ISHLT JOURNAL WATCH
MCS PEDIATRICS. JUNE '21

Shahnawaz Amdani, MD
Cleveland Clinic Children's, Cleveland, OH, USA

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Hepatorenal dysfunction assessment with the Model for End-Stage Liver Disease Excluding INR score predicts worse survival after heart transplant in pediatric Fontan patients

Amdani et al. The Journal of Thoracic and Cardiovascular Surgery, February 2021

STUDY HIGHLIGHTS

Does an easily calculated objective marker of hepato-renal dysfunction, the MELD-XI, identify Fontan patients at increased risk for post-heart transplant mortality?

Pediatric Fontan patients undergoing heart transplant from 2005-2018 included

MELD-XI calculated in 421 patients at listing & 524 at transplant

High MELD-XI cohort; score ≥ 11.5

Low MELD-XI cohort; score <11.5

Pre-transplant High MELD-XI cohort more likely to have:

- Brain natriuretic peptide
- Mechanical ventilation, ECMO and VAD use
- Mean Fontan pressures
- Pulmonary capillary wedge pressures

Post-transplant High MELD-XI cohort more likely to have:

- 1 year survival
- 5 year survival

VAD use and post-heart transplant outcomes in Fontan

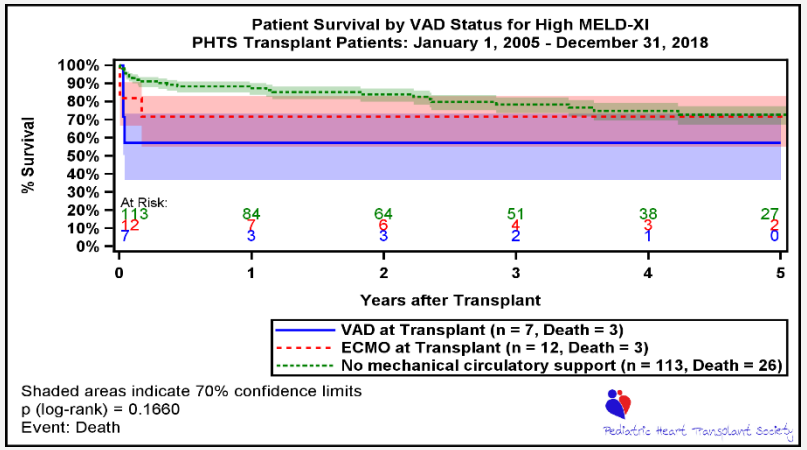
VAD utilized in 29 Fontan patients at heart transplant

VAD type	Fontan patients supported with device N (%)
Implantable continuous	11 (37.9)
Paracorporeal pulsatile	10 (34.5)
Paracorporeal continuous	5 (17.2)
Implantable pulsatile	1 (3.5)
Temporary	1 (3.5)

VAD use improved MELD-XI in Fontan patients:

	in MELD-XI scores N=30	improvement in MELD-XI scores N=95	p-value
VAD	6 (20)	6 (6.3)	0.04*
No VAD	24 (80)	89 (93.7)	

Once MELD-XI high no bridging strategy superior



REVIEWER'S COMMENTS

VAD implantation may reverse hepato-renal dysfunction in Fontan patients with heart failure

VAD implantation in a Fontan patient, once advanced hepato-renal dysfunction is present may not improve post-transplant outcomes

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Neha Bansal, MD
Children's Hospital at Montefiore, Bronx, NY USA

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Early experience with the HeartMate 3 continuous flow ventricular assist device in pediatric patients and patients with congenital heart disease: A multicenter registry analysis

O'Connor et al. The Journal of Heart and Lung Transplantation, June 2020

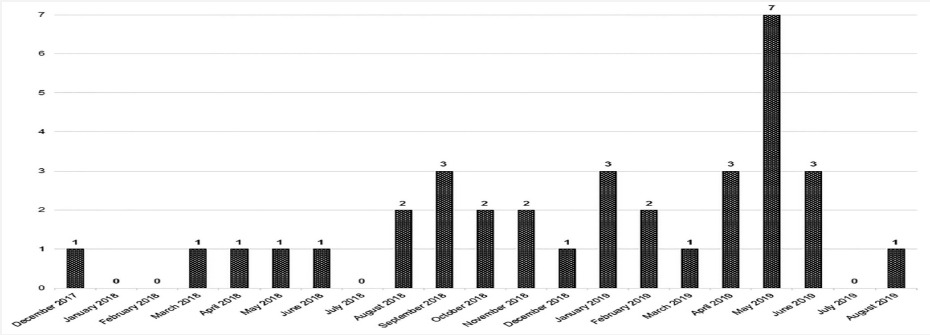
STUDY HIGHLIGHTS

-Initial experience of use of the HM3 in children and older patients with CHD at ACTION centers
-ACTION - multicenter learning network of pediatric hospitals actively involved in the implantation and management of VADs in children & adults with CHD

35 HM3 in 35 patients from ACTION registry

Characteristic	n (%) or median(range)
Age, years	15.7 (8.8–47.3)
Female gender	10 (29%)
BSA	1.74 (0.78–2.36)
Weight, kg	65.7 (19.1–114.1)
Dilated cardiomyopathy	22 (63%)
Dilated cardiomyopathy with neuromuscular disease	7 (20%)
Fontan circulation	5 (14%)
INTERMACS profile 1	1 4 (11%)
INTERMACS profile 2	2 17 (49%)

