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Original Article / Özgün Makale

The Levitronix CentriMag ventricular assist device as a bridge to decision in patients with end-stage heart failure: Our single-center experience

Son dönem kalp yetmezliği olan hastalarda karara köprülemede Levitronix CentriMag ventriküler destek cihazı: Tek merkez deneyimimiz

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ABSTRACT

Background: In this study, we report early outcomes of Levitronix CentriMag device implantation for bridge to decision for patients with end-stage heart failure in a single center.

Methods: We retrospectively analyzed data of a total of 41 patients (30 males, 11 females: mean age 30.2±15 years; range 7 to 59 years) with end-stage heart failure who received a Levitronix CentriMag support for bridge to decision between December 2010 and September 2014. Devices were implanted in the left (n=38), right (n=1), or biventricular (n=2) configuration. Support was continued until recovery, transplantation or implantation of a long-term ventricular assist device.

Results: The mean preoperative left ventricular ejection fraction was 17±2.3%. The mean support time was 38 (range 1 to 192) days. Sixteen patients (39%) survived and moved on to the next phase of the treatment. Of these patients, 11 (27%) underwent cardiac transplantation operations and five (12%) received long-term ventricular assist devices. After the CentriMag implantation, 30-day survival rate was 49% in 20 patients. Bleeding requiring re-operation was observed in 13 patients (32%). Two patients (4.8%) had sternal wound infections. Device dysfunction was observed in one patient (2.4%). Non-survivors had a higher rate of sepsis and renal failure, compared to the survivors ($p<0.05$).

Conclusion: The CentriMag system provides an effective temporary mechanical circulatory support for cardiac failure. The ease of implantation and high rate of successful device weaning encourage the use of CentriMag system as a temporary ventricle support.

Keywords: Cardiogenic shock; end-stage heart failure; ventricular assist device.

ÖZ

Amaç: Bu çalışmada tek bir merkezde son dönem kalp yetmezliği olan hastalarda karara köprülemede Levitronix CentriMag ventriküler destek cihazı implantasyonunun erken dönem sonuçları sunuldu.

Çalışma planı: Aralık 2010 - Eylül 2014 tarihleri arasında, karara köprüleme amacıyla Levitronix CentriMag desteği uygulanmış olan toplam 41 son dönem kalp yetmezliği hastasının (30 erkek, 11 kadın; ort. yaş 30.2±15 yıl; dağılım 7-59 yıl) verileri retrospektif olarak incelendi. Cihazlar sol (n=38), sağ (n=1) veya biventriküler (n=2) konfigürasyonda yerleştirildi. Destek iyileşmeye, transplantasyona veya uzun dönem ventriküler destek cihazı takılana kadar sürdürüldü.

Bulgular: Hastaların ameliyat öncesi ortalama sol ventrikül ejeksiyon fraksiyonları %17±2.3 idi. Ortalama destek süresi 38 (dağılım 1-192) gündü. On altı hasta (%39) yaşamını sürdürdü ve tedavinin bir sonraki aşamasına geçti. Bu hastalardan 11'ine (%27) kalp nakli yapıldı ve beş hastaya (%12) uzun dönem ventriküler destek cihazı yerleştirildi. CentriMag yerleştirildikten sonra 30 günlük sağkalım oranı 20 hastada %49 idi. On üç hastada (%32) yeniden ameliyat gerektiren kanama gözlendi. İki hastada (%4.8) sternal yara enfeksiyonları vardı. Bir hastada (%2.4) cihaz disfonksiyonu gözlendi. Sağkalan hastalara kıyasla, kaybedilen hastalarda daha yüksek oranda sepsis ve renal yetmezlik vardı ($p<0.05$).

Sonuç: CentriMag sistemi kalp yetmezliğinde etkili bir geçici mekanik dolaşım desteği sağlamaktadır. İmplantasyon kolaylığı ve başarılı şekilde cihazdan ayrılma oranının yüksek oluşu, geçici ventriküler destek olarak CentriMag sisteminin kullanımını desteklemektedir.

