CONGENITAL CARDIOLOGY TODAY

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BUENOS AIRES, ARGENTINA | SPECIAL SYMPOSIUM EDITION | SEPTEMBER 2005

WELCOME TO PICS IX / ENTICHS III

Dear Colleagues,

Ziyad M. Hijazi, MD

Welcome to Buenos Aires! We hope you had a safe trip here. We are very excited about this course and delighted that you could join us here in this beautiful city. We know that many of you have traveled many hours and thousands of miles (some as many as 24 hours) to attend this meeting and we thank you for coming!

Over the next three days, you'll have the opportunity to listen to the best in the field and observe the most talented operators in the world performing live cases.

With over 800 attendees from around the globe, this course promises to be yet another huge success!

Let us go over the course briefly: the first day (Thursday), two important sessions will take place: the oral abstract presentations where the best 30 abstracts have been chosen for oral presentation. Over 140 abstracts have been submitted this year to PICS/ ENTICHS, a record number! It was very difficult to choose the best 30, however, a panel of 5 reviewers have selected these best 30 abstracts. This session is followed by Meet The Expert Session, where you have the opportunity to discuss any case you may have with the leaders in the field. Following the sessions, we welcome all of you to join us for a Welcome Reception from 6:30-8:30 PM here at the hotel.

(Continued on page 3)

WELCOME TO THE 4TH WORLD CONGRESS OF PEDIATRIC CARDIOLOGY AND CARDIAC SURGERY

Dear Colleagues,

It is an honour and a great pleasure for the Argentine community of pediatric cardiologists and cardiovascular surgeons to host and welcome you to the 4th World Congress of Pediatric Cardiology and Cardiac Surgery in beautiful Buenos Aires.

Guillermo Kruetzer, MD

This year, is the 25th anniversary of the 1st World Congress held in London and as with all previous World Congresses, we will provide a forum for discussion of a broad spectrum of topics ranging from issues concerning countries with emerging economies to the cutting-edge knowledge in the cardiovascular field and latest technology.

Horacio Capelli, MD

It will be shared by over 2,500 delegates from all over the world in a friendly atmosphere at the Buenos Aires Sheraton Hotel Convention Center. The four-day programme includes 7 Plenary Sessions which will provide overviews of new and exciting developments in the field, 20 controversies on hot issues to be lively debated in these popular sessions and 48 symposia to allow an in-depth discussion of most aspects of Pediatric Cardiology and Pediatric Cardiovascular Surgery.

We will also be holding 24 sessions of oral communications and there will be a room for posters. A named lec-

(Continued on page 4)

INSIDE THIS SPECIAL ISSUE | **www.CongenitalCardiologyToday.com** | **September 2005**

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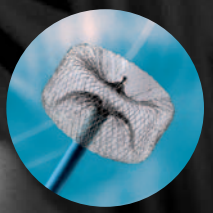

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(Continued from page 1)

Tango in Buenos Aires. Photograph courtesy of Mira Productora. See Stock.XCHNG for more works by this photographer.

Friday, is promised to be a very busy day, where many lectures will be given and live cases will be transmitted from Santiago, Chile where Felipe Heusser is hosting his teacher Bill Hellenbrand; from Sao Paolo, Brazil where Carlos Pedra and Cesar Esteves are hosting Zahid Amin and Larry Latson for a fun day in their cath lab; from Mexico City, Mexico where Carlos Zabal is hosting David Nykanen and finally, from Miami, FL where the one and only one, Evan Zahn is operating on his own!!!.

After a long day of work, we deserve a night of fun!!

The PICS Gala Dinner will be held on Friday, September 16th at the beautiful La Rural in Buenos Aires. The event will begin with a cocktail reception at 7:30pm followed by an elegant dinner at 8:30pm. During the evening we will be entertained by some of the most well known Tango dancers in Buenos Aires. Our guests will dance the night away with music provided by a very talented international orchestra. During the Gala, we'll present our annual PICS achievement award to a distinguished physician. Transportation will be provided round-trip from the Hilton Buenos Aires for our guests.

