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Evaluation of cardiac arrhythmia in pediatric patients with Left Ventricular Assist Device (L-VAD)

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Abstract. – OBJECTIVE: Pediatric heart failure is an important cause of morbidity and mortality in childhood. Left ventricular assist devices (L-VAD) are used for bridging to transplantation in patients with indications for heart transplantation.

PATIENTS AND METHODS: The children included in the study were patients who underwent implantation of an L-VAD due to advanced heart failure at Ege University Faculty of Medicine Hospital between January 2009 and January 2023.

RESULTS: Of the 33 patients who underwent L-VAD implantation, 16 (48.5%) were female and 17 (51.5%) were male. The median age at surgery was 13 years (IQR, 9.5-15). The median weight was 44 kg (IQR, 25.65-52), the median height was 158 cm (IQR, 134.5-168.5), and the median body surface area was 1.37 m^2 (IQR, 0.95-1.51). All patients who underwent L-VAD implantation had an echocardiographic diagnosis of dilated cardiomyopathy. The patients underwent a median of 16 (IQR, 9-21) ECGs, and the median number of 24-hour Holter ECGs obtained was 3 (IQR, 2-5). Arrhythmias that occurred after L-VAD implantation were classified as atrial and ventricular. Ventricular arrhythmia included ventricular tachycardia (VT) lasting for more than 30 seconds (sustained VT), VT lasting for less than 30 seconds (nonsustained VT), and ventricular fibrillation. Atrial arrhythmias included atrial flutter, atrial fibrillation, supraventricular tachycardia, and atrial ectopic tachycardia. During the follow-up, atrial or ventricular arrhythmias were observed in 11 (33%) patients. The most common rhythm disturbances before L-VAD implantation were ventricular arrhythmias, while after the surgery, atrial arrhythmias were found to be the most frequent. A total of 5 patients underwent cardioversion (n=2) or defibrillation (n=3) due to arrhythmia.

CONCLUSIONS: In patients undergoing L-VAD implantation, rhythm disorders that could normally lead to hemodynamic instability are frequently encountered. In these rhythm disorders, medical therapy should be attempted before resorting to cardioversion or defibrillation, and subsequently, more aggressive treatment methods should be considered.

Key Words:
Ventricular assist device, Pediatrics, Arrhythmia.

Introduction

Pediatric heart failure is an important cause of morbidity and mortality in childhood. Although heart transplantation is the best treatment option for patients with terminal heart failure[1], a left ventricular assist device (L-VAD) is used as a bridge to heart transplantation (due to difficulty finding an organ donor), during recovery (as in myocarditis) or as a last-resort treatment option (in those with systemic disease). L-VADs, also known as mechanical circulatory assist devices, are implantable mechanical pumps that help deliver blood from the lower chambers of the heart to the rest of the body. These devices are generally implanted in patients who have dilated cardiomyopathy (DCM) presenting with left ventricular dysfunction. Although electrocardiogram (ECG) findings are not disease-specific, patients with DCM may exhibit left atrial enlargement, biatrial dilation, left ventricular hypertrophy or biventricular enlargement, left bundle branch block, left axis deviation, and ST change[2,3]. Apart from these alterations, life-threatening malignant atrial and ventricular arrhythmias are also seen[4]. Adult patients with L-VADs have an increased risk of both ventricular and atrial arrhythmias[5].

There are very few studies[6] evaluating the frequency of arrhythmias after L-VAD implan-

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tation in pediatric patients. The aim of this study was to evaluate cardiac arrhythmias in patients with L-VADs who have been under our Center's care since 2009, having received various brands of L-VADs (Berlin Heart EXCOR – Berlin Heart AG, Berlin, Germany), HeartMate III (Abbott, Abbott Park, IL, USA), or HeartWare (Medtronic, Minneapolis, MN, USA). We aimed to compare our experience with previous studies through a retrospective review of the existing literature.

Patients and Methods

Study Design and Patient Selection

We performed a retrospective data review of all consecutive pediatric patients (aged 0-18 years) who had been implanted with an L-VAD for advanced heart failure in our institution between January 2009 and January 2023 (Figure 1). Clinical, procedural, and follow-up data were collected and comprehensively analyzed. Approval from the Ethics Committee of Ege University Faculty of Medicine (Date: 08.06.2023, Decision number 23-6T/47) was obtained. Written informed consent was signed by the patients or their legal guardians to perform the procedure and to use their clinical records for publication.

