Original Article

Assessment of the Nursing Care Based on Orem's Self-Care Model in Patients with Left Ventricular Assist Device: A Quasi-experimental Study

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Abstract

Background: Left Ventricular Assist Device (LVAD) provide long-term circulatory support by taking over the load of the left ventricle and increasing cardiac output. Despite of the clinical efficacy of LVAD, certain responsibilities including care, follow-up, device management and complication management must be considered after the implantation.
Aim: In this study, it was aimed to assess the effectiveness of nursing care based on Orem's Self Care Model in patients with left ventricular assist device
Methodology: The research was carried out with twenty-one Left Ventricular Assist Device (LVAD) implemented patients at a University Hospital in Turkey. Patients in the control group received standard nursing care in the postoperative period. Nursing interventions were applied towards Orem's Self-Care Model for patients in the experimental group. Data were collected preoperatively, before discharge, and 6 months after surgery using the Self-Care Agency Scale and the Heart Failure Questionnaire for Living with Minnesota.
Results: All of patients self-care agency and quality of life scores post operative 6th month were found significantly higher than the pre-operative and pre-discharge scores ($p<0.05$). However, there was no significant difference in both quality of life and self-care ability scores between the groups at these three time points ($p>0.05$).
Conclusion: LVAD intervention increases the quality of life and self-care capacity for patients. The use of models in nursing care is very important in providing holistic care and developing nursing philosophy. In this context, may be said that Orem's Self Care model is effective for nursing care of patients with LVAD. Prospective studies are needed in this patient group.

Keywords: Left ventricular assist device, Orem's Self-Care Model, Self-care agency, Quality of life.

Introduction

Left Ventricular Assist Device (LVAD) provide long-term circulatory support by taking over the load of the left ventricle and increasing cardiac output, frequently preventing patients from becoming bedridden (Byram, 2012; Tchoukina et al., 2018). Reports in the literature indicate that quality of life is generally better after LVAD implantation than before (Ozturk et al., 2012; Jakovljevic et al., 2014; Jorde et al., 2014; Cowger et al., 2018). Despite of the clinical efficacy of LVAD, certain responsibilities including care, follow-up, device management and complication management must be considered after the implantation. (Felix et al., 2012; Kato et al., 2014; Casida & Wu, 2016; Chmielinsk & Koons, 2017; Han et al., 2018). During the postoperative period, physiological complications such as bleeding, infection, right ventricular failure, stroke, poor equipment, organ failure and neurological disorders may be observed (Felix et al., 2012; Smith & Franzwa, 2015; Chmielinsk & Koons, 2017; Han et al., 2018; Emani, 2018). In addition

to physical complaints, patients with LVAD may develop psychological problems such as sleeplessness, changes in body image, stress, sense of failure, fear, anxiety and depression (Casida et al., 2009; Byram, 2012). The long-term success of a LVAD support requires comprehensive care programme. Patients with LVAD need to be adequately prepared for discharge, with planned nursing care designed to take over their self-care responsibilities and manage their devices with the goal of increasing and maintaining their quality of life. (Byram, 2012; Feldman et al., 2013; Kato et al., 2014, Smith & Franzwa, 2015). LVAD nurses can develop the self-care skills and evaluate their adaptation to self-care behaviors of individuals with LVAD with their caregiver and education roles. Thus, they may contribute to increasing the quality of life as a result of reducing complications.

Orem's Self-Care Model can describe an individual's performance, allowing him or her to take responsibility of his or her own health, thereby reducing healthcare costs and increasing care quality (Orem, 2001). Orem's Self-Care Model contains elements that are considered as essential for providing nursing care to patients with LVAD, particularly the home care strategy which represents a safe environment for the patient (Kato et al., 2014; Orem, 2001). There is a lack of evidence-based literature on self-care in LVAD (Ben Gal & Jaarsma, 2013; Kato et al., 2014, Casida et al., 2018a). In the literature, there are studies (training with simulation, self-management application, etc.) on self-care of individuals with LVAD (Casida et al., 2018b; Barsuk et al., 2019).

However, in the literature, there is a lack of interventional studies showing the results of monitoring patients with a planned nursing care and follow-up programme, and that of the evaluation of those results in terms of self-care agency and quality of life. This study was conducted to fill these gaps.

