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INSIDE THIS ISSUE

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9008 Copenhaver Drive, Ste. M
Potomac, MD 20854 USA
Tel:+1.301.279.2005
Fax: +1.240.465.0692
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COARCTATION OF THE AORTA: THE NEED FOR INNOVATION

By Michael C. Slack, MD

Introduction

Coarctation of the aorta is the eighth most common form of congenital heart disease and affects roughly 1 in 10,000 liveborns (Figure 1). It occurs in males about three times more often than females. Put into context for the congenital cardiovascular specialist, aortic coarctation is present in 8-11% of patients treated with congenital heart disease. It occurs in isolation or in combination with a host of additional congenital cardiovascular abnormalities including: bicuspid aortic valve (BAV), hypoplasia of the aortic arch, patent ductus arteriosus (PDA), ventricular septal defects

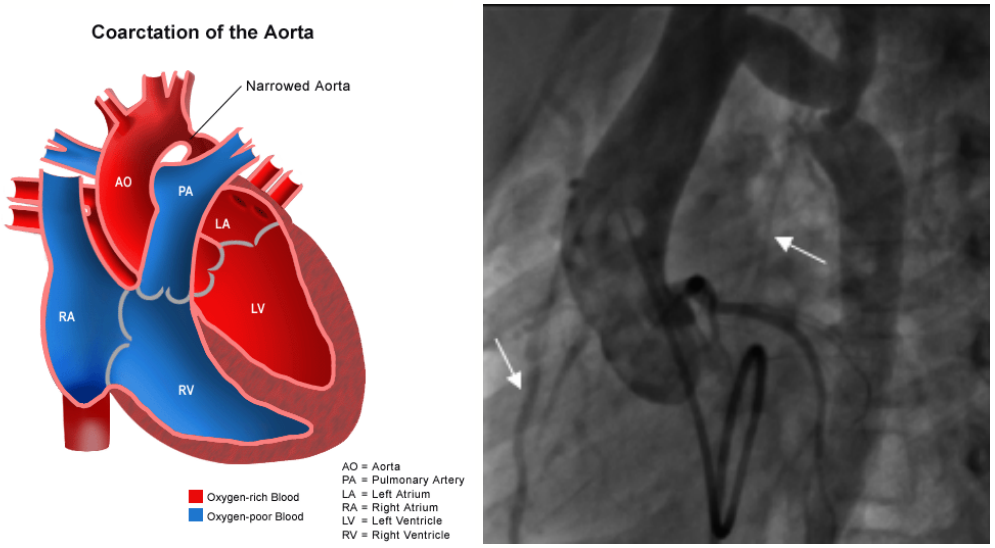

Figure 1. Idealized representation along with actual angiographic representation of an aortic coarctation. Picture reprinted with permission from Greystone.net. Angiogram shows lateral view of a native aortic coarctation in a five year old female prior to stent angioplasty. Note: the typical features including: enlongated ascending aorta, exaggerated spacing between the initial aortic arch branches and the left subclavian artery. Collaterals are also evident (white arrows).

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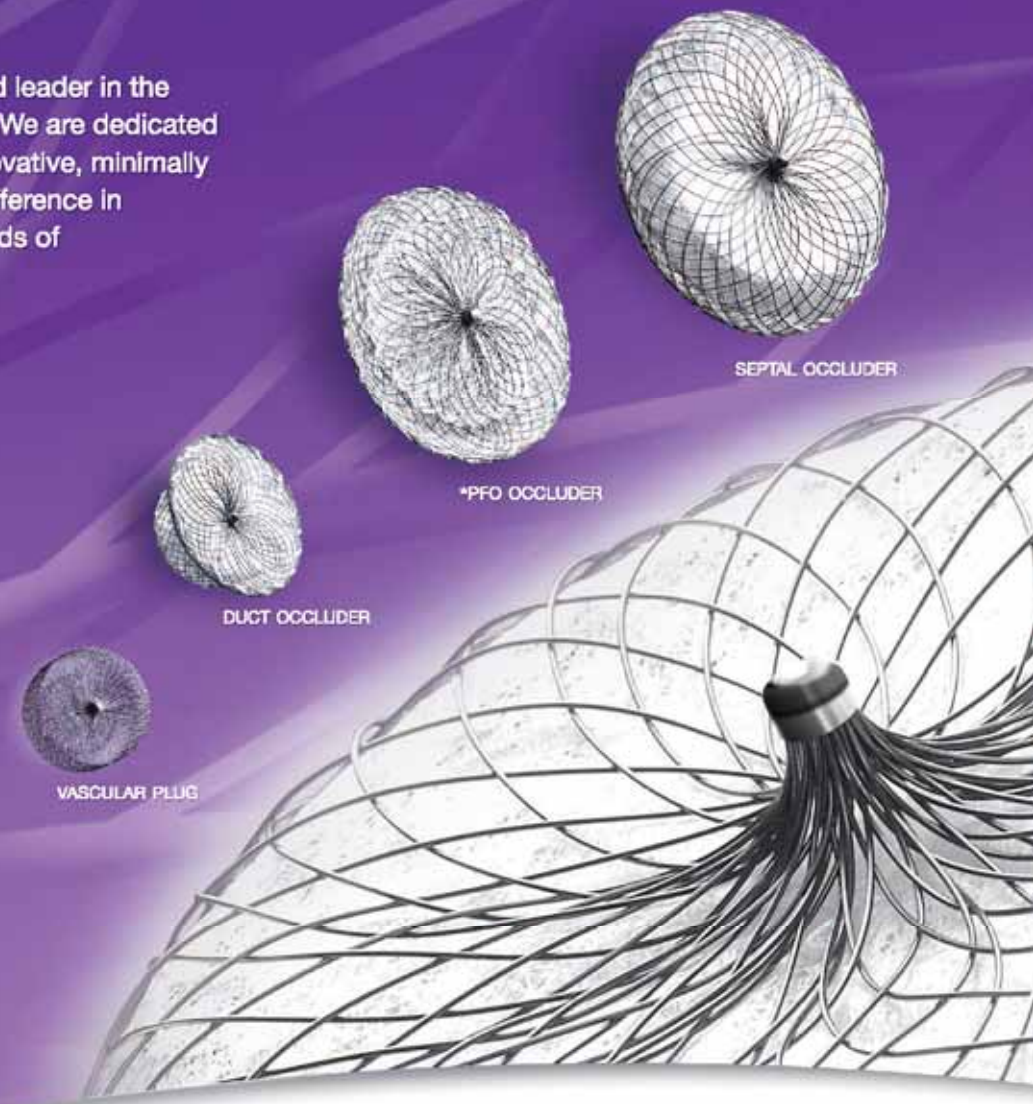

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(VSD), aortic valve stenosis, mitral valve abnormalities, Hypoplastic Left Heart Syndrome (HLHS), Truncus Arteriosus (TA), rare types of Double Outlet Right Ventricle (DORV), among others. It is also associated with certain genetic syndromes most notably Turner's Syndrome.

Current Approaches to Treatment

Treatment of aortic coarctation began with surgical repair in 1945.[1] This resulted in an immediate reduction in coarctation mortality from approximately 70% untreated to approximately 35% with surgical treatment, then later with 12% mortality reported in longer term studies.[2] Surgery prevailed as the only form of treatment until the mid 1980s when balloon angioplasty was introduced as an alternative to surgery.[3] Stent treatment of aortic coarctation began in early 1990 and has since become the preferred treatment for selected patients in many centers.[4] Interestingly, despite over 200 publications spanning two decades describing the successful results of catheter-based treatment of aortic coarctation, including many comparing their results to those reported in surgical series, the mode of treatment for native aortic coarctation remains intensely controversial at many congenital heart centers. An informal survey of over 40 congenital heart center Websites on the internet, revealed almost half stated that "surgical repair is recommended" without any mention of catheter-based treatment alternatives!