Heart Failure Diagnosis

Patients who were being followed up for a diagnosis of DCM and were scheduled to undergo L-VAD implantation were discussed by a multidisciplinary heart transplant council. Despite clear guidelines for heart transplant listing[7-9], there are no universally accepted criteria for L-VAD implantation. In our study, L-VAD im-

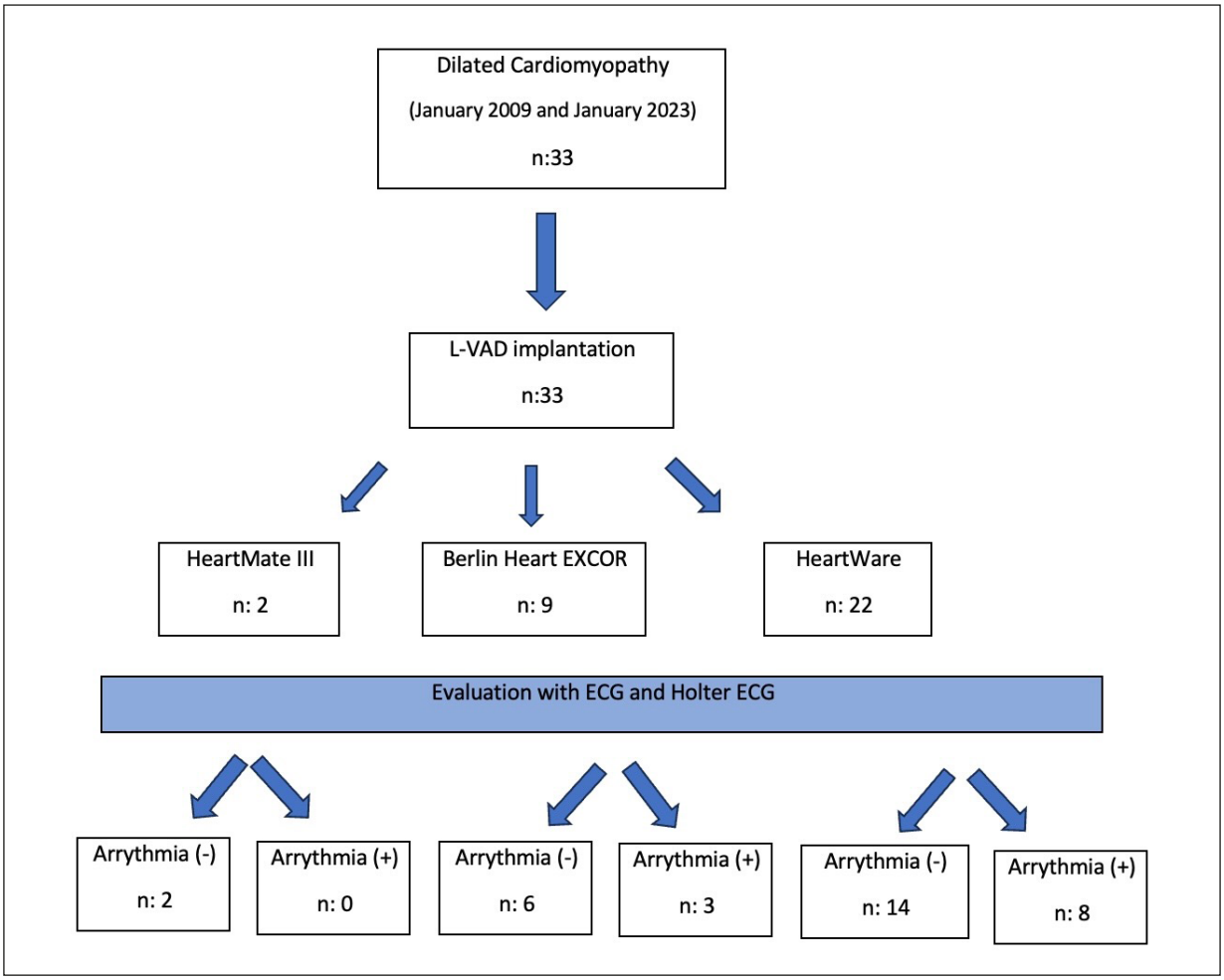

Figure 1. Flow diagram of the study. *Abbreviations:* L-VAD = Left ventricular assist device; ECG = electrocardiogram.

plantation was performed in patients who met the following criteria: presence of New York Heart Association (NYHA) class IIIb-IV symptoms for at least 45 of the last 60 days; nonresponse of heart failure symptoms to optimal medical management; left ventricular ejection fraction <25%; peak oxygen consumption <14 mL/kg/min or continued need for intravenous (IV) inotropic therapy because of symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; use of IV inotropic medications for ≥14 days; and use of intra-aortic balloon pump support for ≥7 days.

