

Insufficienza cardiaca avanzata

Il programma LVAD in Italia Stato dell'arte, volumi, tempistiche e percorso del paziente

Claudio Francesco Russo



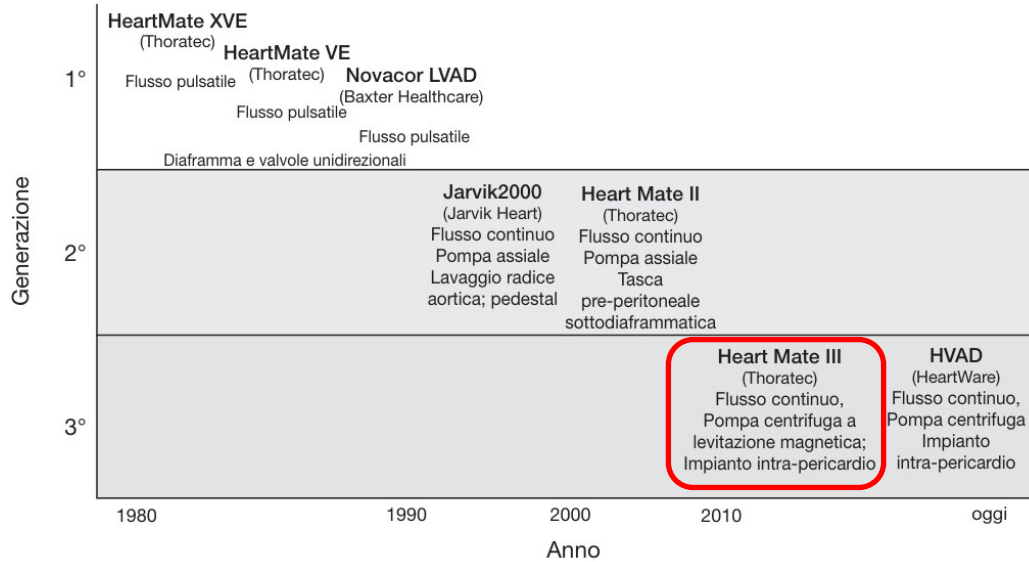
No conflicts of interests to disclose



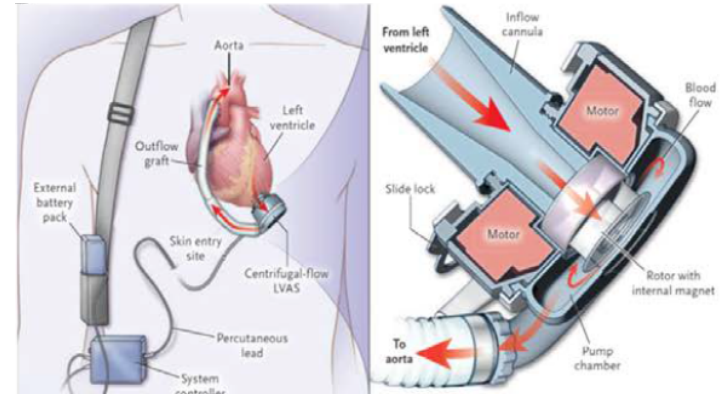
Historical developments

A generational story... and one winner?

- HVAD removed from market in 2021
- Almost only HM3 in Western countries



- Consolidated results from international trials
- Decreased rates of adverse events
- Significant improvements over the previous generations



Circulation. 2019;139:e967–e989. DOI: 10.1161/CIR.0000000000000673



Results of LVAD

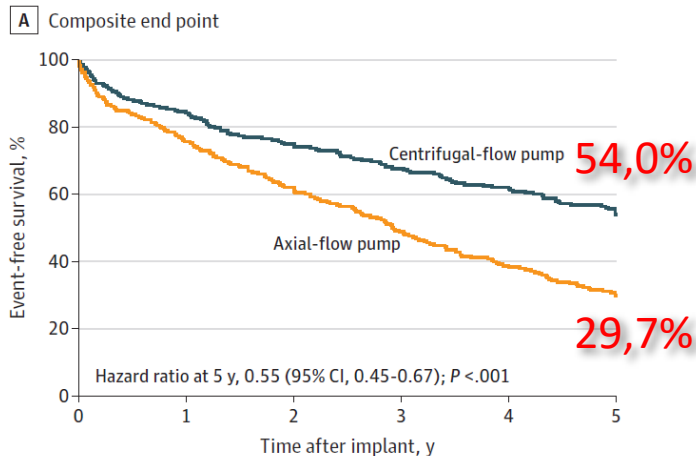
JAMA | Original Investigation

Five-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices in the MOMENTUM 3 Randomized Trial

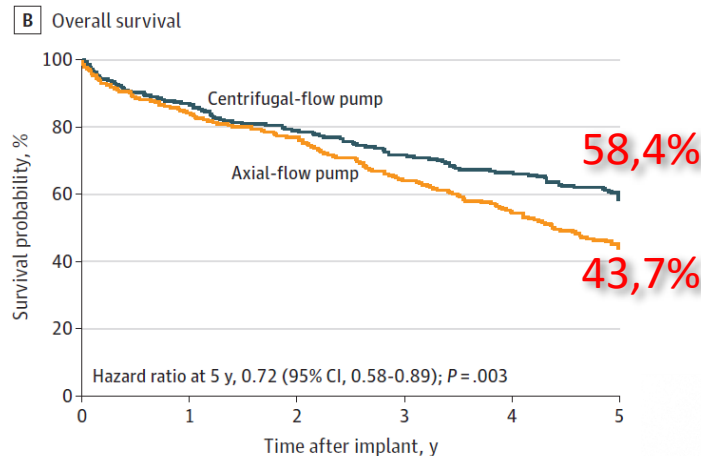
Mandeep R. Mehra, MD, MSc; Daniel J. Goldstein, MD; Joseph C. Cleveland, MD; Jennifer A. Cowger, MD, MS; Shelley Hall, MD; Christopher T. Salerno, MD; Yoshifumi Naka, MD, PhD; Douglas Horstmannshof, MD; Joyce Chuang, PhD; AiJia Wang, MPH; Nir Uriel, MD, MSc

JAMA. 2022;328(12):1233-1242.

- Lower mortality at 5 years
- Significantly lower rates of adverse events
 - Stroke, bleeding, pump thrombosis



No. of patients						
Centrifugal-flow pump	515	373	280	208	177	138
Axial-flow pump	505	321	223	147	106	71

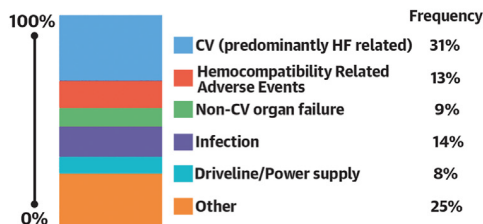


Centrifugal-flow pump	515	383	289	213	184	141
Axial-flow pump	505	339	247	165	124	85



Long-term results of LVAD

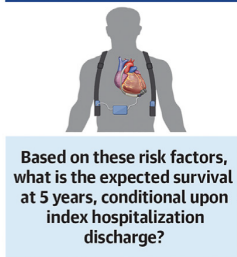
Proportional Causes of 5-Year Mortality



None of the risk predictors were associated with a specific cause of death

- MOMENTUM 3 trial → 485/515 patients (94%) discharged
- Long-term survival keeps improving and is strongly influenced by baseline risk factors and peri-operative implant events
- >90% freedom from malfunctioning at 2 years
- **No significant difference among BTT and DT patients**
- Patients without baseline risk factors (>1/3) have long-term survival comparable with HTx

5-Year Survival



Based on these risk factors, what is the expected survival at 5 years, conditional upon index hospitalization discharge?

