

CONGENITAL CARDIOLOGY TODAY

RELIABLE INFORMATION IN CONGENITAL CARDIOLOGY

INTERNATIONAL EDITION

WWW.CONGENITALCARDIOLOGYTODAY.COM

VOL. 3, ISSUE 8 SEPTEMBER 2005

Formerly Pediatric Cardiology Today

INSIDE THIS ISSUE

Mechanical Circulatory Assist Devices in Children with Therapy-Refractory Heart Failure: a Review 1
by Felix Berger, MD and Brigitte Stiller, MD

Highlights from the Association for European Paediatric Cardiology LX Annual General Meeting, Copenhagen, 18 – 21 May 2005 10
by Joes Ramsøe Jacobsen, MD

Development of an International Congenital Heart Disease Cardiac Catheterization Database to Measure Long-Term Outcomes 12
by Allen D. Everett, MD

DEPARTMENTS

Medical Conferences 9

NEWS: AGA Medical Shareholder Litigation has been Settled 14

CONGENITAL CARDIOLOGY TODAY
9008 Copenhaver Drive, Ste. M
Potomac, MD 20854 USA
www.CongenitalCardiologyToday.com

© 2005 by Congenital Cardiology Today (ISSN 1554-7787-print; ISSN 1554-049 - online). Published monthly. All rights reserved. Statements or opinions expressed in Congenital Cardiology Today reflect the views of the authors and are not necessarily the views of Congenital Cardiology Today.

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

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].

“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.”

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

CONGENITAL CARDIOLOGY TODAY

© 2005 by Congenital Cardiology Today
(ISSN 1554-7787 - print; ISSN 1554-049 - online)
Published monthly. All rights reserved.

Publishing Management

Tony Carlson, Founder

Richard Koulbanis, Publisher & Editor

John W. Moore, MD, MPH, Medical Editor/Editorial Board

Editorial Board

Teiji Akagi, MD

Zohair Al Halees, MD

Mazeni Alwi, MD

Felix Berger, MD

Jacek Bialkowski, MD

Fadi Bitar, MD

Philipp Bonhoeffer, MD

Anthony C. Chang, MD, MBA

Bharat Dalvi, MD, MBBS, DM

Horacio Faella, MD

Yun-Ching Fu, MD

Felipe Heusser, MD

Ziyad M. Hijazi, MD, MPH

Ralf Holzer, MD

Marshall Jacobs, MD

R. Krishna Kumar, MD, DM, MBBS

Gerald Ross Marx, MD

Tarek S. Momenah, MBBS, DCH

Toshio Nakanishi, MD, PhD

Carlos A. C. Pedra, MD

Daniel Penny, MD

James C. Perry, MD

Shakeel A. Qureshi, MD

Andrew Redington, MD

Carlos E. Ruiz, MD, PhD

Girish S. Shirali, MD

Horst Sievert, MD

Hideshi Tomita, MD

Gil Wernovsky, MD

Carlos Zabal, MD

To Contact an Editorial Board Member

Email to: BOARD@CCT.bz. Place the Board Member's name in the Subject line.

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 modu-

lation of the cytokine 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

“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.”

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

**PICS/ENTICHS- 2005**

Pediatric Interventional Cardiac Symposium

and Emerging New Technologies in Congenital Heart Surgery

SEPTEMBER 15-18, 2005 at the Hilton Buenos Aires, Buenos Aires, Argentina

LAST CHANCE TO JOIN US IN BUENOS AIRES

www.picsymposium.com

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

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.

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



AMPLATZER® Vascular Plug

Simple. Reliable. Repositionable.

For more information visit: www.amplatzer.com or call: 763-513-9227
Toll free in the US: 888-546-4407



Non – pulsatile VAD	Pulsatile VAD
Biomedicus Pump Biomedicus, Minneapolis, MN, USA	Berlin Heart Mediport Kardioteknik, 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.



English - Spanish - Italian - Portuguese - French

Intra-departmental • Institutional • Global

www.PedCath.com

Scientific
Software
Solutions

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 dif-

ferent 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.



NuMED

www.numed.on.ca

NuMED, Inc.

Hallenweg 40, 5683 CT Best, The Netherlands

Tel: +31 (0)499 377388 Fax: +31 (0)499 377456

Manufacturer of angioplasty and valvuloplasty catheters, has a long standing commitment in meeting our customer's expectations by providing a high quality product. At NuMED, we see quality improvement as a continual process, aimed at satisfying these expectations and requirements at every stage.

