakeholders were also identified purposively from the same tertiary care hospital with a dedicated HF management unit.

In-depth interviews were conducted by an experienced researcher (RS). The interviewer used a semi-structured interview guide to gather information about symptoms, disease severity and impact on QoL.

Further, the interviewer discussed the severity of signs and symptoms and strategies adopted for coping and general QoL in HF patients. We continued the in-depth interviews until we achieved the saturation of information. The interviews were audio recorded and transcribed. The place and time for the interview were selected according to the preference of the informant. Interviews were conducted in the participant's mother tongue (Malayalam). The interviews were recorded with the consent of the participants. The participants were encouraged to take up each topic and talk in their own words. To visualise a comprehensive picture of HF burden, probing was done occasionally to fill up the blanks in response.

Thirdly, an expert (RS) in qualitative methods conducted clinical observations in the outpatient departments and in-patient wards of a tertiary care hospital in Trivandrum, Kerala, India. The behaviour of the patient and the impact of symptoms on the physical and mental condition of the patients were observed. The observations were discussed with a panel of experts, essential items were generated, and new items were added to the item pool.

2.2. Validity assessment

2.2.1. Content validity

The QoL tool was given to cardiologists ($n = 3$), public health experts ($n = 2$), nurses ($n = 2$), patients caregivers of varying socio-economic class ($n = 10$), and people from the general population ($n = 3$) and assessed face validity. The participants were asked to check the assessment tool's inclusiveness of all relevant domains.

Independent experts (cardiologist = 8, public health expert = 4) reviewed the domains, items, and the corresponding assessment tool and examined the content validity. We also tested the level of agreement among the experts. The experts reviewed the items and determined the degrees of their relevance on a three-point scale (Essential, relevant but not essential, not relevant and can be avoided). The experts were also asked to comment if any domains or items were omitted. The draft QoL tool was modified after considering the written and oral feedback of the experts. After content validation, we translated the questionnaire to the local language and ensured appropriateness by back-translation to the English version.

2.2.2. Face validity

The 57 items selected after content validity were given to 10 participants (Including patients, caregivers, cardiologists, nurses, and public health experts). The impact score for each item was calculated using the following formula, "Impact score = Frequency (%) × Importance." "Frequency" in the formula was the number of patients rated the item 4 or 5, while "Importance" was the mean score of the item on the 1–5 rating scale. Things were kept in IHFQoL if they obtained an impact score of 1.5 or more. The impact score was 1: Not essential, 2: Slightly important, 3: Somehow important; 4: Important; and 5: Very important [17]. After assessment, 44 items were selected.

2.3. Reliability assessment

2.3.1. Internal consistency reliability

Cronbach's alpha coefficient measured internal consistency. We recruited 270 independent physician-diagnosed consecutive HF patients, aged 18 years and above, from the HF clinic of a tertiary care hospital in Kerala, India. The QoL tool with all selected items was administered to the selected 270 participants.

2.3.2. Test-retest reliability

To establish the consistency across the items, a test-retest reliability assessment was done. It was performed by administering the questionnaire to a sample of 20 HF patients on two occasions with a gap of 21 days.

