ISHLT2023 Roving Reporters – Reports from Mechanical Circulatory Support (MCS)

- **Wednesday, 19 April, 2023**
  - SESSION 11 (SYMPOSIUM). A Mile High in Denver: Elevating Our Understanding and Management of Pediatric and Adult MCS Infections
  - SESSION 15 (SYMPOSIUM). La Vida Loca: Expanding the Heart Donor Pool with DCD – Pearls and Pitfalls
  - SESSION 19 (ORAL). A Short Bridge to Heart Transplantation: Are We Building it Right?
  - MINI ORAL 05. After the Dust Settles: Long-Term MCS Outcomes
- **Thursday, 20 April, 2023**
  - SESSION 29 (SYMPOSIUM). The Right MCS Devices for the Right Patients
  - SESSION 37 (SYMPOSIUM). I Spy With My Little Eye: Multimodal Imaging in Durable Mechanical Circulatory Support
  - SESSION 43 (SYMPOSIUM). Would You Rather: Choices at the End of the Shock Road
  - SESSION 48 (ORAL). Sex, Race and Social Determinants of Health in MCS Care
- **Friday, 21 April, 2023**
  - SESSION 58 (SYMPOSIUM). For All Ages: MCS Support in Congenital Heart Disease in Children and Adults
  - SESSION 78 (SYMPOSIUM). Acute Mechanical Circulatory Support: Guidelines, Consensus and Practical Issues
  - SESSION 63 (ORAL). How Long is My Bridge? ECMO and Durable VAD Outcomes
  - SESSION 69 (ORAL). MCS: Bleeding and Clotting – We Just Can't Win!
  - SESSION 76 (ORAL). Spotlight on Nursing and Allied Health MCS Intervention Science
- **Saturday, 22 April, 2023**
  - SESSION 87 (ORAL). Durable MCS: Staying Alive!
  - SESSION 96 (ORAL). Unbreak My Heart: Recovery and Weaning in MCS Patients

Thank you to all of our ISHLT2023 Roving Reporters.

ADVANCED HEART FAILURE AND TRANSPLANTATION (AHFTX)

Jason Goldberg, MD, MS, Inova LJ Murphy Children's Hospital, Fairfax, VA USA
Luise Holzhauser, MD, University of Pennsylvania, Philadelphia, PA USA
Pei Jun Zhao, MD, MPH, London Health Sciences Centre / Western University, London, ON Canada

ADVANCED LUNG FAILURE AND TRANSPLANTATION (ALFTX)

Lourdes Chacon Alberty, MD, MCTM, Texas Heart Institute, Houston, TX USA
Rebecca Klingbeil, MSN, DNP, CRNA, Mayo Clinic, Jacksonville, FL USA

MECHANICAL CIRCULATORY SUPPORT (MCS)

Anju Bhardwaj, MD, University of Texas / McGovern Medical School, Houston, TX USA
Anjan Tibrewala, MD, Northwestern University, Chicago, IL USA

PULMONARY VASCULAR DISEASE (PVD)

Nancy Luo, MD, MHS, Sutter Health, Sacramento, CA USA

SESSION 11. A Mile High in Denver: Elevating Our Understanding and Management of Pediatric and Adult MCS Infections

In this session, we saw updated mechanical circulatory support (MCS) device infection definitions, considerations for pediatric patients, and discussion of medical and surgical treatments for device-related infections. This session was co-chaired by **Stephanie Pouch, MD, MS** of Emory University in Atlanta, and **Lara Danziger-Isakov, MD** of Cincinnati Children's Hospital Medical Center.

The opening presentation was titled "**Name that Infection: 2023 ISHLT Definitions for Infections of Mechanical Circulatory Support Devices**", and was given by **Ezequiel Molina, MD** of Piedmont Heart Institute/Samsky Advanced Heart Failure Center in Atlanta. The presentation provided an overview of the background and content of the soon to be published consensus document sponsored by the MCS Interdisciplinary Network of ISHLT. Given (1) various non-standardized definitions for infections by different medical societies, (2) newer durable ventricular assist devices (VAD) without a pump pocket, and (3) increased utilization of acute temporary MCS, the writing committee sought to develop an updated and standardized approach to the discussion of infection related to durable and temporary MCS. Notably, recommendations on management are beyond the scope of this consensus document.

The following presentation was given by **Scott Auerbach, MD** of the University of Colorado in Denver, and titled "**Tiny Humans, Big Devices: Incidence and Impact of Infections in Pediatric MCS**." He highlighted the heterogenous nature of pediatric MCS patients based on variability in the patients (age, size, underlying diagnosis including congenital malformations) and device type (temporary vs durable, paracorporeal vs intracorporeal) and patient. Based on Pedimacs and the ACTION Registry, infections affect ~25-30% of pediatric durable MCS patients, typically occurring early after implant and not directly related to the pump. These infections adversely affect survival while on VAD support, but do not significantly affect post-transplant outcomes.

The subsequent talk was "**Make It Go Away: Lotions, Potions, and Phages**," given by **Saima Aslam, MD, MS**, from the University of California San Diego. During this presentation, she focused on the potential that phages may eventually have in the treatment of MCS-related infections. Phages are viruses that can infect and lead to lysis of bacterial cells without affecting human cells. In her work, phages have been used in intravenous and/or topical formulations for VAD patients and have been more effective in treating localized infections. Challenges with phage treatment of bloodstream infections may include ineffective bacterial serum neutralization, prophage mediated defense, and/or changes in antibiotic susceptibility patterns. Phages may soon be considered for a compassionate use indication if approved by the Food and Drug Administration, but a larger clinical trial is needed in the future.

The closing presentation was given by **Ivan Knezevic, MD, PhD** of University Medical Centre in Ljubljana, Slovenia and titled "**All It Takes is a Knife: Surgical Perspective on VAD Infections**." He discussed the surgical role in both the prevention and treatment of VAD-related infections. His

suggestions for preventing VAD infections include consideration of less invasive approaches, shortening surgical time, limited personnel in operating room, and maintaining glycemic control and normothermia. Surgical approaches to treatment of infection are based on infectious pathogen, location, duration, and device strategy including possible bridge to transplant.

VIEW SESSION DETAILS

– Commentary by Anjan Tibrewala, MD

SESSION 15. La Vida Loca: Expanding the Heart Donor Pool with DCD – Pearls and Pitfalls

This session opened with considerations for donation after circulatory death (DCD) in the context of heart transplantation. The session concluded with a debate on normothermic regional perfusion versus direct procurement and perfusion for DCD heart transplant. The session co-chairs were **Amy Fiedler, MD**, of University of California San Francisco; **Are Holm, MD**, PhD, of Oslo University Hospital; and Gerin Stevens, MD, PhD, of Northwell Health in New York.

The opening presentation was titled "**Rolling the Dice: How to Start a DCD Heart Transplant Program**," given by **Andreas Zuckermann, MD** of Medical University of Vienna. He gave the audience practical guidance on how to develop a DCD program, and highlighted the following steps:

1. Understand the rules and laws for DCD applicable to your center. For certain countries, developing a National Consensus Document could be helpful.
2. Learn from experiences of abdominal and lung transplant teams.
3. Use a collaborative approach, particularly including ICU and Anesthesiology teams.
4. Understand the rules for procurement.
5. Establish donor selection criteria for your center.

As centers complete the requisite preliminary steps, it is essential to implement and train a core group of personnel that form a DCD team.

The next presentation was "**Playing One's Hand: Donor and Recipient Selection for DCD**," by **Emily Granger, MBBS** of St. Vincent's Hospital in Sydney, Australia. She focused on donor selection for DCD heart transplant in the context of direct procurement and perfusion. In assessment of a donor, she highlighted:

1. Presence of brainstem reflexes.
2. Ventilatory requirement.
3. ICU team assessment of donor's likelihood to progress to circulatory death following withdrawal of life support.

As a donor progresses to circulatory death, assessment of contractility, rhythm, and biomarkers including lactate are important. Furthermore, limiting warm ischemic time can improve outcomes. Specifics including targeting ⩽30 minutes from SBP ⩽ 90mmHg to cardioplegia and ⩽15 minutes from asystole to cardioplegia.

The next presentation was given by **Arne Neyrinck, MD, PhD** of Leuven University Hospitals in Leuven, Belgium and called "**Keeping Your Cards Close: Selecting and Prognosticating the DCD Donor**." Dr. Neyrinck discussed the importance of (1) recognizing futility, (2) predicting the agonal phase (i.e., warm ischemic time), (3) steps for withdrawal of life support. Futility describes when an ICU patient will not have a meaningful recovery. An ICU decision process should form a consensus of futility and takes a median of ~4 days. Accurately predicting the agonal phase based

on ventilatory, hemodynamic, and neurologic criteria is essential for eligibility of DCD donation. Although prognostic tools exist, ICU specialists have been shown to be up to 80% accurate in predicting progression to circulatory death. Withdrawal of life support should be intentional and sequential. The presenter concluded by highlighting the importance of combining donation after brain death (DBD) and DCD into a unified definition of death in the context of organ donation.