"The PICS Gala Dinner will be held on Friday, September 16 at the beautiful La Rural in Buenos Aires."

Saturday also promises to be a busy day! Again, many talks will take place and, of course, live cases! From Buenos Aires, Hospital Garrahan, Horacio Faella will be hosting Ziyad Hijazi for cases from their lab and Miguel Granja will be hosting John P. Cheatham and his nurse practitioner Sharon Hill for a busy day in their lab. If we are lucky and the baby with HLHS is born, then Mark Galantowicz and Jorge Makarovsky will join them for the action and from Cordoba, Argentina, Alejandro Peirone is hosting Lee Benson and Throng Le for some action from there.

Finally, Sunday will feature many important talks that I'm sure you'll appreciate. Both Saturday and Sunday also will feature new breakout sessions that were designed to give our colleagues in nursing and perfusion an opportunity to learn more about catheter intervention and what we do in the cath lab and OR.

We hope you'll enjoy this course and we hope to see you next year in Las Vegas!!! We have chosen the best hotel there, Bellagio and what this resort has to offer all of us. See you next year!!

Sincerely,

Ziyad M. Hijazi, MD, MPH

William E. Hellenbrand, MD

(Continued from page 1)

Cabildo in Buenos Aires. Photograph courtesy of Bahia Blanca, bs, Argentina. See Stock.XCHNG for more works by this photographer.

In this part of the world, spring has started. Faro de Claromeco, sur de Buenos Aires. Photograph courtesy of iFioriti, Diseño. See Stock.XCHNG for more works by this photographer.

ture in tribute to our pioneers will be addressed each day.

A complete and interesting Nursing Programme will be held during the meeting. The PICS / ENTICHS and the CHSS pre-congress meetings will enhance the academic attraction of the World Congress. There will also be a technical exhibition of equipment, pharmaceutical products and publications.

"The PICS/ ENTICHS and the CHSS pre-congress meetings will enhance the academic attraction of the World Congress."

Participants will have the opportunity to acquaint themselves with some of the latest technical innovations in each field.

In this part of the world, spring has started.

There is a variety of appealing activities and places of interest that you may find worth visiting. In Buenos Aires itself, you can enjoy visiting our famous opera house (Colón Theatre), tango shows, art galleries, exciting shopping opportunities, and also attend soccer or polo matches.

In addition, you can also visit interesting spots in Argentina like the glaciers in the south, vineyards in the Andes and the Iguazú Falls in the northeast.

We look forward to a memorable 4th World Congress of Pediatric Cardiology and Cardiac Surgery and to welcome you all to Buenos Aires.

Sincerely,

Horacio Capelli, Co-Chair

Guillermo Kruetzer, Co-Chair

The 5th World Congress of Paediatric Cardiology and Cardiac Surgery, will be sponsored by the Cardiac Society of Australia and New Zealand, and take place June 22-26, 2009 in Cairns, Queensland, Australia. For more information go to: www.pccs2009.com

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

Editor's Note

This article was originally published in the regular September 2005 editions of Congenital Cardiology Today and is reprinted here for this Special Symposium 2005 edition.
www.CongenitalCardiologyToday.com

By Felix Berger, MD and Brigitte Stiller, MD

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 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 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,

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.

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.

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].

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 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

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.

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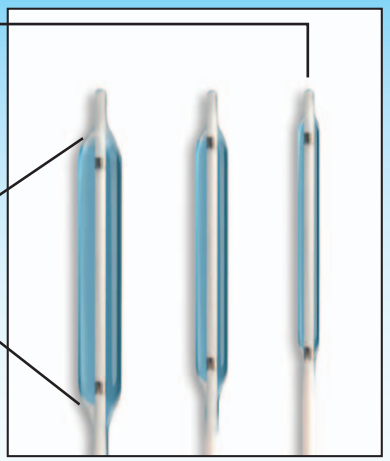