Anahtar sözcükler: Kardiyojenik şok; Son dönem kalp yetmezliği; ventriküler destek cihazı.

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Despite many advances in the management of patients with acute heart failure, the outcomes for patients with refractory acute cardiogenic shock still remain disproportionately poor.[1-3] In addition, the vast majority of these patients are often admitted to hospitals where no sophisticated circulatory support technologies or resources are available to optimally manage these patients. Although there is a need for wider application of temporary circulatory support for such patients, questions regarding the ideal support system, the optimal duration of temporary support and the ideal timing of bridging to a long-term device still exist. The Levitronix CentriMag ventricular assist device (VAD) (Levitronix LLC, Waltham, MA, USA) was specifically designed for the treatment of patients with acute cardiogenic shock of any etiology, including acute myocardial infarction, myocarditis, and cardiotomy.[4]

In the present study, we aimed to assess and report the early outcomes of a short-term VAD (Levitronix CentriMag) implantation for bridge to decision for patients with end-stage heart failure in a single center.

PATIENTS AND METHODS

We retrospectively analyzed data from a total of 41 patients (30 males, 11 females; mean age 30.2±15 years; range 7 to 59 years) who received a Levitronix CentriMag support for bridge to decision between December 2010 and September 2014. The patients were included regardless of perioperative status and severity of heart failure. Post-transplant patients and patients suffering from post-cardiotomy cardiogenic shock were excluded from the study. All preoperative, intraoperative and postoperative data were reviewed retrospectively from the hospital database. All surgical notes and discharge summaries were also reviewed for supplementary information. The patients were assessed under two groups as survivors (n=16) and non-survivors (n=25). Survivors were those who survived and moved on to the next phase of the treatment, while non-survivors were those who died and were unable to move on to the next phase.

The study protocol was approved by the Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The Levitronix CentriMag pump (Levitronix LLC, Waltham, MA, USA) is a magnetically levitated paracorporeal VAD. The Levitronix CentriMag VAD is composed of a single-use centrifugal blood pump, a motor, a console and a flow probe.[4,5] The Levitronix CentriMag system differs from other devices in its design allowing it to work without mechanical bearing or seals.[6]

Surgical technique

The surgical procedure was performed through median sternotomy. The operation was performed either by total pericardiotomy or mini-pericardiotomy technique as reported before.[7] In the left ventricular assist device (LVAD) configuration, the inflow cannula was inserted in the left atrium at the level of the junction between the right superior pulmonary vein and the left atrium. The outflow cannula was placed directly into the ascending aorta. The inflow cannula was placed in the right atrium and the outflow cannula was inserted in the main pulmonary artery in cases of right-side support. The cannulas were secured with dual, pledgeted purse-string sutures for hemostasis and the sutures were tied around the cannulas. The right and left outflow cannulas were placed anteriorly at the front of the heart, whereas the inflow cannulas were lying in the pericardium on the right side of the right atrium. All cannulas were brought outside the body through separate incisions and secured to the skin using 1-0 nylon sutures. The CentriMag pump head and tubing were primed on the back table with normal saline, deaired, and attached to the inflow and outflow cannulas. The speed of the pump was, then, gradually increased to achieve adequate flows of 4 to 6 L/min. The sternotomy was closed using surgical steel wires, and the patients were monitored in the intensive care unit.

Once bleeding from each chest tube was less than 50 mL/hour for 4 to 6 hours, heparin infusion was initiated and was gradually increased to achieve an activated clotting time of 160 to 200 sec. Warfarin was also started after extubation to maintain an international normalized ratio between 2 and 2.5. All patients received antiaggregant therapy with acetylsalicylic acid (150 mg/day) and clopidogrel (75 mg/day).

Statistical analysis

Statistical analysis was performed using the PASW for Windows version 17.0 software (SPSS Inc., Chicago, IL, USA). Continuous data were expressed in mean ± standard deviation (SD), while ordinal and nominal data were expressed in number and percentage (%). Pre- and postoperative variables of both groups were compared using the Student's t-test and chi-square test. A p value of <0.05 was considered statistically significant.