Purpose: The study's purpose is to assess the effectiveness of nursing care based on Orem's Self Care Model in patients with left ventricular assist device. Therefore, the experimental hypotheses were as follows; (1) Care given to patients in accordance with Orem's Self-Care Model will increase self-care agency. (2) Care given to patients in accordance with Orem's Self-Care Model will increase quality of life.

Methodology

This study was a quasi-experimental design. The study was conducted on patients implanted with HeartWare® LVAD (HeartWare Inc., Miami Lakes, Fl, USA) from July 2013 to August 2014 at the Cardiovascular Surgery Clinic of a a university hospital situated in a western Turkey. Inclusion criteria were being HeartWare type LVAD implanted, age 18 or older, oriented, and able to speak and understand Turkish. Exclusion criteria included a confirmed neurological or psychiatric medical diagnosis.

Before the study, in the year 2012, the number of the patients with LVAD implantation that comply with the sample criteria in the same hospital was 24. Thirty patients (15 intervention, 15 control) were included in the study. Nine patients (5 intervention, 4 control) were excluded from the study due to various reasons. Thus, the study was completed with a total of 21 patients (Figure 1).

The first 15 patients who were implanted with a LVAD at department of cardiovascular surgery were included in the control group. In order to avoid influencing the research results, firstly the control group data were collected. Then 15 patients implanted with a LVAD constituted the intervention group.

Procedure: The first interview with patients scheduled for LVAD implantation was held in the cardiology clinic. Before explaining the purpose of the research, the researcher first introduced themselves and then obtained written consent from the patients. The control group was provided with routine care at the clinic during the time the study was conducted. After discharge, the usual hospital protocol was applied. The data have collected preoperatively, two days before they were discharged and sixth postoperative month. After data collection, the individuals in the control group were provided with educational booklets and counselling, when in need, to maintain ethical standards. The application of instruments was completed in 20-25 minutes for each measurement (Figure 1).

Nursing care interventions based on Orem's Self Care Model were applied to the patients in the intervention group. At this stage, patients were interviewed 9 times and interventions appropriate for the determined nursing diagnoses were applied (Table 1). Data collection forms were applied to the intervention group preoperatively, pre-discharge and at 6 months. A educational booklet prepared by the researchers according to the literature was given to the intervention group (Ben

Gal & Jaarsma, 2013; Feldman et al., 2013; Felix et al., 2012; Byram, 2012). The booklet includes information on the anatomy of the heart, the purpose of LVAD, to whom it is applied, the components of LVAD, the control unit parameters that must be monitored, complications and their management, troubleshooting alarms, wound management, medical therapy, required changes in life style.

Information needed by patients was included in face-to-face interviews. In the first week after surgery taking into consideration the readiness of the patients, the earliest possible training was planned, as stated in the circulatory support manual (Feldman et al., 2013; Kato et al., 2014; Trojahn et al., 2013; Ben Gal & Jaarsma, 2013; Felix et al., 2012; Orem, 2001).

On the day that patients were taken from the intensive care unit to the surgical ward, they and their relatives were given training by the researchers on correct device management (purpose of LVAD, sections of LVAD, control unit parameters to be monitored, complications and their management, troubleshooting alarms, medical therapy and required changes in life style). Further training for the patients or their relatives was scheduled to be as soon as possible.

At the second training session, information about the care of percutaneous exit sites (dressing change steps, aseptic technique to be applied, infection symptoms/findings, dressing change day, when to consult a physician) was given, and a demonstration was given to show how to do a dressing change.

Each training session lasted for approximately 40-45 minutes, and was reinforced with educational booklets given to the patients. With the supplied individual education and educational booklet, we tried to increase, the patients' awareness and knowledge. In case of any incorrect information /practice regarding the self-care of patients were determined and corrected. Over the period of the study, the patients were allowed to call the researcher whenever they wanted to ask a question and receive advice on any topic they wanted (Figure 1). One of the researchers collected the data (KK).

Data Collection Instruments

Patient Information Form: A simple 10-question form was used to collect information about the sociodemographic characteristics of patients.

