Artificial
Organs

Quality of Life and Emotional Distress Early After Left Ventricular Assist Device Implant: A Mixed-Method Study

*Maddalena Modica, *Maurizio Ferratini, *Anna Torri, †Fabrizio Oliva, ‡Luigi Martinelli, §Renata De Maria, and †Maria Frigerio

*Cardiac Rehabilitation S. Maria Nascente, IRCCS Fondazione Don Gnocchi; and †Heart Failure and Heart Transplant Program, ‡Cardiac Surgery, and §CNR Clinical Physiology Institute, CardioThoracic and Vascular Department, Niguarda Ca' Granda Hospital, Milan, Italy

Abstract: Patients who temporarily or permanently rely on left ventricular assist devices (LVADs) for end-stage heart failure face complex psychological, emotional, and relational problems. We conducted a mixed-method study to investigate quality of life, psychological symptoms, and emotional and cognitive reactions after LVAD implant. Twenty-six patients admitted to cardiac rehabilitation were administered quality of life questionnaires (Short Form 36 of the Medical Outcomes Study and Minnesota Living with Heart Failure Questionnaire), the Hospital Anxiety and Depression Scale, and the Coping Orientation for Problem Experiences inventory, and underwent three in-depth unstructured interviews within 2 months after LVAD implant. Quality of life assessment (Short Form 36) documented persistently low physical scores whereas mental component scores almost achieved normative values. Clinically relevant depression and anxiety were observed in 18 and 18% of patients, respectively; avoidant coping scores correlated significantly with both depression and anxiety (Pearson correlation coefficients 0.732, $P < 0.001$ and 0.764, $P < 0.001$, respectively). From qualitative interviews, factors that impacted on LVAD acceptance included: device type, disease experience during transplant waiting, nature of the assisted organ, quality of patient–doctor communication, the opportunity of sharing the experience, and recipient's psychological characteristics. Quality of life improves early after LVAD implant, but emotional distress may remain high. A multidimensional approach that takes into account patients' psychological characteristics should be pursued to enhance LVAD acceptance. **Key Words:** Mechanical circulatory support—Quality of life—Qualitative interview—Avoidant coping—Left ventricular assist device—Psychological symptoms.

Over the last 20 years, the insufficient supply of transplantable organs and the growing number of patients with contraindications to heart transplant (HTx) has prompted the development of temporary and permanent mechanical circulatory support by left ventricular assist devices (LVADs) for severe heart failure (HF) refractory to optimal medical therapy. LVADs are currently indicated for end-stage HF, as a bridge in patients awaiting HTx and as destination therapy in those who are ineligible for transplantation (1). With technological progress, the introduction in clinical practice of second-generation nonpulsatile flow pumps has allowed increasingly longer support and better survival rates that achieve 80 and 70%, at 1 and 2 years, respectively (2), without significant differences between LVAD and HTx recipients.

Latest generation LVADs are mechanically reliable, smaller, less noisy, more durable, and less complex to manage than previous models. However, the burden of complications remains high, with only about one-third of patients free from major adverse events at 1 year. Living with a device that mechanically supports cardiac function creates complex and peculiar psychological problems concerning the process of consensual acceptance and acceptability, that is, the possibility of adjusting to and living with an LVAD.

The studies that combined assessment of LVAD efficacy, in terms of improved hemodynamics,

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Address correspondence and reprint requests to Dr. Maurizio Ferratini, Cardiac Rehabilitation S. Maria Nascente, IRCCS Fondazione Don Gnocchi, Via Capecelatro 66, Milan 20148, Italy. E-mail: mferratini@dongnocchi.it

survival, and complications, with an evaluation of patients' perception of changes in quality of life (QOL), mainly focused on physical functioning (3–9). Discrepancies in perception of well-being between physicians and patients have long been recognized (10): clinicians generally focus on the physical manifestation of the disease, whereas patients consider vitality, role limitations, emotional problems, and mental health as critical determinants of overall disease burden. Qualitative methods to assess QOL have been demonstrated to yield information that would be missed using only quantitative questionnaires (11). The experience of living with a transplant and the psychosomatic integration of the graft have been well described (12,13). Previous qualitative studies in continuous flow LVADs (14–16) included small numbers of patients interviewed at different times, and often late, after the procedure, and did not concomitantly obtain quantitative QOL measures.

The aim of the present study was to investigate quality of life, psychological symptoms in conjunction with the emotional and cognitive reactions to LVAD implantation, and device acceptance and acceptability in the early period after implant.

