ISHLT 2022 DAILY ACCESS



ISHLT2022 Roving Reporters – Reports from Mechanical Circulatory Support (MCS)

- Wednesday, 27 April, 2022
 - o SYMPOSIUM SESSION 08: The Cardiogenic Shock Journey: Shock Therapy
 - o ORAL SESSION 04: Should We or Not? Patient Selection for MCS and Transplantation
 - ORAL SESSION 18: Know Your Enemies: Cardiac and Other Complications During LVAD Support
 - MINI ORAL 03: How to Do It: Influence of Surgical Techniques and Other Factors on Successful MCS Outcomes
- Thursday, 28 April, 2022
 - Featured Abstract 4 at Plenary Session 2: Characteristics and Outcomes of Patients Supported with Impella at Pediatric Institutions: An ACTION Collaborative
 - <u>SUNRISE 03: How to Heal a Broken Heart: Using Durable VADs to Promote</u> <u>Myocardial Recovery</u>
 - <u>SUNRISE 05: Keep it Less Complicated: Minimizing and Treating Complications in</u> <u>LVAD Patients - From Bleeding to Infection</u>
 - <u>SYMPOSIUM SESSION 25: The Risky Arrhythmia: Matching Risks and Benefits of</u> <u>Cardiac Devices in LVAD Patients</u>
 - <u>SYMPOSIUM SESSION 32: Unique Challenges for Women and Children Supported</u> with MCS
 - ORAL SESSION 36: Blood Creeps Where It Cannot Flow, When It Stops... You Know: Drug Support for MCS Therapy
 - ORAL SESSION 39: Exercise Capacity and Possible Determinants of Intolerance After LVAD Implantation
- Friday, 29 April, 2022
 - <u>SUNRISE 13: Poised for Success: Tips and Pearls on Manuscript Submission and</u> <u>Effective Peer Review</u>
 - <u>SYMPOSIUM SESSION 50: Double Trouble: End-Stage Renal Failure in End-Stage</u> <u>Heart Failure</u>
 - SYMPOSIUM SESSION 53: Structural Heart, Mitral and Tricuspid Valve Disease in LVAD Patients: Current Insight and Controversies

- o ORAL SESSION 46: Next Exit (Site): Infections in MCS
- ORAL SESSION 67: Everything Gets Better: Novel Technology for Unmet Needs and Improved Outcomes in MCS
- ORAL SESSION 70: Little Patients with Big Hearts Need Our Support: MCS in Pediatrics
- Saturday, 30 April, 2022
 - o <u>SUNRISE 15: The Right to MCS: Are We Still Allowed To Say NO?</u>

ISHLT 2022 DAILY ACCESS

Thank you to all of our ISHLT2022 Roving Reporters.

ADVANCED HEART FAILURE AND TRANSPLANTATION (AHFTX)

Anju Bhardwaj, MD, University of Texas / McGovern Medical School / Memorial Hermann Hospital, Houston, TX, USA
Rachna Kataria, MD, Massachusetts General Hospital, Boston, MA, USA
Brian Wayda, MD, Stanford University School of Medicine, Stanford, CA, USA

ADVANCED LUNG FAILURE AND TRANSPLANTATION (ALFTX)

Prangthip Charoenpong, MD, MPH, LSU Health Science Center Shreveport, Shreveport, LA, USA **Grant Turner, MD, MHA**, UCLA, Los Angeles, CA, USA

MECHANICAL CIRCULATORY SUPPORT (MCS)

David Bearl, MD, MA, Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, TN, USA **Varinder Randhawa, MD, PhD**, Cleveland Clinic / University of Toronto, Toronto, ON, Canada

PULMONARY VASCULAR DISEASE (PVD)

Nicholas Kolaitis, MD, MAS, UCSF, San Francisco, CA, USA

SESSION 08: The Cardiogenic Shock Journey: Shock Therapy

The International Society for Heart and Lung Transplantation (ISHLT) got back to where it left off the last in-person meeting in 2019 with a jam-packed few days of the current state of the field, late-breaking science and new devices. **Christopher Barnett, MD**, of University of California, San Francisco and **Edith Boyes, APN**, of AMITA Health (Schaumberg, Illinois) chaired this early afternoon <u>session</u>.

Jaime Hernandez-Montfort, MD, MPH, of Baylor Scott and White Health (Austin, Texas) started it off with "*Etiology Doesn't Matter, It's All in the Phenotype*." He argued that three distinct phenotypes exist: non-congested, cardiorenal and cardiometabolic. This order also reflects worsening mortality with cardiogenic shock that appears non-congested having less mortality risk than cardiorenal which in turn has less mortality risk than cardiometabolic phenotype.

Pascal Leprince, MD, PhD from Sorbonne University in Paris, France joined on recorded session called "*Right Support, Right Time – Temporary MCS in Cardiogenic Shock*." He recreated a beautiful table outlining the options for temporary mechanical circulatory support including intra-aortic balloon pump, a couple sizes of Impella®, TandemHeart®, peripheral ECMO, and Levitronix®. With a series of + and -, he showed the strengths of weakness of each option: speed of deployment, ease of deployment, bedside placement, cost, efficiency with LV unloading, respiratory support and biventricular support. "The right timing is more important than the ideal device."

Hannah Copeland, MD, from Lutheran Hospital (Fort Wayne, Indiana) went next with her live talk *"Patient is on Temporary Circulatory Support: ICU Considerations in Optimizing Physiology.*" She discussed the pros and cons of inotropic support and left ventricular decompression. She concluded that Impella is overall better than IABP (except in the setting of LV thrombus) because of LV unloading, which allows weaning of inotropes, decreased myocardial demand, and decreases CVP and PCWP.

Following Dr. Copeland's debate, **Jerry D. Estep, MD**, from Cleveland Clinic in Ohio spoke on *"Temporary MCS Weaning and Explant: Can One Size Fit All?"* Dr. Estep highlighted the recent publication in JACC 2021 – "A Pragmatic Approach to Weaning TMCS." He focused on the 5 steps process: 1) Readiness to Wean, 2) Wean Trial, 3) Wean Success, 4) Readiness to Explant, and finally 5) Explant.

Varinder Randhawa, MD, PhD, from Cleveland Clinic and University of Toronto followed with *"When 'Shockingly Breathless' to Vent and Bundle Care Even in Critically III Cardiac Patients?*" She eloquently spoke about the risks and benefits of different modes of respiratory support including everything from simple nasal cannula to invasive ventilation and oxygenator support in MCS and emphasized the importance of critical care bundles. Towards the end of the presentation, she had the best image of the conference—an extremely muscular man (think The Rock) cannulated through the neck on VA ECMO. **"To Somewhere Over the Rainbow: Role of the Post-Shock and Rehab Clinics**" was presented by **Jose Gonzalez-Costello, MD**, from Belvitge Hospital (Barcelona, Spain). Dr. Gonzalez-Costello made two important points: 1) there are no guidelines or good evidence to help guide transition from ICU -> Rehabilitation, and 2) that the rule in the United States that there be 6 weeks between HF discharge and cardiac rehabilitation is unnecessary.

Lastly (and fittingly), **Michael McDonald**, **MD**, from Toronto General Hospital in Canada discussed in a pre-recorded session, "*When All Else Fails: Dignifying End-of-Life Considerations*," the importance and sometimes difficulty of addressing advanced directives, palliative care consultation, and hospice care. He also emphasized the lack of guidelines and evidence in this important area of cardiogenic shock while acknowledging the challenging scenario of sudden onset and rapidly evolving situations that are using to the field (as opposed to acute on chronic decline in CHF). Importantly, the studies he highlighted showed no difference in mortality, but a decrease is mental health issues and increase in quality of life for those who were connected with palliative care as part of their hospitalization.

All in all, a whirlwind through the state of cardiogenic shock, and a great way for me to start my conference experience.

VIEW SESSION DETAILS

SESSION 04: Should We or Not? Patient Selection for MCS and Transplantation

Patient characteristics play an intrinsic role in the candidacy of advanced heart failure patients for durable mechanical circulatory support (MCS) and heart transplantation. This **oral abstract session** reviews how the new heart allocation change, regionalized systems of care, drug vs device-based bridging strategies, and sarcopenia can impact functional status, post-transplant survival or multi-organ transplant. A novel machine learning algorithm to predict survival in LVAD patients was also debuted at this session.

