CONFERENCE PROCEEDINGS

Volume 11, June 2015

The Proceedings of the Eleventh International Conference on

Pediatric Mechanical Circulatory Support Systems & Pediatric Cardiopulmonary Perfusion

Giovanni Battista Luciani, MD & Akif Ündar, PhD, *Editors*

June 10-13, 2015, Verona, Italy

PENNSTATE HERSHEY Children's Hospital

PENNSTATE HERSHEY Pediatric Cardiovascular Research Center

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Welcome to the Eleventh International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion

Giovanni Battista Luciani, MD[1], and Akif Ündar, PhD[2]

[1]Division of Cardiac Surgery, Department of Surgery, University of Verona, Verona, Italy, and
[2]Department of Pediatrics, Surgery, and Bioengineering, Penn State College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, U. S. A.

We are honored to welcome you to the 11th International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion at the Polo Zanotto, University of Verona School of Medicine, Verona, Italy, June 10-13, 2015.

Throughout the years the overall objective of the conference has been and still remains to bring together internationally known clinicians, bioengineers, and basic scientists involved in research on pediatric mechanical circulatory support (MCS) systems and pediatric cardiopulmonary bypass (CPB) physiology. The primary focus of the conference has been the definition of the issues relating to current pediatric MCS and CPB systems, methods and techniques during acute and chronic support and identifying strategies to solve clinical problems and guide future research. The structure of the conference has not only allowed to meet our primary objective, but also it has grown by integrating it with wet-labs organized to test leading-edge technology and conduct animal experiments (1,2).

The international conference has since grown into the most accredited forum to share technological advancements in the field of pediatric MCS and CPB and to enhance networking among international experts, allowing the participation of more than 2,400 leading scholars from 33 countries in the past decade. More than 415 peer-reviewed publications, including original articles, editorials, special reports, letters and case reports published in Artificial Organs document the phenomenal scientific achievements generated by the international conference.

For the first time since its inception, this year's edition will be held in Europe in the magnificent city of Verona, since awarded World Heritage Site status by UNESCO, with over two-thousand years of history and well known world-wide as the setting of some of the most famous of Shakespeare's plays.

But most notably, the University of Verona School of Medicine, ranked last year as the leading institution in terms of biomedical research among Italian universities, has a long-standing interest in pediatric and congenital cardiovascular medicine, having hosted the first ever national meeting of the Italian Society for Pediatric Cardiology, the first chair in Pediatric Cardiac Surgery and one of the first University Schools for Cardiovascular Perfusion Technicians in Italy, starting with the early 70's.

The scientific committee of the 11th International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion is a joint project of Penn State Hershey College of Medicine, University of Verona School of Medicine, and the Congenital Domain of the Italian Society of Cardiac Surgery.

Event Details

Giovanni Battista Luciani, MD, is the local scientific chair. The co-chairs of the event are Lorenzo Galletti, MD, Antonio Amodeo, MD (the Chairman and Scientific Secretary of the Congenital Domain of the Italian Society of Cardiac Surgery, respectively), and Akif Ündar, PhD.

First day (June 11, 2015)

The scientific program of the 11th event will start on June 11th, 2015, with the first Key Note Lecture, entitled "Cardiac pathology leading to heart failure in pediatric age" by Gaetano Thiene, MD, who is the Professor and Head of Cardiovascular Pathology at the University of Padua School of Medicine, Padua, Italy. The program will continue with the first plenary session entitled "Pediatric Mechanical Circulatory Support Systems: 2015 Update". Then the second Key Note Lecture will follow entitled "Thirty years of cardiac

transplantation in Italy" by Giuseppe Faggian, MD, Professor of Cardiovascular Surgery at the University of Verona School of Medicine and Head of the Department of Cardiac Surgery, Verona. In the early afternoon, the winners of the Young Investigator awards will be celebrated. In the later afternoon, the second plenary session will take place, entitled "ECLS: Utilization, Management, and Outcomes". The scientific program of the day will be closed by the first podium presentation session, dealing primarily with MCS scientific contributions.

Second day (June 12, 2015)

The second day of the 11th event will start on June 12th, 2015, with the third Key Note Lecture, entitled "Future of neonatal cardiopulmonary bypass in the era of hybrid surgery" by Emile Bacha, MD, FACS, who is the Calvin F. Barber Professor of Surgery at Columbia University; Chief of the Division of Cardiac, Thoracic & Vascular Surgery at Columbia University Medical Center; and Director of Pediatric Cardiac Surgery at Morgan Stanley Children's Hospital and NewYork–Presbyterian Hospital, New York, NY, USA. The program will continue with the third plenary session entitled "Minimizing adverse effects of CPB in neonates and infants: Global multi-disciplinary team approach". Then the fourth Key Note Lecture will follow, entitled "Myocardial protection in infants and children: building an evidence-based strategy" by Massimo Caputo, MD, Professor of Congenital Cardiac Surgery, RUSH University Medical Center, Chicago, USA and Consultant Congenital Cardiac Surgeon, University of Bristol/University Hospital Bristol NHS Foundation Trust, Bristol, UK. The last morning event will be a Key Note Lecture entitled "Stem cell therapy in congenital heart disease" by Prof. Shunji Sano, M.D., Ph.D., Head of Cardiovascular Surgery, Okayama, Japan. The afternoon will start with the second podium presentation session, dealing with ECMO and CPB scientific contributions. The scientific program of the day will be closed by two parallel sessions, one entitled "Hands-On Experience with the Newest Pediatric CPB/ECLS/MCS Systems" consisting in Wet-Labs organized by the industry, and the other entitled "Pediatric ECLS/ECMO Simulation" organized by Matteo Di Nardo, MD, and, Francesca Stoppa, MD, from the Ospedale Pediatrico Bambino Gesù, Rome, Italy, aided by the staff of Cardiovascular Perfusion of the Department of Cardiac Surgery, from the Univeristy of Verona School of Medicine.

Third day (June 13, 2015)

The final day of the event will start with the fourth plenary session, entitled "Experimental Approach to Pediatric Cardiovascular Medicine", dealing with basic research models applicable to pediatric cardiovascular medicine. There will follow the third and last podium presentation session, where bioengineering scientific contributions will be discussed. The conference will be closed by final considerations of the scientific chairs.

Artificial Organs

The May 2015 issue of Artificial Organs is dedicated to abstracts accepted for the conference. In addition, The January 2016 issue of the Artificial Organs will be dedicated to our conference manuscripts (all peer-reviewed). Special thanks to Carol Malchesky, Editorial Assistant, Angela T. Hadsell, Executive Editor, and Paul Malchesky, D. Eng, Editor-in-Chief, for making this issue possible and for their continued support year after year.

Financial support

We thank Penn State Hershey Pediatric Cardiovascular Research Center, Penn State College of Medicine, Penn State Hershey Children's Hospital, and the International Society for Pediatric Mechanical Cardiopulmonary Support for providing financial support to this event year after year. In addition, we received confirmations or funds from the following companies:

Sorin Group (Italy);
Xenios Pediatrics (Germany);
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Gada S.r.l., (Italy);
Medtronic-Europe (Switzerland),
Terumo Europe (Italy),
Tecnohealth Srl (Italy) and
Wiley-Blackwell (USA).

Further information

Further details regarding this event, including the scientific program, Young Investigator Awards, and publications, can be accessed via the conference website available at: http://pennstatehershey.org/web/pedscpb/home.

Once again, we are honored to welcome each of you to this unique event.

Acknowledgements:

Special thanks go to Shigang Wang, MD and Erlee H. Meyers, MBA from the Penn State Milton S. Hershey Medical Center, for their assistance in the coordination of this event. Parts of this Welcome Letter were extracted from Drs. Luciani and Ündar's earlier publication (3).

References

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2. Ündar A, Wang S, Palanzo D, Weaver B, Pekkan K, Agirbasli M, Zahn JD, Luciani GB, Clark JB, Wilson RP, Kunselman AR, Sano S, Belli E, Pierce WS, Myers JL. Outcomes of the ninth international conference on pediatric mechanical circulatory support systems and pediatric cardiopulmonary perfusion. Artif Organs 2014 Jan;38(1):5-10.

3. Luciani GB, Ündar A. Welcome to the Eleventh International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion [Invited Editorial]. Artif Organs 2015; 39(5) (in press).

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Final Scientific Program

WEDNESDAY, June 10, 2015

1:00 – 5:00pm **ON-SITE REGISTRATION (Only if Space is Available)**

THURSDAY, June 11, 2015

7:00 – 8:00am **Conference Registration**

8:00 – 8:15am **WELCOME**
Giovanni Battista Luciani, MD, Verona, Italy (Local Chair)
Akif Ündar, PhD, Hershey, PA, USA

Alfredo Guglielmi, M. D.
Dean, University of Verona School of Medicine Verona, Italy

A. Craig Hillemeier, M.D.
Dean, Penn State College of Medicine
CEO, Penn State Hershey Medical Center and Health System
Senior Vice President for Health Affairs, Penn State, Hershey, PA, USA

8:15 – 8:45 am **Key Note Lecture #1:**

Cardiac Pathology Leading to Heart Failure in Pediatric Age
Gaetano Thiene, MD, Padua, Italy

8:45 - 10:15 am **PLENARY SESSION #1:**

Pediatric Mechanical Circulatory Support Systems: 2015 Update

(15 min Each)

Moderators: William S. Pierce, MD, Hershey, PA, USA, Lorenzo Galletti, MD, Bergamo, Italy, and Brigitte Stiller, MD, Freiburg, Germany

IL1. Pediatric Heart Failure and Transplantation in the VAD Era
Luca Ragni, MD, Bologna, Italy

IL2. The Excor VAD in Children: the Newcastle Experience
Massimo Griselli, MD, Newcastle-upon-Tyne, United Kingdom

IL3. The Heartware VAD in Children: the Zurich Experience
Michael Huebler, MD, Zurich, Switzerland

IL4. The Jarvik VAD in Children as Destination Therapy: the Rome Experience
Antonio Amodeo, MD, Rome, Italy

IL5. The VAD Update: the North American Experience
Chitra Ravishankar, MD, Philadelphia, PA, USA

Discussion: 15 min

10:15 - 11:00am	**Coffee Break/Exhibits/Posters**
11:00 – 11:30am	**Key Note Lecture #2:**
	Thirty Years of Cardiac Transplantation in Italy
	Giuseppe Faggian, MD, Verona, Italy
11:30-11:45am	**Presentation of Young Investigators' Awards**
Noon – 1:00 pm	**Lunch Break**
1:00 - 3:00 pm	**PLENARY SESSION #2:**
	ECLS: Utilization, Management, and Outcomes (15 min Each)
	Moderators: Antonio Amodeo, MD, Rome, Italy, and Michael Huebler, MD, Zurich, Switzerland
	IL6. Role of ECMO in Neonatal and Pediatric End-Stage Heart Patients *Brigitte Stiller, MD, Freiburg, Germany*
	IL7. Timing of VA ECMO in Infants and Children *Luca Lorini, MD, Bergamo, Italy*
	IL8. Intensive Care Management of Prolonged Pediatric Mechanical Life Support *Paola Cogo, MD, Rome, Italy*
	IL9. Pediatric ECLS – A 30 Year Perspective *Stephen B. Horton, PhD, CCP, Melbourne, Australia*
	IL10. Long-Term Neuropsychological Outcome Following Neonatal ECMO *Raisa Schiller, MSc, Rotterdam, The Netherlands*
	IL11. Impact of the Pulsatile Extracorporeal Membrane Oxygenation *Hideshi Itoh,CCP, Japan*
	IL12. Penn State Hershey ECLS Approach - 2015 Update *Robert K. Wise, CCP, Hershey, PA, USA* **Discussion: 15 min**
3:00 - 3:45 pm	**Coffee Break/Exhibits/Posters/Wet-Labs**
3:45 – 5:45 pm	**REGULAR SLIDE PRESENTATIONS #1 :**
	Moderators: Giovanni Battista Luciani, MD, Verona, Italy and Chitra Ravishankar, MD, Philadelphia, PA, USA. (12 min each – 8 min presentation & 4 minute discussion)
	S1. Early Outcomes with HeartWare (HVAD) as a Bridge to Transplant in Children: A Single Institution Experience *Giuseppe Ferro, MD, Raghav Murthy, MD, Derek Williams, MD, Vinod A. Sebastian, MD, Joseph M. Forbess, MD, Kristine J. Guleserian, MD. Cardiothoracic Surgery, Children's Medical Center, Dallas, Texas, USA*

S2. Heart Transplantation in Failing Univentricular Hearts
Chiara Marrone, MD[1], Paolo Ferrero, MD[1], Simona Marcora, MD[1], Matteo Ciuffreda, MD[1], Laura Preda, MD1, Marco Papa, MD[1], Attilio Iacovoni, MD[2], Roberta Sebastiani, MD[2], Duccio Federici, MD[1], Francesco Seddio, MD[1], Amedeo Terzi, MD[2], and Lorenzo Galletti, MD[1]. Pediatric Cardiology and Cardiac Surgery Unit[1], Heart Transplantation Unit[2], Cardiovascular Department, Papa Giovanni XXIII Hospital, Bergamo, Italy

S3. Pediatric Heart Transplantation in Patient on ECMO or VAD
Enrico Aidala, MD, Andrea Valori, MD, Maria Teresa Cascarano, MD, Luca Deorsola, MD and Carlo Pace Napoleone, MD. Pediatric Cardiac Surgery, Regina Margherita Children's Hospital, Turin, ITALY

S4. Coagulation and Inflammatory Markers Predict Berlin Heart Excor Thromboembolic Events despite a Steroid Protocol: A Study of 32 Events
Reshma Biniwale, MD[1], Matthew Hung, BS[2], Kian Asanad, BS[2], Anthony Salimbangon, RN, BSN[1], Myke Federman, MD[4]. Department of Cardiothoracic Surgery[1], David Geffen School of Medicine[2], Department of Mechanical Circulatory Support[3], Department of Pediatric Critical Care[4], Ronald Reagan Medical Center, CA, USA

S5. Survival Outcomes in Children Less Than 10 Kg Bridged To Transplant with the Berlin Heart EXCOR Ventricular Assist Device
G. Brancaccio, PhD, Arianna Di Molfetta, PhD, S. Filippelli, PhD, R. Iacobelli, PhD, S. Morelli, MD, I. Favia, MD, P. Cogo, PhD, Antonio Amodeo, MD. Pediatric Hospital Bambino Gesù, Rome-Italy

S6. Evaluation and Incidence of Right Ventricle Dysfunction in Children with Pulsatile Ventricular Assist Devices
R. Iacobelli, A. Di Molfetta, G. Brancaccio, S. Morelli, R. Adorisio, A. Toscano, A. Amodeo. Pediatric Hospital Bambino Gesù, Rome-Italy

S7. Platelet Mapping Assay is Not Suitable to Safely Monitor Antiplatelet Therapy during Ventricular Assist Device
C. Giorni[1], MD, M. Costopoulos[2], C. Bachelot-Loza[3,4], C. Biselli,[1] MD, M. Gabaldon[1], MD, N. Aboumerouane[1], MD, A. Mazzola[1], MD, C. Barbanti[1], MD, P. Pouard[1],MD, D. Borgel[2,5,6], D. Lasne[2,5]. [1]Département d'Anesthésie Réanimation, Hôpital Necker, [2]Service d'Hématologie Biologique, Hôpital Necker, [3]INSERM U1140, [4]Université Paris-Descartes, Sorbonne Paris Cité, [5]INSERM U1176, Kremlin-Bicêtre, [6]Université Paris Sud, UFR de Pharmacie, Chatenay-Malabry, Paris, France

S8. Biventricular Intra-corporeal Ventricular Assist Device in a 10 Year Old Child

Martin Schweiger, MD[1], Anna Cavigelli-Brunne, MD[2], Bernhard Krüger[3], Michael Hübler, MD, Prof[1]. University Children's Hospital Zurich, Department of Congenital Cardiovascular Surgery[1], University Children's Hospital Zurich, Department of Pediatric Cardiology[2], University Children's Hospital Zurich, Department of Anesthesiology[3], Zurich, Switzerland

FRIDAY, June 12, 2015

7:00 – 8:00 am	**Conference registration**
8:00 – 8:30	**Key Note Lecture #3**
	The Future of Neonatal Cardiopulmonary Bypass in the Era of Hybrid Surgery *Emile Bacha, MD, FACS, New York, NY, USA*
8:30 – 10:15am	**PLENARY SESSION #3:**
	Minimizing Adverse Effects of CPB in neonatates and infants: Global Multi-disciplinary Team Approach (15 min Each) *Moderators: Emile Bacha, MD, FACS, New York, NY, USA and Massimo Griselli, MD, Newcastle Upon Tyne, UK* **IL13. Anticoagulation during Pediatric Cardiopulmonary Bypass** *Marco Ranucci, MD, Milan, Italy* **IL14. Paediatric Cardiopulmonary Bypass – an RCH Perspective** *Stephen B. Horton, PhD, CCP, Melbourne, Australia* **IL15. Selective Cerebral and Myocardial Perfusion for Neonatal Arch Repair** *Emanuela Angeli, MD, Bologna, Italy* **IL16. The Role of Hybrid Stage I in Averting Cardiopulmonary Bypass Risk in Neonates** *Adriano Carotti, MD, Rome, Italy* **IL17. Risk Management in Pediatric Cardiopulmonary Bypass** *Frank Merkle, CCP, Dipl-med.paed., Berlin, Germany* **Discussion: 30 min**
10:15 – 11:00am	**Coffee Break/Exhibits/Posters**
11:00 – 11:30	**Key Note Lecture #4**
	Myocardial Protection in Infants and Children: Building an Evidence-Based Strategy *Massimo Caputo, MD, Chicago, USA*
11:30 – 12:00	**Invited Lecture 18**
	Impact of Pulsatile Flow on Vital Organ Recovery during CPB in Neonates and Infants *Akif Ündar, PhD, Hershey, PA, USA*
Noon – 1:00pm	**Lunch Break**

1:00 – 3:00pm REGULAR SLIDE PRESENTATIONS #2:

Moderators: Atif Akcevin, MD, Istanbul, Turkey, Carlo Pace Napoleone, MD, Turin, Italy and Akif Ündar, PhD, Hershey, PA, USA (12 min each – 8 min presentation & 4 minute discussion)

S9. Improved Outcome of Cardiac ECMO in Infants and Children Using Magnetic Levitation Centrifugal Pumps
Giovanni Battista Luciani, MD, Luca Barozzi, MD, Rungatscher A, MD, Salvatore Torre, MD, Stiljan Hoxha, MD, Tiziano Menon, CCP, Giuseppe Faggian, MD. Division of Cardiac Surgery, Department of Surgery, University of Verona School of Medicine, Verona, Italy

S10. Early results of Infants Requiring Postoperative Extracorporeal Membrane Oxygenation after Norwood Palliation for Hypoplastic Left Heart Syndrome
Ko Yoshizumi, MD, Shingo Kasahara, MD, Yasuhiro Kotani, MD, Takuya Kawabata, MD, Yosuke Kuroko, MD, Sadahiko Arai, MD Shunji Sano, MD. Department of Cardiovascular Surgery, Okayama University Graduate School of Medicine, Dentistry and pharmaceutical Sciences, Okayama, Japan

S11. Impact of Anticoagulation Strategy on ECMO Bleeding and Thrombotic Complications
Hinah Parker, BS[1], Pippa Simpson, PhD[2], Mahua Dasgupta, MS[2], Robert A Niebler, MD[1]. Department of Pediatrics, Sections of Critical Care[1] and Quantitative Health Sciences[2], Medical College of Wisconsin; Milwaukee, WI, USA

S12. ECLS Experience of Hacettepe University Ihsan Dogramaci Children's Hospital
Murat Tanyildiz, MD[1], Selman Kesici, MD[1], Benan Bayrakci, MD[1], A. Filiz Yetimakman, MD[1], Burcak Bilgin, MD[1], H. Hakan Aykan, MD[2], Oktay Korun, MD[3], Ulas Kumbasar, MD[3], Metin Demircin, MD[3]. Pediatric Critical Care Unit[1], Pediatric Cardiology[2], Department of Cardiovascular Surgery[3],Hacettepe University Ihsan Dogramaci Children's Hospital, Ankara, Turkey

S13. Continuous Metabolic Monitoring in Infant Cardiac Surgery: Towards an Individualized Cardiopulmonary Bypass Strategy
Salvatore Torre, MD, Elisa Biondani, CCP, Tiziano Menon, CCP, Diego Marchi, CCP, Mauro Franzoi, CCP, Daniele Ferrarini, CCP, Rocco Tabbì, CCP, Stiljan Hoxha, MD, Luca Barozzi, MD, Giuseppe Faggian, MD, Giovanni Battista Luciani, MD. Division of Cardiac Surgery, Department of Surgery, University of Verona School of Medicine, Verona, Italy

S14. Implementation of a Perioperative Transfusion Protocol Decreases Blood Product Exposure after Cardiopulmonary Bypass
Timpa J, O'Meara C, Jackson K, Goldberg K, Phillips J, Crawford J, Alten J. Department of Cardiovascular Perfusion, Children's of Alabama, Birmingham, Alabama, USA

S15. A New Perspective in Cardioplegia: Valsartan Improves Myocardial Protection and Oxidative Stress Tolerance during Ischemia/Reperfusion in Isolated Neonatal Rat Heart
Gianluca Lucchese[1,3], MD, PhD, Giovanni Battista Luciani[1], MD, Stiljan Hoxha[1], MD, Ian Cummings[3], MD, Mohamed Nassar[3], MD, PhD, Pietro Amedeo Modesti[2], MD, PhD, Giuseppe Faggian[1], MD.[1]Pediatric Cardiac Surgery Unit, University of Verona, Italy. [2]Department of Medical and Surgical Critical Care, University of Florence, Italy. [3]Cardiac Surgery Department, Evelina London Children's Hospital and Guy's & St Thomas' NHS Foundation Trust.

S16. A Pilot Study of Antithrombin Replacement Prior to Cardiopulmonary Bypass in Neonates
Robert A. Niebler[1], Katherine Woods[1], Nancy Ghanayem[1], George Hoffman[2], Michael Mitchell[3], Rowena Punzalan[1], John Paul Scott[1], Pippa Simpson[4], James Tweddell[3]. Departments of Pediatrics[1], Anesthesia[2], Cardiothoracic Surgery[3], and Quantitative Health Sciences[4], Medical College of Wisconsin, Milwaukee, WI, USA

S17. Multisite Near-Infrared Spectroscopy during Cardiopulmonary Bypass in Pediatric Heart Surgery
Enrico Cetrano[1], M.D, Zaccaria Ricci[2], M.D, Paola Cogo[2], M.D, Ondina La Salvia[1], Adriano Carotti[1], M.D. Department of Pediatric Cardiology and Cardiac Surgery[1], Department of Pediatric Anestesiology[2], Bambino Gesù Children's Hospital, IRCCS, Rome, Italy

S18. Effects of Mini-Volume Priming on Clinical Outcomes in Low-Body-Weight Neonates: Less Transfusion and Post-operative ECMO Support
Sang Yoon Kim, MD[1], Sungkyu Cho, MD[1], Eunseok Choi, MD[2], Woong-Han Kim, MD, PhD[1]. Department of Thoracic and Cardiovascular Surgery, College of medicine, Seoul National University Hospital, Seoul, Korea[1], Department of Thoracic and Cardiovascular Surgery, Cardiovascular Center, Sejong General Hospital, Bucheon, Republic of Korea[2]

3:00pm – 3:45pm **Coffee Break/Exhibits/Posters/Wet-Labs**

3:00 – 3:45pm	**POSTER PRESENTATIONS (at the Exhibit Hall)**
	Moderators: Giovanni Battista Luciani, MD, Verona, Italy , Lucia Rossetti, MD, Verona, Italy and Mauro Franzoi, CCP, Verona, Italy
	Each poster presenter will be present in front of her/his posters for questions and discussion.
3:45 – 6:45pm	**PARALLEL SESSIONS**
3:45 – 6:45pm	**WET-LABS (at the Exhibit Hall)**
	Moderators: Robert K. Wise, CCP, Hershey, PA, USA, Tiziano Menon, CCP, Verona, Italy, Daniele Ferrarini, CCP, Verona, Italy, Mauro Franzoi, CCP, Verona, Italy, and Aldo Milano, MD, Verona, Italy
	Hands-On Experience with the Newest Pediatric CPB/ECLS/MCS Systems - Wet-Labs by the industry
	Each wet-lab starts with a brief introduction (< 10min) of the ECLS or CPB circuitry, followed by questions and answers (>10min) and hands-on experience (>15 min). Each session will be 45 minutes and will be repeated 4 times so everyone can participate in all of the wet-labs. There will be max. of 30 participants for each session.
	Value of In-Line Non -invasive Patient Monitoring in the Extracorporeal Circuit - Spectrum M4 Monitoring System ***Instructor: Mr Giovanni Cocomazzi, Clinical Specialist Medtronic Italy***
	Advanced safety through integrated sensors and interventions in CARDIOHELP-i ***Instructor: Davide Ghitti, Papa Giovanni XXIII Hospital, Bergamo, Italy***
	SynCardia's new 50cc temporary Total Artificial Heart ***Instructor: Oliver Voigt, PhD, CCE***
	The Medos deltastream system in pediatrics – practical aspects and safety features ***Instructors: Andreas Spilker, CCP and Dr. Jüergen Böhm, Xenios Pediatrics, Germany***
3:45 – 6:45pm	**Pediatric ECLS/ECMO Simulation (at the Exhibit Hall)**
	Moderators: Matteo Di Nardo, MD, Rome, Italy, Francesca Stoppa, MD. Rome, Italy, Rocco Tabbì, CCP Verona, Italy and Diego Marchi, CCP, Verona, Italy
	(advanced registration is required: max 30 participants)

SATURDAY, June 13, 2015

8:00 – 10:00am **PLENARY SESSION #4:**

Experimental Approach to Pediatric Cardiovascular Medicine (15 min Each)

Moderators: Christian Vergara, PhD, Milan, Italy and Amy Throckmorton, PhD, Philadelphia, PA, USA

IL19. Mechanical Circulatory Assistance of the Fontan Physiology

Amy Throckmorton, PhD, Philadelphia, PA, USA

IL20. The Use of VAD in Univentricular Physiology: The Role of Numerical Models
Arianna Di Molfetta, PhD, Rome, Italy

IL21. Computational Study of the Fluid-Dynamics in Ascending Aorta in Presence of a Normally Functioning Bicuspid Valve
Christian Vergara, PhD, Milan, Italy

IL22. Real-Time Tracking of Novel Biomarkers during Neonatal Extracorporeal Circulation
Jeffrey D. Zahn, PhD, Piscataway, NJ, USA

IL23. Experimental Small Animal Models of Extracorporeal Circulation and Right Heart Failure: a Window for Translational Research in Pediatric Cardiac Surgery
Alessio Rungatscher, MD, Verona, Italy

Discussion: 30 min

10:00 – 10:45am **Coffee Break/Exhibits/Posters/Wet-Labs**

10:45 – 12:45 pm **REGULAR SLIDE PRESENTATIONS #3:**

Moderators: Luca Barozzi, MD, Verona, Italy, Jeffrey D. Zahn, PhD, Piscataway, NJ, USA. (12 min each – 8 min presentation and 4 minute discussions)

