More than 5 million Americans are living with heart failure, with an additional 500,000 cases diagnosed each year. Ongoing improvements in patient management will only increase the number of patients surviving to develop severe refractory heart failure (stage D). Approximately 5% to 10% of all heart failure patients are classified as stage D and defined as patients who continue to have symptoms of dyspnea or fatigue at rest despite optimal medical management. Mechanical circulatory support (MCS) is an advanced surgical therapy for the treatment of stage D heart failure. Last year, >1500 patients in the United States were implanted with a left ventricular assist device (LVAD), an implantable system that supports the failing left ventricle. Implantation of an LVAD is an effective strategy to prolong survival and to improve the quality of life (QOL) of patients living with stage D heart failure. The indications for LVAD support include bridge to recovery (BTR), bridge to transplantation (BTT), or destination therapy (DT). The purpose of this article is to discuss QOL for patients supported on an LVAD. The discussion begins with an overview of QOL and how it is measured, followed by an in-depth review of QOL results in patients supported on an LVAD.

Quality of Life

QOL is a subjective evaluation that reflects a person’s overall appraisal of how happy, satisfied, and content he or she is with life. It differs from person to person on the basis of that person’s life experience, expectations, attitudes, values, and beliefs. Here, we define QOL as a person’s perception of the impact of a disease or treatment on her/his life. QOL is a multidimensional concept and includes aspects of physical, mental, and social functioning. Because it is a subjective evaluation, it cannot be measured directly. QOL can be measured indirectly with health status questionnaires or rating scales or described through qualitative research methodology.

Health status questionnaires describe a person’s functioning in 1 or more domains, eg, physical and emotional. Patients are asked to answer a series of questions designed and tested to represent the concepts or constructs of interest. QOL is “quantified” by converting answers to numeric scores that can be summed to provide total and subscale scores. Health status questionnaires can be generic or disease specific. Generic instruments such as the Short Form-36 provide information on QOL that is applicable to a number of disease states (see Table 1). These generic tools are useful for general survey research in which results can be compared across disease groups.

The Minnesota Living With Heart Failure Questionnaire (MLHFQ) and Kansas City Cardiomyopathy Questionnaire are reliable and validated health status questionnaires specific to patients living with heart failure (see Table 1). When used to measure the effectiveness of an intervention, the MLHFQ and the Kansas City Cardiomyopathy Questionnaire should be administered with a measure of physical functioning (see Table 1). Cardiopulmonary testing is the most comprehensive measure of physical function but requires specialized equipment and trained personnel, which limit its use. The 6-minute walk test measures the distance a patient can walk on level ground in 6 minutes. It is inexpensive, reproducible, objective, and simple to use and has been shown to be an adequate alternative to cardiopulmonary testing.

Visual analog rating scales are 100-mm vertical or horizontal lines that measure a patient’s overall perception of their QOL. The lines have anchor points of 0 (extremely poor QOL) and 100 (excellent QOL). Patients are asked to place a mark across the line that they feel represents their overall QOL. The number of millimeters between the anchor point and the patients’ line represents the score. Rating scales are quick, simple, and inexpensive with documented reliability and validity and have been shown to correlate with other measures of QOL.

Qualitative measures have also been used to describe the experience of patients living on LVAD support. A qualitative study usually represents a specific philosophical perspective that may then prescribe specific techniques for the collection and analysis of data. Sample sizes are small, but each participant contributes a considerable amount of information.
The data are then analyzed to identify concepts and relationships common to the sample as a whole. Results from qualitative studies provide insight into the challenges patients face when living with heart failure or when on MCS.