The Self-Care Agency Scale (SCAS): The Turkish validation of SCAS was used for the self-care agency (Nahcivan, 2004). The SCAS is orginally of 43 items and the scale was adapted to Turkish by Nahcivan, who arranged it into 35 items (Nahcivan, 2004). Each item was rated from 0 to 4 on a 5-point Likert-type scale. The highest overall score is 140 and the lowest is 35 and highest scores indicate the higher self-care agency (Kearney & Fleischer, 1979; Nahcivan, 2004). The Cronbach alpha coefficient was .89 (Nahcivan 2004). The Cronbach α-coefficients (preoperatively, pre- discharge and at 6 months) were: .75, .78, .82.

Minnesota Living with Heart Failure Questionnaire (MLHFQ): The Turkish validation of MLHFQ was used for the quality of life assessment. The MLHFQ is composed of 21 questions. The patient is expected to grade each question from 0 to 5. Scoring must be based on how much their heart condition influenced the specific activity over the last month. The best score is 0 and the worst is 105 (Rector, 1987; Asik Ozdemir, 2009). The Cronbach α-coefficient was .85 (Asik Ozdemir, 2009). The Cronbach α-coefficients (preoperatively, predischarge, at 6 months) for this study were .80, .74, .78.

Data Analysis: The research data were analysed by the Department of Biostatistics and Medical Informatics, Faculty of Medicine, Ege University, using IBM SPSS for Windows, Version 21.0. Because the sample size was <30, non-parametric tests were used for the statistical comparisons. These included the chi-square, Mann–Whitney *U*, Kruskal–Wallis, and Friedman tests. For all results, a value of $p < 0.05$ was considered statistically significant.

Ethics: The written informed consent was approved by the University Hospital Ethical Committee (Approval Number: 13-5.1/9 / 11.06.2013) In addition, written permission was obtained from the University Hospital. The researcher obtained the patients' written and verbal consents after explaining to them the purpose of the research, the process of data collection and the study's implementation, informing them that they may withdraw from the study at any time and that their names would be kept in confidentiality. The studies comply with the Declaration of Helsinki.Approval was obtained from the institutions where the study was conducted were taken and the Ethics committee approval was obtained with the decision dated 2013 June 11 and having the protocol number of 13-5.1/9 of the Ethics Committee of Ege University Faculty of Medicine in order to conduct the research. The study was carried out is Ege University, Department of Cardiovascular Surgery, Izmir.

Table 1. Nursing Care Based on Orem's Self-Care Model

Domain	Nursing Diagnosis	Aim	Nursing Interventions
Universal self care requisites	**Disruption in sleep patterns** ** Fear (breakdown of the device),* ** The presence of the device disrupts the comfort*	Ensuring that the individual gets adequate sleep and rest	- The sleep patterns and habits of the patient should be determined. - The patient should be allowed to express his fear - Measures that make it easier for the patient to sleep should be taken in line with their habits (warm milk, relaxation techniques, etc.) - Necessary information should be provided about the use of the device, solution of technical problems, etc.
	Risk of nutritional excess: * *Nutrition more than the body needs (depending on calorie consumption in snacks)*	Ensuring that it remains within the normal body mass index range	The nutritional status of the patient should be evaluated Daily weight tracking should be done An exercise program suitable for the patient should be determined. A diet suitable for the patient should be determined in cooperation with the dietician. Information should be given about the complications he/she may encounter if he/she does not comply with diet and exercise programs.
	Risk of change in blood pressure ** Decrease in mean arterial pressure and insufficient flow due to insufficient fluid intake* ** Increase in mean arterial pressure due to excessive salt intake*	Keeping blood pressure within normal limits No symptoms of cerebral bleeding due to hypertension	- Adequate fluid intake should be ensured - Intake and extracted fluid should be followed up - The patient should eat low in salt - The patient should be informed about regular medication use - blood pressure should be Monitored with Doppler (mean pressure 75-80 mmHg) - the values should be followed from the control unit of the device (cardiac output) - Alarms should be ensured effective management
	Lack of self-care	The patient can perform self-care with support	- The patient should be allowed to express their fears while fulfilling their self-care needs. - A safe environment should be created where the patient can take a shower with the device. - While taking a shower, it should be supported by the patient's relative. - The contact of the catheter area with water should be prevented, -It should be placed in the shower bag to prevent the device from contacting with water. - Dressing change should be provided after showering
	Instrumental self-care deficit *****_Regarding device management_	No device-related complications	-Training on the management of the device should be provided - LVAD values should be recorded daily and abnormal values should be reported. - LVAD's battery replacement and charging operations should be done properly. - The alarm conditions and management of the device should be explained to the patient. - The patient should be informed about device-related lifestyle changes and avoided situations.
Developmental self care requisites	**Body Image Disturbed** *****_Dependent on living with LVAD (a bag that has to constantly carry and a visible cable from the outside)_	Having a positive body image	- Encouraging the patient to express their experiences with LVAD -Patient's strengths should be revealed - If necessary, referral for psychiatric support
	Ineffective sexual pattern *****Dependent on living with LVAD	Ensuring a healthy sex life	-The problem related to sexual life should be determined. -The patient should be given the opportunity to express his feelings and thoughts. - Information should be given based on the effective use of the device -If necessary, should be guided for professional support

