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RIGHT VENTRICLE TO PULMONARY ARTERY SHUNT VS. BLALOCK-TAUSSIG SHUNT FOR THE NORWOOD PROCEDURE

By Kevin O. Maher, MD, William I. Norwood Jr., MD, PhD

The management of hypoplastic left heart syndrome (HLHS) continues to evolve from the initial surgical procedures advanced over twenty-five years ago. Norwood and colleagues first reported their surgical treatment of HLHS in 1980, with further modification occurring over the next few years. (1) The central features of the operation have not changed significantly since the New England Journal of Medicine report in 1983: transection of the distal main pulmonary artery, reconstruction of the ascending aorta and aortic arch and amalgamation with the main pulmonary artery, atrial septectomy, and placement of a systemic arterial to pulmonary artery shunt. (2) The majority of patients who have undergone the Norwood procedure have had a systemic artery to pulmonary artery shunt to supply and regulate pulmonary blood flow. Most surgeons utilize a modified Blalock-Taussig (BT) shunt from the base of the innominate artery to the right pulmonary artery. This type of shunt restricts blood flow, protecting the heart and lungs from the detrimental effects of excessive pulmonary flow and pressure, yet allows for enough pulmonary blood flow to provide adequate systemic oxygenation. A major disadvantage of the systemic arterial to pulmonary artery shunt is the diastolic flow into the pulmonary circulation. This flow results in a decreased aortic diastolic pressure and a decreased coronary perfusion pressure, compromising coronary circulation. As an alternative for patients with HLHS, a right ventricle to pulmonary artery (RV-PA) shunt can provide pulmonary blood flow without the inherent decre-

ment in coronary perfusion. Several surgeons now use a RV-PA shunt instead of a BT shunt to supply pulmonary blood flow.

The RV-PA shunt for HLHS was first reported by Norwood and colleagues in 1981, who used a 12 mm Dacron tube graft which was narrowed centrally. (3) This graft was relatively large and stiff for the neonatal mediastinum, and was soon replaced with a modified Blalock-Taussig shunt. Kishimoto and colleagues utilized the RV-PA shunt in the 1990's, finding a more stable postoperative circulation. (4) This was followed by Imoto,

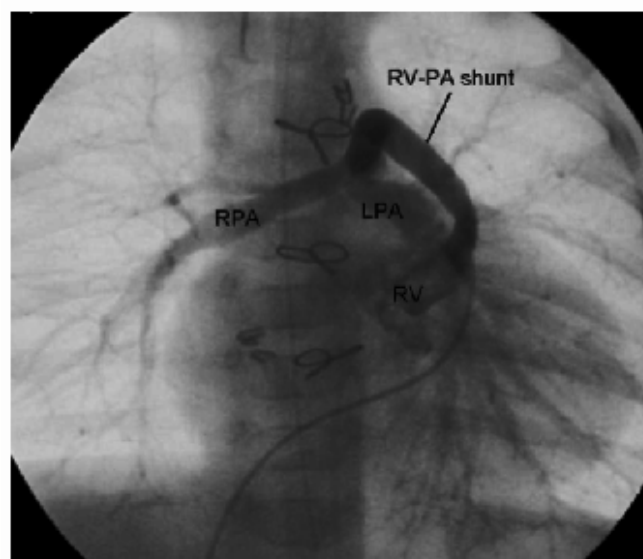


Figure 1. Angiogram of a patient with HLHS, s/p the Norwood procedure with RV-PA shunt. Angiographic catheter was advanced from the inferior vena cava to the RV, and into the proximal shunt for injection. The shunt and branch pulmonary arteries are well visualized.

using a non-circulatory arrest method of the Norwood procedure and a RV-PA shunt. (5) Because of the potential physiological benefit to coronary perfusion, we began routinely using 5-mm Goretex® tube grafts from the right ventricle to the pulmo-

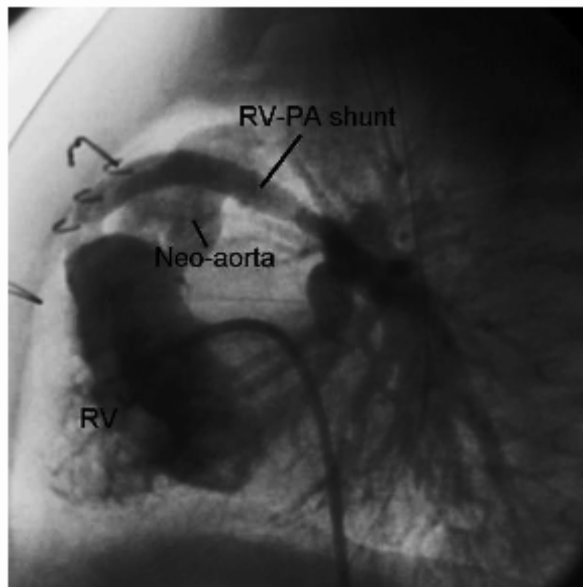


Figure 2. Lateral view of an angiogram in a patient with HLHS, s/p Norwood and RV-PA shunt. The RV, Neo-aorta, and RV-PA shunt are demonstrated.