PATIENTS AND METHODS

We studied 28 patients implanted with an LVAD at the CardioThoracic and Vascular Department of Niguarda Hospital from March 2010 to November 2013, who were consecutively discharged to our Cardiac Rehabilitation Unit. Patients gave informed consent to participate in the study, which was approved by the Institutional Ethics Committee. Patients aged >18 years with a good command of the Italian language were enrolled. The indication for LVAD was bridge to transplant in 22 patients and destination therapy in six patients.

All patients underwent three or more face-to-face in-depth psychological interviews during the second month after LVAD implant. Interviews were performed by MM, a psychologist experienced in cardiac rehabilitation, in the inpatient setting, when the patient was clinically stable. Unstructured, open-question, interviews lasting about 1 h focused on the experience of disease before implant and recovery thereafter. Field notes were reviewed and main themes were highlighted by quoting patients' own words or sentences.

QOL was assessed by validated instruments previously used in studies on LVAD patients (9), the Short Form 36 of the Medical Outcomes Study (SF36) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Psychological characteristics related to disease experience were investigated using the Hospital Anxiety and Depression Scale (HADS) (17) and the Coping Orientation for Problem Experiences (COPE) inventory (18). HADS attempts to measure anxiety and depression without the confounding effects of somatic symptoms of physical disorders. COPE measures coping styles in our national context and is based on a model that identifies five-factor solution: (i) social support; (ii) avoidance strategies; (iii) positive attitude; (iv) planning/activity; and (v) turning to religion.

A subgroup of 15 patients also underwent the study assessments before LVAD implant and another subgroup of eight subjects after 6 months.

Statistical analysis

Data are presented as mean and standard deviation or frequency (%). Correlations between HADS scores and COPE—Nuova Versione Italiana (COPE-NVI) items were explored by Pearson's correlation coefficient. Pre- and postimplant values in QOL indices and HADS scores were compared by paired Student's *t*-test. Statistical analysis was performed using the Statistical Package for the Social Sciences SPSS 17.0 software (SPSS, Inc., Chicago, IL, USA). Significance level was set at $P < 0.05$.

RESULTS

Patients

The clinical characteristics of study patients are summarized in Table 1. Type of device implanted was HeartMate II (Thoratec Corporation, Pleasanton, CA, USA) in 26 patients and HeartWare in 2 (HeartWare, Framingham, MA, USA). Mean duration of mechanical support was 16 ± 12 months (range 1.5–38). After 10 ± 2.5 months, four patients were eventually transplanted; one of these died soon after HTx due to right HF. Eight patients died after 19 ± 11 months. Causes of death were lymphoma in one patient, cerebral hemorrhage in three, sepsis in three, and suicide in one. This patient had not achieved autonomous management of the device 18 months after LVAD implant, and was dependent on his wife for everyday activities; he hanged himself at home, soon after the hospitalization of his wife and caregiver for cancer.

Quality of life and psychological symptoms

QOL, coping scores, and psychological symptoms are depicted in Table 2.

TABLE 1. *Characteristics of the study population*

	$N = 28$
Age, years	54 ± 11
Years since diagnosis of HF	9 ± 6
Male	27 (96%)
Lives alone	3 (11%)
Etiology of HF	
Ischemic	15 (54%)
Idiopathic	13 (46%)
INTERMACS level	
1 Critical cardiogenic shock	3 (11%)
2 Progressive decline on inotropes	10 (36%)
3 Stable but inotrope dependent	9 (32%)
4 Symptoms at rest, repeated hospitalizations ("frequent flyer")	6 (21%)
Short-term complications*	
Major hemorrhage	6 (21%)
Driveline infection	7 (25%)
Intravascular thrombosis	2 (7%)
Arrhythmia	4 (14%)

* A patient may have more than one complication (1). Data are mean ± SD or number (frequency percent).

Early postimplant findings at the generic QOL instrument SF36 showed consistently lower physical symptom scores than observed in the general population, whereas emotional scores almost overlapped with normative data (19). Coping styles did not consistently differ from general population data, with the notable exception of higher values for avoidant coping and lower scores for planning activity items. QOL scores by the disease-specific questionnaire MLHFQ were roughly consistent with findings in HF patients in New York Heart Association class II–III (8).