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 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

1. Ho KKL, Pinsky JL, Kannel WB, Levy D. The epidemiology of heart failure: the Framingham Study. *J Am Coll Cardiol.* 1993; 22 (Suppl A):6A-13A.
2. Auslender M, Artman M. Overview of the management of pediatric heart failure. *Prog Pediatr Cardiol.* 2000; 11 (3):231-41.
3. Auslender M. Pathophysiology of

AMPLATZER®

Muscular VSD Occluder



Simple. Reliable. Repositionable.

For more information visit: www.amplatzer.com or call: 763-513-9227
Toll free in the US: 888-546-4407

CAUTION: Investigational device. Limited by USA law to investigational use.



pediatric heart failure. *Prog Pediatr Cardiol.* 2000; 11 (3):175-84.

4. Lee KJ, McCrindle BW, Bohn DJ, Wilson GJ, Taylor GP, Freedom RM, et al. Clinical outcomes of acute myocarditis in childhood. *Heart.* 1999; 82 (2):226-33.

5. Beghetti M, Rimensberger PC. Mechanical circulatory support in pediatric patients. *Intensive Care Med.* 2000; 26 (3):350-2.

6. Sable CA, Shaddy RE, Suddaby EC. Impact of prolonged waiting time of neonates awaiting heart transplantation. *J Perinatol.* 1997; 17:481-8.

7. Morrow WR, Naftel DC, Chinnock RE. Outcome of listing for heart transplantation in infants younger than six months: Predictors of death and interval of transplantation. The Pediatric Heart Transplantation Study Group. *J Heart Lung Transplant.* 1997; 16:1255-66.

8. Boucek M, Edwards L, Keck B, Trulock E, Taylor D, Mohacsi P, et al. The registry of the international society for heart and lung transplantation: Fifth Official Pediatric Report-2001 to 2002. *J Heart Lung Transplant.* 2002; 21 (8):827-40.

9. Auslender M. New drugs in the treatment of heart failure. *Prog Pediatr Cardiol.* 2000; 12 (1):119-24.

10. Shekerdemian L. Nonpharmacologic treatment of acute heart failure. *Curr Opin Pediatr.* 2001; 13 (3):240-6.

11. Koerner MM, Loebe M, Lisman KA, Stetson SJ, Lafuente JA, Noon GP, et al. New strategies for the management of acute decompensated heart failure. *Curr Opin Cardiol.* 2001; 16 (3):164-73.

12. McNamara DM, Rosenblum WD, Janosko KM, Trost MK, Villaneuva FS,

Demetris AJ, et al. Intravenous immune globulin in the therapy of myocarditis and acute cardiomyopathy. *Circulation.* 1997; 95 (11):2476-8.

13. Yacoub MH. A novel strategy to maximize the efficacy of left ventricular assist devices as a bridge to recovery. *Eur Heart J.* 2001; 22 (7):534-40.

14. Delius RE, Caldarone C. Mechanical support of the pediatric cardiac patient. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu.* 2000; 3:179-85.

15. Marx M, Salzer-Muhar U, Wimmer M. Extracorporeal life support in pediatric patients with heart failure. *Artif Organs.* 1999; 23 (11):1001-5.

16. Duncan BW, Hraska V, Jonas RA, Wessel DL, Del Nido PJ, Laussen PC, et al. Mechanical circulatory support in children with cardiac disease. *J Thorac Cardiovasc Surg.* 1999; 117 (3):529-42.

17. Throckmorton AL, Allaire PE, Gutgesell JH, Matherne JG, Olsen DB, Wood HG, et al. Pediatric circulatory support systems. *Asaio J.* 2002; 48 (3):216-21.

18. Karl TR. Extracorporeal circulatory support in infants and children. *Semin Thorac Cardiovasc Surg.* 1994; 6 (3):154-60.

19. Jensen C, Hill CS. Mechanical support for congestive heart failure in infants and children. *Crit Care Nurs Clin North Am.* 1994; 6 (1):165-74.

20. del Nido PJ. Extracorporeal membrane oxygenation for cardiac support in children. *Ann Thorac Surg.* 1996; 61 (1):336-9; discussion 40-1.

21. Duncan BW. Mechanical circulatory support for infants and children with cardiac disease. *Ann Thorac Surg.* 2002; 73 (5):1670-7.

