



Quality of Life and Influential Factors in Patients Implanted With a Left Ventricular Assist Device

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Background: Improving quality of life (QOL) has become an important goal in left ventricular assist device (LVAD) therapy. We aimed (1) to assess the effect of an implantable LVAD on patients' QOL, (2) to compare LVAD patients' QOL to that of patients in different stages of heart failure (HF), and (3) to identify factors associated with patients' QOL.

Methods and Results: The QOL of 33 Japanese implantable LVAD patients was assessed using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and Short-form 8 (SF-8), before and at 3 and 6 months afterwards. After LVAD implantation, QOL significantly improved [MLHFQ, SF-8 physical component score (PCS), SF-8 mental component score (MCS), all $P < 0.05$]. Implanted LVAD patients had a better QOL than extracorporeal LVAD patients ($n=33$, 32.1 ± 21.9 vs. $n=17$, 47.6 ± 18.2), and Stage D HF patients ($n=32$, 51.1 ± 17.3), but the score was comparable to that of patients who had undergone a heart transplant ($n=13$). In multiple regression analyses, postoperative lower albumin concentration and right ventricular failure were independently associated with poorer PCS. Female sex and postoperative anxiety were 2 of the independent factors for poorer MCS (all $P < 0.05$).

Conclusions: Having an implantable LVAD improves patients' QOL, which is better than that of patients with an extracorporeal LVAD. Both clinical and psychological factors influence QOL after LVAD implantation. (*Circ J* 2015; **79**: 2186–2192)

Key Words: Heart failure; Mechanical circulatory support; Patient-reported outcomes; Quality of life

Left ventricular assist device (LVAD) therapy is expected to be increasingly indicated as a bridge to transplant or/and destination therapy. However, studies focusing on the effect of LVAD therapy on patients' quality of life (QOL) are limited.^{1–3} In Japan, the number of LVAD patients has been increasing since implantation became covered by health insurance in 2011. It is important to know the effect of LVAD therapy from the patients' perspective.

Comparison of the QOL of patients with an implantable LVAD and those in different stages of heart failure (HF) might help healthcare professionals to understand how much improvement in QOL can be expected from implantable LVADs. Several studies have shown that implantable LVAD patients have a better QOL than heart transplantation (HTx) patients.^{4–6}

Meanwhile, there are no studies evaluating the difference in QOL between implantable and extracorporeal LVAD patients. The 2 types of LVADs provide similar results in terms of systemic circulation assist and cardiac unloading effect, but the effect on patients' QOL may differ.

It is important to understand the factors associated with patients' QOL in order to outline management strategies for LVAD patients that do not only focus on objective goals, but also on the patients' perceptions. Prior studies have shown limited associations between psychological distress and QOL,^{1,7} suggesting that factors other than psychological problems may be important in determining QOL after LVAD implantation.

The purpose of the present study was (1) to evaluate the effect of an having an implantable LVAD on patients' QOL,

Received May 7, 2015; accepted July 6, 2015; released online August 10, 2015 Time for primary review: 41 days

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ISSN-1346-9843 doi:10.1253/circj.CJ-15-0502

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Table 1. Pre- and Postoperative Characteristics of Study Patients at 3 Months After LVAD Implantation (n=33)

Demographic and clinical characteristics	
Sex, male	27 (82%)
Age, years	38±12
Marital status, married	14 (42%)
Body mass index, kg/m ²	20.4±3.0
Body surface area, m ²	1.66±0.15
Heart failure etiology	
Dilated cardiomyopathy	25 (76%)
Ischemic cardiomyopathy	4 (12%)
Preoperative clinical parameters	
Systolic BP, mmHg	83±9
Diastolic BP, mmHg	54±9
LVEF, %	19.2±7.6
Plasma BNP, pg/ml, geometric mean (95% CI)	608 (446–831)
Cardiac index, L·min ⁻¹ ·m ⁻²	2.2±0.4
PCWP, mmHg	18.0±9.7
CVP, mmHg	8.5±4.7
Serum creatinine, mg/dl	0.93±0.38
Serum albumin, g/dl	3.8±0.5
Serum total bilirubin, mg/dl	1.2±0.7
Serum hemoglobin, g/dl	11.3±2.1
HAD-anxiety score (n=24)	5.6±2.4
Preoperative therapy	
Intravenous inotropes	22 (67%)
IABP	8 (24%)
Extracorporeal LVAD	10 (30%)
ACE inhibitor and/or ARB	28 (85%)
β-blocker	33 (100%)
Aldosterone blocker	29 (88%)
Cardiac resynchronization therapy	19 (58%)