Psychological characteristics highlighted the deep and lasting psychological effects of chronic severe HF: half of the patients had HADS scores diagnostic for both depression or anxiety, which were of borderline severity in 29 and 29% of subjects and clinically relevant in 18 and 18%, respectively. At the time of psychological assessment, 53% of the patients with diagnostic HADS scores for anxiety or depression were receiving benzodiazepines or selective serotonin reuptake inhibitors.

Avoidant coping significantly correlated with both anxiety and depression scores (Pearson's correlation coefficients 0.732, $P < 0.001$ and 0.764, $P < 0.001$, respectively).

Although no difference achieved statistical significance, the small group of patients who were examined at an average of 8.5 months postimplant showed improved HF symptoms, as assessed by the MLHFQ,

TABLE 2. *Quality of life scores and psychological characteristics*

	Postimplant time		Normative data*
	Early $N = 28$	Late $N = 8$	
SF36			$N = 1433$
Physical component	36.1 ± 7.1	37.5 ± 6,3	52.7 ± 7.7
Mental component	44.7 ± 11.2	46.6 ± 11.8	47.6 ± 10
COPE			$N = 472$
Social support	25.7 ± 6.9	24 ± 13.7	27.7 ± 8.4
Avoidance strategies	25.6 ± 6.9	23.2 ± 12	23.5 ± 5.1
Positive attitude	31.9 ± 8.5	30.1 ± 14.6	30.9 ± 6.0
Planning/activity	28.7 ± 10.5	24.7 ± 13.9	32.0 ± 6.7
Turning to religion	22.5 ± 4.3	17.1 ± 9.8	22.7 ± 5.6
MLHFQ			
Total score	43 ± 24	33 ± 22	
Physical dimension	16 ± 10	10 ± 10	
Emotional dimension	9 ± 7	10 ± 7	
HADS			
Anxiety	6.7 ± 5.2	9.4 ± 8	
Depression	6.4 ± 4.6	9.4 ± 7	

* Normative data are from Sica et al. and Ware et al. (18,19). Data are mean ± SD.

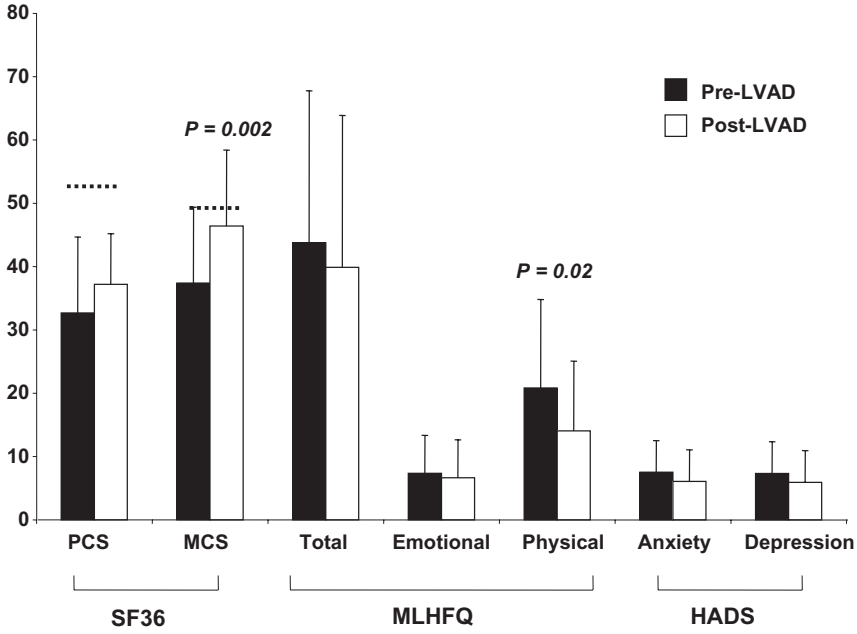

FIG. 1. Comparison of preimplant (dark bars) and postimplant (empty bars) values in quality of life scores and psychological symptoms in the 15 patients who were assessed before and after the procedure. The hatched lines mark normative values for the Italian population. MCS, mental component score; PCS, physical component score.

and normalized mental component SF12 scores; conversely, physical dimension scores still lagged behind (Table 2). However, psychological distress did not improve, as documented by higher average anxiety and depression scores, and a higher proportion of subjects with clinically relevant anxiety (29%) and depression (43%). Furthermore, worsening in coping items such as social support, planning, and turning to religion, was observed with respect to the early postimplant period.

When compared with patients with a bridge-to-transplant indication, subjects in whom an LVAD was implanted as destination therapy were unsurprisingly older (56 ± 11 vs. 63 ± 4 years, $P = 0.013$), but no other differences were observed in QOL or psychological distress.