nary artery for patients with HLHS in January 2001. Although patients were remarkably stable following surgery, assessment of systemic and pulmonary blood flow remained an

"It is our experience that the RV-PA shunt as part of the Norwood procedure for HLHS contributes to the ongoing improvements in outcome for these children."

important aspect of the postoperative management for these patients.

In an effort to evaluate the outcome, postoperative course, and hemody-

namic consequences of the RV-PA shunt, we reviewed the records of 56 consecutive patients who underwent a Norwood procedure for HLHS. Data was collected from our institution and from the Polish-American Children's Hospital in Cracow, Poland. The center in Cracow also began using the RV-PA shunt in 2001. The first 36 patients undergoing the Norwood procedure with a RV-PA shunt (2001-2002) were compared to the immediately preceding 20 patients that had the Norwood procedure with a modified BT shunt. This comparison demonstrated the RV-PA shunt group to have a significantly higher survival (90% vs. 70%), less need for extracorporeal support (1.4% vs. 40%), and decreased postoperative manipulation of ventilation to balance the systemic and pulmonary circulations (14% vs. 35%).(6)

To investigate the hemodynamic differences between the RV-PA shunt and the BT shunt, we compared the catheterization data obtained prior to the hemi-Fontan procedure for these two groups. (7) The RV-PA shunt group had a higher aortic diastolic pressure (55 vs. 42 mmHg), a higher coronary perfusion pressure (46 vs. 32 mmHg), lower Qp/Qs (0.92 vs. 1.42), and a lower mean pulmonary artery pressure (12.8 vs. 16.6 mmHg). These hemodynamic findings were consistent with a more favorable distribution of the systemic, pulmonary and coronary circulations, i.e., less systemic to pulmonary runoff and coronary compromise.

Theoretical disadvantages of the RV-

PA shunt include regional wall motion abnormalities at the RV insertion site, arrhythmias due to ventricular-free wall incision, altered or compromised

"A number of institutions have now reported improvements in survival for patients with HLHS following the Norwood procedure with a RV-PA shunt."

pulmonary artery growth, and increased ventricular volume load from shunt regurgitation. Wall motion abnormalities have not been detected in our cohort of patients by echocardiographic evaluation, or by angiography at pre hemi-Fontan catheterization. There was no change in the incidence of atrial or ventricular dysrhythmias for the RV-PA shunt group; however, a formal comparison has yet to be completed. To evaluate pulmonary artery growth, patients in the BT shunt group were compared to those in the RV-PA shunt group at pre hemi-Fontan catheterization. A ratio of the branch pulmonary artery diameters to the descending thoracic aortic diameter was obtained for each patient. The RV-PA group had a slight, but significant increase in this ratio, with no significant difference in descending thoracic aorta diameter, consistent with appropriate pulmonary artery growth. With regard to RV-PA shunt regurgitation, a small amount of retrograde flow was present in diastole as demonstrated by color Doppler echocardiography; however, no shunt regurgitation was evident angiographically with RV or pulmonary artery contrast injection during pre hemi-Fontan catheterization. The lack of significant shunt

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regurgitation may be explained by a higher resistance in the RV-PA shunt vs. the pulmonary vascular bed, resulting in preferential forward flow into the pulmonary arteries. From a surgical standpoint, the placement of the Goretex® tube graft from the right ventricle to the pulmonary artery does not require significant additional technical skill as compared to the modified Blalock-Taussig shunt placement.

A number of institutions have now reported improvements in survival for patients with HLHS following the Norwood procedure with a RV-PA shunt. We now utilize the RV-PA shunt routinely for all patients requiring a surgically created shunt to supply pulmonary blood flow. This ventricular to pulmonary shunt has been successfully applied in patients with HLHS, unbalanced AV canal, hypoplastic right ventricle, complex transposition with hypoplasia, and other forms of complex congenital heart disease. It is our experience that the RV-PA shunt as part of the Norwood procedure for HLHS contributes to the ongoing improvements in outcome for these children.