Postoperative parameters

Systolic BP	95±12
Heart rate, beats/min	77.0±9.1
LVEF, %	19.2±12.2
LVDD, mm	64.6±15.4
LVDS, mm	59.1±16.5
Plasma BNP, pg/ml, geometric mean (95% CI)	217 (172–274)
Cardiac index, L·min ⁻¹ ·m ⁻²	2.6±0.6
PCWP, mmHg	8.4±4.6
CVP, mmHg	8.8±5.0
CVP/PCWP ratio	1.3±0.9
Serum sodium, mmol	138.8±2.6
Serum creatinine, mg/dl	0.88±0.23
Serum albumin, g/dl	3.9±0.5
Serum ALT, U/L	20.0±9.9
Serum AST, U/L	25.0±7.8
Serum total bilirubin, mg/dl	0.80±0.38
Serum hemoglobin, g/dl	12.4±1.5
HAD-anxiety score	4.3±2.5
Implantable LVADs	
EVAHEART	15 (45%)
DuraHeart	9 (27%)
HeartMate II	9 (27%)
Postoperative therapy	
ACE inhibitor and/or ARB	18 (55%)
β-blocker	33 (100%)
Aldosterone blocker	28 (85%)

ACE, angiotensin-converting enzyme; ALT, alanine aminotransferase; ARB, angiotensin II receptor blocker; AST, aspartate aminotransferase; BNP, B-type natriuretic peptide; BP, blood pressure; CVP, central venous pressure; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; LVDD, left ventricular end-diastolic diameter; LVDS, left ventricular end-systolic diameter; LVEF, left ventricular ejection fraction; PCWP, pulmonary capillary wedge pressure.

(2) to compare implantable LVAD patients' QOL to that of patients in different HF stages, and (3) to identify factors associated with patients' QOL after LVAD implantation.

Methods

Study Patients and Procedure

We used data from a follow-up study of LVAD patients and data from a cross-sectional study of HF patients from the University of Tokyo Hospital between December 2011 and August 2014.

Follow-up Study A prospective, observational, repeated-measure design was chosen to characterize changes in QOL over time among patients undergoing LVAD implantation. The study participants were consecutive patients who underwent continuous-flow implantable LVAD therapy, including DuraHeart (Terumo Heart, Ann Arbor, MI, USA), HeartMate II (Thoratec Corporation, Pleasanton, CA, USA), and EVAHEART (Sun Medical, Nagano, Japan) as a bridge to transplant. Patients were instructed to complete the questionnaire at the hospital before implantation and at the home 3 and 6 months after implantation.

Cross-Sectional Study At 3 months after LVAD implantation we compared the patients' QOL to that of patients in different stages of HF: (1) stage D HF patients without any

LVAD, who were listed for HTx, (2) patients receiving a pulsatile-pump extracorporeal LVAD (NIPRO-VAD, National Cardiovascular Center/Toyobo ventricular system) within 2 years, and (3) patients at 3 months after HTx. They were instructed to complete the questionnaire at hospital or at home.

The study was approved by the Institutional Review Board at the University of Tokyo Hospital (No. 3265-1). All participating patients provided written informed consent.

QOL

Disease-specific QOL was examined by the Minnesota Living with Heart Failure Questionnaire (MLHFQ).⁸ The MLHFQ has 21 items that cover HF-related physical, psychological, and social impairments, and is one of the most widely used questionnaires for evaluating HF-specific QOL in patients on implantable LVAD support. The total MLHFQ score is obtained by adding the scores for all 21 items (range 0–105), with higher scores indicating worse QOL. The psychometric properties of the MLHFQ have been confirmed.^{8–10} Generic QOL was assessed using the Medical Outcomes Study 8-item Short-Form Health Survey (SF-8),¹¹ which is compatible with SF-36. The physical health component summary score (PCS) and mental health component summary score (MCS) were measured using the Japanese Norm-Based Scoring method.¹¹ For PCS and MCS, higher scores represent better QOL. The valid-