No Risk Factors
(35% of the cohort):
77.4%

Preimplant Risk Factors Only
(23% of the cohort):
69.7%

Postimplant Risk Factors Only
(15% of the cohort):
52.1%

Pre- and Postimplant Risk Factors
(27% of the cohort):
43.5%

Risk Predictors for Long-Term Mortality

	Frequency	HR
Preimplant		
Elevated BUN (per mg/dL)	*	1.02
Prior CABG or surgical valve procedure	23%	1.47
Postimplant		
eGFR <60 mL/min/1.73 m ² at discharge	32%	1.63
Index hospitalization serious ventricular arrhythmias	11%	1.95
Index hospitalization hemocompatibility related adverse events	8%	2.11

* 36% with BUN ≥30 mg/dL

JACC VOL. 82, NO. 1, 2023

JULY 4, 2023:70-81

Hemocompatibility-Related Adverse Events (HRAE)



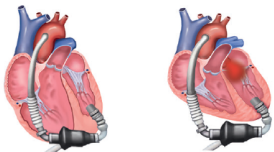
	Pump Thrombosis	Stroke	Bleeding
Heart Mate 3	1.2%*	9.9%*	43.7%*
0-2 Year Incidence	P <0.01*	P <0.01*	P <0.01*
Heart Mate II	18.6%*	19.4%*	55.0%*
Heart Mate 3	2.8% [†]	2.2% [†]	28.1% [†]
2-5 Year Incidence	P <0.05*	P <0.01*	P = 0.21*
Heart Mate II	17.9% [†]	7.7% [†]	32.5% [†]

JACC VOL. 82, NO. 9, 2023

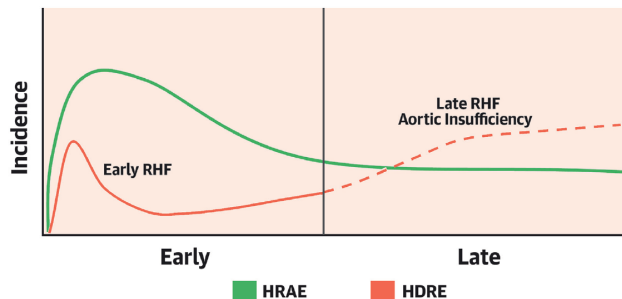
AUGUST 29, 2023:771-781

Hemodynamic effects

Hemodynamic-Related Events (HDRE)



- Continuous hemodynamic assessment and optimization
- Postoperative RV failure requiring tMCS up to 46%
- Consider early RVAD support for refractory RV failure



HM3

HM2

HM3

HM2

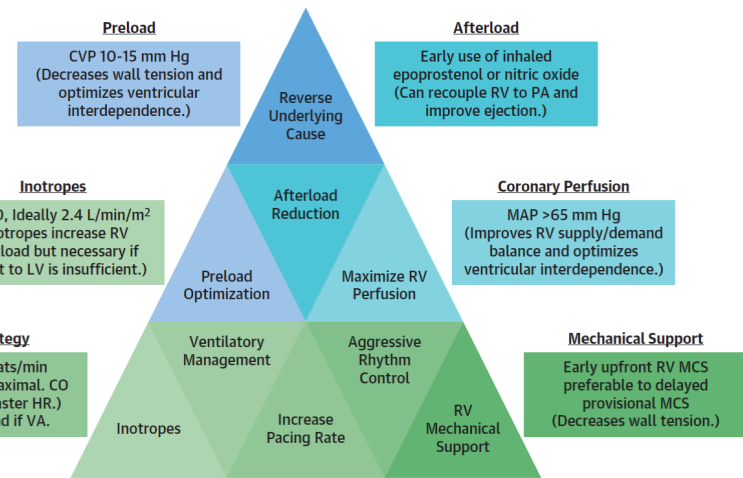
	Right Heart Failure	Aortic Insufficiency
HM3	34.2%*	5.6%**
HM2	$P = 0.18^*$	$P < 0.01^{**}$
HM3	28.3%*	11.5%**
HM2	5.1% ⁺	?
HM3	$P < 0.05^+$	
HM2	4.3% ⁺	19-35% ⁺⁺

Adverse Hemodynamic Consequences of Continuous Left Ventricular Mechanical Support

JACC Review Topic of the Week

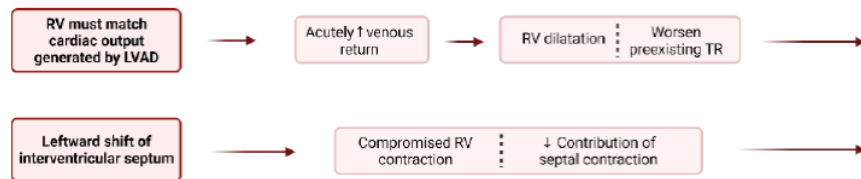
Jonathan Grinstein, MD,^a Mark N. Belkin, MD,^a Sara Kalantari, MD,^a Kevin Bourque, MSME,^b Christopher Salerno, MD,^c Sean Pinney, MD^a

JACC VOL. 82, NO. 1, 2023
JULY 4, 2023:70-81

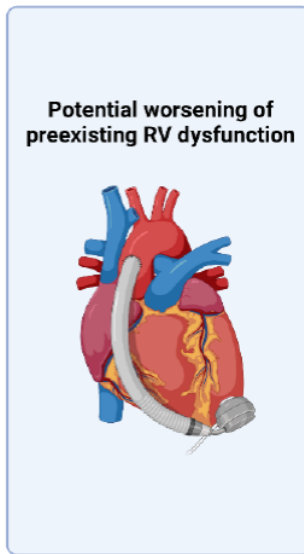
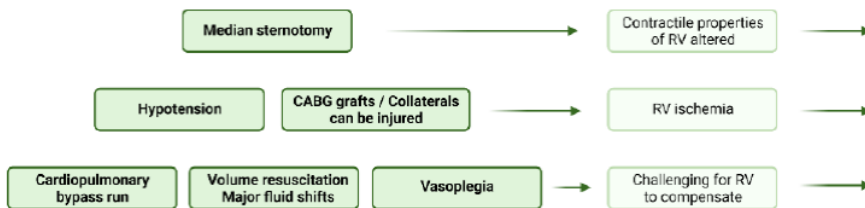


RV dysfunction

- Potential worsening of preexisting RV dysfunction → important patient selectio **LVAD Influence**



Perioperative Effects



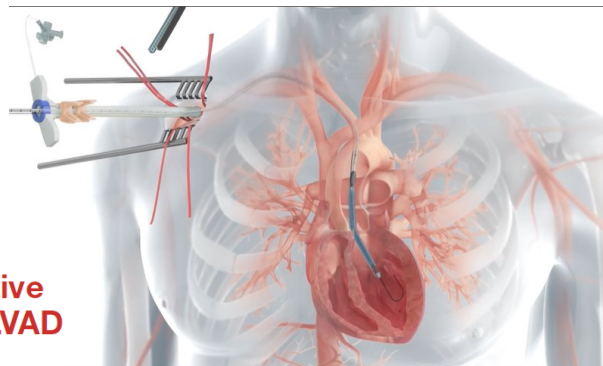
Pre-operative conditioning

- In addition to pre-implantation hemodynamic and imaging workup, isolated left tMCS might test RV tolerance to LVAD physiology
- **Paracorporeal LVAD**
- Recent description of **Impella 5.5** for better convenience
- Both as planned strategy or as bridge from short-term to durable MCS



Microaxial flow pump in cardiogenic shock: a retrospective cohort study on outcomes and feasibility as a bridge to LVAD implantation

Jan-Willem Balder · Adriaan Kraaijeveld · Mariusz Szymanski · Linda van Laake · Einar Hart · Michiel Voskuil · Joep Droogh · Faiz Ramjankhan · Tim van de Hoef · Jeannine Hermens · Pim van der Harst · Kevin Damman · Erik Lipsic · Gabija Pundziute · Michael Dickinson

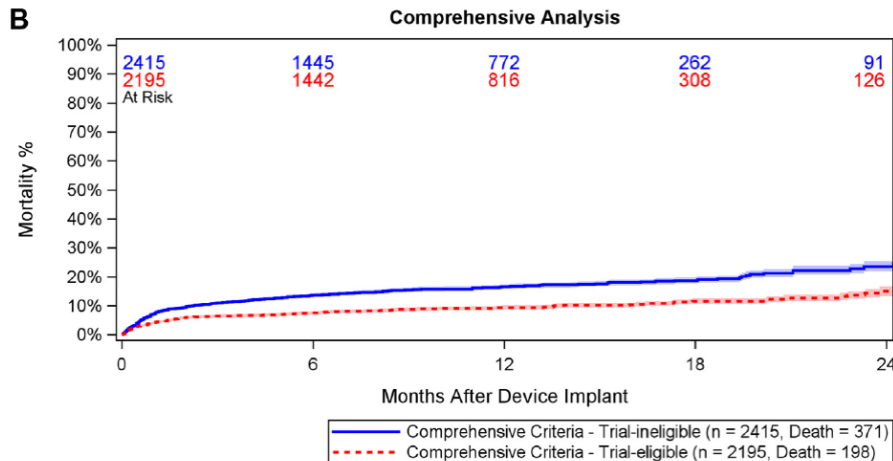


Neth Heart J (2025) 33:226–231



Modern results of LVAD

- High long-term survival with continuous-flow LVAD
- ~30,000 LVAD implanted in 2013-2022 (INTERMACS registry)
- In 2009 LVAD implants outnumbered HTx in U.S.
- Results confirmed across multiple registries and patient populations



