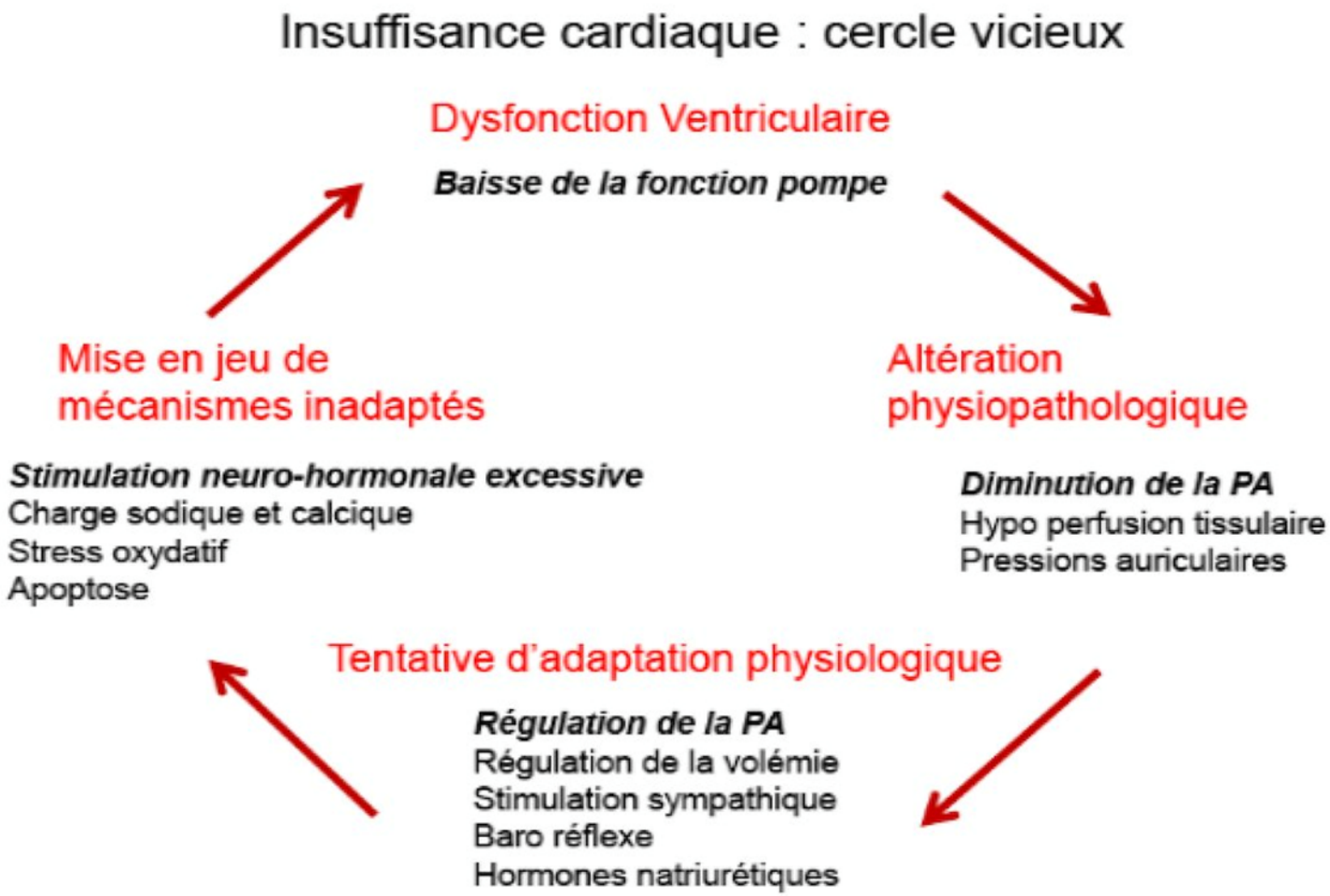
# Assistances circulatoires : nouvelles perspectives

Cristian Mirabile
Cardiac Intensive Care Unit
Sidra Medicine
Doha, Qatar
13 Mars 2026

# AUCUN CONFLIT D’INTÉRÊTS

# POURQUOI IMPLANTER UNE ASSISTANCE CHEZ UN ENFANT ?

# Physiopathologie insuffisance cardiaque



سدرة للطب
Sidra Medicine

# INTERMACS

**Interagency Registry for Mechanically Assisted Circulatory Support**

# PEDIMACS

**Pediatric Interagency Registry for Mechanically Assisted Circulatory Support**

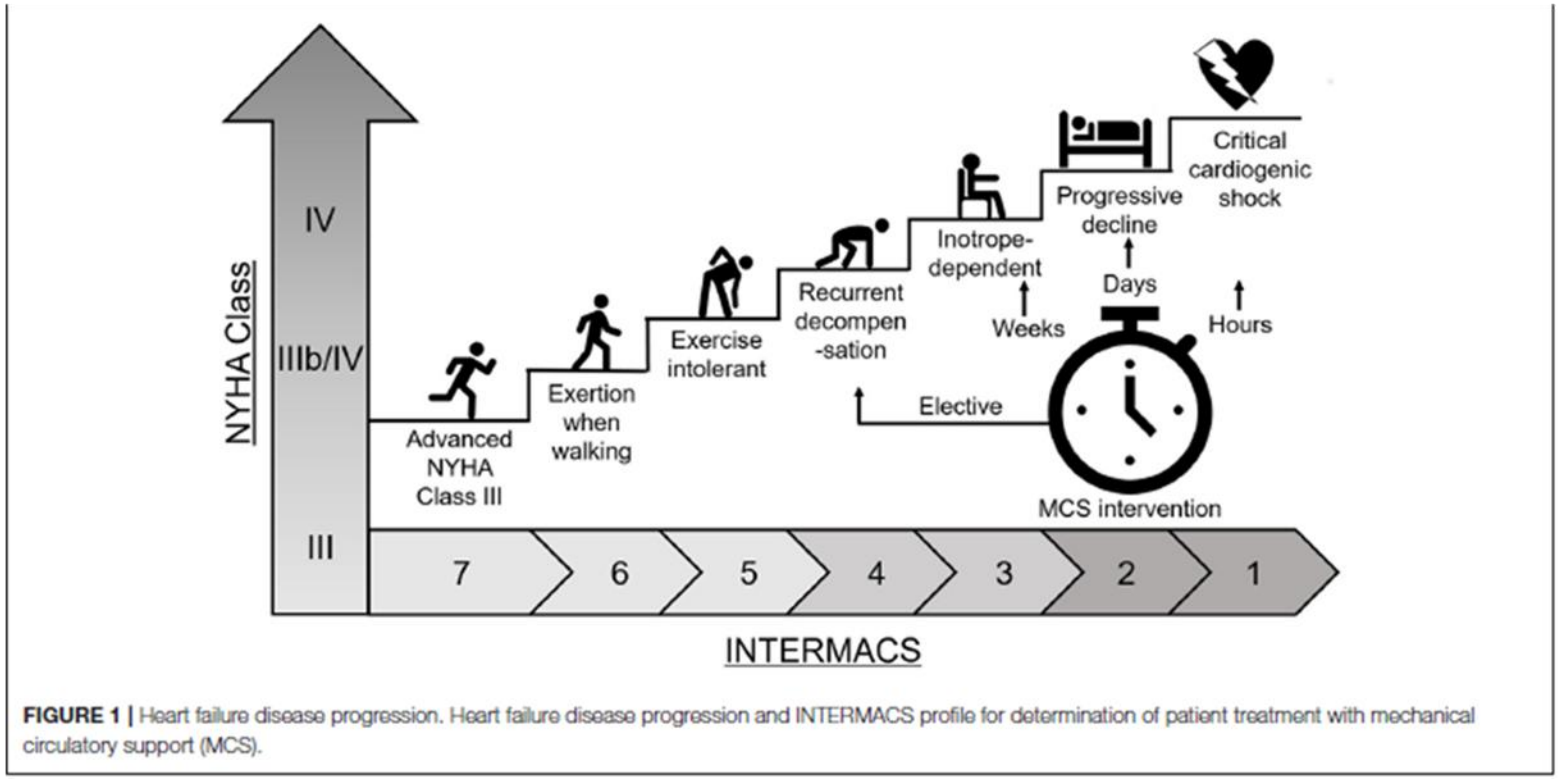



**FIGURE 1 |** Heart failure disease progression. Heart failure disease progression and INTERMACS profile for determination of patient treatment with mechanical circulatory support (MCS).

| INTERMACS Profile | Description | SCAI Shock Stage | Description | Comments |
|---|---|---|---|---|
| 7 | Advanced New York Heart Association class III | A | At risk for cardiogenic shock | SCAI A generally corresponds to less severe INTERMACS profiles (4–7), representing patients at risk of shock. |
| 6 | Exertion limited | | | |
| 5 | Exertion intolerant, housebound | | | |
| 4 | Resting symptoms on oral therapy | | | |
| 3 | Stable but inotrope dependent | B | Beginning shock | SCAI B could align with INTERMACS 3, where patients require inotropic support but are relatively stable. |
| 2 | Progressive decline on inotropes | C | Classic cardiogenic shock | SCAI C to E correlate with the most severe INTERMACS profiles (1–2), representing declining patients and those in extreme shock. |
| 1 | Critical cardiogenic shock | D | Deteriorating | |
| | | E | Extremis | |

| Indication | Percentage |
| --- | --- |
| Bridge to Transplant (BTT) | 60–75% |
| Bridge to Recovery (BTR) | 5–15% |
| Bridge to Decision (BTD) | 10–20% |
| Destination Therapy (DT) | 5–10% |

# Analysis of UNOS: Ventricular Assist Device as a Bridge-to-Transplant in Pediatric Patients with Congenital Heart Disease

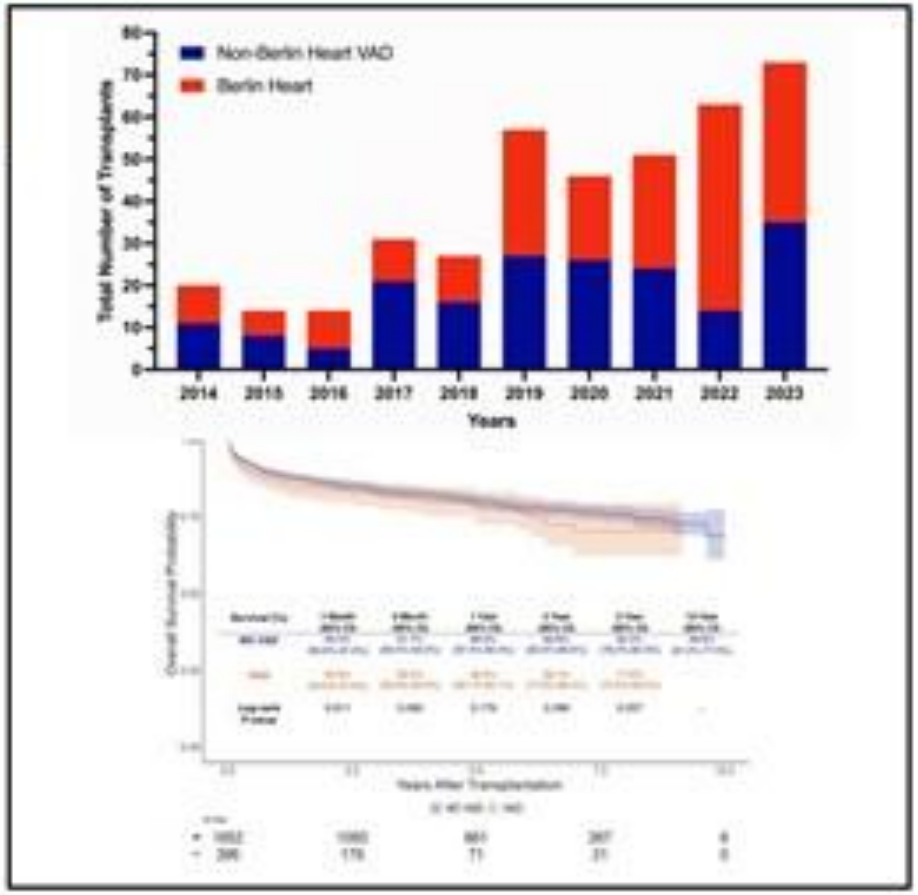
## Summary

**Population:** Patients<18 years with congenital heart disease (CHD) listed for cardiac transplantation at 65 centers

**Intervention:** VAD-support amongst CHD patients<18 bridged-to-transplant.

**Comparison:** Outcomes of bridge-to-transplant with and VAD.

**Outcome:** Patients<18 years with CHD bridged-to transplant with VAD achieve post-transplant outcomes and long-term survival similar to those bridged without VAD.




Legend: VAD = ventricular assist device, CHD = congenital heart disease

UNOS = United Network for Organ Sharing

Bilgili A et al . Eur J Cardiothorac Surg. 2025

سدرة للطب
Sidra Medicine

# CHD Patients <18 Years: VAD vs No VAD (UNOS 2014–2023)

| Parameter | VAD | No VAD |
|---|---|---|
| Total listed (n=3394) | 561 (16.5%) | 2833 (83.5%) |
| Transplanted | 396 (70.6%) | 1852 (65.4%) |
| Waitlist mortality | 25.7% | 16.2% |
| Post-Tx stroke | 6.4% | 4.5% |
| Acute rejection | 15.2% | 16.5% |
| 5-year survival | No significant difference (P=0.257) | No significant difference |

**Bilgili A et al . Eur J Cardiothorac Surg. 2025**

# Outcome of ventricular assist devices in adults with congenital heart disease – A single center case series

*International Journal of Cardiology Congenital Heart Disease 23 (2026) 100648*

Ahmed Younis [a], Zeyad M. Kholeif [b], William R. Miranda [d], Heidi M. Connolly [d], Mauricio T. Villavicencio [c], Joseph A. Dearani [c], Alexander C. Egbe [b,*]

**Table 1**
Baseline characteristics.

| | N = 11 |
|---|---|
| Age, years | 42 (31; 59) |
| Male sex | 8 (73 %) |
| Body surface area, $m^2$ | 2.05 (2.0; 2.15) |
| Body mass index, $kg/m^2$ | 31 (29; 36) |
| Systemic oxygen saturation, % | 94 (94; 98) |
| CIED | 11 (100 %) |
| **Anatomy/Physiology** | |
| Biventricular physiology | |
| Systemic LV | 3 (27 %) |
| Systemic RV | 6 (55 %) |
| Fontan physiology | 2 (18 %) |
| **Comorbidities** | |
| Atrial arrhythmias | 10 (91 %) |
| CKD III-V | 8 (73 %) |
| Cirrhosis | 6 (55 %) |
| Protein losing enteropathy | 2 (18 %) |
| COPD | 4 (36 %) |
| **Laboratory data** | |
| NT-proBNP, pg/ml | 3598 (1426; 7522) |
| MELD-XI score | 15.92 (11.90; 22.59) |
| Estimated GFR, ml/min/1.73 $m^2$ | 54 (41; 95) |
| Creatinine, mg/dl | 1.43 (1.17; 2.27) |
| Hemoglobin, g/dl | 11.1 (9.6; 13.8) |
| Platelet count | 158 (96; 244) |
| **Echocardiographic indices** | |
| Systemic ventricular ejection fraction, % | 20 (15; 25) |
| ≥ Mod systemic ventricular AVVR | 2 (18 %) |
| Systemic ventricular cardiac index, $l/min/m^2$ | 2.42 (2.01; 2.84) |
| Non-systemic ventricular ejection fraction, % | 45 (33; 51) |
| ≥ Mod non-systemic ventricular AVVR* | 6 (67 %) [N = 9] |
| RA pressure, mmHg* | 10 (10; 15) [N = 9] |
| RVSP, mmHg* | 57 (40; 69) [N = 9] |
| **Cath indices (Biventricular physiology)** | **N=9** |
| RA pressure, mmHg | 18 (12; 26) |
| PA mean pressure, mmHg | 38 (26; 44) |
| PAWP, mmHg | 24 (20; 29) |
| Cardiac index, $l/min/m^2$ | 2.54 (1.85; 2.85) |
| **Cath indices (Fontan physiology)** | **N=2** |
| Fontan pressure, mmHg | 32 (30; 34) |
| PAWP, mmHg | 24 (22; 27) |
| Cardiac index, $l/min/m^2$ | 2.63 (2.45; 2.81) |

**Abbreviations:** AVV: Atrioventricular valve; CKD: Chronic kidney disease; CIED: Cardiac implantable electronic device; GFR: Glomerular filtration rate; MELD-XI: Model for end-stage liver disease excluding international normalized ratio; NTproBNP: N terminal pro hormone brain natriuretic peptide; RV: Right ventricle; PAWP: Pulmonary artery wedge pressure.

**Footnote:** Data presented as median (Q1, Q3), or count (percent), as appropriate. * Echocardiographic indices of nonsystemic ventricular function and hemodynamics were based on the 9 patients with biventricular physiology.

11 adults with congenital heart disease (median age 42 years)

- Stage D heart failure
- 64% Destination Therapy, 36% Bridge-to-Transplant
- 18% Fontan physiology
- Severe baseline status: LVEF 20%, 73% CKD, 55% cirrhosis

- HeartMate III (55%), HeartWare (36%), HeartMate II (9%)
- 18% required perioperative ECMO
- No significant improvement in NT-proBNP or MELD-XI at 30 days
- Complications: Sepsis 27%, Bleeding 18%, Pump thrombosis 9%

- In-hospital mortality: 18%
- Survival: 30-day 91%, 1-year 64%, 3-year 36%
- Better survival excluding Fontan patients requiring ECMO

Conclusions

- Feasible procedure with acceptable early outcomes, but limited long-term survival
- Small population → need multicenter registry

سدرة للطب
Sidra Medicine

*Review*

# Mechanical Circulatory Support in Congenital Heart Disease

Áine Lynch [1,*] and Aamir Jeewa [2]

*Children* 2025, *12*, 306

- Pediatric HF= resource use, prolonged hospital/ICU stays, **in-hospital mortality 6–7%**
- CHD now drives **>50%** of pediatric HF ICU admissions; **survival to discharge is lower (≈75–81%)** in these patients
- Improved early surgical outcomes have expanded the growing cohort of children/young adults living with repaired CHD, frequently **residual lesions** → later HF
- Unlike adult acquired heart failure, pediatric/CHD-related HF has a **relative lack of evidence-based pharmacologic options**, so many patients progress to end-stage disease
- MCS—**ECMO and VADs**—is used to restore CO, relieve symptoms, and preserve end-organ function as **bridge to decision, bridge to transplant, or bridge to recovery**; **destination therapy** in selected cases
- Structural complexity, especially **SV physiology**, adds major technical/physiologic challenges for VAD implantation and for maintaining **balanced systemic vs pulmonary blood flow**; the text focuses on indications, outcomes, and management challenges of MCS in CHD

- **Indication:** failure of medical therapy in anatomically/physiologically suitable patients

- Early HF recognition in CHD; **proactive VAD** before shock/end-organ damage improves outcomes

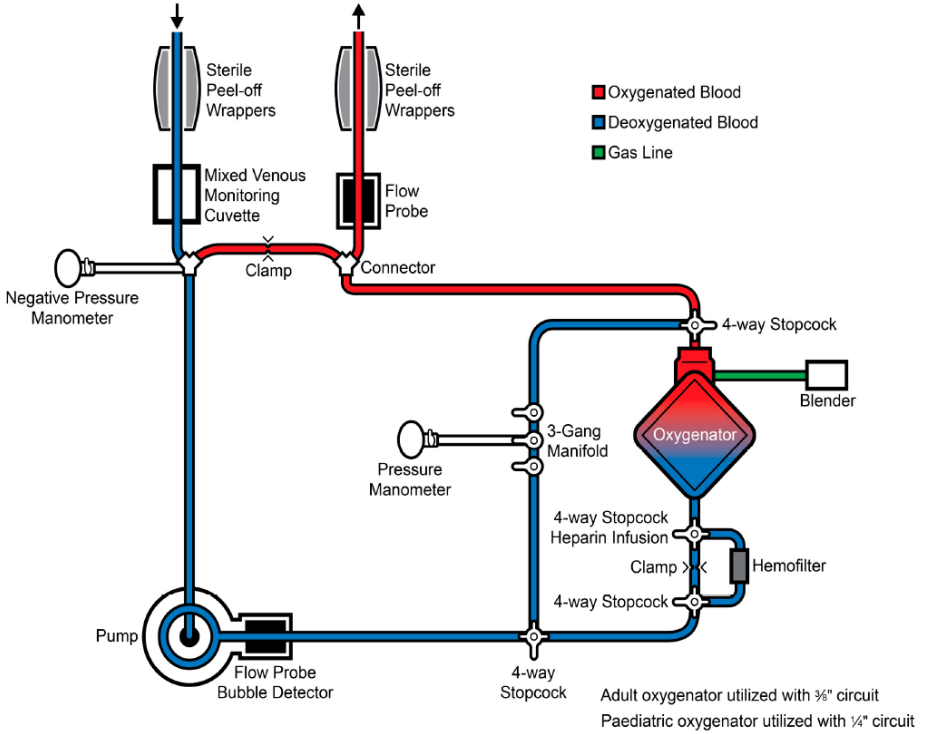
- Refer if **feeding issues, FTT, respiratory distress, fluid retention, oliguria, exercise intolerance**

- Consider size, anatomy, hemodynamics, comorbidities, psychosocial support

- Prefer **semi-elective, early MCS** before ventilator/renal dependence

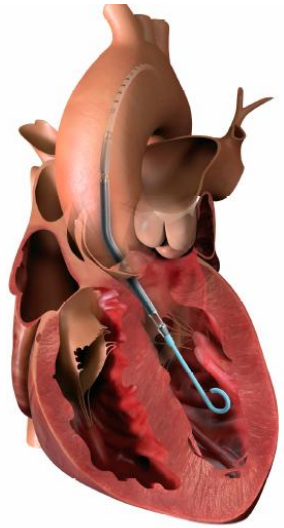
## ECMO

- Urgent/emergent short-term MCS; rapid ICU deployment
- Provides **full cardiopulmonary support** (oxygenator included)
- Central (post-CPB failure) or peripheral (shock, acute decompensation).
- May require LV decompression
- Mainly bridge to recovery; possible bridge to VAD/transplant (higher mortality vs VAD alone).
- Common in CHD, especially <10 kg, single ventricle, eCPR, pre-op stabilization