Literature Review

A systematic search of the MEDLINE and CINAHL databases was conducted through the use of search terms for ventricular assist devices, percutaneous, paracorporeal, or intracorporeal devices implanted as a BTR, bridge to candidacy (BTC), BTT, or DT. Search terms for QOL included health status indicators, specific scales used to measure QOL, physical functioning status, and emotional response to heart failure. The search used “all age groups” to ensure that pediatric studies were included. Titles and abstracts of 939 identified studies were reviewed (by J.M.), and potential studies for further screening were collected. Additional studies were identified by searching the reference list of reviewed publications. Studies were included if they reported QOL, physical functioning, or emotional/psychological distress of patients supported on a VAD. There were no studies that assessed QOL and/or physical and emotional functioning for pediatric patients supported on extracorporeal membrane oxygenation or VAD or for any patients supported on biventricular devices or a total artificial heart or requiring temporary support with a percutaneous or paracorporeal device. Fifty-seven studies assessing QOL, physical functioning, and emotional health of patients implanted with an LVAD were identified. A summary of QOL results from LVAD clinical trials is displayed in Table 2. The remaining discussion focuses on QOL issues that are pertinent to current and future care of patients supported on an LVAD.

Important Trends

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) is a mandatory US registry that collects and reports data on the use of Food and Drug Administration–approved devices in the United States. INTERMACS categorizes VAD patients on the basis of patient eligibility for transplantation—BTR, BTT, bridge to candidacy (BTC)—or as DT. Analysis of the 2011 INTERMACS report suggests 3 important trends that affect our understanding of QOL for patients on MCS.

1. The proportion of North American patients who recover cardiac function and have the device explanted remains small.
2. The majority of patients continue to be implanted under the BTT or DT strategy, and the QOL for these groups has been well described in the literature. There has also been a marked increase in the number of patients implanted under the DT strategy since the HeartMate II (HM2) was approved for this use in February 2010.
3. A considerable number of patients are being implanted under the BTC strategy, a strategy that does not have Food and Drug Administration approval, including patients who are implanted without any definitive decision on transplantation eligibility. QOL has not been adequately described for this group.

Table 1. Summary of Instruments Used to Measure Quality of Life, Physical Function, and Emotional Health for Left Ventricular Assist Device–Supported Patients

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Scoring</th>
<th>Interpretation</th>
<th>Clinical Significance (Approximate Values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLHFQ&lt;sup&gt;5,7&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>0–105</td>
<td>Higher scores = worse QOL</td>
<td>NYHA I, &lt;20</td>
</tr>
<tr>
<td>Physical</td>
<td>0–40</td>
<td></td>
<td>NYHA II, 20–40</td>
</tr>
<tr>
<td>Emotional</td>
<td>0–25</td>
<td></td>
<td>NYHA III, 40–60</td>
</tr>
<tr>
<td>NYHA IV, &gt;60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KCCQ&lt;sup&gt;6&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall summary score</td>
<td>0–100</td>
<td>Higher scores = better QOL</td>
<td>NYHA I, &gt;80</td>
</tr>
<tr>
<td>Clinical summary score</td>
<td>0–100</td>
<td></td>
<td>NYHA II, 60–80</td>
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<tr>
<td>NYHA III, 35–60</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NYHA, &lt;35</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Short Form-36&lt;sup&gt;6&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total (physical and mental components)</td>
<td>0–100</td>
<td>Higher scores = better QOL</td>
<td>Population norms (US), 50</td>
</tr>
<tr>
<td>Euro-Qol, VAS&lt;sup&gt;9&lt;/sup&gt;</td>
<td>0–100</td>
<td>Higher scores = better QOL</td>
<td>Minor depression, 10–18</td>
</tr>
<tr>
<td>Moderate depression, 19–30</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Major depression, &gt;30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BDI&lt;sup&gt;10&lt;/sup&gt;</td>
<td>1–63</td>
<td>Higher scores = greater depression</td>
<td>NYHA III, 14–16 mL·kg&lt;sup&gt;−1&lt;/sup&gt;·min&lt;sup&gt;−1&lt;/sup&gt;</td>
</tr>
<tr>
<td>NYHA IV, &lt;14 mL·kg&lt;sup&gt;−1&lt;/sup&gt;·min&lt;sup&gt;−1&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Peak V&lt;sub&gt;O2&lt;/sub&gt;&lt;sup&gt;11&lt;/sup&gt;</td>
<td></td>
<td>Higher scores = better peak VO2</td>
<td>NYHA III, 371 m</td>
</tr>
<tr>
<td>NYHA IV, 324 m</td>
<td></td>
<td></td>
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<tr>
<td>6MWT&lt;sup&gt;11&lt;/sup&gt;</td>
<td></td>
<td>Distance walked on level ground in 6 min</td>
<td>NYHA III, 371 m</td>
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<tr>
<td>NYHA IV, 324 m</td>
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</table>