Table 2. Characteristics of Study Patients in 4 Groups

	All (n=95)	Implantable LVAD (n=33)	Stage D (n=32)	Extracorporeal LVAD (n=17)	Heart transplant (n=13)	P value
Demographic and clinical characteristics						
Sex, male	72 (76%)	27 (82%)	23 (72%)	14 (82%)	8 (62%)	0.44
Age, years	39±12	38±12	42±12	36±11	41±13	0.41
Marital status, married	42 (44%)	14 (42%)	18 (56%)	6 (35%)	4 (31%)	0.35
Ischemic etiology	10 (11%)	4 (12%)	2 (6.3%)	3 (18%)	1 (7.7%)	0.92
LVEF, %	28.0±21.1	18.8±12.0	21.0±13.6	26.1±12.9	70.7±7.1*	<0.001
BNP pg/ml	399±405	263±167	749±497*	194±212	153±113*	<0.001
BNP pg/ml, geometric mean (95% CI)	259 (213–314)	217 (172–274)	593 (455–773)*	134 (86–209)	124 (83–185)	<0.001
Therapy						
ACE inhibitor and/or ARB	73 (77%)	18 (55%)	30 (94%)*	15 (88%)	10 (77%)	0.001
β-blocker	89 (94%)	33 (100%)	31 (97%)	16 (94%)	9 (69%)*	0.003
Aldosterone blocker	76 (80%)	28 (85%)	28 (88%)	15 (88%)	5 (39%)*	0.003
Cardiac resynchronization therapy	47 (49%)	19 (58%)	17 (53%)	4 (24%)	7 (54%)	0.12
Implantable cardioverter defibrillator	47 (49%)	19 (58%)	17 (53%)	4 (24%)	7 (54%)	0.12
Time on LVAD support or time elapsed since heart transplant, days, median (Q1–Q3)	113 (92–161)	115 (102–142)		90 (55–512)	136 (108–174)	

Values are n (%) or mean±SD. *P<0.05 vs. implantable LVAD patients by Dunnett's multiple comparison test for continuous variables with a normal distribution or Bonferroni correction for continuous variables with a non-normal distribution and categorical variables. CI, confidence interval. Other abbreviations as in Table 1.

ity and reliability of SF-8 have been demonstrated.¹¹

Pre- and Postoperative Characteristics

To assess the patients' pre- and postoperative status, the following clinical and demographic variables were collected from medical records: age, sex, and HF etiology; systolic blood pressure; B-type natriuretic peptide (BNP); left ventricular ejection fraction (LVEF); LV end-diastolic/systolic diameters (LVDD/LVDS); hemodynamic parameters including cardiac index; laboratory parameters such as serum albumin; medical and mechanical therapies; postoperative right ventricular failure (RVF), which is defined as persistent RV stroke work index <4.0 g/m² at any rotation speed or saline infusion at 5 weeks after the implantation;¹² hospitalizations for LVAD complications. The patients' anxiety level was also measured using the Hospital Anxiety and Depression Scale (HADS).^{13,14} The HADS consists of 14 items and has 2 subscales: anxiety (7 items), and depression (7 items). In this study, we used the anxiety subscale. The score for anxiety ranges from 0 to 21, with a higher score indicating severe symptoms. The psychometric properties of the HADS have been demonstrated.^{13,14}

Statistical Analysis

Categorical data are presented as frequencies and percentages. For continuous variables, mean and standard deviations or median and interquartile ranges (IQR) are reported. For BNP, we first performed logarithmic transformation and then analyzed the data using parametric methods. The values of BNP in the Results are shown after the antilogarithm. To assess changes in QOL score, linear mixed effects modeling was used. When there was a statistical significance in the scores, we performed posthoc comparisons using Dunnett's method, with baseline data as a control. In order to compare characteristics among patients in different HF stages, we performed an ANOVA, Kruskal-Wallis test, chi-square test or Fisher's exact test as appropriate. When there was a statistical significance, we conducted posthoc comparisons as a control of implantable LVAD patients using Dunnett's method for continuous vari-

