Journal of The Cardiovascular Thoracic Anaesthesia and Intensive Care Society

GKDA Derg 2022;28(4):295-299
DOI: 10.14744/GKDAD.2022.64935

Research Article / Araştırma

Analysis of Clinical Results for Decision Making for Short- and Long-Term Ventricular Support in INTERMACS I and II Patients

INTERMACS I ve II hastalarında Ventrikül Destek Sistemi Uygulamalarında Kısa ve Uzun Dönem Destek için Karar: Klinik Sonuçların Değerlendirilmesi

Sevinç Bayer Erdoğan, Osman Murat Baştopçu, Murat Acarel, Halit Er

Department of Cardiovascular Surgery, University of Health Sciences, Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital, İstanbul, Türkiye

Sağlık Bilimleri Üniversitesi, Dr. Siyami Ersek Göğüs Kalp ve Damar Cerrahisi Eğitim ve Araştırma Hastanesi, Kalp ve Damar Cerrahisi Anabilim Dalı, İstanbul, Türkiye

ABSTRACT

Objectives: The choice of ventricular mechanical support for end-stage patients presenting with Inter-Institutional Registry for Mechanical Assisted Circulatory Support (INTERMACS) profiles I and II is still controversial. In this study, we aimed to analyze the INTERMACS I and II patients who underwent extracorporeal membrane oxygenation (ECMO) or left ventricular assist device (LVAD) as a bridge to decision.

Methods: Twenty-four patients were retrospectively analyzed as Group 1: ECMO and Group 2: LVAD implanted due to critical clinical status at INTERMACS profile I and II during 2014 and 2022.

Results: Mechanical support was ECMO in 9 patients and LVAD in 15 patients. The baseline characteristics of patients receiving ECMO and LVAD were not different in terms of comorbidities or cardiac parameters. Total mortality was 17 (70.8%) in INTERMACS I and II patients. Mortality did not differ between patients with ECMO and directly implanted LVAD. (p=0.669).

Conclusion: As both types of mechanical support will be highly mortal, in multiorgan failure with severe metabolic disorder, ECMO shall be the first choice. On the other hand, LVAD can be the therapy of choice when there is no organ failure or metabolic disorder. Additionally, the availability of organ transplantation should be considered in final decision making on a patient basis.

Keywords: End-stage heart failure, extracorporeal membrane oxygenation, inter-institutional registry for mechanical assisted circulatory support, ventricular assist device

ÖZ

Amaç: INTERMACS profil I, II ile takip edilen son dönem kalp yetmezliği hastalarında cerrahi kalp yetmezliği tedavisi seçimi hala tartışmalıdır. Bu çalışmada, transplantasyona köprü olarak ekstrakorporeal membran oksijenasyonu (ECMO) veya sol ventrikül destek cihazı (LVAD) uygulanan INTERMACS I ve II hastalarını analiz etmeyi amaçladık.

Yöntem: 2014 ve 2022 yıllarında INTERMACS profili I ve II'deki kritik klinik durum nedeniyle Grup 1: ECMO ve Grup 2: LVAD implante edilmiş olan 24 hasta geriye dönük olarak analiz edildi.

Bulgular: Mekanik destek dokuz hastada ECMO ve 15 hastada LVAD idi. Hastalar komorbiditeler veya kardiyak parametreler açısından farklı değildi. INTERMACS I-II hastasında toplam mortalite 17 (%70,8) idi. Mortalite, LVAD öncesi ECMO ve direkt LVAD implante edilen hastalar arasında farklılık göstermedi (p=0,669).

Sonuç: Her iki tip mekanik destek de oldukça ölümcül olacağından, şiddetli metabolik bozukluğu olan çoklu organ yetmezliğinde ECMO ilk tercih olacaktır. Öte yandan, organ yetmezliği veya metabolik bozukluk olmadığında LVAD tercih edilen tedavi olabilir. Ek olarak, hasta bazında nihai karar verilirken organ naklinin mevcudiyeti göz önünde bulundurulmalıdır.

Anahtar sözcükler: Son dönem kalp yetmezliği, ekstrakorporeal membran oksijenasyonu, INTERMACS, ventriküler destek cihazı

Please cite this article as: "Bayer Erdoğan S, Baştopçu OM, Acarel M, Er H. Analysis of Clinical Results for Decision Making for Short- and Long-Term Ventricular Support in INTERMACS I and II Patients. GKDA Derg. 2022;28(4):295-299".