MLHFQ indicates Minnesota Living With Health Failure Questionnaire; QOL, quality of life; NYHA, New York Heart Association; KCCQ, Kansas City Cardiomyopathy Questionnaire; VAS, visual analog scale; BDI, Beck Depression Inventory; and 6MWT, 6-minute walk test.
Bridge to Recovery

BTR refers to patients who are supported on an LVAD and demonstrate adequate cardiac recovery to allow device explantation. The number of patients in North America who recover left ventricular function and have the device removed is small.3 The Royal Brompton and Harefield NHS Trust reported a 63% rate of cardiac recovery and LVAD explantation in patients with nonischemic dilated cardiomyopathy supported on an HM2 with median support duration of 248 days.24 Patients supported on an HM2 who recovered function and had the device explanted (BTR; n = 14) had significantly better QOL and emotional health than patients who were supported on an HM2 and were transplanted (BTT; n = 29) or were transplanted without LVAD support (transplantation; n = 29).25,26 Physical health was also higher in the BTR group than either the BTT or transplantation group but was not statistically significant.25 It is important to note that the patients supported on an HM2 were on average 36 years of age, almost a decade younger than patients who participated in the HM2 LVAD clinical trials.25 Age has been shown to affect QOL ratings and is an important variable to note when QOL results are compared across studies.27–30 The results of these studies suggest that QOL is better for patients who recover cardiac function and have the device removed than for patients who go on to transplantation either bridged by LVAD or not bridged. However, the Royal Brompton and Harefield NHS Trust remains the only center reporting these high recovery rates for patients on LVAD support.

QOL: LVAD Clinical Trials

Results from LVAD clinical trials suggest that improvements in QOL can be seen as early as 1 to 3 months after implantation and are sustained for the duration of support.20–23,31 Table 2 provides a summary of quality of life measurements for left ventricular assist device clinical trials.

<table>
<thead>
<tr>
<th>Device/Trial</th>
<th>Actuarial Survival, %</th>
<th>QOL</th>
<th>Implant LOS, d (% Discharged)</th>
<th>Comment</th>
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<tbody>
<tr>
<td></td>
<td>3 mo</td>
<td>6 mo</td>
<td>12 mo</td>
<td>24 mo</td>
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<tr>
<td>Pulsatile pumps</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HeartMate VE/REMATCH18 (n = 68)</td>
<td></td>
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<tr>
<td>Short Form-36 (mean), %</td>
<td>62</td>
<td>52</td>
<td></td>
<td></td>
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<tr>
<td>Physical function</td>
<td></td>
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<tr>
<td>Emotional role</td>
<td></td>
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<td></td>
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<tr>
<td>MLHFQ (mean)</td>
<td></td>
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<tr>
<td>Heartmate XVE–DT arm HM2 trial19 (n = 59)</td>
<td></td>
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<tr>
<td>MLHFQ (mean)</td>
<td>75</td>
<td>75</td>
<td>55</td>
<td>24</td>
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<tr>
<td>KCCQ (mean)</td>
<td></td>
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<tr>
<td>Axial flow pumps</td>
<td></td>
<td></td>
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<tr>
<td>HeartMate II–BTT arm HM2 trial20 (n = 281)</td>
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<tr>
<td>MLHFQ (mean)</td>
<td>82</td>
<td>73</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>KCCQ (mean)</td>
<td></td>
<td></td>
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<tr>
<td>HeartMate II–DT arm HM2 trial19 (n = 133)</td>
<td></td>
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<tr>
<td>MLHFQ (mean)</td>
<td>80</td>
<td>68</td>
<td></td>
<td></td>
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<tr>
<td>KCCQ (mean)</td>
<td></td>
<td></td>
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<tr>
<td>HeartMate II–FDA postapproval study21 (n = 168)</td>
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<tr>
<td>EQ-5D VAS</td>
<td></td>
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<tr>
<td>Jarvik 200022 (n = 29)</td>
<td></td>
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<tr>
<td>MLHFQ (mean)</td>
<td>90</td>
<td>85</td>
<td></td>
<td></td>
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<tr>
<td>Centrifugal pump</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Heartware23 (n = 50)</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>KCCQ (mean; n = 28)</td>
<td>90</td>
<td>84</td>
<td>79</td>
<td></td>
</tr>
</tbody>
</table>