The subgroup of 15 patients who were assessed both before and after LVAD implant showed improved QOL scores (Fig. 1) that achieved statistical significance for the SF36 mental component ($P = 0.002$) and the MLHFQ physical dimension score ($P = 0.02$). Psychological symptoms were not significantly different from baseline findings.

QOL results were used to complement the interpretation of qualitative findings obtained from personal unstructured interviews.

Qualitative interviews

Six main concepts were identified as important in influencing LVAD acceptance: the characteristics of the device, the experience of disease during the waiting time for HTx, the nature of the assisted organ, the quality of patient–doctor communication, the possibility of sharing the experience, and the psychological characteristics of the recipient.

The characteristics of the device

> "LVAD makes you independent from heart failure but does not allow an independent life."

Mechanical ventricular assistance has only recently been introduced into clinical practice, and most patients experience a certain mistrust for what is seen as a still unusual and extraordinary device, and about its reliability over time. They tend to perceive the LVAD as "experimental" and as less trustworthy than more common devices, such as pacemakers or defibrillators, or than interventions that are now considered consolidated surgical procedures such as HTx. Furthermore, the physical characteristics of the device make it a "prosthetic organ." LVAD management is related to the patient's cognitive ability and psychological status, as well as to the presence of a caregiver. An LVAD has a substantial impact on patients' perceived quality of life, as its complex management prevents them from recovering a satisfactory level of autonomy. The device also limits patients' social and relational life, and makes them dependent on caregivers, physicians, and specialized medical facilities.

The experience of disease

> "Waiting for a heart is like climbing: tiring, uncertain, dangerous. All available energy must be addressed to reach the top—the transplant."

The indication for an LVAD has become a part of the wait for HTx. This period is clinically marked by severe functional limitations, recurrent HF episodes, and frequent hospitalizations, and emotionally characterized by distress, impatience, frustration, and fear of dying, which often give rise to anxious/depressive syndromes (20–22). There is also a strong desire to return to lead a normal life. Patients often strive to cope by developing cognitive, emotive, and behavioral reactions aimed at preserving sufficient physical and emotional stability to reach the goal of HTx (22). The announcement that an LVAD is needed may jeopardize this effort, disorient the patient, and break the unstable equilibrium between the hope for life and the anxiety about death, amplifying fear. Patients defend themselves by means of more or less extended denial mechanisms that can have major effects on their perception of disease severity and device acceptance. LVAD may therefore be seen as an excessively invasive procedure and inappropriate for the severity of the disease.

The peculiar nature of the heart as diseased organ

> "When I think about transplantation, I feel guilty because I will change my heart."

The autonomous movement of the heart not only marks the beginning of life and death, but also accompanies the emotional life of any human being. The heart is an organ imbued with symbolic values, feelings, spirituality, and vitality. HTx is a profoundly transforming experience that is accompanied by feelings of guilt, "magic" thoughts that have to do with lost or acquired aspects of personality (23), and a need to ensure first the physical, and then the psychological and emotional integration of the new organ (*embodying*).

The implantation of a vicarious mechanical device also represents a complex transforming experience that has profound emotional and psychological implications related to the patient's sense of identity and integrity. The device remains a prosthetic organ, and its presence and the dependence it implies cannot and must not be forgotten. This cohabitation is characterized by the need to be attentive (the positioning of the external cable, care of the device, manual dexterity when changing the batteries, etc.) and rhythmically marked by the sound of acoustic alarms: its presence is both a physical and psychological encumbrance. Unlike the transplanted heart, it seems more appropriate to speak of temporary acceptability of the device rather than of an embodying process, which is in any case never actually complete.

Doctor–patient communication

> "I was able to think over the need of implanting an LVAD, because doctors did not communicate this option in an aggressive way; they described its potential as a bridge to transplantation."

The fear of not being able to survive until the time of transplantation, the fear of death, is accompanied by feelings of mistrust and worries about the possibility of slipping down the waiting list and being forgotten. Candidates to HTx may see the announced need for an LVAD as a threat. They become aware that to change the course of their disease, they must undergo more than one surgical intervention. They realize that the uncertain and prolonged waiting period for HTx will be further extended.

