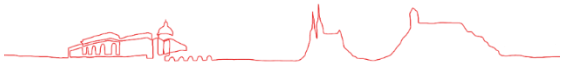
INDIKACE A DLOUHODOBÁ PÉČE O PACIENTY S LVAD

Eva Ozábalová, H. Poloczková, J. Krejčí
I. Interní kardioangiologická klinika FN USA Brno

MUNI MED

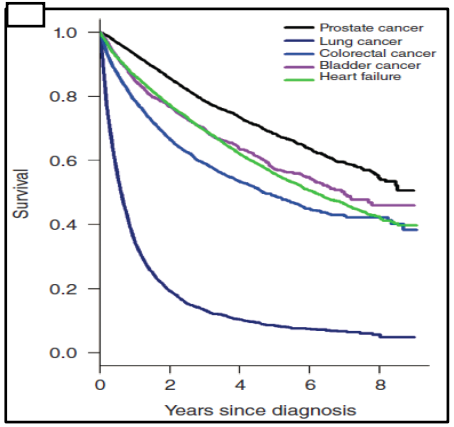


I. INTERNÍ KARDIOANGIOLOGICKÁ KLINIKA FNUSA A LF MU

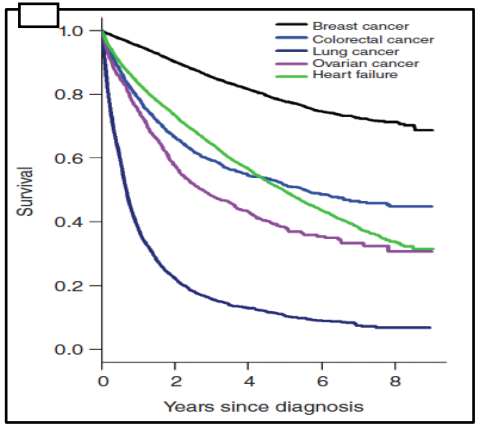
FAKULTNÍ NEMOCNICE U SV. ANNY V BRNĚ

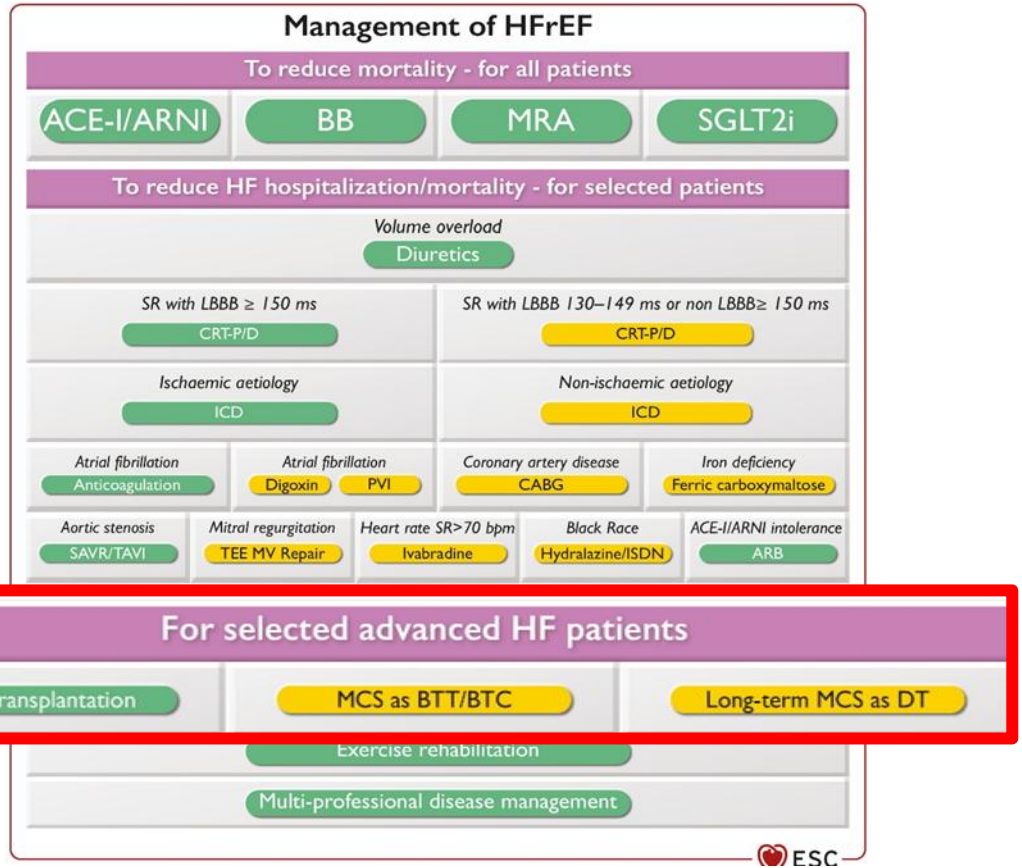
CHRONICKÉ SRDEČNÍ SELHÁNÍ – PROGNÓZA

- **stále velmi nepříznivá**
- **40-50% pacientů umírá do 5 let od stanovení diagnózy**

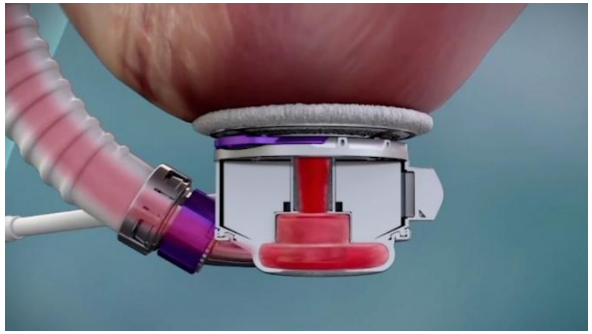


Mamas et al. Eur J Heart Fail. 2017;19(9):1095-1104




Management of HFrEF
To reduce mortality - for all patients
ACE-I/ARNI
BB
MRA
SGLT2i
To reduce HF hospitalization/mortality - for selected patients
Volume overload
Diuretics
SR with LBBB ≥ 150 ms
CRT-P/D
SR with LBBB 130–149 ms or non LBBB≥ 150 ms
CRT-P/D
Ischaemic aetiology
ICD
Non-ischaemic aetiology
ICD
Atrial fibrillation
Anticoagulation
Atrial fibrillation
Digoxin
PVI
Coronary artery disease
CABG
Iron deficiency
Ferric carboxymaltose
Aortic stenosis
SAVR/TAVI
Mitral regurgitation
TEE MV Repair
Heart rate SR>70 bpm
Ivabradine
Black Race
Hydralazine/ISDN
ACE-I/ARNI intolerance
ARB
For selected advanced HF patients
Heart transplantation
MCS as BTT/BTC
Long-term MCS as DT
Exercise rehabilitation
Multi-professional disease management
ESC