HM3 utilization in pediatric patients



Post-Operative Course and Adverse Events

Characteristic	n (%) or median(range)
Median number of device days	78 (2–646)
Median hospital LOS	29.5 (2–170) (34 patients)
Discharged on device	20/35 (57.1%); median LOS 30.5 days (8–137)
Pump thrombosis/Stroke	0 (0%)
Bleeding	4 (11.4%)
Driveline infection	4 (11.4%)
Right heart failure	7 (20%)
Arrhythmia	3 (8.6%)

Anticoagulation used

Medication	n (%)
Unfractionated heparin	28 (77.8%)
Low-molecular-weight heparin	4 (11.1%)
Bivalirudin	8 (22.2%)
Warfarin	31 (86.1%)
Aspirin	34 (94.4%)

- First experience of HM3 in Peds and CHD
- Favorable outcomes
  Low adverse events
- Smallest pt 19.1 kg, BSA 0.78 m2.
- Destination therapy in the neuromuscular patient cohort
- These and supplemental data (not included here) led to FDA approval for Pediatric pts in 2020

FDA APPROVED

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KYLE HOPE, MD
Texas Children's Hospital, Houston, TX USA

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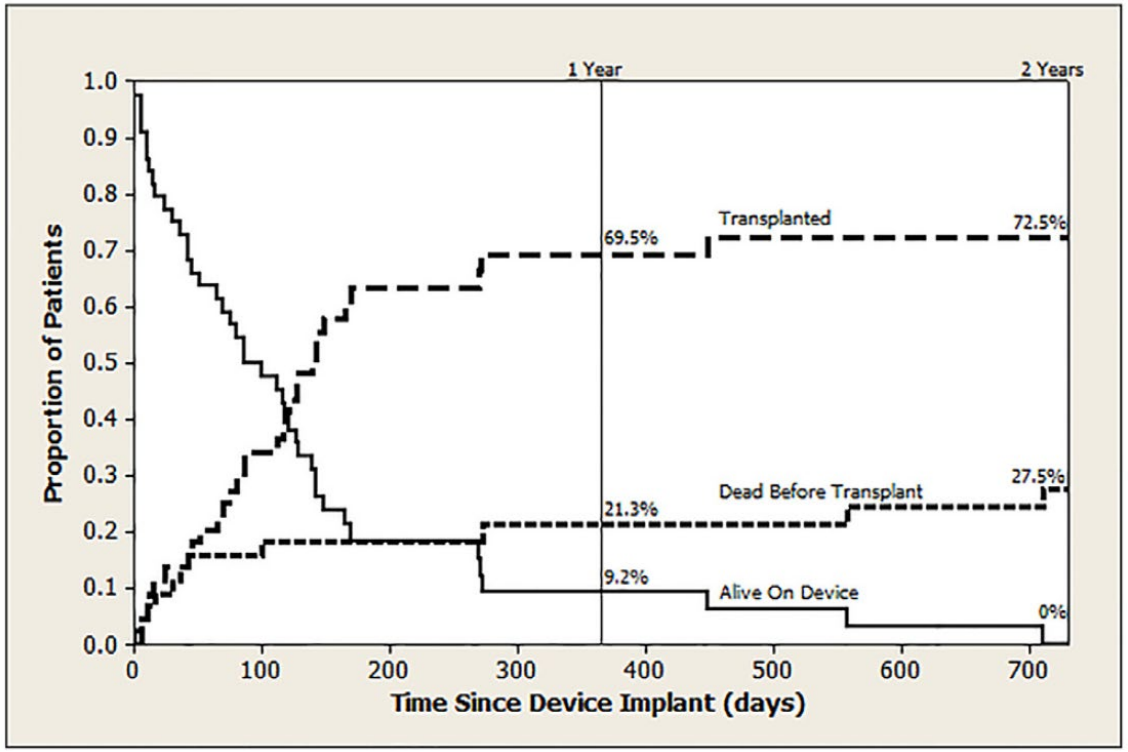
Systemic Ventricular Assist Device Support in Fontan Patients: A Report by ACTION.

Cedars et al. The Journal of Heart and Lung Transplantation, May 2021

STUDY HIGHLIGHTS

- Heart failure in patients with Fontan palliation is increasing in prevalence as this cohort ages and short-term survival through childhood improves
- Data characterizing VAD support in these patients is limited to case reports
- In the ACTION registry, 45 individuals had undergone a Fontan palliation followed by VAD
- Most patients were INTERMACS profile 1 (11/45, 25%) or 2 (24/45, 56%) at time of VAD implant
- These patients predominantly had morphologic right ventricles (31/45, 69%) with severely depressed function (29/42, 69%)
- Majority of patients were supported by the Medtronic HeartWare HVAD (25/45, 56%)
- Thirteen patients (29%) were able to be discharged following VAD implant
- Adverse events were common: 31 of 45 patients (69%) experienced at least 1 adverse event
- Most common adverse events were neurologic events (21/45, 47%), major bleeding (19/45, 42%), and infection (17/45, 38%), with 50% of adverse events taking place within the first 30 days

CENTRAL FIGURE



Competing outcomes analysis depicting time to death, transplantation, or continued device support for patient with Fontan palliation followed by VAD placement

ACTION: Advanced Cardiac Therapies Improving Outcomes Network
INTERMACS: Interagency Registry for Mechanically Assisted Circulatory Support

REVIEWER'S COMMENTS

- Largest study to date of VAD support in a patient population with unique physiologic considerations
- Even with most patients possessing high acuity (INTERMACS 1-2) at time of implant, the majority of patients were able to be successfully bridged to transplant
- Adverse events while on support are unfortunately common in this population

LIMITATIONS:

- Small, heterogeneous patient cohort even with multicenter registry data
- Multivariate modeling unable to be performed to help better elucidate predictors of death, adverse events, successful support
- Minority of patients had hemodynamic data while on VAD support