QOL indicates quality of life; LOS, length of hospital stay at implantation; REMATCH, Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure; MLHFQ, Minnesota Living With Health Failure Questionnaire; HM2, HeartMate II; KCCQ, Kansas City Cardiomyopathy Questionnaire; BTT, bridge to transplantation; DT, destination therapy; FDA, Food and Drug Administration; EQ-5D VAS, EuroQoL visual analog scale.

*P < 0.001.
†P < 0.05.
functioning. Studies using cardiopulmonary testing to measure physical function in LVAD-supported patients suggest that patients achieve their peak \( V\dot{O}_2 \) \( \approx 50\% \) to 60\% predicted for age and sex, by 3 months after implantation.\(^{32-34}\) For patients supported on an HM2, repeat testing at 6 months demonstrated significantly higher peak \( V\dot{O}_2 \) compared with results at 3 months.\(^{33}\) Additionally, implantation of an HM2 LVAD significantly increased the distance that patients could walk between baseline (42 m) and 3 months after implantation (292 m).\(^{31}\) Improvements in 6-minute walk test distance were maintained but did not change significantly for the duration of the follow-up period.\(^{20}\) At 1 year, patients implanted with either a HeartMate XVE or an HM2 device were able to walk an average of 393 m, which the authors described as comparable to the distance that patients with NYHA functional class I or II symptoms of heart failure could walk.\(^{35}\) These objective measures of physical functioning suggest that patients have the aerobic capacity for normal activities of daily living by 3 months after implantation.\(^{31-35}\) However, detailed data describing which activities patients are engaging in after implantation are negligible. Understanding the rationale for nonparticipation may help clinicians tailor programs that meet patients’ needs while promoting exercise. Patients need to understand that exercise is an important component that allows them to take an active role in their recovery.

In a subset analysis of the BTT arm of the HM2 trial, Bogaev et al\(^{36}\) compared the outcomes of 361 men and 104 women. There was no difference in survival between the 2 groups at 18 months. Women had longer support times with an average of 422 days compared with 315 days for men. The greatest improvement in QOL for men was realized at 1 month, whereas women took up to 3 months to achieve similar results. The MLHFQ scores at 1 month (men, 58; women, 73) were different, suggesting that women on LVAD support have poorer QOL early after implantation. However, by 6 months, there was no statistical difference between the 2 groups.

The results of this study suggest that women supported on an HM2 device have QOL and survival outcomes similar to those of men. However, women had longer support times, possibly explained by higher levels of panel reactive antibodies, which may make finding a suitable donor organ more challenging. Currently, \( \approx 22\% \) of BTT patients are women.\(^3\) The fact that there are fewer women than men on LVAD support has previously been attributed to the larger body size of women, which may make finding a suitable donor organ more challenging. Currently, \( \approx 22\% \) of BTT patients are women.\(^3\) The availability of smaller, continuous-flow pumps means that more women will be considered candidates for MCS. Moreover, we may see an increase in the number of women implanted with an LVAD as centers choose to support highly sensitized patients for an extended duration while waiting for an appropriate donor heart to be found.\(^{37}\)

