Original article

Quality of life of family caregivers of patients with a left ventricular assist device in Japan

Naoko P. Kato (RN, PhD)[a,b,*], Ikuko Okada (RN, MS)[a], Yukie Kagami (RN, AS)[c],
Miyoko Endo (RN, MS)[c], Masaru Hatano (MD, PhD)[a], Minoru Ono (MD, PhD, FJCC)[d],
Tiny Jaarsma (RN, PhD)[b], Koichiro Kinugawa (MD, PhD, FJCC)[e]

[a] Department of Therapeutic Strategy for Heart Failure, The University of Tokyo Graduate School of Medicine, Tokyo, Japan
[b] Department of Social and Welfare Studies, Faculty of Medicine and Health, Linköping University, Linköping, Sweden
[c] Department of Organ Transplantation, The University of Tokyo Hospital, Tokyo, Japan
[d] Department of Cardiovascular Surgery, The University of Tokyo Graduate School of Medicine, Tokyo, Japan
[e] The Second Department of Internal Medicine, University of Toyama, Toyama, Japan

ARTICLE INFO

ABSTRACT

Background: The role of caregivers is important for the successful support of left ventricular assist device (LVAD) patients. We aimed to (1) evaluate quality of life (QoL) of caregivers pre-and post-LVAD implant and (2) identify factors associated with caregivers' QoL.
Methods: The caregivers' QoL was assessed with the Short Form-8 before implant, at 3 and 6 months after LVAD implantation. The physical and mental component summary (PCS and MCS) scores were calculated. Caregiver burden was evaluated using the 8-item Zarit Caregiver Burden Interview.
Results: Data were collected from LVAD patients as bridge-to-transplant and their family caregivers in Japan. No significant changes were found in caregivers' PCS scores during the follow-up (before 52.7 ± 7.1; at 3 months 49.7 ± 6.5, and at 6 months 50.7 ± 6.4, $n = 20$). Compared with the scores before implant (38.9 ± 9.3), the caregivers' MCS scores improved after LVAD implantation at 3 months $(44.2 \pm 7.7; p = 0.03)$ and at 6 months $(46.2 \pm 7.4, p = 0.003)$, but they were still lower than those of the Japanese general population $(p < 0.01)$. In multiple regression analysis at 3 months $(n = 40)$, caregivers' lower PCS scores were associated with older patient age [standard partial regression coefficients $(s\beta)$ $= -0.36, p = 0.02$] and caregiver unemployment $(s\beta = 0.30, p = 0.04)$, whereas being female $(s\beta = -0.26, p = 0.03)$, being the patient's spouse $(s\beta = -0.23, p = 0.03)$, and having a mild to moderate caregiving burden $(s\beta = -0.63, p < 0.001)$ were associated with lower MCS scores among caregivers.
Conclusions: LVAD implantation improves caregivers' mental QoL. Since caregivers' MCS scores are lower than the general population, it is important to identify family caregivers at risk for low QoL and reduce their caregiving burden.

Introduction

Heart failure remains a major burden economically and in terms of morbidity and mortality in both Japan and Western countries. The remarkable success of therapies to reduce mortality from acute cardiovascular disease has resulted in a large population of patients living with chronic heart failure [1]. Less than 1% of these patients can be classified as having advanced heart failure that is refractory to conventional therapies [2]. Heart transplant is the gold standard treatment for these patients, but there is an extreme shortage of donated organs. The implantation of a left ventricular assist device (LVAD) is therefore an important alternative therapeutic option. LVAD therapy has been shown to prolong patients' lives and improve their quality of life (QoL) [3,4]. In Japan, the implantable LVAD as a bridge to transplant (BTT) has been covered by health insurance since 2011. Consequently, the number of patients with implantable LVAD has been increasing steadily, amounting to 560 patients as of 2016 [5]. LVAD implantations are expected to continue increasing with improvements in technology, continued scarcity of donor hearts, and population aging worldwide [6].

After LVAD implantation, postoperative care, and convalescence in the hospital, patients are expected to take care of themselves at

* Corresponding author at: Department of Therapeutic Strategy for Heart Failure, The University of Tokyo Graduate School of Medicine, 7-3-1, Hongo, Bunkyo-ku, Tokyo 113-8655, Japan.
E-mail address: naokat-tky@umin.ac.jp (N.P. Kato).

home. Successful long-term LVAD support requires a high degree of self-care by patients as well as comprehensive care by a multidisciplinary team. Caregivers play an important role in the care of LVAD patients [7]. Caregivers' responsibilities vary from simple tasks, such as changing dressing, changing batteries, and monitoring daily weights, to more complex procedures, such as troubleshooting alarms and responding to emergency situations [7,8]. These tasks are complex for a layperson and the burden of responsibilities can create a significant amount of stress for caregivers, potentially affecting their health and QoL [9].