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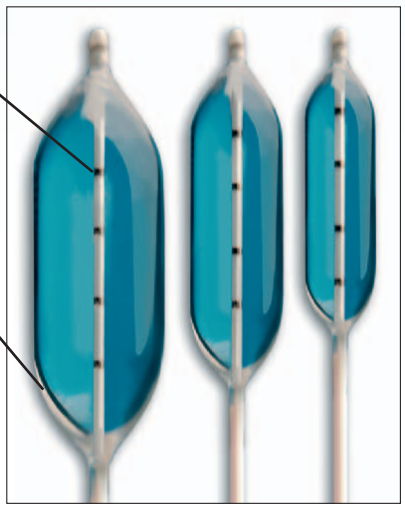

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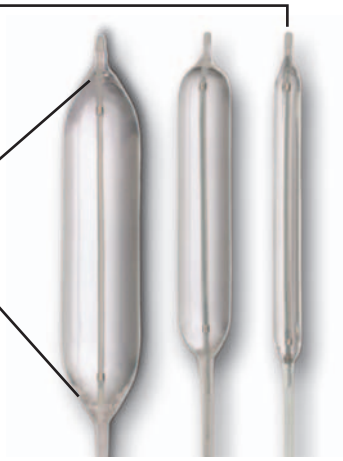

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flow devices. Table 2 lists the different VAD systems currently in use in pediatric patients.

Non-pulsatile devices consist of centrifugal blood pumps based on the vortex technology, or implantable axial flow pumps with turbine spins of up to 10,000 – 20,000 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 an 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 Corporation, 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 reasonably 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 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

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.

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].

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 pre-transplantation 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.

References

The complete list of references may be read in the original article from the September 2005 issue of Congenital Cardiology Today at:
www.CongenitalCardiologyToday.com

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

Editor's Note

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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

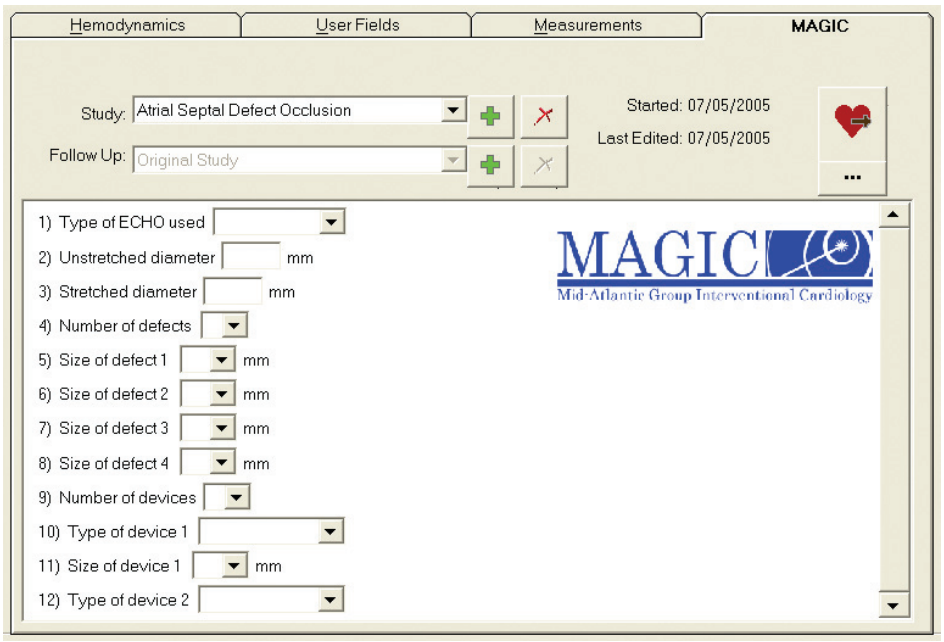

Figure 1. an example of limited data to be collected on a frequent procedure-ASD Occlusion.

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

Hopkins (Allen Everett and Richard Ringel), University of Virginia (Scott Lim), Duke University (John Rhodes) and Vanderbilt University (Tom Doyle) investigators. 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.

