Society of Thoracic Surgeons

Intermacs/Pedimacs User Group Webinar

September 29, 2021
The Intermacs Data Warehouse Team

Patricia Potter: Intermacs Data Warehouse Quality RN

Jeanne Anne Love: Intermacs Data Warehouse, Patient Management Director and Data Quality advisor

Ryan Cantor, PhD, Statistician, Director of Reporting, Intermacs DCC

Rama Rudraraju, PhD, Director of Programming

Maceo Cleggett: Clinical Data Analyst, Intermacs DCC

John Pennington: Senior Data Manager, Intermacs DCC
Pedimacs Monthly Webinar

• Welcome and Introductions
•STS Updates
•AQO 2021
•Dr. Awais Ashfaq
•User Feedback
Covid -19 Update

• Tele visits encouraged
• QOL surveys may been done over the phone or by mail
• If follow-up visits are done outside of the visit window, please enter the last date of the follow-up date visit into the database
• Sites have 30 days after the follow-up window due date to enter the data for the C-19 exception
Contact Information
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Database Operational Questions
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Resources

- **STS National Database Webpage**
- **Intermacs and Pedimacs Webpage** (All things Intermacs and Pedimacs, Database user guides, Data collection forms, QOL surveys, FAQs, V 6 Training Video, Research opportunities)
- **Intermacs-reports@uabmc.edu** (Reporting questions, Uploader, DQR, Missing Variable, Dashboard, Password and Login)
- **Updated Participant Contact Form**
- **DQ Report Validation Form**
Upcoming Intermacs Webinars

User Group Webinar

• October 27th @ 1pm CT

Dashboard Analytics and Updated Adverse Events

• TBD
Pediatric mechanical circulatory support

Pedimacs User Group Webinar

Awais Ashfaq MD
Assistant Professor, Congenital Cardiac Surgery
Things To be discussed today

• Indications
• Temporary VAD
• Durable VAD
• BiVAD

• Will not discuss ECMO
Indications

- Cardiomyopathy / Myocarditis
- Malignant arrhythmia
- Postcardiotomy
  - Failure to wean from bypass or postoperative cardiac arrest
- Single ventricles
  - Failing Fontans
- Transplant associated vasculopathy
  - Retransplant
Temporary support

• Postoperative
  – Failure to wean from bypass
  – Bridging between different forms of mechanical support
  – Temporary right ventricle support (RVAD)

• Low cardiac output state (potential for recovery)
  – Myocarditis
  – Cardiomyopathy
  – Transplant related
Centrimag (Thoratec Corp, Pleasanton, MA)

- No size restriction
- Duration of support – days to weeks
- Univentricular or biventricular
- Continuous pump flow
Rotaflow (MAQUET Medical Systems, Wayne, NJ)

- No size restriction
- Duration of support – days to weeks
- Univentricular or biventricular
- Continuous pump flow
TandemHeart (Cardiac Assist, Inc, Pittsburg, PA)

- Percutaneous
- Duration of support – days
- Univentricular
- Continuous flow
- Size based on access
Impella (Abiomed Inc, Danvers, MA)

- Different pump sizes
  - 2.5, RP, 3.0, 3.5 and 5.0
- Duration of support – days
- Univentricular
- Continuous
Durable support
Berlin Heart EXCOR (Berlin Heart, Inc, Berlin, Germany)

- Weight > 3 kg
- Duration of support in years
- Uni or biventricular
- Pulsatile flow
- Labeled for children
Driver (IKUS) - Console

- IKUS control the Berlin pump
- Houses compressors and pressure/suction regulators
- 30 min battery
- Hand pump (loss of power)
- 220 pounds
Prospective Trial of a Pediatric Ventricular Assist Device (Fraser et al. NEJM)

- Primary end point
  - time to death
  - Weaning from device with an unacceptable neurologic outcome
• Four outcomes were tracked
  – Death
  – Heart transplantation
  – Weaning from device (dying or neurologic outcome within 30 days)
  – Weaning from device with outcomes as above

• Survival rates significantly higher with VAD vs ECMO

• Serious adverse events occurred in majority of patients
Berlin Heart EXCOR and ACTION post-approval surveillance study report (Zafar et al. JHLT)
HeartWare HVAD (HeartWare Inc, Framingham, MA)

- Weight > 15 kg
- Years of support
- Uni or biventricular
- Continuous flow
Medtronic Stops Distribution and Sale of HeartWare HVAD System Due to Risk of Neurological Adverse Events, Mortality, and Potential Failure to Restart

The recall described in this notice is the same one that was announced in the Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers on June 3, 2021.

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

The recall described in this notice is the same one that was announced in the Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers on June 3, 2021.
Heartmate III (Thoratec Lab Corp, Pleasanton, CA)

- Most widely used VAD pump
- BSA > 1.3 (have been used for smaller)
- Years of support
- Uni or biventricular
- Continuous flow
• The primary end point - composite of survival free of disabling stroke or reoperation to replace or remove a malfunctioning device at 24 months after implantation.

• A fully magnetically levitated centrifugal-flow left ventricular assist device was associated with less frequent need for pump replacement.

• Superior with respect to survival free of disabling stroke or reoperation to replace or remove a malfunctioning device.
Syncardia TAH (Syncardia Systems, Inc, Tucson, AZ)

- 50cc and 100 cc pump
- Years of support
- Biventricular
- Pulsatile
70CC TAH

Device Selection Criteria

Patients with a T10 measurement* ≥ 10 cm. Patients supported by the 70cc TAH typically have a body surface area (BSA) ≥ 1.7m².

Approvals & Clinical Studies

- Bridge to Transplant
- Destination Therapy
  - Undergoing an FDA clinical trial in the U.S.

*posterior sternum to anterior spine measurement at T10

50CC TAH

Device Selection Criteria

Patients with adequate T10 measurement* or adequate room in the chest as determined by 3D imaging assessment or by other standard clinical assessments. The 50cc TAH is intended to support patients with a BSA ≤ 1.85m².

Approvals

- Bridge to Transplant
  - Approved in Europe (2014), Canada (2016), and the U.S. (2020)

*posterior sternum to anterior spine measurement at T10
Jarvik (jarvik Heart Inc, New York, NY)

- Smallest pump
- 3-15 kg
- Univentricular
- Pump for kids, infants and neonates - PUMPKIN trial (ongoing)
Thank you
Open Discussion

Please use the Q&A Function.

We will answer as many questions as possible.

We encourage your feedback and want to hear from you!
THANK YOU FOR JOINING!