S19. Surgical Options for the Treatment of Right Ventricular Failure in LVAD Patients: A Simulation Study
Arianna Di Molfetta, PhD[1], Gianfranco Ferrari, PhD[2],Maria Giulia Gagliardi, PhD[1], Libera Fresiello, PhD[3], Roberta Iacobelli, PhD[1], Alessandra Toscano, PhD[1], Sergio Filippelli, PhD[1], and Antonio Amodeo, PhD[1]. Pediatric Hospital Bambino Gesù[1], Rome-Italy; CNR, Institute of Clinical Physiology[2], Rome-Italy; Catholic University of Leuven[3], Leuven-Belgium

S20. Application of CFD-modelling in the Development of Russian Pediatric VAD Systems

Valentin Morozov, PhD[1], Leonid Belyaev, PhD[1], Georgy Itkin, PhD[2], Alexander Ivanchenko, PhD[1], Alexey Zhdanov, PhD[1]. Department of Mechanical Engineering[1], Department of Biotechnical Systems Engineering[2]. Vladimir State University named after Alexander and Nikolay Stoletovs[1], Federal State Budgetary Institution "Academician V.I.Shumakov Federal Research Center of Transplantology and Artificial Organs". Ministry of Health of the Russian Federation[2], Vladimir[1], Moscow[2], Russia

S21. Mechanically Assisted Total Cavopulmonary Connection with an Axial Flow Pump: Computational and in Vivo Study

Gandolfo F°, Brancaccio G°, Donatiello S, Filippelli S°, Perri G', Iannace E^, D'amario D', Testa G^, Grigioni M*, Amodeo A° °Department of Pediatric Cardiac Surgery, Bambino Gesù Children's Hospital IRCCS, Rome, Italy; *Department of Technology & Health, Italian National Institute of Health, Rome, Italy; ^ Department of Pediatric Cardiac Surgery, Bambino Gesù Children's Hospital IRCCS, Rome, Italy; 'Department of cardiology, Policlinico A. Gemelli, Rome, Italy*

S22. The Use of a Numerical Model to Simulate the Cavo-Pulmonary Assistance in Fontan Circulation: A Preliminary Verification

Arianna Di Molfetta, PhD[1], Gianfranco Ferrari, PhD[2], Fabrizio Gandolfo, M.D.[1], Giuseppina Testa, M.D.[1] and Antonio Amodeo, M.D.[1] Pediatric Hospital Bambino Gesù[1], Rome-Italy; CNR, Institute of Clinical Physiology[2], Rome-Italy

S23. Effect of the Pulsatile Extracorporeal Membrane Oxygenation on Hemodynamic Energy and Systemic Microcirculation under Acute Cardiac Failure Model in Piglets

Hideshi ITOH[1, 2], Shingo ICHIBA[2], Yoshihito UJIKE[2], Takuma DOUGUCHI[3], Hideaki OBATA[6], Shuji INAMORI[1], Tatsuo IWASAKI[5],Shingo KASAHARA[4], Shunji SANO[4], Akif Ündar[7]. Junshin Gakuen University, Department of Medical Enginieering[1]. Fukuoka, Japan. Okayama University Graduate School of Medicine, Department of Emergency and Intensive Care Medicine[2], Department of Clinical Engineering[3], Department of Anesthesiology[5], Department t of Cardiovascular Surgery[4], Okayama, Japan. Okayama University of Science, Department of Biomedical Engineering[6],Okayama, Japan; Department of Pediatrics, Surgery & Bioengineering, Penn State Hershey Pediatric Cardiovascular Research Center, Penn State College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA[7]

S24. In-Vivo Hemodynamic Performance Evaluation of Novel ECG-Synchronized Pulsatile and Non-pulsatile Cardiac Assist System in an Adult Swine Model

Shigang Wang, MD[1], Jenelle M. Izer, DVM, MS[2], Joseph B. Clark, MD[1,3], Sunil Patel, MBBS[1], Linda Pauliks, MD, MPH[1], Allen R. Kunselman, MA[4], Donald Leach, BS[1], Timothy K. Cooper, DVM, PhD[2,5], Ronald P Wilson, VMD, MS[2] and Akif Ündar, PhD[1,3,6] Penn State Hershey Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Comparative Medicine[2], Surgery[3], Public Health and Sciences[4], Pathology[5] and Bioengineering[6]. Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

S25. Insensible Water Loss from the Medos Hilite 2400 LT Oxygenator: An In Vitro Study

Killian O'Shaughnessy, CCP, Martin Gill, CCP. Perfusion Department, Heart Centre for Children, The Children's Hospital at Westmead, Westmead, NSW, Australia

1:00 pm CLOSING REMARKS

THURSDAY 8:00 am - SATURDAY 1:00 pm

POSTERS:

Moderators: Giovanni Battista Luciani, MD, Verona, Italy , Lucia Rossetti, MD, Verona, Italy and Mauro Franzoi, CCP, Verona, Italy

P1. Clinical Outcome of Benign Cardiac Tumors Detected Prenatally: A Ten-Year Experience

Camilla Sandrini, MD, Stiljan Hoxha, MD, Lucia Rossetti*, MD, Micol Rebonato*, MD, Antonia Maria Prioli*, MD, Salvatore Torre, MD, Luca Barozzi, MD, Corrado Vassanelli*, MD, Giuseppe Faggian, MD, Giovanni Battista Luciani, MD. Division of Cardiac Surgery, Department of Surgery, and Division of Cardiology*, Department of Medicine, University of Verona School of Medicine, Verona, Italy*

P2. Laboratory Evaluation of Hemolysis and Systemic Inflammatory Response in Neonatal Nonpulsatile and Pulsatile Extracorporeal Life Support Systems

Shigang Wang, MD[1], Conrad Krawiec, MD[1,2], Sunil Patel[1,3], Allen R. Kunselman, MA[4], Jianxun Song, PhD[5], Fengyang Lei, PhD[5], Larry D. Baer, CCP[6], and Akif Ündar, PhD[1,7]. Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Pediatric Critical Care Unit[2], Pediatric Cardiology[3], Department of Public Health Sciences[4], Microbiology & Immunology[5], Heart and Vascular Institute[6], Surgery and Bioengineering[7], Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

P3. Childhood Obesity and Extracorporeal Membrane Oxygenation: Where do We Draw the Line?

Reshma Biniwale, MD[1], Amit Iyengar, MS[2], Kian Asanad, MS[2], Jessica Samson, CCP[3]. Department of Cardiothoracic Surgery[1], David Geffen School of Medicine[2], Department of Perfusion Services[3], Ronald Reagan Medical Center, CA, USA

P4. Development of Microfluidic Immunoassays for Multiplexed Biomarker Measurements

Mehdi Ghodbane, Lawrence A. Sasso, Andrew Pskowski, Eamon Collins, Rene S. Schloss, Martin L. Yarmush, and Jeffrey D. Zahn. Department of Biomedical Engineering, Rutgers University, Piscataway, New Jersey, USA

P5. In-vitro Hemodynamic Evaluation of Five 6 Fr and 8 Fr Arterial Cannulae in Simulated Neonatal CPB Circuits

Shigang Wang, MD[1], David Palanzo[2], Allen R. Kunselman, MA[3], and Akif Ündar, PhD[1,4], Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Perfusion Department, Penn State Heart and Vascular Institute[2], Public Health Sciences[3], Surgery and Bioengineering[4], Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

P6. Role of Oxygenator in Producing Leucocyte Activation and Systemic Inflammatory Response in Experimental Model of Extracorporeal Circulation

Elisabetta Milani, MD[1], Alessio Rungatscher, MD, PhD, FAHA[1], Maddalena Tessari, PhD[1], Daniele Linardi, MD[1], Tiziano Menon, MSc[1], Chiara Stranieri, PhD[2], Erika Solani, PhD[2], Alessio Montresor, PhD[2], Giovanni Battista Luciani, MD[1], Giuseppe Faggian, MD[1]. Department of Surgery, Division of Cardiac Surgery[1], Department of Pathology[2], University of Verona, Verona, Italy

P7. Twenty-Year Outcome after RVOT Repair Using Heterotopic Pulmonary Conduits in Infants and Children

Stiljan Hoxha, MD, Salvatore Torre, MD, Alessio Rungatscher, MD, Micol Rebonato, MD, Luca Barozzi, MD, Giuseppe Faggian, MD, Giovanni Battista Luciani, MD. Division of Cardiac Surgery, Department of Surgery, University of Verona School of Medicine, Verona, Italy

P8. Extracellular Histones May Be a Rapid Prognostic Indicator for Children after Open-Heart Surgery

Hongxiang GAO, Xi MO, Wei WANG. Department of Pediatric Thoracic and Cardiovascular Surgery, Shanghai Children's Medical Center, China

P9. The Intraoperative Pulmonary Flow Study Is a Sensitive Predictor for Ventricular Septal Defect Closure after Complete Unifocalization in Patients with Pulmonary Atresia, Ventricular Septal Defect and Major Aortopulmonary Collateral Arteries

Matteo Trezzi, Antonio Albano, Enrico Cetrano, Sonia B. Albanese, Adriano Carotti. Unit of Pediatric Cardiac Surgery, Bambino Gesù Children Hospital IRCCS, Rome, Italy

P10. Use of CDI 500 during ECMO: Reliability of Data and Benefits

Ghitti Davide, CCP EBCP[1], Fumagalli Elisabetta. CCP[1], Grazioli Lorenzo, MD[2], Cattaneo Sergio. MD[2], Federici Duccio, MD[3], Didedda Giovanni, MD[2], Galletti Lorenzo, MD[3], Lorini F. Luca, MD[2]. Perfusion Service[1], Departement of Anesthesia and Intensive Care[2], Pediatric Cardiac Surgery Unit[3], Azienda Ospedaliera "Papa Giovanni XXIII" Bergamo - Italy

P11. Potential Danger of Pre-pump Clamping on Negative Pressure-Associated Gaseous Microemboli Generation during ECLS - An In-Vitro Study

Shigang Wang, MD[1], Brian J Chin[1], Frank Gentile[1], Allen R. Kunselman, MA[2], David Palanzo, CCP[3], and Akif Ündar, PhD[1,4]. Penn State Hershey Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Public Health and Sciences[2], Perfusion Department, Penn State Heart and Vascular Institute[3], Department of Surgery and Bioengineering[4], Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

P12. Impact of Pulsatility and Flow Rates on Hemodynamic Energy Transmission in an Adult ECLS System

Rachel Wolfe[1], Ashton Strother[1] , Shigang Wang, MD[1], Allen R. Kunselman, MA[2], and Akif Ündar, PhD[1, 3]. Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Public Health Sciences[2], Surgery and Bioengineering[3], Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

P13. Drowning Accident with Deep Hypothermia

Theodor Tirilomis, MD, PhD[1], Martin Friedrich, MD, PhD[1], Anselm Braeuer, MD, PhD[2], Daniel Heise, MD, PhD[2], Christian Bireta, MD[1], Michael Steinmetz, MD, PhD[3] and Wolfgang Ruschewski, MD, PhD[1]. Department of Thoracic, Cardiac, and Vascular Surgery[1], Department of Anesthesiology[2], Department of Pediatric Cardiology[3], University Hospital Göttingen, Germany

P14. In Vitro Model of Ventricular Support after Shunted Single Ventricle Palliation: the "delVAS SYSTEM"

Ghitti Davide, CCP, EBCP[1], Federici Duccio, MD[2], Viscardi Silvia, CCP[1], del Pesco Federica, CCP[1], Genova Stefania, CCP[1], Ariano Andrea, CCP[1], Cattaneo Sergio, MD[3], Didedda Giovanni, MD[3], Lorini Luca, MD[3], Galletti Lorenzo, MD[3]. Perfusion Service[1], Pediatric Cardiovascular

Surgery Unit[2], Departement of Cardiovascular Desease[3], Azienda Ospedaliera "Papa Giovanni XXIII" – Bergamo – Italy

P15. Patient-Specific Computer-Aided Planning of Pulmonary Outflow Patch Reconstruction in Pediatric Congenital Heart Patients - Proof of Concept

Tijen Alkan-Bozkaya[1,3], Senol Piskin[2], Banu Kose[3], Atif Akcevin[4], Halil Turkoglu[4], Tufan Paker[1], Kerem Pekkan[2,5]. VKV American Hospital and Medical School, Koc University[1], Koc University[2], Istanbul Medipol University, Dept.of Bioengineering[3] and Dept.of Cardiovascular Surgery[4], Carnegie Mellon University[5]

P16. The Results and Correlations between Hepatic Near-Infrared Spectroscopy Measurements and Portal Vein Flow Dynamics and Early Postoperative Outcomes in Pediatric Cardiac Surgery

Alkan-Bozkaya T[1], Ormeci T[2], Ozyuksel A[1], Kılıçarslan R[2], Ersoy C[1], Akcevin A[1], Turkoglu H[1], Ündar A[3]. Dept. of Cardiovascular Surgery[1] and Dept. of Radiology[2], Istanbul Medipol University; and Dept. of Pediatrics, Surgery and Bioengineering[3], Penn State College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA.

KL1. Cardiac Pathology Leading to Heart Failure in Pediatric Age

Gaetano Thiene, MD
Department of Medical Diagnostic Sciences and Special Therapies, the University of Padua Medical School, Padua, Italy

KL2. Thirty Years of Cardiac Transplantation in Italy

Giuseppe Faggian, MD, and Giovanni Battista Luciani, MD

Division of Cardiac Surgery, Department of Surgery, University of Verona School of Medicine, Verona, Italy

Heart transplantation (HTx) started in Italy on November 14, 1985 under the leadership of the late Prof. Gallucci and our group, then working at the University of Padua. Similar to most Western European countries, in the mid-80s Italy followed the trail of North America, where the introduction of cyclosporine A in 1980 paved the way for modern solid organ transplantation. Since 1985, over 10000 Htx have been performed in Italy among the 16 approved cardiac transplant Units. Whereas significant improvements have been witnessed in the medical management of transplant-related complications, including rejection and infection, the issue of organ donation and thus, organ allocation, has remained the single most important deterrent to application of HTx to patients with end-stage heart failure. Constant strive to expand eligibility criteria for cardiac donation, by extending maximum age, safe duration of myocardial ischemia and by including select donors with active infection or malignancy, has not substantially solved the issue of chronic scarcity of organ donors. For reasons still waiting to be determined, the problem has further accrued in the last decade throughout Europe. Perhaps, the greatest factor which has changed the profile of HTx during the last decade in Italy and world-wide has been the advent of safer and more reliable totally implantable left ventricular assist devices. Moving from the first generation LVAD in the 90s, where biocompatibility and mechanical failure remained significant drawbacks, thus relegating LVAD therapy to (short) bridge to transplant, second generation devices have revolutionized the field of HTx in the third millennium. Indeed, survival identical to HTx has been shown out to five years after LVAD implant essentially expanding the objectives of chronic mechanical life support to include destination therapy and, occasionally, bridge to recovery, besides bridge to transplantation. In Italy, this major clinical landmark has caused further decrease of number of HTx performed yearly, with most Units, including the University of Verona, performing as many LVAD implants as HTx, when not more. As a direct consequence, HTx without prior mechanical life support has become unlikely and HTx has been progressively limited to select patients with contraindications to LVAD therapy using marginal donors. It is expected that this trend may further affect comparative outcome of HTx and LVAD in the long-term period.

KL3. The Future of Neonatal Cardiopulmonary Bypass in the Era of Hybrid Surgery

Emile Bacha, MD

Professor and Chief, Cardiothoracic Surgery, Columbia University/Morgan Stanley Children's Hospital of NewYork-Presbyterian

The emergence of Hybrid Therapies as well as endovascular structural interventions in Congenital Heart disease provided a paradigm shift for some lesions traditionally treated with open-heart surgery. These include Hypoplastic Left heart Syndrome, Muscular ventricular septal defects, and Valve replacements therapies. Unlike what one might have expected, these new strategies did not result in less open-heart repairs. In addition, more high-risk pregnancies come to fruition, and premature babies' survival is increasing. This has resulted in increased need for neonatal cardiopulmonary bypass (CPB), including CPB in very low birth weight neonates. Furthermore, improved CPB technologies, including improved biocompatible tubing, smaller priming volumes, better oxygenators and pumps have resulted in smoother and less morbid pump runs. This includes ECMO technology, which used to be extremely high-risk in <2kg infants, but is now tolerated better. We will review what the future holds for neonatal CPB and how the hybrid therapies might have an impact.

KL4. Myocardial Protection in Infants and Children: Building an Evidence-Based Strategy

Massimo Caputo, MD, FRCS

Department of Congenital Heart Surgery, Rush University Medical Center, Chicago, Il, USA

Bristol Heart Institute, University of Bristol, UK

Objective: Today there are a lot of different types of cardioplegia solutions and cardiopulmonary bypass (CPB) strategies and methods used in pediatric cardiac surgery. Most of these strategies have been adopted from techniques developed for adult cardiac surgery. The infant heart is at high risk of damage from poor protection or wrong CPB strategy as a result of preoperative hypertrophy, cyanosis, and ischemia. These factors may also make the immature (pediatric) heart more sensitive to cardioplegic arrest compared with the mature (adult) heart. Nevertheless no clear recommendation concerning pediatric myocardial protection and CPB strategy is available nowadays, as a result of the very few prospective randomized studies that have been published.

My lecture will describe the experimental infrastructure and subsequent clinical applications of cardioplegic and CPB strategies aiming at limiting intraoperative injury and improving postoperative outcomes in pediatric patients undergoing cardiac surgery. I will describe some of the relevant basic science and small and large animal models used to validate myocardial protection strategies. Furthermore I will present data from two major control randomized trials, comparing normothermic vs hypothermic (THERMIC) and hypoxic vs normoxic (OXIC) CPB in pediatric patients. The relationship between chronic hypoxia and gene expression, and the molecular mechanisms underlying the effects of re-oxygenation injury on organ dysfunction in cyanotic heart patients undergoing surgical repair will also be explored. Finally I will discuss the most recent international trends of myocardial protection and CPB strategies in pediatric heart surgery.

Applications of these concepts should improve the safety of protection of the infant heart and reduce postoperative morbidity and mortality.

IL1. Pediatric Heart Failure and Transplantation in the VAD Era

Luca Ragni, MD, Andrea Donti, MD
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Pediatric heart failure is a clinical and pathophysiological syndrome due to ventricular dysfunction, volume or pressure overload, that can act alone or in combinations. This syndrome is characterized by several symptoms and signs such as fatigue, poor growth, feeding difficulties, respiratory distress and exercise intolerance. The annual incidence of pediatric heart failure from heart muscle disease is 0,87 % per 100000 children under 6 years of age. This condition can lead to death and heart transplantation in 50% of patients at five years from diagnosis. Moreover medical therapy, that gives good results for adult heart failure, is not so effective in pediatric population. This is due to several reasons; the first is that the molecular characteristic of pediatric heart failure may be markedly different from those of adult. In additions sometimes, the ventricular systolic dysfunction doesn't belong to a ventricle with a left morphology but to a ventricle with a right morphology, such as the right systemic ventricle. And at the end always more patients are surviving to surgery of single ventricle palliation, which sometimes may be the responsible of the heart failure in pediatric age. These and other reasons can explain why several studies could not demonstrate that beta-blockers and ACE-Inhibitors have the same efficacy in pediatric heart failure such as in adult heart failure. Regarding to all these facts, the best strategy to solve unresponsive heart failure in pediatric age is heart transplantation. Unfortunately there are several limits for this therapeutic strategy. First of all the availability of organs is poor, and the mortality rate on waiting list is quite high. Second the half-life of the implanted heart is too short for children and the immunosuppressant therapy is burdened by several and severe side effects which can worsen the morbidity or mortality of these young patients.

For all these reasons other studies have to be performed to improve the medical therapy of heart failure, and, above all, to reduce side effects of the immunosuppressant strategy in heart transplanted patients improving morbidity and mortality. To face the high rate of mortality on waiting list it is important to ameliorate the mechanical assist heart device in pediatric age as bridge to heart transplant, or as destination therapy in those patients who are not suitable for heart transplantations.

IL2. The Excor VAD in Children: the Newcastle Experience

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Orthotopic heart transplant (OHTx) remains the gold standard treatment for heart failure in children, but the number of patients requiring this treatment far outweighs the donor availability. It is therefore not surprising to see the popularity of various MCS modalities, with different devices ranging from veno-arterial extra corporeal membrane oxygenation (VA-ECMO) to ventricular assist devices (VADs). Indication, timing and the choice of the type of mechanical support are crucial so in order to avoid potential lethal complications such as hemorrhage, thrombo-embolism and infections.

In the pediatric population, MCS is used mainly as bridge to transplantation but can be used as bridge to recovery in patients with acute myocarditis or following open-heart surgery. The only labeled VAD available for neonates and infants is the Berlin Heart Excor (BHE). BHE facilitates support of both the left and right ventricle. Furthermore, the availability of different sizes of cannulae and pumps allows it to be used in all children regardless of their size and weight. BHE is a second-generation device and neurological complications vary between 25% and 30%.

From 1998 to March 2014, our institution performed a total of 127 MCS episodes as bridge to OHTx. The leading cause of MCS requirement was CMPs in two-thirds of these patients. A total of 87 Excor Berlin Heart devices were implanted as well as five HeartWare and seven Medos devices. VA-ECMO was performed in 23 cases and Levitronix devices implanted in six. Twenty-nine patients had end-stage HF following correction or palliation for CHDs: 15 with biventricular and 14 with univentricular physiology. In the univentricular group, seven patients were assisted with VA-ECMO (four after Fontan completion, two after cavo-pulmonary shunt and one after Norwood stage I), and seven patients with Excor Berlin Heart (five after cavo-pulmonary shunt, one after Norwood stage I and one after Damus-Kaye-Stansel anastomosis and modified Blalock-Taussig shunt). The overall survival to OHTx or explant in all CHDs patients was 72%, and survival to discharge was 59%, with no statistical difference between those with univentricular or biventricular circulation.

IL3. The Heartware VAD in Children: the Zurich Experience

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Objective: The pulsatile Berlin Heart EXCOR® ventricular assist device (VAD) for uni- or biventricular support has been the mainstay of long term mechanical circulatory assistance for children. The development of continuous-flow pumps has led to a miniaturization and intrapericardial placement of the devices and improvement of outcomes. We report our experience with the use of the HeartWare® VAD (HVAD) in the pediatric age group and in the setting of congenital heart disease.

Methods: A total of 9 children (6–16 yr old, BSA 0.7 – 2.0sqm) underwent 10 HVAD implantations. 8 patients had been diagnosed dilative cardiomyopathy, one child suffered from failing Fontan after staged repair for hypoplastic left heart syndrome. In 8 patients the implantation was intended as a bridge-to-transplantation. One child received the HVAD as a bridge-to-decision and eventually bridge-to-recovery. The same child underwent secondary BiVAD-Implantation with two HVAD pumps.

Results: All patients had effective mechanical circulatory support by the HVAD LVAD/RVAD or BiVAD. Pump speed varied from 2300 revolutions per minute (rpm) to 2800 rpm with a calculated flow rate of 2.1 to 5.8 liters per minute. Two patients had to be re-explored for bleeding. Median support time was 75 days (range 1 day to 351 days). None of the patients suffered a thromboembolic event or an infection. All patients could be successfully transplanted.

Conclusions: Our experience demonstrated the successful use of the HVAD in the pediatric age group with the smallest child 6 years old with a body surface area of 0.7 sqm. The HVAD can be used as single ventricle and biventricular support system with extremely low complication rate and improved quality of life.

IL4. The Jarvik VAD in Children as Destination Therapy: the Rome Experience

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Objective: End-stage dilated cardiomyopathy (DCM) is one of the most challenging complications in patients with Duchenne Muscolar Dystrophy. We report our experience with use of left ventricular assist device (LVAD) as destination therapy (DT) for the management of this new subgroup of children

Methods: From February 2011 to February 2015 five children with Duchenne syndrome and DCM were assisted with a LVAD. The median age at surgery was 15.6 years (range 14.2-17.4). Preoperatively, all patients underwent a multidisciplinary assessment. All children were admitted at our Institution for acute heart failure. In all patients we use the LVAD as destination therapy. Four children received VAD after long-term medical inotropic support while one underwent implantation after 12 days of VA-ECMO.

Results: All children survived to hospital discharge. All patients after early extubation required non-invasive positive pressure ventilation and cough machine cycles. The early post- operative course was characterized in one patient by mediastinal re-exploration. One year late he developed osteolysis at device pedestal site which required surgical revision with displacement of pedestal position. The second child, for iatrogenic spleen lesion, required several abdominal surgeries. He underwent heparin discontinuation for 35 days for persistent abdominal bleeding. The last two patients had uneventful post op. At mean follow-up time of 21.2 months (range 1-44.8), we have two late death, both not related to cardiac causes. One child died at 44.8 months from implantation for sepsis secondary to pulmonary infection while the second died in a peripheral hospital for massive bleeding due to a otorhinolaryngology maneuver 28.6 months after surgery.

Conclusions: Our experience showed the possibility to use VAD as DT in Duchenne with end stage DCM. Given the increasing pediatric and adult population of Duchenne DCM, our results represent a significant stepforward for the treatment of these patients with otherwise no therapeutic option.

IL5. The VAD Update: the North American Experience

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Ventricular Assist Devices (VAD) are being increasingly used in children with decompensated heart failure both due to cardiomyopathy and congenital heart defects. The choice of devices has expanded due to advances in technology. The Berlin Heart Excor device, which is a paracorporeal pneumatic device, is the most widely used VAD in North America and is currently the only available device for infants and young children. 204 children across 47 centers in North America were supported with the Excor device from 2007-2010. One-year survival was 75%; 64% survived to heart transplantation, 6% recovered and 5% were alive on the device. In multivariable analysis, lower weight at implantation, higher serum bilirubin and need for biventricular support were independently associated with early mortality. Higher bilirubin and renal dysfunction were independently associated with late mortality. Neurologic event occurred in nearly a third of subjects and was the leading cause of morbidity. This device is currently approved by the FDA for use in children. Additional analysis has revealed inferior outcomes for children weighing less than 10 kg, particularly for those with congenital heart defects.

The choice of devices is much wider in older children. The HeartMate II and HeartWare are continuous flow intracorporeal devices that can be implanted in young children with cardiomyopathy and congenital heart defects. VAD support remains a challenge for patients with single ventricle heart defects through all stages of surgical palliation. As VAD technology improves, we remain in search of the ideal device to meet the unique needs of the Pediatric population.

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IL6. Role of ECMO in Neonatal and Pediatric End-stage Heart Patients

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Extracorporeal membrane oxygenation is a commonly used form of mechanical circulatory support in children with heart disease who suffer cardiac arrest or acute deterioration of chronic heart failure. For end-stage heart children, the goal is to survive until heart transplantation. With > 180 days median waiting time on HTx-list in the Eurotransplant-region, there is no chance to “bridge to transplant” via ECMO.

