



Place de l'assistance cardiaque de longue durée dans l'insuffisance cardiaque

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Insuffisance cardiaque

○ Problème de santé publique : données épidémiologiques 2022

- 150 000 nouveaux patients/an
- 1 376 692 patients prévalents en France en 2022
- Dépenses de santé considérables
- 181 178 hospitalisations /an
- 24 645 DC/an

○ Traitements :

- Education thérapeutique
- Réadaptation cardiovasculaire
- Traitement médicamenteux (IEC, BB, ARM, Entresto®, Forxiga®),
- Traitement électrique (DAI, CRT)
- Traitement chirurgical (valvulopathie, revascularisation)

Insuffisance cardiaque avancée

○ Définition

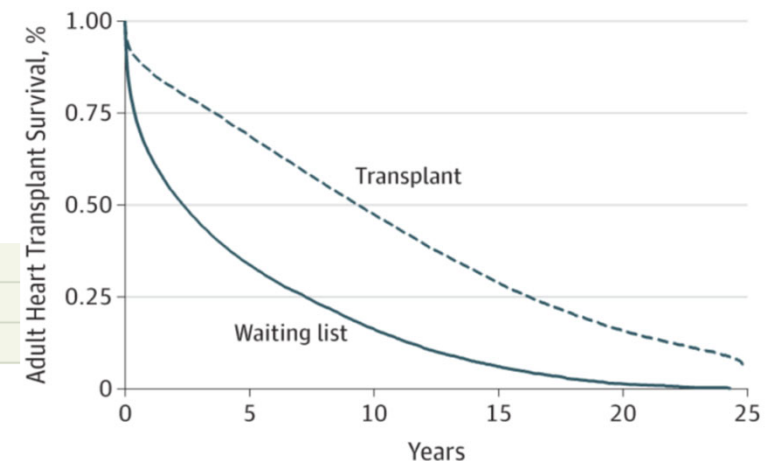
- Stade avancé de l'insuffisance cardiaque chronique
- NYHA 3-4
- Malgré traitement optimal (médical, électrique et chirurgical)

○ Traitement de référence → Transplantation cardiaque

○ Mauvais pronostic

Table 2. Survival Benefit of Solid-Organ Transplant After Propensity Score Matching

Transplant Type and Patient Category	No. of Patients	Unadjusted Median Survival, y	No. of Patients After Matching	Median Survival After Matching, y
Heart				
Waiting list	38 578	2.3	31 086	2.7
Transplant	54 039	9.5	53 173	9.5



Survival Benefit of Solid-Organ Transplant in the United States, JAMA Surg. 2015

No. at risk	0	5	10	15	20	25
Waiting list	23 945	3 332	1 070	265	39	1
Transplant	41 763	23 272	11 378	4 080	902	12

Insuffisance cardiaque avancée

- CI à la greffe (Age, comorbidités ...)
- Pénurie de greffon

Tableau C1. Évolution du devenir des candidats à une greffe cardiaque

	2017	2018	2019	2020	2021	2022	2023
Liste d'attente							
Candidats en liste d'attente active au 1er janvier*	235	183	258	261	300	289	201
Candidats en liste d'attente inactive au 1er janvier**	92	131	113	132	144	151	161
Nouveaux inscrits dans l'année	546	628	574	544	539	453	
Décédés dans l'année	44	68	62	69	76	61	
Sortis de la liste d'attente	48	53	65	54	58	59	
- dont sortis de la liste d'attente pour aggravation	17	22	22	21	24	21	
Greffes	467	450	425	370	409	411	
Greffes (pmh)	7,0	6,7	6,3	5,5	6,0	6,0	.

942 inscrits pour 414 greffes en 2024

*Un candidat est en liste d'attente active au 1er janvier si il n'est pas en contre-indication temporaire au 1er janvier.

**Un candidat est en liste d'attente inactive au 1er janvier si il est en contre-indication temporaire au 1er janvier

Données extraites de CRISTAL le 07/03/2023



Assistance cardiaque de longue durée

Objectifs

- Permettre au patient de vivre une vie pratiquement normale sous support mécanique.

- Eviter les longs séjours à l'hôpital pour limiter:
 - Les infections nosocomiales,
 - L'ennui et la dépression,
 - Les problèmes sociaux.

- Libérer les ressources de l'hôpital via la création d'une « filière soin » adaptée bien définie.

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

Table 1 Triggers for Referral of Heart Failure Patient for Advanced Therapies Evaluation

I	IV Inotropes
N	NYHA IIIB/IV or persistently elevated Natriuretic peptides
E	End-organ dysfunction
E	EF \leq 35%
D	Defibrillator shocks
H	Hospitalizations >1
E	Edema despite escalating diuretics
L	Low blood pressure, high heart rate
P	Progressive intolerance or downtitration of GDMT

Les indications

Table 13.1 Terms describing various indications for mechanical circulatory support

Bridge to decision (BTD)/ Bridge to bridge (BTB)	Use of short-term MCS (e.g. ECLS or ECMO) in patients with cardiogenic shock until haemodynamics and end-organ perfusion are stabilized, contra-indications for long-term MCS are excluded (brain damage after resuscitation) and additional therapeutic options including long-term VAD therapy or heart transplant can be evaluated.
Bridge to candidacy (BTC)	Use of MCS (usually LVAD) to improve end-organ function in order to make an ineligible patient eligible for heart transplantation.
Bridge to transplantation (BTT)	Use of MCS (LVAD or BiVAD) to keep patient alive who is otherwise at high risk of death before transplantation until a donor organ becomes available.
Bridge to recovery (BTR)	Use of MCS (typically LVAD) to keep patient alive until cardiac function recovers sufficiently to remove MCS.
Destination therapy (DT)	Long-term use of MCS (LVAD) as an alternative to transplantation in patients with end-stage HF ineligible for transplantation or long-term waiting for heart transplantation.

Recommendations for implantation of mechanical circulatory support in patients with refractory heart failure

Recommendations	Class ^a	Level ^b	Ref ^c
An LVAD should be considered in patients who have end-stage HFrEF despite optimal medical and device therapy and who are eligible for heart transplantation in order to improve symptoms, reduce the risk of HF hospitalization and the risk of premature death (Bridge to transplant indication).	IIa	C	

Recommendations for implantation of mechanical circulatory support in patients with refractory heart failure

An LVAD should be considered in patients who have end-stage HFrEF despite optimal medical and device therapy and who are not eligible for heart transplantation to, reduce the risk of premature death.	IIa	B	605, 612, 613
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2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

European Journal of Heart Failure (2016)

Les indications

Table 13.2 INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) stages for classifying patients with advanced heart failure

INTERMACS level	NYHA Class	Description	Device	1y survival with LVAD therapy	
1. Cardiogenic shock "Crash and burn"	IV	Haemodynamic instability in spite of increasing doses of catecholamines and/or mechanical circulatory support with critical hypoperfusion of target organs (severe cardiogenic shock).	ECLS, ECMO, percutaneous support devices	52.6±5.6%	14%
2. Progressive decline despite inotropic support "Sliding on inotropes"	IV	Intravenous inotropic support with acceptable blood pressure but rapid deterioration of renal function, nutritional state, or signs of congestion.	ECLS, ECMO, LVAD	63.1±3.1%	36%
3. Stable but inotrope dependent "Dependent stability"	IV	Haemodynamic stability with low or intermediate doses of inotropics, but necessary due to hypotension, worsening of symptoms, or progressive renal failure.	LVAD	78.4±2.5%	30%
4. Resting symptoms "Frequent flyer"	IV ambulatory	Temporary cessation of inotropic treatment is possible, but patient presents with frequent symptom recurrences and typically with fluid overload.	LVAD	78.7±3.0%	15%
5. Exertion intolerant "Housebound"	IV ambulatory	Complete cessation of physical activity, stable at rest, but frequently with moderate fluid retention and some level of renal dysfunction.	LVAD	93.0±3.9% ^a	3%
6. Exertion limited "Walking wounded"	III	Minor limitation on physical activity and absence of congestion while at rest. Easily fatigued by light activity.	LVAD / Discuss LVAD as option	-	
7. "Placeholder"	III	Patient in NYHA Class III with no current or recent unstable fluid balance.	Discuss LVAD as option	-	

A
I
G
U

C
H
R
O

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

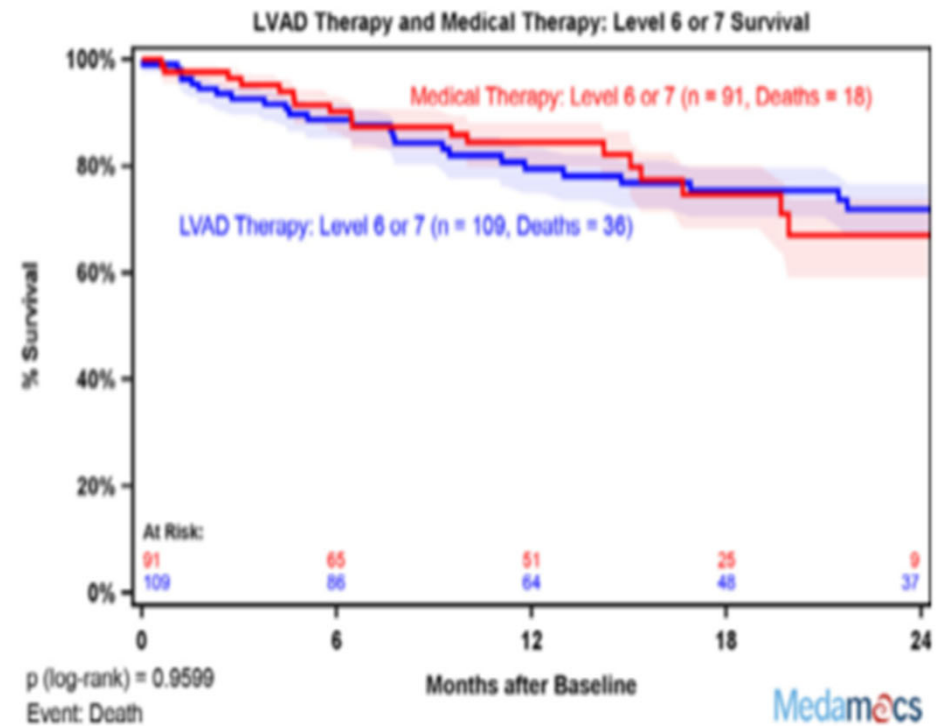
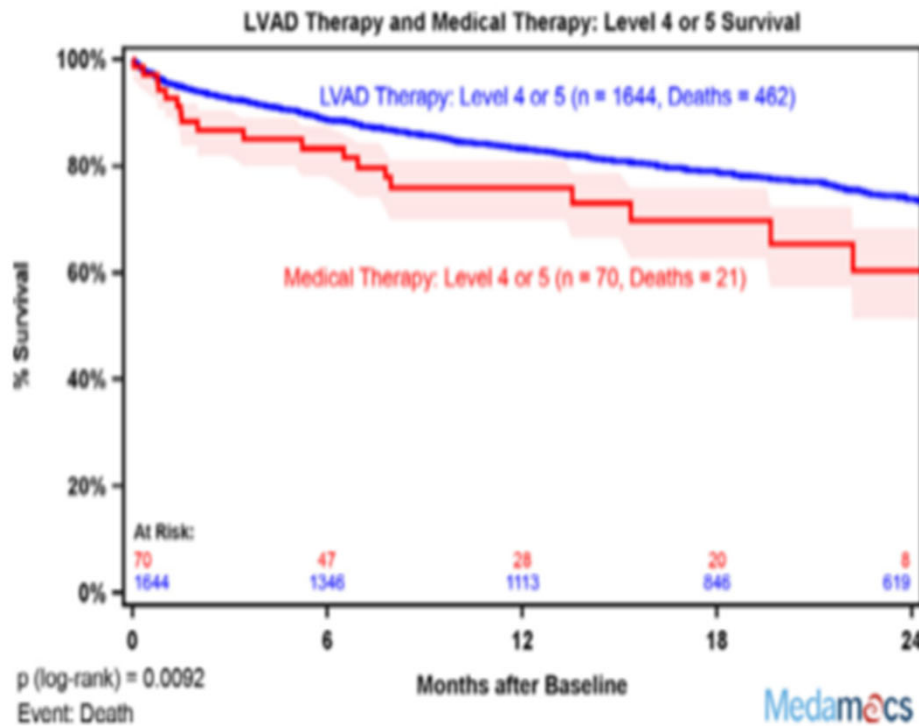
European Journal of Heart Failure (2016)

Seventh INTERMACS annual report: 15,000 patients and counting

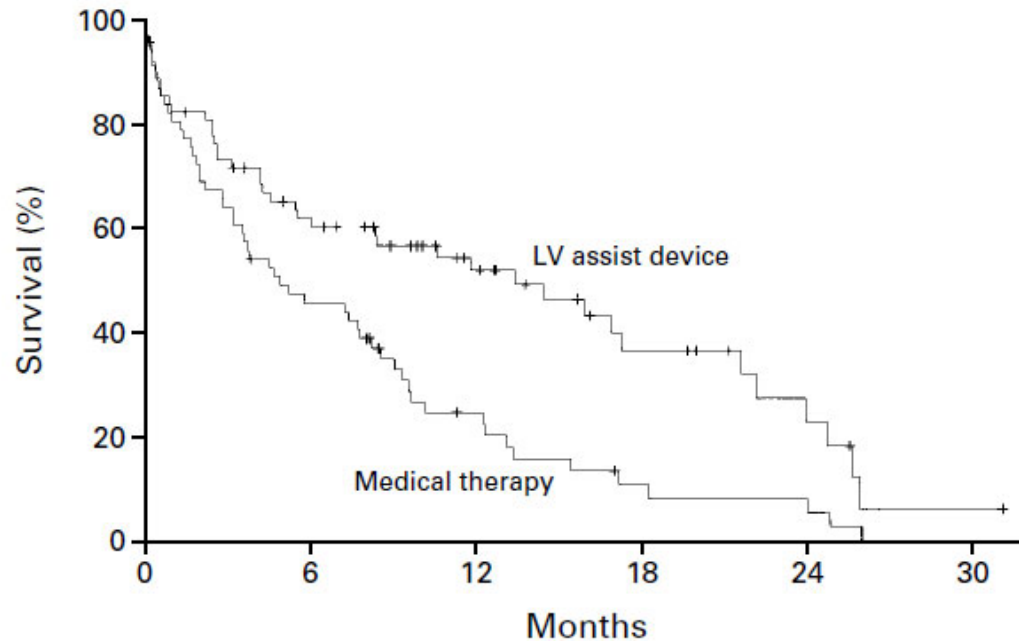
J Heart Lung Transplant 2015;34:1495–1504

Les indications

Outcomes with ambulatory advanced heart failure from the Medical Arm of Mechanically Assisted Circulatory Support (MedaMACS) Registry



LVAD en destination therapy



- Etude Rematch
- 129 patients
- 2 groupes: tt med ou LVAD
- Patients stade 4
- Inéligibles à la greffe
- LVAD pulsatile

Améliore la survie et la qualité de vie

No. AT RISK

LV assist device	68	38	22	11	5	1
Medical therapy	61	27	11	4	3	0

VOLUME 345

NOVEMBER 15, 2001

NUMBER 20



LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE FOR END-STAGE HEART FAILURE

ERIC A. ROSE, M.D., ANNETINE C. GELJINS, PH.D., ALAN J. MOSKOWITZ, M.D., DANIEL F. HEITJAN, PH.D.,

N Engl J Med 2001;345(20):1435-43.