Effects of the New Heart Allocation System on Choice of Mechanical Circulatory Support as a Bridge to Transplant

Selena S. Li, MD, Massachusetts General Hospital, Boston, MA USA

The United Network for Organ Sharing (UNOS) implemented a new heart allocation system on 18 October, 2018, which has doubled the number of patients on temporary left ventricular assist devices (LVADs) who also have a higher priority status than those on durable LVAD support. This study evaluated the choice of LVAD on survival outcomes in the post-allocation change era. Of 1,232 adult heart transplant recipients identified in the UNOS database until March 2021, 202 with temporary LVADs had shorter waitlist times by one-third (27 vs 134 days, p<0.001). This study found regional variations in LVAD choice and a lower mortality risk with temporary LVADs as a bridge to transplant (adjusted HR 0.26, p=0.019), without any differences in the rates of post-transplant rejection or infection. Those with durable LVADs who had worse survival outcomes (propensity-matched p=0.049) received more hearts from donors aged >40 years (p=0.03) and from donation after cardiac death (p=0.007).

Time to Reconsider Bridging Older Children on Outpatient Inotrope in an Era of Outpatient VADs

David L. S. Morales, MD, Cincinnati Children's Hospital, Cincinnati, OH USA Combining PHIS and UNOS database analyses (2012-2020), this study evaluated whether bridging with inotropes vs VADs influenced clinical outcomes. Of 691 pediatric patients aged <18 years, ~25% had inotropic or VAD support as a bridge to heart transplantation. VAD patients were more likely male, weighed more, and had dilated cardiomyopathy. Although short-term transplant survival was comparable to patients on inotropes (p=0.28), VAD patients were found to have greater functional status and better long-term transplant survival (p=0.05).

Patients Receiving Durable LVADs at Centers without Transplant Are Less Likely to Undergo Transplant: An Analysis of the STS Intermacs Database

Thomas Cascino, MD, MSc, University of Michigan, Ann Arbor, MI USA

Heart transplant has increased overall since 2012, but donor hearts remain insufficient for all patients who suffer advanced heart failure. This study asked whether center-capability for heart transplantation impacted access to LVAD as bridge-to-transplant (BTT) and subsequent heart transplant since the CMS policy change, using an STS Intermacs analysis (2012-2020). Those who had LVAD insertion at VAD-only centers were older, sicker with a higher Intermacs class, and more likely to be Medicare-users and transplant-ineligible. LVAD implantation at a VAD-only vs VAD-transplant center was associated with lesser odds of BTT intent (OR 0.53, p< 0.0001) or

actual heart transplant at 2 years (HR 0.74, p<0.0001). Policy changes impacting regionalization of systems of care need further refinement to identify and overcome barriers to accessing heart transplantation in patients undergoing LVAD as BTT.

Ventricular Assist Devices Are a Viable Method to Support Patients to Multi-Organ Transplant Jonathan B. Edelson, MD, Children's Hospital of Philadelphia, Philadelphia, PA USA Often patients with advanced heart failure may also have multi-organ involvement, including lung, kidney, and liver. In this retrospective UNOS database analysis (2004-2019), LVAD use in patients requiring multi-organ transplant was evaluated. About 22% of heart-kidney (HK) recipients had VAD support vs heart-liver (HLi; 4%) or heart-lung (HLu; 3%), with the median age ranging from 55-47 years old. While VAD vs no VAD support improved waitlist survival to transplant in HK patients (p<0.05), there was no difference seen for HLi and HLu recipients with or without VAD support. One-year post-transplant survival did not differ between the three cohorts, namely HKi, HLi, and HLu.

The Sarcopenia Index Correlates with Computed Tomography Quantified Muscle Measures in Patients with Advanced Heart Failure

Zeina Jedeon, MD, University of Minnesota, Minneapolis, MN USA

Frailty, sarcopenia and cachexia play key roles in survival outcomes. Cogswell and colleagues highlight the first sarcopenia biomarker in LVAD patients, with the potential to objectively evaluate the impact of clinical interventions (e.g., nutrition or rehab). Each 10 unit increase in the sarcopenia index (serum creatinine/cystatin C x 100) was shown to correlate with a 0.43 cm2/m2 (p=0.009) or 3.47 HU (p<0.0001) increase in pectoralis muscle mass indexed to body surface area and attenuation, respectively, on chest CT in 60 LVAD patients. The majority of LVAD patients were men (73%) who had destination therapy LVADs (67%).

Predicting Survival of End Stage Heart Failure Patients Receiving HeartMate-3 LVAD with Machine Learning: An STS-INTERMACS Analysis

Renzo Loyaga-Rendon, MD, PhD, Spectrum Health, Grand Rapids, MI USA

Artificial intelligence technologies have been burgeoning. In their contemporary analysis, Loyaga-Rendon explores a novel machine learning elastic-net (MLEN) algorithm to predict one-year survival in 3642 patients with HM3 LVAD support in the STS Intermacs database (1/2014-6/2020). Non-survivors were significantly older (p<0.001) and less male (p=0.01), had more chronic heart failure (p=0.004) and prior history of cardiac surgery (p<0.001) and concomitant cardiac surgery (p=0.02), and required more ECMO (p<0.001) and dialysis (p<0.001). Using this novel MLEN algorithm, the study identified a 9-variable score predictive of one-year survival with an AUC of 0.72, of which age, right atrial pressure and MELD-XI were the most important predictive factors.

VIEW SESSION DETAILS

- Summary by Varinder Kaur Randhawa, MD, PhD

SESSION 18: Know Your Enemies: Cardiac and Other Complications During LVAD Support

The aim of **this session** was to recognize the most common adverse events in LVAD support so that we as practitioners can prevent them, if possible, or recognize them early to limit the damage. The session was co-chaired by **Annalisa Angelini**, **MD**, from the University of Padua (Padova, Italy) and **Jeffrey Teuteberg**, **MD**, from Stanford University (Palo Alto, California).

Danny Ramzy, MD, PhD, from Cedars-Sinai Medical Center (Los Angeles, California) started the session off with his research "*Improved Clinical Outcomes Associated with the Impella 5.5 Compared to Impella 5.0 in Contemporary Cardiogenic Shock and Heart Failure Patients*." While the title was a mouthful, his research was straight-forward and showed the benefits of the next-generation Impella device in acute myocardial infarction, cardiomyopathy and percutaneous coronary cardiogenic shock (survival to explant of 70% vs 57%, 88% vs 77%, and 76% vs 56%, respectively).

Themis Chamogeorgakis, MD, from Onassis Cardiac Surgery Center (Athens, Greece) presented *"Right Ventricular Failure Following Left Ventricular Assist Device Implant: An Intermacs Analysis."* Among 3 groups (>14 days inotropes, temporary MCS and durable MCS) for RV failure treatment, the latter group with durable MCS fared the best. That said, outcomes still were not ideal, with 12-month mortality of 30% and transplant at 40%, which was statistically significant compared to the other treatment options.

Michael I. Brener, MD, from Columbia University (New Rochelle, New York) presented his work titled "*Interventricular Interaction and Right Ventricular Function in LVAD Recipients: Insights from Pressure-Volume Analyses*." Using the LVAD as an "ideal" model for interventricular interactions, his team reviewed 10 patients including a RAMP study, RV pressure-volume loops, and 3D echocardiography. Of the 10 patients, most had a stereotypical response with no significant change in systolic function but increased ventricular compliance (improved diastolic indices), while the non-stereotypical response showed neither improvement in systolic or diastolic performance. This, he suggested, means that interventricular interactions only provide modest changes in LVAD performance, while increased pulmonary vascular resistance and depressed RV function are the main drivers of poor performance.

Sara Inglis, MB BCh, BAO, from Mayo Clinic (Rochester, Minnesota) followed with her work on *"Interventricular Septal Output (ISO) While Supported on LVAD Therapy*." To start, she explained that ISO is the difference in interventricular septal dimensions in end-systole and end-diastole multiplied by heart rate. She found that ISO decreased overtime without change in LV ejection fraction, was not associated with LVAD pump speed, and that a decrease in ISO by 20% predicts RV failure-free survival.

Jonathan Grinstein, MD, from MedStar Heart and Vascular Institute (Chicago, Illinois) had a prerecorded presentation titled "*Optimization of Flow Dynamics During HeartWare HVAD to HeartMate 3 Exchange: A Computational Study Assessing Differential Surgical Techniques*." (For those following the ISHLT program, this was different than project originally listed for this session.) Nonetheless, his presentation effectively showed some of the nuances that can help with performing a successful device exchange.

Finally, **Mahwash Kassi**, **MD**, from Houston, Texas presented "*Association of Outflow Cannula Angulation with Adverse Neurological Events in Patients with CF-LVAD*." With some beautiful images, including 2D and 3D, she showed that outflow angulation of > 53° by 2D and 83° by 3D was associated with acute neurologic events including stroke. Interestingly, inflow cannula angle, mean arterial pressure and INR did not correlate with adverse neurologic events in her study. The debate towards the latter half of this session was excellent with some thoughtful questions from the audience that helped the audience better understand the translation of some of this work to the operating room and post-VAD care.



