Assistances circulatoires : nouvelles perspectives

Cristian Mirabile

Réanimation Cardiaque Congénitale

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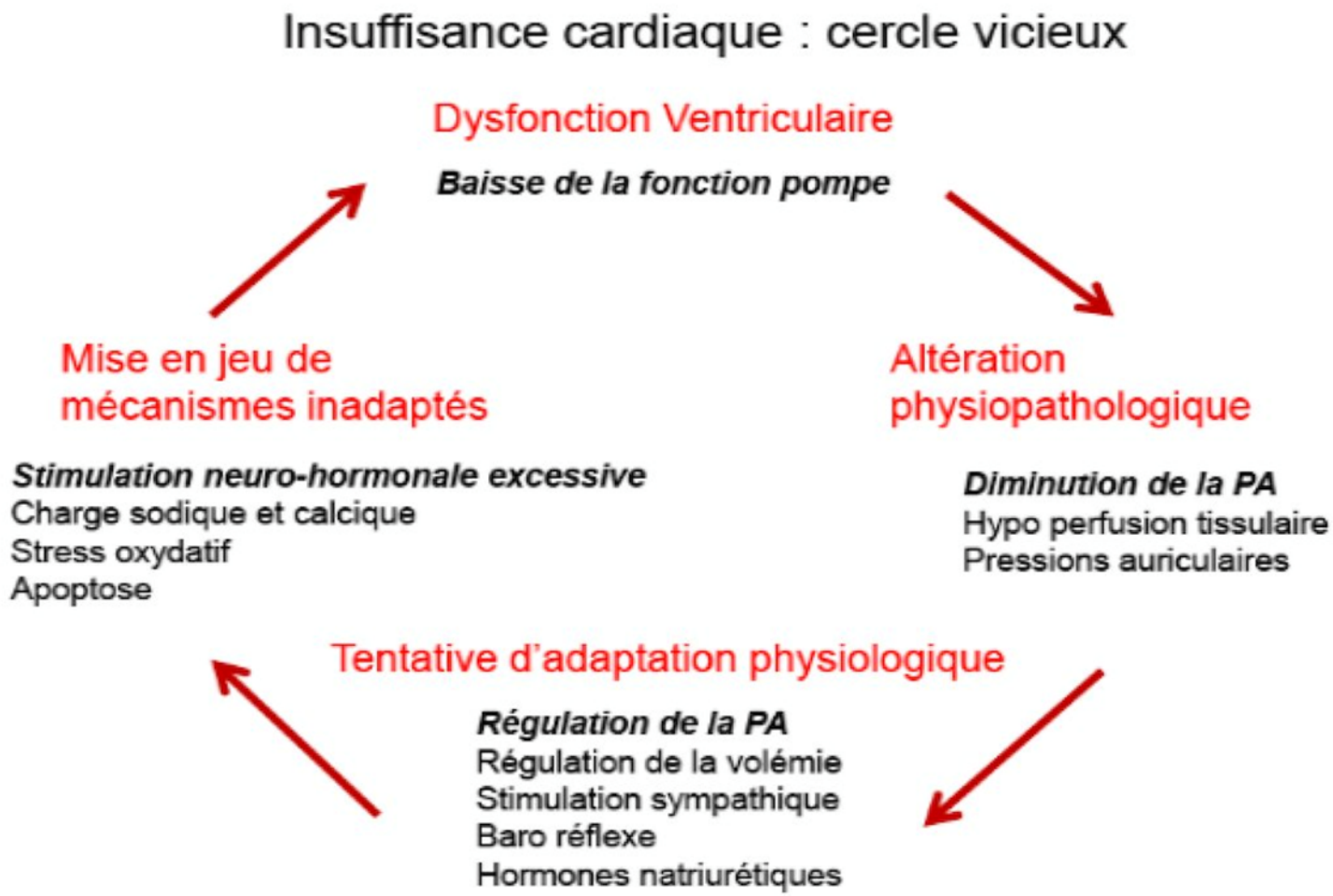
Physiopathologie insuffisance cardiaque



HÔPITAUX Paris Saint-Joseph Marie-Lannelongue

Journal of *Clinical Medicine*

Review

Chronic Heart Failure in Children: State of the Art and New Perspectives

J. Clin. Med. **2023**, *12*, 2611

Biagio Castaldi [1], Elena Cuppini [1,*], Jennifer Fumanelli [1], Angela Di Candia [1,2], Jolanda Sabatino [1,2], Domenico Sirico [1], Vladimiro Vida [3], Massimo Padalino [2,3] and Giovanni Di Salvo [1,2]

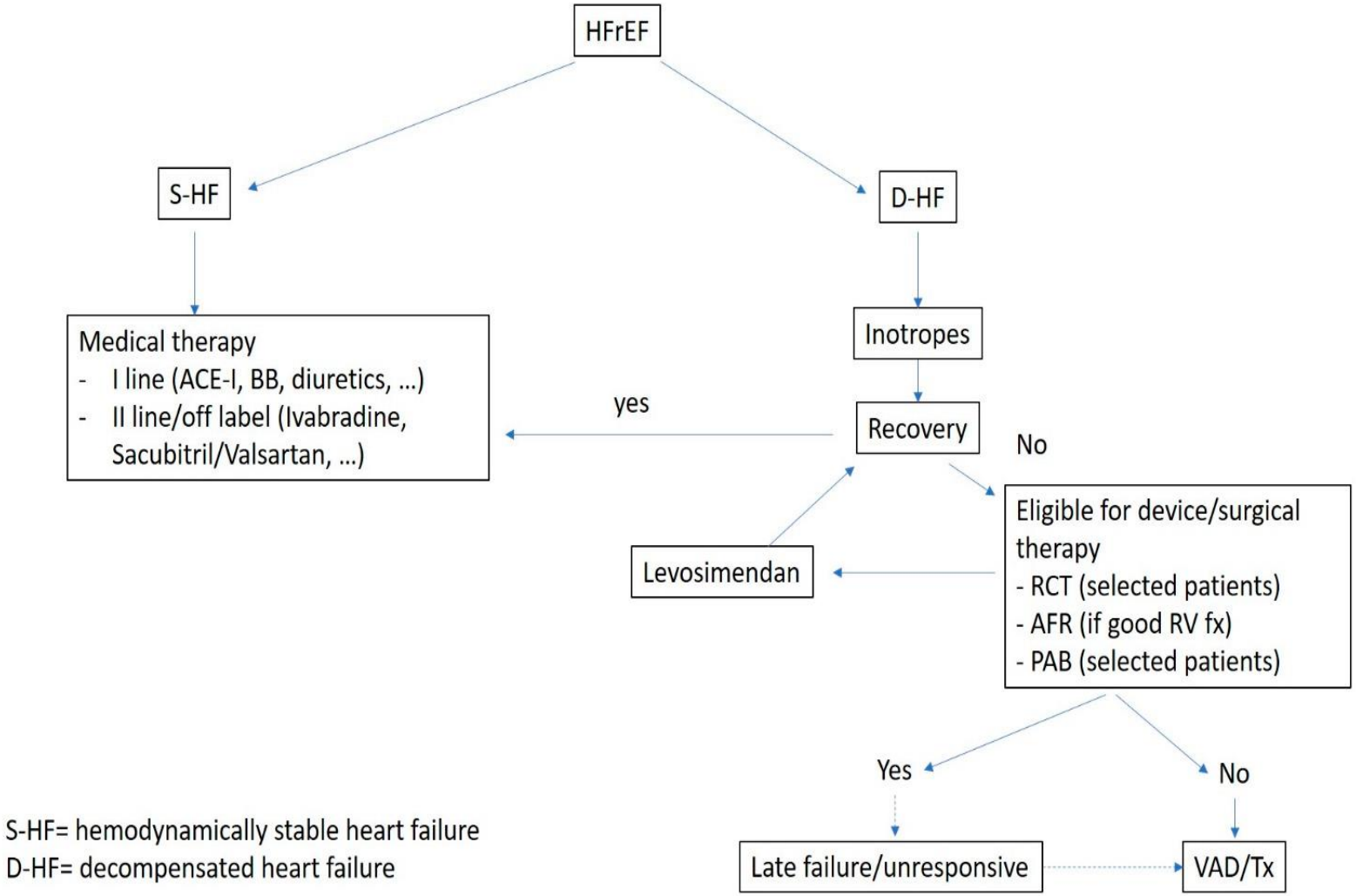
Category	Diagnoses in Category
Congenital heart disease (CHD)	An anomalous left coronary artery from the pulmonary artery (ALCAPA), critical aortic stenosis, coarctation of the aorta, and single-ventricle congenital heart disease.
Inherited cardiomyopathy	HCM, RCM, DCM, ARVC, LVNC, fatty acid oxidation disorder mitochondrial disorders, Barth syndrome, Danon disease, and limb-girdle dystrophy.
Acquired conditions	Myocarditis, Kawasaki disease, arrhythmia, systemic lupus erythematosus, dermatomyositis, rheumatic heart disease, and chemotherapy.

ACE inhibitors	
Captopril	0.5–2 mg/kg/dose 2–5 times/day (max 25 mg/dose)
Enalapril	0.1–0.5 mg/kg/day (max 20 mg/dose)
Lisinopril	0.05–2 mg/kg/die once or twice/day
Angiotensin receptor blockersc (ARB)	
Losartan	0.5–2 mg/kg/day
Beta-blockers	
B1 selective	
Bisoprolol	0.05–0.2 mg/kg/day 1–2 times/day
Metoprolol	0.1 mg/kg dose 2 times/day (max 1 mg/kg dose)
B1 + B2 selective	
Propranolol	
Carvedilol	0.1 mg/kg 2 times/day
Diuretics	
Furosemide	0.5–2 mg/kg/die
Spironolacton	0.5–2 mg/kg/die
Hydrochlorothiazide	0.5–1 mg/kg/die

Table 3. Summary of the clinical trials on new drugs for HF in pediatric and adult populations.

Ivabradine		worsening heart failure.			
	Pediatric	Ivabradine in children with DCM and symptomatic chronic HF trial: a randomized, double-blind, placebo-controlled trial with 12-months follow-up [21]	N = 116; Ivabradine safely reduced the resting HR of children with chronic HF and CMD and an improvement in ejection fraction, functional class, and NT-pro BNP was noted.	Dose: 0.02–0.05 mg/kg × 2v/die < 40 kg, >40 Kg 2.5 mg × 2/die	FDA approval in 2019 EMA off label
Sacubitril/Valsartan		Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure (PARADIGM-HF) [22]	N = 8442 patients with class NYHA II, III, or IV and FE ≤ 40% to receive either S/V (at a dose of 200 mg twice daily) or enalapril (at a dose of 10 mg twice daily), in addition to recommended therapy. S/V was superior to enalapril in reducing the risks of death and hospitalization for heart failure.	24/26 mg, 49/51 mg, and target dose 97/103 mg twice a day	FDA and EMA approval
	Pediatric	Design for the sacubitril/valsartan (LCZ696) compared with enalapril study of pediatric patients with heart failure due to systemic left ventricle systolic dysfunction (PANORAMA-HF study) [32]	N= 393 patients waiting for all subjects to complete the 52 weeks of therapy before performing data analysis.	<40 kg, the starting dose is 1.6 mg/kg of the combined amount of both valsartan and sacubitril. Aum every 2 weeks upward from 2.3 mg/kg up to a max dose of 3.1 mg/kg based on tolerance.	In October 2019, the FDA patients with symptomatic heart failure with LV systolic dysfunction, >1-year-old
Drugs	**Population**	**Title**	**Key Findings**	**Dose**	**Approval**
Dapaglifozin	Adult	Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction [23] Effect of Empagliflozin on the Clinical Stability of Patients With Heart Failure and a Reduced Ejection Fraction [24]	N = 4744 patients with HFrEF, dapagliflozin reduces the risk of worsening heart failure or death from CV causes compared to placebo N = 3730 patients with HFrEF double-blind treatment with placebo or empagliflozin, reduced the risk and total number of inpatient and outpatient worsening HF events, with benefits seen early after 12 days	10 mg once daily	FDA and EMA approval
	Pediatric	Early Clinical Experience with Dapagliflozin in Children with Heart Failure [26]	N = 38 patients dapagliflozin was added to the HF regimen, and after 312 days of therapy, LVEF increased significantly from 32 to 37.2%	0.1–0.2 mg/kg once daily (max 10 mg)	No approval
Omecamtiv	Adult	Cardiac Myosin Activation with Omecamtiv Mecarbil in Systolic Heart Failure [27]	N = 8256 patients with HFrEF receive omecamtiv mecarbil or a placebo, in addition to standard heart-failure therapy, reduce the incidence of a composite of a heart-failure event or death from cardiovascular causes	25 mg, 37.5 mg, or 50 mg twice daily	No approval
	Pediatric	No data	No data	No data	No data
Vericiguat	Adult	Vericiguat in Patients with Heart Failure and Reduced Ejection Fraction (VICTORIA trial) [29]	N = 5050 patients with HFrEF, vericiguat reduced risk of cardiovascular death, all-cause death, and HF hospitalization (phase 3)	starting dose 2.5 mg orally once daily with food. Double the dose every 2 weeks to reach the target e dose of 10 mg once daily	FDA and EMA approval in 2021
	Pediatric	No data	No data	No data	No data

Devices inter-atriales
Resyncronisation electrique
Cerclage TAP
Nutrition
VAD (mini-VAD)



S-HF= hemodynamically stable heart failure
D-HF= decompensated heart failure

Castaldi, J. Clin Med. 2023

INTERMACS

Interagency Registry for Mechanically Assisted Circulatory Support

PEDIMACS

Pediatric Interagency Registry for Mechanically Assisted Circulatory Support

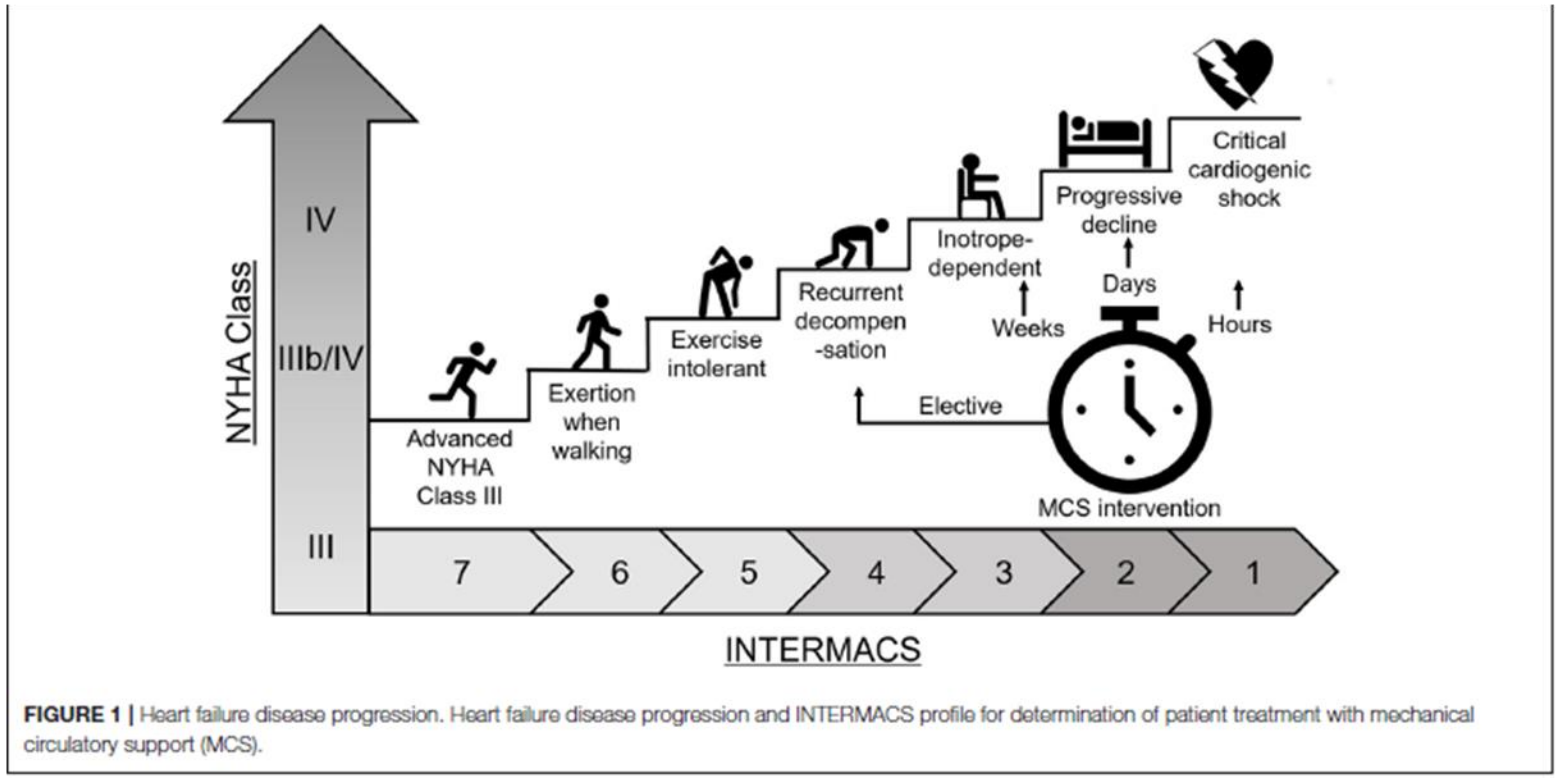


FIGURE 1 | Heart failure disease progression. Heart failure disease progression and INTERMACS profile for determination of patient treatment with mechanical circulatory support (MCS).

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Published by Elsevier Inc.
0003-4975/$36.00
https://doi.org/10.1016/j.athoracsur.2022.10.042

THE SOCIETY OF THORACIC SURGEONS PEDIMACS ANNUAL REPORT

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Sixth Annual Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs) Report: The Society Of Thoracic Surgeons Pedimacs Annual Report

Iki Adachi, MD,[1] David M. Peng, MD,[2] Seth A. Hollander, MD,[3] Kathleen E. Simpson, MD,[4] Ryan R. Davies, MD,[5] Jeffrey P. Jacobs, MD,[6] Christina J. VanderPluym, MD,[7] Francis Fynn-Thompson, MD,[8] Dennis A. Wells, MD,[9] Sabrina P. Law, MD,[10] Shahnawaz Amdani, MD,[11] Ryan Cantor, PhD,[12] Devin Koehl, MSDS,[12] James K. Kirklin, MD,[12] David L. S. Morales, MD,[9] and Joseph W. Rossano, MD,[13] for the Pedimacs Investigators

ABSTRACT

BACKGROUND The Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs), supported by The Society of Thoracic Surgeons, provides detailed information on pediatric patients supported with ventricular assist devices (VADs).

METHODS From September 19, 2012, to December 31, 2021, there were 1355 devices in 1109 patients (<19 years) from 42 North American Hospitals.

RESULTS Cardiomyopathy was the most common underlying cause (59%), followed by congenital heart disease (25%) and myocarditis (9%). Regarding device type, implantable continuous (IC) VADs were most common at 40%, followed by paracorporeal pulsatile (PP; 28%) and paracorporeal continuous (PC; 26%). Baseline demographics differed, with the PC cohort being younger, smaller, more complex (ie, congenital heart disease), and sicker at implantation ($P < .0001$). At 6 months after VAD implantation, a favorable outcome (transplantation, recovery, or alive on device) was achieved in 84% of patients, which was greatest among those on IC VADs (92%) and least for PC VADs (69%). Adverse events were not uncommon, with nongastrointestinal bleeding (incidence of 14%) and neurologic dysfunction (11% [stroke, 4%]), within 2 weeks after implantation being the most prevalent. Stroke and bleeding had negative impacts on overall survival (P [.002 and $P < .001$, respectively).

CONCLUSIONS This Sixth Pedimacs Report demonstrates the continued evolution of the pediatric field. The complexity of cardiac physiologies and anatomic constraint mandates the need for multiple types of devices used (PC, PP, IC). Detailed analyses of each device type in this report provide valuable information to further advance the care of this challenging and vulnerable population.

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Accepted for publication Oct 29, 2022.

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European Journal of Cardio-Thoracic Surgery 2022, 62(2), ezac355
https://doi.org/10.1093/ejcts/ezac355 Advance Access publication 27 June 2022

REPORT

Cite this article as: de By TMMH, Schweiger M, Hussain H, Amodeo A, Martens T, Bogers AJJC *et al*. The European Registry for Patients with Mechanical Circulatory Support (EUROMACS): third Paediatric (Paedi-EUROMACS) report. Eur J Cardiothorac Surg 2022; doi:10.1093/ejcts/ezac355.

The European Registry for Patients with Mechanical Circulatory Support (EUROMACS): third Paediatric (Paedi-EUROMACS) report

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Received 21 February 2022; received in revised form 23 May 2022; accepted 25 June 2022

Abstract

OBJECTIVES: A third paediatric report has been generated from the European Registry for Patients with Mechanical Circulatory Support (EUROMACS). The purpose of EUROMACS, which is operated by the European Association for Cardio-Thoracic Surgery, is to gather data related to durable mechanical circulatory support for scientific purposes and to publish reports with respect to the course of mechanical circulatory support therapy. Since the first report issued, efforts to increase compliance and participation have been extended. Additionally, the data provided the opportunity to analyse patients of younger age and lower weight.

METHODS: Participating hospitals contributed pre-, peri- and long-term postoperative data on mechanical circulatory support implants to the registry. Data for all implants in paediatric patients (<19 years of age) performed from 1 January 2000 to 31 December 2020 were analysed. This report includes updates of patient characteristics, implant frequency, outcome (including mortality rates, transplants and recovery rates) as well as adverse events including neurological dysfunction, device malfunction, major infection and bleeding.

†The first two authors Contributed equally to this report

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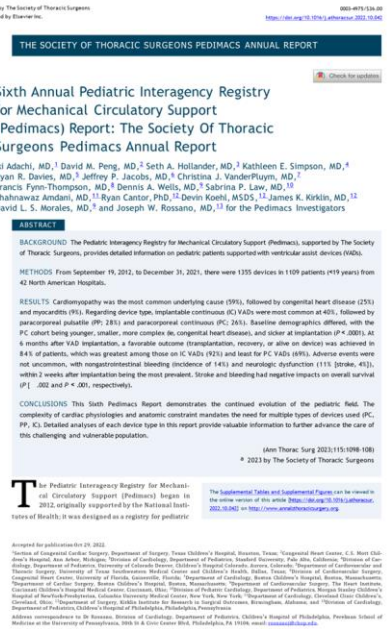
- **Septembre 2012 - 31 décembre 2021**
- **1355 machines**
- **1109 patients de < 19 ans)**
- **42 Hopitaux Amérique du Nord**
- **Pedimacs vs Intermacs :**
- **# pts vs devices ;**
- **# longue + courte vs longue durée ;**
- **# EIs évalués différemment (changement VAD)**

TABLE 1 Characteristics of Pedimacs Patients (N ¼ 1109), September 19, 2012–December 31, 2021

Characteristics	Overall (N ¼ 1109)	Paracorporeal Pulsatile (n ¼ 306)	Paracorporeal Continuous (n ¼ 293)	Implantable Continuous (n ¼ 448)	P Value[a]
Age, y	7.6 ± 6.4	2.7 ± 3.5	3.3 ± 4.7	13.0 ± 3.9	<.0001
Age group					
<1 year	298 (26.9)	147 (48.0)	149 (50.9)		<.0001
1-5 years	236 (21.3)	120 (39.2)	86 (29.4)	26 (5.8)	<.0001
6-10 years	164 (14.8)	23 (7.5)	26 (8.9)	102 (22.8)	<.0001
11-19 years	411 (37.1)	16 (5.2)	32 (10.9)	320 (71.4)	<.0001
Weight, kg	32.5 ± 30.5	11.9 ± 12.2	14.7 ± 16.9	55.1 ± 28.7	<.0001
Weight					
<5 kg	138 (12.5)	65 (21.3)	72 (24.7)		<.0001
5-9 kg	219 (19.8)	114 (37.4)	100 (34.4)	2 (0.4)	<.0001
10-20 kg	202 (18.3)	94 (30.8)	67 (23.0)	39 (8.7)	<.0001
21-40 kg	185 (16.7)	22 (7.2)	25 (8.6)	121 (27.1)	<.0001
41-70 kg	223 (20.2)	8 (2.6)	22 (7.6)	170 (38.0)	<.0001
71-100 kg	103 (9.3)	1 (0.3)	5 (1.7)	86 (19.2)	<.0001
>100 kg	35 (3.2)	1 (0.3)		29 (6.5)	<.0001
Diagnosis					
Cardiomyopathy	654 (59.1)	186 (61.0)	108 (36.9)	334 (74.9)	<.0001
Dilated	611 (93.4)	167 (89.8)	97 (89.8)	321 (96.1)	.008
Restrictive	26 (4.0)	11 (5.9)	7 (6.5)	8 (2.4)	.06
Hypertrophic	15 (2.3)	8 (4.3)	3 (2.8)	4 (1.2)	.08
Myocarditis	98 (8.9)	23 (7.5)	34 (11.6)	31 (7.0)	.03
Congenital heart disease	274 (24.8)	75 (24.6)	121 (41.3)	67 (15.0)	<.0001
Single ventricle	172 (62.8)	40 (53.3)	87 (71.9)	43 (64.2)	<.0001
Biventricular	102 (37.2)	35 (46.7)	34 (28.1)	24 (35.8)	.002
Other	80 (7.2)	21 (6.9)	30 (10.2)	14 (3.1)	.0004
Patient profile level					
1. Critical cardiogenic shock	348 (31.5)	95 (31.1)	136 (46.6)	87 (19.5)	<.0001
2. Progressive decline	620 (56.1)	179 (58.7)	132 (45.2)	280 (62.6)	<.0001
3. Stable but inotrope dependent	116 (10.5)	27 (8.9)	19 (6.5)	68 (15.2)	.0004
4-7. Resting symptoms or less sick	21 (1.9)	4 (1.3)	5 (1.7)	12 (2.7)	.4
Device type					
LVAD	913 (82.3)	235 (76.8)	220 (75.1)	404 (90.2)	<.0001
RVAD	48 (4.3)	7 (2.3)	28 (9.6)	12 (2.7)	<.0001
BiVAD	144 (13.0)	64 (20.9)	45 (15.4)	32 (7.1)	<.0001
TAH	4 (0.4)	.	.	.	.
Device strategy					
Bridge to transplant—listed	553 (49.9)	230 (75.2)	115 (39.2)	195 (43.5)	<.0001
Bridge to candidacy	394 (35.5)	70 (22.9)	89 (30.4)	221 (49.3)	<.0001
Destination therapy	20 (1.8)	2 (0.7)		16 (3.6)	.0003
Bridge to recovery	102 (9.2)	2 (0.7)	73 (24.9)	14 (3.1)	<.0001
Other	40 (3.6)	2 (0.7)	16 (5.5)	2 (0.4)	<.0001
Previous cardiac operation	477 (43.0)	139 (45.4)	173 (59.0)	138 (30.8)	<.0001
ALT >100 U/L	229 (21.6)	49 (16.8)	57 (20.9)	103 (23.7)	.1
Bilirubin >1.2 mg/dL	352 (36.5)	86 (30.7)	101 (39.5)	147 (38.3)	.06
eGFR, mL/min per 1.73 m^2					
<30	41 (3.8)	9 (3.0)	22 (7.8)	8 (1.8)	.002
30-60	206 (19.0)	60 (20.1)	66 (23.3)	65 (14.7)	.01
>60	835 (77.2)	230 (76.9)	195 (68.9)	369 (83.5)	<.0001
Intubated	579 (54.9)	209 (72.8)	224 (79.4)	109 (25.5)	<.0001
Inotropes	1051 (94.9)	286 (93.5)	279 (95.5)	425 (94.9)	.5
Paralyzed	285 (27.4)	107 (37.8)	110 (39.4)	49 (11.7)	<.0001
Feeding tube/TPN dependent	660 (68.5)	252 (92.3)	225 (90.0)	156 (39.2)	<.0001

[a]P value compares characteristics across the 3 device classifications. Categorical variables are presented as number (percentage). Continuous variables are presented as mean ± standard deviation. ALT, alanine aminotransferase; BiVAD, biventricular assist device; eGFR, estimated glomerular filtration rate; LVAD, left ventricular assist device; RVAD, right ventricular assist device; TAH, total artificial heart; TPN, total parenteral nutrition.



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Published by Elsevier Inc. https://doi.org/10.1016/j.athoracsur.2022.10.042

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Iki Adachi, MD,[1] David M. Peng, MD,[2] Seth A. Hollander, MD,[3] Kathleen E. Simpson, MD,[4] Ryan R. Davies, MD,[5] Jeffrey P. Jacobs, MD,[6] Christina J. VanderPluym, MD,[7] Francis Fynn-Thompson, MD,[8] Dennis A. Wells, MD,[9] Sabrina P. Law, MD,[10] Shahnawaz Amdani, MD,[11] Ryan Cantor, PhD,[12] Devin Koehl, MSDS,[12] James K. Kirklin, MD,[12] David L. S. Morales, MD,[9] and Joseph W. Rossano, MD,[13] for the Pedimacs Investigators

ABSTRACT

BACKGROUND The Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs), supported by The Society of Thoracic Surgeons, provides detailed information on pediatric patients supported with ventricular assist devices (VADs).

METHODS From September 19, 2012, to December 31, 2021, there were 1355 devices in 1109 patients (<19 years) from 42 North American Hospitals.

RESULTS Cardiomyopathy was the most common underlying cause (59%), followed by congenital heart disease (25%) and myocarditis (9%). Regarding device type, implantable continuous (IC) VADs were most common at 40%, followed by paracorporeal pulsatile (PP; 28%) and paracorporeal continuous (PC; 26%). Baseline demographics differed, with the PC cohort being younger, smaller, more complex (ie, congenital heart disease), and sicker at implantation ($P < .0001$). At 6 months after VAD implantation, a favorable outcome (transplantation, recovery, or alive on device) was achieved in 84% of patients, which was greatest among those on IC VADs (92%) and least for PC VADs (69%). Adverse events were not uncommon, with nongastrointestinal bleeding (incidence of 14%) and neurologic dysfunction (11% [stroke, 4%]), within 2 weeks after implantation being the most prevalent. Stroke and bleeding had negative impacts on overall survival (P [.002 and $P < .001$, respectively).

CONCLUSIONS This Sixth Pedimacs Report demonstrates the continued evolution of the pediatric field. The complexity of cardiac physiologies and anatomic constraint mandates the need for multiple types of devices used (PC, PP, IC). Detailed analyses of each device type in this report provide valuable information to further advance the care of this challenging and vulnerable population.

(Ann Thorac Surg 2023;115:1098-108)

The Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs) began in 2012, originally supported by the National Institutes of Health; it was designed as a registry for pediatric

The Supplemental Tables and Supplemental Figures can be viewed in the online version of this article https://doi.org/10.1016/j.athoracsur.2022.10.042 on http://www.annalsthoracicsurgery.org.

Accepted for publication Oct 29, 2022.

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TABLE 2 Characteristics of Patients by Diagnosis (N ¼ 838), Pedimacs: September 19, 2012–December 31, 2021

Characteristics	Cardiomyopathy (n ¼ 654)	Congenital Heart Disease (n ¼ 274)	*P* Value
Age, y	8.5 ± 6.5	4.8 ± 5.4	<.0001
Age group			
<1 year	161 (24.6)	109 (39.8)	<.0001
1-5 years	112 (17.1)	80 (29.2)	<.0001
6-10 years	97 (14.8)	37 (13.5)	.6
11-19 years	284 (43.4)	48 (17.5)	<.0001
Weight, kg	37.6 ± 32.8	18.7 ± 20.7	.07
Weight			
<5 kg	59 (9.1)	59 (21.6)	<.0001
5-9 kg	130 (20.0)	69 (25.3)	.07
10-20 kg	92 (14.1)	71 (26.0)	<.0001
21-40 kg	112 (17.2)	37 (13.6)	.2
41-70 kg	151 (23.2)	27 (9.9)	<.0001
71-100 kg	79 (12.1)	8 (2.9)	<.0001
>101 kg	28 (4.3)	2 (0.7)	.005
Patient profile level			
1. Critical cardiogenic shock	179 (27.4)	95 (34.9)	.02
2. Progressive decline	390 (59.7)	152 (55.9)	.3
3. Stable but inotrope dependent	74 (11.3)	21 (7.7)	.09
4-7. Resting symptoms or less sick	10 (1.5)	4 (1.5)	.9
Device type			
LVAD	571 (87.3)	211 (77.0)	<.0001
RVAD		39 (14.2)	<.0001
BiVAD	82 (12.5)	22 (8.0)	.04
TAH	1 (0.2)	2 (0.7)	.2
Device class			
Paracorporeal pulsatile	334 (51.1)	67 (24.5)	.7
Paracorporeal continuous	108 (16.5)	121 (44.2)	<.0001
Implantable continuous	186 (28.4)	75 (27.4)	<.0001
Percutaneous	25 (3.8)	9 (3.3)	.2
TAH	1 (0.2)	2 (0.7)	.7
Device strategy			
Bridge to transplant—listed	341 (52.1)	150 (54.7)	.5
Bridge to candidacy	256 (39.1)	86 (31.4)	.03
Destination therapy	16 (2.4)	3 (1.1)	.2
Bridge to recovery	32 (4.9)	24 (8.8)	.02
Other	9 (1.4)	11 (4.0)	.01
Previous cardiac operation	141 (21.6)	241 (88.0)	<.0001
ALT >100 U/L	141 (22.3)	37 (14.5)	.008
Bilirubin >1.2 mg/dL	191 (33.3)	118 (48.8)	<.0001
eGFR, mL/min per 1.73 m^2			
<30	18 (2.8)	13 (4.9)	.1
30-60	116 (18.0)	51 (19.1)	.7
>60	509 (79.2)	203 (76.0)	.3
Intubated	289 (46.4)	180 (69.2)	<.0001
Inotropes	620 (94.8)	262 (95.6)	.6
Paralyzed	149 (24.3)	83 (32.3)	.02
Feeding tube/TPN dependent	355 (62.5)	204 (82.9)	<.0001

Categorical variables are presented as number (percentage). Continuous variables are presented as mean ± standard deviation. ALT, alanine aminotransferase; BiVAD, biventricular assist device; eGFR, estimated glomerular filtration rate; LVAD, left ventricular assist device; RVAD, right ventricular assist device; TAH, total artificial heart; TPN, total parenteral nutrition.