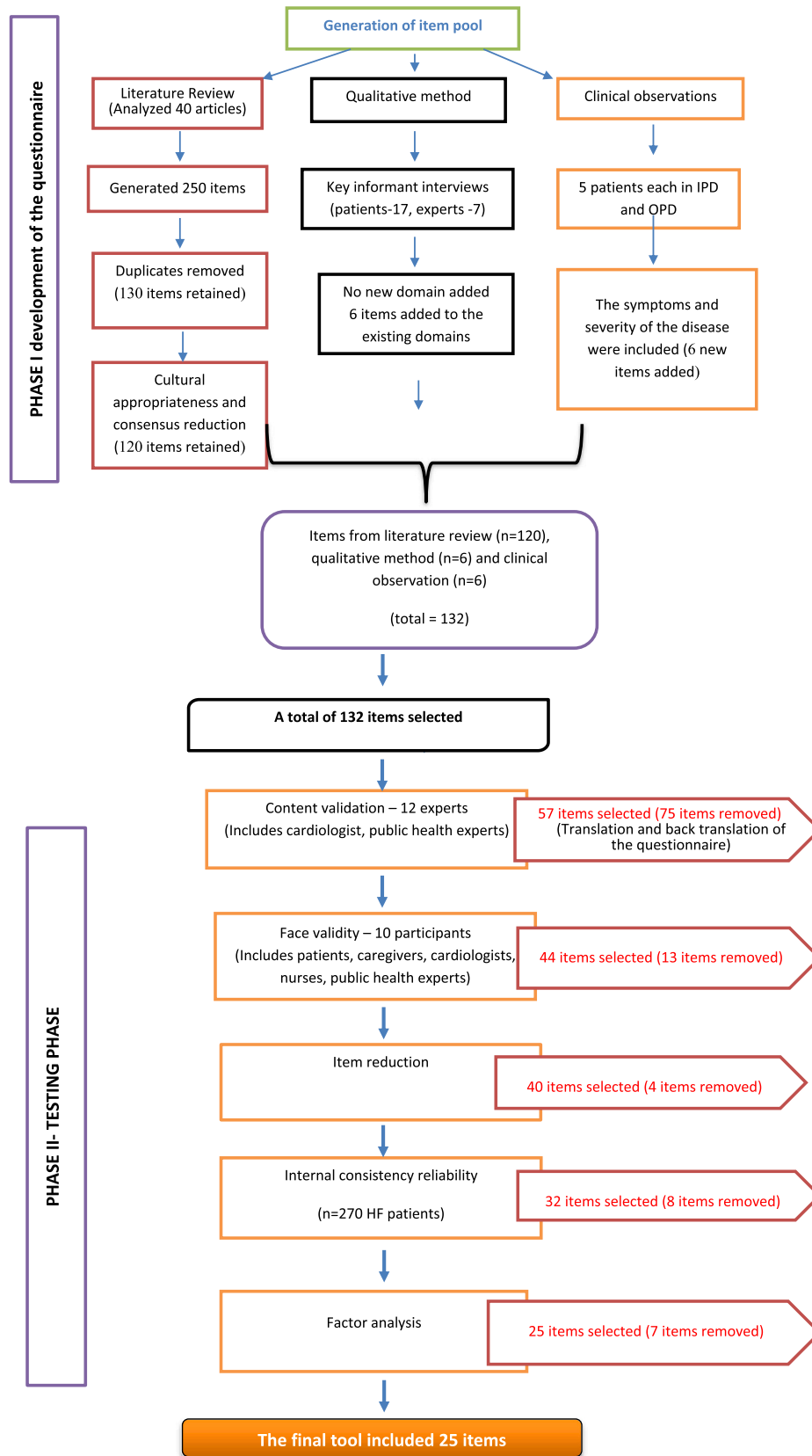


Fig. 1. Development and testing of heart failure specific quality of life questionnaire. The study was conducted in two phases. The Development and testing phase. After the development phase 132 items were selected. After the testing phase 25 items were selected.



Fig. 2. Domains of assessment of quality of life in heart failure patients in India.

2.3.3. Responsiveness

Responsiveness is the reverse of reproducibility and assesses the sensitivity of the questionnaire to clinical change. The responsiveness data were collected six months after the baseline data collection. The disease-specific part of the assessment tool was used for responsiveness assessment. Thirty independent patients with heart failure were selected to answer the questionnaire [14].