Generalizability of Trial Data to Real-World Practice: An Analysis of The Society of Thoracic Surgeons InterMACS Database

Alexander A. Brescia, MD, MSc, Tessa M. F. Watt, MD, MSc, Francis D. Pagani, MD, PhD, Thomas M. Cascino, MD, MSc, Min Zhang, PhD, Jeffrey S. McCullough, PhD, Supriya Shore, MD, MSc, Donald S. Likosky, PhD, Keith D. Aaronson, MD, MS, Ryan S. Cantor, PhD, Luqin Deng, PhD, James K. Kirklin, MD, and Michael P. Thompson, PhD

Ann Thorac Surg
2022;114:1307-17

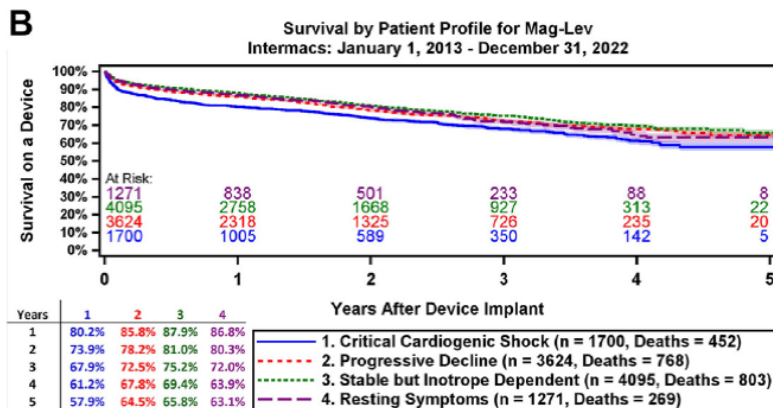
- Importance of patient selection to optimize survival



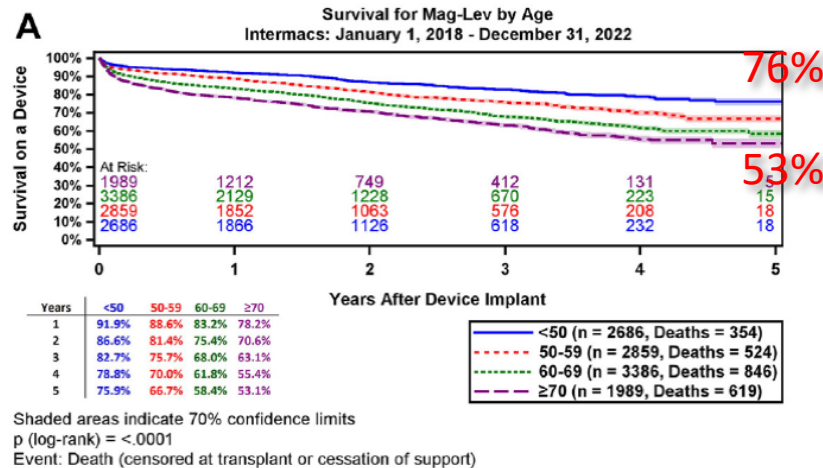
The Society of Thoracic Surgeons Intermacs 2023 Annual Report: Focus on Magnetically Levitated Devices

Ulrich P. Jorde, MD,¹ Omar Saeed, MD, MSc,¹ Devin Koehl, MSDS,²
Alanna A. Morris, MD, MSc,³ Katherine L. Wood, MD,⁴ Dan M. Meyer, MD,⁵
Ryan Cantor, PhD,² Jeffrey P. Jacobs, MD,⁶ James K. Kirklin, MD,²
Francis D. Pagani, MD, PhD,⁷ and J. David Vega, MD⁸

(Ann Thorac Surg 2024;117:33-44)

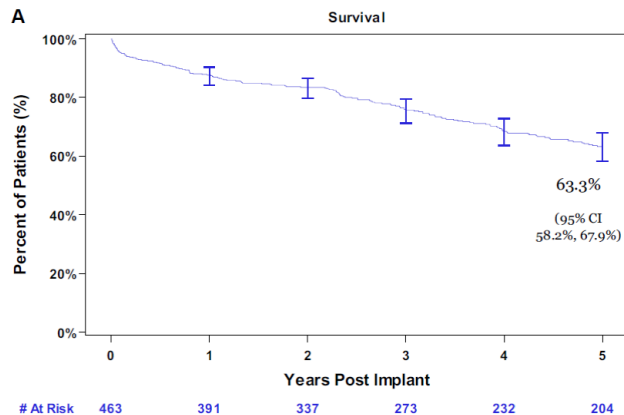


Shaded areas indicate 70% confidence limits
p (log-rank) = <.0001
Event: Death (censored at transplant or cessation of support)



- Satisfactory results with significant differences according to INTERMACS class, age, era of implant, device and indication



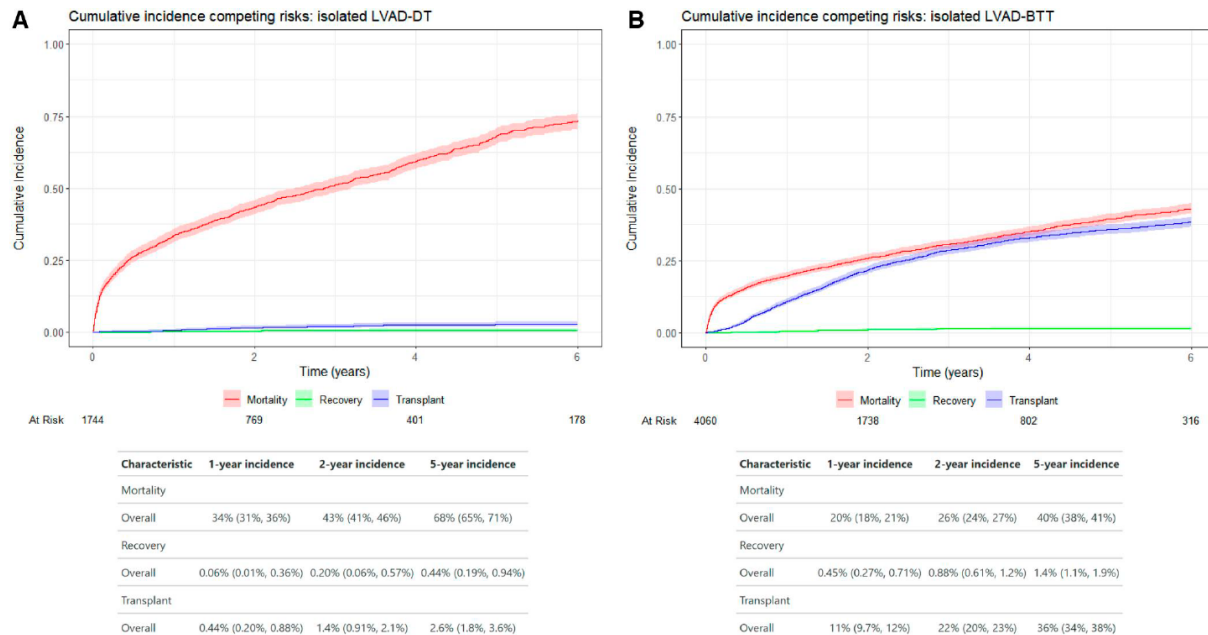


Fully magnetically centrifugal left ventricular assist device and long-term outcomes: the ELEVATE registry

Jan D. Schmitto^{1*}, Steven Shaw^{2†}, Jens Garbade³, Finn Gustafsson⁴, Michiel Morshuis⁵, Daniel Zimpfer⁶, Jacob Lavee⁷, Yuriy Pya⁸, Michael Berchtold-Herz⁹, Aijia Wang¹⁰, Carlo Gazzola¹⁰, Evgenij Potapov^{11†}, and Diyar Saeed^{12†}; on behalf of the ELEVATE Registry Investigators

European Journal of Cardio-Thoracic Surgery 2025, 67(2), eza016

The fourth report of the European Registry for Patients with Mechanical Circulatory Support (EUROMACS) of the European Association for Cardiothoracic Surgery: focus on standardized outcome ratios