Types de Dispositifs : dispositifs intracorporels (IC) (40 %), suivis des dispositifs pulsatiles paracorporels (PP) (28 %), des dispositifs continu paracorporels (PC) (26 %) et percutanés (< 5%)

Volumes Hospitaliers : implantations réalisées dans différents volumes hospitaliers (1-15/15-30/30-60/>60) avec la plus grande proportion d'implants réalisés dans les grands hôpitaux (>60 patients signalés à Pedimacs)

Taux de Survie : Le temps de suivi médian sur VAD était de 2 mois, la majorité des patients recevant des transplantations (DIFFERENCE IMPORTANTE avec Paedi-Euromacs). La courbe de survie Kaplan-Meier montre la survie globale pour le groupe de patients recevant des implants pendant la période spécifiée, stratifiée par l'âge à l'implantation, le type de dispositif et le profil du patient

Caractéristiques des Patients : La cardiomyopathie la cause la plus courante de défaillance cardiaque (59 %), suivie de la cardiopathie congénitale (25 %) et de la myocardite (9 %). Parmi les patients atteints de cardiopathie congénitale, la majorité VU. Les caractéristiques des patients variaient en fonction du type de dispositif, les patients plus jeunes et ceux atteints de cardiopathies congénitales étant plus susceptibles de recevoir des VAD PP et PC par rapport aux VAD IC

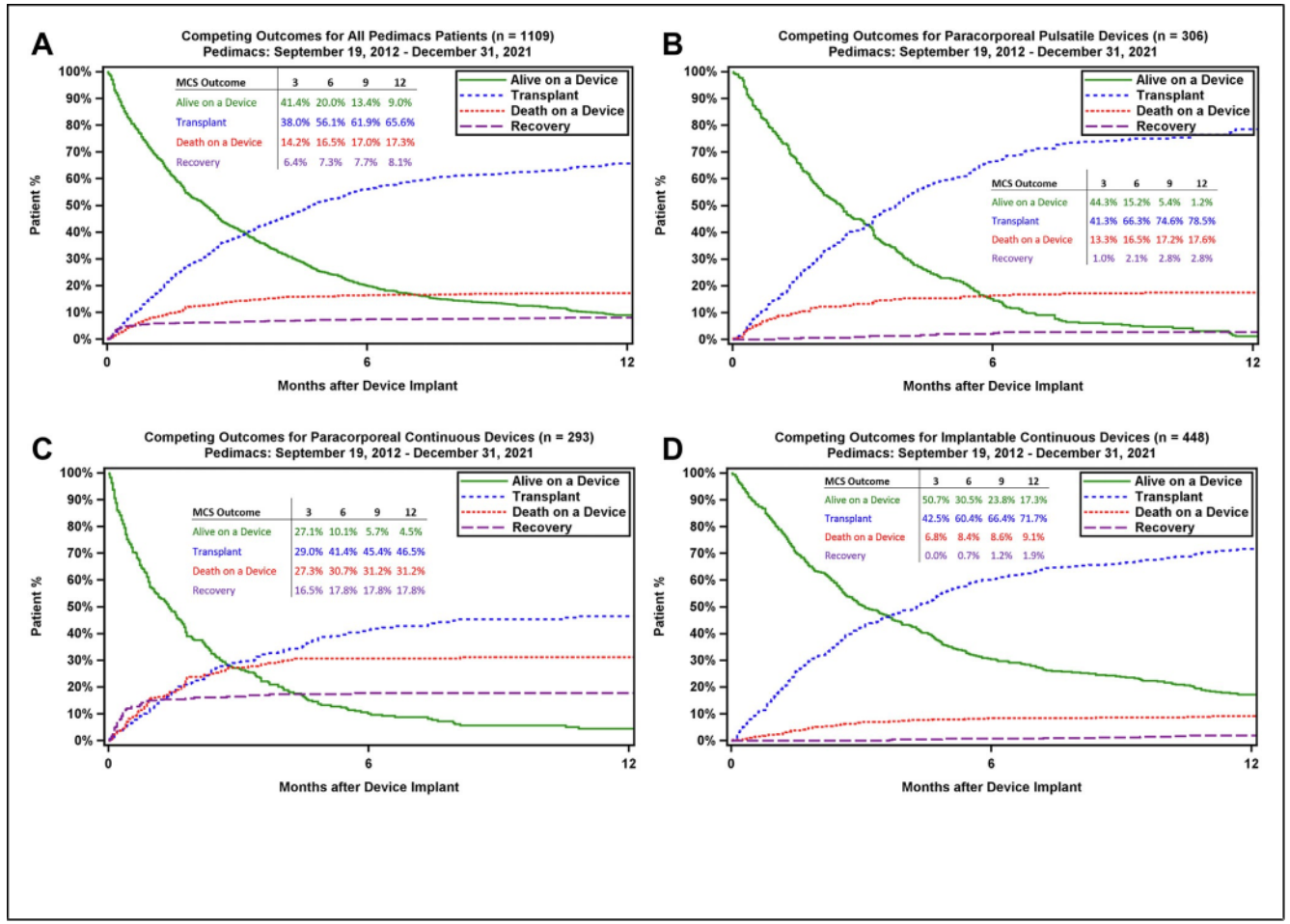


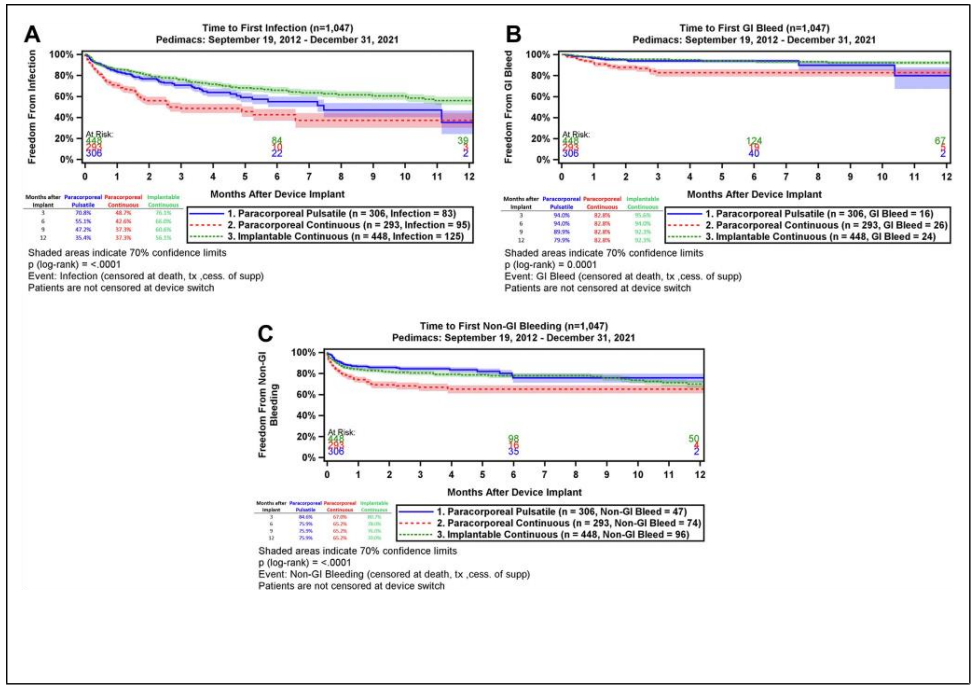
TABLE 3 Mode of Death, Pedimacs Patients (N ¼ 196), September 19, 2012–December 31, 2021

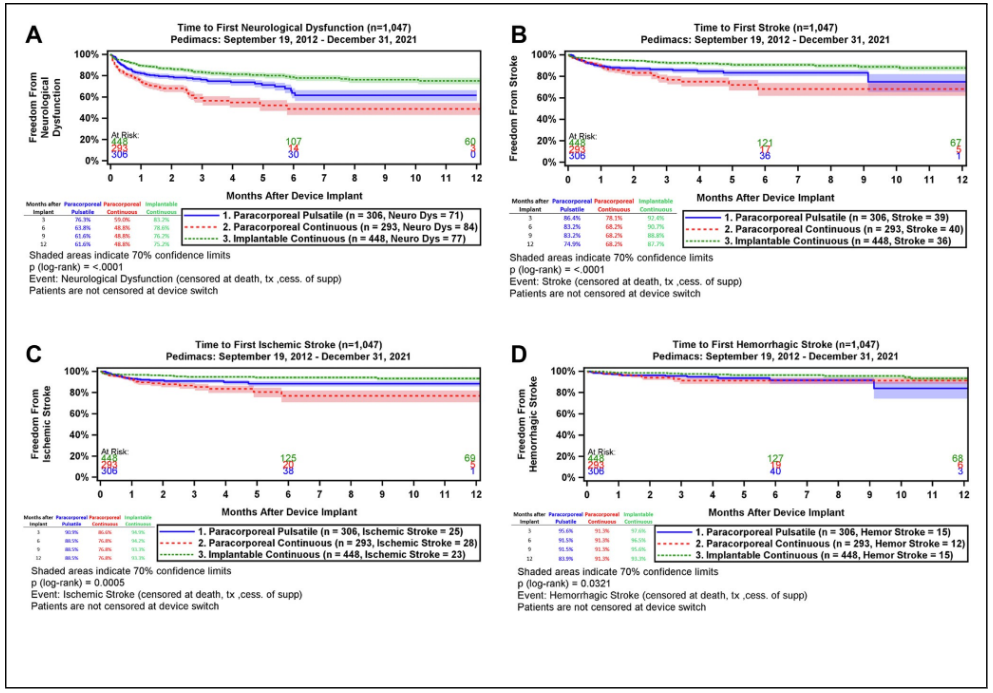
Variable	Overall (N ¼ 196)	Paracorporeal Pulsatile (n ¼ 53)	Paracorporeal Continuous (n ¼ 83)	Implantable Continuous (n ¼ 52)	*P* Value
Mode of death					.4
Circulatory	39 (19.9)	10 (18.9)	15 (18.1)	13 (25.0)	
Device malfunction	1 (0.5)	.	.	1 (1.9)	
Digestive: gastrointestinal	52 (26.5)	12 (22.6)	28 (33.7)	10 (19.2)	
Multisystem organ failure	44 (22.4)	12 (22.6)	19 (22.9)	9 (17.3)	
Major infection	11 (5.6)	6 (11.3)	3 (3.6)	2 (3.8)	
Neurologic	27 (13.8)	7 (13.2)	9 (10.8)	10 (19.2)	
Other	14 (7.1)	3 (5.7)	5 (6.0)	6 (11.5)	
Respiratory	8 (4.1)	3 (5.7)	4 (4.8)	1 (1.9)	

TABLE 4 Adverse Events, Pedimacs Patients (N ¼ 1047), September 19, 2012–December 31, 2021

		All (PP þ PC þ IC)			Paracorporeal Pulsatile			Paracorporeal Continuous			Implantable Continuous		
Event	Period[a]	Patients, %	Rate[b]	Device Incidence, %	Patients, %	Rate	Device Incidence, %	Patients, %	Rate	Device Incidence, %	Patients, %	Rate	Device Incidence, %
GI bleeding	Early	2	0.7	6	2	0.5	5	5	25.0	5	1	0.2	5
	Late	5	0.2		4	0.2		5	14.0		5	0.1	
Non-GI bleeding	Early	14	4.4	21	10	2.8	15	19	7.0	25	12	3.9	21
	Late	9	0.4		6	0.3		9	1.3		11	0.3	
Infection	Early	12	4.1	29	9	2.6	27	19	8.1	32	10	2.8	28
	Late	21	1.2		22	1.7		21	2.7		22	0.8	
Device malfunction/thrombus	Early										3	0.8	13
	Late										11	0.3	
Neurologic dysfunction	Early	11	3.3	22	11	3.6	23	16	5.9	29	6	1.7	17
	Late	14	0.5		14	0.8		15	1.2		12	0.3	
CVA	Early	4	1.3	11	6	1.5	13	6	1.9	14	3	0.8	8
	Late	7	0.3		8	0.4		8	0.6		6	0.1	
Ischemic stroke	Early	3	0.9	7	3	0.8	8	4	1.3	10	3	0.7	5
	Late	6	0.2		6	0.3		6	0.4		3	0.1	
Hemorrhagic stroke	Early	1	0.3	4	2	0.5	5	2	0.5	4	.2	0.06	3
	Late	3	0.09		3	0.1		3	0.2		3	0.1	

[a]Early is within 2 weeks after implantation; late is beyond 2 weeks after implantation; [b]Rates are reported per patient-year. CVA, cerebrovascular accident; GI, gastrointestinal; IC, implantable continuous; PC, paracorporeal continuous; PP, paracorporeal pulsatile.





European Journal of Cardio-Thoracic Surgery 2022, 62(2),

The European Registry for Patients with Mechanical Circulatory Support (EUROMACS): third Paediatric (Paedi-EUROMACS) report

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<19 ans, 25 hopitaux, 1 Jan 2000-31 Déc 2020, 537 implantations, 480 pts

CMP 59% > CHD 15% (25% PediMACS), myocardite 14%

Outcome + 86% (greffe, récupération, on VAD)

Mortalité 1an 20.8%, 2ans 22%

Peu de greffes à 6 mois (33%, ≠ avec registre NA PediMACS)

Mortalité >> si < 12 mois âge implantation et < 20 kgs

Que VAD longue durée (≠ PediMACS)

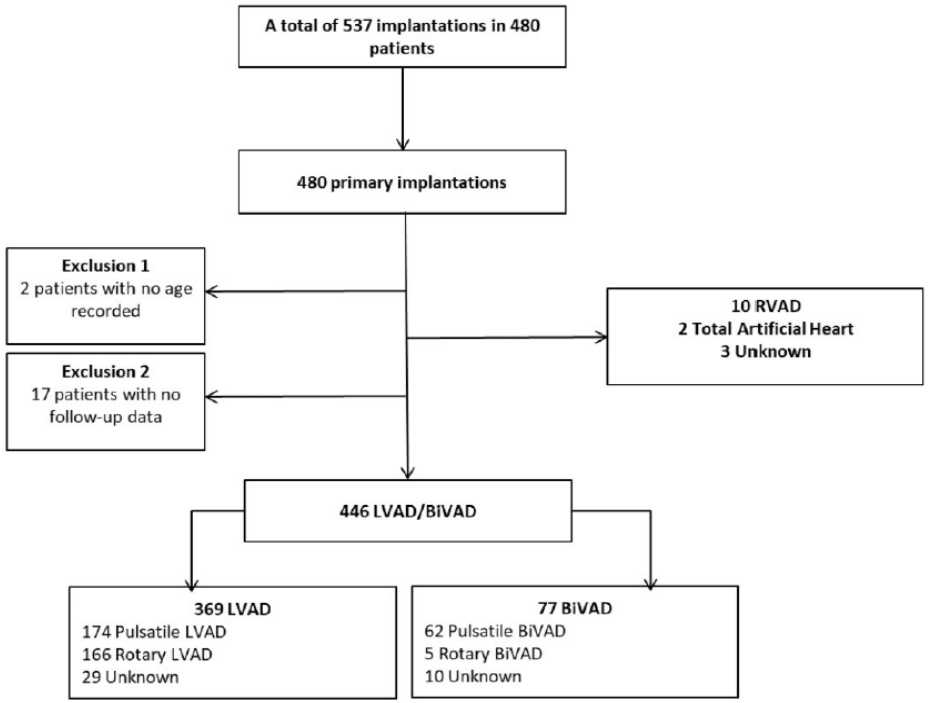

Figure 1: Selection flowchart

HÔPITAUX Paris
Saint-Joseph
Marie-Lannelongue

Table 1: Patient characteristics

	Overall (n = 461)	Era I (≤2014) (n = 181)	Era II (≥2015) (n = 280)	P-value
Age (years)				0.523
Median (range)	8 (0–19)	9 (0–19)	8 (0–19)	
Mean ± SD	8.13 ± 6.53	8.37 ± 6.85	7.97 ± 6.32	
Age categories (years), n (%)				0.068
<1 y	90 (19.52)	42 (23.20)	48 (17.14)	
1–5 y	110 (23.86)	37 (20.44)	73 (26.07)	
6–10 y	68 (14.75)	20 (11.05)	48 (17.14)	
11–19 y	193 (41.87)	82 (45.30)	111 (39.64)	
Sex, n (%)				0.663
Male	254 (55.10)	102 (56.35)	152 (54.29)	
Female	207 (44.90)	79 (43.65)	128 (45.71)	
Weight, n (%)				0.102
<5 kg	40 (8.8)	22 (12.15)	18 (6.43)	
5–9 kg	84 (18.22)	37 (20.44)	47 (16.79)	
10–20 kg	95 (20.1)	32 (17.68)	63 (22.50)	
21–40 kg	87 (18.87)	29 (16.02)	58 (20.71)	
41–70 kg	108 (23.43)	45 (24.86)	63 (22.50)	
71–100 kg	38 (8.24)	15 (8.29)	23 (8.21)	
>101 kg	9 (1.95)	1 (0.55)	8 (2.86)	
Body surface area (m^2)				0.076
Median (range)	0.86 (0–12.57)	0.78 (0–2.93)	0.89 (0–12.57)	
Mean ± SD	0.99 ± 0.93	0.91 ± 0.64	1.05 ± 1.08	
Body mass index (kg/m^2)				0.193
Median (range)	15.28 (0–127.31)	15.05 (0–127.31)	15.47 (0–37.65)	
Mean ± SD	15.52 ± 8.36	14.81 ± 11.12	15.99 ± 5.81	
Total bilirubin levels (mg/dl)				0.33
Median (range)	0.48 (0–25)	0.41 (0–25)	0.52 (0–25)	
Mean ± SD	1.21 ± 2.72	1.06 ± 2.53	1.31 ± 2.84	
Creatinine (mg/dl)				0.21
Median (range)	0 (0–2.5)	0 (0 2.5)	0 (0–1.6)	
Mean ± SD	0.07 ± 0.25	0.09 ± 0.30	0.06 ± 0.21	
Primary diagnosis, n (%)				0.357
Dilated cardiomyopathy	247 (53.58)	90 (49.72)	157 (56.07))	
Congenital heart disease	69 (14.97)	33 (18.23)	36 (12.86)	
Myocarditis	65 (14.01)	26 (14.36)	39 (13.93)	
Restrictive cardiomyopathy	20 (4.34)	6 (3.31)	14 (5.00)	
Hypertrophic cardiomyopathy	5 (1.08)	2 (1.10)	3 (1.07)	
Valvular heart disease	4 (0.87)		4 (1.43)	
Cancer	1 (0.22)		1 (0.36)	
Unknown	50 (10.85)	24 (13.26)	26 (9.29)	
INTERMACS patient profile, n (%)				0.255
INTERMACS 1	122 (26.52)	51 (28.18)	71 (25.36)	
INTERMACS 2	228 (49.46)	87 (48.07)	141 (50.36)	
INTERMACS 3	67 (14.53)	33 (18.23)	34 (12.14)	
INTERMACS 4	21 (4.56)	7 (3.87)	14 (5.00)	
INTERMACS 5–7	12 (2.60)	2 (1.10)	10 (3.57)	
Unknown	11 (2.39)	1 (0.55)	10 (3.57)	
Number of inotropes, n (%)				0.227
0	53 (11.50)	19 (10.50)	34 (12.14)	
None–2	225 (48.81)	80 (44.20)	145 (51.79)	
3–4	72 (15.62)	33 (18.23)	39 (13.93)	
≥5	4 (0.87)	3 (1.66)	1 (0.36)	
Unknown	107 (23.21)	46 (25.41)	61 (21.79)	
Mechanical ventilation, n (%)	125 (27.11)	42 (23.20)	83 (29.64)	0.047
Circulatory support, n (%)				
IABP	6 (1.30)	4 (2.21)	2 (0.71)	0.228
ECLS	86 (18.66)	27 (14.92)	59 (21.07)	0.043
Device type, n (%)				0.002
LVAD	369 (80.04)	133 (73.48)	236 (84.29)	
RVAD	10 (2.17)	3 (1.66)	7 (2.50)	
BiVAD	77 (16.70)	44 (24.31)	33 (11.79)	
Total artificial heart	2 (0.43)		2 (0.71)	
Unknown	3 (0.65)	1 (0.55)	2 (0.71)	
Current device strategy, n (%)				0.535
Bridge to transplantation listed	291 (63.12)	113 (62.43)	178 (63.57)	
Possible bridge to transplant	117 (25.38)	44 (24.31)	73 (26.07)	
Destination therapy	1 (0.22)		1 (0.36)	
Bridge to recovery	25 (5.42)	12 (6.63)	13 (4.64)	
Other	23 (4.99)	12 (6.63)	11 (3.93)	
Unknown	4 (0.87)		4 (1.43)	
Device Brand, n (%)				0.000
HeartAssist 5	2 (0.43)	1 (0.55)	1 (0.36)	
HeartMate II	17 (3.69)	13 (7.18)	4 (1.43)	
HeartWare HVAD	125 (27.11)	40 (22.1)	85 (30.36)	
HeartMate 3	19 (4.12)		19 (6.79)	
HeartWare MVAD	1 (0.22)	1 (0.55)		
Berlin Heart INCOR	3 (0.65)		3 (1.07)	
Berlin Heart EXCOR	246 (53.36)	109 (60.22)	137 (48.93)	
Thoratec PVAD	5 (1.08)	5 (2.76)		
Other[a]	43 (9.33)	12 (6.63)	31 (11.07)	

- **Plus 11-19 ans**
- **Plus ECMO après 2015**
- **Plus LVAD après 2015**
- **Plus sous VM après 2015**
- **Plus BiVAD avant 2014**
- **5 hopitaux > 30 VAD/année (54%), 9 hopitaux 15-30/année, 11 hopitaux <15/année**
- **88% bridge to transplantation ou to candidacy**

Table 2: Device strategy at the time of first implant, stratified by age categories

Device strategy	<1 y	1–5 years	6–10 years	11–19 years	Total
Bridge to recovery	8	7	2	8	25
Bridge to transplant	50	74	44	123	291
Possible bridge to transplant	25	23	19	50	117
Rescue therapy	0	0	0	1	1
Unknown/other	7	6	3	11	27
Total	90	110	68	193	461

VAD-P 236 (52.9%), VAD-R 171 (38.3%), inconnus 39 devices (8.7%)
53.4% Berlin Heart EXCOR
3.7% HeartMate II, 4.1% HeartMate 3
0.4% HeartAssist 5
27.1% HeartWare HVAD
LVADs 369 (80.04%) pts, RVADs 10 (2.17%) et BiVADs in 77 (16.7%)
27 (6%) RVAD temporaire (15% mortalité)
Durée moyenne 5.6mois, ICU LOS 24 jrs (0-422)
Greffe : 1 an 45% 2 ans 54% 3 ans 55%
103 pts décédés : 59 pendant hospi, 44 après sortie

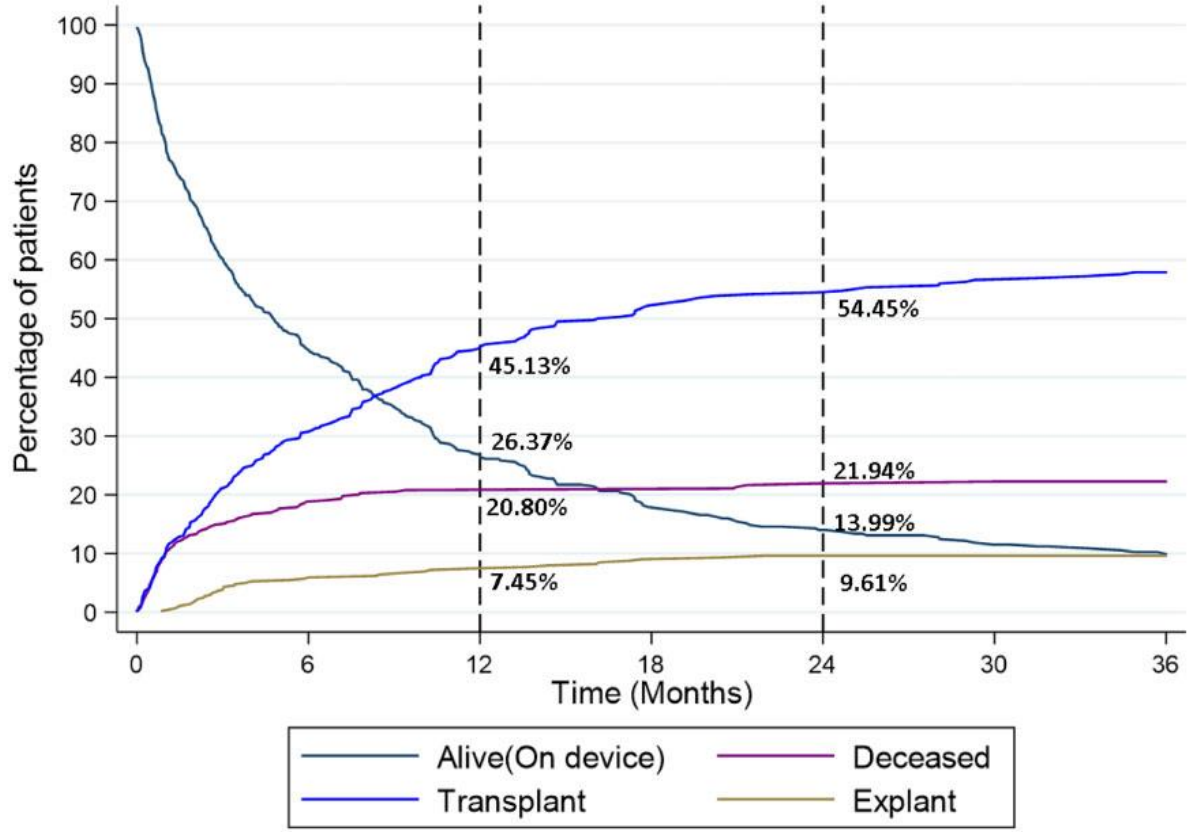

Table 3: Aetiology adjusted patient outcomes

Primary diagnosis	On device	Endpoint			Total
		Dead	Transplant	Wean	
Dilated cardiomyopathy	36 (14.6)	48 (19.4)	146 (59.1)	17 (6.9)	247
Restrictive cardiomyopathy	4 (20.0)	6 (30.0)	10 (50.0)	0 (0)	20
Hypertrophic cardiomyopathy	0 (0)	1 (20.0)	3 (60.0)	1 (20.0)	5
Myocarditis	4 (6.2)	12 (18.5)	30 (46.2)	19 (29.2)	65
Congenital heart disease	3 (4.3)	22 (31.9)	34 (49.3)	10 (14.5)	69
Cancer	0 (0)	0 (0)	1 (100.0)	0 (0)	1
Valvular heart disease	0 (0)	0 (0)	4 (100.0)	0 (0)	4
Unknown	7 (14.0)	14 (28.0)	26 (52.0)	3 (6.0)	50

VAD-P = VAD Pulsatile (B-H, Excor)

VAD-R = VAD Rotary (pompes centrifuges)

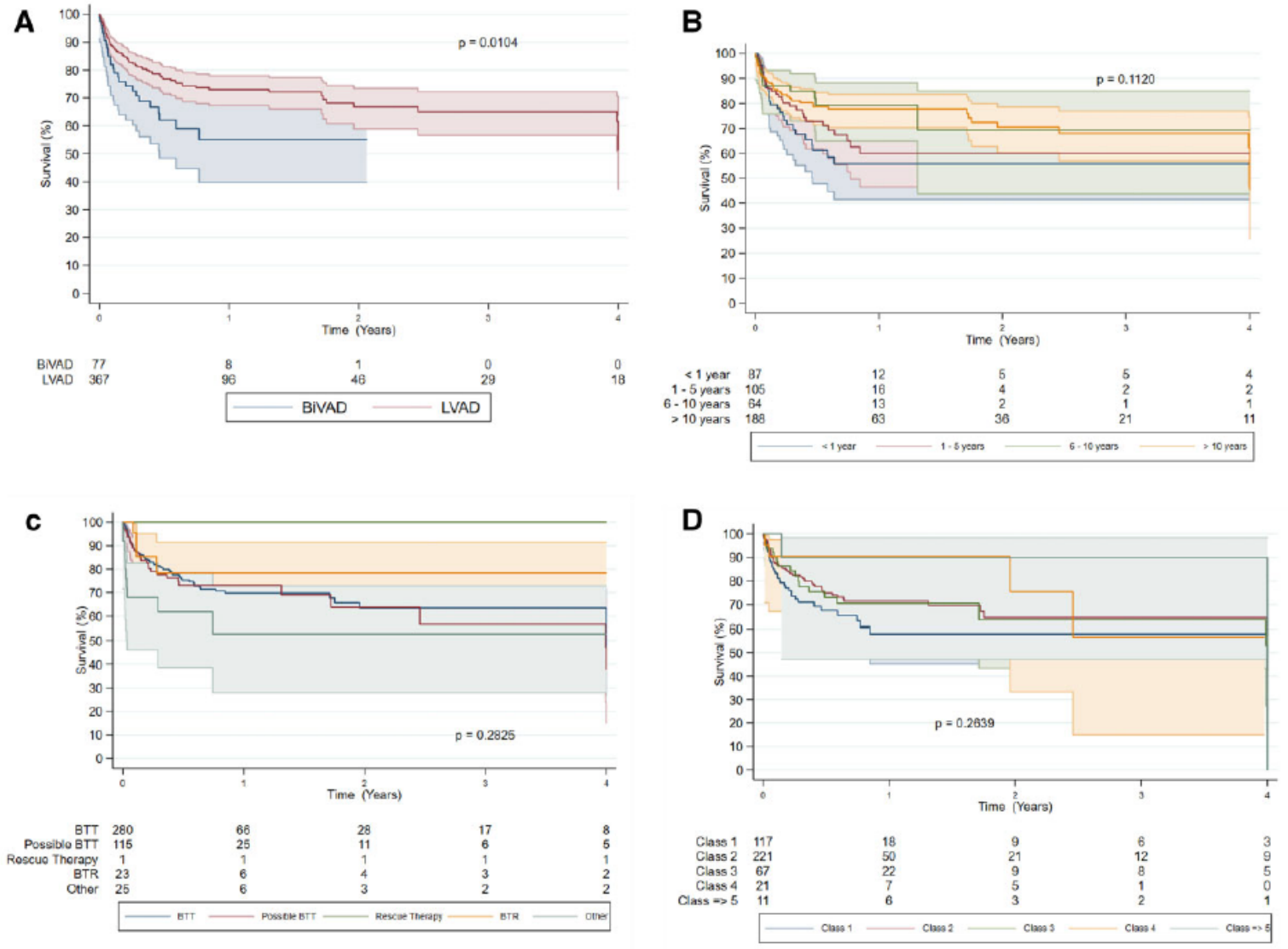

Figure 3: (**A**) Survival analysis by device type. (**B**) Survival analysis by age. (**C**) Survival analysis by device strategy. (**D**) Survival analysis by INTERMACS profile.

3nd Paedi-EUROMACS

Table 4: Major adverse events

Major adverse events	Within 3 months after implant		More than 3 months after implant	
	Event counts	Events per patient–year	Event counts	Events per patient–year
Device Malfunction	126	1.59	178	0.67
Major bleeding	55	0.70	13	0.05
Major infection	62	0.78	111	0.42
Neurological event	56	0.71	29	0.11

- **Plus souvent dysfonction pompe**
- **1ere cause décès AVC (25%)**
- **EIs plus avant 3 mois**
- **Infections plus après 3 mois**

3nd Paedi-EUROMACS

HÔPITAUX Paris
Saint-Joseph
Marie-Lannelongue

Survival in Pediatric Patients With Ventricular Assist Devices: A Special Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs) Report

Ann Thorac Surg
2023;116:972-9

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- **Analyse registre PEDIMACS : recherche facteurs prédictifs mortalité**
- **< 19 ans, 1355 VAD sur 1109 pts, 42 hôpitaux**
- **Gravité du patient avant VAD facteur principal pour mortalité et suivie au longue terme→ assister tôt et optimiser avant**
- **Comparer entre type de VAD pas utile car lié à taille-poids-gravité-timing-diagnostique-stratégie- âge**
- **Patients assistés avant (2012-2016) et après (2017-2021) = même mortalité**
- **Analyser par VAD et classes cliniques (<10 kgs, CHD)**

Prospective examination of HLA sensitization after VAD implantation in children and adults

Madeleine Townsend[a,b,*], Tara Pidborochynski[a,b], Ryan S. Cantor[c], Michael Khoury[a,b,e,g], Patricia Campbell[d,e,f], Anne Halpin[a,d,e,f], Simon Urschel[a,b,e,g,h,i], Daniel Kim[e,f,h], Susan Nahirniak[d], Lori J. West[a,b,d,e,g,h,i], Holger Buchholz[b,f,j], Jennifer Conway[a,b,e]

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Transplant Immunology 80 (2023) 101892

- **VAD → Transplantation → Compatibilité Greffon-Greffé**
- **Etude monocentrique : évaluer facteurs de risque pour développement AC anti-HLA à la suite de l'implantation de VAD**
- **Congénitale = du NN à l'adulte**
- **41 adultes et 17 ped (<19 ans)**
- **> 1/3 nouveaux AC anti-HLA (I > II) après l'implantation pas détectés avant ou augmentation de niveaux très faibles de MFI**
- **AC anti-HLA pré-VAD facteurs indépendants associés au développement des HLA-Ab après l'implantation → 70 % des patients présentant des HLA-Ab détectés pré-VAD ont ensuite développé de nouveaux HLA-Ab post-VAD = réponse de mémoire stimulée par inflammation (chirurgie majeure) → rôle prédictif cellules B et T**
- **Sexe F – Grossesse**
- **C'est la chirurgie et pas le VAD le catalyseur pour la réactivation des lymphocytes B à mémoire dormante préexistants**
- **AC persistants vs transitoires → nécessité de tests sériels des HLA-Ab en attendant une HTx afin d'éviter de limiter le pool potentiel de donneurs et de mieux prédire le risque d'activation post-HTx → 1 fois par mois sous VAD**
- **Rôle des transfusions non confirmé**

Ventricular Assist Device Training and Emergency Management Among Pediatric Cardiac Intensive Care Physicians – Multicenter Cross-Sectional Survey

World Journal for Pediatric and Congenital Heart Surgery
1-7

DOI: 10.1177/21501351231205804
journals.sagepub.com/home/pch

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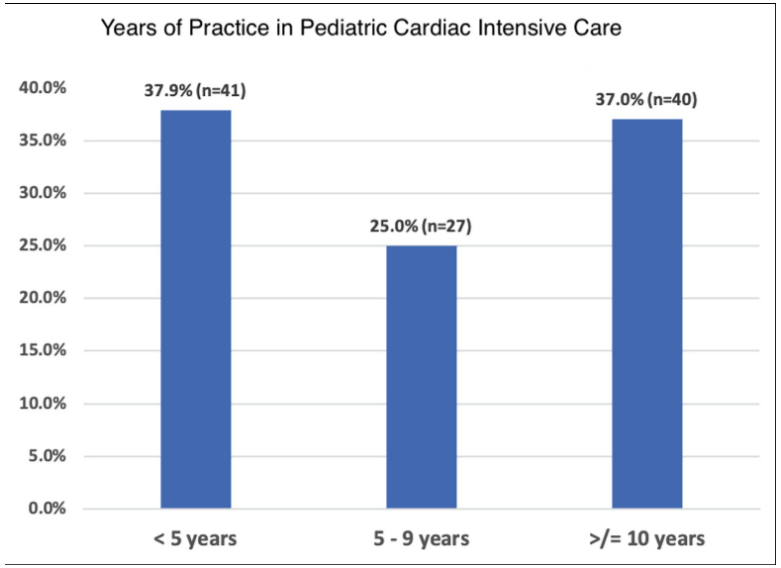

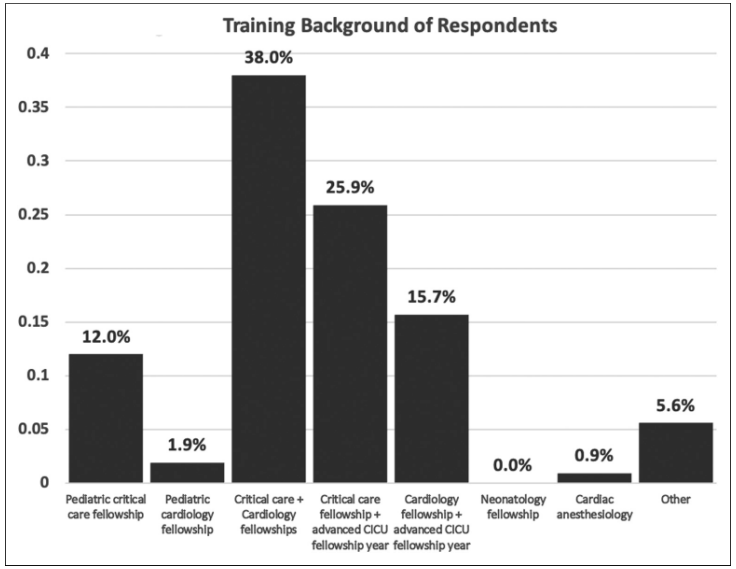

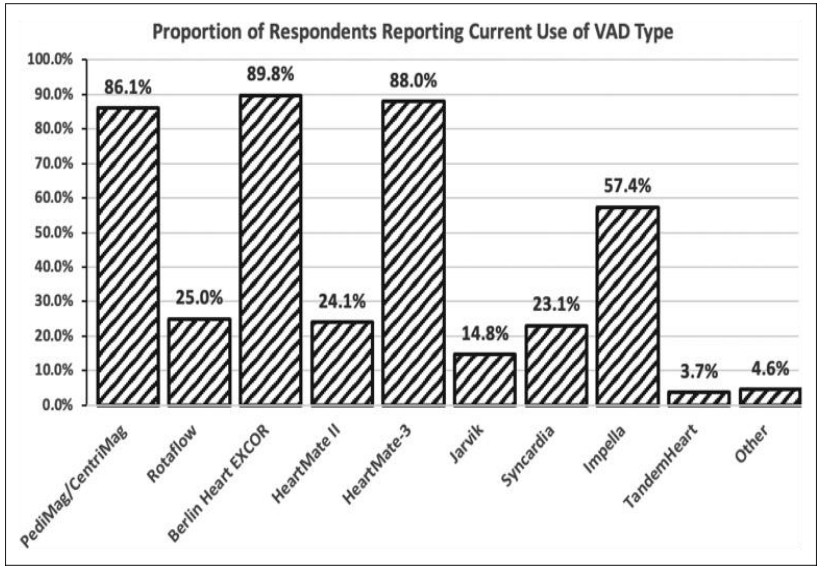

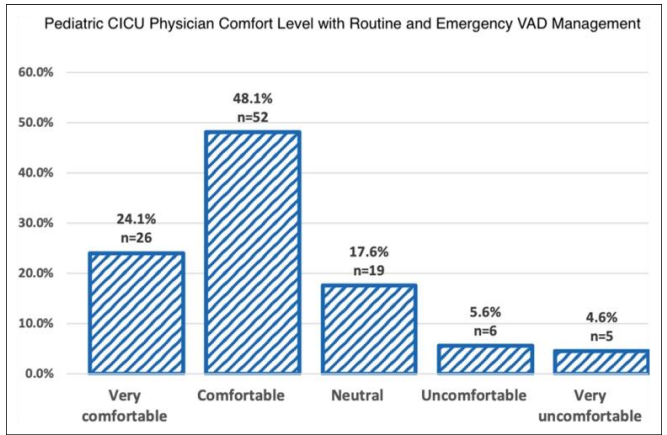

- **Survey USA – Canada**
- **Interview praticiens Réa Cardiaque Congénitale**
- **ACTION**
- **Formation VAD essentielle**
- **Partie ok routine et urgences**
- **Réanimation : utilité PROTOCOLE de SERVICE car pas de recommandations spécifiques**

HÔPITAUX Paris
Saint-Joseph
Marie-Lannelongue

Outcomes of Children Supported With Pulsatile Paracorporeal Ventricular Assist Device: Congenital Versus Acquired Heart Disease

World Journal for Pediatric and Congenital Heart Surgery
2023, Vol. 14(6) 708-715

