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Initial Psychometrics of a New Instrument

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Background: Patients with a left ventricular assist device are a unique and growing population who deserve their own valid, reliable instrument for health-related quality of life. Objective: We developed and tested the Health-Related Quality of Life with a Left Ventricular Assist Device (QOLVAD) questionnaire. Methods: In a prospective, descriptive study, patients from 7 sites completed the QOLVAD and comparator questionnaires. Construct validity was tested using confirmatory factor analysis. Convergent validity was tested using correlations of QOLVAD scores to well-established measures of subjective health status, depression, anxiety, and meaning/faith. Reliability and test-retest reliability were quantified. Results: Patients (n = 213) were 58.7 ± 13.9 years old; 81.0% were male, 73.7% were White, and 48.0% had bridge to transplant. Questionnaires were completed at a median time of 44 weeks post ventricular assist device. The 5 QOLVAD domains had acceptable construct validity (root mean square error of approximation = 0.064, comparative and Tucker-Lewis fit indices > 0.90, weighted root mean square residual = 0.95). The total score and domain-specific scores were significantly correlated with the instruments to which they were compared. Internal consistency reliability was acceptable for all subscales (α = .79–.83) except the cognitive domain (α = .66). Unidimensional reliability for the total score was acceptable (α = .93), as was factor determinacy for multidimensional reliability (0.95). Total test-retest reliability was 0.875 (P < .001). Conclusion: Our analysis provided initial support for validity and reliability of the QOLVAD for total score, physical, emotional, social, and meaning/spiritual domains. The QOLVAD has potential in research and clinical settings to guide decision making and referrals; further studies are needed.

KEY WORDS: cardiac assist device, health-related quality of life, instrument development, LVAD, quality of life

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Although disease-specific measures of health-related quality of life (HRQOL) and quality of life (QOL) have been used for years among patients with cardiovascular disorders, there is no established instrument for patients living with a left ventricular assist device. Instead, patients with left ventricular assist device have been routinely assessed with heart failure disease-specific metrics well validated in the general population with disease-specific and heart failure–specific and instruments had sufficient sensitivity and contained enough items specific to left ventricular assist device concerns to demonstrate validity in this unique population. For example, if generic heart failure–specific instruments do not contain items related to satisfaction of cognitive well-being (such as improved or reduced memory or clarity of thought), patient-reported alterations in cognition secondary to left ventricular assist device therapy may be missed. In response to this need, we report psychometric evaluation of the Health-Related Quality of Life in Ventricular Assist Device (QOLVAD), a new unique, theory-based, comprehensive HRQOL assessment post left ventricular assist device.

Clarifying Terminology

Assessment of patient-reported outcomes is deemed integral to achieving medical device approval by the Food and Drug Administration. Patient-reported outcomes are described as “any report of the status of a patient’s (or person’s) health condition, health behavior, or

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experience with healthcare that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.⁸

For the past few decades, QOL and HRQOL have been increasingly recognized as patient-reported outcomes that are “multidimensional,” “dynamic,” and “subjective.”⁹,¹⁰ The term “QOL” was described in early influential publications as including several domains of life.¹¹⁻¹³ In contrast, the narrower term “HRQOL” has been used to delineate areas of life more likely to be influenced by a health condition, such as physical and emotional status after a major illness or surgery.⁹ However, several domains need to be assessed to reflect the multidimensional nature of HRQOL. For example, Osoba¹⁴ advised researchers to describe their study as measuring HRQOL only if at least 3 life domains are assessed. Major life domains have been referred to as physiological, psychological, and sociological.¹⁵ Others contend that, for some patient populations, a spiritual domain is important.¹¹,¹⁶ Patients with an left ventricular assist device need comprehensive assessment, but the ideal balance of comprehensive measurement without subject burden presents a challenge because so many areas of life are affected by living with an left ventricular assist device.

Among the general (non-left ventricular assist device) population with heart failure, using a generic as well as a heart failure–specific instrument is a logical approach. Investigators have typically used a generic instrument (eg, EuroQol¹²) to allow for comparisons across patient populations, supplemented by a disease-specific instrument.¹⁷ However, asking patients post left ventricular assist device to complete heart failure–specific questionnaires at repeated intervals beyond the initial recovery period has been reported by patients to feel burdensome because many feel heart failure concerns are no longer applicable.⁵ A more suitable approach for repeated measurement may be to use an left ventricular assist device–specific instrument supplemented by a brief generic instrument.

**LIMITATIONS OF EXISTING DISEASE-SPECIFIC INSTRUMENTS FOR PATIENTS WITH A LEFT VENTRICULAR ASSIST DEVICE**

Investigators have typically used heart failure–specific measures among patients living with an left ventricular assist device (eg, the Minnesota Living with Heart Failure¹⁸ questionnaire measuring disease-specific QOL and the Kansas City Cardiomyopathy Questionnaire [KCCQ]¹⁹ measuring subjective health status). However, these were developed in non-left ventricular assist device populations with heart failure and thus miss assessment questions integral to describing life on left ventricular assist device support. Furthermore, the vast majority of patients surviving post left ventricular assist device (78%) no longer report heart failure symptoms after the first year, so many of the questions on these measures are not relevant.²⁰ Instead, new concerns develop post left ventricular assist device. For example, a patient post left ventricular assist device who no longer has orthopnea would say “no” to an item on the KCCQ asking whether the patient has difficulty sleeping due to needing to sleep upright. However, the same patient may have difficulty with sleep due to the left ventricular assist device interfering with a position of comfort while lying in bed. Frustration and anger related to loss of independence or ignorance of others (eg, airport security) have been reported,⁵ but neither is assessed on the aforementioned questionnaires.²¹ Other examples of concerns often inadequately addressed by commonly used existing measures include changes in self-image (ie, clothing to adjust for device controller and batteries) and sexuality.³⁻⁶,²²