Broader LVAD implantation

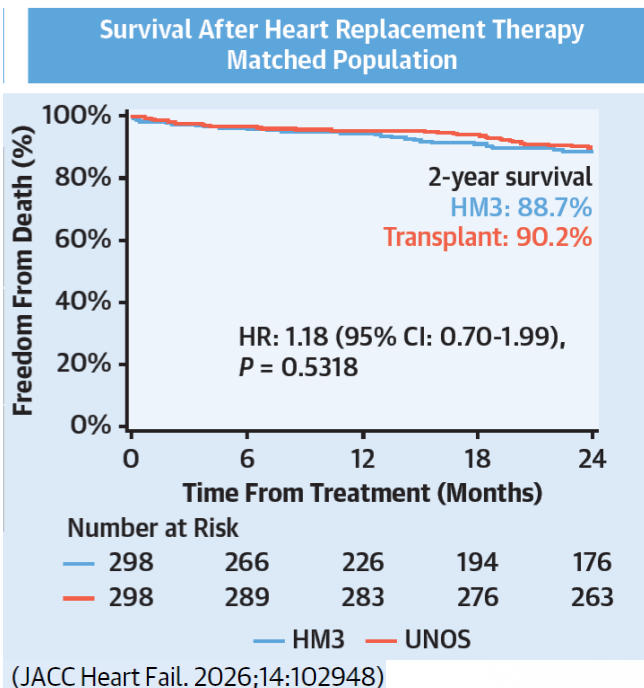
- First-line consideration of LVAD in young patients (<50 y.o.) vs. HTx

Heart Replacement Therapy in Young Patients

A Comparative Analysis of HeartMate 3 LVAD and Heart Transplant Using MOMENTUM 3 and UNOS Registry

Nir Uriel, MD, MSc,^a Gabriel T. Sayer, MD,^a Boaz Elad, MD,^a Justin A. Fried, MD,^a Jayant K. Raikhelkar, MD,^a Dor Lotan, MD,^a Daniel J. Goldstein, MD,^{b,c} Ulrich P. Jorde, MD,^c Joseph C. Cleveland, Jr, MD,^d Mandeep R. Mehra, MD, MS,^e Stavros G. Drakos, MD, PhD,^f Katherine L. Wood, MD,^g John D. Henderson, MS,^h Fei San Lee, PhD,^h Manreet K. Kanwar, MD,ⁱ Kevin J. Clerkin, MD, MSc^a

Adverse Events				
		HM3	Transplant	P Value
	Renal dysfunction requiring dialysis	5.0%	10.4%	0.016
	Stroke	3.4%	0.3%	0.027
	Infection leading to hospitalization	24.8%	34.2%	0.012



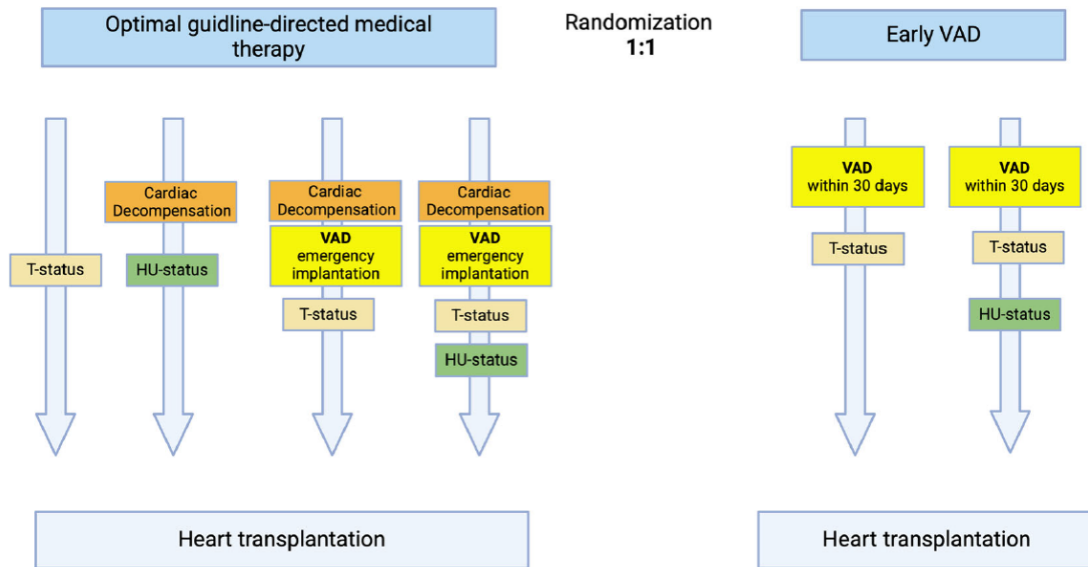
Broader LVAD implantation

Rationale and design of the randomized 'early ventricular assist device'—Trial (VAD-DZHK3)

Christoph Knosalla^{1,2,3,4*} , Gloria Färber⁵ , Andreas J. Rieth^{6,7} , Rolf Wachter^{8,9,10} , Marius Placzek^{11,12} , Wolfgang Albert^{1,2,3} , Gerd Hasenfuß^{9,10} , Volkmär Falk^{1,2,3,10} , Tim Friede^{11,12}  and for the VAD-DZHK3 Investigators

ESC Heart Failure 2025; **12**: 3731–3740

Severe HF patients in T-status on HTx waiting list meeting inclusion criteria of increased mortality risk



- Good results of LVAD have led some to promote early LVAD implantation RCTs





European Heart Journal (2021) 42, 3599–3726
doi:10.1093/eurheartj/ehab368

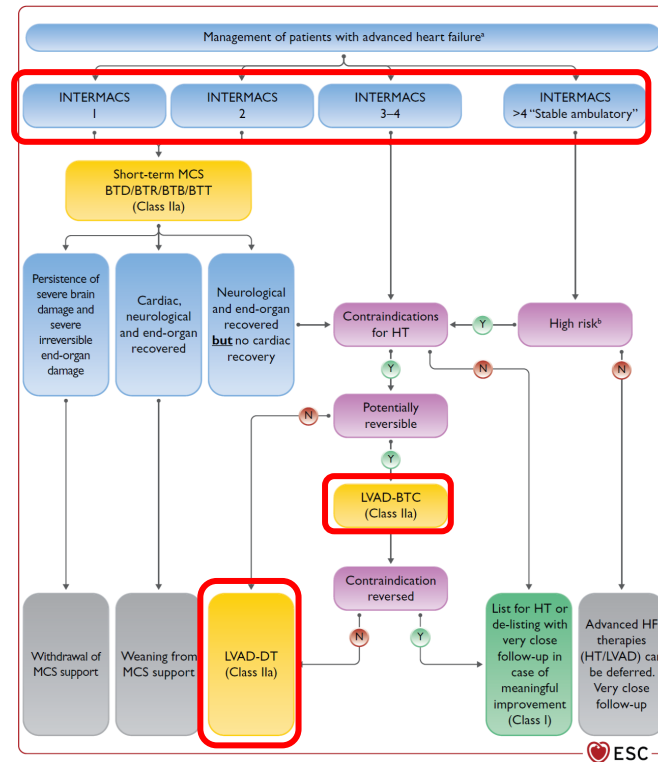
ESC GUIDELINES

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

Developed by the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

With the special contribution of the Heart Failure Association (HFA) of the ESC

- Based on INTERMACS stage
- Primary role of short-term MCS in acute HF
- Buy time → BTD – BTC – BTB – BTT
- Early consideration for HTx (Class I)
- **LVAD as BTC, BTT or DT**
 - Less frequent BTD and BTR



Indication to LVAD

Recommendations	Class ^a	Level ^b
Patients being considered for long-term MCS must have good compliance, appropriate capacity for device handling and psychosocial support. ^{414–416}	I	C
Long-term MCS should be considered in patients with advanced HFrEF despite optimal medical and device therapy, <u>not eligible for heart transplantation</u> or other surgical options, and without severe right ventricular dysfunction, to reduce the risk of death and improve symptoms. ^{378,396,397,401,402,404,417}	IIa	A
Long-term MCS should be considered in patients with advanced HFrEF refractory to optimal medical and device therapy as a <u>bridge to cardiac transplantation</u> in order to improve symptoms, reduce the risk of HF hospitalization and the risk of premature death. ^{398–400,402,404}	IIa	B
Renal replacement therapy should be considered in patients with refractory volume overload and end-stage kidney failure.	IIa	C
Continuous inotropes and/or vasopressors may be considered in patients with low cardiac output and evidence of organ hypoperfusion as bridge to MCS or heart transplantation. ^{389,390}	IIb	C
Ultrafiltration may be considered in refractory volume overload unresponsive to diuretic treatment. ^{391,392}	IIb	C

Table 16 Patients potentially eligible for implantation of a left ventricular assist device

Patients with persistence of severe symptoms despite optimal medical and device therapy, without severe right ventricular dysfunction and/or severe TR, with a stable psychosocial background and absence of major contraindications*, and who have at least one of the following:

- LVEF <25% and unable to exercise for HF or, if able to perform cardiopulmonary exercise testing, with peak VO_2 <12 mL/kg/min and/or <50% predicted value.
- ≥ 3 HF hospitalizations in previous 12 months without an obvious precipitating cause.
- Dependence on i.v. inotropic therapy or temporary MCS.
- Progressive end-organ dysfunction (worsening renal and/or hepatic function, type II pulmonary hypertension, cardiac cachexia) due to reduced perfusion and not to inadequately low ventricular filling pressure (PCWP ≥ 20 mmHg and SBP ≤ 90 mmHg or cardiac index ≤ 2 L/min/m²).