Health deviation self care requisites	**Infection Risk** **(Around the Driveline outlet)** ***Due to not proper maintenance of** *the driveline outlet area*	-Driveline (the line that provides communication between the pump and the controller) failure to observe signs of infection in the outlet zone	- Signs of infection (systemic and local) should be followed up - Aseptic technique should be used in dressings. - Dressing change should be done every 2 days as long as there is no discharge (if there is discharge, as it gets dirty)
	Bleeding Risk ** Anticoagulant treatment,* ** Due to the pump disrupting the structure of thrombocytes in the blood.*	No bleeding Laboratory findings in the normal range (INR, Ptz, Hgb, Htc)	- The patient should be informed about the use of anticoagulants. Trauma must be prevented - It should be stated that the patient complies with the control dates. -Laboratory findings should be monitored (INR, Ptz, Hgb, Htc) - The patient's vital signs should be checked -The patient's signs of active bleeding (LVAD low volume alarm, hypotension, sweating, etc.) should be observed. - It should be checked whether the values of LVAD are within normal limits. - In the presence of bleeding, the cause of the bleeding should be determined and reported to the physician. -Training about foods that will increase INR level should be given
	Thromboembolism Risk ** Due to thrombus development in the area of the device that comes into contact with the blood*	No thrombus developmen	-Early signs of thromboembolism should be monitored (decrease in device flow, increase in the energy indicator (watt) consumed by the device, tea-colored urine) -The patient should be educated about the early symptoms of thrombus. - The patient should be monitored in terms of signs and symptoms that may develop in case of embolism. - The patient should be informed about anticoagulant drugs. - Training should be given to foods that will reduce the targeted INR value
	Risk of decreased cardiac output ** Depends on the device not working effectively*	Ensuring adequate perfusion	-The patient should be provided with sufficient fluid intake - Fluid volume should be evaluated (blood pressure monitoring etc.) - Symptoms of congestive heart failure should be monitored - Trauma must be prevented - Device values should be monitored - Alarms must be managed correctly
	Anxiety * Dependent on living with LVAD	Relief of anxiety	- Anxiety level should be evaluated - Expressing his/her anxieties about living with LVAD -Support for coping methods for his anxiety - Trainings should be started in the early postoperative period - It should be provided to ask questions about the device - The patient's preparedness for discharge should be evaluated - Consultancy should be provided after discharge

Table 2: Demographic and clinical features of the patients.

Clinical Features	Intervention Group		Control Group		Total		p
	n	%	n	%	n	%	
Sex							
Female	3	27.3	2	20.0	5	23.8	1.000
Male	8	72.7	8	80.0	16	76.2	
Marital status Married							
Single	10	90.9	8	80.0	18	85.7	0.586
	1	9.1	2	20.0	3	14.3	
Educational Status							
Primary school							
High school	6	54.5	5	50.0	11	52.4	*
University	4	36.4	4	40.0	8	38.1	
	1	9.1	1	10.0	2	9.5	
Smoking							
Yes	-	-	-	-	-	-	0.080
No	2	18.2	6	60.0	8	38.1	
Quit smoking	9	81.8	4	40.0	13	61.9	
Chronic illness							
Yes	5	45.5	8	80.0	13	61.9	0.183
No	6	54.5	2	20.0	8	38.1	
Heart Failure Class							
3rd degree							
4th degree	5	45.5	8	80.0	13	61.9	0.183
	6	54.5	2	20.0	8	38.1	
Total	11	100	10	100	21	100	