LVAD en pont à la transplantation

Use of a Continuous-Flow Device in Patients Awaiting Heart Transplantation

Leslie W. Miller, M.D., Francis D. Pagani, M.D., Ph.D., Stuart D. Russell, M.D.,
 Ranjit John, M.D., Andrew J. Boyle, M.D., Keith D. Aaronson, M.D.,
 John V. Conte, M.D., Yoshifumi Naka, M.D., Donna Mancini, M.D.,
 Reynolds M. Delgado, M.D., Thomas E. MacGillivray, M.D.,
 David J. Farrar, Ph.D., and O.H. Frazier, M.D.,
 for the HeartMate II Clinical Investigators*

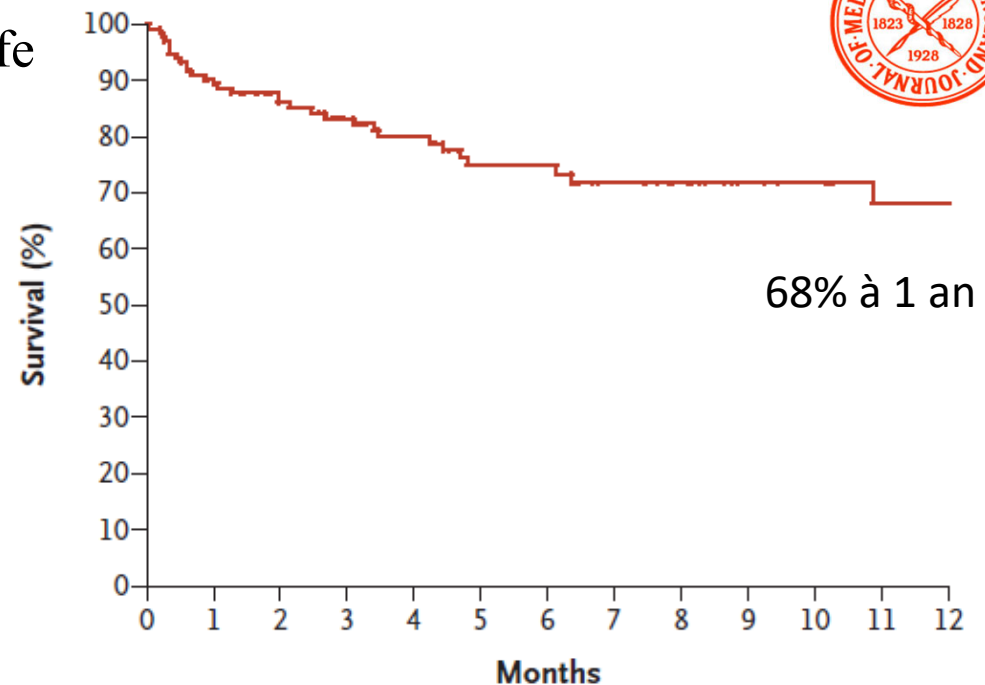
Avant la greffe



- 133 patients inscrits sur liste de greffe
- NYHA 4, FEVG 16%
- 90% sous inotropes
- 133 LVAD (HM2)

Résultats :

- Meilleure survie
- Meilleure capacité fonctionnelle (80% NYHA1 ou 2 à 6 mois)



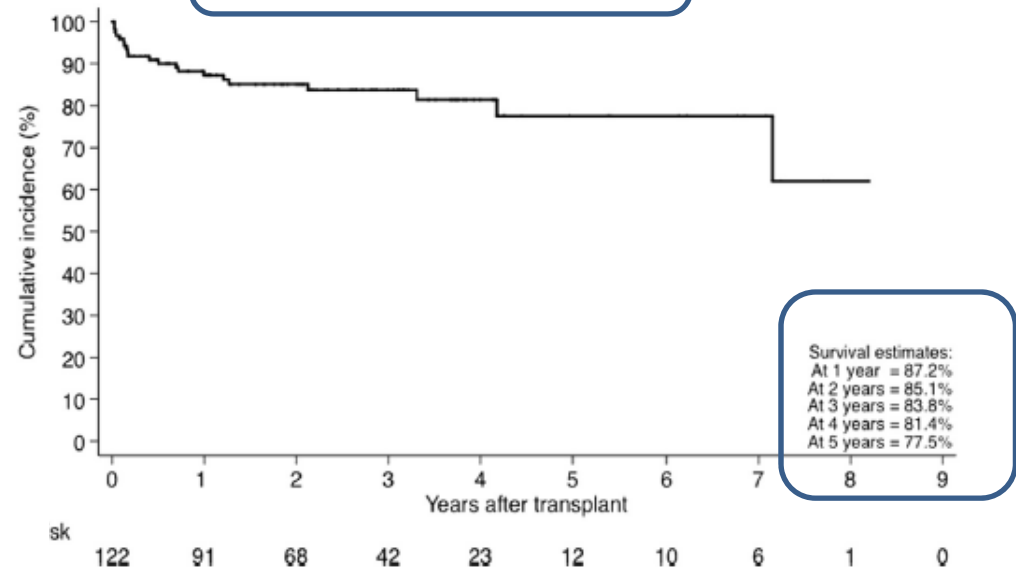
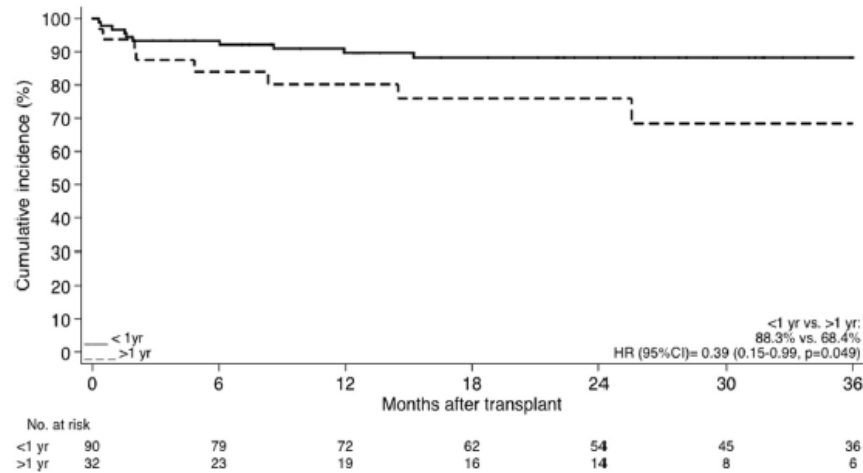
No. at Risk 133 96 68 48 35 26 17

N Engl J Med 2007;357:885-96.

LVAD en pont à la transplantation

192 patients avec HMII en BTT
New York 2004 – 2013

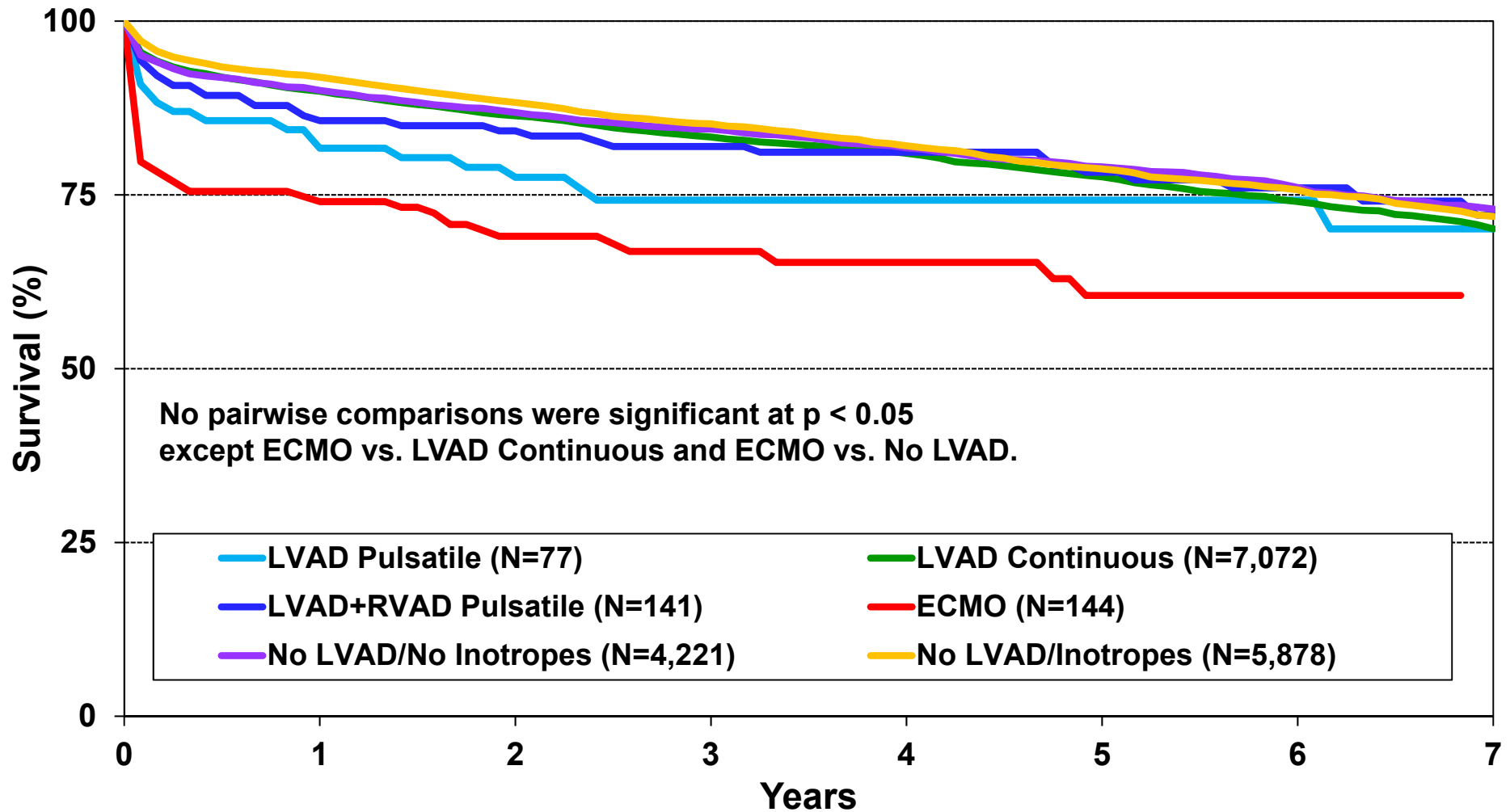
Après la greffe



Outcome of cardiac transplantation in patients requiring prolonged continuous-flow left ventricular assist device support

Adult Heart Transplants

Kaplan-Meier Survival by Pre-Transplant Mechanical Circulatory Support Use (Transplants: January 2010 – June 2017)



Sélection des patients

- NYAH stade III ou IV échappant aux traitements médico-chirurgicaux
- FEVG < 25 -30%
- Age < 80ans
- Fonction VD peu altérée

→ réalisation du bilan pré-implantation

LVAD ou BiVAD : Fonction VD ??

- Conséquences LVAD sur VD
 - Diminution PTDVG / post charge VD
 - Majoration pré-charge VD
 - Attraction septale vers le VG
 - Perte de la part septale dans la contraction VD
 - Dilatation de l'anneau : majoration IT
 - Altération FEVD
- Prédire la fonction VD post implantation ??

Fonction VD et LVAD

Comment la prédire la dysfonction droite après LVAD

1. ETT
2. Cathétérisme cardiaque
3. Scores
 - Matthews (2008)
 - Fitzpatrick (2008)
 - Kormos (2008)
 - Atluri (2013)

Recommendations for assessing RV function:^{102,130-139}

Class I:

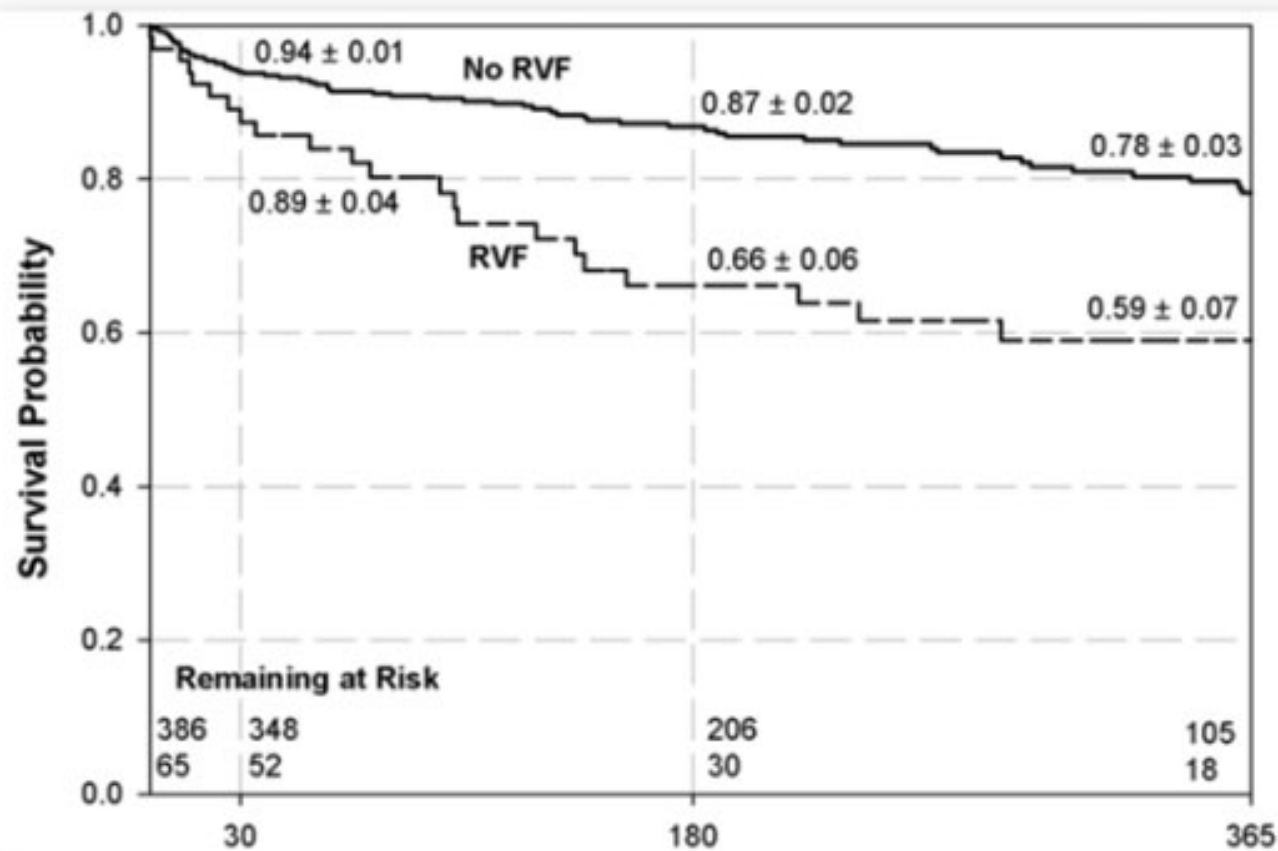
1. All patients should have an echocardiographic assessment of RV function prior to MCS/D implantation.
Level of evidence: C.
2. All patients should have invasive assessment of intracardiac filling pressures prior to MCS/D implantation, with a particular emphasis on RV hemodynamics.
Level of evidence: C.

The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: Executive summary

Right ventricular failure in patients with the HeartMate II continuous-flow left ventricular assist device: Incidence, risk factor and effect on outcomes

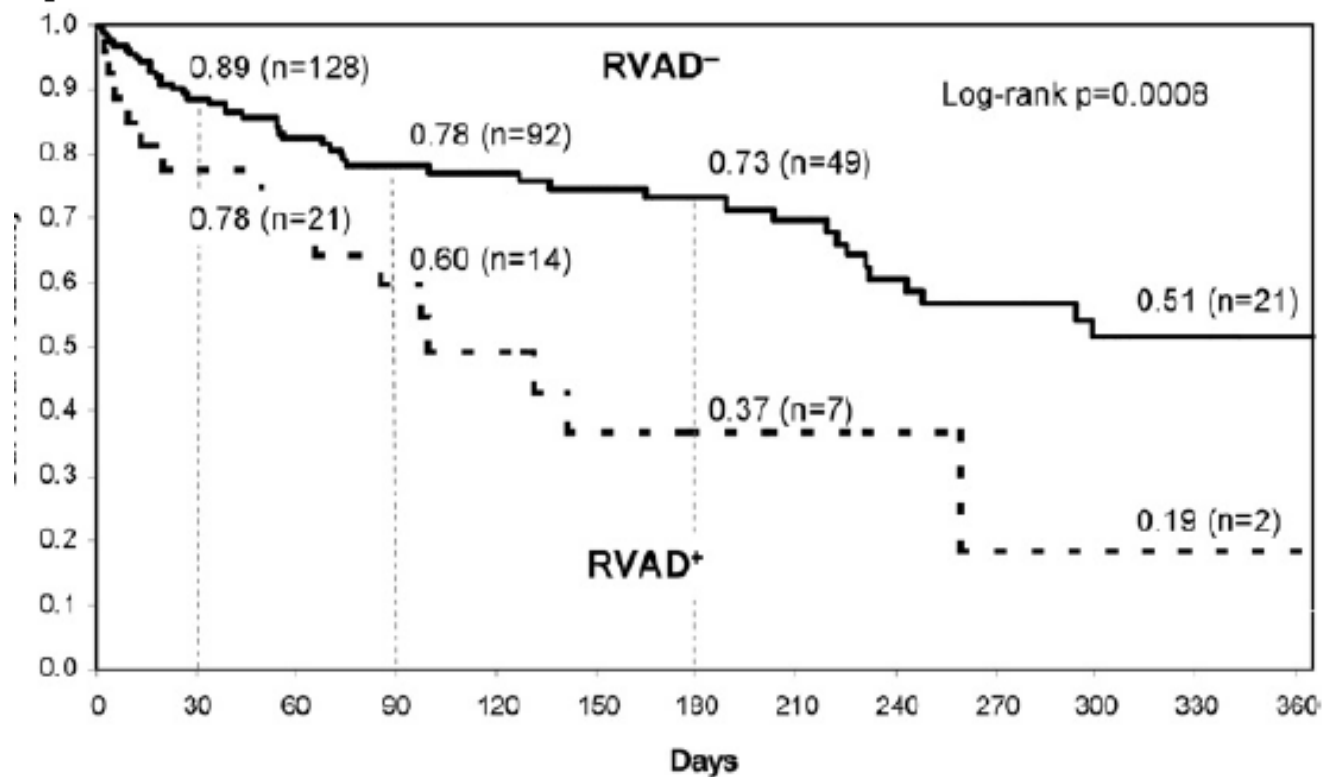
The Journal of Thoracic and Cardiovascular Surgery • May 20

Robert L. Komos, MD,^a Jeffrey J. Teuteberg, MD,^b Francis D. Pagani, MD,^c Stuart D. Russell, MD,^d



Decision tree for adjuvant right ventricular support in patients receiving a left ventricular assist device

J Heart Lung Transplant 2012;31:140–9



Données échographiques

Table 2 Echocardiographic Parameters Correlated with Right Ventricular Failure After Left Ventricular Assist Device