In a single-center subgroup analysis of the HM2 data, Adamson et al\(^{38}\) compared the outcomes of patients <70 years (n=25) and \( \geq 70 \) years (n=30) of age supported on an HM2. Support times, survival rates, and hospital lengths of stay were comparable between the 2 groups. QOL measured with the MLHFQ and the Kansas City Cardiomyopathy Questionnaire improved over time, and at 6 months, there was no difference between the 2 groups. However, the data showed that younger patients experienced a 20-point improvement in MLHFQ scores between 1 and 3 months, whereas older patients did not experience similar improvements in MLHFQ scores until 3 to 6 months after implantation. Similar results are reported for both the Kansas City Cardiomyopathy Questionnaire and the 6-minute walk test. Older age has always been a factor in decision making in terms of candidacy for heart transplantation or LVAD implantation. Some programs have established age cut points that prohibit transplantation; others consider age a relative contraindication and consider older patients for transplantation if the remainder of the assessment is acceptable. Many older patients who are not eligible for transplantation may be candidates for MCS. However, there is concern about the ability of older patients to adapt to the technology and to perform the activities required for safe device maintenance. For example, osteoarthritis may limit manual dexterity and make battery and controller changes challenging. The results of this study suggest that older patients who are deemed appropriate candidates will adapt to the technology and over time will experience an acceptable level of QOL.

The DT arm of the HM2 trial was a head-to-head comparison of patients supported by either the HeartMate XVE (n=66) or the HM2 (n=134).\(^{39}\) QOL was significantly better 3 months after implantation with no difference between groups. At 1 year, patients supported on the HM2 had significantly better QOL as measured by the MLHFQ than patients supported on the HeartMate XVE. Slaughter et al\(^{39}\) suggested that improvements in QOL could be explained by the lower rates of device failure and driveline infection and fewer hospital readmissions for device-related complications in patients on the HM2.

Rogers et al\(^{39}\) compared QOL and functional outcomes between patients enrolled in the BTT arm (n=281) and the DT arm (n=374) of the HM2 trial. Patients enrolled in the DT arm were significantly older, more frequently had an ischemic type of heart failure, had lower systolic blood pressure, had worse renal function, and were less likely to be on intravenous inotropes compared with BTT patients. There were no differences in QOL or 6-minute walk test scores at baseline or 3 or 6 months after implantation. Rogers et al\(^{39}\) compared their results with the results of cardiac resynchronization therapy for patients with stage C heart failure.\(^{39,40}\) At 6 months, patients in the DT arm of the HM2 trial were able to walk 100 m further and had lower NYHA functional class than patients in the cardiac resynchronization therapy trial.\(^{39,40}\) Although not a randomized study, this provocative comparison suggests that at 6 months patients implanted with an HM2 have better functional status than patients receiving cardiac resynchronization therapy. This finding may be relevant to decision making for patients considering LVAD implantation as an alternative to transplantation. Patients who express a preference for QOL may prefer to forgo cardiac resynchronization therapy and proceed directly to LVAD implantation. Earlier implantation of an LVAD would allow them to achieve the improvements in overall QOL and functional status sooner rather than waiting to see whether cardiac...
resynchronization therapy is effective. Results from the Randomized Evaluation of VAD Intervention Before Inotropic Therapy (REVIVE-IT), a clinical trial randomizing patients with NYHA functional class III heart failure to LVAD versus optimal medical management, will provide us with more objective information describing and comparing the differences in QOL between these 2 patient groups.