RESULTS

Among the patients who received Levitronix CentriMag support for bridge to decision, 41 met the inclusion criteria and were included in the study.

The etiology of heart disease was dilated cardiomyopathy in 35 (85%), ischemic cardiomyopathy in two (5%), and viral myocarditis in four patients (10%). According to the Interagency Registry for Mechanically-Assisted Circulatory Support (INTERMIX) score, 64% of the patients were in Class I (critical cardiogenic shock) and 24% were in Class II (progressive decline). The mean preoperative left ventricular ejection fraction (LVEF) value was 17±2.3%.

Levitronix CentriMag VAD was used as a LVAD (n=38), right ventricular assist device (RVAD) (n=1), and biventricular assist device (BVAD) (n=2).

The mean duration of Levitronix CentriMag support was 38 (range 1 to 192) days. During the first days of support, all patients received inotropes and 22 patients received intra-aortic balloon pump (IABP) support.

Survivors (n=16/41; 39%) moved on to the next phase of the treatment; while non-survivors (n=25/41; 61%) were unable to move on to the next phase. Baseline characteristics of the survivors and non-survivors were all comparable (p>0.05 for all) (Table 1).

The 30-day survival rate after Levitronix Centrimag implantation was 49% (n=20) in all patients. Among the survivors (n=16) who moved on to the next phase of the treatment, five underwent successful bridging to long-term VAD implantation after CentriMag support (mean support time 40 days; range 7 to 85 days); two were discharged from the hospital; two had heart transplantation; and one died after 20 days of long-term support. A total of 11 patients underwent successful bridging to heart transplantation after CentriMag support (mean support time 57 days; range: 3 to 112 days); seven patients were discharged from the hospital; and four patients died (Figure 1). The causes of death of the non-survivors (n=25) were multiorgan failure (n=10), renal failure (n=6), sepsis (n=5), bleeding (n=2), and cerebrovascular accidents (n=2).

Bleeding requiring re-operation occurred in 13 patients (32%) who had severe coagulopathies. Two patients (4.8%) had sternal wound infections. Gastrointestinal bleedings necessitating large transfusions of blood and blood products during

Table 1. Preoperative patient characteristics (n=41)

	Survivors (n=16)			Non-survivors (n=25)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			25.7±12.2			33.8±15.8	0.061
Gender							
Male	12	75		18	72		0.833
Diabetes mellitus	0	0		1	4		0.418
Coronary artery disease	1	6		2	8		0.834
INTERMACS profiles							0.337
Class I (critical cardiogenic shock)	8	50		18	72		
Class II (progressive decline)	5	31		5	20		
Class III (stable, but inotrope-dependent)	3	19		2	8		
Mean pulmonary artery pressure (mmHg)			58.1±7.3			55.4±4.3	0.139
Left ventricular ejection fraction (%)			16.4±1.8			17.5±2.5	0.122
Intra-aortic balloon pump	8	50		14	56		0.707
Etiology							0.173
Dilated cardiomyopathy	13	81		22	88		
Viral myocarditis	3	19		1	4		
Ischemic cardiomyopathy	0	0		2	8		
Urea (mg/dL)			33.8±6.5			38.2±10.7	0.151
Creatinine (mg/dL)			1.14±0.4			1.2±0.3	0.485
Aspartate aminotransferase (U/L)			296.8±142.5			366.8±190.9	0.217
Alanine aminotransferase (U/L)			110.8±37.9			127.2±58.9	0.331
Hemoglobin (g/dL)			11.5±1.3			10.8±1.8	0.179
White blood cell ($\times 10^3/\mu L$)			11.3±1.9			11.7±2.5	0.576

SD: standard deviation; INTERMACS: The Interagency Registry for Mechanically Assisted Circulatory Support.