Nevertheless ECMO has its role as a rescue procedure for acute hemodynamic deterioration:

- ECMO can be installed outside the operating room. In many clinics it has become a routine part of standard resuscitation. In these cases ECMO offers the chance to survive the transport to a transplant center.
- ECMO offers time in the acute phase of terminal decompensation in chronic end-stage patients with progressive deterioration not only of cardiac function but with multiple organ failure.
- ECMO offers time after acute resuscitation as „time-to-decision“, to communicate with the care givers and to prove neurology, before the decision of implanting a long-term VAD.
- With the anytime available option for ECMO implantation, the time at which an LVAD is implanted in chronic heart failure can be delayed in many patients.

After the rescue application of ECMO for short-term support (within 1-2 weeks), ECMO can be surgically switched to a suitable VAD as a bridge for medium- or long-term support to wait for a suitable donor.

In case of temporary pulmonary failure while on LVAD, additional VV-ECMO establishes oxygenation until pulmonary recovery. In this case VV cannulation using a double-lumen cannula via the right internal jugular vein can allow the chest to stay closed and preserve the carotid artery.

With an increasing demand on the supply of organs available for heart transplant, alternative strategies are being sought to maintain patients with end-stage cardiac failure for longer periods of time.

ECMO and VADs are complementary used in modern bridging concepts providing essential support to critically ill children. Both are not without their own significant associated risks.

To conclude: ECMO can be rapidly deployed, is far less expensive compared to VADs, and can be used in the initial period of support while the diagnosis is investigated and the condition of the patient is reassessed. It is well known that beyond the first 2 weeks of support, ECMO is not the mode of support that should be favored. ECMO has been shown to be inferior to VAD as a bridge to transplantation in children. Transition to another form of support should be considered when there have been no signs of myocardial recovery after 2 weeks, at the very latest.

IL7. Timing of V-A ECMO Support in Infants and Children?

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It is challenging to define the correct time to establish mechanical support in pediatric patients due to the variety of conditions it supports. Pathologies include perioperative congenital heart lesions, myocarditis, myocardiopathies and toxic drug overdose.

Whilst determining a rule that works for each or every group is hard, over time a trend has emerged for institution of support at an earlier stage.

A focus on oxygen delivery is fundamental to guide the clinician when mechanical support may be required. In extremis, the body oxygen requirement will exceed the delivery which will result in anaerobic metabolism, a lactic acidaemia and cell apoptosis.

The mismatch between the amount of oxygen carried and the consumption by the body should be paramount when considering the institution of ECMO, since early recognition and treatment of oxygen debt is associated with improved outcome.

In addition, early ECMO support can decrease the need for inotropes, help to unload the ventricle and reduce the stress and the oxygen consumption on a stunned myocardium, encouraging its recovery.

Paediatric patients are fragile and there is often less time to decide when to provide mechanical support. ECMO is considered a valid option as a bridge to treat the underline causes; a special chapter has to be dedicated to the use of the VA ECMO in the univentricular palliation, .

In conclusion, understanding the underlying pathophysiology can aid the clinician with deciding when to start V-A ECMO support but it remains challenging.

IL8. Intensive Care Management of Prolonged Pediatric Mechanical Life Support

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Objective: The number of children in need of mechanical circulatory support (MCS) has increased substantially, due to the technological progress made in surgery and intensive care. In addition, primary myocardial dysfunction related to myocarditis or dilated cardiomyopathy may cause end-stage cardiac failure in children or infants, although not as frequently as in adults. The need for MCS may be either temporary until spontaneous myocardial recovery, or prolonged until heart transplantation in the absence of recovery. Two types of mechanical circulatory devices are suitable for the pediatric population: extracorporeal membrane oxygenation (ECMO) for short-term support; and ventricular assist devices for long-term support as a bridge to transplantation. ECMO is a rescue therapy for life-threatening respiratory or circulatory failure. Although outcomes are favorable with short-term ECMO therapy, data on the outcomes of prolonged ECMO therapy as well as of prolonged MCS for cardiomyopathy or irreversible heart failure in children are very limited. We aimed to report morbidity and mortality associated with prolonged MCS in children and the implication for their management.

Methods: We retrospectively analyzed the records of children presenting with prolonged MCS to our institution between January 2006 and February 2015 and conducted a systematic literature review. We recorded information on patient demographic, diagnosis, indication for MCS, MCS support details, medical and surgical history, organ dysfunction, complications, and patient outcomes. The outcome variables included survival to MCS de-cannulation or to heart transplant, survival to hospital discharge, and current survival with emphasis on neurologic, renal, pulmonary, and other end organ function.

Results: 1. Support following cardiac surgery. Remarkable recovery of myocardial function has been observed after periods of support extending to 2 weeks. Beyond 2 weeks, it is likely that the only hope for these patients would be transitioning to ventricular assist device (VAD), allowing long term support. The largest published case series of prolonged ECMO support among children managed at a single institution over a 20 year-span showed that of the 22 ECMO runs exceeding 28 days, only four patients survived to hospital discharge. All the survivors needed dialysis after discharge, and only a single patient survived without neurological injury. We performed 169 MCS over 9 years. Among them, 29 were ECMO runs longer than 14 days and 4 (19%) were transitioned to ventricular assist devices (VAD). The mean duration was 22±10 days and mortality was 71%.Twelve (57%) were post-surgery ECMO, seven (33%) were ECPR and 10 (48%) required CVVH. Bleeding and coagulopathies were the most dangerous complications. **2. Primary myocardial dysfunction.** In these instances, either ECMO or VAD may be instituted. ECMO can be rapidly deployed, is far less expensive, and may be used in the initial period of support while the diagnosis is investigated and the condition of the patient is reassessed. Beyond the first 2 weeks of support, ECMO has been shown repeatedly to be inferior to VAD as a bridge to transplantation in children. Over 9 years we admitted 43 children after VAD implantation at our CICU, five of them (12%) required VAD after cardiac surgery. Mean ± SD duration of VAD was 111±130 days and mean age was 61±73 months. Mortality was 19%, one patient required CVVH and 6 patients required more than one MCS (3 patients transitioned from ECMO to VAD). Early extubation and aggressive correction of coagulopathies played a significant role on patient outcome.

Conclusions: Prolonged MCS remains a high risk strategy to support children with poor cardiac function. Transitioning appropriate patients from ECMO to a VAD as soon as possible may be an option to reduce morbidity and mortality. Optimization of cannulation strategies, aggressive correction of non-heparin related coagulopathies and early spontaneous breathing may help improve patient outcome.

IL9. ECLS – A 30 Year Perspective

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The Royal Children's Hospital started its ECMO program in 1988, and since then has treated more than 600 patients. Over this time we have seen a significant change in the type of pathology that support is offered for, initially this was primarily for pulmonary hypertension then increasingly cardiac support.

In 2000 we started using central access routinely for patients with life threatening sepsis as these patients were not being supported satisfactorily when cannulated peripherally. All septic patients were hypotensive with evidence of inadequate end-organ perfusion (persistent metabolic acidosis and renal failure) despite adequate fluid resuscitation and high-dose inotropic support (adrenaline > 1µg/kg/min or the need for repeated bolus doses of adrenaline). Septic patients treated with ECMO require high flows for adequate metabolic and circulatory support. Central cannulation via sternotomy makes this achievable and appears to substantially reduce mortality.

Novel anticoagulation strategies have also been embarked upon to improve anticoagulation management in an increasingly complex patient population.

The introduction of aprotinin in 1994 and the development and use of new thrombin (eg. hirudin, argatroban), Xa (eg, low-molecular-weight heparin compounds), and platelet (eg. abciximab, eptifibatide, tirofiban) inhibitors and new fibrinolytic agents (eg. recombinant tissue plasminogen activator) has made clinical management more complex. The introduction of antithrombin III concentrates has created a new way to manage heparin resistance. The introduction of heparin-bonded circuits and other surface modifications has created clinical management controversies that test the practitioner's knowledge and judgement.

As technology has changed we have changed some aspects of our equipment. & potentially the way in which we will manage these patients in the future (ie pulsatile flow, NO administered to oxygenator). By maintaining primed circuits we have decreased our response time from 45 minutes to less than 10 minutes also reducing patient morbidity.

This review highlights the significant adaptations that we have undertaken & looks to the future innovations that will improve patient management & morbidity.

IL10. Long-Term Neuropsychological Outcome Following Neonatal ECMO

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Objective: The objective is to give an overview of the neuropsychological outcome of neonatal ECMO survivors evaluated by a structured, standardized, nationwide follow-up program employed in the Netherlands.

Methods: The Erasmus Medical Center-Sophia Children's hospital in Rotterdam and the Radboud University Medical Center in Nijmegen have provided ECMO to approximately 800 neonates (before 28 days of life) since 1989 and started a multidisciplinary follow-up program in 2001. The program consists of standardized medical, physical and neuropsychological assessments at one, two, five, eight (Rotterdam and Nijmegen), twelve and seventeen years old (Rotterdam). At two, five and eight years old, mental outcome/IQ and neuropsychological outcome have been analyzed for both centers and at seventeen for the children in Rotterdam.

Results: Mental outcome/IQ at two, five and eight years old has been found to remain stable and within the normal range compared to healthy peers in neonatal ECMO survivors ($\mu x = 99$, $\sigma x = 15$). More elaborate neuropsychological assessment at eight years of age showed attention fluctuations as well as working-speed problems. Furthermore, more ECMO survivors (39%) have reported the need for extra help at school or attended special education (9%) compared to the general population at this age. At seventeen years old, preliminary analyses showed working-speed as well as visual memory, auditory memory and attention to be affected.

Conclusions: Neonatal ECMO survivors are at risk for adverse neuropsychological development and school failure. The neuropsychological impairment may represent a 'growing into deficit' phenomenon. Future research by our group will focus on improving attention and working-memory by studying the effect of Cogmed working-memory training with an RCT using functional Magnetic Resonance Imaging and neuropsychological assessment.

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IL11. Impact of the Pulsatile Extracorporeal Membrane Oxygenation

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Mechanical circulatory support systems have successfully improved clinical outcomes for cardiac and respiratory dysfunction patients. The current ECMO pump is a mainly non-pulsatile centrifugal pump, which has the advantage of smaller size, lower priming volume, higher efficiency, non-occlusion, operating at lower membrane oxygenator inlet pressure and thus reduces blood cell damage. However, its disadvantage is that peripheral tissue perfusion is low and thus requires a higher pump flow output of 20-30% to match the bioavailability of a pulsatile pump. Also tissue oxygenation and oxygen exchangeability in the membrane oxygenator are not as effective as for the pulsatile pump. Only a few centrifugal pumps can generate pulsatile flow, but a lower pulsatility and back flow issues, which obstruct development of centrifugal pumps for pulsatile use in the clinical practice. Considerable research has been conducted to try to develop a pulsatile flow generator device though; there are many problems associated with providing pulsatile blood flow. One is that the device must be structurally complex; another is that any sudden high pressure produced upstream of the membrane oxygenator damages blood cells. Moreover, these preventing factors have discouraged usage of pulsatile ECMO. Several investigators have suggested that pulsatile flow is more beneficial than conventional non-pulsatile perfusion during mechanical circulatory support such as cardiopulmonary bypass, ventricular assist device and ECMO. Under and his colleague have been researching and showing many evidences the effect of pulsatile flow perfusion very actively. On this lecture, we will introduce our pneumatic pulsatile ECMO system and will show our experimental data of pulsatile ECMO and non Pulsatile ECMO in piglet models. Our focus will discuss about the impact of pulsatile ECMO in pediatric patients.

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IL12. Penn State Hershey ECLS Approach: 2015 Update

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Extracorporeal life support continues to be a viable modality for patients with severe respiratory failure, cardiogenic shock, extended cardiopulmonary resuscitation or pulmonary embolism. From June of 2008 through December of 2014, we have had 379 patients on ECMO at our institution. The number of neonatal, pediatric and adult cases for 2014 totaled 85.

Results for the patients placed on ECMO for 2014 were:

Diagnosis	Average Days on Support	Survived ECLS	Survived to Discharge or Transfer	Average Days from Decannulation to Discharge or Transfer
Neonatal				
Cardiac (1)	13.0	100%	100%	40.0
Respiratory (1)	4.0	100%	100%	22.0
Pediatric				
Respiratory (3)	20.5	100%	100%	33.0
Adult				
Respiratory (37)	15.0	73%	65%	12.5
Cardiac (30)	13.2	63%	53%	30.0
ECPR (13)	7.9	54%	31%	11.7
Total	13.3	68%	58%	19.2
Subsets				
Influenza (15)	17.7	86%	79%	15.3

In addition to our clinical load, we continue to perform translational research through the Pediatric Cardiovascular Research Center to better understand all of the aspects of ECMO and improve upon the current equipment and techniques. Our more recent studies have investigated a new pump design and ECG synchronized pulsatile flow with an ECMO system.[1-5]

The use of ECMO will continue to increase as our outcomes improve by choosing to place patients on support earlier in their course and finding other applications for this care modality.

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IL13. Anticoagulation during Pediatric Cardiopulmonary Bypass

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Pediatric cardiopulmonary bypass has some important aspects that differentiate it from the standard practice in adults. This basically applies to the procedures in newborns and in general, to small-sized patients, where packed red cells are usually included in the priming volume.

Developmental coagulation

The coagulation system at birth is far different from its final pattern in adults. Basically, the following differences can be detected:

Test/Factor	Newborn	Adult
INR	1.7	1.1
aPTT (sec)	44	33
II (%)	43	98
IX (%)	32	105
X (%)	40	99
V (%)	90	100
XII (%)	70	101
AT (%)	60	100
PC (%)	32	101
TFPI (%)	38	72

Basically, the pattern of the newborn is downregulated, with a low activity of both coagulation factors and natural anticoagulants. Overall, the standard coagulation tests are more on the side of prolonged coagulation values. However, a shorter bleeding time is common in newborns, due to an increased activity of the von Willebrand factor. This increased primary hemostasis balances the decreased coagulation factors activity, in clinical terms.

The anticoagulation management during CPB is strongly dependent on the effects of hemodilution, which is more relevant the lower is the body surface area of the patient. In small-sized babies and newborns, there are basically two strategies for priming the CPB circuit.

1. Fresh Frozen plasma (FFP). The use of FFP for priming the circuit of newborns is based on the concept of preserving the colloid-osmotic pressure and maintaining the levels of circulating coagulation factors and antithrombin. This means preserving the thrombin generation capacity. To counteract thrombin generation, adequate doses of UFH should be administered, to maintain the target ACT.

2. Albumin 5%. This strategy preserves colloid-osmotic pressure but accepts a strong dilution of coagulation factors, namely fibrinogen. The thrombin generation potential is reduced, and lower doses of UFH are usually required to reach and maintain the target ACT. The concept is "anesthesia of the coagulation system" during CPB. To awake the system, after protamine administration, adequate doses of FFP or coagulation factors/fibrinogen are required.

In both strategies, platelet count is strongly reduced during CPB, due to hemodilution. Platelets are natural scavengers of heparin, and the circulating heparin is therefore usually higher than in adults. At present, we are still lacking a sound information on the best anticoagulation management during CPB in newborns. It appears that the adequate strategy should comply with a number of additional features (i.e. level of hemodilution; nature of the priming volume; cyanotic/acyanotic disease). Therefore, this issue cannot probably be addressed simply in terms of UFH dose and target ACT. Additionally, the pediatric patients poses specific concerns not only in terms of bleeding, but even of postoperative thrombosis, especially in specific surgeries (i.e. cavo-pulmonary connections, Fontan operations).

IL14. Pediatric Cardiopulmonary Bypass – An RCH Perspective

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Congenital cardiac surgery has progressed to an increasing emphasis on complete repair of heart defects early in life. Very low mortality (< 2%) is generally achieved because of innovative techniques allowing restitution of normal anatomy and physiology before adaptation to the abnormal congenital physiology. Cardiopulmonary bypass (CPB) can be a significant challenge in these small patients due to the relative size and volume ratio of the circuit to the patient, even with circuit miniaturization. Neonates have increased metabolic requirements, and are exposed to increased ranges of temperature, flow, blood pressure, hematocrit and pH. This may have a more pronounced effect on their outcome. CPB strategies differ among various institutions. Over the past decade research related to neonatal and infant CPB has resulted in some changes in the pattern of how CPB is provided to this population of patients. The practice patterns for CPB reflect that although there have been changes as it was used there are still few definitive standards in care that describe what should or should not define contemporary practice.

Also aortic arch surgery with interrupted cerebral perfusion carries a risk of brain injury. Various protective techniques have been advocated to reduce this risk including deep hypothermic arrest (DHCA) and retrograde or selective antegrade perfusion. DHCA enables a precise anatomical reconstruction by creating a bloodless operative field; however, it has been associated with immediate and late neurodevelopmental morbidities. Understanding the pathophysiologic consequences of deep hypothermia, may determine when to initiate circulatory arrest and for how long. Selective antegrade cerebral perfusion has become a preferred method of brain protection; however, the delivery conditions and optimal perfusate constitution require further investigation.

Although there are many different techniques dealing with these issues, our experience at the Royal Children's Hospital Perfusion Unit is described. We have evolved our CPB technique to minimize these consequences including pharmacologic protective strategies to reduce the effects of excitatory amino acids and apoptotic pathways.

IL15. Selective Antegrade Cerebral and Myocardial Perfusion for Neonatal Arch Repair

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Objective: Immature myocardium, brain and other organs can be adversely affected by prolonged ischemia and deep hypothermia. We retrospectively reviewed our experience of aortic arch repair with antegrade selective cerebral (ASCP) and myocardial perfusion (SCP) avoiding deep hypothermia and prolonged ischemia in neonates.

Methods: Between June 2004 and December 2014, 25 consecutive neonates with interrupted aortic arch or diffuse arch hypoplasia with aortic coarctation underwent surgical repair on beating heart with antegrade selective cerebral perfusion and continuous myocardial perfusion through a second arterial cannula positioned into the aortic root. Internal body temperature was lowered to 27°C in all patients and main pump flow during selective cerebral and myocardial perfusion was maintained at 10ml/Kg/min and adjusted to guarantee a radial/temporal artery pressure of 30-40mmHg, a venous oxygen saturation above 60% and no ECG modifications. Hematocrit level was maintained at 30%. Continuous ECG monitoring was performed. A real-time monitoring of oxygen saturation (rSO_2) in different regions of the brain and kidneys was provided using INVOS system. For our study, surgical and clinical records were reviewed and statistical analysis was performed. Descriptive variables were expressed by means and standard deviation.

Results: Mean age at operation was 9±5 days (range 2-24 days). Mean weight was 2.83 ± 0.5 Kg (range 1.250-3.6 Kg). Mean cardiopulmonary bypass time was 85±22min and mean ASCP/SCP time was 29±7 minutes. For 13 patients (50%) a pulmonary artery banding was also performed for the evidence of a ventricular septal defect. Two patients (8%) died in the early postoperative period. No ECG modifications or CPK-MB and Troponin I level suggestive for myocardial injury were observed during postoperative period, and no neurological events were reported. No significant reduction of cerebral rSO_2 was observed during ASCP (**Figure 1**).

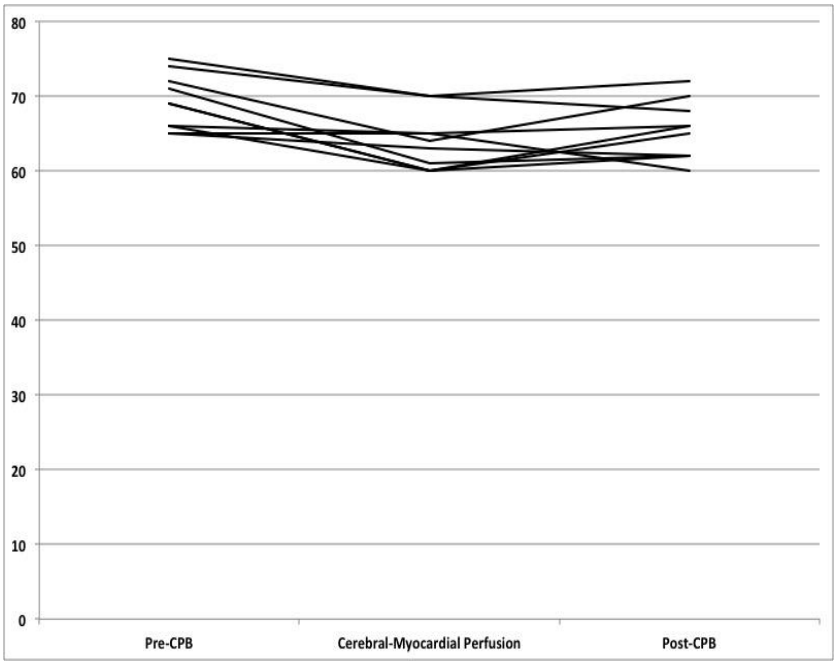

Figure 1. Cerebral rSO_2 during CPB.

Conclusions: Continuous brain and myocardial perfusion is associated with reduced neurological and early postoperative complications. The regular use of SCP during aortic arch reconstruction phase can avoid or significantly reduce the cardiac ischemic time with potential positive impact on post-operative recovery.

IL16. The Role of Hybrid Stage I in Averting Cardiopulmonary Bypass Risk in Neonates

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Objective: Newborns with CHD show immaturity of the brain that makes them particularly susceptible either to newly occurring brain damage or to worsening of pre-existing lesions when subjected to cardiopulmonary bypass (CPB) surgery, hypothermia and potentially circulatory arrest, all required to carry out aortic arch reconstruction. Based on this rationale, we have routinely adopted the hybrid procedure (HP) for first stage palliation in all patients with hypoplastic left heart syndrome (HLHS) or borderline left ventricle, in order to delay the use of CPB, when possible, beyond the terms of the neonatal period. Herein we report our result with such approach.

Methods: From September 2011 to date, all patients with HLHS with aortic arch obstruction and borderline left ventricle underwent HP by means of bilateral pulmonary artery (PA) banding and concomitant transpulmonary ductal stenting. Restrictive atrial communication was simultaneously ballooned, when required, or stented at a later date in a separate procedure.

Results: Among 29 patients constituting our consecutive hybrid stage I patient population, no early mortality occurred. Stenting of the restrictive atrial communication was performed in 6 cases, with stent displacement occurring in 3. Seven patients (24%) were converted to Norwood procedure (St1N) 64±44 days from HP with 2 late deaths, 11 (38%) underwent comprehensive II stage (CompSt2) 192±76 days from HP with no deaths, 8 (28%) underwent biventricular repair 156±87 days from HP with one early death, and 3 (10%) are still waiting for treatment 31±19 days from the HP. Restrictive atrial communication (n=3), poor hemodynamics with marginal somatic growth (n= 2), reverse coartation (n=1), and ductal stent displacement (n=1) constituted indication to conversion to St1N. Follow-up for patients who underwent CompSt2 was 596±345 days. Five of them required multiple reinterventions on the PAs: before Fontan completion (n=2), at Fontan takedown (n=1), or while awaiting Fontan (n=2), whereas 1 underwent shunt rehabilitation of an excluded left PA. Amongst survivors of St1N conversion, followed for 285±308 days, 3 underwent successfull superior cavopulmonary connection, while 2 are still awaiting. Although none of them has reached the stage of Fontan yet, pulmonary arteries distortion does not appeared to be an issue so far.

Conclusions: There are no data in the literature to support the superiority of the HP on neurodevelopmental outcome of patients with HLHS. If HP in LV borderline hypoplasia is probably the procedure of choice as a bridge to decision and by promoting LV growth, the hybrid treatment of HLHS poses huge problems mainly related to the distortion of pulmonary arterial branches. Under such circumstance, a four-stage approach including elective St1N conversion beyond the neonatal age, may constitute the optimal algorithm for treatment of HLHS.

IL17. Risk Management in Pediatric Cardiopulmonary Bypass

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Objective: Cardiopulmonary bypass (CPB) is a complex technology with inherent risks. Pediatric CPB may contain specific risks as compared to CPB in adult cardiac patients. Risk management aims at minimizing risks by identifying and analyzing potential hazards in order to prevent incidents, or, where these have occurred, at minimizing their negative impacts. For the conduct of pediatric CPB, a detailed analysis of risks and the outline of a successful risk management process are not yet available.

Methods: A literature research to identify risks and risk management strategies associated with pediatric CPB has been conducted. A review of institutional standard operating procedures has accompanied data acquisition.

Results: Risks associated with cardiac operations with the use of CPB may be allocated to technical failures, procedural hazards, patient co-morbidities, and human factors. For pediatric CPB, specific risks can be defined. These specific risks may be attributed to the pathophysiology of congenital cardiac defects, to the limitations of contemporary CPB equipment, and to procedural hazards, such as hemodilution. Successful risk management strategies include choice of appropriate CPB technology, choice of appropriate procedures, close teamwork of all perioperative departments, and a focus on human factors.

Conclusions: Risks associated with the use of CPB in pediatric cardiac patients may be managed effectively when technical limitations of the CPB devices, patient co-morbidities and teamwork are considered.

IL18. Impact of Pulsatile Flow on Vital Organ Recovery during CPB in Neonates and Infants

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Despite advances in surgical techniques and medical management, congenital heart defects still have a significant impact on morbidity, mortality, and healthcare costs. Vital organ injury during neonatal and pediatric cardiopulmonary bypass procedures is multi-factorial. Hundreds of articles have already been published on these major causes including systemic inflammatory response syndrome, deep hypothermic circulatory arrest (DHCA), ischemia/reperfusion, hematocrit levels, degree of hypothermia, pH vs alpha stat strategies, and non-pulsatile vs. pulsatile perfusion. In this presentation, we will focus only on pulsatile vs. non-pulsatile flow during neonatal and pediatric CPB procedures. Every single component of the cardiopulmonary bypass (CPB) circuitry is equally important for generating adequate quality of pulsatility, not only the pump. Therefore, translational research is a necessity to select the best components for the circuit. Generation of pulsatile flow depends on an energy gradient; precise quantification in terms of hemodynamic energy levels is, therefore, a necessity, not an option. We suggest that comparisons between perfusion modes should be done after these basic steps have been taken.

In addition, we will also share our the most recent results, including the component selection details, about the cardiopulmonary bypass (CPB) circuitry, criteria for pulsatile flow, and recent clinical results at our institution as well as other institutions with which we have collaborated on this topic during the past several years. This presentation will only contain the data generated at the Penn State Hershey Pediatric Cardiovascular Research Center and other collaborating institutions around the globe.