## Impella

- Percutaneous microaxial pump; **partial cardiac support**
- Requires residual native ventricular function.
- Rapid cath-lab implantation; avoids sternotomy
- Can combine with ECMO (“ECpella”) or biventricular support (“BiPella”)



| Modality | Key Points | Main Messages |
|---|---|---|
| Durable VADs | Intracorporeal or paracorporeal; pulsatile or continuous flow; LVAD/BiVAD options; require RV assessment | Early planning critical; CHD patients younger, often need paracorporeal devices |
| Continuous-flow (HeartMate 3™) | Intracorporeal; home management possible; size constraints (~19 kg minimum reported) | Lower risk profile; effective bridge to transplant, including Fontan |
| Pulsatile (Berlin Heart EXCOR®) | Paracorporeal; mainstay <20 kg; multiple pump sizes | Essential in small children; higher risk <10 kg |
| Total Artificial Heart (SynCardia™ 50 cc) | Replaces ventricles; for complex anatomy unsuitable for VAD | Option in complex CHD; ~56% positive outcomes |

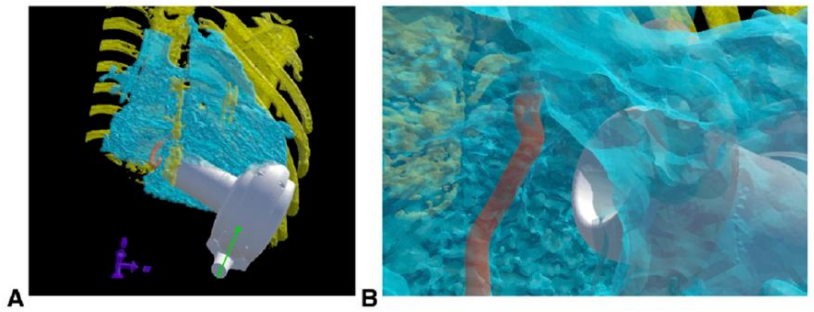
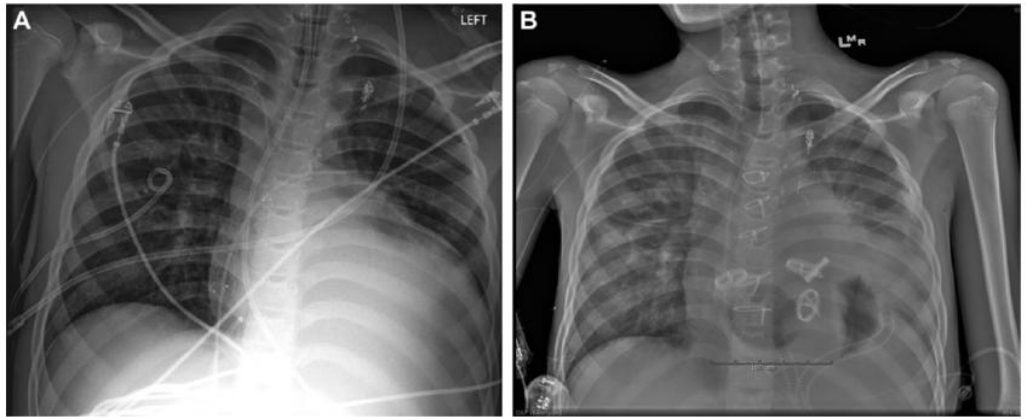



**Figure 3.** Computed tomography 3D reconstruction of the HeartMate 3™ to assess for device fit within the chest cavity. Image courtesy of Davies et al. 2020, JTCVS Techniques [13]. (**A**) Placement of the ventricular assist device (white) within the reconstructed heart (blue) and ribcage (yellow). (**B**) View of the tricuspid valve annulus (red) and ventricular assist device (white).




سدرة للطب
Sidra Medicine

- **CHD** patients on VAD show **higher mortality** (36.4% vs 12.1%) and **lower transplant rates** (29.1% vs 59.9%) than non-CHD on devices

- Greater early **respiratory failure risk**

- Similar major adverse events (bleeding, thrombosis, infection, neurologic)

- Post-transplant survival comparable

- **Mortality risk: renal failure, ventilation, hyperbilirubinemia**

- **Pre-transplant VAD may improve end-organ function and outcomes**

## Biventricular Failure

- RV failure frequent in pediatric LV dysfunction, especially CHD (e.g., TOF)
- BiVAD relatively low (~15%)
- RV dysfunction on LVAD may persist (up to 42%).
- Management: inotropes, temporary pacing, pulmonary vasodilators (NO, sildenafil)
- BH most common BiVAD; temporary RVAD if recovery anticipated

## Systemic RV

- Systemic RV (e.g., ccTGA): high HF risk (dilation/dysfunction)
- VAD implantation challenging: RV geometry, coarse trabeculations → septal injury risk
- TV displacement complicates cannulation
- 3D-CT aids surgical planning
- AV valve repair/replacement sometimes required
- Successful bridge-to-transplant reported in small series

## Single Ventricle

- Single-ventricle CHD: survival not significantly worse than biventricular disease
- Fontan patients on VAD show better outcomes than post-Norwood/Glenn
- Glenn physiology: dual venous return, collaterals, hypoxemia complicate MCS
- Pre-Glenn VAD: highest risk (37–46% mortality)
- Up to 80% adverse events, mainly major infection

- **Multidisciplinary** VAD management essential
- Careful **anticoagulation**: balance thrombosis vs bleeding; **bivalirudin ± antiplatelets** (pulsatile), heparin/DTI then **warfarin or oral DTI (continuous-flow**)
- Strict **infection prevention**, especially driveline
- Optimized **nutritional** support
- Strong **psychosocial support** for child and family

- **MCS in CHD improves** bridge-to-transplant candidacy, nutrition, rehabilitation, survival, and quality of life

- Requires **expertise, careful selection, early referral**; long-term support carries bleeding, infection, stroke, device risks

- **Growing CHD population drives innovation**

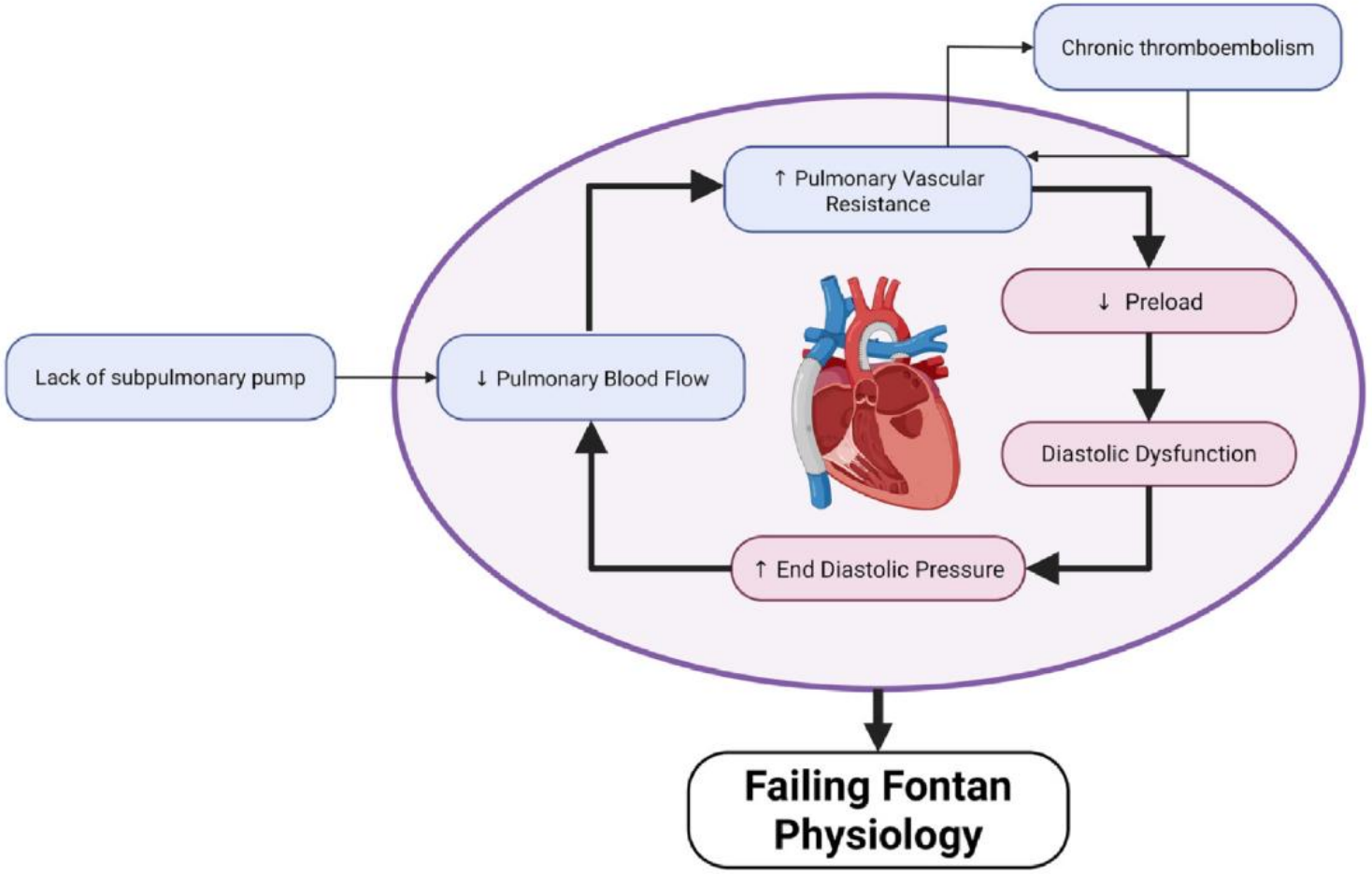
- **Durable VADs (e.g., HeartMate 3) may expand in pediatrics**, including destination therapy, despite HLA-related challenges

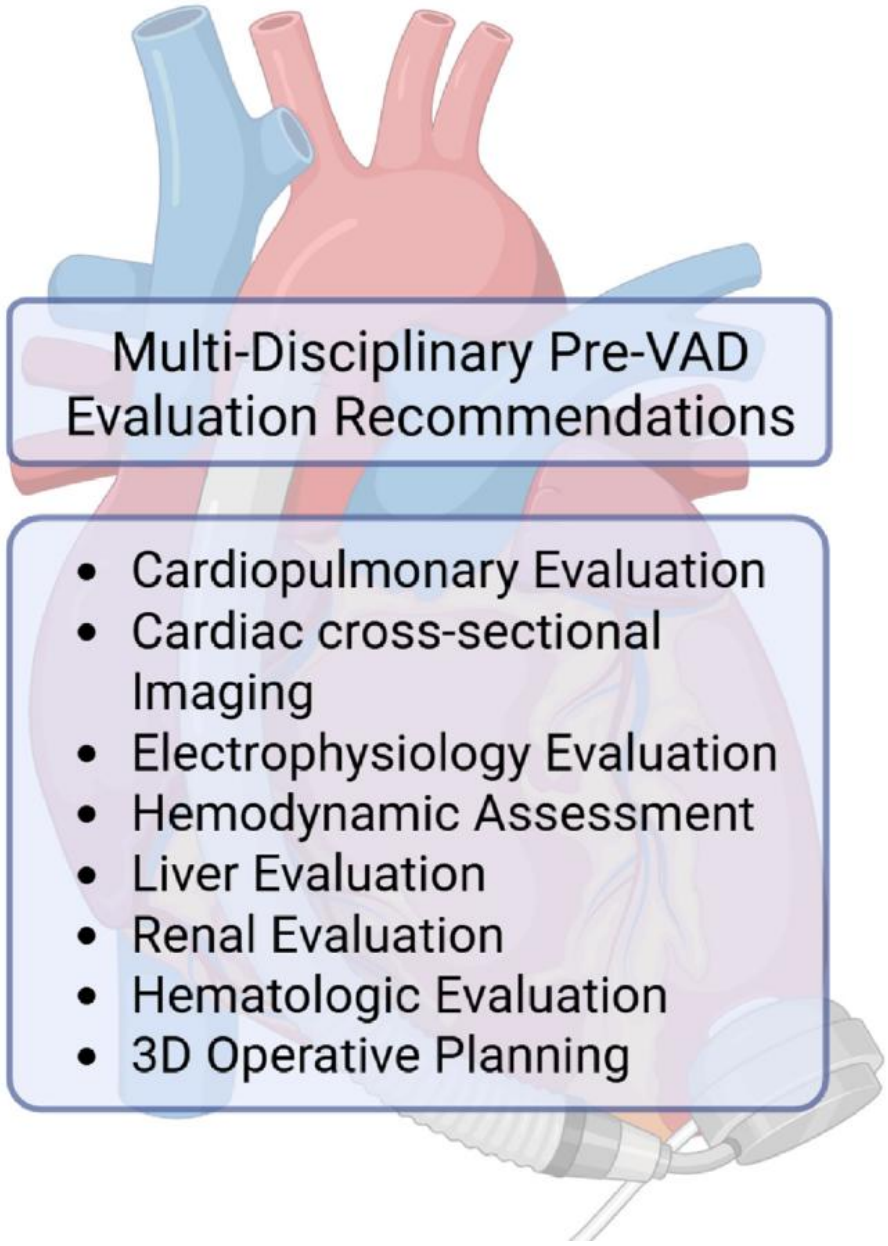
# The increasing utilization of ventricular assist devices in fontan failure

Darren Turner, MD,[*,1] Amir Mehdizadeh-Shrifi, MD Grant Chappell, BS and David L. Morales, MD

JHLT Open, Vol 9C, August 2025

- Fontan: **1971**; final stage of single-ventricle palliation; survival improved (94% at 10 years, 87% at 20 years)
- Growing population (**~70,000 worldwide)**
- **Long-term complications**: venous hypertension, systolic/diastolic dysfunction, LCOS
- Limited evidence for durable medical therapy; ~1/3 require transplant within 35 years
- Donor shortage increases **MCS/VAD use as bridge to transplant**






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

# Cardiopulmonary Workup

- Close significant **collaterals if** indicated; balance against benefits F. fenestration (supports VAD filling)
- Address **cavopulmonary obstruction, PVR, atrial connection obstruction** before VAD
- Consider arrhythmias, AV valve regurgitation, systemic RV in planning (worse outcomes)
- Many exhibit **restrictive lung disease**; perform PFTs (Pulm. Func. Test) for risk stratification
- **Plastic bronchitis**: optimize medically/bronchoscopically; may improve with VAD, unpredictably reversible
- **Hemodynamics crucia**l: differentiate systemic vs subpulmonary failure; mixed phenotypes common
- **High LVEDP/restrictive physiology** may limit benefit of isolated subpulmonary or systemic VAD; use **catheterization** a and cautious fluid challenge
- Optimize shock preoperatively: **temporary support** (Impella®, CentriMag®); ECPR → central ECMO ?
- **Consider atrial decompression**; Impella® for systemic unloading when feasible

# Liver Evaluation

- Fontan circulation predisposes to progressive **congestive hepatopathy and end-stage liver disease** (No standardized selection guidelines)
- Early disease often **silent**: monitor with CT, ultrasound, elastography; low threshold for biopsy (patchy fibrosis limits accuracy)
- MELD-XI aids assessment
- End-stage disease: consider combined **heart–liver transplant**, often bridged with **VAD**

# Renal Evaluation

- Fontan hemodynamics **reduce renal perfusion and GFR**
- **Preoperative renal dysfunction** predicts **worse VAD outcomes**
- Evaluate with GFR, creatinine, and cystatin-C (greater sensitivity in sarcopenia)
- Perform renal risk stratification
- VAD may be implanted despite renal impairment, aiming at **renal recovery,** though with increased risk

# Hematologic Evaluation

- Post-Fontan thromboembolism: 17–33%; risk factors include arrhythmias, high PVR, non-pulsatile flow
- Liver dysfunction and PLE alter coagulation profile
- Optimal anticoagulation debated; **rivaroxaban vs ASA** show similar safety
- **Individualized risk assessment** essential
- **Iron supplementation** important: cyanosis → high Hb/Hct but low iron stores, reduced exercise capacity

# Operative Modeling and Precautions

- **3D modeling and virtual planning** increasingly used in CHD to optimize VAD/TAH implantation (pump position, AV valves, great vessels); improves spatial understanding and size assessment, especially in children/young adults
- **Frailty** prevalent (~33%) and often underrecognized; driven by surgeries, exercise intolerance, PLE, social factors
- Frailty predicts adverse outcomes; consider **pre/post-VAD rehabilitation and counseling**

# Mechanical support bridge to transplant outcomes

**Table 1** Contemporary Characteristics at Time of Implant and Outcomes of Fontan VAD Support

| | Bedzra et al. (N=55) | Cedars et al. (N=45) | Chen at al. (N=106) |
|---|---|---|---|
| Age (median, IQR) | 10.2 [6.4–16.9] | 10 (4.5–18) | 10 [4.5–16.3] |
| Body surface area (m2) | 1.2 ± 0.5 | 1 ± 0.5 | 1.0 [0.6–1.6] |
| INTERMACS Profile at Implant | | | |
| 1 | 30% (16) | 25% (11) | 28% (30) |
| 2 | 62% (33) | 56% (24) | 58% (61) |
| 3 | 6% (3) | 5% (2) | 8% (8) |
| 4–7 | 2% (1) | 14% (6) | 7% (7) |
| Device Type | | | |
| Implantable, Continuous | 64% (35) | 73% (33) | 58% (61) |
| Paracorporeal, Continuous | 20% (11) | 18% (8) | 19% (20) |
| Paracorporeal Pulsatile | 13% (7) | 13% (6) | 18% (19) |
| Percutaneous | 2% (1) | 0% (0) | 5% (5) |
| TAH | 2% (1) | 0% (0) | 0% (0) |
| Device Strategy | | | |
| Bridge to Transplant, listed | 51% (28) | 76% (34) | 69% (73) |
| Bridge to Candidacy. | 35% (19) | 22% (10) | 26% (28) |
| Destination Therapy | 2% (1) | 0% (0) | 2% (2) |
| Bridge to Recovery | 4% (2) | 2% (1) | 2% (3) |
| Other | 9% (5) | 0% (0) | 0% (0) |
| Duration of Support (median, IQR) | 114 [18–207] | 42 [18–280] | 113 [43–266] |
| ECMO Before Implant | 29% (16) | 18% (8) | 26% (29) |
| Laboratory Values | | | |
| Albumin (mg/dL) | 3.5 ± 0.8 | 3.5 ± 0.6 | 3.5 [3.1–4] |
| Bilirubin (mg/dL) | 1.8 ± 1.1 | 2.1 ± 81.4 | 1.6 [0.9–2.8] |
| eGFR (mL/min/1.73m2) | 87.0 ± 44.9 | 99.4 ± 39.6 | 87 [58–108] |
| 12 Month Outcomes | | | |
| Transplant | 56% (31) | 70% (32) | 53% (56) |
| On Device | 16% (9) | 9% (4) | 27% (29) |
| Recovered | 6% (3) | 0% (0) | 2% (2) |
| Mortality | 22% (12) | 21% (9) | 18% (19) |

Values reported as % (N), Median [IQR], or Mean ± SD as available. ECMO: Extracorporeal membrane oxygenation, eGFR: Estimated Glomerular Filtration Rate.