2.4. Statistical analysis

All quantitative data were entered in Microsoft Excel and analysed using the statistical package SPSS, version 21. Data summary statistics were described as mean \pm standard deviation for interval variables and count (percent) for categorical variables. The reliability of IHFQoL was examined in terms of internal consistency and 2-week test-retest reliability. The ICR was estimated by Cronbach's method, while the test-retest examined with the intraclass correlation coefficient (ICC). Cronbach's alpha was calculated to determine the internal consistency of items. Cronbach's alpha coefficient for each identified factor, with a coefficient of >0.70 , was considered acceptable. Intra-class correlation coefficient was used to show the reliability of the assessment tool. A correlation coefficient of 0.3 was considered good. The study's sample size was estimated as 270 based on item-to-subject ratio (1:10). Item-level descriptions were performed to explore the distribution of responses. Principal component factor analysis (PCA) was employed to assess the dimensionality and to reduce the number of items. Eigen value of >1 (Kaiser's criterion) was considered to determine the main components. Varimax rotation was used to identify the prominent factors. Factor loadings ≥ 0.45 were considered central and entered into the final assessment tool. To assess the responsiveness, we calculated the mean and standard deviation of change and the standardized mean response, defined as the mean change divided by the standard deviation of change.

3. Results

3.1. Qualitative interviews

We conducted ten key informant interviews with patients and their caregivers. An additional seven interviews were conducted with experts (cardiologist ($n = 3$), nurses ($n = 2$), public health professionals ($n = 2$)). Six of the ten patients were males. The age of patients ranged from 41 to 69 years, with a mean of 58.4 ± 9.1 years. The routine follow-up frequency of each patient ranged from once in three-months to once in a year. Three of the seven physicians involved in the study were consultant cardiologists; the remaining were senior residents in the Department of Cardiology. The nurses who participated in the interview had at least 3 years' experience in managing and treating HF patients. The interviews were conducted to understand the severity of the disease faced by the people. Patients with HF reported their QoL about the severity of heart failure and their general quality of life. People perceived symptoms such as shortness of breath, chest pain, and fatigue, which negatively impacted their QoL. Informants explained the symptoms they face while doing routine activities. The general QoL expressed by HF patients includes performing personal and social activities and having a happy and satisfied life. The cardiologist and nursing officers reported that spending time to hear the patients' concerns, and motivating them to have positive thoughts help cope with the symptoms of HF (Supplementary file: appendix 1).

3.2. Clinical observations

The researcher observed five patients attending the OPD and five admitted to the cardiology ward of a tertiary care hospital (males = 8, females = 2, mean age = 56.3 ± 12.6). The OPD patients were relatively stable. The common symptoms observed were fatigue, occasional swelling in ankles or feet, and breathlessness. The clinical observation in the cardiology ward recorded symptoms of dyspnea, concentration, palpitation, restlessness, and difficulty in the getting adequate sleep (supplementary file: appendix 2). The items generated from clinical observations were included in the domain of the severity of symptoms (supplementary file: Table S2).

3.3. Item pool for the quality-of-life questionnaire

The information obtained from literature review ($n = 120$), qualitative research ($n = 6$), and clinical observation ($n = 6$) were summarised, and duplicates were removed. Finally, there were 132 items in the assessment tool, which were used for further validation (Fig. 1).

The findings from the questionnaire were discussed with experts, and consensus was reached after the iterative process of item review, drafting, and revision. The final domains identified were (Fig. 2) physical symptoms (questions 1a-h), change in symptom over time (2a-f), coping with disease (1,2,3), psychological (4,5), social interaction (questions 7,7,8,9), social support (question 10), and cognitive domains (question 11) (supplementary file: Appendix 3). The items were carefully formatted for gender neutrality, interpretability, and clarity in wording and meaning. A 4-point Likert scale with meaningful gradation was developed to capture the responses. A two-week time frame was selected to allow patients to recall the symptoms and severity of the disease. A three-month time frame was chosen to recall the general QoL among HF patients.

3.4. Validity

The experts selected for the study assessed the questionnaire for its content adequacy and item sufficiency. The average content validity ratio (index) obtained was 0.90. The experts were asked to comment if any domains or items needed to be included. The draft was modified based on the written and oral feedback of the experts. The content of the

final version was further re-assessed by the expert team. There were 44 items in the assessment tool after content validation (supplementary files: Table S3).