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IL19. Mechanical Circulatory Assistance of the Fontan Physiology

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The treatment of the thousands of patients with complex single ventricle anomalies is a formidable challenge for clinicians. Without surgical intervention, single ventricle physiology is lethal. As a treatment approach, the concept of a total right ventricular bypass, first introduced by Fontan and Baudet in the late 1960s, is a palliative surgery aimed at separating the systemic and pulmonary circulations, eliminating venous blood mixing. The final procedure, called the Fontan completion, creates the total cavopulmonary connection. To compensate for the underdeveloped pulmonary circulation, the cavopulmonary completion is implemented in 3 stages, progressively separating the systemic and pulmonary circulations and gradually increasing blood flow to the lungs. This produces a vessel configuration in which the single functional ventricle pumps blood through the systemic circulation and then draws blood from the pulmonary vascular beds. The single ventricle experiences a lower preload pressure and an increase in venous pressure to compensate for the lack of a pressure boost provided by a right ventricle. The absence of this right ventricle in high-risk Fontan patients places significant limitations on the amount of energy available to drive blood through the pulmonary vascular beds

Modifications to surgical palliation, coupled with better management, have improved surgical outcomes reducing post-operative mortality to a repair level comparable to that of simpler congenital cardiac defects. However, patients are subjected to longer-term complications, such as thrombosis, arrhythmias, ventricular dysfunction, and protein losing enteropathy. Over their lifespan, these patients utilize healthcare resources disproportionate to their numbers. Collectively, their hospitalization costs exceed $1 billion/year, constituting an emerging public health concern. For years, surgical optimization of the total cavopulmonary connection has been the focus of clinicians seeking to streamline vessel connections and to minimize energy losses. Advances in pharmacologic and novel surgical treatments have reached a plateau with little forward progress, resulting in the need for alternative therapeutic options for these patients. A heart transplant for these patients is a treatment option, if they can survive the waiting period.

The implementation of mechanical assistance, such as extracorporeal membrane oxygenation, has improved hospital survival and simplified postoperative management in a small number of patients with single physiology. Survival, however, is only 40%-50%, with hemorrhage or thrombosis as common causes of failure. Ventricular assist devices are valid options and their clinical use is on the rise for children and adolescents. Clinically available pulsatile and continuous flow blood pumps have been adapted to treat severely dysfunctional single ventricle physiologies, but produce pressures exceeding the desired range to be used for cavopulmonary support. Due to the significant limitations of existing medical devices and clinically-approved blood pumps, there still exists a substantial unmet therapeutic need for alternative treatment options that are specifically designed for patients with dysfunctional single ventricle physiology. An update of the global progress in the development of mechanical cavopulmonary assist devices for Fontan patients will be presented along with identified knowledge gaps and future directions.

IL20. The Use of VAD in Univentricular Physiology: the Role of Numerical Models

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Objective: Failing single ventricle (SV) patients might benefit from VADs as a bridge to heart transplantation. Considering the complex physiopathology of SV patients and the lack of established experience, the aim of this work is to realize and test a lumped parameter model of the cardiovascular system able to simulate SV hemodynamics and VAD implantation effects.

Methods: Data of 30 SV patients (10 Norwood, 10 Glenn and 10 Fontan) were retrospectively collected and used to simulate patient's baseline. Then, the effect of VAD implantation was simulated. Additionally, both the effects of ventricular assistance and cavopulmonary assistance were simulated in different pathological conditions on Fontan patients.

Results: The model can well reproduce patients baseline. Simulation results suggest that the implantation of VAD: (a) increases the cardiac output (CO) and the mean arterial systemic pressure (Pas) in all the three palliation conditions (Norwood 77.2% and 19.7%, Glenn 38.6% and 32.2% and Fontan 17.2% and 14.2%); (b) decreases the SV external work (EW) (Norwood 55%, Glenn 35.6% and Fontan 41%); (c) increases the mean pulmonary arterial pressure (Pap) in particular in the Norwood circulation (Norwood 39.7%, Glenn 12.1% and Fontan 3%). In Fontan circulation, with systolic dysfunction, the LVAD increases CO (35%) and Pas (25%). With RVAD a decrement of inferior vena cava pressure (Pvci) (39%) was observed with 34% increment of CO. With the BIVAD an increment of Pas (29%) and CO (37%) was observed. With diastolic dysfunction, the LVAD increases CO (42%) and the RVAD decreases the Pvci. With pulmonary vascular resistance increment, the highest CO (50%) and Pas (28%) increment was obtained with an RVAD with the highest decrement of Pvci (53%). The SVEW increases (decreases) increasing the VAD speed in cavopulmonary (ventricular) assistance.

Table 1. Simulation outcomes of SV patients undergoing VADs implantation

Time	Group	Cardiac Output [l/min]	Single Ventricle External work [J]	Mean Pulmonary Arterial Pressure [mmHg]	VAD power consumption [l*mmHg/min]
Norwood	Baseline	1.6±0.7	0.13±0.06	13.5±7.5	
	LVAD	2.9±1.0	0.06±0.03	20.5±11.1	30.4±16.0
Glenn	Baseline	2.3±1.2	0.21±0.1	14.0±5.5	
	LVAD	3.3±1.2	0.14±0.07	18.4±7.5	64.5±24.6
Fontan	Baseline	2.5±0.9	0.51±0.27	13.6±4.5	
	LVAD	3.2±1.1	0.29±0.16	14.1±4.7	40.3±13.9
Fontan-systolic dysfunction	Baseline	1.7±0.7	0.09±0.04	12.2±4.5	
	LVAD	2.3±0.8	0.08±0.03	13.3±4.6	21.1±12.7
	RVAD	2.3±0.9	0.15±0.07	18.6±7.5	10.6±2.7
	BIVAD	2.7±1.1	0.13±0.06	19.2±6.6	20.1±13.8
Fontan-diastolic dysfunction	Baseline	1.2±0.5	0.05±0.03	12.8±4.6	
	LVAD	2.1±0.7	0.05±0.02	14.3±4.7	21.6±12.6
	RVAD	1.7±0.7	0.09±0.04	20.2±7.7	2.1±3.6
	BIVAD	2.3±0.9	0.07±0.03	20.5±7.8	19.9±15.6
Fontan-pulmonary resistance increment	Baseline	1.3±0.5	0.07±0.04	17.7±6.2	
	LVAD	1.6±0.6	0.05±0.03	18.5±6.2	17.1±15.4
	RVAD	2.6±1.0	0.2±0.1	31.3±12.7	6.1±10.4
	BIVAD	3.2±1.1	0.1±0.06	34.7±13.5	46.5±33.3

Conclusions: Numerical models could be helpful in this challenging and innovative field to support patients and VAD selection to optimize the clinical outcome and personalize the therapy.

IL21. Computational Study of the Fluid-Dynamics in Ascending Aorta in Presence of a Normally Functioning Bicuspid Valve

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Objective: Aim of this study is to compare the fluid-dynamics of a functioning bicuspid aortic valve and of a tricuspid one, to highlight the abnormalities characterizing the former case which are thought to be related to an increased tendency of aneurysm formation observe in bicuspid patients.

Methods: We started from MRI images acquired on bicuspid patients with a normally functioning valve and we reconstructed the related 3D geometries to obtain the computational meshes, which are composed by tetrahedra and are the starting point of computational methods (see Figure 1, left). Then, inspired by the radiological images, we drew different possible valve orifices representing different scenarios, such as different degrees of stenoses or of orientation of the bicuspid valve, the tricuspid case, the inclusion of the leaflets, etc. Then, we performed several computational studies by running numerical simulations which allowed to predict the blood fluid-dynamics in the ascending aorta and to compare different scenarios.

Results: The numerical results highlighted that the fluid-dynamics in the case of a bicuspid valve is abnormal. In particular, an asymmetric jet and high wall shear stresses are found at the systole, which are not present in the case of a tricuspid configuration. Moreover, in presence of a dilated ascending aorta, also systolic helicoidal patterns develop, which again completely absent in the tricuspid case, see Figure 1, middlle and right.

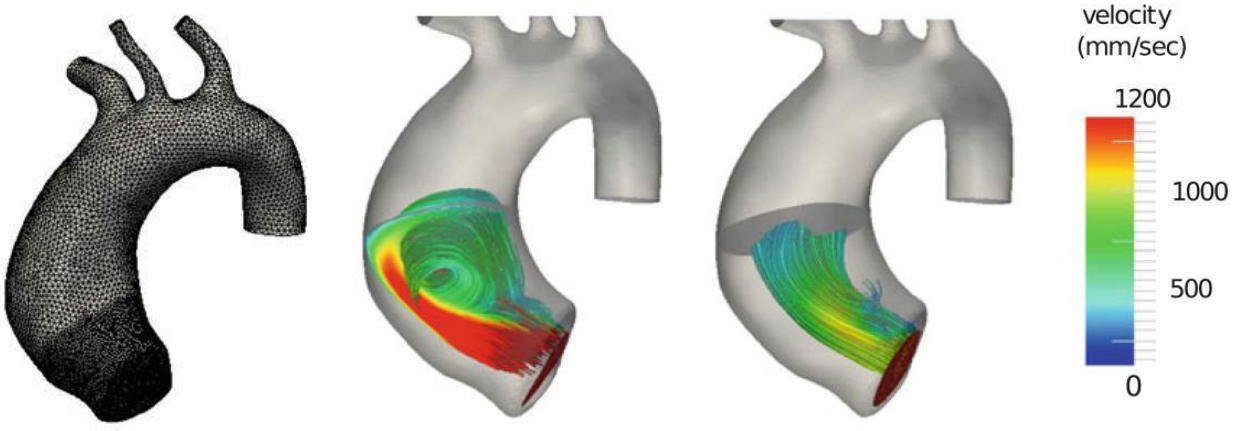

Figure 1. Computational mesh (left), systolic velocity patterns for the bicuspid (middle) and the tricuspid (right) case.

Conclusions: Our study highlighted through predictive tools the importance of the hemodynamics in creating abnormal conditions which could facilitate the aneurysm formation also in bicuspid patients with a normally functioning valve.

IL22. Real-time Tacking of Novel Biomarkers during Neonatal Extracorporeal Circulation

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Objective: Pediatric heart surgery is a costly intervention with a high risk of morbidity and mortality in hospitals. The multi-faceted nature of complications after neonatal heart surgery requires monitoring of multiple biomarkers to determine correlation to injury and best clinical practices for treatment. Our objective is to assess the suitability of high frequency monitoring of novel biomarkers by a point-of-care microdevice during neonatal cardiac surgery as potential surrogate markers of clinical outcome.

Methods: In line with this objective we are designing a microanalytical monitor that can quantify the concentration of novel biomarkers (FABP, MPO, PAPP-A, PAI-1, t-PA, and GFAP) as well as classical complements (C3a, C4a, C5a) and pro- inflammatory cytokines (IL-1, IL-6, IL-8, & TNF-α) at high temporal resolution by automating blood sampling and the serial incubation steps required for multiplexed immunofluorocytometry. Potential biomarkers of myocardial damage include heart-type fatty-acid–binding protein (FABP), myeloperoxidase (MPO) and pregnancy associated plasma protein (PAPP-A) which surge minutes after CPB initiation. Plasminogen activator inhibitor-1 (PAI-1) is a pro-coagulant, pro-inflammatory and pro-fibrotic molecule. PAI-1 is frequently expressed in injured tissues, the myocardium in particular, and the PAI-1/tissue plasminogen activator (t-PA) ratio is indicative of a patient's fibrinolytic balance indicating thrombus and stroke risk. Glial fibrillary acidic protein (GFAP) is a biomarker indicative of intracerebral hemorrhage (ICH) in patients with symptoms of acute stroke. Classical complements and cytokines will be used to validate the devices in an exvivo CPB circuit.

Results: Our clinical team recently conducted limited pediatric patient studies consisting of seriological testing of multiple biomarkers to assess the inflammatory and hemostatic response to cardiopulmonary bypass[1]. This study assessed the suitability of using Multi-Analyte Profiling (MAP) (Rules Based Medicine, Austin, TX) in neonatal/pediatric cardiac surgery as potential surrogate markers of clinical outcome in plasma samples (200-300 µl) collected at different time points during and following surgery; 1) before mid-line incision, 2) on CPB for 3 to 5 min., 3) at the end of CPB, 4) 1 hr. after CPB, 5) 24 hr. after CPB. As potential biomarkers of myocardial damage, FABP, MPO and PAPP-A surge minutes after the initiation of CPB. MPO and PAPP-A were the earliest markers to rise with a 49 and 18 fold increase 3-5 minutes after the onset of CPB, respectively. A striking increase of 25, 193, 151 and 4 fold was noted for FABP at times 2 to 5. The surge in these markers of injury was followed by classical markers of inflammation (i.e., C-reactive protein, interleukins) peaking 24 hr after CPB. At the same time clinical studies were conducted, we also designed a series of blood handling and analysis microdevices and these devices have been connected to extracorporeal circulatory support equipment[2-5]. These devices automate the serial incubation steps required when using immunofluorcytometric magnetic bead immunoassays, such as those based on the Luminex® xMAP technology which can analyze up to 100 different protein markers simultaneously. We have demonstrated the ability to track the concentration of a time-varying sample with multiple analytes simultaneously (cytokines IL-6 and TNF-α) as well as measuring 6 proteins in 32 samples simultaneously using only 4.2 µL of sample volume[6].

Conclusions: We believe these studies can be used to improve the treatment of children with congenital heart disease, and, consequently, to reduce the morbidity and mortality associated with neonatal cardiopulmonary bypass.

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IL23. Experimental Small Animal Models of Extracorporeal Circulation and Right Heart Failure: a Window for Translational Research in Pediatric Cardiac Surgery

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Over the past decade, numerous animal models have been developed in attempt to reproduce miniaturized extracorporeal circulation in vivo. However, the successful translation of results observed from bench to clinical setting remains low. To overcome this issue, we presented a rat model of extracorporeal circulation with standard clinical characteristics. This model has been used in several studies related to pediatric cardiac surgery and extracorporeal life support.

Congenital heart defects and pulmonary vascular disorders are associated with major changes in loading conditions of the right ventricle. Several experimental models of right ventricular failure have been developed over the past three decades providing a particular insight in right ventricular pathophysiology. Mechanisms involved in the transition from right ventricle adaptive hypertrophy to maladaptive remodeling and failure in conditions of chronic right ventricle volume overload are of a great interest but not yet completely understood. Further investigations are needed to find new therapeutic approaches for right ventricle failure and pulmonary arterial hypertension. Current small animal models and emerging concepts of translational research will be detailed in the present review.

S1. Early Outcomes with HeartWare (HVAD) as a Bridge to Transplant in Children: A Single Institution Experience

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Objective: Heart transplantation remains the gold standard for the management of end stage heart failure. Limited organ availability has prompted the use of LVAD's, however, few are designed and approved for use in children. We describe our experience with the use of HeartWare HVAD as a bridge to transplant in the pediatric population.

Methods: Retrospective chart review of all HeartWare HVAD implants performed at our institution between May 2013 and February 2015 was performed. Seven children between the ages of 9 to 17 years underwent implantation of the HVAD as a bridge to transplant.

Results: Patients demographics and outcomes are summarized in Table 1. Five patients were successfully bridged to transplant. One patient is currently being supported. All transplanted patients are alive at a median f/u of 358 days (Range: 258-530 days).

Table 1. Patients demographics and operative results.

Characteristics	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Age (yrs)	14	13	9	9	9	17	16
Gender	M	M	F	F	M	M	M
Weight (Kg)/ BSA(m^2)	70/1.8	40/1.38	36.2/1.21	59.4/1.5	29.4/0.99	58.2/1.66	81/2.09
Diagnosis	DCM	DCM	DCM LV thrombus	DCM, Coxsackie myocarditis, pre-op ARF	Heterotaxy, DORV, hypoplastic LV, unbalanced AVC	DCM, pre-op thrombo-embolic stroke	DCM
Previous Surgery	ICD	None	None	None	s/p TAPVR repair, PDA ligation, PA ligation, Glenn, Impella, VA ECMO	ICD	None
LVEDD (mm)	72	75.2	60.5	68	N/A	75	75
EF %	23	15	11	14	N/A	15	22
PVR (Wood units)	1.2	6.7	5.13	4.64	NA	2.11	3.17
Pre-op inotropes	Milrinone	Milrinone	Milrinone, Epinephrine	Milrinone	Milrinone, Epinephrine	Milrinone	Milrinone
INTERMACS	2	2	2	1	1	2	2
Extubation (POD)	2	1	2	2	4	2	1
Days of HVAD support	36	40	71	94	12	13	2*
Complications	Ventricular ectopy	None	None	VRE, sepsis	Reintubation pneumonia, ARF, hepatic vein clot, multisystem organ failure	Ventricular ectopy	None
Outcome	Txplt	Txplt	Txplt	Txplt	Death	Txplt	Awaiting transplant

* Currently on mechanical support

Conclusions: The HeartWare HVAD can successfully be used as a bridge to transplant in children. The smaller HeartWare MVAD will likely/should allow for use in smaller patients. Outcomes for patients with failing single ventricle physiology remain to be determined.

S2. Heart Transplantation in Failing Univentricular Hearts

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Objective: Heart transplantation (HTx) in children with univentricular physiology is a challenge. As one of the national referral centres for heart transplantation in children, we reviewed our records presenting a large single-center experience over 25 years in this specific and complex pediatric population.

Methods: Between November 1985 and December 2014, among 87 patients who underwent HTx for congenital heart diseases (CHDs), 43 orthotropic cardiac transplants were performed in 41 children with univentricular hearts (UVHs) in our institution. Outcomes were reviewed using medical records and transplant databases.

Results: Children were listed following stage I (n=9, 21%), including 2 patients without any surgery; Glenn (n=8, 19%) or Fontan (n=24, 58%) operation. Among Fontan patients listed, 9 (37%) had an atrio-pulmonary connection, 6 (25%) an extracardiac conduit, 5 (20%) a lateral tunnel and 4 (16%) an intra-atrial conduit.

At time of listing twelve patients had protein-loosing enteropathy (PLE) and six had panel reactive antibodies (PRAs) >10%. Median age at HTx was 14,6 years. Three patients were on extra corporeal membranous oxygenation (ECMO) at time of HTx and 8 cases required reconstruction of the great vessels. Hospital mortality was 8/43 (18%); 4 patients belonging to the Fontan group and 4 to stage I. Causes of early death were sepsis, low cardiac output, epileptic attack and acute rejection. Late mortality was 7/35 (20%), due to sepsis, acute and chronic rejection and re-transplant in two cases. Overall survival at 1, 10 and 15 years was 72%, IC 95% (58,85); 62%, IC 95% (46,77) and 49%, IC 95% (29,68), respectively. There was no significant difference in 10 and 15-years survival for HTx in UVHs compared to CHDs (62% vs 67% and 49% vs 58%, respectively).

Conclusions: HTx is a feasible option for patients with failing univentricular circulations and late survival is comparable to children with CHDs.

S3. Pediatric Heart Transplantation in Patient on ECMO or VAD

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Objective: To compare the result of heart transplantation (HT) in children on ECMO, VAD and without any cardiocirculatory assistance.

Methods: From 2002 to 2014 31 HT were performed in 29 patients. Five (group 1) were previously on ECMO, 7 (group 2) on VAD and 17 (group 3) were not on any assist device. Induction therapy was obtained with Tymoglobulin or Basiliximab and maintenance with Tacrolimus and Mycophenolate and a short period of steroid.

Results: Age, weight, height and mismatch D/R were similar in three groups (p=NS). Median period on ECMO was 7 days (1-28), while was 37 days on VAD (6-522). Cross clamping time was not different. Post-operative ECMO support was needed in 2 patients in group 1 (40%), both died, in 2 in group 2 (28%), both weaned and one discharged, and 2 patients in group 3 (11%), both weaned and discharged (p=NS). Two hyperacute rejections were present in group 2 (28%), one treated, the other successfully retransplanted but died 2 months later for cerebral hemorrage. In group 3 there were 8 acute rejections (47%), one leading to successful retransplantation. Major neurologic complications, mainly critical patient neuropathy or posterior reversible encephalopathy syndrome (PRES), were 2 in group 1, 3 in group 2 with reliquates in 2, and 2 in group 3 (p=NS). Early mortality was 80% (4/5) in group 1, 14% (1/7) in group 2 and 6% (1/17) in group 3 (p=0.07 1vs2, p=0.003 1vs3), while late mortality was 0 in group 1 and 2 and 12.5% (2/16) in group 3 (p=NS). All surviving patients are in good clinical conditions at a mean follow-up of 45±40 months in group 2 and 70±35 months in group 3 (p=0.1).

Conclusions: Pediatric HT while on VAD shows acceptable results, requiring accurate immunological evaluation and care for neurological complication. Patients assisted on ECMO show poor prognosis.

S4. Coagulation and Inflammatory Markers Predict Berlin Heart Excor Thromboembolic Events despite a Steroid Protocol: A Study of 32 Events

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Objective: The objective of this study is to identify the association between coagulation and inflammatory markers and hemorrhagic and thrombotic events during Berlin Heart ExCor support.

Methods: Temperature, white blood cell count (WBC), C-reactive protein (CRP), fibrinogen, Prothrombin Time (PT), Partial Thromboplastin Time (PTT) and platelet count were measured at 48 and 24 hours before and after a bleed or thrombosis event. The same parameters were measured during a control period where subjects did not experience either event. All patients were treated using the anticoagulation regimen recommended by Berlin Heart and a methylprednisolone protocol was used for 5 of the 9 patients.

Results: Of nine patients, who underwent Berlin ExCor ventricular assist device placement, 8 subjects had hemorrhagic events and 5 had thrombotic events. There were no differences between either event and the control condition for weight, temperature, CRP or WBC count. PTT levels were higher before and after a bleeding (Δ17.14, p=0.003) and thrombosis (Δ7.14, p=0.016) event relative to control. There were no differences in heparin dose surrounding a bleeding event. Heparin dose decreased after a thrombosis event (Δ-5.67, p=0.097) and this decrease was significantly different from control (p=0.028).

Before a bleeding event, fibrinogen levels were not different from control (Δ20.58, p=0.667), however after the event, fibrinogen levels were lower than control (Δ-72.69, p=0.076) resulting in an interaction effect (p=0.036). There were no differences in fibrinogen for a thrombosis event. After both bleeding and thrombotic events, platelet levels decreased (Δ-43.10/, Δ-74.89 p=0.014) and this decrease was significantly different from control (p=0.038/ p=0.034). Prior to the thrombosis event, platelet levels were not different from control.

Conclusions: This study demonstrates that increased PTT occurs both before and after thrombotic and hemorrhagic events. It is unclear if this is a cause for hemorrhage or thrombus formation or a change in heparin response. Heparin dose was significantly higher pre-event in both bleed and thrombus groups. Fibrinogen level did not predict thrombotic or hemorrhagic events despite being an inflammatory marker. Platelet levels did not predict thrombotic or hemorrhagic events, but did decrease after both types of events likely due to a consumptive process. The role of inflammation in the development of thrombus or hemorrhage needs to be studied further.

S5. Survival Outcomes in Children Less Than 10 Kg Bridged To Transplant with the Berlin Heart EXCOR Ventricular Assist Device

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Objective: Although the remarkable advances with the use of ventricular assist devices (LVAD) in adults, and the well-established experience with adolescents, pneumatic pulsatile support in small children is still limited. The aim of this work is to report a retrospective review of our experience on the use of VADs in very small children (<10 kg of body weight).

Methods: Data of 30 consecutive children weighing less than 10 kg undergoing mechanical support with Berlin Heart (Berlin Heart AG, Berlin, Germany) as a bridge to heart transplant from March 2002 to March 2015 were retrospectively collected.

Results: The mean patient age was 12.7±10.8 months. The mean patient weight was 6.5±1.7 Kg. Prior to VAD implantation, all children were managed by multiple intravenous inotropes or extracorporeal membrane oxygenation (13%). Three patients required biventricular mechanical support (among patients implanted before 2010) and two patients had single ventricle physiology. The mean duration of VAD support was 115.8±64.7 days and increases over the time from 2002 to 2015. Eight (27%) deaths occurred. However, in the last 20 patients (implanted between 2010 and 2015), mortality decreased to 4 patients (20%). Cause of death was neurological complication (13%) and sepsis (7%). Sixteen patients (53%) were successfully bridged to heart transplantation and six other patients (20%) are still on VADs waiting for heart transplantation. Two (7%) patients required surgical revision for a large haematoma around the aortic cannula, while 16 patients (53%) required at least one pump change.

Table 1. Summary of patient's data and outcomes.

Patients (n)	30	**Heart Transplantation (n)**	16 (53%)
Age (months)	12.7±10.8	**On VADs (n)**	6 (20%)
Weight (Kg)	6.5±1.7	**Pump Change (n of patients)**	16 (53%)
ECMO	4 (13%)	**Trombus (n patients)**	5 (17%)
BIVAD (n)	3 (10%)	**Bleeding**	2 (7%)
Day of Assistance	115.8±64.7	**Neurological Complications**	10 (33%)
Death (n)	8 (27%)		

Conclusions: Mechanical support in smaller children with end-stage heart failure is an effective strategy for bridging patients to heart transplantation.

S6. Evaluation and Incidence of Right Ventricle Dysfunction in Children with Pulsatile Ventricular Assist Devices

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Objective: Left ventricular assist devices (LVADs) for the treatment of children with end-stage heart failure (HF) is an effective strategy as a bridge to heart transplantation even in the presence of significant right ventricular (RV) dysfunction, lowering the risk of long-term complications compared to biventricular mechanical support (BiVAD).

Methods: Data of 30 consecutive children treated with VAD (March 2007 - February 2015) were retrospectively collected focusing on RV function before and after VAD implantation.

Results: HF etiology was: 21 dilative cardiomyopathy (secondary to myocarditis in 5), 4 restrictive cardiomyopathy and 5 left ventricular uncompaction. LVAD was used in 24 pts (group I) while BiVAD was placed in 6 pts (group II). Median weight was 9.4±8.7Kg and 16.8±13.7Kg respectively. VAD support duration was 112.7±66.8 days and 57.4±54.0 days, respectively. 6pts are still on LVAD. Overall mortality was 23%: 50% in group II and 25% in group I, where 17 pts were successfully bridged to heart transplant and 7 deaths. In group I, preoperative RV dysfunction diagnosed by echocardiography was present in 10 pts (41%), while the incidence of postoperative RV dysfunction was 15 patients (62%). LVAD pts with RV dysfunction showed moderate to severe tricuspid regurgitation, low RV fractional area change and TAPSE. Group I pts received inotropes and vasopressors. Pulmonary vascular resistance was managed by selective pharmacological agents and oral sildenafil after extubation. Oral drug therapy to increase reverse remodeling of both ventricles included standard use of β-blockers and Ace-I.

Conclusions: There is a wide spectrum of response in RV performance to VAD implantation especially in younger patients. The use of pulmonary vasodilators and inotropic agents and improved patient selection can avoid the use of BiVAD in paediatrics with better outcomes, in contrast with adults. Preoperative and postoperative RV function echocardiographic monitoring is useful in identifying higher risk patients.

S7. Platelet Mapping Assay is Not Suitable to Safely Monitor Antiplatelet Therapy during Ventricular Assist Device

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Objective: Berlin Heart (BH) is a ventricular assist device suitable for small children. Thrombosis in this context remains an issue. Thus, a multi-system anticoagulation protocol is recommended, including dual antiplatelet therapy by dipyridamole and aspirin (ASA). TEG Platelet Mapping (TEG-PM) is required by BH's manufacturer to monitor platelet inhibition (PI). We report the results of the TEG-PM in the first child assisted by a BH in our institution and results obtained in controls in order to establish reference values and to understand the limit of TEG-PM.