**Table 2** CCHMC Fontan VAD Outcomes From 2017–2023

| CCHMC VAD Outcomes | n =12 |
|---|---|
| Mean age (years) | 22 |
| Female (n, %) | 3 (25%) |
| Race White (n,%) | 8 (67%) |
| Diagnosis | |
| HLHS | 8 (67%) |
| Tricuspid Atresia | 2 (17%) |
| DOLV | 1 (8%) |
| DILV | 1 (8%) |
| Weight at VAD (kg) | 70 (46–72) |
| VAD duration (days) | 109 (49–238) |
| Pre-VAD EDP (Median, IQR) | 15 (13–17) |
| Pre-VAD PVRi (Median, IQR) | 1.9 (1.3–2.8) |
| Pre-VAD Fontan pressure (Median, IQR) | 17 (15–19) |
| INTERMACS (Mean) | 2 |
| PLE (n, %) | 2 (17%) |
| PB (n, %) | 0 (0%) |
| Inotropes prevad (n, %) | 8 (67%) |
| Fontan Fenestration at time of VAD | 12 (100%) |
| VAD to transplant duration (days) | 251 (241–298) |
| Outcomes | |
| Neuro dys (n, %) | 2 (17%) |
| Hemorrhage (n, %) | 5 (42%) |
| AKI (n, %) | 2 (17%) |
| MV duration (Median, IQR) | 4 (1–8) |
| Driveline infection (n, %) | 3 (25%) |
| Transplantation | 8 (67%) |
| Bridge to candidacy | 2 (17%) |
| Mortality (n, %) | 2 (17%) |

# Outpatient surveillance and VADs as destination therapy

- Close collaboration outpatient + advanced HF cardiologists ↓**delayed referral** for VAD/transplant and mortality
- **Structured Fontan surveillance**: echo, catheterization, MRI, exercise testing; failure may be subclinical
- Referrals not symptom-driven alone
- VADs may serve **long-term** (>1–3 years, even >15 years) as **destination therapy**
- Multidisciplinary coordination essential for optimal outcomes

# EXCOR venous cannula and the Fontan pump

- "**Biventricula**r" (subpulmonary + subaortic) support in Fontan is **challenging** due to apical cannulation design of standard VAD circuits
- Berlin Heart **EXCOR®** Venous Cannula enables **subpulmonary support** by directing systemic venous return to pulmonary circulation
- First reported use (12-year-old) combined with subaortic support; 2-month rehabilitation before transplant listing
- Potential role: **pulmonary "reconditioning" to pulsatile flow pre-transplant**
- **Novel dedicated cavopulmonary pump (Rodefeld):** low-pressure, high-volume augmentation; may prevent long-term Fontan failure; ongoing development

# Conclusions

- Fontan population growing; chronic Fontan complications increasingly lead to transplantation
- VAD as bridge-to-transplant shows **promising outcomes**
- Major need: **earlier HF detection and optimized pre-implant evaluation** to improve device/transplant results
- Future studies should stratify VAD outcomes by device type and support strategy, tailoring therapy to failure phenotype
- Potential role for **chronic right-sided/subpulmonary support**
- **Next-generation total artificial heart** could address both subpulmonary and systemic ventricular failure

## *Systemic VAD Support in Fontan Patients (ACTION Registry)*

Chen S., Simpson KE et al. ASAIO Journal 2025;71:588–595

- **Retrospective ACTION registry analysis** (2012–2022)
- **106** Fontan patients with systemic VAD support (median age 10 yrs; 20% adults)
- **High acuity at implant**: 58% ≥2 inotropes, 26% ECMO, 41% intubated
- Median VAD support duration: 113 days (IQR 43–266)
- 12-month outcomes: 53% transplanted, 27% ☮ alive on device, 2% recovered, **18% died**
- **Adverse events in 75%:** mainly bleeding, infection, neurologic complications
- Conclusion: VAD support in failing Fontan circulation can **effectively bridge** many patients to transplant or ongoing survival

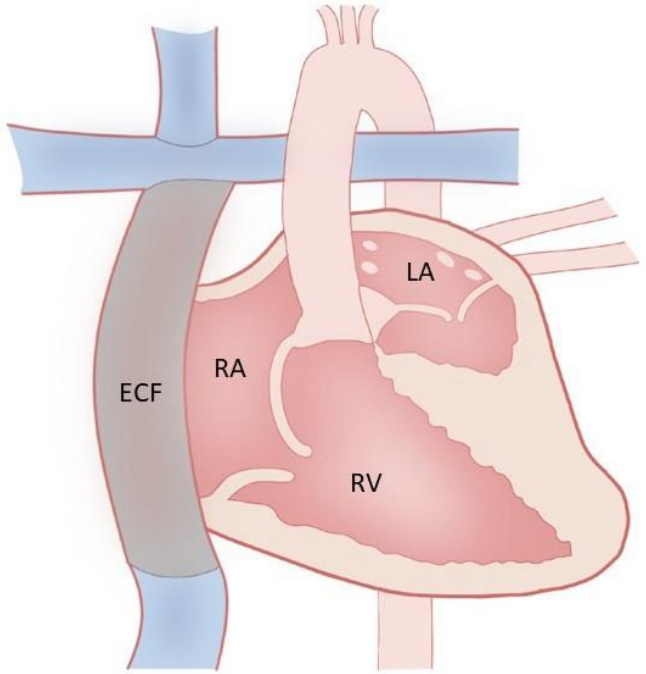
Journal of
*Clinical Medicine*

*Review*

# Contemporary Management of the Failing Fontan

*J. Clin. Med.* **2024**, *13*, 3049

**Prashanth Venkatesh [1], Hans Gao [1], Islam Abudayyeh [2], Ramdas G. Pai [3] and Padmini Varadarajan [3,*]**




## Causes of Fontan Circulatory failure

Systolic dysfunction

Diastolic dysfunction

Anatomic obstruction

Lymphatic insufficiency/protein-losing enteropathy/plastic bronchitis

Arrhythmia

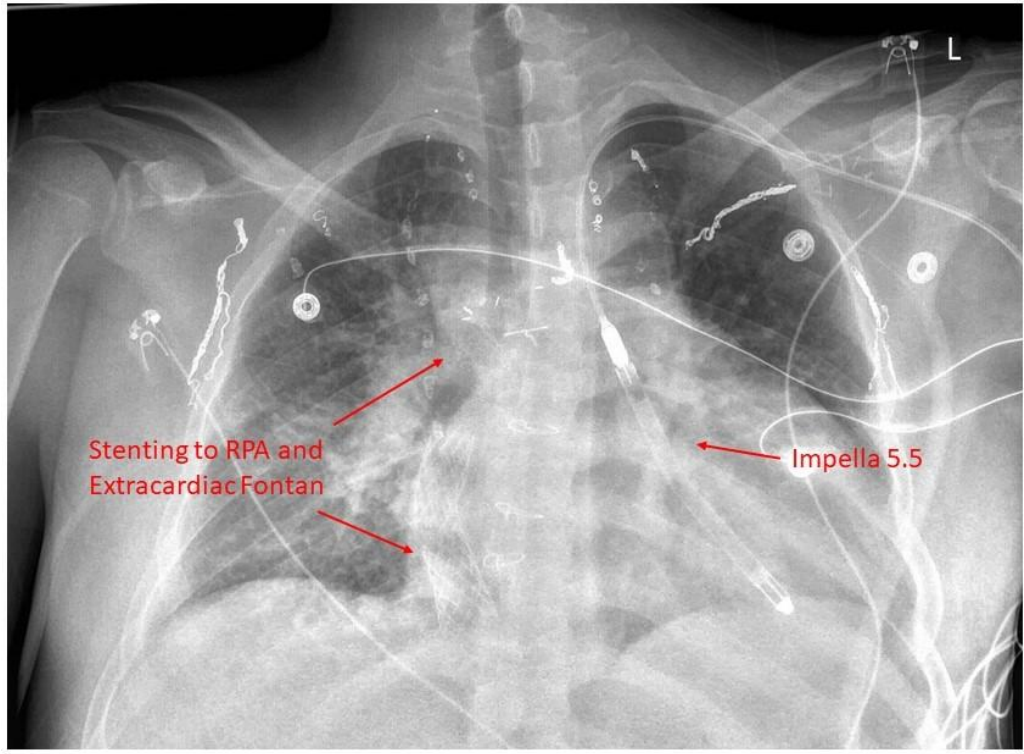
Atrio-ventricular valve regurgitation

سدرة للطب
Sidra Medicine

**19. Mechanical Circulatory Support**

With adults with CHD outnumbering children with CHD, the number of patients with Fontan failure is growing. The need for heart transplantation is also increasing, while organ supply is increasingly short, with long wait times on the transplant list driving the need for durable mechanical circulatory support (MCS) (Figure 2). The use of MCS will not address the underlying cause of Fontan failure. Usually, MCS is beneficial for patients with systolic ventricular dysfunction rather than other phenotypes of Fontan failure [63]. MCS is gaining momentum in the failing Fontan patients [64,65]; however, outcomes are worse compared to those with heart failure with biventricular circulation [66–68]. The use of MCS is fraught with many challenges, even though the field is evolving and improving. A history of multiple cardiac surgeries in childhood leads to challenging redo sternotomy

and dissection. The orientation of the single ventricle may make the positioning of cannulas challenging [68]. Similarly, the single ventricle may have dense trabeculations, making the placement of inflow cannulas difficult and requiring extensive trabeculectomy [63]. Nandi et al., in their paper, have discussed the use of novel approaches such as atrial cannulation and excision of the atrioventricular (AV) valve to enable device placement in smaller patients [69]. Villa et al. were the first to report the use of MCS as a bridge to combined heart and liver transplantation (CHLT) in a 22-year-old man with Fontan circulatory failure [70]. Since the first report, about 400 patients have undergone placement of a ventricular assist device (VAD), with about 40 ending up with CHLT [71]. Similarly, there are a few case reports on the use of the Syncardia total artificial heart and single subpulmonary VAD in Fontan circulatory failure but without wide acceptance [72,73]. There are also reports of using temporary VAD along with Impella support in a limited number of Fontan patients, both adult and pediatric, with cardiogenic shock. [74,75]. This use of MCS may be beneficial as a bridge to recovery or used for longer term support.




- Peu de donneurs
- Hétérogénéité des patients « Failing Fontan »
- Challenge chirurgicale
- Multidisciplinarité (Cœur-Foie)
- Approche intégré chirurgie-cardiologie interventionnelle
- Congénitalistes avec compétences sur l’adulte

# 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

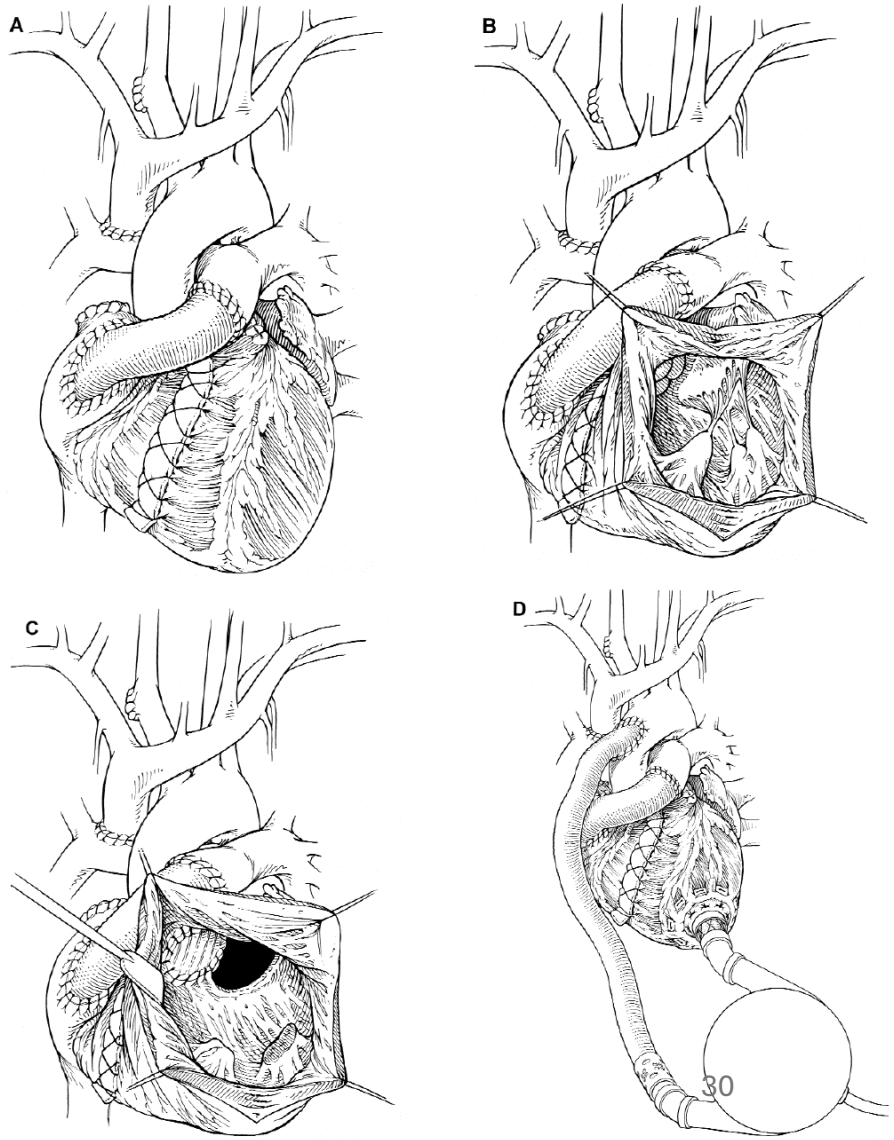
*(Tex Heart Inst J 2005;32:402-4)*

*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
- Insuffisance ventriculaire pure
- 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 ventricle systemique à fonction systolique conservée

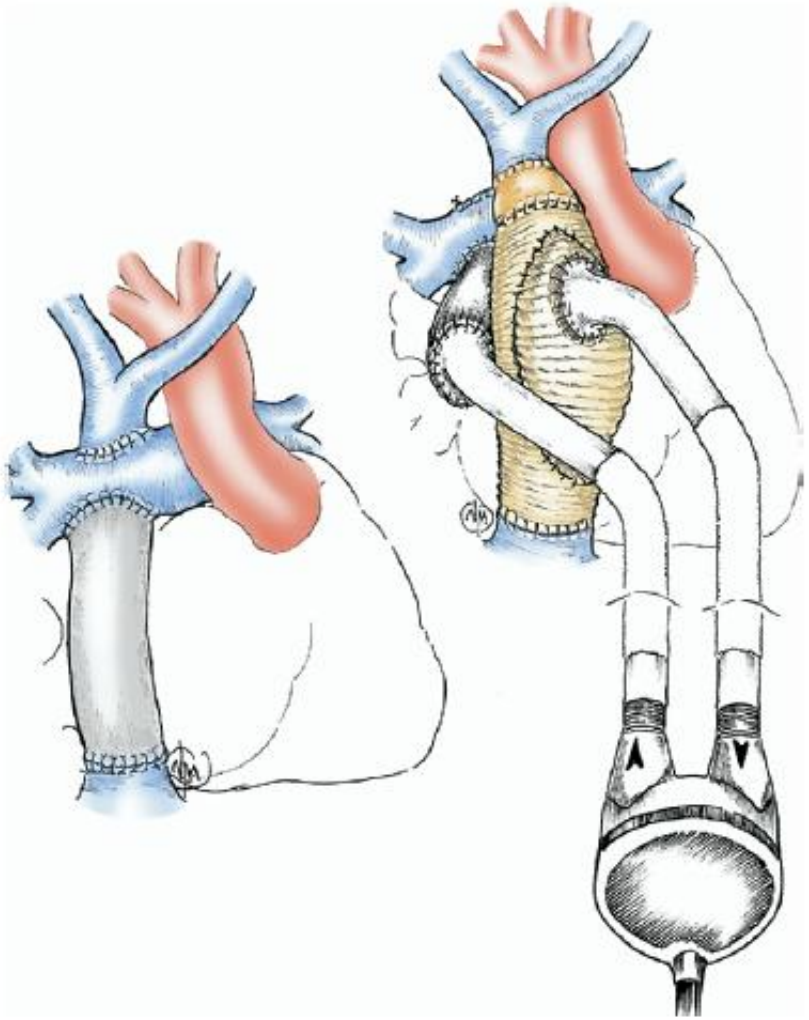
## Right-Sided Univentricular Cardiac Assistance in a Failing Fontan Circulation

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.

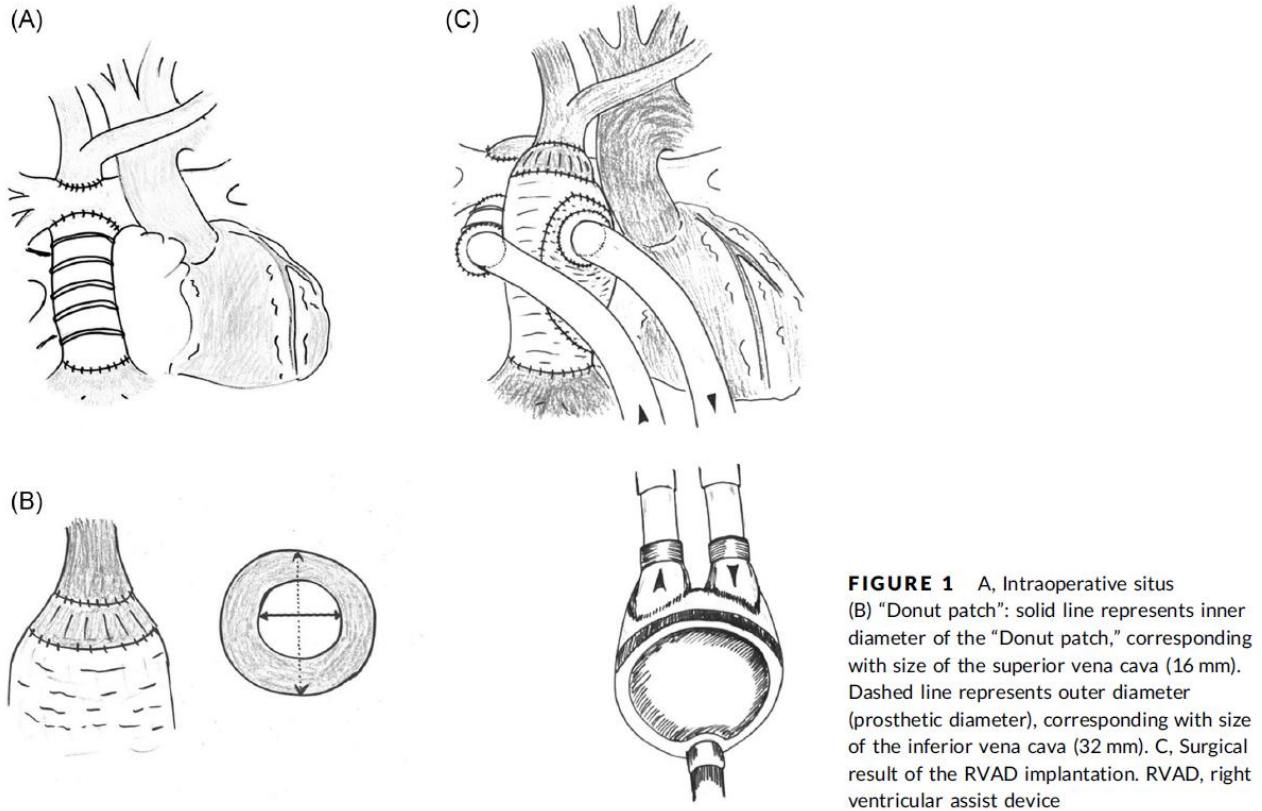
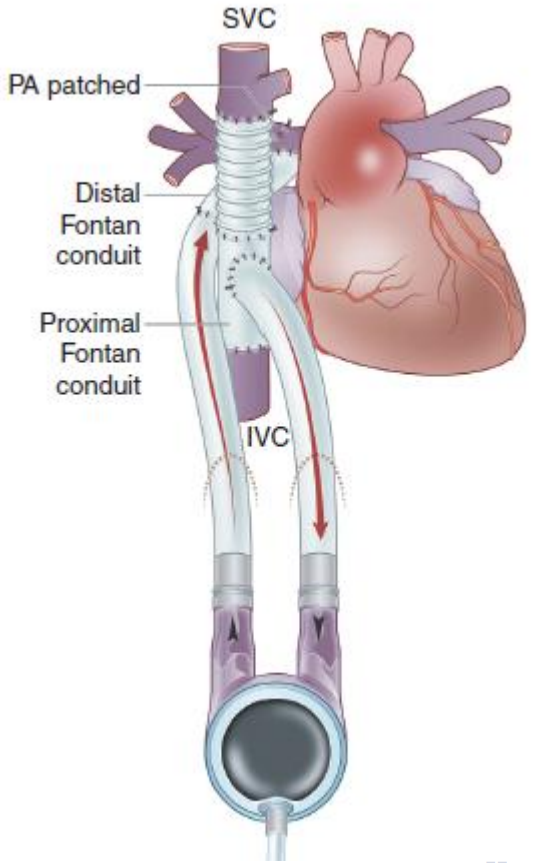



**FIGURE 1** A, Intraoperative situs (B) "Donut patch": solid line represents inner diameter of the "Donut patch," corresponding with size of the superior vena cava (16 mm). Dashed line represents outer diameter (prosthetic diameter), corresponding with size of the inferior vena cava (32 mm). C, Surgical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

# Et si Failing Fontan précoce ?

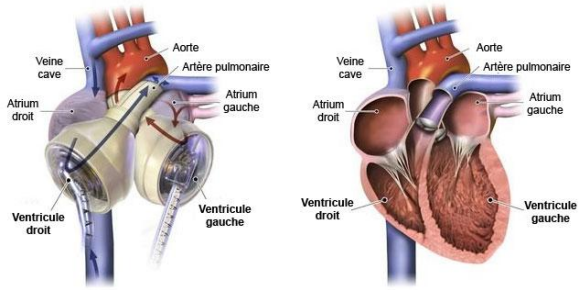
lowering of pulmonary resistance. The is exemplified by our recent Fontan patient with normal systolic function of the single ventricle and severe plastic bronchitis and protein-losing enteropathy. This 5-year-old girl could not be weaned off ventilatory support and deteriorated rapidly, requiring urgent 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] JTCVS Techniques • June 2022

