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Highlights of the Sixteenth International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion

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The *16th International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion* was held virtually via Zoom using facilities and technical support at the Cincinnati Children's Heart Institute, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, United States of America, August 26 to 27, 2021. The co-chairs of the scientific program were Angela Lorts, MD, MBA, David L.S. Morales, MD, James Reagor, MPS, CCP, FPP, and Akif Ündar, PhD, Summarized herein are the highlights of this unique symposium which brought together members of the scientific community utilizing a virtual platform.

The primary objective of all 16 International Conferences on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion has been to create a platform to exchange scientific data in the interest of improving the outcomes of pediatric heart failure patients and complex congenital heart surgery patients who rely upon acute or chronic mechanical circulatory support (MCS). In particular, participants are encouraged to emphasize both positive and negative experiences with the devices and techniques, so that lessons can be shared, and mistakes will not be repeated case after case in these most fragile patient populations. We are proud that many new clinical and research collaborations have been started around the globe as a result of the unique, collegial, and approachable atmosphere shared among key experts and participants during our past 16 events. All local organizers have also offered hands-on experiences in their state-of-art simulation facilities with new Cardiopulmonary Bypass (CPB), Extracorporeal Membrane Oxygenation (ECMO), and Ventricular Assist Device (VAD) equipment and techniques, along with special tours of neonatal and pediatric intensive care units. These one-to-one training opportunities with the experts from high-volume centers in this underserved field may significantly impact the outcomes of heart failure and complex heart disease patients around the globe.

Sixteenth Event Details

All of the scientific program details are presented in Supplemental Table 1. The scientific program included a keynote lecture, 27 invited lectures, and 18 digital posters selected from submitted abstracts.

The keynote lecture was given by Dr Richard Wampler and titled "History of Ventricular Assist Devices: An Engineer's Perspective." We felt quite fortunate hearing the perspective and insights about the field of mechanical circulatory support from arguably the most successful engineer at bringing VADs from concept to market. He not only gave as a unique assessment of the field from an engineering standpoint but a glimpse into his personal journey of curiosity, failures, and success. His inability to stop seeing the possibilities of new and better mechanisms to motorize VADs was highlighted by his newest concept while in retirement, of using nutation which was borrowed from the mechanism of water meters that we all have in our houses. His talk was very inspiring for any scientist because it was a wonderful example and reminder to stay curious and observant, keep questioning if things can be

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done better, lean into failure so you extract all you can from it, and enjoy the journey.

The lectures on the use of MCS ranged from the timing of support for a variety of populations to the different strategies of MCS for the most challenging cohorts like Fontan and Bidirectional Glenn patients, to new and innovative ways to care for these children once on support. Intermingled with these lectures were case reports of unique patients being supported with devices in innovative ways, as well as an opportunity to see great science being done by fellows, residents, and other scientists presented via virtual poster sessions during break periods between oral presentations. The last session was a series of debates that was a wonderful forum that elevated discussion and participation and covered topics from the best way to get a pediatric VAD to market to pulsatile versus continuous flow to support infant single ventricle patients. Most gratifying, for many of the authors who have been attending this meeting for over a decade, was to see how much the field has matured. A decade ago, our concepts and issues were light years behind where the adult field was but now, we remain small in number but seem to have even surpassed the adult field in some ways (eg, anticoagulation, standardization of protocols). We strongly believe that this has been possible by our commitment to cooperation and sharing rather than competition, which at the end is the essence of this meeting. There is no better example of this than the Advanced Cardiac Therapy Improving Outcomes Network (ACTION). The history and current work of ACTION was summarized during this meeting. Briefly, the network is a learning health system that brings all stakeholders (providers, families, regulatory agencies, and industry) together to improve the care of children with heart failure. The network was conceived in 2017 with five centers working together. As of 2021, the network now has 57 institutions from eight countries working together on projects ranging from decreasing adverse events in VAD patients to expanding the way we evaluate size matching of donors and recipients to improve the utilization of donor organs. The network is also using real-world data for regulatory purposes to expand FDA labeling and improve access to more advanced therapies to more children.