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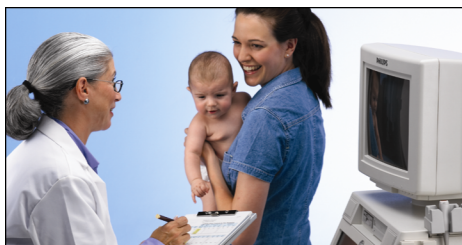
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TRANSCATHETER PATCH OCCLUSION OF HEART DEFECTS

By E. B. Sideris, MD

Introduction

Disk device heart defect occlusion has emerged as an alternative to surgery with several limitations including imperfect centering and need for adequate rim. Device related problems are mostly wire related. They include wire fractures and parts embolization, perforation and valve leaflet perforation. Chronic atrial perfora-

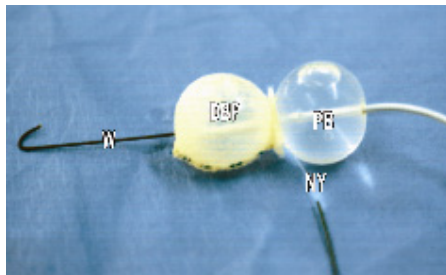


Figure 1. Transcatheter Patch: The patch is mounted on the distant balloon (DBP). The proximal balloon (PB) is inflated. The nylon thread (NY) attached to the patch can be seen.

tions and aortic erosions are a concern and long-term nickel toxicity problems cannot be ruled out.

Wire related problems are obviously avoided by the use of wireless devices. Furthermore, balloon deliverable wireless devices (i.e. transcatheter patch), are 3-dimensional with inherent excellent centering and minimal rim requirements.

The Transcatheter Patch

The transcatheter patch device (Figure 1) consists of the following components: The sleeve patch, the double balloon support catheter and the double nylon thread. The transcatheter patch is tai-

lored from polyurethane foam; it is made in the form of a sleeve covering the distal balloon of the support catheter. The patch is connected to a double nylon thread for retrieval/retraction purposes.

The supporting patch double balloon is made by two balloons mounted on a three lumen catheter. Each balloon can be independently filled with dilute contrast, while the central lumen can be used for over-the-wire insertion of the device. Double latex and nylon balloon catheters are available.

Method

The procedure of transcatheter patch introduction and release is performed under fluoroscopy and echocardiography and includes the following steps:

1. Introduction of the balloon/patch through a long sheath over a wire in the inferior vena cava; it is then advanced over the wire in the left atrium, avoiding the risk of air embolism. The balloon patch can be introduced over a wire for the VSD and PDA application.
2. The occluding balloon/patch (distal balloon) is inflated at volumes predetermined by test balloon inflation. A balloon/patch diameter 2mm larger than the test occluding diameter is selected.
3. The balloon/patch is pulled to the septum and occludes the defect.
4. The proximal balloon is inflated. Heparin is only used during the procedure (100 U/Kg). Antibiotics (Cephalosporins) are started in the cath lab and continue for 72 hours. Accelerated fibrin formation principles are used for all PDA occlusions and some VSD applications; accelerated fibrin formation

method includes: (a) No Heparin use, (b) Use of pre-formed clot on the patch carrying balloon.

5. Important advances on the immobilization of the balloon catheter and the long sheath have been introduced (Figure 2). A luer-lock placed on the catheter shaft of the balloon is used to immobilize the balloon catheter. External

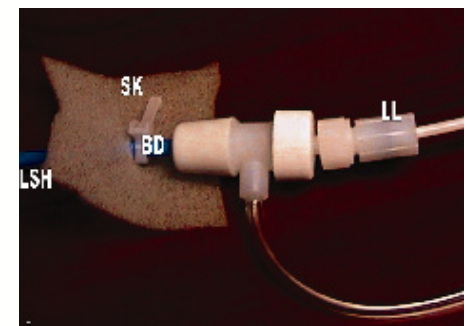


Figure 2. Transcatheter patch immobilization: A luer-lock (LL) device is immobilizing the balloon catheter on the hemostat valve of the introducing sheath (LSH). The introducing sheath is immobilized by a band (BD) on the skin (SK) (simulated by the foam).

bands and sutures are used to immobilize the long sheath on the skin.

6. The patient is taken to the Intensive Care Unit or his room under monitoring. Bed confinement without restraint is applied. Chest x-ray is obtained in bed in 12 hours and trans-thoracic echocardiography in 24 hours.

7. The patch is released in 24-48 hours from the placement as follows:

- ♦ The distal balloon is first deflated.
- ♦ The proximal balloon is deflated.
- ♦ The tip of the long sheath is advanced against the patch.



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- ♦ The double balloon catheter is extracted through the sheath.
- ♦ The double nylon thread is extracted as a single strand.
- ♦ The long sheath is extracted.

Results

A feasibility trial started in December 1999. Various heart defects, most of them inappropriate for disk device repair were taken to the cath lab for transcatheter patch occlusion. They included forty-five cases of ASD, sixteen cases of membranous VSD and ten cases of large patent ductus arteriosus.