Several qualitative studies have described caregivers' experiences in handling this new responsibility and emotional stress, such as anxiety and feelings of fear and loss [10–14]. However, few studies have examined the impact of LVAD implantation on the caregivers' QoL in longitudinally quantitative studies, and it remains to be seen whether the caregivers' QoL is impaired in comparison with that of the general population. Prior studies showed that some caregivers experienced an increase in caregiving burden after the LVAD patients' discharge [10,12,13]. Such a caregiving burden might influence caregivers' QoL. However, little is known about factors influencing caregivers' QoL. Understanding the risk factors of impaired QoL of LVAD caregivers is crucial for healthcare providers who are developing care for both patients and their caregivers. The purpose of this study was as follows: (1) to evaluate the QoL of caregivers pre- and post-LVAD implant and (2) to identify factors associated with caregivers' QoL.

Methods

Study patients and study procedure

To evaluate QoL of caregivers pre- and post-LVAD implant, a longitudinal study was performed. A prospective, observational, and repeated-measure design was chosen in order to characterize changes over time in the QoL of patients undergoing LVAD implantation and their caregivers. Patients and their primary family caregivers were consecutively invited to complete the questionnaire at the hospital, before the LVAD implantation, and at home, 3 and 6 months after the implantation. Data were collected from the University of Tokyo Hospital in Japan between December 2011 and August 2015. The study participants received continuous-flow implantable LVAD therapy, including DuraHeart (Terumo Heart Inc., Ann Arbor, MI, USA), HeartMate II (St. Jude Medical Inc., St. Paul, MN, USA), EVAHEART (Sun Medical Inc., Nagano, Japan), Jarvik 2000 (Jarvik Heart Inc., New York, NY, USA), and HVAD (Medtronic Inc., Minneapolis, MN, USA) as a BTT.

Exclusion criteria were age less than 20 years, physical inability to complete the questionnaire, serious psychological distress, and inability or unwillingness to give informed consent. When patients were hospitalized at 3 and 6 months, we waited to send them the questionnaires until after discharge, for a maximum of 4 weeks. Approximately 1 month after patients' discharge, we asked patients and caregivers to complete the questionnaire. In cases where inpatients needed to spend more time in the hospital, the patients and their caregivers were not invited to complete the questionnaire. In this longitudinal study, the caregivers who completed the questionnaire at all 3 time points, which is before the LVAD implantation, and at 3 and 6 months after the implantation, were analyzed.

To identify factors associated with caregivers' QoL, we performed cross-sectional study where we used all of questionnaire data from caregivers at 3 months, regardless of whether we had their questionnaire data before implant and at 6 months. LVAD patients and their caregivers who could not participate in the questionnaire survey before implant because of insufficient patient's condition or missing data were also asked to complete the questionnaire at 3 months. 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.

Quality of life

QoL was assessed using the Medical Outcomes Study 8-item Short Form Health Survey (SF-8) [15], which is compatible with the SF-36. The SF-36 is a generic patient-reported outcome measure composed of the following 8 multi-item scales: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. This scale is suitable for both healthy individuals and individuals with a disease. The physical health component summary (PCS) and mental health component summary (MCS) scores were calculated using the Japanese Norm-Based Scoring method [15]. For PCS and MCS, higher scores represent a better QoL. The validity and reliability of the Japanese version of the SF-8 have been demonstrated [15]. National standard scores of the PCS and MCS were 48.6 ± 7.24 and 49.4 ± 6.8 in Japanese population ($n = 2284$).

Other measurements

Caregiver burden was evaluated using the Japanese version of the 8-item Zarit Caregiver Burden Interview (CBI) [16,17] with higher scores indicating a greater burden (range 0–32). Caregivers were asked to complete 8 questions about the impact of the patient's disabilities on their life, such as "Do you feel that your relative currently affects your relationship with other family members and friends?" and "Do you feel that your social life has suffered because you are caring for your relative?" For each item, caregivers indicated how often they felt that way (with possible responses being never, rarely, sometimes, quite frequently, or nearly always). The validity and reliability of the Japanese version of the 8-item CBI has been confirmed by Arai et al. [16].

The following demographic and clinical variables of patients and their caregivers were collected from questionnaires and medical records: age, sex, marital status, employment status, INTERMACS profile at implant, type of LVAD, duration of heart failure before LVAD implantation, and the relationship to the patient.

Statistical analysis

Categorical data are presented as frequencies and percentages. For continuous variables, means and standard deviations, or medians and interquartile ranges (IQRs) are reported. To compare characteristics of patients and their family caregivers, we performed a Student's t-test, the Mann–Whitney U test, chi-square test or Fisher's exact test as appropriate. To assess changes in QoL scores, linear mixed-effects modeling was used. When it was likely that there were differences in the scores ($p < 0.15$), we performed post hoc comparisons using Dunnett's method, with baseline data as the control. To identify factors associated with QoL, a univariate analysis was initially performed. Pearson's correlation coefficient, or Student's t-test was used. After assessing multicollinearity, we performed a multiple regression analysis with a backward method, in which we included variables related to the QoL scores at $p < 0.10$ in the univariate analysis. The number of missing data for items was estimated using the average score for the valid items in the questionnaire. When missing data accounted for more than 50% of the questionnaire, we excluded them 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).