The primary focus of this conference was the application of MCS in the pediatric and congenital population. Presentations on MCS centered mainly on the management of and prevention of the inherent risks and elevated incidence of bleeding and hypercoagulability events. Among the highlights of this year's talks, Dr Thangappan, Dr Zafar, and colleagues from Cincinnati Children's Hospital Medical Center (CCHMC), using updated United Network for Organ Sharing (UNOS) data, reaffirmed the benefit of MCS on positive waitlist outcomes. In addition, they reported that this benefit was also observed among patients with elevated pulmonary vascular resistance (PVR), with no significant differences in waitlist outcome depending upon the severity of PVR elevation.[1]

Dr Schill and colleagues at Washington University School of Medicine in St. Louis presented their institution's retrospective study, the largest to date, comparing anticoagulation with heparin versus bivalirudin during 55 extracorporeal life support runs. They observed no difference in neurologic abnormalities, circuit interventions, or survival between groups.[2] Along a similar vein, the group from Le Bonheur Children's Hospital in Tennessee discussed their initial experience with the novel reversible platelet $P2Y_{12}$ antagonist Cangrelor. Five patients on VAD support were given the drug for a mean of 42 days. VAD circuit thrombosis requiring circuit intervention complicated the courses of two of the five patients. Two patients had non-severe bleeding events responsive to withholding the medication. But no thromboembolic events were noted. The authors state that the reversibility and short half-life of Cangrelor make it a desirable agent for use with VADs, and their report—while limited by size—certainly adds to the discussion of whether this drug might be beneficial on a wider scale.[3]

Presentations focused, too, on hypercoagulability and cerebrovascular events associated with MCS use. Dr Thangappan and associates shared their findings from data compiled from UNOS and Pediatric Health Information System (PHIS), showing that patients who suffer from stroke while on MCS experienced similar post-transplant survival in comparison to those without stroke, but that the risk of repeat stroke post-transplant was higher (unpublished data). Studies with greater longitudinal follow-up can better assess the long-term impact of waitlist stroke in these patients.

Consistent themes throughout the conference were: (1) the use of intracorporeal VADs continues to increase in congenital heart surgery programs with earlier placement. The reasons for earlier placement include the stroke rate is <4% due in most part to the work of ACTION, the improving performance of the current technology, and the use of the device to treat medically resistant heart failure rather than solely as a bridge to transplant, although that is the eventual endpoint for the vast majority of pediatric patients. (2) Use of VADs has increased in the Fontan patient population, although the knowledge of who are the best candidates and issues regarding fenestration still require further study through multicenter collaboration. (3) There is ongoing discussion regarding neonatal and infant single ventricle patients and the question of whether it is better to support these patients with paracorporeal pulsatile flow devices, paracorporeal continuous flow devices, or a combination of both types of devices. (4) The use of paracorporeal continuous flow VADs as an alternative to ECMO support has been shown to be efficacious in the setting of temporary inflammatory causes of heart failure such as myocarditis and acute graft dysfunction.

Included, along with these important discussions around VAD support of some of our most critically ill patients, were topics examining techniques related to the optimization of cardiopulmonary bypass (CPB). Children's Hospital of Philadelphia's (CHOP) Chief of Perfusion, Tami Rosenthal described the history of modified ultrafiltration (MUF), how it became a mainstay, and the benefits of MUF. Recently, the necessity of MUF has been questioned in the face of smaller

cardiopulmonary bypass circuit design. Mrs. Rosenthal described these arguments and ultimately explained why her institution continues to employ the technique utilizing a novel MUF circuit.

Braley Hendrix described a study at CCHMC examining neonatal prime quality. Every pediatric perfusionist understands how important the quality of the CPB circuit prime is to the conduct of bypass. Mrs. Hendrix presented her institution's historical practice, the study which critically examined that practice, and the modifications made to improve the quality of the neonatal prime in her presentation "Building the Perfect Prime." The investigators at CCHMC examined the chemistry and hematology of blood-primed circuits for neonates and how their measurable properties change over time. Base deficit/excess, pH, pO_2, pCO_2, HCO_3, glucose, sodium, potassium, calcium, hematocrit, lactate, and osmolality were analyzed. Among all measured parameters, various rates of change were observed. While most changes in the parameters were found to be statistically significant, those changes may not be clinically significant based on clinician interpretation. Hendrix and associates concluded that attention to the prime quality beyond the immediate post-priming period may be beneficial. Should the time period between validation of the prime quality and initiation of bypass be extended, it may be advisable to reevaluate the prime quality.[4] Another exciting avenue of research is the addition of nitric oxide to the "sweep gas" of the CPB circuit. The group from the Medical College of Wisconsin presented the findings of their randomized, double-blinded, placebo-controlled trial in infants undergoing CPB, which showed that nitric oxide did not impact clinical outcomes and did not appreciably affect the preservation of platelet count or responsiveness, but did lead to a non-toxic elevation of methemoglobin levels.[5] Much more remains to be learned about the applications of nitric oxide during CPB.