LVAD – HEART MATE 3



LVAD

- Které pacienty vybrat k implantaci LVAD
- Kdy indikovat implantaci LVAD
- Co nás/pacienta čeká po implantaci LVAD

LVAD

- **Které pacienty vybrat k implantaci LVAD**
- Kdy indikovat implantaci LVAD
- Co nás/pacienta čeká po implantaci LVAD

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

Diyar Saeed, MD, PhD,[1] David Feldman, MD, PhD,[2] Aly El Banayosy, MD,[3] Emma Birks, MD,[4] Elizabeth Blume, MD,[5] Jennifer Cowger, MD, MS,[6] Christopher Hayward, MD,[7] Ulrich Jorde, MD,[8] Jamila Kremer, MD,[9] Guy MacGowan, MD,[10] Simon Maltais, MD, PhD,[11] Simon Maybaum, MD,[12] Mandeep Mehra, MD,[13] Keyur B. Shah, MD,[14] Paul Mohacsi, MD,[15] Martin Schweiger, MD,[16] Sarah E. Schroeder, ACNP-BC, MSN, RN,[17] Palak Shah, MD, MS,[18] Marvin Slepian, MD,[19] Laurens F. Tops, MD, PhD,[20] Paulino Alvarez, MD,[21] Francisco Arabia, MD,[22] Saima Aslam, MD,[23] Louis Benson-Louis, IV, MD,[24] Edo Birati, MD,[25] Holger W. Buchholz, MD,[26] Ari Cedars, MD,[27] Dawn Christensen, RN,[28] Agnieszka Ciarka, MD,[29] Erin Coglianese, MD,[30] Rebecca Cogswell, MD,[31] Jennifer Cook, MD,[32] Jack Copeland, MD,[33] Jose Gonzalez Costello, MD,[34] Stavros G Drakos, MD, PhD,[35] Pirooz Eghtesady, MD, PhD,[36] Tonya Elliot, RN, MSN,[37] Jerry D. Estep, MD,[38] Jaime-Juergen Eulert-Grehn, MD,[39] De Rita Fabrizio, MD,[40] Jens Garbade, MD, PhD,[41] Jill Gelow, MD,[42] Maya Guglin, MD,[43] Jaime Hernandez-Montfort, MD,[44] Doug Horstmanshof, MD,[45] Ranjit John, MD,[46] Manreet Kanwar, MD,[47] Feras Khaliel, MD,[48] Gene Kim, MD,[49] Sachin Kumar, MD,[50] Jacob Lavee, MD,[51] Marzia Leache, MD,[52] Pascal Leprince, MD,[53] Sern Lim, MD,[54] Antonio Loforte, MD,[55] Jiri Maly, MD,[56] Samer Najjar, MD,[57] Ivan Netuka, MD,[58] Salpy V. Pamboukian, MD,[59] Snehal R Patel, MD,[60] Sean Pinney, MD,[61] Christina Vander Pluym, MD,[62] Evgenij Potapov, MD,[63] Desiree Robson, RN,[64] Yogita Rochlani, MD,[65] Stuart Russell, MD,[66] Kristin Sandau, PhD, RN,[67] Elena Sandoval, MD,[68] Gabriel Sayer, MD,[69] Sarah Schettle, PA,[70] David Schibilsky, MD,[71] Thomas Schlöglhofer, MSc,[72]

Review

How to Select Patients for Left Ventricular Assist Devices? A Guide for Clinical Practice

Daniele Masarone [1,*], Brian Houston [2], Luigi Falco [1], Maria L. Martucci [1], Dario Catapano [1], Fabio Valente [1], Rita Gravino [1], Carla Contaldi [1], Andrea Petraio [3], Marisa De Feo [4], Ryan J. Tedford [2] and Giuseppe Pacileo [1]

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Figure 1. Risk/benefit ratio of LVAD implantation according to INTERMACS class. Red weights represent the risks; blue weights represent the benefits.

There are three main indications for LVAD implantation:

- Bridge to Transplant (BTT): Indicated in patients on the orthotopic heart transplant list unable to maintain adequate end-organ perfusion with GDMT alone;
- Bridge to Candidacy (BTC): Suitable in selected patients with temporary contraindications to orthotopic heart transplantation that could be reversed after support with an LVAD (e.g., increased pulmonary vascular resistance, functional kidney disease);
- Destination Therapy (DT): Recommended in patients with an absolute and permanent contraindication to orthotopic heart transplantation, in whom an LVAD is used as a long-term therapy.