Address for correspondence: Sevinç Bayer Erdoğan, MD. Sağlık Bilimleri Üniversitesi, Dr. Siyami Ersek Göğüs Kalp ve Damar Cerrahisi Eğitim ve Araştırma Hastanesi, Kalp ve Damar Cerrahisi Anabilim Dalı, İstanbul, Türkiye

Phone: +90 505 689 14 63 **E-mail:** drsbayer@gmail.com

Submitted: October 04, 2022 **Revised:** November 01, 2022 **Accepted:** November 02, 2022 **Available Online:** November 24, 2022

Introduction

Mechanical assist devices (mechanical circulatory support [MCS]) can maintain vital organ perfusion, drain the failing ventricle, and reduce myocardial wall stress and oxygen consumption. Thus, long-term mechanical assist devices allow time for heart transplantation or myocardial recovery (bridge to recovery). Despite technological improvements, there are early and late side effects such as bleeding, infection, stroke, pump failure, and the development of pump thrombus and organ failure. Therefore, patient selection and timing are critical.[1,2]

With the development of MCS technology and the significant impact of patient selection on outcomes, risk scores and classification have been developed to aid medical decision making. Advanced classification for Inter-Institutional Registry for Mechanically Assisted Circulatory Support (INTERMACS): Includes patients with Class III or IV symptoms of the New York Heart Association classification that limit daily activity despite optimal therapy adjustment with approved heart failure drugs. The classification consists of 7 clinical (Table 1).[3,4] The mortality rate is high, especially in the INTERMACS profiles I and II, representing cardiogenic shock's preclinical and clinical status.[5,6]

According to the INTERMACS 2020 annual report, extracorporeal membrane oxygenation (ECMO) support before left ventricular assist device (LVAD) implantation was 36.8%, decreasing to 26% in the new data. It shows that 74% of patients were implanted with LVAD without ECMO bridging in many centers. Another remarkable data from the same report is that 50% of the patients who underwent LVAD application were in the INTERMACS I and II profile before the procedure.[1]

This study aimed to discuss the timing and type of ventricular mechanical support based on the INTERMACS I, II profile cardiomyopathy patients. We analyzed our data to determine whether the choice between ECMO and LVAD for mechanical support differs in outcomes and the rationale for decision making in cardiogenic shock patients.

Methods

Patients with cardiomyopathy under follow-up in our advanced heart failure clinic who underwent ventricular mechanical support, either with ECMO or LVAD, during the 2014–2022 years were included in the study. Approval was obtained from the institutional academic board (E-28001928-604.01.01) for this study.

The decision to implant LVAD and ECMO was made by the heart team according to the recipients' availability status for transplantation and availability for bridging. As mechanical support, ECMO (Veno-Arterial) as short-term support and HeartMate II (Abbott, Pleasanton, CA, USA), HeartMate III (Abbott, Pleasanton, CA, USA), Heartware (Medtronic, Mounds View, MN, USA), and Heartasist 5 (ReliantHeart Inc., Houston, TX, USA) as long-term devices were used. The preimplantation clinical data and post-operation clinical findings were recorded retrospectively and analyzed.

Statistical Analysis

Statistical Package for the Social Sciences, IBM, USA v25.0 program was used for statistical analysis. Continuous parameters are given as mean and standard deviation, while categorical parameters are given as numbers and percentages. The Chi-squared test was applied to compare categorical variables. Student-t test was used for comparisons between two groups of normally distributed quantitative variables, and Mann-Whitney U test was used for comparisons between two groups of non-normally distributed quantitative variables.

Results

Between 2014 and 2022, 24 heart failure patients at INTERMACS stage I or II received mechanical support in our institution and were included in the study. The mean age of these patients was 45.1±14.1, and 4 (16.7%) were female. The etiology of heart failure was dilated cardiomyopathy in 10 (41.7%) patients, ischemic cardiomyopathy in 11 (45.8%) patients, and postpartum cardiomyopathy in 3 (12.5%) patients. The mechanical support was ECMO in nine patients and LVAD in 15 patients. The baseline characteristics of the patients who received ECMO and LVAD are compared in Table 2. The patients had similar comorbidities or cardiac parameters preimplantation.

The outcomes of INTERMACS I and II patients after mechanical support are summarized in Table 2. Overall mortality in these patients was 17 (70.8%). The mortality did not differ with the choice of initial mechanical support. Renal failure, reoperation for bleeding, cerebrovascular event, or early right heart failure (RHF) were not different in patients who received an LVAD or an ECMO (Table 3). Of the nine patients with ECMO, one recovered, two were bridged to LVAD, and one was bridged to transplantation. Of the 15 patients with LVAD were discharged.