22. Pennington DG, Swartz MT. Circu-

latory support in infants and children. *Ann Thorac Surg.* 1993; 55 (1):233-7.

23. Minich LL, Tani LY, Hawkins JA, Orsmond GS, Di Russo GB, Shaddy RE. Intra-aortic balloon pumping in children with dilated cardiomyopathy as a bridge to transplantation. *J Heart Lung Transplant.* 2001; 20 (7):750-4.

24. Akomea-Agyin C, Kejriwal NK, Franks R, Booker PD, Pozzi M. Intra-aortic balloon pumping in children. *Ann Thorac Surg.* 1999; 67 (5):1415-20.

25. Pantalos GM, Minich LL, Tani LY, McGough EC, Hawkins JA. Estimation of timing errors for the intraaortic balloon pump use in pediatric patients. *Asaio J.* 1999; 45 (3):166-71.

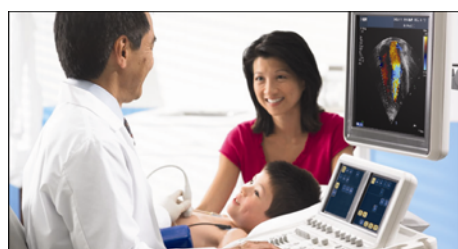
26. Minich LL, Tani LY, McGough EC, Shaddy RE, Hawkins JA. A novel approach to pediatric intraaortic balloon pump timing using M-mode echocardiography. *Am J Cardiol.* 1997; 80 (3):367-9.

27. Meliones JN, Custer JR, Snedecor S, Moler FW, O'Rourke PP, Delius RE. Extracorporeal life support for cardiac assist in pediatric patients. Review of ELSO Registry data. *Circulation.* 1991; 84 (5 Suppl):III168-72.

28. Mehta U, Laks H, Sadeghi A, Marelli D, Odum J, Alejos J, et al. Extracorporeal membrane oxygenation for cardiac support in pediatric patients. *Am Surg.* 2000; 66 (9):879-86.

29. Aharon AS, Drinkwater DC, Jr., Churchwell KB, Quisling SV, Reddy VS, Taylor M, et al. Extracorporeal membrane oxygenation in children after repair of congenital cardiac lesions. *Ann Thorac Surg.* 2001; 72 (6):2095-101; discussion 101-2.

30. Walters HL, 3rd, Hakimi M, Rice MD, Lyons JM, Whittlesey GC, Klein MD. Pediatric cardiac surgical ECMO:



**Introducing the iE33 intelligent echo system ...
for better visualization of congenital heart defects**

Learn more at:
www.medical.philips.com/iE33
or call 800-229-6417

PHILIPS

multivariate analysis of risk factors for hospital death. *Ann Thorac Surg.* 1995; 60 (2):329-36; discussion 36-7.

31. Black MD, Coles JG, Williams WG, Rebeyka IM, Trusler GA, Bohn D, et al. Determinants of success in pediatric cardiac patients undergoing extracorporeal membrane oxygenation. *Ann Thorac Surg.* 1995; 60 (1):133-8.

32. Bavaria JE, Ratcliffe MB, Gupta KB, Wenger RK, Bogen DK, Edmunds LH, Jr. Changes in left ventricular systolic wall stress during biventricular circulatory assistance. *Ann Thorac Surg.* 1988; 45 (5):526-32.

33. Kato J, Seo T, Ando H, Takagi H, Ito T. Coronary arterial perfusion during venoarterial extracorporeal membrane oxygenation. *J Thorac Cardiovasc Surg.* 1996; 111 (3):630-6.

34. Duncan BW, Bohn DJ, Atz AM, French JW, Laussen PC, Wessel DL. Mechanical circulatory support for the treatment of children with acute fulminant myocarditis. *J Thorac Cardiovasc Surg.* 2001; 122 (3):440-8.

35. Stiller B, Lange PE, Hetzer R. Left ventricular assist device. *N Engl J Med.* 2002; 346 (13):1023-5; discussion -5.

36. Konertz W, Hotz H, Schneider M, Redlin M, Reul H. Clinical experience with the MEDOS HIA-VAD system in infants and children: a preliminary report. *Ann Thorac Surg.* 1997; 63 (4):1138-44.

37. Ibrahim AE, Duncan BW, Blume ED, Jonas RA. Long-term follow-up of pediatric cardiac patients requiring mechanical circulatory support. *Ann Thorac Surg.* 2000; 69 (1):186-92.