Finally, 2 key domains have been neglected in past measures for patients with an left ventricular assist device: subjective cognitive well-being and spiritual well-being. Cognitive function after an left ventricular assist device is understudied, as an objective or subjective outcome. Cognitive function has been reported as improved post left ventricular assist device, but only for those who did not sustain a perioperative stroke.²³ Neurologic dysfunction is the third most common reason for hospitalization post left ventricular assist device (with bleeding and infection being more common).²⁴ Yet, there are few reports describing how clinicians or investigators ask patients about self-perceptions of cognitive function for daily tasks or hobbies important to them. Among non-left ventricular assist device patients, terms such as subjective cognitive decline⁵ and subjective impairment²⁶ have been used, emphasizing the importance of this concept but from a deficit-based approach.

In an approach to holistic assessment as a part of HRQOL, we propose the term subjective cognitive well-being to describe the way in which patients self-assess satisfaction with their memory, clarity of thought, and mental ability to perform daily tasks or hobbies important to them. Given the lack of studies among patients with an left ventricular assist device, inclusion of cognitive well-being is deserving of exploration when asking an left ventricular assist device recipient to evaluate overall well-being. Asking patients about their perceived cognitive well-being offers the potential to identify patients who may benefit from further assessment and interventions²³ (ie, for safety and medication adherence).

Similarly, spiritual well-being is an important domain that has been neglected among patients with an left ventricular assist device. Asking patients about faith resources, meaning, and purpose in life may assist in the identification of patients who may benefit from referral to spiritual care or counseling. In our earlier work,⁵ patients described the importance of the interaction between
faith and their mechanical circulatory support experience (experiencing peace with past decisions and hope during an uncertain time). Importantly, patients who did not express a particular faith described looking for meaning, peace, and connection to others and nature, as well as a loss of purpose in life (eg, related to self-identity if unable to work or provide for family). Therefore, we consider a spiritual/meaning domain an essential metric to include for patients who are seriously ill and potentially facing mortality. Importantly, elements from the meaning/spiritual domain have been identified as significant by both patients with and without self-identified faith.

CONCEPTUAL FRAMEWORK AND DEVELOPMENT OF THE HEALTH-RELATED QUALITY OF LIFE IN VENTRICULAR ASSIST DEVICE (QOLVAD)

This quantitative study builds upon our previously published grounded theory work in which we first established the following conceptual definition for QOL from the perspective of patients living with an left ventricular assist device, “Being well enough in my life overall to the extent that I can do and enjoy day-to-day activities that are important to me.”\(^5\) As previously described, 11 patients agreed to participate in 2 separate semistructured interviews to provide a foundation for understanding and measuring QOL among patients with an left ventricular assist device. In the first interviews, patients were asked to describe aspects or domains of QOL affected by their left ventricular assist device. This resulted in identification of 5 domains for QOL (physical, emotional, social, cognitive, and meaning/spiritual). These domains were supported by a review of literature and became the 5 subscales for the QOLVAD questionnaire (Figure 1).\(^5\) Important issues of left ventricular assist device-specific satisfaction or concerns were elicited through use of concept maps (diagrams showing a visual representation of data), from which individual questionnaire items were generated.

![Quality of life with a left ventricular assist device. Model of domains with salient examples. (Sandau, K.E. & Hoglund, B.A.). Copyright 2013. Used with permission. LVAD, left ventricular assist device.](image-url)
During the second interview, patients reviewed early drafts of the questionnaire developed by 2 of the authors (K.E.S. and B.H.) for face validity and provided feedback on clarity, comprehensiveness of items, missing items, and redundancy. Patients gave verbal feedback during the interview and written feedback directly on the questionnaire, allowing for further revisions. In terms of format for delivery, patients preferred having the questionnaire divided into 5 subscales, facilitating clarity about the intent of each question. Participants felt a left ventricular assist device-specific QOL questionnaire was important and that the drafts reviewed took an acceptable amount of time to complete. Patients agreed that a recall period of “in the last 2 weeks” was appropriate for the instructions for completing the questionnaire; longer could potentially allow for inaccurate recall. No further items were suggested during the final 2 interviews, supporting saturation. Through this interview process with patients, (K.E.S. & B.H) we developed a preliminary QOLVAD questionnaire that included 61 Likert items for review by expert clinicians.