Post-operative recurrent coarctation continues to occur at variable but significant rates. Despite 60 years of coarctation surgery using a variety of techniques, there has been little in the way of meaningful surgical innovations that have resulted in any significant change in the long term outcomes for patients with aortic coarctation. After surgical repair approximately 20% of patients will eventually requiring further treatment for early or late recurrent aortic coarctation.[5] Even in the remaining 80% fortunate enough to remain "asymptomatic" 20 years after surgical repair, there is an increased risk of cardiovascular complications including: systemic hypertension, heart failure, myocardial infarction, aortic rupture, and cardiovascular accidents.[6] Whether this increased long term risk of cardiovascular disease is related to incompletely treated coarctation from residual long standing (even mild) obstruction, either in the proximal arch or at the surgical repair site or from some inherent cardiovascular predisposition remains to be determined. Once recurrent coarctation has occurred after surgery, the treatment using catheter-based techniques is the unanimous recommendation.

The treatment of native aortic coarctation, however, remains the subject of continuous debate. The age of presentation appears to be a deciding factor for many in selecting the recommended treatment modality. For patients presenting with aortic coarctation in the newborn period, often with an open ductus arteriosus, the majority of centers recommend surgery based on the perception that limited catheter-based treatment options exist for this subset of patients. Despite this bias, palliative balloon angioplasty has been successfully performed in this setting. The bias against balloon angioplasty to treat newborn aortic coarctation includes assumptions that the ductus cannot be concomitantly closed without compromising the coarctation angioplasty site, that recurrence rates are higher with balloon angioplasty, and even that the risk of pseudoaneurysm formation is unacceptably higher. These conclusions are based on multiple factors, some fact-based and others not, including personal interpretation of published data, but more commonly personal and institutional experience with individual patients. Yet, surgical repair of aortic coarctation in this group of patients continues to yield less than optimal outcomes with as many as one third suffering from early recurrence within six to eight weeks after repair and requiring an early second intervention (usually catheter-based). It is important to realize that, to date, there has never been a randomized clinical trial to scientifically compare surgery to catheter-based treatment in any age group. Simply assuming that the treatment modality that has been around the longest is the best, is clearly scientifically unsound. Consequently, it is reasonable to conclude, at least for this group of aortic coarctation patients, that definitive therapy currently does not exist. Without doubt, this is a group for which new innovative therapeutic approaches are needed (see below).

The treatment of native aortic coarctation outside the newborn period stands out as the group of patients for which cardiovascular specialists remain the most deeply divided.

With surgical repair arriving earliest as the established "first kid on the block," catheter-based treatment has had to prove itself in the setting of the potentially flawed surgical superiority assumption. Again, while case series after case series, line up on either side of the aisle, there is no clear winner. While it is evident from an objective read of the available literature that equivalent acute and long term results can be achieved by either surgical or catheter-based approaches, superiority of either approach has not been

Figure 2. The CP Stent (NuMED, Hopkinton, NY) shown in its unexpanded configuration. It is composed of 0.013 platinum/iridium wire that is arranged in a zig pattern, laser welded at each joint and over brazed with 24k gold to resist fracture. It allows expansion from 8.0mm to 24.0mm vessel diameters. The Covered CP Stent consists of the bare CP Stent with the addition of an expandable sleeve of ePTFE attached on the outside (not shown).

convincingly proven with the possible exception of catheter-based treatment in post-operative recurrent coarctation. Fortunately, there may soon be some scientific relief from this perennial debate. Recently a consortium group, founded by Tom Forbes, MD called the Congenital Cardiovascular Interventional Study Consortium (CCISC) 7 plans a multi-center prospective study of the outcomes of surgical compared with catheter-based treatments. Although undoubtedly a step in the right direction, a randomized clinical trial format would likely yield the most convincing data.

Emerging Innovative Treatment Strategies

A. The Role of Covered Stents

The use of intravascular balloon expandable stents is the most recent strategy added to treatment of aortic coarctation. The experience with treating both native and recurrent aortic coarctation has increased dramatically since the early 1990s.[8] In one of the most recently published series comparing stenting to balloon angioplasty for treatment of discrete native aortic coarctation in adolescents and adults, Sousa, JE, et. al,[9] reported improved gradient reduction (99% vs. 87%) and greater coarctation site diameters (16.9mm vs.12.9mm) for the stent group. Stents used in the study included: Palmaz XL (Cordis, Miami, FL), the CP bare metal stent, and CP covered stent (NuMED, Hopkinton, NY). At one year follow-up, durable gradient reductions and blood pressures were found equivalently in both groups, however, the stent group had a significantly smaller percent residual stenosis (6.1% vs. 15.6%). There has been much interest recently in the use of covered stents and, in fact, many centers outside the U.S. describe using covered stent grafts as first line treatment for aortic coarctation. In a recent series by Ewert P, et al,[10] the results of 36 patients with both native and recurrent aortic coarctation treated with the bare metal and covered versions of the CP stent (NuMED, Hopkinton, NY) are reported from the Berlin heart center. The CP stent is a platinum iridium alloy stent with a zig-zag strut pattern, laser welded at selected joints with the joints brazed with 24k gold to prevent joint fracture (Figure 2). The covered version adds an expandable sleeve of extracardiac polytetraflluoroethylene (ePTFE) adhesively bonded to the outside of the bare

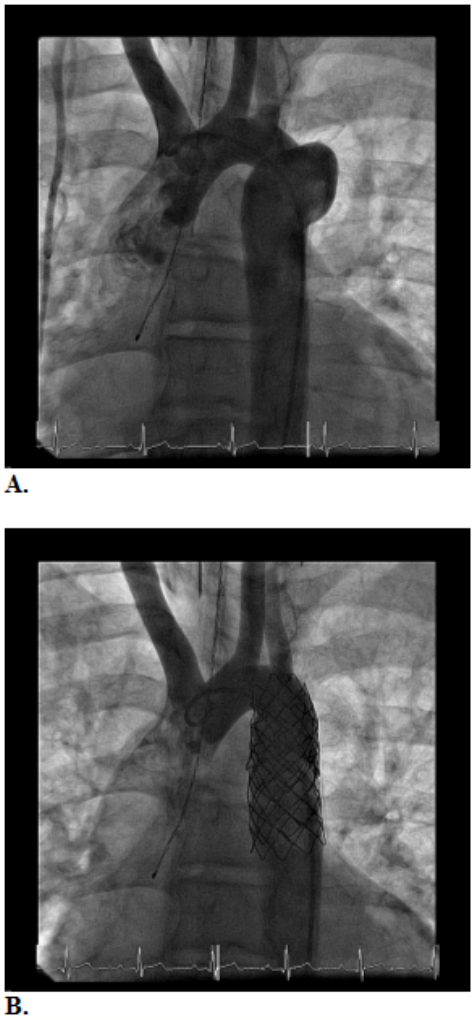

Figure 3. Pre (A) and Post (B) angiograms demonstrating a recurrent post surgical aortic coarctation in a 15 year old male associated with a significant pseudoaneurysm. The coarctation repair was performed using a primary resection with end to end reanastomosis technique at age one month. The pseudoaneurysm and the recurrent coarctation are simultaneously treated using two overlapping ePTFE covered CP stents (NuMED, Hopkinton, NY). Note: after implantation of the stents (B), the recurrent aortic coarctation is eliminated and the pseudoaneurysm is isolated from the neo-aortic lumen).

Figure 4. Magnesium absorbable metal stent (Biotronik, Bulach, Switzerland) constructed of absorbable magnesium alloy. It is balloon expandable. The stent is currently produced only for investigation use in 3 and 3.5mm diameters with a length of 10 & 15mm.

metal stent. Importantly, the stents are MRI compatible. Twelve of the 36 patients in the Berlin series had the covered CP stent implanted to treat aortic coarctation with one of those to concomitantly treat a pseudoaneurysm. Arterial pressure gradients decreased from a mean of 33mmHg (range 20-80mmHg) to a mean of 5mmHg (range 0-10mmHg). Despite the requirement for a large introducer sheath (10-14 Fr), patients weighing as little as 28 kg were successfully treated without significant femoral artery complications. Contemporary absorbable suture-based arterial closure devices were used to reduce the incidence of re-bleeding and hematoma formation.