Follow-up

Our institution developed a tailored post-implantation monitoring protocol for pediatric L-VAD recipients to ensure optimal outcomes and enhance overall care quality for our young patients. The following outlines key components based on our institutional experience. In the immediate post-implantation period, meticulous daily monitoring includes assessments of vital signs, laboratory values, and device parameters. During the initial month post-implantation, pediatric patients receive weekly follow-up visits. These include thorough physical examinations, age-appropriate developmental assessments, and specialized blood tests. Pediatric-specific growth charts monitor changes in height and weight, ensuring a comprehensive understanding of each child's unique response to the L-VAD. The team addresses concerns related to the child's adaptation, including psychosocial aspects. From the second to the sixth month, monthly evaluations focus on pediatric growth and developmental milestones. Incorporating pediatric-specific quality-of-life assessments allows valuable insights into the overall well-being of our young patients. Continuous monitoring of coagulation studies and hematological parameters, with adjustments to medication regimens as needed, reflects our commitment to personalized and adaptive care. The multidisciplinary team collaborates seamlessly to address pediatric-specific challenges and provide holistic care.

Holter ECG Monitoring

Patients were followed up periodically in the pediatric cardiology outpatient clinic from the time of diagnosis. ECG and Holter ECG recordings from before L-VAD implantation were obtained. Postoperative echocardiogram and ECG were performed at 1 week, 2 weeks, and monthly thereafter. Holter ECG was done yearly or more frequently for patients who were symptomatic or had arrhythmia on ECG. Holter ECG recordings were obtained over 24 hours using a 6-channel Holter ECG device (DMS 300-7 HolterReader; DMS, Stateline, NV, USA) and evaluated using the CardioScan 12.0 program (DM Software, Inc., DMS, Stateline, NV, USA). After artifact removal, the patients' traces were assessed by pediatric cardiologists experienced in reading Holter data. Arrhythmias that developed during postoperative follow-up and the treatment methods were noted.

Arrhythmia Classification

Arrhythmias that occurred after L-VAD implantation were classified as atrial and ventricular. Ventricular arrythmias included ventricular tachycardia (VT) lasting for more than 30 seconds (sustained VT), VT lasting for less than 30 seconds (nonsustained VT), and ventricular fibrillation. Atrial arrhythmias included atrial flutter, atrial fibrillation, supraventricular tachycardia, and atrial ectopic tachycardia. Left atrial expansion, biatrial dilation, left ventricular hypertrophy or biventricular enlargement, left bundle branch block, left axis deviation, and ST changes observed in patients with DCM before the procedure were not evaluated as arrhythmias associated with L-VAD implantation.

Statistical Analysis

Statistical analyses were performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Categorical variables were reported as frequency and percentage, and continuous variables were represented as median with interquartile range (IQR). The normality of measurements was assessed using the Shapiro-Wilk test. Statistical analyses were conducted using Mann-Whitney U test for continuous variables and by Chi-square test and Fisher's exact test for categorical variables as appropriate. A p-value <0.05 was considered statistically significant. All reported p-values are two-sided.

Results

Patient Demographics

Of the 33 patients who underwent L-VAD implantation, 16 (48.5%) were female and 17 (51.5%) were male. The median age at surgery

was 13 years (IQR, 9.5-15). The median weight was 44 kg (IQR, 25.65-52), the median height was 158 cm (IQR, 134.5-168.5), and the median body surface area was 1.37 m^2 (IQR, 0.95-1.51). All patients who underwent L-VAD implantation had an echocardiographic diagnosis of DCM. All patients were assessed for coronary artery pathologies by imaging with coronary angiography computed tomography or conventional angiography.