Six expert clinicians provided review of the preliminary 61 Likert items for content validity following patient contributions to establish face validity of the questionnaire. Experts included a cardiothoracic surgeon, an advanced heart failure cardiologist, 2 advanced heart failure nurse practitioners, an left ventricular assist device nurse coordinator, and a cardiovascular research nurse. A statistician provided edits for item clarity. Review by the content experts was performed through an iterative, one-on-one discussion by the principal investigator (K.E.S.) with each expert to allow for a rich discussion about depth and breadth of content for the first version of this new questionnaire. Each of the 6 experts evaluated items for relevancy and for any suggested additions, deletions, and revisions. No additional items were suggested by content experts. Minor suggestions for changes in wording were incorporated for items rated as relevant according to content experts. The content validity evaluation by experts resulted in deletion of 13 items based on relevancy and redundancy, resulting in a preliminary version of the questionnaire containing 48 Likert items.

Of these 48 Likert items, 2 were dropped before the confirmatory factor analysis after review by the author team. The first item was dropped because of clinical site variability in restrictions for post-left ventricular assist device care related to drinking alcohol. The second item was dropped because it was a listing of postoperative complications deemed not relevant to the 5 domains of HRQOL. Finally, an additional 3 items were deleted from the analysis because of poor item discrimination: “avoidance of water activities,” “being bothered by how the ventricular assist device affects the way one fits in chairs or cars,” and “feeling like it’s hard to stay balanced due to the ventricular assist device.” Therefore, the analyses reported in this study were performed using the remaining 43 Likert items for HRQOL subscales of the QOLVAD (version 1).

A final content validity analysis was performed on the 43 items by 8 newly identified experts working with mechanical circulatory support patients. Four physicians and 4 nurse practitioners (one of whom was a psychometrician) assigned each item a rating for relevance. The mean item content validity index was 0.91 (individual item ratings ranged from 0.75 to 1).

The questionnaire’s readability was assessed as Flesch reading ease score of 77.8 (fairly easy) and Flesch-Kincaid grade level of 4.9 (very easy). The pencil-and-paper questionnaire contains a brief introduction: “This questionnaire is for people with a ventricular assist device as they often have special concerns about the way ventricular assist device therapy affects different parts of life…. Please respond according to your experiences over the past 2 weeks.” Item statements, response options, and the domains for actual items of the questionnaire are listed in Table 1. For each subscale (physical, emotional, social, cognitive, meaning/spiritual), patients select from 1 of 5 Likert responses: “not at all,” “a little,” “somewhat,” “very much,” and “always.” For a few select items (eg, “I worry when I travel a distance from my primary ventricular assist device center”), a “not applicable” option is available.

Six additional “summary” items are included on the QOLVAD questionnaire that fall outside the 5 domains. These summary items address perceived adjustment and improvement (2 items), decision making (2 items), and a global QOL (1 item). Finally, an open-ended question (1 item) allows patients to write in comments about QOL with an left ventricular assist device. The open-ended question will remain during early trials using the QOLVAD, to help further assess validity of this new instrument. These 6 “summary” items were not used to calculate any of the domain scores nor were they included in the calculation of total scores. Because these 6 items were not used in any part of the psychometric analysis, they are not reported here.

In summary, this study is an important part of the overall process for developing a patient-reported outcome,27 which included our previously published identification of the need for new patient-reported outcomes (as evidenced by patients, experts, and literature review), defining of the concept, and describing of our conceptual model.5 In the present report, we describe item generation, item improvement (literacy review, cognitive interviews), revisions, initial testing, analysis, and clinical validation study.27 The current report describes a multi-center evaluation of the psychometric properties of the QOLVAD’s 5 domain scores and total score (43 Likert items) across 7 advanced heart failure centers.