Table 3: Distribution of Patients in Intervention and Control Groups According to Self-Care Agency Score

	Intervention(n=11) median (IR)	*Control (n=10) median (IR)*	*p* Z*
Self-Care Agency Score (Preoperatively)	110.00 (29.00) (min: 60 max:122)	122.50 (24.00) (min: 94 max:137)	Z=-2.502 p*=0.052
Self-Care Agency Score (Before Discharge)	113.00 (19.00) (min: 64 max:130)	123.00 (22.00) (min:102 max:137)	Z=-1.797 p*=0.072
Self-Care Agency Score (6th month)	120.00 (13.00) (min: 80 max:139)	128.50 (14.75) (min:110 max:139)	Z=-1.412 p*=0.158
p** **X^2**	**p**=0.0001** X^2=20.18	**p**=0.0001** X^2=17.89	

p*: Mann-Whitney U Test p**: Friedman Test

Table 4: Distribution of Patients in Intervention and Control Groups According to Minnesota Heart Failure and Living Questionnaire Score

	Intervention(n=11) median (IR)	*Control (n=10) median (IR)*	*p* Z*
Quality of Life Score (Preoperatively)	93.00 (11.00) (min:53.00 max:99.00)	69.50 (41.00) (min:48.00 max:102.00)	p*=0.090 Z=-1.693
Quality of Life Score (Before Discharge)	75.00 (22.00) (min:53.00 max:88.00)	57.00 (29.00) (min:38.00 max:73.00)	p*=0.059 Z=-1.186
Quality of Life Score (6th month)	31.00 (21.00) (min:16.00 max:85.00)	28.50 (10.50) (min:19.00 max:40.00)	p*=0.216 Z=-1.238