In the US, the CP stents, in both its bare metal and ePTFE covered versions are not FDA approved. The covered stent has been implanted in humans in the context of a small number of registry patients predominately to treat acute aortic perforations ('emergency use') and for treatment of patients with aortic pseudoaneurysms associated with recurrent post operative coarctation. At Children's National Heart Institute, we have successfully treated a small number of patients with the covered CP stent to repair late recurrent aortic coarctation associated with pseudoaneurysm (Figure 3). Use of this unapproved stent requires FDA compassionate use approval obtained prior to stent implantation. Presently, however, requests to the FDA for further compassionate use of this stent have been disapproved. The time has come for a formal IDE study of the CP stents and plans are underway to launch a multi-center IDE clinical trial (personal communication, Rich Ringel, MD, Johns Hopkins University).

B. Absorbable Metal Stent

Thus far, due in large part to size limitations of the conventional balloon-expandable metal stent profiles, stenting has been rarely used in patients under 1 year of age. An additional disadvantage is the need to perform subsequent further expansions of the permanent metal stent to accommodate for patient growth. This may be about to change with the advent of a new absorbable metal stent. The Magnesium Biocorrodible Stent (Biotroniks, Bulach, Switzerland) is an innovative stent made of a magnesium alloy (WE43) that also contains Zirconium (<5%), Yttrium (<5%), and rare earths (<5%). The stent is laser-cut from a single tube of magnesium alloy (Figure 4). Although the magnesium alloy is not radio-opaque, two markers on the delivery catheter assist with precise positioning. The stent is completely MRI compatible. Current versions of the stent can be delivered through a 5 French sheath when there is a relatively straight course as in the case of the distal aortic arch. Preclinical animal studies have shown the stent to be bioabsorbable largely through a process of local corrosion without a significant inflammatory cellular effect. Interestingly, the magnesium appears to exert some inhibitory effect on smooth muscle cell ingrowth yet allowing for rapid homogenous neo-endothelialization of the luminal stented surface.[11] It appears from preclinical studies that the time course for the corrosion is approximately 2-3 months with minimal stent recoil and good circumferential stability for at least 4 weeks.[12]

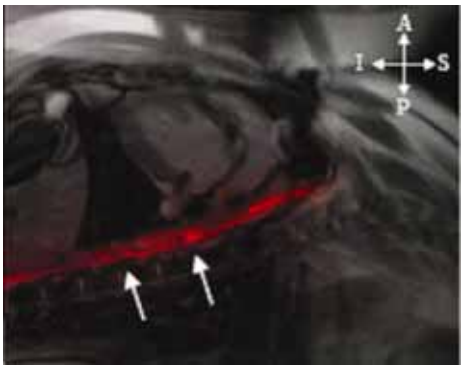

Figure 5. Use of the "active" Intercept guidewire in the aorta (Surgi-Vision, Columbia, Maryland) to enhance visualization of the wire course within the aorta in preparation for rtMRI stenting (Note: the wire has been randomly assigned the red color.). Reprinted with permission. See end of this article.

Thus far, the Magnesium stent has been studied in humans to treat peripheral vascular disease where preliminary studies presented at the EuroPCR 2005 meeting reported it 94% effective in lower limb salvage with 79% patency rates at 6 months follow-up. The first pediatric use of this novel stent was recently reported by Zartner P, et al[13] in a unique case of an intra-operative stenting of the left pulmonary artery after accidental surgical ligation of the LPA instead of the intended patent ductus arteriosus. Magnesium blood levels remained well below the clinically toxic levels, despite the small size and abnor-

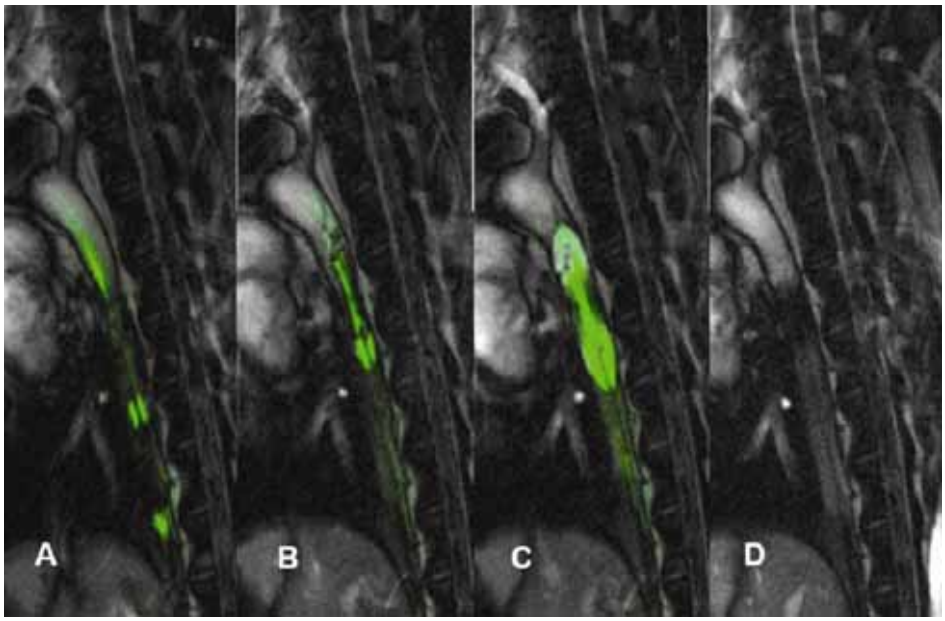

Figure 6. Stent delivery sequence using rtMRI. (A) Stent/balloon advancing over "active" guidewire. (B) Positioning stent within pre-determined MRI defined tissue landmarks. (C) Balloon inflation using Gd-DTPA (5mM). (D) Fully expanded CP stent in coarctation. (Note: "shielding" artifact darkens stent portion of aorta after active wire is removed.). Reprinted with permission. See end of this article.

mal renal function of this preterm infant (1.7 kg). The LPA was angiographically patent at 33 days follow-up and the proximal vessel had returned to a more anatomically neutral curvature presumably from degradation of the metal stent. Clearly, much more experience is necessary, however, the potential use of this new technology to treat newborn aortic coarctation is of great interest, in that it could potentially overcome many of the limitations of permanent metal stent implantation.

Innovative Imaging: Real-time MRI guided aortic coarctation treatment

The use of real-time MRI (rtMRI) to guide interventional cardiovascular procedures in patients with congenital heart disease is clearly on the horizon.[14] The feasibility of ASD closure as well as trans-septal puncture in animals have both been demonstrated.[15][16] Our collaborative research group (Cardiovascular Branch , N.I.H. and Children's National Heart Institute) has recently reported a preclinical study in which we used rtMRI to guide the stent treatment of an animal model of recurrent post-surgical aortic coarctation in a customized combination Xray-MRI catheterization laboratory (Miyabe, Siemens) setting.[17] Thirteen juvenile NIH miniswine (23-38 kg) underwent primary stent treatment of surgically created aortic coarctation using rtMRI guidance. The MRI compatible bare metal CP platinum-iridium stent was implanted using the BIB balloon ((NuMED, Hopkinton, NY) over an FDA approved MRI "active" guidewire called the Intercept (Surgi-Vision, Columbia, MD) which incorporates an MRI antennae into a guidewire. The use of the active guidewire allows unique color-coded definition of the wire in the gray scale MRI image for reliable visualization of wire/catheter position in real-time (Figure 5). Balloon and stent positioning was made possible by using Gd-DTPA to inflate the balloon, creating visible small "dumbbells" which enhanced MRI visibility (Figure 6). Stents were successfully deployed in all 13 animals. Typical results, with conventional reference X-ray angiographic images are shown in Figure 7. All coarctation peak systolic gradients were reduced to less than 5mmHg. In four animals, intentional balloon over-dilation was then performed to the point of aortic rupture with near instantaneous identification of the vessel wall compromise visible by rtMRI. The potential benefits of rtMRI are significant, including avoidance of the risks of ionizing radiation to the patient and staff, plus lack of need for wearing heavy lead aprons. The most striking benefit, however, is the ability to visualize both the intravascular space and the surrounding tissue within the same imagining modality. This type of image hybridization yields particular benefits including the ability to characterize abnormalities in the vessel lumen and vessel wall plus rapidly identify perforation with extravasations that may develop giving the potential for more immediate intervention. There are however, disadvantages that need to be overcome, one of the most notable being the high level of noise contamination in the rtMRI environment presenting significant communication and logistic challenges.