# Vue d'ensemble



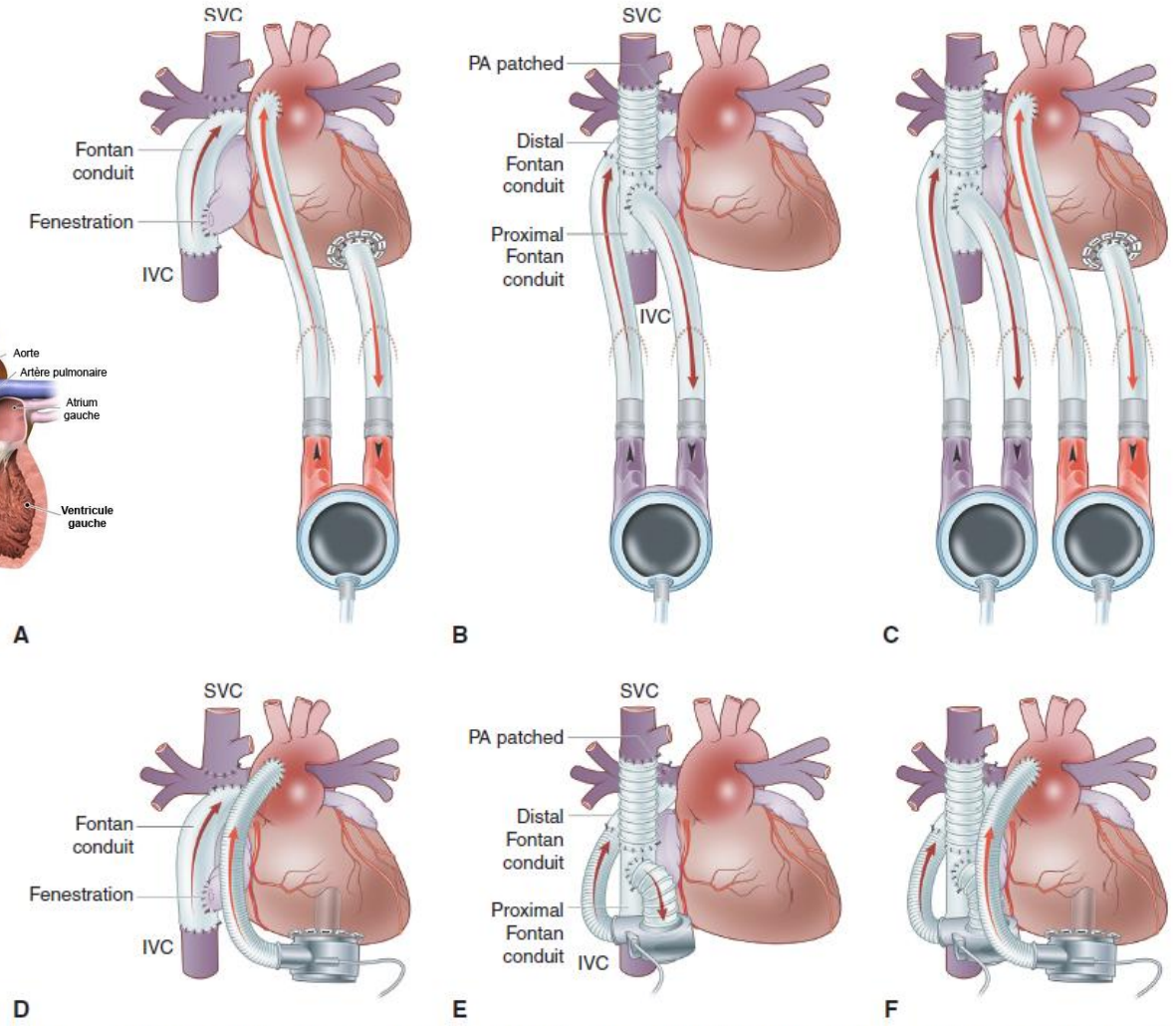
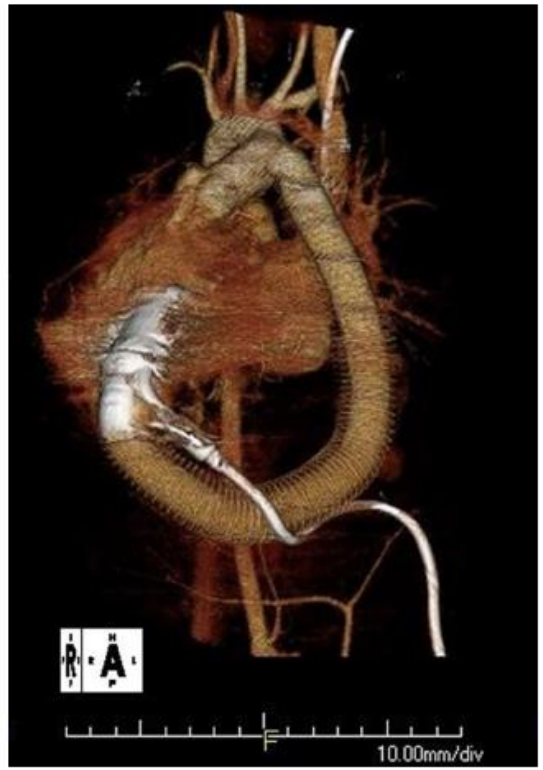




**FIGURE 2.** Durable VAD support in patients with Fontan circulation. Pulsatile VAD is used to support systemic (A) or pulmonary (B) circulation or both (C) in smaller children, whereas continuous flow VAD is used to support systemic (D) or pulmonary (E) circulation or both (F) in older children and 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] JTCVS Techniques • June 2022

سدرة للطب
Sidra Medicine

*Review*

# Local Infections Associated with Ventricular Assist Devices: Materials-Related Challenges and Emerging Solutions

Klaudia Cholewa [1,2,*], Przemysław Kurtyka [2], Agnieszka Szuber-Dynia [1,2], Artur Kapis [2] and Maciej Gawlikowski [1,2]

*Materials* 2025, *18*, 4541

- **Review**, synthesis available data, key shortcomings of current materials

- Need for **next-generation biomaterials**:
    - Enhanced biocompatibility
    - Resistance to microbial
    - Adhesion, and intrinsic/functionalized antimicrobial activity

- **Advances** essential to **improve the long-term safety and clinical outcomes** of MCS pts

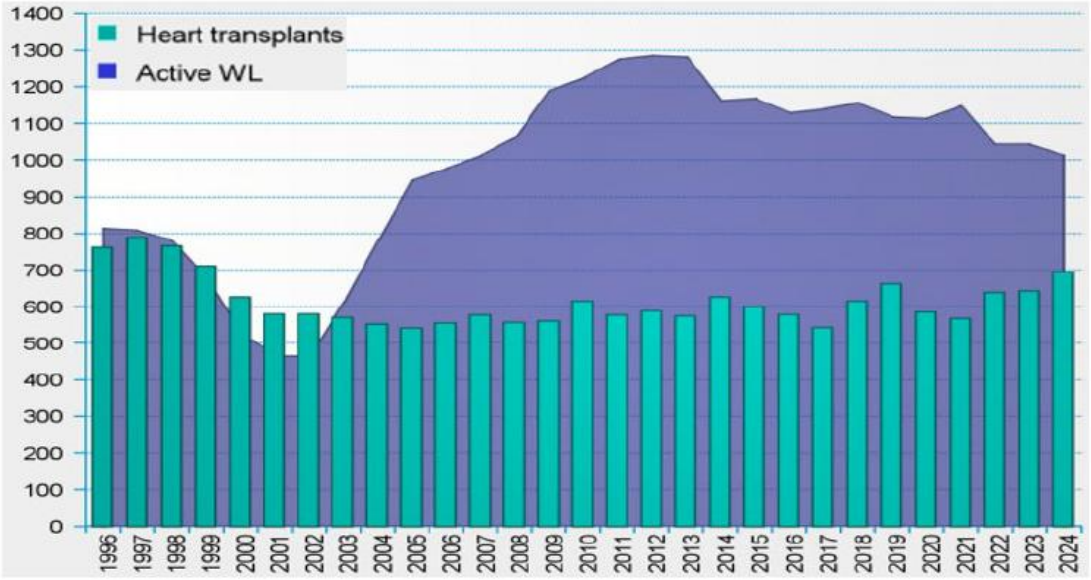



**Figure 1.** Number of heart transplants vs. active waiting list in the Eurotransplant (1996–2024) [1].

Persistent mismatch between transplant demand and donor availability

Progress in pharmacotherapy + advanced MCS technologies→ lower mortality patients with AHF

- **First-generation** MCS are **extracorporeal pulsatile pumps using pneumatic or electric** actuation with a membrane-driven chamber, partially mimicking native cardiac output and requiring external controllers and hospitalization

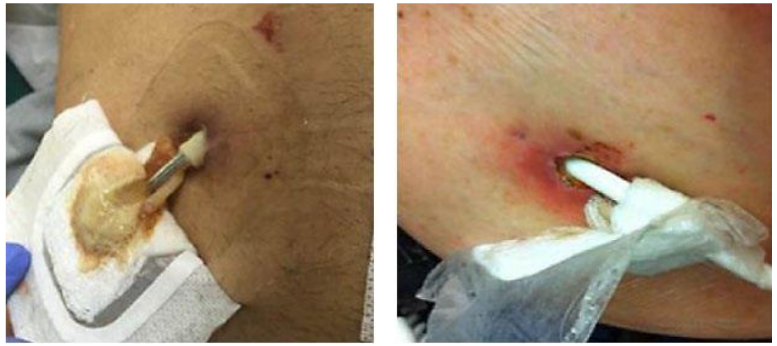
- **Second-generation** VADs are **implantable axial-flow continuous pumps** with mechanical bearings, smaller size, improved ventricular unloading, and suitability for long-term therapy

- **Third-generation** VADs use **magnetic or hydrodynamic levitation**, eliminating mechanical contact, reducing shear stress, hemolysis, thrombosis, and improving durability and long-term outcomes

- **Complications and incidence**: Despite the clinical benefits of MCS, major complications persist, including right ventricular failure, bleeding, and percutaneous site infections (18–59%), with risk increasing over time. Driveline and cannula infections are the most frequent device-related infections and remain a major unresolved challenge

- **2024 classifications and clinical features JHLT**: A revised system distinguishes uncomplicated from complicated infections. Complicated cases involve bacteremia, resistant or fungal pathogens, abscesses, fluid collections, or imaging-confirmed tunnel involvement

- **Clinical impact and perspectives**: Infections may progress to sepsis, endocarditis, stroke, and death. Current preventive strategies are insufficient; this review focuses on material-based antimicrobial approaches for durable skin–device interface protection



# Materials for exit sites

- First-generation MCS cannulas are polymeric blood-contact conduits (6–12 mm diameter)

- VAD drivelines consist of a Teflon–polyurethane core within a silicone (PDMS) sheath; a Dacron (PET) velour cuff promotes dermal ingrowth and biological sealing.Velour enhances tissue integration but increases bacterial adhesion; **exposed segments are associated with higher infection rates (>20%)**

- Subcutaneous **tunneling creating a silicone–skin interface** reduces infections (~1.7%) but provides weaker mechanical anchorage

- Extracorporeal systems face greater micromotion and mechanical stress at exit sites

- Current materials lack intrinsic antibacterial properties, favoring biofilm formation; **durable antimicrobial surface modifications remain essential**

## Epidemiology of Local VAD Infections

- **Mechanism**: irritation, trauma, compromission of skin barrier, promotion bacterial invasion
- Duration of VAD support is the main risk factor, with peak incidence between **3–6 months**
- **Comorbidities (**high BMI, diabetes, kidney disease, autoimmune disorders) increased risk
- **Younger age**, because longer duration
- Poor hygiene, substance abuse, and limited caregiver support raise infection rates
- Evidence is mainly retrospective and heterogeneous

## Etiology of Local Infections

- **Gram +**, particularly ***Staph Aureus*** and ***Staph Epidermidis***, most common causative organisms
- Their ability to form **biofilms** increases virulence, impairs antibiotic penetration, and facilitates bloodstream infection, even without overt antimicrobial resistance
- **MRSA** and **MSSA** strains are prevalent, with MRSA further complicating treatment
- Others ***Enterococcus* spp.**, ***Escherichia coli***, environmental Gram-negative bacteria such as ***Pseudomonas aeruginosa*** (more frequent in late infections), and fungal organisms, with **fungemia** associated with very high mortality (70-90%)
- Persistence of genetically identical strains at the exit site over months to years indicates **long-term colonization** and recurrent infection rather than isolated acute episodes

## Biofilm Formation at Transcutaneous Exit Sites

- **Biofilm formation** at transcutaneous exit sites results from bacterial adhesion to cuff materials, favored by **prolonged implantation, advanced age, diabetes, and immunosuppression**
- Fibrin **deposits**, wound exudate, moisture, minor trauma, and driveline micromotion impair tissue integrity and promote microbial persistence
- **Cuff physicochemical properties** (porosity, roughness, hydrophobicity, surface energy) determine **attachment strength**
- **Biofilm limits antimicrobial penetration** facilitates extension along subcutaneous tunnels, and promotes deep infection; **surface modification** may reduce adhesion and delay biofilm development

## Diagnostic approaches

- **Uncomplicated infection**: negative blood cultures, no systemic signs, no abscess on imaging, local erythema or pain, and response to antibiotics
- **Blood and exit-site cultures identify pathogens**
- Ultrasound detects superficial collections; CT assesses depth ; **(PET?)**
- **Differentiating colonization from deep infection remains challenging**
- **Clinic first**
- **How to monitor colonization?**
- **Cleaning solution with antibiotic?**

- Exit-site infections require a **multidisciplinary approach**. Uncomplicated cases are treated with oral or IV antibiotics for several weeks; ISHLT recommends 2–4 weeks of oral or IV antibiotics for superficial infections; **complicated** infections require **6–8 weeks of IV therapy**, often with surgical intervention or device exchange
- For **Staphylococcus aureus**, treatment depends on depth and susceptibility: MSSA (cephalosporins, nafcillin, cefazolin), MRSA (vancomycin, doxycycline, linezolid). Rifampin may be added in biofilm-associated infections
- Advanced or resistant infections frequently necessitate **surgical debridement and driveline relocation**, increasing procedural risk
- Overall management remains suboptimal due to antimicrobial resistance and morbidity associated with repeated surgical interventions

Double antibiotic, and, if possible, TDM of antibiotics through measurement of plasma (or serum) concentrations

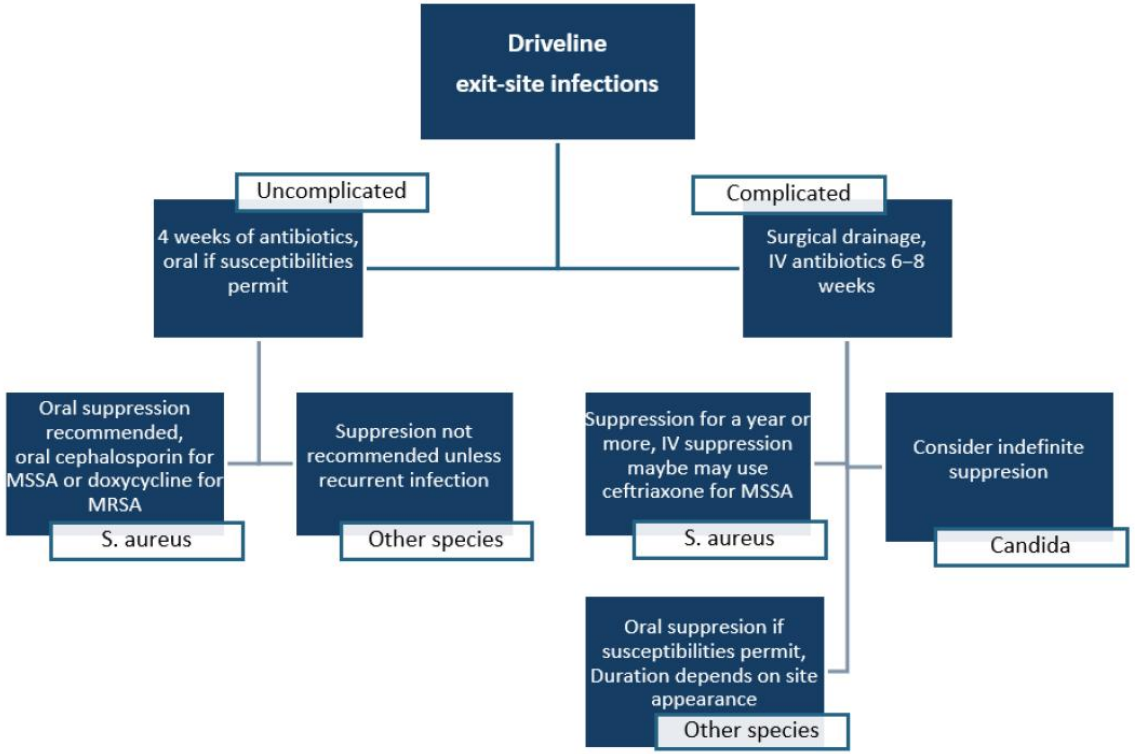
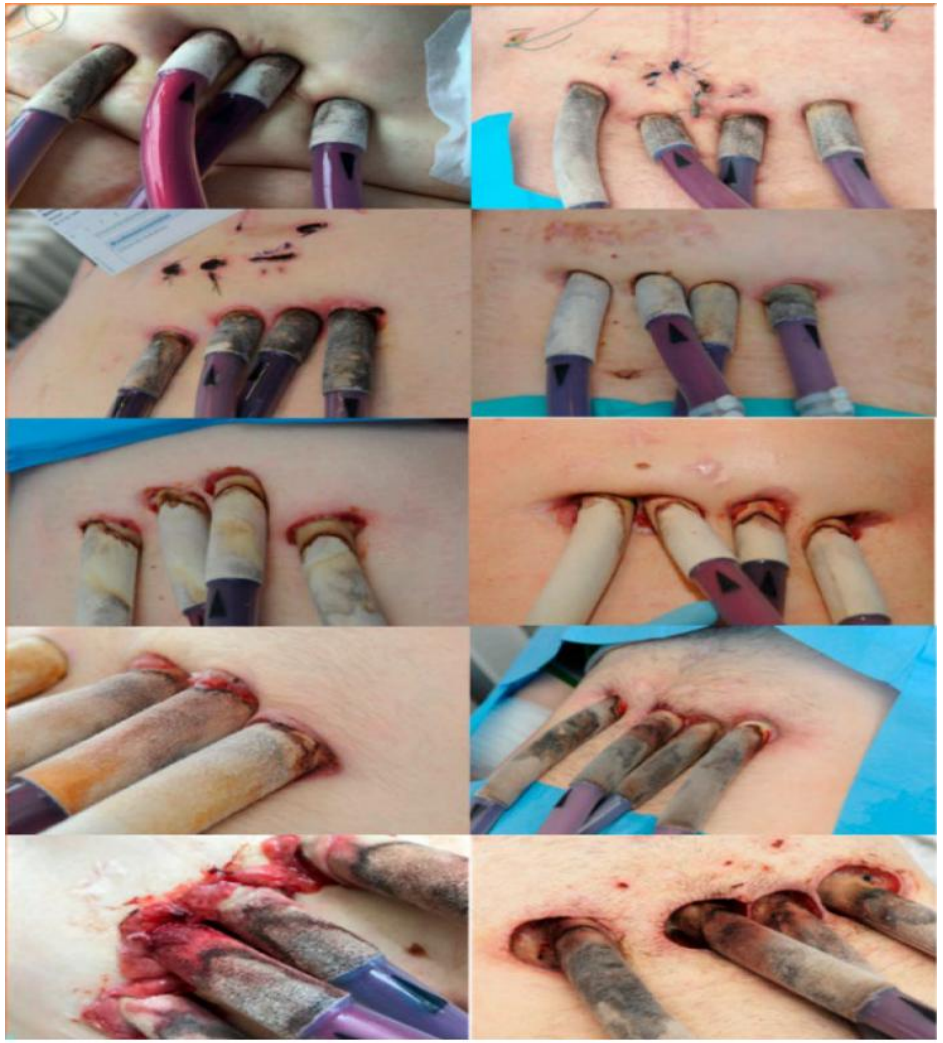



**Figure 4.** Management algorithm for percutaneous exit-site infections based on literature data [11].



# Innovative Solutions and Future Directions

| Material / Strategy | Mechanism of Action | Main Advantages | Key Limitations |
|---|---|---|---|
| **Zinc oxide (ZnO)** | $Zn^{2+}$ ions and ROS damage bacterial membranes and cellular components | Active vs Gram+ / Gram− and fungi; cost-effective | Efficacy depends on coating properties; long-term durability uncertain |
| **Silver (Ag)** | $Ag^{+}$ disrupts membranes, proteins, and DNA | Broad-spectrum; widely used in biomaterials | Cytotoxicity concerns; reduced ion release over time; coating instability |
| **Copper (Cu)** | $Cu^{2+}$ damages membranes and enzymes; rapid bacterial inactivation | Effective against resistant strains; cost-effective | Coating stability issues; potential cytotoxicity |
| **Titanium dioxide ($TiO_2$)** | Light-activated ROS production inhibits growth and biofilm | Biocompatible; stable; durable coatings | Nanoparticle inhalation safety concerns |
| **Antibiotic-eluting coatings** | Local antibiotic diffusion inhibits adhesion and early biofilm | Targeted effect; reduced systemic exposure; adaptable to pathogens | Short release duration; resistance risk; coating stability under stress uncertain |
| **Smart dressings** | Triggered antibiotic/peptide release (pH, enzymes, moisture) | On-demand delivery; reduced systemic therapy; monitoring potential | Limited long-term evidence; mechanical and release reproducibility challenges |
| **Antibacterial peptides** | Membrane disruption or intracellular interference | Low resistance risk; dual strategies (immobilized or release systems) | Activity limited to contact zones; stability issues |

## Shared Challenges in Other Clinical Applications

- Percutaneous device-related infections also **affect peritoneal dialysis catheters, tunneled central venous catheters, and nephrostomy tubes**
- Exit sites remain **persistent entry points** for microbial colonization and biofilm formation
- **Consequences** include peritonitis, recurrent infections, urosepsis, device removal, prolonged antibiotics, and rehospitalization
- Significant psychological and economic burden
- **Preventive advances** in MCS may have cross-disciplinary translational impact

## Economic Considerations

- Driveline infections increase rehospitalization, prolong hospital stay, and reduce quality of life
- Average hospitalization costs are substantial (£7662 UK; ~$13,600 US), varying by healthcare system
- Severity, surgery, and antibiotic resistance further raise expenses
- Current estimates underestimate total costs, often excluding prolonged therapy and staff resource utilization

سدرة للطب
Sidra Medicine

- Percutaneous exit-site infections remain **a major barrier to long-term** MCS success, contributing to significant morbidity and mortality
- Current preventive measures **reduce but do not eliminate** infection risk due to the permanent skin breach
- **Material-based strategies** (nanoparticles, antibiotic coatings, antimicrobial peptides, surface functionalization) show promise but face limitations in **durability, resistance, cytotoxicity, and clinical validation**
- No approach yet ensures sustained **antimicrobial efficacy, mechanical stability, and biocompatibility**
- **Multifunctional biomaterials and fully implantable** systems represent future directions
- Further in vitro and preclinical in vivo research is necessary for clinical translation

# Experience with Berlin heart support in children with a focus on device removal

JTCVS Open 2025;28:479-94

Valerii Iaprintsev, MD,[a,b,c] Igor E. Konstantinov, MD, PhD, FRACS,[a,b,c,d] Edward Buratto, MD, PhD, FRACS,[a,b,c] Tyson A. Fricke, MBBS, PhD, FRACS,[a,b,c] Lucas Eastaugh, MBBS, FRACP,[b,c,d,e] Christian P. Brizard, MD, MS,[a,b,c] Stephanie Perrier, MD,[a,b,c] and Jacob Mathew, MBBS, FRACP[b,c,d,e]