MINI ORAL 03: How to Do It: Influence of Surgical Techniques and Other Factors on Successful MCS Outcomes

There are not enough hearts to go around. And so, durable left ventricular assist devices (LVADs) play an integral role in the support of patients with advanced heart failure. In this **mini oral abstract session**, different surgical technologies are explored for their impact on mechanical circulatory support (MCS) outcomes.

Less Invasive Left Ventricular Assist Device Implantation is Safe and Feasible in Patients with Smaller Body Surface Area

Katherine L. Wood, MD, University of Rochester Medical Center, Rochester, NY USA In this retrospective single-center analysis, 32 patients with body surface area (BSA) 1.8m2 or less were compared with 184 patients with BSA > 1.8m2 who underwent LVAD implantation. The smaller BSA cohort had significantly more women (50% vs 13%, p<0.001) and decreased pump flow (4.1 vs 4.6 L/min, p<0.001) and speed (5200 vs 5400 rpm, p<0.001) at discharge. No differences were seen in terms of post-operative complications, hospital length of stay, and survival to discharge or 6 months after implantation.

Exploring the Benefit of Thoracotomy LVAD Implant on Subsequent Sternal Entry for Heart Transplantation

Sam Emmanuel, MBBS, BHSc (Hons), St Vincent's Hospital (Sydney), Darlinghurst, Australia 2:1 propensity-matched analysis of 12 thoractomy vs 24 sternotomy patients who had LVAD insertion were evaluated for impact of the primary surgical technique at LVAD implantation on subsequent heart transplantation at this single center. No difference was noted in between-group baseline or peri-operative characteristics, nor in post-operative outcomes including mortality, length of stay or need for dialysis. 83% of patients were male, aged 58-60 years old with a BMI of 27.

Optimization of Flow Dynamics During the HeartWare HVAD to HeartMate 3 Exchange: A Computational Study Assessing Differential Surgical Techniques

Jonathan Grinstein, MD, University of Chicago, Chicago, IL USA

With HeartWare LVAD discontinuation, this study sought to identify the optimal surgical configuration for connecting the 10 mm HVAD outflow graft to the 14 mm HM3 outflow graft. The study evaluated 4 variations of the outflow cannula, including anastomoses near the pump or aorta, from the aorta or along the entire cannula using computational flow dynamic models. The highest maximum velocity occurred in the configuration with longer 10 mm graft, resulting in greater blood volume exposed to very high shear rate and greater right and left coronary flows. This will become important in patients needing revision of the HearWare LVAD to the HM3 LVAD.

Hemodynamic Response and Periprocedural Right Ventricular Function During a Lateral Thoracotomy versus Median Sternotomy Surgical Approach to Implantation of a Left Ventricular Assist Device - A Pilot Study

Jay D. Pal, MD, PhD, University of Washington, Seattle, WA USA

In this pilot study, 21 patients were randomized to receive LVAD implant via median sternotomy (MS) vs lateral thoracotomy (LT) on cardiopulmonary bypass. In the MS vs LT group, right atrial pressure but not mean pulmonary artery pressures decreased along with contractility.

Impact of Concomitant Cardiac Valvular Surgery During Implantation of Continuous-Flow Left Ventricular Assist Devices: A European Registry for Patients with Mechanical Circulatory Support (EUROMACS) Analysis

Antonio Loforte, MD, PhD, S. Orsola University Hospital, IRCCS Bologna, Bologna, Italy In this EUROMACs analysis (2006-2018), 533 of 2760 LVAD patients had concomitant valvular surgical procedures that significantly increased pump and OR time (p<0.001). Although no difference was seen in mortality (e.g., hospital (p0.074) or 1-, 3- and 5-year (p=0.25) survival) there was greater associated morbidity: longer ICU stay (p<0.0001), duration of mechanical ventilation (p=0.001), temporary right VAD support (p=0.033) and need for dialysis (p=0.014).

Bridging to Transplant with HeartMate 3 Left Ventricular Assist Device in the 2018 Heart Allocation System

Matan H. Uriel, MD, Columbia University Irving Medical Center, NYC, NY USA The new heart allocation system revised the priority status of patients on LVAD support to status 3 or 4. This analysis compared its impact on adults with HM3 durable LVAD in the UNOS registry before and after the new heart allocation system. Fewer patients with HM3 were waitlisted in the post-allocation change era (449 vs 1094 patients). And though there was no difference in heart transplant rates (p=0.76) and death or delisting for worsening status (p=0.43) at one year after listing, one-year survival post-transplant was significantly lower (p<0.001) in the new vs old heart allocation system. Predictors of post-transplant graft survival by multivariable analysis included age >60 years, ischemic etiology, poor functional status, renal dysfunction (>1.8 mg/dL), pulmonary hypertension and listing in the new allocation system.

Predictors of Failure to Rescue After Left Ventricular Assist Device Implantation

James W. Stewart II, MD, University of Michigan, Ann Arbor, MI USA

Of 13,617 patients with primary LVAD implantation in the STS Intermacs database (2012-2017), there were 4,839 patients who had major post-operative complications of which 854 patients had failure to rescue (FTR). This interesting analysis identified four pre-op predictors of FTR after durable LVAD implant: CABG or valve surgery (OR 1.5), dialysis (OR 2.3) and ECMO (OR 4.3). Those with post-op complications of right heart failure (75%), reintubation (45%), major infection (39%) and dialysis (34%) had the highest FTR, highlighting potential avenues for earlier targeted post-operative care interventions.

Characterizing Outflow Graft Narrowing over Time

Sean McCarthy, MD, Wayne State, Detroit, MI USA

This interesting study of 72 LVAD patients supported with HM2 or HM3 over a median of 1230 days demonstrated a median of 7% narrowing of the outflow graft over time. Time from device implant (p<0.001) but not wrapping of the outflow graft (p=0.071) was associated with this narrowing over time. There was no correlation of outflow graft narrowing with survival (HR 1.04), stroke (0.94), HF hospitalization (HR 1.06) or VAD alarms (HR 0.93).

Evaluation of the Stanford Integrated Psychosocial Assessment for Transplantation on Clinical Outcomes Following Left Ventricular Assist Device Implantation

Dongbo Yu, MD, PhD, University of Chicago, Chicago, IL USA

This retrospective single-center analysis of 145 durable LVAD implants (1/2010-4/2020) demonstrated no correlation of the SIPAT score, a validated psychosocial risk assessment tool, with survival (1 year, p=0.888; 3 years p=0.743) or freedom from readmission (3 years, p=0.389) between the 3 different patient groups (SIPAT score <6 [excellent] vs 6-20 [good] vs >20 [acceptable or poor]). The SIPAT score was not found to be a significant predictor for survival (at 1 year, HR 0.995, p=0.897; at 3 years, HR 0.989, p=0.66). The majority of patients were male (68%) who had a mean age of 55 years and mean SIPAT score of 12.4.

VIEW SESSION DETAILS

- Summary by Varinder Kaur Randhawa, MD, PhD

Featured Abstract 4 at Plenary Session 2: Characteristics and Outcomes of Patients Supported with Impella at Pediatric Institutions: An ACTION Collaborative

Presenter: Sebastian C. Tume, MD, Texas Children's Hospital, Houston, TX USA

After a riveting talk on the history of the Boston marathon by the Boston Athletic Association CEO **Tom Grilk**, and an inspirational speech by the 2022 ISHLT Lifetime Achievement Award Recipient **Hannah Valantine**, **MD**, **FRCP**, **MBBS** the plenary session featured a <u>pediatric-focused</u> <u>research study</u> by **Sebastian Tume**, **MD**, of Texas Children's Hospital.

Cardiogenic shock is not just a problem in adults, but affects children as well. Historically, this has been exclusively treated with venoarterial extracorporeal membrane oxygenation (ECMO). Some early pediatric experience with Impella (a percutaneous continuous flow VAD designed for adults) showed mixed results, but were generally better than ECMO. Using the power of ACTION – Advanced Cardiac Therapies Improving Outcomes Network – Dr. Tume et al. set out to describe the broader use of Impella in pediatric patients with cardiogenic shock.

Retrospective data was collected from 2014-2021. Any use of Impella as an adjunct to ECMO (i.e., LV unloading) was excluded from the study. The authors showed exponential growth in the use of Impella over time. Total patients were 47 with 52 devices, notably 20 of those in 2021. Most of those were supported with the Impella CP device (64%). Most of the patients had prior cardiac surgery (60%). The most common indications were transplant graft dysfunction (40%) and myocarditis/dilated cardiomyopathy (31%). The smallest patient supported was only 27 kg with a BSA of 1.05 m2 with an Impella 2.5.