In the debate that concluded the session, **Ashish Shah, MD** of Vanderbilt University and **Andreas Zuckermann, MD**, advocated for normothermic regional perfusion (NRP) whereas **Are Holm, MD, PhD**, and Emily Granger, MBBS, debated for direct procurement and perfusion (DPP).

The arguments in favor of NRP included:

- similar post-transplant survival rates compared to DPP
- increased utilization and improved outcomes in liver and kidney transplant
- potentially increased heart organ donation and allocation
- improved cost effectiveness

The arguments in favor of DPP included:

- irreversibility of death
- improved resource efficiency
- better feasibility in systems of care
- less technically challenging
- increased lung allocation

As evidenced by the back-and-forth during the session on the timely topic, more data and experience will be necessary to reach more definite conclusions.

VIEW SESSION DETAILS

– Commentary by Anjan Tibrewala, MD

SESSION 19. A Short Bridge to Heart Transplantation: Are We Building it Right?

This session focuses on the perioperative use of short-term devices in the setting of heart transplantation, and is co-chaired by **Claudius Mahr, DO**, of the University of Washington in Seattle, and **Emil Najjar, MD, PhD**, of the Karolinska University Hospital in Stockholm.

Use of Mechanical Circulatory Support in Orthotopic Heart Transplantation: A 10 Year Analysis

Chidiebere Peter Echieh, FWACS, University of Calabar, Calabar, Nigeria

Cardiac transplantation is still the standard surgical care in medically refractory heart failure. The United Network for Organ Sharing (UNOS) was established to ensure equitable allocation of donor organs, and the UNOS policy was updated in 2018 to add more granularity by expanding the high priority class 1A to 3 classes. The aim of this change was to decrease waiting time and waitlist mortality. Early reports did suggest improved waitlist outcomes (Killic et al JAMA Cardiol, 2021). Higher priority is given to patients on non-dischargeable mechanical circulatory support, ventricular arrhythmias, and multiple or single high dose inotropes. With use of MCS, may lead to differential transplantation of acutely ill patients and may be susceptible to gaming.

The aim of this study was to evaluate trends in the frequency of use of temporary MCS-ECMO & IABP, before and after the most recent change in UNOS allocation policy, and post-transplant survival at 1000 days. Echieh et al queried UNOS database for isolated heart transplants in 2013-2022. Waitlist data was divided into 2 periods. The study analyzed for waitlist time, use of MCS, length of hospital stay, and cumulative patient survival at 1000 days. They noted that waiting times in period B was significantly lower, but length of stay was lower in period B. On sub-group analysis, status 1 had lowest waitlist time, and status 3 have longest wait list time. In terms of use of MCS, more patients on IABP were transplanted in Period B (26.1 vs 6.8%, $p < 0.001$)) and more patients on ECMO were transplanted in period B (5.8% vs 1.4%, $p< 0.001$). They also noted that cumulative survival at 1000 days was lower in patients on ECMO 85.9% vs 75.2%, $p< 0.001$) in period B.

Thereby, they concluded that there was increase in post-transplant length of stay, sicker patients were prioritized for organ transplantation. There has been a decrease in survival in Period B, which questions the judgement in prioritizing morbid candidates who may not maximize the benefit of the donor hearts. We need to prioritize improved post-transplant survival and quality of life over reducing waitlist time.

Prehabilitation Maximizing Functional Mobility in Patient with Cardiogenic Shock Supported on Axillary Impella

Anju Bhardwaj, MD, University of Texas, Houston, TX USA

Patients presenting with cardiogenic shock may require temporary MCS for stabilization and may need to be considered for advanced therapies if there is no chance for recovery. Not all patients

may qualify for transplant, and they may need durable left ventricular assist devices as a bridge to transplant or destination therapy. Biventricular failure, acute renal failure, acute liver failure, frailty, etc., are associated with poot outcomes with LVAD. Therefore, patients may need temporary MCS and normalization of end organ function.

In this single center retrospective study, 37 patients deemed indeterminate or denied for LVAD underwent rehabilitation and physical therapy while transitioned with axillary Impella using a formalized protocol. Major reasons for denial included medical condition, malnutrition, and deconditioning. The Activity Measure for Post-Acute Care (AM-PAC) Basic Mobility tool assessed the functional status at different points during admission; those data along with demographic and clinical data were collected and analyzed. Once rehabilitated, these patients underwent LVAD implantation.

Of 37 patients, 12 were INTERMACS 1, 22 were INTERMACS 2, and 3 were INTERMACS 3. All patients survived to hospital discharge and remained alive at 6 months. Post Impella, the median AM-PAC score 12.7, median scores pre LVAD was 18.4, which dropped to 15.7 on post op day 7. This improved to 18.3 post LVAD day 14. At the end of therapy, all patients were able to ambulate a median of 516 feet (IQR 225-550). There was no statistical difference between LOS (P = .44) b/w all INTERMACS. There was no complication reported.

Bhardwaj et al concluded that it is feasible to "prehabilitate" critically ill patients on MCS, who may safely participate in PT. These critically ill patients initially deemed "questionable" candidates may be rehabilitated on temporary MCS while maximizing functional activities and can get LVAD placement, with good long term outcomes. They recommended a mobility protocol for the patient supported on Impella is of benefit to maximize safety. A well-designed prospective study of ambulating on temporary MCS may provide more detailed information about treatments described in this study.

Mid-Term Survival in Patients with Advanced Heart Failure Receiving an Impella Device Intended as a Bridge to Transplantation

Rohan Goswami, MD, Mayo Clinic, Jacksonville, FL USA

Since the allocation policy change in 2018, early data shows increased use of temporary MCS, this has influenced waitlist and peri-operative events. Of 148 heart, 17 heart kidney and 2 heart liver between October 2018 and Aug 2022, 41 patients were supported with Impella 5.5 intended as bridge to transplant. No patients died or got delisted prior to organ transplantation. Of these 2 patients, developed RV failure with 1 patient getting ProTek Duo and another required ECMO. They noted that renal function improved with Impella. 24 of these 41 patients have reached the 1 year survival after transplant time frame with 96% 1 year survival. There was no need for renal replacement therapy at 1 year, nor any increased incidence of vasculopathy was noticed.

Impact of Heart Failure Etiology and ECMO on Heart Transplant Outcomes

Manuj Shah, BS, BA, The Johns Hopkins University, Baltimore, MD USA

Heart transplantation was indicated for patients with refractory advanced heart failure. Given the shortage of donors and long waitlist times, these patients may require mechanical circulatory support. Previous data shows that ECMO is associated with lower survival rates and higher morbidity. Since the allocation criteria change in 2018, ECMO use has increased from 1.7 to 6%. The team sought to assess the differential impact of ECMO on post-transplant outcomes based on underlying etiology of heart failure. All isolated heart transplants were stratified according to etiology (ischemic, DCMP, Restrictive, retransplant, congenital) and then if ECMO used or not for each etiology. They concluded that patients on ECMO were younger and spent fewer days on waiting list. Preoperative ECMO didn't increase post-transplant morbidity, but had higher risk of mortality (HR: 1.71). But restrictive and congenital patients didn't have increased mortality.

Extracorporeal Membrane Oxygenation Bridging to Orthotopic Heart Transplantation: Updated Analysis Following the 2018 Allocation Change

Nicholas Hess, MD, University of Pittsburgh, Pittsburgh, PA USA

ECMO support affords highest degree of prioritization within the current United States allocation system. Early reports have suggested trends of decreased post-transplant survival under current allocation system. So the team sought to assess outcomes of patients who are listed for heart transplant while being supported on ECMO, and patients who actually received transplant while on ECMO and compared old (May 7,2015- October 17, 2017) and new (October 18, 2018-March 31, 2021) allocation policy. They noted a marked increase in ECMO bridging to transplant. Outcomes for patients supported with ECMO have improved under the new allocation policy with increased sub-hazards for transplantation within a year, decreased sub-hazards for de-listing due to death & deterioration, and improved post-transplant survival. One year survival is now comparable to the patients not bridged with ECMO.

Waitlist and Transplant Outcomes in Heart Transplant Candidates Bridged with Temporary Right Ventricular Assist Devices

Jennie Kwon, MD, Medical University of South Carolina, Charleston, SC USA

Mechanical bridging strategies for heart transplant in the US have shifted following the 2018 change in heart allocation policy. Technological advances in devices available for temporary MCS have compounded the practice change, but there is limited regarding outcomes of patients bridged to transplant with newer endovascular temporary RVADs. The aim of this study was to describe practice trends, waitlist outcomes, and post-transplant outcomes of patients supported with temporary RVADs while awaiting heart transplant. UNOS database was analyzed. Patients who received heart transplant between January 2009 to June 2022 and were grouped into temporary RVAD on any time on waitlist vs no RVAD throughout the waitlist period. 133 waitlist candidates of 41057 (0.3%) had a temporary RVAD. They concluded that even though rare, BTT with RVAD is increasing in frequency, and may be incentivized over durable RVADs in current

allocation system deprioritizing durable LVADs. Temporary RVADs are associated with increased risk of mortality both for waitlist candidates and transplant recipients. Waitlist outcomes are particularly poor for candidates with temporary RVAD and concomitant temporary LVAD, and policy implications should be considered.