- Qualitative right ventricular dysfunction
- Tricuspid annular plane systolic excursion (TAPSE)
- Fractional area change
- Right ventricular index of myocardial performance
- Right ventricular systolic and diastolic longitudinal strain
- Right ventricle short-axis-to-long-axis ratio
- Right ventricle end-diastolic dimension-to-left ventricle end-diastolic dimension ratio
- Tricuspid annular dilation without significant tricuspid regurgitation
- Left ventricular ejection fraction
- Left ventricular end diastolic dimension
- Tricuspid regurgitation duration corrected for heart rate
- Peak systolic (S') velocity of the right ventricular free wall at the tricuspid annulus assessed with tissue Doppler
- Early diastolic (E') velocity of the right ventricular free wall at the tricuspid annulus assessed with tissue Doppler
- Right ventricular E/E' ratio
- TAPSE increase in response to dobutamine infusion
- Severity of tricuspid regurgitation
- 3-Dimensional right ventricular end-systolic and end-diastolic volume index

Echocardiographic parameters associated with right ventricular failure after left ventricular assist device: A review

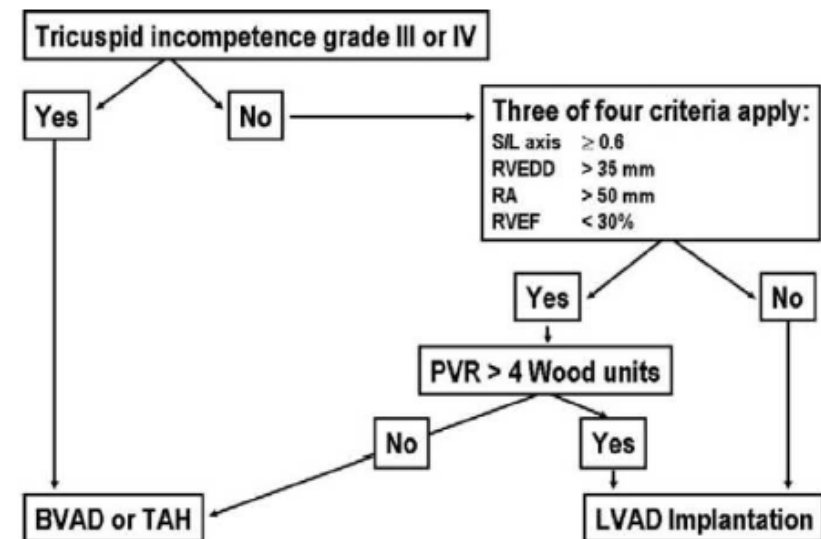
The Journal of Heart and Lung Transplantation, Vol 35, No 3, March 2016

Kukucka ¹²	2011	115	Pulsatile 56% Continuous 44%	1. RV-to-LV end-diastolic diameter (R/L) ratio obtained from transesophageal echo
Grant ¹³	2012	117	Continuous 100%	1. RV free wall peak longitudinal strain
Kato ¹⁴	2012	111	Pulsatile 29% Continuous 71%	1. LVEDD 2. LV ejection fraction 3. Left atrial diameter/LVEDD 4. Total bilirubin 5. Albumin
Atluri ¹⁵	2013	167	Pulsatile 51% Continuous 49%	6. RV stroke work index 1. CVP > 15 mm Hg 2. Severe RV dysfunction 3. Preoperative intubation 4. Severe tricuspid regurgitation 5. Heart rate > 100 beats/min
Vivo ¹⁶	2013	109	Pulsatile 15% Continuous 85%	1. RV-to-LV end-diastolic diameter (R/L) ratio obtained from transthoracic echo
Kiernan ¹⁷	2015	24	Continuous 100%	1. RV end-systolic volume index 2. RV end-diastolic volume index
Potapov ¹⁰	2008	54	Pulsatile 31% Continuous 69%	1. Tricuspid incompetence 2. RV end-diastolic diameter > 35 mm 3. RV ejection fraction < 30% 4. Right atrial dimension < 50 mm 5. Short-/long-axis ratio > 0.6

Données échographiques

IT

Parameter	OR	Confidence interval	p
S/L axis of RV	4.4	1.4–13.7	0.011
TI III-IV	4.7	1.26–17.65	0.012
CVP	1.24	1.04–1.47	0.019
SAPS II	1.14	1.01–1.28	0.03
Inotropic score	1	0.99–1.12	0.057
CI	0.25	0.056–1.12	0.069
SVR	1	1–1.01	0.05
CrP	1.12	1–1.26	0.048
NT-proBNP	1	1–1.002	0.1
INR	1.37	0.53–3.52	0.051



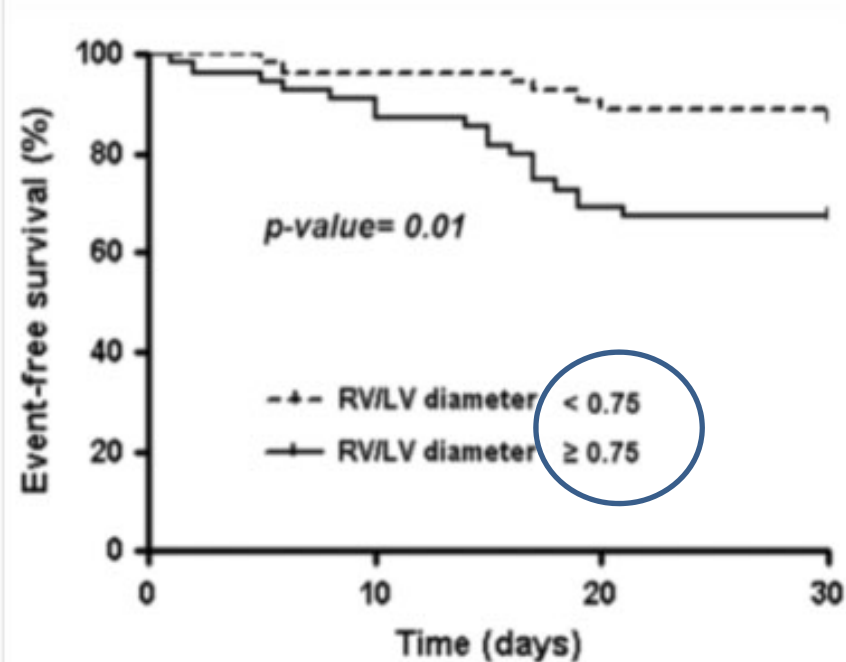
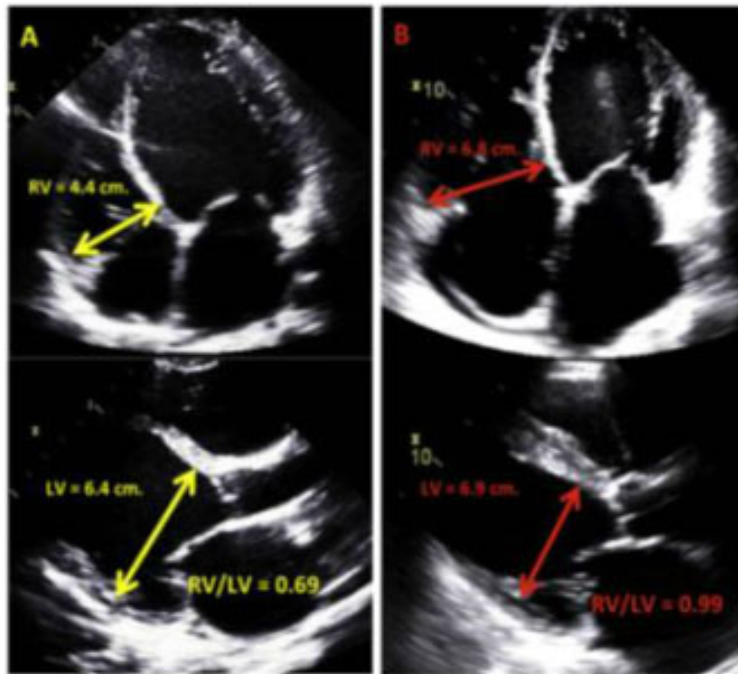
Tricuspid Incompetence and Geometry of the Right Ventricle as Predictors of Right Ventricular Function After Implantation of a Left Ventricular Assist Device

J Heart Lung Transplant 2008;27:1275–81.

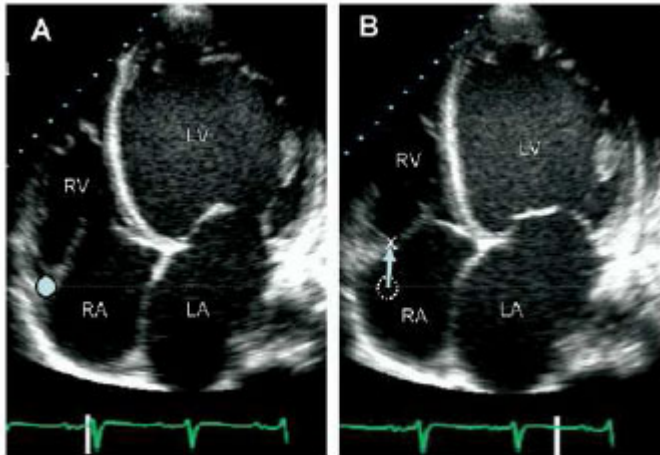
VD/VG

Increased right-to-left ventricle diameter ratio is a strong predictor of right ventricular failure after left ventricular assist device

J Heart Lung Transplant 2013;32:792-799



TAPSE



Tricuspid Annular Motion as a Predictor of Severe Right Ventricular Failure After Left Ventricular Assist Device Implantation

J Heart Lung Transplant 2008;27:1102–7.

Cut Off fixé à 7,5 mm

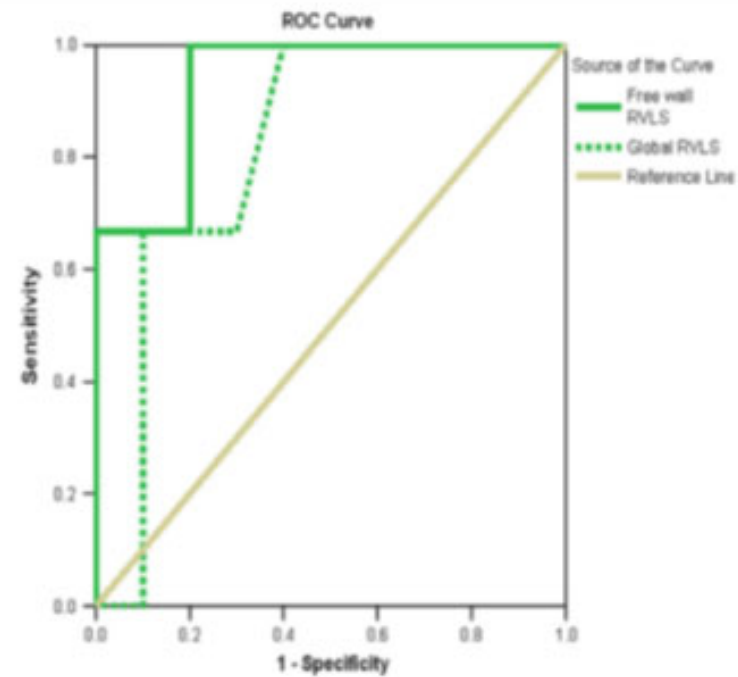
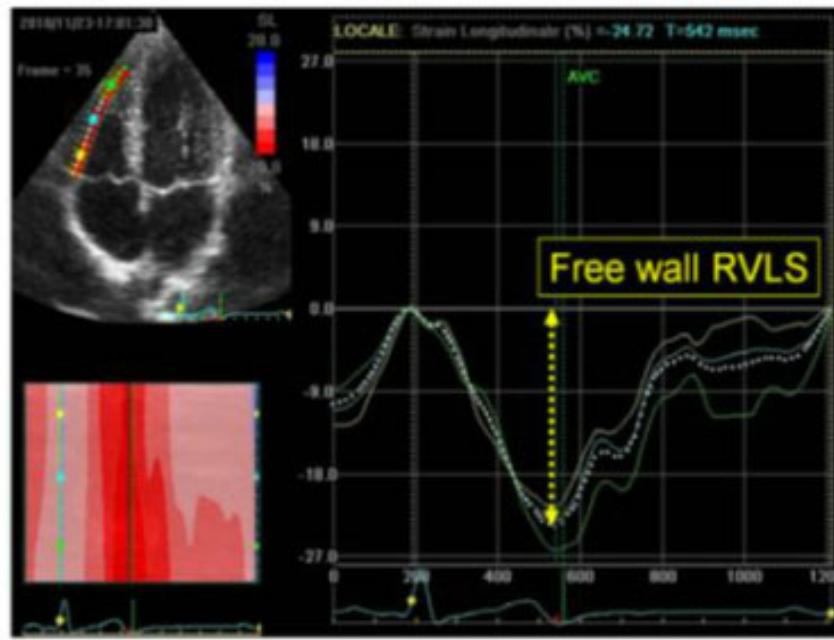
Table 3. Right Heart Echocardiographic Variables

Variable	RV failure, mean ± SD	No RV failure, mean ± SD	p value (univariate)
→ Tricuspid annular motion, mm (No.)	8 ± 4 (11)	15 ± 6 (22)	<0.01 ^a
RV fractional area change, % (No.)	37 ± 15 (10)	45 ± 12 (19)	0.18
RA volume, ml (No.)	98 ± 36 (11)	100 ± 77 (22)	0.41
RA volume index, ml/m ² (No.)	48 ± 19 (11)	48 ± 36 (22)	0.55
Hepatic vein variables			
Systolic forward flow, cm/s (No.)	-3 ± 35 (8) ^b	12 ± 38 (17)	0.66
Diastolic forward flow, cm/s (No.)	37 ± 17 (9)	34 ± 19 (17)	0.66
Diastolic reversal flow, cm/s (No.)	32 ± 19 (8)	33 ± 12 (13)	0.69
RIMP	0.94 ± 0.37 (11)	0.77 ± 0.36 (18)	0.38
Moderate to severe TR, n (No.)	3 (11)	10 (22)	0.47
→ RVSP, mmHg (No.)	60 ± 14 (10)	46 ± 11 (19)	0.02 ^a
LVEF, % (No.)	22 ± 6 (11)	19 ± 4 (22)	0.11

Strain VD

Speckle tracking echocardiography as a new technique to evaluate right ventricular function in patients with left ventricular assist device therapy

J Heart Lung Transplant 2013; 32: 424–430



Cut Off fixé à - 10 %

Données hémodynamiques

Facteurs pronostics de défaillance droite post op:

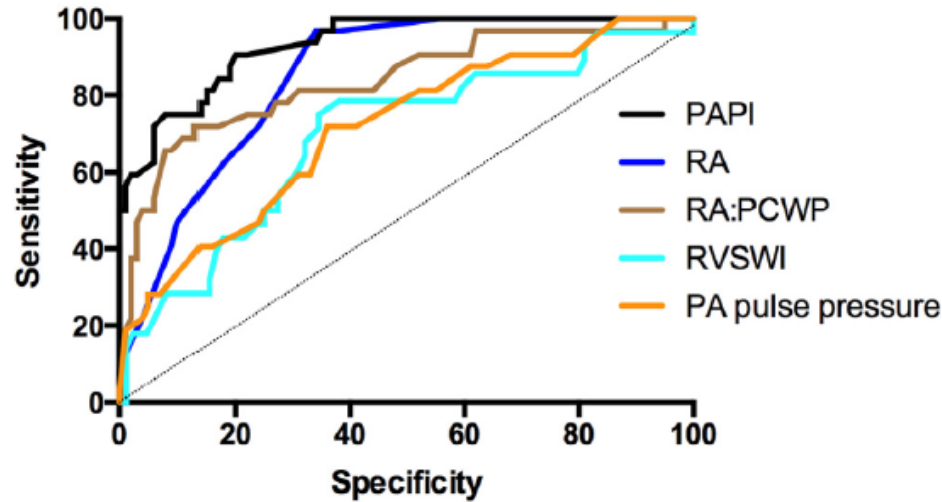
1. CVP > 15 mm Hg
2. CVP / PAPO > 0.63
3. RVSWI < 300/600
4. PAPI < 2

$$RVSWI = (PAP_m - PVC) * SV / BSA$$

$$PAPi = (PAP_s - PAP_d) / CVP$$

5. PACi < 0.89

$$PACi = (PAP_s - PAP_d) * SV / BSA$$



$$PAPi = \frac{(PA_{systolic} - PA_{diastolic})}{RA}$$

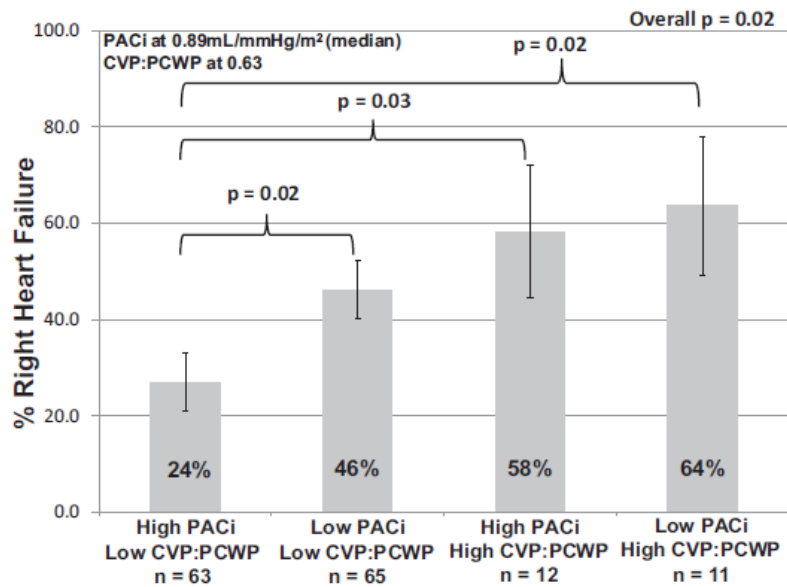
Table 3. Receiver Operating Characteristic Curve Analysis for Hemodynamic Determinants of Right Ventricular Failure