The majority of information on LVAD QOL has been generated from LVAD clinical trials conducted in patients who were either accepted and listed on the transplant waiting list (BTT trials) or deemed ineligible for transplant (DT trials). However, results from the INTERMACS annual report identify that within the last year, 43% of LVAD recipients were implanted under the BTC strategy. Patients implanted under the BTC strategy are patients who are deemed ineligible for transplantation typically because of potentially reversible conditions such as pulmonary hypertension or renal impairment that may correct on LVAD support. During recruitment for clinical trials, BTC patients would have been included in the DT group. In the DT arm of the HM2 trial, 26% of patients became transplant eligible and received a transplant after a period of support on the HM2 device. Patients implanted as BTC make the decision to proceed with LVAD implantation, knowing that they may become eligible for transplantation or may live the remainder of their lives on support. For some BTC patients, not knowing their transplant eligibility status may increase uncertainty until they have a decision. Living with uncertainty increases emotional distress and may have a negative effect on overall QOL. The BTC group represents a large segment of the LVAD population in whom QOL has not been adequately assessed. Longitudinal studies measuring QOL, physical functioning, and emotional health are required to understand how patient decisions to proceed with BTC and transplant eligibility affect outcomes and to describe how QOL changes over the course of BTC support.

Emotional Distress
Results from LVAD clinical trials suggest that overall QOL and physical functioning are significantly improved after LVAD. However, emotional distress is an important component of QOL that has not been adequately assessed in LVAD clinical trials. The majority of information on emotional distress was generated in psychosocial studies during the era of pulsatile support. Although this information is largely historical, it provides relevant information on the emotional challenges patients face after LVAD implantation. The immediate postoperative period has been associated with an increase in negative emotions resulting from having heart surgery, fear of device failure, and being hospitalized. During this period, patients and their families must learn the day-to-day management of the device, troubleshooting alarm states while recovering from major cardiac surgery. Learning may be compromised by postoperative pain, fatigue, anxiety, and/or the cognitive changes associated with heart failure. Studies during the era of pulsatile support suggest that levels of emotional distress did not change from before to after LVAD implantation. It is difficult to determine if the absence of any significant change is due to static levels of specific emotions or, as we suspect, if a decrease in depression is offset by an increase in anxiety. Depression seems to decrease immediately after surgery, although not statistically significantly. Other studies have reported a significant decrease in depressive symptoms after discharge home. Potential device complications and device failure have been identified as increasing anxiety after implantation of an LVAD. It takes time for patients and their families to feel comfortable managing the day-to-day care and to become proficient at handling alarm states.

Very little research has been done describing the emotional responses of patients supported on a continuous-flow device. Moreover, the emotional response described in early studies was conducted with samples of BTT patients with a limited support time until transplantation. It is important to understand how specific emotions change over the course of LVAD support. The improved reliability and durability of the continuous-flow devices may decrease anxiety associated with managing the device and being dependent on a LVAD to sustain life. On the other hand, the improved reliability and durability mean that LVAD patients are supported longer, and anxiety or depression may increase later in the course of support. We do not know how the emotional responses differ for patients with longer support times or those nearing end of life (EOL). Finally, the majority of studies measuring emotional distress for patients supported on an LVAD use quantitative instruments that have documented reliability and validity. These instruments focus on a medicalized interpretation of emotional distress: depression, anxiety, and posttraumatic distress disorder. Results from qualitative studies suggest that patients may be experiencing emotional distress not easily captured by quantitative instruments. Research using mixed methods or qualitative analysis is needed to advance the knowledge of emotional distress during LVAD support.

Cognitive Function
Cognitive functioning is a component of emotional health that has been shown to be compromised by LVAD support. Patients supported on a pulsatile pump had significantly worse scores on the Mini-Mental Status Examination at 2, 7, and 12 months after heart transplantation compared with patients who did not have LVAD support before heart transplantation. After heart transplantation, patients supported on a pulsatile pump also had higher levels of social isolation and lower participation rates in social activities than patients who were not LVAD supported before transplantation. Understanding how cognition changes from before to after LVAD implantation and again after heart transplantation is challenging. Many patients do not have the energy to complete the complex battery of tests required for the comprehensive assessment of cognitive function before LVAD implantation. Results from the BTT arm of the HM2 trial suggest that overall cognitive function did not decrease over the duration of support and that significant improvements were seen in memory, executive function, and motor speed at 3 months. More research is needed to better understand the effects of LVAD support on cognitive function.