In the era of "big data" and our ability to collect perfusion-related data during CPB cases, the manner in which we can utilize that data to improve outcomes is the next step in our evolution. James Reagor reflected on the experience implementing electronic perfusion records at Cincinnati Children's Hospital. Mr Reagor described the evolution of the electronic perfusion record and how it has grown from simply an electronic version of a paper chart to a storehouse of valuable data, and ultimately, a source of information to improve the quality of perfusion practice.

Young Investigator Awards

Each year, young investigators compete to receive *the John A. Waldhausen, MD, Young Investigator Award* or *the William S. Pierce, MD, Young Investigator Award* based on their presentations, including posters. This year six awardees shared the two awards. Supplemental Table 2 summarizes the names and the presentation titles of each awardee.

Special Education & Service Plaque

Dr Angela Lorts, Dr David Morales, MD, and James A. Reagor, MPS, CCP, FPP, shared the *Special Education & Service Plaque* in appreciation of their valued participation, continuous support, and generous donation of their time as the Co-Chairs of the Scientific and Planning Committees of the 16th International event.

In summary, the Sixteenth International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion was successfully held using a virtual platform, with invited lecturers and participants around the globe, including Australia, Brazil, Canada, China, Malaysia, New Zealand, Peru, Philippines, Russian Federation, Thailand, United Kingdom, and the United States.

Author's Statement

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Supplemental Material

Supplemental material for this article is available online.

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Supplemental Table 1

Details of the 16th International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion

THURSDAY, AUGUST 26, 2021- SESSION 1

10:00 – 10:10am **Welcome Remarks/Housekeeping- *Angie Lorts, MD, MBA and David Morales, MD***

Moderators: *David Morales, MD and Akif Undar, MS, MSE, PhD*

10:10-10:25am	Choosing the Right Device in Regards to Type and Acuity of Heart Failure *Iki Adachi, MD (Houston, TX)*
10:25-10:40am	Outcomes and Factors Associated with Early Mortality of Extracorporeal Membrane Oxygenation in Pediatric Cardiac Surgery *Yu Jin, MD (Beijing, China)*
10:40-11:00am	Evaluation of Combined ECLS and CRRT on Hemodynamic Performance and gaseous microemboli handling ability in a simulated neonatal ECLS systems *Akif Ündar, PhD (Hershey, PA)*
11:00-11:20am	CASE #1 Total Artificial Heart in the Infant *Adam Szadkowski, MD (Milwaukee, WI)*
11:20- 11:40am	**Panel Discussion**
11:40 – 11:45am	**Presentation of Young Investigators' Awards**
11:45 – 12:00pm	**DIGITAL POSTERS/BREAK**
12:00 – 12:40pm	**Keynote Lecture** History of Ventricular Assist Devices: An Engineer's Perspective *Richard Wampler, MD (Sacramento, CA)*

Moderators: *Angie Lorts, MD, MBA and David Cooper, MD, MPH*

12:40 – 1:00pm	Durable Ventricular Assist Device Support for Failing Glenn Physiology

Jiyong Moon, MD (Houston, TX)

1:00- 1:20pm Electronic Data Captures Role in Improving Perfusion Practice
James Reagor, MPS, CCP, FPP (Cincinnati, OH)

1:20-1:40pm CASE #2 ECMO and COVID
Shriprasad Deshpande, MBBS, MS (Washington, DC)

1:40-2:00pm **Panel Discussion**

THURSDAY, AUGUST 26, 2021- SESSION 2

4:00-4:10pm **Welcome Remarks/Housekeeping (Lorts)**

Moderators: Angie Lorts, MD, MBA and Tanya Perry, DO

4:10-4:30pm New Anticoagulation Modalities for MCS
Christina J. VanderPluym, MD (Boston, MA)

4:30-4:50pm Novel Use of Cangrelor in Pediatrics: A Case Series Demonstrating Use in Ventricular Assist Devices
Sarah Fahnhorst, DO (Cincinnati, OH)

4:50-5:10pm CASE #3 MCS in CHD
Sabrina Law, MD (New York, NY)

5:10-5:30pm **Panel Discussion**

5:30-5:40pm **DIGITAL POSTERS/BREAK**

Moderators: Chet Villa and Katrina Fields

5:40-6:00pm Stroke on Mechanical Support Has Improved Significantly: Where do we go from here?
Chet Villa, MD (Cincinnati, OH)