VIEW SESSION DETAILS

– Commentary by Anju Bhardwaj, MD

MINI ORAL 05. After the Dust Settles: Long-Term MCS Outcomes

In this session, several abstracts were presented in a rapid-fire format to address considerations in long-term management of LVAD patients. The session was co-chaired by **Jennifer Cowger, MD, MS**, of Henry Ford Hospitals in Detroit, and **Christopher Salerno, MD**, of the University of Chicago.

Tatsuya Watanabe, MD, PhD, of the University of Chicago, began the session by presenting "***Impact of Non-Cardiac Surgery for Patient with LVAD Support***." In 514 LVAD patients at a single center, 158 non-cardiac surgeries (ENT and General Surgery most commonly) were performed. There were relatively low rates of pump thrombosis or stroke and no cases of 30-day mortality following these surgeries.

Donna Phan, MD, MPH, of Montefiore Medical Center in New York presented "***Comparing Patients Bridged to Transplant with a Fully Levitated Left Ventricular Assist Device Before and After the UNOS/OPTN Allocation Change: An STS-Intermacs Registry Analysis***." Of 2,280 LVAD implants between 2015-21, 692 occurred before the allocation change (PRE cohort) and 1,588 occurred afterward (POST cohort). The PRE cohort was more likely to have GI bleed, stroke, or readmissions, whereas the POST cohort was less likely to receive heart transplant.

Sumita Barua, MBBS, of St. Vincent's Hospital in Sydney presented "***Major Adverse Kidney Events is a Predictor of Reduced Survival in Patients Supported with Ventricular Assist Devices***." Of 173 VAD patients at a single-center, 37 were identified as having major adverse kidney events (MAKE) defined by a drop in eGFR>50%, stage V CKD, initiation of dialysis beyond index admission, or death on dialysis. The MAKE cohort was significantly less likely to survive to heart transplantation.

Max Kilcoyne, DO, of the Medical University of South Carolina, presented "***Progression of Valvular Insufficiency with the Heartmate 3 Left Ventricular Assist Device: An Institutional Experience***." Of 103 VAD patients at a single-center, tricuspid regurgitation most commonly progressed following VAD implant. Age was a significant risk factor for progression of valvular insufficiency.

Rebecca Steinberg, MD, MSc, of Emory University in Atlanta, presented "***Associations Between Pre-Implant Cancer and Left Ventricular Assist Device Outcomes: An Intermacs Registry Analysis***." Of 18,053 VAD implants between 2007-17, 1,124 (6.2%) had history of cancer. Patients with solid tumors were at increased risk of all-cause mortality, bleeding, and pump thrombosis compared to non-cancer patients. Patients with hematologic cancers were more likely to have RV failure, major infection, and renal dysfunction compared to non-cancer patients.

Jagpreet Grewal, MD of the Medical University of South Carolina presented "***Validation of the Heartmate 3 Risk Score in a Real World Patient Cohort***." In 521 patients from 6 sites, the Heartmate 3 risk score (HM3RS) had an AUC of 0.63 to predict 1-year survival. The HM3RS also was also to discriminate between three risk profiles in the cohort.

Alice Vinogradsky, BA of Columbia University presented 3 abstracts during this session. In "***Acute Right Ventricular Dimensional Change Predicts Outcomes in Patients with Heartmate 3***," 188 VAD patients at a single-center were defined as having an non-adapted RV based on increased RV end-diastolic diameter and area following VAD implantation. In 82 patients (44%) with a non-adapted RV, 3-year mortality was significantly higher and a combined endpoint of death or readmission for RV failure was significantly more likely.

In "***Preoperative Left Ventricular Diastolic Dimension Index Predicts Outcomes after Heartmate 3 Implantation***," 252 VAD patients at a single-center were divided into LV diastolic dimension index (LVDDI) ⩽ (n=131) or > (n=121) 33.5 mm/m2. The cohort with smaller LVDDI was significantly associated with increased mortality and increased risk of a combined endpoint of death or readmission due to RV failure or stroke.

In "***Does Lateral Approach Preserve Better Right Ventricular Function After Left Ventricular Assist Device Insertion?***" 195 VAD patients at a single-center were implanted using a lateral thoracotomy (n=55) or sternotomy (n=140). Patients with lateral thoracotomy had significantly smaller RV size and better RV function at 1 month compared to sternotomy, although this difference was not significant at 1 year. There was no significant difference in all-cause mortality.

To finish the session, **Katharine Fetten, MD** of Baylor Scott and White in Dallas presented "***Comparison of Patient Characteristics and Outcomes of Left Ventricular Assist Devices before and after the Heart Transplant Allocation Change***." Of 163 VAD implants at a single center between 2015-2022, 83 were implanted before the allocation change (PRE cohort) and 80 were implanted after the allocation change (POST cohort). RV dysfunction was significantly more common in the POST cohort. There was no significant difference in post-VAD survival between cohorts.

VIEW SESSION DETAILS

– Commentary by Anjan Tibrewala, MD

SESSION 29. The Right MCS Devices for the Right Patients

In this session, HF patients presenting with cardiogenic shock (HF-CS) were discussed. Considerations of etiology, assessment of device strategy and trajectory, and management of RV dysfunction were highlighted. The co-chairs were **Maria Renedo, MD**, of the Hospital Universitario Fundación Favaloro in Buenos Aires, and **Adrian DaSilva-deAbreu, MD, MSc, PhD**, of the Mayo Clinic in Rochester.

The first presentation was titled **In the Pool of Diversity: Individualized Temporary MCS Transitions Beyond Etiologies and Phenotypes** given by **Ivan Netuka, MD, PhD**, of IKEM in Prague. HF-CS occurs in a heterogeneous patient population, of which certain characteristics were discussed. HF-CS patients with higher socioeconomic status (SES) had increased costs of care with more utilization of temporary MCS, although clinical outcomes remained similar compared to patients with lower SES. In females with HF-CS, underlying etiologies with specific management strategies include peripartum cardiomyopathy, Takotsubo syndrome, and spontaneous coronary artery dissection. Obese patients requiring temporary MCS had higher rates of vascular complications, required increased flow, and needed prolonged ventilatory support leading to increased mortality relative to less obese patients.

The following presentation was called **When Appearances are Deceptive: Phenotyping Specific Diagnoses to Target Therapy and Myocardial Recovery**, given by **Linda Van Laake, MD, PhD**, of UMC Utrecht. In considering the etiology of HF-CS, genetic cardiomyopathies remain on the differential. Understanding a patient's genotype can inform prognosis. For example, patients with pathogenic desmosome and LMNA mutation are less likely to recover whereas patients with pathogenic TTN mutation likely improve with medical therapy. Overall, characteristics of patients unlikely to recover in HF-CS include (a) history of chronic HF, (b) MI without viability, (c) non-TTN pathogenic mutations, and (d) untreated reversible causes.

The next presentation was **When Smaller Bodies Turn into Bigger Problems: What's New in MCS in the Pediatric Population?** given by **Martin Schweiger, MBA, FABS, FEBS**, of Children's Hospital Zurich. Temporary and durable MCS consideration for children are unique given patients are younger and have smaller BSA/weight compared to adults. The presenter highlighted use of a novel driving unit for a paracorporeal VAD, utilization of the Impella CP, and a specific cannula for Fontan patients requiring MCS.

The final presentation was titled **To Pulsate or Not to Pulsate: Pulsatile vs Continuous Right Ventricle Support** given by **Yaron Barac, MD, PhD**, of Rabin Medical Center in Petah Tiqva. RV failure occurs in HF-CS, RV infarct, and following LVAD or heart transplant. Severe RV dysfunction defined by: (a) RA/PW >0.86, (b) low RVSWI, and/or (c) PAPi <1.5. Current temporary MCS options for RV failure include Impella RP (Abiomed, Danvers, MA), Protek Duo (LivaNova, Eastbourne Terrace, London), Centrimag (Abbott, Abbott Park, IL), and VA ECMO. However, pulsatile devices such as Perkat RV (NovaPump, Gena, Germany) may better address preload sensitivity, increase unloading, have relatively lower PA pressures, and avoid suction. Thus, the presenter suggested a

clinical trial may be necessary to determine whether pulsatile or continuous flow devices may be better for RV failure.

VIEW SESSION DETAILS

– Commentary by Anjan Tibrewala, MD

SESSION 37. I Spy With My Little Eye: Multimodal Imaging in Durable Mechanical Circulatory Support

Three-Dimensional Virtual Anatomical Fitting of Implantable VADs for improved Clinical Outcomes

Presented by **David Morales, MD**, Cincinnati Children's Hospital, Cincinnati, OH USA

After HM2 approval in 2008, it was attempted to place them in children significantly below BSA and weight ranges, but determining fit without imaging can be erroneous, so virtual implantation is assessed prior to implant. Initially, digital age marked the first generation of virtual implantation. It was accepted by the FDA as a size criterion for the first time for a FDA study. Then the second generation was marked by virtual reality implantation. Initially it included 3D printing, followed by desktop planning, then virtual transplant in complex CHD patients. Most recently, "surgical metaverse," which is a VR collaborative network for surgical planning/consultation/mentoring. Virtual platforms will be the standard of care to determine fit criteria for VAD and TAHs so that this decision is based on an individual's and not general criteria. And they will continue to evolve and find widespread use in this field.