Most of ASD cases were of the secundum type with deficient anterior, inferior, or superior rims. The median diameter of the secundum ASDs was 26mm (range 13-34 mm). The youngest patient was 1.5 years old (range 1.5-58, med. 35). The lowest weight was 11 kg. Most transcatheter ASD patches were supported by large double latex balloons. Double nylon balloons and single nylon balloons with proximal floppy wires have been also used. Transcatheter patches require 9-13 F introduction.

Initial successful implantation was possible in all cases; however three implantations were not successful upon release (48 hours). In the unsuccessful cases,

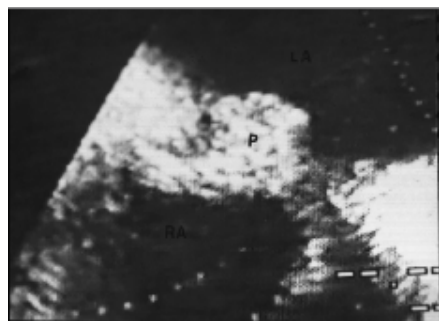


Figure 3A. Transcatheter Patch Secundum ASD Occlusion, TEE pictures: Patch appearance upon release (48 hours).

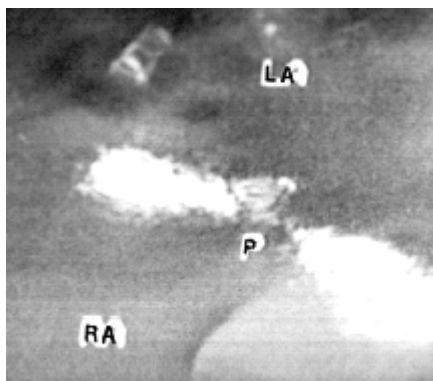


Figure 3B. Transcatheter Patch Secundum ASD Occlusion, TEE pictures: Patch appearance after one year (same patient).

there was either premature deflation of a balloon, or movement of the balloons from the septum. Better balloons are currently used; over-inflation should be avoided and immobilization methods have been improved. Perimembranous VSD occlusion by the transcatheter patch was attempted in 16 surgical candidates including 2 mal-alignment VSD's (Fallot-Tetralogy). The largest VSD was 16 mm, and the youngest patient, 2 years old. A patient with aortic valve prolapse was rejected because of aortic insufficiency concerns and in another one the patch was extracted because of premature balloon deflation. All patients had effective occlusions without aortic insufficiency.

Ten large PDAs were occluded by the transcatheter patch. Most of them had been rejected by other transcatheter methods or were high risk for surgery. The larger PDA had a diameter of 22 mm. All cases had full occlusions and no complications.

Discussion

We have shown that wireless ASD, VSD and PDA occlusion using the transcathe-

ter patch is feasible, effective and relatively safe.

Transcatheter patch placement required 48 hours hospitalization when we started; however, the timing has been shortened for some applications and we project that it should be shortened even more using accelerated fibrin formation and other adhesives.

The transcatheter patch is balloon deliv-

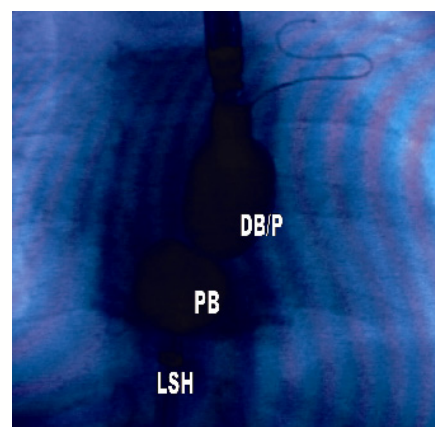


Figure 4A. A 15mm ostium primum ASD - occluded by a double balloon/patch.

ered; therefore, it has the advantages of minimal rim requirement and excellent centering; the device is stable since it is doubly secured inside and outside the heart. The attachment of the patch is fast (24-48 hrs) and it is endothelialized

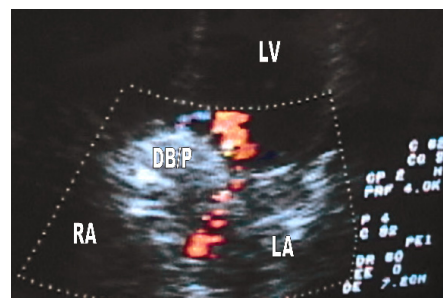


Figure 4B. Figure 4: A 15mm ostium primum ASD - Transthoracic Echo of the same patient: The patch is occluding the defect without mitral valve impairment.