Conclusion

The treatment of coarctation of the aorta continues to challenge us and the various management strategies continue to be vigorously debated. Clearly, the time has come to take a new look at the treatment of aortic coarctation. Not only should this include the use of new device technologies, but also new hybrid imaging tech-

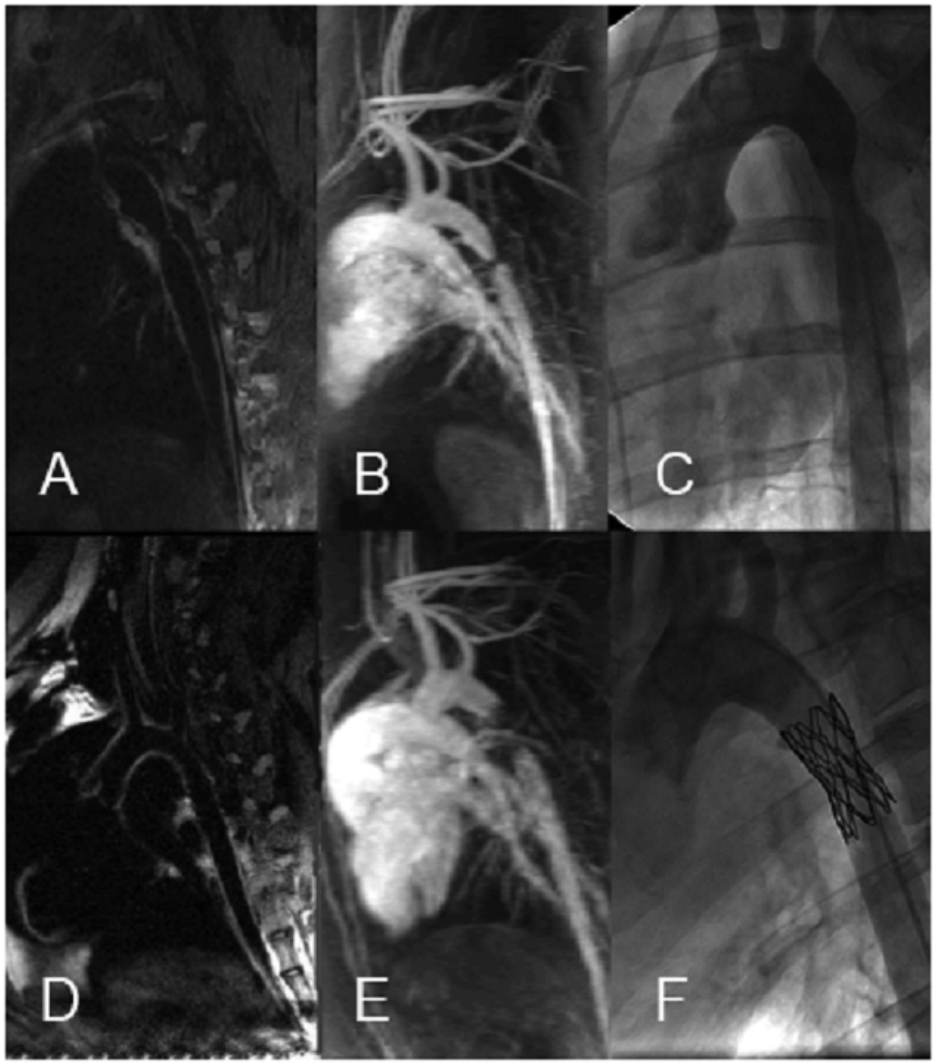

Figure 7. Surgically created aortic coarctation in swine before (A-C) and after stenting (D-E) using rtMRI. Although there is significant shielding artifact with standard contrast-enhanced MRA (B and E), with DIR-FSE MRI imaging, the so called "black blood" technique, the aortic lumen is well seen despite the presence of the stent (D) (Note: C and F are conventional X-ray angiograms for reference.). Reprinted with permission. See end of this article.

nologies. Finally, the time has come for us to stop comparing case series from the sidelines and come out onto the scientific "field" and conduct randomized clinical trials comparing surgery and catheter-based interventions, in order to discover the best and most definitive therapies for our aortic coarctation patients.

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Michael C. Slack, MD, FACC, FSCAI, FAAP
Director, Cardiac Catheterization Laboratories & Interventional Therapies
Children's National Heart Institute at Children's National Medical Center
Co-Director, Adult Congenital Interventional Catheterization Program
Washington Hospital Center
Washington, DC USA
Assistant Professor of Pediatrics
George Washington University Medical Center

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By Gianfranco Butera, MD, PhD, FCSAI; Massimo Chessa, MD, PhD, FSCAI; and Mario Carminati, MD, FSCAI

The oldest international workshop on interventional pediatric cardiology has reached its 5th edition. In fact, Dr. Carminati proposed holding a meeting with a special attention to daily practice in the field of pediatric cardiac catheterization and intervention in 1996 when he was the Head of the Pediatric Cardiology Department in Massa.

As time passed by, the meeting has gained widespread attention and reputation all over the world and it is nowadays, along with the PICS symposium, the most important meeting on cardiac catheterization and intervention in the field of congenital heart disease.

"The next workshop will be held in San Donato, Italy, from 28th –31st of March 2007. Until then you can visit the website (www.workshopIPC.com) where you can consult online for free all the lectures, and where you can buy the Workshop's DVD with lectures and live cases."

The 2005 meeting was held in San Donato Milanese, Italy from the 31st of March to the 2nd of April with more than 400 attendees from 28 countries, including Asia, Africa and America. Furthermore, trainees from US also attended the meeting.

More than 40 lectures were given during the workshop by a faculty of 37 leaders in the field coming from all over the world. These lectures are now fully and freely available online by connecting to the website of the workshop: www.workshopIPC.com. In this way, trainees, people interested in the field, nurses and even experienced pediatric cardiologists, have opportunity to access updated, state-of-the-art interventional techniques used in congenital heart diseases.

On the first day (31st of March), the opening session was dedicated to echocardiographic (TTE and ICE) imaging in ASD and VSD closure by Drs. Ludomirky, Hagler and Bass. During the second morning session Dr. Butera, Dr. De Giovanni and Dr. Hellenbrand described in detail techniques, tips and tricks concerning multiple ASDs and PFO closure, and problems and complications encountered in ASD closure. During the afternoon sessions Dr. Giusti and Dr. Benson gave all attendees interesting insights about PAIV (pulmonary artery-intact septum) and cutting balloons utilised in pulmonary branches stenosis. Dr. Szatmari shared his vast experience on PDA closure. The day concluded with a special session on cardiac problems in developing countries and Dr. Frigiola and Dr. Sidi reported on the unique human and professional challenges present when working in developing countries.

On the 1st of April, the morning session was about stents. Dr. Mullins spoke about how to choose the right stent, Dr. Wilson and Dr. Brzezinska-Rajszys reported tips and tricks in pulmonary arteries and aortic obstruction, respectively. Dr. Amin's speech was about complications in aortic coarctation and Dr. Witsenburg and Dr. Pongiglione reported their experience in stenting baffles and pulmonary veins.

Figure 1. Dr. Mario Carminati, Course Director.

During the afternoon session, Dr. Berger outlined how to proceed with interventional techniques in patients with residual defects after sugery, Dr. Chessa reported the vast experience of San Donato's Pediatric cardiology and GUCH team on the impact of interventional cardiology for the management of GUCH patients, Dr. Cheatham made un update on hybrid procedures for treatment of complex lesions. Finally, the day was concluded with the controversial session

Figure 2: Left and right: Dr. Massimo Chessa and Dr. Gianfranco Butera, Course co-directors. Above in the middle: Dr. Mario Carminati, Course Director.

on transcatheter versus surgical closure of VSD's. A very distinguished panel of surgeons and cardiologists, leading people in the field (Prof. Anderson, Prof. Hijazi, Prof. DeLeval, Dr. Walsh, Dr. Menicanti and Dr. Carminati), reported the results of different techniques of congenital and post-infarction VSD's to all the attendees.