The patients underwent a multidisciplinary evaluation with a detailed investigation of the underlying etiology. As a result of these examinations for comorbidities, genetic and pathology results revealed arrhythmogenic right ventricular dysplasia (ARVD) in 2 patients, Becker muscular dystrophy in 2 patients, Carvajal syndrome in 1 patient, and glycogen storage disease type 4 in 1 patient. Chronic kidney disease was detected in 1 patient before L-VAD implantation, and hemiplegia was detected in 4 patients before admission and during follow-up. Cardiac biopsy was obtained from all patients during HeartMate and HeartWare device implantation and led to the diagnosis of ARVD in 2 patients.

Follow-up

The Berlin Heart EXCOR device, which is suitable for implantation in lighter patients, has been used in a total of 9 (27.3%) patients. Consisting of an external console and an implanted pump, it aids the natural cardiac rhythm, ensuring blood circulation and optimizing oxygenation. Patients implanted during this period required longer hospital stays and had limited mobilization compared to other L-VAD devices. These patients were monitored with the L-VAD for a median of 13.5 months (IQR, 7.5-16.5).

The HeartWare device was implanted in 22 patients (66.7%), and the HeartMate III device was implanted in 2 patients (6.2%). The devices are known for their compact design and continuous-flow technology, providing a viable option for patients awaiting heart transplants or as destination therapy for those ineligible for transplantation. Because of the weight limit for these devices to be placed in the rib cage, heavier patients were preferred for this patient group. As patients have greater mobilization with these devices, the median follow-up period was 25.5 months (IQR, 10.5-35).

The selection of the L-VAD type in patients was based on the availability of devices in our country at that particular time. The choice of device was made in accordance with the prevailing conditions of the period, ensuring the most suitable selection given the circumstances. Following L-VAD implantation, patients underwent ongoing heart failure treatments. Anticoagulant therapy was initiated. Individuals in NYHA Stage 4, without significant complications, achieved a functional status that allowed them to maintain their regular social activities.

Of the 33 patients who underwent L-VAD implantation, 17 (51.5%) underwent orthotopic heart transplantation, and 16 (48.5%) were monitored with the L-VAD. The median follow-up duration for patients was determined to be 19 months (IQR, 9-33). As is known, lifelong follow-up is required in heart transplant patients. In our country, patients are followed in pediatric cardiology clinics up to the age of 18, when they are transferred to adult cardiology teams. Therefore, follow-up times for outpatients were calculated according to the time of transfer to the adult cardiology team, transplantation, or death.

Rhythm Disturbances

The patients underwent a median of 16 (IQR, 9-21) ECGs, and the median number of 24-hour Holter ECGs obtained was 3 (IQR, 2-5). Ventricular extrasystoles were detected in 6 patients on ECGs obtained before implantation. Nonsustained VT was detected in 3 of these patients in pre-procedure Holter ECG recordings. One patient underwent transcatheter implantable cardioverter-defibrillator (ICD) implantation due to a past history of syncope and VT. During the follow-up, atrial or ventricular arrhythmias were observed in 11 (33%) patients. Table I illustrates the rhythm disorders, medical interventions, follow-up durations, and survival outcomes for these patients. As anticipated, patients with initial rhythm disorders continued to exhibit arrhythmias in the follow-up period. In five patients initially without any arrhythmia, including atrial or ventricular arrhythmias, newly developed arrhythmias were identified. Of the 5 patients with detected arrhythmias during follow-up, the earliest occurrence was at one-month post-implantation, while the latest was at 22 months. Before implantation, ventricular arrhythmias were the most frequently observed arrhythmia, whereas following implantation, the frequency of atrial arrhythmias increased. Patients with recently diagnosed arrhythmias were assessed, and atrial arrhythmias were detected in four of them.

A total of 5 patients underwent cardioversion (n=2) or defibrillation (n=3) due to arrhythmia. Two patients were diagnosed with ventricular

Table I. Evaluation of arrhythmia types, treatments, follow-up times, and mortality in the patient group with arrhythmia.