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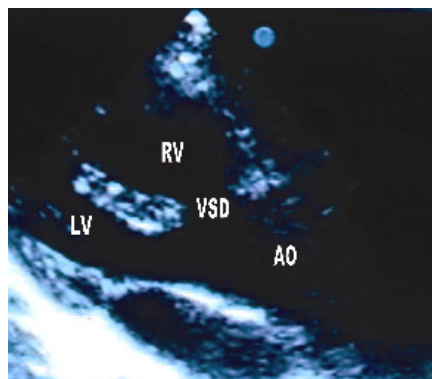


Figure 5A. 14 mm malalignment type membranous VSD - fully occluded by a transcatheter patch.

within 10 days. It is also a more "physiologic" method of occlusion than wire disks, since it is eventually absorbed and replaced by tissue; the patch is virtually indistinguishable from the rest of the septum, within a year in most cases. The initial attachment of the patch to the septum is due to fibrin formation and inflammatory cells (Figure 6B). Heparin use should be avoided, if the accelerated fibrin formation method is followed. Aspirin is started in 24 hrs for one month.

If premature deflation of the supporting balloon is resulting in a significant residual shunt, it is better that the patch is retrieved and replaced by a new one. Retrieval and retraction of the balloon in

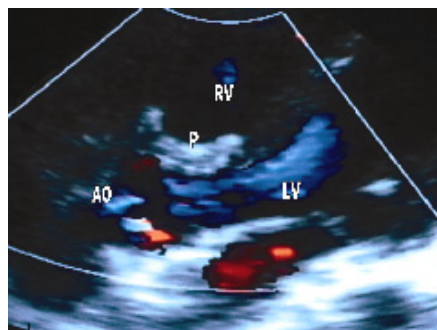


Figure 5B. 14 mm malalignment type membranous VSD - AO=aorta, LV=left ventricle, P=patch, RV=right ventricle.

the introducing sheath is possible the first 24 hours. The transcatheter patch has been found useful in the occlusion of other lesions than secundum ASDs, like sinus venosus ASDs and ostium primum defects, membranous VSDs and large PDAs. The single most useful predictor of a successful patch occlusion is the test occlusion of the defect during sizing.

A full occlusion without impairment of critical structures (mitral stenosis for ASDs, sub-aortic stenosis for membranous VSD and aortic coarctation for

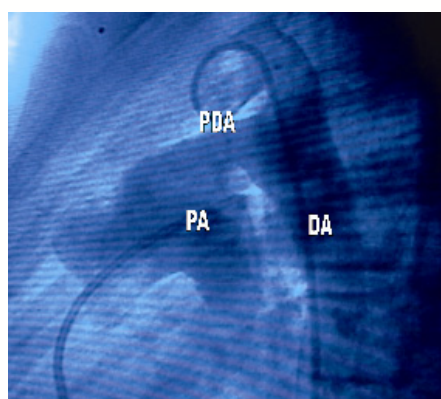


Figure 6A. 15 mm PDA, occluded by a double balloon patch.

PDA) is a good predictor of success. The disadvantage of the transcatheter patch occlusion, is the need for additional hospitalization.

The transcatheter patch is more cost effective than disk devices, since there are only three patch sizes applicable for all defects and defect sizes. Many disk device types and sizes need to be stocked by the cath-lab for the same result.

Current Status

The use of transcatheter patch is experimental and is only used under appropriate protocols, approved in each center. Carefully contacted clinical trials are

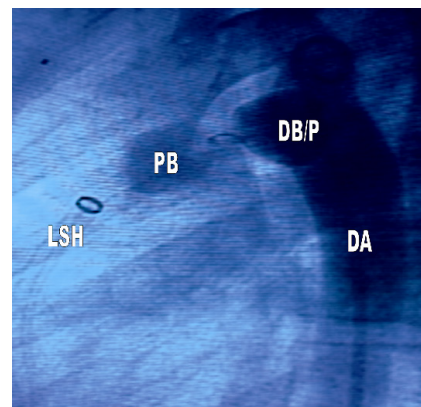


Figure 6B. 15 mm PDA, occluded by a double balloon patch.

used to evaluate transcatheter patch effectiveness and safety.

An investigational device exception has been approved for the performance of FDA approved clinical trials with the transcatheter patch in United States.

Conclusions

The transcatheter patch appears effective and safe in the occlusion of a variety of heart defects and has wider spectrum than disk devices. Larger clinical trials are necessary.

For comments to this article, send email to: APRES@PediatricCardiologyToday.com

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SIEMENS' BIPLANE C-ARM SYSTEM

By Ziyad M. Hijazi, MD

The growing need for sophisticated methods of interventional cardiac treatments in the field of pediatrics requires that today's medical technologies employ advanced features, suitable for imaging a variety of patient sizes, from newborn babies to teenagers. Newer, more advanced technologies are helping to make cardiac treatments more readily available, safer and more com-

fortable for both physicians and patients.

