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MECHANICAL CIRCULATORY ASSIST DEVICES IN CHILDREN WITH THERAPY-REFRACTORY HEART FAILURE: A REVIEW

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Introduction

Acute or chronic heart failure appears in approximately 2% of the population, meaning 1.6 million people of the world's population with a yearly increase of around 160.000 subjects. The 5 year survival rate of these patients is approximately only about 50%, and patients in NYHA functional class IV have a 50% mortality rate within the first year of presentation [1]. These dramatic statistics point to an absolute need for a therapeutic alternative at the end stage of congestive heart failure. In the adult age group, clear therapy strategies have become more and more established, and include mechanical circulatory life support at the end of the cascade of possible treatment modalities, until recovery of the myocardium, or as a bridge to transplantation. In the pediatric age group, however, acute heart failure is unusual, although it justifies aggressive therapy. Pharmacological treatment still remains the mainstay for congestive heart failure of pediatric patients [2,3]. Considering the overall outcome of lymphocytic myocarditis, with nearly 90% complete myocardial recovery in survivors [4], the need for temporary life support systems seems evident, if medical treatment fails in acute life threatening situations and a lethal outcome can be anticipated. The lack of available appropriately miniaturized systems, limited clinical experience, and the reluctance of the industry to invest in and further develop the devices, have delayed the progress of this technology for children compared to that in adults. The most frequent indications for mechanical circulatory support in the pediatric age group are myocardial dysfunction following cardiac surgery, acute decompensation of chronic cardiomyopathy, or fulminant viral myocarditis, or myocardial failure in patients with end-stage congenital heart defect [5]. Even though mechanical circulatory life assist most often aims at recovery of the failing myocardium, it can also offer a bridge to heart transplantation, although in this setting a longer period of support is required, as a result of the prolonged waiting for an appropriate donor. The shortage of donor organs, the estimated 20% mortality while waiting for an organ, and the significant increase of morbidity and mortality after 35 days of being listed for a transplantation further underline the need for more appropriate circulatory life systems [6,7]. A bridge to transplantation seems to be more and more important, as the 10 year survival rate still exceeds 50% [8]. This article gives a short summary about the current therapeutic concepts, lists the indications for mechanical circulatory life support, and the different types of assist systems currently in use.

> ***"Acute or chronic heart failure appears in approximately 2% of the population, meaning 1.6 million people of the world's population with a yearly increase of around 160.000 subjects."***

Acute Heart Failure and Current Treatment Strategies

Although acute heart failure seldom occurs in the pediatric age group, we have to distinguish two different patient populations. On

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one hand there are patients with structurally normal but acutely failing hearts after acute or fulminant myocarditis or cardiomyopathy, and on the other hand are patients suffering from congenital heart disease in the early postoperative phase of corrective or palliative surgery. For both groups so far, pharmacological treatment strives to aggressively manipulate systolic function, in the direction of maximal unloading of the heart [2]. During the last decade, treatment modalities have substantially changed with the introduction of new agents and modification of drug combinations to modulate systolic and diastolic myocardial function, with regards to the optimization of oxygen demand and supply, preload and afterload [9,10]. Because heart failure results from the interplay of hemodynamic, neurohumoral, cellular and developmental factors [3], modern heart failure treatment is a complex and sophisticated modification of the hemodynamics, more than just normalizing cardiac output or improving symptoms. With respect to neuroendocrine stimulation, myocyte remodeling, cellular energetics and myocyte / connective tissue interactions, treatment aims to reduce myocardial stress and workload, thus economizing heart function and allowing the heart to rest. One of the major differences between the adult and the infantile or neonatal myocardium seems the higher potential of the latter two for myocardial recovery [4]. In this sense, pharmacological support of the pediatric heart is also a bridge to recovery, based on the use of diuretics, vasodilators, inotropes combined with neurohumoral modulators like angiotensin converting enzyme inhibitor, b - blockers and aldosterone antagonists, and digoxin as a neurohumoral modulator and less so as an inotropic agent [2,11]. Newer therapies include modulation of the cytokinine response, endothelin receptor antagonists, T - calcium channel blockers, angiotensin converting enzyme inhibitors in combination with angiotensin receptor blockers, renin antagonists, central neurohumoral modulators, immunotherapy and gene therapy, and possibly in the future stem cell implantation, and gene therapy [9,11-13]. Most of those are under clinical investigation in large multi-centric trials in adults, or under evaluation in animal models, and may become a new horizon as new agents for the pediatric patient in the future. However, if all drug support combined with specific ventilation modalities and induced hypothermia fail, mechanical circulatory life support has to be considered, before irreversible end organ damage appears.

"New technical developments are about to come to clinical use in the pediatric age group, and short-term update of treatment strategies are urgently required to keep abreast with the evolving technology."