For more information on MAGIC, visit the website at www.MAGICgroup.org.

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MEDICAL CONFERENCES

The 2005 AAP (American Academy of Pediatrics) National Conference & Exhibition
October 8-11, 2005; Washington, DC USA
www.aap.org/proofed.html

Children's Hospital Los Angeles' 2nd Annual Symposium on the Echocardiographic Evaluation of Congenital Heart Disease
October 22-23, 2005; Santa Monica, CA USA
www.childrenshospitalla.org/echo4chd

Canadian Cardiovascular Society 58th Annual Meeting
October 22-26, 2005; Montréal, Québec, Canada
www.cs.ca

Chest 2005 (American College of Chest Physicians)
October 29-November 3, 2005; Montréal, Québec, Canada
www.chestnet.org/

The 16th Great Wall International Congress of Cardiology / ACC Symposium: Cardiology Update 2005
November 3-6, 2005; Beijing, China
www.apscardio.org

Scientific Session 2005 (American Heart Association)
November 13-16, 2005; Dallas, TX USA
www.americanheart.org

XX Congreso Interamericano de Cardiologia & XXIV Congreso Nacional de Cardiologia
November 19-23, 2005; Cancún, Mexico
www.smcardiologia.org.mx / www.soinca.org

Pediatric Cardiac Intensive Care Symposium (PCICS 2005)
December 7-10, 2005; South Beach, Miami, FL USA
www.cbcbiomed.com

MEDICAL NEWS, NEW PRODUCTS AND INFORMATION

Burden of Cardiovascular Disease will Shift to the Developing World

In a paper published 3 May 2005, in the premier open-access global health journal PLoS Medicine, Majid Ezzati and colleagues from Harvard School of Public Health conclude that a large proportion of the world's population who live in low-income and middle-income countries should be the focus for intervention against risk factors for cardiovascular disease because major cardiovascular risk factors will increasingly be concentrated in these populations. Together with an aging population, this will result in high levels of cardiovascular disease.

Traditionally, cardiovascular diseases have been considered a "Western" disease or a "disease of affluence" and not a pressing public health concern for low-income populations. Ezzati and colleagues examined when interventions should be started by looking at the relationship between nutritional cardiovascular risk factors - overweight and obesity, and elevated blood pressure and cholesterol - and three economic indicators, using data for more than 100 countries.

They found that body mass index (BMI) and cholesterol increased rapidly in relation to national income, then flattened, and eventually declined. Cholesterol showed a similar pattern, but with some delay. The authors also found that as the proportion of people living in cities increased so did BMI and cholesterol, which may be due to changes in patterns of diet and physical activity with city life. Blood pressure levels were independent of the economic development.