The last day (April 2nd) the sessions were dedicated to interesting cases of complications in the catheterization laboratory (Drs. De Giovanni, Qureshi, Gewillig, and Wilson), transcatheter valve treatment (Drs. Bonhoeffer, Hijazi, Cribier, and Ruiz) and to miscellanea (paravalvular leaks by Dr. Hijazi, retrieval techniques by Dr. Benson, embolization techniques by Dr. Weil). Furthermore, at the end of each session during the three days of the workshop, industry had the special chance to present their news and new products to all the attendees.

This interesting exchange is now fully available online on the website of the workshop.

During the workshop 10 very interesting live cases were performed in San Donato Milanese by Dr. Carminati, Dr. Chessa, Dr. Butera and their distinguished guests. Ten more cases were performed in London, Frankfurt, Leuven, Massa and Naples, connected by satellite with the congress venue. Particular interest was raised by the percutaneous closure of a mal-aligned VSD by Dr. Carminati, Dr. Butera and Dr. Bass, the implantation of a covered CP stent in a patient who had a previous implantation of a bare stent and who developed an intrastent aneurysm by Dr. Brzezinska-Rajszys and Dr. Chessa and the implantation of pulmonary valve by Dr. Bonhoeffer. Other interesting cases were the implantation of simultaneous stents in both pulmonary arteries (Dr. Qureshi, Dr. Walsh) , Plaato occlusion of the left atrial appendage (Dr. Sievert) and the use of different devices (Amplatzer, Starflex, Helex, Intrasept, Premere) for ASD or PFO closure (Dr. Sievert, Dr. Gewillig, Dr. Ruiz, Dr. Wilson).

Finally, there were three other interesting cases worth mentioning. First of all, a 5-year-old boy with a very large secundum ASD with absent aortic rim in whom a 24 mm device was chosen and implanted by Dr. Hellenbrand only after various attempts. A 50-year-old man with a severe aortic coarctation and very tortuous isthmus was treated by Dr. Benson with the implantation of a 5014 Palmaz stent. A 7-year-old girl with a perimembranous VSD and aneurysm was treated by Dr. Carminati, Dr. Butera, with the help of Dr. Ludomirsky who performed the echocardiographic evaluation. This was a very interesting case. In fact, during the maneuvers with the long sheath through the defect, the patient became severely desaturated Echocardiographic evaluation showed a restrictive movement of the tricuspid valve, a PFO bulging towards the left atrium and a Right-to-Left shunting. Long sheath was interfering with the tricuspid valve giving a severe obstacle to right ventricle inflow. We decided to remove everything and to start again. The second time the procedure was uneventful. This case as all live cases, taught a lot to everybody, faculty members included.

Finally, attendees had the opportunity to travel to a different century during the Gala Dinner that was held in a Middle Age Castle near Milan. During dinner people coming directly from middle ages animated the atmosphere with fires, plays

and very delightful Italian dishes. All participants had an unforgettable night.

The next workshop will be held in San Donato, Italy, from 28th –31st of March 2007. Until then, you can visit the website (www.workshopIPC.com) where you can consult online for free all the lectures, and where you can buy the Workshop's DVD with lectures and live cases. This is an incredible tool for teaching purposes and an excellent update on the state of the art of the field for your department. Hoping to meet you during the next workshop.

Yours Sincerely,

Dr. Gianfranco Butera
Dr. Massimo Chessa
Dr. Mario Carminati

~CCT~

Corresponding Author:
Gianfranco Butera , MD, PhD, FCSAI
Pediatric Cardiology and GUCH unit
Policlinico San Donato
Via Morandi,30
San Donato Milanese (MI) – Italy
Tel+39 02 52774328
Fax +39 02 52774459

gianfra.but@lycos.com

Massimo Chessa, MD, PhD, FCSAI

Mario Carminati, MD, FCSAI

MAY SYMPOSIUM FOCUS

The Society for Angiography and Interventions 29th Annual Scientific Sessions, Judkins Cardiac Imaging Symposium and Complex Coronary Complications (C3) Summit

May 10-13, 2006
Sheraton Chicago, IL USA
www.SCAI.org

A distinguished faculty will conduct a 4-day program that includes case review, lectures, comprehensive didactic sessions, interactive discussions, taped case presentations, and workshops. The Judkins Cardiac Imaging Symposium, will be conducted Wednesday, May 10, 2006.

The 29th Annual Scientific Sessions will provide physicians the opportunity to learn about many new aspects of interventional cardiology. The topics of the Annual Scientific Sessions are designed to:

~ Provide an overview of the challenges facing interventional cardiologists.

~ Review new approaches to non-surgical management of peripheral vascular disease.

~ Explore cutting edge technology in the field of interventional cardiology.

~ Discuss safety and efficacy of newly developed devices to improve early and late procedural outcome after coronary intervention.

~ Improve techniques through the use of small interactive workshops.

~ And more...

Program Committee: Ted Feldman, MD, FSCAI- Program Chair; David Kandzari, MD, FSCAI- Program Co-Chair; Ziyad M. Hijazi, MD, FSCAI - Congenital Heart Disease Program Co-Chair; Carlos Ruiz, MD, FSCAI - Congenital Heart Disease Program Co-Chair; Warren K. Laskey, MD, FSCAI - Judkins Cardiac Imaging Symposium Chair; Jeffrey J. Popma, MD, FSCAI - C3 Summit Chair; Barry F. Uretsky, MD, FSCAI - President, SCAI; Bonnie H. Weiner, MD, FSCAI - Development Committee Chair

CONGENITAL CARDIAC TOPICS AT 42ND ANNUAL MEETING OF THE SOCIETY OF THORACIC SURGEONS

By Marshall L. Jacobs, MD

Topics of interest and importance to congenital heart surgeons and pediatric cardiologists alike made up a considerable portion of the total scientific program of the recent STS meeting in Chicago. Among the podium presentations during the plenary sessions was the Maxwell Chamberlain Memorial Award winning paper entitled, "Determinants of Left Ventricular Dysfunction after Anatomic Repair of Congenitally Corrected Transposition of the Great Arteries," presented by Victor Bautista-Hernandez from Children's Hospital Boston. The authors reviewed their experience with anatomic repair of ccTGA since 1992, encompassing 44 patients. All had undergone atrial baffle procedures, which were combined with a Rastelli procedure (23 patients) or an arterial switch procedure (21 patients). Early mortality was 4% (n=2) with one late death. Follow up was from one week to 12.4 years (median 2.7 years). Left ventricular function tended to deteriorate in patients with pacemakers (p=0.047). Patients with a Rastelli procedure were more likely to have worse postoperative left ventricular function compared to their preoperative state (p=0.046), while those receiving an arterial switch were not. The potential benefit of resynchronization pacing strategies highlighted the discussion.

Marshall Jacobs presented the Report of the 2005 STS Congenital Heart Surgery Practice and Manpower Survey. This study identified 248 congenital heart surgeons at 121 centers in the United States and 15 at eight Canadian centers. Ultimately, completed survey questionnaires were returned by 217 actively practicing congenital heart surgeons (more than 80% of the target group). Average age of respondents was 48.3+/-8.3 years; range 33 to 78 years. Ninety-five percent are males. Seventy-nine percent are graduates of American medical schools. Fourteen percent received their congenital heart surgery training outside of the U.S. or Canada. Fifty-nine percent perform exclusively congenital heart surgery. Roughly one third do fewer than 100 congenital cases per year, one third do 100 to 199, and one third do more than 200 cases per year. Eleven are in their first year of practice. Three surgeons anticipated retirement within one year of the survey, 25 within five years, and 40 more within ten years. At the same time, 38 fellows will complete post-graduate training this year at 28 centers, and 19 of them will be seeking positions in North America. While this is admittedly a one-year snapshot of the fellowship training process, it appears that the number of young individuals preparing for careers in congenital heart surgery is, at this point, larger than the number who will be leaving the workforce through retirement. This disparity may in fact be lessened by the steadily increasing number of individuals with congenital heart disease surviving to adulthood and needing life-long care. The discussion focused on the establishment of appropriate plans for the training of congenital heart surgeons, and the establishment of a certificate of subspecialization.