Indications for Mechanical Circulatory Assist

If increasing inotropic medical support is followed by inadequate cardiac output or significant malignant arrhythmias, and a realistic chance for recovery exists, a fast and aggressive setup of a mechanical circulatory life support (MCLS) system offers the only way to overcome impending exitus, and allow recovery. There is a wide range of potential indications enclosing the various

etiologies of acute heart failure with presumed reversibility within an acceptable period of time. Table 1 shows a summary of the most often reported indications for considering MCLS in the pediatric age group.

In all situations where MCLS has been necessary, the goal is either recovery of deteriorated myocardial function or bridge to transplantation. The type of life support system used differed according to the underlying cause and to the regional availability of any given circulatory assist system. Due to special structural abnormalities in congenital heart disease, the setup and design of the several life assist systems differ substantially from the models used in the adult population. Except for extracorporeal membrane oxygenation (ECMO), there are no current valid guidelines for initiation of other circulatory support systems in the pediatric age group [14]. These would need to be more firmly established, and early enough, before the onset of any irreversible end organ damage, in order to allow recovery or remodeling of myocardial function, or for a successful bridge to transplantation [15].

Non surgical reasons	Postoperatively
Myocarditis / Cardiomyopathy	Deteriorated myocardial function with good prognosis
Myocardial infarction	ALCAPA; ARCAPA, HLHS; TAPVD
Eisenmenger (as a bridge to heart-lung-transplantation)	Unbalanced ventricular sizes
Chest or heart trauma	Refractory PHT – crisis
Kawasaki disease	Prolonged CPB
Refractory malignant arrhythmias	Resolved intraoperative complications
Temporary respiratory failure (ARDS)	Incorrectable intracardiac status
Neoplasm	Acute rejection after heart transplantation

Table 1. Reported indications for pediatric MCLS in the literature. Abbreviations: MCLS, mechanical circulatory life assist; ARDS, acquired respiratory distress syndrome; ALCAPA, Anomalous left coronary artery connected to a pulmonary artery; ARCAPA, Anomalous right coronary artery connected to a pulmonary artery; HLHS, hypoplastic left heart syndrome; TAPVD, total anomalous pulmonary venous drainage; PHT, pulmonary hypertension; CPB, cardiopulmonary pass.

Current Mechanical Circulatory Assist Systems in Use

Besides the limited experience with intraaortic balloon counterpulsation in the pediatric population, the most widespread method of support with the largest database is ECMO [16,17]. Although both methods appear successful, neither of these techniques is appropriate when mechanical support for a longer period of time is required. Increasing experience with the use of pediatric ventricular assist devices has led to an established alternative, when buying more time is deemed necessary. The choice of system is strongly dependent on institutional experience, country-specific availability, the underlying cause, and on the presence of intracardiac shunts or pulmonary function [18-21]. This chapter gives a short overview on the different assist systems currently used.

Intraaortic Balloon Pump (IABP)

Since the beginning of the 1980s, the pediatric use of counterpulsation with a balloon catheter in the descending aorta was introduced, to augment coronary blood flow and to reduce ventricular afterload [22-24]. Although the available miniaturized balloon catheters have been successfully used in pediatric patients, this method is limited by the normally rapid heart rates of small children, and, therefore, by difficult synchronization for augmentation [25,26]. Furthermore, the efficacy of the method is doubtful because of the high elasticity of the aortic wall and increased aortic compliance in children [24]. The utilization of IABP in children plays a minor role, strongly owing to the fact that isolated left heart failure in the pediatric age group is relatively rare [10].

Extracorporeal Membrane Oxygenation

ECMO remains the most common technique of circulatory assist in pediatric patients, with an extended experience of over two decades [14,20,27-29]. In most cardiac centers and in a few large

Non – pulsatile VAD	Pulsatile VAD
Biomedicus Pump Biomedicus, Minneapolis, MN, USA	Berlin Heart Mediport Kardiotechnik, Berlin, Germany
Hemopump DLP Corp., Grand Rapids, MI, USA	Medos-HIA System Medos Medizintechnik AG, Stolberg, Germany
Jarvik 2000 Jarvik Heart, Inc., New York, NY, USA	Abiomed BVS 5000 Abiomed, Inc., Danvers, MA, USA
Micromed DeBakey VAD Micromed Tech., Inc., The Woodlands, TX, USA	Heartmate VAD Thermo Cardiosystems (Thoratec Corp., Pleasanton, CA, USA)
Heartmate II Thermo Cardiosystems (Thoratec Corp., Pleasanton, CA, USA)	Thoratec VAD Thoratec Corp., Pleasanton, CA, USA
	Novacor Baxter Healthcare, Oakland, CA, USA
	Pierce-Donachy Pediatric System USA
	Toyobo-Zeon pump Japan

Table 2. Different ventricular assist devices for pediatric patients for current and future use.