ables with a normal distribution, or Bonferroni correction for continuous variables with a non-normal distribution and categorical variables (P<0.017). To identify factors related to QOL, a univariate analysis was initially performed. Pearson's correlation coefficient, Student's t-test or Mann-Whitney U-test was used. After assessing multicollinearity, we performed a multiple regression analysis with backward method, in which we included variables related to the QOL score at P<0.15 in the univariate analysis. In this study, we only used a variable LVDD instead of LVDS in the multivariate model, because there were significant associations between these 2 parameters (r=0.97, P<0.01). The amount of missing data for items was estimated with the average score for the valid items in the questionnaire. When the missing data accounted for more than 30% of the questionnaire, we excluded it from the analysis. All statistical tests were two-tailed, and statistical significance was defined as P<0.05. All analyses were performed with SAS version 9.3 (SAS Institute Inc, Cary, NC, USA).

Results

We enrolled and analyzed 33 patients with implantable LVADs in our study (Table 1). The mean age of the implantable LVAD patients was 38±12 years, and 82% were male. In total, 12% had ischemic cardiomyopathy, and 76% had dilated cardiomyopathy. One-third of the patients were preoperatively treated with an extracorporeal LVAD. Of the 33 patients, 15 had the EVAHEART (45%), 9 had the DuraHeart (27%), and 9 had the HeartMate II (27%). After LVAD implantation, mean serum albumin level was 3.9±0.5 g/dl, and HAD-anxiety score was 4.3±2.5 (range 0–21). During the follow-up, 6 patients were hospitalized for ventricular fibrillation and ventricular tachycardia (n=2), transient ischemic attack (n=1), thrombosis (n=1), infection (n=1), and pulmonary hypertension (n=1). Approximately 40% of the patients (n=13) had RVF postoperatively.

The QOL of the implantable LVAD patients was compared with that of 62 patients in different stages of HF, including 32

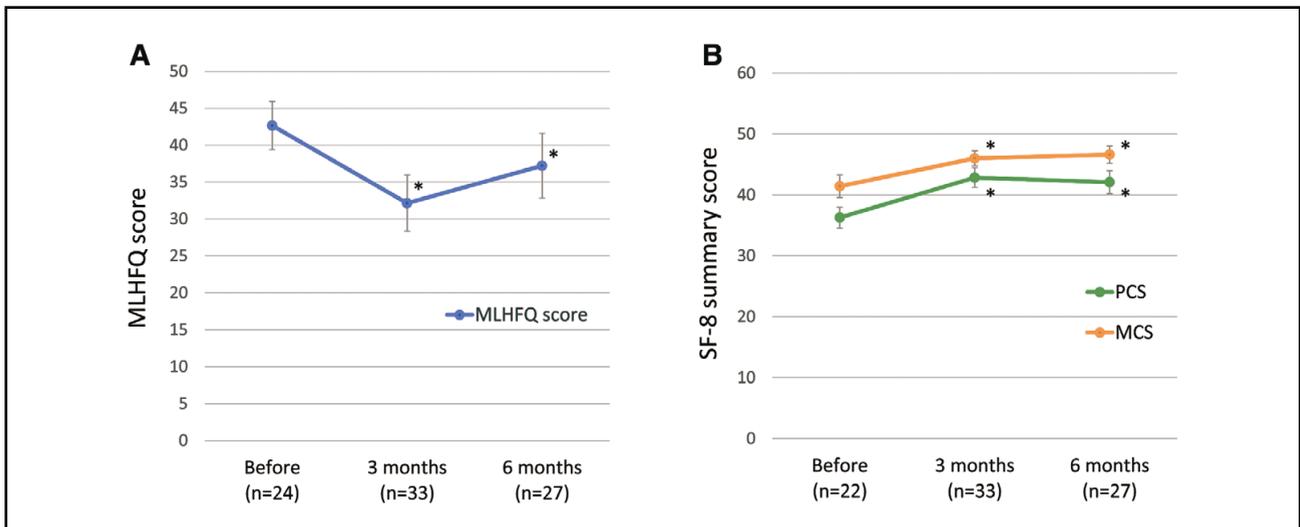


Figure 1. Changes in QOL. (A) Lower scores on the MLHFQ (Minnesota Living with Heart Failure Questionnaire) indicate better QOL. (B) Higher scores on the Short-form 8 (SF-8) indicate better QOL. MCS, mental component summary score; PCS, physical component summary score; QOL, quality of life. *P<0.05 compared with baseline by Dunnett's multiple comparison method.