38. Thuys CA, Mullaly RJ, Horton SB, O'Connor EB, Cochrane AD, Brizard CP, et al. Centrifugal ventricular assist in children under 6 kg. *Eur J Cardiothorac Surg.* 1998; 13 (2):130-4.

39. Karl TR, Sano S, Horton S, Mee RB. Centrifugal pump left heart assist in pediatric cardiac operations. Indication, technique, and results. *J Thorac Cardiovasc Surg.* 1991; 102 (4):624-30.

40. Costa RJ, Chard RB, Nunn GR, Cartmill TB. Ventricular assist devices in pediatric cardiac surgery. *Ann Thorac Surg.* 1995; 60 (6 Suppl):S536-8.

Reinhartz O, Keith FM, El-Banayosy A, McBride LR, Robbins RC, Copeland JG, et al. Multicenter experience with the thoratec ventricular assist device in children and adolescents. *J Heart Lung Transplant.* 2001; 20 (4):439-48.

42. McBride LR, Naunheim KS, Fiore AC, Moroney DA, Swartz MT. Clinical experience with 111 thoratec ventricular assist devices. *Ann Thorac Surg.* 1999; 67 (5):1233-8; discussion 8-9.

43. Ashton RC, Jr., Oz MC, Michler RE, Champsaur G, Catanese KA, Hsu DT, et al. Left ventricular assist device options in pediatric patients. *Asaio J.* 1995; 41 (3):M277-80.

44. Korfer R, El-Banayosy A, Arusoglu L, Minami K, Korner MM, Kizner L, et al. Single-center experience with the thoratec ventricular assist device. *J Thorac Cardiovasc Surg.* 2000; 119 (3):596-600.

45. Korfer R, El-Banayosy A, Arusoglu L, Minami K, Breyman T, Seifert D, et al. Temporary pulsatile ventricular assist devices and biventricular assist devices. *Ann Thorac Surg.* 1999; 68 (2):678-83.

46. Helman DN, Addonizio LJ, Morales DL, Catanese KA, Flannery MA, Quagebeur JM, et al. Implantable left ventricular assist devices can successfully bridge adolescent patients to

transplant. *J Heart Lung Transplant.* 2000; 19 (2):121-6.

47. Helman DN, Rose EA. History of mechanical circulatory support. *Prog Cardiovasc Dis.* 2000; 43 (1):1-4.

48. Hetzer R, Loebe M, Weng Y, Alexi-Meskhisvili V, Stiller B. Pulsatile pediatric ventricular assist devices: Current results for bridge to transplantation. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu.* 1999; 2:157-76.

49. Shum-Tim D, Duncan BW, Hraska V, Friehs I, Shin'oka T, Jonas RA. Evaluation of a pulsatile pediatric ventricular assist device in an acute right heart failure model. *Ann Thorac Surg.* 1997; 64 (5):1374-80.

50. Hetzer R, Loebe M, Potapov EV, Weng Y, Stiller B, Hennig E, et al. Circulatory support with pneumatic paracorporeal ventricular assist device in infants and children. *Ann Thorac Surg.* 1998; 66 (5):1498-506.

51. Stiller B, Dahnert I, Weng YG, Hennig E, Hetzer R, Lange PE. Children may survive severe myocarditis with prolonged use of biventricular assist devices. *Heart.* 1999; 82 (2):237-40.

52. Hetzer R, Muller JH, Weng Y, Meyer R, Dandel M. Bridging-to-recovery. *Ann Thorac Surg.* 2001; 71 (3 Suppl):S109-13; discussion S14-5.

53. Weyand M, Kececioglu D, Kehl HG, Schmid C, Loick HM, Vogt J, et al. Neonatal mechanical bridging to total orthotopic heart transplantation. *Ann Thorac Surg.* 1998; 66 (2):519-22.

54. Konertz W. Mechanical circulatory assist in pediatric patients. *Int J Artif Organs.* 1997; 20 (12):681-3.

55. Thuaudet S. The Medos ventricular assist device system. *Perfusion.* 2000; 15 (4):337-43.



The Fourth World Congress of Pediatric Cardiology and Cardiac Surgery

Buenos Aires, Argentina • September 18-22, 2005

www.pccs.com.ar

56. Noon GP, Lafuente JA, Irwin S. Acute and temporary ventricular support with BioMedicus centrifugal pump. *Ann Thorac Surg.* 1999; 68 (2):650-4.