**- 4 sur 64 pts - LVAD EXCOR - Retrospetive**

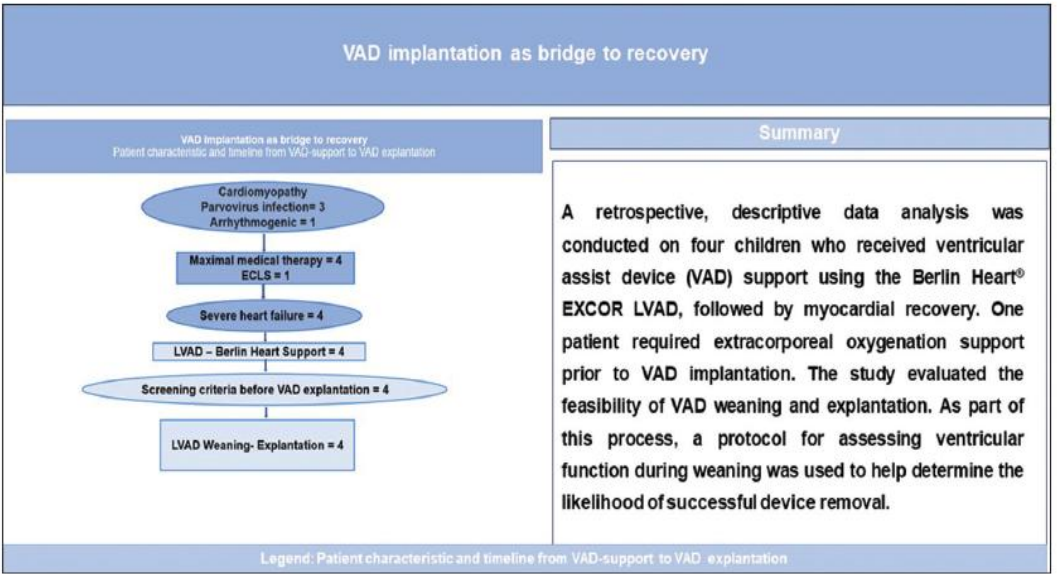



**Table 1: Characteristics of patients with severe cardiac failure at time to ventricular assist device implantation**

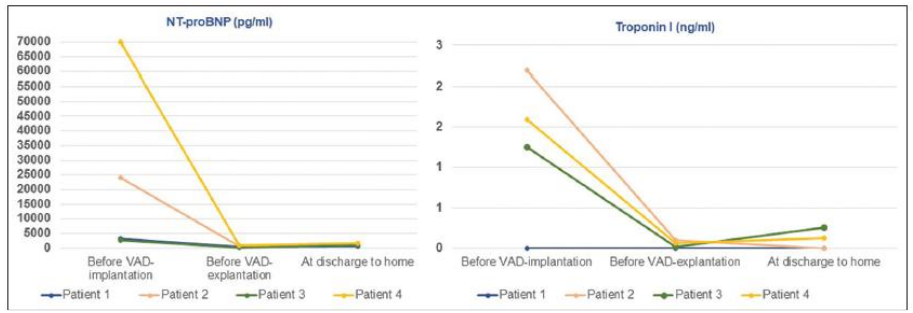
| | Age (months) | Sex | Weight (kg) | BSA (m²) | Diagnosis | Pre-VAD-ECLS |
|---|---|---|---|---|---|---|
| Patient 1 | 14 | Female | 8 | 0.4 | Myocarditis-parvovirus infection-DCM | - |
| Patient 2 | 19 | Female | 8 | 0.4 | Myocarditis-parvovirus infection-DCM | - |
| Patient 3 | 50 | Female | 20 | 0.5 | Arrhythmogenic cardiomyopathy | ECLS |
| Patient 4 | 5 | Male | 7 | 0.2 | Myocarditis-parvovirus infection-DCM | - |

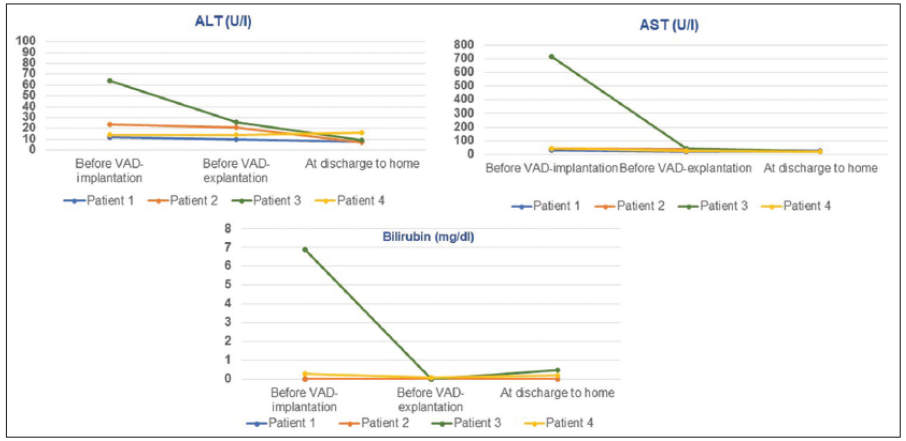
BSA: Body surface area, ECLS: Extra cardiac life support, DCM: Dilatative cardiomyopathy, VAD: Ventricular assist device

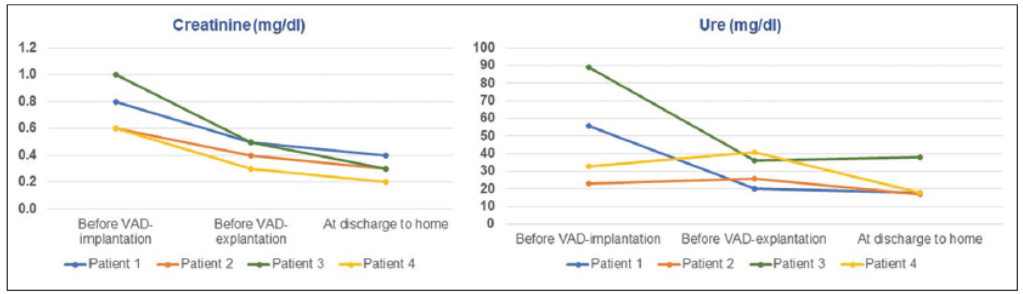
**Table 2: Status of patients postventricular assist device implantation, before ventricular assist device explantation**

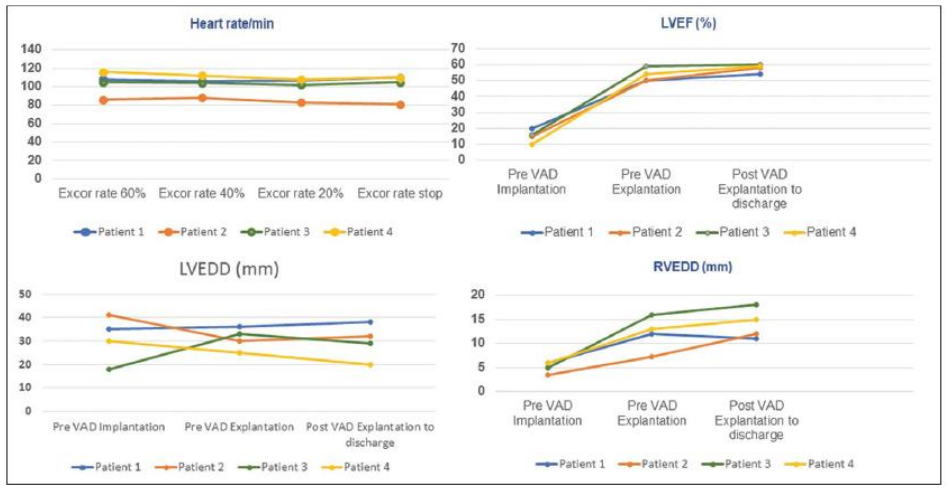
| | VAD period (days) | Cardiac | Renal | Liver | Neurological status |
|---|---|---|---|---|---|
| Patient 1 | 484 | Recovered | Recovered | Recovered | Subarachnoid bleeding right with no residual symptoms |
| Patient 2 | 423 | Recovered | Recovered | Recovered | Stroke left with no residual symptoms |
| Patient 3 | 111 | Recovered | Recovered | Recovered | Left hemispheric bleeding and left-sided stroke with mild to moderate residual |
| Patient 4 | 113 | Recovered | Recovered | Recovered | Left-sided stroke with severe hemiparesis |

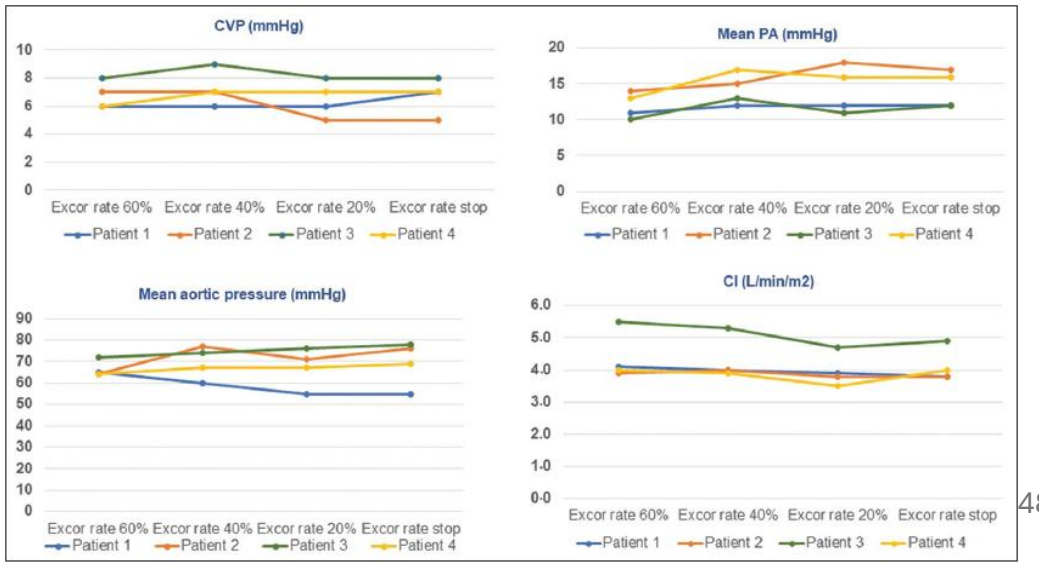
VAD: Ventricular assist device


NT-proBNP (pg/ml)
Troponin I (ng/ml)
Before VAD-implantation
Before VAD-explantation
At discharge to home
Patient 1
Patient 2
Patient 3
Patient 4


ALT (U/l)
AST (U/l)
Bilirubin (mg/dl)
Before VAD-implantation
Before VAD-explantation
At discharge to home
Patient 1
Patient 2
Patient 3
Patient 4


Creatinine (mg/dl)
Ure (mg/dl)
Before VAD-implantation
Before VAD-explantation
At discharge to home
Patient 1
Patient 2
Patient 3
Patient 4


Heart rate/min
LVEF (%)
LVEDD (mm)
RVEDD (mm)
Excor rate 60%
Excor rate 40%
Excor rate 20%
Excor rate stop
Pre VAD Implantation
Pre VAD Explantation
Post VAD Explantation to discharge
Patient 1
Patient 2
Patient 3
Patient 4


CVP (mmHg)
Mean PA (mmHg)
Mean aortic pressure (mmHg)
CI (L/min/m2)
Excor rate 60%
Excor rate 40%
Excor rate 20%
Excor rate stop
Patient 1
Patient 2
Patient 3
Patient 4

- **Long-term oral medical therapy** is often **insufficient** in pediatric end-stage HF; VADs serve as bridge to transplantation, though myocardial recovery remains incompletely understood
- **Myocardial recovery** with successful VAD explantation occurred in **6.3%**; myocarditis showed higher likelihood of recovery than DCM
- **Reversible PAB** may facilitate VAD weaning in selected patients
- Retrospective, single-center design and small sample size limit generalizability

- ✓ Myocardial recovery during VAD support is achievable in selected pediatric patients with **severe myocarditis and cardiomyopathy**
- ✓ **Mechanical unloading** combined with **optimized pharmacological therapy** promotes cardiac recovery and improves systemic organ function
- ✓ VADs may serve not only as bridge to transplantation but **also as bridge to recovery**
- ✓ Larger multicenter studies are needed to optimize selection, refine weaning protocols, and improve long-term outcomes

سدرة للطب
Sidra Medicine

# Efficacy of Impella Microaxial Left Ventricular Assist Device as Bridge to Transplant in Children With End-Stage Heart Disease

Bahaaldin Alsoufi[*,1]; Deborah Kozik[1]; Bradley Oelkers[1]; Sarah Wilkens[2]; Joshua Sparks[2]; Jaimin Trivedi[1]

Interdisciplinary CardioVascular and Thoracic Surgery, 2025, Volume 40, Issue 10

- The **Impella microaxial left ventricular assist device** is increasingly used in pediatric patients listed for **heart transplantation**
- Its role includes **temporary circulatory support** or **bridge to durable VAD** therapy
- However, data regarding **utilization trends and outcomes in children** remain limited
- This study aimed to **evaluate national trends in Impella use and post-transplant outcomes** in pediatric transplant candidates

- **Retrospective analysis of a large national database** including pediatric patients listed for **heart transplantation**
- Evaluation of **Impella use as mechanical circulatory support** during the pre-transplant period
- Devices assessed primarily included **Impella microaxial left ventricular assist systems**, particularly **Impella 5.5**
- Outcomes analyzed included **patterns of device utilization and post-transplant survival**

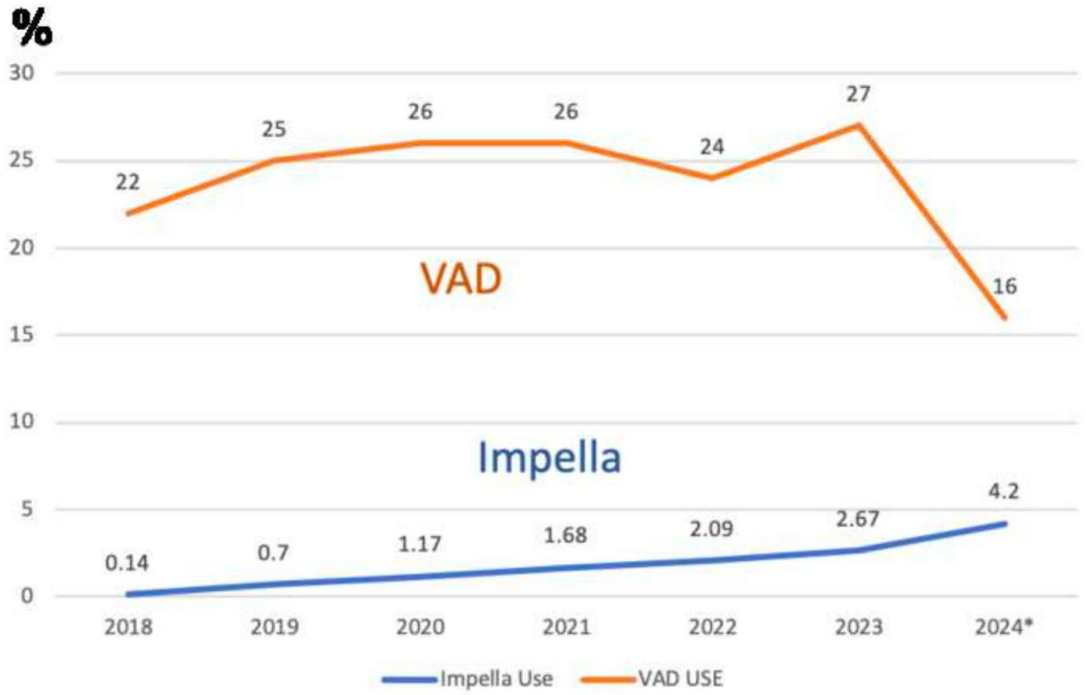
**Table 1.** Comparison of Characteristics of Children Who Received Impella Support (Alone or towards Another VAD), Those Who Received Other VAD Support and Those Who Did Not Receive VAD Support before or While Listed for HT

| | Impella (*n* = 54) | VAD alone (*n* = 942) | No device (*n* = 2045) | *P*-value |
|---|---|---|---|---|
| Transplant age (years) | 15 (13-16) | 6 (1-13) | 5 (0-13) | <.01 |
| Gender (male) | 41 (74%) | 518 (55%) | 1145 (56%) | <.01 |
| BMI | 25 (20-29) | 17 (16-21) | 17 (7-44) | <.01 |
| Weight | 69 (50-81) | 21 (9-50) | 17 (7-44) | <.01 |
| Race | | | | |
| Black | 19 (40%) | 217 (23%) | 368 (18%) | <.01 |
| White | 27 (40%) | 443 (47%) | 1207 (59%) | |
| Other | 8 (19%) | (280) 29% | 470 (23%) | |
| CHD | 7 (12%) | 217 (23%) | 920 (45%) | <.01 |
| Blood group | | | | |
| A | 15 (28%) | 311 (33%) | 798 (39%) | <.01 |
| B | 5 (9%) | 122 (13%) | 266 (13%) | |
| AB | 1 (2%) | 38 (4%) | 61 (3%) | |
| O | 33 (61%) | 481 (51%) | 900 (44%) | |
| Creatinine (mg/dL) | 0.7 (0.6-0.9) | 0.6 (0.5-0.8) | 0.7 (0.6-1.0) | <.01 |
| Bilirubin (mg/dL) | 0.7 (0.6-1.2) | 0.6 (0.4-0.9) | 0.8 (0.5-1.3) | <.01 |
| Inotropes | 27 (56%) | 254 (27%) | 920 (45%) | <.01 |
| Listing stat 1 A | 50 (93%) | 952 (99%) | 1189 (58%) | <.01 |
| Mechanical ventilation | 3 (7%) | 94 (10%) | 348 (17%) | <.01 |

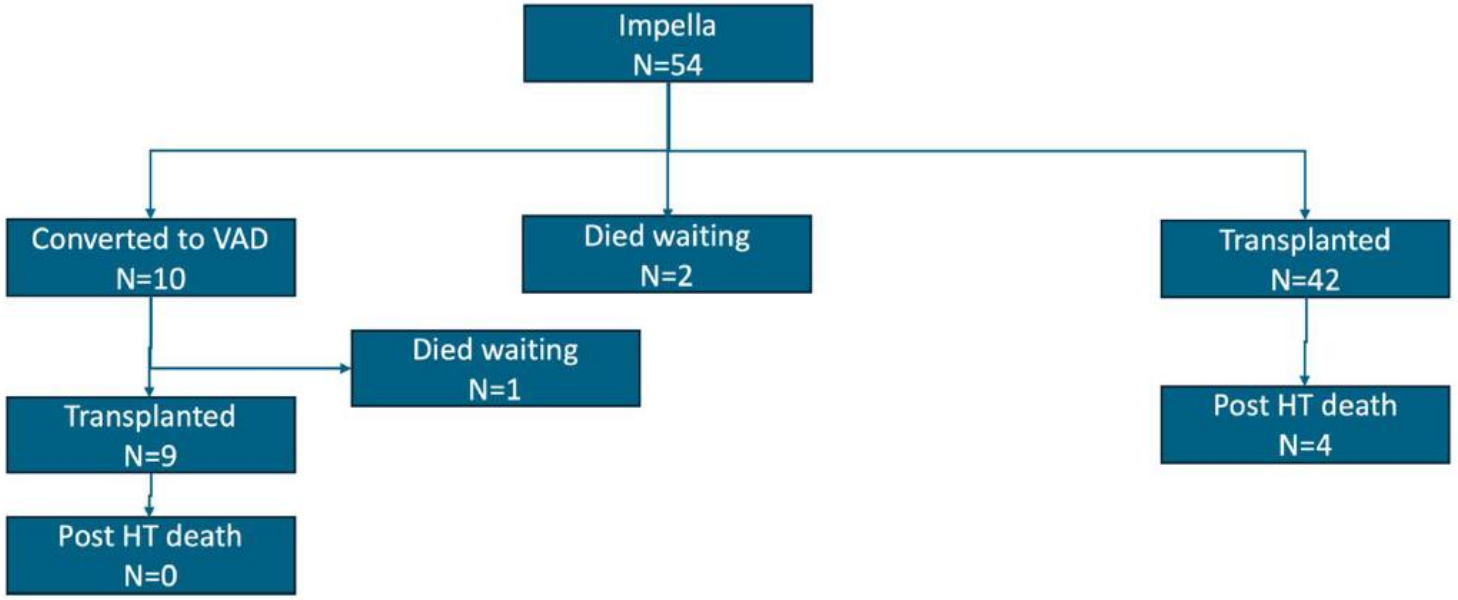
**Table 2.** Comparison of Characteristics of Children Who Received Impella Support (Alone or towards Another VAD), Those Who Received Other VAD Support and Those Who Did Not Receive VAD Support before or While Listed for HT, Adjusted for Age, Weight, BMI, CHD, and Urgency Status

| Adjusted baseline | Impella (*n* = 41) | VAD alone (*n* = 317) | No device (*n* = 256) | *P*-value |
|---|---|---|---|---|
| Transplant age (years) | 15 (13-16) | 14 (12-16) | 14 (12-16) | 0.21 |
| Gender (male) | 41 (74%) | 202 (63%) | 145 (58%) | 0.03 |
| BMI | 25 (20-29) | 22 (18-27) | 21 (17-25) | 0.09 |
| Weight | 69 (50-81) | 58 (45-75) | 54 (43-67) | 0.09 |
| Race | | | | |
| Black | 19 (40%) | 105 (33%) | 54 (21%) | 0.01 |
| White | 27 (40%) | 142 (45%) | 125 (49%) | |
| Other | 8 (19%) | 77 (22%) | 70 (30%) | |
| Blood group | 7 (12%) | | | |
| A | | 94 (34%) | 88 (30%) | 0.22 |
| B | 15 (28%) | 55 (12%) | 30 (17%) | |
| AB | 5 (9%) | 8 (3%) | 9 (3%) | |
| O | 1 (2%) | 160 (51%) | 129 (50%) | |
| Creatinine (mg/dL) | 33 (61%) | 0.6 (0.5-0.8) | 0.7 (0.6-1.0) | <0.01 |
| Bilirubin (mg/dL) | 0.7 (0.6-0.9) | 0.6 (0.4-0.9) | 0.8 (0.5-1.3) | <0.01 |
| Inotropes | 0.7 (0.6-1.2) | 65 (22%) | 124 (48%) | <0.01 |
| Mechanical ventilation | 27 (56%) | 10 (5%) | 26 (10%) | <0.01 |

- A **progressive increase in Impella utilization** was observed among pediatric transplant candidates
- Impella was used either as:
  - ✓ **Isolated temporary circulatory support**
  - ✓ **Bridge to durable ventricular assist device therapy**
- **Impella 5.5** accounted for the **majority of cases used as sole support**
- **Post-transplant survival outcomes were favorable**



- The increasing use of Impella reflects **expanding adoption of temporary mechanical circulatory support** in pediatric advanced heart failure
- The **Impella 5.5 device** appears particularly suited for **isolated pre-transplant support**
- Comparable survival suggests that **Impella support does not negatively impact post-transplant outcomes**
- These findings support the **feasibility of Impella as a bridge strategy in pediatric transplant candidates**



سدرة للطب
Sidra Medicine

# Conclusion

- **Impella use in pediatric patients awaiting heart transplantation is increasing nationally (USA)**
- The device is utilized both as **sole circulatory support and as bridge to durable VAD therapy**
- **Impella 5.5 predominates in isolated support strategies**
- **Post-transplant survival remains comparable** to patients supported with other devices or without mechanical support
- Impella represents a **promising temporary mechanical circulatory support option in pediatric transplant candidates**

سدرة للطب
Sidra Medicine

## Stroke in pediatric ventricular assist device support

Christina VanderPluym, MD,[a,*] Ryan Kobayashi, MD,[a] and Michael Rivkin, MD[b]

JHLT Open, Vol 10C, November 2025

- **Review** → risk of stroke in children with **VAD**
- Describes the **pathophysiological mechanisms** related to:
  - ✓ **Hemocompatibility** (*hemocompatibility-related adverse events, HRAEs*)
  - ✓ **Historical evolution of outcomes**
  - ✓ **Persistent challenges in prevention**
- **Heterogeneous population**, ranging from **neonates to adolescents**, with **different types of devices**.

