

ORIGINAL ARTICLE

PREVALENCE OF SEVERITY-BASED EVALUATION OF HEART FAILURE (PROBE) AND ITS IMPACT ON HEALTH-RELATED QUALITY OF LIFE: AN OBSERVATIONAL STUDY

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Objectives: The study aims to evaluate the severity of heart failure (HF) and its impact on the patient's quality of life (QoL).

Methodology: A multicenter, observational study was conducted across 100 medical facilities in Pakistan. Symptomatic HF patients (NYHA Class-II to IV) diagnosed ≥ 1 year ago, aged ≥ 18 years, and advised for echocardiography were invited. A total of 961 patients agreed to participate. HF severity was assessed based on ejection fraction (EF %) and NYHA class. The Kansas City Cardiomyopathy Questionnaire (KCCQ) was used to assess the effect of HF on the patient's QoL.

Results: The patients' overall health status exhibited poor scores, with a mean KCCQ score of 20.26 ± 8.34 . Concerning left ventricular ejection fraction (LVEF), 25.9% of patients displayed moderate dysfunction (LVEF 30% to 39%), while 29.1% had severe dysfunction (LVEF $< 30\%$). The distribution across NYHA classes was Class II included 451 patients (46.9%), Class III included 317 patients (33.0%), and Class IV included 193 patients (20.1%). High-quality-of-life (HR-QoL) assessments using the KCCQ exhibited significant correlations with both LVEF ($rs = -0.394$, $p < 0.01$) and NYHA class ($rs = -0.615$, $p < 0.01$). Notably, the mean KCCQ score displayed considerable variation across NYHA classes, Class II had a mean score of 25.42 ± 7.95 , Class III had 20.90 ± 7.67 , and Class IV had 16.41 ± 8.94 . Significant predictors of quality of life (KCCQ score) included age and NYHA.

Conclusion: It is concluded from the study results that HR-QoL is significantly correlated with the severity of HF based on ejection fraction and NYHA class.

Keywords: Heart Failure, Ejection Fraction, New York Heart Association Class, Kansas City Cardiomyopathy Questionnaire

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INTRODUCTION

A complicated clinical condition, heart failure has high morbidity and mortality rates. Around 3.6 million new cases of HF are discovered each year, according to the European Society of Cardiology, bringing the global total of those suffering from the ailment to over 26 million. The death rate in the first year ranges from 17 to 45%, and the remaining cases pass away within the following five years. Nearly 1% to 2% of all healthcare costs go to HF management, primarily due to frequent hospital admissions.^{1,2} According to the World Health Organization (WHO), cardiovascular

diseases are responsible for over 29% of all Non-Communicable Diseases (NCD) fatalities, making Pakistan a developing nation with a significant burden of these illnesses. Even if most cases go undiagnosed, the total may change if people with HF who are not reported or undiagnosed are included.³ In Pakistan, the prevalence of HF disease is rising at a double-digit rate.

Heart failure is now considered to be an epidemic due to rising prevalence, medical costs, frequent hospital stays, decreased quality of life, and early mortality. Therefore, early identification, severity assessment,

and efficient treatment are crucial to prevent related morbidity and death. In clinical practice, a medical diagnosis is made based on a patient's medical history, physical exam, and the outcomes of ancillary tests like electrocardiography, echocardiography, etc.^{4,5} The aforementioned diagnostic characteristics are combined to create a number of criteria (Framingham, ESC criteria, etc.), which can be used to identify the existence of HF.⁶

Once HF has been diagnosed, the severity of the condition can be assessed using the NYHA or ACC/AHA Guidelines classification systems. NYHA is based on symptoms and physical activity, concentrating on the patient's ability to exercise and the disease's symptomatology.⁷ While ACC/AHA recommendations based on structural changes and symptoms characterize the phases of heart failure, they emphasize how the condition develops and progresses.

The ability to predict which patients may benefit from treatment for HF with reduced ejection fraction depends on the patient's ejection fraction. In fact, the reason why patients who have echocardiography at the time of heart failure presentation experience better outcomes is probably related to the significance of ejection fraction in deciding on prognostically advantageous medication.⁸ The study's objectives were to estimate the severity of HF based on ejection fraction and NYHA Class and to evaluate its impact on patients' QoL.

METHODOLOGY

This multicenter observational study continued for six months at 100 different sites across Pakistan. The study sites were selected based on the availability of consultant cardiologists with an internal echocardiography facility. The investigators from each respective setting were responsible for the data collection and confidentiality.