Cardiologist William T. Mahle of Atlanta was an invited speaker at the "Congenital Surgical Forum." In a lecture entitled "A Contemporary Understanding of Neurologic Outcomes after Neonatal Heart Surgery," Dr. Mahle shared his view of the complex interaction of preoprerative, operative and postoperative events and their potential impact on neurodevelopmental outcomes of children with congenital heart disease. He emphasized that "neurodevelopmental deficits are the most common long-term morbidity for children and adults with congenital heart disease. While impairments in cognitive function are generally mild, a number of neurodevelopmental domains tend to be disproportionately affected in this population. Children and young adults who have undergone surgery for congenital heart disease have been found to have significant problems with attention, impulsivity, language skills, and visual-motor integration."[1]

He reviewed recent investigations that have helped us to understand the factors that predispose these children to later developmental deficits, pointing out that, "Some of the strongest predictors of later developmental deficits – such as associated genetic anomalies, are not directly related to surgical intervention. In addition there appears to be a critical period immediately following neonatal surgical intervention where poor hemodynamic status may lead to subsequent developmental deficits." He suggested that, "Efforts to optimize the hemodynamic status following newborn heart surgery may result in improved school-age developmental outcomes." He also discussed ongoing efforts to reduce neurologic injury during cardiac surgery by modifying circulatory support and bypass techniques. "Some of these strategies, such as optimizing hematocrit, have been found to be beneficial in randomized trials."[2] He said that other strategies have been proposed as being potentially neuroprotective, though to date

they have not been critically evaluated. One such technique, continuous selective cerebral perfusion, is increasingly being utilized in the clinical realm. " While it's efficacy has been supported by some animal studies, it has not yet been found to be of benefit in clinical studies." Dr. Mahle briefly cited data from a recent report from Cincinnati Children's Hospital Medical Center, wherein brain magnetic resonance imaging revealed that postoperative cerebral ischemic lesions were frequent, occurring in the majority of infants after the Norwood operation, despite the use of regional cerebral perfusion. In comparison to preoperative studies, postoperative NMR imaging demonstrated new or worsened ischemic lesions in 73% of patients, with periventricular leukomalacia and focal ischemic lesions occurring most commonly. Results were compared with preoperative, intraoperative, and postoperative risk factors to identify predictors of neurologic injury. Prolonged low postoperative cerebral oximetry (<45% for >180 minutes) was associated with the development of new or worsened ischemia on postoperative magnetic resonance imaging (P=.029).[3] In closing, Dr. Mahle advised that "A critical appraisal of both intraoperative and postoperative interventions is warranted in order to improve long-term developmental outcome for our patient population." These remarks during the first day of the program, were followed during the next two days by several papers that addressed the very same controversy, shedding some new light and raising still more questions.

Later in the Congenital Cardiac Surgical Forum, Dr. Frank Pigula of Children's Hospital Boston presented a paper entitled "Regional Low Flow Perfusion Versus Circulatory Arrest in Neonates: One-Year Neurodevelopmental Outcome." Thirty one infants with HLHS or related lesions underwent surgery with either Deep Hypothermic Circulatory Arrest or Continuous Regional Low Flow Perfusion as the principle support technique. Neurodevelopmental outcomes were assessed using Bayley Scales of Infant Development. Mental Development Index (MDI) and Psychomotor Development Index (PDI) were similar in the two groups. PDI scores were lower than MDI scores in both groups. Intraoperative hematocrit, Circulatory Arrest time, and duration of ICU stay and hospital stay did not correlate with MDI or PDI. The authors concluded that Regional Low Flow Perfusion is a safe technique, but failed to demonstrate any advantage relative to Hypothermic Circulatory Arrest with regard to neurodevelopmental outcome measured at one year. Discussion of the paper focused on the potential limitations related to sample size, possible selection bias, and the fact that all patients had at least a few minutes of hypothermic circulatory arrest. Dr. Edward Bove of the University of Michigan commented that he will be presenting the interval results of a larger randomized trial comparing the two circulatory support techniques at the upcoming meeting of the American Association for Thoracic Surgery. He indicated that the results that he will be presenting are similar to those reported by Dr. Pigula, with comparable neurodevelopmental outcomes for the two groups.

"These excellent scientific presentations only emphasized how much more there is to learn concerning the circumstances and determinants of neurologic injury associated with congenital heart disease and congenital heart surgery."

In a separate session, Dr. Robert L. Hannan of Miami Children's Hospital gave a paper entitled "Complex Neonatal Single Ventricle Palliation Using Antegrade Cerebral Perfusion Instead of Deep Hypothermic Circulatory Arrest." He and his colleagues adopted the use of Antegrade Cerebral Perfusion in 2001. They have observed improved outcomes with respect to 30 day survival and one year survival during this time period, as compared to patients operated between 1995 and 2001. The survival benefit was less evident for patients stratified to a high risk group (weight < 2.5 kg., associated cardiac lesion). No formal assessment of neurodevelopmental outcome was undertaken. The authors conceded that the change in bypass support technique adopted in 2001 was coincident with several additional programmatic changes in the approach to complex neonatal surgery. The authors believe that Antegrade Cerebral Perfusion offers a survival benefit in their institution.

Finally, Dr. Guido Oppido and associates from the Orsola Hospital University of Bologna (Italy) gave a poster presentation entitled "Moderately Hypothermic Cardiopulmonary Bypass and Low Flow Antegrade Selective Cerebral Perfusion for Neonatal Aortic Arch Surgery." They argued that deep hypothermia could be avoided if selective cerebral perfusion is maintained, and thus performed neonatal aortic arch reconstruction with body temperature at 25 degrees C.

These excellent scientific presentations only emphasized how much more there is to learn concerning the circumstances and determinants of neurologic injury associated with congenital heart disease and congenital heart surgery.

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~CCT~

Marshall L. Jacobs, MD
Chief, Cardiothoracic Surgery
St. Christopher's Hospital for Children
Professor of Cardiac Medicine and Surgery
Drexel University College of Medicine
Philadelphia, PA USA
Phone: 215-427-5109
Fax: 215-427-3860

marshall.jacobs@tenethealth.com

JUNE SYMPOSIUM FOCUS

2006 International Symposium on the Hybrid Approach to Congenital Heart Disease (ISHAC)

June 29-30, 2006
Columbus, OH USA
www.hybridsymposium.com

Topics include:

- Design and Construction of Hybrid Suites and a Dedicated Program
- Hypoplastic Left Heart Syndrome
- Ventricular Septal Defect
- Stents
- Fetal Intervention and Therapeutic Ultrasound
- Live Case Presentations
- Hands-on Workshop

Symposium Objectives:

1. Define the Hybrid approach to congenital heart disease: Why do it? Who are the best patients? What type of procedures should be performed?

2. Discuss the design and utilization of a Hybrid Suite.

3. Review recent case histories of successful Hybrid Procedures and discuss future implications.

Course Directors: John P. Cheatham, MD and Mark Galantowicz, MD

Guest Faculty from North and South America, Europe, and Asia including Hakan Akintuerk, MD; Zahid Amin, MD; Kurt A. Amplatz, MD; Renato Assad, MD; Emile Bacha, MD; Lee Benson, MD; Philipp Bonhoeffer, MD; Redmond Burke, MD; Christopher Caldarone, MD; Qi-Ling Cao, MD plus others.