p**	**p**=0.0001**	**p**=0.0001**
X^2	X^2=16.79	X^2=20.00

p*: Mann-Whitney U Test p**: Friedman Test

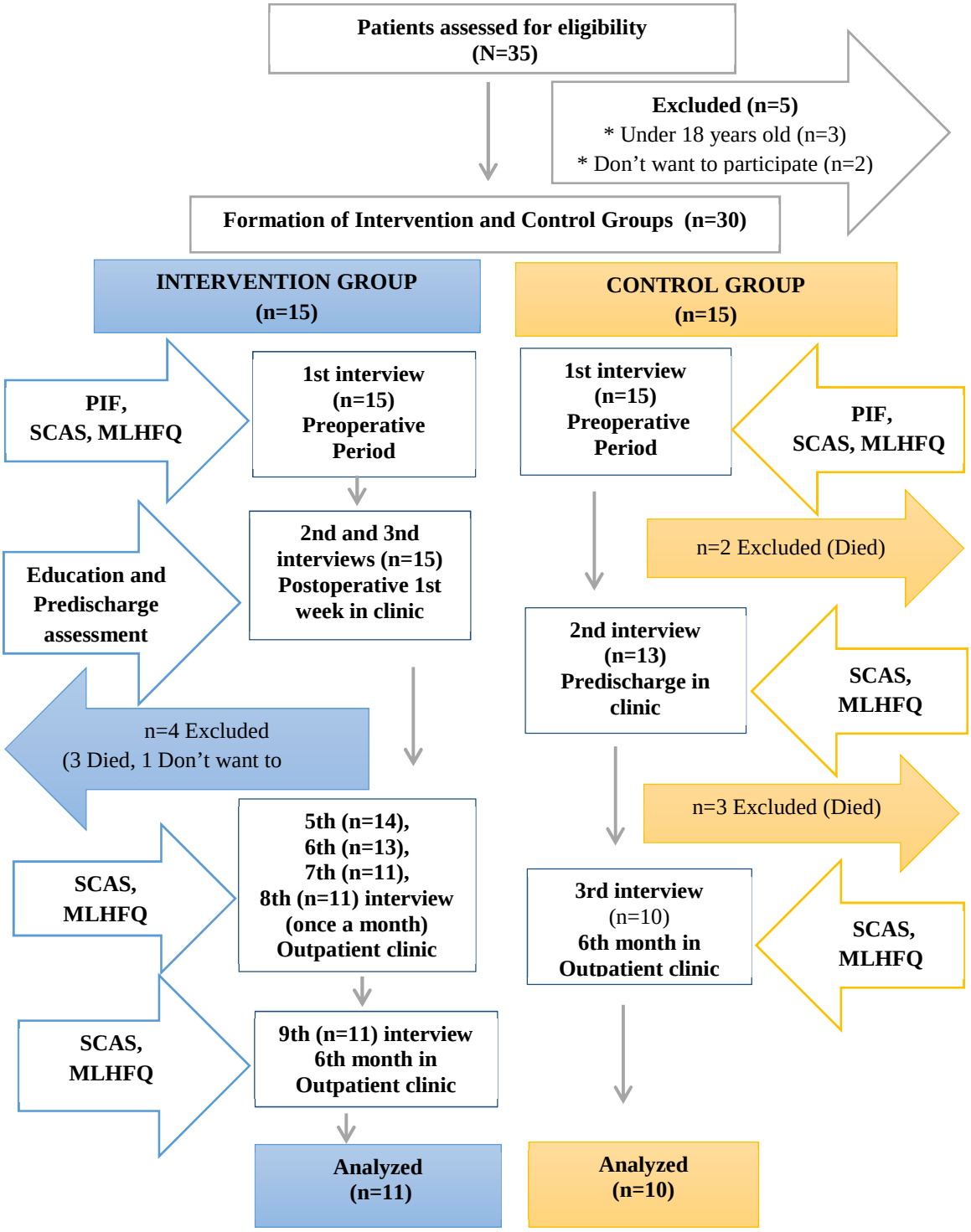

Figure 1. Sample flow diagram and procedure
***PIF:** Patient Information Form, ****SCAS:** The Self-Care Agency Scale,
*****MLHFQ:** Minnesota Living with Heart Failure Questionnaire

Results

Characteristics of the patients: The mean age of the participants was 51.52±10.77 years (range, 29–65 years). Of these, 76.2% (n=16) were male, 85.7% (n=18) were married, 52.4% (n=11) were primary school graduates, 61.9% (n=13) had quit smoking, 61.9% (n=13) had an additional chronic disease, 61.9% (n=13) had grade 3 heart failure and 71.4% (n=7) experienced a postoperative complication.

in the intervention and control groups, no statistically significant difference was found in terms of sex, marital status, educational status, presence of chronic disease, heart failure class or complication rate ($p > .05$) (Table 2).

Self-Care Agency Scores: In the intervention group, a statistically significant difference was found ($\chi^2=20.18$, $p<.001$) between the self-care agency scores preoperatively, before discharge and at the sixth postoperative month.

A statistically significant difference was also found for the self-care agency scores of the control group ($\chi^2=17.89$, $p<.001$) between these three-time points (Table 3). There was no significant difference between the groups these three-time points (Table 3).

Quality of Life Scores: In the intervention group, a statistically significant difference was found ($\chi^2=16.79$, $p<.001$) between the quality of life scores preoperatively, before discharge and at the sixth postoperative month. A statistically significant difference was also found in the quality of life scores of the control group ($\chi^2=20.00$, $p<.001$) between these three-time points (Table 4). There was no significant difference between the groups these three-time points (Table 4).

Discussion

It is thought that the increase in quality of life of both groups resulted from the beneficial effects of LVAD implantation, which improved haemodynamic parameters, and in turn, improved physical functioning and positively affected quality of life. In studies looking at quality of life in patients with LVAD, it has been reported that there is a significant increase in the quality of life of patients after an LVAD is implanted, regardless of age or complication rate (Ozturk et al., 2012; Milano & Simeone, 2013; Jakovljevic, 2014; Jorde et al., 2014; Grady et al., 2016; Cowger et al., 2018). In the study conducted by Ozturk et al. (2012), it was reported that heart failure regressed from stage IV to stage II in 92% of patients (26/28), based on the New York Heart Association criteria. To date, many different scales have been used in the studies that evaluate the quality of life of LVAD patients. Consistent with our findings, these reported that quality of life increased significantly in the postoperative period compared to the preoperative period (Jakovljevic et al., 2014; Jorde et al., 2014; Cowger et al., 2018). The lack of studies analysing the impact of nursing care on quality of life among patients after LVAD meant that no comparison could be made. Instead, only quality of life levels were discussed. On the other hand quality of life scores of preoperative, pre-discharge and the sixth month periods of patients in intervention and control groups was statistically compared, no significant difference between the groups was found. This result is thought to be due to the provision of adequate cardiac output after LVAD implantation in patients. It is a result that is compatible with the literature that only LVAD implantation improves the quality of life in both groups.

