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Original Article / Özgün Makale

The analysis of unplanned readmissions after left ventricular assist device implantation as bridge-to-transplant

Transplantasyona köprüleme olarak sol ventrikül destek cihazı yerleştirilmesi sonrası planlanmamış hastane başvurularının analizi

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ABSTRACT

Background: In this study, we aimed to investigate frequency, patterns, etiologies, and costs of unplanned readmissions after left ventricular assist device implantation.

Methods: Between April 2012 and September 2016, 99 unplanned readmissions of a total of 50 consecutive bridge-to-transplant patients (45 males, 5 females; mean age 46.9±10.3 years; range, 19 to 67 years) who were successfully discharged after left ventricular assist device implantation were retrospectively analyzed. Patient demographic data, hemodynamic measurements before implantation, and readmissions after discharge were recorded. Hospitalizations due to major problems which were unable to be managed in routine outpatient clinic were accepted as unplanned readmissions. Survival analysis was performed.

Results: The readmission rate was 1.7 per year after discharge. Survival of patients who were readmitted within the first 90 days was found to be significantly lower than those without early readmission. The most common reasons of readmissions during follow-up were major infection (23.2%), neurological dysfunction (22.2%), cardiac causes (12.1%), bleeding (11.1%), and device malfunction (10.1%). Neurological dysfunctions (82,005 USD) and device malfunctions (73,300 USD) caused the highest economic burden.

Conclusion: Among patients with a left ventricular assist device, hospital readmissions are common. Development of preventive strategies as well as effective treatment methods focused on long-term adverse events is critical to reduce the frequency and costs of hospital readmissions.

Keywords: Bridge-to-transplant, outcome, readmission, transplantation, ventricular assist device.

ÖZ

Amaç: Bu çalışmada sol ventrikül destek cihazı implantasyonu sonrasında planlanmamış hastane başvurularının sıklığı, paternleri, nedenleri ve maliyetleri araştırıldı.

Çalışma planı: Nisan 2012 - Eylül 2016 tarihleri arasında sol ventrikül destek cihazı implantasyonu sonrasında başarılı bir şekilde taburcu edilen toplam 50 ardışık transplantasyona köprüleme hastasının (45 erkek, 5 kadın; ort. yaş 46.9±10.3 yıl; dağılım, 19-67 yıl) 99 planlanmamış hastane başvurusu retrospektif olarak incelendi. Hastaların demografik özellikleri, implantasyon öncesinde hemodinamik ölçümleri ve taburculuk sonrasında yeniden hastane başvuruları kaydedildi. Rutin poliklinikte tedavi edilemeyen majör nedenlere bağlı hastane yatışları, planlanmamış hastane başvurusu olarak kabul edildi. Sağkalım analizi yapıldı.

Bulgular: Taburculuk sonrası tekrar hastaneye başvuru oranı yıllık 1.7 idi. İlk 90 gün içinde hastane başvurusu olan hastaların sağkalım süresi, erken başvuru yapmayan hastalara göre anlamlı düzeyde düşük bulundu. Takip sırasında en sık hastaneye yeniden başvuru nedenleri enfeksiyon (%23.2), nörolojik disfonksiyon (%22.2), kardiyak nedenler (%12.1), kanama (%11.1) ve cihaz malfonksiyonu (%10.1) idi. Nörolojik disfonksiyon (82.005 USD) ve cihaz malfonksiyonu (73.300 USD) en yüksek ekonomik yüke neden oldu.

Sonuç: Sol ventrikül destek sistemi cihazı olan hastalar arasında tekrar hastane başvurusu sıktır. Hastane yatışlarının sıklığını ve maliyetini azaltmak için önleyici stratejilerin yanı sıra, uzun dönem advers olaylara yönelik etkili tedavi stratejilerinin geliştirilmesi önemlidir.

Anahtar sözcükler: Transplantasyona köprüleme, sonuç, tekrar başvuru, nakil, ventrikül destek cihazı.

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Left ventricular assist device (LVAD) therapy is a suitable option for patients in whom optimal advanced heart failure treatment fails.[1] Although LVADs provide excellent hemodynamic support, long-term use of them eventually induces various multifactorial complications.[2] In bridge-to-transplant (BTT) patients with LVAD, prolongation of support time due to donor scarcity may lead to many unplanned hospital readmissions which health professionals must have to handle.[3] Previous reports have revealed that readmission rate is around 80% during follow-up, and most of them are unplanned.[4,5] Due to the rapid increase and diversification of this specific patient population, it is important to analyze the problems encountered in the outpatient setting.