Parameter	AUC (95% CI)	SE	Sensitivity	Specificity	PPV	NPV
PAPi < 1.85	0.942 (0.904, 0.980)	0.0195	0.938	0.810	0.832	0.928
RA > 11.5 mm Hg	0.846 (0.781, 0.911)	0.0326	0.968	0.650	0.735	0.954
RA:PCWP > 0.59	0.837 (0.749, 0.925)	0.0195	0.719	0.870	0.847	0.756
PA pulse pressure < 22.5 mm Hg	0.742 (0.613, 0.817)	0.0520	0.718	0.640	0.663	0.695
RVSWI < 0.57 mm Hg L ⁻¹ m ⁻²	0.692 (0.576, 0.809)	0.0595	0.786	0.631	0.680	0.747
Moderate-severe TR	0.678 (0.571, 0.783)	0.0542	0.743	0.446	0.603	0.680

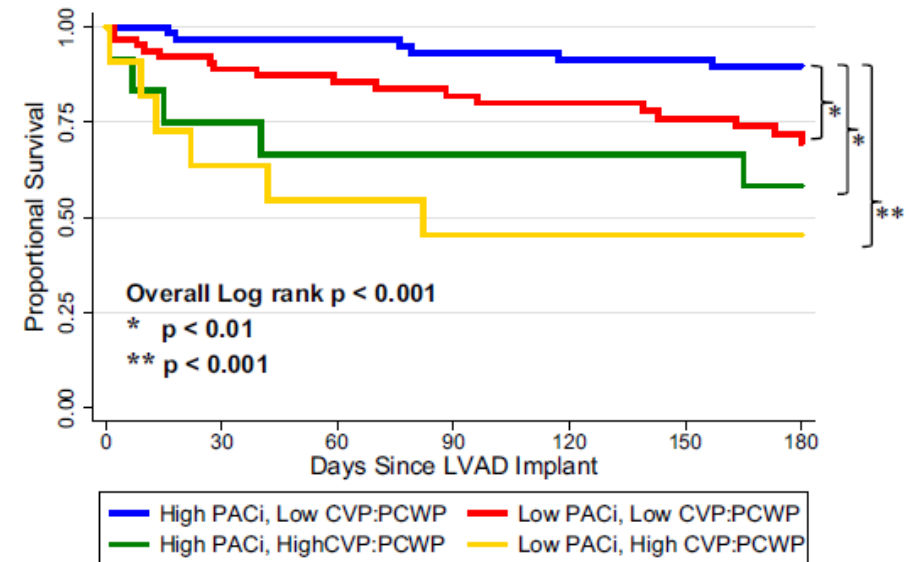
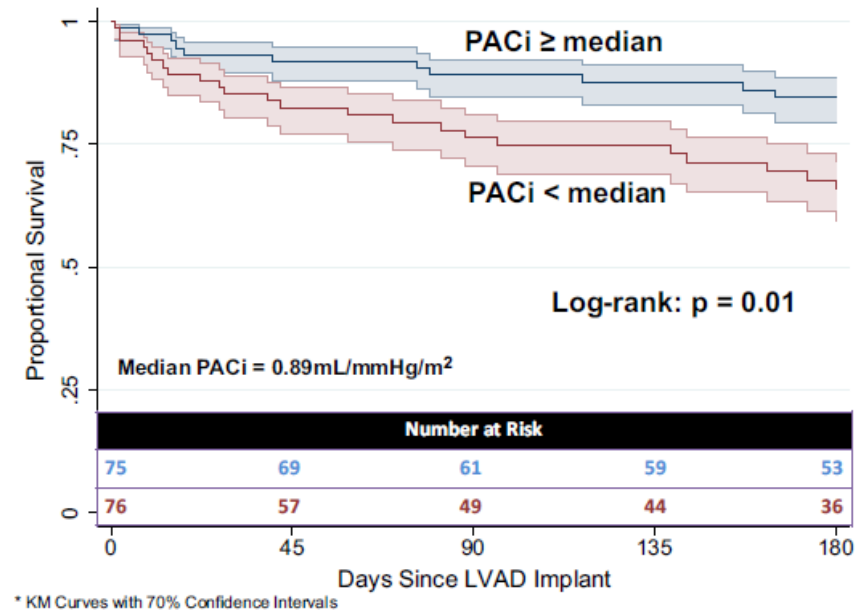
Pulmonary Artery Pulsatility Index Is Associated With Right Ventricular Failure After Left Ventricular Assist Device Surgery

Journal of Cardiac Failure Vol. 22 No. 2 2016

$$PACi = SV / (PAPs - PAPd) / BSA$$



Right ventricular response to pulsatile load is associated with early right heart failure and mortality after left ventricular assist device



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

Recommendations to assess pre-VAD RV function

Class I: All patients should have invasive focused hemodynamic evaluation of the right heart unit before DMCS implantation. Low Pulmonary artery pulsatility index is a prognostic indicator for right ventricular failure after durable LVAD.

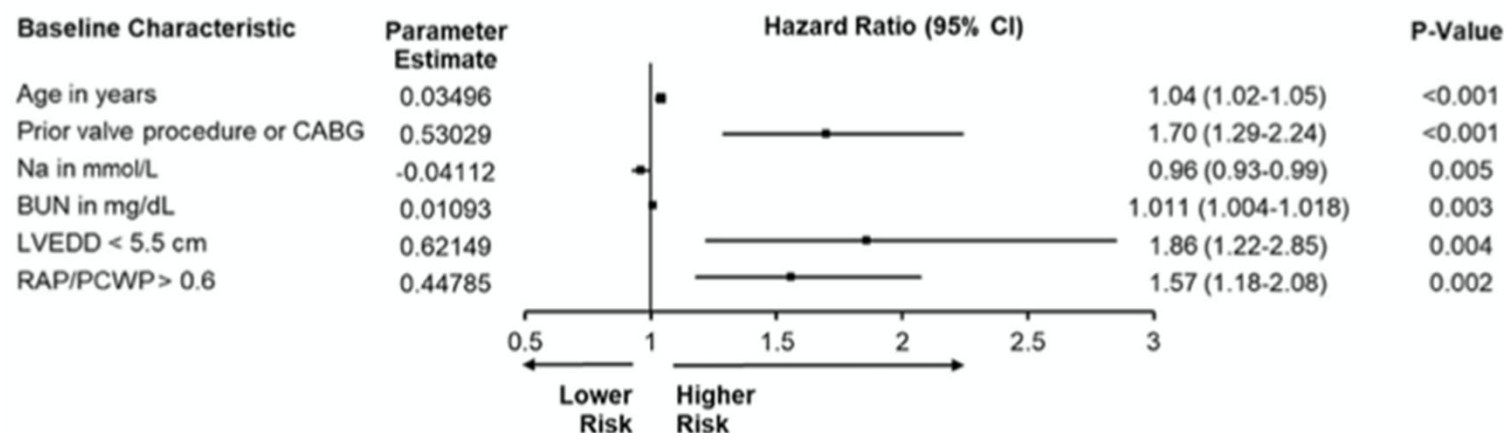
Level of Evidence: B.

Class I: All patients should have invasive hemodynamic evaluation before DMCS integrated with multimodality imaging with echocardiography and/or cardiac MRI focused quantitative parameters of right heart function and tricuspid valve integrity.

Level of Evidence: B.

Prediction of Survival After Implantation of a Fully Magnetically Levitated Left Ventricular Assist Device.

FIGURE 1 Multivariable Model and Risk Score Calculation

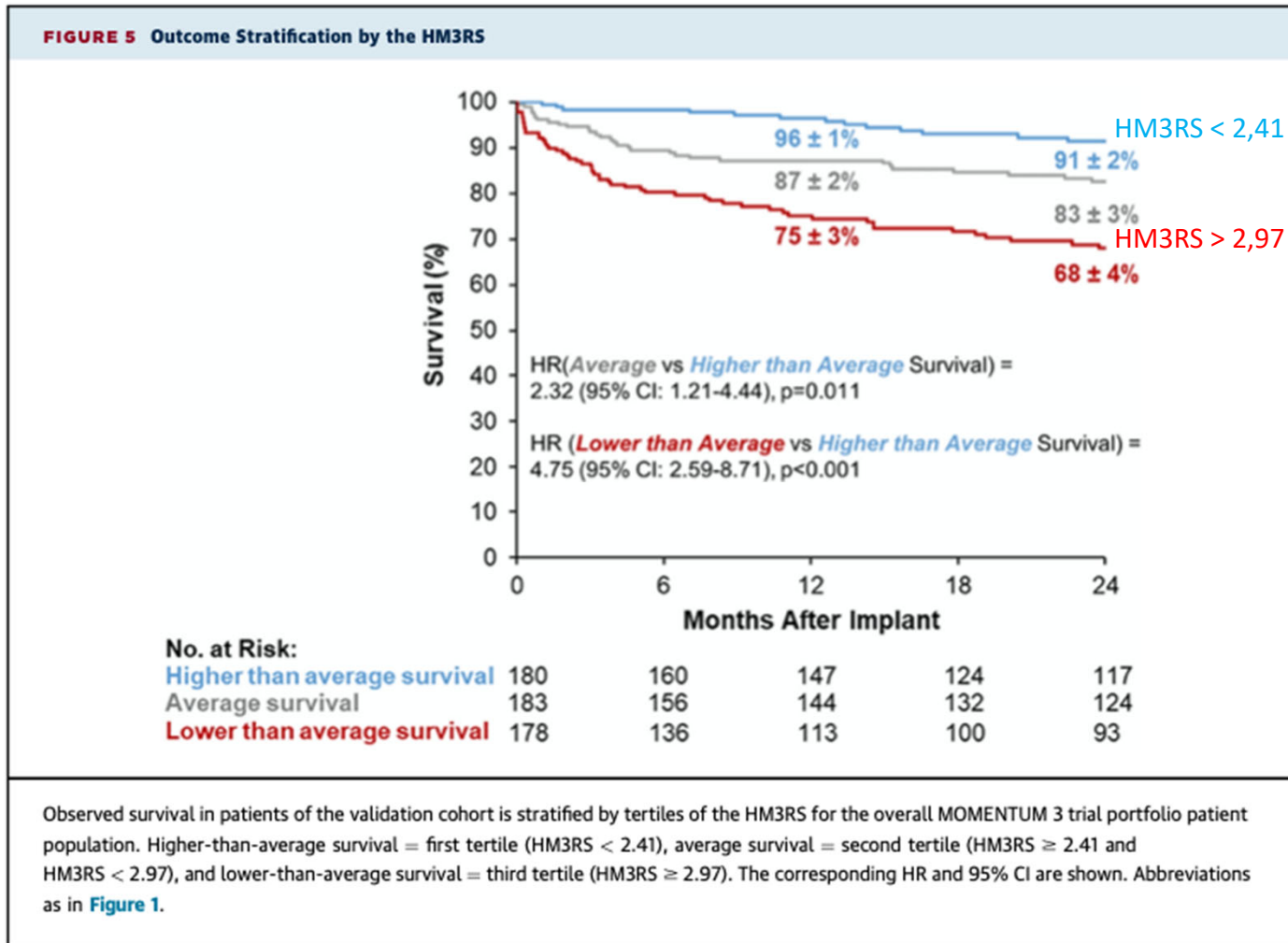


HeartMate 3 Risk Score =

$$0.03496 \times (\text{age in years}) + 0.53029 (\text{if prior CABG or valve procedure}) - 0.04112 \times (\text{Na in mmol/L} - 136^*) + 0.01093 \times (\text{BUN in mg/dL}) + 0.62149 (\text{if LVEDD} < 5.5 \text{cm}) + 0.44785 (\text{if RAP/PCWP} > 0.6)$$

Parameter estimates from the multivariable Cox proportional hazards model and associated HRs with 95% CIs are shown. The formula for the HeartMate 3 Survival Risk Score (HM3RS) is based on the parameter estimates. *For the calculation, subtract 136 mmol/L (average of the MOMENTUM 3 [Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3] trial patient population) from an individual's serum sodium (Na) level before multiplying by the parameter estimate. BUN = blood urea nitrogen; CABG = coronary artery bypass grafting; LVEDD = left ventricular end-diastolic dimension; PCWP = pulmonary capillary wedge pressure; RAP = right atrial pressure.

Prediction of Survival After Implantation of a Fully Magnetically Levitated Left Ventricular Assist Device.



<https://codetoheal.shinyapps.io/HeartMate3RS/>

Bilan pré-implantation

- ECG: ACFA
- ETT/ETO +/- contraste:
 - Fonction VD: taille VD et OD, S', TAPSE et IT
 - Autres: RM, IAo, CIA ou FOP thrombus intraVG
- Coronarographie
- Cathétérisme cardiaque droit:
 - Après stabilisation
 - PVC, PAPO, PAPS, RVSWI, PVC/PAPO, RVP et IC...
- EE VO₂max
- RP, EFR, GDS
- Body scanner sans et avec injection
- Doppler TSA et MI

Evaluation des organes abdominaux

- Exploration de la fonction rénale
 - Urée, créatinine, clairance de la créatinine, ionogramme urinaire et protéinurie des 24h
 - Échographie rénale, de la vessie (et de la prostate chez les hommes+++)

- FOGD, coloscopie longue

- Bilan hépatique:
 - ASAT, ALAT, bilirubine T et C, PAL, GGT et LDH
 - Échographie hépatique,
 - fibroscan, consultation avec un hépatologue +/- biopsie hépatique si cirrhose

Evaluation psycho-neurologique

- Evaluation des fonctions supérieures
- Consultation neurologique si ATCD d'AVC, athérosclérose carotidienne et/ou vertébrale
- Doppler TSA sans oublier les artères vertébrales+++
- TDM cérébrale
- IRM cérébrale si ATCD d'AVC cérébral

- Evaluation psychologique (et sociale)
- Questionnaire de qualité de vie : Minnesota Living with Heart Failure questionnaire

Evaluation biologique et infectieuse

- Bilan d'hémostase complet et spécialisé
 - TP, INR, TCA, FII, FV, fibrinogène
 - Test d'agrégation plaquettaire
 - Dosage du facteur de Von Willebrand

- Bilan infectieux
 - Panoramique dentaire, scanner des sinus
 - Cartographie bactérienne et fongique
 - ECBU
 - Sérologiques virales

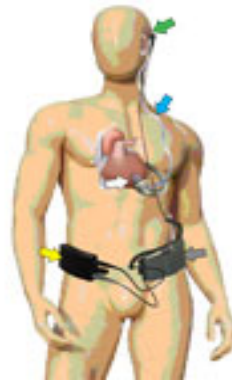
Les critères d'exclusion

- **Age** (> 80 ans : Attention aux comorbidités)
- **Hémodynamique** : instabilité hémodynamique majeure
- **Cancer** : néoplasie active et espérance de vie < de 2 ans
- **Sepsis** :
 - Endocardite : plus de bactériémie depuis 5 jours et ATB depuis 7 jours
 - Infection DAI et PM avec bactériémie
- **Atteinte sévère autres organes** (poumon, cerveau, rein, foie)
- **Consommation active drogues** (y compris alcool)

Les critères d'exclusion

- **Atteinte psychiatrique ou psychologique** (institution ou incapacité à se prendre en charge)
- **ATCD de mauvaise compliance au traitement**
- **Isolement** : patient vivant seul sans personne ressource proche
- **Grossesse**
- **dysfonction VD**