Methods: After BH implantation, PI was adjusted according to TEG-PM results. Following the guidelines of BH, target PI for dipyridamole and ASA is reached with TEG-PM if G_{ADP}<6 dyn/cm^2 and AA inhibition >70% respectively. TEG-PM was also performed in 9 controls, in standard conditions,with various agonists' concentrations and/or after 15 min incubation with inhibitors (apyrase or ASA). Moreover, the effect of apyrase or glycoprotein (Gp) IIb/IIIa inhibitor on maximum amplitude due to fibrin formation alone (MA_{Fibrin}) was also studied.

Results: Aspirin was begun 9 days post implantation at 1 mg/kg/d up to day 15, and then increased to 2 mg/kg/d. Although the G_{ADP} threshold value (6 dyn/cm^2) was never reached, dipyridamole was started 47 days postoperatively to reduce thrombotic risk. The tracings of platelet mapping were sometimes atypical, because MA_{fibrin} never reached stability. In controls, PI in the presence of AA ranged from 0 to 15.6 % and G_{ADP} from 3.1 to 12.1 dyn/cm^2. Surprisingly, atypical pattern was also observed in three controls, corrected after addition of apyrase. The same result was obtained after addition of glycoprotein (Gp) IIb/IIIa inhibitors.

Conclusions: MA_{fibrin} is not totally independent from platelet activation. The ability of TEG-PM to specifically reflect ADP or AA platelet sensitivity becomes questionable.

S8. Biventricular Intra-corporeal Ventricular Assist Device in a 10 Year Old Child

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Objective: Whereas in adult patients number of BVAD implantations is declining incidence of biventricular failure among children remains high ranging from 29 to 43%. To date, the Berlin Heart EXCOR® has been mainstay of long term VAD support for children but it is far from perfect due its unacceptably high risk of thromboembolic events, paracorporeal design that limits mobilization and precludes discharge from hospital. The pediatric population has benefited greatly by the evolution of VADs leading to miniaturization. Device design like the HeartWare® VAD allows for implantation in smaller patients or even as implantable biventricular assist device.

Methods: A ten year old female patient (body surface area 1,02m^2, 27kilograms) waiting since 7 months for heart transplantation was admitted to the intensive care unit due to terminal heart failure. She already had been treated due to heart failure triggered by pneumonia three times within the last four weeks and treatment included Levosimendan all three times. Transthoracal echocardiography revealed heart failure with an estimated ejection fraction of 15%, dilated left ventricle, moderate tricuspid and mitral regurgitation. Despite maximal medical therapy (including milrinone and one course of Levosimendan intravenous), condition further worsened and mechanical circulatory support was indicated.

Results: After implantation of one HeartWare HVAD® device as an LVAD using the left ventricular apex, a second pump was implanted as a right VAD (RVAD). The sewing ring of the HVAD was attached to the lateral wall of the right atrium. The device was implanted so that the axis of the inflow cannula was pointing towards the tricuspid valve. The outflow graft was anastomosed to the pulmonary artery truncus; the outflow graft diameter was not narrowed. Drive line exit site were the right (RVAD) and left (LVAD) lower quadrant of the abdominal wall about 4 fingers above the spina iliaca anterior superior. The chest was primary closed. Anticoagulation with i.v. heparin was started 8 hours postoperatively with a target anti-factor Xa level of 0.3 to 0.6 IU/ml. No inotropic support was necessary, echocardiography revealed small ventricles and a good position of the right sided inflow canula. The patient was extubated after 26 hours and fully mobilized. BVAD setting were: 2300 revolutions per minute, calculated flow: 3.2 liters per minute and 2.7 Watt for the left side and 2080 revolutions per minute, calculated flow: 3.3 liters per minute and 2.1 Watt for the right side.

Conclusions: This case report demonstrates the successful implantation of two HVAD Heartware pumps for biventricular support in a ten year old child. To our knowledge and according to the company this is the youngest and smallest child so far supported with two HVAD pumps.

S9. Improved Outcome of Cardiac ECMO in Infants and Children Using Magnetic Levitation Centrifugal Pumps

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Objective: Extracorporeal Membrane Oxygenation (ECMO) has traditionally been and, for the most part, still is being performed using roller pumps. Use of first generation centrifugal pumps has yielded controversial outcomes, perhaps due to mechanical properties of the same and the ensuing risk of hemolysis and renal morbidity. Latest generation centrifugal pumps, using magnetic levitation exhibit mechanical properties, which may have overcome limitations of first generation devices. This retrospective study aimed to assess the safety and efficacy of V-A ECMO for cardiac indications in neonates, infants and children using standard (SP) and latest generation magnetic levitation (ML) centrifugal pumps.

Methods: Between September 2002 and November 2014, 33 consecutive neonates, infants and young children were supported using V-A ECMO for cardiac indication. There were 21 male and 12 female, with median age of 29 days (4 days-5 years) and a median body weight of 3.2 kg (1.9-18 kg). Indication to V-A ECMO was acute circulatory collapse in ICU or ward after cardiac repair in 16 (49%) patients, failure to wean after repair of complex congenital heart disease in 9 (27%), fulminant myocarditis in 4 (12%), preoperative sepsis in 2 (6%), refractory tachy-arrhythmias in 2 (6%). Central cannulation was used in 27 (81%) patients and peripheral in 6. Seven (21%) patients were supported with SP and 26 (79%) with ML centrifugal pumps.

Results: Median duration of support was 82 hours (range 24-672 hours), with 26 (79%) patients weaned from support. Two patients required a second ECMO run and both died on support. Seventeen (51%) patients required peritoneal dialysis for acute renal failure. Overall survival to discharge was 39% (13/33 patients). All patients with fulminant myocarditis and with refractory arrhythmias were weaned and 5 (83%) survived, whereas no patient supported for sepsis survived. Risk factors for hospital mortality included lower (<2.5 kg) body weight (p=0.02) and rescue ECMO after cardiac repair (p=0.03). During a median follow-up of 34 months (range 4-62 months), there were 3 (23%) late deaths and 2 late survivors with neurological sequelae. Comparison of weaning rate (5/7 versus 21/26, p=NS) and prevalence of renal failure requiring dialysis (4/7 versus 13/26, p=NS) were comparable between SP and ML ECMO groups. Patients supported with ML had a trend toward higher hospital survival (1/7 versus 12/26, p=0.07) and significantly higher late survival (0/7 versus 2/26, p=0.05).

Conclusions: The present experience shows that V-A ECMO for cardiac indications using centrifugal pumps in infants and children yields outcomes absolutely comparable to international registry (ELSO) data using mostly roller pumps. Use of magnetic levitation centrifugal pumps may further improve end-organ recovery, hospital and late survival.

S10. Early results of Infants Requiring Postoperative Extracorporeal Membrane Oxygenation after Norwood Palliation for Hypoplastic Left Heart Syndrome

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Objective: The objective of this review is to assess the early outcome of infants with hypoplastic left heart syndrome (HLHS) who underwent postoperative extracorporeal membrane oxygenation (ECMO).

Methods: We retrospectively reviewed all patients who underwent the Norwood procedure and were supported with ECMO between June 1998 and December 2014. These ECMO patients were then divided into two groups: including patients who underwent Norwood palliation before 2009 and after 2009. We analyzed the weaning from ECMO, survival to ICU discharge and survival to hospital discharge.

Results: One hundred twenty-seven patients underwent Norwood palliation for HLHS and its variants. ECMO was carried out a total of 24 times in 22 patients (17%). The 22 infants that underwent ECMO were divided into two groups based on the period of treatment, including an early period (1998 to 2008) and a late period (2009 to 2014). A total of seven patients underwent bilateral pulmonary artery banding and one patient underwent aortic valuvotomy before the stage 1 Norwood procedure. Sixteen of the 24 ECMO treatments (67%) were successfully weaned from ECMO. Seven patients died with multiorgan failure in 3 patients, sepsis in 2 patients, and arrhythmia in 2 patients after being weaned from ECMO. Two of the 11 patients who had a history of circulatory collapse requiring CPR were able to survive until they were discharged from the hospital. According to a univariate analysis, the risk factors for hospital mortality included a longer duration of ECMO support (P =.014) and multiorgan failure (P = .005) in all patients. Please refer to the table below.

Variable	Early (1998-2008) (n=11)	Late (2009-2014) (n=11)	p Value
Run of ECMO	12	12	
BW (kg) at ECMO	2.5±0.6	3.2±0.3	0.008
Age at ECMO initiation, days	26 (4-79)	61 (2-296)	0.547
indication for ECMO			
Cardiac failure	7	6	
Failure to wean CPB	3	2	
Hypoxia	2	6	
CPR	5	6	
Timing of ECMO initiation			
During Operation	4	5	
After Operation (>30days)	0	5	
Duration of ECMO, hours	380 (16-1440)	148 (20-538)	0.21
Success weaning from ECMO	6 (50%)	10 (83%)	0.041
Survival to ICU discharge	1 (9%)	6 (55%)	0.032
Survival to hospital discharge	1 (9%)	6 (55%)	0.032

Conclusions: A higher rate of successful weaning from ECMO, and survival in the intensive care unit and until hospital discharge, was observed in the late period than in the early period.

S11. Impact of Anticoagulation Strategy on ECMO Bleeding and Thrombotic Complications

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Objective: Extracorporeal membrane oxygenation (ECMO) support necessitates systemic anticoagulation, requiring a balance between anti/pro-thrombotic states to prevent complications. Heparin is the most common anticoagulant used and has traditionally been titrated to a goal activated clotting time (ACT). In 2011, we changed our anticoagulation strategy to target anti-Xa levels with less frequent titrations of heparin. The goal of this study is to assess the impact that change has had on bleeding and thrombotic complications.

Methods: A single institution retrospective chart review was done of all patients receiving ECMO support from January 2006 through October 2014. A switch in ECMO anticoagulation protocol was made in June 2011. The months from March through September 2011 were excluded as to allow for transition from the old to new protocol. Rates of surgical exploration per day supported on ECMO, measured blood loss, transfused packed red blood cell volumes, and incidence of intracranial hemorrhage were compared to assess for hemorrhagic complications. Number of ECMO circuit changes per day supported on ECMO and incidence of thrombosis identified in the patients were compared to assess for thrombotic complications.

Results:

Table 1: Demographics and outcome measures before and after protocol change.

	Before protocol change (n=152 ECMO runs in 129 patients)	After protocol change (n=76 ECMO runs in 71 patients)	p-value
Age (years): Median (IQR)	0.40 (0.02-3.18)	0.30 (0.01-3.07)	0.65[a]
Weight (kg): Median (IQR)	5.60 (3.20-12.40)	4.37 (3.00-11.30)	0.48[a]
Hours on ECMO	94.5 (59.5 – 154.5)	143.2 (61.5-196.5)	**0.008**
Survival to discharge: N (%)	62 (48.1%)	29 (40.8%)	0.33[b]
Circuit changes/ECMO day	0.0 (0.0-0.1)	0.0 (0.0-0.04)	**0.02**
Thrombosis in patient: N (%)	9 (7.0%)	5 (7.0%)	>0.9[c]
Cardiac surgery within 48 hours of ECMO initiation	69 (45.4%)	20 (26.3%)	**0.006**
Explorations/ ECMO day	0.19 (0- 0.42)	0.0 (0.0-0.19)	**0.0001**
Intracranial Hemorrhage	34 (22.4%)	11 (14.5%)	0.16
Blood loss/kg/day	48.0 (8.8-91.6)	26.0 (5.9-56.3)	**0.002**
pRBC volume/kg/day	33.7 (19.9-61.1)	20.7 (11.5-37.8)	**0.0001**
Heparin dose changes/ECMO day	6.2 (3.8-8.0)	1.7 (1.1-2.3)	**<0.0001**
Heparin boluses/ECMO day	4.2 (2.8-6.0)	0.0 (0.0-0.15)	**<0.0001**

a. Mann-Whitney test b. Chi-square test c. Fisher's Exact test d. Repeated measure analysis using patients as clusters. ECMO = extracorporeal membrane oxygenation, pRBC = packed red blood cell

Conclusions: The change in anticoagulation protocol is associated with a significant decrease in hemorrhagic complications and circuit thrombosis requiring circuit change. Other factors including changes in circuit components likely contributed. Prospective trials of ECMO anticoagulation protocols are necessary to confirm these associations and further optimize current protocols.

S12. ECLS Experience of Hacettepe University Ihsan Dogramaci Children's Hospital

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Objective: The objective of this study is to retrospectively analyze last two year (2013-2014) ECLS experience of Hacettepe University Ihsan Dogramaci Children's Hospital.

Methods: Hacettepe University Ihsan Dogramaci Children Hospital is the most prestigious children's hospital in Turkey. ECMO program was first conducted in Hacettepe University Pediatric Intensive Care Unit in 2007. After the" 6 th Istanbul Sypmosium of ECMO in June 22, 2013", ECMO adventure has been accelerated.

Results: In the last two years, ten ECMO has been done. 70 % of them was boy (n=7), 30% of girl (n=3). Median age was 32 months of age (6month-14year of age). Median ECMO duration time was 6 day (7 hour-29 days). 60 % of patient was performed on ECMO after post-operative cardiac surgery. All of the cannulations were veno-arterial. The most observed complication was bleeding. 50 % of patient had bleeding problem. All of the patient who died, had bleeding problem. HIT (heparin induced thrombocytopenia) was observed in 40 % of patient. The increased ECMO duration, the more HIT was observed. We solely used centrifugal pump (70% Medos DP3, 30 % Rotaflow). 30 % of them with Medos Deltastream MDS used pulsatile flow. Weaning and discharge ratio from the hospital was 60 %. Patient's data was summarized in Table-1.

Table 1. ECLS Results of Hacettepe University.

Pt No	Age	Diagnosis	Indication for ECMO	Site of Cannula	Pump Type	Complication(s)	ECMO Duration	Outcome
1	14y	ARVD	Arrhythmia, E-CPR	FA-FV	DP3	None	8hrs	Successful bridge to Tx
2	12y	Systemic Brucellosis	Brucella Myocarditis	RA-Aorta	DP3	Air embolism, hypofibrinogenemia, HIT	7d	Weaned /Survived
3	6m	TOF	Postoperative cardiac stunning	RA-Aorta	DP3	Hypofibrinogenemia, HIT	4d	Weaned /Survived
4	7m	AVSD,TAP VR,PLSVC	Postoperative cardiac stunning	RA--Aorta	DP3	Bleeding at the site of aortic cannula, sepsis	22d	Exitus
5	7y	HRV, PA, FSV	unsuccessful weaning from CPB	RA-Aorta	DP3	Bleeding, hypofibrogenemia, HIT	6d	Weaned /Survived
6	6m	TOF	postoperative SIRS	RA-Aorta	DP3	SIRS, bleeding at the site of aortic cannula, HİT	29d	Exitus
7	15m	TOF	Postoperative cardiac stunning	RA-Aorta	Rotaflow	Peripheral thromboembolism	7d	Weaned /Survived
8	4y	DCM	E-CPR	RA-Aorta	Rotaflow	Bleeding, HİT	> 30d	Still on ECMO support
9	9y	DCM	E-CPR	FA-FV	Rotaflow	SIRS, Pulmonary Edema	5d	Exitus
10	9m	VSD	Postoperative cardiac stunning	RA-Aorta	Rotaflow	Consumption coagulopathy	6d	Weaned /Survived

ARVD: arrhythmogenic right ventricle dysplasia, E-CPR: ECMO-cardiopulmonary Resuscitation, FA: femoral artery, FV: femoral vein, Tx: transplantation, RA: right atrium, HIT: heparine induced thrombocytopenia, TOF: tetralogy of Fallot, AVSD: atrioventricular septal defect, TAPVR: total abnormal pulmonary venous return, PLSVC: persistent left superior venae cavae, HRV: hypoplastic right ventricle, PA: pulmonary atresia, FSV: functional single ventricle, CPB: cardiopulmonary bypass, SIRS: Systemic Inflammatory Response Syndrome, DCM: dilated cardiomyopathy, VSD: ventricular septal defect.

Conclusions: Outcomes of pediatric ECLS patients have been improved in Hacettepe University Ihsan Dogramaci Children's Hospital in recent two years. Now, we can actively use ECMO such that weaning and survival rate is 60 %. Bleeding and HIT are most common problems. We want to increase ECMO success and the number of cases and solve these problems in the future.

S13. Continuous Metabolic Monitoring in Infant Cardiac Surgery: Towards an Individualized Cardiopulmonary Bypass Strategy

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Objective: Neonatal cardiopulmonary bypass (CPB) is associated with postoperative morbidity due to systemic inflammatory response syndrome (SIRS). Strategies aimed at mitigating SIRS include management of perfusion temperature, hemodilution, circuit miniaturization and biocompatibility. Traditionally, perfusion parameters have been based on body weight. However, intraoperative monitoring of hemodynamic (CDI) and cerebral metabolic (NIRS) parameters often suggest that nominal CPB flows may be overestimated. The aim of the current pilot study was to assess the safety and efficacy of continuous hemodynamic and metabolic monitoring as more physiological parameters to manage CPB in infants requiring open heart repair.

Methods: Between December 2013 and October 2014, 31 consecutive infants and young children undergoing surgical repair using normothermic CPB were enrolled in the study. There were 18 male and 13 female, aged 1.4±1.7 years, with a mean body weight of 7.8±3.8 kg and BSA of 0.39 M2. The study was divided in two phases: 1. Safety assessment; the first 20 consecutive patients were managed according to conventional CPB flow parameters (150 mL/min/kg), except for a 20 minutes test during which CPB was indexed to the minimum flow to maintain MVO2 >70% and NIRS >45% (Group A) 2. Efficacy assessment; the following 11 consecutive patients were exclusively managed adjusting flows to maintain MVO2 >70% and NIRS >45% for the entire duration of CPB (Group B). Hemodynamic (CI, MVO2, DO2 and metabolic (NIRS, pH, paO2, paCO2, base excess, lactate, Hb) were recorded at distinct time frames, similar in the two groups (T0: CDI calibration; T1: 5 min after aortic cross-clamp; T2: 5 min after test start; T3: end of 20 min test; T4: after clamp removal). Hospital clinical outcome was also recorded and compared between patient groups.

Results: Analysis of baseline demographic variables showed no significant difference between Group A and Group B patients, except for a non-significantly higher prevalence of left-right shunt lesions (25% vs 55%, p=0.1). In Group A, the 20 minute test allowed reduction of nominal CPB flows greater than 10%, while having no impact on pH, blood gas exchange and lactate production. In Group B patients, CPB exclusively with MVO2 and NIRS monitoring resulted in no significant variation of metabolic and hemodynamic parameters, when compared with Group A patients (standard CPB), except for a 10% of nominal flows. There was no mortality in either group. Hospital morbidity was comparable in the two groups, including: need for inotropic support (9 vs. 1, Group A vs. B, p=0.07), re-exploration for bleeding (1 vs. none, p=NS), renal failure requiring dialysis (none vs. 1, p=NS), prolonged ventilation (9 vs. 4, p=NS) and sepsis (2 vs. 2, p=NS). There was no neurological morbidity.

Conclusions: The present prospective pilot study shows that normothermic CPB in neonates, infants and young children can be safely managed exclusively by systemic (MVO2) and cerebral (NIRS) metabolic monitoring. Under normothermic conditions this strategy allows reduction of at least 10% of CPB flows. The present results lay the ground for further tailoring of CPB parameters to individual patient needs and possibly miniaturization of circuits to mitigate hemodilution and SIRS.

S14. Implementation of a Perioperative Transfusion Protocol Decreases Blood Product Exposure after Cardiopulmonary Bypass

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Objective: Bleeding and blood product exposure is associated with increased morbidity and mortality after pediatric cardiac surgery. A multidisciplinary approach to perioperative blood product management has been endorsed as best practice. This study represents results of a quality improvement (QI) project aimed at decreasing perioperative blood product exposure.

Methods: Initially, data was collected on 99 consecutive patients with goal to identify potential targets for clinical improvement. In general, we found great practice variability in anticoagulation and bleeding/transfusion management among all clinicians. Results were presented at QI conferences during which a management protocol aimed at both eliminating unnecessary practice variation and introducing evidence based best practice was developed by multidisciplinary participants (cardiologists, surgeons, intensivists, anesthesiologists, perfusionists). Protocol included standardized approach to anticoagulation, bleeding/transfusion management in CVOR and CVICU, and implementation of modified ultrafiltration (MUF). 62 consecutive patients received the protocol: 17 without MUF, followed by 45 consecutive with MUF; clinical outcomes were compared to pre-protocol group.

Results: There were no demographic differences, including surgical complexity among groups. Protocolized management led to significant decrease in every blood product post CPB: PRBC 17 vs 7 ml/kg; FFP 19 vs 4 ml/kg; platelets 22 vs 9 ml/kg; cryoprecipitate 7.5 vs 2 ml/kg. Children <2 months had greatest decrease in total blood product administration through first 6 hours of CVICU admission (79 vs 155 ml/kg, $p<0.01$). There was decreased incidence of >10 ml/kg 1st hour CT output (6 vs 26%, $p=0.01$) and mediastinal exploration for bleeding (4 vs 10%, $p=0.3$) in CVICU.

Conclusions: A multidisciplinary perioperative bleeding/transfusion protocol and MUF significantly decrease blood product exposure and bleeding complications after pediatric cardiac surgery.

S15. A New Perspective in Cardioplegia: Valsartan Improves Myocardial Protection and Oxidative Stress Tolerance during Ischemia/Reperfusion in Isolated Neonatal Rat Heart

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Objective: Signal transducers and activators of transcription (STATs) play an important role in the modulation of inflammation and apoptosis after ischemia/reperfusion. Selective inhibition of Angiotension II type 1(AT1) receptor could represent an adjunctive protective mechanism during cardioplegic arrest in neonatal rat myocytes, especially after an ossidative stress.

Methods: Isolated neonatal rat's hearts (n=8 per group) were perfused aerobically (4°C) for 15 min in the Langendorff mode with modified St. Thomas' Hospital no. 2 cardioplegia (MSTH2) (Group 1) and MSTH2+Valsartan 1 μm/L (Group 2). After reperfusion with oxygenated modified Krebs-Henseleit buffer (KHB) until a cardiac rhythm occurred and for 10 min, hearts were again arrested for further 10 min. Left ventricular developed pressure (LVDP), rate-pressure product (RPP), and maximal rate of left ventricular pressure rise (dP/dtmax) and fall (dP/dtmin), expressed as percentage of values, were monitored continuously during reperfusion. Thus, myocytes were isolated, and STAT2, STAT3, STAT5 and CaMK II were investigated by Western blot analysis both in basal condition and after stimulation with reactive oxygen species (ROS).

Results: Times to arrest following initial dose of cardioplegia were 6-14 sec for both groups. Total delivery volume was about 320 mL for a total time of 25 min (split in two times). During reperfusion with modified KHB, an indeterminate cardiac rhythm was visualized after 2.5 - 4.7 min in Group 1 and 3.2 - 5.9 min in Group 2 ($p>0.05$). LVDP, dP/dtmax and dP/dtmin measured during reperfusion were significantly reduced in the Group 1 versus Group 2 ($p<0.05$). Following the second dose of cardioplegia, times to arrest were comparable. The perfusion with Valsartan-supplemented cardioplegia (Group 2), induced a significant reduction in STAT2 and STAT5 phosphorylation (-48 and -56%, respectively, vs. Group 1, $P < 0.05$) both in basal condition and after stimulation with ROS (-65% and -73% respectively vs. Group 1). Decreased activation of STAT2 and STAT5 was accompanied by a reduction of the interleukin-1β ($P<0.05$). Valsartan significantly affected even phosphorylation of CaMK II in our study (- 32% vs. Group 1, $P < 0.05$).

Conclusions: Valsartan added to cardioplegia decreases the inflammatory response of the neonatal rat cardiomyocytes during ischemia/reperfusion and increases oxidative tolerance stress without affecting antiapoptotic and cardioprotective influence provided by activation of STAT3. Furthermore Valsartan might improve the myocardial protection down-regulating the expression of the activated-CaMK II, which is associated with increased apoptosis as well. This mechanism could contribute to improve both the ischemia tolerance and the myocardial protection of the neonatal heart.

S16. A Pilot Study of Antithrombin Replacement Prior to Cardiopulmonary Bypass in Neonates

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Objective: Determine the safety and efficacy of antithrombin replacement to neonates prior to cardiopulmonary bypass.

Methods: A single center, randomized, double-blinded, placebo controlled pilot study of antithrombin replacement to neonates prior to cardiopulmonary bypass was conducted. Pre-operative antithrombin levels determined the dose of recombinant antithrombin or placebo to be given, with a targeted level of 100%. Antithrombin levels were re-measured following the dosing of the drug/placebo, after initiation of bypass, near the completion of bypass, and upon ICU admission. Safety outcomes included mortality, need for ECMO, mediastinal exploration within 24 hours, and evidence of thrombotic disease at discharge. Efficacy outcomes included total heparin dose required, blood loss for 24 hours post-operatively, and pRBC transfusion volume for 24 hours post-operatively.

Results: Eight subjects were enrolled, randomized equally between antithrombin and placebo groups with similar demographics and surgical procedures. No subject had ECMO, thrombosis, or death. Mediastinal exploration occurred in two antithrombin subjects and one placebo subject. Antithrombin levels and efficacy results are displayed in the Table 1.

Table 1: Measured Antithrombin Activity Levels and Efficacy Outcomes

	Antithrombin Group (n=4)	Placebo Group (n=4)	p-value
Pre-operative Antithrombin Activity (u/mL)	0.54 +/- 0.09	0.55 +/- 0.17	0.900
Post-dose Antithrombin Activity (u/mL)	1.23 +/- 0.30	0.50 +/- 0.16	**0.005**
Bypass Start Antithrombin Activity (u/mL)	0.68 +/- 0.12	0.57 +/- 0.18	0.338
Bypass End Antithrombin Activity (u/mL)	0.86 +/- 0.09	0.75 +/- 0.26	0.473
ICU Admit Antithrombin Activity (u/mL)	0.76 +/- 0.11	0.72 +/- 0.19	0.733
Total Heparin Dose/Patient Weight (u/kg)	1120 +/- 320	1610 +/- 250	**0.051**
24 Hour pRBC Transfusion Volume (mL/kg)	68.6 +/- 44.1	49.9 +/- 18.1	0.462
24 Hour Blood Loss (mL/kg)	81.0 +/- 47.1	75.8 +/- 32.6	0.860

All values expressed as mean +/- standard deviation; ICU = Intensive Care Unit, pRBC = packed red blood cell

Conclusions: A single dose of recombinant antithrombin does not maintain 100% activity levels throughout the entire operation. Patients receiving antithrombin required less heparin. Although no safety concerns were identified, a larger trial is necessary to determine clinical efficacy.

S17. Multisite Near-Infrared Spectroscopy during Cardiopulmonary Bypass in Pediatric Heart Surgery

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Objective: Cardiopulmonary bypass (CPB) during congenital heart disease surgery in neonates and small infants is frequently associated with neurologic and multi-organ damage. Multisite Near Infrared Spectroscopy (NIRS) monitoring during CPB may be useful to assess organ perfusion. The aim of our study was to evaluate the presence of predictive factors of organ perfusion during CPB.