- Good psychological compliance
- Good RV function
- Acceptable left ventricular cavity volume
- Not eligible (at least temporarily) for HTx



Indication to LVAD

- NYHA IIIb/IV refractory to maximal medical therapy, inotrope-dependent or on tMCS (I-A) →
- Long-term durable MCS → HTx in short term unlikely, improve HTx candidacy, or DT
- Address all reversible causes of HF and always assess HTx candidacy
- Classification based on **NYHA** and **INTERMACS** → LVAD in INTERMACS 1-3 (I-A), INTERMACS 4 (IIb-B)
- Acute cardiogenic shock → ventricular function unlikely to recovery/wean from tMCS
possible end-organ function recovery
- Regularly assess end-stage HF patients (CPET) for timing and risk stratification
- Disease-specific evaluation (CAD, VHD, CHD), treat arrhythmias
- Role of advanced heart failure team

The Journal of Heart and Lung Transplantation, Vol 42, No 7, July 2023

**The 2023 International Society for Heart and Lung
Transplantation Guidelines for Mechanical
Circulatory Support: A 10- Year Update**



Pre-implant assessment

- Peripheral vascular disease
- Life-limiting comorbidities (especially if > 60 years old)
- Renal function (assess recovery with tMCS)
- Pulmonary hypertension invasive evaluation
- Pulmonary and thoracic assessment
- Neurologic function, coagulation disorders, malignancy, pregnancy, diabetes, infectious status, GI disorders, hepatic function
- Psychological evaluation, adherence to therapy, home environment, financial status, substance addiction, nutrition status, frailty

GUIDELINE

The Journal of Heart and Lung Transplantation, Vol 42, No 7, July 2023

The 2023 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: A 10- Year Update

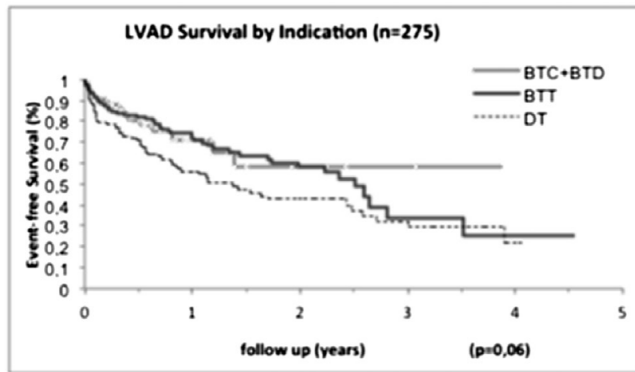
Right ventricular function assessment and preoperative optimization



The Journal of Heart and Lung Transplantation, Vol 34, No 4S, April 2015

Preliminary Results From ITAMACS, the Italian Multi Center Registry for Mechanically Assisted Circulatory Support

G. Feltrin,¹ M. Frigerio,² L. Martinelli,² M. De Bonis,³ M. Rinaldi,⁴ M. Pilato,⁵ F. Musumeci,⁶ G. Faggian,⁷ U. Livi,⁸ M. Maccherini,⁹ A. Iacovoni,¹⁰ A. Barbone,¹¹ G. Di Giammarco,¹² C. Maiello,¹³ G. Marinelli,¹⁴ F. Alamanni,¹⁵ G. Ambrosio,¹⁶ A. Grimaldi,¹⁷ G. Leonardi,¹⁸ F. Pagani,¹⁹ M. Massetti,²⁰ L. Rizzato,²¹ G. Gerosa,²² A. Nanni Costa.²³ ¹Veneto Region, Regional Centre for Transplant



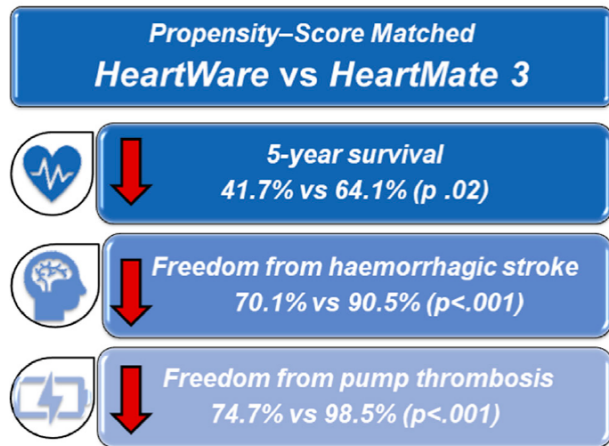
Five-Year Outcome After Continuous Flow LVAD With Full-Magnetic (HeartMate 3) Versus Hybrid Levitation System (HeartWare): A Propensity-Score Matched Study From an All-Comers Multicentre Registry

Alessandra Francica^{1*}, Antonio Loforte^{2,3}, Matteo Attisani³, Massimo Maiani⁴, Attilio Iacovoni⁵, Teodora Nisi⁶, Marina Comisso⁷, Amedeo Terzi⁵, Michele De Bonis⁶, Igor Vendramin⁴, Massimo Boffini³, Francesco Musumeci⁷, Giovanni Battista Luciani¹, Mauro Rinaldi³, Davide Pacini² and Francesco Onorati¹

September 2023 | Volume 36 | Article 11675

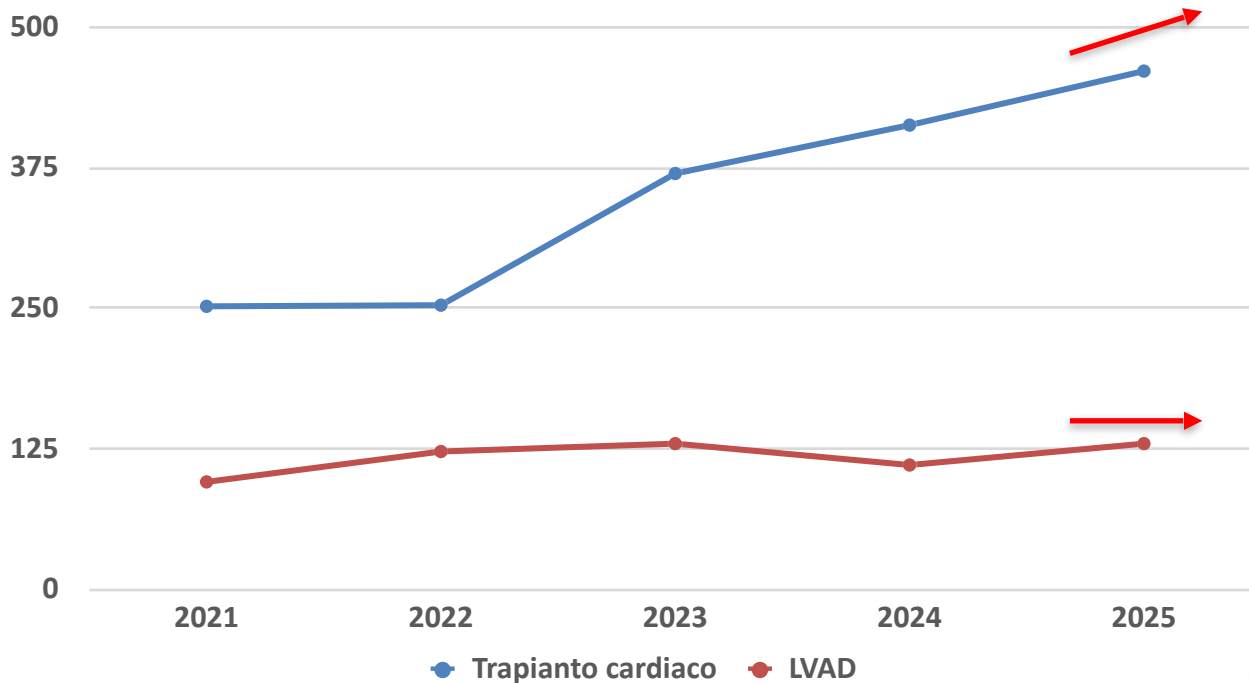
Transpl Int 36:11675.