Utility of Intra- and Post-operative Mapping Systems and Ablation of Ventricular Arrhythmia in LVAD Patients

Presented by **Simon Pecha, MD**, University Heart and Vascular Center Hamburg, Hamburg, Germany

Ventricular arrhythmias are not infrequent in patients supported on LVAD, with different studies reporting different incidences of arrhythmias in different patients—between 18-52%. They may present as varied symptoms including palpitations, ICD shock, dyspnea, syncope, chest discomfort. Different studies have proposed different mechanisms, including apical scarring from LVAD inflow, persistent or recurrent myocardial ischemia, intrinsic arrhythmogenicity due to fibrosis, use of inotropic medications post LVAD, suction events, QTc prolongation from unloading of hearts, changes in ion channel, and gap junction regulation. Per the 12th Interagency Registry for Mechanically Assisted Circulatory support report, they are responsible for 5.1% admissions after LVAD. Per a meta-analysis, post LVAD ventricular arrhythmias are associated with increased risk of all cause mortality with pre-LVAD VA acting as a risk factor.

Treatment options include:

- Intraoperative epicardial mapping and VA ablation: studies suggest that patients with preoperative VTs who underwent perioperative cryoablation had significantly decreased post operative resource use and complications with no recurrent arrhythmias. Given early positive experience with small case series, further studies on surgical endocardial and epicardial ablation during LVAD are warranted.
- Post-operative catheter-based VA-ablation: per system review, it was noted that scar related re-entry was the predominant mechanism of VT (90.3%) and cannula related VT (19.3%). VT ablation should be considered for patients with an LVAD and recurrent VT

resulting in hemodynamic compromise and ICD shocks. There is no strong evidence that VT ablation changes mortality in this patient population, and large-scale studies are needed to explore this further.
- Left cardiac sympathetic denervation: Video-assisted thoracoscopic sympathectomy might be a surgical treatment option in patients with intractable recurrent VTs after catheter ablation of VT reentrant substrate even after minimally invasive LVAD implantation as a bail out strategy.

Role of Computed Tomography Imaging in Diagnosis and Management of LVAD Complications
Presented by **Gloria Farber, MD, PhD**, Uniklinikum Jena, Jena, Germany

Classic adverse events in LVAD patients include stroke, infection, bleeding, and mechanical complications, and early detection may improve outcomes. Computed Tomography (CT) diagnostics is quick and easy to perform and covers a wide spectrum of these complications. It has the advantages of extracardiac visualization, allowing for dynamic evaluation of valves and cardiac chambers as well as the evaluation of cannula position. Its disadvantages include no evaluation of flow, iodinated contrast, and no intraoperative use or portability. It can also be a valuable support in procedural planning, management, and monitoring. Sensitivity and specificity can be increased as a part of multimodality approach.

Anatomic Landmarks and LVAD Malposition Using Chest X-rays and Implications for Adverse Events
Presented by **Thomas Schloeglhofer, MSc**, Medical University of Vienna, Vienna, Austria

Chest x-ray pump position correlates with 3D parameters assessed by CT scans, and both are clinically useful in evaluating LVAD malposition. HVAD, HeartMate II, and HeartMate 3 cannula and pump positions are associated with LV unloading and improved clinical outcomes. Inflow cannula angle and pump position influence pump thrombosis and GI bleeds, as well as heart failure admissions. A small inflow cannula angle < 10 serves as a risk factor of ischemic stroke or worse survival after HeartMate 3 implantation, and a wide IC angle > 28 was associated with higher incidence of death or HF readmissions. Pre-operative chest x-rays help to quantify the risk of HRAEs during HM3 support, with low distance from LV to lung associated with worse HRAEs. The preoperative anatomical landmarks strongly influence the post operative pump position.

Echocardiographic Parameters for Device Optimization: A Path to Better MCS Outcomes and Recovery?
Presented by **Jerry Estep, MD,** Cleveland Clinic, Cleveland, OH USA

Long term goals of LVAD support are to reduce LV filling pressures, to augment cardiac output to improve organ dysfunction, improve quality of life, functional capacity, and projected event free survival. Device optimization is an examination based on hemodynamic parameters and pump speed setting changes to achieve an optimal hemodynamic profile to improve outcomes. Heart failure syndrome remains a top reason for readmission for patients with LVAD. It can be predominantly left sided, predominantly right sided, and both left and right sided HF. Optimal

unloading is associated with higher event free survival (p=0.05) per Simone et al. (JACC CV imaging 2018)

Clinical HF due to inadequate LV unloading while on LVAD support shows dilated V and LA enlargement, persistent secondary mitral regurgitation, systolic pulmonary artery pressure > 40 mm Hg, and elevated right atrial pressures, with mitral valve E/A peak doppler velocity > 2. The differential for partial LV unloading HF on CF LVADs include low pump speed, HTN, kinked outflow cannula, inflow cannula malposition, valvular regurgitation, or pump malfunction. Of these inflow cannula malposition related problems include HF symptoms, LVAD suction events, NSVT/palpitations, device thrombus and hemolysis, and low flow alarms. Echo helps define LVAD related Aortic regurgitation. Pump speed low enough to permit intermittent AV opening in post operative setting is a class IIB recommendation, and should only be addressed after clinically defined heart failure optimization is achieved. For RV failure, an echo ramp study can illustrate potential signs of RV failure with excessive LV unloading. Echocardiography also plays an important role in assessing myocardial recovery. Responders are patients with LVEF > 40%, LVEDD < 60 mm; partial responders are patients with absolute improvement of LVEF > 5% but not > 40%. There is a surveillance echo protocol to detect myocardial recovery.

VIEW SESSION DETAILS

– Commentary by Anju Bhardwaj, MD

SESSION 43. Would You Rather: Choices at the End of the Shock Road

In this session, presenters each advocated for a unique strategy to approach a clinical scenario in which limited information about a hypothetical recipient in cardiogenic shock and potential donor were provided. The session utilized a "Game Show" format in which the audience voted for the winning speaker. The co-chairs were **Matthew Lander, MD**, of Allegheny Health Network in Pittsburgh; **David McGiffin, MBBS, FRACS** of Alfred Health in Melbourne; and rong> of Baylor University Medical Center in Dallas.

The information about the recipient was "a previously healthy woman presents with cardiogenic shock and biventricular failure after her fifth pregnancy. She is blood group O and has 95% panel reactive antibodies (PRA). She improves with temporary mechanical circulatory support (MCS) but is unable to be weaned." The donor is "a 48-year-old male donor who died of cocaine overdose and a brief cardiac arrest. Virtual crossmatch is compatible, and angiogram is unobtainable."

The first presentation was **Transplant Her!** given by **Christopher Hayward, MD**, of St. Vincent's Hospital in Sydney. His principal argument was that heart transplant offers the best long-term outcome for this patient, including without the use of a durable ventricular assist device (VAD) as bridge-to-transplant. In fact, use of a VAD could exposure her to an increased PRA prior to a possible transplant in the future.

The next presentation was **Durable LVAD and Temporary RVAD Wean!**, given by Anna Meyer, MD, of the University of Heidelberg. She indicated that the case had a high (≥17) donor risk score, which predicts increased post-transplant mortality. In addition, the presenter inferred the patient has peripartum cardiomyopathy, which has recovery in 35-75% of patients, but also has increased graft failure and mortality following heart transplant. Thus, using a durable LVAD and temporary RVAD could acutely support the patient. Data supports weaning of the temporary RVAD while on durable LVAD support, and then potential eventual durable LVAD wean or heart transplant.

The following presentation was **Keep the Heart and Put Bivads Now!** given by **Christopher Salerno, MD**, from the University of Chicago. He indicated the using durable biventricular assist devices (BiVAD) with HeartMate III (Abbott, Abbott Park, IL, USA) was strategy by which to support and discharge the patient acutely with potential for heart transplant in the future. He referenced a patient that had BiVAD support with HeartMate III for 4.5 years and then successfully underwent heart transplant. A recent case series of 12 patients also described 18-month survival of 92%.

The final presentation was **Remove the Heart and Move on Mechanically!** given by **Francisco Arabia, MD, MBA**, of Banner University Medical Center in Phoenix. He advocated use of a Total Artificial Heart (TAH) (SynCardia, Tuscon, AZ) as a means by which to acutely support and discharge the patient with eventual plans for heart transplantation. He referenced multiple studies suggesting that 58-75% of TAH patients survived to heart transplantation albeit notable for selection bias in terms of patients being eligible for TAH and being at experienced centers.