# Pathophysiology of stroke in VAD support

**Patient-specific risks**

- **CHD:** markedly ↑risk vs general pediatric population predominantly ischemic
- **Complex CHD:** highest risk in single-ventricle physiology and cyanotic defects
- **Cardiac anomalies:** right-to-left shunts favor paradoxical embolism
- **Artificial materials:** shunts, stents, valves increase thromboembolic burden
- **Cyanosis-related hypercoagulability:** polycythemia, blood viscosity, PLT/endothelial activation, hemolysis, NO scavenging

**Device-specific risks**

- **Artificial surfaces:** non-endothelialized VAD materials trigger prothrombotic and inflammatory responses
- **Hemostatic imbalance:** PLT activation/consumption, coagulation pathway activation, and dysregulated fibrinolysis → consumptive coagulopathy
- **Device type:** higher artificial surface–to–blood interface in paracorporeal devices increases HRAEs risk
- **Stroke-free survival (3 months, Pedimacs):** IC- CF 92.7% > PC- PF 87.0% > paracorporeal CF 76.0%
- **ACTION:** stroke rates highest in BH-EXCOR and PC-CF devices; lowest with IC-VADs (~6.7%)

**Incidence of stroke**

- **Declining incidence:** freedom from stroke at 6 months improved from 80.2% (2012–2016) to 87.9% (2017–2023).
- **Registry data:** overall stroke rate ~13.7% (2.7 events/100 patient-months); mostly ischemic (73%).
- **Early risk:** many events occur within 7 days post-implantation
- **Improvements:** growing clinical experience and adoption of direct thrombin inhibitors (e.g., bivalirudin) reduced thrombotic and bleeding complications

# Clinical presentation and monitoring

- **Highest risk period:** early postoperative phase; neurological assessment often limited by sedation and neuromuscular blockade
- **Key clinical signs:** focal motor deficit, facial asymmetry, aphasia, pupillary changes, confusion, seizures
- **Routine surveillance:** frequent neurological exams; temporary pause of neuromuscular blockade when feasible
- **Monitoring tools:** NIRS (cerebral oxygenation), EEG/SSEP (hypoperfusion detection), TCD (cerebral flow, microemboli), and neuroimaging when indicated

**Table 1** Stroke Monitoring and Diagnosis Summary

| Category | Key Points |
|---|---|
| Neurological Exams | Daily exams recommended. Pause neuromuscular blockers (> 24 h use) to assess movement. Monitor for vitals changes (tachy-/bradycardia, hypertension). |
| NIRS | Non-invasive monitoring of cerebral oxygenation. Rapid drops or > 90% saturation may indicate stroke. Used intra- and post-op. |
| EEG & SSEP | Detect cerebral hypoperfusion. Consider in high-risk or deeply sedated patients. |
| Transcranial Doppler | Measures cerebral blood flow. Used in sickle cell and critical care. Detects micro-emboli. Limited VAD-specific data. |
| Pre-op Imaging | Preferred: MRI/MRA if stable. CT if unstable or transitioning from ECMO. Head US for neonates with open fontanelle. |
| Post-op Imaging | Not routine unless high risk or clinical concern: abnormal NIRS/EEG, BP swings, major bleeding, seizures, coagulopathy, pump thrombosis, or inability to perform neuro exam.<br>• MRI contraindication<br>• CT/CTA head and neck<br>• Head US if fontanelle open |
| Emerging Technology | Portable low-field MRI (e.g., Hyperfine): safe, fast, bedside-capable, under evaluation in ECMO/VAD patients. |

## Neuroimaging

- **Diagnostic cornerstone:** MRI/MRA preferred pre-operatively to detect prior cerebrovascular events; CT often used when MRI is not feasible
- **Alternative modalities:** head ultrasound in infants with open fontanelle
- **Postoperative imaging:** reserved for high-risk patients (hemodynamic instability, coagulopathy, seizures, pump thrombosis, unreliable exam)
- **Emerging technology:** portable low-field MRI enables bedside detection of early ischemic injury

## Acute stroke management

- **Immediate priorities:** rapid recognition, multidisciplinary coordination, and urgent neuroimaging (CT/CTA)
- **Anticoagulation management:** continuation or early resumption in ischemic stroke; cessation/reversal in hemorrhagic stroke (bivalirudin effect declines rapidly)
- **Thrombolysis:** rarely used in pediatric VAD patients; considered only in highly selected cases
- **Mechanical thrombectomy:** potential option for large vessel occlusion within 6–24 h, with careful multidisciplinary evaluation

## Long-term stroke care and outcomes

- **Secondary prevention:** identify stroke etiology (e.g., pump thrombosis, anticoagulation issues) to reduce recurrent HRAEs
- **Transplant timing:** delaying transplantation >60 days after stroke may improve outcomes; post-transplant survival comparable to non-stroke patients
- **Rehabilitation:** multidisciplinary care essential (neurology, rehabilitation, therapies, neuropsychology)
- **Neuroplasticity:** early, intensive rehabilitation improves functional recovery and long-term outcomes

OPEN

ASAIO Journal 2026

Review

# Ultrasound in Extracorporeal Membrane Oxygenation: An ELSO State-of-the-Art Review

Ghislaine Doufle,*† Erika R. O'Neil,‡§ Susana Abreu,¶ Nada Ali Aljassim,‖ Matteo Di Nardo,# Nchafatso G. Obonyo,**†‡‡ Valentina Pinzon,§§ Susanna Price,¶ ¶‖‖ Kollengode Ramanathan,##*** and Martin Balik†††

- **Review**; international expert consensus under the auspices of ELSO
- Based on a structured review of **133 publications**
- Applies to adult, pediatric, and neonatal ECMO patients

- Core Concept → US has become indispensable throughout the entire **ECMO continuum**, including:
- Pre-ECMO assessment
- Cannulation guidance
- Monitoring during support
- Troubleshooting complications
- Weaning and post-decannulation follow-up

- Evidence-based **recommendations** and a **standardized framework** for ultrasound integration in ECMO programs worldwide

# Role of Ultrasound Before ECMO Initiation

## 1) Pre-ECMO Cardiopulmonary Assessment

**Objectives**

- Evaluate **biventricular morphology and function**
- Assess **valvular disease**
- Detect **contraindications**:
  - ✓ Severe aortic regurgitation (VA ECMO)
  - ✓ Aortic dissection
  - ✓ Tamponade
  - ✓ Tension pneumothorax
- Assess vascular anatomy and patency

**Configuration Guidance**

- **VA vs VV ECMO based on**:
  - ✓ Cardiac index (VTI)
  - ✓ RV function (TAPSE)
  - ✓ Pulmonary pressures
  - ✓ Reversibility of dysfunction

**Ultrasound is fundamental in selecting the appropriate ECMO strategy**

# Ultrasound-Guided Cannulation

**1) Real Time Procedural Guidance**

**Indications:**

- **Vessel identification and sizing**
- **Guidewire** confirmation
- **Cannula positioning**
- **Prevention of**
  - ✓ Arterial misplacement (VV ECMO)
  - ✓ Cardiac perforation
  - ✓ Vascular dissection
  - ✓ Inadequate distal limb perfusion

2) **TEE Advantages**:

- **Bicaval** visualization
- Dual-lumen cannula optimization
- Immediate detection of complications

**Post-cannulation echocardiography is mandatory before final fixation**

# Monitoring During ECMO Support

**Cannula Surveillance**

- Confirm **tip position**
- Detect recirculation (especially VV ECMO)
- Identify **thrombus formation**
- Diagnose **drainage insufficiency**
- Color Doppler is essential in dual-lumen configurations

**Cardiac Monitoring**

**On VA ECMO:**

- LVEF (Simpson method)
- LVOT VTI
- Aortic valve opening
- LV distension
- Mitral regurgitation
- Aortic root thrombosis
- RV function

**On VV ECMO:**

- **RV size and function**
- Signs of **acute cor pulmonale**
- Indications for configuration change

**Ultrasound findings guide escalation or unloading strategies**

**Interpretation must account for ECMO flow and loading conditions**

# Troubleshooting and Extracardiac Applications

**1) Hypoxemia on ECMO**

- **ECMO-related**
  - ✓ Recirculation
  - ✓ Inadequate extracorporeal blood flow
  - ✓ Membrane dysfunction
  - ✓ Differential oxygenation (VA ECMO)
- **Patient-related**
  - ✓ Pneumothorax
  - ✓ Hemothorax
  - ✓ Atelectasis
  - ✓ Consolidation

**2) Tamponade**

- May present **atypically** on ECMO
- Traditional Doppler signs may be absent
- **Requires serial echocardiography**

**3) Vascular Ultrasound**

- **Cannula-associated thrombosis**
- **Limb ischemia**
- **Pseudoaneurysm**
- **Arteriovenous fistula**
- Routine **post-decannulation** vascular ultrasound is recommended

# Ultrasound in ECMO Weaning

**1) VV ECMO**

- Lung ultrasound recovery score
- RV function normalization
- Absence of significant pulmonary hypertension

**2) VA ECMO (Adults)**

**- Parameters associated with successful libération:**

- LVEF > 20–25%
- LVOT VTI > 10 cm
- Mitral annular S’ > 6 cm/s
- Adequate RV function
- Favorable response to stepwise flow reduction

**- Dynamic changes during flow reduction are more predictive than isolated values (POC)**

# Rehabilitation in children with ventricular assist devices

Matthew J. O'Connor JHLT Open, Vol 9C, August 2025

**Table 1** Commonly Utilized Ventricular Assist Devices in Children

| Device type | Potential for hospital discharge |
|---|---|
| Paracorporeal Continuous-Flow | |
| • Pedimag (Abbott) | N |
| • Centrimag (Abbott) | N |
| • Rotaflow (Getinge) | N |
| Paracorporeal Pulsatile-Flow | |
| • Berlin Heart EXCOR (Berlin Heart)[a] | N |
| Percutaneous Continuous-Flow | |
| • Impella (Abiomed)[b] | N |
| Intracorporeal Pulsatile-Flow | |
| • Syncardia Total Artificial Heart (Syncardia) | Y[c] |
| Intracorporeal Continuous-Flow | |
| • HeartWare (Medtronic)[d] | Y |
| • HeartMate 3 (Abbott) | Y |

Device type is listed with manufacturer in parentheses.

Of the above devices, the Berlin Heart, Impella, and HeartMate 3 devices are US Food and Drug Administration-approved for use in children.

[a]Available in 10 ml, 15 ml, 25 ml, 30 ml, 50 ml, and 60 ml pump sizes.

[b]Available in various catheter sizes with variable flow rates.

[c]With the use of the Freedom driving unit.

[d]Removed from the market in 2021.

## What is rehabilitation?

- It is defined as the process **"to restore to a previous condition"** or **"to return something to its normal or proper condition"**
- In the context of VAD, rehabilitation aims to re-establish the patient's health status and functional capacity prior to heart failure (HF)
- Cardiac rehabilitation is an integral component of HF management and includes:
  - ✓ **Exercise training and physical activity counseling program**
  - ✓ **Dietary recommendations**
  - ✓ **Psychosocial support**
  - ✓ **Education regarding medical adherence**
- In children with chronic HF supported by VAD, rehabilitation focuses primarily on exercise, nutrition, and psychosocial support, which collectively contribute **to improved functional status and quality of life**

## Exercise training and physical activity counseling

- **Inactivity is a hallmark of advanced heart failure**, driven by reduced cardiac output, sarcopenia, poor nutrition, respiratory insufficiency, and barriers to mobility
- VAD implantation **restores** cardiac output and **reverses** the HF phenotype, enabling increased physical activity and structured rehabilitation
- Evidence from adult and limited pediatric studies shows that **structured exercise programs** improve functional status and patient-reported health status
- Pediatric exercise rehabilitation programs typically include:
  - ✓ **Baseline cardiopulmonary exercise testing**
  - ✓ **Individualized exercise prescriptions**
  - ✓ **Aerobic and resistance training (2–3 sessions per week, 30–60 minutes)**
  - ✓ **Early mobility and ambulation after VAD implantation are associated with improved survival and successful discharge**
- However, exercise rehabilitation remains **underutilized** due to barriers such as limited staff, space, and patient travel distance.

سدرة للطب
Sidra Medicine

**Table 2** Exercise Rehabilitation Program for Ventricular Assist Device Patients at Children's Hospital of Philadelphia

- Early ambulation and mobility (within 2 days of initial postoperative extubation)
- Baseline cardiopulmonary exercise test (cycle ergometer) if following criteria are in place:
  - o >14 days from implant
  - o >6 years of age
  - o Off vasoactive infusions
  - o No active hematologic concerns
  - o No wound infection concerns or poor wound healing
  - o No active myocarditis
  - o No arrhythmia burden refractory to medical therapy
- Baseline cardiopulmonary exercise test characteristics
  - o 3 minutes unloaded warm-up pedaling period
  - o Ramped increase in work rate to achieve predicted maximal work rate within 10–12 minutes
  - o Assessment of metabolic and ventilatory data using metabolic cart
  - o Exercise parameters measured: heart rate, VAD flow, work rate, maximal oxygen consumption ($VO_2$), pulsatility index, oxygen saturation at rest, anaerobic threshold, and maximal exercise
  - o Respiratory exchange ratio ≥1.1 defines maximal exercise
- Chronic exercise rehabilitation program components (individualized based on patient characteristics)
  - o Moderate aerobic exercise with heart rate at ventilatory aerobic threshold
  - o Resistance exercises for upper extremities, lower extremities, torso (9 exercises in total, with 2 sets of 15 repetitions)
  - o 2–3 sessions per week, with each session 30–60 minutes
- Safety considerations
  - o Limited to moderate exercise intensity
  - o Prolonged gradual warm-up and cool-down periods (10–15 minutes each)
  - o Avoidance of breath-hold or Valsalva maneuver
  - o Stabilization of VAD driveline/cannulas
  - o Avoidance of running, rowing, swimming, abdominal exercises, bilateral arm extension above the head
  - o Close supervision by practitioners familiar with VAD technology

VAD, ventricular assist devices.
Refer to reference Burstein et al.[13] for details.

## Dietary management

- Children with chronic HF frequently present with malnutrition, poor oral intake, and sarcopenia, which negatively affect wound healing, mobility, and rehabilitation
- VAD support can promote renourishment and improvement in anthropometric indices, including weight-for-age and height-for-age scores
- Nutritional recovery requires multidisciplinary management involving physicians, nurses, nutritionists, and gastroenterologists

## Psychological aspects of pediatric VAD support

- HF significantly impacts quality of life, mental health, coping ability, and social relationships
- Psychiatric disorders such as depression, anxiety, and adjustment disorder are common in children awaiting transplantation with VAD support
- Regular mental and behavioral health assessment is essential to improve adherence, rehabilitation effectiveness, and overall well-being

## Rehabilitation efforts at Children's Hospital of Philadelphia

- Multidisciplinary programs integrate physical therapy, occupational therapy, speech therapy, exercise physiology, and psychosocial support
- Intensive inpatient rehabilitation may involve 5–7 therapy sessions per week with up to 3 hours of daily therapy

سدرة للطب
Sidra Medicine

**Table 3** Intensive Rehabilitation Program for Inpatient Ventricular Assist Device Patients at Children's Hospital of Philadelphia

- Acute Phase
  - Started as soon as clinical stability is achieved following VAD implant
  - Therapies offered twice weekly
- Intensive Phase
  - Offered to patients >12 months of age once clinically determined to be appropriate for increased rehabilitation frequency
  - Therapies offered 5–7 days per week, up to 3 hours per day
  - Infants 4–12 months of age receive "developmental intensive" therapy to provide developmental skills during a crucial window of development
- Conditioning Phase
  - Begins when therapy team determines that patient is at baseline level of conditioning or has plateaued in skill development and continues through the duration of VAD

VAD, ventricular assist devices.
Therapies include physical therapy, speech therapy, occupational therapy, and exercise rehabilitation. Therapies are provided "in place" when appropriate. Maintenance of a consistent schedule of therapies is crucial.

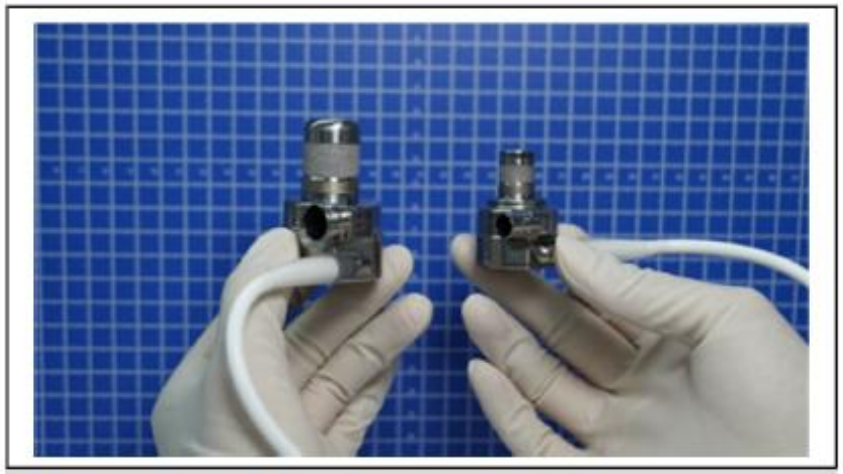
## Conclusions

- Rehabilitation in pediatric VAD patients encompasses exercise, nutritional, and psychosocial domains
- These interventions improve quality of life and post-transplant outcomes, but significant opportunities remain to expand exercise rehabilitation and psychosocial support programs

# Implantation of a novel magnetically levitated biventricular assist device in a 10-year-old patient

Junlin Lai, MD,[a] Wai Yen Yim, MD,[a] Yixuan Wang, MD,[a,b] Guohua Wang, MD,[a] Chenghao Li, MD,[c] Tixiusi Xiong, MD,[a] Wei Su, MD,[a] Cheng Zhou, MD,[a] Jing Zhang, MD,[a] and Nianguo Dong, MD,[a,b]
Wuhan, Hubei, China

JTCVS Techniques • October 2025



The HXCORMED DuoCor and novel third-generation magnetically levitated BiVAD—the D-miniCor

## CENTRAL MESSAGE

The successful implantation of a novel third-generation magnetically levitated biventricular assist device (D-miniCor; HXCORMED) in a low-weight pediatric patient.