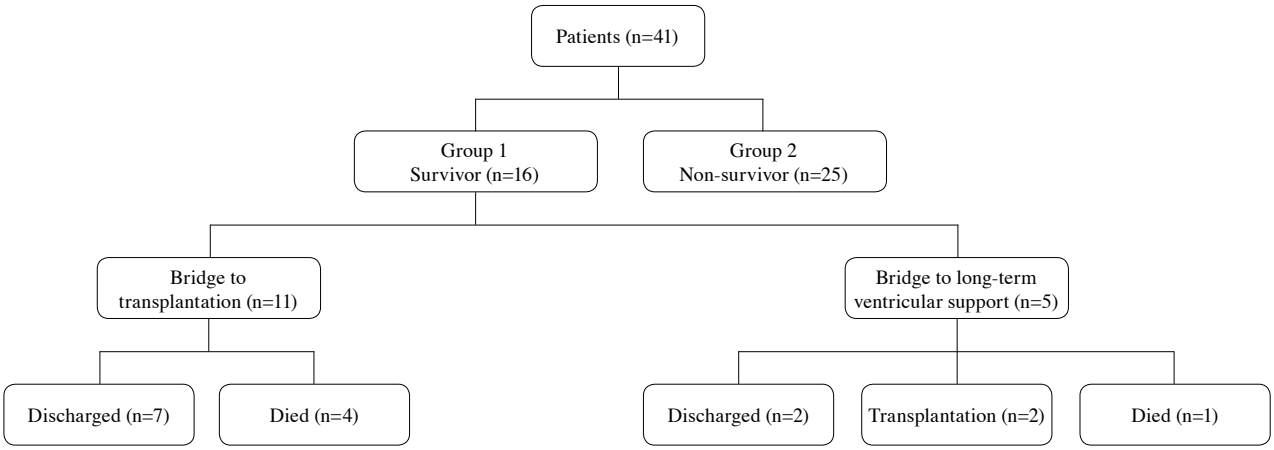

Figure 1. Survival of the study cohort.

mechanical circulatory support were observed in three patients (7.3%). Device dysfunction was seen in one patient (2.4%). Sixteen patients needed prolonged mechanical ventilation, while three patients (7.3%) required attachment of an oxygenator to the circuit due to respiratory failure. Neurological complications were detected in 12 patients (29%). Non-survivors had a higher rate of sepsis and renal failure, compared to the survivors ($p<0.05$). The rates of adverse events of the survivors and non-survivors are presented in Table 2.

DISCUSSION

Patients in cardiogenic shock require early aggressive therapy. Despite inotropic drugs, intubation and control of cardiac rhythm, certain patients remain hemodynamically unstable and refractory to medical therapy, thereby requiring mechanical circulatory support.[8,9] To date, various devices such as the Levitronix CentriMag VAD have been developed and approved for acute circulatory support. Unlike the longer-term devices designed for prolonged use as bridge to transplantation, these devices are more suitable for the acute resuscitative phase. The Levitronix CentriMag VAD was initially used for short-term ventricular support in post-cardiotomy failure following routine cardiac surgery, for primary graft dysfunction after heart transplantation, and for salvage as a bridge to decision in patients with severe decompensated end-stage heart failure.[1,10-13]

Table 2. Early and late adverse events

	Survivors (n=16)		Non-survivors (n=25)		
	n	%	n	%	*p*
Reoperation for bleeding	7	44	6	24	0.185
Wound infection	1	6	1	4	0.744
Sepsis	0	0	5	20	<0.05
Gastrointestinal system bleeding	1	6	2	8	0.834
Pneumonia	1	6	4	16	0.352
Acute renal failure	1	6	8	32	<0.05
Cerebrovascular accident	3	19	9	36	0.236
Device failure	0	0	1	4	0.418
Arrhythmia	8	50	14	56	0.707
Thrombotic, vascular adverse effect	0	0	1	4	0.418
Lent ventricular assist device	15	94	23	92	0.689
Right ventricular assist device	0	0	1	4	0.689
Biventricular assist device	1	6	1	4	0.689
Extracorporeal membrane oxygenator	1	6	2	8	0.834
Prolonged intubation	7	44	9	36	0.620

In our patients, the etiology of heart disease was dilated cardiomyopathy in 85%, while it was ischemic cardiomyopathy in 5%, and viral myocarditis in 10%. The rate of ischemic cardiomyopathy was relatively low due to the younger age of our patient population. As it is known, ischemic cardiomyopathy is more prevalent among older patients.