Methods: Infants and neonates undergoing heart surgery with CPB from July 2012 to March 2013 were enrolled. Retrospective data collection was performed by Data Management System (DMS) that allows the continuous recording of all CPB parameters. Inclusion criteria were age below 1 year and the presence of a forehead and left flank NIRS sensor, placed preoperatively.

Results: Overall, 14 patients with median age 89 days (25th-75th:28-163) and weight 3.75 Kg (25th-75th:3-5.1) were enrolled. Of these, 5 children underwent deep hypothermic circulatory arrest (DHCA). Median CPB duration was 167 minutes (25th-75th:138-247). CPB time weighted median cerebral NIRS values were 69% (25th-75th:61-74) whereas renal NIRS values were 90% (25th-75th:81-92). During CPB, after adjustment for blood flow rate and hematocrit, on multivariable regression analysis renal NIRS appeared to be significantly associated with PaCO2 (r=0.69;p=0.02), temperature (r=0.66;p=0.03) and mean blood pressure (r=0.61;p=0.049). On the other side cerebral NIRS parameters did not appear to be significantly associated to any of these covariates. However, patients undergoing DHCA showed a positive correlation (r=0.5; p=0.45) between CPB blood flow and cerebral NIRS whereas in the remaining patients such correlation was negative (r=-0.26; p=0.49). This association may show a preserved cerebral auto-regulation in patients without DHCA.

Conclusions: During CPB, according to NIRS, renal perfusion is related to CO_2, temperature and means pressure whereas cerebral perfusion appears unpredictable and is not related to any of the evaluated variables: research of correlated factors is urgently needed.

S18. Effects of Mini-Volume Priming on Clinical Outcomes in Low-Body-Weight Neonates: Less Transfusion and Post-operative ECMO Support

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Objective: Mixing of autologous blood with priming volume makes relatively significant effects on blood composition especially in low-body-weight neonates. As an effort of reducing these effects, mini-volume priming (MP) has been applied in cardiopulmonary bypass(CPB). This study was to observe the effect of MP on clinical outcomes of low-body-weight neonates undergoing open heart surgery.

Methods: We retrospectively reviewed medical records of low-body-weight (2.5kg or less) neonates who had undergone open heart surgery in our center from January 2000 to December 2014. Total 64 patients were included. MP started in 2007, and settled down as routine protocol in 2009. Preoperative and intraoperative characteristics included age, body weight, RACHS-1, priming volume, CPB time and aortic cross clamp (ACC) time, transfusion and hematocrit during CPB. Clinical outcomes included 30-day mortality, post-operative ECMO support, open-sternum status, prolonged mechanical ventilation care (>7days), acute renal failure.

Results: MP was utilized in 39 patients and conventional priming (CP) was in 25 patients. The priming volume decreased to 126.0ml in MP group compared to 321.6ml in CP group. Transfusion volume during CPB was 87.3ml vs. 226.8ml (MP vs. CP) and the difference was statistically significant ($P<0.001$). Hematocrits at the end of the CPB and hematocrit change from the start to the end of CPB were not significantly different between two groups. The 30-day mortality was 12.8% vs. 20.0% and post-operative ECMO support was performed in 5.1% vs. 17.4%. Open sternum status was required in 6.3% vs. 7.9%, prolonged ventilator care was required in 33.3% vs. 42.1%. However the difference of frequency was not statistically significant. Larger priming volume and higher RACHS-1 were significant risk factors of post-operative ECMO support, in non-parametric univariate analysis.

Conclusions: MP has benefit in sparing transfusion without affecting the hematocrit. Clinical outcomes did not present significant difference. However larger priming volume was significant risk factor for post-operative ECMO support.

S19. Surgical Options for the Treatment of Right Ventricular Failure in LVAD Patients: A Simulation Study

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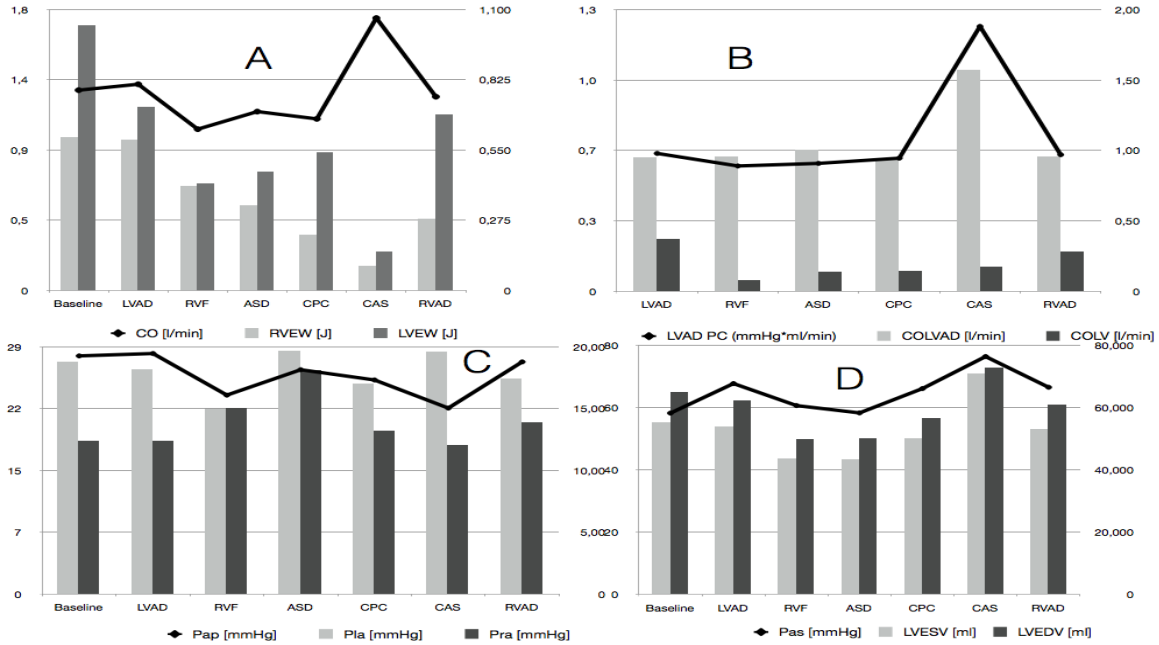
Objective: Right ventricular failure (RVF) is one of the major complications in LVAD patients. Beyond the drugs therapy, the most reliable option is the RVAD implantation. However, BIVAD patients are associated with a poor prognosis and the management of two devices could increase the incidence of complications. Alternative approaches were experimented: the creation of an atrial septal defect (ASD), a cavo-aortic shunt (CAS) and a cavo-pulmonary connection (CPC). This work aims at using a lumped parameter model (LPM) to compare the ASD, CPC, CAS, RVAD effects in LVAD+RVF patients.

Methods: Data of five LVAD patients were retrospectively collected to simulate patient's baseline. The effects of continuous flow LVAD implantation complicated by RVF was simulated for each patient. Finally, the ASD, CPC, CAS and RVAD treatments were simulated for each LVAD+RVF patient.

Results: LPM can well reproduce patient's baseline and the hemodynamic effects of the surgical strategies according to literature data. With the different surgical treatment, an unloading of the right ventricle and an increment of left ventricular preload were observed with an overall improvement of the hemodynamics (total cardiac output (CO) increment: ASD 15%, CPC 10%, CAS 70% RVAD 20%; right ventricular external work (RVEW) decrement: ASD 19%, CPC 46%, CAS 76%, RVAD 32%; LVEW increment: ASD 12%, CPC 28% ,RVAD 64%; Pulmonary to systemic flow ratio (Qp/Qs) decrement: ASD 40%, CAS 80%). (Pap/Pas: pulmonary/systemic pressure; Pla/Pra: left/right atrial pressure; PC: power consumption; LVESV/LVEDV: left ventricular end systolic/diastolic volume)

Fig 1. Simulation outcomes of LVAD patients with RVF undergoing different surgical strategies.



Conclusion: The creation of a calibrated ASD or the RVAD implantation seems to be the more safety and reliable options. However, the RVAD seems to increase more the LVEW. Finally, CAS seems to create a non-favorable Qp/Qs, while CPC could unload the RV, without a significant increment of CO. Simulation could support clinicians in therapy personalization.

S20. Application of CFD-modelling in the Development of Russian Pediatric VAD Systems

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Objective: During the design of children's pulsative pumps, one of the main conditions for the thrombosis minimization is the choice of the optimal type of valves. The objective of this work is to determine the influence of the valve type on the thrombus formation process based on the results of CFD-modelling.

Methods: Simulation of pulsative blood flow inside the VAD was based on a 3D realistic model of the VAD blood chamber. The stroke volume of the system is 30 cc. The pump rate is 75 bpm. The simulation was performed with two commercially available models of mechanical heart valves in the Russia: «MedInzh-2» bi-leaflet valves and «MIKS» tilting disk valves. These valves have a minimal external diameter - 17 mm and a hole area of 1.67 cm2 and 1,54 cm2 respectively. The time intervals of diastole and systole phases were accepted as equal.

Results: The simulation evaluated the hemodynamic parameters such as speed and pressure of the flow inside the pump chamber, and Reynolds shear stresses. The pictures of the flow velocity distribution in the pump chamber indicate the absence of stagnation zones and local zones of the rotational flow. During the application of tilting disc valve was observed a more pronounced rotational flow to the opposite port direction in the systolic phase. This led to a better internal wall washing of the blood chamber and reduces the risk of the thrombus formation. The maximum effect is observed when the angle orientation of the input tilting disc valve is 45 degrees with respect to the membrane plane.

Conclusions: The obtained results allowed to determine the influence of the valve type and its orientation on the thrombus formation process, and to select the valve type for future use. The prototypes of LVAD system was made for further research with using the optical method of flow visualization.

S21. Mechanically Assisted Total Cavopulmonary Connection with an Axial Flow Pump: Computational and in Vivo Study

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Objective: A relevant amount of patients undergoing total cavopulmonary connection (TCPC) experience heart failure (HF). Heart transplant is then the final option when all other treatments fail. The blood axial flow pumps are now the state of the art; however, there is little experience in low-pressure circuits, such as support of the right ventricle (RV) or even a TCPC circulation

Methods: A prototype of mechanically assisted TCPC circuit with the "child version" of the Jarvik axial flow pump, (flow rates between 1-3 L/m in a range of 5.000-to-9.000 rpm) was designed in computational models and then tested in animals (figure). Eight sheep (42-45 Kg) were studied: 2 pilot studies, 4 pump-supported (PS) TCPC for 3 hours and 2 not pump supported (NPS) TCPC. In the PS, the axial pump was titrated to maintain the baseline cardiac output (CO). Pressures, CO, systemic and pulmonary vascular resistance, lactate levels and blood gasses were recorded for three hours.

Results: In the NPS animals, a gradual circulatory deterioration, with increasing lactate levels, occurred rapidly. In the PS animals there were stable cardiac index (CI) of 2.7 ± 1,4 l/min/m2, CVP of 12,3 ± 1 mmHg and a mean PAP of 18,1 ± 6 after 3 hours of support up to 9000 rpm. SVR, PVR, blood gasses and arterial lactate levels remained stable to baseline values. No caval collapse occurred.

Conclusions: A new child axial flow pump provides normal CO and physiologic stability in a new T-shaped model of TCPC. This experimental arrangement will serve to further evaluate the potential for mechanical support in patients with Fontan failure.

S22. The Use of a Numerical Model to Simulate the Cavo-Pulmonary Assistance in Fontan Circulation: A Preliminary Verification

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Objective: The use of ventricular assist devices (VAD) for the cavopulmonary assistance in Fontan circulation is challenging. The lack of an established experience leads to the needs of dedicated VADs development and animal experiments. A dedicated numerical model could support clinical and experimental strategies design and new VADs testing. The aim of this work is to perform a preliminary verification of a lumped parameter model of the cardiovascular system to simulate Fontan physiology and the effect of cavo-pulmonary assistance using experimental data reported in literature.

Methods: Echocardiographic and hemodynamic data of 4 pigs were used to simulate animal's baseline, Fontan circulation and cavopulmonary assisted condition to compare measured (Me) and simulated (Sim) data.

Results: Numerical models can well reproduce experimental data (cardiac output [l/min]: Me= 2.8±1.7, Sim=2.8±1.8; ejection fraction [%]: Me=57±17, Sim=54±17; arterial systemic pressure [mmHg]: Me= 41.8±18.6, Sim=43.8±18.1; pulmonary arterial pressure [mmHg]: Me=15.4±8.9, Sim=17.7±9.9; caval pressure [mmHg]: Me=6.8±4.1, Sim=7±4.6) . In addition, the model permits to evaluate the trend of some hemodynamic variables: the diastolic elastance remains quite constant, whilst the systolic elastance, the arterial systemic and the arterial pulmonary resistances increase (10%,69%,100%) passing from the biventricular circulation to the Fontan physiology and then decrease (21%, 39%, 50%) once the VAD was implanted. From energetics point of view the ventricular external work decreases (71%) passing from the biventricular circulation to the Fontan physiology and it increases three times after the VAD implantation in parallel with the VAD power consumption.

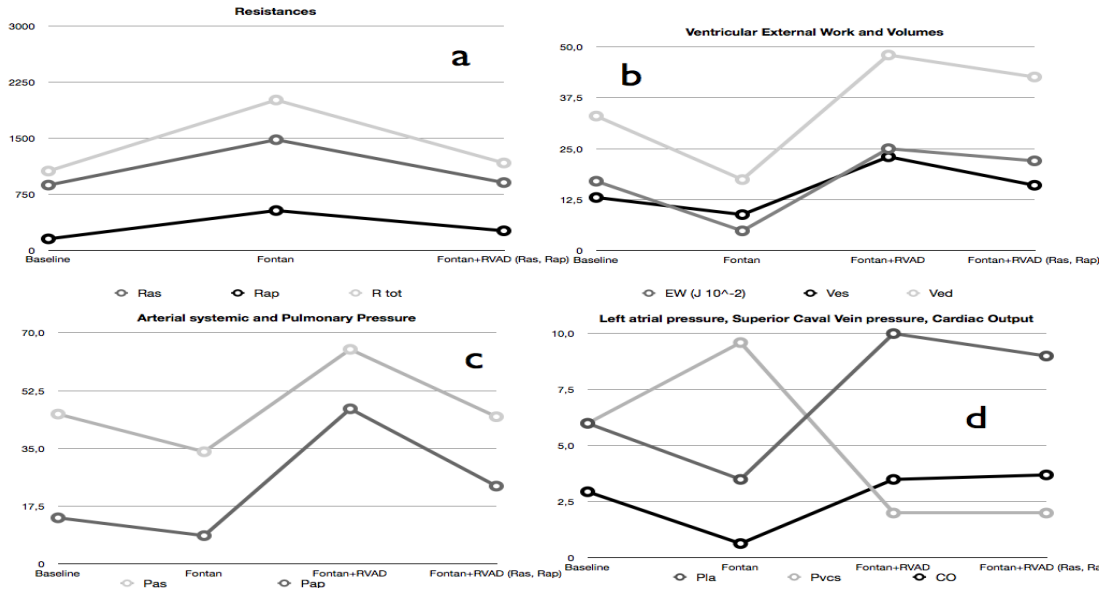

Fig.1 Trends of the hemodynamic variable.

Conclusions: A numerical model could support clinicians in an innovative and challenging field as the use of VAD to assist the Fontan physiology and, in particular, it could be helpful to personalize the VAD insertion on the base of ventricular systolic & diastolic function, circulatory parameters such as peripheral and pulmonary resistances and energetic variables such as ventricular external work and VAD power consumption.

S23. Effect of the Pulsatile Extracorporeal Membrane Oxygenation on Hemodynamic Energy and Systemic Microcirculation in a Piglet Model of Acute Cardiac Failure

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Objective: The objective of this study is to compare the hemodynamic energy and systemic microcirculation of pulsatile Extracorporeal Membrane Oxygenation (ECMO) and non-pulsatile ECMO under acute cardiac failure model in piglets.

Methods: Fourteen piglets with a mean body weight of 6.08±0.86 kg were used for experiments and divided into two groups; pulsatile (n=7) and non-pulsatile (n=7) ECMO groups. The experimental ECMO circuit consisted of HPM 15 centrifugal pump (MERA, Tokyo), Excelung-prime KIDS (MERA) as a membrane oxygenator, and our original pneumatic pulsatile flow generator system. We started non-pulsatile ECMO at the flow rate of 140 ml per kg for first 30 minutes with own heart beating. We kept the rectal temperature at 36ºC. And then, we induced ventricular fibrillation as a cardiac dysfunction model using alternating current 3.5 voltage. Once we had a cardiac dysfunction model, we collected the data with pulsatile and nonpulsatile groups. We weaned off the ECMO at the end of experiment (after 180 minutes when we started the ECMO). The animals did not receive any blood transfusions, inotropic drugs, or vasoactive drugs. Blood sample were collected to measure hemoglobin, methemoglobin, blood gas, electrolyte and lactic acid level. We calculated hemodynamic energy using Shepard's energy equivalent pressure (EEP). We used near-infrared spectroscopy to monitor brain and kidney perfusion (INVOS; Covideien Japan, Tokyo). Data were analyzed using SPSS software for windows version 20 and Sample Power 3.0. All data were expressed as mean ± standard error of means. The Student-t test and Tukey-Kramer tests were used to evaluate differences between groups for statistical significance. A P-value of <0.05 was considered to have statistical significance.

Results: The pulsatile ECMO had higher hemodynamic energy than non-pulsatile ECMO (P vs. NP; P<0.05)(Table 1). The pulsatile ECMO had higher atrial pressure (systole and mean) than non-pulsatile ECMO (P vs. NP; P<0.05)(Table 1). The pulsatile ECMO had significantly higher regional saturation at brain level than non-pulsatile ECMO (P vs. NP; P<0.05) (Table 2). The pulsatile ECMO also tended to produce more methemoglobin level within normal range than non-pulsatile ECMO (Table 2).

Table 1. Hemodynamic change of Pulsatile and Non-Pulsatile ECMO.

		After induction anesthesia	Just before ECMO	After 10min ECMO	After 30min ECMO	After 60min ECMO	After 90min ECMO	After 120min ECMO	After 150min ECMO	After 180min ECMO
P	SAP	85.21±15.21	94.75±21.41	59.67±23.67	53.89±18.21	54.83±11.84	†50.01±3.84	†53.85±10.22	†52.35±5.54	†49.13±6.84
NP	(mmHg)	78.78±21.22	85.49±28.54	52.21±18.75	45.10±13.49	39.33±11.59	37.00±1.73	36.67±5.03	37.00±6.56	36.00±6.08
P	MAP	63.44±7.89	67.33±8.01	45.33±3.87	42.33±5.49	42.33±6.09	42.1±5.33	†41.11±5.67	†42.67±3.21	†39.82±5.12
NP	(mmHg)	58.21±6.22	70.50±14.55	47.00±13.32	39.00±8.92	35.67±10.69	34.67±3.06	33.00±3.46	34.67±5.86	33.33±4.16
P	DAP	52.35±8.75	54.84±5.74	38.44±4.54	37.21±7.54	36.22±9.82	35.6±5.69	34.22±2.01	36.91±8.95	33.37±4.55
NP	(mmHg)	48.09±7.82	59.00±13.74	40.11±5.97	36.81±8.24	34.00±10.81	33.6±3.51	30.33±1.53	31.00±5.57	30.33±3.06
P	CVP	3.02±0.88	3.56±1.91	4.24±0.89	4.95±1.11	4.54±1.20	3.85±2.01	4.30±1.65	4.54±0.88	4.03±3.03
NP	(mmHg)	2.89±1.19	3.75±2.63	3.67±0.88	4.01±2.51	4.00±3.46	4.00±3.46	4.00±3.46	4.33±2.89	4.33±2.89
P	EEP	61.71±5.28	65.87±7.23	41.57±3.65	41.87±6.10	†43.14±8.78	†44.01±6.22	†42.29±7.45	†43.81±8.48	†41.35±4.99
NP	(mmHg)	56.89±5.45	69.71±9.11	45.22±4.08	38.99±4.51	34.71±7.71	33.16±5.58	＊31.91±6.81	33.87±7.56	＊31.84±5.22

Power analyses were higher than 0.6 for all data. †: p< 0.05, pulsatile ECMO vs non-pulsatile ECMO. ＊: p<0.05, Just before ECMO vs After 120 and 180min ECMO.

Table 2. Peripheral Tissue Perfusion data of Pulsatile and Non-Pulsatile ECMO.

		After induction anesthesia	Just before ECMO	After 10min ECMO	After 30min ECMO	After 60min ECMO	After 90min ECMO	After 120min ECMO	After 150min ECMO	After 180min ECMO
P	rSO_2:fore	58.22±3.45	55.92±11.34	42.31±9.12	39.98±5.43	†45.69±5.62	†46.05±7.21	†47.11±10.14	†46.13±6.31	†45.32±8.98
NP	head (%)	55.35±7.82	60.25±26.29	37.40±8.87	38.29±6.66	34.67±4.16	35.00±6.56	38.27±9.87	35.67±8.19	38.21±14.53
P	rSO_2:kid	54.82±6.34	52.0±8.75	50.85±5.69	48.26±3.22	40.00±3.08	38.4±8.25	39.22±10.35	37.45±8.31	37.82±6.42
NP	ney (%)	51.74±7.21	52.0±8.75	53.33±5.13	51.61±4.81	42.00±5.21	37.5±10.61	34.00±14.14	31.00±11.31	31.50±9.19
P	Met Hb	1.45±0.13	1.62±0.28	1.65±0.25	1.78±0.22	1.90±0.35	2.28±0.31	2.59±0.31	2.81±0.19	2.92±0.43
NP	(%)	1.50±0.20	1.78±0.24	1.88±0.12	1.74±0.17	1.59±0.23	1.68±0.35	1.65±0.41	1.78±0.28	1.88±0.51
P	pH	7.42±0.12	7.48±0.80	7.31±0.08	7.31±0.12	7.32±0.19	7.32±0.21	†7.28±0.16	†7.29±0.17	†7.28±0.19
NP		7.38±0.21	7.46±0.10	7.36±0.05	7.33±0.08	7.28±0.16	7.22±0.11	7.18±0.06	7.11±0.11	7.08±0.11
P	BE	1.81±2.99	1.11±3.23	-4.54±1.01	-4.88±1.95	-5.89±3.71	†-7.89±2.14	†-8.07±1.89	†-7.33±3.11	†-8.61±3.10
NP		3.51±1.21	2.5±5.07	-5.11±2.67	-5.32±1.64	-8.33±4.93	-14.33±4.16	-16.67±2.52	-20.33±2.31	-20.67±2.89
P	Lac	0.87±0.52	0.98±0.15	2.73±1.46	2.98±0.91	†2.51±2.34	†3.21±1.45	†3.02±1.30	†3.87±0.81	†4.24±1.53
NP	(mmol/L)	0.54±0.21	0.98±0.15	3.03±1.46	3.22±0.99	4.54±1.34	6.56±2.40	8.02±2.30	8.09±1.61	9.10±1.80

Power analyses were higher than 0.6 for all data. †: $p < 0.05$, pulsatile ECMO vs non-pulsatile ECMO

Conclusions: Our study demonstrated that pulsatile ECMO produces significantly higher hemodynamic energy and improve systemic microcirculation than non-pulsatile ECMO under acute cardiac failure.

S24. In-Vivo Hemodynamic Performance Evaluation of Novel ECG-Synchronized Pulsatile and Non-Pulsatile Cardiac Assist System in an Adult Swine Model

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Objective: The primary objective of this study was to evaluate a novel electrocardiogram (ECG)-synchronized pulsatile cardiac assist system for adult partial mechanical circulatory support for adequate quality of pulsatility and enhanced hemodynamic energy generation in an in-vivo animal model. Secondary aim was to assess end-organ protection during non-pulsatile versus synchronized pulsatile flow mode.

Methods: 10 adult swine were randomly divided into a non-pulsatile group (NP, n=5) and pulsatile group (P, n=5), and placed on ECLS for 24 hours using an i-cor system consisting of an i-cor diagonal pump, an iLA membrane ventilator, an 18 Fr femoral arterial cannula and a 23/25 Fr femoral venous cannula. Trials were conducted at a flow rate of 2.5 L/min using non-pulsatile or pulsatile mode (with assist ratio 1:1). Real-time pressure and flow data were recorded using a custom-based data acquisition system.

Results: To the best of our knowledge, the oxygenator and circuit pressure drops were the lowest for any available system in both groups. The ECG-synchronized i-cor ECLS system was able to trigger pulsatile flow in the porcine model. **Figure 1** presents pressure waveforms in two groups. After 24 hours ECLS, energy equivalent pressure, surplus hemodynamic energy and total hemodynamic energy at pre-oxygenator and pre-arterial cannula sites were significantly higher in P group than those in NP group ($p < 0.05$). Urine output was higher in P vs. NP (3379 +/- 443 ml vs. NP, 2598 +/- 1012 ml), and the P group seemed to require less inotropic support, but both did not reach statistical significances ($p>0.05$).

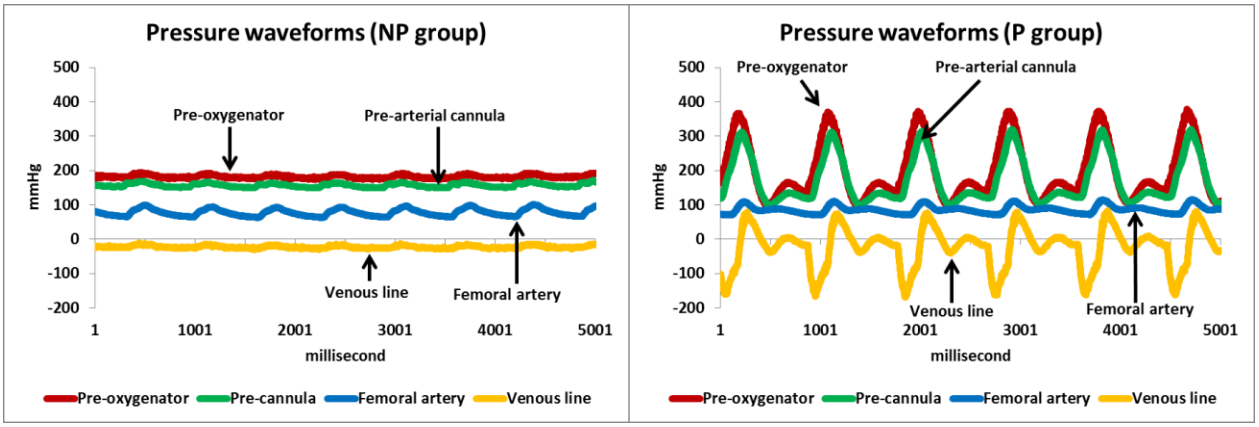

Figure 1. Pressure waveforms in two groups.

Conclusions: The novel i-cor system performed well in the non-pulsatile and ECG-synchronized pulsatile mode in an adult animal ECLS model. The iLA membrane oxygenator had an extremely lower transmembrane pressure gradient and excellent gas exchange capability. Our findings suggest that ECG triggered pulsatile ECLS provides superior end-organ protection with improved renal function and systemic vascular tone.