6:00-6:20pm What To Do When Your MCS Patient is No Longer a Transplant Candidate
Jodie Lantz, APRN, CNS (Dallas, TX)

6:20-6:40pm CASE #4 Managing Failing Bidirectional Glenn Patients with Mechanical Circulatory Support
Michael Mongé, MD (Chicago, IL)

6:40-7:00pm **Panel Discussion**

FRIDAY, AUGUST 27, 2021- SESSION 3

10:00 – 10:10am **Welcome Remarks/Housekeeping Morales**

Moderators : Jim Reagor and Chet Villa

10:10-10:30am Supporting the Failing Fontan Circulation: Lessons Learned
Matt O'Conner, MD (Philadelphia, PA)

10:30-10:50am Is Bivalirudin Comparable to Heparin Anticoagulation for Pediatric Extracorporeal Life Support? Results From a High-Volume Center
Matthew R. Schill, MD (Saint Louis, MO)

10:50-11:10am Techniques in an era of no MUF
Tami Rosenthal, CCP (Philadelphia, PA)

11:10-11:30am**Panel Discussion**

11:30-11:50am **DIGITAL POSTERS/BREAK**

Moderators: Zach Wilkes and Akif Undar MS, MSE, PhD

11:50-12:10pm Nitric Oxide Added to the Sweep Gas of the Oxygenator during Cardiopulmonary Bypass in Infants: A Pilot Randomized Controlled Trial
Robert A Niebler MD (Milwaukee, WI)

12:10-12:30pm What It Takes to Perform Heart–Liver Transplant
Katsuhide Maeda, MD (Philadelphia, PA)

12:30-12:50pm The Latest in ACTION
Angela Lorts, MD, MBA (Cincinnati, OH)

12:50-1:10pm Blood Primed Cardiopulmonary Bypass Circuit Quality Research Project
Barbara Braley Hendrix, CCP (Cincinnati, OH)

1:10-1:30pm **Panel Discussion**

FRIDAY, AUGUST 27, 2021- SESSION 4

4:00-4:10pm **Welcome Remarks/Housekeeping**

Moderators: David Morales and Angie Lorts

4:10-4:30pm	Impact of a Multi-Disciplinary Team Approach to Prevent Avoidable Mistakes for Neonatal CPB Population *Akif Ündar, MS, MSE, PhD (Hershey, PA)*
4:30-4:50pm	Debate #1: Supporting Single Ventricle Infant: Pulsatile VAD is Better Than Continuous Flow VAD *Pro: Joseph Philip, MD, FAAP (Gainesville, FL) & Con: Kathleen Simpson, MD (Aurora, CO)*
4:50-5:00pm	**DIGITAL POSTERS/BREAK**
5:00-5:20pm	Debate #2: Myocarditis: Temporary VAD is the Only Way to Support the Patient *Pro: Iki Adachi, MD (Houston, TX) & Con: Francis Fynn-Thompson, MD (Boston, MA)*
5:20-5:40pm	Debate #3: Pediatric Device Trials Are the Only Way to Bring Pediatric Devices to Market *Pro: Joseph Rossano, MD (Philadelphia, PA) & Con: Chet Villa, MD (Cincinnati, OH)*
5:40-6:00pm	**Panel Discussion**
6:00pm	**Closing Remarks**

Supplemental Table 2

Awards from the 16th International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion

Award	Awardees	Title of the manuscript or poster
John A. Waldhausen, MD, Young Investigator Award	Sarah Fahnhorst, D.O.	"Novel Use of Cangrelor in Pediatrics: A Case Series Demonstrating Use in Ventricular Assist Devices" and
	Jason W. Greenberg, M.D.	"Gender- and Weight- Matching Impacts Survival in Male but not Female Pediatric Heart Transplant Recipients", respectively
William S. Pierce, MD, Young Investigator Award	Matthew R. Schill, M.D.	"Is Bivalirudin Comparable to Heparin Anticoagulation for Pediatric Extracorporeal Life Support? Results From a High-Volume Center"
	Yu Jin, M.D.	"Outcomes and Factors Associated with Early Mortality of Extracorporeal Membrane Oxygenation in Pediatric Cardiac Surgery"
	Catherine Proulx, M.D.	"Successful mechanical thrombectomy after extensive intracranial thromboembolism post implantation of a HeartMate 3 in a pediatric patient"
	Krishna Patel, B.S.	"Assessment of Cerebral Hemodynamics and Degree of Hemolysis in Congenital Cardiac Surgery Patients Utilizing 8 and 10 Fr Arterial Cannulae: Pilot Clinical Trial", respectively.