DOI: 10.1177/21501351231181105
journals.sagepub.com/home/pch

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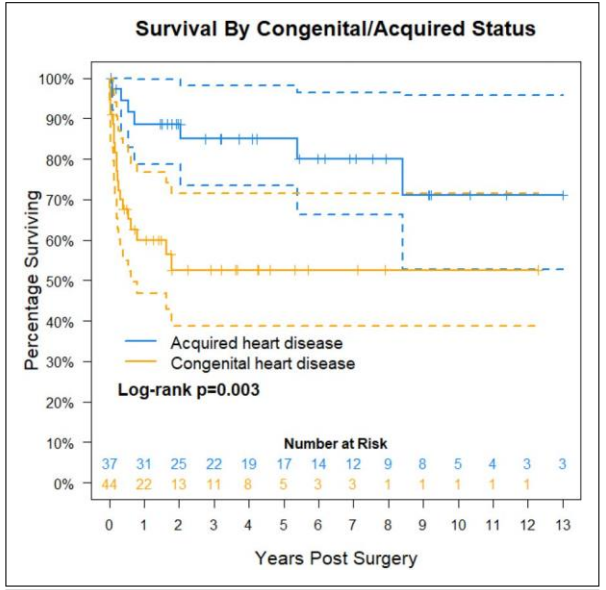
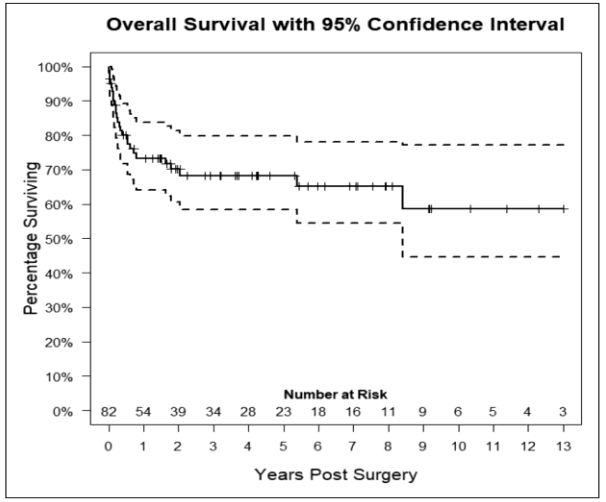
	All patients	CHD	AHD
Number of patients[a]	82	44	37
BiVAD[a]	43/82	8/44	34/37
LVAD	5[b]/82	2[b]/44	3/37
sVAD	34/82	34/44	0/37
Stroke on VAD[a]	25/82	16/44	8/37
Bleeding on VAD[a]	22/82	12/44	9/37
Underwent heart transplant[a]	57/82	28/44	28/37
Death while on VAD	18/82	15/44	3/37
Weaned off VAD	5/82	0/44	5[c]/37
Ongoing support	2/82	1/44	1/37
Death after cardiac transplant	8/82	4/44	4/37
Death prior to hospital discharge from hospitalization for VAD insertion	19/82	16/44	3/37
Death after hospital discharge from hospitalization for VAD insertion	7/82	3/44	4/37
VAD to Tx to D/C: Death prior to hospital discharge from hospitalization for VAD insertion	1/57	1/28	0/28
VAD to VAD removal to D/C: Death prior to hospital discharge from hospitalization for VAD insertion	0/5	0	0/5
One-year survival[a]	73.3% (95% CI = 64.1%-83.8%)	59.9% (95% CI = 46.7%-76.7%)	88.6% (95% CI = 78.8%-99.8%)
Five-year survival[a]	68.3% (95% CI = 58.4%-79.8%)	55.4% (95% CI = 40.8%-75.2%)	85.3% (95% CI = 74.0%-98.2%)





- **1 seul centre Nord USA**
- **Berlin Heart 2016-2021**
- **Cohérent avec ACTION**

- **Les assistance pulsatiles paracorporelles sont bénéfiques pour faciliter le pont vers la transplantation cardiaque chez les nouveau-nés, les nourrissons et les enfants atteints de cardiopathies congénitales**

- **La survie est moins favorable chez les patients atteints de cardiopathies congénitales par rapport à ceux atteints de cardiopathies acquises**

- **Les taux de survie à un an et à cinq ans après l'insertion du VAD sont significativement plus bas chez les patients avec cardiopathies congénitales**

- **Les patients à haut risque, notamment ceux avec des cœurs à une seule cavité, peuvent être stabilisés avec succès par l'insertion d'un VAD pulsé en attendant une transplantation cardiaque, leur permettant d'être extubés, nourris par NE et optimisés pour la transplantation**

<u>Challenges CHD</u>

1. **management hémostase**
2. **surveillance hémostase**
3. **prévention AVC**
4. **VU → switcher de palliation**

Mark S. Bleiweis, WJPCHS 2023

HÔPITAUX Paris Saint-Joseph Marie-Lannelongue

A Single-Institutional Experience with 36 Children Smaller Than 5 Kilograms Supported with the Berlin Heart Ventricular Assist Device (VAD) over 12 Years: Comparison of Patients with Biventricular versus Functionally Univentricular Circulation

World Journal for Pediatric and Congenital Heart Surgery
2023, Vol. 14(2) 117-124

DOI: 10.1177/21501351221146150
journals.sagepub.com/home/pch

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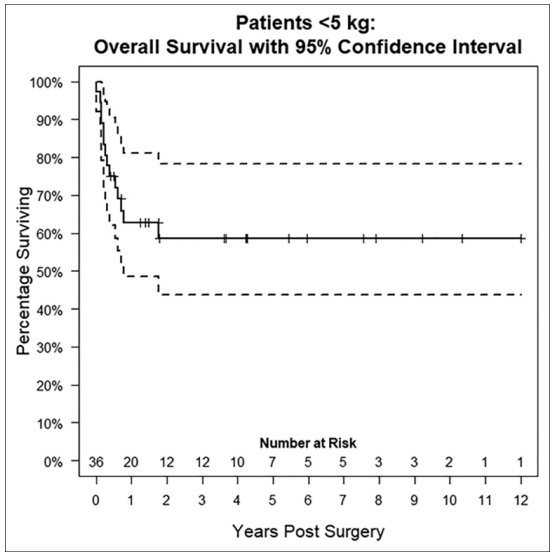
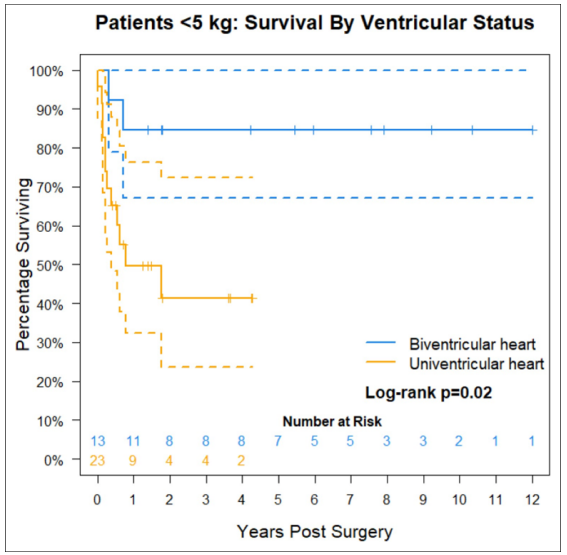
	All patients	Biventricular circulation	Functionally univentricular circulation
Number of patients	36	13	23
BiVAD	12	12	0
LVAD	1	1	0
sVAD	23	0	23
Stroke on VAD	15	5	10
Bleeding on VAD	9	3	6
Underwent Heart Transplant	26	12	14
Death while on VAD	10	1	9
Death after heart transplant	4	1	3
Death prior to hospital discharge from hospitalization for VAD insertion	11	1	10
Death after hospital discharge from hospitalization for VAD insertion	3	1	2
Alive at time of manuscript submission	22	11	11
Dead at time of manuscript submission	14	2	12





- **36 pts ; 1 centre USA ; 2009-2021 ; 2V et VU**
- **Management hémostase : bivalirudine, ASA, dypiridamole ; clopidogrel ; inhibiteurs directs thrombine**
- **Indication assistance pulsatile VU : plus physiologique ; prise en charge plus intuitive pour l'équipe soignante ; moins de risque hyper-débit pulmonaire ; amélioration rénale fonction**
- **B-H utile pour bridge to transplantation NN-Nourrissons < 5 kgs**
- **Survie : 1 ans 2V 85% vs VU 50% / 3 ans 2V 85% vs VU 41%**
- **VAD permet stabiliser VU si dysfonction avant ou après palliation**
- **Possible extubation-NE-optimisation sous VAD**
- **Survie en nette amélioration derniers 4-5 ans pour sVAD ou BiVAD < 5 kgs**

HÔPITAUX Paris Saint-Joseph Marie-Lannelongue

End-of-Life in Pediatric Patients Supported by Ventricular Assist Devices: A Network Database Cohort Study

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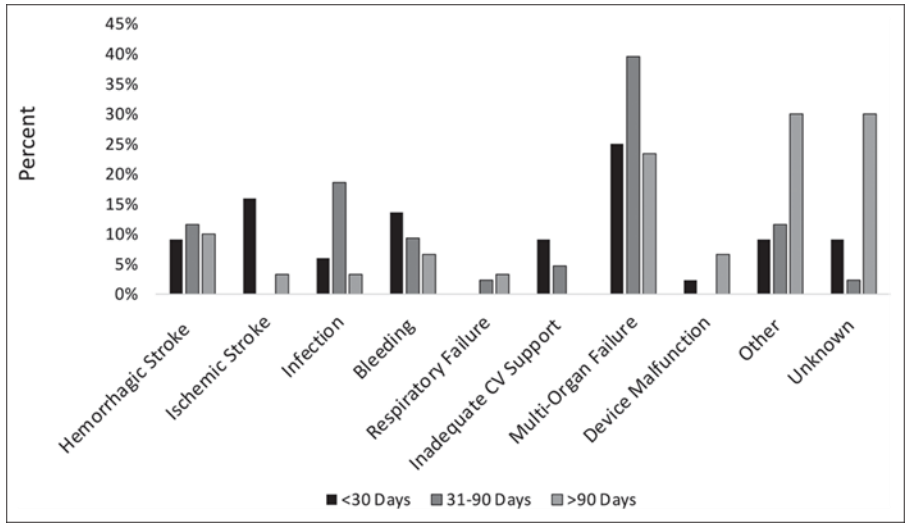
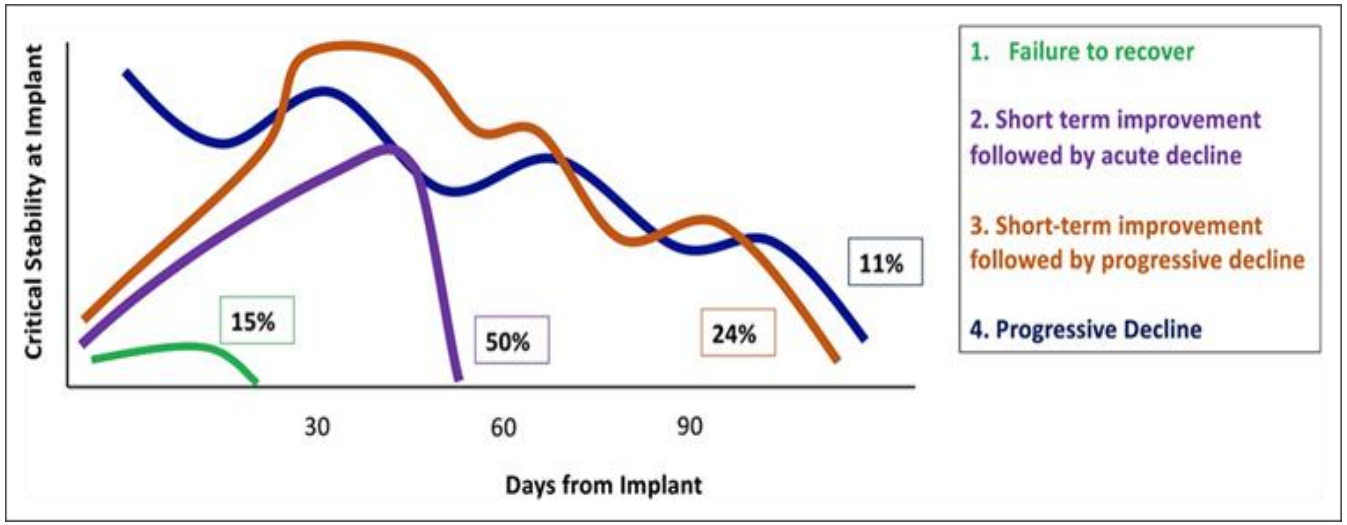
Pediatric Critical Care Medicine January 2023 • Volume 24 • Number 1

Characteristics	Total, Median (IQR) or *n* (%) (*n* = 721)	Survived, Median (IQR) or *n* (%) (*n* = 604)	Died, Median (IQR) or *n* (%) (*n* = 117)
Age at implant (yr)	7 (1-151)	7.8 (1-15)	4 (0-16)
Sex (female)	301 (42)	252 (42)	49 (42)
Initial goal of care			
Bridge to transplant	383 (53)	339 (56)	44 (38)
Bridge to candidacy	204 (28)	144 (24)	60 (51)
Bridge to recovery	110 (15)	99 (16)	11 (9)
Chronic or destination therapy	2 (<1)	0 (0)	2 (2)
Diagnosis (*n* = 711)[a]			
Cardiomyopathy	377 (52)	346 (57)	34 (29)
CHD 2-ventricle	77 (10)	52 (9)	25 (22)
CHD 1-ventricle	166 (23)	121 (20)	45 (39)
Transplant graft loss	43 (6)	35 (6)	9 (8)
Other	48 (7)	41 (7)	3 (3)
Preimplant comorbidities			
History of CVA	84 (12)	66 (11)	18 (16)
History of neurologic brain injury (not CVA)	24 (3)	15 (3)	9 (8)
History of renal failure	35 (5)	19 (3)	16 (14)
Interagency Registry for Mechanically Assisted Circulatory Support status at implant			
1	238 (33)	184 (31)	54 (46)
2	353 (49)	303 (50)	50 (43)
≥ 3	108 (15)	95 (16)	13 (11)
Device type[b]			
EXCOR	246 (34)	206 (34)	40 (26)
CentriMag/PediMag	168 (123)	122 (20)	46 (39)
HeartMate 2/HeartWare HVAD/HeartMate 3	262 (36)	224 (37)	38 (32)
Syncardia	9 (1)	6 (1)	3 (2)
Other	118 (16)	94 (16)	24 (21)
Transplant listing status at time of death (*n* = 273)			
Actively listed	170 (24)	153 (25)	17 (43)
Status 7 (not actively accepting donor offers)/delisted	20 (3)	11 (2)	10 (25)
Never listed	83 (12)	70 (12)	13 (33)
Number of adverse events while on ventricular assist device	1,379	913	466
Adverse event event (per patient rate)[c]			
Neurologic dysfunction	465 (18)	87 (14)	48 (35)
Major bleeding	230 (22)	134 (17)	96 (49)
Major infection	278 (26)	187 (23)	91 (44)
Right heart failure	54 (7)	36 (104)	18 (15)
Other	422 (48)	261 (36)	161 (131)

Therapy	*n* (%)
Receiving vasoactive infusions (epinephrine, dopamine, milrinone, and vasopressin)[a]	62 (62)
Number of infusions at the time of death	
1	28 (28)
2	19 (19)
3	15 (15)
Intubated[a]	75 (75)
Timing of intubation[a]	
Reintubated more than 14 d before death	13 (17)
Reintubated within 14 d of death	28 (36)
Never extubated after surgery	17 (23)
Missing data	17 (23)
Dialysis[a]	36 (36)
Initiated more than 14 d before death (*n* = 36)	22 (61)
Initiated within 14 d of death (*n* = 36)	9 (25)
Dialysis initiated preimplant (*n* = 36)	5 (14)
Paraenteral nutrition[a]	50 (50)
Device change within 14 d of death (*n* = 117)	14 (12)

Characteristics	Median (Interquartile Range) or *n* (%)
Age at death (yr), (*n* = 117)	5 (1-16)
Days between hospital admission and death (*n* = 86)	60 (27-91)
Duration of ventricular assist device support, d (*n* = 116)	43 (17-91)
Device functioning normally at death (*n* = 92)	85 (92)
Died outside of hospital (*n* = 100)	12 (10)





- **Gestes invasifs avant la fin de vie = mauvaise expérience pour pts et familles**
- **Objectifs principaux :**
  1) **comprendre causes décès, traitements invasives, qualité de vie, lieux**
  2) **impact cures palliatives**
  3) **communication sur objectifs - qualité de vie - désactivation émotionnelle pour éviter l' acharnement thérapeutique**
- **Analyse base de données ACTION Network 2012-2021**
- **721 VAD Pédiatriques**
- **39% décès CHD-VU, 22% CHD-2V, 29% CMP, 9% rejet après greffe**
- **75% VMI, > 50% inotropes, > 1/3 dialyse avant implantation → souvent poursuite ou mise en place → associés à mortalité élevée**
- **117/721 décès (16%), médiane implantation 4 ans, médiane décès 5 ans ; décès précoces, trop de traitements invasifs ?**
- **Patients avec différents « trajectoires de fin de vie » → approche heuristique → recherche ++++**

Hollander, PCCM 2023

Perioperative Morbidity and Outcomes in Pediatric Patients Transitioned From Extracorporeal Membrane Oxygenation to Ventricular Assist Device Support: A Study of the Society of Thoracic Surgeons Congenital Heart Surgery Database

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Table 1. Perioperative Characteristics in the Patients Who Received De Novo VAD Compared With Those Who Were Supported on ECMO Before VAD

Parameter	*De Novo* VAD, n = 498 (100%) n (%)	ECMO Pre-VAD, n = 237 (100%) n (%)	*p*
Age, years			
<1	105 (21)	81 (34)	<0.01
1–5	91 (18)	64 (27)	
6–10	60 (12)	21 (9)	
>11	242 (49)	71 (30)	
Gender (male)	280 (56)	148 (62)	0.11
Weight, kg			
<5	56 (11)	49 (21)	<0.01
5–9	80 (16)	43 (18)	
10–20	79 (16)	58 (24)	
21–40	76 (15)	25 (10)	
41–70	121 (24)	35 (15)	
71–100	62 (12)	23 (10)	
>100	24 (5)	4 (2)	
>2 sternotomies before VAD procedure	110 (22)	102 (43)	<0.01
Cardiogenic shock	133 (27)	133 (56)	<0.01
Cardiopulmonary resuscitation	25 (5)	36 (15)	<0.01
On steroids	31 (6)	30 (13)	<0.01
Hepatic dysfunction	43 (8)	36 (15)	<0.01
Coagulation abnormality	107 (21)	117 (49)	<0.01
Neurologic deficit	15 (3)	14 (6)	0.06
Seizure	20 (4)	22 (9)	<0.01
Stroke	16 (3)	26 (11)	<0.01
Use of dialysis	7 (1.4)	28 (12)	<0.01
Mechanical ventilation	182 (36)	204 (86)	<0.01
VAD implant type*			
LVAD	354 (81)	136 (66)	<0.01
RVAD	27 (6)	19 (9)	
BiVAD	45 (10)	45 (22)	
TAH	12 (3)	7 (3)	
VAD indication*			
BTT	370 (85)	168 (80)	0.04
BR	46 (11)	34 (16)	
DT	12 (3)	1 (0.5)	
Postcardiotomy	7 (2)	6 (3)	
Device malfunction	2 (0.4)	0	

Table 2. Postoperative Complications and Mortality in Patients With VAD Placement

Parameter	*De Novo* VAD, N = 498 (100%) n (%)	ECMO Pre-VAD, N = 237 (100%) n (%)	*p*
Reoperation for bleeding	60 (12)	29 (12)	0.9
Reoperation planned	25 (5)	87 (37)	<0.01
Reoperation unplanned (other than for bleeding)	38 (8)	80 (34)	
Renal failure needing dialysis	21 (4)	9 (4)	0.78
Stroke	49 (10)	10 (4)	<0.01
Seizure	24 (5)	5 (2)	0.07
Other neurologic complications	22 (4)	11 (5)	0.89
Arrhythmia	75 (15)	29 (12)	0.3
Multisystem organ failure	27 (5)	13 (5)	0.97
Post-VAD MCS	46 (9)	29 (12)	0.2
Low cardiac output	51 (10)	22 (8)	0.43
Mortality	77 (16)	78 (34)	<0.01
Postoperative length of stay, days, median (IQR)	47 (25–94)	56 (26–113)	0.15
Discharge with VAD	65 (14)	66 (30)	<0.01
VAD removed before discharge	241 (52)	111 (51)	

- **Pts CHD de STS : 2014-2019 ; 735 pts = 498 VAD / 237 ECMO-VAD**
- **Pts sous ECMO pre-VAD mortalité >> pts ECMO d'emblée**
- **Mais pourquoi ?**
- **2 groupes VAD *De novo* vs ECMO-VAD: caractéristiques per-opératoires - morbidité – suivis**
- **Groupe ECMO-VAD : morbidité périopératoire significative - complications postopératoires importantes - mortalité significative**
- **Comprendre les facteurs de risque associés à la mortalité post-VAD**

Groupe ECMO-VAD vs VAD-De Novo

<u>avant implantation</u> plus jeunes, petits, en choc cardiogénique, RCP, insuffisance hépatique, plus troubles hémostase, ATCD pour AVC, dialyse, VM, BiVAD, bridge to recovery ;

<u>après implantation</u>, plus reprises chirurgicales en urgence, plus d'AVC, plus transfusion plaquettes, plus AVC hémorragique ;

<u>mortalité</u> plus élevée (34 vs 16 %)

Facteurs de risque <u>pre-implantation</u> associés mortalité pour les 2 groupes : ECMO, VM, choc cardiogénique

Facteurs de risque <u>post-implantation</u> associés mortalité pour les 2 groupes : IR que nécessite dialyse, saignement postopératoire, AVC

Table 3. Blood Product Utilization in Patients Undergoing VAD Placement

Component Used	De Novo VAD	ECMO Pre-VAD	p
Total plasma	0 (0–1)	0 (0–2)	0.21
Total cryoprecipitate	0 (0–1)	0 (0–1)	0.17
Total red cells	1 (0–3)	1 (0–5)	0.1
Total platelets	0 (0–1)	1 (0–2)	0.03
Total whole blood	0	0	
Any cryoprecipitate	45%	53%	0.07
Any fresh frozen plasma	63%	65%	0.7
Any platelets	62%	67%	0.17
Any red cells	75%	75%	0.28

ECMO, extracorporeal membrane oxygenation; VAD, ventricular assist device.

Table 4. A Comparison of Device-Related Complications Between the Two Groups

VAD-Specific Complications	*De Novo* VAD, N = 498 (100%) n (%)*	Prior ECMO, N = 237 (100%) n (%)*	*p*
Drive line/ cannula infection	8 (2)	7 (4)	0.22
Pump pocket infection	0 (0)	1 (0.5)	
Endocarditis	2 (0.5)	0 (0)	0.99
Hemolysis	15 (4)	7 (4)	0.99
Embolic stroke	28 (8)	12 (7)	0.86
Intracranial bleed	16 (4)	22 (13)	<0.01
Device malfunction	18 (5)	9 (5)	0.99

*Two hundred two patients (137 *de novo*, 65 ECMO) with missing values in the database.

ECMO, extracorporeal membrane oxygenation; VAD, ventricular assist device.

Table 5. Multivariable Regression Analysis for Risk Factors Associated With VAD Mortality

Parameter	Odds Ratio	p
Age	1 (1.00–1.00)	0.5844
Weight at VAD placement	0.991 (0.978–1.004)	0.1933
Gender (male)	1.154 (0.756–1.762)	0.5068
ECMO used pre-VAD	2.107 (1.318–3.368)	0.0018
Cardiogenic shock pre-VAD	1.799 (1.165–2.778)	0.0081
Mechanical ventilation pre-VAD	2.297 (1.331–3.965)	0.0028
Low cardiac output post-VAD	1.487 (0.756–2.925)	0.2506
Arrhythmia post-VAD	0.553 (0.281–1.085)	0.085
Dialysis need post-VAD	25.507 (8.637–75.328)	<0.0001
Bleeding complication post-VAD	1.907 (1.054–3.448)	0.0328
Stroke post-VAD placement	6.291 (3.139–12.608)	<0.0001

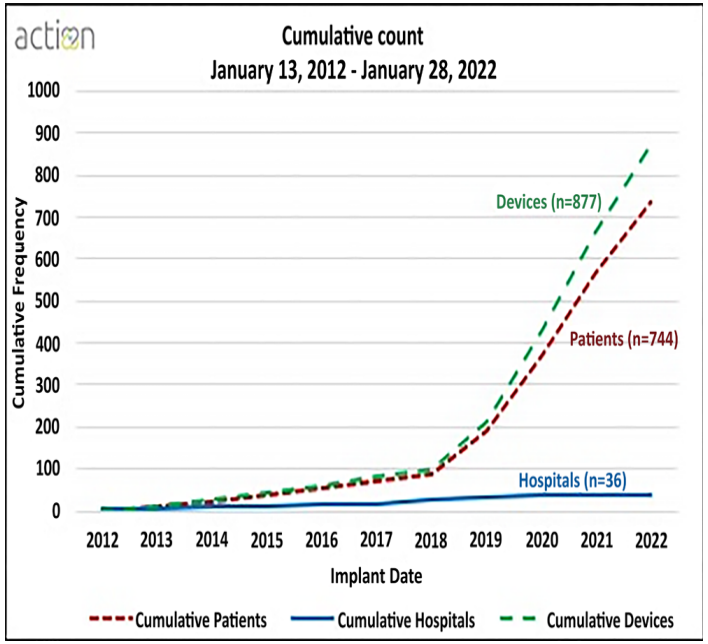
ECMO, extracorporeal membrane oxygenation; VAD, ventricular assist device.

Implantation précoce mieux classes 4-7 vs 2-3 vs 1

Desai, ASAIO 2024

Taking ACTION: A Prognostic Tool for Pediatric Ventricular Assist Device Mortality

KATERINA BOUCEK ,* ANAAM ALZUBI,† FARHAN ZAFAR,† MATTHEW J. O'CONNOR,‡ MARY MEHEGAN,§ DEEPA MOKSHAGUNDAM ,§ RYAN R. DAVIES,¶ IKI ADACHI ,// ANGELA LORTS ,† AND DAVID N. ROSENTHAL #



Characteristics	Overall (744)	Survivors (650)	Non-Survivors (94)
Age (years)	7.5 ± 7.8	7.7 ± 7.8	5.9 ± 8.1
Age Group (years)			
<1	228 (30.6)	186 (28.6)	42 (44.7)
1–10	242 (32.5)	215 (33.1)	27 (28.7)
>10	274 (36.8)	249 (38.3)	25 (26.6)
Height (cm)	110.4 ± 44.9	112.6 ± 44.5	94.7 ± 44.9
Weight (kg)	30.6 ± 30.3	31.8 ± 30.6	22.76 ± 26.1
Weight group (kg)			
<5	97 (13.0)	72 (11.1)	25 (26.6)
5–10	164 (22.0)	141 (21.7)	23 (24.5)
10–20	149 (20.0)	131 (20.2)	18 (19.2)
20–40	107 (14.4)	99 (15.2)	8 (8.5)
>40	227 (30.5)	207 (31.8)	20 (21.3)
Race			
American Indian or Alaska Native	7 (0.94)	376 (57.9)	50 (53.2)
Asian	28 (3.8)	112 (17.2)	14 (14.9)
Black	150 (20.2)	538 (82.8)	80 (85.1)
Native Hawaiian/Pacific Islander	3 (0.4)	48 (7.4)	4 (4.3)
White	433 (58.2)	12 (1.9)	4 (4.3)
Unknown	77 (10.4)	320 (49.2)	43 (45.7)
Other	59 (7.9)	238 (36.6)	64 (68.2)
Ethnicity			
Hispanic	126 (16.9)	112 (17.2)	14 (14.9)
Non-Hispanic	618 (83.1)	538 (82.8)	80 (85.1)
Female gender	318 (42.7)	274 (42.2)	44 (46.8)
Diagnosis			
Dilated cardiomyopathy	381 (51.2)	363 (55.8)	18 (19.2)
Hypertrophic cardiomyopathy	7 (0.9)	4 (0.6)	3 (3.2)
Restrictive cardiomyopathy	12 (1.6)	12 (1.6)	0 (0)
Single ventricle CHD	191 (25.7)	150 (23.1)	41 (43.6)
Two ventricle CHD	85 (11.4)	61 (9.3)	24 (25.5)
Transplant graft dysfunction	16 (2.2)	12 (1.9)	4 (4.3)
INTERMACS profile			
1	229 (30.8)	188 (28.9)	41 (43.6)
2	377 (50.7)	334 (51.4)	43 (45.7)
3	89 (12.0)	83 (12.8)	6 (6.4)
4–7	49 (6.6)	45 (6.9)	4 (4.3)
Previous cardiac surgery	302 (40.6)	238 (36.6)	64 (68.1)
ICU ≤30 days before implant	605 (81.3)	526 (80.9)	79 (84.0)
Need for ≥1 inotrope	624 (83.9)	548 (84.3)	76 (80.9)
First heart failure admission	363 (48.8)	320 (49.2)	43 (45.7)
Mechanical ventilation	350 (46.0)	286(44.0)	64 (68.1)
ECMO	166 (22.3)	130 (20.0)	36 (38.3)
Need for ≥1 inotrope	624 (83.9)	548 (84.3)	76 (80.8)
Medical paralysis	98 (13.2)	77 (11.6)	21 (22.3)
TPN dependent	356 (47.8)	297 (45.7)	59 (62.8)
Need for dialysis	36 (4.8)	25 (3.8)	11 (11.7)
Preimplant eGFR	100.6 ± 65.9	102.9 ± 64.8	84.5 ± 71.5

- ACTION = Advanced Cardiac Therapies Improving Outcomes Network
- 55 hopitaux North USA
- 2012-2022
- 838—94 percut/total heart → 744(650V/94 D)
- Corréler preop et risque de mortalité

Table 1. Patient Baseline Characteristics

Characteristics	Overall (744)	Survivors (650)	Non-Survivors (94)
Age (years)	7.5 ± 7.8	7.7 ± 7.8	5.9 ± 8.1
Age Group (years)			
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Height (cm)	110.4 ± 44.9	112.6 ± 44.5	94.7 ± 44.9
Weight (kg)	30.6 ± 30.3	31.8 ± 30.6	22.76 ± 26.1
Weight group (kg)			
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5–10	164 (22.0)	141 (21.7)	23 (24.5)
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INTERMACS profile			
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3	89 (12.0)	83 (12.8)	6 (6.4)
4–7	49 (6.6)	45 (6.9)	4 (4.3)
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Medical paralysis	98 (13.2)	77 (11.6)	21 (22.3)
TPN dependent	356 (47.8)	297 (45.7)	59 (62.8)
Need for dialysis	36 (4.8)	25 (3.8)	11 (11.7)
Preimplant eGFR	100.6 ± 65.9	102.9 ± 64.8	84.5 ± 71.5

Table 2. VAD Type and Ventricular Configuration

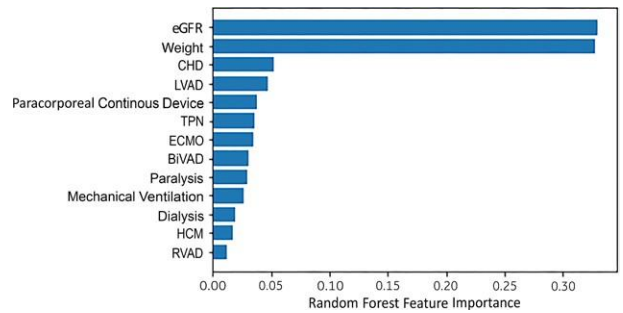
	Overall	Paracorporeal Pulsatile	Paracorporeal Continuous	Implantable Continuous	Unknown
LVAD	460 (61.8)	177 (38.5)	43 (9.4)	223 (48.5)	17 (3.7)
RVAD	15 (2.0)	3 (20)	8 (53.3)	4 (26.7)	0 (0)
BiVAD	83 (11.2)	46 (55.4)	15 (18.1)	17 (20.5)	5 (6)
SVAD	162 (21.8)	64 (39.5)	45 (27.8)	53 (32.7)	0 (0)
Unknown	24 (100)	N/A	N/A	N/A	24 (100)
Total	744	290	111	297	46

Table 3. Cause of Death

Stroke	21 (22.3)
Multi-organ failure	19 (20.2)
Infection	11 (11.7)
Inadequate cardiovascular support*	6 (6.4)
Respiratory failure	6 (6.4)
Bleeding	4 (4.3)
Device malfunction	3 (3.2)
Other	14 (14.9)
Unknown	10 (10.6)
Total	94

Table 4. Univariable Risk-Factor Analysis

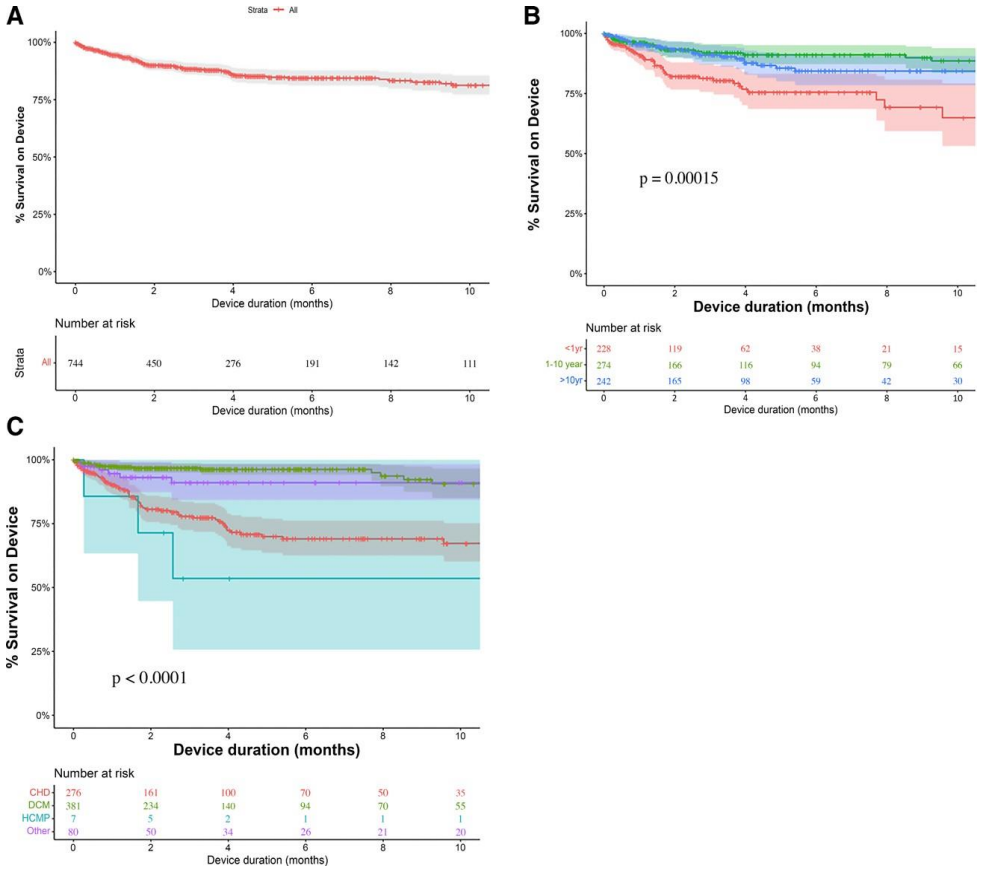
Risk Factor	(95% CI)	*p* Value
Age (years)	0.97 (0.94–1.00)	0.04
Weight (kg)	0.99 (0.98–1.00)	<0.01
Height (cm)	0.99 (0.98–1.00)	<0.01
Race		
American Indian or Alaska Native	(0.00–1000.00)	0.99
Asian	0.82 (0.24–2.79)	0.76
Black	0.73 (0.40–1.30)	0.28
Native Hawaiian/Pacific Islander	(0.00–1000.00)	0.99
White	1.5 (0.97–2.43)	0.07
Unknown	0.79 (0.36–1.69)	0.52
Other	0.62 (0.24–1.60)	0.32
Ethnicity		
Hispanic	0.84 (0.46–1.54)	0.57
Non-Hispanic	1.19 (0.65–2.17)	0.57
Gender		
Male	0.83 (0.54–1.28)	0.39
Female	1.21 (0.78–1.86)	0.39
Diagnosis		
Congenital heart disease	4.66 (2.92–7.53)	<0.01
Single ventricle	2.57 (1.64–4.02)	<0.01
Two ventricle	3.31 (1.91–5.59)	<0.01
Hypertrophic cardiomyopathy	5.32 (1.16–24.17)	0.03
Restrictive cardiomyopathy	(0.00–1000.00)	0.98
Dilated cardiomyopathy	0.18 (0.11–0.31)	<0.01
Transplant graft dysfunction	2.36 (0.65–6.95)	0.14
Other	0.56 (0.20–1.58)	0.27
INTERMACS profile		
1	1.90 (1.22–2.96)	<0.01
2	0.80 (0.52–1.23)	0.31
3	0.46 (0.20–1.10)	0.08
4–7	0.60 (0.21–1.70)	0.33
Previous cardiac surgery	3.69 (2.34–5.93)	<0.01
ICU ≤30 days before implant	1.24 (0.69–2.23)	0.47
Need for ≥1 inotrope	0.79 (0.45–1.37)	0.40
First heart failure admission	0.87 (0.56–1.34)	0.53
ECMO	2.48 (1.56–3.91))	<0.01
Need for dialysis	3.31 (1.57–6.98)	<0.01
TPN	2.00 (1.28–3.13)	<0.01
Mechanical ventilation	2.72 (1.71–4.30)	<0.01
Chemical paralysis	2.14 (1.25–3.68)	<0.01
Preimplant eGFR	0.99 (0.99–1.00)	<0.01
Device type		
Intracorporeal continuous device	0.50 (0.31–0.82)	<0.01
Paracorporeal continuous device	3.51 (2.13–5.70)	<0.01
Paracorporeal pulsatile device	1.02 (0.65–1.58)	0.93
Device strategy		
LVAD	0.24 (0.15–0.37)	<0.01
RVAD	2.58 (0.70–7.73)	0.11
SVAD	2.44 (1.53–3.86)	<0.01
BiVAD	2.95 (1.68–5.03)	<0.01