Device type	Arrhythmia type/ Treatment	Follow-up time (months)/Heart transplant/Death
HeartWare	Supraventricular tachycardia (AVNRT) / Metoprolol	127 / - / -
HeartWare	Nonsustained ventricular tachycardia / Propranolol	6.1 / + / +
HeartWare	Supraventricular tachycardia (AVNRT) / Propranolol	39.9 / + / -
HeartWare	Ventricular tachycardia / ICD implantation, cardioversion, sotalol, amiodarone	19.7 / + / -
HeartWare	Ventricular fibrillation / Defibrillation, amiodarone, mexiletine	19.1 / + / -
HeartWare	Ventricular fibrillation / Defibrillation, amiodarone, propranolol	20.8 / + / +
HeartWare	Atrial fibrillation, ventricular tachycardia, Ventricular fibrillation / Cardioversion, defibrillation, amiodarone, mexiletine	33 / - / +
HeartWare	Nonsustained ventricular tachycardia/Propranolol	45.1 / - / -
Berlin EXCOR	Nonsustained ventricular tachycardia / -	24.3 / + / -
Berlin EXCOR	Supraventricular tachycardia (AVNRT) ventricular tachycardia / Cardioversion, Amiodarone	11.9 / - / +
Berlin EXCOR	Ventricular tachycardi / Amiodarone	6 / + / -

AVNRT: Atrioventricular Nodal Reentrant Tachycardia; ICD: Implantable cardioverter-defibrillator.

fibrillation during outpatient clinic visits. No complaints or symptoms were detected in two patients. Ten patients who presented with arrhythmia underwent medical treatment comprising amiodarone, mexiletine, beta-blocker therapy (propranolol, metoprolol), or sotalol. Arrhythmias were controlled in patients who were started on medical treatment. Due to the positive response to medical treatments, electrophysiological studies were not performed in patients. Medical treatment was ineffective in only one patient with ventricular fibrillation. In this patient, despite defibrillation and medical treatment, no response was obtained. This patient had drug-induced thyrotoxicosis.

Demographic findings, echocardiogram parameters, and angiography results were compared between patients with and without arrhythmia to determine their relationship with the risk of developing arrhythmia (Table II). Of these, only increased left ventricular end-diastolic diameter was associated with the development of cardiac arrhythmia (p=0.014). For the other parameters, there was no significant difference between the two groups, suggesting an impact on the risk of developing arrhythmia. No significant difference was observed in the occurrence of arrhythmia based on the model of the ventricular assist device utilized. There was no significant difference in mortality between the patient groups with and without arrhythmia.

Discussion

Although there are many causes of heart failure in pediatric patients, the most common etiologies are primary cardiomyopathies, rejection

Table II. Comparison of demographic, echocardiographic, and angiographic parameters of the group with and without arrhythmia.

Parameter	Arrhythmia (n=11)	No arrhythmia (n=22)
Weight (kg), median (IQR)	54 (39.5-68.25)	40 (24.5-51)
Height (cm), median (IQR)	168.5 (147-171.5)	159 (145.5-163)
Body surface area (m²), median (IQR)	1.42 (1.07-1.76)	1.41 (1.08-1.50)
Age at surgery (years), median (IQR)	14 (11-15.5)	12 (9.5-15.5)
Left ventricular end-diastolic diameter (cm), median (IQR)*	6.15 (5.95-7)	5.85 (5.5-6.25)
Left ventricular ejection fraction (%), median (IQR)	25 (23-29)	22.5 (19.5-29)
Interventricular septum (cm), median (IQR)	0.70 (0.60-0.90)	0.60 (0.50-0.70)
Tricuspid annular plane systolic excursion (mm), median (IQR)	16 (14-19.5)	8 (16-20)
Transpulmonary gradient, median (IQR)	8.00 (7.6-8.5)	8.18 (7.7-8.6)
Mean pulmonary artery pressure (mmHg), median (IQR)	29 (24.5-35)	32 (29.5-35)

*p-value = 0.014, $p > 0.05$ for other variables.

after cardiac transplantation, myocarditis, and congenital heart defects. L-VADs are used for bridging to transplantation in patients with indications for heart transplantation[10]. However, many complications are seen in patients who undergo L-VAD implantation, including clots, bleeding, infection, and arrhythmias. Malignant arrhythmias can be life-threatening.

In this study investigating arrhythmias in patients with L-VADs, approximately one-third of patients were found to have atrial or ventricular arrhythmias. As the L-VAD provides hemodynamic stability, patients sometimes present to our outpatient clinic with rhythm disorders that could be fatal in a normal patient.