Certain details (e.g., type and duration of temporary MCS) were left intentionally vague to promote discussion, but different scenarios were discussed in the Q&A. Furthermore, the importance of working toward myocardial recovery was emphasized during the Q&A. In the end, the audience response voted for durable LVAD and temporary RVAD as the preferred strategy for this clinical scenario.

VIEW SESSION DETAILS

– Commentary by Anjan Tibrewala, MD

SESSION 48. Sex, Race and Social Determinants of Health in MCS Care

Sex Disparities in the Use of Temporary MCS for Nonischemic Cardiogenic Shock

Presented by **Anju Bhardwaj, MD**, University of Texas, Houston, TX USA

Evidence suggests that non-ischemic cardiogenic shock (CS) is increasing in incidence compared to ischemic shock. Temporary mechanical circulatory support (MCS) devices are increasingly used to hemodynamically support patients with CS. There is limited sex-specific data on patients receiving temporary MCS for ischemic-CS. But even less is known about sex disparities in use of MCS in non-ischemic CS. The National Inpatient Sample (NIS) database 2002-2020 was queried to identify all patients with CS using the standard ICD-9 and ICD-10 codes. The utilization of percutaneous MCS—a composite of intra-aortic balloon pump, Impella, and extracorporeal membrane oxygenation (ECMO)—was compared between male and female patients using logistic regression analysis to calculate odds ratios (OR), adjusted for Elixhauser Comorbidity Index and baseline comorbidities. The yearly trend of MCS utilization was assessed using linear regression.

A total of 2,062,730 hospitalizations of CS were identified, of which 989,824 (48%) were of non-ischemic etiology. Incidence of non-ischemic shock is increasing. Of patients with non-ischemic shock, 58.7% males, 41.3% females, and higher overall incidence of non-ischemic shock was noted in males. The adjusted odds of females receiving MCS ~10.3% vs 13.9% in males (p=<0.0001) with persistently lower utilization of MCS in female patients with non-ischemic CS from 2002-2020. The data isn't granular enough to assess the etiology of shock like HFpEF, RV shock related to Pulmonary HTN, etc. Further dedicated research on nonischemic CS and MCS use with a sex-specific focus is needed to confirm these findings, improve care and ensure equitable outcomes between males and females.

Greater Burden of Biventricular Dysfunction in Female Recipients of Continuous-Flow Left Ventricular Devices

Presented by **Harveen Lamba, MD**, Baylor College of Medicine, Houston, TX USA

LVADs are disparately allocated to men, with men and women differing regarding their post implantation course. Reasons for these differences have not been well studied in the contemporary LVAD era. In this investigation, the INTERMACS database from 2008 to 2017 was queried. After excluding TAH, RVAD, and pulsatile devices, only 21% were women after propensity matching for age, etiology of HF, body surface area, co-morbidities, DT, device type, and INTERMACS 1 or 2. It was noted that women had more incidence of biventricular failure in spite of less "traditional" risk factors. Also, women experience higher morbidity and mortality, likely due to receiving VADs later in the disease course. More research is needed to understand mechanism of RHF in women, contributions to increased mortality, and barriers to early LVAD referral and implantation.

Race and Incidence of Right Heart Failure after LVAD Implantation

Presented by **Arjun Bahl, MD**, University of Washington, Seattle, WA USA

Racial disparities exist among patients with advanced heart failure. Black Americans are sicker at the time of LVAD implantation, and post-discharge outcomes are also correlated with race. When it comes to short-term outcomes after LVAD, race has not been shown to be a predictor, but data is limited. Right heart failure affects 9-24% of LVAD recipients and is associated with prolonged ICU stay and significant mortality and morbidity.

In this study, the aim was to learn if there are racial disparities in the development of acute RHF after LVAD implantation. The INTERMACS database from 2008-2017 was queried for patients implanted with primary CF-LVADs, and a propensity match score was chosen to address confounding. Early severe RHF within a month, which is a composite of death from RHF, RVAD placement, or inotropic dependency for greater than 14 days. They noted an association between race and early RHF after LVAD with higher odds in African Americans. These results increase the importance of research directed at preventing RHF after LVAD, which has a large burden of disease, and is disproportionate based on race.

Social Determinants of Health and Outcomes after Pediatric VAD Implantation
Presented by **Caroline West, MD**, University of Michigan, Ann Arbor, MI US

It was hypothesized that patients with lower SES, nonwhite race, and government insurance will have worse outcomes after LVAD. So the aim of the study was to determine whether social determinants are associated with mortality and morbidity after LVAD. Using STS and Pedimacs data, patients who underwent LVAD implantation from Oct 2012 to July 2022 were studied. Childhood opportunity index was assessed as well. Surprisingly, childhood opportunity level is not associated with survival or with patients getting transplant. White race was associated with reduced survival, with lower rates of recovery and similar rates of transplantation. White patients also had higher rates from Thrombosis. Insurance type is not associated with survival. Standardized social determinants of health measures should be included into registries.

VIEW SESSION DETAILS

– Commentary by Anju Bhardwaj, MD

SESSION 58. For All Ages: MCS Support in Congenital Heart Disease in Children and Adults

This session explored the management of pediatric and adult congenital heart disease (CHD) using temporary and durable mechanical circulatory support (MCS). The co-chairs were **David Morales, MD**, of Cincinnati Children's Hospital, and **Nathalie Roy, MD** of Boston Children's Hospital.

The initial presentation was **Use of ECMO for Acute Decompensated Heart Failure in CHD**, given by **Antonio Amodeo, MD**, of Ospedale Pediatrico Bambino Gesù in Rome. Indications for ECMO in pediatric populations include acute heart failure – cardiogenic shock (HF-CS) and inability to wean from cardiopulmonary bypass. The role of ECMO should be for short-term support as a bridge to VAD, transplant, or recovery. Interestingly, ECMO flows should be adjusted based on the underlying congenital condition to maintain an appropriate degree to cardiopulmonary perfusion.

The next presentation was called **Use of Temporary Circulatory Support for Acute Decompensated Heart Failure in CHD**, given by **Sebastian Tume, MD**, of Texas Children's Hospital in Houston. The prevalence of congenital heart disease in pediatric cardiac admissions has been increasing. CHD is associated with increased ICU stay, use of MCS, and mortality. Although ECMO remains the predominant form of MCS in children, other forms of temporary MCS are available. These include Centrimag (Abbott, Abbott Park, IL), Tandem Heart (LivaNova, London, UK), and Impella (Abiomed, Danvers, MA). However, these devices are at high risk of complications including hemolysis, extremity compromise, aortic insufficiency, and device malfunction.

The following presentation was titled **Long-Term Ventricular Assist Device Selection for CHD: From Neonates to Adults** and given by **Jennifer Conway, MD**, of the University of Alberta in Edmonton. Durable VAD therapy is only used in 2% of CHD patients being bridged to heart transplant. Options include the Heartmate 3 (Abbott, Abbott Park, IL), Total Artificial Heart (SynCardia, Tuscon, AZ), and Excor (Berlin Heart, Berlin, Germany). However, CHD VAD patients have increased risk of adverse events and mortality and lower likelihood of transplant compared to non-CHD VAD patients. Thus, improving outcomes is essential to increasing utilization of VAD in CHD patients. Strategies include refining patient selection, developing novel devices, improving surgical approaches, modifying early post-VAD management, and encouraging earlier referral to HF cardiologists.

The next presentation was **What's the Difference? Pre-VAD Implant Evaluation and Considerations for the Patient with Fontan Circulation**, given by **David Peng, MD** of the University of Michigan in Ann Arbor. As Fontan patients are increasingly surviving to adulthood, the prevalence of HF is increasing. For patients with worsening HF despite treatment of reversible causes (e.g., Fontan stenoses), reverse remodeling therapies, and inotrope, single ventricle assist device (SVAD) can be considered. Fontan patients with SVAD have 80% 1-year survival with 72% of patients eventually receiving heart transplant. The goals of SVAD therapy include improved survival, bridge to heart transplant, improved quality of life, optimization of end-organ function, promotion of physical

rehabilitation, and improved nutritional status.

The final presentation was **What's the Difference? Post-Operative VAD Management and Complications in the Patient with Fontan Circulation** given by **Peta Alexander, MBBS**, of Boston Children's Hospital. The goals of SVAD in Fontan include improving cardiac output, improving end-organ function, and reducing venous hypertension. Strategies to optimize management include post-operative imaging to identify anatomic lesions, maintaining euvolemia including use of peritoneal dialysis as necessary, medical management of pulmonary vascular resistance, effective use of ventilator, and optimizing device function.

VIEW SESSION DETAILS

– Commentary by Anjan Tibrewala, MD

SESSION 78. Acute Mechanical Circulatory Support: Guidelines, Consensus and Practical Issues

Acute mechanical circulatory support (MCS) is a rapidly-evolving field with several considerations for matching patients with appropriate therapies. This session focuses on the guideline and consensus documents that can inform providers and institutions. The co-chairs were **Hannah Copeland, MD**, of Lutheran Medical Group in Fort Wayne, and **David Baran, MD**, of Cleveland Clinic Heart, Vascular, and Thoracic Institute in Parkland.