Boucek, ASAIO 2023

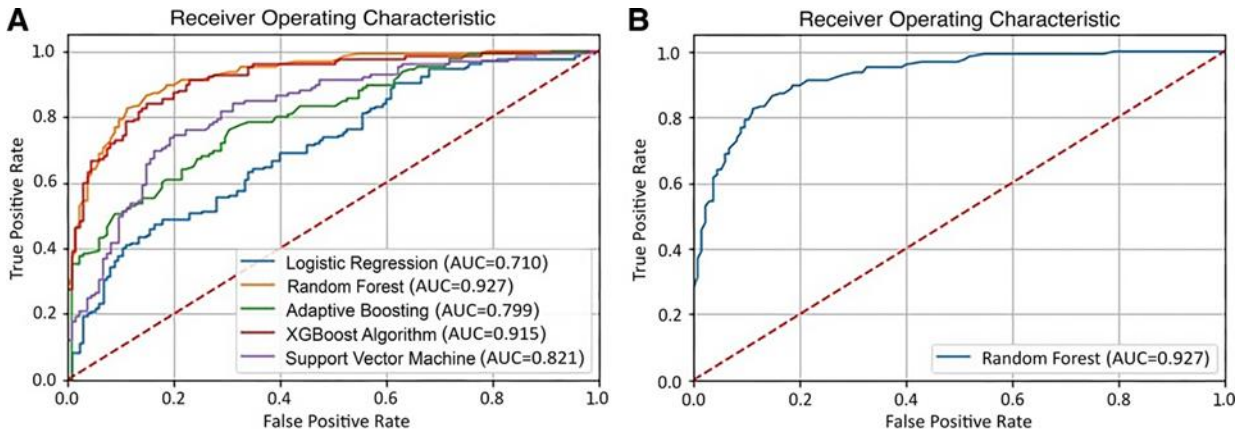
9 facteurs de risque dans le modèle final : **poids, CHD, CMH, DFG, ECMO, NPT, VM, curare et type de VAD**

Les variables prédictives se limitaient à des **éléments pouvant être déterminés avant la mise en œuvre et provenant de facteurs propres aux patients**



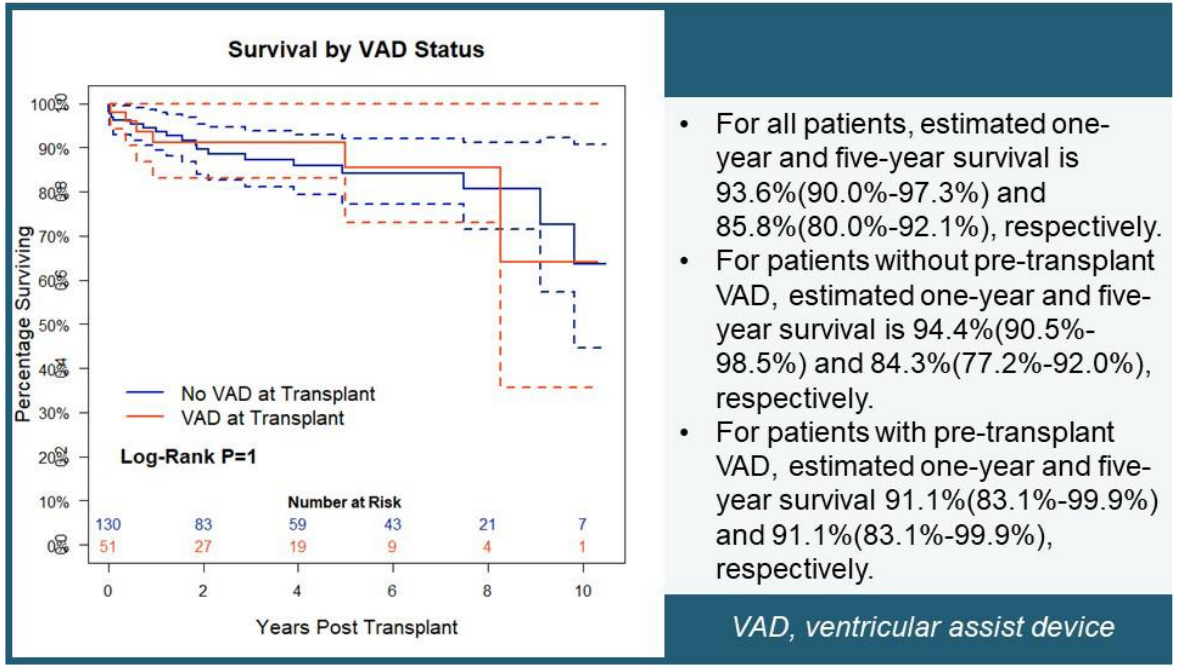
Le rôle essential de **sélection patient, timing et optimiser le malade** avant de l'assister

Ces modèles permettraient d'augmenter la capacité de prédire le pronostic et d'analyser les alternatives de traitement concurrentes pour informer patients et familles mieux et avec plus précision



Boucek, ASAIO 2023

An Analysis of 186 Heart Transplants for Pediatric or Congenital Heart Disease: Impact of Pre-Transplant Ventricular Assist Device



- For all patients, estimated one-year and five-year survival is 93.6%(90.0%-97.3%) and 85.8%(80.0%-92.1%), respectively.
- For patients without pre-transplant VAD, estimated one-year and five-year survival is 94.4%(90.5%-98.5%) and 84.3%(77.2%-92.0%), respectively.
- For patients with pre-transplant VAD, estimated one-year and five-year survival 91.1%(83.1%-99.9%) and 91.1%(83.1%-99.9%), respectively.

VAD, ventricular assist device

THE ANNALS OF THORACIC SURGERY
Official Journal of The Society of Thoracic Surgeons and the Southern Thoracic Surgical Association

Bleiweis, Jacobs, et al 2022
#VisualAbstract #AnnalsImages
@annalsthorsurg

- **En 2021, 488 transplantations cardiaques pédiatriques aux USA (13%). Donneurs insuffisants donc mortalité en liste d'attente élevèe → VAD → baisse de la mortalité en liste**
- **Ce papier : 1 centre North-USA, 2011-2022, 181 pts, 186 transplantations cardiaques, 2 groupes No-VAD 130, VAD 51. Prise en charge peropératoire +++**
- **Facteurs associés à mortalité : ATCD de chirurgie cardiaque; n.ro de chirurgies ; VU ; CHD ; IR pré-transplantation**
- **Groupe VAD : plus jeunes, plus d'interventions cardiaques, plus incompatibilité ABO**
- **Mortalité à 5 ans : groupe No-VAD 84.3% vs VAD 91.1% (Globale 86%)**

Modifiable risk factor reduction for pediatric ventricular assist devices and the influence of persistent modifiable risk factors at transplant

Jason W. Greenberg, MD, MS, Kevin Kulshrestha, MD, MBE, Amalia Guzman-Gomez, BS, Katrina Fields, BSN, RN, David G. Lehenbauer, MD, David S. Winlaw, MBBS, MD, FRACS, Tanya Perry, DO, Chet Villa, MD, Angela Lorts, MD, MBA, Farhan Zafar, MD, MS, and David L. S. Morales, MD

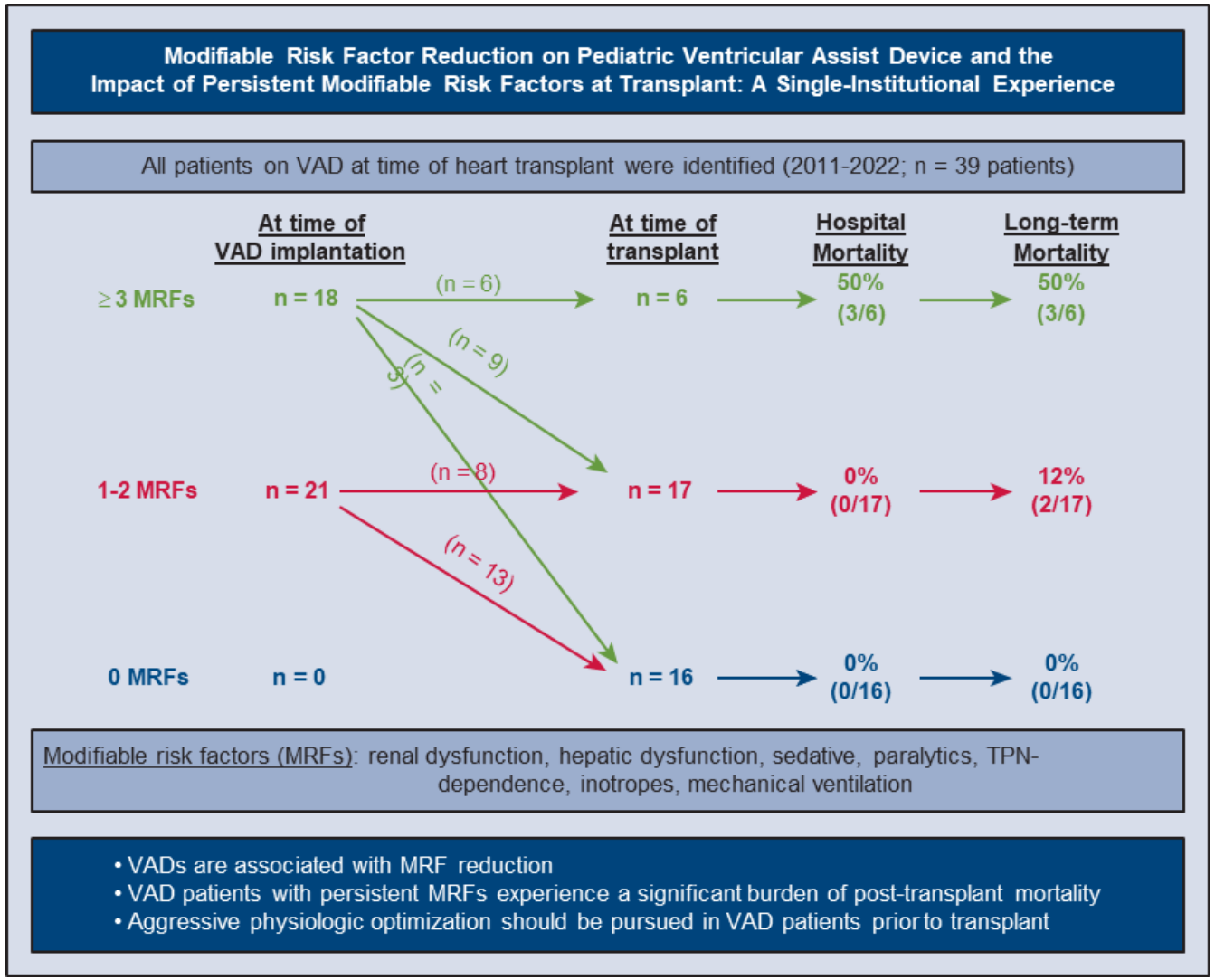
- Renal dysfunction (defined as estimated glomerular filtration rate <60 mL/min/1.73 m^2, measured within 48 hours of transplant, or renal replacement therapy within 48 hours of transplant),
- Hepatic dysfunction (defined as total serum bilirubin ≥ 1.2 mg/dL within 48 hours of transplant),[13]
- Total parental nutrition (TPN) dependence (defined as parenteral nutrition administration without enteral nutrition for >48 hours pretransplant),
- Sedative agents (defined as administration of a sedative agent [eg, benzodiazepine] within 24 hours of transplant),
- Paralytic agents (defined as administration of a paralytic agent within 24 hours of transplant),
- Inotrope-dependence (defined as administration of a continuous inotropic medication within 24 hours of transplant), and
- Mechanical ventilatory dependence (defined as ventilation for>24 hours pretransplant).

Les résultats de l'étude et l'identification de MRF (Modifiable Risk Factor) spécifiques qui sont indépendamment associés à la mortalité précoce peuvent aider à la prise de décision clinique et à la stratification des risques lors de la planification de transplantations cardiaques pour les patients nécessitant une VAD.

Variable	Modifiable risk factors at transplant (a) 0 (n ¼ 16)	(b) 1-2 (n ¼ 17)	(c) ≥3 (n ¼ 6)
MRFs present at VAD implantation			
Renal dysfunction	0 (0)	1 (6)	1 (17)
Hepatic dysfunction	4 (27)	7 (41)	1 (17)
TPN-dependence	3 (19)	9 (53)	5 (83)
Sedatives	2 (12)	8 (47)	6 (100)
Paralytics	1 (6)	4 (24)	5 (83)
Inotropes	16 (100)	15 (88)	6 (100)
Mechanical ventilation	2 (12)	6 (35)	6 (100)
MRFs present at time of transplant			
Renal dysfunction	0 (0)	2 (12)	3 (50)
Hepatic dysfunction	0 (0)	4 (25)	1 (17)
TPN-dependence	0 (0)	0 (0)	2 (33)
Sedatives	0 (0)	10 (59)	6 (100)
Paralytics	0 (0)	0 (0)	3 (50)
Inotropes	0 (0)	13 (76)	6 (100)
Mechanical ventilation	0 (0)	0 (0)	6 (100)

Variable	Modifiable risk factors at transplant (a) 0 (n ¼ 16)	(b) 1-2 (n ¼ 17)	(c) ≥3 (n ¼ 6)	*P* value
Age <1 y at transplant	5 (31)	4 (24)	5 (83)	a-b .708 a-c .084 b-c .055
Female sex	4 (25)	7 (41)	2 (33)	.669
Non-White race/ethnicity	3 (19)	6 (35)	0 (0)	.492
Congenital heart disease	3 (19)	9 (53)	4 (67)	a-b .106 a-c .106 b-c .660
Noncardiac comorbidity	6 (38)	9 (53)	2 (33)	.619
Prior cardiac surgery*	5 (31)	8 (47)	4 (67)	.321
VAD type implanted				
Intracorporeal continuous	9 (56)	7 (41)	0 (0)	.169
Paracorporeal continuous	2 (12)	3 (18)	2 (33)	
Paracorporeal pulsatile	5 (31)	7 (41)	4 (67)	

Variable	Hospital mortality No (n ¼ 36)	Yes (n ¼ 3)	*P* value
Age <1 y at transplant	11 (31)	3 (100)	.040
Female sex	12 (33)	1 (33)	.999
Non-White race/ethnicity	9 (25)	0 (0)	.999
Congenital heart disease	13 (36)	3 (100)	.061
Noncardiac comorbidity	16 (44)	0 (0)	.255
Prior cardiac surgery*	14 (39)	3 (100)	.074
VAD type (implanted)			
Intracorporeal continuous	16 (44)	0 (0)	.077
Paracorporeal continuous	5 (14)	2 (67)	
Paracorporeal pulsatile	15 (42)	1 (33)	
MRFs present at VAD implantation			
Renal dysfunction	2 (6)	0 (0)	.999
Hepatic dysfunction	12 (34)	0 (0)	.538
TPN-dependence	15 (42)	2 (67)	.570
Sedatives	13 (36)	3 (100)	.061
Paralytics	7 (19)	3 (100)	.013
Inotropes	34 (94)	3 (100)	.999
Mechanical ventilation	11 (31)	3 (100)	.040
VAD type (at transplant)			
Intracorporeal continuous	17 (47)	0 (0)	.038
Paracorporeal continuous	3 (8)	2 (67)	
Paracorporeal pulsatile	16 (44)	1 (33)	
MRFs present at time of transplant			
Renal dysfunction	3 (8)	2 (67)	.038
Hepatic dysfunction	5 (15)	0 (0)	.999
TPN-dependence	1 (3)	1 (33)	.150
Sedatives	13 (36)	3 (100)	.061
Paralytics	1 (2)	2 (67)	.012
Inotropes	16 (44)	3 (100)	.106
Mechanical ventilation	3 (8)	3 (100)	.002



- **VAD réduisent les MRF chez les enfants.**
- **MRF persistants à la greffe cardiaque = taux de mortalité élevé**
- **Certains MRF spécifiques à la greffe (VM, curares, NPT et IR) indépendamment associés à la mortalité hospitalière**
- **Transplanter patients sous VAD avec 3 MRF pas prudent**
- **Etudes supplémentaires nécessaires pour déterminer la durée optimale VAD pour la réduction des MRF**
- **Rechercher de manière agressive une optimisation physiologique pré-transplantation des MRF**

Greenberg, JTCVS 2023

0003-4975/$36.00 1
https://doi.org/10.1016/j.athoracsur.2023.11.035

THE SOCIETY OF THORACIC SURGEONS PEDIMACS ANNUAL REPORT

Seventh Annual Society of Thoracic Surgeons Pedimacs Report

David M. Peng, MD,[1] Ryan R. Davies, MD,[2] Kathleen E. Simpson, MD,[3] Svetlana B. Shugh, MD,[4] David L. S. Morales, MD,[5] Jeffrey P. Jacobs, MD,[6,7] Arene Butto, MD,[8] Anna Joong, MD,[9] Jennifer Conway, MD,[10] Kerry Schindler, MSN, RN,[11] Eric R. Griffiths, MD,[12] Devin Koehl, MSDS,[13] Ryan S. Cantor, PhD,[13] James K. Kirklin, MD,[13] Joseph W. Rossano, MD,[14] and Iki Adachi, MD,[15] for the Pedimacs Investigators

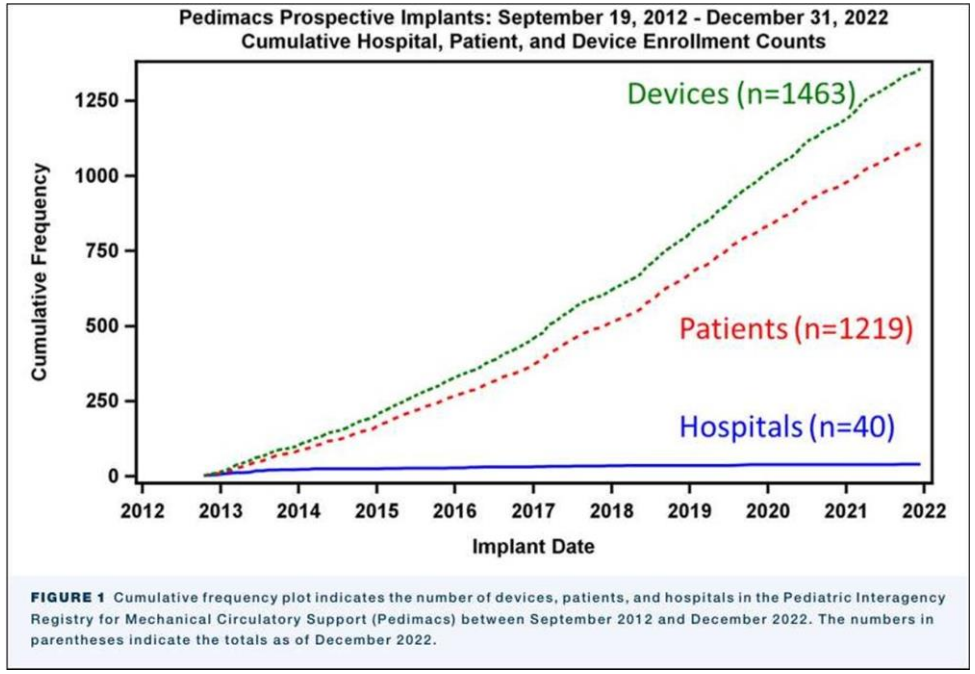


FIGURE 1 Cumulative frequency plot indicates the number of devices, patients, and hospitals in the Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs) between September 2012 and December 2022. The numbers in parentheses indicate the totals as of December 2022.

- **Septembre 2012-31 décembre 2022**
- **1463 machines**
- **1219 patients de < 19 ans**
- **40 Hopitaux Amérique du Nord**
- **Pedimacs vs Intermacs :**
  - ✓ **# pts vs devices ;**
  - ✓ **# longue + courte vs longue durée ;**
  - ✓ **# EIs évalués différemment (changement VAD)**
- **Outcomes par type de VAD et maladie**
- **Evolution sur prise en charge VAD pédiatriques en 10 ans**

HÔPITAUX Paris
Saint-Joseph
Marie-Lannelongue

TABLE 1 Characteristics of Pediatric Interagency Registry for Mechanical Circulatory Support Patients—Coverage: September 19, 2012, to December 31, 2022

Characteristics	Overall (N = 1219)	Paracorporeal Pulsatile (n = 342)	Paracorporeal Continuous (n = 327)	Implantable Continuous (n = 472)	P Value[a]
Age, y	7.5 ± 6.4	2.7 ± 3.6	3.1 ± 4.5	13.1 ± 3.8	<.0001
Age-group, y					
< 1	339 (27.8)	168 (49.1)	170 (52.0)		<.0001
1-5	255 (20.9)	128 (37.4)	97 (29.7)	26 (5.5)	<.0001
6-10	179 (14.7)	27 (7.9)	29 (8.9)	107 (22.7)	<.0001
11-19	446 (36.6)	19 (5.6)	31 (9.5)	339 (71.8)	<.0001
Weight, kg	32.8 ± 31.6	11.8 ± 12.0	14.1 ± 16.3	56.6 ± 30.2	<.0001
Weight, kg					
<5	161 (13.3)	77 (22.6)	84 (25.8)		<.0001
5-9	240 (19.8)	122 (35.8)	114 (35.1)	1 (0.2)	<.0001
10-20	216 (17.8)	104 (30.5)	71 (21.8)	39 (8.3)	<.0001
21-40	198 (16.3)	28 (8.2)	29 (8.9)	127 (27.0)	<.0001
41-70	240 (19.8)	8 (2.3)	22 (6.8)	175 (37.2)	<.0001
71-100	110 (9.1)	1 (0.3)	5 (1.5)	88 (18.7)	<.0001
>100	50 (4.1)	1 (0.3)		41 (8.7)	<.0001
Diagnosis					
Cardiomyopathy	716 (58.7)	204 (59.6)	123 (37.6)	356 (75.4)	<.0001
Dilated	662 (92.5)	180 (88.2)	108 (87.8)	341 (95.8)	.0009
Restrictive	26 (4.0)	14 (6.9)	9 (7.3)	8 (2.2)	.02
Hypertrophic	15 (2.3)	8 (3.9)	4 (3.3)	4 (1.1)	.08
Myocarditis	100 (8.2)	23 (6.7)	33 (10.1)	31 (6.6)	.14
Congenital heart disease	313 (25.7)	92 (26.9)	139 (42.5)	70 (14.8)	<.0001
Single ventricle	195 (62.3)	48 (52.2)	99 (71.2)	45 (64.3)	.01
Biventricular	118 (37.7)	44 (47.8)	40 (28.8)	25 (35.7)	.01
Other	90 (7.4)	23 (6.7)	32 (9.8)	15 (3.2)	.0006
Patient Profile					
1. Critical cardiogenic shock	371 (30.5)	100 (29.3)	146 (44.8)	90 (19.1)	<.0001
2. Progressive decline	689 (56.7)	202 (59.2)	154 (47.2)	294 (62.4)	<.0001
3. Stable but inotrope dependent	130 (10.7)	33 (9.7)	21 (6.4)	74 (15.7)	.0001
4-7. Resting symptoms or less sick	25 (2.1)	6 (1.8)	5 (1.5)	13 (2.8)	.43
Device type					
Left ventricular assist device	988 (81.1)	254 (74.3)	242 (74.0)	424 (89.8)	<.0001
Right ventricular assist device	63 (5.2)	14 (4.1)	36 (11.0)	12 (2.5)	<.0001
Biventricular assist device	162 (13.3)	74 (21.6)	49 (15.0)	35 (7.4)	<.0001
Total artificial heart	6 (0.5)			1 (0.2)	…
Device strategy					
Bridge to transplant—listed	596 (48.9)	251 (73.4)	128 (39.1)	198 (41.9)	<.0001
Bridge to candidacy	449 (36.8)	85 (24.9)	104 (31.8)	241 (51.1)	<.0001
Destination therapy	19 (1.6)	2 (0.6)		16 (3.4)	.0002
Bridge to recovery	109 (8.9)	2 (0.6)	76 (23.2)	15 (3.2)	<.0001
Other	46 (3.8)	2 (0.6)	19 (5.8)	2 (0.4)	<.0001
Previous cardiac operation	528 (43.3)	156 (45.6)	194 (59.3)	143 (30.3)	<.0001
Alanine aminotransferase >100 μ/L	251 (21.7)	57 (17.5)	63 (20.9)	109 (23.9)	.1
Bilirubin >1.2 mg/dL	400 (37.2)	97 (30.9)	120 (41.2)	160 (39.1)	.02
eGFR, mL/min/1.73 m^2					
<30	48 (4.0)	11 (3.3)	25 (7.9)	6 (1.3)	<.0001
30-60	234 (19.7)	68 (20.3)	75 (23.8)	73 (15.7)	.02
>60	906 (76.3)	256 (76.4)	215 (68.3)	387 (83.0)	<.0001
Intubated	637 (54.6)	229 (70.9)	250 (78.9)	114 (25.3)	<.0001
Inotropic agents	1155 (94.8)	321 (93.9)	311 (95.4)	447 (94.7)	.7
Paralyzed	309 (26.9)	113 (35.4)	124 (39.5)	50 (11.3)	<.0001
Feeding tube/TPN dependent	731 (68.8)	281 (91.2)	254 (90.1)	164 (39.2)	<.0001

[a]P value compares characteristics across the 3 device classifications. Data are presented as mean ± SD or n (%). eGFR, estimated glomerular filtration rate; TPN, total parental nutrition.

TABLE 2 Patient Characteristics by Diagnosis (N = 1029) From Pediatric Interagency Registry for Mechanical Circulatory Support: September 19, 2012, to December 31, 2022

Characteristics	Cardiomyopathy (n = 716)	Congenital Heart Disease (n = 313)	P Value
Age, y	8.5 ± 6.5	4.6 ± 5.4	<.0001
Age-group, y			
<1	178 (24.9)	133 (42.5)	<.0001
1-5	121 (16.9)	88 (28.1)	<.0001
6-10	107 (14.9)	40 (12.8)	.4
11-19	310 (43.3)	52 (16.6)	<.0001
Weight, kg	38.5 ± 34.3	17.8 ± 20.1	<.0001
Weight, kg			
<5	65 (9.1)	76 (24.4)	<.0001
5-9	141 (19.8)	78 (25.0)	.06
10-20	98 (13.7)	78 (25.0)	<.0001
21-40	124 (17.4)	40 (12.8)	.07
41-70	160 (22.4)	30 (9.6)	<.0001
71-100	82 (11.5)	8 (2.6)	<.0001
>101	43 (6.0)	2 (0.6)	.0001
Patient Profile			
1. Critical cardiogenic shock	192 (26.9)	102 (32.8)	.05
2. Progressive decline	429 (60.0)	177 (56.9)	.4
3. Stable but inotrope dependent	82 (11.5)	27 (8.7)	.2
4-7. Resting symptoms or less sick	12 (1.7)	5 (1.6)	.9
Device type			
Left ventricular assist device	619 (86.5)	231 (73.8)	<.0001
Right ventricular assist device		53 (16.9)	<.0001
Biventricular assist device	94 (13.1)	27 (8.6)	.04
Total artificial heart	3 (0.4)	2 (0.6)	.4
Device class			
Paracorporeal pulsatile	356 (49.7)	70 (22.4)	.8
Paracorporeal continuous	123 (17.2)	139 (44.4)	<.0001
Implantable continuous	204 (28.5)	92 (29.4)	<.0001
Percutaneous	31 (4.3)	10 (3.2)	.4
Total artificial heart	2 (0.3)	2 (0.6)	.4
Device strategy			
Bridge to transplant—listed	367 (51.3)	168 (53.7)	.5
Bridge to candidacy	291 (40.6)	100 (31.9)	.01
Destination therapy	15 (2.1)	3 (1.0)	.2
Bridge to recovery	33 (4.6)	30 (9.6)	.001
Other	10 (1.4)	12 (3.8)	.01
Previous cardiac operation	156 (21.8)	271 (86.6)	<.0001
Alanine aminotransferase >100 μ/L	159 (23.0)	40 (13.8)	.001
Bilirubin >1.2 mg/dL	220 (34.4)	134 (48.4)	<.0001
eGFR, mL/min/1.73 m^2			
<30	17 (2.4)	18 (5.9)	.01
30-60	132 (18.7)	60 (19.8)	.7
>60	556 (78.9)	225 (74.3)	.1
Intubated	317 (46.3)	203 (67.9)	<.0001
Inotropic agents	679 (94.8)	298 (95.2)	.8
Paralyzed	153 (22.7)	98 (33.1)	.0007
Feeding tube/TPN dependent	388 (62.3)	235 (82.7)	<.0001

Data are presented as mean ± SD or n (%). eGFR, estimated glomerular filtration rate; TPN, total parental nutrition.

- **Type de VAD : IC 472 (39%), PP 342 (28%), PC 327 (27%),**
- **Percutané 73 (6%), TAH 5 (0.4%). 108 pts (9%) hopitaux à petit volume, 176 (14%) hopitaux de volume moyen, 418 (34%) grand volume et 517 (42%) plus grand volume**
- **Follow-up time on VAD 2 mois (1 j -6.5 a) years)**
- **IC VADs 54% à la maison**
- **Cardiomiopathie 59%, CHD 26%), and Myocardite 8%**
- **Groupe CHD 62% VU**
- **CHD plus jeunes, VAD-PP (2.7 + 3.6 a ; 27% CHD) and PC (3.1 + 4.5 a ; 43% CHD) IC VADs 13.1 + 3.8 a ; 15% CHD)**
- **LVAD 81% RVAD 5% BiVAD 13% TAH 0.5%**
- **BTT 49% BTC 37% BTC 23% (mais que 9% ok) DT 1.6% (19 pts)**
- **216 décès (1219, 17.7%) : pire si < poids, CHD, INTERMACS < 2, PC**

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Survie, Age, Type de VAD, classe INTERMACS

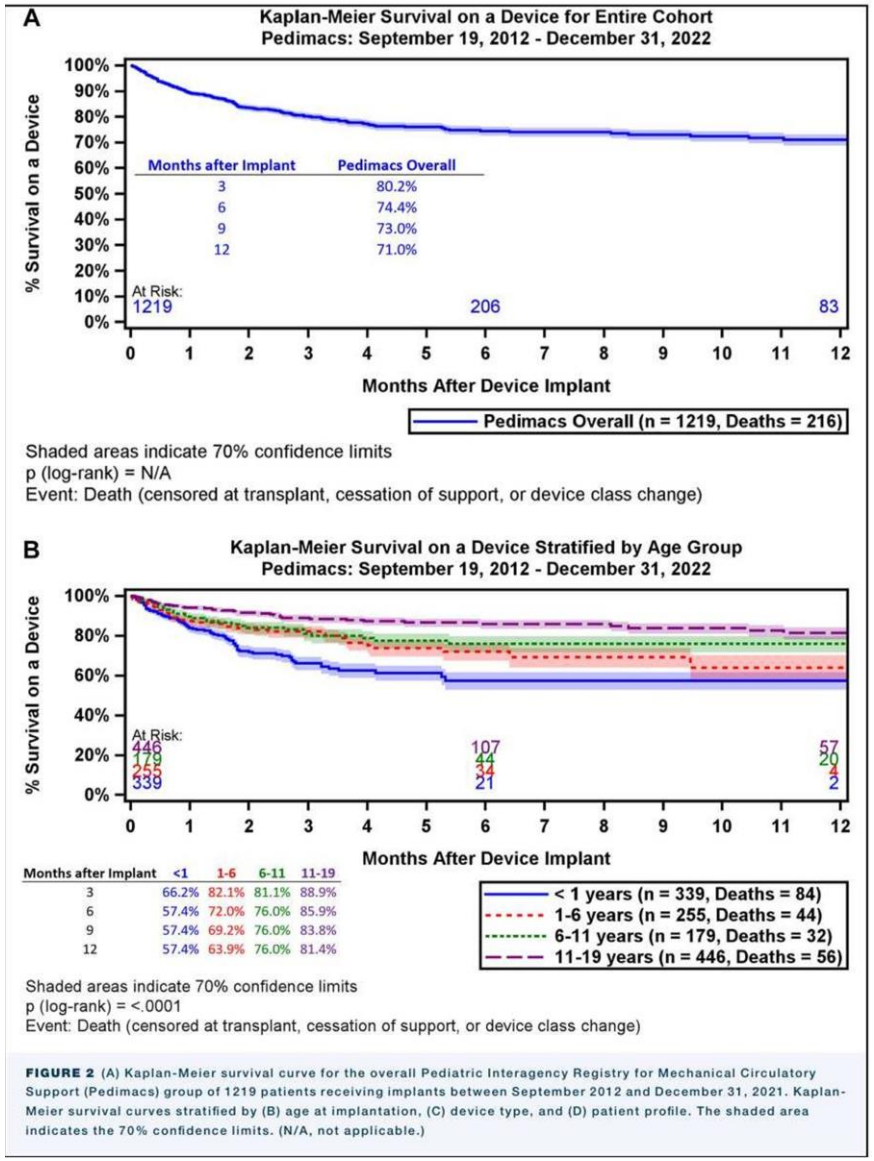

FIGURE 2 (A) Kaplan-Meier survival curve for the overall Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs) group of 1219 patients receiving implants between September 2012 and December 31, 2021. Kaplan-Meier survival curves stratified by (B) age at implantation, (C) device type, and (D) patient profile. The shaded area indicates the 70% confidence limits. (N/A, not applicable.)

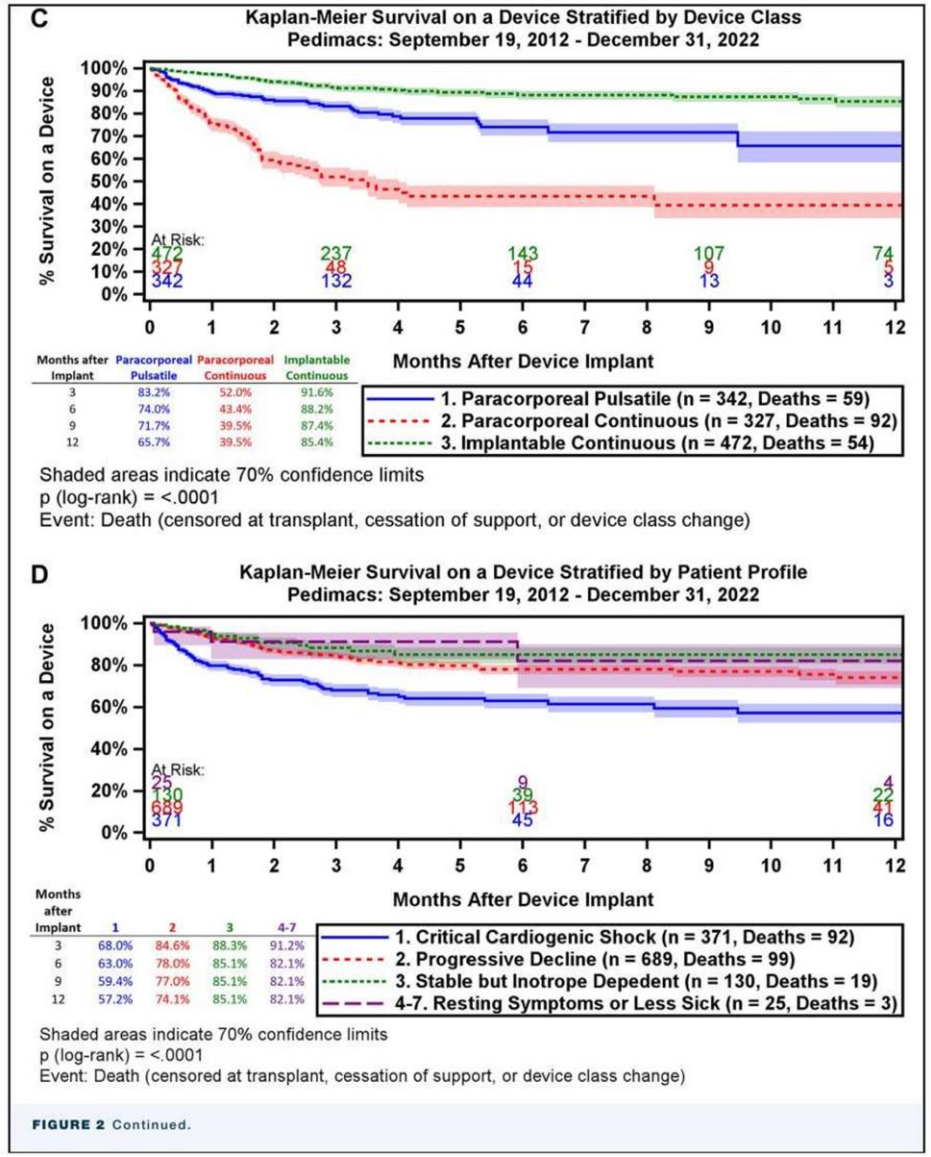

FIGURE 2 Continued.