Les types de LVAD



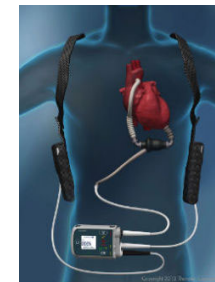
*HMIII,
Abbott®*



*HVAD,
HeartWare®*



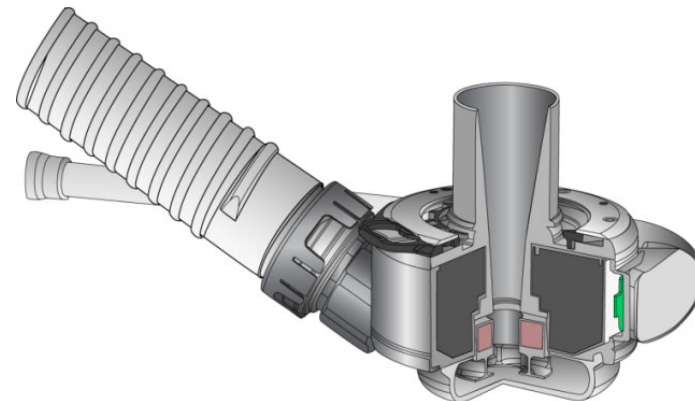
*JARVIK2000,
JarvikHeart®*



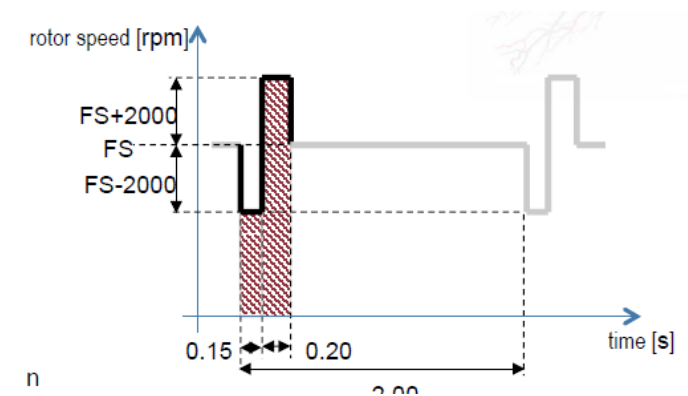
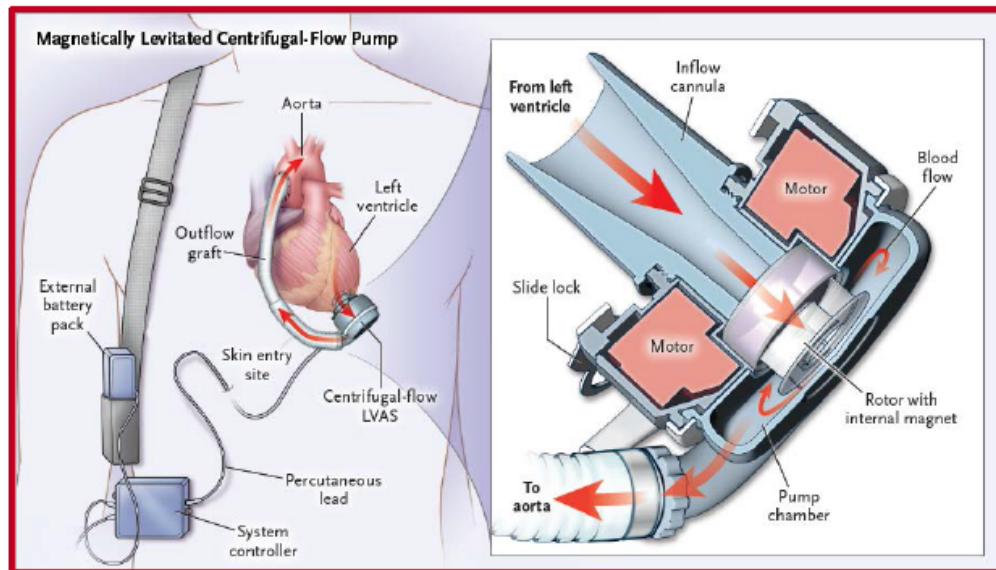
*HMII,
Abbott®*

LVAD : HeartMate3®

- Pompe centrifuge à débit continu
- Dispositif intra-thoracique avec batteries et contrôleur externes
- Câble avec sortie percutanée au niveau abdominal
- Pompe implantable miniaturisée
- Débit jusqu'à 10 litres/mn



LVAD : HeartMate 3®



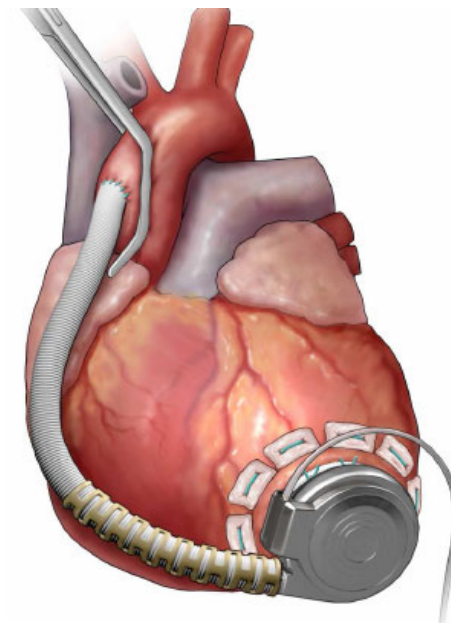
- **Wide** blood-flow passages to reduce shear stress
- **Frictionless** with absence of mechanical bearings
- **Intrinsic Pulse** designed to reduce stasis and avert thrombosis

LVAD : Heart Ware®

- Pompe centrifuge à débit continu
- Dispositif intra-thoracique avec batteries contrôleur externes
- Câble avec sortie percutanée au niveau abdominal



- Pompe implantable miniaturisée (50cc / 160g, 50mm de diamètre externe)
- Débit jusqu'à 10 litres/mn
- Marquage CE 2009-2021
- Approuvé FDA en BTT nov 2012-2021
- SC sup 1,2 m²

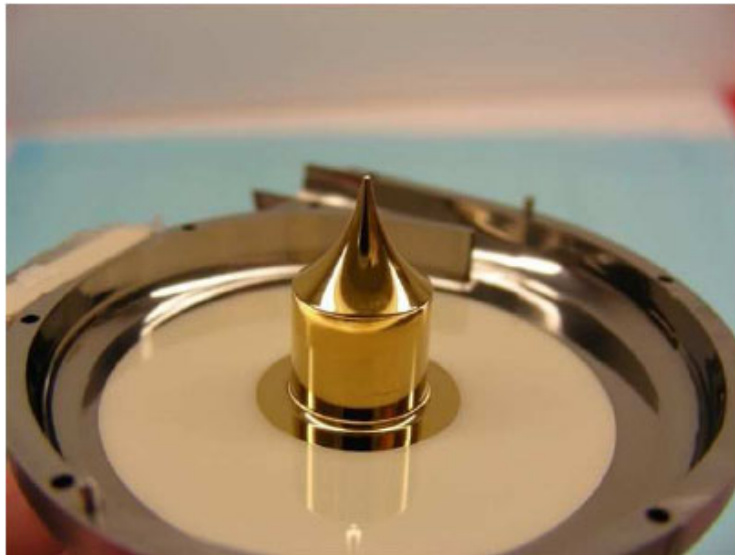


LVAD : Heart Ware®



- Le rotor est l'unique élément mobile
- Suspension Hybride
Magnétique/Hydrodynamique
- Rotation du rotor sans aucun contact mécanique

HeartWare®



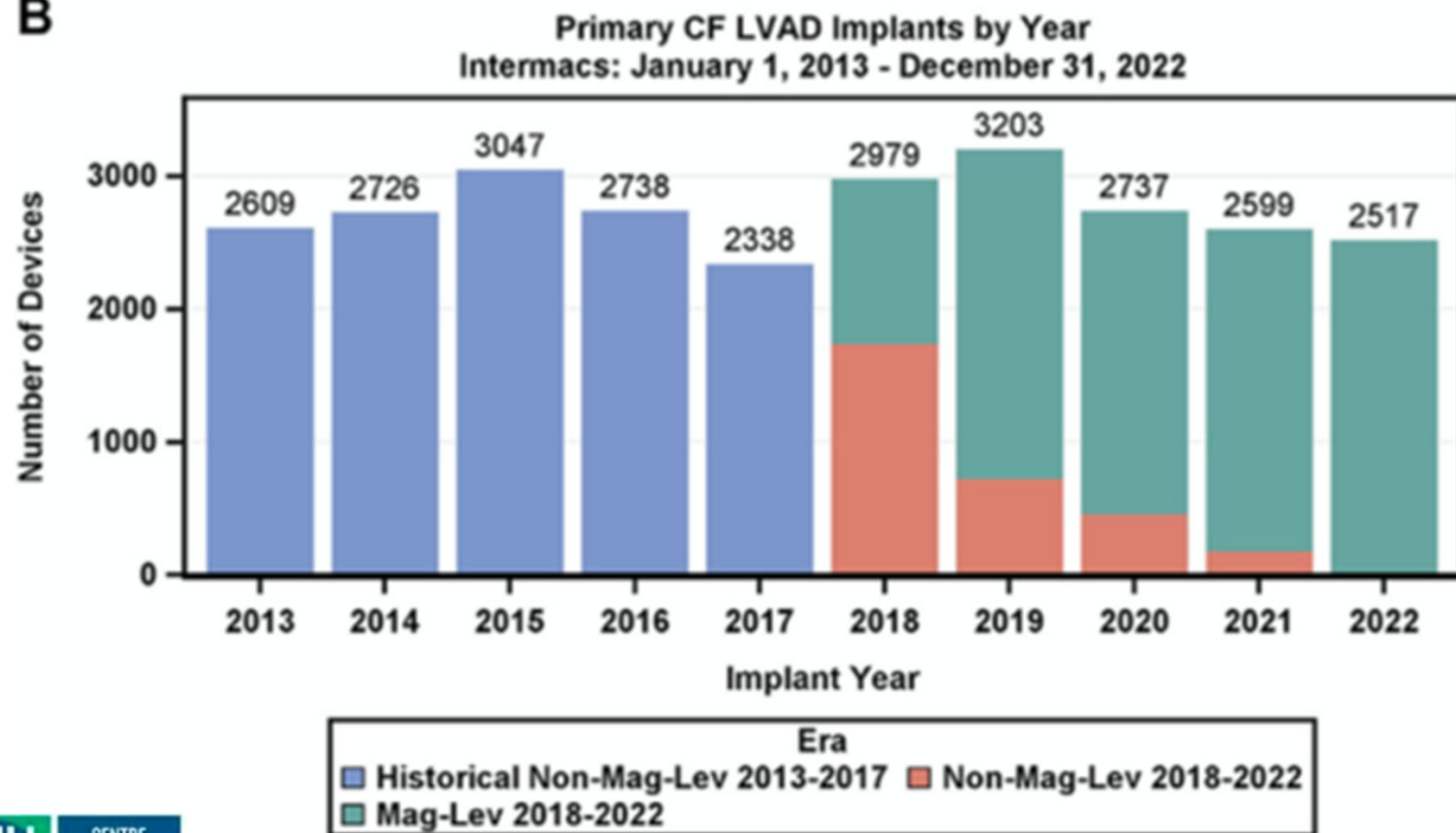
LVAD : Heart Ware®



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

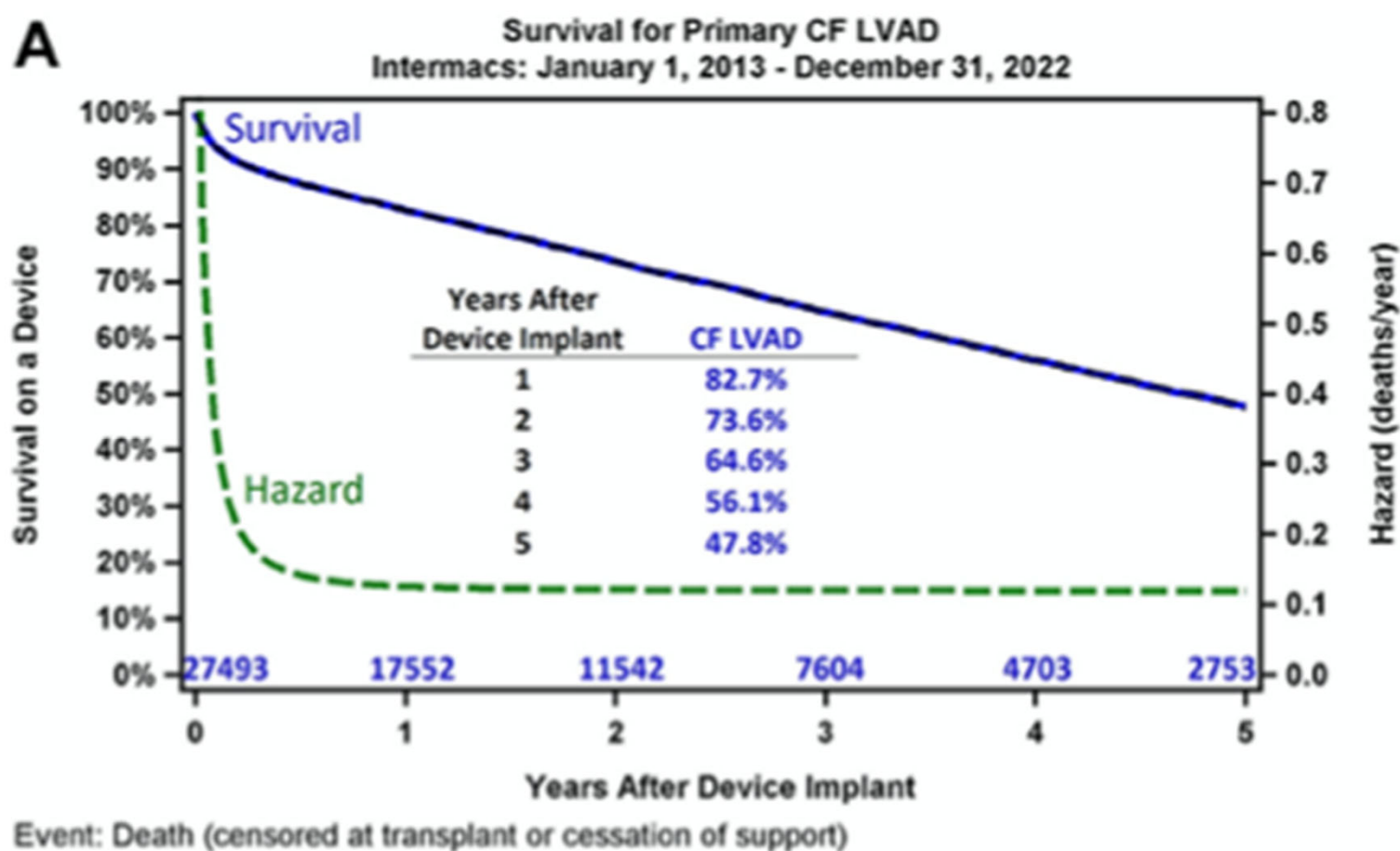
Jorde UP, Saeed O, Koehl D, Morris AA, Wood KL, Meyer DM, Cantor R, Jacobs JP, Kirklin JK, Pagani FD, Vega JD.

B



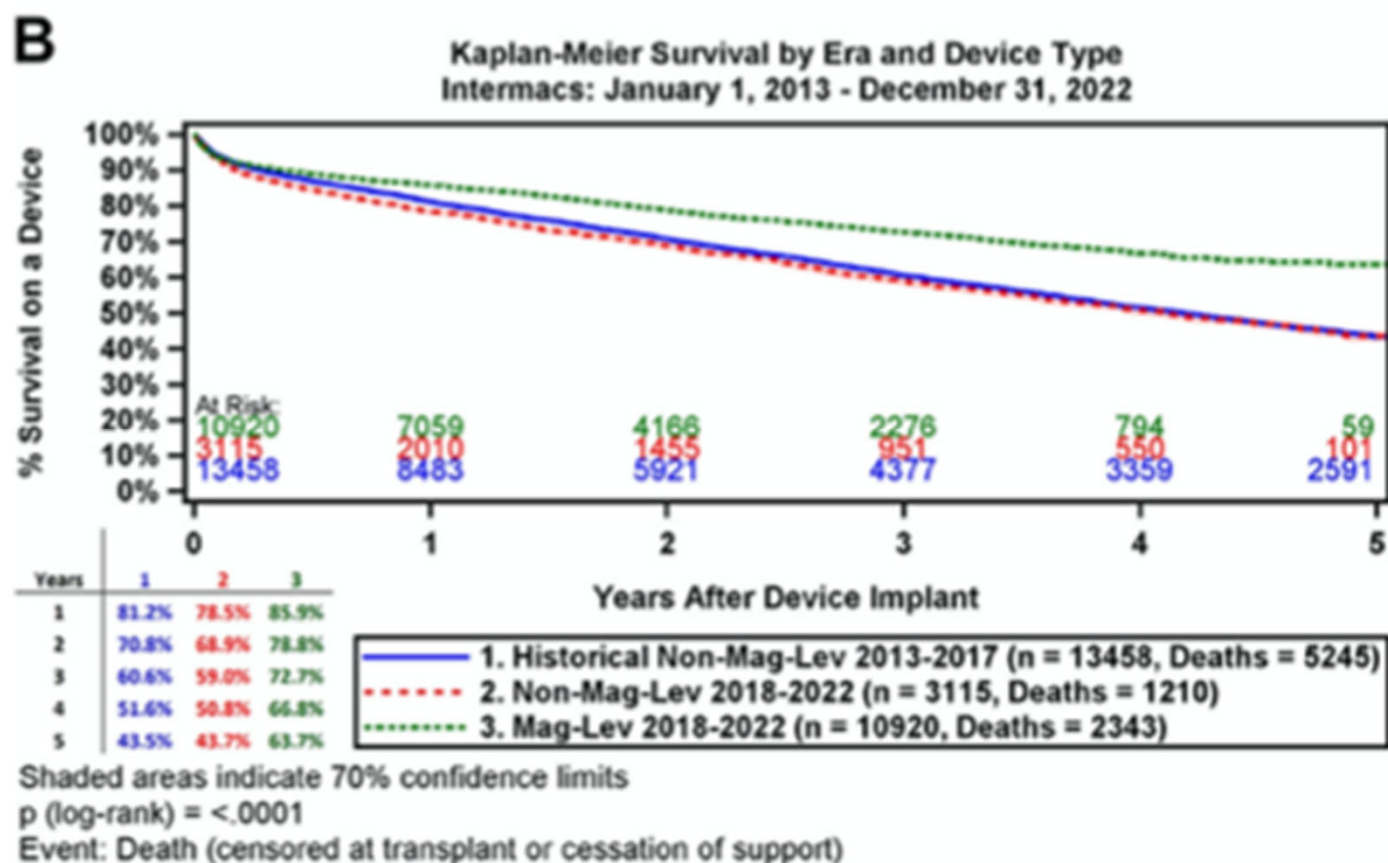
The Society of Thoracic Surgeons **Intermacs 2023** Annual Report: Focus on Magnetically Levitated Devices.

Jorde UP, Saeed O, Koehl D, Morris AA, Wood KL, Meyer DM, Cantor R, Jacobs JP, Kirklin JK, Pagani FD, Vega JD.