**STUDY AIMS**

The aims of this study were to (1) test item function of the newly developed QOLVAD questionnaire, (2) estimate
| Items by Quality of Life Domain | Physical | | Emotional | | Social | |
|---|---|---|---|---|---|
| Not at All | A Little | Somewhat | Very Much | Always | Mean (SD) Item-Rest | r | Discrimination |
| 1. I have been satisfied with my ability to: |  |  |  |  |  |  |  |
| a. bathe (ie, showering or sponging) | 10.8% | 5.6% | 25.4% | 24.9% | 30.0% | 2.60 (1.29) | 0.42 | 1.11 |
| b. get dressed by myself | 1.9% | 2.3% | 9.9% | 26.8% | 56.3% | 3.37 (0.90) | 0.56 | 2.26 |
| c. change my VAD dressing | 19.2% | 2.8% | 8.5% | 15.5% | 32.4% | 2.50 (1.62) | 0.37 | 1.13 |
| d. go shopping | 5.2% | 8.0% | 19.2% | 18.3% | 41.8% | 2.90 (1.23) | 0.67 | 3.24 |
| e. do housekeeping/minor household repairs | 8.0% | 8.5% | 30.0% | 17.4% | 32.4% | 2.50 (1.62) | 0.37 | 1.13 |
| f. drive a car | 11.7% | 6.1% | 8.5% | 17.4% | 44.1% | 2.87 (1.44) | 0.52 | 1.93 |
| 2. I feel satisfied with the quality of my sleep. | 5.6% | 7.5% | 28.6% | 27.2% | 26.8% | 2.65 (1.14) | 0.59 | 1.47 |
| 3. I feel like my appetite is at a healthy level for me. | 4.2% | 6.1% | 17.8% | 34.7% | 32.4% | 2.89 (1.08) | 0.64 | 2.68 |
| 4. I feel like I can do activities that I enjoy. | 6.6% | 18.3% | 31.0% | 18.8% | 23.0% | 2.34 (1.22) | 0.68 | 2.68 |
| 5. I feel satisfied with my physical strength. | 11.7% | 19.2% | 36.6% | 18.3% | 10.8% | 1.97 (1.15) | 0.65 | 2.11 |
| 6. I feel satisfied with how long my energy lasts. | 15.0% | 20.7% | 35.2% | 15.0% | 9.9% | 1.83 (1.18) | 0.66 | 2.28 |
| 7. I am comfortable working with my VAD equipment. | 3.3% | 3.3% | 10.8% | 40.4% | 38.5% | 3.12 (0.97) | 0.36 | 1.00 |
| 8. I have figured out some tricks for daily living with a VAD. | 5.6% | 10.3% | 30.0% | 30.0% | 21.1% | 2.52 (1.12) | 0.32 | 0.81 |
| 9. I feel like I cannot move freely...like I'm "tied down" by my VAD. | 30.5% | 34.3% | 24.4% | 4.7% | 3.8% | 2.85 (1.04) | 0.38 | –0.73 |
| 10. I have physical discomfort related to wearing equipment. | 39.9% | 32.9% | 19.7% | 3.8% | 1.4% | 3.09 (0.94) | 0.34 | –0.61 |
| 11. I feel hopeful. | 6.1% | 4.2% | 16.0% | 38.5% | 33.3% | 2.90 (1.11) | 0.47 | –1.65 |
| 12. I feel sad. | 51.6% | 31.5% | 11.3% | 2.3% | 0.9% | 3.34 (0.85) | 0.46 | 1.42 |
| 13. I worry that my VAD might stop working properly. | 47.4% | 29.6% | 15.5% | 4.2% | 1.4% | 3.20 (0.95) | 0.35 | 0.81 |
| 14. I can laugh. | 1.9% | 4.2% | 8.5% | 27.2% | 54.5% | 3.33 (0.95) | 0.47 | –1.71 |
| 15. I am angry about my heart problems. | 46.0% | 21.6% | 16.0% | 8.5% | 4.2% | 3.00 (1.18) | 0.50 | 1.54 |
| 16. I have found ways to help cope with life's challenges. | 1.4% | 5.6% | 22.5% | 37.6% | 30.0% | 2.85 (1.04) | 0.38 | –0.73 |
| 17. I am confident my healthcare providers can help me if | 1.9% | 1.4% | 5.2% | 29.1% | 60.6% | 3.48 (0.82) | 0.42 | –1.58 |
| I have questions about living with my VAD. | 36.2% | 20.7% | 21.6% | 5.6% | 5.6% | 2.85 (1.20) | 0.33 | 0.77 |
| 18. I worry when I travel a distance from my VAD center. | 54.5% | 20.2% | 13.6% | 6.6% | 2.3% | 3.21 (1.07) | 0.37 | 0.95 |
| 19. I feel stressed by health issues not related to my VAD. | 39.0% | 23.5% | 17.8% | 12.2% | 4.2% | 2.83 (1.21) | 0.58 | 1.46 |
| 20. I am anxious about the uncertainty of my future. | 41.8% | 22.1% | 26.3% | 7.0% | 1.4% | 2.97 (1.05) | 0.55 | –0.94 |
| 21. I am less likely to go places because of my supplies. | 46.9% | 23.9% | 21.1% | 5.6% | 0.9% | 3.12 (1.00) | 0.32 | –0.66 |
| 22. I am burdened by extra costs related to my VAD. | 3.8% | 7.5% | 25.4% | 31.5% | 29.1% | 2.77 (1.08) | 0.41 | 1.38 |
| 23. I can contribute to the well-being of others. | 2.8% | 4.2% | 8.5% | 25.4% | 56.8% | 3.32 (1.00) | 0.49 | 1.82 |
| 24. I have someone I can talk to about my condition. | 62.9% | 14.1% | 12.7% | 5.2% | 3.3% | 3.31 (1.09) | 0.51 | –1.64 |
| 25. It is difficult to talk with healthy people about the challenges I have living with my VAD. | 50.7% | 27.2% | 10.8% | 7.0% | 2.3% | 3.19 (1.05) | 0.41 | –0.84 |
| 26. I am bothered by how my VAD makes me look. | 36.6% | 15.5% | 15.5% | 11.7% | 5.2% | 2.79 (1.30) | 0.35 | –0.75 |
| 27. My VAD keeps me from working outside the home. | 6.6% | 8.5% | 27.7% | 27.7% | 27.2% | 2.62 (1.17) | 0.54 | 2.00 |
| 28. I can do the things I need to fulfill my role in my family. | 5.6% | 6.6% | 16.4% | 26.3% | 36.6% | 2.89 (1.19) | 0.56 | 2.22 |
| 29. I am satisfied with my ability to cuddle/hold loved ones. | 5.6% | 6.6% | 16.4% | 26.3% | 36.6% | 2.89 (1.19) | 0.56 | 2.22 |
the validity and reliability of the QOLVAD questionnaire, and (3) provide preliminary expected ranges of values for use in clinical practice.

**Methods**

**Study Design**

In this multicenter study, we report findings from a prospective, descriptive, quantitative study of adult patients on durable left ventricular assist device support at 7 sites in the United States. Before participating, Institutional Review Board approval and informed patient consent were obtained.