447 patients
(2010-2022)



HTx vs. LVAD in Italy

- Sharp increase in HTx in Italy in recent years unmatched by LVAD implants



Source: Centro Nazionale Trapianti



Adequate HTx-LVAD ratio

- 1:4 ratio for real-life appropriate indication to LVAD vs. HTx
- Highly variable proportions among different Italian centers with few outliers
- Relevant issue for equity of HTx access in scarcity of donor organs

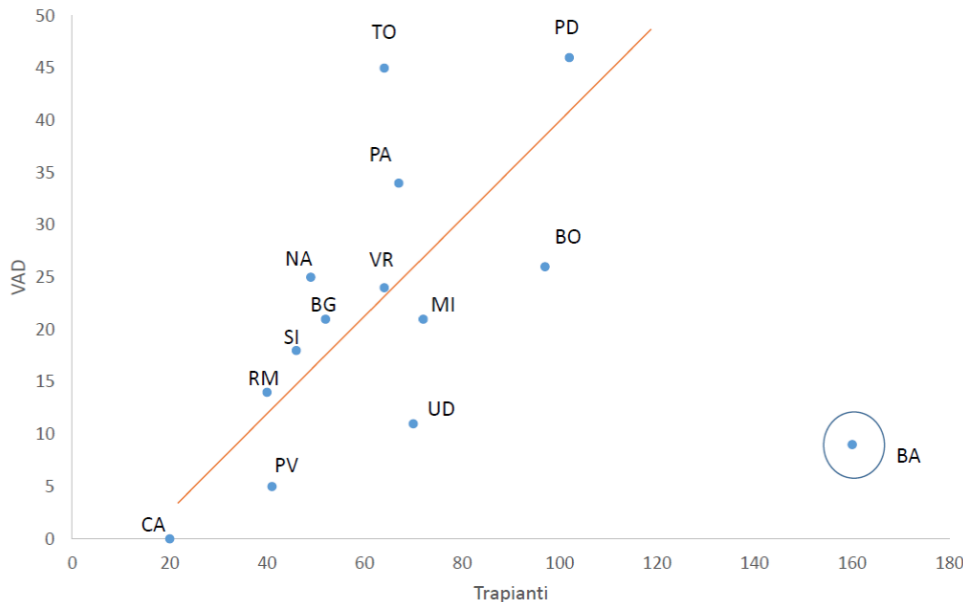
2022-2024

Impact of Center Left Ventricular Assist Device Volume on Outcomes After Implantation

An INTERMACS Analysis

Jennifer A. Cowger, MD, MS,^a John M. Stulak, MD,^b Palak Shah, MD, MS,^c Todd F. Dardas, MD, MS,^d Francis D. Pagni, MD, PhD,^e Shannon M. Dunlay, MD, MS,^f Simon Maltais, MD,^b Keith D. Aaronson, MD, MS,^g Ramesh Singh, MD,^h Nahush A. Mokadam, MD,ⁱ James K. Kirklin, MD,^j Christopher T. Salerno, MD^k

(J Am Coll Cardiol HF 2017;5:691-9)

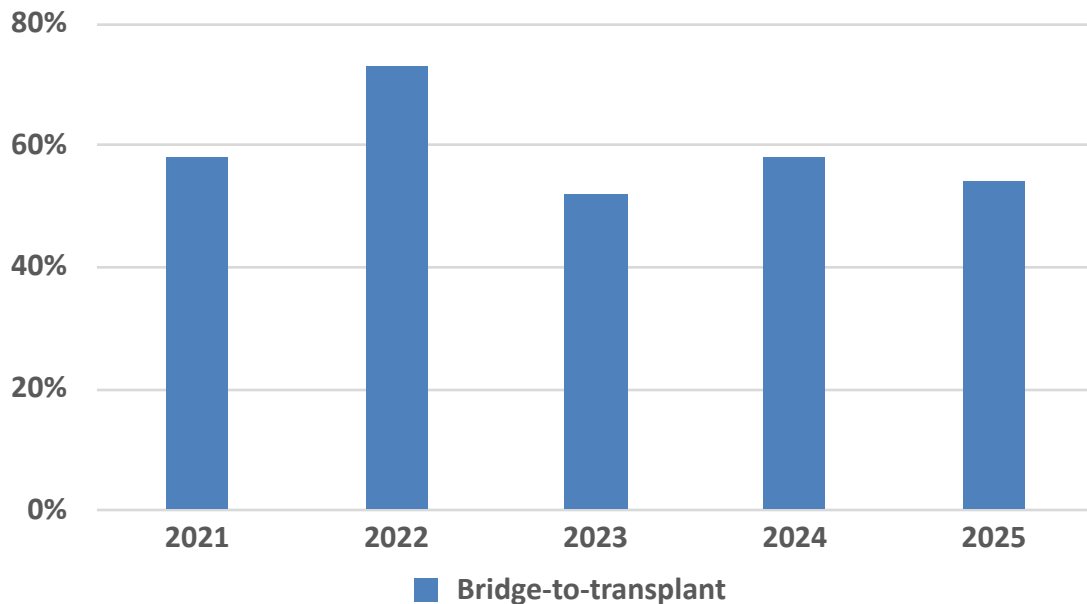


Source: Centro Nazionale Trapianti



Indication to LVAD in Italy

- About 60% of LVAD implanted as BTT (stable)
- Underutilization for DT
- Distrust in real HTx chances for BTT patients

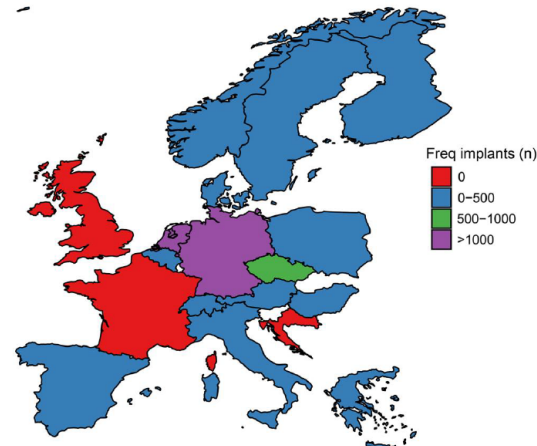


Source: Centro Nazionale Trapianti

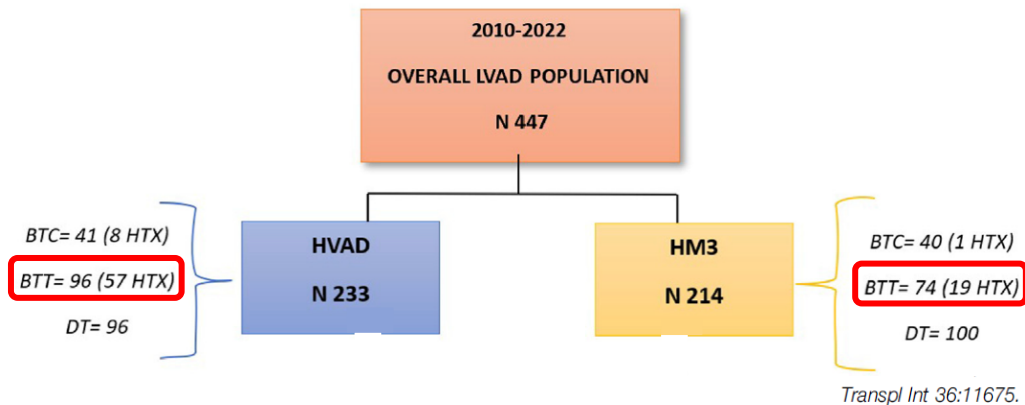


Indication to LVAD

- Italian data in line with most European countries
- Similar rates of indication in Europe
- Different from U.S.
- Patient trajectory matters for indication
- Difficult access to HTx for LVAD patients
- Higher rate of HTx in HVAD (~60%) probably due to higher rates of complications requiring emergent listing upgrade