Symptomatic HF patients (NYHA Class-II to IV) diagnosed ≥ 1 year ago, aged ≥ 18 years, and advised for echocardiography were invited for the study. While non-consenting HF patients using any medicine(s) making them unfit for echocardiography, answering physicians' questions, or having any major thoracic surgery were excluded from the study. A total of 961 were included in the final analysis.

The evaluation of heart failure (HF) severity using the echocardiogram's ejection fraction score (%) NYHA Class was one of the study's main outcomes. LVEF values between 50 and 70 percent were classified as normal, 40 to 49 percent as mild dysfunction, 30 to 39

percent as moderate dysfunction, and values below 30 percent as severe dysfunction. The Kansas City Cardiomyopathy Questionnaire (KCCQ) score was used in the study to measure the effect of heart failure on quality of life (QoL). This 23-item survey covered heart failure-specific symptoms, self-efficacy, physical and social restrictions, and QoL. Higher scores on the KCCQ, which had a scoring range of 0 to 100, indicated better health status. For example, a score of 0 to 24 showed a very bad to poor health status, a score of 25 to 49 suggested a poor to fair status, a score of 50 to 74 indicated a fair to good status, and a score of 75 to 100 indicated a good to exceptional health status. The demographic data, clinical findings, and symptomatic evaluations were recorded on a structured questionnaire.

The study followed Helsinki's Declaration and Standards of Good Clinical Practice. Ethical approval was obtained before study initiation (Reference# LUMHS/REC/-107; Dated 03/06/2021). The collected data was analyzed using SPSS version 22.0; continuous data were expressed using mean and standard deviation and categorical data as frequencies and percentages. The correlation between the QoL and study variables was assessed via Spearman's rank correlation. A multivariable linear regression analysis was performed to explore the predictors of QoL (KCCQ score).

RESULTS

A total of 961 patients participated in the study. Table 1 demonstrates the baseline demographic and clinical characteristics of these patients. The overall health status of the patients was poor based on the KCCQ score (20.26 ± 8.34). Per the LVEF, 25.9% of patients had moderate dysfunction (LVEF 30% to 39%), and 29.1% had LVEF $< 30\%$ (severe dysfunction).

Table 1: Baseline characteristics of the patients

	N (%)
Age (years); Mean\pmSD	55.51 \pm 13.59
Gender	
Female	313(32.6)
Male	648(67.4)
Pulse; Mean\pmSD	83.40 \pm 14.20
SBP (mmHg); Mean\pmSD	124.72 \pm 23.88
DBP (mmHg); Mean\pmSD	85.81 \pm 30.34
Edema	
Yes	439(45.7)
No	522(54.3)
Clinical Examination (LVEF %)	
Normal	72(7.5)
Mild dysfunction	210(21.9)
Moderate dysfunction	330(34.3)
Severe dysfunction	349(36.3)
NYHA class	
Class-II	451(46.9)

Class-III	317(33.0)
Class-IV	193(20.1)
KCCQ score; Mean±SD (n=494)	20.26±8.34
Very poor to poor	341(35.5)
Poor to fair	153(15.9)

SD=standard deviation, SBP=systolic blood pressure, DBP=diastolic blood pressure, KCCQ=Kansas City Cardiomyopathy Questionnaire

There was a strong, significant negative correlation between the KCCQ score and LVEF ($r_s=-0.394$, $p<0.01$) and similarly with NYHA class ($r_s=-0.615$, $p<0.01$). At the same time, blood pressure and edema were positively correlated with the KCCQ score ($p<0.01$).

Table 2: Correlation between the mean KCCQ score and study variables

Variables	KCCQ score
LVEF	-0.394**
NYHA class	-0.615**
Systolic blood pressure	0.173**
Diastolic blood pressure	0.188**
Pulse	-0.047
Edema	0.221**
Age	-0.327**

**Significant correlation at the 0.01 level

LVEF=left ventricular ejection fraction, KCCQ=Kansas City Cardiomyopathy Questionnaire

NYHA class was significantly associated with the KCCQ score ($p<0.05$). Moreover, the mean KCCQ score for NYHA classes significantly varied, i.e., the mean KCCQ score for Class II was 25.42 ± 7.95 , 20.90 ± 7.67 for Class III, and 16.41 ± 8.94 for Class VI.