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

Jorde UP, Saeed O, Koehl D, Morris AA, Wood KL, Meyer DM, Cantor R, Jacobs JP, Kirklin JK, Pagani FD, Vega JD.



Principales complications

- Neurologiques :
 - 11% AVC invalidants (hémorragique et ischémique), 17% AVC/AIT
- Septiques :
 - 20 à 35%, infections liées ou non au LVAD
- Saignements :
 - 41% nécessitant reprise chirurgicale
 - 70% nécessitant transfusion > 2CGR
- Hémodynamiques :
 - 5-20% défaillance VD; 4% hémolyse; 24% arythmie ventriculaire

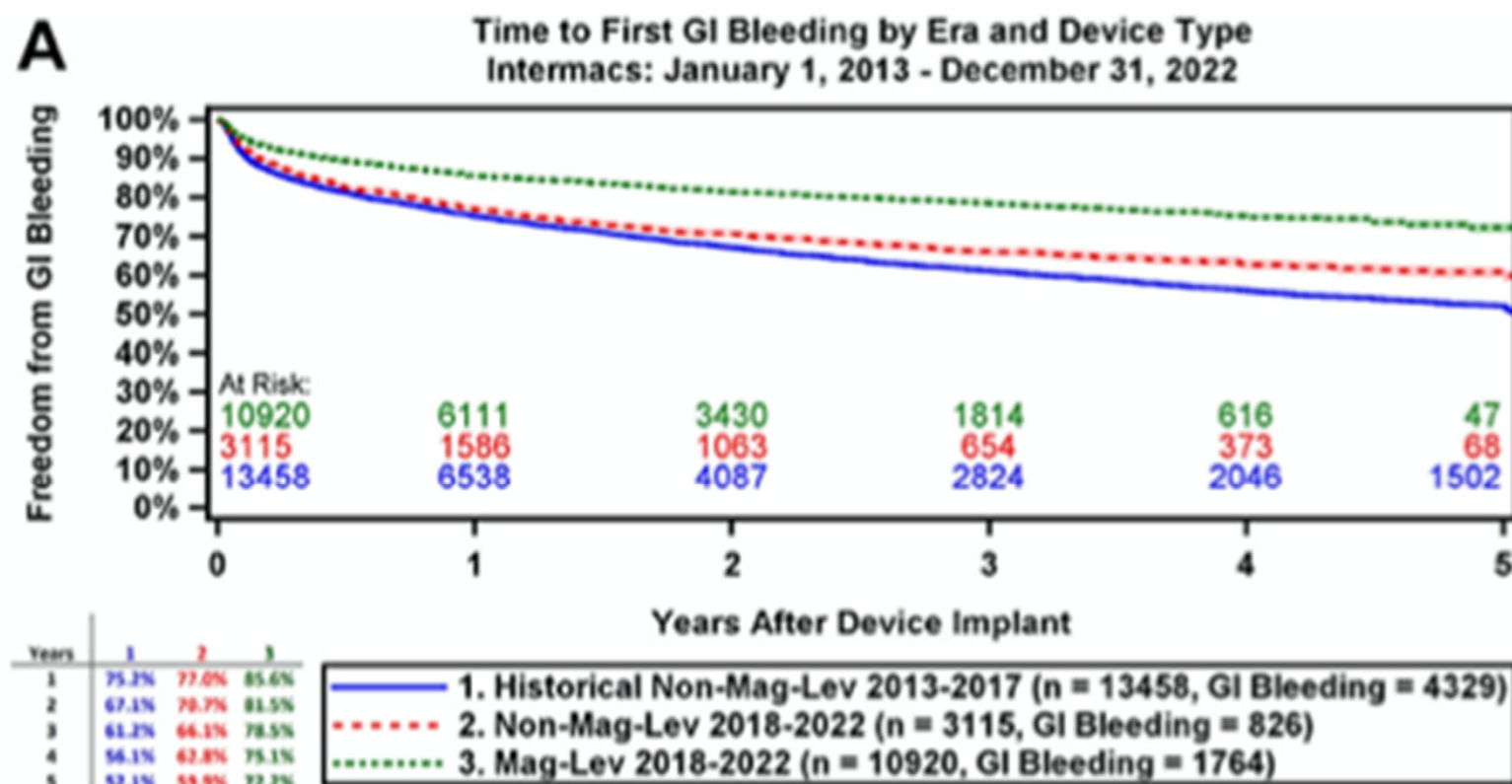
Eur J Cardiothorac Surg 2010;37(2):357-361

N Engl J Med. 2007; 357(9):885-96

N Engl J Med. 2009;361(23):2241-51

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

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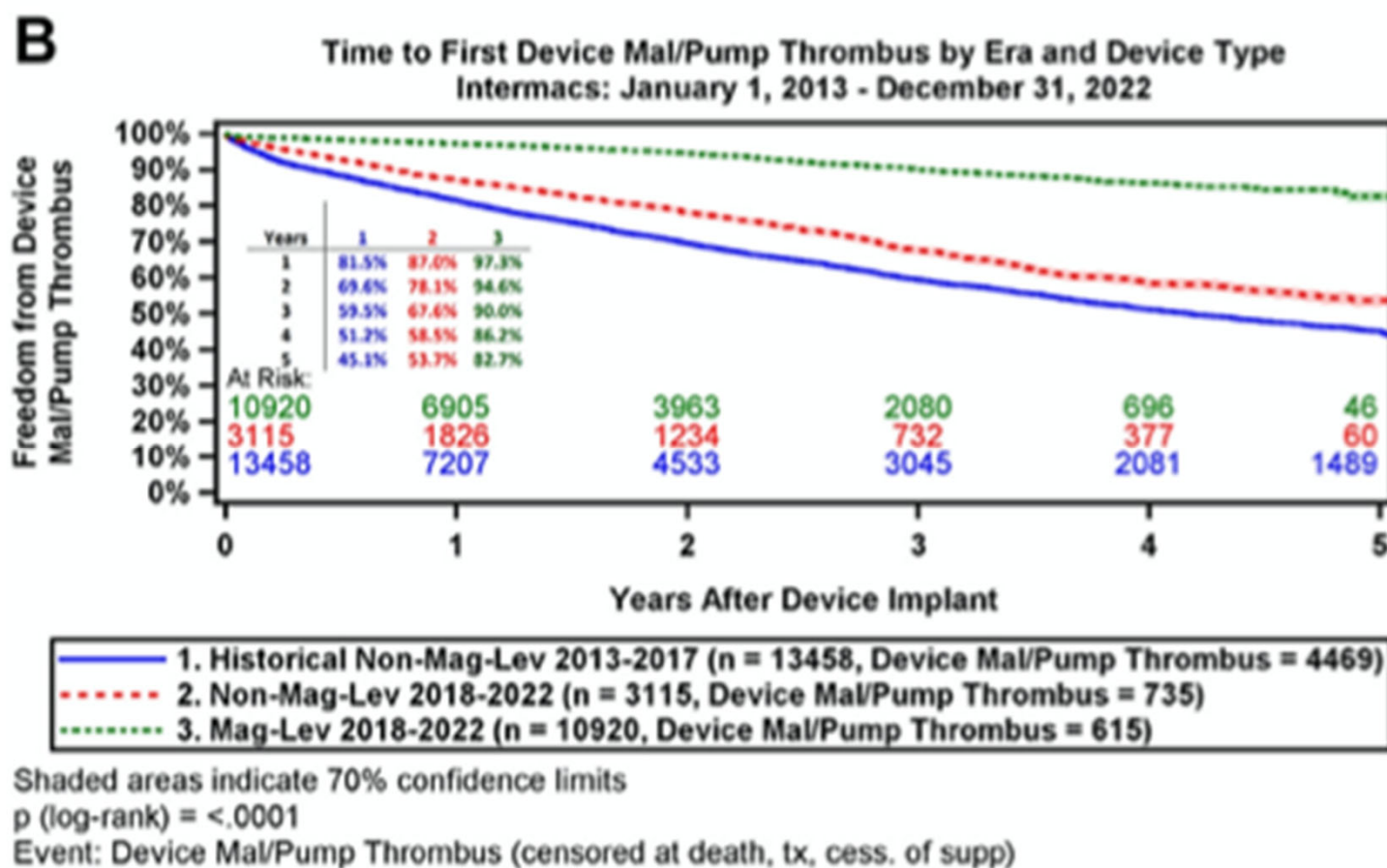
Shaded areas indicate 70% confidence limits

p (log-rank) = <.0001

Event: GI Bleeding (censored at death, tx, cess. of supp)

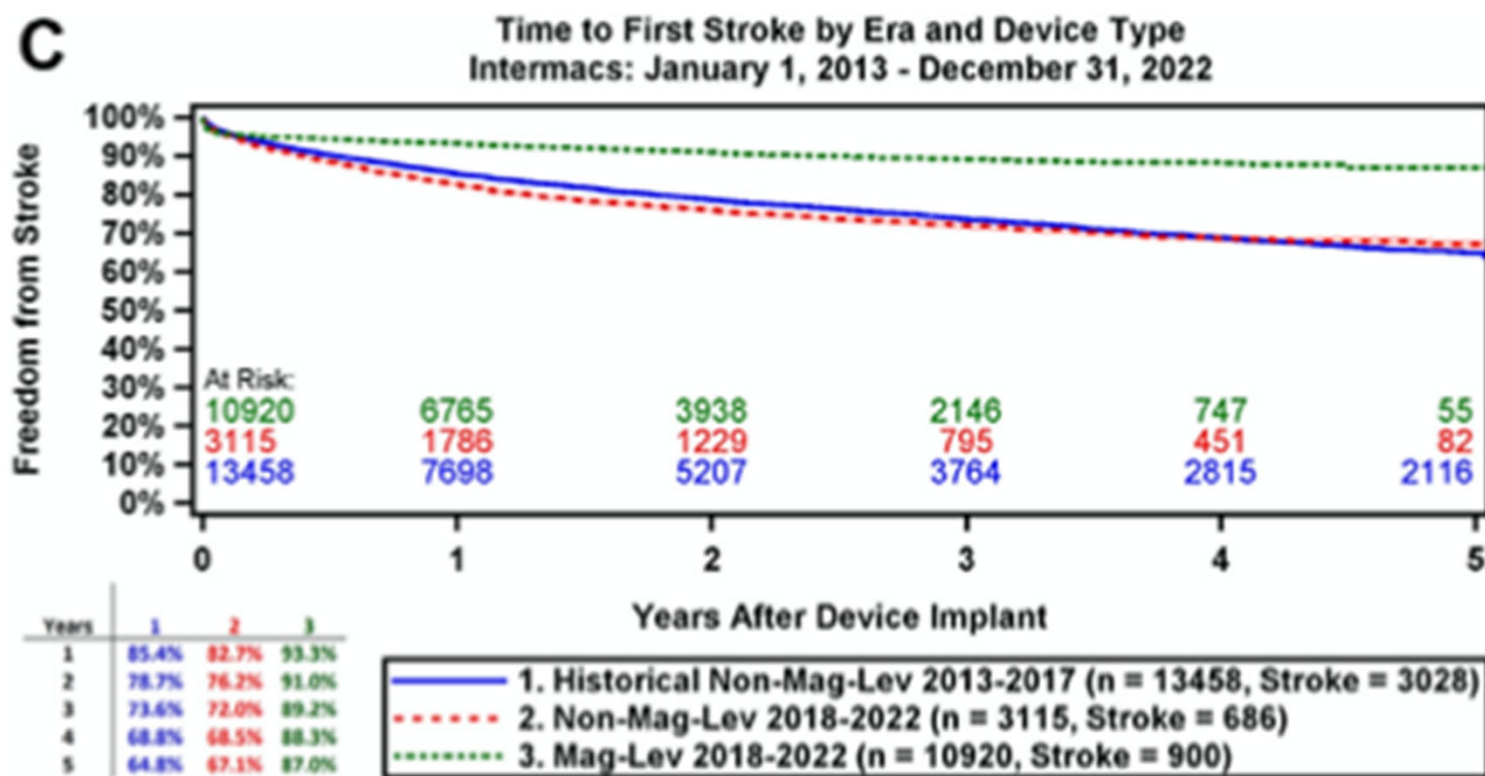
The Society of Thoracic Surgeons Intermacs 2023 Annual Report: Focus on Magnetically Levitated Devices.

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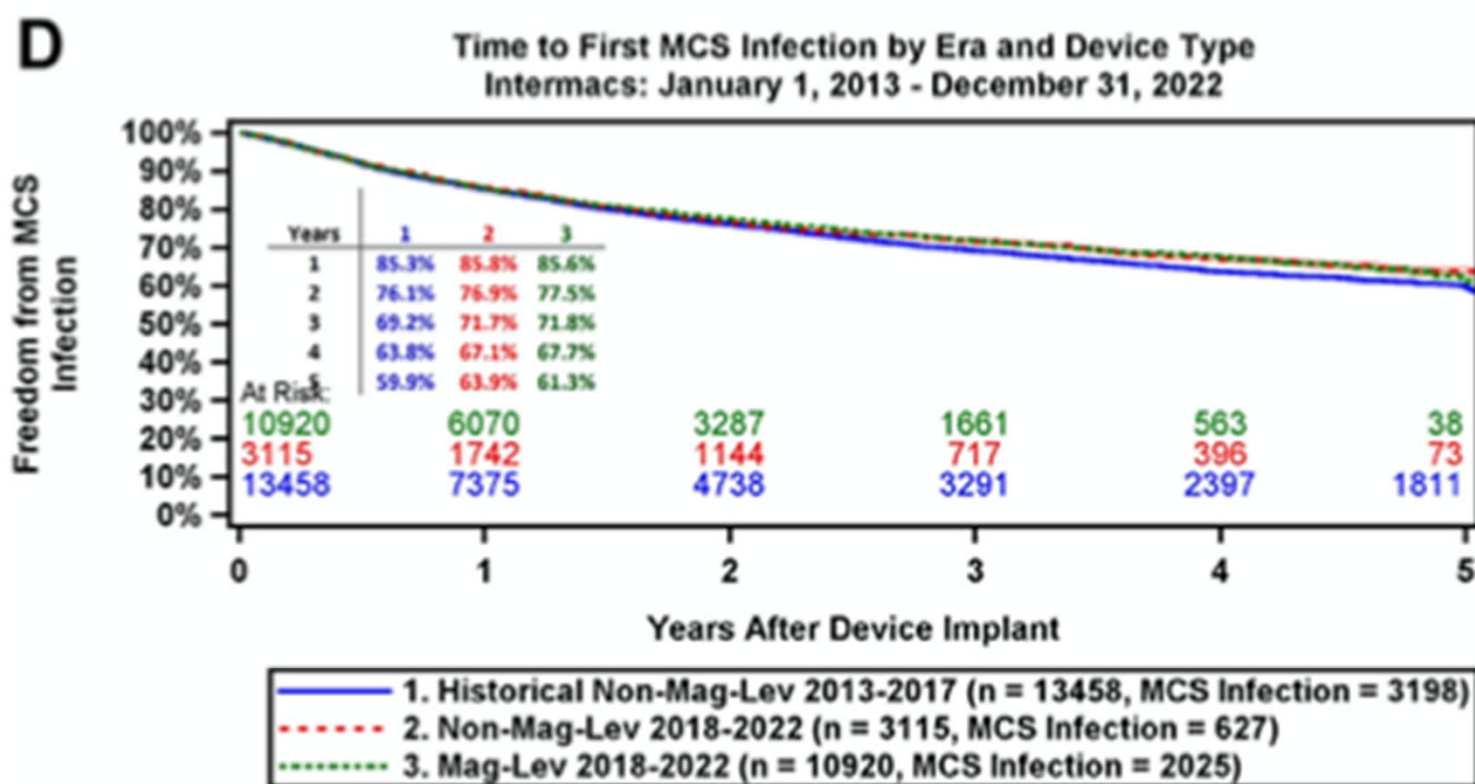
Shaded areas indicate 70% confidence limits

p (log-rank) = <.0001

Event: Stroke (censored at death, tx, cess. of supp)

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

Jorde UP, Saeed O, Koehl D, Morris AA, Wood KL, Meyer DM, Cantor R, Jacobs JP, Kirklin JK, Pagani FD, Vega JD.