Sponsored by Children's Institute of Pediatric Education and Columbus Children's Research Institute

JUNE SYMPOSIUM FOCUS

2nd Toronto Symposium-Contemporary Questions in Congenital Cardiology: The Right Heart

June 10-13, 2006; Toronto, Canada
www.sickkids.ca/cardiologysymposium

Like last year, the overall theme of the meeting will be 'Contemporary Questions...' but this year focusing on 'The Right Heart.' Each session will focus on related topics, but will remain directly relevant to day-to-day practice of pediatric and adult congenital cardiology and surgery. The symposium has attracted a world class faculty of scientists, physicians, surgeons and allied professionals, ensuring the quality of this 'State-of-the-Art' Symposium. The title of each presentation is framed as a question, and the lecturers have one task; to answer it!

Each participant will receive a DVD, with video of the speaker and simultaneous PowerPoint presentation for each of the lectures. See the symposium website for a sample from last year's course DVD.

This year they will produce the second edition of the textbook 'The Right Heart' which will be available to attendees at half price.

Course objectives

- To bring together experts in the field of right heart diseases in children and adults.
- To explore the contemporary understanding of right heart development, physiology and pathophysiology in congenital and acquired heart disease.
- To encourage a multidisciplinary approach to the fetal, preoperative, perioperative and late postoperative management right heart problems.

MEDICAL NEWS, PRODUCTS AND INFORMATION

NMT Medical's MIST Study Indicates That Closing a PFO Has an Effect on Migraine

NMT Medical, Inc., designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of migraine headaches, stroke and other potential brain attacks, announced the results of its MIST (Migraine Intervention with STARFlex® Technology) study at the American College of Cardiology's 55th Annual Scientific, Late-Breaking Clinical Trials Sessions this March.

Drs. Peter Wilmshurst and Andrew Dowson, co-primary investigators of MIST, jointly presented the results. Dr. Wilmshurst is Consultant Cardiologist at Royal Shrewsbury Hospital, Shrewsbury, UK. Dr. Dowson is Director of the King's Headache Service, Kings College Hospital, London, UK

MIST, which was conducted in the United Kingdom, is the first prospective, randomized, double-blinded study to evaluate the effect of PFO (patent foramen ovale) closure on migraine headaches. NMT's proprietary PFO closure technology, STARFlex®, was exclusively used in the study.

The study, which screened 432 migraine with aura patients for a PFO, enrolled 147 patients into the study. A significant finding in the MIST study is that over 60% of those screened had a right to left shunt. Of those patients, almost 40% had a moderate or large PFO, six times greater than the general population.

Dr. Wilmshurst said, "With no prior randomized, double blind study to draw from, MIST was designed and primary endpoints were selected based upon a review and analysis of several previously reported device observational and migraine drug studies. Consistent with what was reported in the observational studies, we selected a challenging primary endpoint of 40% elimination in migraine headache at six months in the treatment group. Preliminary analysis of MIST data did not satisfy that endpoint, however, we are seeing a significant treatment effect and promising trend to support PFO closure with STARFlex® as a treatment option for certain types of migraine."

The MIST results indicated an approximate 37% reduction in migraine burden (number of headaches multiplied by the length, in hours of headache) in those patients who received a STARFlex® implant and a 17% reduction in those who received the sham procedure and no implant. This represents a statistically significant treatment effect. It also was reported that this variance appears to increase over time.

Dr. Dowson added, "For the first time we can see trends in a prospective study to suggest that PFO closure may be an effective way to treat certain types of migraine. The key now will be establishing the criteria that will help to determine which patients should be referred to the interventional cardiologist for further treatment."

John E. Ahern, President and CEO of NMT, said, "Although we were disappointed that MIST did not satisfy its endpoints, the study was designed to help demonstrate clinical relevancy and not to obtain a specific regulatory approval. The study has provided us with significant data that we intend to incorporate into our MIST II and MIST III studies."

NMT Medical is now recruiting participants for the MIST II Trial in the US. For more information on this trial go to: www.pfo-migraine.com. For more information about NMT Medical, visit www.nmtmedical.com.

Treatment of Down Syndrome In Mice Restores Nerve Growth In Cerebellum

Researchers at Johns Hopkins restored the normal growth of specific nerve cells in the cerebellum of mouse models of Down syndrome (DS) that were stunted by this genetic condition. The cerebellum is the rear, lower part of the brain that controls signals from the muscles to coordinate balance and motor learning.

The finding is important, investigators say, because the cells rescued by this treatment represent potential targets for future therapy in human babies with DS. And it suggests that similar success for other DS-related disruptions of brain growth, such as occurs in the hippocampus, could lead to additional treatments - perhaps prenatally - that restore memory and the ability to orient oneself in space.

DS is caused by an extra chromosome 21, a condition called trisomy - a third copy of a chromosome in addition to the normal two copies. Children with DS have a variety of abnormalities, such as slowed growth, abnormal facial features and mental retardation. The brain is always small and has a greatly reduced number of neurons.

A report on the Hopkins work with trisomic mice, led by Roger H. Reeves, PhD, professor in the Department of Physiology and the McKusick-Nathans Institute for Genetic Medicine at Hopkins, appeared in the January 24, 2005 issue of the Proceedings of the National Academy of Sciences (PNAS).

Reeves and his team used an animal model of DS called the Ts65Dn trisomic mouse to show that pre-nerve cells called granule cell precursors (GCP) fail to grow correctly in response to stimulation by a natural growth-triggering protein. This protein, called Sonic hedgehog (Shh), normally activates the so-called Hedgehog pathway of signals in these cells. These signals stimulate mitosis (cell division) and multiplication of the cells in the growing, newborn brain, according to the researchers.

The GCP originate near the surface of the cerebellum and migrate deeper into the brain to form the internal granule layer (IGL), the researchers note. Therefore, the team studied the growth of the cerebellum in Ts65Dn trisomic mice at seven time points -- beginning at birth - to deter-

mine when GCP abnormalities first occurred. The IGL was similar in both normal and Ts65Dn mice at birth, but was significantly reduced in the trisomic mice by day six after birth.

Furthermore, the researchers found that the reduced number of GCP in these mice compared to normal mice was not due to cell death; rather, there were 21% fewer GCP undergoing cell division in Ts65Dn mice. This suggested that stimulating these cells might restore normal numbers of GCP, according to Reeves.

The Hopkins team then showed in test-tube experiments that GCP from the brains of Ts65Dn mice had a significantly lower response to increasing concentrations of a potent form of Shh called ShhNp. That is, increasing concentrations of ShhNp triggered increasing rates of mitosis. Despite their lower response, trisomic cells showed a dose response with increasing ShhNp concentrations.

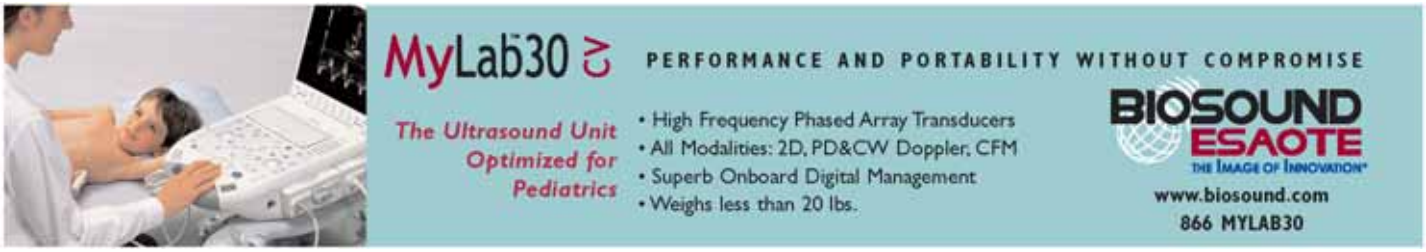
"The fact that trisomic GCP responded to stimulation of their Hedgehog pathway even in a reduced way is significant," says Reeves, the senior author of the PNAS paper. "It suggested that these cells could be stimulated to reach normal levels of cell division by artificially increasing their exposure to Hedgehog growth factor."

Based on this initial discovery, the team injected into newborn Ts65Dn mice a molecule that stimulates the Hedgehog pathway to trigger cell growth. Treatment of the trisomic mice with this molecule, called SAG 1.1, restored both the numbers of GCP and the number of GCP cells undergoing mitosis to levels seen in normal mice by six days after birth.