S25. Insensible Water Loss from the Medos Hilite 2400 LT Oxygenator: An In Vitro Study

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Objective: The objective of this study was to quantify the extent to which free water crosses the polymethylpentene (PMP) membrane fibre in the Medos Hilite 2400 LT oxygenator, a commonly deployed device used for ECMO support in the paediatric patient. The secondary aim of the study was to determine if the addition of heat and/or humidity into the ventilating gas would mitigate the water loss observed.

Methods: An experimental circuit that consisted of a Medos Hilite 2400 LT oxygenator (Medos, Medizintechnik AG, Stolberg, Germany), a Rotaflow centrifugal pump (Maquet Cardiopulmonary AG, Hirrlingen, Germany), a soft shell venous reservoir and PVC tubing with X-Coating (Terumo Corporation, Tokyo, Japan), a haemofilter (Maquet Cardiopulmonary AG, Hirrlingen, Germany) and fluid administration burettes attached to electronic scales was created. The test circuit was primed through the soft shell reservoir using Plasmalyte 148 (Baxter Healthcare, Toongabbie, Australia) with albumin (Albumex, CSL Bioplasma, Broadmeadows, Australia) subsequently added. The heamofilter allowed manipulation of the prime to obtain a colloid osmotic pressure of approximately 23 mmHg. The prime temperature was regulated to 35oC and pressure maintained at 200 mmHg by a restrictive gate clamp at a flow rate of 1000 ml/min. Flow through the reservoir and heamofilter was then ceased and the circuit opened only to the fluid filled burettes, such that any volume lost through the oxygenator would draw volume from the burettes into the circuit enabling measurement of the volume loss. Gas flow through the oxygenator was then commenced using carbogen (BOC, North Ryde, Australia) at 1,3 and 4.8 litres per minute for a period of 24 hours at each flow rate. Water loss was assessed by both visualisation of the fluid level in the burettes and the weight displayed on the digital scales at set points over the 24-hour period.

As a secondary study, the ventilating gas was first heated and then both heated and humidified to assess the impact of this on the amount of water lost from the circuit.

Results: Water loss exhibited a linear relationship with gas flow rates. Over a 24-hour period increasing from 76 ml at 1 L/min to 205 ml at 3 L/min ($p=0.05$) and then to 349 at 4.8 L/min ($p=0.025$). The average water loss per litre of gas flow was 72.4 ml/day.

Heating of the ventilating gas did not demonstrate any change in the evaporative water loss across the membrane, however, the humidification of the gas showed a dramatic reduction in the water loss observed ($p=0.009$).

Conclusions: Our study demonstrated that the insensible water loss through the PMP membrane in the Medos 2400 Hilite LT is directly proportional to the ventilating gas flow rate delivered to the oxygenator and is approximately 3 ml/hr per L/min of gas flow. The humidification of the ventilating gas has a significant impact on ameliorating this water loss.

This insensible water loss may result in electrolyte disturbance, in particular hypernatraemia, if not accounted for in the patient's fluid management. This effect is amplified with the diminutive size of the neonatal patient on ECMO.

P1. Clinical Outcome of Benign Cardiac Tumors Detected Prenatally: A Ten-Year Experience

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Objective: Primary cardiac tumors (PCT) in children are rare disorders with an incidence ranging from 0.027% to 0.08%. Suspicion of congenital heart disease (CHD), family history or fetal cardiac arrhythmias often lead to prenatal diagnosis. Most benign PCT have favorable prognosis, but some still prove fatal due to anatomic location and extension, in spite of improvements in diagnosis and surgical management. The aim of the current study was to define clinical outcome of benign PCT diagnosed at our Institution.

Methods: Between December 2005 and January 2015, ten cases of benign PCT were retrospectively collected, ranging from prenatal period to childhood. We included patients (pts) with pre and postnatal diagnosis, medically and surgically managed. Pre and postnatal examinations, surgical procedures, clinical information before and after surgery, histological diagnoses were reviewed. There were 5 male and 4 female pts, one case decided for termination of pregnancy.

Results: Sixty percent of PCT were detected prenatally with a median gestational age at diagnosis of 23 weeks, while 4 were diagnosed at a mean age of 1.5 yrs (10dys – 5.5yrs). Right ventricle was interested in 5 pts, left ventricle in 3 and biventricular disease in one. Median follow-up time was 5 yrs (2dys – 10yrs). Only one pt had complete mass regression, while in 2 the mass volume remained unchanged without signs of obstruction. Surgery was necessary in 6 pts (67%), at a median age of 2 months (1dy – 5.5 yrs) due to obstruction or impending embolization. In two infants requiring urgent excision due to embolization and obstruction, perioperative support with V-A ECMO and inhaled NO was necessary. Complete excision of the mass was possible in 5/6 cases with 1 (20%) hospital death. One diffusely infiltrating tumor in a newborn was deemed non resectable. At histological examination, 2 pts had familial fetal type of rhabdomyoma, 1 rhabdomyoma, 2 myxoma and 1 pt had a calcified amorphous tumor of the heart. All late survivors were symptom-free, at latest clinical assessment, without echocardiographic evidence of recurrence in 4 operated patients.

Conclusions: Benign PCT have extremely diverse course, some proving fatal in spite of benign histology. Prenatal diagnosis is crucial to plan delivery and neonatal management, as some benign PCT require intensive care management, including extracorporeal life support, and urgent surgical intervention. Complete excision of the mass usually is feasible, but may be limited by young age and extent of cardiac infiltration. Following surgery, patients are generally free from recurrence and symptoms.

P2. Laboratory Evaluation of Hemolysis and Systemic Inflammatory Response in Neonatal Nonpulsatile and Pulsatile Extracorporeal Life Support Systems

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Objective: The objective of this study is to compare the systemic inflammatory response and hemolytic characteristics of conventional roller pump (HL20-NP) and alternative diagonal pump with nonpulsatile (DP3-NP) and pulsatile mode (DP3-P) in simulated neonatal extracorporeal life support (ECLS) systems.

Methods: The experimental neonatal ECLS circuits consist of a conventional Jostra HL20 roller pump or an alternative Medos DP3 diagonal pump, and Medos Hilite 800 LT hollow-fiber oxygenator with diffusion membrane. 18 sterile circuits were primed with freshly donated whole blood and divided into three groups: conventional HL20 with nonpulsatile flow (HL20-NP), DP3 with nonpulsatile flow (DP3-NP), and DP3 with pulsatile flow (DP3-P). All trials were conducted for durations of 12 hours at a flow rate of 500 ml/min at 36ºC. Simultaneous blood flow and pressure waveforms were recorded. Blood samples were collected to measure plasma free hemoglobin (PFH), human tumor necrosis factor- alpha (TNF-α), interleukin-6 (IL-6), and IL-8, in addition to the routine blood gas, lactate dehydrogenase (LDH) and lactic acid levels.

Results: HL20-NP group had the highest PFH levels after 12 hours ECLS run, but the difference among groups did not reach statistical significance (HL20-NP vs.DP3-NP, p=0.06) (**Table 1**). Although there were similar trends but no statistical differences for the levels of proinflammatory cytokines among three groups, HL20-NP group had much greater levels than other groups (P>0.05). Pulsatile flow generated higher total hemodynamic energy and surplus hemodynamic energy levels at pre-oxygenator and pre-clamp sites (P<0.01).

Table 1. Plasma levels of PFH, TNF-α, IL-6, and IL-8 during 12-hour ECLS support.

Time	Group	PFH (mg/L)	TNF-α (pg/ml)	IL-6 (pg/ml)	IL-8 (ng/ml)
After Priming	HL20-NP	35.1±5.7	0.5±0.4	11.7±5.6	0.1±0.1
	DP3-NP	19.3±2.6	1.2±0.8	0.0±0.0	0.1±0.1
	DP3-P	28.1±3.3	2.1±1.2	0.0±0.0	0.0±0.0
Start ECLS	HL20-NP	63.9±14.4	6.2±3.7	4.1±4.0	1.4±1.3
	DP3-NP	32.7±8.5	6.8±1.8	0.0±0.0	0.0±0.0
	DP3-P	43.4±13.6	5.2±2.2	0.0±0.0	0.0±0.0
ECLS 3h	HL20-NP	124.4±31.9	76.8±48.2	40.0±25.3	1.0±0.7
	DP3-NP	58.9±11.7	77.5±26.5	3.2±2.0	0.5±0.4
	DP3-P	87.1±29.6	41.6±25.5	10.8±6.9	1.5±1.5
ECLS 6h	HL20-NP	433.7±196.9	106.9±57.1	122.0±50.6	3.1±1.8
	DP3-NP	90.7±18.1	63.5±15.4	36.3±22.1	1.0±0.3
	DP3-P	134.9±42.7	48.8±27.8	18.9±17.9	4.1±3.9
ECLS 9h	HL20-NP	588.9±213.9 †	157.0±49.9	374.0±301.0	12.3±4.5
	DP3-NP	173.1±53.5	89.7±43.4	60.7±37.8	4.6±1.8
	DP3-P	259.9±138.3	45.9±21.7	32.4±27.9	4.8±4.2
ECLS 12h	HL20-NP	907.6±253.1 †	219.7±42.8 †	705.0±356.7	35.4±11.9 *
	DP3-NP	343.7±163.2 ‡	167.4±58.2	491.7±292.7	22.6±13.1
	DP3-P	407.6±156.6	159.2±62.1	449.9±309.9	27.9±20.1

* p<0.05, † p<0.01, after priming vs. others. ‡ p=0.06, HL20-NP vs.DP3-NP.

Conclusions: Our study demonstrated that the alternative diagonal pump ECLS circuits appeared to have less systemic inflammatory response and hemolysis compared to the conventional roller pump ECLS circuit in simulated neonatal ECLS systems. Pulsatile flow delivered more hemodynamic energy to the pseudo patient without increased odds of hemolysis compared to the conventional, non-pulsatile roller pump group.

P3. Childhood Obesity and Extracorporeal Membrane Oxygenation: Where do We Draw the Line?

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Objective: The objective of this study is to analyze body mass index (BMI) to extracorporeal membrane oxygenation (ECMO) flow ratios and ECMO outcomes in a non-infant pediatric population.

Methods: Retrospective analysis of our institutional ECMO database was performed between January 2008 and August 2014 to identify patients in the weight category of 20kg to 60kg.

The ECMO flow was measured at 4 and 24 hour time points. The ratio of BMI/ECMO flows was calculated. ECMO outcomes included lactate (12, 24 hour, and change), Inotrope Score (IS) = dopamine dose + dobutamine dose + 100 x epinephrine dose in mcg/kg/min).Creatinine (12, 24 hour, and change). Additional parameters tested included hematocrit and arterial blood gas.

Results: 41 pediatric ECMO runs in patients weighing between 20kg and 60kg were identified from our institutional ECMO database. A linear correlation was found between ratio of BMI/ECMO flow at 4 hours and lactate level at 24 hours ($P<0.001$), as well as the change in lactate from 12 hours to 24 hours ($P=0.015$). The BMI/ECMO flow ratio showed positive correlation with 24 hour Creatinine levels ($P=0.013$). Increased BMI/ECMO flow ratio at 4 hours also significantly correlated with increased net inotrope score ($p=0.018$). The base deficit on arterial blood gas did not correlate with BMI/ECMO ratio as this was corrected on ECMO.

Conclusions: In the 20-60kg patients requiring ECMO higher BMI/ECMO flow ratio at 4 hours significantly correlated with decreased end-organ perfusion as evidenced by higher 24 hour Creatinine and lactate. These patients also required higher inotropic support to maintain hemodynamics. The subgroup of patients whose BMI >85th percentile are at high risk for complications related to poor perfusion. This group may be better served by central cannulation to overcome the complications of distal limb ischemia as well as provide enhanced ECMO flows to end organs.

P4. Development of Microfluidic Immunoassays for Multiplexed Biomarker Measurements

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Objective: Immunoassays are widely utilized due to their ability to quantify a vast assortment of biomolecules relevant to biological research and clinical diagnostics. We seek to develop microfluidic approaches to performing multiplex assays capable of simultaneously measuring multiple analytes, especially inflammation markers, in a single sample.

Methods: Several approaches have been explored towards miniaturizing multiplexed immunoassays based on cytometric bead assays. The first approach is a continuous flow immunoassay which automates the serial incubation steps required using magnetic microbeads. The device uses a magnetic actuation scheme to transfer microbeads into a blood sample and subsequent reagents required for the assay. A second device is a batch format which uses a packed bead bed which allows each solution to be serially infused over the packed beads. Finally, we are exploring a semi-batch approach utilizing beads suspended in aqueous droplets. Using magnetic and electrical actuation beads can be separated and recombined with sample, and reagent droplets allowing serial processing of discrete measurements.

Results: We have demonstrated the ability to track the concentration of a time-varying sample with multiple analytes simultaneously (cytokines IL-6 and TNF-α) (**Figure 1**) as well as measuring 6 proteins in 32 samples simultaneously using only 4.2 µL of sample volume (**Figure 2**). We expect the semi-batch approach will allow high frequency sampling and analysis of temporal varying biomarker concentration in blood.

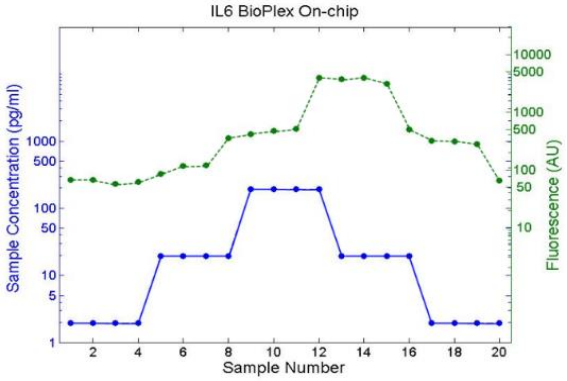

Figure 1. Temporal response of continuous microfluidic Bio-Plex assay for IL-6 with step-wise changes in sample concentration. Incubated beads were collected every 15 minutes and analyzed. TNF-a was simultaneously tracked (Data not Shown)

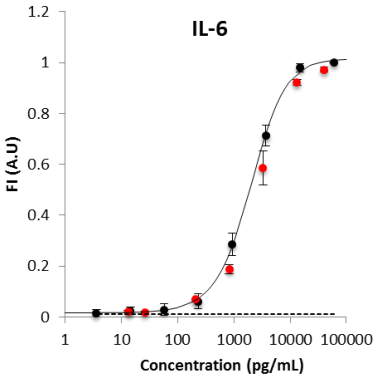

Figure 2. Standard curves, sample measurements, and noise floor for IL-6 in a batch format. Six biomarkers were simultaneously evaluated (Data not shown). Fluorescence intensities of the standards (black circles) and spiked samples of known concentrations (red circles) are shown overlaid on the standard curve generated using a 5-parameter logistic curve fit (black line). The limit of detection (LOD) is represented by the dotted black line. The error bars represent ± S.E.M., n=10 for each data point.

Conclusions: We expect a fully integrated assay to allow high frequency measurements of inflammatory biomarkers during mechanical circulatory support procedures such as CPB and ECMO. Serial determination of biomarker levels during the early post-operative period promises to be a valuable tool for the evaluation of peri-operative morbidity in pediatric patients, especially myocardial and cerebral damage.

P5. In-Vitro Hemodynamic Evaluation of Five 6 Fr and 8 Fr Arterial Cannulae in Simulated Neonatal CPB Circuits

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Objective: Small-bore arterial cannulae may lead to more hemodynamic energy loss and hemolysis during neonatal cardiopulmonary bypass (CPB). The objective of this study is to evaluate five small-bore arterial cannulae (6Fr and 8Fr) in terms of pressure drop and hemodynamic performance in simulated neonatal CPB circuits.

Methods: The experimental circuits consisted of a Jostra HL-20 roller pump, a Terumo Capiox Baby FX05 oxygenator with integrated arterial filter, an arterial and a venous tubing (1/4in, 3/16in, or 1/8in x 150cm), and an arterial cannula (Medtronic Bio-Medicus 6Fr and 8Fr, Maquet 6Fr and 8Fr, or RMI Edwards 8Fr). The circuit was primed using lactated Ringer's solution and heparinized packed human red blood cells (Hematocrit 30%). Trials were conducted at different flow rates (6Fr: 200-400ml/min; 8Fr: 200-600ml/min) and temperatures (35℃ and 28℃). Flow and pressure data were collected using a custom-based data acquisition system.

Results: Higher circuit pressure, circuit pressure drop and hemodynamic energy loss across circuit were recorded when using small-bore arterial cannula and small inner diameter arterial tubing in a neonatal CPB circuit. The maximum pre-oxygenator pressures reached 449.7±1.0 mmHg (Maquet 6Fr at 400 ml/min), and 395.7±0.4 mmHg (DLP 8Fr at 600 ml/min) when using 1/8in ID arterial tubing at 28℃. Hypothermia further increased circuit pressure drop and hemodynamic energy loss. Compared to others, RMI 8Fr arterial cannula had significantly low pressure drop and energy loss ($p<0.01$) (**Figure 1**). Maquet 6Fr arterial cannula had greater pressure drop than DLP 6Fr ($p<0.01$).

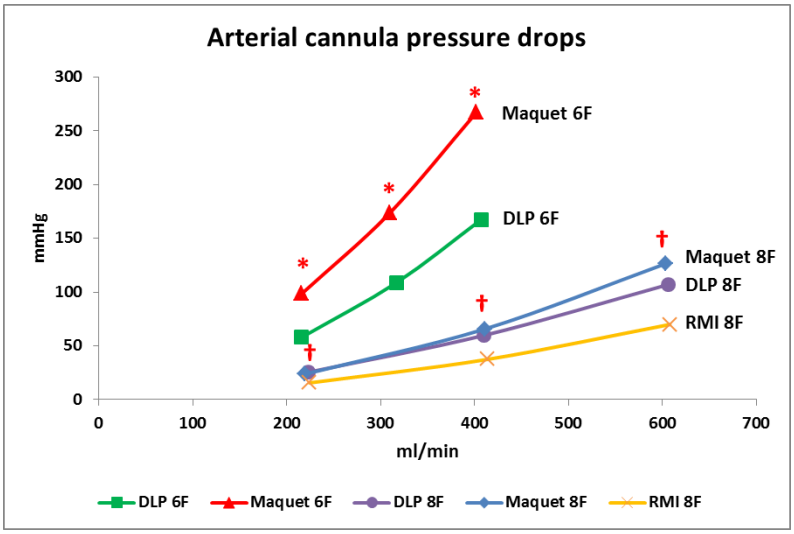

Figure 1. Pressure drops across arterial cannulae using 1/4in ID arterial tubing at 35℃. * p<0.01, DLP 6F vs. Maquet 6F. † p<0.01, RMI 8F vs. Maquet 8F and DLP 8F.

Conclusions: A small-bore arterial cannula and arterial tubing created high circuit pressure drop and hemodynamic energy loss. Appropriate arterial cannula and arterial tubing should be considered to match the expected flow rate. Larger cannula and tubing are recommended for neonatal CPB. Low-resistance neonatal arterial cannulae are needed to be developed.

P6. Role of Oxygenator in Producing Leucocyte Activation and Systemic Inflammatory Response in Experimental Model of Extracorporeal Circulation

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Objective: Several small animal models of extracorporeal circulation (ECC) have been proposed recently. The majority of them are based on homemade, non-standardized and hardly reproducible oxygenators. In the present study we aimed to assess the role of oxygenator industrially manufactured with standard clinical characteristic on leucocyte activation and systemic inflammatory response.

Methods: Twenty male Wistar rats (400-450 g) underwent surgical preparation for ECC and were randomized into two groups. In the first group a hollow fiber oxygenator industrially manufactured with standard clinical characteristic and previously validated was included in ECC circuit. In second group the oxygenator was not accounted into the circuit. ECC was instituted in both groups at a flow rate of 120 ml/kg/min for 60 minutes. Thereafter leukocyte activation was determined by measuring p38 and NF-κB phosphorylation in leukocytes and by flow-cytometry.

Results: Both methods demonstrated leucocyte activation after ECC compared to baseline value but this was significantly higher in ECC+oxygenator group. Tumor necrosis factor α, interleukin-6 and neutrophil elastase plasma levels were significantly higher in ECC+oxygenator group compared to the group without the oxygenator. Furthermore typical lung inflammation, including alveolar congestion, hemorrahage, neutrophil infiltration and increased alveolar wall thickness was observed only in lung tissue from ECC+oxygenator group.

Conclusions: The present results demonstrate that oxygenator has a main role in leucocyte activation and systemic inflammatory response during ECC. Therefore experimental animal models of ECC used in translational research on inflammatory response should be based on standardized, reproducible oxygenators with clinical characteristics.

P7. Twenty-Year Outcome after RVOT Repair Using Heterotopic Pulmonary Conduits in Infants and Children

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Objective: Durability of pulmonary conduits (PC) used for reconstruction of the right ventricular outflow tract (RVOT) may be affected by a variety of factors. Among these, technique used for PC implantation, whether in orthotropic or heterotopic position, strictly dependent upon the underlying anatomy, has been suggested to influence long-term outcome after RVOT repair. To determine the outcome of heterotopic implantation in infants and children treated at our Institution, late results of heterotopic PC in non-Ross patients were analyzed and compared with data of orthotropic PC in age-matched pediatric Ross patients operated during the same time period.

Methods: Between November 1991 and January 2015, 58 infants and children, 32 male and 26 female, with a median age of 9.4 years (range 1 day-18 years) underwent implantation of HPC (31 Homografts, HG and 27 Xenografts, XG) for reconstruction of RVOT. Median age in the XG group was significantly lower than in the HG group (0.87 versus 13.4 years, p=0.01), while male/female ratio was similar. Fifty (86%) patients had undergone one or more prior cardiac operations, while 32 (55%) required associated procedures during PC implantation. Comparison with data in 281 children, aged 9.1 years, receiving orthotropic PC between 1990-2012 (Italian Pediatric Ross Registry) was undertaken. Descriptive, univariate and Kaplan-Meier analysis defined outcome.

Results: There were 4 (6.8%) early and 4 (7.4%) late deaths, during a median follow-up of 7.6 years (range 2 months-23 years). Patients having XG had higher hospital mortality (3/27 versus 1/31, p=0.2), but lower late mortality (1/24 versus 3/30, p=0.3), neither result being significant. Overall survival was 88% and 62%, while freedom from PC replacement was 49% and 21%, at 10 and 20 years, respectively. The latter proved significantly worse than freedom from orthotropic PC replacement, which was 94±2% and 77±9% at 10 and 20 years (p=0.02). When stratified for type of heterotopic PC, late survival proved comparable (81% and 81% for XG versus 92% and 60% for HG, at 10 and 20 years respectively, p=0.7). However, freedom from PC replacement was significantly higher in patients with heterotopic HG (21% and 5% for XG versus 63% and 48% for HG, at 10 and 20 years respectively, p=0.001).

Conclusions: RVOT repair using either XG or HG in heterotopic position is a safe procedure associated with low hospital mortality and satisfactory late survival. Freedom from reoperation is significantly lower than the one observed in age-matched children having orthotropic HG. Freedom from reoperation in heterotopic XG is poorer than in HG, although different baseline demography may have influenced this finding.

P8. Extracellular Histones May Be a Rapid Prognostic Indicator for Children after Open-Heart Surgery

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Objective: The objective of this study was to assess the change of extracellular histones and analyze the relationships among histones and other mediators as well as clinical parameters after cardiopulmonary bypass (CPB) in children.

Methods: Thirty-two children, sixteen with tetralogy of Fallot (TOF) (group 1) and sixteen with ventricular septal defect (VSD) (group 2), undergoing corrective procedure, were prospectively enrolled in this study. Extracellular histones, N-terminal pro-brain natriuretic peptide (NT-pro BNP), procalcitonin (PCT) and C-reactive protein (CRP) were measured at pre-op (T0), post-op hour 0 (T1), post-op hour 4 (T2), post-op hour 24 (T3), post-op hour 48 (T4), post-op hour 72 (T5). Clinical parameters were recorded. The relationships between biomarkers and clinical data were analyzed.

Results: All children survived to hospital discharge. The children in group 1 had longer CPB time (P <.001), cross-clamp time (P <0.001), ventilation time (P=0.001), ICU time (P=0.021), and hospital time (P=0.021).

In both groups, extracellular histones, NT-pro BNP, PCT and CRP increased significantly then decreased after operation. However, they reached the peak levels at different time points. Extracellular histones' peak was at T1, earlier than others'. Higher peak levels of histones (P=0.001), NT-pro BNP (P=0.023), PCT (P=0.043) were found in group 1.

In each group, the peak level of histones was well correlated with peak levels of NT-pro BNP (R=0.782, P=0.003; R=0.884, P＜0.0001), PCT (R=0.764, P=0.003; R=0.898, P＜0.0001), and CRP (R=0.581, P=0.0183; R=0.707, P=0.0022). In addition, there were significant relationships between peak histones level and CPB time, cross-clamp time, ventilation time, ICU time, and hospital time.

Conclusions: Extracellular histones reached peak level more rapidly than NT-pro BNP, PCT and CRP. Furthermore, peak level of histones correlated strongly with some other biomarkers and clinical parameters postoperatively. Extracellular histones can be potentially a rapid prognostic indicator for children after CPB.

P9. The Intraoperative Pulmonary Flow Study Is a Sensitive Predictor for Ventricular Septal Defect Closure after Complete Unifocalization in Patients with Pulmonary Atresia, Ventricular Septal Defect and Major Aortopulmonary Collateral Arteries

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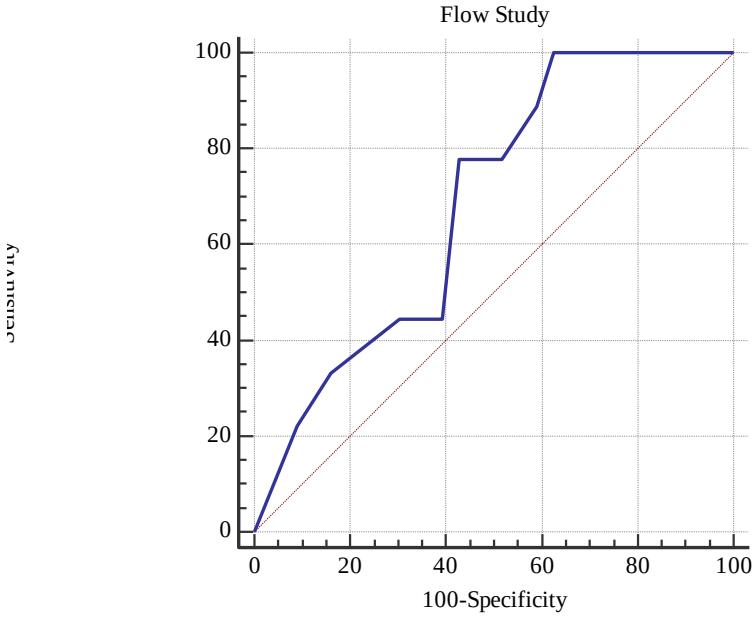
Objective: To evaluate the accuracy of the intraoperative pulmonary flow study in determining the feasibility of concomitant ventricular septal defect closure (VSD) after complete one-stage unifocalization performed in patients with pulmonary atresia with VSD and major aortopulmonary collateral arteries (MAPCAs).