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Survie, Pathologie, Type de VAD

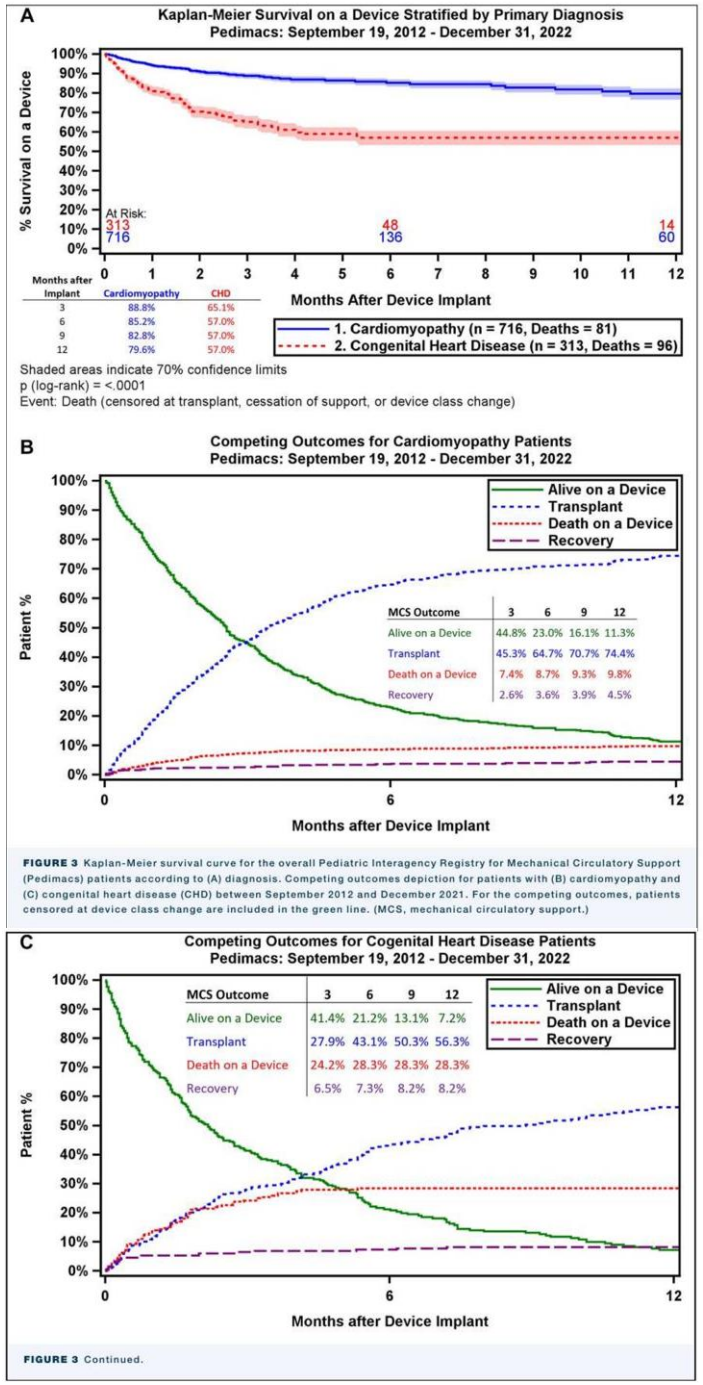

FIGURE 3 Kaplan-Meier survival curve for the overall Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs) patients according to (A) diagnosis. Competing outcomes depiction for patients with (B) cardiomyopathy and (C) congenital heart disease (CHD) between September 2012 and December 2021. For the competing outcomes, patients censored at device class change are included in the green line. (MCS, mechanical circulatory support.)

FIGURE 3 Continued.

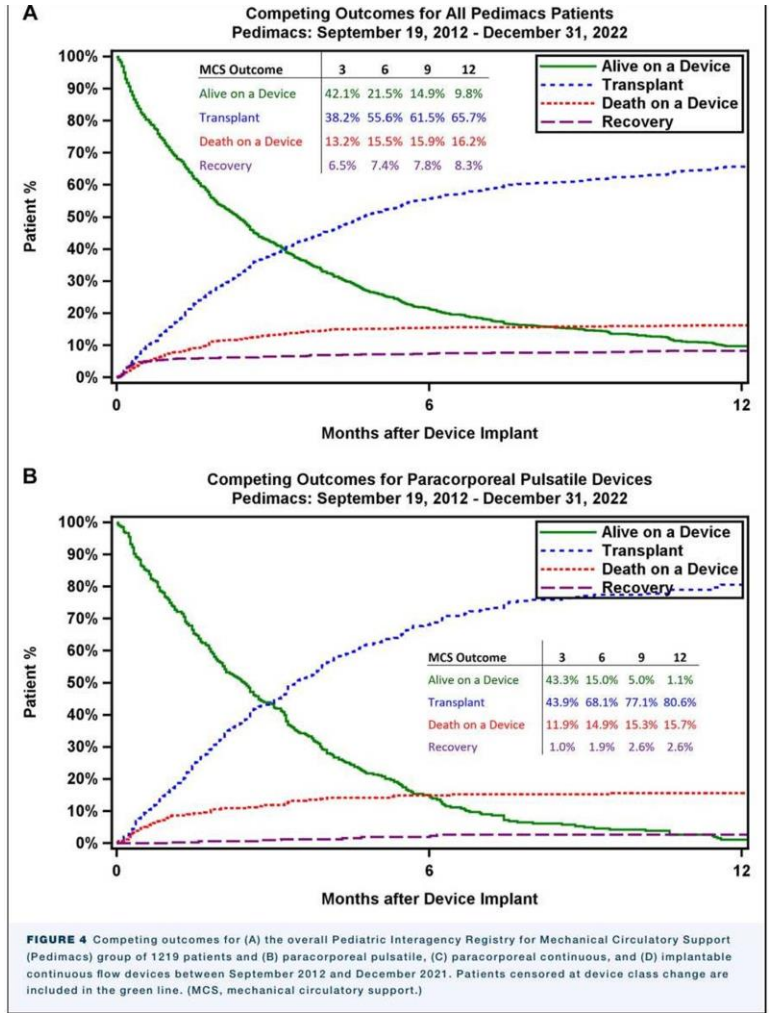

FIGURE 4 Competing outcomes for (A) the overall Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs) group of 1219 patients and (B) paracorporeal pulsatile, (C) paracorporeal continuous, and (D) implantable continuous flow devices between September 2012 and December 2021. Patients censored at device class change are included in the green line. (MCS, mechanical circulatory support.)

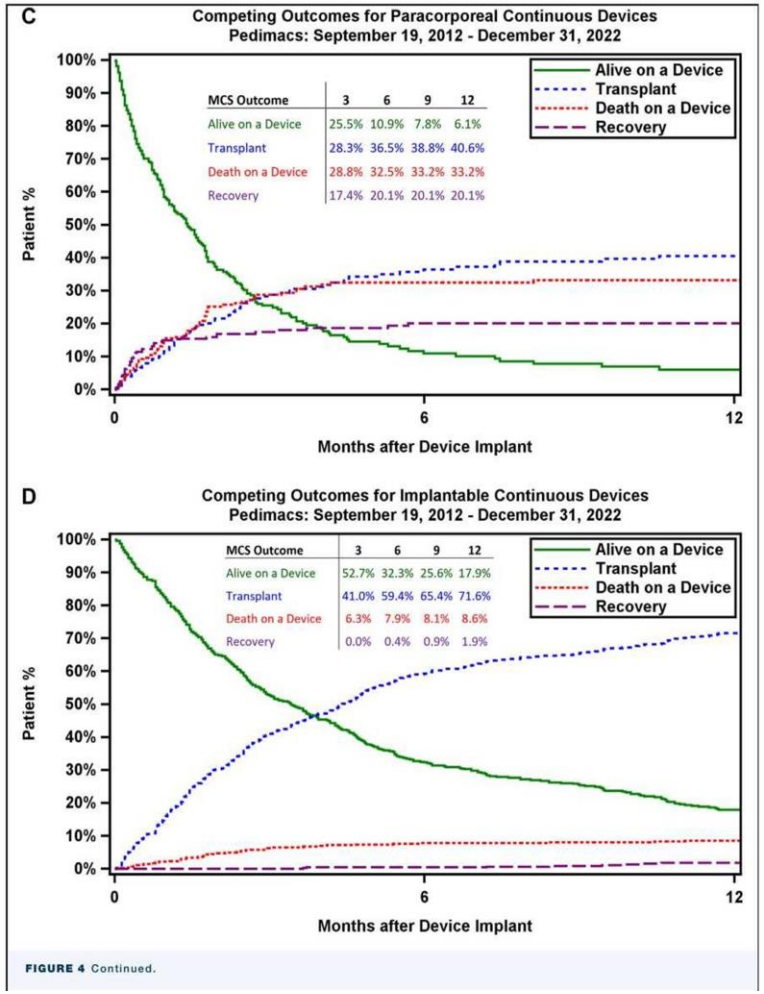

FIGURE 4 Continued.

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Causes décès

TABLE 3 Mode of Death for Pediatric Interagency Registry for Mechanical Circulatory Support Patients—Coverage: September 19, 2012 to December 31, 2022

Mode of Death	Overall (n = 216)	Paracorporeal Pulsatile (n = 59)	Paracorporeal Continuous (n = 92)	Implantable Continuous (n = 54)
Circulatory	41 (19.0)	10 (16.9)	15 (16.3)	13 (24.1)
Device malfunction	1 (0.5)			1 (1.9)
Digestive: gastrointestinal	59 (27.3)	14 (23.7)	31 (33.7)	11 (20.4)
Multisystem organ failure	49 (22.7)	13 (22.0)	22 (23.9)	10 (18.5)
Major infection	11 (5.1)	6 (10.2)	3 (3.3)	2 (3.7)
Neurologic	29 (13.4)	8 (13.6)	10 (10.9)	10 (18.5)
Other	18 (8.3)	5 (8.5)	7 (7.6)	6 (11.1)
Respiratory	8 (3.7)	3 (5.1)	4 (4.3)	1 (1.9)

Data are presented as n (%). *P* values comparing modes of death by device types were not significant ($P = .5$).

Evénements Indésirables

TABLE 4 Adverse Events for Pediatric Interagency Registry for Mechanical Circulatory Support Patients (n = 1141)—Coverage: September 19, 2012, to December 31, 2022

		All (PP+PC+IC)			Paracorporeal Pulsatile			Paracorporeal Continuous			Implantable Continuous		
Event	Period[a]	Patient (%)	Rate[b]	Device Incidence (%)	Patient (%)	Rate	Device Incidence (%)	Patient (%)	Rate	Device Incidence (%)	Patient (%)	Rate	Device Incidence (%)
Gastrointestinal bleeding	Early	2	0.6	6	1	0.5	5	4	1.6	9	1	0.23	5
	Late	5	0.2		3	0.2		6	1.0		4	0.1	
Nongastrointestinal bleeding	Early	13	4.3	20	9	2.6	14	17	7.3	24	12	3.9	21
	Late	9	0.4		6	0.3		8	1.7		11	0.3	
Infection	Early	12	4.1	28	9	2.6	26	18	8.19	32	10	2.84	28
	Late	22	1.3		21	1.6		22	4.4		22	0.8	
Device malfunction/ thrombus	Early	...	...	...	...	...	...	...	...	...	3	0.7	12
	Late	...	...		...	...		...	...		10	0.2	
Neurologic dysfunction	Early	10	3.3	21	11	3.4	23	16	6.12	27	6	1.65	17
	Late	13	0.5		14	0.9		14	1.75		12	0.3	
Cerebrovascular accident	Early	9	0.4	10	6	1.5	12	4	1.7	12	3	0.9	8
	Late	4	1.3		8	0.4		8	0.9		6	0.1	
Ischemic stroke	Early	3	0.9	7	3	0.8	8	3	1.0	9	3	0.8	5
	Late	4	0.2		6	0.3		6	0.6		3	0.1	
Hemorrhagic stroke	Early	1	0.3	4	2	0.5	5	2	0.5	3	4	0.08	3
	Late	3	0.09		3	0.1		2	0.2		0.2	0.1	

[a]Early is ≤2 weeks after implant; Late is >2 weeks after implant; [b]Rates are reported per patient-year. IC, implantable continuous; PC, paracorporeal continuous; PP, paracorporeal pulsatile.

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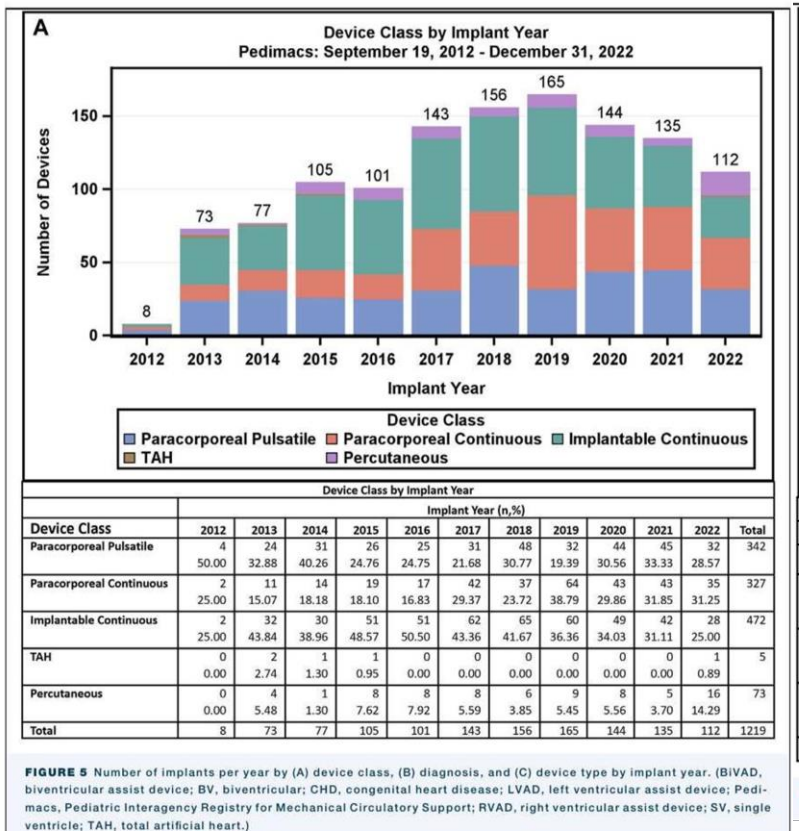
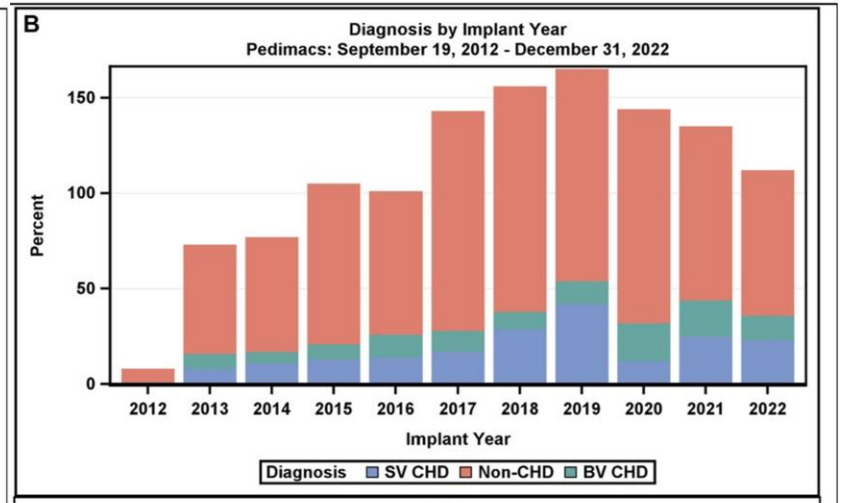
Moins d'implantations sur 3 ans, plus de percutanés, moins d'IC et plus de PP (plus de VAD sur CHD)



Device Class by Implant Year

Device Class	Implant Year (n,%) 2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Total
Paracorporeal Pulsatile	4 50.00	24 32.88	31 40.26	26 24.76	25 24.75	31 21.68	48 30.77	32 19.39	44 30.56	45 33.33	32 28.57	342
Paracorporeal Continuous	2 25.00	11 15.07	14 18.18	19 18.10	17 16.83	42 29.37	37 23.72	64 38.79	43 29.86	43 31.85	35 31.25	327
Implantable Continuous	2 25.00	32 43.84	30 38.96	51 48.57	51 50.50	62 43.36	65 41.67	60 36.36	49 34.03	42 31.11	28 25.00	472
TAH	0 0.00	2 2.74	1 1.30	1 0.95	0 0.00	0 0.00	0 0.00	0 0.00	0 0.00	0 0.00	1 0.89	5
Percutaneous	0 0.00	4 5.48	1 1.30	8 7.62	8 7.92	8 5.59	6 3.85	9 5.45	8 5.56	5 3.70	16 14.29	73
Total	8	73	77	105	101	143	156	165	144	135	112	1219

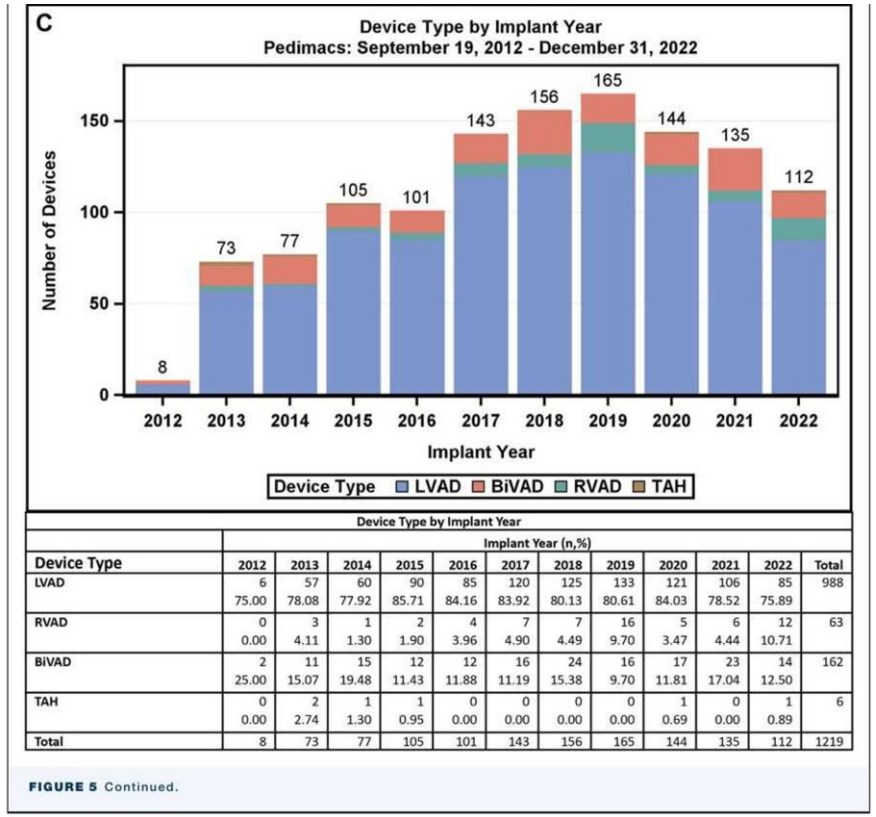
FIGURE 5 Number of implants per year by (A) device class, (B) diagnosis, and (C) device type by implant year. (BiVAD, biventricular assist device; BV, biventricular; CHD, congenital heart disease; LVAD, left ventricular assist device; Pedimacs, Pediatric Interagency Registry for Mechanical Circulatory Support; RVAD, right ventricular assist device; SV, single ventricle; TAH, total artificial heart.)



Diagnosis by Implant Year

Diagnosis	Implant Year (n,%) 2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Total
SV CHD	1 12.50	8 10.96	11 14.29	13 12.38	14 13.86	17 11.89	29 18.59	42 25.45	12 8.33	25 18.52	23 20.54	195
BV CHD	0 0.00	8 10.96	6 7.79	8 7.62	12 11.88	11 7.69	9 5.77	12 7.27	20 13.89	19 14.07	13 11.61	118
Non-CHD	7 87.50	57 78.08	60 77.92	84 80.00	75 74.26	115 80.42	118 75.64	111 67.27	112 77.78	91 67.41	76 67.86	906
Total	8	73	77	105	101	143	156	165	144	135	112	1219

FIGURE 5 Continued.



Device Type by Implant Year

Device Type	Implant Year (n,%) 2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Total
LVAD	6 75.00	57 78.08	60 77.92	90 85.71	85 84.16	120 83.92	125 80.13	133 80.61	121 84.03	106 78.52	85 75.89	988
RVAD	0 0.00	3 4.11	1 1.30	2 1.90	4 3.96	7 4.90	7 4.49	16 9.70	5 3.47	6 4.44	12 10.71	63
BiVAD	2 25.00	11 15.07	15 19.48	12 11.43	12 11.88	16 11.19	24 15.38	16 9.70	17 11.81	23 17.04	14 12.50	162
TAH	0 0.00	2 2.74	1 1.30	1 0.95	0 0.00	0 0.00	0 0.00	0 0.00	1 0.69	0 0.00	1 0.89	6
Total	8	73	77	105	101	143	156	165	144	135	112	1219

FIGURE 5 Continued.

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Stroke Diagnosis Protocol for Children With Ventricular Assist Devices

MICHELE G. MILLS ,* ALLISON REICHHOLD,†,‡ KIM MACIOROWSKI,§ ANNA JOONG,† JONATHAN KURZ,*,¶,// AND ANDREA C. PARDO*,¶

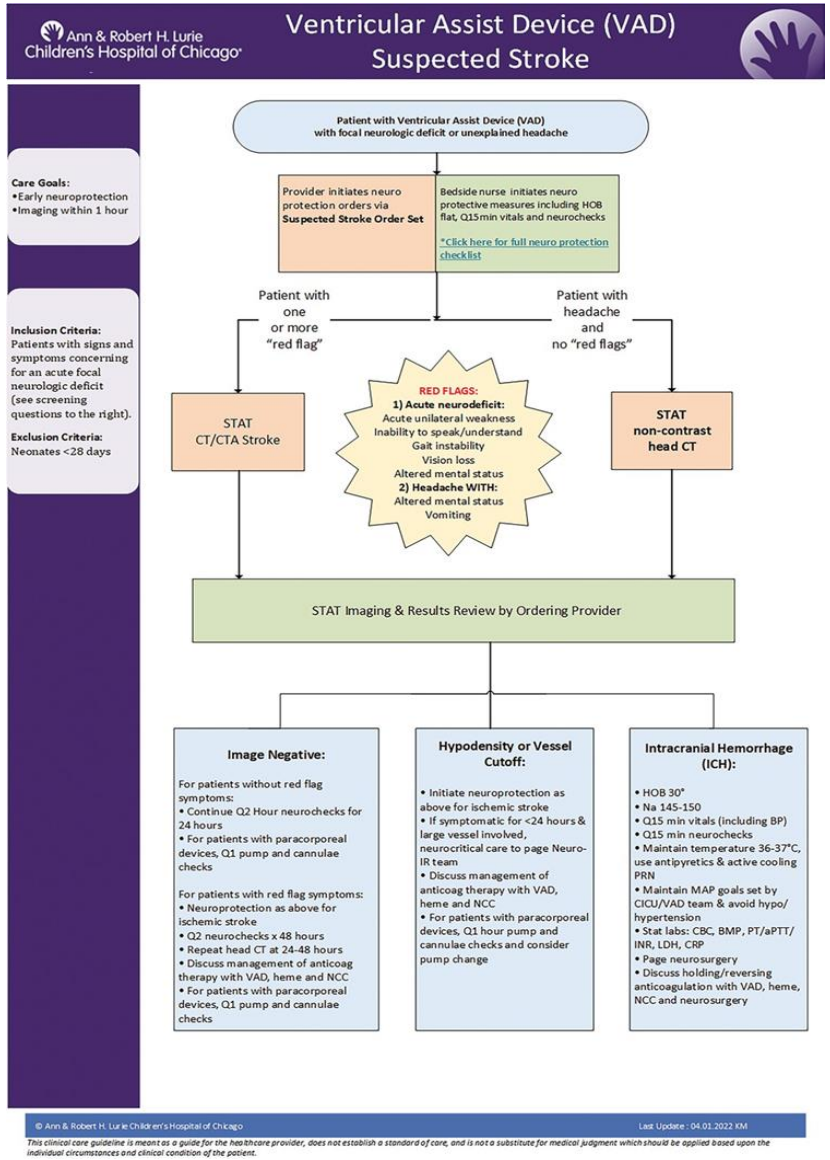

Table 2. VAD Neuroimaging Indications and Findings

	Preimplementation	Postimplementation	*p*
Total patients	25	21	
Imaging for neurologic concern			
Episodes	21	8	0.231
Patients (N, %)	12 (48%)	6 (29%)	
Imaging findings			
Intracranial hemorrhage	4	0	0.114
Subdural hemorrhage	2	2	
Intracranial hemorrhage	2	2	
Ischemic stroke			
Patients	4		0.673
Events	6		
Time from VAD implant to ischemic stroke detection (days, median [Q1–Q3])	27 (19.5–32.25)	4.5 (2–9)	0.155
Imaging indications			
Headache	3	2	0.133
Focal weakness or facial asymmetry	4	6	
Mental status change or irritability	5	1	
Other neurologic symptoms	4	1	
Systemic/nonneurologic symptoms	5	0	
Episodes with last known normal documented (N, %)	9 (43%)	8 (100%)	0.009
Last known normal to Image (minutes, median [Q1–Q3])	436 (246–780)	104.5 (85.75–248.5)	0.038

Neurologic injury remains a significant cause of morbidity and mortality for children receiving VAD therapy. The vast majority of these events occur in the early postoperative period, with children under the care of inpatient cardiac intensive care and cardiology units. Development of inpatient hospital protocols to facilitate regular neurologic surveillance and rapid brain imaging for these children can improve the diagnosis of neurologic injury, allowing for earlier provision of neuroprotective care. As the use of revascularizing therapies in this population becomes better understood, rapid diagnosis may allow more children to be candidates for these therapies.

Myocardial recovery in children supported with a durable ventricular assist device—a systematic review

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European Journal of Cardio-Thoracic Surgery 2023, 64(2), ezad263
https://doi.org/10.1093/ejcts/ezad263 Advance Access publication 27 July 2023

VAD explantation due to myocardial recovery - SR

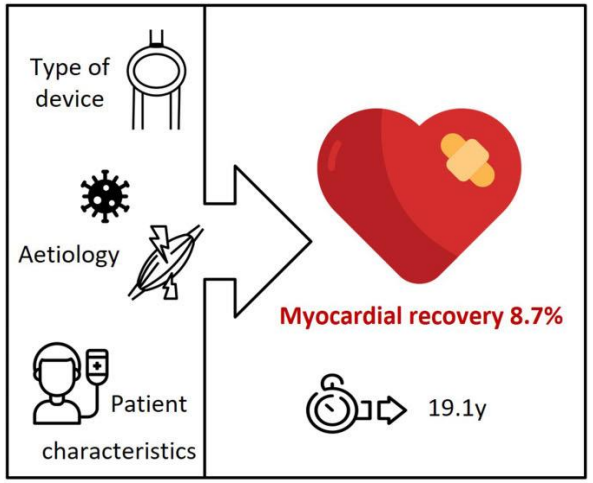
Core findings

Paediatric patients (<18y) on ventricular assist device

8.7% myocardial recovery

Various ages, aetiologies, and device types

Maximum follow up 19.1 years



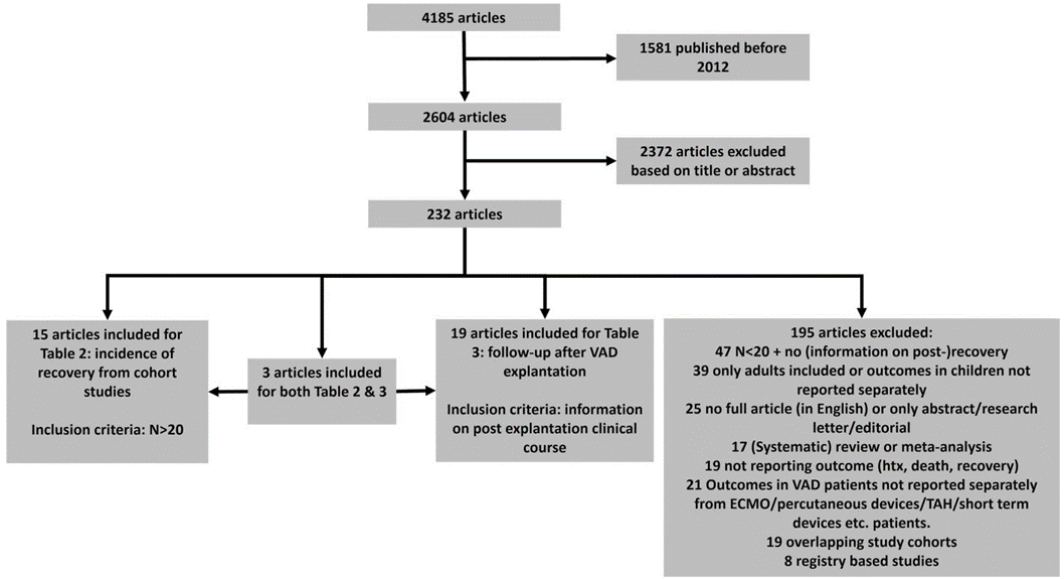
SR = systematic review, y = years

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Published in the last decade (from 2012–May 2022)	No outcomes reported (transplant, death, recovery)
Paediatric patients	Adults or outcomes in adults not separately reported from outcomes in children
Durable ventricular assist devices	Extracorporeal membrane oxygenation Total artificial heart Percutaneous device Short-term device No information on the exact type of device Right ventricular assist device (RVAD)*
English	No full article (in English)
Cohort studies Case series Case reports	Abstracts Research letters Editorials Systematic reviews Meta-analyses

Objectifs de la review :

- **taux d'explantation VAD pour récupération du myocarde**
- **étudier l'évolution clinique après l'explantation**



	First author	Year published	Study type	Study period	Patients	Aetiology*	Prior ECMO	INTERMACS classification†	Type of device	LVAD/BiVAD	Length of support	Outcome	Recovery rate
	Sandica [45]	2016	Single-centre cohort study	2008–2014	n = 38 61% Male	29% Myocarditis 63% CMP 8% CHD	n = 1		29 BHE 9 HVAD	30 LVAD 8 BiVAD	BHE: Med 65 days (IQR 4–619) HVAD: Med 180 days (IQR 1–1124)	27 HTx 4 Died 6 Recovered 1 Ongoing	15.8%
	Miera [7]	2018	Single-centre cohort study	1990–2016	n = 149 54% Male Med 5.8 years Med 17.0 kg	9% Myocarditis 66% CMP 25% CHD		67% 1 29% 2 5% 3 0% 4	128 BHE 32 HVAD	96 LVAD 52 BiVAD 1 RVAD	Med 37 days (IQR 10–79)	79 HTx 48 Died 21 Recovered 1 Ongoing	14.1%
	Iacobelli [17]	2017	Single-centre cohort study	2007–2016	n = 27 55% Male Med 11 months Med 6.3 kg	100% CMP			All BHE	27 LVAD	Med 147 days (IQR 86–210)	20 HTx 6 Died 1 Recovered	3.7%
	Ponzoni [14]	2021	Single-centre cohort study	2004–2021	n = 20	15% Myocarditis 45% CMP 35% CHD 5% Other/undefined			13 BHE 7 HVAD			16 HTx 4 Died	0.0%
Europe	Pawlak [46]	2018	Multicentre cohort study	2009–2015	n = 27 61% Male Med 3.5 years Med 12.5 kg	19% Myocarditis 52% CMP 26% CHD 4% Other/undefined	n = 2	11% 1 56% 2 26% 3 4% 4 4% 5	All BHE	21 LVAD 6 BiVAD	Med 89 days (Range 6–1215)	10 HTx 8 Died 6 Recovered 3 Ongoing	22.2%
	Redondo [18]	2019	Single-centre cohort study	"the experience so far"	n = 116	"Mostly DCM"	n = 42		98 BHE 18 HVAD	83 LVAD 33 BiVAD	BHE: Mean 95 days (SD 148) HVAD: Mean 248 days (SD 346)	92 HTx 13 Died 6 Recovered 5 Ongoing	5.2%
	Rohde [19]	2020	Single-centre cohort study	2007–2018	n = 28 43% Male Med 10.7 years Med 29.9 kg	4% Myocarditis 79% CMP 18% Other/ undefined	n = 11	100% 2	All BHE	25 LVAD 3 BiVAD	Med 37 days (IQR 12–123)	14 HTx 11 Died 2 Recovered 1 Ongoing	7.1%
	Bartfay [13]	2021	Single-centre cohort study	2008–2018	n = 21 52% Male Med 5 years Mean 16 kg	10% Myocarditis 43% CMP 29% CHD 19% Other/undefined	n = 7	60% 1 40% 2–5	All BHE	15 LVAD 5 BiVAD 1 RVAD**	Med 79 days (IQR 39–239)	12 HTx 1 Died 8 Recovered	38.1%
	Fouilloux [22]	2021	Multicentre cohort study	2005–2017	n = 54 54% Male Med 17 months Med 9.8 kg	18% Myocarditis 72% CMP 6% CHD 4% Other/undefined	n = 14		All BHE	27 LVAD 27 BiVAD	Mean 623 days (Range 5–267)	32 HTx 15 Died 7 Recovered	13.0%
North America	Byrnes [21]	2013	Single-centre cohort study	2005–2012	n = 39 Mean 5.5 years BSA mean 0.8 m^2	44% Myocarditis 28% CMP 23% CHD 5% Other/undefined	n = 16		All BHE	21 LVAD 18 BiVAD	Mean 39 days (SD 41)	34 HTx 3 Died 2 Recovered	5.1%
	Bleiweis [20]	2022	Single-centre cohort study	2006–2022	n = 82 Med 191 days Med 5.8 kg	4% Myocarditis 39% CMP 54% CHD 4% Other/undefined			All BHE	5 LVAD 43 BiVAD 34 SVAD	Non-ongoing patients: Med 108 days (Range 4–554)	57 HTx 18 Died 5 Recovered 2 Ongoing	2.4%
	Miller [23]	2015	Single-centre cohort study	2005–2014	n = 48			All 1 or 2	40 BHE 6 HVAD 2 HMII	17 LVAD 31 BiVAD		40 HTx 7 Died/ongoing 1 Recovered	2.1%
	Stein [16]	2016	Single-centre cohort study	2004–2013	n = 50 58% Male Mean 5.4 years Mean 20.5 kg	6% Myocarditis 74% CMP 18% CHD 2% Other/undefined	n = 18		27 BHE 14 PVAD 9 HVAD or HMII	35 LVAD 15 BiVAD	Mean 75 days (range 2–906)	37 HTx 8 Died 5 Ongoing/undefined	0.0%
	Fraser [24]	2019	Single-centre cohort study	1996–2017	n = 117 51% Male	2% Myocarditis 68% CMP 21% CHD 10% Other/ undefined	n = 11	13% 1 56% 2 26% 3 2% 4 1% Unknown	48 BHE 38 HVAD 17 HMII 11 PVAD 3 DeBakey	105 LVAD 9 BiVAD 3 RVAD	Range 2–2259 days	76 HTx 19 Died 7 Recovered 15 Ongoing/undefined	6.0%
	Sen [15]	2020	Single-centre cohort study	2009–2018	n = 27 63% Male Med 12.2 y	96.3% CMP 3.7% CHD			9 BHE 18 HVAD	27 LVAD	Med 413 days (range 30–2010)	15 HTx 5 Died 7 Ongoing/undefined	0.0%
Asia	Sert [25]	2020	Single-centre cohort study	2014–2018	n = 21 52% Male Mean 11.0 years Mean 33.1 kg	"mostly CMP"	n = 2	Mean 2.3 ± 0.75	19 HVAD 1 HM II 1 HM 3	21 LVAD	Mean 421 days (Range 18–1460)	9 HTx 7 Died 1 Recovered 4 Ongoing/undefined	4.8%
	Komori [35]	2022	Single-centre cohort study	2015–2021	n = 20 30% Male Med 10.8 months Med 6.3 kg	15% Myocarditis 75% CMP 10% CHD	n = 10		All BHE	18 LVAD 2 BiVAD	Med 365 days (Range 241–636)	7 HTx 1 Died 5 Recovered 7 Ongoing/undefined	25.0%
AU	Huang [47]	2019	Single-centre cohort study	2009–2017	n = 44 52% Male	14% Myocarditis 89% CMP 18% CHD***	n = 21		34 BHE 10 HVAD	35 LVAD 5 BiVAD 4 SVAD	Med 78 days (IQR 36–144)	27 HTx 8 Died 3 Recovered 6 Ongoing/undefined	6.8%
	18 articles included, 928 patients Recovery rates between 0 and 38.8%; overall recovery rate 8.7%												