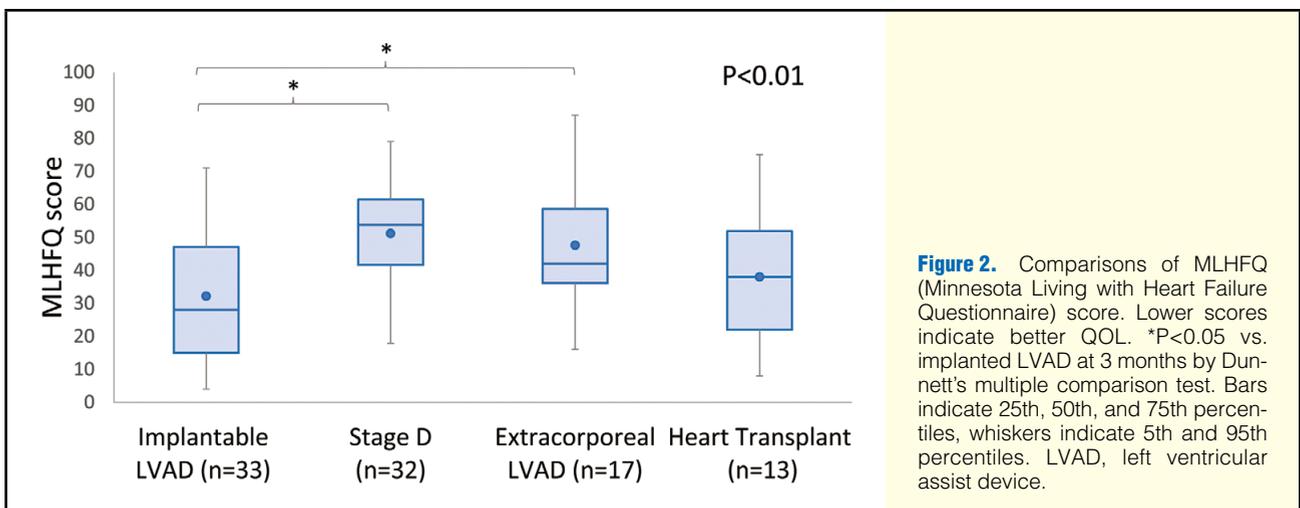


Figure 2. Comparisons of MLHFQ (Minnesota Living with Heart Failure Questionnaire) score. Lower scores indicate better QOL. *P<0.05 vs. implanted LVAD at 3 months by Dunnett's multiple comparison test. Bars indicate 25th, 50th, and 75th percentiles, whiskers indicate 5th and 95th percentiles. LVAD, left ventricular assist device.

stage D HF patients, 17 extracorporeal LVAD patients, and 13 patients who had undergone HTx (Table 2). Compared with patients on implantable LVAD support, the HTx patients had higher LVEF (19% vs. 71%) at the time of data collection, whereas stage D HF patients had higher BNP level (217 pg/ml vs. 593 pg/ml). There were no significant differences in clinical characteristics, including body surface area (1.67±0.14 vs. 1.66±0.13), between implantable and extracorporeal LVAD patients. The time on implantable LVAD support (median 115 days, Q1–Q3 102–142) when they answered the questionnaire was comparable to that of the extracorporeal LVAD patients (90 days, 55–512).

In our study, approximately half of the extracorporeal LVAD patients (n=9, 53%) had undergone LVAD therapy before implantable LVAD was covered by Japanese health insurance in 2011; 6 extracorporeal LVAD patients (35%) had been on LVAD therapy for more than 1 year at the time of data collection; 7 patients (41%) with extracorporeal LVADs eventually

converted to an implantable one. Of the 32 stage D HF patients, 24 (75%) had INTERMACS profile 3, 4 patients (13%) had profile 2 and 4 patients (13%) had the profile 4. The mean INTERMACS profile was 3.0±0.5.