The first session was **30,000 Feet: The ISHLT/HFSA Acute MCS Guidelines** given by **Alexander Bernhardt, MD**, of University Heart and Vascular Center in Hamburg. The ISHLT/HFSA guidelines sought to provide definitions of acute MCS, describe medical and surgical interventions, and inform patient management. There were 4 Task Forces of the Writing Committee: (1) Timing, Patient, and Device Selection of Acute MCS, and Periprocedural and Postprocedural Care for Cardiogenic and Pulmonary Shock, (2) Adjunctive Pharmacologic Management, (3) Specific Patient Populations, and (4) Goals of Care and Role of Palliative Care, Social Work, and Ethics. The guideline is available at: https://doi.org/10.1016/j.healun.2022.10.028.

The next session was titled **Cardiogenic Shock: ISHLT Consensus Conference on HF-Shock**presented by co-chair **David Baran, MD**. This presentation covered conclusions from an expert consensus conference covering acute heart failure—cardiogenic shock (HF-CS) unrelated to acute MI. There were 3 Task Forces addressing different components: (1) Centers: models of HF-CS care, (2) Patients: presentation of HF-CS, and (3) Management: strategies in HF-CS management. An important concept was to establish tiers of care to match facilities with severity of HF-CS. Furthermore, shock teams are being used with increasing frequency to effectively and efficiently triage and manage HF-CS patients using a multidisciplinary approach. Additional conclusions from the conference will be available when the consensus document is published.

The following presentation was **Post-Implant Management: Thin the Blood, Kill the Bugs** by **Ian Hollis, PharmD, BCPS-AQ**, of the University of North Carolina Medical Center in Chapel Hill. Anti-coagulation is often necessary for temporary MCS devices, particularly when used for longer duration. Although heparin is most commonly used, direct thrombin inhibitors can be considered as an alternative. Bivalirudin has a standard monitoring protocol with aPTT, avoids risk of heparin-induced thrombocytopenia and heparin resistance, and is noninferior to heparin in preventing thrombotic complications. In addition, antibiotics should be used for patients with temporary MCS devices when indication present, but prolonged courses should be avoided.

Co-chair **Hannah Copeland, MD**, closed the session with **Use of ERAS – Enhanced Recovery after Surgery – Minimizing Narcotic Use in Mechanical Circulatory Support**. An ERAS protocol that avoids narcotics and incorporates acetaminophen, gabapentin, tramadol, lidocaine patches and/or ketorolac. Prior studies have shown patients demonstrate no difference in pain control or return to function when compared to traditional post-operative pain regimens. Further investigation is

needed to understand the role of ERAS following heart transplant or VAD implantation.

VIEW SESSION DETAILS

– Commentary by Anjan Tibrewala, MD

SESSION 63. How Long is My Bridge? ECMO and Durable VAD Outcomes

Rapid ECMO Deployment Team: Outcomes Associated with an Emerging Inter-Facility Transport Program

Otoniel Espinoza, MSN, Medical City Heart Hospital, Dallas, TX USA

ECMO services have increased dramatically over the last decade, and cohort studies from large ECMO centers have established that transporting patients on ECMO is safe. The ECMO program at Medical City Heart Hospital was established in 2019, with transport services started in 2020. This study performed a retrospective analysis of adult patients transported on ECMO between January 2020 and May 2022. Of 218 total ECMO runs, 52 (24%) required transport (47 primary and 5 secondary). There were 20 VV ECMO transports and 32 VA ECMO transports. Of these, 24 were via ambulance, 21 via helicopter, and 7 via fixed wing. No patient complications or deaths during transport were noted. Overall survival to discharge was 65.4% (34/52). The keys to success were flight team and ECMO team simulation training with quarterly wet lab training.

The Impact of Small Left Ventricular Dimension on Outcomes after HeartMate 3 LVAD Implantation

Ezequiel Molina, MD, Piedmont Heart Institute, Atlanta, GA USA

Small LV size predisposes patients to HF and worse outcomes in patients with older generation LVADs, but the impact of LV size on outcomes in HM3 has not been studied. Impaired pump flow events may occur in patients with smaller LV size. So in this study, the impact of LVEDD on clinical outcomes after HM3 was evaluated. It was found that early mortality is associated with increased HRAE and HF related deaths. Patients with smaller LVEDD have significantly more rehospitalizations, most of which are due to cardiovascular causes (especially more HF) which confer an excess risk of late mortality (> 30 days).

Influence of the Outflow Graft Position on Thromboembolic and Bleeding Complications in Patients with a Left Ventricular Assist Device

Jette Peek, MSc, Erasmus Medical Center, Rotterdam, Netherlands

There has been an increased use of LVADs, but implantation technique remains unchanged. Various complications associated with LVADs include CVAs, aortic insufficiency, early and late bleeding, and infections. The aim of this study was to elucidate the influence of the surgically placed position of the outflow graft on the thromboembolic complications and aortic valve insufficiency, using three-dimensional (3D) reconstructions by standardized reproducible protocol of the thoracic CT scans.

In this retrospective analysis of patients with HM3, available thoracic CT scans were studied, and various outcomes were assessed in relation to the position of LVAD outflow graft. Vertical and horizontal angles and relative distance between aortic valve to outflow graft and to brachiocephalic artery were looked at. They noted that vertical angulation > 107 was associated with increased risk of CVAs and GI bleeding. Horizontal angulation < 10 was associated with

decreased long-term survival.

Heart Transplantation from Donors after Circulatory Death in Patients Supported by Left Ventricular Assist Devices
Sangjin Lee, MD, Spectrum Health, Grand Rapids, MI USA

LVAD is associated with improved outcomes. There is a decrease in LVAD-listed patients following the allocation change, with a decrease in heart transplantation in patients with LVADs under the current allocation system. Hearts for transplantation are most commonly harvested from donors after brain death, but heart transplantation utilizing donors after circulatory death is increasing. Outcomes after transplantation in LVAD patients transplanted with DCD donors are not well-delineated.

This study analyzed UNOS data from 2019 to 2021. Of 8292 patients, 2281 had an LVAD with only 102 patients receiving heart from DCD. One year post heart transplant, survival and outcomes of LVAD patients transplanted with DCD donors are comparable to DBD donors. Even after propensity matching with age, BMI, gender, blood group O, status at time of transplant, donor age, and distance traveled, the outcomes were similar.

The increase in acute rejection with DCD hearts needs to be further clarified. Notably, LVAD patients utilizing DCD donors more commonly have blood type O, are listed status 4 at time of transplant, no worsening of incidence of graft failure and re-transplantation, have shorter wait times on heart transplant waitlist, and shorter hospital length of stay after transplant. We need to evaluate long-term post-transplant outcomes of LVAD patients transplanted with DCD donors and identify risk factors for post-transplant mortality in LVAD patients with DBD and DCD donors.

Preclinical Evaluation of the Bivacor Total Artificial Heart
Daniel Timms, PhD, BiVACOR, Houston, TX USA

To provide a superior therapy for all patients with ESHF while eliminating the reliance on donor heart transplantation, there is a role for a potential artificial heart as good as a transplant. Multiple device iterations have been implanted in more than 30 chronic animal studies for up to 3 month durations. The new BiVACOR pump is durable, has been used in animal studies. It has pulsatile outflow cycle through sleep/rest and exercise conditions. Verification activities demonstrated promising durability, hemocompatibility and physiological interaction in animal studies. These results underpin the progression of the BiVACOR total artificial heart to first in human studies.

Does Extracorporeal Membrane Oxygenation Duration as a Bridge to Total Artificial Heart Affect Outcomes
Jad Malas, MD, Cedars-Sinai Medical Center, Los Angeles, CA USA

The Syncardia total artificial heart provides biventricular support as an FDA-approved bridge to transplantation device. Worldwide experience with TAH remains limited, with just over 1700

implants performed to date. The TAH serves as an effective bridge to transplantation, with over 60% patients undergoing successful heart transplantation by 2 years. All patients receiving VA ECMO will not receive an expeditious donor organ offer, potentially necessitating a sequential bridge with a TAH. The aim of this study was to utilize a prospectively maintained institutional registry of all patients implanted with a TAH to examine the effect of VA ECMO duration > 5 days as a sequential bridge to TAH on patient outcomes. Of 100 patients, 71 were excluded as TAH implant was without ECMO bridge. Of the 29 patients, 17 were supported with ECMO < 5 days, and 12 were supported with ECMO > 5 days.

ECMO durations > 5 days as a sequential bridge to TAH resulted in numerically lower successful bridging to heart transplantation (33% vs 59%) and lower 1 year survival following heart transplantation (50% vs 90%). Patients sequentially bridged to heart transplantation with VA ECMO and TAH remain a high risk cohort.

VIEW SESSION DETAILS

– Commentary by Anju Bhardwaj, MD

SESSION 69. MCS: Bleeding and Clotting – We Just Can't Win!