18 articles
928 pts
Recovery 0-38.8%
Recovery globale 8.7%

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HÔPITAUX Paris Saint-Joseph Marie-Lannelongue

Table 3: Follow-up after explantation of a ventricular assist device

	First Author	Year	Study type	Patient(s)	Aetiology	Prior ECMO	LVAD/BiVAD	Length of VAD support	Outcome after explantation	Length of Follow-up
Berlin Heart EXCOR	George [48]	2013	Case report	n = 1 22 Month-old-Male	PVB19 Myocarditis	Yes	LVAD	152 Days	Minimal symptoms of heart failure (NYHA I), LVEF 65%	3.5 Years
	Irving [8]	2014	Case series	n = 10 40% Male Med 1.1 years Med 10.5 kg	3 Myocarditis 4 DCM 1 HCM 1 CHD 1 Post HTx		5 LVAD 5 BiVAD	Med 36 days (Range 11–120)	6 Stable/normal cardiac function 3 VAD reimplants (8 days, 10 months and 13 months post-explant) 1 died 5 days post-explant (massive cerebral haemorrhage)	
	Sandica [45]	2016	Cohort study	n = 6			6 LVAD	Med 40.5 days (IQR 5–102)	100% Survival	Med 25.7 months (Range: 9–48)
	Urbanska [49]	2016	Case report	n = 2 3 and 3.5 Months 4.3 and 5.9 kg	2 CHD: Bland-White-Garland syndrome 3 weeks and 2 days post-operatively	No	2 LVAD	174 Days and 26 days	Both had normal circulation	
	Kohli [11]	2018	Case report	n = 1 20-Month-old female 13 kg	Pre-excitation- induced ventricular dysfunction	No	BiVAD	48 Days	Normal cardiac function	3 Years
	Fang [50]	2018	Case report	n = 1 6-Month-old male 7.4 kg	Permanent junctional reciprocating tachycardia with DCM	Yes	LVAD	47 Days	2 Weeks post-explant, EF 43%; discharged at 3 weeks	3 Weeks
	Tominaga [34]	2020	Case series	n = 4 0.4–2.1 years 6.1–8.4 kg	All DCM		4 LVAD	3.7–14 Months	Discharged home 5.6–8.2 months after explantation All doing well with no rehospitalization for heart failure	Med 24 months (IQR 17–27)
	Philip [32]	2021	Case report	n = 2 6 and 9 Months 7 and 8 kg	1 DCM 1 CHD	No	2 BiVAD	2 Months and 6 months	Both have normal cardiac function.	18 and 21 Months
	Wilkinson [51]	2021	Case report	n = 1 17-Month-old female 8.4 kg	Left main coronary artery atresia with ischaemic CMP	Yes	LVAD	59 Days	LVEF 60%	12 Months
	Delmo [30]	2021	Multi-institutional cohort study	n = 25 40% Male Med 3.4 years	11 Myocarditis 7 DCM 2 Other CMP 3 Ischaemic 1 Post-HTx 1 Post- cardiotomy	n = 2	18 LVAD 6 BiVAD 1 RVAD	Med 42 days (Range 7–700)	21 (84.0%) Alive with their native hearts 4 Died. No VAD re-implants	Med 7.8 years (range 1.3–19.1)
	Bartlay [13]	2021	Cohort study	n = 8	2 Myocarditis 1 DCM 3 CHD 2 Other/undefined		7 LVAD 1 BiVAD	Range 31–110 days	7 Survivors without recurrent heart failure 1 Died of cardiogenic shock after 3 months	
	Fouilloux [22]	2021	Cohort study	n = 7			Unknown		3 Died after 15 days (cardiac failure), 68 days (septic shock) and 109 days (ventricular arrhythmias) 4 Survived > 120 days	Range 15–120 days
HVAD	Torpocco Rivera [38]	2022	Case report	n = 2 13 Months and 3 months	1 Myocarditis 1 Multiform atrial tachycardia	n = 1	2 LVAD	3 Months and 142 days	1 Normal ventricular function 1 Discharged at 2 weeks with oral heart failure regime	18 Months and at least 2 weeks
	Cavigelli-Brunner [37]	2014	Case report	n = 1 8-Year-old female BSA 0.97 m^2	Anthracycline-induced CMP	No	LVAD	149 Days	Globally reduced biventricular function (LVEF 45%)	4 Months
	Kirk [52]	2016	Case report	n = 1 3-Year-old male 13.5 kg	Post-myocarditis DCM	No	LVAD	149 Days	Fully active, no limitations (Device in situ, decommissioned)	12 Months
	Arslan [53]	2019	Case series	n = 1 12-Year-old male	Tachycardia-induced CMP	Yes	LVAD	1 Month	After 2 years, need for a permanent pacemaker due to an intermittent complete AV block	2 Years
	Puri [33]	2022	Case series	n = 2 14 Years and 7 years	Post-chemotherapy CMP		2 LVAD	12 Months and 9 months	1 With normal ejection fraction 1 With moderately depressed biventricular systolic function (LVEF 36–46%)	6 Years and 3.5 years
HMI	Geoffrion [10]	2021	Case report	n = 1 13-Year-old male	Myocarditis	No	LVAD	1 Day	ECMO and relisting 1 day after explant, survived to HTx	
	Akil [54]	2016	Case series	n = 1 15-Year-old male	Acute transplant rejection		LVAD	2 Months	Died (cause not reported)	87 Months
PVAD	Boston [9]	2019	Case report	n = 1 7 Months	CHD: DORV, hypoplastic aortic arch, common AV canal, hypoplastic RV 2-Month post stage II palliation	No	SVAD	7 Days	Alive and free from transplant and VAD re-implant	16 Months
	Merritt [55]	2022	Case series	n = 4 3.3–4.0 kg	2 SV, prior to surgical palliation 2 SV, post Norwood/hybrid	n = 4	4 SVAD	60–99 Days	2 Alive at discharge 2 Died at discharge (1 failure to wean from ventilator + mitochondrial disorder (diagnosis after explant); 1 persistent cardiopulmonary failure + concomitant MOF)	
Jarvik	Healy [31]	2015	Case report	n = 1 16-Year-old male	Cardiogenic shock; no aetiology was definitely diagnosed	No	LVAD*	12 Months	NYHA 1	3 Months
				22 articles included: 12 case reports, 6 case series and 4 cohort studies 83 patients, 84.3% supported by a BHE Max follow-up, 19.1 year; 14.5% died						

22 articles : 12 case reports, 6 case series and 4 études de cohort
83 patients
84.3% avec Berlin Heart Excor
Max follow-up, 19.1 year
Mortalité 14.5%

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- La Myocardite et la CMP post-cardiotomique pas les seules causes d'insuffisance cardiaque qui récupèrent
- Probablement les patients assistés avec VAD P-P sont 3 fois plus explantés pour recovery (Décharger le VG est la clés)

- La durée support avec VAD influence la récupération : un cœur mis au repos a besoin de temps pour récupérer, difficile avant 40 jours. Cependant : a) si pas de récupération dans quelques mois alors difficile qui le cœur puisse récupérer ; b) si pt greffé dans 6 mois, probablement pas possible voir recovery

- La classification INTERMACS, la présence préalable d'ECMO ou l'intubation précédente n'étaient pas significativement associées aux analyses multivariées chez les enfants pris en charge par BHE

- L'âge (< 2 ans) et la surface corporelle (< 0.53 m2) sont associés à la récupération myocardique

- absence de protocoles universellement acceptés et fondés sur des preuves pour à la fois l'implantation et le possible sevrage du soutien par VAD est susceptible d'influencer les résultats ainsi que les taux de récupération

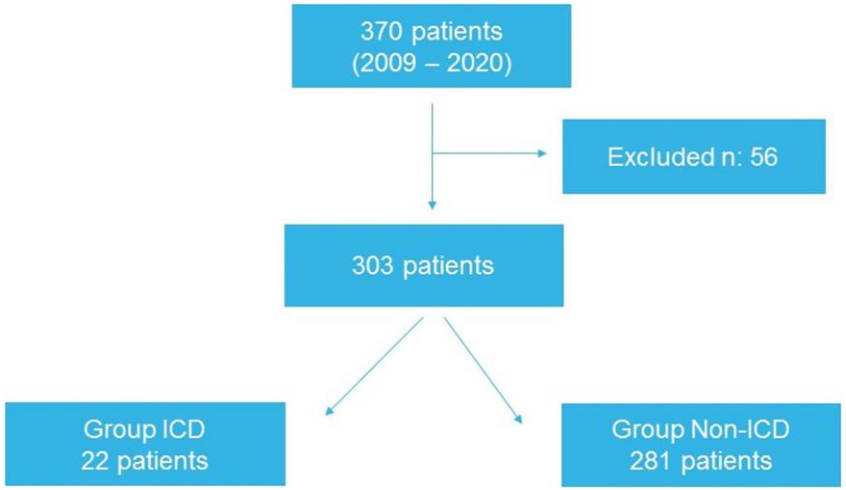
- Les résultats précieux à mieux investiguer : pour optimiser cette stratégie thérapeutique. Les efforts conjoints sont nécessaires → créer un registre des données de suivi après l'explantation

Rhode, EJCTS 2023

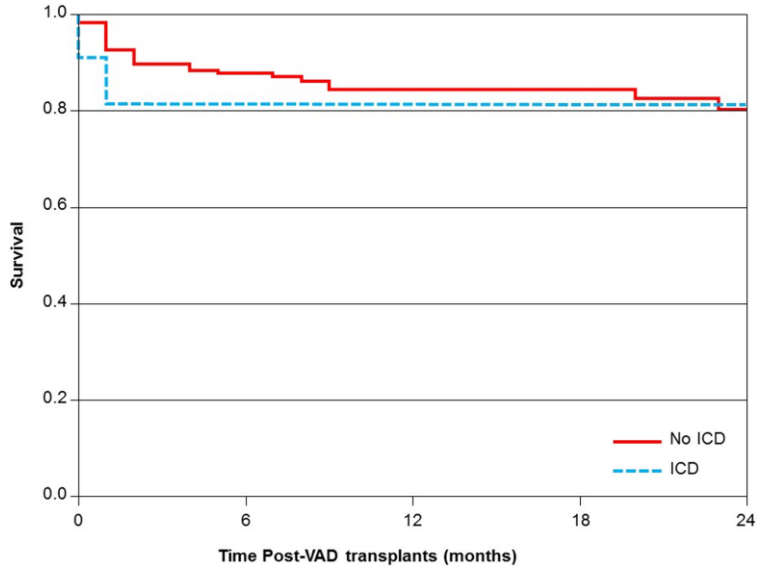
Artificial Organs. 2023;47:1319–1325.

Use of implantable cardioverter-defibrillator in children supported with ventricular assist device: An analysis of data from the EUROMACS registry

Martin Schweiger[1,2] | Antonio Amodeo[2,3] | Juliane Vierecke[4] | Hina Hussein[5] | Florian Berger[2,6] | Theo M. M. H. de By[7] | Daniel Zimpfer[8] | Joanna Sliwka[9] |



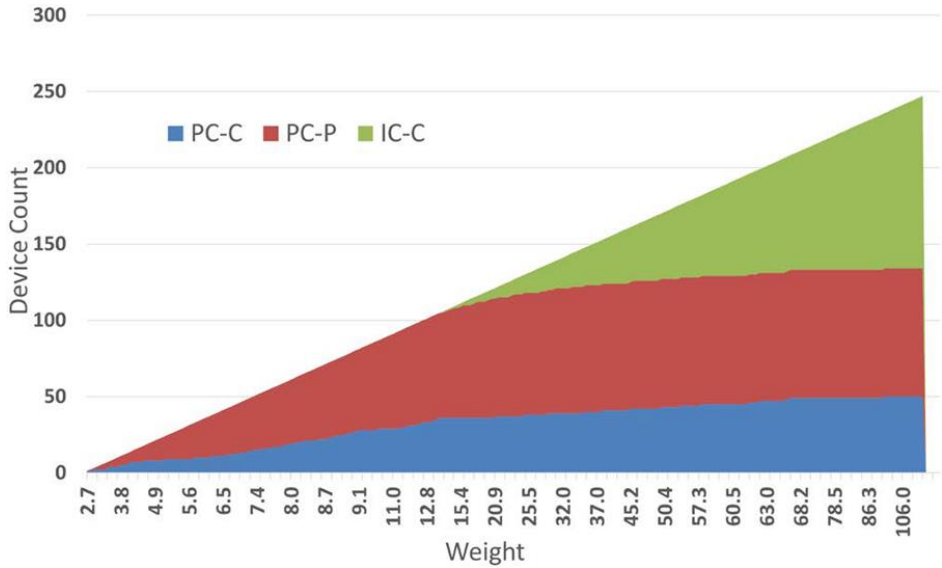
	Group ICD	Group non-ICD	*p*
Patients (*n*)			
n	22	281	
Gender, (*n*)			
Male	15	148	
Age (years)			
Mean ± SD (range)	14.1 ± 2.5 (10–18)	9.5 ± 5.6 (1–18)	0.002
Body height (cm)			
Mean ± SD (range)	161.6 ± 11.5 (144–187)	123.8 ± 42.6 (45–197)	0.02
		30.7 ± 24.3 (2.2–117)	0.0001
Body surface area			
Mean ± SD (range)	1.4 ± 0.3 (1.1–2.1)	0.9 ± 0.5 (0.1–2.5)	0.002
1 (%)	22	19	
2 (%)	45	51	
3 (%)	18	19	
4 (%)	5	3	
5 (%)	5	3	
6 (%)	0	0	
7 (%)	5	3	
Cardiac arrest (%)	22.7%	12.4%	0.34
Dialyse (%)	9.1%	2.5%	0.06
Ventilated prior to VAD surgery (%)	22.7%	35.6%	0.08
Previous Cardiac Surgery (%)	22.7%	12.8%	0.07
On inotropes (%)	86.4%	72.9%	0.4
ECMO (%)	18.2%	20.3%	0.7



The presence of ICD in pediatric patients supported with a VAD is low (7%). Children on VAD support provided with an ICD do not have a survival benefit compared to children without an ICD.

Impact of Weight on Ventricular Assist Device Outcomes in Dilated Cardiomyopathy Patients in Pediatric Centers: An ACTION Registry Study

David M. Kwiatkowski ,* Muhammad Shezad,† Aliessa P. Barnes,‡ Michelle S. Ploutz,§ Sabrina P. Law,¶ Farhan Zafar,† David L.S. Morales,† and Matthew J. O'Connor,‖ on behalf of the ACTION Network Investigators,[a]



Preimplant characteristics	Overall (*n* = 222)	= 53	*N* = 50	*N* = 34	*N* = 85	*p-value**
Total devices implanted	272	70	69	39	94	
Biventricular devices	22/272 (8%)	11/70 (16%)	6/69 (9%)	2/39 (5%)	3/94 (3%)	0.03
Age (y)	9.6 [1.1–15]	0.3 [0.2–0.5]	2.3 [1.4–5.2]	10.6 [9.7–12.1]	15.6 [13.8–16.7]	<0.001
Sex (male)	121 (55%)	23 (43%)	19 (38%)	13 (38%)	66 (78%)	< 0.001
Device strategy		***n = 52/53***	***n = 50/50***	***n = 34/34***	***n = 85/85***	
Bridge to transplant	138 (62%)	40 (76%)	38 (76%)	20 (59%)	40 (47%)	
Bridge to candidacy/ decision	62 (28%)	10 (19%)	8 (16%)	11 (32%)	33 (39%)	0.001
Bridge to recovery	14 (6%)	2 (4%)	4 (8%)	3 (9%)	5 (6%)	
Chronic Therapy	7 (3%)	0	0		7 (8%)	
INTERMACS profile at implant		***n = 51/53***	***n = 50/50***	***n = 33/34***	***n = 84/85***	
1	58 (27%)	13 (25%)	22 (44%)	9 (27%)	14 (17%)	
2	114 (52%)	31 (62%)	20 (40%)	21 (63%)	42 (50%)	0.01
3	39 (18%)	7 (14%)	8 (16%)	2 (6%)	22 (26%)	
4–7	7 (3%)	0	0	1 (3%)	6 (7%)	
ECMO at implant	41 (18%)	9 (17%)	17 (34%)	8 (24%)	7 (8%)	0.002
eGFR at implant (ml/min/1.73 m²)	97[78–126]	86 [72–113]	113 [76–150]	105[88–126]	97 [82–127]	0.34
Dialysis dependent at implant	3 (1%)	0	2 (4%)	0	1 (1%)	0.28
Total bilirubin at implant (mg/dL)	0.7 (0.70) [0.5 –1.2]	0.5 [0.3– 1]	0.8 [0.42–1.1]	0.9 [0.6– 1.6)	0.8 [0.5–1.3]	0.07
Ventilator support (7 days before implant)	85 (38%)	33 (62%)	25 (50%)	9 (27%)	18 (21%)	<0.001
Inotropes (7 days prior)						
No	16 (7%)	4 (8%)	1 (2%)	2 (6%)	9 (11%)	
1 Inotrope	79 (36%)	16 (30%)	15 (30%)	12 (35%)	36 (42%)	0.1
2 Inotrope	104 (47%)	30 (57%)	25 (50%)	15 (44%)	34 (40%)	
3 Inotrope	21 (9%)	3 (6%)	7 (14%)	5 (25%)	6 (7%)	
4 Inotrope	2 (1%)	0	2 (4%)	0	0	
Previous cardiac operation (yes)	20 (9%)	7 (13%)	6 (12%)	1 (3%)	6 (7%)	0.32

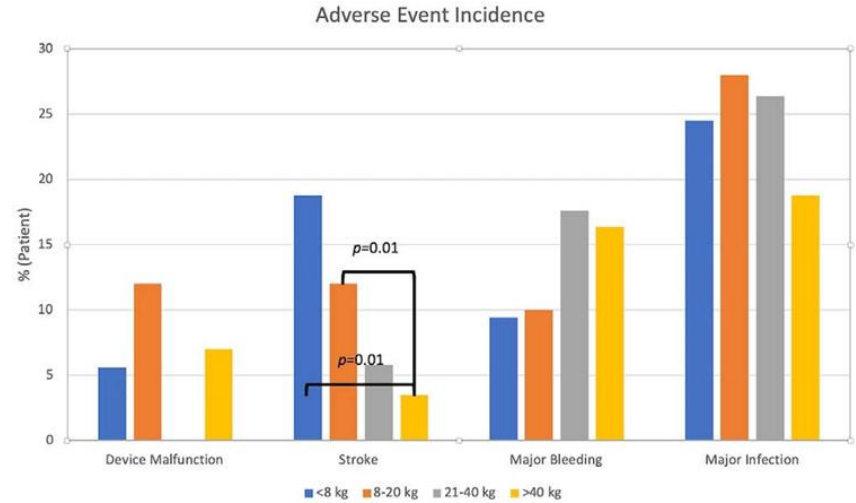
Ventricular assist device	Overall	<8 kg cohort	8–20 kg cohort	21–40 kg cohort	>40 kg cohort
Intracorporeal continuous					
HeartMate 3™ LVAD	56	0	0	12	44
HeartWare™ HVAD™	50	0	7	15	35
Paracorporeal continuous					
CentriMag™ Blood Pump	15	1	6	2	6
PediMag™ Blood pump	30	18	11	1	
Rotaflow centrifugal pump	7	0	3	1	3
Impella© heart pump	4	0	0	1	3
Paracorporeal pulsatile					
Berlin EXCOR® heart pump	100	51	42	7	1
Other					
Syncardia total artificial heart	1	0	0	0	1

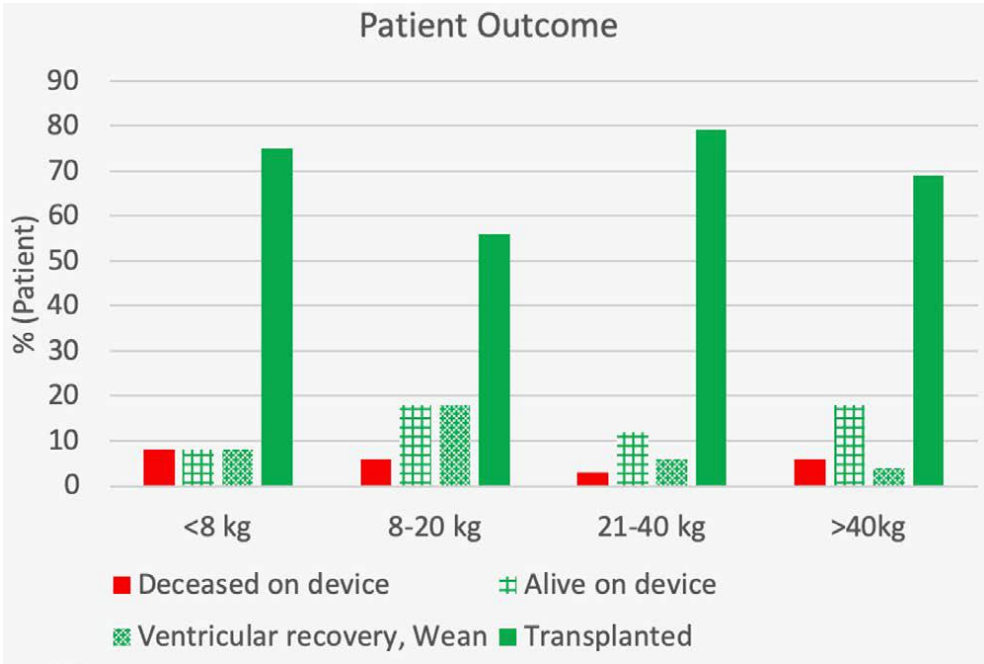
LVAD, left ventricular assist device.

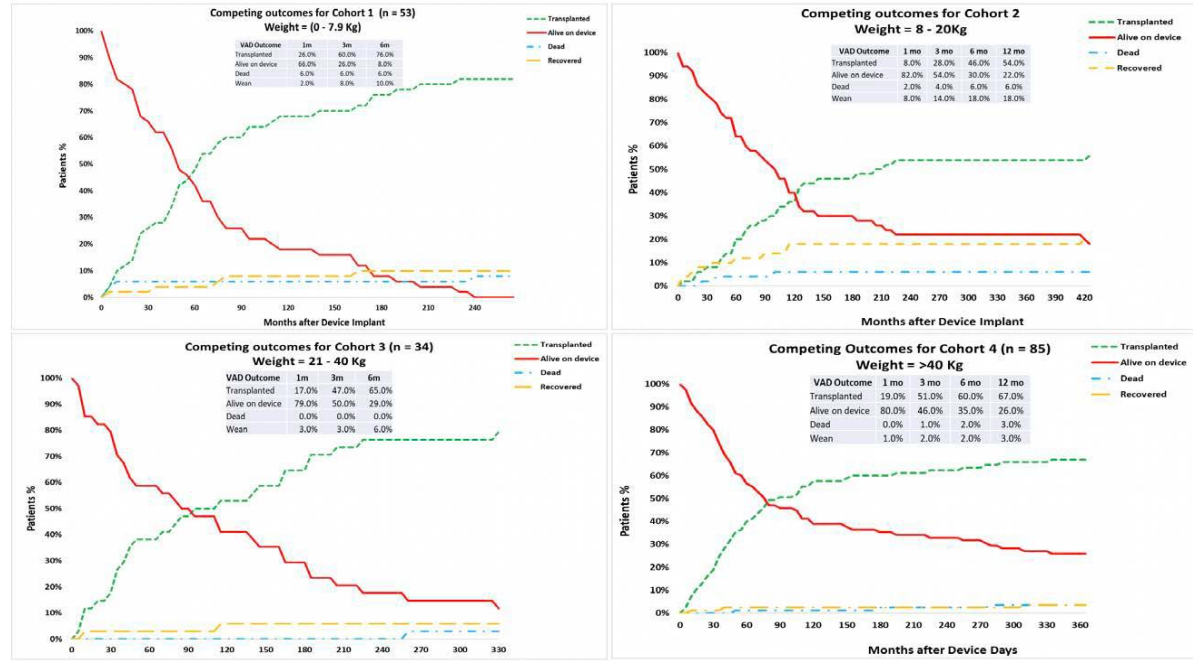
Table 3. Clinical Outcomes

Variable	Overall *N* = 222	<8 kg cohort *N* = 53	8–20 kg cohort *N* = 50	21–40 kg cohort *N* = 34	>40 kg cohort *N* = 85	*p* value
Duration of VAD support (days-all patients)	76 [34–175]	52 [21–112]	97 [45–130]	83 [31–167]	78 [35–302]	
Duration of VAD support (days-transplanted and recovered patients only)	75 [35–170]	56 [23–114]	76 [40–122]	69 [30–152]	49 [27–107]	0.13
Duration of total ICU postimplant (days)	20 [10–39]	16 [7–33]	36 [21–99]	19 [10–38]	16 [9–33]	0.38
Discharged on device	62 (28%; HVAD = 30, HM3 = 32)	0	3 (6%; HVAD = 3)	13 (38%; HM3 = 8, HVAD = 5)	46 (54%; HM3 = 24, HVAD = 22)	0.13 <0.001
Stroke	20 (9%)	9 (17%)	6 (12%)	2 (6%)	3 (4%)	0.03
Other neurologic events	4 (2%)	0	2 (4%)	1 (3%)	1 (1%)	0.33
Major bleeding episode	30 (14%)	5 (9%)	5 (10%)	6 (18%)	14 (16%)	0.36
Major infection episode	52 (23%)	13 (25%)	14 (28%)	9 (26%)	16 (19%)	0.59
Device malfunction	15 (7%)	3 (6%)	6 (12%)	0	6 (7%)	0.18

Data presented as median [IQR] or count (%).
ICU, intensive care unit; VAD, ventricular assist device.







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- **Analyse base de données ACTION**
- **2013-2020**
- **222 pts, 272 implantations**
- **Mortalité globale 6% (vs 13%)**
- **Différents eras ?**
- **Amélioration VAD, stratégies chirurgicales mieux sélection pts**
- **Gestion TA et AC (Bivalirudine ; bedside approach) = < AVC**
- **VAD – PP < 20 kgs**
- **VAD – IC la majorité si > 20 kgs**
- **AVC surtout si < 8 kgs (17%) et 8-20 kgs (12%)**
- **Autres EIs = dans les 4 groupes**
- **Pronostic favorable > 90% ensemble des cohortes = excellents résultats obtenus pour la diversité de la population pédiatrique et jeune adulte atteinte de CMDen utilisant les dispositifs actuellement disponibles, quel que soit leur taille**

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Journal of
Cardiovascular
Development and Disease

Article

Use of Intracorporeal Durable LVAD Support in Children Using HVAD or HeartMate 3—A EUROMACS Analysis

Martin Schweiger [1,2,*], Hina Hussein [3], Theo M. M. H. de By [4], Daniel Zimpfer [5], Joanna Sliwka [6], Ben Davies [7], Oliver Miera [8] and Bart Meyns [9]

- **Mortalité en liste en baisse après start programmes VAD**
- **Mieux VAD directement que ECMO seul**
- **Retrait du commerce du HVAD (HeartWare) le 3 June 2021 a crée un problème global**
- **2020 FDA ok pour Heartmate III pour les enfants**
- **Ce papier analyse rétrospectives de la base de données EUROMACS pour patients LVAD**
- **2009-2021 : 150 implantations, 142 patients (55 F, 87 M)**
- **HM III peut prendre sa place pour assister les enfants ?**

		Entire Cohort	HVAD Group	HM3 Group
Patients		142	118	24
Any form of CMP, n (%)		132 (93%)	109 (92%)	23 (96%)
	DCMP	123 (87%)	102 (86%)	21 (88%)
	RCMP	2 (1%)	2 (2%)	0
	HOCMP	7 (5%)	5 (4%)	2 (8%)
CHD, n (%)		7 (5%)	7 (6%)	0
Unknown, n (%)		3 (2%)	2 (2%)	1 (4%)

Table 2. Baseline characteristics of patients.

	Overall	HVAD	HM3	*p* Value
Age (years)				0.01
Median (range)	13.1 (3–18)	13 (3–18)	15 (9–18)	
Mean ± SD	13.0 ± 3.3	12.8 ± 3.1	14.5 ± 2.7	
Age categories (years), n (%)				
1–5 y	5 (3.3)	4 (3.3)	-	
6–10 y	27 (18.0)	23 (18.9)	1 (14.3)	
11–19 y	118 (78.7)	95 (77.9)	24 (82.1)	
Weight, n (%)				0.005
<5 kg	1 (0.7)	1 (0.9)	-	
5–9 kg	-	-	-	
10–20 kg	13 (9.2)	13 (11.0)	-	
21–40 kg	41 (28.9)	39 (33.0)	2 (8.3)	
41–70 kg	64 (45.1)	50 (42.4)	14 (58.3)	
>71 kg	23 (16.2)	15 (12.6)	8 (33.3)	
Body surface area (m^2)				0.001
Median (range)	1.4 (0.53–2.5)	1.3 (0.53–2.5)	1.6 (1.1–2.1)	
Sex, n (%)				0.130
Male	87 (61.3)	69 (58.5)	18 (75.0)	
Female	55 (38.7)	49 (41.5)	6 (25.0)	

	Overall	HVAD	HM3	*p* Value
Total bilirubin levels (mg/dL)				0.582
Median (range)	0.7 (0–25)	0.7 (0–25)	1.1 (0–9)	
Mean ± SD	1.4 ± 2.7	1.3 ± 2.9	1.7 ± 2.0	
Creatinine (mg/dL)				0.635
Median (range)	68 (16–8079)	67 (20–8079)	69 (16–202)	
Mean ± SD	145.4 ± 740.9	161.6 ± 826.5	79.2 ± 36.7	
Primary diagnosis, n (%)				0.611
DCMP	121 (85.2)	100 (84.8)	21 (87.5)	
RCMP	2 (1.4)	2 (1.7)	-	
CHD	7 (4.9)	7 (5.9)	-	
CMP	2 (1.4)	2 (1.7)	-	
HOCMP	7 (4.9)	5 (4.2)	2 (8.3)	
Unknown	3 (2.1)	2 (1.7)	1 (4.2)	
INTERMACS patient profile, n (%)				0.129
INTERMACS 1	23 (16.2)	20 (17.0)	3 (12.5)	
INTERMACS 2	70 (49.3)	61 (51.7)	9 (37.5)	
INTERMACS 3	31 (21.8)	25 (21.2)	6 (25.0)	
INTERMACS 4	10 (7.0)	8 (6.8)	2 (8.3)	
INTERMACS 5–7	8 (5.6)	4 (3.4)	4 (16.7)	
Number of inotropes, n (%)				0.042
No	31 (21.8)	22 (18.6)	9 (37.5)	
Yes	111 (78.2)	96 (81.4)	15 (62.5)	
Mechanical ventilation, n (%)				0.425
No	103 (72.5)	84 (71.2)	19 (79.2)	
Yes	39 (27.5)	34 (28.8)	5 (20.8)	
ECMO support, n (%)	27 (19.0)	22 (18.6)	5 (20.8)	0.803

Schweiger, J. Cardiovasc. Dev. Dis. 2023

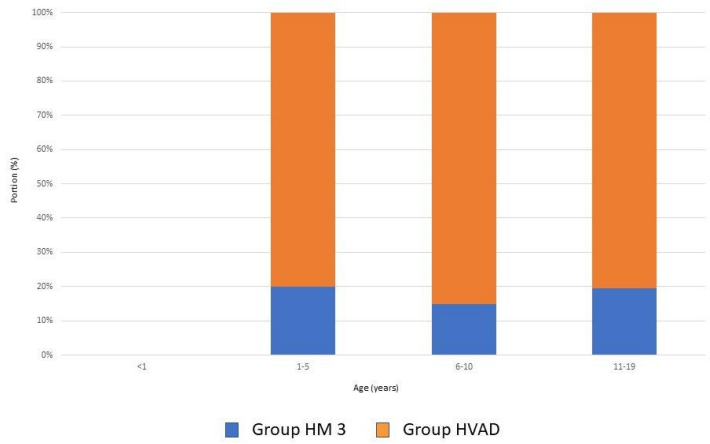


Figure 1. Distribution of devices according to age group.

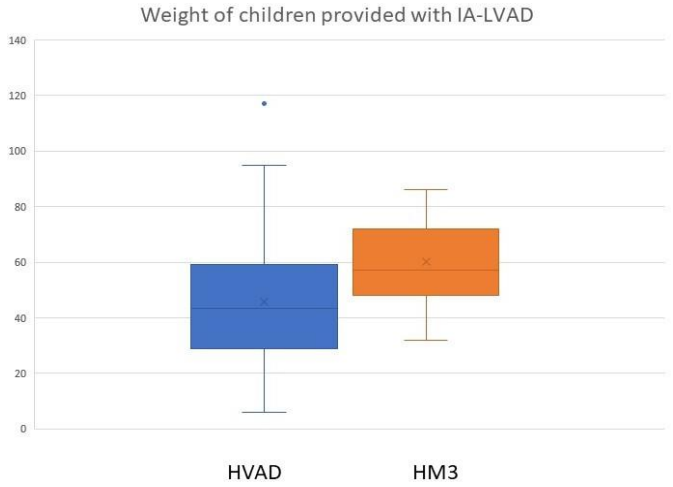


Figure 2. Differences in body weight between the HVAD and HM3 groups

Table 3. Reasons for death. N: number; CAV: cerebrovascular accidents.

Reason for Death	HVAD Group	HM3 Group
Death, n (%)	16 (14%)	3 (12%)
CVA, n	4 (25%)	0
Infection, n	4 (25%)	1 (33%)
Multi-organ failure, n	6 (37%)	2 (67%)

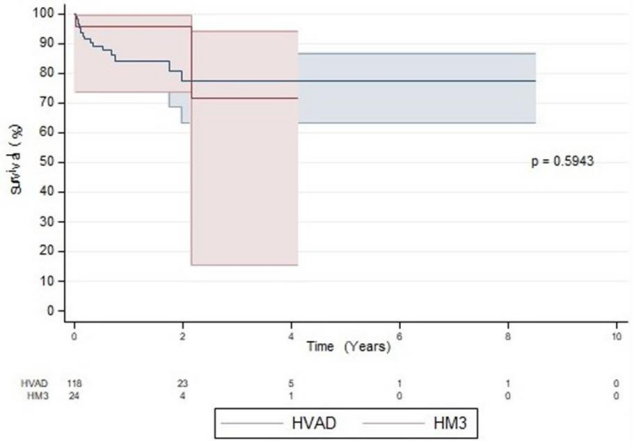


Figure 4. Kaplan–Meier analysis of survival of patients with HeartMate 3 and HeartWare ventricular assist devices.

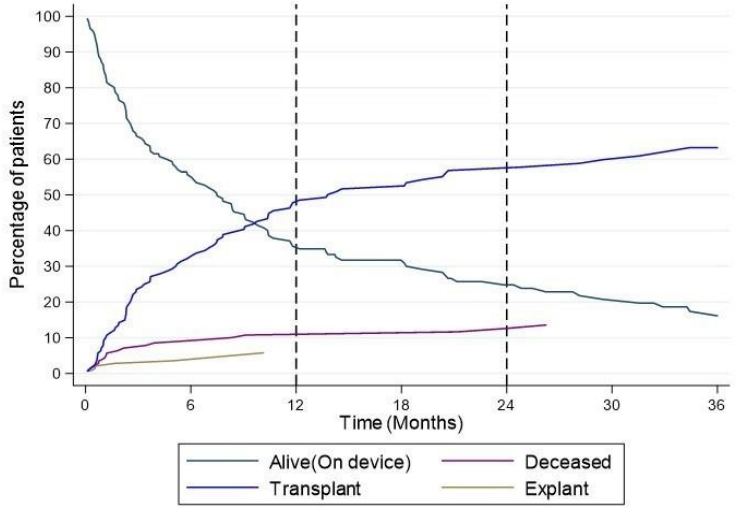
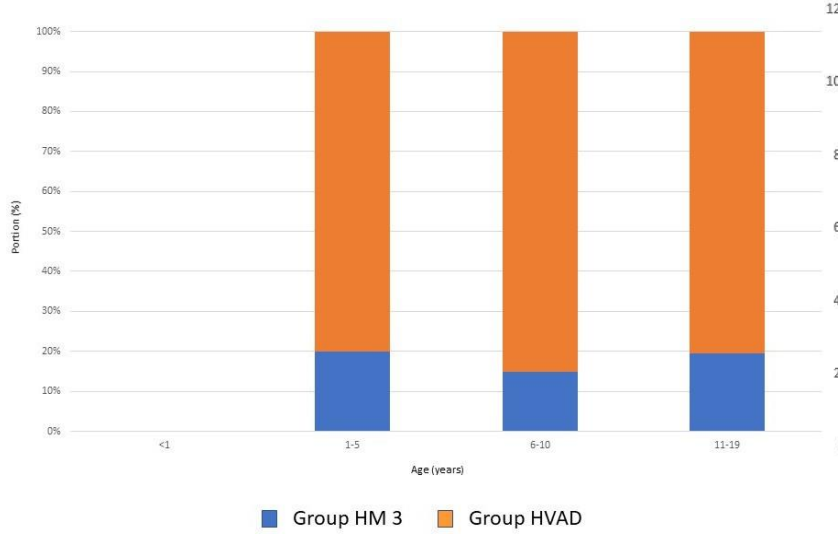


Figure 3. Competing outcome curves for the whole study population.