intensive care units, an ECMO circuit is available and rapidly deployable. The capability of ECMO to provide cardiac circulatory and/or respiratory support offers a relatively easy way to maintain circulation in children, especially in those with congenital heart defects. The extended possibility of use in patients with intracardiac defects and concomitant respiratory disorders makes it to a flexible emergency rescue system, and the additional use of a left-sided vent or balloon atrial septostomy allows complete cardiac decompression with maximal unloading of the heart. Despite survival rates of 40 to 60% [14,15,20,27,29,30], ECMO only offers short-term cardiac life support, with an increasing onset of complications and lethal outcome beyond the tenth day of use [29-31]. Although sufficient cardiac output with unloading of the poorly contracting heart can be established with ECMO, potential negative side effects also exist. These are increasing wall stress of the left ventricular wall due to increased afterload with increasing flows, concomitant increased myocardial oxygen consumption, and the significant decrease of coronary blood flow during ECMO [32,33]. The use of ECMO should not be considered if: organ failure is anticipated not to be reversible, the underlying cause is of uncorrectable nature, there is uncontrollable hemorrhage, or mid- or long-term support is required. Success rates of nearly 80% in patients with acute fulminant myocarditis who require mechanical circulatory support have been achieved, representing the best indication for ECMO [34]. The use of ECMO as an extracorporeal life support (ECLS) setting is limited to patients in whom restoration of myocardial function is anticipated in a short period of time (3-8 days), or in whom a severe respiratory disorder coexists. It is important to weigh the consequences of changing ECMO to a ventricular assist device if recovery of myocardial function does not occur within a maximal period of time of 10 days, before considering ceasing therapy.

Ventricular Assist Devices

Ventricular assist devices (VAD) have been designed to maximally unload the target ventricle and establish a sufficient cardiac output in order to achieve either recovery of myocardial function, or to serve as a bridge to transplantation. Until the late 1990`s, the lack of appropriate miniaturized devices limited the use in younger children, but specially designed equipment for smaller patients has become available, allowing the extended utilization of ventricular assist device systems even in neonates and small infants [35,36]. The VAD as a mechanical circulatory life assist setting has important advantages compared to an ECMO circuit [21,37]. It requires less anticoagulation and significantly fewer blood and platelet transfusion, which are major benefits, besides the possibility of mobilization of the patient in the long-term setting [21]. Despite the relatively small number of pediatric patients who are candidates for an assist device, the population is growing, and the market is surely justified to further develop these systems. There are essentially different assist devices which can be subdivided into several subgroups, into pulsatile or non-pulsatile devices, extracorporeal and intracorporeal, and intraventricular axial flow devices. Table 2 lists the different VAD systems currently in use in pediatric patients.

Non-pulsatile devices consist of centrifugal blood pumps based on the vortex technology, or implantable axial flow pumps with turbine spins of up to 10000 – 20000 rpm. These VAD systems can relatively easily create flows of up to 5-6 l/min and 3-4 l/min, respectively, and have been mostly used for temporary assist of a stunned left ventricular myocardium. The Biomedicus pump has especially been used for pediatric patients as an assist system in deteriorated congestive heart failure, and for the acute postoperative course of patients with anomalous origin of the left pulmonary artery [18,36,38-40]. These VAD systems are designed as a isolated left or right heart support, and, therefore, have a significant limitation in use, because in postcardiotomy patients after complex cardiac surgery, biventricular support is more often required.

The pulsatile VAD systems like the Heartmate VAD (Thermo Cardiosystems, Inc. [Thoratec Corp., Pleasanton, CA, USA]), Thoratec (Thoratec Corp., Pleasanton, CA, USA) and Abiomed BVS 5000 (Abiomed Inc., Danvers, MA, USA), were originally designed only for adults, but have also been used for adolescents and older children with encouraging results [41-47]. The major disadvantage of these devices is the limitation of their use in patients above 1.2 m2 and flows more than 2 l/min [42-44]. The only VAD systems specially designed for children of every age, including neonates and small infants, are the Berlin Heart VAD (Berlin Heart AG, Berlin, Germany) and the Medos HIA VAD (Helmholtz Institute, Aachen, Germany) [48,49]. Both VAD systems consist of pneumatically driven pump chambers, and have demonstrated their efficiency and reliability even in small infants, which so far had only been treatable with ECMO. The advantages of long-term mechanical circulatory assist, less anticoagulation, and mobilization of the patient with low complication rates, should make these VAD systems the treatment of choice, if locally available. Table 3 gives an overview of the experience with different VAD systems in pediatric patients.