Improvements in Cath Lab Features

Many features are being incorporated into interventional cardiac technologies to meet the needs of cardiologists. Biplane catheterization labs utilizing flat panel technology are being designed for the interventional pediatric cardiologist who deals with patients ranging from tiny babies with heart defects to adults with congenital heart disease. Labs are becoming more

user and patient friendly, lessening the learning curve, and therefore, increasing efficiency. Superior image resolution and quality has the potential to reduce radiation dose and scatter, which may be especially significant for pediatric patients. Quiet and durable X-ray tubes also serve as a benefit, as does technology with both a C-arm and lateral arm that can move without interfering with laboratory operations. The ability to create images from either of the planes in a single mode fashion is essential, and the frontal plane should have the ability to move in a way that will facilitate imaging of the lower extremities.

Excellent image quality is essential in the imaging of pediatric patients. Biplane flat panel detectors can provide superior imaging that can result in contrast and dose reduction for the patient. This is of high importance for pediatrics.

IT's Role in the Cath Lab

The integration of information technology (IT) with the latest imaging and cardiovascular catheterization labs also furthers workflow efficiency significantly and enables seamless data transfer. The ability to send stored reference images from the case into the final report while the exam is in progress not only saves time, but is critical for facilitating communication with referring physicians. A system that incorporates angiographic, fluoroscopic and other data to the final report improves use of staff time in the lab. In addition to good record keeping, the integration of IT enables physicians to call up images and studies while in other departments, a separate office or home.

Advanced Cath Lab Technologies

The AXIOM Artis dBC is a highly flexible, cardiac and angiography system for diagnostic and therapeutic cardiac interventions. Developed by Siemens



The AXIOM Artis dBC, from Siemens Medical Solutions, is among the world's first biplane C-arm systems equipped with new digital flat panel detectors in both planes, which enables the system to reach all imaging speeds necessary for cardiology. The system's flexible architecture enables optimal configuration for diagnostic and interventional cardiology. Photography courtesy of Siemens Medical Solutions.

"Biplane flat panel detectors can provide superior imaging that can result in contrast and dose reduction for the patient."



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Medical Solutions, the system is a bi-plane C-arm equipped with digital flat panel detectors in both planes, which enables it to reach all imaging speeds necessary for cardiology procedures and interventions. The system's flexible architecture enables optimal configuration for both physicians' diagnosis and cardiac interventions.

With touch-screen operation and pre-programmed exam positions, the Artis dBC is designed to optimize cath lab workflow and patient comfort. Additionally, the flat panel detectors on the system offer better visibility without deterioration, artifacts or distortion common in conventional X-rays. The system is capable of running at all cardiac-relevant framing speeds. With two 25 cm diagonal digital flat panel detectors that convert X-ray data into digital images, the system delivers excellent contrast resolution and allows clinicians to visualize the finest vascular structures in detail, including those of infants. The system is compatible with the AXIOM Sensis from Siemens to further optimize cath lab workflow. The Sensis system provides and records accurate calculations of hemodynamic and electrophysiologic data obtained during catheterization, and presents the data clearly and concisely, using Microsoft Word® templates to organize final reports.

These technologies provide added features for clinicians working in the cath lab. For example, these systems enable clinicians to store fluoroscopy studies. Additionally, the C-arm is moveable in such a way that allows for scanning of the entire body, and the table can move in various directions.

An advanced feature, Multispace, provides a second working peripheral C-arm position, which is extremely impor-


tant for patients who undergo catheterization under transesophageal echocardiography (TEE) guidance, as the echocardiographer and machine can be positioned in a way that does not interfere with lab operations. Patients who undergo catheterization from the neck vessels present a better position for the catheterizer away from the C-arm, and clinicians can work com-

"The integration of Information Technology with the latest imaging and cardiovascular catheterization labs also furthers workflow efficiency significantly and enables seamless data transfer."

fortably with unobstructed access to the patient. Because of the system's flexibility, a family member can be present in the room to provide support for the patient, without hindering the clinician.

The full tableside functionality of the AXIOM Artis and Sensis systems helps reduce the amount of time the operator needs to review the images and process data. From the table, the clinician has full capabilities to review images, measure distances required for balloon angioplasty or valvuloplasty, and store important images.


Viewing multi-modality images in the lab enables staff to import and view images obtained from other departments, helping to save time and improve patient care. Rather than interrupt the procedure or send someone out of the lab to retrieve studies, clini-



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cians can view the necessary image with the push of a button, without leaving the lab. This enables better diagnosis and treatment planning.

These interventional cardiac technologies are the much-needed solution to making pediatric care more efficient. As we move toward the future, these advancements will aid doctors and clinicians in saving children's lives.