Previous studies[11] have used the transpulmonary gradient, pulmonary vascular resistance, and age at implantation as predictors of early mortality in patients implanted with L-VADs. We also evaluated these parameters in our study but did not find them to be significant predictors of arrhythmia development. When the patients' age, weight, height, and echocardiographic parameters (left ventricular end-diastolic diameter, left ventricular ejection fraction, interventricular septum thickness, and TAPSE) were analyzed in relation to the development of atrial or ventricular arrhythmia, only an increase in end-diastolic diameter was found to be significantly associated with arrhythmia. The end-diastolic diameter depends on the pump speed of the ventricular assist device, but the values recommended by the manufacturer for patients with hemodynamic stability were selected.

In our country, finding a heart donor is challenging, and there is a limited number of available organ donors. Compared to the follow-up periods reported previously in other centers[12,13], the VAD follow-up time was also very long in our center. The long wait for a heart transplant is associated with many complications, of which life-threatening arrhythmias are among the most common ones.

In similar studies[6] in the literature, the most common rhythm disorders were ventricular arrhythmias, atrial fibrillation, flutter, and atrial ectopic rhythms. In a study conducted by Pompa et al[6], the rate of arrhythmia development after L-VAD implantation was found to be 47%. Consistent with the literature, the prevalence of arrhythmia was 33% in our study. An increase in the rate of arrhythmia can be expected if the number of donors and rate of transplantation remain this low. In another study[14], the risk of ventricular arrhythmia was found to be between 25% and 50%, but ICD implantation and ventricular arrhythmias were shown to have no effect on mortality. The two asymptomatic patients who were diagnosed with ventricular fibrillation during outpatient follow-up in our study support this theory. In this patient group, it may be appropriate to try medical therapy before resorting to more aggressive treatment methods. Given the high rate of wide QRS arrhythmias in the patients, antiarrhythmic drugs with a wide spectrum of activity were preferred, such as amiodarone, mexiletine, and sotalol. The use of similar treatment options has been reported in the literature[15].

Two patients in our study were diagnosed with ARVD incidentally as a result of our L-VAD implantation protocols. As expected, arrhythmia was more common among these two patients. It should be kept in mind that ARVD may be detected in patients with poor left ventricular systolic function, albeit rarely. The rhythm disorders that developed in 2 of our patients were more frequent and less responsive to treatment than in patients with other L-VADs.

One patient using amiodarone developed thyrotoxicosis during clinical follow-up and died due to malignant arrhythmia. Patients should be monitored for the adverse effects of the medicines used. As stated in previous literature, patients should be managed with the fewest and least aggressive treatment methods possible.

Our study represents one of the longest-followed pediatric patient groups undergoing L-VAD treatment in the literature. The investigation revealed an increased risk of arrhythmia development during long-term follow-up, with atrial arrhythmias emerging as the most prevalent among newly occurring rhythm disorders. It was determined that the enlargement of the left ventricular end-diastolic diameter contributes to the heightened risk of arrhythmia. Additionally, it was demonstrated that meticulous monitoring of assist device settings is crucial to minimize strain on the ventricle. Echocardiography should be employed to assess ventricular diameters and device flows at each hospital visit. Even if patients remain asymptomatic during each assessment, it is imperative to conduct an electrocardiogram (ECG) evaluation.

Limitations

Due to the dimensions of L-VADs, implantation of the device in the chest of pediatric

patients is challenging, and it cannot be applied to patients with insufficient chest circumference. As a result, the number of pediatric patients is limited. However, the rhythm disorders and their treatments detected in our study support the high number of adult studies in the literature. Pediatric studies with a larger patient number are needed.

Conclusions

In patients monitored with an L-VAD for an extended period, malignant arrhythmias are observed. These devices allow for the asymptomatic presentation of patients with severe arrhythmias, making initial diagnosis challenging. It is essential to assess the electrocardiograms of these patients during each hospital admission, and regular intervals of Holter ECG monitoring are recommended. Furthermore, due to the hemodynamic support provided by the ventricular assist device, medical treatments should be explored before considering aggressive interventions such as defibrillation or cardioversion.

Conflict of Interest
The authors declare no conflict of interest.

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Ethics Approval
This study was approved by the Ethics Committee of Ege University Faculty of Medicine (Date: 08.06.2023, Decision number 23-6T/47), in accordance with the Declaration of Helsinki.

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Authors' Contributions
All authors equally contributed to the present manuscript preparation.

Informed Consent
Written informed consent was signed by the patients or their legal guardians to perform the procedure and to use their clinical records for publication.

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