In this study, we present a detailed analysis of readmissions of BTT patients with LVAD and aimed to identify the frequency, pattern, etiology, and costs of unplanned readmissions.

PATIENTS AND METHODS

This single-center, retrospective study included 99 unplanned readmissions of a total of 50 consecutive BTT patients (45 males, 5 females; mean age 46.9±10.3 years; range, 19 to 67 years) who were successfully discharged after LVAD implantation between April 2012 and September 2016. Exclusion criteria were as follows: previous LVAD implantation as a destination therapy (DT); having pulsatile-flow ventricular assist device (VAD); in-hospital mortality after LVAD implantation; previous heart transplantation before discharge after LVAD implantation; and having LVAD in an external center and being under follow-up at our hospital. A written informed consent was obtained from each patient. The study protocol was approved by the Istanbul Kartal Koşuyolu Yüksek Ihtisas Training and Research Hospital Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

All decisions for LVAD implantation and candidacy for heart transplantation were made by the Multidisciplinary Heart Transplantation Council. The follow-up examinations including first week after discharge, monthly for six months, then every three months, and after surgery were performed by a certain dedicated team focused on the patients with LVAD. The transplant eligibility of patients with LVAD was reassessed on a regular basis (every six months in stable medical conditions) with detailed echocardiography, cardiac catheterization, and laboratory tests including panel-reactive antibodies. The patients who were applied to suburban hospitals and required follow-up or treatment were transferred immediately to our center within 24 hours. In our routine practice, the outpatient LVAD team always stays in contact with the patients, as well as the manufacturer for any kind of VAD alarms. As the patients with LVADs need special considerations, they are always able to get in touch with emergency on-call VAD coordinator, who also make regular calls to patients. In our study, all LVAD patients requiring hospitalization for any reasons were managed primarily at the reference center. Although anticoagulation goals for LVAD vary between reported studies, we maintained with a target INR of 2.0 to 3.0 and aimed to preserve the INR in the upper limits of target range in HVAD™ pump patients with our clinical experience by warfarin according to the guidelines, device type, and recommendations of the manufacturer.[6] Antiplatelet regimens ranged from no treatment to dual therapy during concomitant warfarin treatment. We preferred to administer dual antiplatelet therapy (acetylsalicylic acid 150 mg daily and clopidogrel 75 mg daily) targeting more than one pathway of platelet activation without a high risk of bleeding based on our own experience. Antithrombotic therapies of patients at risk of bleeding, hemolysis or thrombosis were re-arranged individually.

Patient demographic data, hemodynamic measurements before implantation, and readmissions after discharge were evaluated retrospectively. Index hospitalizations were defined as admissions that had a LVAD implantation performed. According to the decision of the heart team, hospitalizations to facilitate elective evaluations after discharge were defined as planned readmissions. Reasons for unplanned readmissions during the study period are shown in Table 1. The remaining hospitalizations due to major problems which were unable to be managed in routine outpatient clinic were accepted as unplanned readmissions. Unplanned readmissions due to any adverse event were classified according to the Interagency Registry for Mechanically Assisted

Table 1. Reasons for unplanned readmissions

Etiology of planned readmissions	Number of readmissions
Cardiac catheterization	3
Heart transplantation	4
Transplant eligibility assessment	1
Pulmonary vasodilator therapy	1
ICD generator exchange	1
LVAD pump speed optimization	2
Desensitization therapy	1

ICD: Implantable cardioverter defibrillator; LVAD: Left ventricular assist device.

Table 2. Baseline characteristics of patients (n=50)

	n	%	Mean±SD
Age (year)			46.9±10.3
Gender			
Male	45	90	
Body mass index (kg/m^2)			25.6±4.5
Etiology			
Ischemic	25	50	
Non-ischemic	25	50	
Machanical ventilation	6	12	
Intra-aortic balloon pump	11	22	
Mechanical circulatory support (temporary)	2	4	
Prior sternotomy	11	22	
Hemodynamic measurements			
Ejection fraction (%)			20±5
Cardiac index (liters/min/m^2)			1.7±0.3
Pulmonary capillary wedge pressure (mmHg)			25±8
Systolic pulmonary artery pressure (mmHg)			58±21
Central venous pressure (mmHg)			14±6.1
Device			
HeartMate 2	24	48	
HeartMate 3	9	18	
HeartWare	16	32	
Heart Assist 5	1	2	

SD: Standard deviation.