Amongst all the devices which have so far been employed in the recent years, the Berlin Heart pulsatile VAD has demonstrated a high reliability and its superiority. After more than a decade, clearly, it has proven its flexible possibility to sustain either a single or biventricular circulation over a long period of time, with a reasonable low complication and an encouraging success rate [35,50,51]. Besides patients with cardiomyopathy and fulminant myocarditis, postcardiotomy patients after surgical correction of complex congenital heart disease have been treated with the Berlin Heart VAD [48,52]. Because of the similarity between the Berlin Heart and the Medos HIA, the same success rate and safety may also be anticipated for the Medos HIA in future routine use [53-55]. Due to the lack of global availability of these systems, especially in the USA, many centers continue using ECMO or centrifugal pumps, like the Biomedicus pump, in

No. of patients	Age range [yrs]	Duration [days]	% weaned or transplanted	VAD System	Reference
58	7-17	1-86	70	Thoratec VAD	Reinhartz et al. 2001 [41]
34	0.1-16	17.3 ± 24.2	56	Berlin Heart VAD	Hetzer et al. 1999 [48]
28	0.01-15	2-98	72	Berlin Heart VAD	Stiller et al. 2002 [35,65]
3	Neonates	14-98	66	Medos HIA VAD	Weyand et al. 1998 [53]
6	0.1-8	0.4-17	76	Medos HIA VAD	Konertz et al. 1997 [36]
9	0.1-15	1-11	88	Abiomed BVS 5000 / Biomedicus Pump	Ashton et al. 1995 [43]
12	11-20	0-397	77	Heartmate LVAD	Helman et al. 2000 [46]

Table 3. VAD experiences in pediatric patients. Abbreviations: VAD, ventricular assist device.

pediatric patients for temporary use [20,43,56]. The major disadvantages of these support systems are the short time window to achieve myocardial recovery or bridge to transplant, and the significantly higher complication rate. On the other hand, all the other pulsatile VAD systems have been designed for adults, and, therefore, only offer a solution in patients with a body surface greater than 1.2 m2. Otherwise, ongoing developments and research are expected to provide further miniaturized devices such as the Pierce-Donachy pediatric VAD, the Gyro Pump, and the Toyobu-Zeon pump [57-59]. Furthermore, the extended use of axial flow pumps is expected in the pediatric age group, and with further developments of the total artificial heart, its use also in children may become realistic in the near future [60-63].

"Mechanical circulatory life support of pediatric patients currently plays an important role in the treatment of the failing heart, and it is difficult to imagine management of these patients without these milestone advances."

All mechanical circulatory assist systems show a wide range of possible complications, of which bleeding and thromboembolic complications are the most often and serious problems. Infections, hemolysis, pulmonary edema, and multi organ failure have also been reported. The use of pulsatile VAD systems instead of ECMO seems to significantly lessen the complication rate, especially if circulatory assist exceeds 3 - 8 days [20,29]. The pulsatile VAD systems have also demonstrated lesser residual neurological defects, and better quality of life in surviving patients, and thus represent a circulatory support modality of choice [37].

Summary

Despite substantial improvements and changes in medical therapy, deterioration of cardiac function sometimes can not be controlled or improved. Therefore, mechanical circulatory support has become an important tool for the treatment of children with congestive heart failure, regardless of its cause. Survival rates of 40 to 80% can be achieved, depending on the chosen method and on the underlying cause. The encouraging data on the satisfying quality of life for long-term survivors of patients after mechanical circulatory support justify aggressive therapy in life-threatening situations, in which death or irreversible organ damage from insufficient circulation is expected [37]. The choice of the mechanical circulatory assist system is mainly dependent on the availability of the devices in a given center. The use of ECMO should be restricted to patients with significant residual intracardiac lesions or cyanotic congenital heart defects, patients with combined respiratory failure, and for patients in whom recovery of myocardial function can be expected within a reasonable period of time, namely 3 - 8 days [16,29-31]. Due to the shortage of donor organs, and, therefore, long waiting on a pretransplantation list, ECMO should not be considered as a bridging tool to transplant [64]. The encouraging results of pediatric heart transplantation demonstrate the absolute necessity of a mechanical circulatory support system that enables stabilization and improvement of the patient until recovery of myocardial function, or transplantation when a corresponding heart can be found [8,17,21]. This goal can be reached utilizing ventricular assist devices [17]. Because non-pulsatile VAD systems also show limitations and decreased success rates during longer circulatory assist, pulsatile VAD systems should be used wherever available. Of these pulsatile VAD systems, the Berlin Heart VAD and the Medos HIA VAD are the only ones with specially designed pump chambers for small infants and children with encouraging results [35,36,48,50,51,53]. These ventricular assist devices now offer the possibility for long-term assist of pediatric patients, and listing for transplantation can now be delayed to wait for potential myocardial recovery. It is hoped that new concepts in medical treatment, and / or the combination with the early use of mechanical circulatory life support, will further improve outcome. New technical developments are about to come to clinical use in the pediatric age group, and short-term update of treatment strategies are urgently required to keep abreast with the evolving technology. Mechanical circulatory life support of pediatric patients currently plays an important role in the treatment of the failing heart, and it is difficult to imagine management of these patients without these milestone advances.