Sleep Disruption
Sleep disruption has also been reported for patients supported on either a pulsatile- or continuous-flow device. In a small
sample of 38 patients supported on a pulsatile pump, the position of the driveline and noise from the device were associated with a significant reduction in physical, emotional, and social functioning and overall QOL. Specifically, patients who identified a concern with driveline position and noise during sleep were more likely to have higher levels of anxiety and depression than those who were less concerned with these issues. Issues with noise have been eliminated with the silent operation of continuous-flow devices. However, a recent study on LVAD-disrupted sleep suggests that sleep remains an issue for patients supported on continuous-flow pumps. Casida and colleagues asked 13 patients to wear a wrist actigraph (an objective measure of sleep) for 3 consecutive days and nights at 6 different times while supported on an HM2. Patients reported marked sleep disruptions that persisted up to 6 months after implantation. On average, patients took almost 20 minutes to fall asleep, had poorer sleep efficiency, and had a total sleep time of 6.5 hours. The results of these studies suggest that patients supported on an LVAD experience sleep disruptions that may be associated with significant increases in levels of anxiety and depression. Future studies are needed to elucidate the relationship between sleep and emotional distress. Strategies that improve sleep duration and quality may help lessen the emotional distress that patients experience during LVAD support.

Sexual Activity and Driving Restrictions

Two common concerns voiced by LVAD patients that have received very little attention in the research literature are sexual activity guidelines and driving recommendations. Samuels et al reported sexual concerns raised by 9 male patients supported on a HeartMate XVE. All patients were sexually interested and 5 were sexually active within 1 month of going home. All were concerned about the position of the driveline during intercourse. Women of childbearing age need to be counseled about birth control. The discussion needs to include information on effective birth control, the effective use of barrier methods, and options should pregnancy occur. Engaging in sexual activity and intimacy can improve QOL and make life more enjoyable for both patients and their partners.

Anecdotal evidence and first-person accounts suggest that driving restrictions increase dependence on others and reduce QOL. Most VAD centers err on the cautious side and counsel patients to avoid driving. In Canada, the Canadian Cardiovascular society has recently recommended that patients 2 months post continuous-flow device implant, who are doing well, are fit to hold noncommercial drivers’ licenses (www.ccs.ca). Despite recommendations to avoid driving, patients drive. In a single-center report, Emani et al conducted an anonymous survey to determine the proportion of patients who were driving and the device failure rates while driving. The survey response rate was only 30%, made up mostly of men between 56 and 65 years of age on HM2 support. Results suggest that almost 80% of their patients were driving, 3 had experienced a nonurgent alarm state, and 3 needed to change batteries while driving. No accidents occurred. Patients reported that the need to drive was related to activities of daily living: doing errands, buying groceries, and going to appointments. These results correspond to anecdotal and first-person accounts of driving activity within VAD programs. A larger study including both DT and BTC patients supported on continuous-flow pumps is needed. Driving promotes independence and normalizes routines and activities that patients think are important components of an acceptable QOL.

EOL Issues

Implantation of an LVAD is a treatment, not a cure, and the decision to proceed must be made in this context. Treatment goals should include what the patient/family is hoping to achieve with implantation—heart transplantation, survival time, and/or improved QOL—and a discussion about patient EOL treatment preferences. Advanced care directives, or living wills, are documents that allow mentally competent patients to maintain control over their medical care should they lose their decision-making capacity. They include information on what decisions should be made and who should make them (the identification of a substitute decision maker or surrogate). Working through the decisions surrounding advanced care directives gives patients a way to think about dying and facilitates discussions with their family and the healthcare team about their wishes. Engaging in open and frank EOL discussions before LVAD implantation gives patients a sense of control over their lives and helps minimize the burden of decision making for family should the patient become incapacitated.