Circulatory Support (INTERMACS) definitions.[7] The overall follow-up information of the patients were collected until the date of June 2017. Long-term outcome measures of the study were as follows: all-cause mortality during LVAD therapy; heart transplantation; and LVAD removal due to myocardial recovery. All in-hospital data of the patients were available in a well-documented hospital electronic records. Survival data were obtained from the national database. We calculated the direct hospital cost for each readmissions based on the insurance reimbursements. All costs were adjusted to the January 2017 consumer price index of Turkey comparing with the relative economic burden of various adverse events.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 23.0 software (IBM Corp., Armonk, NY, USA). Categorical variables were presented in number and frequency, while continuous variables were presented in mean ± standard deviation (SD) or median (min-max) values. The Mann-Whitney U test was used to compare continuous variables. Log-rank tests were used to analyze statistical significance in survival differences between the groups. Survival curves were demonstrated with the Kaplan-Meier method. Linear regression method was used to reveal the relationship between annual readmission frequency

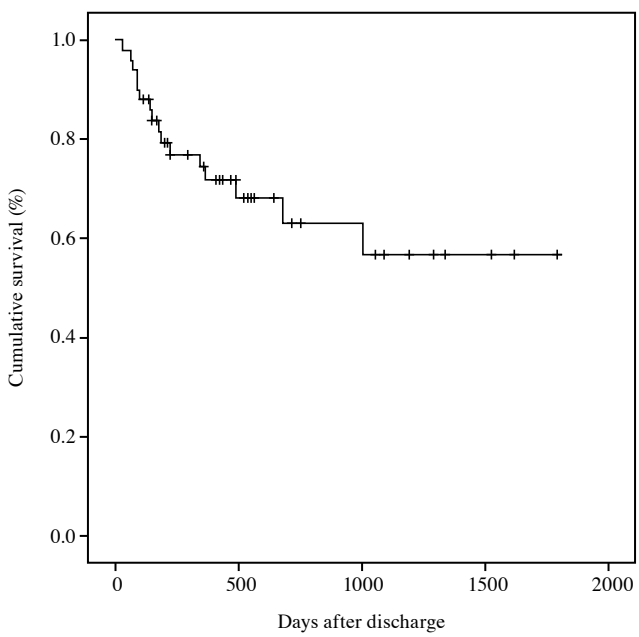

Figure 1. Cumulative survival of the patients with left ventricular assist device.

and follow-up time. A two-tailed *p* value of <0.05 was considered statistically significant.

RESULTS

All patients included in the study received continuous-flow LVADs as BTT. Overall data of index hospitalizations are shown in Table 2. The median hospital length of stay (LOS) after LVAD implantation was 32 (range, 7 to 200) days. The median follow-up period after discharge was 428 (range, 29 to 1,790) days. Five patients (10%) underwent heart transplantation. Sixteen patients (32%) died during LVAD therapy. Termination rate of LVAD therapy was 2% (n=1) due to myocardial recovery. Cumulative survival of the cohort is shown in Figure 1.

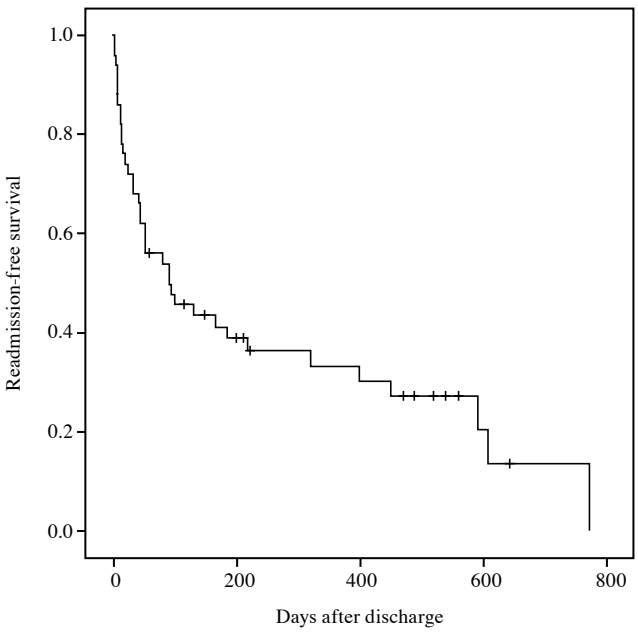

Figure 2. Readmission-free survival of the patients with left ventricular assist device.