Discussion

End-stage heart failure is a significant health problem. Heart transplantation is the gold standard for selected patients. However, the low number of donors for heart transplantation necessitated permanent and short-term mechanical support devices to prolong the life of this patient group.[6,7] In patients with INTERMACS 1 and 2 profile who develop cardiac decompensation, venoarterial ECMO is commonly used

Table 1. INTERMACS scale for classifying patients with advanced heart failure

Profiles	Definition	Description
INTERMACS 1	"Crash and burn"	Hemodynamic instability in spite of increasing doses of catecholamines and/or mechanical circulatory support with critical hypoperfusion of target organs (severe cardiogenic shock)
INTERMACS 2	"Sliding on inotropes"	Intravenous inotropic support with acceptable blood pressure but rapid deterioration of kidney function, nutritional state, or signs of congestion
INTERMACS 3	"Dependent stability"	Hemodynamic stability with low or intermediate, but necessary due to hypotension, doses of inotropics, worsening of symptoms, or progressive kidney failure
INTERMACS 4	"Frequent flyer"	Temporary cessation of inotropic treatment is possible, but the patient presents frequent symptom recurrences and typically with fluid overload
INTERMACS 5	"Housebound"	Complete cessation of physical activity, stable at rest, but frequently with moderate water retention and some level of kidney dysfunction
INTERMACS 6	"Walking wounded"	Minor limitation on physical activity and absence of congestion while at rest. Easily fatigued by light activity
INTERMACS 7	"Placeholder"	Patient in NYHA functional class II or III with no current or recent unstable water balance

INTERMACS: Interagency registry for mechanically assisted circulatory Support; NYHA: New York heart association.

Table 2. Patients characteristics

	LVAD (n=15)		ECMO (n=9)		p
	n	%	n	%	
Age	41.4±15.0		47.3±13.5		0.332
Gender					0.615
Male	13	86.7	7	77.8	
Female	2	13.3	2	22.2	
HT	3	30.0	1	11.1	1.000
DM	4	26.7	1	11.1	0.615
BMI	24.4±2.9		26.4±6.4		0.734
Creatinine	1.15±0.66		0.92±0.25		0.975
ALT	45.3±52.3		52.0±31.6		0.318
AST	39.7±21.2		163.6±273.3		0.907
INR	1.6±0.4		2.3±1.0		0.123
LVEF	17.1±4.7		18.3±7.9		1.000
PVR	3.5±0.9		3.0±1.4		0.428
PCWP	31.3±3.6		29.0±9.2		0.839
TAPSE	14.9±6.0		13.8±3.4		0.635
Cardiac Index	1.71±0.66		2.24±1.3		0.859

LVAD: Left ventricular assist device; ECMO: Extracorporeal membrane oxygenation; HT: Hypertension; DM: Diabetes mellitus; BMI: Body mass index; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; INR: International normalized ratio; LVEF: Left ventricular ejection fraction; PVR: Pulmonary vascular resistance; PCWP: Pulmonary capillary wedge pressure; TAPSE: Tricuspid annular plane systolic excursion.

Table 3. Outcomes of INTERMACS I-II patients

	LVAD (n=15)		ECMO (n=9)		p
	n	%	n	%	
Reoperation for bleeding	9	60.0	2	22.0	0.105
Renal failure	7	46.7	5	55.6	1.000
Cerebrovascular event	1	5.7	1	11.0	1.000
Early right heart failure	7	46.7	3	33.3	0.678
Short-term mortality	10	66.7	7	77.8	0.669

INTERMACS: Interagency registry for mechanically assisted circulatory support; LVAD: Left ventricular assist device; ECMO: Extracorporeal membrane oxygenation.

to maintain organ perfusion and as a bridge to decision or recovery.[7–9] ECMO is an advanced therapy and requires specialized equipment and dedicated care teams in specialized intensive care units. Reza et al.[10] in their cost analysis study found that ECMO, as a bridge to transplant or LVAD is an expensive treatment but less than LVAD implantation. On the other hand, patients with myocarditis and postpartum cardiomyopathy may not need bridging to transplantation or LVAD after ECMO as the myocard may show recovery.[11] The ideal timing for permanent LVAD or short-term ECMO therapy in patients with end-stage heart failure presenting with INTERMACS I and II remains controversial.