3.5. Face validity

Both Malayalam and English versions were submitted to the experts to ensure translational validity. The assessment tool was also introduced to 20 experts. Thirteen questions were removed after face validity (supplementary files: Table S4 and S5).

3.6. Internal consistency and reliability

3.6.1. Sociodemographic characteristics of study participants included in the assessment of reliability

In total, 270 participants were included. The mean age of the participants was 55.6 ± 13.3 years (Table 1). Three of four (74.8 %) participants were males. Almost two of five (38 %) participants were unemployed. Three of five (60 %) participants belonged to low economic class. Sixty-five percent of the participants reported a high school education. Almost nine of ten (85.6 %) participants were married.

3.7. Item reduction

In the principal component factor analysis, four items showing either negative loading value, value <0.3 , and cross loading were removed (supplementary files: Table S6).

3.8. Internal consistency

The internal consistency was done on 40 items. The Cronbach's alpha for the overall questionnaire was 0.915 (supplementary files: Table S7). Correlation among individual items showed that all questionnaire items correlated positively (supplementary files: Table S8). The Cronbach's Alpha, item statistics, and total items statistics showed good internal consistency of the items in the questionnaire.

Table 1

Sociodemographic profile of study participants.

Variables	Patients (n = 270)
Age, mean \pm SD	55.6 \pm 13.3
Gender, n (%)	
Male	202 (74.8)
Female	68 (25.2)
Marital status, n (%)	
Married	231(85.6)
Education, n (%)	
Primary	45 (16.7)
Secondary and above	179 (66.3)
Graduation and above	41 (15.2)
Occupation, n (%)	
Unemployed	103 (38)
Homemaker	54 (20)
Self-employed	42 (15.6)
Retired	29 (10.7)
Color of ration card (Socio-economic status), n (%)	
Above poverty line	108 (40)
Below poverty line	144 (53.3)
NYHA class, n (%)	
I	19 (7)
II	169 (62.6)
III	78 (28.9)
IV	4 (1.5)
Type of heart failure, n (%)	
HF _r EF	143 (53)
HF _m EF	64 (23.7)
HF _p EF	63 (23.3)

3.9. Test-retest reliability

Test-retest reliability, or reproducibility, was assessed in 20 patients, who were considered clinically stable between the two-time points (i.e., baseline data collection and after 20 days). The mean age of the participants was 49.9 ± 16.2 years (males = 11, females = 9). The average Inter Class correlation coefficient (ICC) of the items was 0.734 (P value <0.001).

3.10. Responsiveness

The responsiveness was studied in 20 participants. The mean age of the participants was 51 ± 16.8 years (males = 12, females = 8). The mean \pm SD of the change in response was 46 ± 12.4 with a standardized response mean of 3.7.

3.11. Final factor analysis

In the final principal component factor analysis with varimax rotation, nine components chosen based on Kaiser's criterion (Eigenvalue = 1.0) explained 61.4 % of the common variance shared by the items (supplementary files: Table S9). Bartlett's test of sphericity was significant ($\chi^2 = 4850.8$, $df = 780$; $P < 0.001$). Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) was 0.867, and the degree of shared variance among the items was "meritorious." All the factor loadings were in acceptable range (0.45 to 0.80). The items included were structured by five components (Table 3). The first component included ten items, and they belonged to original categories of symptoms of HF. These items referred to symptoms the patients experienced in the previous two weeks. The second component included three items, which consisted of items related to psychological support in HF, such as patients' personal feelings. The third component consisted of 5 items, which dealt with the patients' social interaction. The fourth component consisted of 4 items related to the severity of HF symptoms. The fifth component, with 3 items, were related to adherence to medication in HF (Table 3). We generated the final QoL assessment tool (India Heart Failure Quality of Life tool: IHFQoL) with the above five components and developed it as a self-administrated tool, which requires an average of 10 min to administer (supplementary files: Appendix 3, Table 4).