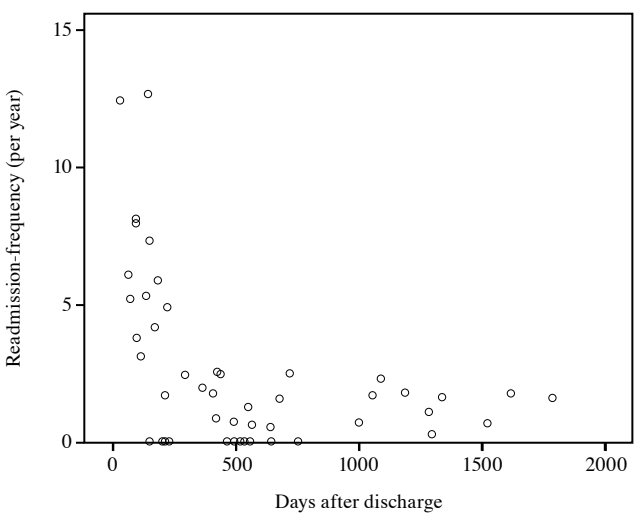

Figure 3. Relationship between follow-up period and readmission frequency (Scatter/dot plot).

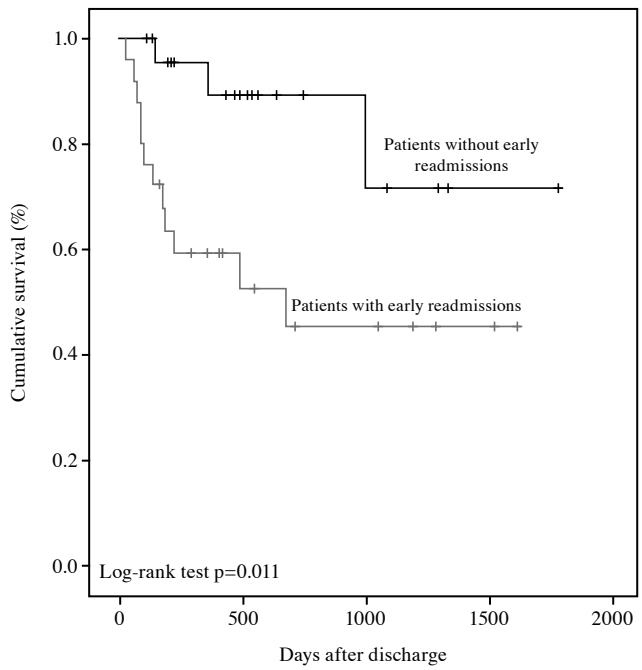

Figure 4. Kaplan-Meier survival curves of patients with and without early (first 90-day) readmissions after discharge.

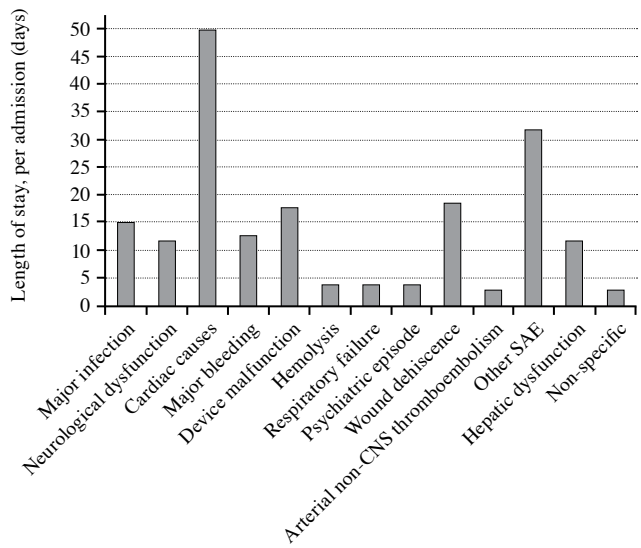

Figure 5. Mean length of hospital days according to various etiologies.

SAE: Serious adverse events; CNS: Central nervous system.