For comments to this article, send email to:
APRZH@PediatricCardiologyToday.com

~PCT~



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SEPTEMBER CONFERENCE FOCUS

8th Pediatric Interventional Cardiac Symposium (PICS-VIII) & Emerging New Technologies in Congenital Heart Surgery (ENTICHS-II)

September 19-22, 2004
Marriott Downtown Hotel
Chicago, IL U.S.A.

www.picsymposium.com

More than 30 live case demonstrations will be transmitted live via satellite, from more than ten cardiac centers in Europe, Canada and the U.S. This year's course will demonstrate the latest technologies in devices, implantable valves, stents, balloons and much more.

Special sessions during this course will include: closure of all types of Ventricular Septal Defects; management of Complications encountered during interventional procedures; everything you need to know about Stents, Radiofrequency Applications in the interventional laboratory, closure of Large and Complex ASD's, Fetal Intervention, Hybrid intervention Embolization Techniques, and Percutaneous Valve Insertion/repair and much more.

Other sessions include, "My Nightmare Case in the Cath Lab", "Meet the Expert" and Abstract presentations, and this year, will feature a "Debate" at the end of each day, focused on controversial subjects.

Sponsored by The University of Chicago Children's Hospital and Pritzker School of Medicine, Children's Hospital of New York, and the Society for Cardiac Angiography and Interventions



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CLINICAL TRIAL ABSTRACTS (CLINICALTRIALS.GOV)

Immunologic Evaluation in Patients With DiGeorge Syndrome or Velocardiofacial Syndrome*~ currently recruiting patients~*

Sponsor: National Center for Research Resources (NCRR) Children's Hospital of Philadelphia

Purpose: OBJECTIVES: I. Determine the pattern of immunologic reconstitution in patients with T-cell compromise due to DiGeorge syndrome or velocardiofacial syndrome. II. Determine any correlation between immunologic function in these patients and chromosome 22 deletion breakpoints.

III. Determine presence of sustained immunologic compromise in older patients.

Condition: DiGeorge Syndrome; Shprintzen syndrome; Chromosome Abnormalities; Abnormalities, Multiple; Conotruncal Cardiac Defects

Study Type: Observational

Study Design: Natural History

Further Study Details: PROTOCOL OUTLINE: Blood samples are collected at diagnosis of chromosome 22q11 deletion and assessed for lymphocyte proliferation in response to mitogens phytohemagglutinin, pokeweed mitogen, and concanavalin A (mitogen stimulation analyses). These analyses are repeated at 4 months along with a quantitative analysis of immunoglobulin.

At 8 months, patients are tested for their lymphocytes' ability to respond to antigens (candida, tetanus, and diphtheria). At 1 year, patients have lymphocyte subset, IgG, IgA, and IgM analyses performed. Quantitative evaluations of antibody titers to diphtheria, tetanus, Haemophilus influenza, and hepatitis B are also performed.

Over 1 year of age, all studies are performed if the patient is seen for a single visit.

Eligibility: Both genders

Criteria: Conotruncal cardiac lesion to be

repaired by surgery AND Chromosome 22q11 deletion by FISH

Expected Total Enrollment: 11

Location and Contact Information: Children's Hospital of Philadelphia, Philadelphia, PA 19104; Recruiting—Kathleen E. Sullivan, 215-590-1697

Study chairs or principal investigators: Kathleen E. Sullivan, Study Chair, Children's Hospital of Philadelphia

*Study ID Numbers NCRR-M01RR00240-1571; CHP-IRB-95-903; CHP-GCRC-1571
Study Start Date January 1995
Record last reviewed December 2003
NLM Identifier NCT00005102
ClinicalTrials.gov processed this record on 2004-01-16*

Girls Health Enrichment Multi-Site Studies (GEMS)*~ currently recruiting patients~*

Sponsor: National Heart, Lung, and Blood Institute (NHLBI)

Purpose: To develop and test interventions to prevent obesity by decreasing weight gain during the high-risk transitional period from pre-puberty to puberty in African-American girls who are at high risk for developing obesity.

Condition: Cardiovascular Diseases; Heart Diseases; Obesity

Treatment or Intervention: Behavior: diet, reducing

Phase: Phase II

Study Type: Interventional

Study Design: Prevention

Further Study Details: BACKGROUND: The increased prevalence of obesity in Black females is present during childhood, and the prevalence of obesity is increasing faster in African-American girls than in Caucasian girls.

Recent data from the third National Health and Nutrition Examination Survey (NHANES III) showed that during preadolescence, age 6-11 years, 30.7% of African-American girls, compared with 22.0% of Caucasian girls, were overweight.