- **Implantations HM3 était relativement faible par rapport au groupe témoin HVAD, MAIS le premier implant HVAD inclus dans cette analyse a eu lieu en octobre 2009, alors que le premier rapport de placement de HM3 date de 2015.**
- **Descendre en termes de poids et surface corporelle pour implants HMIII**
- **L'HMIII est une bonne alternative**
- **Sortie à la maison**
- **Suivie superposable**



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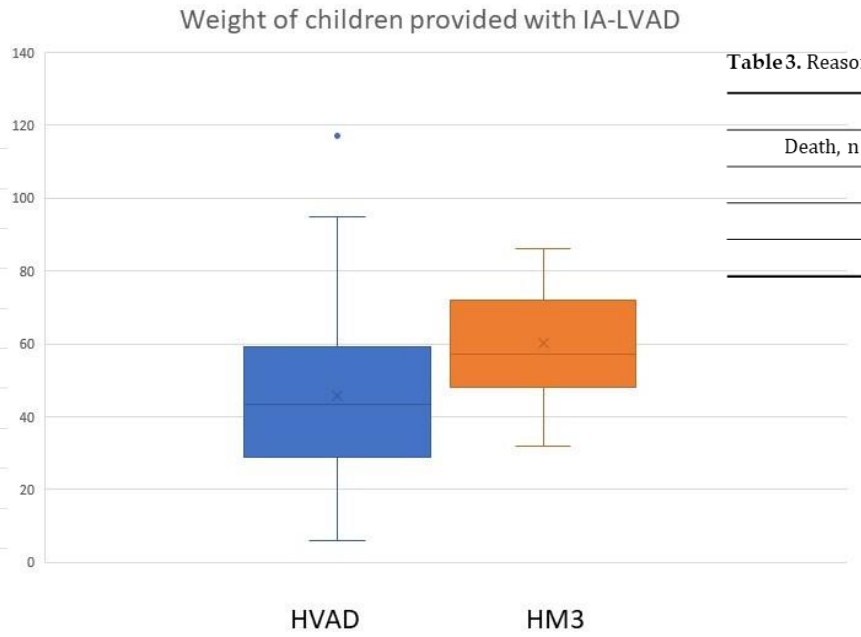

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Multi-organ failure, n	6 (37%)	2 (67%)

- **HMIII valide alternative**
- **Sortie à la maison**
- **Suivie superposable**
- **Pts avec poids/sc plus basses**

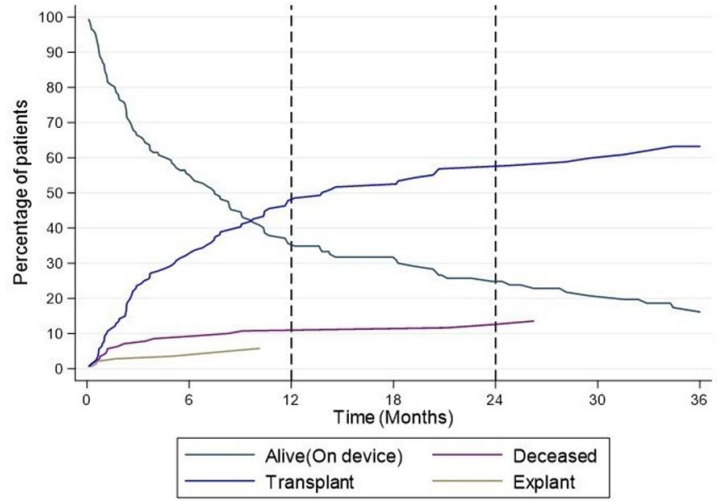

Figure 3. Competing outcome curves for the whole study population.

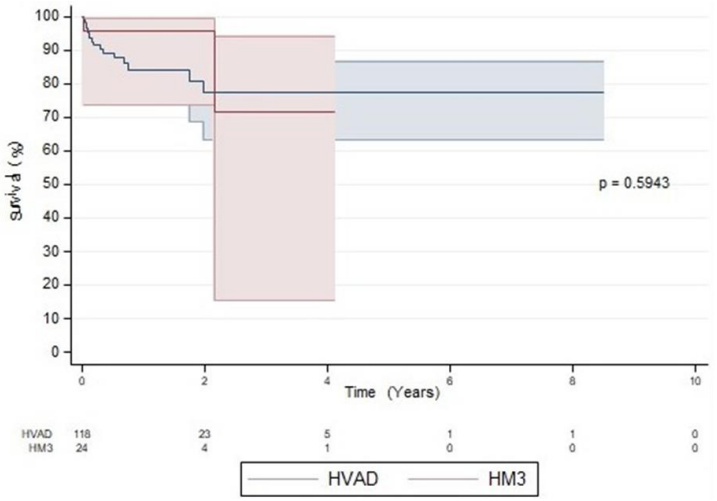

Figure 4. Kaplan–Meier analysis of survival of patients with HeartMate 3 and HeartWare ventricular assist devices.

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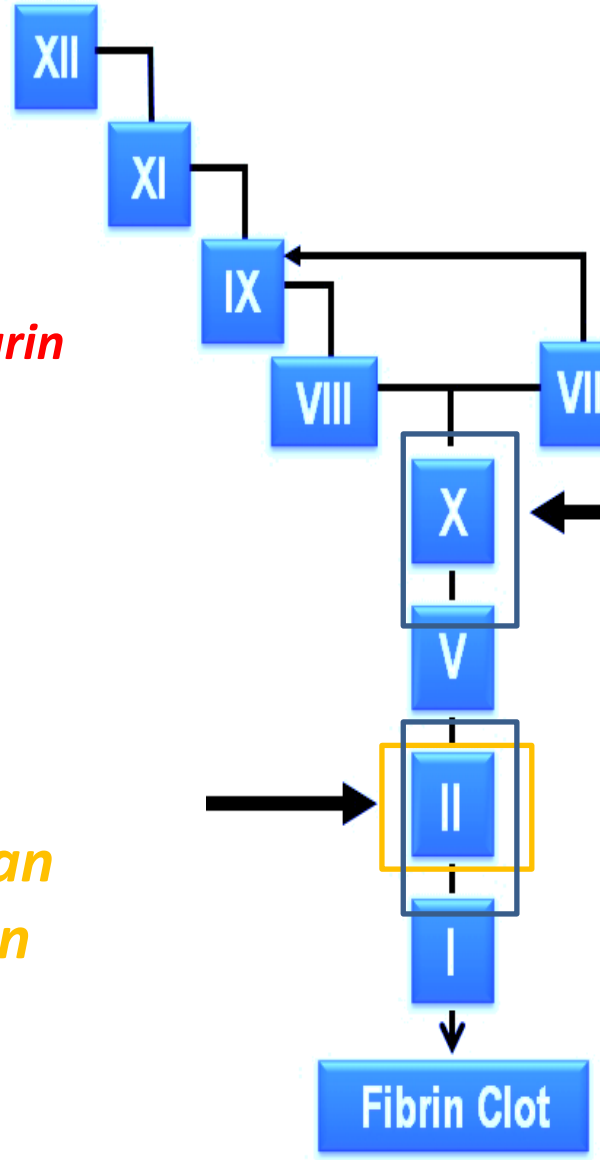
Médicaments AC et interactions

AC
↓
INIB activ C
↓
Eviter EI sur VAD

Unfractionated heparin
Enoxaparin
• FII, FX, FIX, FXI, FXII

Warfarin
• FII, FVII FIX, FX

Argatroban
Bivalirudin
• FII



Héparine non fractionée (UFH)
•Besoin rempl ATIII
•Resistance
•Limitations PK pour lien proteins plasma (PF4)
• Risque TIH (NN 0-1.7%, Enfants 1.3-52%)

HBPM
- Ponction BID, long term QOL
- Demi-vie long, no rev agent

Warfarin (→VKOR Enzime)
➢Interactions, alimentation, diff AND, Infections

Bivalirudin, Argatroban
>No reversal agent
>Little data

Massicotte, Edmonton, Canada
Giorni, Rome, Italie

Bivalirudin *Versus* Unfractionated Heparin in Patients With Cardiogenic Shock Requiring Venoarterial Extracorporeal Membrane Oxygenation

Marissa N. Uricchio ,* Raj Ramanan,†‡ Stephen A. Esper ,§ Holt Murray,†‡ David J.Kaczorowski,¶ Brandon D'Aloiso ,// Hernando Gomez,†‡ Christopher Sciortino,# Pablo G. Sanchez ,** Penny L. Sappington,†††‡ and Ryan M. Rivosecchi*

Results

Overall, 143 patients were included in our analysis with 54 having received bivalirudin and 89 having received UFH (Supplemental Figure 1, http://links.lww.com/ASAIO/A807). Median age was 53 (interquartile range [IQR], 40-61) years, and

Table 2. ECMO-Associated Thrombotic Endpoints

Variable	Bivalirudin (n = 54)	UFH (n = 89)	*p*
Thrombosis per ECMO day*	0.04 (0.16)	0.10 (0.26)	<0.001
Any thrombosis on ECMO, N (%)	11 (20)	31 (35)	0.06
In-circuit thrombosis, N (%)	9 (17)	18 (20)	0.66
Systemic thromboembolism, N (%)			
Ischemic stroke	1 (2)	10 (11)	0.052
DVT/PE	1 (2)	5 (6)	0.41
Postdecannulation thrombus	4 (7)	5 (6)	0.73

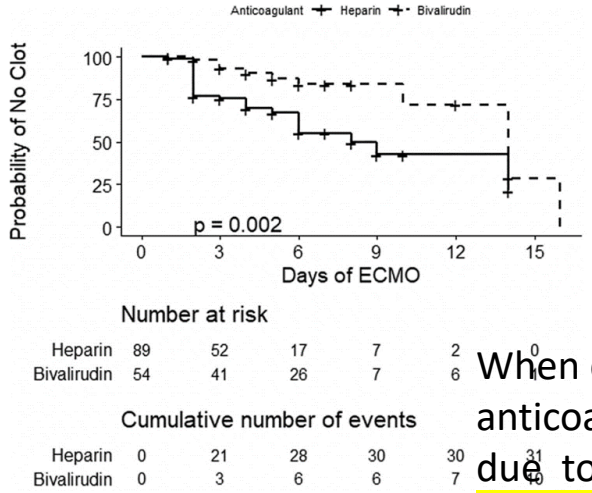


Table 3. Multivariate Cox Regression: Factors Influencing Time to Thrombotic Event During ECMO

Model #	Variable	*B*	Exp(*B*)	95% CI for Exp(*B*)	*p*
Model 9	Bivalirudin		3.81	1.652–8.782	0.00
	Diabetes		0.53	0.271–1.043	0.07

CI, confidence interval; ECMO, extracorporeal membrane oxygenation.

Table 4. Secondary Safety Endpoints

Variable	Bivalirudin (n = 54)	UFH (n = 89)	*p*
Major bleeding event,[a] N (%)	16 (29)	44 (49)	0.02
Intracranial, N (%)	0	1/44 (2)	
Gastrointestinal, N (%)	4/16 (25)	8/44 (18)	
Retroperitoneal/pulmonary, N (%)	2/16 (12)	6/44 (14)	
Cannula site, N (%)	4/16 (25)	9/44 (21)	
Hemoglobin drop over 24 hours, N (%)	6/16 (38)	20/44 (45)	
Minor bleeding event[a], N (%)	7 (13)	13 (15)	0.49
Total PRBC,[b] ml[c]	1,147 (1,897)	1,777 (2,077)	0.04
Total FFP,[b] ml[c]	196 (676)	571 (2,262)	0.03
Total PLT,[b] ml[c]	267 (601)	288 (949)	0.53
PRBC[b] per ECMO day, ml[c]	202 (246)	451 (1,413)	0.004
FFP[b] per ECMO day, ml[c]	41(114)	165 (663)	0.03
PLT[b] per ECMO day, ml[c]	37 (108)	70 (182)	0.26

When comparing bivalirudin with UHF-based systemic anticoagulation for patients requiring VA ECMO support due to cardiogenic shock, we demonstrated that bivalirudin is a safe and efficacious alternative to UFH. Our study illustrates the utility of bivalirudin in this population as established by a reduction in ECMO associated adverse events with improved survival to ECMO decannulation when compared with UFH. Further study into the comparison of bivalirudin and UFH in VA ECMO is warranted in a multicenter, randomized fashion.

Volume 42 Number 3 •
The Journal of 2023
Heart and Lung Transplantation

Cost-effectiveness of bivalirudin in pediatric ventricular assist devices

Danielle Burstein, MD, MSCE, Stephen Kimmel, MD, MSCE, Mary Putt, PhD, Joseph Rossano, MD, MS, Christina VanderPluym, MD, Ashish Ankola, MD, Angela Lorts, MD, MBA, Katsuhide Maeda, MD, PhD, Matthew O'Connor, MD, Jonathan Edelson, MD, Kimberly Lin, MD, Holger Buchholz, MD, and Jennifer Conway, MD MS

- **Enfants 0-6 ans VAD entre 2009 et 2021 USA**
- **691 pts, 1 ans âge moyenne, 44% bivalrirudine (vs 90% en 2021)**
- **Bivalirudine mortalité plus basse que HNF (26 vs 32%)**
- **Hospitalisation post-VAD groupe Bivalirudine > HNF (91 vs 64 jrs)**
- **Cout-moyen-jour bivalirudine vs HNF 0.87, donc en faveur de la bivalirudine**
- **Augmentation coûts de pharmacie compensée par la baisse des coûts d'imagerie, de laboratoire, d'approvisionnement et de hotellerie**
- **Incremental Cost-Effectiveness Ratio (ICER) estimé Bivaluridine – HNF est en de $61,192 ($ 27,673 et $ 131,243) "Per Quality-Adjusted Life Year gained" mesure utilisée dans l'évaluation économique des interventions en santé. Elle permet de comparer les coûts d'une intervention médicale aux avantages qu'elle procure en termes de qualité de vie et de durée de vie**

Bivalirudin Compared to Heparin as the Primary Anticoagulant in Pediatric Berlin Heart Recipients

VICTORIA FRENIERE ,* DAVID M. SALERNO ,* HEATHER CORBO ,* SABRINA LAW,† JENNIE MCALLISTER,† CINDY NEUNERT ,† AND JUSTIN K. CHEN *

- **1er étude BIVALIRUDINE vs HNF pour Berlin Heart âge pédiatrique (< 18 ans)**
- **Rétrospective, single-center, 2013-2021 (du 2017 1ere choix)**
- **Objectif principal : le temps nécessaire pour atteindre aPTT / AntiXa thérapeutiques et % de temps apTT / AntiXa dans les ranges**
- **Objectifs secondaires : complications / EI selon INTERMACS - PediMACS → 1) saignement majeure 2) besoin de changer la pompe pour thrombose (dysfonction majeure VAD) 3) complications neuro 4) survie après transplantation cardiaque lou sevrage VAD**
- **31 pts, 65% bivalirudine et 35% HNF ; âge moyenne 2.9 ans ; CMD 61% CHD 26%**
- **Résultats :**
  1) bivalirudine meilleur profile car range thérapeutique atteinte plus vite (5.7 vs 69.5 heurs), plus de valeurs thérapeutique (52 vs 24%), plus heures en range (67 vs 32%)
  2) Groupe bivalirudine > fois Hb plasmatique élevée et markers inflammation ; dose plus élevée car application du protocole de Stanford
- **NECESSAIRE ETUDE MULTI-CENTRIQUE POUR TROUVER SI SE TRADUIT DANS UNE AMELIORATION DE L'OUTCOME DES MALADES**

Nouvelles méthodes pour obtenir l'Hb plasmatique : un index de hémolyse entre fiabilité et rentabilité

Automated Measurement of Plasma Cell-Free Hemoglobin Using the Hemolysis Index Check Function

March 2020 | 05:02 | 281–289 | JALM 281

Mustafa A. Barbhuiya,[a,#] Edward C. Pederson,[a] Monica L. Straub,[a] Terri L. Neibauer,[a] Wayne F. Salter,[a] Eric L. Saylor,[a] Sofia C. Scott,[a] and Yusheng Zhu[a,*]

Ce travail montre une excellente fiabilité du test de compétence de l'Hb comme index d'hémolyse : le test est simple et rentable

Using the hemolysis index of Abbott's Alinity c for the measurement of plasma free hemoglobin in ECMO patients

Carmen Bürki [a], Martin Volleberg [b], David Brunner [c], Markus Schmugge [c], Martin Hersberger [b,*]

[a] *Medica Medizinische Laboratorien Dr. F. Kaeppeli AG, Zurich, Switzerland*
[b] *Division of Clinical Chemistry and Biochemistry, Children's Research Center, University Children's Hospital Zurich, University of Zurich, Switzerland*
[c] *Division of Hematology, Children's Research Center, University Children's Hospital Zurich, University of Zurich, Switzerland*

Le HI utilisé comme un paramètre quantitatif sur le système Alinity c de Abbotts, sans interférences significatives et avec une large plage de mesure.
HI permet une méthode simple et rapide pour déterminer les concentrations d'hémoglobine plasmatique, sans coûts de réactifs et à tout moment, de jour comme de nuit

Schapira AJ, Lunte K, Hennequin C, Vicca S, Beaudeux JL, Alkoury R, Nivet-Antoine V, Raynor A, Cottart CH. **Analytical performance of Abbott C-16000 analyser haemolysis index and its potential use in measuring plasma cell-free haemoglobin.** *Ann Biol Clin (Paris). 2023 Mar 15;81(1):44-51*

↓

Cette étude démontre que l'analyseur Abbott C-16000 HI est fiable et mesure avec précision les concentrations plasmatiques de fHB dans des conditions pathophysiologiques, sauf en cas de concentrations sanguines élevées de triglycérides.

Frontiers in Medicine | www.frontiersin.org

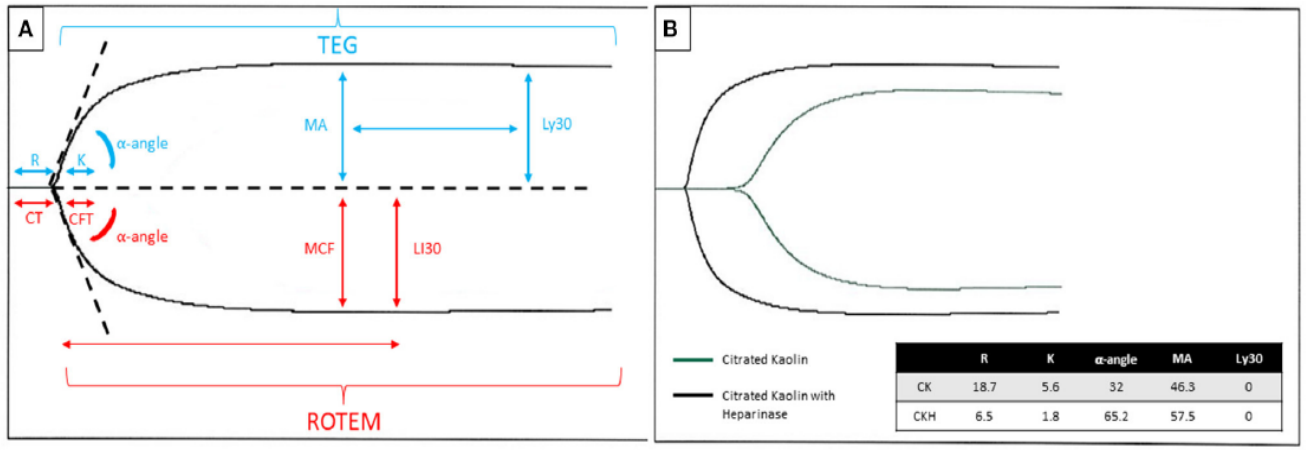
Viscoelastic Testing in Pediatric Mechanical Circulatory Support

Katherine Regling[1*], *Arun Saini*[2*] and *Katherine Cashen*[3*]

May 2022 | Volume 9 | Article 854258

- Review
- Médicaments
- Conséquences cliniques
- Techniques classiques
- Tests viscoélastiques (TEG, ROTEM)
- Thrombose vs saignement COVID-19
- Différences adultes vs enfants

- Analyse biblio +++
- Perspectives
- TVE, part. TEG^{R} 6S, idéal pour Bedside approach
- Utile pour inhibiteurs directs thrombine
- Analyse plus complète, déficit méconnus. Plus efficacité avec moins d'HNF



	R	K	α-angle	MA	Ly30
CK	18.7	5.6	32	46.3	0
CKH	6.5	1.8	65.2	57.5	0

FIGURE 1 | (A) Graphical tracing produced by the TEG® (blue font color)/ROTEM® (red font color) with parameters labeled for each respective test. The R/CT and K/CFT may be affected by heparin or other anticoagulants and coagulation factor deficiencies. The MA/MCF may be affected by fibrinogen level, absolute platelet count, or platelet dysfunction. The Ly30/LI30 may be affected by hyperfibrinolytic states or inherited/acquired factor XIII deficiency. **(B)** An example of a TEG® tracing in a patient on ECMO with citrated kaolin +/- heparinase. Legend: Blue arrow depicts the timepoint to measure Ly30, measured at 30 min after the MA. The red arrow shows the time point to measure LI30, measured at 30 min after the CT. R, reaction time, CT, clotting time; K, kinetic time; CFT, clot formation time; MA, maximum amplitude; MCF, maximum clot firmness; Ly30, lysis time 30 min after maximum amplitude; LI30, lysis time 30 min after clotting time; CK, citrated kaolin; CKH, citrated kaolin with heparinase.

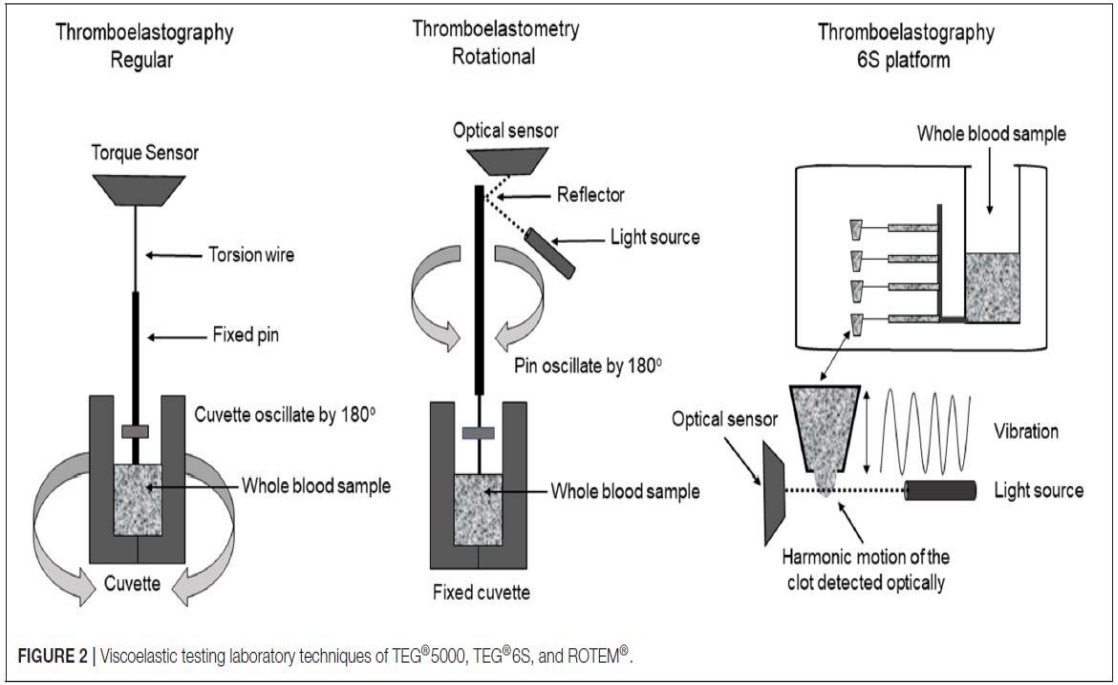


FIGURE 2 | Viscoelastic testing laboratory techniques of TEG®5000, TEG®6S, and ROTEM®.

TABLE 1 | Description of TEG® and ROTEM® parameters.

Description and interpretation	TEG® variable	ROTEM® variable
Duration from start of test until the clot reaches 2 mm amplitude; representative of coagulation factors	Reaction time (R)	Clotting time (CT)
Time it takes the amplitude to go from 2 to 20 mm; represents clot propagation	Kinetic time (K)	Clot formation time (CFT)
The slope between R or CT and K or CFT; represents rate of clot formation	Alpha angle (α-angle)	Alpha angle (α-angle)
Measurement of maximum clot strength; influenced by fibrinogen and platelet count	Maximum amplitude (MA)	Maximum clot firmness (MCF)
The difference between the MA or MCF and the amplitude of the curve after 30 min	Percent lysis at 30 min (Ly30)	Lysis index 30 (LI30)

TABLE 2 | Description of the ROTEM® tests available based on activator utilized.

ROTEM® test based on activator used	Description and interpretation
INTEM	Contact activation; provides information similar to aPTT
EXTEM	Tissue factor activation; provides information similar to PT
HEPTEM	Contains heparinase to neutralize unfractionated heparin; compared with INTEM to assess heparin effect
APTEM	Contains aprotinin to inhibit fibrinolysis; compared with EXTEM to assess fibrinolysis
FIBTEM	Uses cytochalasin-D to block the platelet contribution to clot formation; compared with EXTEM to assess fibrinogen contribution to clot strength independent of platelets

Regling, Frontiers in Medecine, 2022

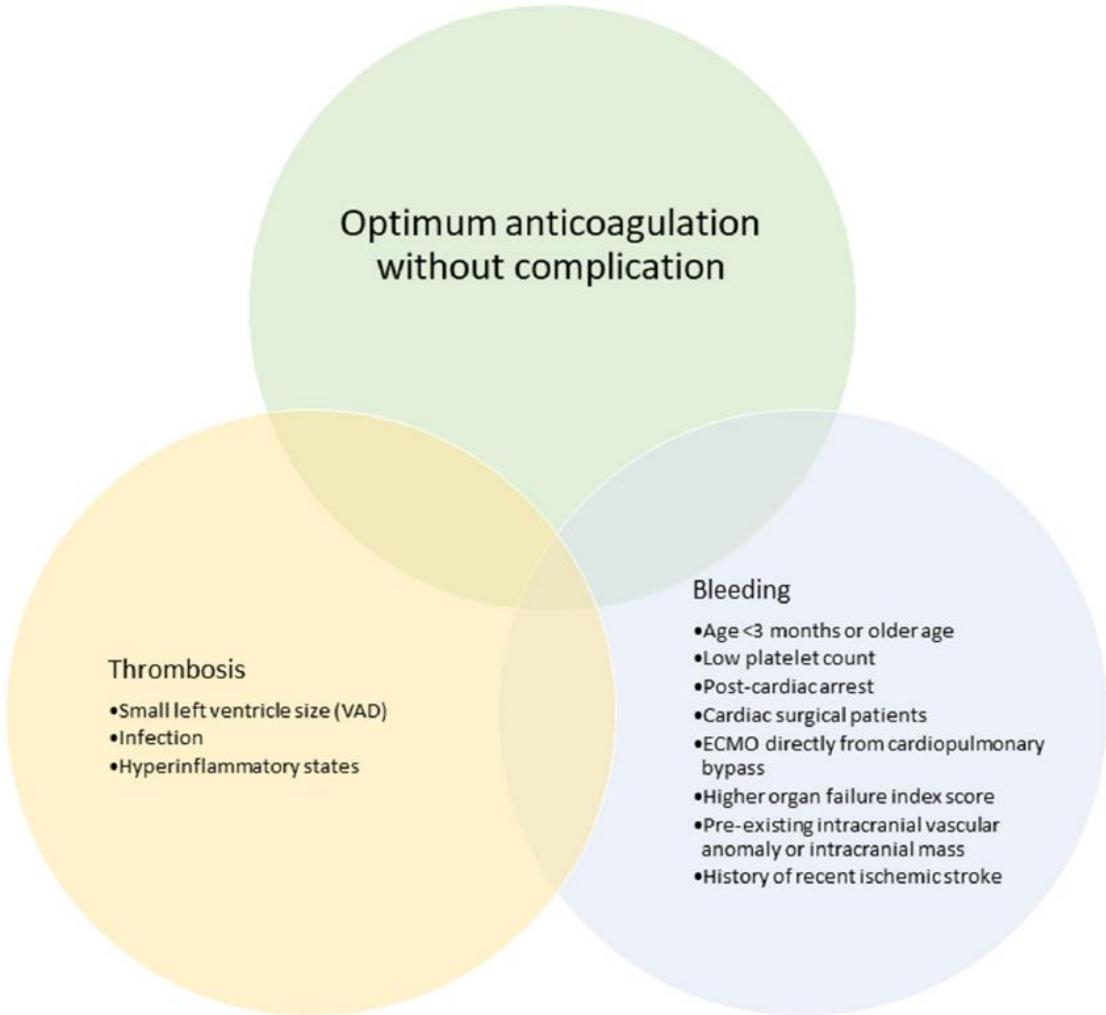


FIGURE 3 | Clinical features that have been associated with bleeding and thrombotic complications in pediatric ECMO and VAD.

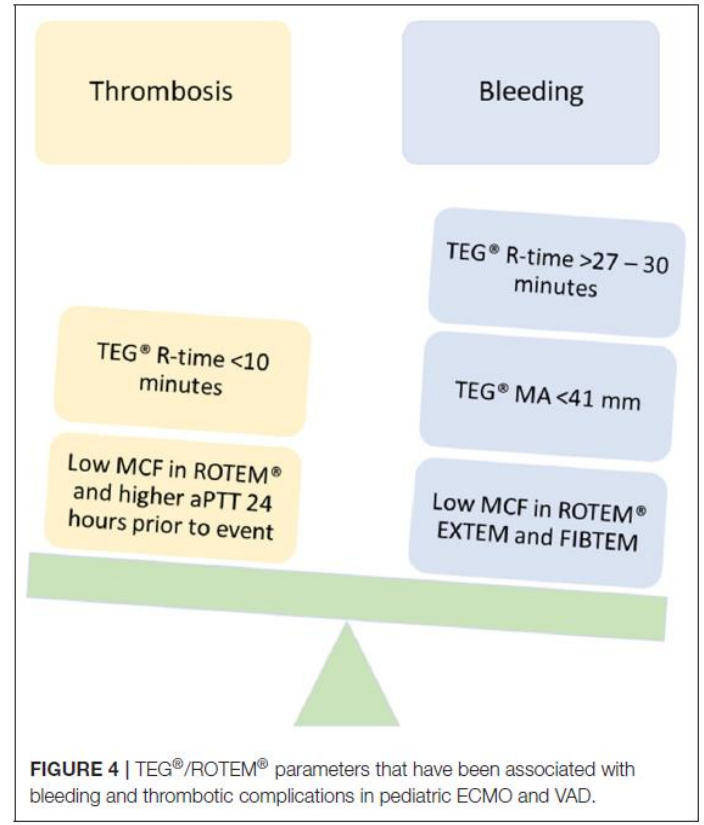


FIGURE 4 | TEG®/ROTEM® parameters that have been associated with bleeding and thrombotic complications in pediatric ECMO and VAD.

Regling, Frontiers in Medecine, 2022

frontiers in Cardiovascular Medicine
September 2021 | Volume 8 | Article 671241

Pediatric Mechanical Circulatory Support: Pathophysiology of Pediatric Hemostasis and Available Options

Chiara Giorni[1], Alessandra Rizza[1], Isabella Favia[1], Antonio Amodeo[2], Fabrizio Chiusolo[3], Sergio G. Picardo[3], Matteo Luciani[4], Giovina Di Felice[5] and Luca Di Chiara[1]*

TABLE 3 | Characteristics of conventional coagulation tests.

Monitoring tests	ACT (s)	aPTT (s)	Anti Xa (UI/ml)
Type of test	Measure of clotting time in whole blood Coagulation activated by kaolin or celite Exploration of common and intrinsic pathway Context-sensitive: changes depending on UFH levels but also on temperature, pH, calcium, PLT count, FBN levels, and red blood cell contribution	Platelet-poor plasma Exploration of common and intrinsic pathway Coagulation activated with phospholipids Partially context-sensitive: ignores PLT count but partially depends on FBN concentration	Platelet-poor plasma Measure of the ability of heparin to antagonize F Xa Uses a reagent and a chromophore substrate to quantify the heparin–AT complex Not context-sensitive: ignore PLT count and FBN concentration
Strengths	Results in seconds Bedside test	Rapid results	Results in minutes, not influenced by coagulation factor concentrations
Limitations	Not specific to the effects of heparin	Influenced by deficiencies or defects of intrinsic clotting cascade, vit K deficiency, and Factor VIII	Affected by hyperbilirubinemia and high PfH, hyperlipidemia Highly dependent on serum AT levels

ACT, activated clotting time; aPTT, activated partial thromboplastin time; anti F Xa, anti Factor X activated; PfH, plasma-free hemoglobin; PLT, platelet; FBN, fibrinogen; UFH, unfractionated heparin; AT, antithrombin.

TABLE 4 | Pharmacokinetic characteristics of DTIs.

Characteristic	Bivalirudin	Argatroban	Dabigatran
Route of administration	Intravenous	Intravenous	Oral
Plasma half-life	25 min	45 min	12 h
Main site of clearance	Kidney, liver, other sites	Liver	Kidney

TABLE 5 | ACTION Harmonization recommendations for bivalirudin infusion for VADs.

Initial bival dosing	maintenance bival titration
Goal: aPTT *High risk (of bleeding): aPTT 50–60 s*	Goal: aPTT • *Standard risk: aPTT 60–80 s* • *High risk (of thrombosis): aPTT 70–90 s*
Renal function (GFR)	*If aPTT 5 to 15 s out of range:* • Increase or decrease by 15% (round up to closest 2nd decimal) • Recheck 2–3 h after dose change
Normal (>60 ml/min/1.73 m²) 0.3 mg/kg/h IV infusion	*If aPTT in target range, no change.* • Recheck after 2–3 h, then can decrease frequency when stable
Mild-moderate (30–60 ml/min/1.73 m²) 0.2 mg/kg/h IV infusion	*If aPTT ≥15–30 s out of range* • Increase or decrease by 25% (round up to closest 2nd decimal) • Recheck 2–3 h after dose change
Severe (<30 ml/min/1.73 m²) 0.1 mg/kg/h IV infusion	*If aPTT >3× baseline or ~120 s:* • With normal renal function: hold 15 min and reduce by 30% • With mild to moderate renal dysfunction: hold for 45 min and reduce by 40% • With severe renal dysfunction: hold 2 h and recheck PTT before restarting

aPTT, activated partial thromboplastin time; bival, bivalirudin; GFR, glomerular filtration rate.

ANTICOAGULATION et ANTIGGREGATION à HML pour le Berlin - Heart

- HNF starting dose 400 UI/kg/jr avant H24 (si saignement < 0.5 ml/kg/h plus de 6heures et PLT > 80x10*^{9}/L
- Cibles : TCA 2.5-3-5 vn / héparinémie 0.3-0.6 UI/ml
- J1 dypiridamole 1-1.5 mg/kgx4/jr IV
- Ablation drains précoce (même à J2) → start aspirine plus tôt possible (1.5 mg/kg/jr) IV
- Surveillance : TP, TCA, héparinémie, fibrinogène x2/jr jusqu'à J5, après 1 fois/jr
- Monitorage TCA/héparinemie H+6 si changement vitesse HNF
- Dosage ATIII si dose HNF > 800 UI/kg/jr et anticoagulation inefficace
- Aclotine : si activité ATIII < 60% + AC inefficace avec HNF > 800 UI/kg/jr
- Antiaggregation : 1ere aggregometrie optique à J7 après start aspirine ; ensuite, 7 jours après chaque changement dose aspirine +/- dypiridamole et si augmentation poids > 5%
- Cibles AG : inhibition acide arachidonique > 80% (mieux >90%) ; inhibition ADP > 50%
- AG IV jusqu'à apport calorique entérale < 50% besoins quotidiens
- HNF → Warfarin si apport calorique entérale régulière et > 50% besoins quotidiens
- Cible INR 2.7 – 3.2 vn
- Les premières 7 jours depuis démarrage Coumadin : 1 INR et 1 Coaguceck par jour → en suite passer à Coauguceck 1 fois/j ou 1 fois/2 jr si taux stables
- Si INR < 2.5, dose rescue HBPM 80-100 UI/kgx1/jr

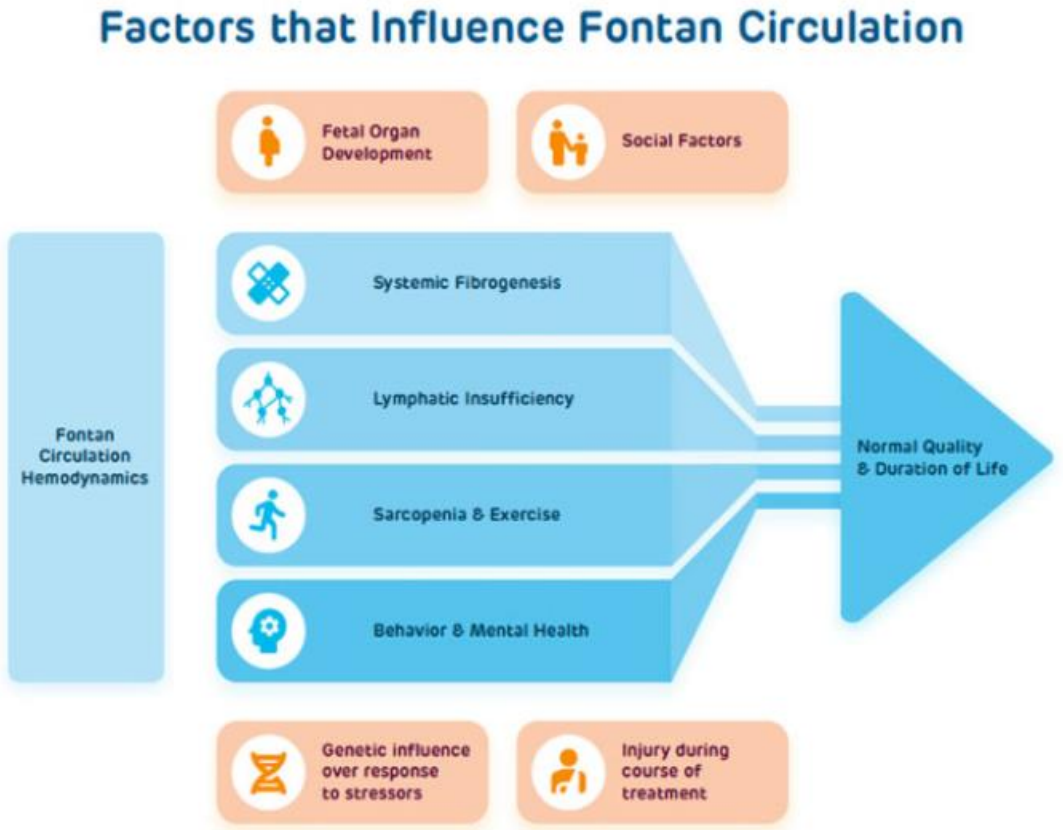
«Est-ce qu'il y a deux individus avec la même circulation de Fontan ?»