Methods: Between January 1994 and January 2015, a total of 122 consecutive patients underwent either one-stage unifocalization or rehabilitation of native pulmonary arteries. In 92 of those, an intraoperative pulmonary flow study was performed before aortic crossclamping, at a temperature of 25° C with beating heart and collapsed lungs, achieving a CI of 2.5 l/min/m^2. The cut-off value for VSD closure was a mean pulmonary arterial pressure of 30 mmHg.

Results: Fifty-nine patients underwent concomitant unifocalization and VSD closure. Of the 33 patients who did not have the VSD closed, 9 showed a false reassuring flow study pressure (i.e. < 30 mmHg) which initially led to an attempted primary closure of the defect and subsequently to a VSD patch fenestration. In the remaining 24 patients, the VSD was left open according to the flow study results. The pulmonary flow study sensitivity was 96.61% while specificity was 72.73% with a positive predictive value of 86.36% and a negative predictive value of 92.31%. A ROC analysis was performed utilizing the flow study data of the patients with a flow study pressure < 30 mmHg. Those patients had a median of 3 MAPCAs unifocalized (range 1-6). The area under the curve (AUC) was 0.685 (0.557-0.794 95% CI). The average mean pulmonary arterial pressure in the 9 patients in which the study was misleading was 26.8 mmHg, almost borderline according to published criteria.



Conclusions: Our study confirms the usefulness of the pulmonary flow study performed during one-stage unifocalization procedures according to the original protocol. Its predictive value is particularly accurate to select patients in which the VSD should be left open.

P10. Use of CDI 500 during ECMO: Reliability of Data and Benefits

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Objective: Continuous inline blood parameter monitoring is commonly used during cardiopulmonary bypass in heart surgery. Yet, very little is reported in literature about its use on ECMO circuits. The aim of this study is to evaluate and analyze the efficacy of a continuous inline blood gas monitoring tool (CDI-500) on patients who needed ECMO support.

Methods: We integrated CDI 500 on ECMO circuit in both adult and paediatric patients (VA and VV ECMO) as shown in Tab 1. Data were exported from the CDI by using a software created a software in collaboration with Heart Surgery Division of GADA ITALIA s.r.l. (dealer of Terumo Cardiovascular product in Italy) Arterial and venous blood gas obtained with CDI were matched with the results from the hospital laboratory. We perform analysis of FPH (free plasma Haemoglobin) to verify the incidence of haemolysis. We compared the CDI patients to an historic ECMO group (44 patients with similar case mix). Wilcoxon test was used to compare the two populations.

Tab1

ECMO Modality	Pediatric Vs Adult	Indication	Mean ECMO Time (h)	Mean CDI Measure (n)	Recording Intervall (min)
VV (6)	Pediatric	RDS (4) MPACAS (1) CDH (1)	225	3413	5
VV (11)	Adult	Bridge to LTX (8) ARDS (3)	213	2515	5
VA (8)	Pediatric	Post-Cardiotomic (6) ECPR (2)	199	2865	5
VA (13)	Adult	Cardiogenic Shock (5) Post-Cardiotomic (4) LTX(1) ECPR(4)	226	3387	5

Results: Thirty-eight patients were enrolled in the study. Measurements of HCO_3^- and K^+ were significantly higher when measured with CDI compared to BGA (Blood gas analysis) (as shown in table 2) in all venous lines of all subgroups. In adult patients treated with VV ECMO, CDI measured higher pCO_2 than BGA (53 mmHg, 31-82 mmHg vs 52.4, 32.2-84.9 mmHg, p=.029). Base Excess (BE) was significantly higher on CDI in venous lines of Adults treated with VV and VA ECMO and children treated with VA ECMO (table 2). CDI underestimated only the arterial saturation on Adult VA ECMO (99%, 91-100% vs 99.1, 93-99.9%, p=0.024).

Tab2

		ECMO VV PED					ECMO VA PED					ECMO VV ADU					ECMO VA ADU				
		Range		Median		p value	Range		Median		p value	Range		Median		p value	Range		Median		p value
		BGA	CDI	BGA	CDI		BGA	CDI	BGA	CDI		BGA	CDI	BGA	CDI		BGA	CDI	BGA	CDI	
Arterial	pH						7,18;7,56	7,23;7,82	7,510	7,490	0,799						7,09;7,6	7,11;7,62	7,5	7,5	0,672
	pCO2						21,9;44,8	22;41	34,0	36,0	0,646						25;50,8	26;50	35,2	35,0	0,831
	PO2						118;330	120;337	264,0	268,0	0,196						62,1;559	62;553	204,8	204,0	0,055
	Be						-13,4;8,9	-11;10	6,2	3	0,929						-18,8;33,1	-18;30	2,7	4	0,005
	HCO3						14,1;32,3	15;35,7	28,0	28,0	0,756						9,6;35,5	9;34	26,2	26,0	0,473
	Sat						98,7;99,3	97;100	99,0	99,0	0,677						93;99,9	91;100	99,1	99,0	0,024
	HCT																				
	Hb																				
	k																				
Venous	pH	7,28;7,51	7,26;7,56	7,4	7,395	0,432	7,23;7,56	7,29;7,56	7,390	7,390	0,087	7,33;7,55	7,28;7,59	7,4	7,4	0,176	7,2;7,48	7,24;7,55	7,39	7,39	0,185
	pCO2	35,8;75,2	29;82	54,65	53	0,495	32,6;66	34;67	50,000	51,000	0,204	32,2;84,9	31;82	52,4	53,0	0,029	29,5;60,4	27;60	43,65	44,00	0,603
	PO2	22,2;53	26;56	35,3	35	0,989	27;57,2	23;57	35,800	33,000	0,369	26,8;60	23;66	40,4	41,0	0,298	23,7;63	22;65	35,05	36,00	0,704
	Be	-4;16,8	-2;18	9,5	9	0,363	-0,6;14,1	3;19	5,3	6,3	0,03	-3,3;16,4	0;18	6	8	<0,001	-13,6;5,7	-9;8	1,95	2	<0,001
	HCO3	21,9;43,5	23;53	34,7	35	0,014	25;38,3	28;44	28,500	30,700	0,001	21,5;47	23;47	30,0	33,0	<0,001	12,8;34	5;33	26,40	27,00	<0,001
	Sat	39,6;82	49;88	67,75	67	0,107	32;88,4	39;88	69,500	70,000	0,129	20,6;93	56;93	75,2	75,0	0,589	30;96	29;95	71,85	72,00	0,980
	HCT	24;42	23;44	33,5	34	0,780	25;46	25;44	34,000	35,000	0,178	21;41	22;42	32,0	32,0	0,173	20;40	20;40	31,00	31,00	0,180
	Hb	8;14,4	7,6;14,6	11,4	11,3	0,819	8,5;15,5	8,8;14,9	11,500	11,900	0,055	7,3;13,9	7,7;14,5	10,9	10,9	0,457	6,9;13,6	7;13,8	10,50	10,40	0,260
	k	2,7;4,7	2,4;5,9	3,6	4,3	<0,001	3,2;5,06	1,8;7,1	3,800	4,200	<0,001	1,45;6	2,8;5,8	3,9	4,2	<0,001	1,3;6,4	2,3;6,9	4,10	4,20	0,001

Conclusions: CDI demonstrates to be reliable in monitoring BGA parameters in ECMO circuits offering an online monitoring of the patient reducing the number of conventional blood gas. It overestimated the HCO_3^-, BE and K^+ in particular subgroups.

P11. Potential Danger of Pre-pump Clamping on Negative Pressure-Associated Gaseous Microemboli Generation during ECLS - An In-Vitro Study

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**The first authors, Wang and Chin, contributed equally to this work.*

Objective: The objective of this study is to investigate the relationship between revolution speed of a conventional centrifugal pump and negative pressure at inlet of the pump by clamping tubing upstream of the pump, and to verify whether negative pressure leads to gaseous microemboli (GME) production in a simulated adult ECLS system.

Methods: The experimental circuit, including a Maquet Rotaflow centrifugal pump and a Medos Hilite 7000 LT PMP membrane oxygenator, was primed with packed red blood cells (Hematocrit 35%). Negative pressure was created in the circuit by clamping the tubing upstream of the pump for 10 seconds, and then releasing the clamp. An emboli detection and classification (EDAC) quantifier was used to record GME volume and count at pre and oxygenator sites, and pressures and flow rates data were collected using a custom-based data acquisition system. All trials were conducted at 36℃ at revolution speeds of 2000-4000 rpm (500 rpm increment).

Results: The flow rates were 1092.5-4708.4 ml/min at the revolution speeds of 2000-4000 rpm. Higher revolution speed generated higher negative pressure at pre-pump site when clamping the tubing upstream of the pump (-108.3±0.1 to -462.0±0.5 mmHg at 2000-4000 rpm). Moreover, higher negative pressure was associated with a larger number of and volume of GME at pre-oxygenator site after de-clamp (GME count 10572.6±270.6 at pre-oxygenator site at 4000 rpm) (**Table 1**).

Table 1. GME total volume, count and size distribution at pre- and post-oxygenator sites

RPM	Site	Total volume (ml)	Total count	GME size distribution		
				0-20 μm	20-40 μm	>40 μm
2000 rpm	**Pre-oxy**	1.2E-7±1.5E-7	12±4	9±4	3±2	1±1
	Post-oxy	0.0±0.0	0±0	0±0	0±0	0±0
2500 rpm	**Pre-oxy**	1.3E-7±8.0E-8	25±9	19±7	5±2	1±1
	Post-oxy	2.9E-8±5.2E-8	4±5	3±4	1±1	0±0
3000 rpm	**Pre-oxy**	7.7E-6±5.5E-6*	413±133*	285±80*	95±38*	33±20*
	Post-oxy	2.9E-7±2.0E-7	32±16†	23±11†	8±4†	1±1
3500 rpm	**Pre-oxy**	5.0E-4±1.2E-4*	4342±822*	2264±476*	1208±208*	871±144*
	Post-oxy	1.7E-4±4.6E-5	4250±720	2073±291†	1352±244†	825±190
4000 rpm	**Pre-oxy**	5.0E-2±9.1E-3*	10573±271*	4837±213*	2922±80*	2813±65*
	Post-oxy	1.0E-2±4.8E-4†	5358±94†	2414±48†	1459±50†	1485±39†

Pre-oxy: Pre-oxygenator site; Post-oxy: Post-oxygenator site. * p<0.01, 2000rpm vs. others. † p<0.01, pre-oxygenator site vs. post-oxygenator site.

Conclusions: The results showed that there was a potential danger delivering gaseous microemboli to the patient when clamping pre-pump tubing during ECLS using a centrifugal pump. Our results warrant further clinical studies to investigate this phenomenon.

P12. Impact of Pulsatility and Flow Rates on Hemodynamic Energy Transmission in an Adult ECLS System

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Objective: The objective of this study is to investigate the total hemodynamic energy (THE) and surplus hemodynamic energy (SHE) transmission of a novel adult ECLS system with non-pulsatile and pulsatile settings and varying pulsatility. The study intends to provide insight into what level of pulsatility is the most effective setting in this ECLS system.

Methods: The circuit consisted of an i-cor diagonal pump, an XLung membrane oxygenator, an 18 Fr Medos femoral arterial cannula, a 23/25 Fr Estech RAP femoral venous cannula, 3/8 in ID x 140 cm arterial tubing, and 3/8 in ID x160 cm venous tubing. The circuit was primed with lactated Ringer's solution and packed red blood cells (HCT 36%). The trials were conducted at flow rates 1-4 L/min (1 L/min increments) under non-pulsatile and pulsatile mode, with differential speed values 1000 rpm-4000 rpm (1000 rpm increments) at 36℃. Flow and pressure data were collected in real time using a custom-based data acquisition system for analysis.

Results: Mean pressures across the circuit increased with increasing flow rates, but increased insignificantly with increasing differential speed values. **Figure 1** presents post-arterial cannula pressure waveforms at 2 and 4 L/min. Pulsatile flow created more THE than non-pulsatile flow at the pre-oxygenator site (P<0.01). Of the different components of the circuit, the arterial cannula created the greatest THE loss. THE loss across the circuit ranged from 24.8-71.4%. Still, under pulsatile mode, more THE was delivered to the pseudo patient at low flow rates. No SHE was created with non-pulsatile flow, but SHE was created with pulsatile flow, and increased with increasing differential speed values. The circuit pressure drop values across all flow rates were 33.1-244.1 mmHg, and were slightly higher under pulsatile mode than non-pulsatile mode.

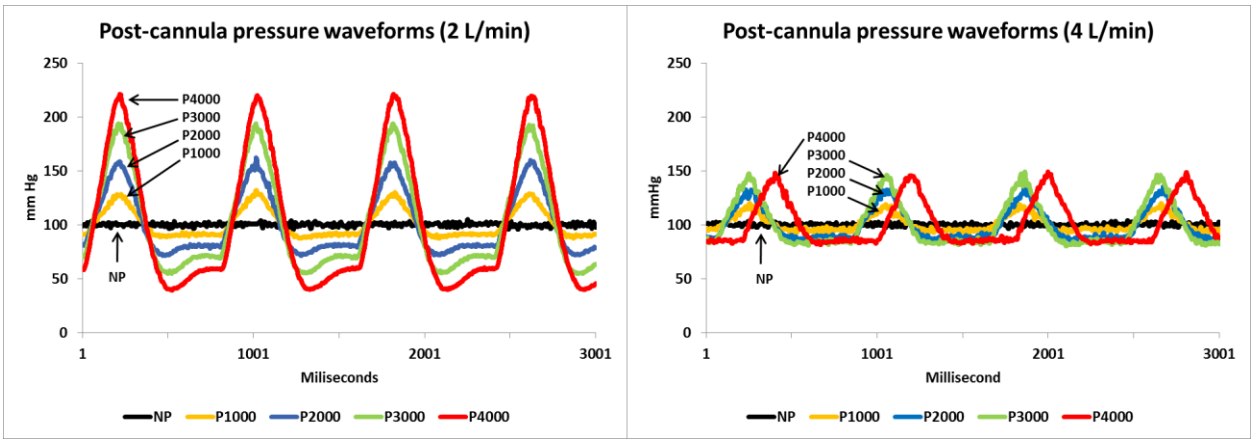

Figure 1. Post-arterial cannula pressure waveforms at 2 and 4 L/min. The pulsatile amplitudes decreased with lower differential speed values and higher flow rates.

Conclusions: The i-cor diagonal pump creates satisfactory pulsatile and non-pulsatile flow, and can easily change the pulsatile amplitude and energy transmission. The XLung membrane oxygenator is low resistance, low energy loss and creates acceptably low pressure drops at all flow rates and differential speed values. The arterial cannula creates the highest pressure drop of all components of the circuit. Pulsatile flow did not significantly affect the pressure drops across the circuit, but did transmit more hemodynamic energy to the pseudo patient.

P13. Drowning Accident with Deep Hypothermia

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Objective: Accidents in winter time may result to additional severe hypothermia. Deep hypothermia in children may develop very quick requiring active re-warming.

Case report: The case of a 3-year old boy (95 cm, 17 kg) with drowning accident is presented. The accident itself was not observed. The child was found unconscious in cold water. Due to circulatory arrest, resuscitation started immediately. Initial core temperature was 22°C (71.6°F). Because cardiopulmonary stabilization could not be achieved, the boy was transferred to our department. After arrival, the child was immediately connected to the cardiopulmonary bypass (CPB) and re-warming was started. Temperature was 23.6°C and pH 6.8. Weaning from CPB (at 34°C core temperature) was not possible due to respiratory failure with massive pulmonary edema. Therefore, the patient was connected to extracorporeal membrane oxygenation (ECMO). During the next 24 hours, severe capillary leak syndrome and global edema developed. Creatine kinase levels increased to 37,057 U/L. Due to multi-organ failure the boy died within 48 hours after the drowning accident.

Conclusions: Drowning with deep hypothermia is a catastrophic situation and although re-warming on cardiopulmonary bypass is the treatment of choice, outcome is very poor. Pre-hospital management is essential.

P14. In Vitro Model of Ventricular Support after Shunted Single Ventricle Palliation: the "delVAS SYSTEM"

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Objective: Hemodynamic vulnerability after shunted single ventricle palliation procedure for Hypoplastic Left Heart Syndrome (HLHS) is due to impaired myocardial function, and instability in the balance of parallel circulations. The objective of this paper is to set a system of ventricular support ("delVAS System") in the operating room to assist patients with hemodynamic instability after Norwood procedure who cannot be weaned from cardiopulmonary bypass (CPB). The idea is to use the same CPB circuit with the simple exclusion of the oxygenator

Methods: We realized an experimental model of ventricular assist device, studied for patients with univentricular physiology. The CPB circuit can be easily converted in delVAS System by excluding the reservoir, the roller-pump and the oxygenator, with the addition of centrifugal pump in the artero-venous shunt of CPB circuit.

Conclusions: In our opinion this kind of circuit could be the better way to assist patients with normal lungs and failure of systemic ventricle early.

P15. Patient-Specific Computer-Aided Planning of Pulmonary Outflow Patch Reconstruction in Pediatric Congenital Heart Patients - Proof of Concept

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Pre-surgical hemodynamic planning integrated with the three dimensional rapid-prototyping technology has recently emerged as a useful tool in the surgical management of complex congenital cardiovascular defects. On our recent studies that investigated the hemodynamic performance of valved-PTFE right ventricular outflow conduits indicated an improved performance when customized valve leakage area and orientation are considered. In this study we hypothesize that a similar improvement could be possible for the customized patched conduits and proposed a novel methodology to predict an optimal patient-specific surgical patch shape before the in vivo execution.

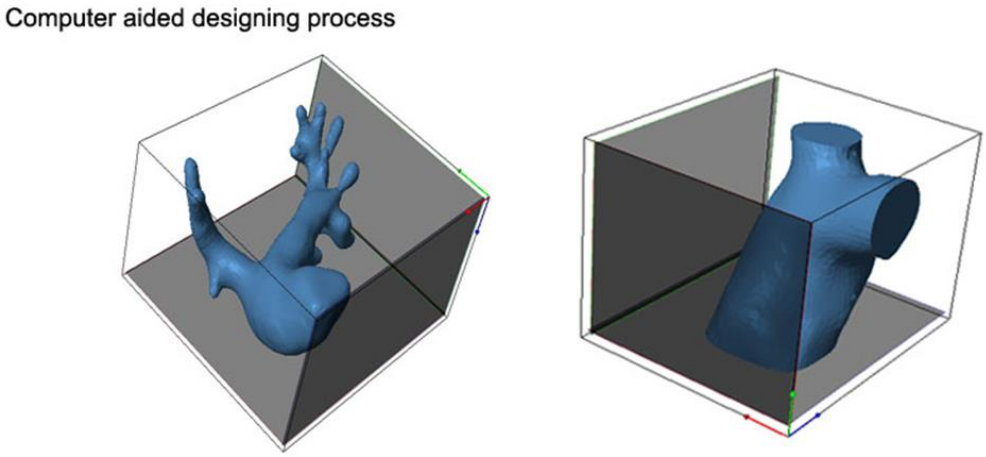

Figure 1: Left to right: Patient specific pulmonary artery with branches after image segmentation of DICOM slizes, Defined pulmonary artery model with two outflows by computer aided design methods.

Pre-surgical anatomies and great vessel flows are reconstructed for 3 selected Tetralogy of Fallot patients whom underwent 1st stage pulmonary artery reconstruction (**Figure 1**). Using our in-house sketch-based conduit-planning tool we sketched ideal smooth conduits for each patient (**Figure 2**), and marked the possible patched region on the 3D reconstruction. Left right pulmonary flow splits, energy loss and outflow velocity profiles are computed using flow simulation solver (OpenFoam and/or Fluent) providing the basic hemodynamic performance of the surgical conduit. 3D rapid-prototype models of the anatomies are utilized as a master during planning. Using a commercial finite-element code (ADINA) the unloaded (zero transmural pressure) configurations of the outflow tracks are computed. Material parameters of conduits are acquired through biaxial mechanical tests (Bose systems). After a flatting development operation performed in the computer, this solid-mechanics simulation provided the patch shape that needs to be cut and implanted to the patient during the operation. Our conduit and patch shapes are compared with the actual surgical reconstructions performed for the patients. Utility and predictive capability of the proposed methodology is discussed.

For the surgical palliative repair approach of complex congenital heart disease pulmonary artery reconstruction is a fundamental operation. The success of this stage influences significantly the optimal hemodynamics of later stages where the proposed methodology can be useful.

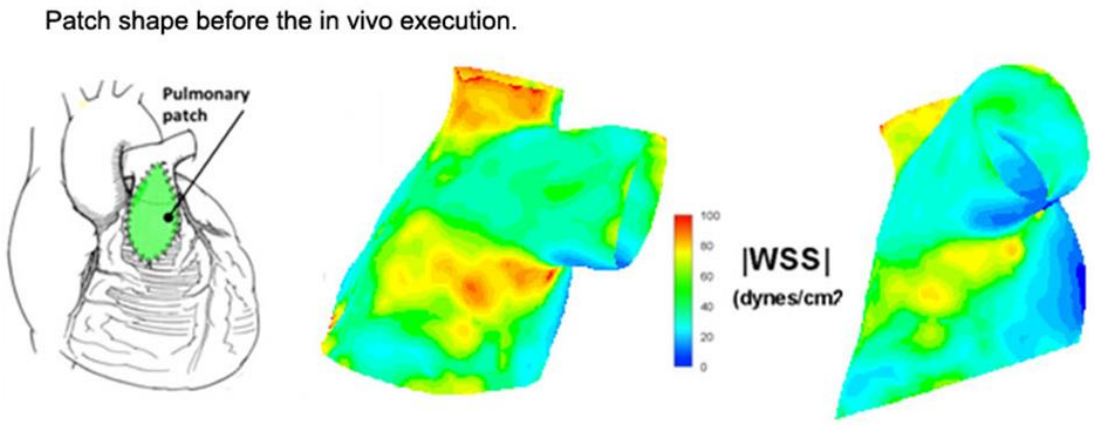

Figure 2: Left to right: Right ventricular outflow reconstruction via a pulmonary patch, wall shear stress (WSS) distribution of two right ventricular outflow tracks simulation using computational fluid dynamics.

P16. The Results and Correlations between Hepatic Near-Infrared Spectroscopy Measurements and Portal Vein Flow Dynamics and Early Postoperative Outcomes in Pediatric Cardiac Surgery

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Objective: The overall mortality in pediatric cardiac surgery has progressively declined to a value under 3%. Despite this, surviving patients continue to display a relatively high incidence of morbidity because of postoperative organ injuries especially in renal, brain and liver. The first 12-24 hours after cardiac surgery are the most critical and vulnerable period for managing the risk of these organs.

Near infrared spectroscopy (NIRS) is a very useful and noninvasive tool for the real time tissue oxygenation level for the somatic organs. Lower NIRS levels in cerebral, renal and hepatic tissues during this critical early postoperative period is associated with negative postoperative outcomes and interventions designed to optimize hemodynamics and improve systemic oxygen delivery may thus reduce organ injuries and morbidities.

Methods: From May 2014 to December 2014, 35 consecutive pediatric patients who were under 4 years old and had congenital heart defects underwent cardiac surgery electively with cardiopulmonary bypass with moderate hypothermia. Data were recorded in our study. All of these patients were operated on because of Tetralogy of Fallot by the same surgical team in one center.

We monitored cerebral and two somatic sides which are renal and hepatic oxygen saturations via NIRS in early postoperative period in the first critical 2 days and we assessed the correlations with variables and outcomes. Hemodynamical parameters, serum lactate, hemoglobin, inotropic support, urine output, liver enzymes levels, CRP, serum creatinine levels, intubation times, intensive care unit and hospital stay durations were also recorded in all patients. Doppler measurements were taken at the early postoperative first 2 or 4 hours when the patients were still under sedation. At the same time we recorded the cerebral and somatic NIRS values.

Results: A major decline in portal vein blood flow was seen with severe hypoxemia while there was no significant change to total hepatic blood flow. We found a moderate correlation (r = 0.54) between the changes in hepatic oxygenation parameters measured by NIRS and portal vein flow rate (PVFR, mL/min). The correlations between the cerebral and somatic NIRS values and PVFR were respectively; c-NIRS 0,51; r-NIRS 0,83 and abdominal aortic NIRS 0,72. We found an adverse moderate relationship (-0,43) with the lactate levels and hepatic NIRS values. There was no significant correlation with these parameters and hepatic enzyme levels in the early postoperative period. All the patients survived. There were no significant differences in intensive care unit and hospitalization periods.

Conclusions: Measurement of hepatic tissue oxygenation and portal vein blood flow rate results for liver flow, reflects oxygen supply and consumption. NIRS can be used to monitor hepatic tissue oxygenation. There was a good correlation between the tissue oxygenation parameters measured by NIRS and PVFR. In addition to the reduction of intracellular oxygenation, severe hypoxemia can be demonstrated only by NIRS. All patients should be followed up for a long time interval postoperatively.

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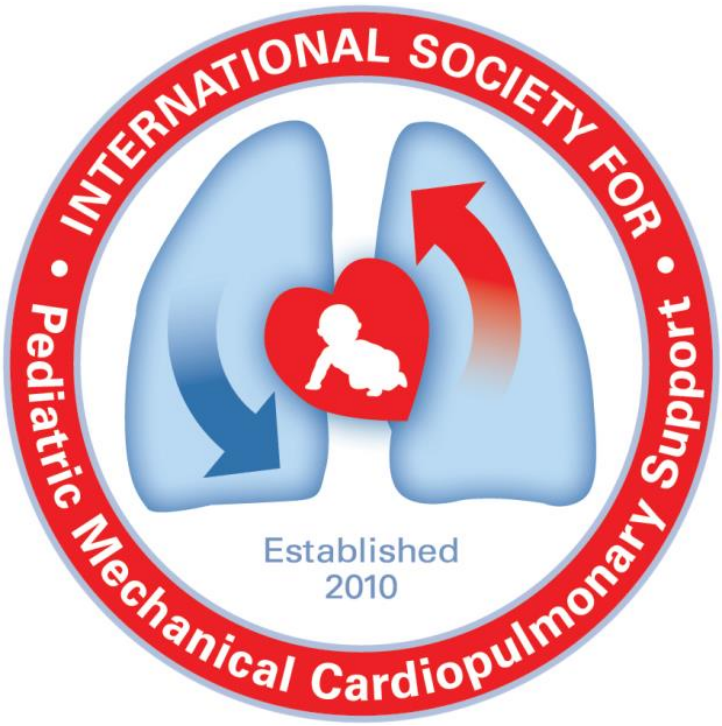

The mission of this society is to focus on the current problems associated with pediatric cardiac patients during and after acute or chronic cardiac support. The society will bring together as many distinguished clinicians, bioengineers, and basic scientists as possible to precisely define current problems and suggest novel approaches and solutions.

Our motto continues to be:

IF THE COURSE OF JUST ONE CHILD'S LIFE IS IMPROVED AS A RESULT OF THIS SOCIETY, WE HAVE REACHED OUR GOAL.

Akif Ündar, PhD, Founder and President

International Society Web Site: http://www.cvent.com/d/7cqc1m