DESIGN NARRATIVE: The Girl's health Enrichment Multi-site Studies (GEMS) is a collection of studies designed to develop and test interventions to prevent excessive weight gain by African-American girls as they enter and proceed through puberty. The research is being conducted as four inter-dependent, clinical trials.

In Phase I, several distinct and separate interventions were developed. Interventions addressed diet, physical activity, and psychosocial and familial influences. In Phase II, individual clinical trials will be supported to test the efficacy of interventions developed in Phase I.

Eligibility: Females, ages 8 - 10 years

Criteria: African-American girls, age 8-10 years.

Location and Contact Information: Stanford Univ. School of Medicine, Stanford, CA; Recruiting—Thomas N. Robinson, Study Chair, 650-723-5331, TOM.ROBINSON@STANFORD.EDU; Univ. of Memphis, Memphis, TN; Recruiting—Robert C. Klesges, 901-678-1705; BKLESGES@CC.MEMPHIS.EDU

Study chairs or principal investigators: Tom Baronowski, Baylor College of Medicine; Robert Klesges, Univ. of Memphis; Thomas Robinson, Stanford Univ.; James Rochon, George Washington Univ.; Mary Story, Univ. of Minnesota.

*Study ID Numbers 118
Study Start Date August 1999; Estimated Completion Date November 2006
Record last reviewed July 2003
NLM Identifier NCT00000615
ClinicalTrials.gov processed this record on 2004-01-16*

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FDA APPROVES HEART ASSIST DEVICE FOR CHILDREN

MicroMed Technology, Inc., a global leader in miniaturized heart pump technology, announced that it has received Food & Drug Administration (FDA) Humanitarian Device Exemption (HDE) approval to provide transplant centers with the DeBakey VAD® Child heart pump, designed to improve blood flow for children aged 5 to 16 who are awaiting a heart transplant. It is estimated that fewer than 100 children a year in the U.S. will be candidates for the new device.

"After so many years of development in the VAD industry, we are very proud and excited that we will be able to help support children who have devastating heart diseases," said Betty Silverstein Russell, MicroMed executive vice president. The DeBakey VAD Child utilizes the technology of the implanted adult pump and further miniaturizes it for use in children. This is the first VAD (Ventricular Assist Device) approved by the FDA for use in children. Until now, the usual method of circulatory support in children was a heart-lung bypass setup in the intensive care unit. The new VAD will not replace the bypass needed for primary lung failure.

"This represents our intent to continue to add value to the mechanical heart support sector," said Dallas Anderson, MicroMed president and CEO. "For the first time, recovering children will be able to move from the intensive care unit to a more comfortable setting." Designed in collaboration with NASA, the Baylor College of Medicine and Drs. Michael DeBakey and George Noon, the DeBakey VAD is intended for end-stage heart failure patients who



Figure 1. DeBakey VAD® Child - H030003.

can no longer provide necessary blood flow with their native heart. The DeBakey VAD system has been awarded the CE mark for commercial distribution in Europe, with over 240 VADs implanted worldwide. The implanted device is the size of a "C" cell battery, is silent, and weighs less than four ounces.

The MicroMed DeBakey VAD® is an investigational device and is limited by federal law for investigational use in the U.S.

For comments to this article, send email to:
APRES@PediatricCardiologyToday.com

~PCT~

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8965 Interchange Drive
Houston, TX 77054 USA
Phone: 713.838.9210
Fax: 713.838.9214
www.micromedtech.com

FDA INFORMATION: Humanitarian Device Exemptions Humanitarian Use Device

HDE: an application similar to a premarket approval (PMA) application, but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD).

HUD: a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.

For further information on HDE and HUD:

Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers; Final Guidance for Industry - Document issued on July 12, 2001

www.fda.gov/cdrh/ode/guidance/1381.pdf

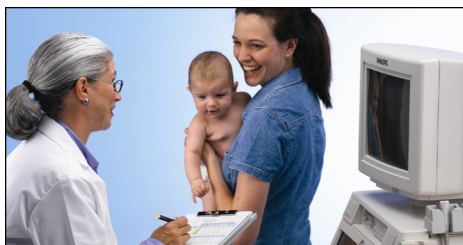
Humanitarian Use Device Regulations - [Federal Register: June 26, 1996 (Volume 61, Number 124)]
www.fda.gov/orphan/humuse.htm

For more FDA Information on the DeBakey VAD® Child heart pump:

FDA Talk Paper:
www.fda.gov/bbs/topics/ANSWERS/2004/ANS01280.html

FDA - Center for Devices and Radiological Health (CDRH) - Consumer Information:
www.fda.gov/cdrh/MDA/DOCS/h030003.html

FDA - Center for Devices and Radiological Health (CDRH) - Approval Letter:
www.fda.gov/cdrh/pdf3/H030003a.pdf



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