European Journal of Cardio-Thoracic Surgery 2025, 67(2), eza016



LVAD patient trajectory

Causes for higher priority listing to HTx in LVAD patients

Status 1

- **LVAD with ≥ 1 severe complication**

- Pump thrombosis
 - *First episode* → emergency status withdrawn in case of resolution
 - *Recurrent episode* → emergency status maintained as long as patient requires hospitalization
- Deep infection requiring in-hospital IV antibiotic treatment
- Any device failure causing immediate risk of death

Status 2

- **LVAD developing chronic HF due to RV failure or severe AR** requiring hospitalization and continuous IV therapy
 - Inotrope need documented with C.I. < 1.8 L/min/m² or worsening hepatic/renal function improved by inotrope therapy
 - Confirm every 7 days → impossibility to wean patient from inotropes



LVAD patient trajectory

Causes for higher priority listing to HTx in LVAD patients

Status 2

- **LVAD patients requiring hospitalization with:**
 - Previous single event of pump thrombosis
 - Severe AR
 - HF requiring >100 mg/d Furosemide or impossibility to achieve adequate LV unloading
 - Recurrent GI bleeding not manageable with drugs/endoscopy
 - Device-related not invalidating CVAs
 - Chronic driveline infection resistant to targeted antibiotic therapy
 - PRA >75%
- **Grace period for LVAD patients >18 months and ≤65 y.o.**
 - 30 days/year

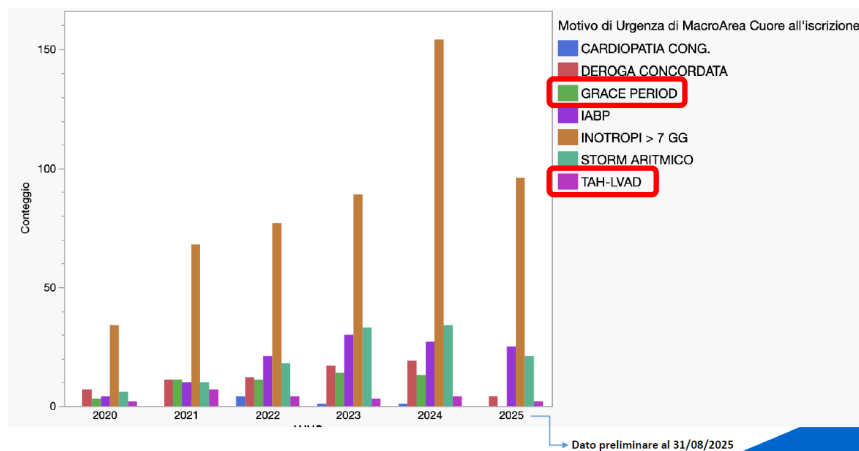
Status 1 and 2 are denied for patients eligible for LVAD implantation



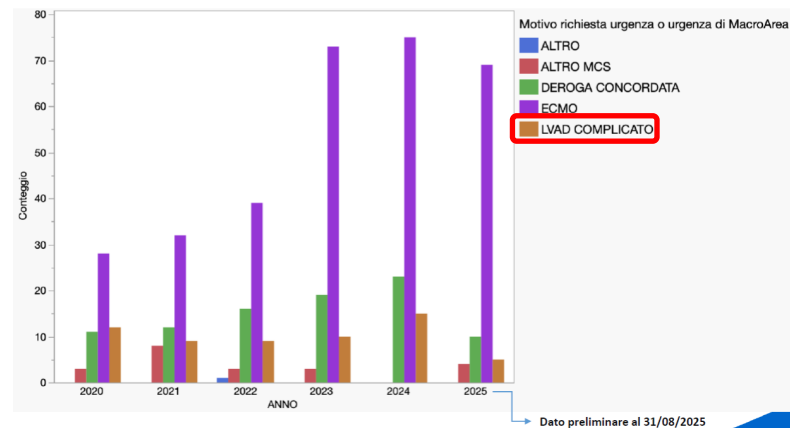
LVAD patient trajectory

- LVAD patients may wait for HTx until severe complications occur or may never receive a heart
- Virtual number of patients receiving HTx during Grace period

Criteri per macroarea



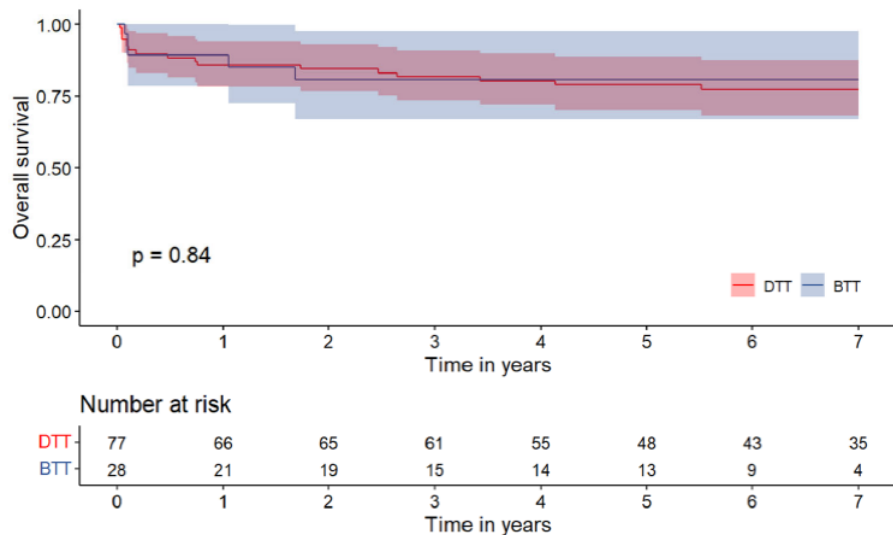
Urgenze nazionali



Source: Centro Nazionale Trapianti



Direct HTx vs. LVAD-BTT



- HTx from LVAD more challenging procedure
- No difference in operative mortality
- No difference in 1-y and 7-yy survival
- Adverse neurological events in 39,6% in BTT patients

J. Clin. Med. 2025, 14, 275



Article

Clinical Outcomes of Cardiac Transplantation in Heart Failure Patients with Previous Mechanical Cardiocirculatory Support

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- So, why choosing LVAD-BTT in this situation?



LVAD patients trajectory

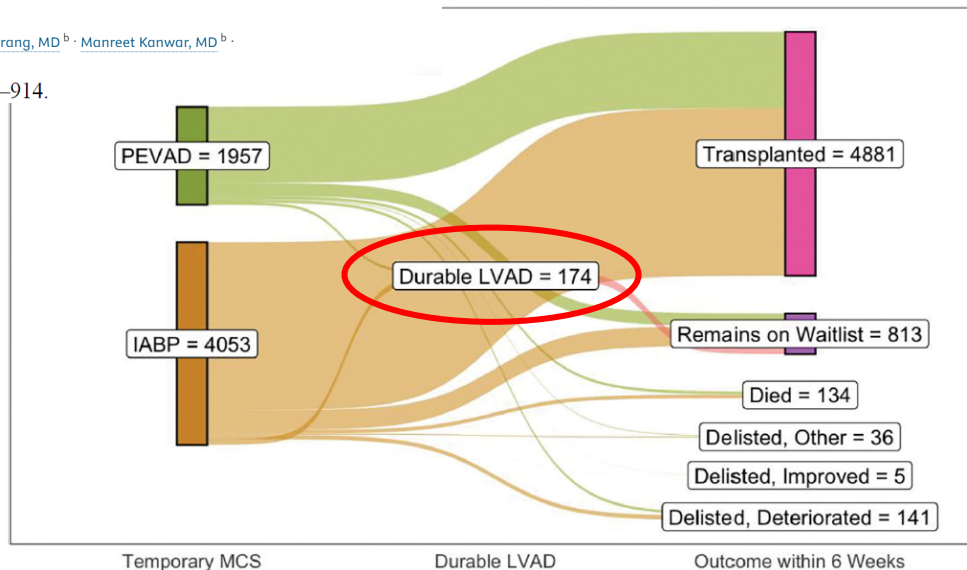
- Similar situation in U.S. after 2018 revision of allocation criteria for HTx
- Allocation criteria are focused on HTx access, but do not consider the potential role of LVAD as temporary HTx alternative for selected patients

Low rates of inotropic support and durable left ventricular assist device placement among status 2 heart transplant candidates with temporary mechanical circulatory support