**Procedure for Testing the Health-Related Quality of Life with a Left Ventricular Assist Device**

The QOLVAD was compared with established patient-reported outcome measures commonly used in studies of patients on left ventricular assist device support. The 12-item KCCQ\(^\text{15}\) was selected as a heart failure measure for subjective health status and is commonly used among patients with a left ventricular assist device. The 9-item Patient Health Questionnaire (PHQ-9)\(^\text{28}\) was used as a well-validated screen for depressive symptoms. The 12-item Functional Assessment of Chronic Illness Therapy-Spiritual Well-being Scale\(^\text{29}\) was selected for use because of its previous use among patients with heart failure.\(^\text{30}\) The 4-item Patient-Reported Outcomes Measurement Information System Anxiety Short Form 4-a\(^\text{31,32}\) was selected because of its brevity and previous use among patients with heart failure. At the time of protocol development, we could find no established instrument for subjective cognitive well-being used in heart failure, so in an effort to avoid burdening patients with a nonestablished comparator, we chose to use the KCCQ’s summary score (as a metric for the gradient of cognitive dysfunction with worse heart failure).

Outpatients on durable left ventricular assist device support were recruited from July 2014 to November 2018. Sites included universities and private institutions. We excluded patients unable to read English (either by self-report or inability to read aloud the first paragraph of the consent) or those who had significant psychiatric illness precluding completion of testing. There are no guidelines for sample size calculations for structural equation modeling. Several conventional rules are available,\(^\text{33,34}\) including minimum sample sizes of 100 to 200 and ratio of N to factors of 5 to 10. On the basis of these guidelines, we aimed to recruit a sample of at least 200 for our analysis. Strategies to reduce bias included use of standardized questionnaires, multiple sites, and description of sample so representativeness of patients with contemporary left ventricular assist device could be evaluated.

**TABLE 1 Health-Related Quality of Life with a Left Ventricular Assist Device Item Analysis by Theoretical Domain (N = 213), Continued**

<table>
<thead>
<tr>
<th>Items by Quality of Life Domain</th>
<th>Cognitive</th>
<th>Meaning/Spiritual</th>
<th>Physical</th>
<th>Emotional</th>
<th>Social</th>
<th>Environmental</th>
<th>Psychological</th>
<th>Role</th>
<th>Psychosocial</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>30. I am satisfied with my ability to be intimate</td>
<td>1.9%</td>
<td>6.0%</td>
<td>10.0%</td>
<td>17.0%</td>
<td>25.0%</td>
<td>30.0%</td>
<td>32.0%</td>
<td>30.0%</td>
<td>30.0%</td>
<td>30.0%</td>
</tr>
<tr>
<td>31. I am clear enough to do my everyday activities</td>
<td>0.0%</td>
<td>0.4%</td>
<td>2.0%</td>
<td>3.0%</td>
<td>9.0%</td>
<td>13.0%</td>
<td>24.0%</td>
<td>30.0%</td>
<td>28.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>32. I am clear enough to concentrate for longer than 30 min.</td>
<td>0.0%</td>
<td>0.4%</td>
<td>2.0%</td>
<td>3.0%</td>
<td>9.0%</td>
<td>13.0%</td>
<td>24.0%</td>
<td>30.0%</td>
<td>28.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>33. My mind is clear enough to do my everyday activities</td>
<td>0.0%</td>
<td>0.4%</td>
<td>2.0%</td>
<td>3.0%</td>
<td>9.0%</td>
<td>13.0%</td>
<td>24.0%</td>
<td>30.0%</td>
<td>28.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>34. My mind is clear enough to do my everyday activities</td>
<td>0.0%</td>
<td>0.4%</td>
<td>2.0%</td>
<td>3.0%</td>
<td>9.0%</td>
<td>13.0%</td>
<td>24.0%</td>
<td>30.0%</td>
<td>28.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>35. I have peace no matter what happens</td>
<td>0.0%</td>
<td>0.4%</td>
<td>2.0%</td>
<td>3.0%</td>
<td>9.0%</td>
<td>13.0%</td>
<td>24.0%</td>
<td>30.0%</td>
<td>28.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>36. I feel support from others who share my faith</td>
<td>0.0%</td>
<td>0.4%</td>
<td>2.0%</td>
<td>3.0%</td>
<td>9.0%</td>
<td>13.0%</td>
<td>24.0%</td>
<td>30.0%</td>
<td>28.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>37. I believe God or a Higher Power cares for me</td>
<td>0.0%</td>
<td>0.4%</td>
<td>2.0%</td>
<td>3.0%</td>
<td>9.0%</td>
<td>13.0%</td>
<td>24.0%</td>
<td>30.0%</td>
<td>28.0%</td>
<td>28.0%</td>
</tr>
</tbody>
</table>

Domain items from the QOLVAD questionnaire, version 1. Sandau, K.E. & Hoglund, B.A. Copyright 2013. Used with permission.

Bold indicates the highest score.