Clinical Effects of Hemoadsorption in Patients Undergoing Left Ventricular Assist Device Implantation
Zaki Haidari, MD, University Hospital Essen, Essen, Germany

This retrospective analysis included heart failure patients undergoing LVAD implantation with cardiopulmonary bypass (CPB). Propensity score matching was performed to obtain comparable groups. Patients operated with hemoadsorption device incorporated in CPB (hemoadsoprtion) were compared to patients operated without hemoadsorption device in CPB (control). The endpoints included the incidence of postoperative vasoplegia and 30 and 90-day mortality. Vasoplegia was defined as the need for norepinephrine >0.2 µg/kg/min and/or any dose vasopressin combined with a cardiac index >2.2 l/min/m2 for ⩾12 hours starting within 72 hours postoperatively. Between December 2010 and June 2022, 267 patients underwent LVAD implantation with CPB. After propensity score matching, 80 pairs were analyzed.

Intraoperative hemoadsorption significantly reduced the incidence of Vasoplegia following LVAD. 30 and 90 day mortality is lower in patients with intra-operative hemoadsorption. Prolonged ventilation was often necessary in patients receiving intraoperative hemoadsorption.

Lysis Therapy vs. Pump Exchange for Intra-Pump Thrombosis of Left Ventricular Assist Devices
Isabell A. Just, MD, German Heart Center Berlin, Berlin, Germany

Signs and symptoms of pump thrombosis include high power alarms, increase in power consumption, high calculated LVAD flow, hemolysis, and no signs of low cardiac output. Per guidelines, in case of pump thrombosis of HeartWare HVAD, pump exchange should be considered (IIa) and thrombolysis may be considered (IIb). In a retrospective single center analysis, HVAD patients (between 2010 to 2020) presenting with pump thrombosis and treated with lysis (55) or pump exchange (37) were evaluated. Compared to pump exchange, lysis treatment is associated with shorter hospital stay and early discharge. No difference in 30-day and 6-month survival between the two groups. Main cause of death after exchange was infections and cerebral bleeding after lysis. Outflow graft obstruction was noted with lysis therapy in 24.5% patients. Possibly a risk stratification model for complications associated with lysis could lead to better outcomes.

Glycoprotein (GP)Ibα Protein Expression is Reduced in HeartMate 3 Patients with Non-Surgical Bleeding Complications Within the First 3 Months
Kristin Klaeske, MD, Heart Center Leipzig, Leipzig, Germany

Non-surgical bleeding remains the most critical complication in LVAD patients. Exposure to LVAD-induced non-physiological shear stress leads to platelet activation and receptor shedding. GPib-IX-V is the most abundant receptor complex and exclusively expressed on platelets and is involved in the initial steps of platelet adhesion in response to vascular injury. In a prospective study, 82 patients with HM3 implantation were divided into bleeder (27) and non-bleeder (55)

groups. The bleeders within the first 3 months were labeled as early bleeders (n=19) and after 3 months were labeled as late bleeders (n=8). The mRNA expression of GPIbα, GPIX and GPV did not differ between bleeders and non-bleeders. But reduced protein expression of GPIbα was observed in early bleeders, and analysis of its receptor shedding was comparable between bleeders and non-bleeders. We need to evaluate if patients with low GPIbα expression need anticoagulation to avoid potential bleeding complications.

Platelet Function and Sildenafil Use During Left Ventricular Assist Device Support
Omar Saeed, MD, MS, Montefiore Medical Center, New York, NY USA

Observational studies show that PDE-5 inhibitors such as sildenafil are associated with lower ischemic stroke, thrombosis, and mortality during LVAD support. Platelet activation may affect clot related adverse events, but its relation to sildenafil use is unknown. The aim of this single center, prospective, cross-sectional study was to determine if sildenafil is related to lower platelet activation and aggregation during LVAD support. Stable outpatients on HM3 support were recruited to participate in the study. Blood samples for analysis were taken for analysis of platelet activation and aggression, which was assessed by impedance aggregometry. These blood samples were exposed to platelet agonists (collagen, thromboxane, ADP) and impedance was measured, with higher impedance indicating greater platelet activation and aggregation. Patients were grouped as sildenafil users and non-users. It was noted that sildenafil use is associated with lower collagen and thromboxane induced platelet activation and aggregation during HM3 support. Further studies are needed to determine mechanistic and clinical causality towards clotting, bleeding, and stroke with sildenafil during LVAD support.

VIEW SESSION DETAILS

– Commentary by Anju Bhardwaj, MD

SESSION 76. Spotlight on Nursing and Allied Health MCS Intervention Science

The highlights of this session included shared-decision making for mechanical circulatory support (MCS), social work assessments, caregiver strain, and improved clinical outcomes. The science was led primarily by nursing and allied health professionals, and the session was co-chaired by **Edward Horn, PharmD**, of the University of Pittsburgh, and **Desiree Robson, RN, BSc (Hons)**, of St. Vincent's Hospital in Darlinghurst.

Dan Matlock, MD, of the University of Colorado School of Medicine in Denver, presented "***Patients' Experiences Around Shared Decision Making for Left Ventricular Assist Devices: Results from I-DEVICE-LVAD***" A pamphlet and video I-DECIDE-LVAD decision aid has been shown to improve decision quality prior to LVAD. This study conducted a patient survey to understand patients' experience using the decision aid. There were 205 responses from 16 LAD programs. On the decision process measure, the decision aid scored 2.8/4 and on the CollaboRATE measure scored 8.5/9. In addition, 83.6% of patients thought the aid was helpful in the decision-making process. 56.4% of patients thought the decision aid was balanced, whereas 23.5% thought slanted toward getting an LVAD. The decision aid is available at: www.patientdecisionaid.org/lvad.

The next abstract was "***Impact of a Novel Social Worker Psychosocial Assessment (6D-SW) on the Prospective Outcomes in HeartMate 3 Patients***," presented by **Annamaria Ladanyi, MD**, of Columbia University Irving Medical Center in New York. A novel psychosocial assessment tool called 6D-SW assesses patient risk in 6 domains: caregiver support, substance misuse, mental illness, insurance, housing, and transportation. Each domain was scored 1 if concern or 0 if no concern. The 6D-SW was done in 111 HeartMate 3 implants. A higher 6D-SW was associated with increased all-cause readmission and driveline infection.

The following presentation, "***Improving Veno-Veno Extracorporeal Membrane Oxygenation (VV ECMO) Survival to Discharge by Implementing a Goal-Oriented Expected Progression Patient Management Guideline***," was given by **Omar Hernandez, RN, BSN**, of Medical City Plano. The VV ECMO Progression guideline describes goal-oriented stages with suggestive interventions: (1) resuscitative stage, (2) decision stage, (3) wean sedation, (4) progressive mobility, (5) trial-off stage. Of 125 VV ECMO patients, 78 were given the intervention. The patients that received the intervention had increased survival to discharge (81% vs 58%, $p<0.01$), but lower ECMO duration, ICU length of stay, and hospital length of stay.

Frances Ber, MFT, of Scripps Memorial Hospital in La Jolla, presented "***The Effect of the ENABLE-LVAD Program on Caregiver Strain and Sleep Quality in Ventricular Assist Device Caregivers.***" The Educate, Nurture, Advise Before Life Ends (ENABLE) is an evidence-based training program to support LVAD caregivers. Twelve caregivers were given the intervention. Compared to pre-intervention, caregivers were noted to have significantly decreased strain following the intervention using the Modified Caregiver Strain Index. There was no significant difference in sleep quality based on the Pittsburgh Sleep Quality Index. The training program is available

at: www.patientdecisionaid.org/enable-lvad.

VIEW SESSION DETAILS

– Commentary by Anjan Tibrewala, MD

SESSION 87. Durable MCS: Staying Alive!

Initial Safety Cohort Analysis: Prospective Multi-Center Randomized Study for Evaluating The EVAHEART®2 Left Ventricular Assist System (The COMPETENCE Trial)

Mark Slaughter, MD, University of Louisville School of Medicine, Louisville, KY USA

LVADs have demonstrated improved survival and quality of life for patients with ESHF, however its growth has been limited by adverse events. The EVAHEART®2 LVAD has new design features to potentially reduce adverse events related to inflow cannula, diminished pulsatility, and blood trauma. It has a hydrodynamic levitation system, with unique impeller design. It has a novel tipless inflow with low pump speed with minimal blood trauma and preserved aortic pulsatility. It is a centrifugal pump, with an adjustable modulation called EVAHEART PSM, that reduces/adjusts pump speed for adjustable duration usually set at 5 seconds and facilitates AV opening.

The COMPETENCE trial was a randomized controlled trial which included 138 pumps (92 EVA2 and 46 HM3 in 6 months) and 399 pumps (266 EVA2 and 133 HM3). It was a staged study with an initial safety cohort of 15 EVA2, followed by a full cohort of 399 patients. The primary endpoint is a composite of survival to transplant, recovery, or 6- or 24-month survival on the primary LVAD free from disabling stroke (modified Rankin score > 3) or predefined severe RHF. Secondary endpoints include STS- INTERMACS AEs & device malfunction, reoperation, rehospitalizations, quality of life, and functional status (6MWT & NYHA). A substudy included VonWillebrand factor analysis (35 EVA2 vs 35 HM3). Inclusion criteria: Age > 18 yrs, BSA > 1.4 m2, NYHA class III or class IV, LVEF < 30%, inotrope dependence, CI < 2.2 (while not on any inotropes) and one of the following- refractory HF, IABP dependence > 7 days or Impella dependent for 3 days.