Changes in QOL Scores

The MLHFQ score of the implanted LVAD patients decreased over time, indicating an improvement in QOL (P<0.01, Figure 1A). When compared with the MLHFQ score (42.6±16.1) before implantation [median 24 days before implantation (Q1–Q3, 11–57)], patients' QOL scores significantly improved at 3 months (32.1±21.9, P<0.01), as well as at 6 months (37.2±8.1, P=0.049). PCS and MCS also improved over time (Figure 1B, both P=0.02). Compared with the PCS and MCS scores before implantation (PCS, 36.2±8.1; MCS, 41.4±8.7), the scores were significantly higher at both 3 months (PCS, 42.8±9.3, P=0.02; MCS, 46.0±7.0, P=0.03), and 6 months (PCS, 42.1±9.9, P=0.049; MCS, 46.6±7.3, P=0.01).

Table 3. Factors Associated With QOL Among Implantable LVAD Patients at 3 Months in a Univariate Analysis

QOL score	Total MLHFQ score			SF-8, physical score		SF-8, mental score	
	n	Mean±SD or r	P value	Mean±SD or r	P value	Mean±SD or r	P value
Demographic and clinical parameters at baseline	33	32.1±21.9	–	42.8±9.3	–	46.0±7.0	–
Sex							
Male	27	29.9±20.0	0.22	42.9±9.7	0.98	47.0±6.7	0.07
Female	6	42.1±28.8		42.7±8.4		41.3±7.3	
Preoperative parameters							
Systolic BP, mmHg	33	0.254	0.15	0.183	0.31	–0.347	0.048
Heart rate, beats/min	33	0.272	0.13	–0.068	0.71	–0.300	0.09
HAD-anxiety score	24	0.409	0.047	0.108	0.61	–0.171	0.42
Postoperative parameters							
LVDD, mm	33	0.038	0.83	0.432	0.01	–0.057	0.75
LVDS, mm	33	0.057	0.75	0.417	0.02	–0.079	0.66
Log plasma BNP, pg/ml	33	0.290	0.10	–0.064	0.72	0.037	0.84
PCWP, mmHg	33	0.187	0.30	0.296	0.09	–0.230	0.20
CVP, mmHg	33	0.305	0.08	0.117	0.52	–0.210	0.24
CVP/PCWP ratio	33	0.001	0.99	–0.326	0.06	0.149	0.41
Serum creatinine, mg/dl	33	0.263	0.14	0.133	0.46	–0.354	0.04
Serum albumin, g/dl	33	–0.119	0.51	0.404	0.02	0.101	0.57
Serum AST, U/L	33	–0.062	0.73	0.328	0.06	–0.054	0.76
Serum total bilirubin, mg/dl	33	–0.153	0.40	0.041	0.82	0.338	0.05
HAD-anxiety score	33	0.326	0.06	–0.213	0.23	–0.317	0.07
RVF							
No	20	28.9±21.5	0.30	45.7±10.1	0.03	46.9±7.3	0.35
Yes	13	37.2±22.3		38.5±6.0		44.5±6.5	
Hospitalization for LVAD complications							
No	27	29.7±22.9	0.07	43.3±9.8	0.59	46.0±7.5	0.97
Yes	6	43.3±12.7		40.9±7.0		46.1±4.5	

Table 3 shows results of univariate analysis in which some variables were related to QOL scores at $P < 0.15$. Other results are shown in Table S1. For the Minnesota Living with Heart Failure Questionnaire, higher scores represent more impaired QOL. For the SF-8 summary scores, higher scores represent better QOL. QOL, quality of life; RVF, right ventricular failure. Other abbreviations as in Table 1.

QOL Comparison

Patients with implantable LVADs (32.1±21.9) had significantly better QOL than those with stage D HF (51.1±17.3), and those with extracorporeal LVAD (47.6±18.2) (both $P < 0.05$, **Figure 2**). However, the patients' QOL at 3 months after LVAD implantation was comparable to that of patients at 3 months after HTx (38.0±19.5).

Factors Associated With Patients' QOL

Table 3 and **Table S1** show the results of univariate analysis to identify factors associated with QOL at 3 months after LVAD implantation. In the multiple regression analysis (**Table 4**), a preoperative higher level of anxiety [standard partial regression coefficients ($s\beta$)=0.35, $P=0.08$], and history of hospitalization for LVAD complications ($s\beta=0.36$, $P=0.07$) showed a tendency to be associated with lower QOL (higher MLHFQ). Lower levels of postoperative serum albumin ($s\beta=0.36$, $P=0.03$), and RVF ($s\beta=-0.34$, $P=0.04$) were independent factors related to lower PCS. Determinants of lower MCS were female sex ($s\beta=-0.50$, $P < 0.01$), higher preoperative systolic blood pressure ($s\beta=-0.37$, $P=0.01$), higher postoperative levels of serum creatinine ($s\beta=-0.29$, $P=0.04$), and higher postoperative levels of anxiety ($s\beta=-0.31$, $P=0.049$).