Abbreviation: VAD, ventricular assist device.
Eligible patients were approached by research associates or site investigators. Consenting outpatients on durable left ventricular assist device support completed a brief demographic questionnaire, the QOLVAD, and comparator subjective health status instruments. Patients completed the questionnaires unassisted in the clinic setting. To obtain data for test-retest reliability, patients were asked to complete the QOLVAD a second time at home, mailing it back to their respective sites within 1 week after initial questionnaire completion. There are no set guidelines regarding the time interval between test administrations. Selection of the optimal time intervals for test-retest reliability testing is influenced by the construct under investigation, the stability of the construct over time, and the population under investigation influence. Time intervals ranging from 2 days to 2 weeks are common in research on QOL instruments, and there is evidence that reliability is not affected significantly if a researcher selects a short or long time interval. For our analysis, a 1-week period was selected because a prolonged period could potentially increase the likelihood that a participant might have a complication or significant life event that did not exist when completing the first questionnaire.

**Statistical Analysis**

Scores for each of the 5 QOLVAD domains were standardized to range from 0 to 100, with higher scores indicating better QOL. Total scores were the mathematical average of the 5 domain scores and therefore also ranged from 0 to 100, with higher scores indicating better QOL. We calculated means, standard deviations, and item-rest correlations (ie, the correlation between scores on an individual item and scores on the scale that is formed by all other items within that scale) for each item. Correlations ranged from 0 (weak) to 1 (strong). As per published guidelines, correlations of 0.1 were considered small, 0.3 were considered medium, and 0.5 were considered large.

We also quantified difficulty of items (ie, item difficulty: the proportion of participants who provided the response indicating the highest QOL) and how well each item discriminated between patients with high and low QOL (ie, item discrimination: slope of item response theory-based item characteristic curves across response options). Indicators were handled as ordered categorical data. Our previous theoretical work indicated that the overarching construct of QOL encompassed 5 domains: physical, emotional, social, cognitive, and meaning/spiritual with identified examples for each domain. As there was an a priori hypothesis about the theoretical structure from this work, confirmatory factor analyses were used to test structural validity of the QOLVAD questionnaire. Overall fit of these data to the theoretical structure was assessed using root mean square error of approximation, comparative fit indices, Tucker-Lewis indices, and weighted root mean square residuals. Good fit was defined as a root mean square error of approximation close to 0.06, weighted root mean square residual close to 0.90, and comparative fit index and Tucker-Lewis index close to 0.95.

Convergent validity (eg, how well the domains matched with established comparator measures) was tested using Pearson correlations for the following comparisons: QOLVAD physical with KCCQ physical domains, QOLVAD emotional with PHQ-9 and Patient-Reported Outcomes Measurement Information System anxiety scores, QOLVAD social with KCCQ social limitations score, QOLVAD cognitive with KCCQ summary score, QOLVAD meaning/spiritual with Functional Assessment of Chronic Illness Therapy meaning and faith scores, and total scores for QOLVAD with KCCQ. Definitions of correlations are provided previously. We anticipated significant and moderate associations of each subscale with its preassigned comparator measure.

Because the QOLVAD is multidimensional, 2 separate measures of reliability were necessary. Cronbach α was calculated as an index of unidimensional internal consistency (subscales and total score), and a factor determinacy score was calculated as a metric of multidimensional reliability (subscales within total score). Pearson correlations and Bland-Altman testing were used to quantify test-retest reliability.

Scores in each domain and total QOLVAD scores are meaningless to clinicians without guidelines regarding what is normal and what is abnormal. For example, if a clinician calculated that a patient’s emotional QOL score was 50, they may not know whether this is normal or whether the patient would benefit from intervention. To facilitate understanding of scores, preliminary ranges of QOLVAD domain scores to be expected in clinical practice were estimated using item response theory-based test characteristic curves.

Missing data were handled using full information maximum likelihood estimation. Confirmatory factor analyses were conducted using Mplus v.8 (Los Angeles, California). All other analyses were completed using Stata v15 (College Station, Texas).

**Results**

Seven sites contributed a total of 213 participating patients to this nonconsecutive, convenience sample. Characteristics of this sample were compared with the 2014–2018 cohorts described by the Society of Thoracic Surgeon’s Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry, a North American registry for the clinical outcomes of patients who receive an Food and Drug Administration–approved mechanical circulatory support device to treat advanced
heart failure. In comparison, the current sample (Table 2) was similarly composed of mostly men (81%) (vs 78% in INTERMACS) in a similar age range (58.7 ± 13.9 years) (vs 57 years in INTERMACS), but with less diversity (White, 73.7%) (vs 64%–66% in INTERMACS).24 Approximately half of the participants (48%) had an left ventricular assist device as a bridge to transplantation. Participants had been living with a left ventricular assist device for an average of 1.59 ± 1.87 years at the time of enrollment. A majority of patients (69.5%) had a HeartMate II (Abbott, Illinois) device, 20.7% had a HeartMate 3 (Abbott, Illinois) device, and 9.8% had an HVAD (Medtronic, Minnesota) device.

Estimates were provided by site investigators for most common reasons for nonparticipation. Listed in order of frequency, reasons given by staff for not inviting patients to participate included “lack of available staff to consent,” “lack of available staff to administer surveys,” and “lack of available rooms.” Larger university sites described “competing studies” as a barrier to recruitment. Few patients declined to participate (median, 2%). Those who disclosed a reason for nonparticipation described primarily “not enough time” or “too many survey studies offered.”