Dr. Tume noted that this group is definitely challenging and a total of 59 adverse events were recorded. 39% of patients experienced hemolysis and 15% with significant bleeding. Importantly, there were 0 acute neurological events, which has plagued other temporary VAD and ECMO in pediatrics. Overall, and this was the big point, there was an 85% positive clinical outcome of either survival to explant (77%) or alive on device (8%), with only 15% mortality. He acknowledged that more work is needed to optimize its use and improve patient selection, but the Impella devices provide another important mechanical circulatory support option for children.



SUNRISE 03: How to Heal a Broken Heart: Using Durable VADs to Promote Myocardial Recovery

This bright-and-early **sunrise session** was a rapid-fire jaunt through the state of the field of myocardial recovery co-chaired by **Matthew Lander, MD** of Allegheny Health Network (Pittsburgh, Pennsylvania) and **Jacob Schroder, MD** of Duke University (Durham, North Carolina).

The morning featured a pre-recorded review of the *Physiological Underpinnings of Myocardial Recovery Across All Ages* by **Filio Billia, MD, PhD**, from the Toronto General Research Institute in Toronto, ON Canada. Patients with myocardial recovery had less cardiac and systemic inflammation compared to those that don't recover—and she stressed that recovery requires metabolic and genetic factors.

Caitlin Dadhania, PharmD, from Tufts Medical Center in Boston, MA USA then presented an overview of medical therapy that may promote recovery, entitled *Pushing the Boundaries with Medical Therapy in Durable VADs: Promoting Myocardial Recovery?* She showed several studies exploring how typical heart failure regimens including ACEi or ARB, beta blocker, and spironolactone decreased mortality on VAD support. Now there are preliminary data from several studies and abstracts (including a couple at ISHLT this year) that show some beneficial effects from ARNIs and SLGT2 inhibitors.

Martin Schweiger, MD, PhD, of Children's Hospital Zurich in Switzerland next presented data in children: *Tapping into the Fountain of Youth: Myocardial Recovery in Children*. His main point was that recovery in children is very low, < 10% regardless of era, geography (Europe vs United States), or even intention to treat (except in cases of known myocarditis). That all said, he was excited to share a very memorable case involving a child who had been implanted with a Berlin Heart EXCOR that recovered and was explanted after 700 days on device.

Evgenij Potapov, MD, of the German Heart Institute in Berlin, Germany articulated with data and personal experience the pros and cons of LVAD explant strategies in his talk *Purge the Device or Keep It In? Handling the Question of LVAD Explant*. He reiterated earlier numbers with a prevalence of 3.1-3.8% explant rate. What's the best strategy? The short answer was apical plug plus driveline removal. He only recommended alternative strategies (complete removal, pump removal + apical ring removal and LV reconstruction, or decommissioning) if there were specific infectious concerns or significant patient instability.

The early bird session concluded with an important but difficult topic by **Stavros Drakos, MD, PhD, FACC**, from the University of Utah in Salt Lake City, UT USA, titled *Post-Recovery: Now What?* The goal, he said, is a "sustained remission from recurring heart failure events." He showed some great data regarding the value of explant compared to post-transplant survival (no difference) and compared to continued LVAD support (better 5-year survival, 76% vs 46%). He suggested value in using pulmonary artery pressure monitoring (CardioMEMS) to guide LV unloading therapy, and mentioned an upcoming study called the TARGET LOAD study. Finally, he highlighted many opportunities for better science including evaluating the durability of recovery post-LVAD, the effects of new HFrEF medications (as mentioned by Dr. Dadhania earlier), need for ongoing ICD post-LVAD explant, and best surgical approaches for recovery.



SUNRISE 05: Keep it Less Complicated: Minimizing and Treating Complications in LVAD Patients - From Bleeding to Infection

This **sunrise session** highlighted a potpourri of strategies to address several complications in LVAD patients that have marked impact on the quality of life of the LVAD patient, including gastrointestinal bleeding, infection, and hemorrhagic stroke.

AVMs and Other Mechanisms Associated with GI Bleed After LVAD Implantation **Oksana Volod, MD**, Cedars Sinai Medical Center, Los Angeles, CA USA

Stop the Bleeding: Pharmacologic Interventions for GI Bleed After LVAD **Sara Strout, PharmD**, Johns Hopkins, Baltimore, MD USA

There is a high incidence of GI bleeding (18-40%) in durable and temporary LVAD recipients. The first talk presented an overview of several pathophysiological mechanisms that contribute to GI bleeding, namely AVM malformation (low pulsatile state), acquired vWF deficiency (high shear stress), platelet dysfunction (thrombocytopenia, RV dysfunction, antiplatelets) and angiogenesis (angiopoietin-2). In addition to highlighting strategies that minimize bleeding, e.g., reducing pump speed to minimize shear stress, withholding antithrombotic therapy and lowering target INR, reversal with vitamin K and prothrombin complex concentrate, administration of proton pump inhibitors, and endoscopic clipping or cautery, the second talk discusses pharmacological interventions (see ISHLT MCS 2013, ATS 2020 and AGI-CGI 2020 documents). Study outcomes for primary (i.e., ACEi/ARB, digoxin, omega-3) and secondary (i.e., octreotide, danazol, thalidomide, bevacizumab, tamoxifen, transexamic acid, desmopressin, vWD replacement, and doxycycline) prevention, along with their molecular pathways are discussed. Retrospective analyses including of STS Intermacs on these interventions demonstrate variable clinical outcomes, and further studies focused on HM3 are needed.

Mitigating Strategies to Prevent Infections in Durable VADs

Stephanie Pouch, MD, Emory University School of Medicine, Atlanta, GA USA

From Early Treatment of Driveline Infections to Late Treatment Considerations to Manage Central LVAD Infections: What Do VAD Centers Need to Know?

Alexander M. Bernhardt, MD, University Heart Center Hamburg, Hamburg, Germany

Infections contribute to LVAD readmissions (13.5%) and death (5.8%), with sepsis and driveline infections most seen within 30 days or after 90 days post-implant, respectively. *Staphylococcus aureus* or *CNST*, *Pseudomonas* or *MRSA*, and *Candida spp*. have been commonly associated with LVAD infections. These two talks highlight the various risk factors for infections and the strategies to reduce peri-operative and post-operative infection rates including addressing nutritional status and certain comorbidities (e.g., dental and skin disorders, glycemic control), early discontinuation of catheters and lines, and antimicrobial prophylaxis based on institutional epidemiology (see ISHLT MCS infection and AST documents). The second talk further reviews the standardized

DESTINE approach for staging of infections, driveline exit site care and plasmatherapy for difficult to resolve infections. Patient and caregiver education, anchor immobilization to minimize repeat trauma, and aseptic dressing changes improves one-year freedom from driveline infection from 82% to 92%.

The Domino Effect: Risk Factors and Risk Mitigation Strategies for Hemorrhagic Strokes in LVAD Recipients

Sern Lim, MD, Queen Elizabeth Hospital, Birmingham, UK

This talk focuses on hemorrhagic strokes—highlighting a 61% 1-year and 42% 2-year survival post-stroke—with 53% being intraparenchymal in nature. Patient (hypertension and cerebral amyloid angiopathy worsen risk), pump (HM3 vs HMII in the short-term (OR 0.46) and long-term (OR 0.23) is protective), and precipitant factors (MAP >90 mm Hg (OR 9.9), anti-platelet (OR 8.8), anti-coagulant (OR 5.1) and infection (OR 5.97) worsen risk) were discussed, along with targeted mitigation strategies.

VIEW SESSION DETAILS

- Summary by Varinder Kaur Randhawa, MD, PhD

SESSION 25: The Risky Arrhythmia: Matching Risks and Benefits of Cardiac Devices in LVAD Patients

<u>This symposium</u> discusses the impact of arrhythmias and device therapies in LVAD patients, and the implications of battery generator changes.

Arrhythmias in LVAD Patients: From the Atrium to the Ventricle **Natasha Aleksova, MD**, Toronto General Hospital, Toronto, ON Canada

DEBATE: Cardiac Devices in LVAD Patients: the More the Merrier? All LVAD Patients Should Have an ICD

(PRO) Elena Sandoval, MD, FEBCTS, Hospital Clinic, Barcelona, Spain

(CON) Jason N. Katz, MD, MHS, University of North Carolina, Chapel Hill, NC, USA These talks highlight the relatively high prevalence of atrial and ventricular arrhythmias in the LVAD patients (i.e., 20-50% within the first 30 days). Ventricular arrhythmias can impair RV function leading to RV failure, RV thrombosis, and reduced LVAD flows if sustained. Arrhythmias pre-LVAD portend the greatest risk for arrhythmias (ventricular HR 5.36, atrial HR 3.1) post-LVAD, and contribute to early all-cause mortality. The VT-LVAD score is described, and of note, the presence of \geq 3 risk factors for VT can lead to a 30% higher risk of electrical storm. ISHLT and AHA recommend considering ICD therapy in those with impaired LVAD flow, RV dysfunction, and systemic hypoperfusion in the setting of ventricular arrhythmias. However, ICD therapy is not without risk. Balancing the risks of RV failure and poor hemodynamics from recurrent arrhythmias in the absence of an ICD against the risk of inappropriate shocks, device complications and need for battery generator changes in its presence should be considered at each stage.