Programs must be able to manage patients who are symptomatic as a result of complications of VAD support. The inability to accurately predict which patients will have significant post-VAD complications that may limit survival time or QOL suggests that clinicians need to be aware of patients’ treatment goals and advanced care directives. Treatment goals and advanced care directives should be reviewed when the patient experiences any significant untoward event that changes the goals of support. Postoperative catastrophic sepsis or stroke may result in a patient having no reasonable chance of receiving a heart transplant, surviving to leave the hospital, or experiencing any meaningful recovery. Most programs are comfortable initiating discussions about LVAD withdrawal in these situations. Other postoperative complications such as renal failure necessitating hemodialysis, chronic driveline infection, device endocarditis, or persistent right heart failure should also trigger a review. These situations could result in transplant ineligibility or could result in a reasonable life expectancy but with an overall poor QOL. Patients who are experiencing poor QOL may want to alter treatment goals or to proactively plan for LVAD withdrawal. In a study of 69 DT patients, Brush et al found that a reduction in overall QOL and reduced physical capacity triggered EOL discussions. Twenty patients actively participated in the decision to withdraw support: 17 elected to actively withdraw support and 3 preferred to wait until they lost consciousness before having the device turned off. Time from discussion to device withdrawal ranged from 1 to 14 days, and death occurred within 20 minutes of stopping the pump. Future research needs to identify what that QOL threshold is to help clinicians develop effective guidelines for EOL decision making.
Some patients consider LVAD implantation for relief of the unpleasant symptoms associated with refractory heart failure despite the risk of surgery and/or limited survival time. It may seem paradoxical, but advances in pump design and minimally invasive approaches suggest that LVAD implantation could soon be considered a palliative strategy. Palliative care is directed at improving QOL based on patient and family needs, independently of prognosis and in conjunction with other therapies that are intended to prolong life. Collaborating with members of the palliative care team can help LVAD clinicians develop the skills required to effectively manage this challenging patient population. Providing effective palliative care means being prepared to manage patients with unexpected or complicated outcome; to assess and treat pain, dyspnea, and depression; and to ensure that care reflects patient wishes concerning EOL care as much as possible. Developing programs that include palliative care and effectively address LVAD EOL is necessary to meet the needs of this growing patient population.

Conclusions
LVADs significantly improve quality of life and QOL for patients living with stage D heart failure. Improvements in QOL and physical functioning are seen at 3 months after implantation and remain acceptable throughout the duration of support for patients supported on either a pulsatile-flow or continuous-flow device. Although outcomes are the same as in other LVAD-supported patients, women and older patients take longer to achieve significant improvements in QOL. Longer transplant wait times and high panel reactive antibodies suggest that the proportion of patients being implanted with an LVAD device will continue to increase. Similarly, the proportion of patients being implanted as DT has risen since the HM2 was approved for DT in the United States. Understanding the factors that affect QOL may help us appreciate how QOL changes for different groups of patients on support.

Many patients continue to experience at least some level of emotional distress after implantation. Emotional distress is related to living on a device and includes uncertainty, fear of device failure, and anxiety, types of distress not easily captured by quantitative instruments. Future research needs to consider the use of mixed methods and qualitative studies in addition to health-related QOL measures to better understand how emotional health changes on support. Information on QOL for patients on LVAD support was generated in samples of patients supported on pulsatile pumps. The majority of patients currently implanted with an LVAD are supported on continuous-flow pumps implanted as BTC or for DT. Future research needs to include prospective studies with QOL metrics across the duration of support. Issues such as sleep, driving recommendations, and sexual activity guidelines are important to patients. Research studies that address these patient-generated concerns are an important element of effective patient care that could have considerable impact on QOL.

As the MCS field continues to evolve, we can anticipate that a greater number of patients will be implanted with an LVAD and will have longer support times. Advanced care directives need to be addressed before implantation of an LVAD and revisited with any significant change in patient status. Strategies that include LVAD EOL and palliative care are necessary to manage patients supported for long periods of time or patients who are living with unpleasant symptoms caused by complications of support.

Disclosures
None.

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