Schibilsky et al.[12] showed a significant improvement in liver and kidney parameters in patients with ECMO before LVAD implantation and thus recommended ECMO for bridging to the decision. In a similar study, Tsyganenko et al.[13] explain that liver and kidney failure are independent predictors of mortality in similar patient profiles. These data showed that ECMO as the first choice for INTERMACS I and II patients seems a rational decision.

On the contrary, Molina et al.[1] recommended LVAD application without ECMO bridging in patients presenting with CS. Although LVAD implantation is still associated with a high risk of RHF, cerebrovascular events, infection, pump thrombosis, and hemolysis in patients presenting with CS, their study concludes that LVAD implantation should be performed without delay due to extreme donor organ shortage. They found a significant improvement in survival and a decrease in periprocedural complications.

RHF is a significant complication in patients undergoing LVAD implantation, occurring in 20–50% of all LVAD implantations.[14] Zhigalov et al.[5] defined a 16.8% incidence of RHF after LVAD implantation in patients presenting with INTERMACS profiles I and II. In another study by Zubarevich,[15] reported a similar rate (22.9%) in patients who presented with CS and INTERMACS profile I and were supported with ECMO before LVAD implantation. However, in this patient group, all patients were weaned from ECMO, and then LVAD was applied. Our study showed right heart dysfunction in 46% and 33.3% of patients, respectively, for LVAD and ECMO.

Various studies support both types of ventricular mechanical support in INTERMACS I and II patients. Each clinic decides its protocol according to its heart team experience and cost-effectiveness.

In our study, we did not find a significant difference in terms of post-operative complications and mortality. LVAD implantation without an ECMO bridge can be performed in the appropriate patients.

In our study did not find a significant difference in post-operative complications, renal failure, cerebrovascular events, renal failure, and bleeding.

In our study, there was no difference in terms of mortality and complications in patients with both groups. Both ECMO and LVAD were highly mortal and morbid in INTERMACS I and II patients. LVAD did not alter results in favor of survival or discharge. On the other hand, it was significantly an expensive alternative. A cost comparison could not be given due to the liability of costs, but by all means, the cost of LVAD implantation was considerably higher.

Bridging patients presenting in CS with ECMO may be an appropriate approach to achieve acceptable survival rates and significant improvement in end-organ function.[16] Several factors should be questioned in decision making. The complications of the devices should be evaluated individually for each patient. The patient group with the INTERMACS I and II profile is the most critical group of patients.[17,18]

With our findings, we recommend that in critical cardiogenic shock status and organ shortage, the decision making should be based on the hemo-metabolic results. As both types of mechanical support will be highly mortal, in multiorgan failure with severe metabolic disorder, ECMO shall be the first choice. The aim will be to recover multiorgan failure and metabolic parameters first, and ECMO may be an effective and less costly therapy. On the other hand, LVAD can be the therapy of choice when there is no organ failure or metabolic disorder. In addition, the availability of organ transplantation should be considered in final decision making on a patient basis.

Disclosures

Ethics Committee Approval: The study was approved by The Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital Ethics Committee (Date: 29/09/2022, No: E-28001928-604.01.01).

Informed Consent: Written informed consent was obtained from all patients.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Financial Disclosure: The authors declared that this study has received no financial support.

Authorship Contributions: Concept – S.B.E.; Design – S.B.E., O.M.B.; Supervision – S.B.E., M.A.; Fundings – S.B.E., H.E.; Materials – S.B.E.; Data collection &/or processing – S.B.E., H.E.; Analysis and/or interpretation – O.M.B.; Literature search – S.B.E., M.A.; Writing – S.B.E.; Critical review – S.B.E.

Etik Kurul Onayı: Çalışma Dr. Siyami Ersek Göğüs Kalp ve Damar Cerrahisi Eğitim ve Araştırma Hastanesi Etik Kurulu tarafından onaylandı (Tarih: 29/09/2022, Numara: E-28001928-604.01.01).

Hasta Onamı: Hastalardan yazılı onam alınmıştır.

Hakem değerlendirmesi: Dışarıdan hakemli.

Çıkar Çatışması: Çıkar çatışması bulunmamaktadır.

Finansal Destek: Yazarlar bu çalışmanın herhangi bir finansal destek almadığını beyan etmişlerdir.

Yazarlık Katkıları: Fikir – S.B.E.; Tasarım – S.B.E., O.M.B.; Denetmeler – S.B.E., M.A.; Kaynaklar – S.B.E., H.E.; Malzemeler – S.B.E.; Veri Toplanması ve/veya İşlemesi – S.B.E., H.E.; Analiz ve/veya Yorum – O.M.B.; Literatür Taraması – S.B.E., M.A.; Yazıyı Yazan – S.B.E.; Eleştirel İnceleme – S.B.E.