'Fontan circulatory signature'

Although the haemodynamic state is fundamental, there are several other domains that similarly demand exploration and characterization. A deeper understanding of these Fontan-associated domains could create the opportunity for development of a more robust set of characteristics that accurately define wellness in this unique population.

The perturbations created by a Fontan circulation are potentially quite broad. Myriad biological systems and health processes outside of the cardiovascular system are at risk, which contribute to the overall burden of disease. Variability in outcomes can be quite wide. Why do some individuals manifest numerous broad complications while others, just isolated, show unique types of problems? Why do some exhibit resilience to these challenges?

health intervention? Proactive identification at an early phase may provide the optimal opportunity for treatment and course correction.



You can only change what you measure: an argument for more detailed characterization in the Fontan circulation

Jack Rychik[1,2*] European Heart Journal (2022) **43**, 2385–2387

Quel tableau clinique ?

Considerations for Advanced Heart Failure Consultation in Fontan Patients:

Guidance for primary cardiologists

action
ADVANCED CARDIAC THERAPIES IMPROVING OUTCOMES NETWORK

HARMONIZED PROTOCOL

BACKGROUND

To aid in decision-making on timing of referral of Fontan patients for advanced heart failure consultation with the aim of improving timely referral and facilitating collaborative care to enhance patient outcomes.

Patient population: Fontan patients

Considerations for referral by type of clinical Fontan dysfunction
(recognizing overlap exists between categories)

Cardiac/Systemic Ventricular Dysfunction

1) Severe[1] systolic dysfunction by echocardiogram, MRI, or cardiac catheterization.
2) Moderately depressed (by qualitative assessment) systolic function on imaging when accompanied by ≥moderate systemic AV valve regurgitation.
3) Significant growth derangement or failure to thrive including cachexia or linear growth failure
4) Decreasing exercise tolerance by patient report or as measured on sequential formal exercise testing or 6-minute walk
5) Significant electrophysiologic abnormalities, including recurrent arrhythmias despite therapy, implantation of a cardiac pacemaker, or aborted sudden cardiac death event

Fontan Pathway Dysfunction

1) Symptomatic, chronic fluid overload persisting despite new or increasing diuretic therapy
2) Occurrence of chronic pleural effusions or ascites, chylous or nonchylous, refractory to therapy and occurring outside the initial Fontan post-operative period
3) Major hemodynamic disturbance *resulting in symptoms* despite therapy including: low systemic cardiac output, diastolic ventricular failure, significantly elevated Fontan pressure, or symptomatic cyanosis

Lymphatic Dysfunction

1) Protein-losing enteropathy that has failed medical therapy and requires multiple hospital admissions in a 12-month period or PLE requiring repeated albumin infusions to treat symptoms despite standard PLE medical therapy
2) Plastic bronchitis requiring chronic therapy

Extra-cardiac Dysfunction

1) Hemoptysis requiring evaluation that is unrelated to an infection and persists after standard intervention
2) Liver disease with impaired synthetic function/abnormal liver function testing or undergoing evaluation for liver transplantation
3) Chronic kidney disease – Stage 3 or greater[2]

«Can’t manage what you don’t measure»

TABLE 1. Consulting services engaged for preoperative ventricular assist device evaluation

Clinical service	Indications for evaluation*
Consultations obtained in all patients	
Hepatology	FALD including hepatocellular carcinoma
Cardiac rehabilitation	Functional assessment, frailty
Palliative care	Advanced care planning
Consultation obtained as needed	
Nephrology	Chronic kidney disease, severe acute kidney disease
Hematology	History of thrombosis
Neurology	History of stroke, concerns on preoperative neurologic imaging
Pulmonology	Evaluation of plastic bronchitis

FALD, Fontan-associated liver disease. *Common considerations/reasons for evaluation are listed. Patient-specific concerns should be addressed accordingly.

Consultation

The complications and physiologic derangements present in the failing Fontan circulation can lead to multiple complications, as noted earlier. With this in mind, routine consultation of a number of services is generally prescribed, with some services engaged as needed (Table 1). Our center has tried to engage specific subspecialists in the given field who have experience with the Fontan circulation. This is especially important regarding hepatology consultation given the rapidly evolving data on FALD.

Mechanical support for the failing single ventricle after Fontan

JTCVS Techniques • June 2022

Chet Villa, MD, Jason W. Greenberg, MD, and David L. S. Morales, MD

…alors…

- 50000 -70000 Fontan dans le monde
- Amélioration suivie moyen / longue terme
- Vivants 90% à 10-15 ans
- Age 30 ans suivie 90-95%, 40 ans suivie 80%
- Mortalité après adolescence pour défaillance cardiaque
- Après 1ere hospitalisation pour défaillance cardiaque sur Fontan : mortalité 1 ans 24%, 3 ans 35%
- Comorbidités multiples

- mauvasise qualité de vie
- à la greffe trop tard, pas de donneurs
- patient trop malade = pire outcome à la transplantation cardiaque

Virage ou échec ? 1ere VAD in Fontan

Total Circulatory Support with an LVAD in an Adolescent with a Previous Fontan Procedure

O.H. Frazier, MD
Igor D. Gregoric, MD
Gregory N. Messner, DO

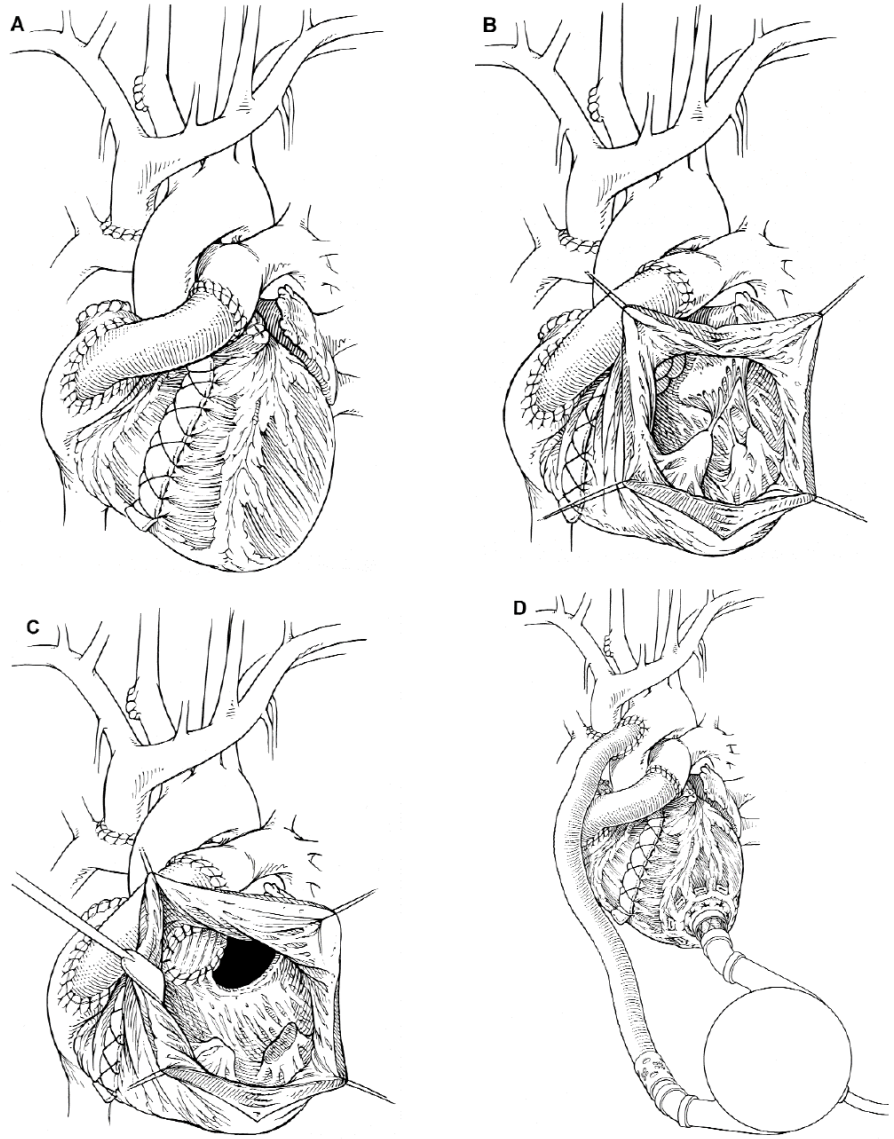
(Tex Heart Inst J 2005;32:402-4)

We report the case of a 14-year-old boy who developed ischemic contracture of the heart after open heart surgery to correct complex congenital heart disease. Because he had no cardiac function, an extracorporeal, continuous-flow device was used to support him until he was transferred to our institution. Shortly after his arrival, an implantable, long-term left ventricular assist device was implanted. The univentricular pump provided total cardiac support for this critically ill patient. After normalization of end-organ function, the patient underwent successful orthotopic cardiac transplantation.

The heart was small, contracted, and nonfunctional.

Catheterization showed a thrombotic occlusion of the left coronary artery.

The low pulmonary vascular resistance in this patient facilitated successful univentricular support; however,



Quel patient, quel tableau clinique, quelle machine, quelle technique chirurgicale? Un exemple de BRIDGE-To-CANDIDACY

- Anatomie : situs solitus, levocardie, atresie tricuspide, hypoVD, pas de CIV. APS et VPs ok
- <u>Insuffisance ventriculaire pure</u>
- RVP basses
- Insuffisance hepato-renale en progressione sous MCS courte durée
- Challenge chirurgicale : ablation VAV ; possibilité de faire la place pour la canule de drainage (VS petit) ; patch pour fermer la VAo car fuite +++
- Surface corporelle 1.9 m^2
- Même si SC adéquate pour le plus gros HeartMate il a été implanté un HeartMate IP LVAS (HeartMate implantable pneumatic left ventricular assist system, Thoratec Corp.; Pleasanton, Calif), plus versatile, flexible, résistent

Signes de défaillance droite sans VD : Failing Fontan à VS à fonction conservée

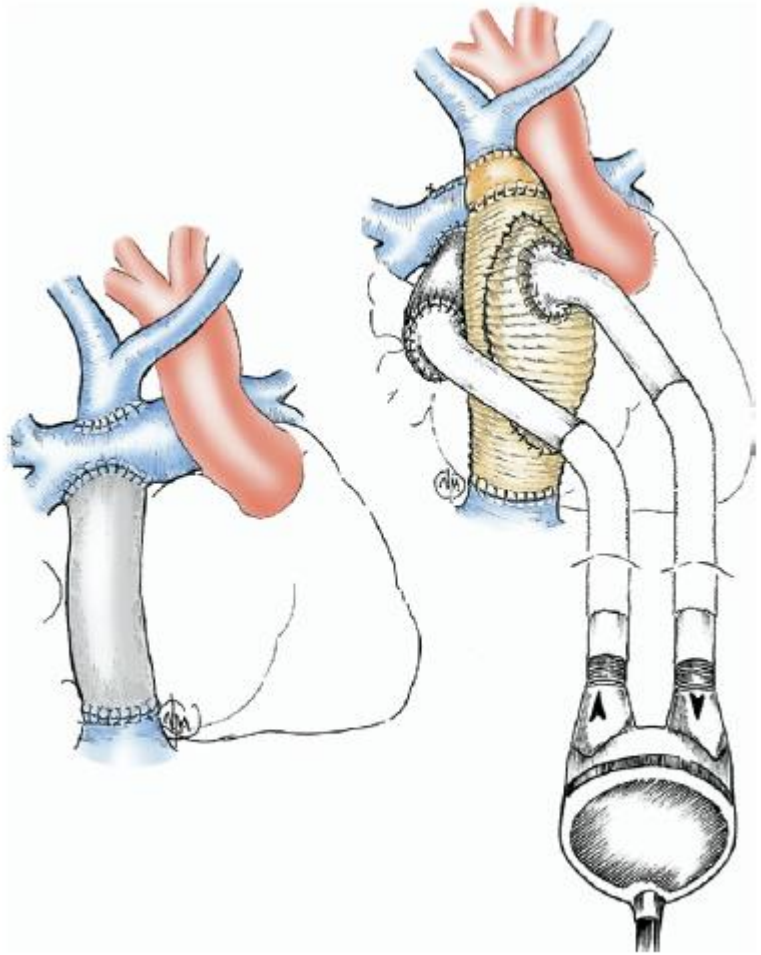
Right-Sided Univentricular Cardiac Assistance in a Failing Fontan Circulation

René Prêtre, MD, Achim Häussler, MD, Dominique Bettex, MD, and Michele Genoni, MD

Cardiovascular Surgery and Cardiac Anesthesia, Department of Surgery, University Hospital, Zürich, Switzerland

Fontan patients are doomed to a circulatory failure and many of them will require a circulatory assistance as a bridge to transplantation. The univentricular heart with a total cavopulmonary connection presents a special challenge for the insertion of an assist device. We report a patient in multiple organ dysfunction and failure who was supported by right-sided univentricular assistance. Technically, a new chamber was created between both vena cava for implantation of the inflow cannula, and the extracardiac conduit was used to set the outflow cannula. The patient dramatically recovered and is currently in the best condition for heart transplantation.

(Ann Thorac Surg 2008;86:1018–20)



Un autre cas de bridge to candidacy

CASE REPORT

JOURNAL OF CARDIAC SURGERY WILEY

RVAD implantation in a Fontan patient with protein-losing enteropathy as a bridge to transplant: Prêtre modification

Julia Moosmann MD[1] | Sven Dittrich MD[1] | Ariawan Purbojo MD[2] | Robert Cesnjevar MD[2]

J Card Surg. 2020;1–4.

In Fontan patients with preserved ejection fraction of the systemic ventricle, implantation of a subpulmonary VAD (RVAD) can drop central venous pressure and, therefore, improve congestion and end-organ damage. Our patient was recovering extremely well from malnutrition and end-organ injury, which confirms the observation of Prêtre et al[5] in a 27-year old patient who underwent successful cardiac transplantation 13 months after RVAD implantation. The overall clinical benefits of RVAD support have to be balanced against the typical risks of Berlin Heart Assist systems including bleeding and the need for transfusions, which might have influenced outcome of transplantation.

However, we are encouraged by the fact that RVAD implantation in Fontan patients with preserved ejection fraction and "failing" circulation due to PLE represents a promising method for bridge to transplant.

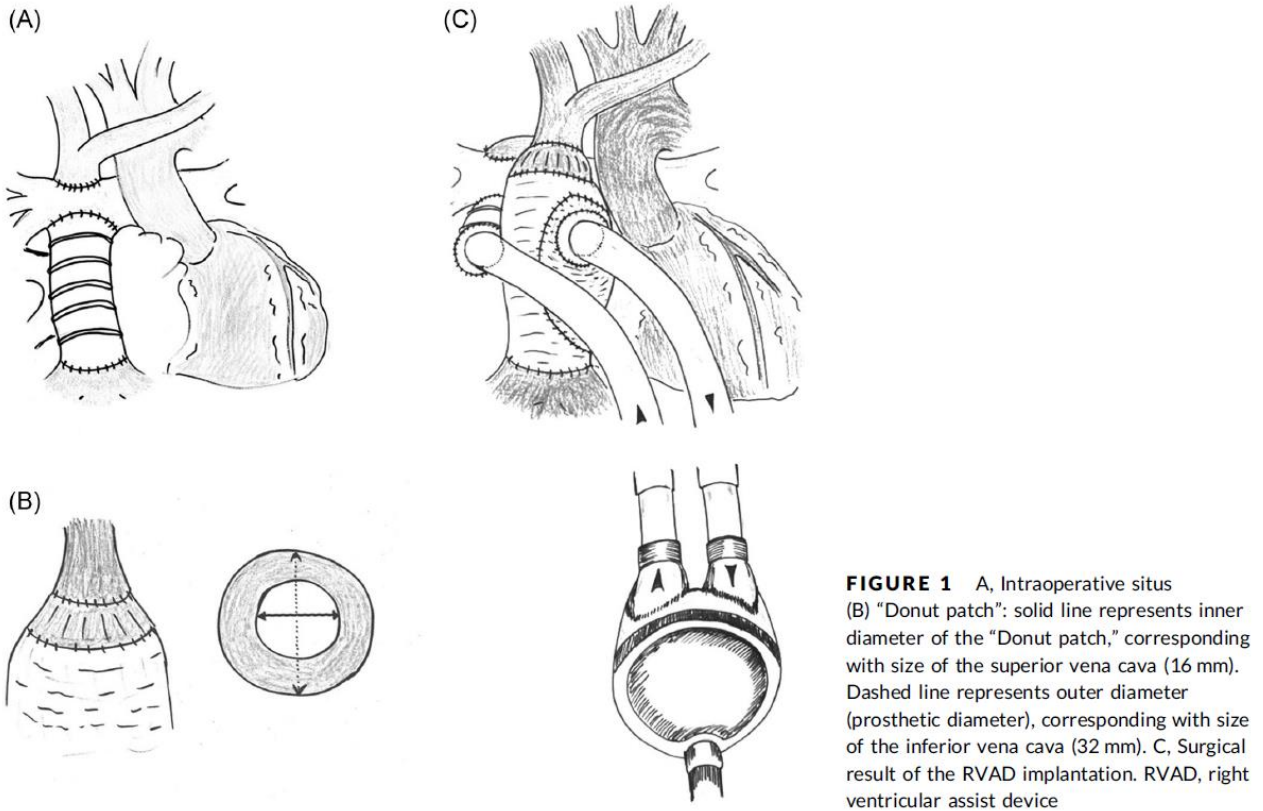
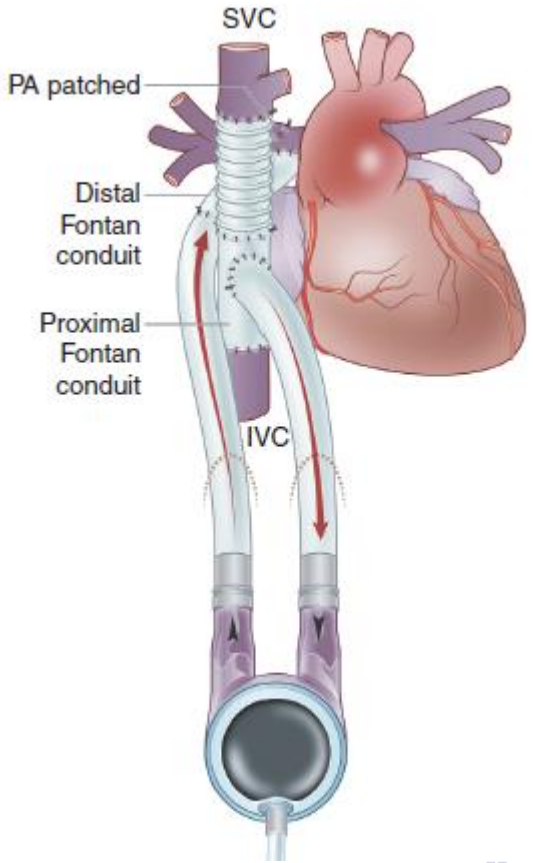


FIGURE 1 A, Intraoperative situs (B) "Donut patch": solid line represents inner diameter of the "Donut patch," corresponding with size of the superior vena cava (16 mm). Dashed line represents outer diameter (prosthetic diameter), corresponding with size of the inferior vena cava (32 mm). C, Surgical result of the RVAD implantation. RVAD, right ventricular assist device

Et si Failing Fontan précoce ?

lowering of pulmonary resistance. The is exemplified by our recent Fontan patient with normal systolic function of the single ventricle and severe plastic bronchitis and protein-losing enteropathy. This 5-year-old girl could not be weaned off ventilatory support and deteriorated rapidly, requiring urgent extracorporeal membrane oxygenator support. In this state, the patient was not a candidate for heart transplantation. Cavopulmonary VAD insertion (Figure 2, *B*) resulted in complete resolution of protein-losing enteropathy and plastic bronchitis. She is has been supported by VAD for 588 days until she underwent successful heart transplantation. We and others have previously emphasized this approach as a bridge to candidacy for heart transplantation in patients with failing Fontan circulation and preserved single ventricle function.[16,21,22] Yet, the current



Heart transplantation after Fontan operation

Igor E. Konstantinov, MD, PhD, FRACS,[a,b,c,d] Antonia Schulz, MD,[a] and Edward Buratto, MBBS, PhD, FRACS[a,b,c]

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Vue d'ensemble

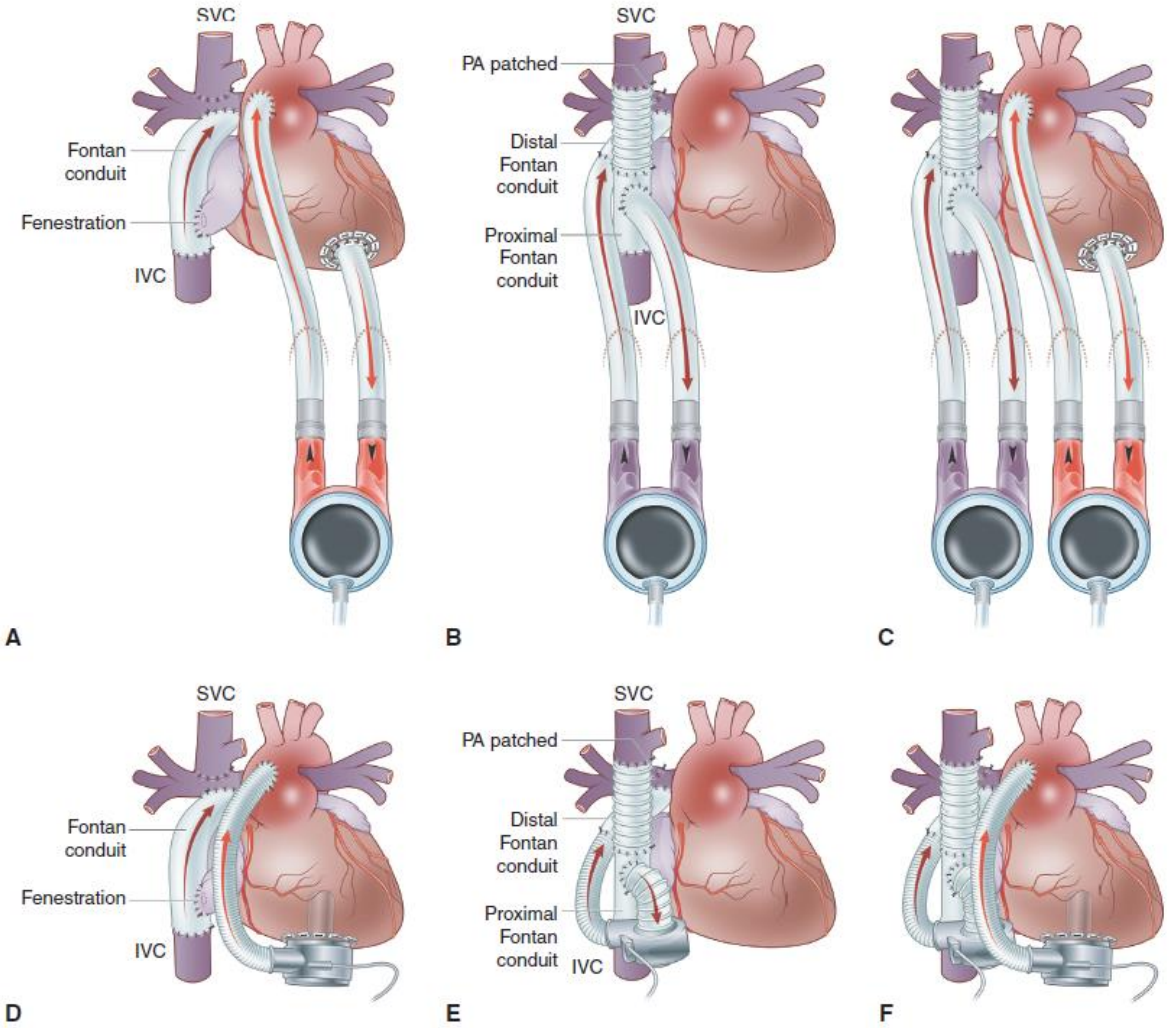
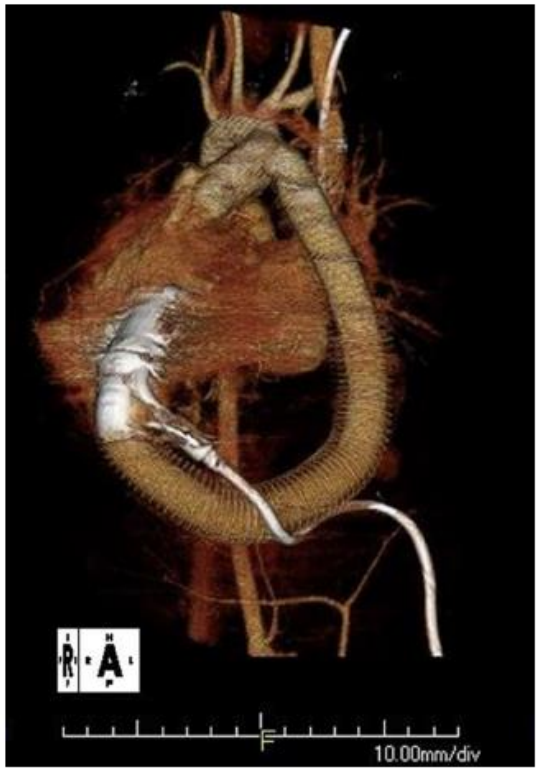


FIGURE 2. Durable VAD support in patients with Fontan circulation. Pulsatile VAD is used to support systemic (A) or pulmonary (B) circulation or both (C) in smaller children, whereas continuous flow VAD is used to support systemic (D) or pulmonary (E) circulation or both (F) in older children and adults. *SVC*, Superior vena cava; *IVC*, inferior vena cava; *PA*, pulmonary artery.



Jarvik 2000 axial flow ventricular assist device in right single ventricle after Fontan operation

Journal of Artificial Organs August 2019

Yoshihisa Tanoue[1] · Takeo Fujino[1] · Hideki Tatewaki[2] · Akira Shiose[2]

Heart transplantation after Fontan operation

Igor E. Konstantinov, MD, PhD, FRACS,[a,b,c,d] Antonia Schulz, MD,[a] and Edward Buratto, MBBS, PhD, FRACS[a,b,c]

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VAD et Fontan : une question de timing, patient, cible et technique

- Symptômes, âge, dimensions, anatomie (le VU est D ou G ? Ascite ?)
- Si pt résistent à l'escalade thérapeutique → VAD ?
- VAD in INTERMACS II - III MIEUX que INTERMCAS I = choc (PediMACS, PEdiEUROMACS)
- Eviter de passer par ECMO
- Dysfonction du ventricule systémique, augmentation RVP ou les 2 ?

Je ne peux pas venir au bout d'un de FAILING FONTAN si le tableau clinique est le résultat d'une PRECHARGE INADAPTÉE (RETOUR PULMONAIRE PASSIVE INSUFFISANT)

QUEL PATIENT ?

- Prédicteurs mortalité précoce : male, Fontan Ao-Pulm, tube ExtraC, chirurgie VAV avant Fontan, épanchements pleuraux persistants
- TdR A., entéropathie prot.disp., dysfonction VU tardive : facteurs predict. fortes (Poh, 2021)
- Dysfonction VU / fuite VAV → VAD V-Ao (Systémique) → amélioration hémodynamique
- Etat clinique pré-VAD ←→ outcome immédiat post-VAD
- INTERMACS 1, intubation → mauvaise suivie → traitement médicale, conversion de Fontan, fenestration, greffe

QUEL PATIENT ?

↑ chronique PVC +++, ↑ GTPm (> 6mmHg), RVPI > 3W, obstruction écoulement V ou P

↓

insuffisance cardiaque ou complications spécifiques bronchite plastique, entéropathie (LPS), FALD, cirrhose hépatique avec K

↓

RVAD – traitment sténose – conversion de Fontan BiVAD – TAH (Synacardia)

QUAND ?

- Signes : dysfonction hépatique / rénale, insuffisance respiratoire (Intubation), baisse SvO2, acidose lactique
- Intolérance NE, baisse seuille test d'effort
- RVPI > 2W/m2, bas débit (<2.5 L/mn/m2)
- BNP, PTH
- ECMO V-A Rescue : J-C vs F-F, max 10-14 jours → VAD longue durée
- Contre-indications absolues VAD longue durée : complication organe irréversible (Neuro), infection en cours

Avant décompensation avec insuffisance d'organe

Villa, et al. JTCVS Techiques, June 2022

HÔPITAUX Paris
Saint-Joseph
Marie-Lannelongue

QUEL TYPE D'ASSISTANCE ?

Table 2. Available VADs for paediatric patients

Device	Type	Location	Min. patient size (approximate)	Additional information
HeartMate 3 (Abbott)	Single VAD Continuous flow Centrifugal pump	Intracorporeal	BSA $\geq$ 1.2 m^2	
~~HeartWare (Medtronic)~~	~~Single VAD Continuous flow Centrifugal pump~~	Intracorporeal	BSA $\geq$ 1.0 m^2	~~Implantation with BSA as low as 0.6 m2 has been described, but has a higher risk of pump thrombosis Removed from market in June 2021~~
EXCOR (Berlin Heart)	Single VAD Pulsatile flow Pneumatic pump	Extracorporeal	Weight > 2 kg	Available in 10, 15, 25, 30, 50, 60 and 80 ml pump sizes
SynCardia (SynCardia Systems)	Total artificial heart Pulsatile flow Pneumatic pump	Intracorporeal	BSA > 1.2 m^2	Available in 50 and 70 ml pump sizes

Ventricular assist device for Fontan: who, when and why?

Curr Opin Anesthesiol 2022, 35:12–17

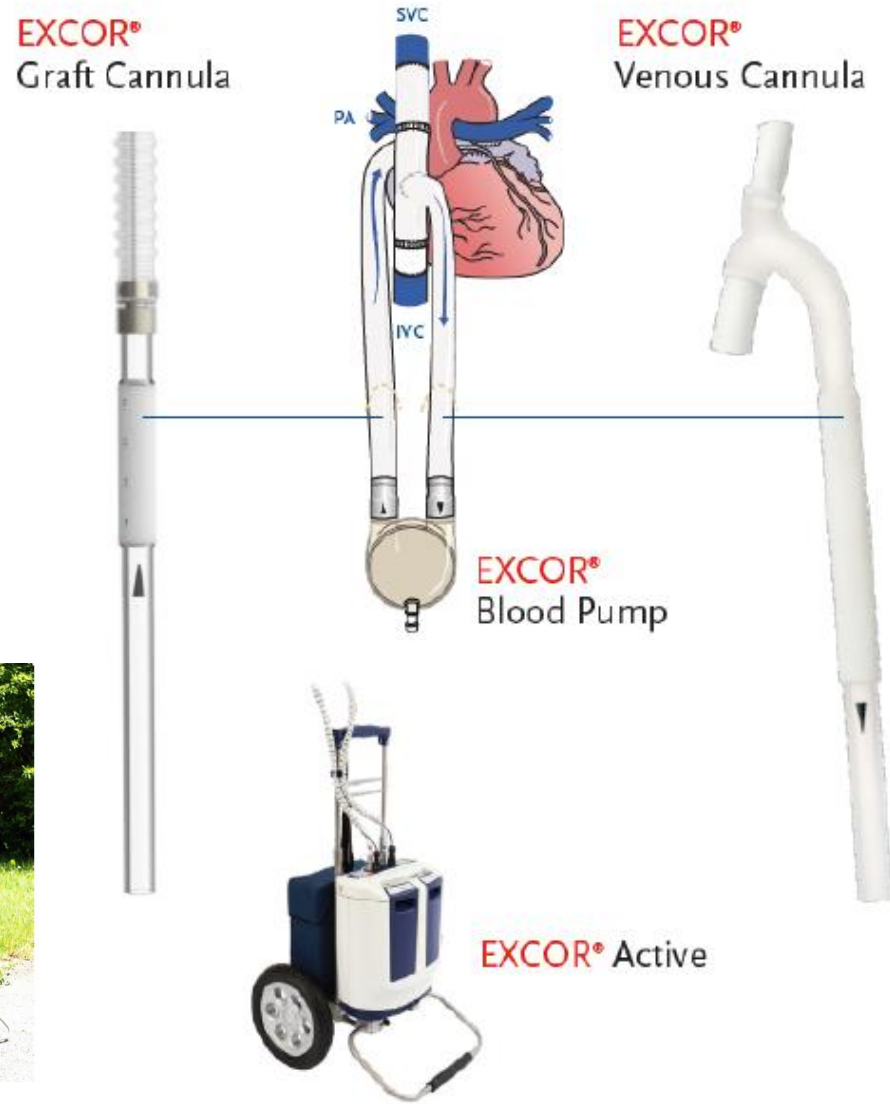
Catherine S. Reid[a], Heiko A. Kaiser[a,b], Paul Philipp Heinisch[c,d], Thomas Bruelisauer[e], Sebastian Michel[c,d], and Matthias Siepe[f,g]

HÔPITAUX Paris
Saint-Joseph
Marie-Lannelongue

EXCOR® Revive

Berlin Heart®

- EXCOR® Revive is intended for either sub-pulmonary support (univentricular) or in combination with systemic support (biventricular)
- A new EXCOR® Venous Cannula was designed to establish the function of the missing right ventricle
- The cannula collects the blood flow returning from the body and intends to improve pulmonary circulation by means of an active and pulsatile blood flow



"Cavopulmonary support with a modified cannulation technique in a failing Fontan patient"

EACTS PROGRAM HIGHLIGHT

Friday, 15 October 2021, 16:45

S. Michel, Munich, J. Pabst Von Ohain, Munich, M. Hermann, Munich, A. K. Menon, Berlin, E. Sandica, Bad Oeynhausen, C. Hagl, Munich, N. Haas, Munich, J. Hörer, Munich

EXCOR® ACTIVE

Berlin Heart®

QUEL TYPE D'ASSISTANCE ?

- Type de dispositif durable ←→ type d'insuffisance cardiaque

- **L'insuffisance ventriculaire systémique** peut être principalement due à un dysfonctionnement systolique ou diastolique
- **Dysfonctionnement systolique** VAD en flux continu ou un VAD en flux pulsatile (HeartWare, HeartMate 3 ; CentriMag et/ou PediMag VAD court terme sans oxygénateur)
- Appareils pulsatiles = Berlin Heart

- Princ. **dysfonctionnement diastolique** sont probablement mieux traités avec des continous VAD car dispositifs à débit pulsatile → inversion du débit veineux pulmonaire (Reverse flow)

- Si fonction ventriculaire ok + gradient transpulmonaire élevé → difficulté → VAD sous-pulmonaire. Obligatoire démonter le Fontan et détourner le sang de VCS et VCI vers chambre de collecte / réservoir sang pour remplissage du VAD → Outflow graft anastomose aux APs

Mechanical Support of the Failing Fontan Circulation

Christopher E. Mascio, MD Semin Thoracic Surg 33:454–458 © 2020

QUEL TYPE D'ASSISTANCE ?

- **Défaillance de type Fontan mixte** (VS dysfonctionnel + > GTP), les deux sous-pulmonaires et le soutien ventriculaire systémique sont nécessaires

- **Configuration** de dispositif d'assistance biventriculaire avec en utilisant des appareils existants (deux HeartWare, deux HeartMate 3, deux Berlin Heart, etc.) ou en utilisant la Syncardia coeur artificiel total

Mechanical Support of the Failing Fontan Circulation

Christopher E. Mascio, MD

Semin Thoracic Surg 33:454–458 © 2020

…donc…

- **Centre spécialisé = plus d'opportunités**
- **Timing**
- **Compétences et multidisciplinarité**
- **Techniques chirurgicales (Fenestration)**
- **Connaissances**
- **Network, réseau, registre**

QUESTIONS TIME

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