Shaded areas indicate 70% confidence limits

p (log-rank) = 0.0139

Event: MCS Infection (censored at death, tx, cess. of supp)

Le Suivi

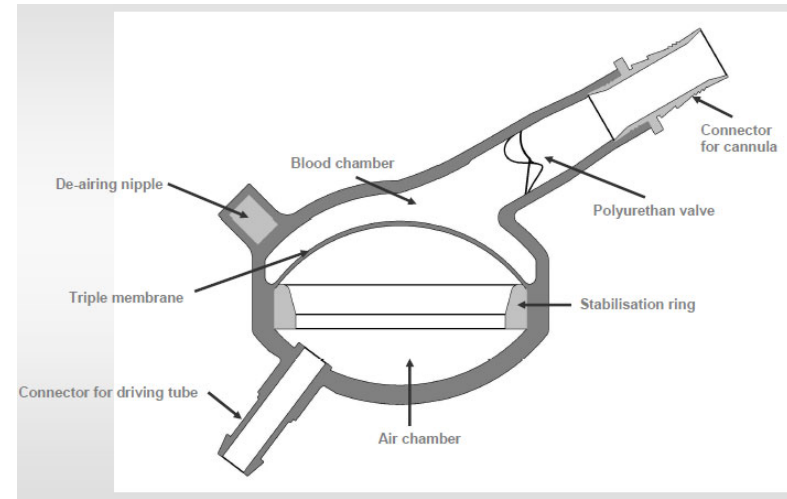
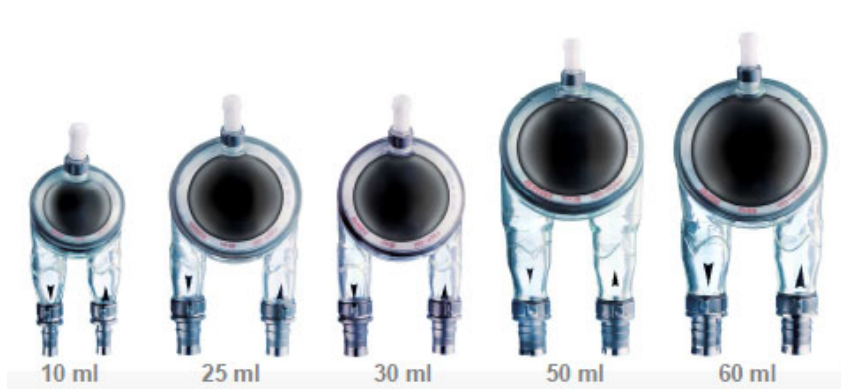
- Hôpital de jour
- Interrogatoire, examen clinique, ECG
- Bon fonctionnement du dispositif
- Pansement infirmier : IDE spécialisée pour la consultation
- Bilan bio: NFS, coag, Iono, BNP, bilan d'hémolyse
- RP
- ETT: recherche de complications, fonction VD
- +/- Contrôle rythmo, équilibre diabète, etc..

Traitement médical

- Traitement de l'insuffisance cardiaque (BB, IEC, ARM...)
- Contrôle la PA
 - PAM entre 70 et 80 mmHg
 - Facteur de risque AVC
- Anticoagulation +/- AAP
- Autre traitement si nécessaire

Berlin Heart®

- Assistance bi ventriculaire pneumatique pulsatile
- Para corporelle
- Enfants, adolescents et adultes de petit gabarit
- Pont à la greffe ou pont à la récupération



HeartMate 6

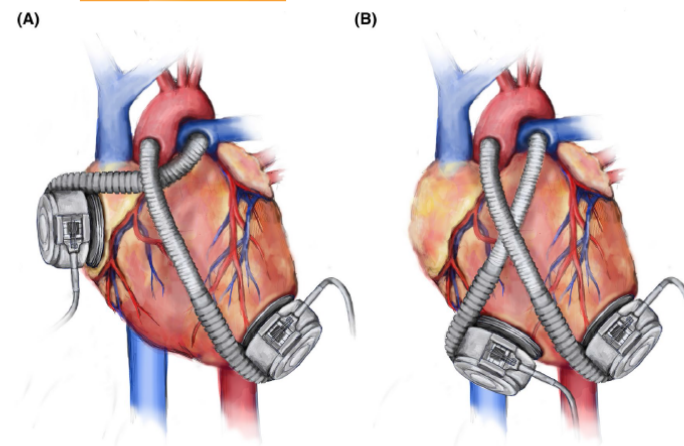
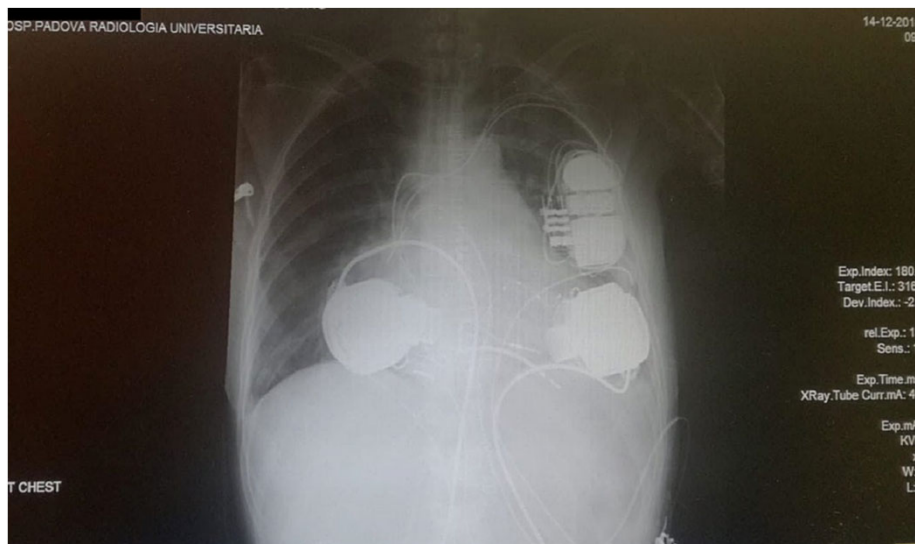


FIGURE 1 Commonly used biventricular support configurations utilizing HeartWare HVAD. A, Right atrial HVAD. B, right ventricular HVAD. Illustration by C.T.W [Color figure can be viewed at wileyonlinelibrary.com]

HeartMate 6



FEATURED PAPERS

An international multicenter experience of biventricular support with HeartMate 3 ventricular assist systems

Jacob Lavee, MD,^a Johanna Mulzer, MD,^b Thomas Krabatsch, MD,^b Silvana Marasco, MD,^c David McGiffin, MD,^c Jens Garbade, MD,^d Jan D. Schmitto, MD,^e Daniel Zimpfer, MD,^f and Evgenij V. Potapov, MD^b

From the ^aHeart Transplantation Unit, Department of Cardiac Surgery, Leiviv Heart Center, Sheba Medical Center, Tel Aviv University, Tel Aviv, Israel; ^bCardiac, Thoracic and Vascular Surgery, German Heart Center, Berlin, Germany; ^cThoracic Surgery & Transplantation, The Alfred Hospital, Melbourne, Victoria, Australia; ^dHeart Center, University of Leipzig, Leipzig, Germany; ^eDepartment of Cardiac, Thoracic, Transplantation and Vascular Surgery, Hannover School, Hannover, Germany; and the ^fDepartment of Cardiac Surgery, Medical University Vienna, Vienna, Austria

KEYWORDS:
bi-ventricular assist device;
ventricular failure;
continuous flow ventricular assist device;
left ventricular assist device;

Significant right ventricular failure accompanying left ventricular failure was the fully magnetically levitated centrifugal HeartMate 3 ventricular assist (BIVAD) support in 14 patients at 6 medical centers worldwide. The clinical center experience are presented. Nine of these patients (64%) were alive as of the 9 have continued on BIVAD support for 95 to 636 (mean 266) days; 7 fully transplanted after 98 days of support.
J Heart Lung Transplant 2018;37:1399-1402.
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The Journal of Heart and Lung Transplantation
http://www.jhltonline.org



ORIGINAL CLINICAL SCIENCE

The results of a single-center experience with HeartMate 3 in a biventricular configuration

David McGiffin, MD,^a Christina Kure, PhD,^a Janelle McLean, RN,^b Silvana Marasco, MD, PhD,^a Peter Bergin, MD,^b James L. Hare, MD, PhD,^b Angeline Leet, MD,^b Hitesh Patel, MD, PhD,^b Adam Zimmet, MD,^a Julia Rix, RN,^b Andrew Taylor, MD, PhD,^b and David Kaye, MD, PhD^b

From the ^aDepartment of Cardiothoracic Surgery and Transplantation, The Alfred Hospital and Monash University, Melbourne, Australia; and the ^bDepartment of Cardiology, The Alfred Hospital, Melbourne, Australia.

KEYWORDS:
Heartmate III;
biventricular;
cardiomyopathy;
mechanical circulatory support;
pump thrombosis

BACKGROUND: Right ventricular (RV) failure after left ventricular assist device (VAD) implantation is a difficult problem. One solution is the implantation of continuous-flow VADs in a biventricular configuration. Disappointing survival and a concerning incidence of right-sided pump thrombosis have been previously reported.
METHODS: From May 2017 to April 2020, a total of 12 patients underwent implantation of HeartMate 3 (HM3) biventricular VADs (BIVADs) as a bridge to cardiac transplantation. The right-sided pump was implanted in the right atrium in all cases. Adverse events and patient outcomes were determined.
RESULTS: Patients were male, and the mean age was 44 years. The etiology was dilated cardiomyopathy (6 patients), sarcolemmal heart disease (2 patients), ischemic cardiomyopathy (1 patient), anthracycline cardiomyopathy (1 patient), non-compaction cardiomyopathy (1 patient), and arrhythmogenic RV cardiomyopathy with biventricular involvement (1 patient). There was 1 death from multisystem failure. There were 3 episodes of right VAD thrombus (thrombosis or clot ingestion); 1 managed medically, 1 recognized intraoperatively treated with clot retrieval, and 1 requiring pump exchange. There were 3 driveline infections. At 18 months after the procedure, 5 patients (41.7%) had undergone cardiac transplantation, 5 patients (41.7%) were alive and on biventricular support, 1 patient had died (8.3%), and 1 patient had VAD explantation for myocardial recovery (8.3%). Actuarial survival at 18 months was 91.7%.
CONCLUSIONS: In this small study, HM3 BIVAD in these critically ill patients was used with low mortality. This suggests that the timely deployment of biventricular support with HM3 can be associated with favorable outcomes.
J Heart Lung Transplant 2020;000:1-8

The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

The results of a single-center experience with HeartMate 3 in a biventricular configuration

David McGiffin, MD,^a Christina Kure, PhD,^a Janelle McLean, RN,^b Silvana Marasco, MD, PhD,^a Peter Bergin, MD,^b James L. Hare, MD, PhD,^b Angeline Leet, MD,^b Hitesh Patel, MD, PhD,^b Adam Zimmet, MD,^a Julia Rix, RN,^b Andrew Taylor, MD, PhD,^b and David Kaye, MD, PhD^b

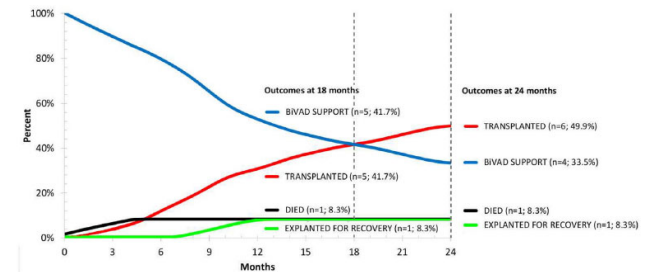


Figure 5 Competing outcomes depiction for HM3 biventricular support. At any point in time, the sum of the proportions for each outcome equals 100%. BIVAD, biventricular assist device; HM3, HeartMate 3.

ASAIO Journal 2021

Case Report

The HeartMate 6 and CardioMEMS for Fixed Pulmonary Hypertension

PHILIPP ANGLEITNER,^{*} THOMAS SCHLÖGLHOFER,^{*} DOMINIK WIEDEMANN,^{*} JULIA REIBANDT,^{*} ANDREAS STRASSL,[†] JULIA MASCHERBAUER,[‡] MATTHIAS KAINZ,[§] GÜNTHER LAUFER,^{*} ANDREAS ZUCKERMANN,^{*} AND DANIEL ZIMPFER^{*}

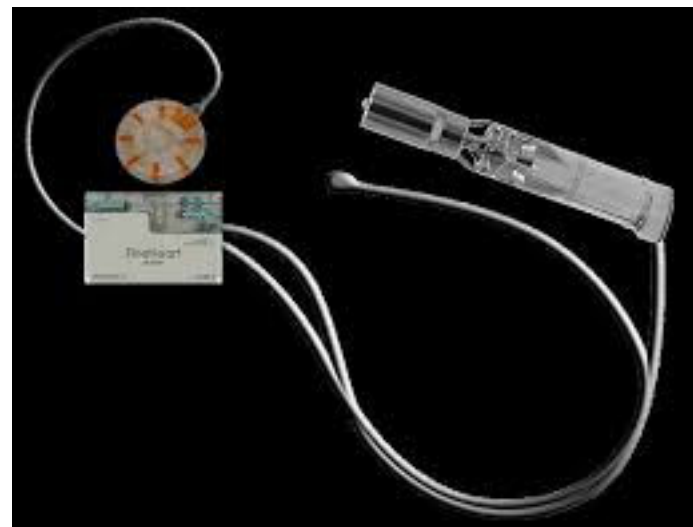
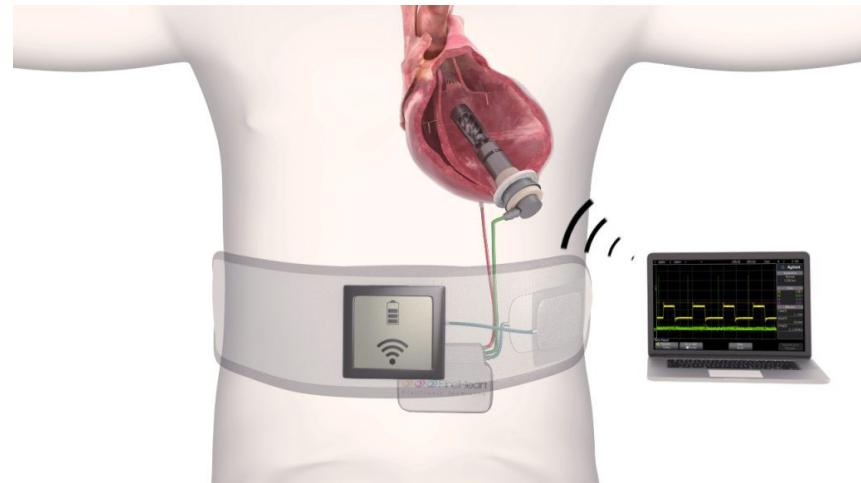
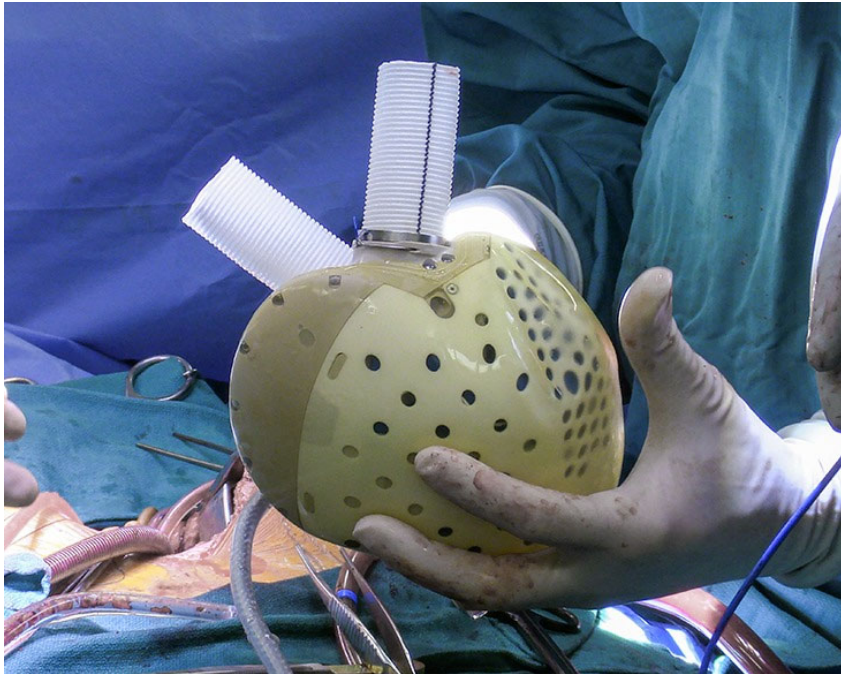
Abstract: Fixed pulmonary hypertension (FPH) is a contraindication for heart transplantation (HTX). However, this condition might be reversed by continuous left-ventricular unloading with a left-ventricular assist device. We present a case of apical hypertrophic cardiomyopathy with extensive left-ventricular endocardial calcification and severe FPH (systolic pulmonary artery pressure, 102 mm Hg). To bridge the patient to candidacy for HTX, two Abbott HeartMate 3 ventricular assist devices were implanted in a total artificial heart (TAH) configuration ("HeartMate 6"). Before TAH implantation, an Abbott CardioMEMS pressure sensor was implanted to assess reversal of FPH before listing for HTX. ASAIO Journal 2021; XX:00-00

transpulmonary gradient, 28 mm Hg; pulmonary vascular resistance: 5.4 Wood units). Given the severe left-ventricular endocardial calcification combined with FPH, our patient had an indication for TAH implantation as a bridge to candidacy (BTC) for heart transplantation (HTX).²

Technique

To continuously measure PAP values after elective TAH implantation, an Abbott CardioMEMS pressure sensor was implanted into the pulmonary arterial tree in standard technique.² Percutaneous femoral venous access was obtained to catheterize the left-sided pulmonary artery. A dorsal lower-lobe branch with a diameter of approximately 8 mm was localized to place the sensor's body and distal loop (Figure 7A and B).