Masarone et al. J Med Clin 2023; 12

ISHLT (2023)		
Indications	COR	LOE
As a bridge to transplant AdvHFrEF patients with severe symptoms (NYHA functional class IIIB–IV) refractory to maximal medical management, who are inotrope dependent or on temporary mechanical circulatory support if transplant is unlikely to occur in the short term	I	A
As destination therapy AdvHFrEF patients ineligible for heart transplant with severe symptoms (NYHA functional class IIIB–IV) refractory to maximal medical management, who are inotrope dependent or on temporary mechanical circulatory support	I	A

ESC Guidelines (2021)		
Indications	COR	LOE
AdvHFrEF patients with severe symptoms despite GDMT and device therapy who have at least one of the following: - LVEF < 25%, peak VO2 < 12 mL/kg/min, and/or <50% predicted value - More than three HF-related hospitalizations - Inotrope dependence - Mechanical circulatory support dependence - Worsening renal and/or hepatic function or type II pulmonary hypertension due to reduced perfusion (CI < 2 L/min with PCWP > 20 mmHg)	NA	NA

Masarone et al. J Med Clin 2023; 12

POKROČILÉ SRDEČNÍ SELHÁNÍ

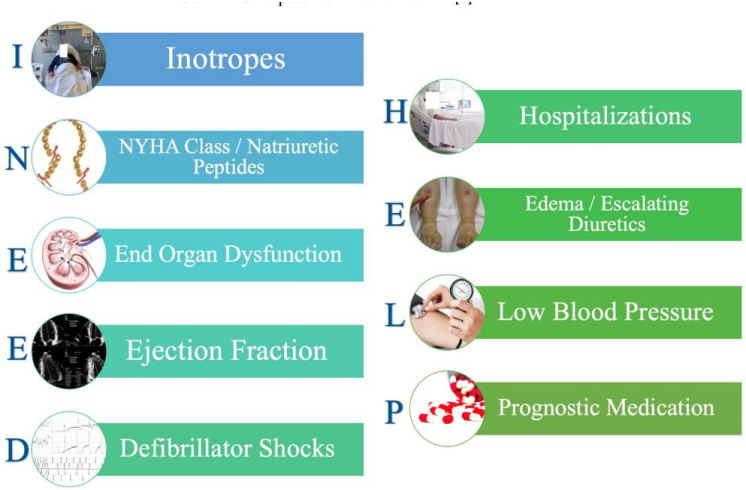
Advanced heart failure: a position statement of the Heart Failure Association of the European Society of Cardiology

Maria G. Crespo-Leiro[1]*, Marco Metra[2], Lars H. Lund[3], Davor Milicic[4],

Crespo-Leiro et al. Eur J Heart Fail 2018; 20(11):1505-1535

POKROČILÉ SRDEČNÍ SELHÁNÍ

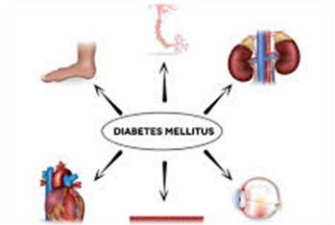
- Previous or ongoing requirement for dobutamine, milrinone, dopamine, or levosimendan
- Persisting NYHA class III or IV and/or persistently high BNP or NT-proBNP
- Worsening renal or liver dysfunction in the setting of heart failure
- Very low ejection fraction <20%
- Recurrent appropriate defibrillator shocks

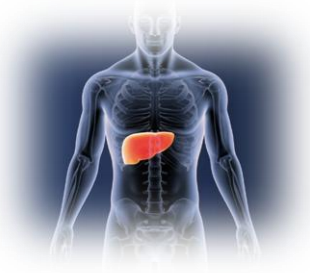


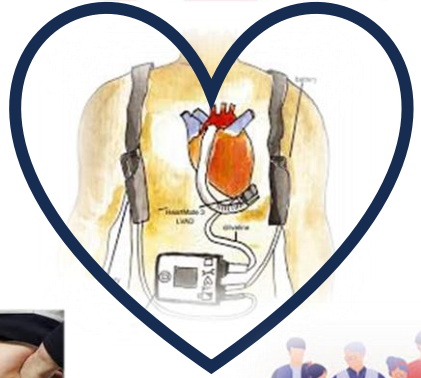
- More than 1 hospitalization with heart failure in the last 12 months
- Persisting fluid overload and/or increasing diuretic requirement
- Consistently low BP with systolic <90 to 100 mmHg
- Inability to up-titrate (or need to decrease/cease) ACEI, beta-blockers, ARNIs, or MRAs

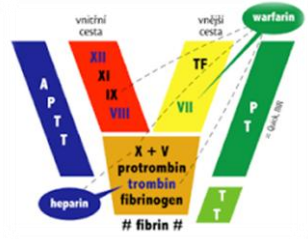
Crespo-Leiro et al. Eur J Heart Fail 2018; 20(11):1505-1535

CHSS – nejen ♥ trpí









Před implantací LVAD - PK

ECHO

- TAPSE < 8 mm
- TDI S´< 5-8 cm/s
- FAC < 25 – 30%
- E/e´ > 10

Pravostranná srdeční katetrizace

Hemodynamic Parameter	Cut-Off Associated with RVF
Preoperative CVP	>10 mmHg
CVP/PCWP	>0.63
MAP/CVP	<7.5
PAPi	<1.85
RVSWI	<0.30 mmHg/L/m^2
SVI	<22.1 mL/m^2 during systemic vasodilator drug challenge
PACI	<0.89 mL/mmHg/m^2

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Před implantací LVAD - ??

Aortic Valve Disease:

Class I:

1. More than mild aortic regurgitation should be addressed at the time of LVAD implant. Aortic valve replacement using a biologic valve should be performed, if necessary.

Level of evidence C. *(Modifi*

Class IIb:

1. Aortic valve closure tech
   mild aortic regurgitation

Level of evidence C. *(Modifi*

Aortic Stenosis:

Class I:

1. *Continuing approval without change*

Tricuspid Valve Regurgitation:

Class IIb:

1. Concomitant tricuspid valve interventions may be considered during LVAD implantation in patients with greater than moderate tricuspid regurgitation. Tricuspid valve repair or replacement using a bioprosthetic valve can be performed.

Level of evidence B. *(Modified)*

Mitral Valve Regurgitation:

Class IIb:

1. Concomitant mitral valve interventions may be considered during LVAD implantation. Mitral valve repair or mitral valve replacement using a bio-
   ssed heart.

1. Significant mitral stenosis needs to be addressed during LVAD implant. Commissurotomy or mitral valve replacement using a bioprosthetic valve can be performed on the beating decompressed heart.

Level of evidence C. *(Modified)*

JHLT, vol 42, No 7, July 2023

Před implantací LVAD - ??