In this study, all patients were critically ill and in a moribund state (INTERMACS Profiles Class I, II and III). They had severe end-stage cardiac failure refractory to medical treatment and/or IABP, and their conditions were severely deteriorated. Similarly, Worku et al.[14] reported that 85% of the patients were on IABP support, 70% were on vasopressors, and 44% were on more than one inotrope. In the aforementioned study, the INTERMACS score was Class I in 67% of the patients and Class II in 33% of the patients.

The currently available short-term VADs include the widely used Bio-Medicus systems (Medtronic), ABIOMED BVS (ABIOMED, Inc., Danvers, Mass), and CentriMag Levitronix system. Samuels et al.[15] reported 31% hospital discharge for patients with acute cardiac failure supported by the ABIOMED BVS system. CentriMag has been used for several indications, including post-cardiotomy failure leading to a successful weaning rate of 83% and a discharge rate of 45%.[16] Although extracorporeal membrane oxygenation (ECMO) is the most optimal option for patients requiring full cardiopulmonary support, major disadvantages include a limited duration of support, a high incidence of complications with increasing duration of support, and the need for fairly stringent anticoagulation. According to a recent report from the Cleveland Clinic, the survival rate of 202 adults who received ECMO for cardiac failure and were followed up to 7.5 years was 76% on Day 3, 38% on Day 30, and 24% at five years.[17] The patients surviving 30 days had a 63% chance of survival at five years, demonstrating that high early mortality remains the Achilles heal of this technology. On the other hand, the patients who were weaned or bridged to transplantation had a higher overall survival (40% and 45%, respectively). In another study, Hoefer et al.[18] reported excellent results with ECMO support in patients with cardiogenic shock.

The CentriMag system is easy for use and it allows rapid assessment of ventricular recovery, weaning, and explantation.[6] In this study, the mean duration of CentriMag support was 38 (range: 1 to 192) days. De Robertis et al.[11] used the Levitronix device as a bridge to decision in critically ill patients for a mean duration of 50 days and reported a one-month survival rate higher than 80%. Recently, the use of this device as a direct bridge to transplantation has been reported in selected cases with duration of support as long as three months.[19] In our institution, at the time of implantation, it was unclear what strategy would follow at later stages. After the CentriMag implantation, 30-day survival was 49% (n=20). In our patients, higher mortality rates might be related to lower INTERMACS profiles and being in cardiogenic shock at presentation.

In our study, 16 patients (39%) moved on to the next phase of the treatment, five underwent successful bridging to long-term VAD implantation, and 11 underwent successful bridging to heart transplantation after the CentriMag support. The remaining 25 patients (61%) survived for a mean duration of 29.2 (range 1 to 192) days. In the literature, due to the heterogeneity in populations or patient selection criteria, controversial results have been reported for short-term outcomes of the Levitronix support. Similar to our results, Orhan et al.[20] used short-term mechanical support devices in 28 acute cardiogenic shock patients. When the post-cardiotomy patients were excluded, 14 patients received ECMO (n=8) or CentriMag (n=6). Five of these patients (35.7%) survived; two recovered; one underwent transplantation, and two received long-term ventricular support devices. In another study, De Robertis et al.[11] reported that 11 patients (68.7%) survived; two patients recovered and had the Levitronix device explanted; six patients were upgraded to a long-term device; and three patients were bridged directly to transplantation. The actuarial survival at one, six, and 12 months were 85.7%, 64.9%, and 64.9%, respectively. In addition, Takayama et al.[21] reported 143 patients who underwent CentriMag VAD implantation as bridge to decision therapy. The survival rate was 69% at 30 days and 49% at one year. After the CentriMag VAD implantation, 30% of the patients recovered, 18% received heart transplantation, and the device was exchanged to an implantable VAD in 15%. In their study, Zeriouh et al.[22] retrospectively analyzed data of 66 patients who received a short-term LVAD support prior to implantation of a long-term LVAD or heart transplantation and found the overall survival on support to be 60% (n=40). The surviving patients recovered (n=12), underwent heart transplantation (n=12), or received a long-term VAD (n=16).