A total of 96.2% of the patients were outside the hospital during follow-up. Twelve patients (24%) did not readmit after discharge. Readmission-free survival curve of the patients is shown in Figure 2. The remaining 38 patients (76%) had a total of 112 readmissions. Of these, 99 readmissions (88.4% of all readmissions) were unplanned. The median readmission frequency was 1.7 (range, 0 to 12) per year. Readmission frequency of patients decreased significantly as the follow-up period extended (p=0.002) (Figure 3). The median time to first readmission was 91 (range, 1 to 772) days. Half of the patients were admitted to the hospital within the first 90 days. Survival of patients who were hospitalized within the first 90 days was found to be significantly lower than those without early readmission (log-rank=0.011) (Figure 4). Additionally, in the subsequent follow-up of patients requiring early readmission, the annual frequency of readmission and also cost indices (total admission cost/follow-up period) were significantly higher than the others (p=0.001 and p=0.03, respectively).

The most common reasons for unplanned readmissions were major infection (23.2%), neurological dysfunction (22.2%), cardiac causes (12.1%), bleeding (11.1%), and device malfunction (10.1%). However, cardiac causes were characterized with the longest LOS for each admission (Figure 5). When total costs were considered, it was found that readmission due to neurological dysfunction (82,005 USD), device malfunction (73,300 USD) and cardiac reasons (56,449 USD) led to the highest costs,

Table 3. Analysis of unplanned readmissions according to specific etiologies

Etiology of readmissions	Number of readmissions	Number of patients	Lethal outcome	Total LOS (days)	Total cost (TRY)	Total cost (USD)
Major infection	23	12	1	353	135,772	38,695
Driveline infection	12	6	-	229	99,040	28,226
Pocket infection	1	1	-	7	1,463	417
Localized non-device infection*	9	4	-	106	29,195	8,321
Sepsis	1	1	1	11	6,074	1,731
Neurological dysfunction	22	15	9	249	287,737	82,005
Intracranial hemorrhage	13	10	7	132	238,326	67,923
Transient ischemic attack	5	2	-	47	3,555	1,013
Ischemic stroke	2	2	2	33	42,483	12,108
Vertigo	2	1	-	37	3,373	961
Cardiac causes	12	8	3	602	198,067	56,449
Right heart failure	6	5	1	89	35,946	10,245
Arrhythmia	6	3	2	513	162,121	46,204
Major bleeding	11	7	1	146	36,398	10,373
Gastrointestinal	8	5	-	122	28,595	8,150
Non-gastrointestinal**	3	2	-	24	7,803	2,224
Device malfunction	10	6	1	190	257,193	73,300
Pump thrombosis	6	4	1	111	200,551	57,157
Minor device malfunction***	4	2	-	79	56,642	16,143
Hemolysis	1	1	-	4	1,249	356
Respiratory failure	4	2	-	17	2,311	659
Psychiatric episode	4	3	-	16	1,398	398
Wound dehiscence	4	2	-	77	2,5621	7,302
Arterial non-CNS thromboembolism	2	2	-	6	6,118	1,744
Other SAE****	2	2	-	65	16,467	4,693
Hepatic dysfunction	1	1	1	12	44,628	12,719
Non-specific	3	2	-	11	1,285	366

LOS: Length of stay; CNS: Central nervous system; SAE: Serious adverse events; * 6 pneumonia, 2 urinary tract infection, 1 thrombophlebitis; ** 2 vaginal, 1 nasal; *** 2 interconnecting cables problem, 2 pump alarm (without suspected pump thrombus); **** 1 malignancy., 1 autoimmune gastritis.

respectively. Etiologies of unplanned readmissions are summarized in Table 3.

DISCUSSION

The efficacy of LVADs for different patient populations is universally confirmed.[1,8,9] Increased clinical experience and extended indications have led to a rapid augmentation in the number of patients with LVAD in recent years.[9] After implantation, in addition to risks of normal population, patients must also cope with LVAD-related complications.[10] Nevertheless, LVAD therapy has been shown to improve the quality of life, compared to medical therapy.[12] As a parameter of quality of life, patients spend an overwhelming majority of their time outside hospital after discharge.[13,14] In our study, patients spent 96.2% of their time at home. The rate of unplanned readmission was 1.7 per year in our cohort, consistent with the previously published data.[4,15,16] In addition, the frequency of readmissions reduced monotonically during follow-up, which indicates that LVAD therapy is associated with further recovery in overall medical profile of patients over time in this population.

Despite many positive effects of LVADs, high readmission rate in which the majority was unplanned according to the previous reports also remained unchanged in our study.[5] A large-scale population study form the United States reported a 90-day readmission rate of 53.1%.[17] In our study, the 90-day readmission rate was 50%. Additionally, patients with early readmission showed a poorer prognosis in the long-term in our study. However, there is no consensus on scoring systems about measuring the quality of life and predicting the readmissions in patients with LVAD. Although several risk factors have been identified for different patient groups, the length of initial hospital stay seems to be the most emphasized predictor. We believe that pre-existing comorbidities during index hospitalization and at discharge are associated with early readmissions and also with long-term mortality. Unfortunately, this study is not feasible for the analysis of predictors due to the small sample size and numerous variables.