Type of Prosthetic Valve	Recommendation	Note
Functioning biological prostheses (regardless of the anatomical site)	No removal or replacement at the time of implant (COR I, LOE C)	A biological valve, whether in the aortic or mitral position, is well tolerated during LVAD support
Mechanical aortic valve	Replacement with a bioprosthetic valve during LVAD implantation (COR I, LOE B) or path closure when no other options are feasible (COR IIb, LOE C)	Mechanical aortic valves may result in thromboembolic events due to blood stasis around the valve and intermittent valve opening
Mechanical mitral valve	Replacement of a properly functioning mechanical mitral valve is not recommended (COR III, LOE C)	Exchanging a mechanical mitral valve is technically very complex

Concomitant valve surgery with LVAD implantation increases the surgical risk due to the prolonged extracorporeal circulation time and increased incidence of postoperative RVF [57]. These factors must be considered during the patient selection process.

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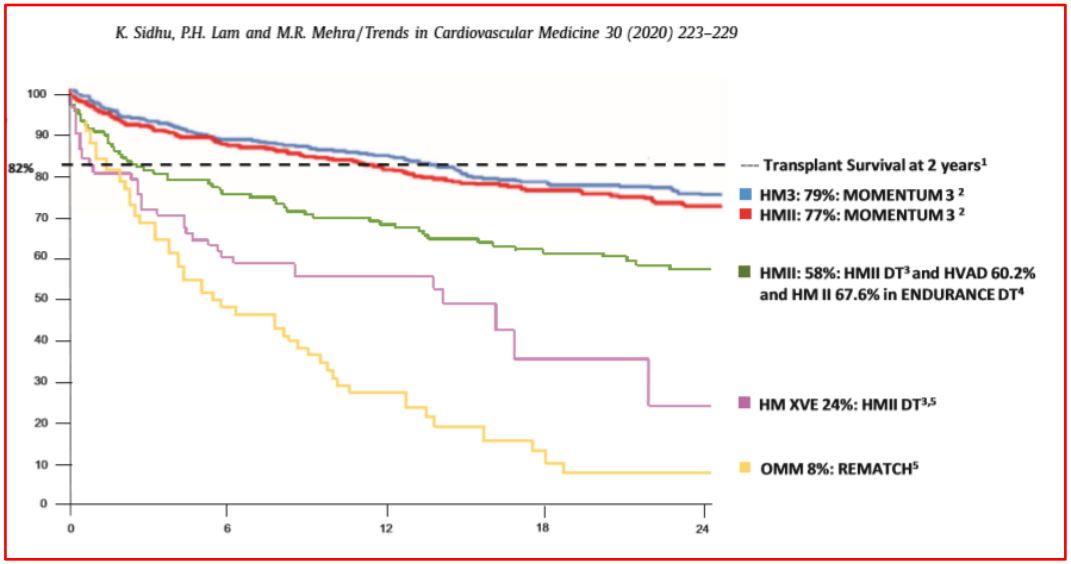
JHLT, vol 42, No 7, July 2023

Evolving trends in mechanical circulatory support: Clinical development of a fully magnetically levitated durable ventricular assist device ☆

Kiran Sidhu, Phillip H. Lam, Mandeep R. Mehra*

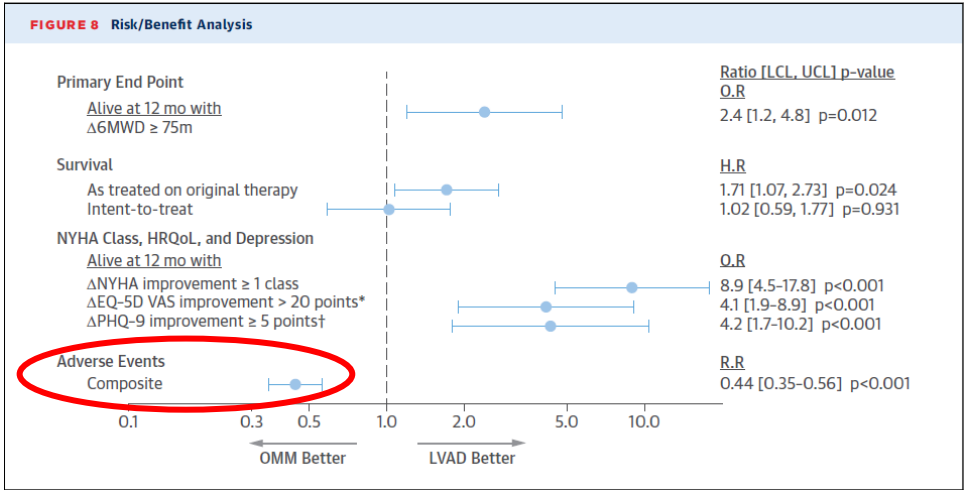
Brigham and Women's Hospital and Harvard Medical School, Boston, MA, United States



Sidhu et al. Trends Caardiovascular Med 2020 May; 30 (4):223 - 229

Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients

Results From the ROADMAP Study



	Yr 1	
	OMM AE Rate (eppy) 79.7 Patient-Yrs	LVAD AE Rate (eppy) 82.4 Patient-Yrs
Bleeding	0.03	1.49*
GI bleeding	0.01	0.92*
Infection	0.09	0.97*
Driveline infection	NA	0.13§
Sepsis	0.01	0.23*
Pump thrombus	NA	0.07‡
Stroke	0.025	0.12‡
Ischemic	0.013	0.07
Hemorrhagic	0.013	0.05
Arrhythmias VT/VF	0.10	0.33§
Worsening heart failure	0.90	0.16*
Right heart failure	0.03	0.11‡
Rehospitalizations	1.77	2.67‡
"Composite" event rate	1.05	2.31*
Relative risk [95% CI]	OMM/LVAD: 0.46 [0.31-0.68]*	

J Am Coll Cardiol 2015;66:1747-61

LVAD

- Které pacienty vybrat k implantaci LVAD
- **Kdy indikovat implantaci LVAD**
- Co nás/pacienta čeká po implantaci LVAD

KDY LVAD

Tabulka 13.2 – Stadia INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) pro klasifikaci pacientů s pokročilým srdečním selháním

