The Impella Experience in Pediatrics

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DISCLOSURES

• No relevant financial disclosures

• I will be discussing the off-label use of devices

• I will not be discussing the Impella RP today





Background

Past

Present

Future

CARDIOGENIC SHOCK

- Children with acute decompensated heart failure account for 6% of admissions to pediatric CICU's
- ECMO: standard of care for short term MCS
 - 50% of children supported with ECMO die prior to hospital discharge

Lasa, *Circ HF* 2020 Paden, *ASAIO* 2013



IMPELLA

- Percutaneous implanted ventricular assist device
- Continuous flow device
- Uses an external power supply and purge system
- Provides <u>hemodynamic support</u> and <u>unloading</u>



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DEVICE TYPES

Device Type	Cardiac Output	Primary Method of Insertion
2.5	2.5 L/min	Percutaneous
СР	4.3 L/min	
5.0	5.0 L/min	Surgical Arteriotomy
5.5	6.0 L/min	



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PEDIATRIC EXPERIENCE: 2009-2015

Median age: 16yrs (4-21) Median weight: 62 kg (15-134) CHD Diagnosis N=11 (28%)

Impella Device Type

- 2.5 N=15 (38%)
- CP N=19 (49%)
- 5.0 N=5 (13%)



PEDIATRIC EXPERIENCE: INDICATION





PEDIATRIC EXPERIENCE: 2009-2015

Median support time: 45 hrs

• 6 patients > 10 days

Major adverse events

- Hemolysis (N=3)
- Access Related (N=2)
- Bleeding (N=2)
- Device Malfunction (N=1)
- Infection (N=1)

Device repositioning: 38%

Dimas, *CCI* 2017

PEDIATRIC EXPERIENCE: OUTCOMES

- 7 day survival: 85%
- 30 day survival: 68%





ACTION DATA: 2014-2021





ACTION DATA: 2014-2021

- 15 pediatric centers
- 47 patients/52 devices
 - Excluded patients on ECMO

Patient Characteristics	N=47
Age (years)	16 (6-34)
Weight (kg)	62 (29-124)
INTERMACS Category N (%)	N=45
1	20 (43)
2	20 (43)
3	4 (9)
Inotropes at 7 days peri-implant	
1	10 (21)
2	21 (45)
3	13 (26)
Ventilator Support N (%)	21 (45)
Prior Cardiac Operation	28 (60)



ACTION DATA: SUPPORT STRATEGY





DEVICE CHOICE

Device Type	Count and Percentage	Duration of Support (days) Median (range)
2.5	N=1, 2%	4 (3-5)
CP	N=33, 64%	5.5 (0-116)
5.0	N=9,17%	21.5 (8-143)
5.5	N=9,17%	27 (6-64)



OUTCOMES

- No neurologic events
- Adverse Events: Hemolysis (39%), Major bleeding (15%), Device malfunction (15%), Arterial thrombus (14%)
- Outcomes: <u>77% survived to explant and 8% alive on device</u>
 → 36% transplanted



IMPELLA AS A BRIDGE TO TRANSPLANT

- 14 yo m w/DCM and LQT
 - 2019: central ECMO, ICD placement
 - 2021: represented with worsening heart failure→ ventricular arrythmias→ ECMO and Impella 5.5
- Impella support 76 days → transplant

Transinnominate Impella 5.5 insertion as a bridge to transplantation in a pediatric patient in refractory cardiogenic shock

Ismail Bouhout, MD, PhD,^a Stephanie N. Nguyen, MD,^a Oliver M. Barry, MD,^b Emile A. Bacha, MD,^a and Andrew B. Goldstone, MD, PhD,^a New York, NY

JTCVS Techniques





WHAT WE KNOW

- Impella is an effective tool for treating cardiogenic shock in pediatric patients
- Major issues: hemolysis, positioning, access sites
- Impella 5.0 and 5.5 are emerging as effective methods for bridging certain pediatric patients to heart transplant



FUTURE DIRECTIONS: ECMELLA

Circulation

ORIGINAL RESEARCH ARTICLE

Left Ventricular Unloading Is Associated With Lower Mortality in Patients With Cardiogenic Shock Treated With Venoarterial Extracorporeal Membrane Oxygenation Results From an International, Multicenter Cohort Study

Schrage, Circ 2020



FUTURE DIRECTIONS ECMELLA



Schrage, Circ 2020



FUTURE DIRECTIONS: DISCHARCHABLE DEVICE

Impella BTR

- Dischargeable device
- >6.0 L/min
- Intended to provide up to 1 yr of support

Initial Study

- 10 adult patients, 5 centers
- First patient recently implanted at Northwestern





Management of cardiogenic shock

Bridge to transplant

Study of ECMELLA, Dischargeable device

THANK YOU