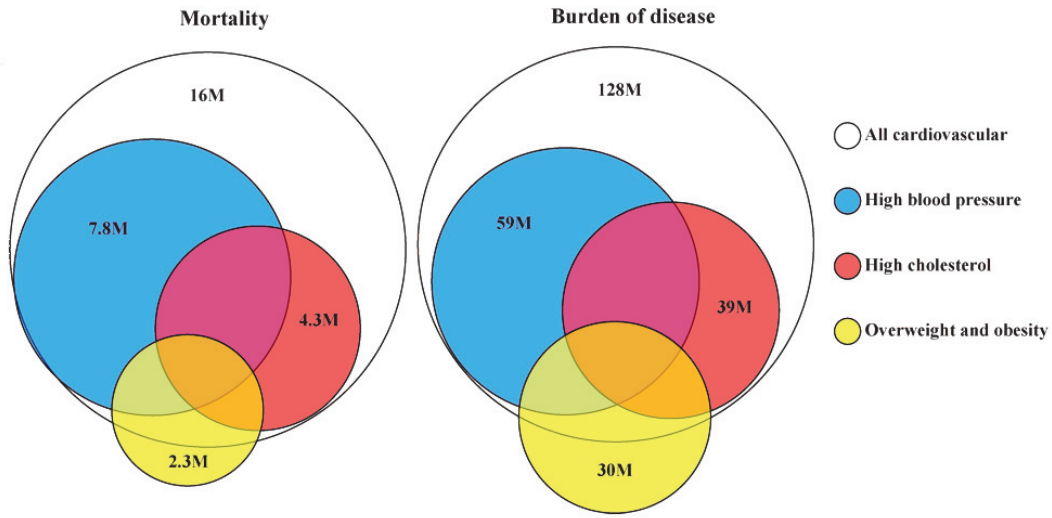

Figure 1. Global Mortality and Burden of Disease Attributable to Cardiovascular Diseases and Their Major Risk Factors for People 30 years of Age and Older.

The size of each circle is proportional to the number of deaths (left) or burden of disease (right; measured in disability-adjusted life years) (in millions). Overweight and obesity affect non-cardiovascular diseases, including diabetes, endometrial and colon cancers, post-menopausal breast cancer, and osteoarthritis, shown as the portions of yellow circles that fall outside the cardiovascular disease circle [57]. The mortality estimates exclude osteoarthritis, which results in morbidity but not direct deaths. Disease burden does include nonfatal health outcomes associated with diabetes and osteoarthritis (hence the larger size of the circle for overweight and obesity relative to those for blood pressure and cholesterol). Source: re-analysis of data from Ezzati et al. [57,58].

The authors conclude that changes in patterns of living along with economic development and adoption of clinical interventions for blood pressure and cholesterol in high-income countries mean that the burden of cardiovascular risk factors is being shifted to the developing world; as a result, low-income and middle-income countries will simultaneously face the burden of infectious disease and cardiovascular risk factors.

Unless better interventions are pursued, we will face a world in which all major diseases are the diseases of the poor, the authors warn.

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Citation: Ezzati M, Vander Hoorn S, Lawes CMM, Leach R, James WPT, et al. (2005)

Rethinking the "diseases of affluence" paradigm: Global patterns of nutritional risks in relation to economic development. PLoS Med 2(5): e133.

Source: PLoS Medicine (www.plosmedicine.org).

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The Heart Valve Society of America (HVSA)

The Heart Valve Society of America (HVSA) - including the Heart Valve Trialists Society - has been formed by a founding board of nationally and internationally prominent cardiologists and cardiothoracic surgeons in the heart valve disease field.

The mission of the Society is to:

- promote research
- educate medical professionals about the evaluation and treatment of heart valve diseases
- serve as an informational resource for government, private industry, healthcare providers, the media and public
- encourage and facilitate education of future heart valve disease specialists

"Heart valve diseases can be considered 'mystery killers,'" said Jeffrey S. Borer, MD of Weill Medical College of Cornell University, president of the Society. "Too often, they progress slowly and imperceptibly, yet are capable of causing sudden and unexpected death. The founding board believes a vehicle is needed to bring cardiologists, cardiothoracic surgeons, anesthesiologists, pathologists, internists, basic scientists, other medical and allied health professionals together, in order to further research and educate caregivers and patients about this important public health problem."

Since receiving its nonprofit status in late October 2004, HVSA membership has grown to close to 200 members. In April, the Society had it first annual meeting and conference at Valves in the Heart of the Big Apple IV: Evaluation & Management of Valvular Heart Diseases 2005 in New York City, NY USA. Almost 350 participants from the US and abroad attended the two and one-half day conference, which featured top presenters in the field.

Membership is open to international medical and allied health professionals involved/interested in the field, as well as individuals who work for corporations, academic and service institutions, and foundations interested in valvular heart disease.