Úroveň INTERMACS	Třída NYHA	Popis	Přístroj	Jednoroční přežití při léčbě pomocí LVAD
1. Kardiogenní šok („Crash and burn“)	IV	Hemodynamická nestabilita i přes zvyšující se dávky katecholaminů a/nebo mechanickou oběhovou podporu spolu s kritickou hypoperfuzí cílových orgánů (těžký kardiogenní šok).	ECLS, ECMO, přístroje pro perkutánní podporu	52,6 ± 5,6 %
2. Progredující zhoršování i přes podporu inotropními léky („Sliding on inotropes“)	IV	Intravenózní podpora inotropními látkami s přijatelným krevním tlakem, avšak rychlé zhoršování renálních funkcí, nutričního stavu nebo známek městnání.	ECLS, ECMO, LVAD	63,1 ± 3,1 %
3. Stabilizovaný, avšak závislý na inotropních látkách („Dependent stability“)	IV	Hemodynamická stabilita při nízkých nebo středně vysokých dávkách inotropních léků, které jsou však nezbytné kvůli hypotenzi, zhoršování symptomů nebo progredujícímu selhávání renálních funkcí.	LVAD	78,4 ± 2,5 %
4. Symptomy v klidu („Frequent flyer“)	IV ambulantní	Je možné dočasně přerušit léčbu inotropními léky, u pacienta však často dochází k recidivě symptomů a typicky se u něj vyskytuje retence tekutin.	LVAD	78,7 ± 3,0 %
5. Nesnášející zátěž („Housebound“)	IV ambulantní	Úplné ukončení fyzických aktivit, stabilizovaný v klidu, ale často se středně těžkou retencí tekutin a jistým stupněm renální dysfunkce.	LVAD	93,0 ± 3,9 %[a]
6. Omezení zátěže („Walking wounded“)	III	Menší omezení fyzické aktivity a v klidu bez městnání. Nenáročná činnost je snadno unaví.	LVAD/jako možnost prodiskutovat použití LVAD.	–
7. Osoby nevycházející nikdy z domu („Placeholder“)	III	Pacient ve třídě III podle NYHA bez nestabilní tekutinové bilance v současnosti nebo v poslední době.	Jako možnost prodiskutovat použití LVAD.	–

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

JHLT, vol 42, No 7, July 2023

Risk Stratification to Determine Timing of DMCS Therapy based on INTERMACS Classification:

Class I:

1. INTERMACS profile 1-3 patients benefit in terms of survival from implantation of a LVAD.

Level of Evidence: A. (New)

Class IIb:

1. INTERMACS profile 4 may benefit in terms of survival from implantation of a LVAD.

Level of Evidence: B. (New)

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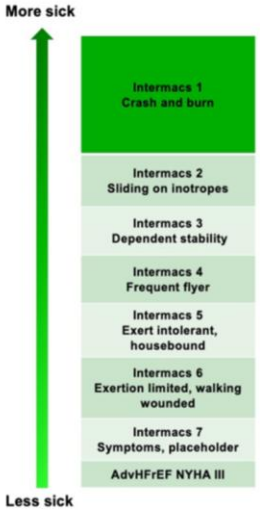

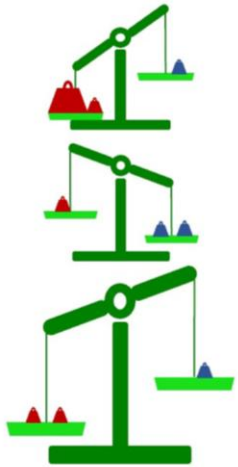

Masarone et al. J Med Clin 2023; 12

Factors associated with the use of guideline-directed medical therapy in patients with left ventricular assist device

Michel Chedid El Helou[1,2†], Phoo Pwint Nandar[1,2†], Larisa G. Tereshchenko[1,3], Miriam Jacob[1,2], Pavan Bhat[1,2], Amanda R. Vest[1,2], Sanjeeb Bhattacharya[1,2], Eileen Hsich[1,2], Patrick Collier[1], W.H. Wilson Tang[1,2], Edward Soltesz[2], Michael Z. Tong[2], Randall C. Starling[1,2], and Trejeeve Martyn[1,2*]

[1]Department of Cardiovascular Medicine, Heart, Vascular & Thoracic Institute, Cleveland Clinic, Cleveland, OH, USA; [2]George M. and Linda Kaufman Center for Heart Failure and Recovery, Cleveland Clinic, Cleveland, OH, USA; and [3]Department of Quantitative Health Sciences, Lerner Research Institute, Cleveland Clinic, Cleveland, OH, USA

El Helou et al. Eur J Heart Failure 2025; 27, 650 - 655

Table 1 Baseline characteristics of the HeartMate 3 cohort

Demographics	
n	270
Age, years, mean (SD)	63.0 (13.3)
<50, *n* (%)	53 (19.6)
51–60, *n* (%)	62 (23.0)
61–70, *n* (%)	92 (34.1)
>70, *n* (%)	63 (23.3)
Male sex, *n* (%)	207 (76.7)
Race, *n* (%)	
White	198 (73.3)
Black	62 (23)
Other	10 (3.7)
Device strategy, *n* (%)	
Destination therapy (not eligible for transplant)	197 (73.0)
Bridge to transplant (listed at the time of study)	63 (23.3)
Possible bridge to transplant	10 (3.7)
Comorbidities, *n* (%)	
Atrial fibrillation	152 (56.3)
Chronic kidney disease	131 (48.5)
Chronic obstructive pulmonary disease	36 (13.3)
Diabetes mellitus	125 (46.3)
Coronary artery disease	137 (50.7)