Discussion

The major findings of the study were that (1) QOL improved after LVAD implantation, and those patients' QOL was better than that of extracorporeal LVAD patients, and (2) lower postoperative albumin levels and RVF are independent factors related to lower physical QOL at 3 months after LVAD implantation. Female sex and higher postoperative level of anxiety are 2 of the independent factors associated with lower mental QOL.

We believe this is the first study to show a significant effect of RVF on physical QOL at 3 months after LVAD implantation. RVF occurs in approximately 10–40% of patients undergoing LVAD implantation.^{12,15,16} Despite significant advances in device technology and pre- and postoperative care, RVF remains a major cause of death, higher rate of re-operation for bleeding and renal failure, and longer hospital stay.^{12,15,16} Our study expands these findings and highlights the importance of appropriate RVF management and prevention to improve patients' QOL as well as clinical outcomes.

The preoperative albumin level is considered an important risk factor for death after LVAD implantation,^{17,18} but our study did not confirm this. However, we found a positive relationship between postoperative albumin levels and physical QOL

Table 4. Factors Associated With QOL Among Implantable LVAD Patients at 3 Months in a Multiple Regression Analysis (n=33)

	Total MLHFQ score			SF-8, physical score			SF-8, mental score		
	β	s β	P value	β	s β	P value	β	s β	P value
Sex, female							-8.92	-0.50	0.001
Preoperative systolic BP, mmHg							-0.29	-0.37	0.01
Preoperative HAD-anxiety score	2.42	0.35	0.08						
Postoperative serum albumin, g/dl				7.35	0.36	0.03			
Postoperative serum creatinine, mg/dl							-9.03	-0.29	0.04
Postoperative serum total bilirubin, mg/dl							4.41	0.24	0.09
Postoperative HAD-anxiety score							-0.87	-0.31	0.049
Postoperative RVF				-6.37	-0.34	0.04			
Hospitalizations for LVAD complications	15.73	0.36	0.07						
R ² (adjusted R ²)	0.293 (0.225)			0.277 (0.228)			0.571 (0.491)		

For the Minnesota Living with Heart Failure Questionnaire, higher scores represent more impaired QOL. For the SF-8 summary scores, higher scores represent better QOL. We entered all variables that were associated with the QOL score in the univariate analysis at $P < 0.15$, and then we selected variables with a backward selection ($P = 0.10$). s β , standard partial regression coefficients. Other abbreviations as in Tables 1,3.

after LVAD implantation. Postoperative normalization of albumin levels was associated with improved survival in an earlier study.¹⁹ Although we expected that serum albumin levels would be related to RVF, this was not observed ($r = -0.12$, $P = 0.51$). Lower albumin levels in our study might reflect a multifactorial derangement, including inflammation, malnutrition and volume status, rather than liver function. These results suggest the importance of postoperative albumin level as a factor influencing patients' survival, as well as QOL. Hospitalization for LVAD complications was also likely to influence HF-specific QOL. Similar results have been found in a qualitative study.²⁰ In the present study, 2 of 6 patients were hospitalized for ventricular fibrillation or ventricular tachycardia. Such life-threatening complications might have a more negative effect on the QOL of these patients.

Higher postoperative level of anxiety was one of the independent determinants of lower mental QOL after LVAD implantation, similar to a prior study.⁷ Patients need to learn new strategies to manage the physical and psychosocial issues associated with living with a LVAD.^{21,22} Some patients successfully coped with the reality of living with the LVAD, but other patients were anxious about adjusting to the device.^{20,21} Despite the remarkable advancements in LVAD technology, anxiety remains the most common distressing symptom contributing to poor QOL.^{21,23} Although all of our patients received preoperative psychological care from liaison nurses, the results emphasize the need for postoperative psychological assessment and care to support patients after LVAD implantation.