In our study, non-survivors had a higher rate of sepsis and renal failure, compared to the survivors. Worku et al.[23] found that factors associated with mortality were the diagnosis of post-cardiotomy shock or graft failure, female gender, and a total bilirubin

level higher than 5.2 mg/dL on postoperative Day 3. According to the findings of Zeriouh et al.,[22] higher rates of preoperative extracorporeal life support, postoperative renal failure, and multiorgan failure were significantly associated with mortality.

In the present study, bleeding requiring re-operation was detected in 13 patients (32%). Gastrointestinal bleeding during mechanical circulatory support that might have resulted from overanticoagulation and/or preoperative conditions (i.e., coagulopathy, acute renal failure) was seen in three patients. The number of events directly attributable to the device, however, was relatively low. Device dysfunction was seen in one patient. Neurological complications, which are common in patients with LVADs, occurred in 12 patients in our series. These included six strokes, three seizures, and three cases of delirium.

In their study, De Robertis et al.[5] reported that 44% of the patients were re-operated for bleeding. There were no instances of mechanical failure of the device throughout the duration of support. Shuhaiber et al.[13] also found that re-operation for bleeding occurred in eight patients, while clinical evidence of cerebral thromboembolism was present in three, overwhelming sepsis in one, and aortic thrombus formation in one patient. Clot formation in the tubing was also observed in one patient, necessitating emergent replacement at bedside, which was successful. Complications reported at a recent multi-center study were bleeding (21%), infection (5%), respiratory failure (3%), hemolysis (5%), and neurological dysfunction (11%).[24] Takayama et al.[21] also reported similar rates for major bleeding events (33%) and cerebrovascular accidents (14%).

A systematic literature review and meta-analysis of observational studies conducted by Borisenko et al.[25] included 53 publications with data of a total of 999 patients. The authors reported the survival rate while on support as 62-83%, and 30-day survival as 41-66%, depending on the placement indication. Complication rates were 28% for bleeding requiring exploration, 28% for renal complications, and 24% for infections. Thrombosis and neurological complication rates were both 7%; hemolysis occurred in 3%, and device failure was observed in 0.08% of the patients.

In Turkey, according to 2014 data of the National Coordination System, patients waiting for heart transplantation were recorded as about 600, while only 75 of them (15% of the patients on the waiting list) underwent transplantation.[26] This scarcity of available donor hearts and patient-related factors (i.e., organ failure, infection, or neurological damage) leads to long waiting times for patients in need of a heart transplantation. Therefore, support by temporary ventricular assist systems is considered an ideal option in rapidly deteriorating patients. The ease of use of the CentriMag system allows for rapid assessment of ventricular recovery, weaning, and potential explantation. However, it should not be overlooked that it is a short-term support device. Long-term use of the CentriMag systems may lead to higher mortality rates resulting from multiorgan failure, sepsis, and coagulation disorders. Therefore, patients with unclear myocardial weaning and neurological status should quickly be bridged to heart transplantation or implantation of a permanent VAD.

Nonetheless, our study has several limitations. The first is its retrospective design. Due to the urgency of rescuing these patients, it is difficult to design prospective, randomized-controlled studies. Another limitation is its relatively small sample size. Finally, short follow-up period can be regarded as another limitation.

In conclusion, the Levitronix CentriMag system seems to be safe and effective in the treatment of patients with end-stage heart failure when bridging to decision. With low rates of device-related complications, it is an ideal option for cases requiring bridging to decision. Based on our study results, we suggest its use for the patients whose myocardial weaning and the neurological status are not clear for bridging to heart transplantation or permanent implantation of ventricular assist system.

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