3.12. Quality of life score

The maximum score of IHFQoL was 100, which represented the best quality of life. The minimum score was 25, which meant poorest quality of life. The scores of 76–100 were considered good quality of life, 51–75 as fair quality of life, and 25–50 as poor quality of life (Table 2). Based on the participant's (n = 270) responses to 25 selected items of the IHFQoL (no missing responses), 14 % and 8.5 % of participants were categorised in the "poor" and "good" QoL groups, respectively (supplementary files: Table S10). Ceiling effects are seen in 23 (8.5) participants, while floor effects are seen in 38 (14) participants.

4. Discussion

We developed and validated the HF-specific QoL assessment tool for Indian patients. We followed a comprehensive methodology and included items identified from the literature review, qualitative

Table 2

Summary score of IHFQoL.

Summary Score (points)	Classification	n(%)
25–50	Poor	38 (14)
51–75	Fair	209 (77.4)
76–100	Good	23(8.5)
	Total	270

Table 3
Factors and items included in IHFQoL.

Items	Factors				
	1	2	3	4	5
Having a bath or shower	0.767				
Carrying weight, such as carrying groceries	0.593				
Dressing	0.734				
During or after meals	0.711				
Walking	0.770				
Doing your household work	0.799				
Running, such as for a bus	0.520				
How often did you feel swelling in your feet, ankles, or legs bothered you?	0.782				
Picking up light objects off the floor	0.723				
How often did you wake up from sleep due to shortness of breath?	0.609				
Are they gotten along well with other people?		0.612			
Someone to confide in or talk to about yourself or your problems?		0.816			
Are you being able to control your emotions?		0.483			
How much did you have fatigue or lack of energy?			0.488		
How often did you have to limit your social activities because of your illness?			0.667		
Are you trying to get advice or help from other people?			0.761		
Do you ever feel tensed up?			0.471		
Have you had difficulty visiting relatives or friends?			0.624		
Had difficulty participating in community activities, such as religious services, social activities, or volunteer work?			0.601		
How many times did you have chest pain?				0.723	
How many times did you feel dizziness or loss of balance?				0.646	
How many times did you feel the palpitation?				0.513	
How often do you forget to take your medicines?					0.684
Do you purposefully skip taking medicines (diuretics) while traveling					0.691
How often do you run out of medicines?					0.507

interviews with patients and experts, and clinical observations in the newly developed tool to assess QoL in HF patients. The questionnaire exhibited good psychometric properties during the initial testing with clear thresholds for defining clinically important differences.

There are many available and validated questionnaires for assessment of QoL in HF patients [13,20–23]. However, most of them are not ideal for the Indian population owing to the societal and cultural differences. Therefore, we used a mixed methodology approach to identify all the domains about QoL in the Indian context. The newly developed tool has a broader range of clinically essential items, including the symptoms and severity of the disease and a comprehensive assessment of how HF had affected their mental health, social interaction, and factors associated with medication adherence.

Although many tools are available to measure the QoL in HF patients, most ignore key domains like coping and depressive symptoms, stress, fear, and anxiety [24–28]. We have included these domains and considered the sensitivity to change in clinical symptoms in the newly developed tool. The qualitative interviews that we conducted in the early stage of tool development identified good psychological support from family and friends and social interactions as critical domains of QoL in HF patients in India. Further, adherence to medications also

Table 4
Factors and items included in the final version of the India Heart Failure Quality of Life tool (IHFQoL).