- A **10-year-old (28 kg, BSA 1.06 m²) pediatric heart transplant recipient** developed **chronic allograft dysfunction** with **chronic rejection and superimposed acute cellular rejection** after a decade of stable tacrolimus-based immunosuppression
- The patient presented with **cardiac arrest**, requiring **emergency VA-ECMO and percutaneous atrial septostomy**
- **Retransplantation was contraindicated** due to **high panel-reactive antibody class II (75%)**
- After **10 days of ECMO stabilization**, **BiVAD implantation** was performed to treat **biventricular failure**

سدرة للطب
Sidra Medicine

## Surgical approach

- Implantation performed through **median sternotomy under cardiopulmonary bypass**
- **Aortic cross-clamping and cardioplegic arrest** achieved with cold blood-based high-potassium cardioplegia

### LV pump implantation

- **Fixation ring LV apex** using **10–12 interrupted horizontal mattress sutures (3-0 Prolene, PTFE pledgets,** U configuration)
- A circular apical opening created using a coring knife
- The left ventricular pump inserted into the apex and secured to the fixation ring
- Aortic cross-clamp removed to restore myocardial perfusion

### Right-sided pump implantation

- **Fixation ring sutured to the right atrium** with **10–12 mattress sutures (4-0 Prolene with PTFE patches)**
- Ring positioned **13 mm from the interatrial septum and 18 mm from the IVC orifice**
- **Right atrial opening created**, and pump inserted **7.5 mm into the atrial cavity**, oriented toward the **tricuspid valve**

### Outflow graft configuration

- **Outflow grafts oriented at the 4–5 o'clock direction** to align with physiologic blood flow
- Anastomosis performed for **aorto-pulmonary circulation**

### Initial pump settings

- LV pump: **2200 RPM**
- RV pump: **1500 RPM**
- Final adjustment based on **flow balance and septal position** before weaning from CPB

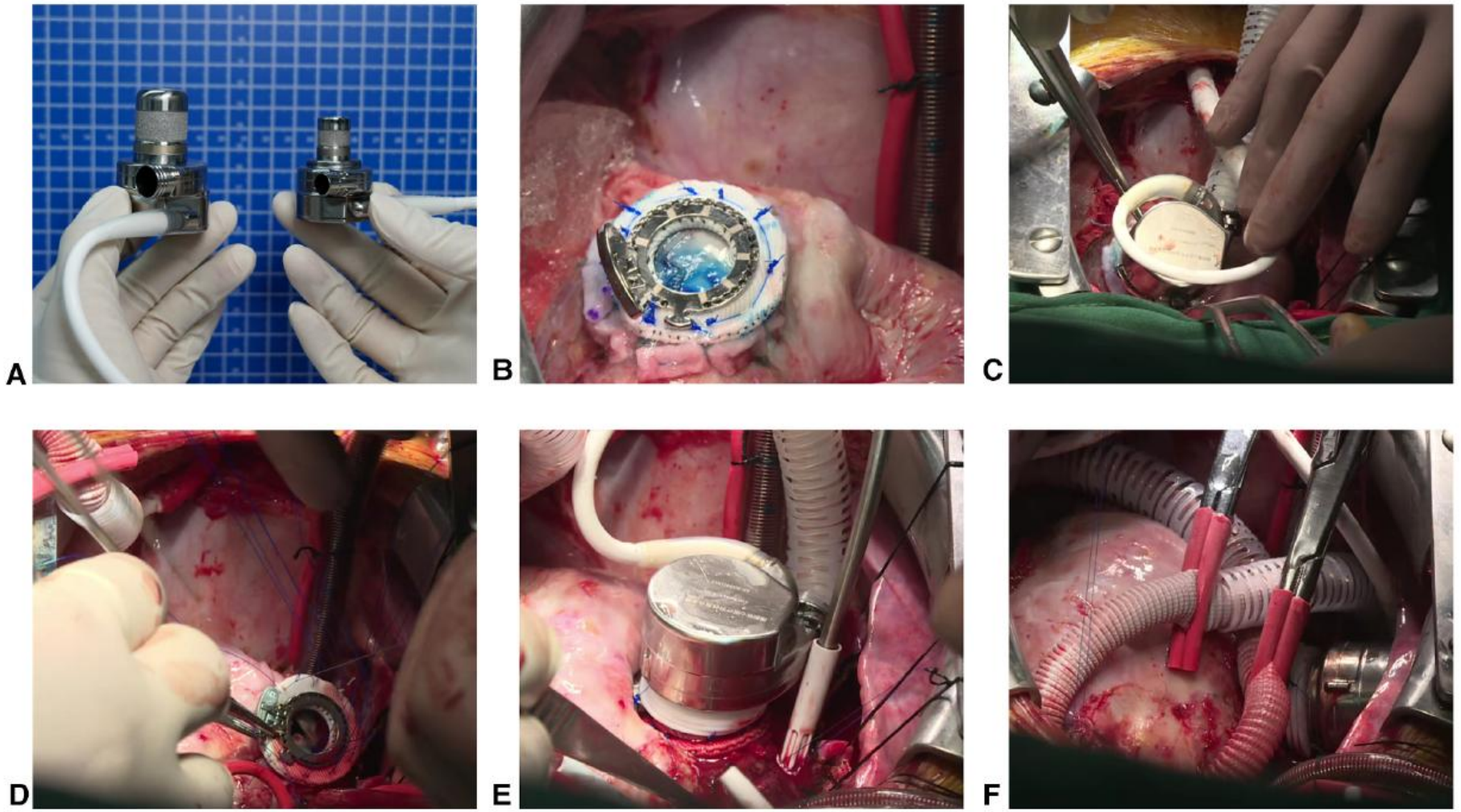



**FIGURE 1.** A, HXCORMED DuoCor pump (*left*); D-miniCor pump (*right*). B through E, Intraoperative images showing the sewing of the ring to the apex (B) insertion of a Shenzhen Core Medical Technology Co Ltd Corheart 6. C, Anastomosis of the right atrial ring to the right atrium (D) and insertion of the Corheart 6 (E). F, The D-miniCor successfully implanted into the chest cavity.

# Key features and clinical considerations of the D-miniCor system

## Device design

- **Third-generation fully magnetically levitated biventricular assist device (BiVAD)**
- **Pediatric-optimized dimensions: 45 g per pump**, **29 mm diameter**, **24 mm thickness**
- **Operating range: 1500–3600 RPM**, delivering **up to 6 L/min flow**

## Technological innovations

- **Integrated control system** managing **rotor rotation and magnetic levitation with a single coil set**, reducing pump size
- **Full axial magnetic levitation**, improving **hemocompatibility**
- **Low power consumption (2–4 W)** to reduce **thermal output and shear-related thrombosis risk**
- **5 mm percutaneous driveline cables**, potentially lowering infection risk

## Clinical advantages

- **Miniaturized design suitable for pediatric patients** with **0.5–1.2 $m^2$ body surface area**
- Reduced dimensions compared with HeartMate 3, facilitating implantation in **limited thoracic space**
- **Follow-up stable hemodynamics; absence of device-related bleeding, thromboembolism, or neuro events**

Sidra Medicine

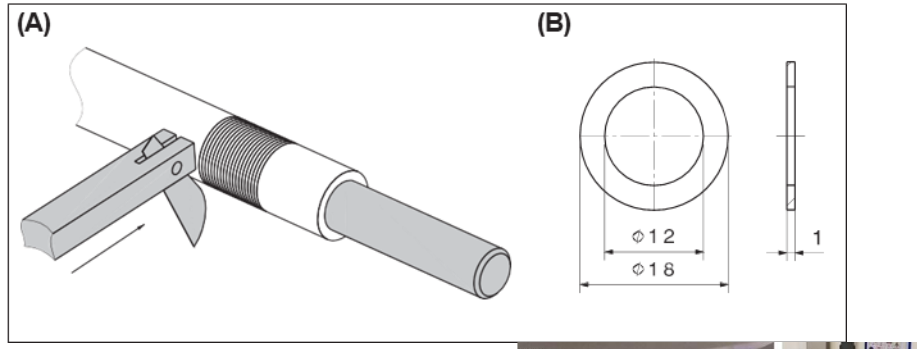
Artif. Organs. 2025;49:256–265

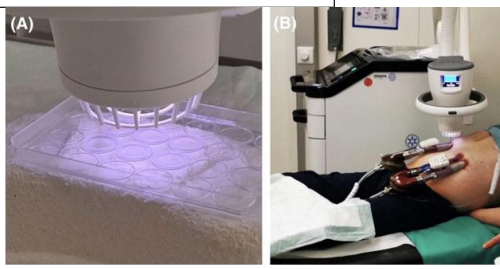
Artificial Organs

WILEY

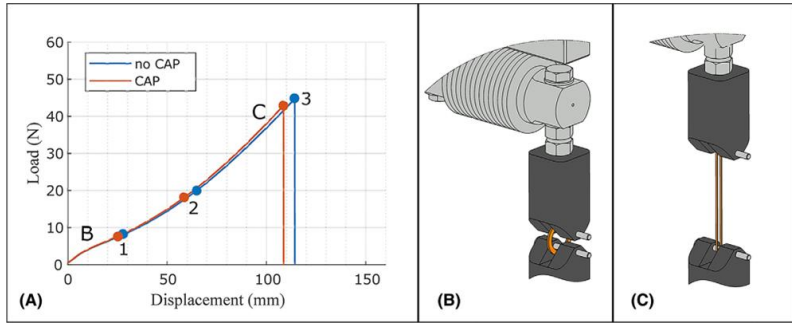
# Cold atmospheric plasma therapy as a novel treatment for Berlin Heart EXCOR pediatric cannula infections

Johanna Schachl[1] | Markus Königshofer[2] | Martin Stoiber[2,3] | Martina Socha[1] | Christian Grasl[2,3] | Theodor Abart[1] | Ina Michel-Behnke[4] | Dominik Wiedemann[1] | Julia Riebandt[1] | Daniel Zimpfer[1] | Thomas Schlöglhofer[1,2,3]




- The shortage of donor organs in pediatric patients makes VAD essential as a bridge to heart transplantation
- BH-EXCOR is the most commonly used VAD in children under 6 years of age (87.2%)
- Early complications: bleeding, device malfunction, infection, and neurological events
- Infection: the main complication after 3 months of support
- CAP therapy may help treat infections at VAD driveline exit sites
- CAP reduces bacterial load without adverse effects on the skin
- A study investigates the impact of CAP on the mechanical resistance of EXCOR cannulas
- **CAP is an innovative technology that uses energized gas to eliminate bacteria and promote wound healing**



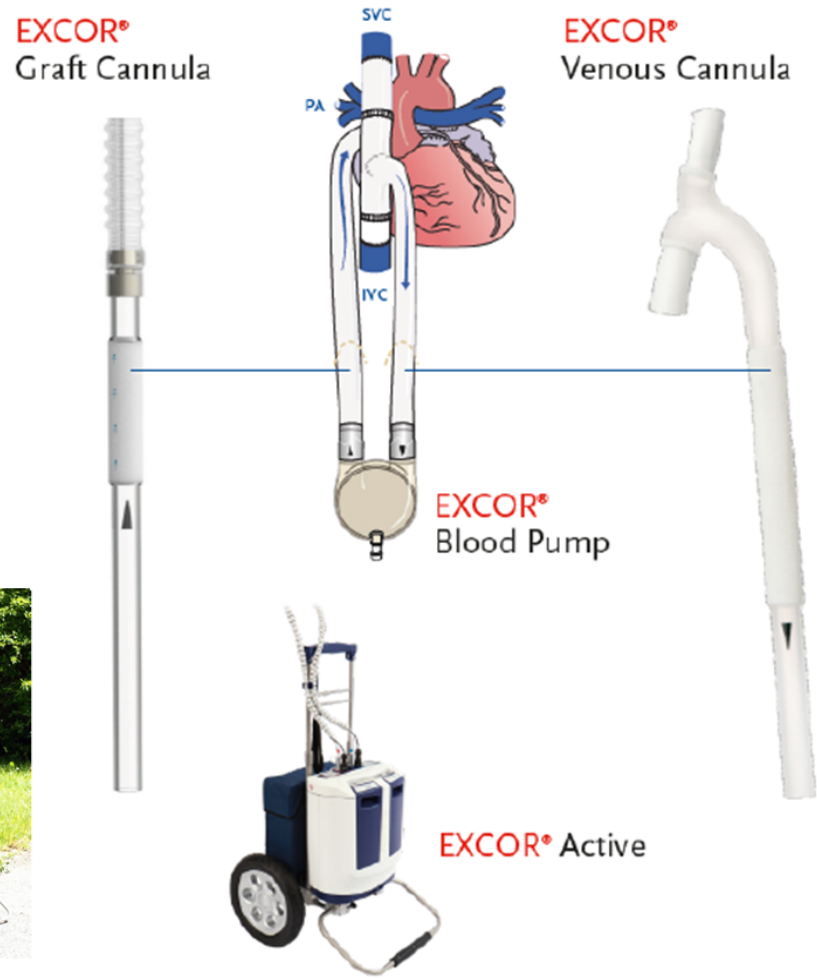
- ♂, 13 years, 42 kg, 140 cm, BSA 1.29 $m^2$, HLVS, Fontan procedure at age 4
- 8 years post-Fontan: subaortic + subpulmonary ventricular failure → BH-EXCOR. support on systemic ventricle + Dt (new cannula)
- “Stage 2b – local infection” (DESTINE): purulent drainage at cannula exit site; polymicrobial infection, E. coli +++
- Start: local care (frequent dressing changes), targeted antibiotics, bacteriostatic dressings for 125 days from POD 196, no improvement
- **CAP therapy**: 321 days after implantation, off-label pediatric use
- 28 sessions-100 days, treatment time reduced from 5 → 4 min per site after improvement
- Adjunct care: antiseptic cleansing + absorbent dressings + silver bacteriostatic dressings (Aquacel™, Mepilex® Transfer Ag)
- **Monitoring:** CRP, leukocytes, fibrinogen, quantitative bacterial cultures (scarce/moderate/abundant), DESTINE classification
- Each site = 119 min CAP, close follow-up to evaluate treatment efficacy

سدرة للطب
Sidra Medicine

# 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

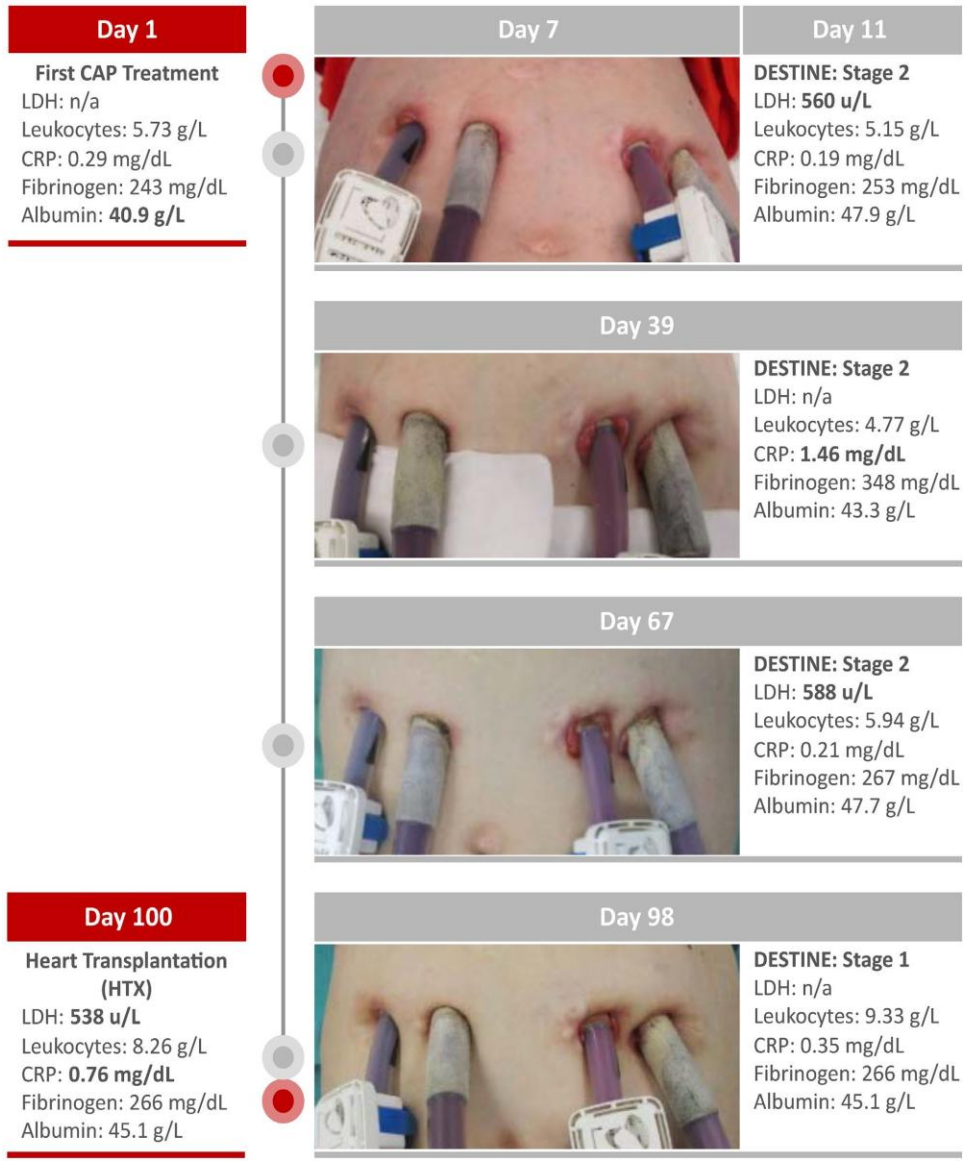



**"Cavopulmonary support with a modified cannulation technique in a failing Fontan patient"**

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




- **In vitro** measurements showed no significant changes in the mechanical resistance or surface structure of EXCOR cannulas after CAP treatment

- Consistent with studies in the adult population, cold atmospheric plasma (CAP) appears to be a **safe and effective adjunctive therapy** for EXCOR cannula exit-site infections in a pediatric patient

- **Further studies** are required to better evaluate and validate this therapeutic approach

# Heparin Versus Bivalirudin in Pediatric Patients Assisted With Mechanical Circulatory Support: A Retrospective Before-and-after Study

C. Giorni et al. / Journal of Cardiothoracic and Vascular Anesthesia 00 (2025) 1–8

**Study Design**
- Retrospective, single-center, before–after study
- Pediatric patients requiring MCS
- Heparin (2015–2017) vs Bivalirudin (2018–2020)

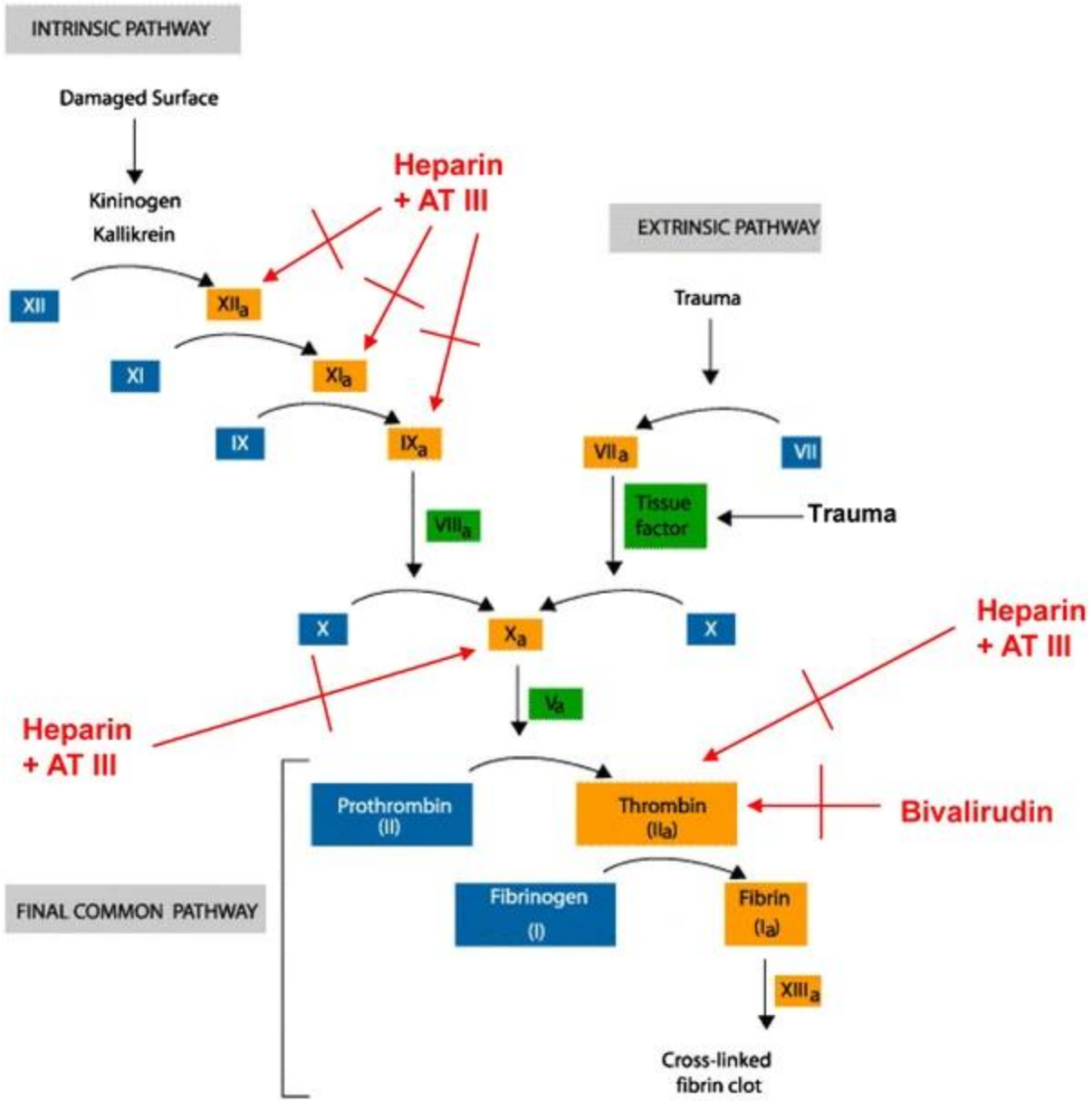
**Population**
- ECMO and Berlin Heart (comparative analysis)
- Bivalirudin group also included continuous-flow VADs
- Inclusion: complete anticoagulation data (first 30 days in PCICU)

**Primary Outcome**
- Thrombosis incidence within 30 days
- Stratified by ECMO vs Berlin Heart

**Secondary Outcomes**
- Cerebrovascular events (CVE)
- Survival
- Dose–PTT relationship

**Anticoagulation Targets**
- Berlin Heart: PTT 80–90 s
- ECMO: PTT 70–80 s

**Statistical Analysis**
- t-test, Chi-square
- Linear regression (dose–PTT)
- Kaplan–Meier (freedom from thrombosis)
- Significance: $p < 0.05$




Massicotte, Edmonton, Canada (1955-2020)

https://www.1800noclots.com/history-of-dr-patricia-massicotte

**Study Population**

- Total patients: 43
- Comparative analysis: 36 (18 bivalirudin vs 18 heparin)
- Berlin Heart (BH): 8 bivalirudin vs 10 heparin
- ECMO: 10 bivalirudin vs 8 heparin