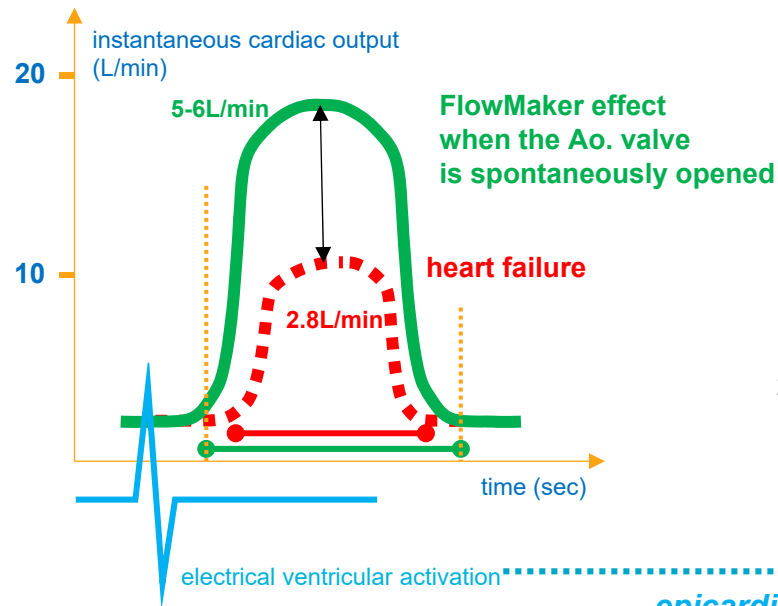
L'Avenir



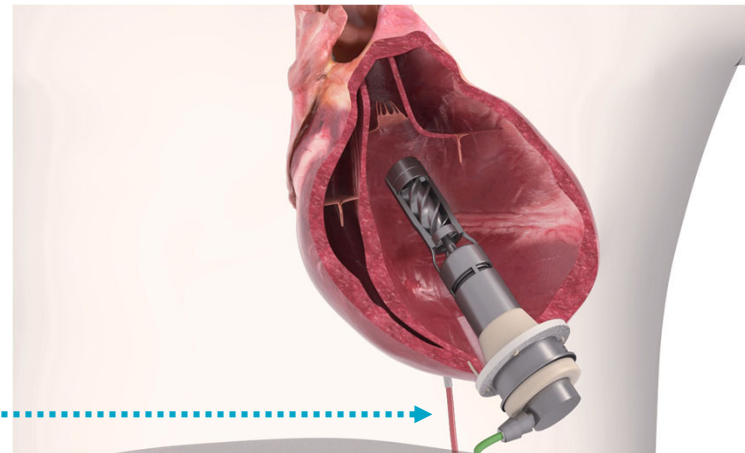


FlowMaker concept

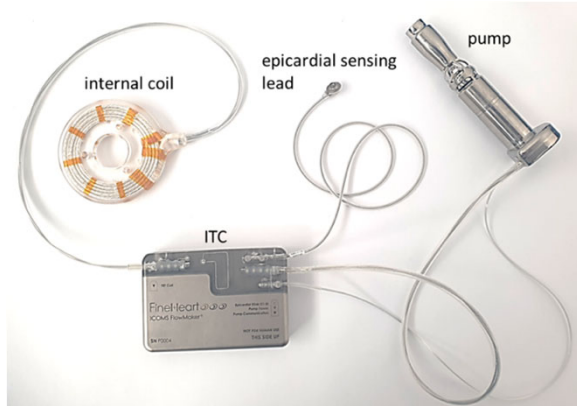
- The pump waits for the Ao. valve opening
- Physiological pump exit: under the Ao. valve
- Systolic-synchronized pulsatile operating mode
- Two rotational speed regimens (diastolic & systolic)
- Filling phase not disturbed with low rotational speed



pump speed
2,000-6,000rpm



Implantable Components

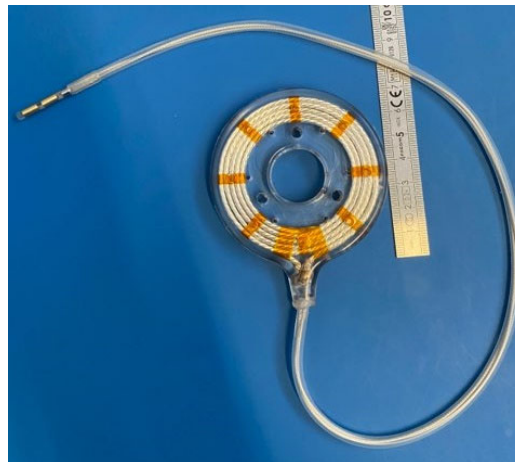


ITC: internal therapy controller
 90x65x16mm



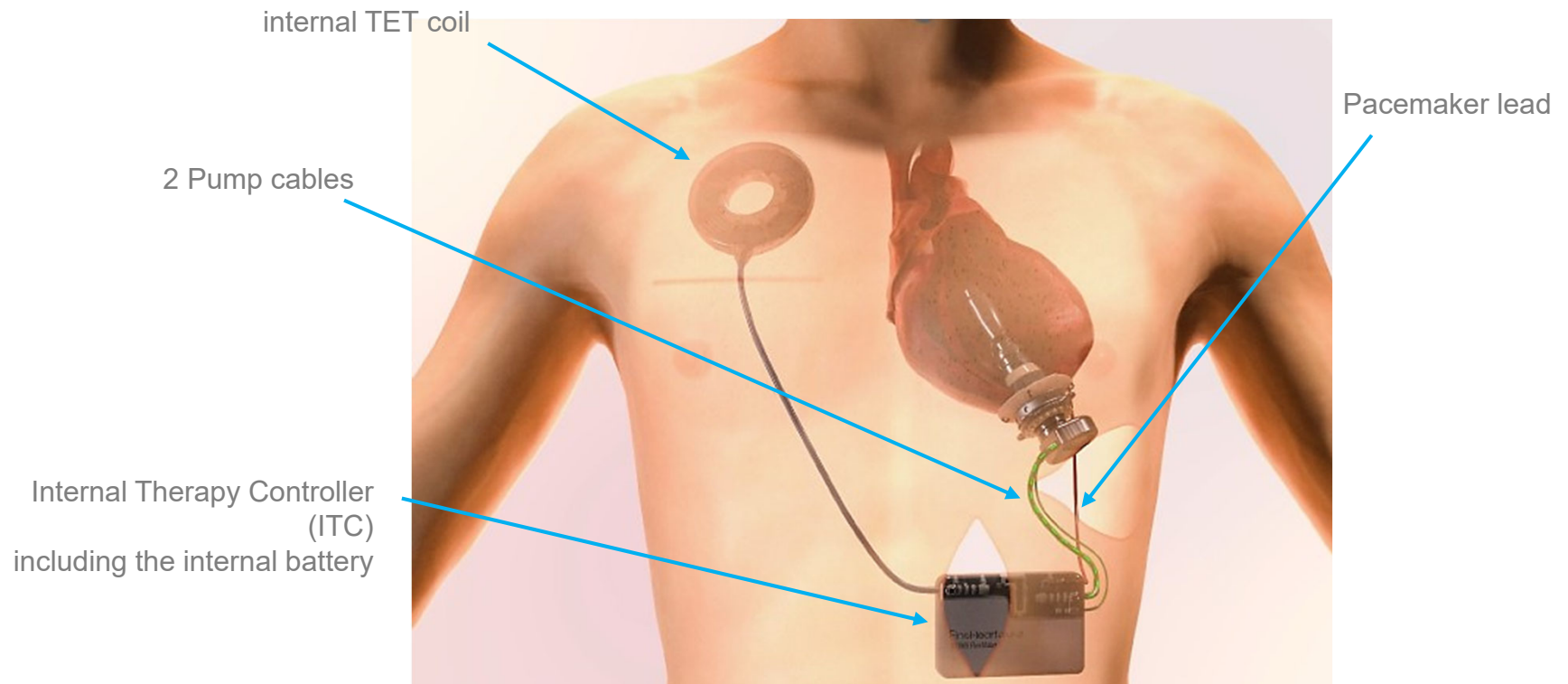
leadless ICD
 95x68x16mm

diameter: 70mm
 thickness: 08mm





In Summary ...



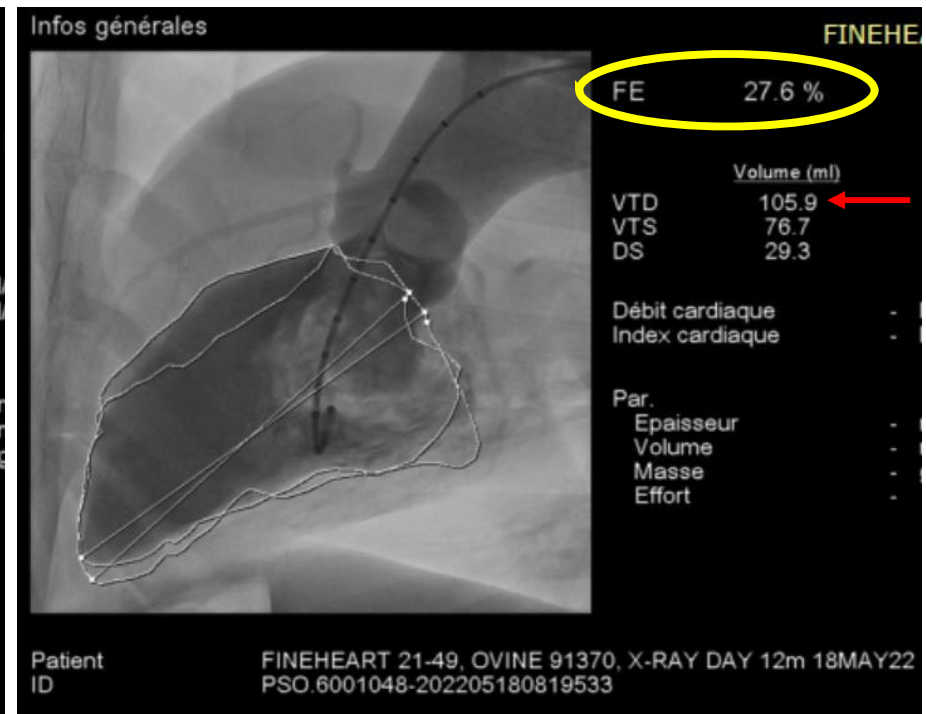
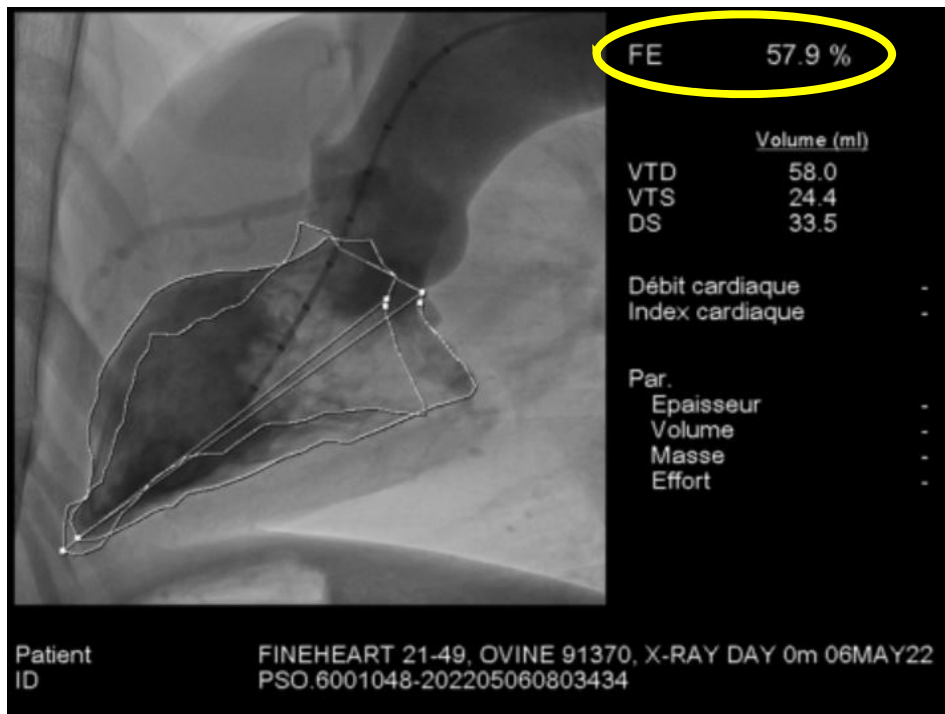


Ewe #91370 - severe chronic heart failure (6 ewes)

Induction of severe chronic heart Failure by 2 series of coronary μ -embolization

Ejection Fraction Day #0 before coronary μ -embolization

Ejection Fraction Day #12 after coronary μ -embolization



Strictly Confidential





In Summary ...

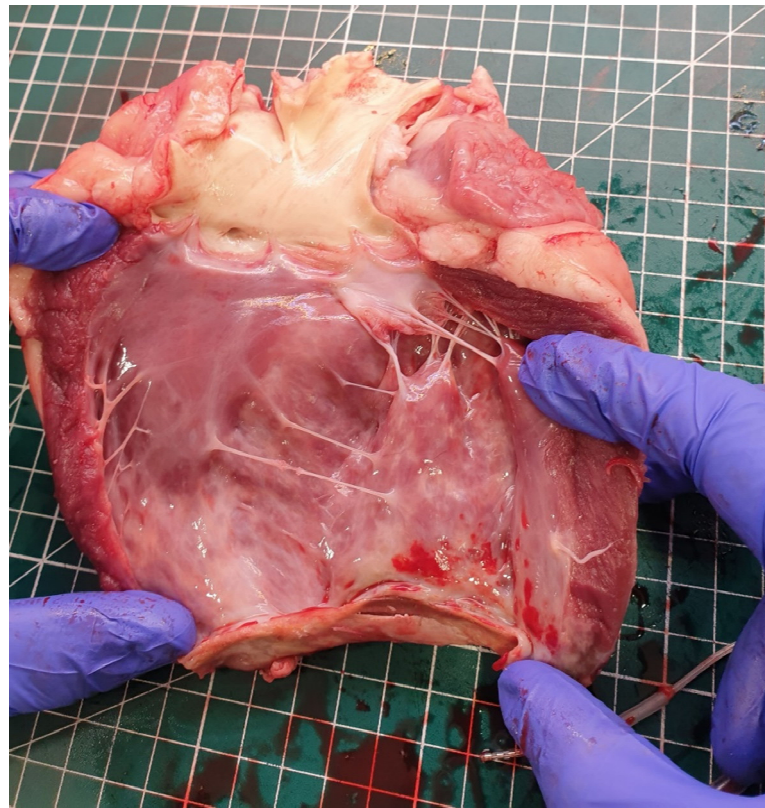
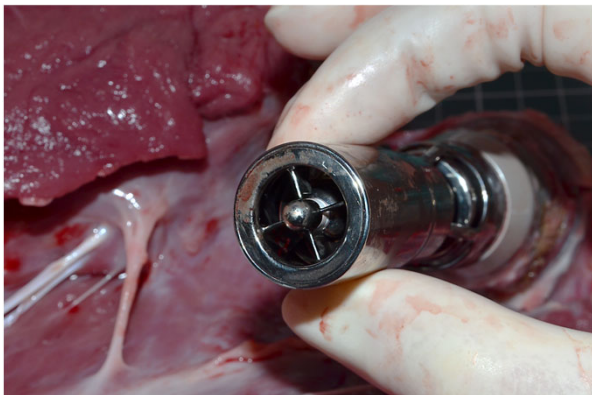
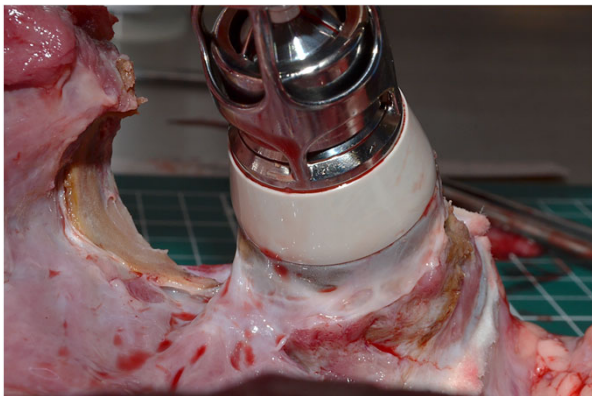
severe chronic heart failure in adult sheep

by using coronary μ -embolization – 2 procedures

Recovery results	LVEF baseline (%)	D+14	D+30	Pump removed	D+60 with pump reimplanted
Ewe #1	27	55	65	26	59
Ewe #2	27	48	63	25	61
Ewe #3	28	56	67	-	-
Ewe #4	33	49	61	-	-
Ewe #5	21	42	64	-	-
Ewe #6	22	58	62	-	-
mean\pmSD	27 \pm 4	56 \pm 6	63 \pm 2		



Fixation Tube endothelialization & protective tube upper part



protective
based-PEEK layer

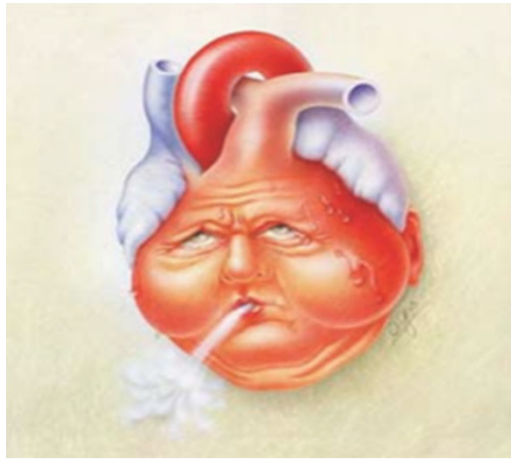
sand-blasted μ -spheres
of Ti

Conclusion

- **IC terminale**
 - De + en + fréquente
 - Mauvais pronostic
 - Pénurie de greffon et nombreuses contre indication à la greffe

- **ACM de longue durée** : progrès évidents et majeurs

- **Place dans l'IC systolique terminale**
 - Aigues ou chroniques
 - Après éventuelles assistances de courte durée
 - Indication : BTT / DT / BTR / BTD



Merci de votre attention