Patients with LVAD are reported to encounter severe complications (Emani, 2018; Milano & Simeone, 2013). After LVAD implantation, device-related complications can occur (e.g. bleeding, infection, arrhythmia, right heart failure etc.) (Felix et al., 2012, Topkara et al., 2014; Smith & Franzwa, 2015; Chmielinsk & Koons, 2017; Emani, 2018; Han et al., 2018) for which nursing interventions can do little to prevent. Some of these complications may also occur in the late postoperative period. Therefore, patients must take on self-care responsibility for the devices, especially in the postoperative period (Kato et al. 2014). Daily maintenance and monitoring of the LVAD requires psychomotor and cognitive skills for proper device functioning and to allow for satisfying levels of independence in activities of daily living. Self-care demands may seem overwhelming to the LVAD patient and lay caregiver (Widmar et al., 2014). The leading causes of death with LVAD are stroke and infection, both of which are intimately tied to device care. Building the capacity of patients and their caregivers to take on these necessary duties is an important quality and safety initiative. Self-care with LVAD patients includes care for the system and the driveline, maintaining a healthy lifestyle, and adhering to the medical regimen (Kato et al, 2014; Chmielinski & Koons, 2017;

Casida et al., 2018a). Casida et al. (2016) reported that higher cognitive function is associated with higher LVAD self-efficacy, higher LVAD adherence, lower LVAD care dependency, and greater QOL. In our study a statistically significant increase was found in the self-care agency scores of patients in both groups ($p < 0.05$). However no statistically significant differences between preoperative, pre-discharge and sixth month self-care agency scores of the patients in intervention and control groups was found ($p>0.05$). There is no significant difference between the mean scores of self-care agency, probably because all patients with LVAD are functionally more active postoperatively. But we can say that Orem's Self-Care Model is effective in patients' self-care in the long term. This provided a holistic view of the care of patients with LVAD and it motivated the patients to take care of themselves. Because in the control group, some patients did not record device values properly, gained weight. Furthermore, when filling in their forms, some patients in the control group expressed that they did not want to be discharged, despite being hemodynamically stable and approved as being fit for discharge. These can be considered as important secondary consequences. Yarboro et al. (2016) demonstrated that a multidisciplinary approach including rigorous education of patients and caregivers significantly reduced driveline site infections. Unfortunately, because of the lack of studies effect of the nursing care evaluating the self-care agency of patients with LVAD, commonly the data in this section were compared to other studies in which self-care agency of patients with heart failure were evaluated. Strömberg et al. (2003) stated that nursing interventions significantly increased the self-care behaviours, while Trojahn et al. (2013) stated that the impact of education on self-care behaviours for the patients with heart failure was of significance. Our findings are consistent with the existing literature and will guide the care of patients with LVAD with a nursing model.

Study Limitations: Our study had several limitations. The research was conducted at a single-center. Since there were differences (drug doses, normal values of device parameters, common complications, etc.) depending on the implanted device, only patients with a HeartWare type device were included in the study. The follow- up duration was only 6 months.

Conclusion

As a result, it was determined that LVAD implantation alone improved quality of life and self-care agency scores in as little as 6 months. However, patients require serious support to adapt to living with LVAD and to prevent complications. In this context, nursing models provide a framework for the care to be given to these patients. In this study Orem's Self-Care Model provided a professional perspective. Although we recommend that this model can be used to direct the care of patients with LVAD, we also suggest that the model's impact on quality of life be assessed in larger cohorts. Further data are needed to support our preliminary observations and to explore long-term quality of life and self care agency. In addition, qualitative studies about the postoperative experiences of these patients can provide valuable information about how they experience this adaptation process.

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