Participants spent approximately 15 to 30 minutes completing all the questionnaires assigned, with approximately 10 minutes being spent on the QOLVAD. More than 86% of the participants in this study had an educational level equivalent to a high school degree or higher, which suggests that they would not have difficulty interpreting the questions.

### Item Difficulty and Differentiation

The QOLVAD questionnaire’s distribution of item responses, difficulty, and discrimination is reported in Table 1. Bolded values for each item indicate the response that reflects the highest HRQOL (the most optimal/best response). Item difficulty in this context reflects issues that are most taxing on HRQOL for patients with an LVAD. For example, the most difficult item for patients was feeling satisfied with how long their physical energy lasts. Hence, low satisfaction with physical energy is common and tends to negatively influence physical HRQOL. Item discrimination reflects the ability of each item to differentiate between patients with good versus poor HRQOL. For instance, “Feeling that my life has meaning and purpose” was a large differentiator between patients with high meaning/spiritual HRQOL versus those with poor meaning/spiritual HRQOL.

### Validity

The results of the confirmatory factor analysis are presented in Figure 2. Factor loadings describe the relative importance of an item in representing a specific domain of HRQOL. In summary, QOLVAD items demonstrated large, significant associations with total HRQOL and the 5 specific domains. Indices of model fit were acceptable (Figure 2) indicating that the data matched the theoretical factor structure well. Specifically, root mean square error of approximation was 0.064 (90% confidence interval, 0.059–0.069), weighted root mean square residual was 0.95, and Tucker-Lewis index and comparative fit index were 0.903 and 0.908, respectively.40 Finally, each domain of the QOLVAD demonstrated significant correlations with established measures, supporting convergent validity, and demonstrated moderate-to-large effect sizes (Table 3).

### Reliability

Internal consistency reliability was acceptable for all QOLVAD domains except cognitive well-being, with Cronbach α scores of 0.88, 0.79, 0.78, 0.66, 0.83,
and 0.93 on the physical, emotional, social, cognitive, and meaning/spiritual subscales and total QOLVAD score, respectively. Factor determinacy score, testing multidimensional reliability, was acceptable (0.95). Each QOLVAD subscale had strong correlations (range, 0.72–0.85) between test and retest assessments (the same patient taking the QOLVAD up to 1 week later), with the total QOLVAD score test-retest reliability strongest (0.88). All Bland-Altman plots and tests confirmed acceptable test-retest reliability (range, −0.02 to −2.01).

**Expected Norms**

Item response theory-based total characteristic curves were used to estimate expected QOLVAD score ranges that may be expected in clinical practice (Table 4). Expected norms were based on the scaled domain scores that ranged from 0 to 100, with higher scores indicating better HRQL. Expected scores were highest on the meaning/spiritual scale and lowest in the cognitive domain.

**DISCUSSION**

In this article, we described and reported the development and evaluation of the QOLVAD, a conceptually grounded, multidimensional (physical, emotional, social, cognitive, and spiritual/meaning) instrument for capturing HRQL unique to patients living on durable left ventricular assist device support. In our analyses, reliability and validity were supported for the QOLVAD’s 5 subscale scores for HRQL. The QOLVAD total score and individual QOLVAD subscales demonstrated acceptable multidimensional reliability, test-retest reliability, internal consistency reliability for subscales, and total internal consistency reliability (α = 0.93). Among the 5 domains, the physical subscale had the highest internal consistency reliability (and most items), whereas the cognitive domain had the lowest reliability (and fewest items, likely contributing to the relatively lower α).

The QOLVAD total and domain subscales had significant convergent validity with known measures. Moderate to strong, but not perfect, correlations are desirable with the known measures, because the new questionnaire is measuring novel concepts (eg, how the left ventricular assist device affects QOL) in addition to usual concepts (satisfaction with physical activity). Among the 5 domains, the emotional subscale had a higher correlation with its comparator for anxiety symptoms (Patient-Reported Outcomes Measurement Information System anxiety) compared with its comparator for anxiety symptoms (Patient-Reported Outcomes Measurement Information System Neuro-QOL) have become available but are as yet underused in the left ventricular assist device population with advanced heart failure. Future studies including both subjective and objective cognitive well-being may strengthen understanding of the complex effect of an left ventricular assist device on patients’ cognitive well-being.

---

**TABLE 3** Health-Related Quality of Life with a Ventricular Assist Device Convergent Validity Testing

<table>
<thead>
<tr>
<th></th>
<th>KCCQ Physical</th>
<th>PHQ9 Anxiety</th>
<th>PROMIS Social</th>
<th>KCCQ Summary</th>
<th>FACIT-Sp Meaning/Peace</th>
<th>FACIT-Sp Faith</th>
<th>KCCQ QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical</td>
<td>0.609&lt;sup&gt;a&lt;/sup&gt;</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Emotional</td>
<td>—</td>
<td>−0.303&lt;sup&gt;a&lt;/sup&gt;</td>
<td>−0.643&lt;sup&gt;a&lt;/sup&gt;</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Social</td>
<td>—</td>
<td>—</td>
<td>0.501&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.444&lt;sup&gt;a&lt;/sup&gt;</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Cognitive</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.634&lt;sup&gt;a&lt;/sup&gt;</td>
<td>—</td>
<td>—</td>
<td>0.490&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Meaning/spirituality</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.625&lt;sup&gt;a&lt;/sup&gt;</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