DEBATE: CRT Should Be Turned On in LVAD Patients

(PRO) Brian Houston, MD, Medical University of South Carolina, Charleston, SC, USA (CON) Evan P. Kransdorf, MD, PhD, Cedars-Sinai Heart Institute, Los Angeles, CA, USA Have you ever thought, "Is an LVAD enough for treating advanced heart failure (HF)?" CRT reduces HF readmissions (by 37%) and all-cause mortality (by 22%), but is this needed in all LVAD patients if this sub-group are likely CRT non-responders? This session presents the latest data on the risks and benefits of CRT in LVAD patients. This includes fewer ICD shocks, less HF hospitalizations, and improved load-independent RV contractility vs more generator changes and VT in CRT nonresponders, along with lower 6-minute walk distance and quality of life.

ICD and CRT-D Battery Depletion in an LVAD Patient: Change? Downgrade?

Jaime-Juergen Eulert-Grehn, MD, German Heart Institute, Berlin, Germany

Almost 70% of LVAD patients need a first battery change, and 40% need a second battery change, which occur every 4-5 years. This talk discusses peri-procedural complications in the setting of bridging vs no bridging, highlighting an overall 4-fold risk of hematoma and 16-fold risk of infection. With each revision, there comes an increased risk of hematoma (3.5-16%) and infection (2.4% without hematoma, 11% with hematoma). For these reasons, it is crucial at each generator change in the LVAD patient to consider whether there is an ongoing need for ICD or CRT-D

therapy, or whether these devices can be turned off.



- Summary by Varinder Kaur Randhawa, MD, PhD

SESSION 32: Unique Challenges for Women and Children Supported with MCS

The Thursday afternoon **symposium** focused on mechanical circulatory support, and featured six presentations on the differences, and sometimes inequities, of MCS and VAD support in women and children. The session was co-chaired by **Mirnela Byku**, **MD**, from University of North Carolina Chapel Hill and **Rachna Kataria**, **MD**, from Massachusetts General Hospital in Boston, MA USA.

Mary Norine Walsh, MD, MACC, from St. Vincent Heart Center in Indianapolis, IN USA; Anique Ducharme, MD, MSC, from the Montréal Heart Institute in Montréal, QC Canada; Juliane Vierecke, MD, from University of Cincinnati Health in Cincinnati, OH USA; and Heike Spaderna, PhD, from University of Trier in Trier, Germany, all focused on women and MCS, while Jamila Kremer, MD, from University Hospital Heidelberg in Heidelberg, Germany touched on both women and children, and Ryan Davies, MD, from Children's Health at University of Texas Southwestern in Dallas, TX USA had a pediatric-centered presentation.

Dr. Walsh's *The Heart of a Woman* presentation outlined the incidence, prevalence, and heart failure medical therapy studies that addressed the potential differences in women compared to men. She said it "is appalling" that women are less likely to be prescribed statins, aspirin, or exercise therapy and less likely to receive a device.

Dr. Ducharme addressed three features in her talk *Cardiogenic Shock in Pregnancy*: 1) spontaneous coronary dissection, 2) peripartum cardiomyopathy, and 3) mechanical circulatory support in pregnancy. She noted that percutaneous coronary interventions (PCI) are less successful and have more complications for spontaneous coronary dissection, peripartum cardiomyopathy has a high mortality rate (25-50%) and may reoccur, and early MCS improves mortality significantly but must be managed carefully given the effects of cardiogenic shock and MCS on both mother and baby.

In the middle of the symposium, the addition of pediatric discussion was presented by Dr. Kremer who noted the unique challenges in her talk *Temporary Circulatory Support (TCS) Options in Women and Children*. Important considerations often had to do with size including cannula size, oxygenator size, and pump size. And she noted the theme of the session: "We need more data for women and children."

Dr. Davies took up the pediatric mantle in regard to durable support with his talk *How Low can You Go: Durable LVAD Considerations for Smaller Patients*. He noted that smaller left ventricular internal dimension during diastole (LVIDD) led to worse LVAD outcomes, which did not always correlate well with patient body surface area (BSA). For smaller patients, he highly recommended 3D virtual fit testing with CT or MRI for best surgical planning.

Dr. Vierecke highlighted the important of importance of estrogen in heart failure and MCS in her talk *Hello Estrogen!* She discussed the important of contraception while on VAD, but strongly recommended against estrogen-containing birth control, and instead used either an intrauterine device (IUD) or progestin-only pill. However, she said there have been at least 6 reported

pregnancies while on VAD with 5 leading to successful delivery. That's amazing!

Dr. Spaderna rounded out the symposium emphasizing (again) the inequalities that women face with her talk *Equal Opportunity: Why are Women Less Likely To Be Referred for LVAD and How Can We Overcome These Barriers?*



SESSION 36: Blood Creeps Where It Cannot Flow, When It Stops... You Know: Drug Support for MCS Therapy

<u>Session 36</u>, which was co-chaired by **Edward Horn, PharmD**, from the University of Pittsburgh in Pittsburgh, PA USA and **Ivan Netuka, MD, PhD**, from Institute Clinical and Experimental Medicine in Prague, Czech Republic, featured novel studies to address LVAD complications.

First up was a pre-recorded talk by **Kristin Klaeski, MRS**, from Leipzig Heart Center in Leipzig, Germany, titled *Gastrointestinal Bleeding after LVAD Implantation: Is It Predictable?* She presented important background for her talk and the few to follow: that GI bleeding affects up to 30% of LVAD recipients and causes include arteriovenous malformations, acquired von Willebrand disease, and GI angiodysplasia. Her study looked at 36 patients and looked at the differences between "bleeders" and "non-bleeders." While demographics, baseline CBC and platelet aggregation were the same, the "bleeders" had less P-selectin and GPIIb/IIIa compared to "non-bleeders."

Kathryn Cavallo, BS, from Inova Heart and Vascular Institute in Falls Church, VA USA, followed with *Protein Biomarkers Predict Risk of Gastrointestinal Bleeding in Left Ventricular Assist Device Patients*. Specifically, she described the use of GDF-15, which is released by stress myocardium and inhibits immune cell and platelet aggregation, as a protein biomarker. She found that increased GDF-15 plus NT-proBNP was associated with higher incidence of GI bleeding and death, but GDF-15 was not associated with NT-proBNP. She built a multivariable model that could stratify LVAD patients into low-risk for GI bleeding (8.2%) compared to high-risk (36.6%).

Next up, **Amanda Fernandes**, **MD**, from Boston Medical Center in Boston, MA USA, evaluated treatment for GI bleeding with her talk *Octreotide for Recurrent Gastrointestinal Bleeding in Patients with Left Ventricular Assist Device: A Systematic Review and Meta-Analysis*. In the study, she reviewed 5 studies that included 261 patients. She ultimately concluded that octreotide made no difference in recurrent GI bleeding for this group of patients.

What about Omega-3 fatty acids for GI bleeding? **Zhaozhi Li** from the University of Chicago in Chicago, IL USA, evaluated that concept in her conclusively titled talk **Omega-3 is Not Associated** *with Reduced Gastrointestinal Bleeding in HeartMate 3 Left Ventricular Assist Device Patients*. In 75 patients and with none, low-dose, or high-dose Omega-3, there was no difference seen.

In a slight shift on the theme, the next talk by **Navin Kapur, MD**, of Tufts Medical Center in Boston, MA USA, was verbosely called *Single Acute Mechanical Circulatory Support Device Use is Associated with Reduced Mortality Compared to Multi-Agent Drug Therapy Alone for Cardiogenic Shock: An Analysis of the Cardiogenic Shock Working Group Registry*. Evaluating 3,171 CS patients, half with HF and a quarter with STEMI, in-hospital mortality was lower for those who received a device compared to multi-drug therapy. Not surprisingly, there was a direct association with inhospital mortality and SCAI stages. The session wrapped up with a talk by **John Leonard, MD**, from the University of Minnesota in Minneapolis, MN USA. His talk, titled *Stroke Risk in the Contemporary Era of Left Ventricular Assist Device Support*, was a single-center evaluation (N=318) of stroke risk between HeartMate 2 and HeartMate 3 patients. He found no difference in all-cause stroke through 1 year of LVAD support, but interestingly the odds of thrombotic stroke in the first 60 days post-LVAD implantation was higher in the HeartMate 3 group (OR 2.5, 95% CI 0.86-7.12, p=0.093). It is unclear why there would be such a significant difference, but he suggested that material ingestion into the pump during implantation could be a cause. All in all, another successful day at ISHLT.