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~CCT~

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HIGHLIGHTS FROM THE ASSOCIATION FOR EUROPEAN PAEDIATRIC CARDIOLOGY LX ANNUAL GENERAL MEETING, COPENHAGEN, 18 – 21 MAY 2005

By Joes Ramsøe Jacobsen, MD

The AEPC (Association for European Paediatric Cardiology) meeting in Copenhagen this year assembled close to 500 participants from countries all over the world for a rich and varied programme. It was a privilege and pleasure to host this great annual event in paediatric cardiology. Dr. Gudrun Björkhem, Lund, Sweden was co-chairman.

The first AEPC meeting was in Lyon, France in 1963. Two annual meetings were not held because there were World Congresses in the spring of 1980 in London and the spring of 1993 in Paris.

In recent years the conference itself has been preceded by a "teaching course" primarily meant for trainees, but attended by many more fully-trained paediatric cardiologists. This year's course "Genetics and Molecular Biology in Childhood Heart Disease" was organized by the Working Group for Basic Science and Genetics. Basic genetics, techniques, as well as clinical aspects, were covered and a special section was devoted to the 22q11 Microdeletion Syndrome. Previous courses have focused on fetal cardiology and on interventional paediatric cardiology.

On 18 May, the opening session of the Annual Meeting was attended by our patroness Princess Alexandra. The early description of tetralogy in Copenhagen in 1673 by the Danish anatomist Niels Stensen (also known as Nicolaus Steno) was commemorated. There was entertainment by a "Hans Christian Andersen Parade" – a troupe of actors and children from Odense, the birth place of the renowned author. The troupe performed excerpts from Hans Christian Andersen's famous tales.

A yearly highlight, the "Mannheimer Lecture" was held by fetal cardiology pioneer Prof. Lindsey Allan, of London, talking on "The Mystery of Nuchal Translucency." Afterwards the assembly went to a welcome reception at the Copenhagen City Hall, where plenty of delicious food and good Danish beer was served! In addition to the welcome reception, the social events included a junior's gathering, a "Tivoli dinner" and an after-congress excursion via the new tunnel-and-bridge connection to Sweden, where attendees visited the medieval castle, Glimmingehus, and had dinner with dishes made from medieval recipes.

The formal programme included a series of Working Group Symposia with invited speakers on "Imaging the Coronaries", "Paediatric Pacing: What Sites and How Many?", "Genetics in Congenital Heart Disease", "The Bicuspid Aortic Valve", "Isolated Fetal Complete Heart Block" and a session called "Complications in the Cath Lab." The later is a yearly, and very popular event, which demonstrates a number of unwanted, and at times scary experiences from the lab. Other topics included "Communication Matters in Paediatric Cardiology", "Imaging in the Cath Lab.", and "Current Management of Hypoplastic Left Heart Syndrome." There were two state-of-the-art lectures. The first was given by Fiona Walker of London on "Thrills, Pills and Implanons – Contraception for the GUCH Patient" relevant also to paediatric cardiologists, considering the low age of sexual debut in western countries. The other was presented by Tom Karl from San Francisco, California, entitled "The Coronary Arteries in Congenital Heart Surgery."

The 13 abstract sessions included 81 abstracts and 160 posters, 30 of which were also presented orally as "short abstracts." They covered a wide variety of topics. In addition, there were industry-sponsored sessions on pulmonary hypertension, echocardiography and other imaging techniques, pacing, interventional closure and opening the ductus arteriosus and metabolic heart disease – a topic rarely treated in paediatric cardiology meetings. The programme and the abstract book were published in *Cardiology in the Young*, volume 15; supplement 2.

Nowadays there are many meetings dedicated to specific, sub-specialized areas within paediatric cardiology, e.g. interventions and dysrhythmias, but there are few besides the four-yearly World Congresses, which offer an opportunity to broadly upgrade one's knowledge. Most of us need to be well informed about the whole field of paediatric cardiology. The annual meetings of AEPC rotate among many of the beautiful and historical cities of Europe. These meetings offer continuing medical education (accredited for CME by the European Board for Accreditation in Cardiology [EBAC] www.ebac-cme.org), as well as the opportunity to meet with friends and colleagues from all over the world.

The XLI Annual Meeting of AEPC will take place next year in Basel, Switzerland, 24–27 May. For more information see the AEPC website - www.aepc.org.