The main reasons for recurrent readmission in our study group are universal well-defined causes.[14,18] Infection, neurological dysfunction, cardiac causes, device malfunction and bleeding are the most pronounced reasons not only for hospitalizations, but also for prolonged LOS and higher total costs. In several series, major infection was shown as one of the most common causes of readmissions.[5,14,19,20] In our study group, it was also the frequent and repetitive cause for hospitalization. Subgroup analyses revealed that 56% of all readmissions due to infection were device-related. The majority of LVAD-related infections were driveline infections (92%; total 6 patients, 12 readmissions). Readmissions due to driveline infections resulted in longer LOS and also higher costs, compared to other infection-related hospitalizations. However, infection-related hospitalizations were often more benign than other adverse events.

Furthermore, neurological deficits were found to be associated with a high mortality risk (40.9%, n=9/22) and caused the highest total cost. Although ischemic brain infarction is rare, it is characterized by prolonged hospitalization. Additionally, the mortality rate was 100% for these patients. The major challenge for patients with neurological dysfunction is the difficult management of delicate balance between bleeding and thrombosis in LVAD.[21] In our daily practice, neurological sequelae also cause a major dilemma in terms of the assessment of transplantation availability, particularly in young patients. In patients with LVAD, we suggest that non-specific symptoms which may be related to neurological disorders need to be more aggressively evaluated than in non-LVAD patients. In our initial experience, all patients were treated with dual antiplatelet therapy and standard anticoagulant therapy (at the upper limit of therapeutic range). However, individualized antithrombotic therapy is definitely reasonable to reduce LVAD-related bleeding (neurological and gastrointestinal).

Another reasons for readmissions are cardiac causes (arrhythmia and right heart failure) characterized by prolonged hospitalization periods. These patients usually wait for an emergency transplant in the hospital due to persistence of cardiac comorbidities. Finally, it should be kept in mind that the majority of readmission studies, as in our study, are based on the first presentation to classify each readmission. However, a substantial proportion of hospitalizations may become complicated over time due to the interaction of different adverse events.

Despite the proportional decrease in costs over time, the increase in the number of patients with LVAD may cause an important financial burden cumulatively.[22] In our study, most of the follow-up costs were related to LVAD-related adverse events. In addition, in terms of total health costs, management of the adverse events with highest cost requires intense effort due to emergency heart transplant necessity (device failure and cardiac causes) or high mortality risk (neurological causes). Akther et al.[18] reported

that the most expensive reasons for readmission were device malfunction, cardiac causes, and neurological disorders. In our study, the cost of readmission for neurological reasons was the highest, followed by device malfunction and cardiac causes. In our study group consisting of only BTT patients, we often preferred to refer the patients who were admitted due to a device malfunction to a heart transplant as a first step rather than device exchange. Although adverse events with LVAD are frequent, we believe that it is not feasible to make a cost-effective analysis, due to donor scarcity and lack of medical therapy of comparable to LVAD in efficacy.

Nonetheless, the present study has some limitations. Its retrospective design is the main limitation. In addition, although data of study patients were perfectly recorded and fully available, possible external readmissions and minor complications not requiring hospitalization might have caused a potential bias. Also, our relatively small sample size reflects our initial experience. Therefore, conservative approaches may have resulted in prolonged stays of length and increased costs. The cost analysis was also based on insurance reimbursement, and patient expenditures, employee salaries, and other social care costs were excluded. Finally, this study does not reflect the total economic impact of patients with LVAD, since it only focuses on the proportional financial burdens of etiologies.

In conclusion, unplanned readmission after left ventricular assist device implantation is common, despite the improvement of ventricular assist device technologies and dedicated healthcare. Patients with early readmission have worse survival than those not early readmitted. Major infection, neurological dysfunction, cardiac causes, device malfunction, and bleeding are the most common causes of readmissions. Readmissions due to neurological dysfunction and device malfunction are also associated with high costs. Further studies investigating the causes which induce readmissions may greatly contribute to the long-term survival of patients with a left ventricular assist device and to the improvement of the quality of life of patients.

Declaration of conflicting interests

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