VIEW SESSION DETAILS

SESSION 39: Exercise Capacity and Possible Determinants of Intolerance After LVAD Implantation

This **oral abstract session** provides an overview of various measures of exercise capacity and how it impacts clinical outcomes.

Mobilized Pediatric Patients on Veno-Arterial ECMO Have Improved Outcomes

Jonathan B. Edelson, MD, Children's Hospital of Philadelphia, Philadelphia, PA USA Immobility is associated with rapid deconditioning and myopathy. In this talk, early mobilization of pediatric patients on VA-ECMO is shown to be safe and feasible at some level (>10%) with reduction of narcotic and neuromuscular blockade use. More mobile vs non-mobile pediatric patients were discharged home alive off VA-ECMO or transplanted.

Multicenter-Derived Clinical Score Predicts Structural and Functional Cardiac Improvement in Chronic Heart Failure Patients Undergoing Mechanical Circulatory Support

Christos P. Kyriakopoulos, MD, U.T.A.H. Cardiac Transplant Program (University of Utah Health & School of Medicine, Intermountain Medical Center, George E. Wahlen VA Medical Center), Salt Lake City, UT USA

LVAD weaning is a complex decision, depending on evidence of reverse remodeling (LVEF >40%, LVEDD <6 cm at 12-months post-LVAD). Patient with acute HF, hypertrophic or infiltrative cardiomyopathy, LVEF >40% and <3 months of post-LVAD follow-up were excluded.

The Value of Physiotherapeutic Tests Next to Cardiopulmonary Exercise Test to Assess Exercise Capacity in Left Ventricular Assist Device Patients

Steven A. Muller, MD, University Medical Center Utrecht, Utrecht, Netherlands This study reviews several physiotherapeutic tests for their correlation to exercise capacity in LVAD patients as by CPET. The grip strength (RR 0.55, p<0.001) and 6-MWT (RR 0.49, p<0.001) as opposed to MIP best correlated with VO2 max.

Metabolic and Hemodynamic Determinants of Exercise with the HeartMate 3 LVAD

Afsana Rahman, MD, Northshore University Hospital, Manhasset, NY USA In this 10-patient study of HM3 LVAD patients, limitation in maximal exercise (pVO2 13 mL/kg/min and VE/VCO2 slope 42.4) was noted due to significantly elevated filling pressures (RA 13 mm Hg, mean PA 42 mm Hg, and PCWP 32 mm Hg).

Exercise Performance and Quality of Life of Left Ventricular Assist Device Patients After Long-Term Phase 3 Cardiac Rehabilitation

Thomas Schlöglhofer, MSc, Medical University of Vienna, Vienna, Austria This study showed that long-term phase 3 cardiac rehabilitation improved submaximal exercise performance, mobility, and strength without changing maximal aerobic exercise capacity. The relative peak VO2 (AUC 0.88, p<0.001) and 6-MWT (0.78, p<0.029) have prognostic value for hospital readmissions.

Safety and Efficacy of Home-Based Exercise Rehabilitation Using Remote Monitoring in New Left Ventricular Assist Device Recipients

Himabindu Vidula, MD, University of Rochester, Rochester, NY USA

This pilot MOVE-LVAD RCT study in HM3 LVAD patients sought to evaluate physical activity levels, and secondarily adherence, safety, readmission burden, 6-MWT and quality of life. Adults with a new HM3 LVAD implantation capable of independent ambulation and access to use of a smartphone app were randomized to usual care (n=6) vs intervention care (n=8). Usual care included instruction to ambulate for 30 min up to 5 times weekly, while intervention care provided instruction to walk for 10 min up to 5 times weekly along with 1-2 sets of 12-15 reps of weights up to 3 times weekly with video call reminders by an exercise physiotherapist. This study found that at 1 week, both groups ambulated >1500 steps daily. By 24 weeks, the intervention arm walked 4500 steps daily vs 1800 steps daily.

VIEW SESSION DETAILS

- Summary by Varinder Kaur Randhawa, MD, PhD

SUNRISE 13: Poised for Success: Tips and Pearls on Manuscript Submission and Effective Peer Review

<u>This session</u> provided an overview for individuals interested in contributing to The Journal of Heart and Lung Transplant (JHLT) community through manuscript submission or editorial board experience.

Case Presentation: Taking an Idea to Manuscript and JHLT Submission and Case Presentation UPDATE Kiran Mirza, MD, Rigshopitalet, Copenhagen, Denmark

These two talks provided a five-step approach to JHLT manuscript submission. This includes being well versed in the topic of interest, translating thoughts onto paper, then seeking input and review from advisors, formulating a plan, and finally executing your plan.

Great Ideas to Great Manuscripts: Pearls for Early Career Investigators

Michelle M. Kittleson, MD, PhD, Cedars Sinai Heart Institute, Los Angeles, CA, USA This talk highlighted how to write your manuscript. First, choose the focus of the manuscript and ensure that the research question meets the FINER criteria. Once data are gathered, they should be analyzed for statistical significance and presented in tables and/or figures. The methods can be tackled next, before a deeper dive is taken into the literature to help shape the introduction, discussion with a limitations section and lastly the abstract. In the end, be sure to seek advisor input.

What We Look for at JHLT: Manuscript Workflow and Review Process

Daniel R. Goldstein, MD, University of Michigan, Ann Arbor, MI, USA

The Peer Review Process: How to Shine

Yael Peled, MD, Sheba Medical Center, Kiryat Ono, Israel

Give Us Your Top Do's and Don'ts at JHLT

Christine Lau, MD, MS, University of Maryland, Baltimore, MD, USA These last three talks provided an overview of the manuscript review process, shared what reviewers are responsible for, and highlighted the top do's and don'ts at JHLT. The Editor-in-Chief oversees a large task force including deputy, section, statistical, technology and digital and social media editors. The editorial board evaluates for novelty, duplicity, writing style and multicenter

VIEW SESSION DETAILS

- Summary by Varinder Kaur Randhawa, MD, PhD

studies.

SESSION 50: Double Trouble: End-Stage Renal Failure in End-Stage Heart Failure

The **big MCS symposium** for the day, set up in the expansive Hall D, focused on the all-toocommon problem of combined kidney and heart failure. This session was co-chaired by **Michael Kiernan, MD**, of Tufts Medical Center in Boston, MA USA and **Sanem Nalbantgil, MD**, of Ege University in Izmir, Turkey.

The first presentation was a pre-recorded talk by **Michelle Kittleson, MD, PhD**, of Cedars Sinai Heart Institute in Los Angeles, CA USA entitled *Leading With Electrolytes: Urinary Sodium to Empower Nursing Algorithms for Decongestion in the Unresponsive Patient*. In her talk, she outlined the importance of diuretic resistance and assessment of diuretic responsiveness to guide diuretic dosing. She argued that protocolization is possible for the bedside nurse and is associated with better outcomes.

The first live session was presented by **Paolo Colombo, MD**, from Columbia University Medical Center in New York, NY USA to discuss *LVAD Therapy and Kidney Function: Chicken, Egg or Cystatin C*? His talk focused on the deficiency of serum creatinine and the more effective estimation of kidney function and estimated glomerular filtration rate using cystatin-C, including in the intensive care setting. His main point: "ISHLT should change their recommendation guidelines" to include cystatin-C.

Finn Gustafsson, MD, PhD, of Rigshospitalet in Copenhagen, Denmark next presented *Assessing Thresholds for MCS and Transplantation: Whose Kidneys Will Improve?* He started out by noting that ISHLT guidelines say the eGFR < 30 and dialysis are relative contraindications to heart-only transplantation. The highlight of the talk, though, was the data that showed MCS improves serum creatinine initially, but almost always returns to baseline over a relatively short time.

Another pre-recorded session followed, presented by **Satoshi Saito, MD, PhD**, of Tokyo Women's Medical University in Tokyo, Japan with her presentation *Assessment of Combined Transplants: To Do or Not To Do?* She presented the conflicting data on heart-kidney vs heart-only transplantation, but noted that the survival benefit was inversely proportional to pretransplant eGFR. Specifically, combined heart-kidney was better if the pre-transplant eGFR was < 30 or the patient was on dialysis, but an eGFR of 30-40 showed no difference between combined heart-kidney compared to kidney-after-heart transplantation.