~CCT~

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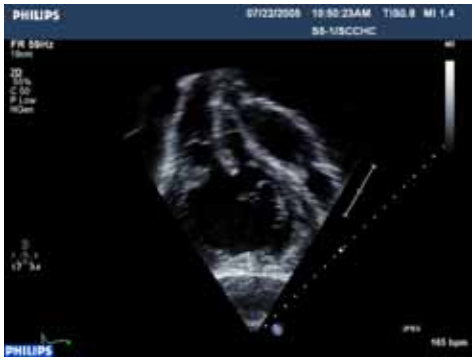

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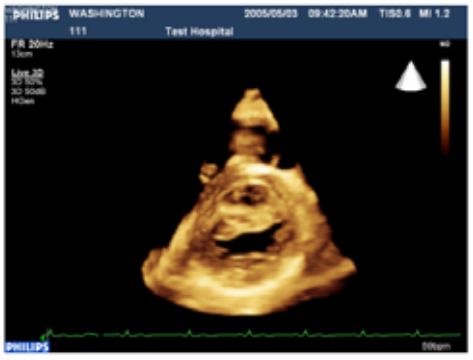

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HIGHLIGHTS FROM THE FIFTH INTERNATIONAL PEDIATRIC CARDIOVASCULAR SYMPOSIUM: MANAGEMENT OF COMPLEX CONGENITAL HEART DISEASE FROM INFANCY TO ADULTHOOD

By Janet Simsic, MD

Children's Healthcare of Atlanta hosted the Fifth International Pediatric Cardiovascular Symposium: Management of Complex Congenital Heart Disease From Infancy to Adulthood June 23rd through 26th, 2005 at the Ritz-Carlton on Amelia Island. The symposium addressed several important topics: Neurological protection and outcomes, hypoplastic left heart syndrome (HLHS) update and innovations, and the older patient with congenital heart disease. Guest faculty included our keynote speaker, Dr. Aldo Castaneda, pediatric cardiac surgeon from Guatemala City, Guatemala, Dr. Saraja Bharati, cardiac pathologist from Chicago, Illinois, Dr Anthony Chang, cardiac intensivist from Houston, Texas, Dr. Joseph Forbess, pediatric cardiac surgeon from Dallas, Texas, Dr. William Gaynor, pediatric cardiac surgeon from Philadelphia, Pennsylvania, Patricia O'Brien, nurse practitioner from Boston Massachusetts and Dr. Deepak Srivastava, cardiologist from San Francisco, California.

Table 2. Dr. Castaneda and Dr. Bharati at the "breakfast with the experts" at their table entitled "Past, Present and Future"

The highlight of the symposium was Dr. Aldo Castaneda's keynote address on the history of surgical treatment of congenital heart disease. Dr. Castaneda reviewed the development of cardiac surgery beginning with extracardiac procedures, hypothermia, early open-heart surgery with cross-circulation progressing to cardiopulmonary bypass as we know it today. He also discussed the philosophy of primary repair in infancy versus palliation followed by elective repair at a later age. He ended his address with the following quote "Past efforts of pediatric cardiac surgeons and of cardiologists, anesthesiologists, intensivists, pathologists, nurses and technicians have produced impressive advances over these past 67 years. Yet I am convinced that the most exciting advances of our specialty are still to come."

The neurological protection and outcomes session began with Dr. Gaynor's presentation of his research involving periventricular leukomalacia and genetic markers of neurological injury. Dr. Paula Bokesch discussed her research with biomarkers of neurologic insult and cardiopulmonary bypass. Dr. Steven Tosone presented current perioperative strategies in monitoring including SVO2, NIRS and serum lactate. Kathy Spitzer explained the cardiopulmonary bypass strategy of regional low flow perfusion, and Dr. William Mahle reviewed his research involving neurologic outcomes in newborns with congenital heart disease undergoing neonatal repair. Dr. Castaneda reviewed the Boston circulatory arrest study and presented his thoughts about this exciting topic. The session ended with a lively pro/con debate: genetic, anatomic insult vs. surgical insult.

Faculty dinner. Seated from left to right are: Paula Bokesch, Aldo Castaneda, Paul Kirshbom, Bill Gaynor, Janet Simsic, Bob Vincent, Ruth Vincent and Dennis Kim.

The second day's session, HLHS update, began with a talk on the molecular etiologies of single ventricle defects by Dr. Srivastava. This was followed by Dr. Chang's discussion of preoperative hemodynamic stabilization and neurological monitoring of the single ventricle newborn. Dr. Forbess' discussed the modifications to the Norwood procedure. Dr. Bharati presented path specimens of HLHS illustrating the anatomy and some of the surgical modifications. Dr. Martha Clabby discussed the Sibley Heart Center's high-risk outpatient clinic management strategy for shunt-dependent infants. Surgical techniques to achieve Fontan circulation were reviewed by Dr. Paul Kirshbom. This was followed by Dr. Bharati's presentation of Fontan path specimens illustrating those surgical

techniques. Dr. Mahle reviewed his research involving functional outcomes following Fontan operation. Dr. Michael McConnell and Dr. Forbess debated the question of compassionate care as an option for HLHS. The afternoon provided options for small group review of the path specimens with Dr. Bharati or enjoying the outdoor activities.