Factor	Symptoms of heart failure
Factor 1	<ul style="list-style-type: none"> • Running, such as for boarding a bus (S1) • Walking (S2) • Doing your household work (S3) • Carrying weight, such as carrying groceries (S4) • Having a bath or shower (S5) • Dressing (S6) • Picking up light objects off the floor (S7) • During or after meals (S8) • How often did you feel swelling in your feet, ankles, or legs? (S9) • How often did you wake up from sleep due to shortness of breath? (S10)
Factor 2	<p><u>Psychological support in heart failure</u></p> <ul style="list-style-type: none"> • Do you avoid people as you could not get along with them? (P1) • How often do you try to talk to people about yourself or your problems? (P2) • Are you being able to control your emotions? (P3)
Factor 3	<p><u>Social interaction</u></p> <ul style="list-style-type: none"> • How often did you have to limit your social activities because of your illness? (SI1) • How often do you seek emotional support from other people? (SI2) • Do you feel stress? (SI3) • Had difficulty visiting relatives or friends? (SI4) • Had difficulty participating in community activities, such as religious services, social activities, or volunteer work? (SI5)
Factor 4	<p><u>Severity of disease</u></p> <ul style="list-style-type: none"> • How many times did you feel the palpitation? (SD1) • How many times did you feel a lack of concentration in the day? (SD2) • How many times did you feel dizziness or loss of balance? (SD3) • How many times did you have chest pain? (SD4)
Factor 5	<p><u>Adherence to medication</u></p> <ul style="list-style-type: none"> • How often do you run out of medicines? (A1) • Do you purposefully skip taking medicines (diuretics) while traveling (A2) • How often do you forget to take your medicines? (A3)

emerged as a key domain and was related to both the symptoms of HF and financial distress due to the disease. We have, therefore retained these domains in the newly developed tool for assessment of QoL in HF patients.

Our results suggest that the newly developed tool has excellent properties to qualify it as a standard tool for the measurement of QoL in HF patients from India. The reliability testing demonstrated perfect internal consistency among items and high test-retest reliability. We followed all the essential steps described in the literature in developing and validating a new tool.

The newly developed IHFQoL tool is relatively easy to administer in the assessment of QoL. It is a self-administered tool that captures one of the central patients reported outcomes in clinical trials and quality improvement studies. It is also helpful for clinicians to assess the progress in the disease process as it is sensitive to changes even within a shorter period of six months. Incorporating this tool into clinical management may help the health care providers provide patient-centered care, clinical handover of information related to disease progress to patients and facilitates discussions to intensify treatment strategies. The clinicians can briefly assess whether the patient is doing better or worse compared to the prior visit by employing the IHFQoL tool for the assessment of QoL. The new tool can be easily incorporated into the health system and used for measuring the performance or quality of health care delivery in managing HF in India.

There are several limitations to this study. Firstly, our key informants were not fully representative of the HF patients. However, we tried to include representatives from all sectors of the HF patient pool and health care providers for key informant interviews. Secondly, there was a delay in collecting the information from participants due to the impact of

covid-19. The time period of data collection was nearly 1.5 years. For validity testing we did not correlate the tool with any clinical or objective measures.

5. Conclusion

The IHFQoL is a valid (measures what is supposed to measure), reliable (same measurement after repeated administration), sensitive (able to reflect clinically meaningful differences in quality of life) and responsive (detects changes when the patients' conditions change) tool to measure quality of life in HF patients in India. The new tool can be applied in daily clinical practice, research and health system for patients with HF in India.

CRedit authorship contribution statement

Sivadasanpillai Harikrishnan: Conceptualization, Funding Acquisition, Methodology, Writing – Review & Editing.

Reethu Salim: Conceptualization, Methodology, Writing – Original Draft Preparation, Project administration.

Sanjay Ganapathi: Conceptualization, Funding Acquisition, Writing – Review & Editing.

Meenakshi Sharma: Conceptualization, Writing – Review & Editing. Divya Prasad: Conceptualization, Methodology, Resources.

Greeva Phlipip: Conceptualization, Methodology, Formal analysis.

Panniyammakal Jeemon: Conceptualization, Funding Acquisition, Methodology, Writing – Review & Editing.

Ethical statement

Our study is approved by the institutional ethics committee (IEC) of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum (SCT/IEC/1313.7/February-2019). Written informed consent was obtained from all participants.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ahjo.2023.100329>.

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