57. Daily BB, Pettitt TW, Suter SP, Pierce WS. Pierce-Donachy pediatric VAD: progress in development. *Ann Thorac Surg.* 1996; 61 (1):437-43.

58. Yoshikawa M, Nakata K, Ohtsuka G, Takano T, Glueck J, Fujisawa A, et al. Feasibility of a tiny Gyro centrifugal pump as an implantable ventricular assist device. *Artif Organs.* 1999; 23 (8):774-9.

59. Takano H, Nakatani T. Ventricular assist systems: experience in Japan with Toyobo pump and Zeon pump. *Ann Thorac Surg.* 1996; 61 (1):317-22.

60. Noon GP, Morley DL, Irwin S, Abdelsayed SV, Benkowski RJ, Lynch BE. Clinical experience with the Micro-Med DeBaKey ventricular assist device. *Ann Thorac Surg.* 2001; 71 (3 Suppl):S133-8; discussion S44-6.

61. Westaby S, Frazier OH, Beyersdorf F, Saito S, Siegenthaler MP, Pigott DW, et al. The Jarvik 2000 Heart. Clinical validation of the intraventricular position. *Eur J Cardiothorac Surg.* 2002; 22 (2):228-32.

62. Maher TR, Butler KC, Poirier VL, Gernes DB. HeartMate left ventricular assist devices: a multigeneration of implanted blood pumps. *Artif Organs.* 2001; 25 (5):422-6.

63. Mehta SM, Pae WE, Jr., Rosenberg G, Snyder AJ, Weiss WJ, Lewis JP, et al. The LionHeart LVD-2000: a completely implanted left ventricular assist device for chronic circulatory support. *Ann Thorac Surg.* 2001; 71 (3 Suppl):S156-61; discussion S83-4.

64. Kocis KC. Pediatric cardiac extracorporeal membrane oxygenation: sup-

porting life or prolonging death? *Crit Care Med.* 2000; 28 (2):594-5.

65. Stiller B, Dahnert I, Berger F, Weng Y, Loebe M, Alexi-Meskishvili V, et al. [Artificial heart in terminal stage of dilated cardiomyopathy in childhood]. *Z Kardiol.* 2000; 89 (11):1039-45.

~CCT~



Corresponding Author:
 Felix Berger, MD
 Department of Congenital Heart Disease
 German Heart Institute Berlin
 Augustenburger Platz 1
 13353 Berlin, Germany
 Phone: +49 30 45932800
 Facsimile: +49 30 45932900

berger@dhzb.de



Brigitte Stiller, MD
 Department of Congenital Heart Disease
 German Heart Institute Berlin
 Augustenburger Platz 1
 13353 Berlin, Germany

MEDICAL CONFERENCES

British Society Cardiovascular Research - "Stress Signals in the Cardiovascular System"
 September 15-16, 2005; London, UK
www.bsccr.org

PICS-IX and ENTICHS-III (9th Pediatric Interventional Cardiac Symposium & Third Emerging New Technologies in Congenital Heart Surgery)
 September 15-18, 2005; Buenos Aires, Argentina
www.picsymposium.com

The 4th World Congress of Pediatric Cardiology and Cardiac Surgery
 September 18-22, 2005; Buenos Aires, Argentina
www.pccs.com.ar/

9th Annual Meeting of the Midwest Pediatric Cardiology Society
 October 20-21, 2005; Iowa City, IA, USA
www.mwpcociety.org

Canadian Cardiovascular Society 58th Annual Meeting
 October 22-26, 2005; Montréal, Québec, Canada
www.ccs.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 Cardiología & XXIV Congreso Nacional de Cardiología
 November 19-23, 2005; Cancún, Mexico
www.smcardiologia.org.mx

PedHeart Suite
 Congenital Heart Education

The most in-depth teaching materials
 for Congenital Heart Disease - anywhere!

From Patient Education to Senior Staff Review

www.PedHeart.com

Scientific
 Software
 Solutions

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~

Joes Ramsøe Jacobsen, MD
Head of Paediatric Cardiology
The Juliane Marie Centre,
Rigshospitalet
Blegdamsvej 9, DK-2100 Copenhagen,
Denmark

joes.ramsøe.jacobsen@rh.hosp.dk

NuMED



www.numed.on.ca

NuMED, Inc.