**TABLE 4** Expected Health-Related Quality of Life with a Ventricular Assist Device Score Ranges<sup>a</sup>

<table>
<thead>
<tr>
<th></th>
<th>95% CI LL</th>
<th>Mean</th>
<th>95% CI UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical</td>
<td>25.17</td>
<td>52.33</td>
<td>83.85</td>
</tr>
<tr>
<td>Emotional</td>
<td>42.00</td>
<td>45.50</td>
<td>48.75</td>
</tr>
<tr>
<td>Social</td>
<td>37.50</td>
<td>45.75</td>
<td>50.75</td>
</tr>
<tr>
<td>Cognitive</td>
<td>32.74</td>
<td>37.82</td>
<td>61.48</td>
</tr>
<tr>
<td>Meaning/spiritual</td>
<td>38.30</td>
<td>93.50</td>
<td>100.00</td>
</tr>
<tr>
<td>Total</td>
<td>41.02</td>
<td>56.07</td>
<td>63.91</td>
</tr>
</tbody>
</table>

*Based on item response theory–based total characteristic curve.

**Abbreviations:** FACIT-Sp, Functional Assessment of Chronic Illness Therapy - Spiritual Well-being Scale; KCCQ, Kansas City Cardiomyopathy Questionnaire; PHQ, Patient Health Questionnaire; PROMIS, Patient-Reported Outcomes Measurement Information System; QOL, quality of life.

<sup>a</sup>P < .001, Pearson correlation coefficient.
FIGURE 2. Confirmatory factor analysis of the 5 QOLVAD domains. Model-based factor loadings and standard errors are presented for each item. Model-based associations among factors are presented as correlations. Subscale loadings onto the multidimensional construct of QOL are presented. CFI, comparative fit index; FDS, factor determinacy score; QOL, quality of life; QOLVAD, Quality of Life with a Left Ventricular Assist Device; RMSEA, root mean square error of approximation; TLI, Tucker-Lewis index; WRMR, weighted root mean square residuals.
The expected ranges (Table 4) can be used to direct interpretation in the clinical setting. For example, the expected values for the physical domain based on this sample ranged from 25.17 to 83.83. Using these values as a guide, if a patient had a physical domain score of 50, the clinician would know this reflected average physical QOL. Similarly, the expected scores for the social domain ranged from 37.50 to 50.75. Therefore, if a patient presented with a social domain score of 50, the clinician would understand that this was reflective of very high social QOL. The range of scores in clinical practice is expected to be narrower for the emotional domain than for the other domains (Table 4), indicating that there is less variation among scores. This may be a finding unique to the current sample, and further evaluation is needed.

**Interpretability, Expected Norms, and Use of the Health-Related Quality of Life with a Left Ventricular Assist Device**

By providing expected norms for each subscale, we hope to provide clinicians with more easily recognizable ranges for areas of higher well-being versus lower well-being—areas for which their patients may benefit from discussion and referral (ie, for values out of expected range). For example, patients with low QOLVAD social domain scores may benefit from referral to their left ventricular assist device social worker, whereas those with decreasing scores in the emotional domain may warrant psychology or psychiatric referral. Patients with heart failure who report spirituality as important to their well-being may benefit from early engagement of their spiritual leaders during the left ventricular assist device evaluation process to assist with stress mitigation and emotional consolation. The QOLVAD may help identify patients in need of further education and/or counseling, especially those stressors that patients may be uncomfortable freely discussing with medical providers. For example, patients who report concerns about intimacy per the QOLVAD may benefit from counseling on strategies for improving sexual activity with an left ventricular assist device. Patients who score poorly on the QOLVAD physical domain may benefit from reenrollment into cardiopulmonary rehabilitation or evaluation for other comorbidities such as sleep apnea. Further longitudinal study is needed to identify responsiveness and clinically meaningful change in scores.

**Limitations**

Recruitment was conducted through nonsystematic convenience sampling. In this initial study of psychometrics, limitations include minimal data regarding clinical characteristics and a relatively small sample for psychometric analysis. In comparison with characteristics from the contemporary cohorts described from 2014 to 2018 in the INTERMACS report, the characteristics of the present sample were fairly reflective of age, gender, and reason for left ventricular assist device but less so for racial diversity. A predominately male sample is a persistent limitation among studies of patients with an left ventricular assist device. Data from 7 different sites represented generalizability for geographic areas and clinical practices, but evaluation of the QOLVAD among other ethnicities and cultures is necessary, including testing for translation into other languages. Many patients in this sample had lived with a ventricular assist device for more than a year (43%, >2 years). Longitudinal scores would be needed to assess validity at different time points but, more importantly, to assess for responsiveness and minimally important differences.

**Conclusion**

In summary, we devised and tested a theoretically grounded HRQOL questionnaire for use in patients on durable left ventricular assist device support. Our findings support the initial reliability and validity of the QOLVAD; continued research is needed to confirm these psychometric qualities. With further testing, the QOLVAD has potential for use as an outcome in research studies as well as in clinical settings to facilitate shared decision making and mutual awareness of a patient’s perceived deficits and strengths, as well as to guide resources and referrals. Future longitudinal studies are needed to evaluate translatability, responsiveness, and clinically meaningful scores.

**REFERENCES**