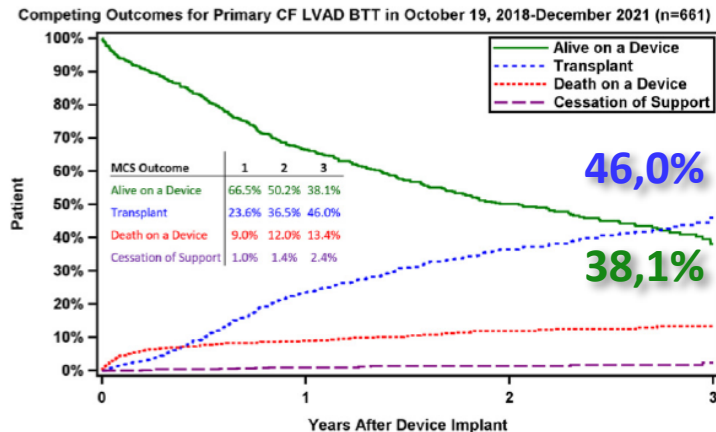
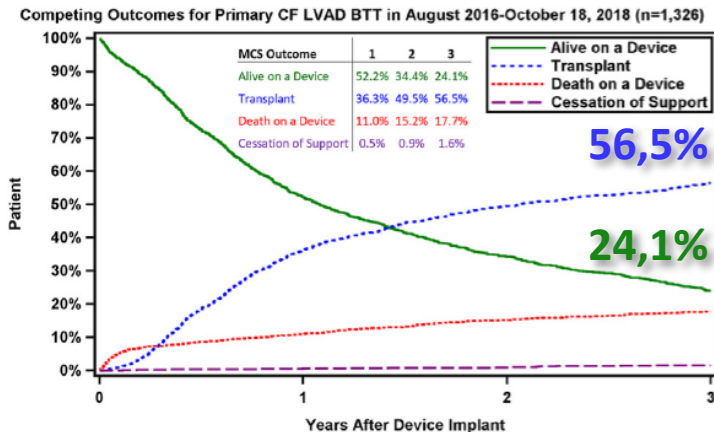
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LVAD patients trajectory



- Significantly higher rate of LVAD patients with ongoing support at 3 years with new allocation criteria

(Ann Thorac Surg 2023;115:311-28)

The Society of Thoracic Surgeons Intermacs
2022 Annual Report: Focus on the 2018 Heart
Transplant Allocation System

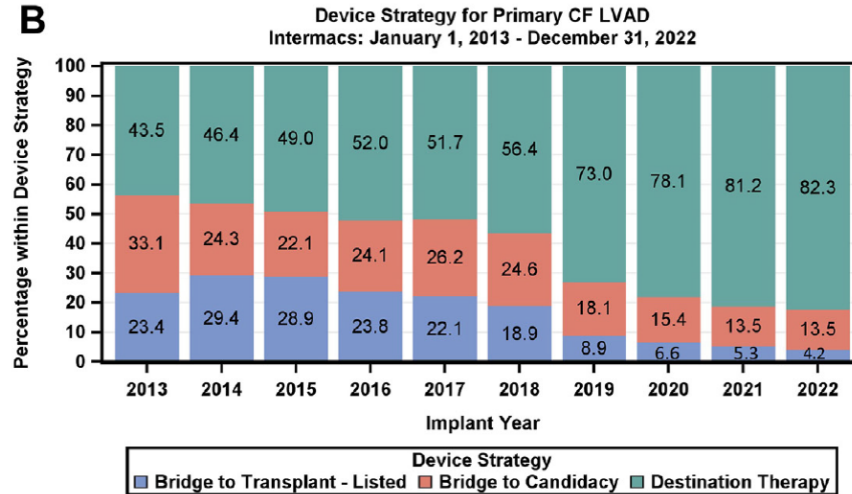


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Destination therapy

- Low access rate to HTx for LVAD patients have contributed to a significant change in the indications to LVAD in the U.S.
- Vast majority of implants as DT → headed to 90%
- Not quite similar to Italy or Europe (<50%)



Ann Thorac Surg

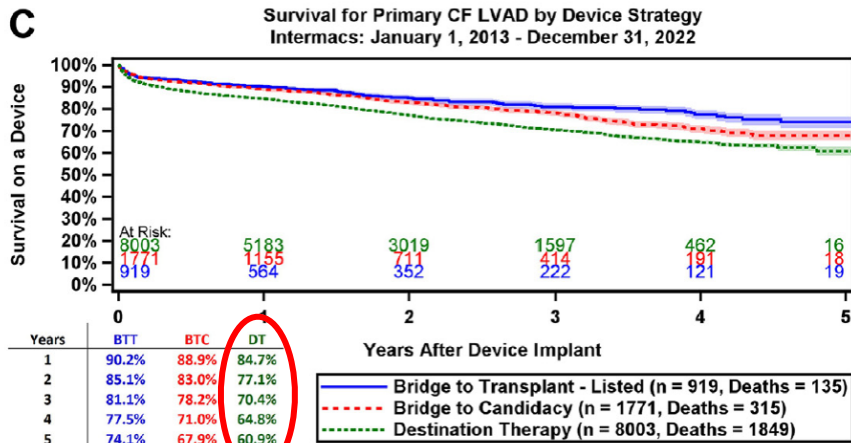
2024;117:33-44

Profiles 5-7 comprise <3% of implants and not depicted in this figure



Destination therapy

- Significantly lower survival than BTT, but still good

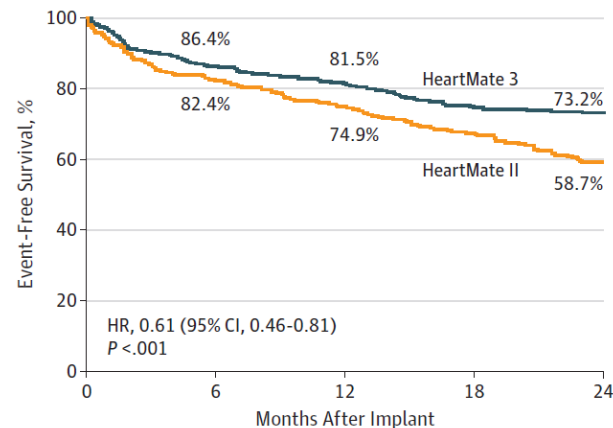


Shaded areas indicate 70% confidence limits

p (log-rank) = <.0001

Event: Death (censored at transplant or cessation of support)

B DT (n = 624)



No. at risk

HeartMate 3	317	272	243	214	197
HeartMate II	307	248	212	181	154

JAMA Cardiol. 2020;5(4):411-419.



Critical aspects

- HeartMate 3 is almost the only device available in Western countries
- Introduced in 2015, it overturned the competitors with lower rates of mortality and severe adverse-related events
- These results granted an undisputed control over the market
- **No real competitor → no stimulus to improvement**
- No meaningful technological advancements over the past decade
- In fact, the state-of-the-art is “outdated”
- High reliability of the device does not mean it has no complications at all
- Reluctant attitude of some countries to wide adoption of LVAD even for DT
- *Looking for competitors...*



Other devices available



Corheart 6
(China)



CH-VAD
(China)



EVAHEART
(Japan)

- Potential alternatives currently available worldwide
- And... what else?

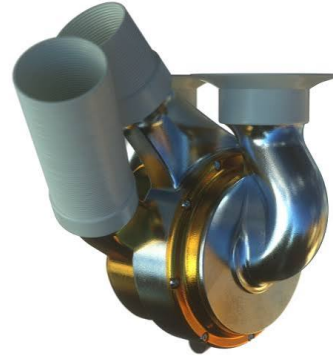


- Collect published data on the **updated situation in Italy** regarding durable MCS (ITAMACS, MIRAMACS)
- **Revision of allocation criteria** to provide fair access to HTx for LVAD patients
- More rigid monitoring of the appropriate **LVAD:HTx ratio** of Italian centers to protect equality of access and correct indication to HTx
- Larger adoption of **LVAD as DT** for patients not suitable for HTx, especially considering the consolidated results of LVAD and the declining long-term survival of HTx with the adoption of progressively more marginal donors



Future needs and directions

- Push the companies to continuous improvements in the field of durable MCS
- LVAD unaddressed needs
 - Smaller devices
 - Totally implanted with no need of external driveline
 - Better hemocompatibility
- New devices for durable MCS in patients with biventricular failure





Thank you