"The normal mouse cerebellum attains about a third of its adult size in the first week after birth," says Randall J. Roper, PhD "This is the time during which SAG 1.1 treatment of Ts65Dn restored GCP populations and the rate of mitosis of those cells," he adds. "However, further research is needed to determine if it's possible to reverse the effects of trisomy in other parts of the DS mouse." Roper is a postdoctoral fellow in the laboratory of Reeves and a co-first author of the PNAS paper.

The other authors of the Hopkins paper include Drs. Laura L. Baxter, Nidhi G. Saran, Donna K. Klinedinst, and Philip A. Beachy. Baxter is a co-first author of this paper and is currently at the National Human Genome Research Institute of the National Institutes of Health (Bethesda, MD, USA). This work was supported in part by the Public Health Service. P.A.B. is a Howard Hughes Medical Institute investigator.

For more information: www.hopkinsmedicine.org.



CAMP BRAVEHEART - EVERY CHILD'S POSSIBILITIES ARE ENDLESS

By Cheryl White and Michelle Harmon

Ansley Flynn was born with severe congenital heart defects. Her parents, Kathy and Roger, wanted Ansley to have as much of a normal life as possible. Unfortunately, they knew that Ansley would never be able to attend a regular summer camp, so they decided to create a camp specifically for children with cardiac problems. During the first year of camp, the Flynn family and a few volunteers, took about 20 children for a fun-filled weekend at camp. Much has changed since that first year at "Heart Camp," which was later named "Camp Braveheart." Since 2000, Children's Healthcare of Atlanta has organized and facilitated the camp in Ansley's memory. Ansley lived to the age of 10, and enjoyed camp every year she could. Her family takes great comfort knowing that so many children enjoy the "normal" summer camp experience just as she once did.

Children ages 7 to 18 can attend the camp at no cost, through the generous support of private foundations, corporations and individuals. Campers enjoy swimming, horseback riding, rock wall climbing, archery, biking, arts & crafts, and more. Camp volunteers include doctors, nurses and other healthcare professionals who provide medicine and treatment when needed. Parents can be rest assured that their child is exploring life in a safe and caring place. Community volunteers serve as counselors and activity leaders to help each child build friendships and share lasting memories. Each year, the interest in camp has increased. In 2006, Camp Braveheart will host about 120 campers for a week-long session.

Camp Braveheart is many things to these special children. It is a safe place. It is a place where their doctors and nurses can interact with them outside of the hospital - to get to know them as kids, and not just as patients. At camp, kids are free to be themselves. They are no longer the child who can't do what the other kids are doing, or the child with all the scars. It's a place where all the kids take medicine, need frequent rest breaks, and know what it's like to have been in the hospital. At Camp Braveheart, campers build friendships and make memories to last a lifetime.

"Children ages 7 to 18 can attend camp at no cost through the generous support of private foundations, corporations and individuals."

A few years ago, a teenage camper, despite being ill and weak, attended camp, simply because she was passionate about it, and looked forward to it all year. She had to be pushed in a wheelchair to all the activities, and often had to go to her cabin to lie down. The girls in her cabin took turns pushing her wheelchair, and skipping activities to be with her so she would not feel lonely and left out. That was her last year at camp, and though she was sick, she had a great time and her cabin mates were glad to share that special time with her. Campers at Camp Braveheart have a true sense of compassion for each other.

Every year as new campers arrive, the staff and volunteers spend time with the parents and children who have been through surgeries and hospitalizations together. By the first mealtime, new campers typically feel comfortable, and are already making new friends. Soon after, campers are having the time of their lives while enjoying being independent and doing things that they have never done before. The next year, those once-scared little campers are supporting the next group of new campers, showing them all the fun activities at camp.

Giving these children the chance to experience a "normal camp" builds their confidence outside of camp. Many parents are delighted that their child returns home feeling more confident and secure. The children learn that just because they have "special hearts," does not mean that they can't accomplish great things. Every child needs to feel special—a child with congenital and acquired heart defects is no different. At Camp Braveheart, the only requirements are to laugh, play, grow and explore.

Facts about Camp Braveheart

In 2005, Camp hosted 114 campers who were either affected by heart disease or were heart transplant recipients —an increase in attendance of 40% over the previous year.

Camp is held at Camp Twin Lakes in Rutledge, GA. Camp Twin Lakes is the only camping facility in Georgia for children with serious illnesses and other special needs. Visit their Web site at www.camptwinlakes.org.

Camp volunteers include Children's Healthcare of Atlanta staff, nurses, physicians and caring members of the community. It is staffed 24 hours a day with medical professionals from Children's. For more information about Camp Braveheart, visit www.choa.org/cardiology.

~CCT~

Corresponding Author:

Cheryl White
Program Development Coordinator,
Cardiac & Transplant Services
Director, Camp Braveheart
Children's Healthcare of Atlanta

cheryl.white@choa.org

Michelle Harmon
Administrative Coordinator
Camp Braveheart
Mother of Zoe Harmon, (Heart Patient and Camper)

michelleharmon@bellsouth.net

CALL FOR RESEARCH PROPOSALS

The Children's Heart Foundation Calls Upon All Investigators to Submit Clinical Research Proposals on Congenital Heart Disease by June 2, 2006

The Medical Advisory Board of The Children's Heart Foundation will review these proposals in late Fall 2006. Those recommended will receive funding in December 2006.

Investigators should contact The Children's Heart Foundation for an application, or download an application from the website: www.childrensheartfoundation.org

Thirty-five copies of each grant with an abbreviated CV are required, including any published work in the research proposal area. If sending copies via US mail, please send to:

The Children's Heart Foundation
P.O. Box 244
Lincolnshire, IL 60069-0244

If sending copies via FedEx, UPS, etc., please send to:

The Children's Heart Foundation
15801 W. Aptakisic Road
Prairie View, IL 60069-4309

For more information, please visit them online or contact:

The Children's Heart Foundation
Phone (847) 634-6474
Fax (847) 634-4988
www.childrensheartfoundation.org

CONGENITAL CARDIOLOGY TODAY

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iE33 – INTELLIGENT ECHO FOR EVERY STAGE OF LIFE

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.

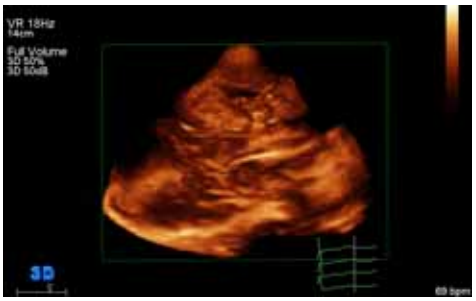
From fetal echo to mature adult, the iE33 system supports the assessment of congenital heart disease through every stage of life and provides new diagnostic information that is changing patient management. Everything about the system is designed to meet the specific needs of pediatric cardiology. Unique 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.

"One of the challenges we've had has been echocardiographic imaging of adolescents and adults with congenital heart disease. Due to multiple surgeries and chest wall deformities, and because they're larger and older, it's more difficult to get the type of imaging we want. Our initial experience has shown that the iE33's new PureWave crystal transducer technology allows us to get better penetration with high resolution, which is improving our accuracy and diagnostic capabilities in this difficult age group."

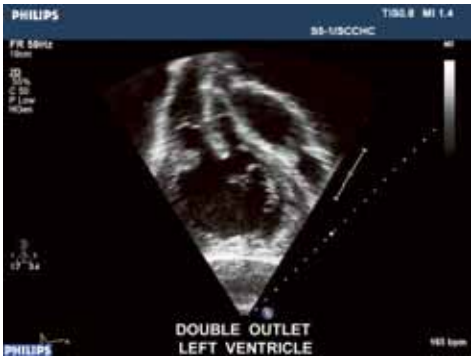
~Gerald R. Marx, MD
Boston Children's Hospital

A full complement of cardiac transducers, including pediatric and adult TEEs, enables 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.



Live 3D Echo



PureWave Crystal Technology

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

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