The third day's session, focusing on the older patient with congenital heart disease, began with a review of heart failure therapy by Dr. Chang. Dr. Robert Vincent examined options for failed single ventricle palliation including cardiac transplantation. Dr. Patricio Frias discussed re-synchronization pacing, followed by Dr. Dennis Kim presenting cardiac catheterization options for the adult with single ventricle physiology. The session concluded with Dr. Wendy Book introducing medical issues unique to the adult single ventricle patient.

Sunday morning began with "breakfast with the experts", a time for our conference attendees to meet in small groups with our guest and local faculty to discuss specific topics of interest. Not unexpectedly, the most popular table was Dr. Castaneda and Dr. Bharati's entitled "Past, Present and Future."

The symposium concluded with a half-day nursing session. The highlight of the nursing session included a presentation by Patricia O'Brien, RNC, MSN, PNP from Boston Children's Hospital on feeding infants with heart disease. Other topics included Donna Ramaswamy, PNP, nursing coordinator for the high risk clinic discussing the follow-up of shunt-dependent infants in a high-risk cardiac clinic. This was followed by Mary-Beth Norwood, RN, CICU, presenting her research project entitled infant massage therapy in the CICU. And Lynne Coyle, RN, Cardiac Cath, examined medicolegal issues in the care of infants and children with congenital heart disease.

The symposium was an excellent educational (and social) opportunity for cardiologists, nurses, perfusionists, surgeons, and pediatricians, attributed to the variety of current topics, esteemed guest and local faculty, and wonderful resort location.

~CCT~

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DEVELOPMENT OF AN INTERNATIONAL CONGENITAL HEART DISEASE CARDIAC CATHETERIZATION DATABASE TO MEASURE LONG-TERM OUTCOMES

By Allen D. Everett, MD

Over the past 20 years, cardiac catheterization of patients with congenital heart disease (1 in 1000 live births/year, > 1,000,000 adults with congenital heart disease, in the US) has moved from the realm of diagnosis to therapy. Greater than 70% of cardiac catheterizations for congenital heart disease are now therapeutic. However, there presently exists no means, at a broad international level, to analyze the number and outcomes of these therapeutic procedures in children and adults. Existing large databases do not address patients with congenital heart disease. As a result, our therapeutic decision making in the care of children and adults with congenital heart disease is guided by relatively small numbers of patients from single institutions rather than by evidence based approaches.

There are significant obstacles to the development of outcome studies for catheter based techniques. One is the physical requirement of data entry. The mechanics of data submission - adding data to forms and then submitting the information in the context of a busy clinical program - doom the collection process to non-compliance and failure. Also, most of the catheter based therapy in the US is delivered by medium sized clinical programs (200-500 cases/year). To understand outcomes in the "real world," results from these centers have to be included. Another problem is how to empower clinicians at such programs to design and conduct clinical research through collaboration with other centers. It is important that methods are devised to minimize or remove these obstacles and facilitate the collection of cardiac catheterization data for the future of the field.

To address these problems, we took advantage of an existing congenital heart disease cardiac catheterization database used by centers around the world, PedCath™ (www.PedCath.com). Working with the developer, we modified PedCath™ to function as a catheterization data submission tool and developed a database to house the data at Johns Hopkins. The primary goal in the design was that very little extra data entry would be required. This is possible because PedCath™ already contains patient demographics, hemodynamic data, calculations, diagnosis, procedure and billing codes. The only supplementary data is whatever the investigators for a clinical study require. The secondary goal was to design the system so that long-term follow-up data (such as Echo results, etc.) for patients in a study could also be added in PedCath™.

To pilot this system, we developed the Mid-Atlantic Group of Interventional Cardiology (MAGIC), a consortium of Johns Hopkins (Allen Everett and Richard Ringel), University of Virginia (Scott Lim), Duke University (John Rhodes) and Vanderbilt University (Tom Doyle) investiga-