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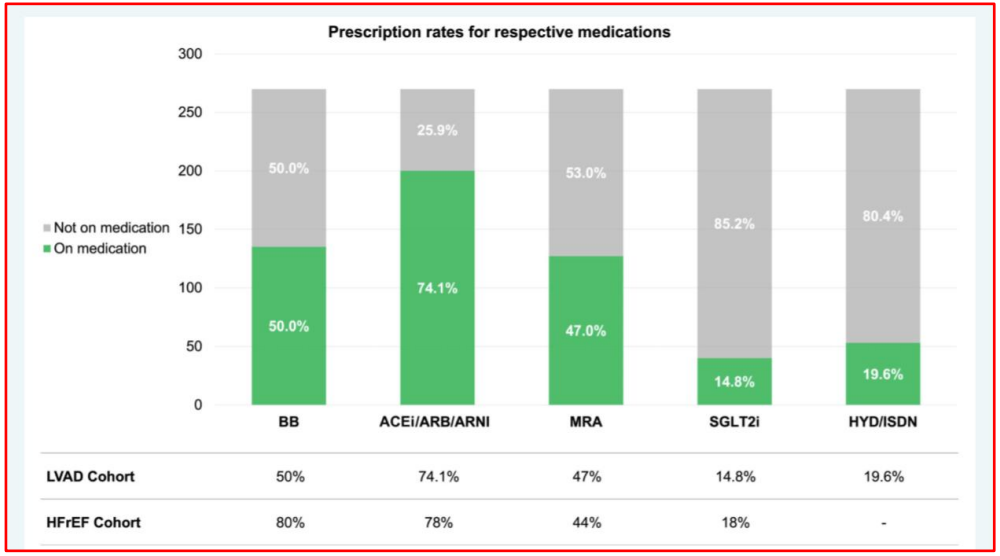


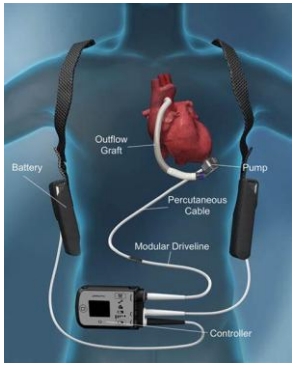
	BB	ACEi/ARB/ARNI	MRA	SGLT2i	HYD/ISDN
LVAD Cohort	50%	74.1%	47%	14.8%	19.6%
HFrEF Cohort	80%	78%	44%	18%	-

El Helou et al. Eur J Heart Failure 2025; 27, 650 - 655

LVAD

- Které pacienty vybrat k implantaci LVAD
- Kdy indikovat implantaci LVAD
- **Co nás/pacienta čeká po implantaci LVAD**

Guidance on the management of left ventricular assist device (LVAD) supported patients for the non-LVAD specialist healthcare provider: executive summary



Infekce:

15-40%

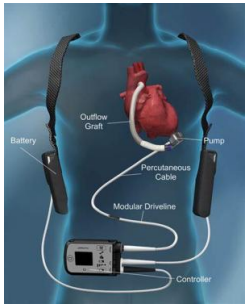
LVAD specifické – **driveline,** inflow/outflow graft

LVAD související – endokarditidy, mediastinitidy,

Běžné – respirační, močové, GIT

Tuvia Ben Gal et al. Eur J Heart Failure 2021; 23, 1597=1609

Guidance on the management of left ventricular assist device (LVAD) supported patients for the non-LVAD specialist healthcare provider: executive summary

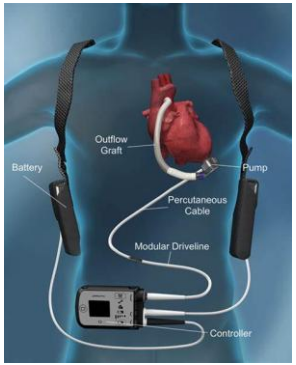


Krvácení:

- 32-44%
- Antikoagulační terapie
- GIT A-V malformace (věk, ženské pohlaví, nízké BMI, kouření)
- GFS, kolonoskopie, kapslová endoskopie

Tuvia Ben Gal et al. Eur J Heart Failure 2021; 23, 1597=1609

Guidance on the management of left ventricular assist device (LVAD) supported patients for the non-LVAD specialist healthcare provider: executive summary



CMP:

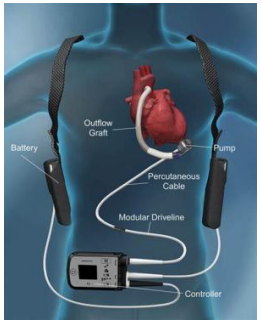
iCMP - trombolýza není doporučena, mechanická trombektomie

ICH, SAK – ženy, IABP před implantací,

- snížení MAP < 90 mm Hg, NCH intervence

Tuvia Ben Gal et al. Eur J Heart Failure 2021; 23, 1597=1609

Guidance on the management of left ventricular assist device (LVAD) supported patients for the non-LVAD specialist healthcare provider: executive summary



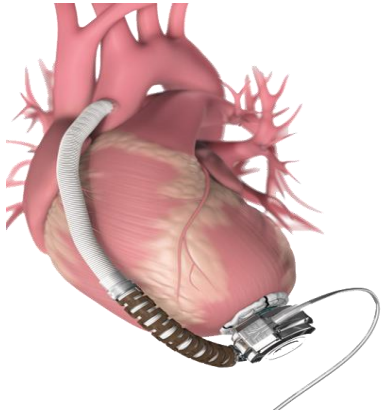
Tromboza LVAD:

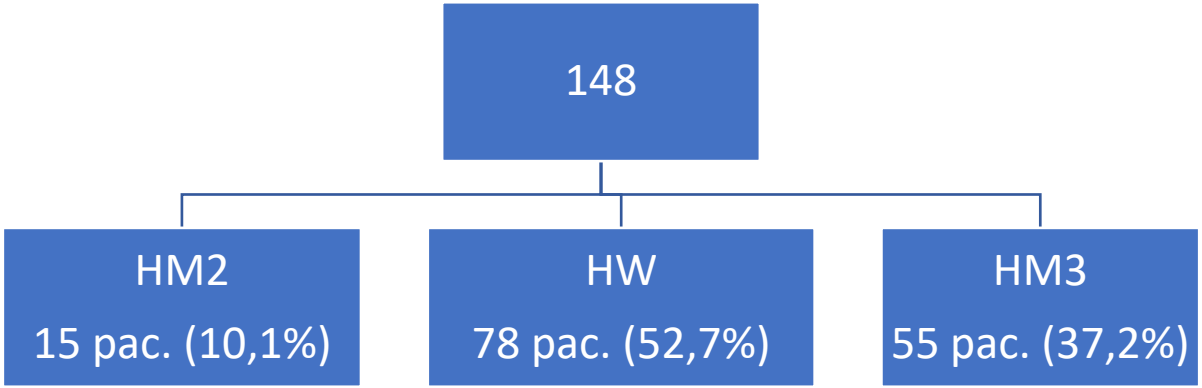
- Do 10%
- Dušnost, low flow alarmy, hemolýza (LD, Hb, volný.., tmavá moč..)
- ECHO – otevírání ao chlopně, zhoršení MR, dilatace LK
- CT angiografie