Jennifer Cowger, MD, of Henry Ford Hospitals in Detroit, MI USA, was up next with her talk *Pumped and Distended: Assessing Optimal Dialysis Modalities in Patients with Pumps*. She prefaced her talk with a great line, which is often all too true in this line of work: "No data ahead." She hypothesized the longer session with slower ultrafiltration rates for dialysis was helpful. She also hypothesized that more sessions in a week could help reduce total volume per session. Finally, she highly recommended a pulmonary artery monitor to further manage fluid shifts on dialysis and LVAD.

This big symposium was closed out by **Amanda Ingemi, PharmD**, of Sentara Norfolk General Hospital in Norfolk, VA USA, with her live session *Save the Kidneys! A Technical View on Immunosuppressive Therapies for Renal Protection After Cardiac Transplantation*. She reviewed the literature on kidney-sparing regimens and highlighted several things. Sirolimus without calcineurin inhibitor (CNI) was better for the kidneys but led to more rejection in the first year. Tacrolimus is less nephrotoxic than cyclosporine. Extended-release (ER) tacrolimus was either worse or showed no significant difference in kidney function compared to standard-release tacrolimus. And finally, basiliximab and belatacept could be used as CNI-sparing immunosuppression. So, when taking care of the heart, don't forget the kidneys.

VIEW SESSION DETAILS

SESSION 53: Structural Heart, Mitral and Tricuspid Valve Disease in LVAD Patients: Current Insight and Controversies

<u>This session</u> discussed the natural history of mitral and tricuspid valve disease, and provided an overview of percutaneous and surgical valvular interventions.

Pathophysiology and "Natural History" of Tricuspid Regurgitation in LVAD Patients **Kadir Caliskan, MD, PhD**, Erasmus Medical Center, Rotterdam, Netherlands

Concomitant TR Surgery in LVAD Implantation: Yes or No? Ivan Netuka, MD, PhD, Institute for Clinical and Experimental Medicine, Prague, Czech Republic

Alternate Therapies and Future Perspectives for Tricuspid Valve Pathologies in LVAD Patients Daniel Zimpfer, MD, MBA, Medical University of Vienna, Vienna, Austria These first three talks discussed the pathophysiology and management of tricuspid regurgitation (TR). About 30% of pre-LVAD patients have moderate-to-severe TR, which has been shown to decrease at one-year post-LVAD implantation. Risk factors for TR include older age, being female, device-related TR, pulmonary hypertension, mitral valve disease, left atrial enlargement or right atrial or ventricular (RV) enlargement that can result in functional TR. The clinical impact of uncorrected TR is worsening RV failure, which portends greater mortality.

Data on clinical outcomes is variable due to the heterogeneity, small sample size and retrospective nature, although studies have shown normalization of RV remodeling with improvement of TR by echocardiogram. ISHLT, AATS and ESC recommendations are to address moderate-to-severe TR with repair or revision. Novel strategies for tricuspid valve repair are also highlighted, including edge-to-edge repair techniques and the cardioband. Concomitant TV procedures at LVAD implantation are associated with increased bleeding, arrhythmias and stroke.

Take It or Leave It: Is There a Benefit of Concomitant Mitral Valve Repair at the Time of LVAD Implantation or Should We Leave the Valve Alone?

Jan D. Schmitto, MD, PhD, MBA, FCCP, FRCS, Hannover Medical School, Hannover, Germany

Mitra Clip Prior to LVAD Implantation: A Viable Option of Mitral Repair? **Dina De Bock, MD**, Antwerp University Hospital, Edegem, Belgium

Pre-existing Mitra Clip in Patients Undergoing LVAD Implantation: Boon or a Bane

Paul C. Tang, MD, PhD, University of Michigan, Ann Arbor, MI USA These series of talks reviewed clinical outcomes in the setting of mitral valve repair done concomitantly or with Mitra Clip pre-LVAD implantation or heart transplant. The severity of mitral regurgitation (MR) and/or stenosis (MS) should be evaluated in candidates for advanced therapies, as severe MR or MS could have implications in the flow through the LVAD.

Revascularize or Not a Critical Coronary at the Time of LVAD Implant

John M. Stulak, MD, Mayo Clinic, Rochester, MN USA This talk discussed whether there is a role for concomitant CABG or PCI during LVAD implantation. In the setting of destination therapy-LVAD, or the presence of a dominant RCA or multiple in-stent stenoses, concomitant CABG may have a role if the patient has ongoing ischemia and symptom burden. But why revascularize the LAD when the patient is undergoing LVAD implantation? Despite a high prevalence of CAD or ischemic cardiomyopathy, there is a low incidence of angina, myocardial infarction, or PCI (EPPY 0.2-0.003) during 645 patient-years of CF-LVAD support in 342 patients followed between February 2007 and July 2016.



- Summary by Varinder Kaur Randhawa, MD, PhD

SESSION 46: Next Exit (Site): Infections in MCS

Shortly after the Sunrise Sessions, another round of interesting talks about infections related to mechanical circulatory got underway. **Next Exit (Site): Infections in MCS** was co-chaired by **Rebecca Kumar, MD**, of Medstar Georgetown University Hospital in Washington, DC USA and **Matthew Lander, MD**, from Allegheny General Hospital in Pittsburgh, PA USA.

Neha Bansal, MD, from Children's Hospital at Montefiore in Bronx, NY USA kicked things off with *The Initial Analysis of Infectious Adverse Events in Pediatric Ventricular Assist Devices Reported to the ACTION Registry*. Of the 506 patients in the registry, 27.5% had an infectious complication. Less than 1/3 were device-related, with a large minority (46%) being bacterial. Maybe not surprisingly, patients with paracorporeal devices had a higher risk of infectious adverse events that those with intracorporeal devices.

Lutz Hilker, MD, from Klinikum Karlsburg in Kalsburg, Germany presented some interesting findings in his talk, *Successful Cold Atmospheric Plasma Therapy of Driveline Infections in Patients with Left Ventricular Assist Devices*. A few takeaways from his talk were:

- 1. Daily cold atmospheric plasma (CAP) was more effective than intermittent CAP therapy
- 2. Driveline infections still require systemic antibiotics on top of CAP therapy
- 3. Unfortunately for some, this therapy is not available in the United States yet.

Next, **Karola Jering, MD**, of Brigham and Women's Hospital in Boston, MA USA presented her work *Antibody Responses to COVID-19 Vaccination in Left Ventricular Assist Devices*. She found that Black/Hispanic race, prior COVID-19 infection, and Moderna > Pfizer vaccine were associated with higher titers at 9 months post-vaccination, while low absolute lymphocyte counts and the Johnson & Johnson vaccine were associated with lower titers at 9 months. Importantly, among the patients in her study, there were no vaccine complications, no hospitalizations and only 2 of 67 who contracted COVID-19 during the study period.

Alisson Estrada-Roman, MD, from the University of Minnesota in Minneapolis, MN USA next looked at the *Incidence of Blood Stream Infection and Impact on Survival in Patients on Left Ventricular Assist Device Support*. Highlights of her work included association of blood stream infection with higher INTERMACS level (1 and 2), diabetes mellitus, and destination therapy. Most importantly, she found that blood stream infection increases the risk of mortality in both unadjusted (HR 1.96, 95% CI 1.02-3.76) and adjusted models (2.00, 95% CI 1.03-3.88).

Another speaker from the Unvieristy of Minnesota, **Zeina Jedeon, MD**, presented her work on the *Impact of HIV Infection on Outcomes After Left Ventricular Assist Device Implantation: An INTERMACS Analysis*. Of 15,465 patients in the registry, there were 49 with HIV infection, which was associated with a statistically significant decrease in survival compared to those without HIV, even after adjusting for other risk factors.

The morning session was rounded out by **Ahmed El Banayosy, MD**, from the INTEGRIS Baptist

Medical Center in Oklahoma City, OK USA, with his abstract *Impact of Surgical Debridement with or without Omental Wrap on Deep LVAD Infections*. Deep LVAD infections are life-threatening, but combining omental wrap with surgical debridement and antibiotics seems to be more effective than debridement and antibiotics. Results included decreased readmissions, ability to transition to oral antibiotics, and a staggering improvement in survival (18% mortality with and 92% without omental wrap). All I can say after that is: that's a wrap!



SESSION 67: Everything Gets Better: Novel Technology for Unmet Needs and Improved Outcomes in MCS

<u>This session</u> introduced novel technologies to address certain clinical gaps in patients undergoing LVAD implantation.

Large Animal Investigation of Cardiopulmonary Support for Acute-on-Chronic Right Ventricular Failure: Physiologic and Hemodynamic Consequences of Circuit Configuration

Rei Ukita, PhD, Vanderbilt University Medical Center, Nashville, TN USA This talk highlighted a combined LVAD-PAD (pulmonary assist device) support system for pulmonary hypertension (PH) therapy. The RA-LA configuration was found to have that lowest pump need for target flow, along with the lowest inotropic dependence and best ventricular restoration (i.e., less RV pressure overload).