Female sex was also related to lower mental QOL. Currently, approximately 20% of patients in the United States on LVAD support as a bridge to transplantation are women.²⁴ In our study, women accounted for approximately 20% and most of their caregivers were men. Caregiving is known to be experienced differently by men and women and, likewise, receiving care might also be different for the different sexes.²⁵ Additionally, in Japanese culture, women usually play the caregiver role in the family. Under such conditions, it is often difficult for male caregivers to cope and adapt to the new situation, which might influence the QOL of the LVAD patient.

To date there are no studies comparing the QOL of patients with implantable and extracorporeal LVADs. It is noteworthy that we demonstrated that patients undergoing LVAD implantation have a better QOL than extracorporeal LVAD patients. Considering that there were no significant differences in the

1-year survival rate between the 2 types of LVAD,²³ our result is important with respect to the different effects of LVADs on patients' QOL. The disadvantages of extracorporeal LVADs in Japan is that the use of this device is restricted to inside the hospital.²⁶ The advantage of an implantable LVAD is that patients can be discharged from hospital, which might influence the QOL scores. On the other hand, one-third of patients received extracorporeal LVAD and eventually converted to an implantable LVAD. The preoperative physiological and psychological conditions of those patients might be different from patients who received an implantable LVAD directly, which might influence QOL after LVAD implantation.

Meanwhile, no significant differences in QOL scores were observed between the HTx and implantable LVAD groups, which is not in agreement with earlier results^{6,27} showing that HTx patients had a better QOL. This discrepancy might be influenced by the fact that their LVAD patients' MLHFQ scores were slightly higher (ie, worse QOL) than our score (54–57 vs. 32). Further studies with larger sample sizes are necessary to confirm these observations.

Our result showing that an implantable LVAD enhances patients' QOL is consistent with earlier studies.^{2,28–30} In the present study, patients were implanted with 3 different types of continuous-flow LVAD (DuraHeart, HeartMate II, and EVAHEART) as a bridge to transplant, and in Japan they are regularly followed up. Our MLHFQ score at 6 months (37 ± 23) is consistent with the score reported by the HeartMate II study^{28,29} (eg, Slaughter et al,²⁸ 37 ± 22), which suggests that implantable LVADs could achieve equivalent effects on QOL in the Japanese setting.

Clinical and Research Implications

The use of implantable LVADs is increasing among patients with advanced HF. Our study confirms the findings from Western countries, showing that implantable LVADs can enhance patients' QOL in the Japanese setting. However, postoperative RVF, lower albumin levels, anxiety, and female sex are some important factors affecting patients' QOL after LVAD implantation. Appropriate postoperative assessment of these factors and specific care/management of these patients are essential.

Study Limitations

First, the small, single-center sample limits the generalizability of our findings. Second, because of the sample size, we could

not include numerous variables in the multivariate analysis, and it was not possible to stratify our results for the type of LVAD. Third, although there were no significant differences in time spent on LVAD support between implantable and extracorporeal LVAD patients, 6 extracorporeal patients were on LVAD support for more than 1 year, which might influence our findings. Fourth, patient selection for implantable LVAD and the circumstances around extracorporeal LVADs changed during the recruiting period of the study. For example, some patients receiving extracorporeal LVAD therapy before 2011 could have received an implanted LVAD in 2014. These changes potentially affected the results. However, in terms of the effect of the LVAD device on patient's QOL, these changes would not have had much influence on our results. Finally, patients who could not participate in the study might have suffered from more impaired QOL. Therefore, our results could represent an overestimation of the health status experienced by patients.

Conclusions

In Japan, patients undergoing LVAD implantation as a bridge to transplantation have a better QOL after the implantation. Implantable LVAD patients have a better QOL than extracorporeal LVAD patients. Postoperative RVF and postoperative lower levels of albumin are independent risk factors for poor physical QOL at 3 months after LVAD implantation. Female sex and higher levels of postoperative anxiety are independently associated with lower mental QOL of LVAD patients.

Acknowledgments

This work was supported in part by a domestic collaborative research grant 2013 from the Pfizer Health Research Foundation to N.P.K. and K.K.

Conflict of Interest

None.

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Supplementary Files

Supplementary File 1

Table S1. Factors associated with QOL among implantable LVAD patients at 3 months in a univariate analysis

Please find supplementary file(s);
<http://dx.doi.org/10.1253/circj.CJ-15-0502>