Tuvia Ben Gal et al. Eur J Heart Failure 2021; 23, 1597=1609

Program LVAD CKTCH – I.IKAK Brno 1/2009 – 4/2025

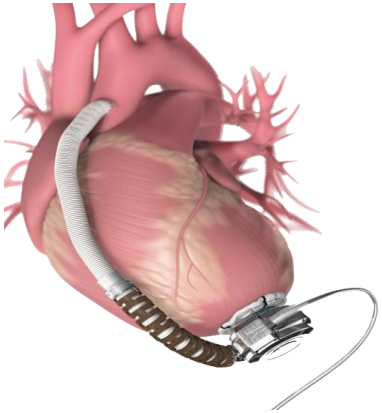
Průměrný věk (roky)	56 (18-68)
Pohlaví (muži/ženy)	135 (91,2%) x 12 (8,8%)

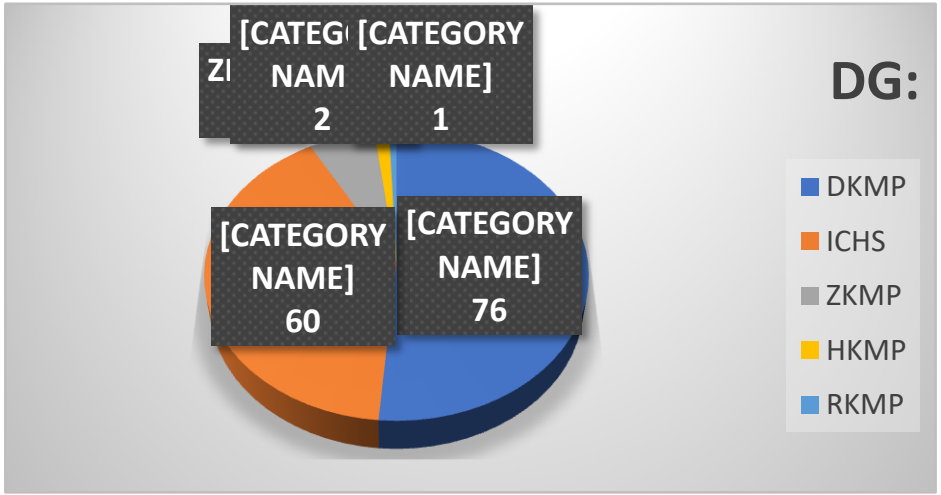




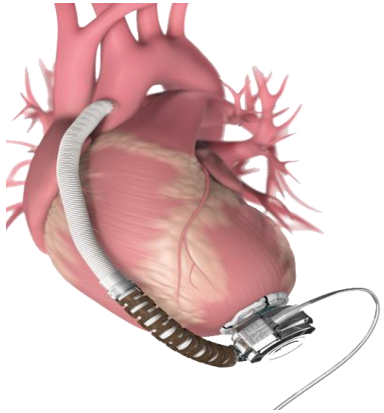
Program LVAD CKTCH – I.IKAK Brno 1/2009 – 4/2025

Průměrná EF LK 15,6%





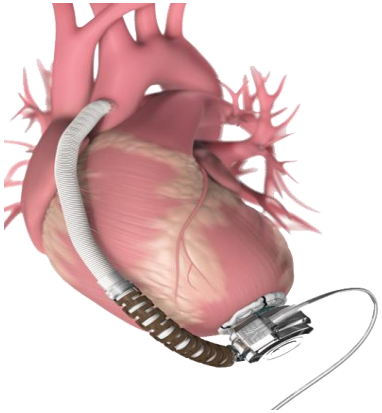
Program LVAD CKTCH – I.IKAK Brno 1/2009 – 4/2025



LVAD		
BTT 90 (60,8%)	BTC 19 (12,8%)	DT 39 (26,4%)

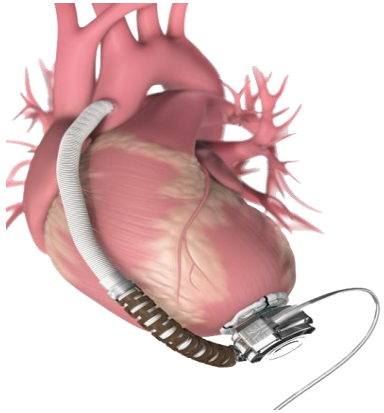
Výstupy z LVAD			
OTS 82 (55,4%)	Recovery 2 (1,4%)	EL na LVAD 40 (27%)	Na LVAD 24 (16,2%)

Program LVAD CKTCH – I.IKAK Brno 1/2009 – 4/2025



INTERMACS	Počet pacientů	
1	6	4,1%
2	36	24,3%
3	41	27,7%
4	45	30,4%
5	19	12,8%
6	1	0,7%

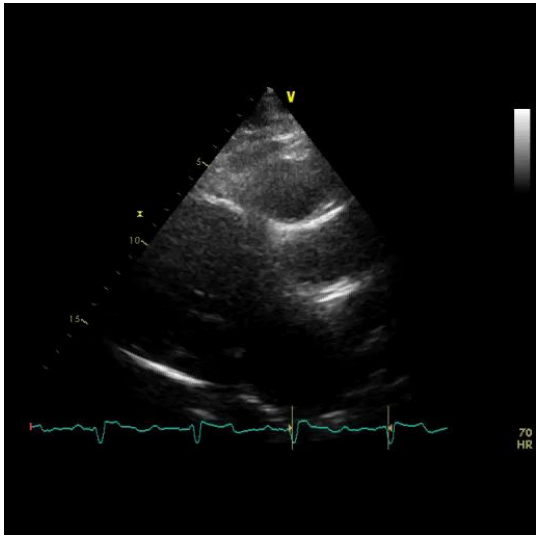
Program LVAD CKTCH – I.IKAK Brno 1/2009 – 4/2025