Hallenweg 40, 5683 CT Best, The Netherlands

Tel: +31 (0)499 377388

Fax: +31 (0)499 377456

Manufacturer of angioplasty and valvuloplasty catheters, has a long standing commitment in meeting our customer's expectations by providing a high quality product. At NuMED, we see quality improvement as a continual process, aimed at satisfying these expectations and requirements at every stage.

INTRODUCING THE IE33 PEDIATRIC ECHO SYSTEM ECHO SOLUTIONS FOR EVERY STAGE OF LIFE



Philips iE33 Pediatric Echo System

In the last 20 years, there has been a revolution in caring for children with congenital heart disease. Thanks to advances in diagnostics, surgery and treatment, many of these children are living into adulthood and enjoying active lives. With dedicated pediatric cardiology capabilities, the iE33 echo system answers your need for high-performance, non-invasive diagnostic imaging for these patients.

From fetal echo to mature adult, the iE33 system supports the assessment of congenital heart disease through every stage of life and provides new diagnostic information that is changing patient manage-

ment. Everything about the system is designed to meet the specific needs of pediatric cardiology. Unique ergonomic features make it possible to successfully image the tiniest premie or the largest teenager in many different environments. Pediatric analysis follows your workflow. And advanced technologies provide best-in-class 2D imaging and Live 3D Echo and give clinicians and surgeons structural information to make decision making more efficient and outcomes more effective.

A full complement of cardiac transducers, including pediatric and adult TEEs, en-

“A new analysis package for congenital heart disease assessment includes: LT/RT inflow, LT/RT outflow, shunt evaluation, chamber evaluation, valve investigation.”

ables you to image a complete range of patient types – regardless of age, disease state or body composition.

In addition, a unique analysis package truly follows the patient the way you do – so you don't have to fit your requirements into an analysis package designed for adult echocardiography.

The biggest breakthrough in transducer material in 40 years, PureWave crystal



PureWave Crystal Technology



Live 3D Echo

technology provides significantly better acoustic properties for a radical leap forward in 2D image quality.

Dedicated to your pediatric cardiology clinical and workflow requirements, our commitment goes beyond the system and its technologies. Global educational programs, outstanding service and worldwide centers of excellence help you to get the most out of your system every day.

**Pediatric echo from Philips...
it just makes sense.**

Transducer	Application/Patient
S12-4 broadband sector array	Neonates and small pediatric patients
S8-3 broadband sector array	School-aged children
S7-3t broadband sector array	Pediatric transesophageal echo
C5-2 broadband curved array	Fetal echo
S5-1 with PureWave crystal technology	Young adult and adult
S7-2omni	Adult transesophageal echo
X3-1 matrix array	Live 3D Echo imaging

A transducer for every need.

FOR MORE INFORMATION

Philips Medical Systems
22100 Bothell Everett Highway
Bothell, WA 98021
+1 (425) 487 7000
1 (800) 285-5585

www.medical.philips.com/ultrasound

PHILIPS

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.

Do You Want to Recruit a Pediatric Cardiologist?

Advertise in the only monthly publication totally dedicated to pediatric and congenital cardiology. For more information:

Recruitment@CCT.bz

“MAGIC’s mission is to determine the long-term outcomes of therapeutic interventions in the cardiac catheterization laboratory.”

tors. We developed data panels in Ped-Cath™ 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, spear-

headed 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~



*Allen D. Everett, MD
Pediatric Cardiology
Johns Hopkins University
Johns Hopkins Hospital
600 N. Wolfe St.
Brady Building, 5th Floor, Rm. 522
Baltimore, MD 21287 USA
Phone: 1-410-502-0699
Fax: +1-410-955-0897
aeveret3@jhmi.edu*

MAGIC

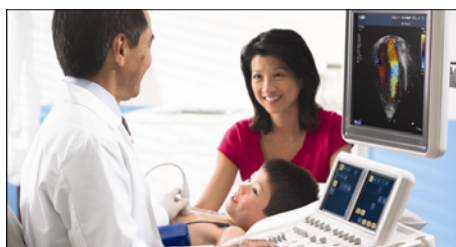
For more information on MAGIC and how to become a member go to: www.MAGICgroup.org or send an email to: Information@MAGICgroup.com

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 health-care 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 strokes. 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



Introducing the iE33 intelligent echo system ... for better visualization of congenital heart defects