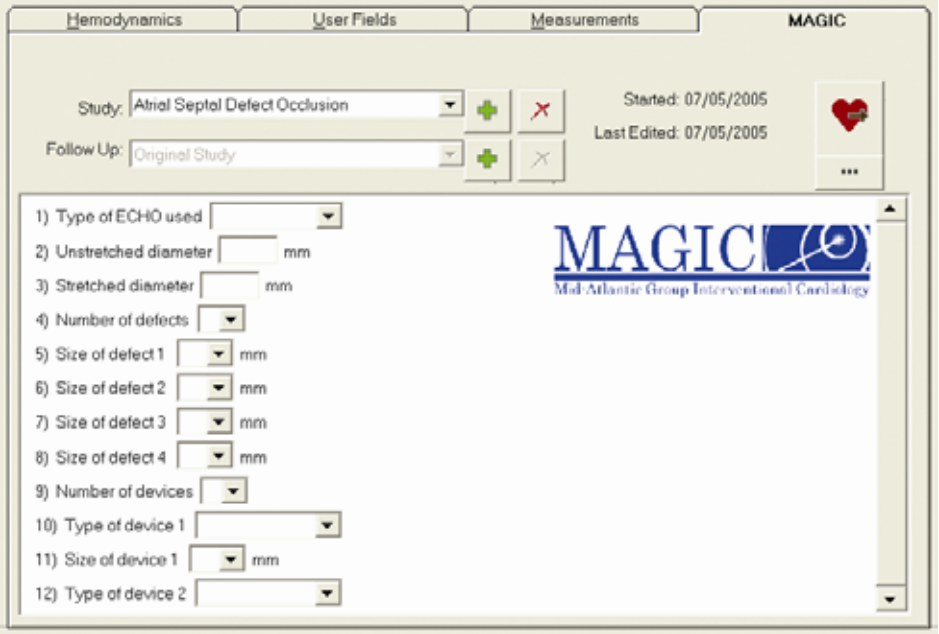

Figure 1. an example of limited data to be collected on a frequent procedure-ASD Occlusion.

"MAGIC's mission is to determine the long-term outcomes of therapeutic interventions in the cardiac catheterization laboratory."

tors. We developed data panels in PedCath™ to collect limited supplemental data, such as in a registry, and more detailed supplemental data, as in a specific clinical study on interventions for coarctation, atrial septal defect closure and pulmonary and aortic valve stenosis. Data panels were also developed to collect follow-up data for each of the studies. Once data is entered into the panel with the click of a button (red heart in Figure 1), the data is stripped of HIPAA identifiers and immediately transferred by FTP (file transfer protocol) to the data warehouse at Johns Hopkins for storage and analysis by the investigators. The database at Johns Hopkins performs automated queries, with summary data analysis of each study emailed weekly to all investigators for review.

MAGIC's mission is to determine the long- term outcomes of therapeutic interventions in the cardiac catheterization laboratory. To address this mission, MAGIC was designed as an open international consortium with study proposals initiated by individual investigators, with approval by an Oversight Committee composed of representatives of all the participating institutions. Our goal is to add as many additional US and international centers as wish to participate and have participating centers submit new protocols for study.

The significance of efforts such as MAGIC and the CCISC Project, spearheaded by Tom Forbes to study coarctation of the aorta, is that they allow comparison of present and future therapies. This information is important at many levels, from facilitating FDA approval of new devices to defining the best approach/device for therapy with the lowest complication rate.

In summary we have developed a facilitated process for International collaborative research on the outcomes of therapeutic cardiac catheterization interventions. Based on the estimates from the current participants in MAGIC, if 50 centers were members, we could study the outcomes of more than 6,000 therapeutic interventions a year. That's some really "BIG MAGIC."

~CCT~

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MAGIC

For more information on MAGIC and how to become a member go to: www.MAGICgroup.org or send an email to: Information@MAGICgroup.com

NEWS: AGA Medical Shareholder Litigation has been Settled

On July 28, 2005, AGA Medical officially announced the long shareholder litigation had been settled. Franck Gougeon was named president and CEO, as well as a director and majority shareholder of the company. Tommy Thompson, former Secretary of the US Health and Human Services, and former Governor of the state of Wisconsin, was named Chairman of the Board. Dr. Kurt Amplatz was returned to the company as a board member and research consultant in prenatal and adult cardiology. And finally, Welsh, Carson, Anderson & Stowe, the largest private equity investor in the US healthcare industry assumed a significant ownership position in the company.

Under the settlement agreement, Michael Afremov sold all his shares and will have no further association with AGA Medical. In addition, the authority of the court-ordered leadership that helped the company through the last few years has expired with the closing of the agreement, and the company has returned to normal operation. "I would never underestimate the power of loyal physician friends around the world who continued to believe in our work at AGA medical and the quality to our products. We will not disappoint you as we move forward. Together with our new strategic partner, we expect to further strengthen our leadership position in the cardiology device industry. We will continue with our RESPECT (Randomized Evaluation of Recurrent Stroke comparing PFO Closure to Established Current Standard of Care Treatment) clinical trial in preventing recurrent stokes. We will also begin to address the needs of migraine headaches. Finally, we will work even harder to bring new products to market to address current unmet physician and patient needs," Franck Gougeon said.

In 2006 AGA Medical plans to consolidate operation into a newly redesigned, high-tech manufacturing facility on a large suburban Minneapolis campus. For more information see www.Amplatzer.com

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