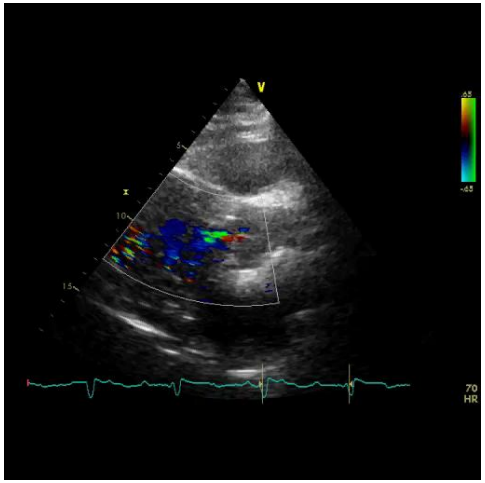


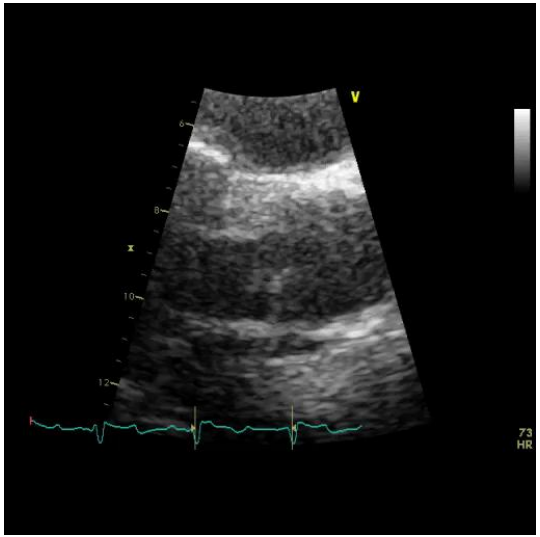
Bridge to transplant – CKTCH

Destination therapy – I.IKAK FN USA

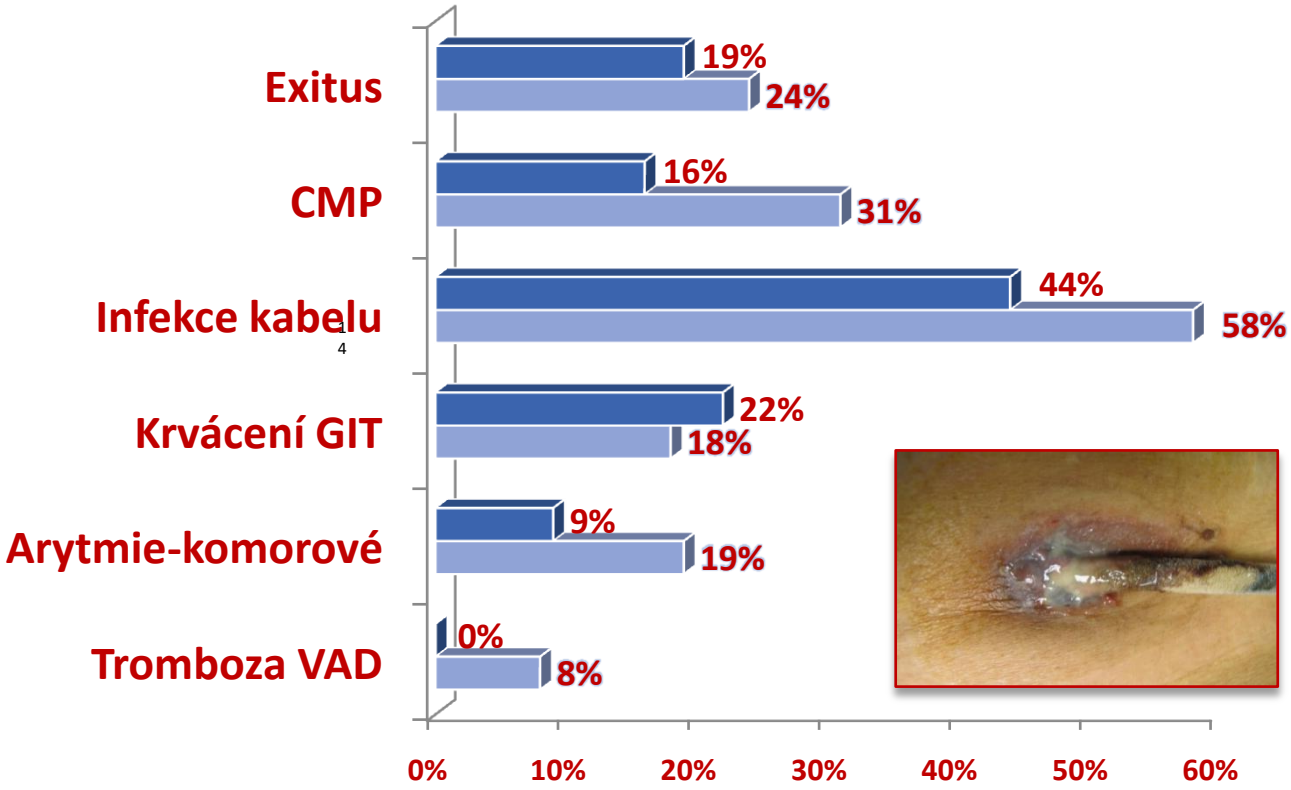
- kontroly INR 1x týdně – tel.
- kontroly po 6t
  - – ECHO, lab., TK,
  - kontrola a stěr výstupu kabelu
  - parametry nastavení LVAD, alarmy


V
70
HR


V
70
HR


V
73
HR

Komplikace pacientů
s HM3 (n = 32), HW HVAD (n = 78)



ZÁVĚR:

Včasné odeslání pacienta do specializovaného centra

Sorry. Vypadla nám elektřina.

DĚKUJI ZA POZORNOST