Patients supported with EVA2 have over 7000 days of support with 10 patients supported for over 12 months and 2 over 24 months. Initial safety cohort of first 15 patients enrolled in 3 batches demonstrated 100% survival at 30 & 90 days. Current initial safety cohort data have been reviewed by DSMB & FDA and the study is approved and ongoing. Patients with EVA2 had better KCCQ and better NYHA score at POD30.

uSTOP LVAD BLEED: Utilization of Umbilical Cord Lining Stem cells to Prevent Left Ventricular Assist Device Associated Angiodysplastic Bleeding

Mustafa Ahmed, MD, University of Florida, Gainesville, FL USA

HM3 has an improved HRAE profile compared to legacy devices. Despite this, bleeding remains a common complication after LVAD implantation. Dysregulation of angiogenic factors have been implicated in the pathophysiology of bleeding. Stem cells may provide a therapeutic option as they modulate pro-inflammatory cytokines and promote vascular stabilization by paracrine mechanisms including secretion of Amgiopoetin-1. Intramyocardial injection of stem cells during LVAD implantation was associated with decreased incidence of GI bleeding in older generation devices. IV delivery may provide a more reproducible platform, but its safety in the LVAD

population is unknown, as is the efficacy of cell therapy in a contemporary LVAD population.

The aim of this study was to evaluate the safety and tolerability of escalating doses of umbilical cord lining stem cells in stable HM3 recipients to ameliorate angiogenic dysregulation. The primary safety endpoints include infusion-related adverse events, adjudicated clinical thromboembolic events, and changes in PRA levels. Exploratory secondary endpoints include change in Ang 1, Ang 2 and occult GIB as evidenced by quantitative fecal immunochemical test (qFIT). 3 subjects were given an ascending dose trial that was a 45 min clinic infusion and assessed for response after each dose. Assessment of adverse events was done via phone call day 3, and study visit day 7 & 30. For assessment of sensitization, PRAs were drawn at baseline, day 30 and day 90.

The findings of this pilot study confirm the safety & tolerability of IV ULSCs in LVAD patients. The exploratory endpoints are suggestive of a signal of early efficacy, which should be explored in a larger, late phase study with appropriate power to detect a change in clinical outcomes. Even though the sample size & trial design was appropriate for phase Ia study with primary safety endpoint, it has limited interpretation of exploratory findings. Use of Angiotensin-II antagonist was mandatory, but dose & adjustments were not standardized.

Clinical Predictors of 5-year Outcomes Following HM3 Left Ventricular Assist Device Implant: The Momentum 3 Trial

Aditi Nayak, MD, Harvard Medical School, Boston, MA USA

The 5-year survival on the centrifugal flow HM3 pump in advanced HF patients irrespective of therapeutic intent was 58.4%. Improvement in NYHA class I-II was noted in 68% and 6MWD increased by more than 200 meters. To facilitate shared decision making for LVAD implant, a HM3 risk score was created using MOMENTUM3 data. It was noted that 6 pre-implant clinical characteristics were predictive of 1- and 2- year outcomes. There were 3 distinct tiers of risk identified.

This study investigated clinical predictors for long term outcome by including pre-implant, implant surgery & index hospitalization events associated with 5-year survival in HM3 LVAD recipients conditional upon discharge after pump implantation. Of 515 patients implanted with HM3, 485 patients (94%) were discharged. Their preimplant characteristics, surgical implant procedure, and index hospitalization course were evaluated. Predictors with univariable hazard ratio with $p<0.2$ included age, DT, ischemic HF, prior CABG or valve procedure, BMI, BUN, h/o DM, ICU stay above median, surgical bleeding, Adverse events including HRAE, RHF, Infection, and serious ventricular arrhythmias, discharge GFR < 60, Index hospital stay above median, and discharge to other medical facility.

In this population of largely destination therapy patients, 94% pf HM3 LVAD recipients were successfully discharged with 5-year survival of ~ 62%. In patients without identified predictors of risk, 5-year survival in DT LVAD patients was 77.4% that was comparable to transplant recipients.

Among the cohort with at least 1 or more risk predictors within the model, 5-year survival was 54.3%.

VIEW SESSION DETAILS

– Commentary by Anju Bhardwaj, MD

SESSION 96. Unbreak My Heart: Recovery and Weaning in MCS Patients

This session was co-chaired by **Maryjane Farr, MD**, of the University of Texas Southwestern Medical Center in Dallas, and **Cesar Guerrero-Miranda, MD, FACC**, of Baylor University Medical Center in Dallas.

Impella 5.0/5.5 Support in AMI CS Patients: How to Increase Myocardial Recovery Chances

Marina Pierri, MD, IRCCS San Raffaele Scientific Institute, Milan, Italy

Myocardial recovery is the primary goal in patients with AMICS supported with temporary MCS. Axillary Impellas are powerful pumps in terms of unloading efficacy and forward flow, with axillary access allowing prolonged support through different possible pathways of care. The minimally invasive upper body approach facilitates patients' recovery. Native heart recovery may be observed in up to 30% of patients surviving the acute phase of shock. Chances of weaning or recovery dramatically decrease after durable LVAD implant. Early parameters associated with native heart recovery in CS patients are largely unknown. This single center retrospective analysis aimed to assess native heart recovery rate in AMICS patients on axillary Impella 5/5.5 support at a referral center for MCS in Italy, and to identify simple and early clinical parameters that may be associated with myocardial recovery in this population. Native heart recovery was defined in the presence of sustained weaning from inotropes and tMCS, with no recurrence of HF at last available follow up.

35 patients with AMI-CS were included, of which 33 patients received Impella 5.0, and 2 patients were implanted with Impella 5.5. 89% were male with mean age 61±11 years. Median Impella support duration was 12 days (4-39 days). Inpatient survival was 69%, with 12 patients discharged after recovery and 15 bridged to advanced therapy (9 to LVAD & 8 to OHT). Patients who had recovery had 100% survival rate with no recurrence of HF at the longest available follow up. Parameters associated with recovery include: prompt and complete revascularization, early upgrade to full hemodynamic support, with best chances of recovery in first 7-10 days of support.

Long-Term Clinical Trajectory after Durable LVAD Weaning: An International Registry Report

Snehal R. Patel, MD, Montefiore-Einstein, Bronx, NY USA

From 1995-2009, 92 patients who had LVAD went to either HT (52) or device explantation (40). Explanted LVADs included 18XVE, 15HM2, 3 Jarvik, 1 HVAD, 3 Levitronix. Long term survival post-LVAD weaning was comparable to post HT. The aim of the VAD Wean Registry was to determine long term clinical outcomes in a large multicenter real-world experience after LVAD explantation (remission vs. recovery). A multicenter investigator-initiated registry was created with voluntary involvement. Only patients who had undergone LVAD explant were included. Data points were separated into pre-implant, pre-explant and post explant.

38 sites had a total of 371 patients and 293 patients met institutional criteria for recovery. The rest had a LVAD complication along with simultaneous variable degrees of cardiac impairment, so

the device was explanted, of which only 341 had 1-year follow up. Of these, 283 (83%) remained alive, 9 (2.5%) underwent reimplantation of LVAD, 12 (3.5%) had HT and 37 (11%) patients were deceased. Long term outcomes after LVAD explant compared favorably with that of HT.

Multicenter Development and Validation of a Machine Learning Model to Predict Myocardial Recovery During LVAD Support: The UCAR Score

Christos Kyriakopoulos, MD, University of Utah School of Medicine, Salt Lake City, UT USA

Subset of patients significantly improved LV function and structure on LVAD known as reverse remodeling which is a pre-requisite for LVAD removal. LVAD removal is a complex decision, which entails patient goals and willingness, plus center protocols and experience. Existing predictive models are confounded by equating cardiac recovery to LVAD removal. Of these, 10% were responders (> 40% LVEF), 30% were partial responders (> 10% improvement in LVEF but not to 40%), and 60% were non-responders. The purpose was to predict patients with high potential to significantly improve their heart function.

782 advanced HF patients received CF-LVAD across 8 US centers. 528 patients were included in the final study cohort, of which 78 (14.8%) recovered. UCAR score was used to predict cardiac reverse remodeling during LVAD unloading. Various parameters included were age, sex, HF etiology, HF duration, NYHA class, LVEDD, and the use of meds like diuretics, beta-blockers, and MRA. They noted that UCAR score helps in patient selection for recovery and assist in implementation of diagnostic and therapeutic protocols to promote myocardial recovery. This needs further external validation.

VIEW SESSION DETAILS

– Commentary by Anju Bhardwaj, MD