References

1. Molina EJ, Shah P, Kiernan MS, Cornwell WK 3rd, Copeland H, Takeda K, et al. The society of thoracic surgeons intermacs 2020 annual report. Ann Thorac Surg 2021;111:778–92.
2. Orhan G, Mete EMT, Sargın M, Kudsioğlu T, Erdoğan SB, Güvenç TS, et al. Are mechanical assist devices life-saving in acute cardiogenic shock?. Turk Gogus Kalp Dama 2016;24:454–61.
3. Ni hIci T, Boardman HM, Baig K, Stafford JL, Cernei C, Bodger O, et al. Mechanical assist devices for acute cardiogenic shock. Cochrane Database Syst Rev 2020;6:CD013002.
4. Stevenson LW, Pagani FD, Young JB, Jessup M, Miller L, Kormos RL, et al. INTERMACS profiles of advanced heart failure: The current picture. J Heart Lung Transplant 2009;28:535–41.
5. Zhigalov K, Van den Eynde J, Chrosch T, Goerdt L, Sá MPBO, Zubarevich A, et al. Outcomes of left ventricular assist device implantation for advanced heart failure in critically ill patients (INTERMACS 1 and 2): A retrospective study. Artif Organs 2021;45:706–16.
6. Truby LK, Rogers JG. Advanced heart failure: Epidemiology, diagnosis, and therapeutic approaches. JACC Heart Fail 2020;8:523–36.

7. Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JGF, Coats AJS, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J 2016;37:2129–200.
8. Garan AR, Eckhardt C, Takeda K, Topkara VK, Clerkin K, Fried J, et al. Predictors of survival and ability to wean from short-term mechanical circulatory support device following acute myocardial infarction complicated by cardiogenic shock. Eur Heart J Acute Cardiovasc Care 2018;7:755–65.
9. Sun T, Guy A, Sidhu A, Finlayson G, Grunau B, Ding L, et al. Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) for emergency cardiac support. J Crit Care 2018;44:31–8.
10. Reza J, Mila A, Ledzian B, Sun J, Silvestry S. Incremental cost-effectiveness of extracorporeal membranous oxygenation as a bridge to cardiac transplant or left ventricular assist device placement in patients with refractory cardiogenic shock. JTCVS Open 2022;11:132–45.
11. Płonka J, Gawda R, Sacha J, Bugajski J, Brzostowicz T, Molsa M, et al. Fulminant myocarditis and acute heart failure in the light of new American Heart Association 2020 guidelines. Mechanical cardiac support and endomyocardial biopsy. What should be first? Cardiol J 2022;29:714–7.
12. Schibilsky D, Haller C, Lange B, Schibilsky B, Haeberle H, Seizer P, et al. Extracorporeal life support prior to left ventricular assist device implantation leads to improvement of the patients INTERMACS levels and outcome. PLoS One 2017;12:e0174262.
13. Tsyganenko D, Gromann TW, Schoenrath F, Mueller M, Mulzer J, Starck C, et al. Predictors of mid-term outcomes in patients undergoing implantation of a ventricular assist device directly after extracorporeal life support. Eur J Cardiothorac Surg 2019;55:773–9.
14. Argiriou M, Kolokotron SM, Sakellaridis T, Argiriou O, Charitos C, Zarogoulidis P, et al. Right heart failure post left ventricular assist device implantation. J Thorac Dis 2014;6(Suppl 1):S52–9.
15. Zubarevich A, Zhigalov K, Szczechowicz M, Arjomandi Rad A, Vardanyan R, Torabi S, et al. Rescue extracorporeal life support as a bridge to durable left ventricular assist device. Int J Artif Organs 2022;45:371–8.
16. Boyle AJ, Ascheim DD, Russo MJ, Kormos RL, John R, Naka Y, et al. Clinical outcomes for continuous-flow left ventricular assist device patients stratified by pre-operative INTERMACS classification. J Heart Lung Transplant 2011;30:402–7.
17. Lim HS, Ranasinghe A, Quinn D, Chue C, Mascaro J. Outcomes of temporary mechanical circulatory support in cardiogenic shock due to end-stage heart failure. J Intensive Care Soc 2022;23:170–6.
18. Lamba HK, Kim M, Santiago A, Hudson S, Civitello AB, Nair AP, et al. Extracorporeal membrane oxygenation as a bridge to durable left ventricular assist device implantation in INTERMACS-1 patients. J Artif Organs 2022;25:16–23.