Preclinical Assessment of a Rapid Anastomotic Device for HeartMate 3 Apical Cuff Implantation

Max B. Mitchell, MD, University of Colorado, Aurora, CO USA

This talk highlighted how a rapid anastomotic device serves as a sequential and synchronous rapid delivery tool, leading to an interference-free pump connection, good hemostasis, and reducing the myocardial footprint.

Soft Robotic Dynamic Cardiomyoplasty with Electrically Contractile Artificial Muscle (AHM)

Arjang Ruhparwar, MD, PhD, University Hospital Essen, West-German Heart and Vascular Center, Essen, Germany

The authors herein discuss the utility of carbon nanotubes in multiple medical settings. In particular, this work showcases the use of carbon nanotubes as electrically contractile polymers or "artificial muscle," with the capacity to preserve the biological surface and pulsatility.

The CorWave LVAD - Synchronized Pulsatility with Improved Hemodynamics

Trevor A. Snyder, PhD, CorWave, Clichy, France

This talk showcases the CorWave LVAD, which aims to mimic physiological pulsatility. The pump transitions between a low or high level in diastole or systole, respectively. With the presence of arrhythmias, increased preload and afterload, and suction, the system is autoregulated to transition to a continuous mode of operation to maintain LVAD flow.

Prognostic Value of Pressure-Volume Measures in Hemocompatibility-Related Clinical Adverse Events

Aaron Gunawan, BMed (Hons)/MD, St Vincent's Hospital, Darlinghurst, Australia Hemocompatibility-Related Clinical Adverse Events (HRAEs) include pump failure, neurological events, and non-surgical bleeding. In this talk, the prognostic value of pressure-volume measures in HRAEs were evaluated through prospective assessment over 12 months of 36 patients implanted with HVAD. The patients evaluated had a mean age of 56 years, with a BMI of 26 kg/m2. Most patients were male (83%), with non-ischemic cardiomyopathy (69%). This study highlights the ability of pressure-volume loops to depict the physiological changes found in the setting of various HRAEs. With such knowledge, the ability to mitigate the pathophysiological sequelae in HRAEs may be better addressed.

Modular Physiological Control for Left Ventricular Assist Devices: A Clinical Pilot Trial

Martin Maw, MSc, Medical University of Vienna, Vienna, Austria

Currently, pump speed is adjusted periodically to aid mechanical unloading on the basis of symptoms, echocardiographic parameters and biventricular filling pressures. This clinical pilot trial evaluated the safety and feasibility of a sensorless modular physiological control system in six patients implanted with HVAD LVADs in response to real-time changes in physiological demand, with the ultimate goal of lower rates of adverse events from suction and increased quality of life from improved unloading. The controller had supervision, heart rate, pulsatility, and suction modules, along with a safety switch. The patients were subjected to orthostatic shifts, Valsalva manoeuvres and submaximal ergometry. Postural changes resulted in lower speeds in the supine vs standing positions, with suction occurring during the transition to standing. With Valsalva, the highest suction burden and speed reduction happened in the late straining period. During ergometry, speed was generally increased. Future studies will need to explore compatibility with other continuous flow pumps.

VIEW SESSION DETAILS

- Summary by Varinder Kaur Randhawa, MD, PhD

SESSION 70: Little Patients with Big Hearts Need Our Support: MCS in Pediatrics

The highlight of my visit to ISHLT came late on Friday afternoon with a <u>session on mechanical</u> <u>circulatory support in pediatric patients</u>. It was co-chaired by **David Peng, MD**, of University of Michigan in Ann Arbor, MI USA, and **Jodie Lantz, MSN, APRN, PCNS-BC**, of University of Texas Southwestern Children's Health in Dallas, TX USA.

Bibhuti Das, MD, of Children's Hospital of Mississippi (Jackson, Mississippi) started this off with a pre-recorded abstract on *Impact of the 2016 Organ Procurement and Transplantation (OPTN) Pediatric Heart Allocation Policy Change on Use of Durable Ventricular Assist Devices and Heart Transplantation Rates in Children with Congenital Heart Disease versus Cardiomyopathy*. Highlights included an increase in overall VAD numbers, but not as a percent of those on the waitlist. More were transplanted by 90 and 180 days, and there was actually in increase in waitlist mortality for those with congenital heart disease in the more recent era.

Manan Desai, MD, of Stanford University in Palo Alto, CA USA then presented *Perioperative Morbidity and Outcomes of Transitioning from ECMO to VAD Support in Pediatric Patients: A STS Study*. Out of 735 patients, he noted VAD only were typically older (usually > 11 years old) compared to the ECMO->VAD group (usually infants). Also, not surprisingly the VAD mortality was significantly less than ECMO->VAD (16% vs 34%). On multivariable modeling, important risk factors were ECMO, cardiogenic shock, mechanical ventilation, dialysis (this one with a whopping OR of 25!), stroke and head bleed.

David Sutcliffe, MD, of Children's Mercy Hospital in Kansas City, MO USA, presented his work from a single center study at UT Southwester Children's Health Dallas called *Continuous Flow Paracorporeal in Children: A Single Center Experience*. He noted the success of the Dallas cfVAD-only strategy (no Berlin Hearts) including in the littlest patients. 12-month survival was 82% (5 deaths) and relatively low (compared to previously published data) adverse events such as stroke (11%), major bleeding (39%), and infection (32%), while 25% had no adverse events.

Tanya Perry, MD, of Cincinnati Children's Hospital in Cincinnati, OH USA followed up a major symposium theme from Thursday when she presented *Ventricular Assist Devices are Underutilized in Female Children*. She noted that while heart failure hospitalizations in children were equal by gender, of those heart transplant patients supported with VAD, only 44% were female. Of the 505 supported with an intracorporeal device, the percent of females was even lower at 38%. This all despite no major differences in demographics, or post-transplant outcomes.

Sydney Carrington, RN, BSN, of Children's Health Dallas (there's a big Texas representation) presented *Remote Monitoring of Pediatric VAD Patients: Early Recognition for Improved Management*. She described their experience in 13 patients over 2,519 VAD-days using a tablet or phone with an app. It included pump settings, symptoms, fluid intake, diuretics use, weight, PA pressure monitoring if available, and even pictures! It was a great success, she said, and they will continue to use it for their discharged VAD patients.

Finally, the session concluded with **Desiree Machado**, **MD**, of University of Florida Shands Hospital in Gainesville, FL USA presenting her views on *End of Life in Children on Mechanical Circulatory Support*. She, as she has done at several other venues in the past, elaborated on the importance of end-of-life care in this patient population. And while we as providers never like to admit defeat (death), there are ample opportunities to help families (and staff and providers) deal with the occasionally inevitable loss.



SUNRISE 15: The Right to MCS: Are We Still Allowed To Say NO?

<u>This session</u> explored therapeutic considerations including palliation in patients with advanced heart failure where options are limited.

A Life After ECMO Is (Not) Possible: When Nobody Wants Your Patient Silvia Mariani, MD, Hannover Medical School, Hannover, Germany

A Life After ECMO Only As Destination Therapy Alessandro Barbone, MD, PhD, Humanitas Research Hospital, Rozzano, Italy

A Life After ECMO Is (Always) Possible: The Perspective of an LVAD and Transplant Center **Udo Boeken, MD**, University of Düsseldorf, Düsseldorf, Germany

When the Doctor Says NO: Ethical Implications of a Difficult Choice **Shunichi Nakagawa, MD**, Columbia University Medical Center, New York, NY USA

Systems of care are regionalized throughout the world, such that not every center has capacity for advanced therapies. Have you ever wondered what happens to your patient on veno-arterial extra-corporeal membrane oxygenation (VA-ECMO) when there are no options, limited options, or full options for advanced therapies at your center? The first three talks of this symposia, presented by Drs. Mariani, Barbone, and Boeken, reviewed important considerations for patient care under these different circumstances and center-specific perspectives, including how to wean a patient from VA-ECMO or when to engage palliative care when there is futility, and when and how to safely transfer patients to centers with advanced therapies when your center has limited capacity for mechanical heart pumps or heart transplant

The final talk, presented by Dr. Nakagawa, reviewed a three-stage protocol for how to approach difficult decisions when a patient is ineligible for advanced therapies:

- 1. Share knowledge around the prognosis of the patient in futile ECMO as a bridge to "nowhere," the confinement to the ICU, and the limited survival from days to weeks.
- 2. Clarify goals of care by trying to understand what is important to the patient, to understand their hopes and worries, and to understand what is meaningful.
- 3. Negotiate treatment options within this discussion—using shared decision making and discussing the involvement of palliative care.

VIEW SESSION DETAILS

- Summary by Varinder Randhawa, MD, PhD