Doctor–patient communication can play a pivotal role in favoring the process of short- and long-term acceptance, provided that it responds to the patient's need for support and reassurance, and the possibility of exercising some sort of control over the disease. It is therefore essential that the method of communication be empathic and shared rather than authoritarian. Communication should aim to help the patient understand the positive effects of ventricular assistance and the need for mechanical circulatory support, without minimizing potential problems and adverse events related to an LVAD.

The opportunity to share the experience

Unlike other more widely used and accepted circulatory aids, LVADs are little known and commonly believed to be a therapeutic extreme. Sharing and knowing the experiences of other patients currently on LVAD, or who have previously had one implanted, allow LVAD candidates to express their fears and fantasies, offer the possibility of mirroring and minimizing the sense of loneliness and isolation, and provide an opportunity to acquire specific information concerning the practical aspects.

Psychological characteristics of the patient

Different people confront situations of change in different and specific ways. Patients not only have to face their fear of the disease and HTx, but they must also come to terms with the difficult process of adjusting to the physical, emotional, familial and social changes that an LVAD involves. The emotional/cognitive reactions to the implant are greatly influenced by patients' social and psychological characteristics: their personality, the presence of any psychological disorders, the degree of support they receive from their families and friends, cultural and religious factors, and the significance attributed to

the disease in relation to age, previous experiences, and future expectations (24).

DISCUSSION

The main finding of our mixed-method investigation, designed to assess the living experience of LVAD patients early after implant, is that, although perceived QOL improves, emotional distress may be sustained even in the mid term.

Quantitative QOL assessment and qualitative interviews appear to catch different aspects of patients' reactions and adjustment to such a complex life-transforming experience. Patient-reported outcomes and QOL studies in LVAD recipients have been recently reviewed (7,8). Suggestions for future research specifically addressed the need for mixed methods adding qualitative studies to health-related QOL measures to better understand emotional changes.

We used validated instruments previously employed in LVAD research to quantify changes in perceived QOL. MLHFQ has been specifically designed for use in patients with chronic HF. In LVAD cohorts, scores seem to decrease rapidly in the first 1 to 3 months after the procedure, and plateau thereafter (7,8). In our patients, who had a mean HF history of 8 years, MLHFQ findings were consistent with previous results obtained early after LVAD implant in patients on continuous flow support, and documented comparable improvements in physical and emotional dimensions linked to HF symptoms. Conversely, values of the generic instrument SF36, which tracks a broader dimension of QOL, closely approached normative data for the mental health component, while still showing significant limitations in physical scores, in accordance with the relatively short distance elapsed from the surgical procedure.

QOL questionnaires may however underestimate emotional distress, as areas that are problematic for LVAD recipients may not be specifically addressed. Moreover, a response bias, that is, answering what patients suppose that health personnel wants to hear, may also exist. Investigation in psychological symptoms confirmed that in our series emotional distress was common early after implant and did not decrease with time. Anxiety and depression were observed in 29% of our patients and were clinically relevant in almost one-fifth of subjects. Depression has been associated with higher mortality and readmission rates and poorer QOL in HF patients (25,26). Our findings for depressive symptoms were consistent with estimates for patients with advanced HF (25) and HTx candidates (21). Prevalence and prognostic significance of anxiety are controversial in HF patients (25,26), while most studies in patients on mechanical circulatory support were conducted on pulsatile flow LVAD (7).

Interestingly, psychological symptoms did not improve in the medium term, as demonstrated by higher average anxiety and depression scores than early postimplant, likely influenced by a complicated clinical course. Intercurrent complications have a deep impact on patients' perception of LVAD benefits. Patients with no or resolved complications showed better acceptance of the device and deeper trust in the health system than those who developed severe complications or prolonged in-hospital stays while on LVAD. These latter patients appeared dependent on health personnel, and at the same time intolerant of treatments, hospital setting, and LVAD, as highlighted by their frequent refusal to fill in follow-up QOL questionnaires; conversely they showed sustained appreciation for qualitative interviews and the opportunity to express their feelings.

Findings at qualitative interviews need to be put in perspective of our current national practice. In our country, the experience with mechanical circulatory support is still relatively limited: in 2012, 80 LVADs were implanted versus 231 HTx procedures. HTx is still considered the gold standard for refractory HF by both physicians and patients, LVAD is primarily used for patients who are too ill to wait for a donor heart or have size or blood group compatibility problem, while cardiac cachexia or end-organ damage is still contraindications for an LVAD.