For more information visit: www.heartvalvesocietyofamerica.org

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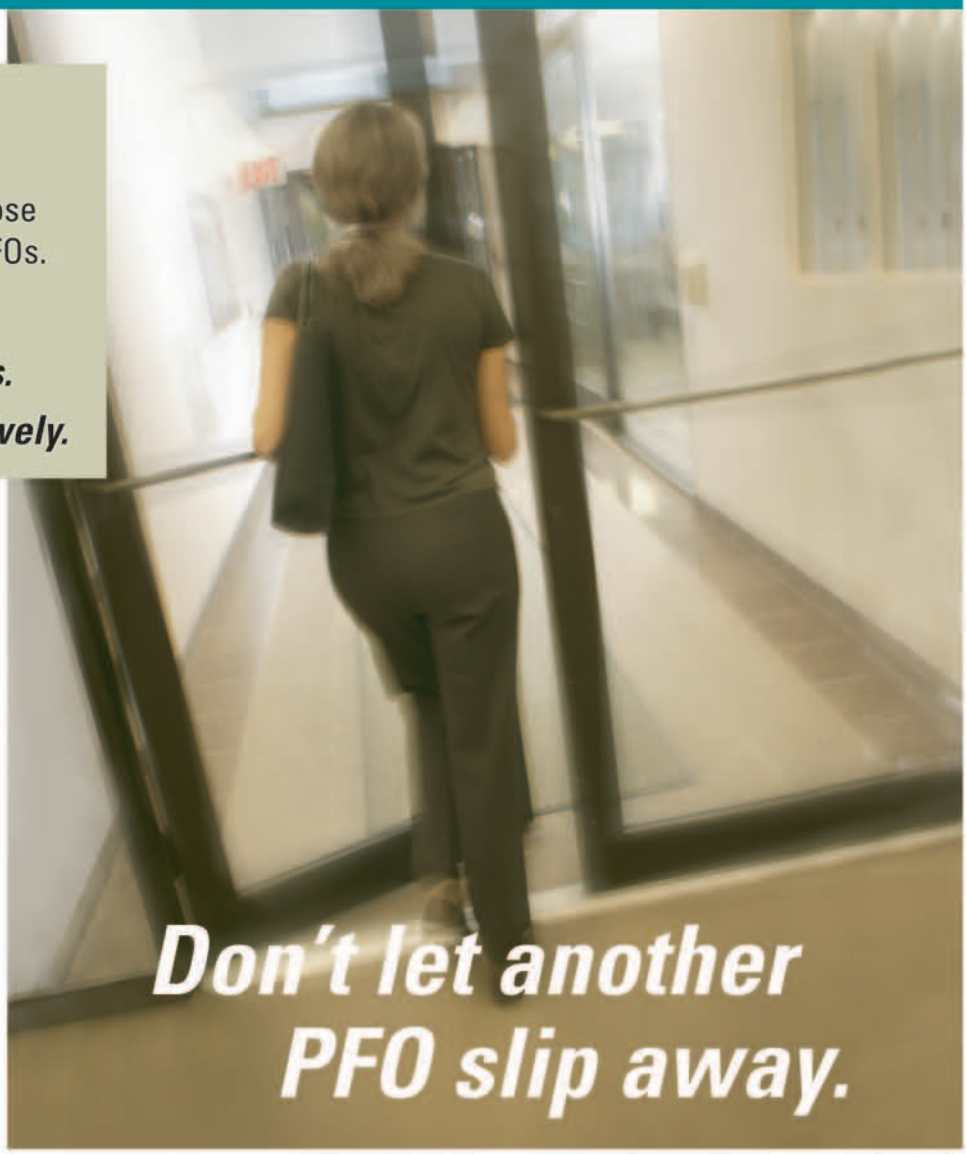

A new protocol using the PMD100 Transcranial Ultrasound System was shown to be significantly more sensitive and more accurate in detecting right-to-left shunts than either TEE or TTE[1].

Technology	Sensitivity	Accuracy
PMD100 System	98%	94%
TEE	91%	88%
TTE	64%	63%

[1]Spencer MP, Moehring MA, Jesurum J, Gray WA, Olsen JV, Reisman M. Power M-Mode Transcranial Doppler for diagnosis of patent foramen ovale and assessing transcatheter closures. J Neuroimaging 2004; 14:342-349.

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