Learn more at:
www.medical.philips.com/iE33
or call 800-229-6417



CONGENITAL CARDIOLOGY TODAY®

RELIABLE INFORMATION IN CONGENITAL CARDIOLOGY™

INDEX OF SPONSORS

AGA Medical Corporation - Pages 3, 9
www.amplatz.com/international/index.html

The Fourth World Congress of Pediatric Cardiology and Cardiac Surgery - Page 8
www.pccs.com.ar

NuMed - Pages 5, 10
www.numed.on.ca

PICS/ENTICHS- 2005 (Pediatric Interventional Cardiac Symposium and Emerging New Technologies in Congenital Heart Surgery) - Page 2
www.picsymposium.com

Philips Medical Systems - Pages 7, 11, 13
www.medical.philips.com/iE33
www.medical.philips.com/ultrasound

Scientific Software Solutions - Pages 4, 9
www.PedHeart.com

UPCOMING ARTICLES

Estimates of the Burden of Congenital Heart Disease in the Developing World by *Balu Vaidyanathan, MD, DM and R. Krishna Kumar, MD, DM*

Experiences in Central America and the Pediatric Cardiology Program in Nicaragua, or Why we Need to Teach Fishing by *Elaine Urbina, MD*

Highlights From The Fourth World Congress of Pediatric Cardiology and Cardiac Surgery

Highlights From PICS/ENTICHS 2005 by *Ziyad Hijazi, MD*

Practical Tools To Improve Communication, Compliance And Outcomes by *Debbie Hilton Kamm, co-founder and president of California Heart Connection*

Report of the 1st Annual Toronto Symposium by *Andrew N. Redington, MD*

Tools and Strategies for Improving Physician-Parent Communication at Diagnosis by *Debbie Hilton Kamm, co-founder and president of California Heart Connection*

© 2005 by Congenital Cardiology Today (ISSN 1554-7787-Print; ISSN 1554-049-online). All rights reserved. Photocopying, reproduction or quotation either in full or in part is strictly prohibited without the written permission of the publisher. For permission, send an e-mail to: Permission@CCT.bz. Statements or opinions expressed in Congenital Cardiology Today reflect the views of the authors and are not necessarily the views of Congenital Cardiology Today.

Article Submission

Article@CCT.bz

Information

Info@CCT.bz

Medical Editor/Medical Editorial Board

John W. Moore, MD, MPH, FACC
jwmoore@mednet.ucla.edu

Contact the Editorial Board

See page 2 for a complete list of Editorial Board members and how to contact them.

New Product Submission

PR@CCT.bz

Article Reprint Information

Reprint@CCT.bz

Web Site Information

Web@CCT.bzom

Symposium Submission

Symposium@CCT.bz

Medical Website Submission

URL@CCT.bz

How to Reference CCT

Reference@CCT.bz

FREE Subscription

Congenital Cardiology Today® is published monthly and FREE to qualified professionals worldwide in congenital and pediatric cardiology, and related fields.

Print subscriptions are available in the U.S. and Canada for the North American edition.

Electronic subscriptions (in Adobe PDF format) are available in the International edition. To subscribe to either the International or North American edition, send an email with your name, title, organization, phone, address and email to: Subs-Sep@CCT.bz. Or fax your request to +1.240.465.0692

Advertising Production

Production@CCT.bz

Letters to the

Letters@CCT.bz

Sales & Marketing

Sales@CCT.bz

Recruitment/Fellowship Advertising

Recruitment@CCT.bz

Publishing Management

Tony Carlson, Founder

Tel: +1.301.279.2005

Fax: +1.240.465.0692

TonyC@CCT.bz

Richard Koulbanis, Editor & Publisher

RichardK@CCT.bz

Virginia Dematatis, Editorial Consultant

VirginiaD@CCT.bz

Loraine Watts, Editorial Assistant

Caryl Cornell, Editorial Assistant

Sales Office

CONGENITAL CARDIOLOGY TODAY

9008 Copenhaver Drive, Suite M

Potomac, MD 20854 USA

Tel: +1.301.279.2005

Fax: +1.240.465.0692

Editorial Office

CONGENITAL CARDIOLOGY TODAY

19509 Pine Cone Court, Suite 100

Gaithersburg, MD 20879 USA

[Edit@CCT.bz](mailto>Edit@CCT.bz)

www.CongenitalCardiologyToday.com