**Primary Outcome – Thrombosis (30 days)**

- Berlin Heart: 12.5% (bivalirudin) vs 80% (heparin), p = 0.005
- ECMO: No significant difference

**Secondary Outcomes (Berlin Heart)**

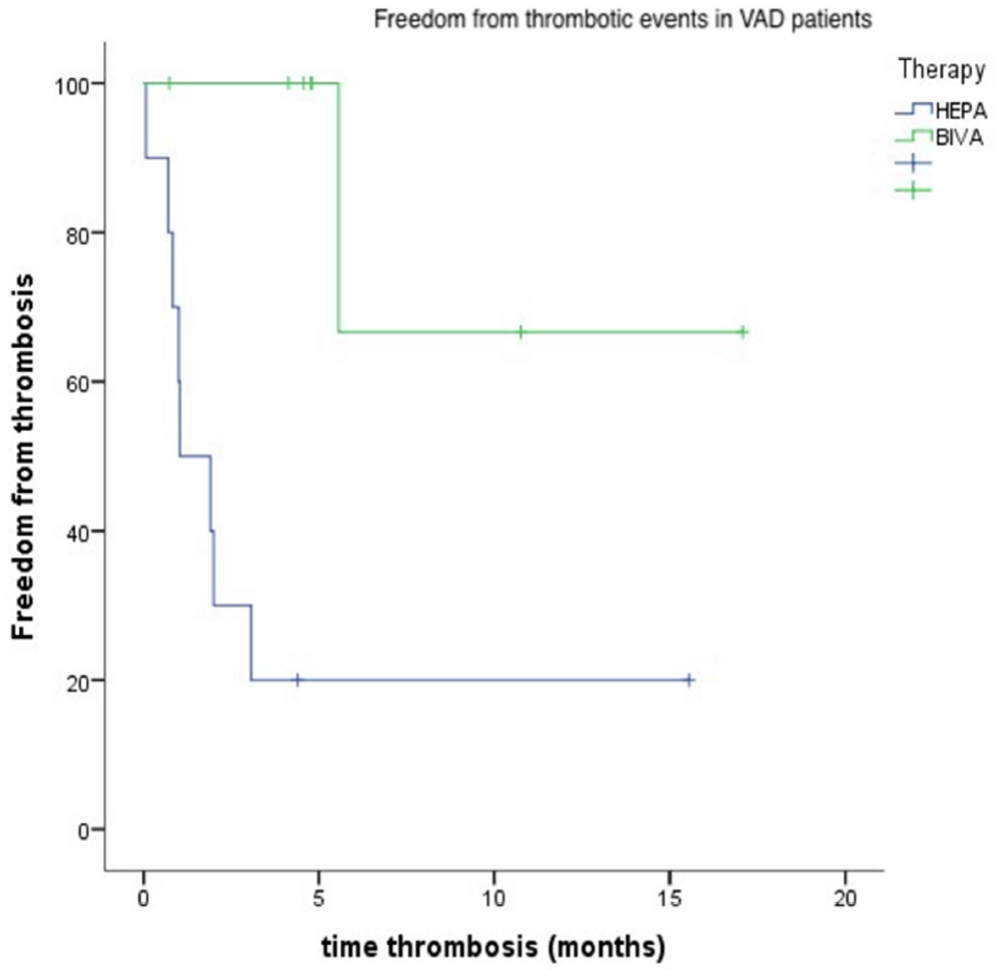
- Cerebrovascular events: 0% vs 30%
- Mortality: 0% vs 30%
- Trend favoring bivalirudin (p = 0.054)

**Anticoagulation Control (PTT Performance)**

- Berlin Heart mean PTT: 85 ± 15 s vs 67 ± 28 s (p < 0.0001)
- ECMO mean PTT: 76 ± 17 s vs 48 ± 13 s (p < 0.0001)
- Out-of-range PTT (BH): 35% vs 76% (p < 0.0001)
- Out-of-range PTT (ECMO): 34% vs 84% (p < 0.0001)

**Dose–PTT Relationship**

- Significant correlation in all groups (p < 0.0001)
- Correct PTT response after dose adjustment ≈ 80%




plan–Meier analysis showing freedom from thrombotic events in VAD patients treated with heparin and bivalirudin (log-rank = 0.005). VAD, ventricu-
device.

- **Bivalirudin reduced thrombosis in Berlin Heart patients** compared with heparin
- **More consistent and stable PTT control** with bivalirudin in both BH and ECMO
- **Easier dose–response management with bivalirudin** (more predictable PTT adjustments)
- **Heparin** associated with:
  - Variable response
  - Possible tolerance over prolonged support
  - Higher proportion of out-of-range PTT values
- In **BH** patients, trend toward:
  - Fewer CVEs
  - Lower mortality (small sample)
- **Correlation between dose and PTT** present in both groups, but slightly stronger and more stable with bivalirudin

**Clinical Interpretation**

- Pediatric MCS remains high-risk for both bleeding and thrombosis.
- Despite baseline differences and small sample size, **bivalirudin provided superior anticoagulation performance**
- Findings support bivalirudin as a **potentially preferable first-line strategy** in pediatric MCS

**Main Limitations**

- Small, retrospective cohort
- Era effect (historical heparin vs contemporary bivalirudin)
- Baseline differences (age, platelet count, support duration)
- Sample size calculated post hoc

سدرة للطب
Sidra Medicine

# Take-Home Messages

- **BIVAL significantly reduced thrombotic events in Berlin Heart patients** compared with heparin
- **BIVAL achieved more consistent in-range PTT control** in both ECMO and BH patients
- **PTT values responded reliably to bivalirudin dose adjustments**, with predictable anticoagulation management regardless of MCS type

# Bridging gaps in pediatric device development: The power of ACTION – a collaborative learning network

Deepa Mokshagundam, MD,[a] David N. Rosenthal, MD,[b] Lauren Smyth, MHA,[c] and Angela Lorts, MD, MBA[c] The Journal of Heart and Lung Transplantation, Vol 44, No 4, April 2025

## Background / Clinical Problem

- Ventricular Assist Devices (VADs) have significantly improved the management of **end-stage heart failure in children**
- Despite these advances, **pediatric device development remains limited** due to:
  - ✓ **small and heterogeneous patient populations**
  - ✓ **high development costs**
  - ✓ **regulatory barriers**
- Traditional randomized clinical trials are **difficult to conduct in pediatric populations**
- As a result, there is **inequity in the availability of medical devices for children compared with adults**
- Innovative approaches are therefore required to generate **high-quality real-world evidence** to support pediatric device development

# Methods / Structure of the ACTION Network

- The **Advanced Cardiac Therapies Improving Outcomes Network (ACTION)** was created in **2017**
- ACTION functions as a **collaborative learning network** involving multiple pediatric heart centers
- Key components of the network include:
  - ✓ a **multicenter registry** collecting detailed clinical data
  - ✓ shared **quality improvement initiatives**
  - ✓ standardized **data collection and outcome reporting**
  - ✓ collaboration between clinicians, researchers, regulators, and industry
- The network leverages **real-world evidence** to evaluate device safety and effectiveness.
- ACTION facilitates:
  - ✓ **multicenter data sharing**
  - ✓ **faster learning cycles**
  - ✓ **improved clinical decision making**

# Results / Impact and Future Implications

- ACTION has contributed to **improved outcomes in pediatric patients supported with VADs**
- The network enables:
  - ✓ better understanding of **patient selection**
  - ✓ improved **anticoagulation strategies**
  - ✓ optimization of **clinical management protocols**
- Registry data provide **real-world evidence** that can support:
  - ✓ regulatory approval processes
  - ✓ device innovation
  - clinical guideline development
- The collaborative model helps **bridge the gap between clinical practice, research, and regulatory science**
- Future directions include:
  - ✓ expansion of the registry
  - ✓ further integration with regulatory agencies
  - ✓ accelerating **pediatric device innovation**

سدرة للطب
Sidra Medicine

# Mechanical circulatory support as a cornerstone in advanced heart failure and transplantatior

Marta Braga[1,2†], Ana Isabel Pinho[1,2†], Ulrich Jorde[3] and José González-Costello[4,5,6*] Frontiers in Cardiovascular Medicine
24 October 2025

## Clinical Background

**Advanced Heart Failure: Current Challenges**

- Heart transplantation remains the **gold standard treatment** for end-stage HF
- Median survival after transplant ≈ **12–14 years**
- Major limitation: **shortage of donor hearts**
- Consequences:
- Increasing number of patients with **advanced HF**
- Growing need for **mechanical circulatory support**
- Today, MCS is used for:
- Hemodynamic stabilization
- Bridge to transplant
- Bridge to recovery
- Long-term therapy in non-transplant candidates

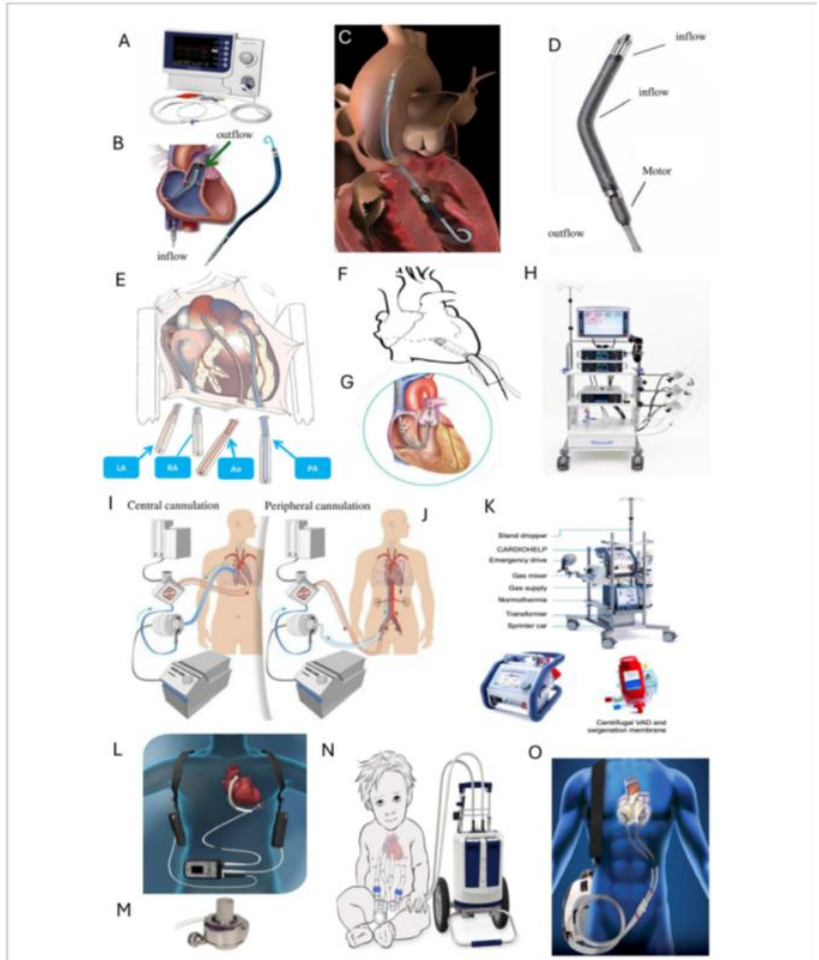



FIGURE 1
Examples of mechanical circulatory support (MCS) devices and configurations. Upper panel: Impella devices (Abiomed, Johnson & Johnson®, Massachusetts, USA) (A) Impella console, (B) Impella RP, (C) Impella CP, and (D) Impella 5.5. Middle upper panel: (E) Cannulation of the great vessels with Centrimag (Abbott®, Illinois, USA), (F) Cannulation of the left ventricle with Centrimag, (G) ProtekDuo (LivaNova®, London, UK), and (H) Centrimag console. Middle lower panel: (I) VA-ECMO with central cannulation, (J) VA-ECMO with peripheral cannulation, and (K) ECMO console and oxygenator. Lower panel: Durable mechanical circulatory support devices (L) Overview of the left ventricular assist device (LVAD) system, HeartMate 3 (Abbott®, Illinois, USA), (M) HeartMate 3 LVAD cannula, (N) Berlin Heart EXCOR® (Berlin Heart GmbH, Berlin Germany), and (O) Total Artificial Heart (SynCardia®, Tucson, USA). Ao, aorta; LA, left atrium; PA, pulmonary artery; RA, right atrium. Images provided by: A–D: Johnson and Johnson; E, F, H, L, M: Abbott; G: Palex; I, J: Hospital Universitari de Bellvitge; K: Gettinge; N: BerlinHeart; O: Mercé.

سدرة للطب
Sidra Medicine

# Types of Mechanical Circulatory Support

## Temporary MCS (tMCS)

- Duration: **hours to weeks**
- Devices include:
  - Intra-aortic balloon pump (IABP)
  - Impella devices
  - TandemHeart
  - VA-ECMO
  - Centrimag
- Clinical roles:
  - Cardiogenic shock
  - Bridge to decision
  - Bridge to recovery
  - Bridge to durable support or transplantation

| Device characteristics | Temporary mechanical circulatory support | | | | | | |
|---|---|---|---|---|---|---|---|
| | IABP | Impella (Abiomed, Johnson & Johnson®, Massachusetts, USA) | | | TandemHeart (LivaNova®, London, UK) | Centrimag (Abbott®, Illinois, USA) | VA-ECMO |
| | | CP | 5.5 | RP | | | |
| Percutaneous | Yes | Yes | No | Yes | Yes | No | Yes[a] |
| Ventricular support | LV | LV | LV | RV | LV (but possible RV[b] and BiV) | LV, RV or BiV | BiV |
| Placement | Descending Ao via FA[c] | LV via FA or AA | LV via AA or directly into ascending Ao | RA to PA via FV | Inflow: LA via FV. Outflow: Abdominal Ao via FA | Inflow: LV or RA Outflow: Ascending Ao or pulmonary artery | Inflow: RA via IJV or FV Outflow: Abdominal Ao via FA[a] |
| Hemodynamic support (L/min) | 0.5–1.0 | 4.0 | Up to 6.2 | 4.0 | 4.0 | Up to 10 | Up to 10 |
| Mechanism of action | Counterpulsation balloon pump | Axial flow pump | | | Centrifugal extracorporeal pump | Centrifugal extracorporeal pump | Centrifugal extracorporeal pump + external membrane oxygenation |
| LV unloading | Yes | Yes | | N/A | Yes | Yes | LV overloading |
| Myocardial oxygen demand | ↓ | ↓ | | | ↔↓ | ↓ | ↔ or ↑ |
| Systemic anticoagulation | Recommended | Yes | | | Yes | Yes | Yes |
| Durability of support | Days | Days | Weeks to a month[d] | Days to weeks | Days to weeks | Weeks | Days to weeks |
| Major contraindications | Severe aortic insufficiency, aortic dissection, peripheral vascular disease | Severe aortic stenosis, prosthetic aortic valve, LV thrombus, peripheral vascular disease, aortic dissection | | Severe right valvular disease or prosthetic valves, PA disorders | Atrial thrombus, severe aortic insufficiency, aortic dissection, peripheral vascular disease | Unable to tolerate anticoagulation | Peripheral vascular disease, severe aortic insufficiency, aortic dissection |
| Major complications | Vascular injury, bleeding, hemolysis, thrombocytopenia, aortic dissection | Hemolysis, access complications (vascular and nerve injury), bleeding, valve injury, ventricular arrhythmia, device dislodgement, thrombosis | | | Vascular injury, thromboembolism, cardiac perforation, hemolysis | Thromboembolism or air embolism, bleeding, hemolysis, arrhythmias | Vascular injury, hemolysis, thromboembolism, Harlequin syndrome, increase in LV pressure. |
| Additional considerations | ECG/pulse-dependent, easy to insert and adjust, cath lab not mandatory, increases coronary flow | Impella CP proved to decrease all-cause mortality in STEMI-related cardiogenic shock. Impella 5.5 features Smart Assist technology for remote monitoring and real-time hemodynamic parameter calculation. Its tip lacks a pigtail shape, reducing thrombus accumulation risk and enabling longer implant duration. Enables ambulation. | | | Transseptal puncture required | Allows for patient mobility, possible minimally invasive insertion technique | Bedside insertion, full circulatory support even in resuscitation situations, may require strategies to decompress the LV |

## Durable MCS (dMCS)

Duration: **months to years**

Examples:

- HeartMate 3 LVAD
- Jarvik 2000
- Berlin Heart EXCOR
- Total Artificial Heart

Clinical roles:

- Bridge to transplant (BTT)
- Bridge to candidacy (BTC)
- Destination therapy (DT)

| Device characteristics | Durable Mechanical Circulatory Support | | | | | |
|---|---|---|---|---|---|---|
| | HeartMate 3 (Abbott®, Illinois, USA) | HeartWare HVAD (Medtronic®, Minneapolis, USA) | Jarvik 2000 (Jarvik Heart® Inc., NY, USA) | EXCOR® (Berlin Heart GmbH, Berlin, Germany) | TAH (SynCardia® Systems, LLC, Tucson, USA) | Aeson® (Carmat TAH, Vélizy-Villacoublay, France) |
| Ventricular support | LV[a] | LV[a] | LV | BiV, LV or RV[a] | BiV | BiV |
| Placement | Inflow: LV apex Outflow: ascending Ao | Inflow: LV apex; Outflow: ascending Ao | Inflow: LV apex; Outflow: descending Ao | Inflow: LV apex or RA Outflow: ascending Ao or pulmonary artery | Replaces both ventricles | Replaces both ventricles |
| Hemodynamic support (L/min) | Up to 10 | Up to 10 | Up to 7 | Up to 6.5 | Up to 9.5 | Up to 9.5 |
| Mechanism of action | Intracorporeal fully magnetically levitated continuous flow centrifugal pump | Intracorporeal magnetic and hydrodynamic levitated continuous flow centrifugal pump | Intracorporeal continuous flow axial pump | Paracorporeal, pneumatic pulsatile flow pump | Intracorporeal pneumatic pulsatile flow pump | Intracorporeal biocompatible, sensor-based autoregulated pulsatile flow pump |
| LV unloading | Yes | Yes | Yes | Yes | N/A | N/A |
| Systemic anticoagulation | Yes | Yes + Aspirin 100 mg OD | Yes + Aspirin 100 mg OD | Yes + Aspirin 100 mg OD | Yes | Low dose anticoagulation + Aspirin 100 mg OD |
| Durability of support | Years | Years | Years | Months | Months to years | Months to years |
| Major specific contraindications | Inability to tolerate anticoagulation, right heart failure | | | Inability to tolerate anticoagulation, non-correctable anatomical issues | Inability to tolerate anticoagulation, body size incompatibility | Body size incompatibility |
| Main complications | RV failure, device failure, stroke, driveline infection, gastrointestinal bleeding | Ischemic and hemorrhagic stroke, RV failure, device failure, pump thrombosis, driveline infection, gastrointestinal bleeding | Pump failure, thrombosis, bleeding, endocarditis, driveline infection, neurological events, gastrointestinal bleeding | Thrombosis, stroke, infection, bleeding, device malfunction, limited mobility | Neurologic events, thrombosis, bleeding, driveline infection, device malfunction, renal or liver failure | Driveline infection, atelectasis left lower lobe, device-related complications, renal/liver failure |
| Additional considerations | Current standard of care for advanced HF; reduced thrombotic and hemolytic complications compared to earlier devices | Recently discontinued but still in use in many patients | The power cable for the pump exits through the retroauricular region reducing the risk of driveline infection | Currently, the only VAD specifically designed and approved for the pediatric population in the USA, Europe, and Canada. | The only TAH to receive full FDA approval; 2 sizes according to body surface area (50cc and 70 cc). | Bioprosthetic materials. Commercially available in Europe only. |

# Main Clinical Indications

## Cardiogenic Shock

**Common etiologies:**

- Acute myocardial infarction
- Acute decompensated HF
- Myocarditis
- Post-cardiotomy shock
- Refractory arrhythmias

**Objectives of MCS:**

- Restore systemic perfusion
- Reduce ventricular workload
- Improve end-organ function

## Advanced Chronic Heart Failure

**Consider MCS in patients with:**

- NYHA class IIIB–IV
- Inotrope dependence
- Recurrent HF hospitalizations
- Progressive organ dysfunction

# MCS Strategies in Transplant Candidates

**Three main strategies**

- **Bridge to Transplant (BTT)**
  - ✓ Stabilizes patients awaiting a donor heart
  - ✓ LVAD frequently used

- **Bridge to Candidacy (BTC)**

Used to improve transplant eligibility by correcting:

  - ✓ Pulmonary hypertension
  - ✓ Renal dysfunction
  - ✓ Frailty or malnutrition

- **Destination Therapy (DT)**

For patients **not eligible for transplant**

  - ✓ Durable LVAD becomes **permanent therapy**

## Impact on Post-Transplant Outcomes

- The type of MCS influences transplant outcomes
- Key observations:
- **Durable LVAD bridging** → better post-transplant survival
- **Temporary support (ECMO)** → higher early mortality and complications
- **Impella 5.5** → promising results as bridge to transplant
- Reasons:
✓ improved hemodynamic stabilization
✓ better patient conditioning before transplant

## Impact on Transplant Allocation Systems

- Modern allocation systems prioritize **sicker patients**, often those on **temporary MCS**
- Examples:
- Spain
- Eurotransplant
- United States (UNOS system)

Consequences:
- Increased use of **temporary MCS as bridge to transplant**
- Reduced use of durable LVAD as primary bridge

- This raises important **ethical and resource allocation issues**

# Take - Home Messages

1) Mechanical circulatory support is now a **cornerstone in advanced HF management**
2) MCS plays a **central role** in:
- cardiogenic shock
- transplant candidate optimization
- long-term HF therapy

3) Device selection must be **individualized, based on**:
- clinical severity
- hemodynamics
- transplant eligibility
- institutional expertise

4) **Future developments** aim to improve:
- device durability
- hemocompatibility
- patient mobility
- physiologic circulatory support

**MCS is transforming the treatment paradigm of advanced heart failure**

سدرة للطب
Sidra Medicine

# MERCI