Table 3: Multivariable linear regression model to predict QoL (via KCCQ score)

Variables	Coefficient [95% CI]	P-value
Gender	1.604 [-1.465 to 4.674]	0.305
Age	-0.128 [-0.207 to -0.05]	0.001
Pulse	0.099 [-0.006 to 0.204]	0.065
Systolic blood pressure	0.053 [-0.019 to 0.125]	0.147
Diastolic blood pressure	0.001 [-0.042 to 0.043]	0.98
Edema	1.182 [-1.922 to 4.285]	0.455
LVEF	-0.485 [-2.163 to 1.193]	0.570
NYHA Class	-6.903 [-8.916 to -4.891]	<0.001

CI=confidence interval

Age emerged as a key predictor of QoL among the predictor variables, an inverse connection showed that QoL ratings were lower in older people, $B = -0.128$ ($p = 0.001$). Additionally, the NYHA Class exhibits a strong influence, as seen by its significant negative beta coefficient of -6.903 ($p<0.001$). This emphasizes the strong correlation between higher NYHA Classes and a significant decline in QoL scores among heart failure patients.

DISCUSSION

The collective health status of the patients, as indicated by the Kansas City Cardiomyopathy Questionnaire (KCCQ) score, was notably poor. Among the patients, 25.9% exhibited moderate dysfunction in terms of left ventricular ejection fraction (LVEF), while 29.1% experienced severe dysfunction with LVEF levels below 30%.

Maintaining a good QoL is a recognized goal in shared decision-making for HF patients; it is as important as survival.⁹ Compared to other chronic illnesses or healthy populations, HF patients tend to have marked impairment in life quality.¹⁰⁻¹² Many clinical trials have demonstrated the use of several recognized HR-QoL tools to assess the impact of HF patient characteristics on QoL. Still, its use in routine clinical practice remains limited. The present study used KCCQ to assess the patient's health status. It is evident from the existing literature that the disease-specific measures of QoL are more accurate in determining the HR-QoL of HF patients compared to the generic ones.¹³ Furthermore, KCCQ has shown the finest performance concerning validity and sensitivity to change among all other disease-specific HR-QoL tools.^{14,15}

It was observed that the NYHA class was significantly correlated with the KCCQ score, and the correlation was negative ($r_s=-0.615$, $p<0.01$). This negative association between HRQoL scores and worsening NYHA has been studied earlier.^{16,17} A study reported that the NYHA class significantly correlates with various HR-QoL tools, i.e., KCCQ and MLHFQ.¹⁸ Moreover, the present study also defines a significant variation in the mean KCCQ score with each NYHA class. Besides the NYHA class, our results also demonstrate a strong negative correlation between KCCQ score and LVEF (HR-QoL (KCCQ) was significantly correlated with LVEF ($r_s=-0.394$, $p<0.01$). In contrast, Gallagher et al. reported no significant correlation between the KCCQ score and LVEF ($r=0.074$).¹⁸ Similarly, previous studies also indicate no change in the HR-QoL with respect to LVEF and biomarker levels such as NT-proBNP over time.^{19,20} Sepehrvand et al. reported that the KCCQ score was more likely to change with low LVEF and higher right ventricle systolic pressure levels.²¹

Age and NYHA class were significant predictors of QoL (KCCQ score). In contrast, other studies reported only NYHA class as the only independent predictor of HR-QoL.²² Lewis et al. also reported, and Allen et al.

identified that comorbidities and older age affect self-care management, resulting in poor HR-QoL.²³⁻²⁵

It is suggested that using KCCQ in routine clinical practice can readily identify the most ill patients requiring more resources, signifying its prognostic importance and overall supporting population health. Further research is recommended to ensure the diagnostic benefits and employ its use in clinical care. In addition to strengths like diverse population and multicenter design, the study limitations must also be considered. The potential introduction of sample bias as a result of the exclusive selection of people who were advised to have echocardiography by consultant cardiologists may have an impact on the generalizability of the result. Additionally, the lack of a socio-demographic evaluation compromises the study's full understanding by limiting knowledge of the potential impact of these characteristics on patients' health-related quality of life (HR-QoL).

CONCLUSION

In conclusion, HR-QoL significantly correlates with LVEF. The QoL of a heart failure patient is most affected as NYHA class worsens and LVEF decreases.

AUTHORS' CONTRIBUTION

AGM, MNK, and HM: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. FAM, MIK, FA, AF, KQ, and ARS: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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