In the first period of the mechanical circulatory support experience in our country, patients received an indication as bridge to transplant or destination therapy a priori, based on age and clinical characteristics, and this situation is reflected in the lack of QOL differences, besides older age, in our patients on destination therapy. However, this demarcation has now blurred due to the prolonged waiting times that patients on LVAD as bridge to HTx have to face because of limited donor availability.

In-depth interviews highlighted the coexistence of ambivalent emotions in the living experience of LVAD recipients. Although LVAD improves symptoms, it is perceived as an unsatisfactory solution when compared with HTx. Patients rate the external driveline as a significant encumbrance, while they pay far less attention to the potential complications of immunosuppression. So patients who are bridged to HTx seem to adapt worse to an LVAD than those on destination therapy. However, perception of mechanical circulatory support as a temporary condition can help patients to accept an LVAD as a passage

to a better life provided by HTx. Anyway, the waiting time of LVAD-supported patients is likely to be very long, because in our country uncomplicated LVAD does not confer priority for organ allocation with respect to standard outpatients on oral therapy. As clinical results of continuous flow LVAD improve and approximate those of HTx, the perspective of long-term LVAD therapy should be explained to patients who are bridged to HTx, as well as to those who are offered destination therapy. Better knowledge at a societal level of HF burden and of the opportunities offered by LVAD therapy could help LVAD recipients to feel less "exceptional" and to cope better with their life-saving device.

The main negative perceived aspects of LVADs included the unsettling experience of the announcement of LVAD implant, when the patient is striving to concentrate on attaining HTx, the boundaries set by the device to personal autonomy, the cohabitation with a prosthetic device that requires manual and cognitive dexterity and constant care and hence seems to be at this early stage only temporarily acceptable. Conversely, factors that fostered device acceptance included an emphatic doctor–patient communication style and the possibility of sharing the experience with other patients. All these complex and ambivalent perceptions may be greatly amplified by patients' psychological characteristics. The association between maladaptive coping and depression and anxiety in HF patients has been previously reported (25,27). Avoidant coping also seems to hinder the acceptance process in LVAD patients.

Psychological assessment can provide a useful feedback to cardiologists and cardiac surgeons to improve patient–doctor communication. Answering to psychological and social needs of patients, along with treatment of physical symptoms, improves quality of life in different chronic diseases. Coping style can be positively influenced by psychological treatment and encouragement from friends, professionals, and peers. Psychological intervention may help patients to express their fears and communication needs with healthcare personnel and to focus on their goals for lifestyle adjustments. Psychological support appears particularly warranted for patients who suffer severe or prolonged complications.

Study limitations

Some important limitations of our study should be kept in mind. The investigation was conducted in a single setting, yet our QOL data are consistent with those published in multicenter reports. Patients were interviewed at a relatively early time, that is, between the first and second month after LVAD implant, when they were clinically stable and ready for discharge, but had not yet left the hospital environment and returned home. Persistence of perceived significant functional impairment may be due to the relatively short time elapsed between surgery and QOL evaluation and to the severe preoperative impairment, as shown by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile. Furthermore, concerns and anxiety about lack of autonomy and reliance on caregivers might be amplified in the early postimplant period and gradually resolve after discharge. It has been previously suggested that women tend to have worse QOL early after LVAD implant (8). Female gender was underrepresented in our series, therefore the findings cannot directly be extended to women.

Clinical implications

Some suggestions derived from the experience of this study may be useful to cardiologists and cardiac surgeons in the daily care of LVAD patients. To foster LVAD acceptability, clinicians should endeavor to establish a trust relationship with LVAD candidates. They should provide patients with clear indications on what to expect, with particular reference to the duration of mechanical support, which, if uncomplicated, may become enduring or definitive. High technology and specialized medicine typical of this clinical setting should be coupled to a multidisciplinary approach to ensure for these patients not only support for a failing circulatory system, but also holistic care. Based on our experience as a rehabilitation center, we endorse the practice of group meetings where patients may interact with different health professionals: physicians, nurses, psychologists, bioengineers, physiotherapists. Group meetings offer the opportunity to share emotions and to acquire practical notions for optimal device management at the same time, thus becoming a precious interface between humanity and technology, living experience and knowledge.

CONCLUSION

Left ventricular assist device recipients achieve improved quality of life early after implant, but emotional distress may remain high. Psychological intervention is crucial for creating a model of care that takes into account the importance of all of the factors associated with the individuality of the person receiving the implant, by offering support in relation to the experience of disease and the need for the device. A multidimensional approach addressing patients'

psychological and social characteristics should be pursued to enhance the acceptability of a complex device such as an LVAD.

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