# PEDIATRIC CARDIOLOGY TODAY®

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## Departments




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# PICS-VII & ENTICHS-I (Pediatric Interventional Cardiovascular Symposium & Emerging New Technologies In Congenital Heart Surgery) Recap

***By Ziyad M. Hijazi, MD, MPH, FACC, FSCAI***

**PICS-VII & ENTICHS-I** (*Pediatric Interventional Cardiovascular Symposium & Emerging New Technologies in Congenital Heart Surgery*) was held at the Ritz-Carlton Orlando, Grande Lakes, FL from September 21-24, 2003. More than 600 cardiologists from over 50 countries attended the meeting.

**Sunday (October 21)**

The meeting started Sunday morning by a special symposium sponsored by AGA Medical Corporation. Many physicians made presentations with topics related to the different Amplatzer devices (for atrial septal defects, for muscular and membranous ventricular septal defects, for patent foramen ovale and for patent ductus arteriosus).

Sunday afternoon, there were three oral abstract sessions simultaneously covering approximately 50 abstracts. At the same time there was a *meet the expert session*. All sessions were very busy and dynamic.

**Monday (October 22)**

Monday witnessed a very busy day with live case demonstrations from London; Paris; New York; Frankfurt and Cleveland. From London, Drs. Bonhoeffer and Wilson performed five live cases including percutaneous pulmonary valve insertion; mitral valvuloplasty; Helex device closure of atrial septal defects and Helex device closure of a Fontan fenestration. From Paris, Dr. Piechaud performed three cases including device closure of membranous ventricular septal defect; device closure of paravalvular mitral leak and stent implantation in the right ventricular outflow tract in a neonate with tetralogy of Fallot. From New York, Dr. Hellenbrand performed two cases including left pulmonary artery angioplasty and stent implantation for left pulmonary artery stenosis in another child. From Frankfurt, Drs. Sievert and Amin performed a case of device closure of membranous VSD using a modified Am-

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PICS-VII & ENTICHS-I

www.picsymposium.com

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**The University of Chicago Children's Hospital and**
**The Pritzer School of Medicine**

www.uchospitals.edu

**Children's Hospital of New York**

www.chony.org

**The Society of Cardiac Angiography & Interventions (SCAI)**

www.scai.org

## USEFUL WEB LINKS

### Medical Associations/ Foundations/Boards

**Administrators in Medicine (AIM)**

www.docboard.org

**Alliance of Cardiovascular Professionals (ACVP)**

www.acp-online.org

**Alliance for Continuing Medical Education (ACME)**

www.acme-assn.org

**American Board of Medical Specialties (ABMS)**

www.abms.org

**The American College of Cardiology (ACC)**

www.acc.org

**ACC - Cardiosource**

www.cardiosource.org

**ACC - National Cardiovascular Data Registry (ACC-NCDR)**

www.acc.org/ncdr/index.htm

**The American College of Chest Physicians**

www.chestnet.org

**American College of Healthcare Executives (ACHE)**

www.ache.org

**The American Academy of Family Physicians (AAFP)**

www.aafp.org

platzer membranous VSD device. Finally, Dr. Latson performed a case of ASD closure using the Helex device and from the animal laboratory; he demonstrated in utero fetal intervention. He demonstrated the complex infra structure needed to conduct fetal intervention. The model he used was a pregnant sheep.

*"During the 3 1/2 day course, there were many didactic lectures by course-distinguished faculty."*

**Tuesday (October 23)**

On Tuesday, live case demonstrations were performed from Chicago; Columbus and Ulm, Germany. From Chicago, Dr. Hijazi performed device closure of membranous VSD using the Amplatzer Membranous VSD device that has been just approved by the FDA for a phase-I trial in the USA. Also, Drs. Bacha and Hijazi performed from the operating room a case of perventricular device closure of a muscular VSD using the Amplatzer Muscular VSD device without the use of cardiopulmonary bypass. Finally, Dr. Hijazi performed device closure of an ASD in a child using the Amplatzer septal occluder under intracardiac echocardiographic guidance using the AcuNav catheter under sedation. From Columbus, Drs. Cheatham and Galantowicz performed a modified stage one Norwood in two neonates with HLHS. They have championed a new approach to this difficult condition. They performed intraoperative banding of both pulmonary arteries and stent implantation in the ductus arteriosus. Finally, Dr. Martin Hoeher from Ulm Germany performed two cases of PFO closure using the new Cardia device.

**Wednesday (October 24)**

On Wednesday, cases were performed from Houston, Miami and Toronto. From Houston, Dr. Grifka performed three cases including PDA closure using the Amplatzer duct occluder and an attempt to close a type C ductus using both GGVOD and the Amplatzer duct occluder. Finally, he was able to recanalize an occluded IVC with stent implantation. From Miami, Dr. Zahn performed stent implantation in a sick infant. In another case, Drs. Burke and Zahn performed intraoperative stent implantation. Finally, Dr. Nykanen performed recanalization

### Live Case Demonstrations

Children's Hospital of New York (USA)

Institut Jacques Cartier (France)

Cleveland Clinic Foundation (USA)

Hospital for Sick Children's Great Ormond Street (UK)

Cardiovascular Center, Sankt Katharinen, (Germany)

The University of Chicago Children's Hospital (USA)

Columbus Children's Hospital (USA)

University Hospital, Ulm, (Germany)

Texas Children's Hospital (USA)

Toronto General Hospital (Canada)

Miami Children's Hospital (USA)

*Figure 1: Allen Tower, President & CEO of NuMED, was presented the 7th PICS Long-Time Achievement Award at the PICS Gala Dinner*

of an occluded subclavian vein using the Baylis radiofrequency perforation system; then in the same patient he was able to occlude a brachial arteriovenous fistula. Finally, Dr. Benson and McLaughlin from Toronto performed three cases including coarctation stent; an ASD closure using the Amplatzer septal occluder under intracardiac echocardiographic guidance using the AcuNav catheter and a PFO closure using the Cardioseal device.

During these live cases, there was direct interaction between the operators, the moderators, the panelists and the attendees.

During the 3 1/2 day course, there were many didactic lectures by the course-distinguished faculty - most importantly, fetal intervention; percutaneous valve insertion; emerging new technologies for congenital heart surgery and many more. Abstract poster presentations took place daily.

**PICS Long-Term Achievement Award (Tuesday - October 24)**

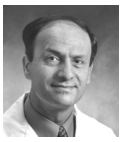
On Tuesday, the *7th PICS Long-Time Achievement Award* was given to Allen Tower, president of NuMED Inc. (Figure 1) for his contribution and innovation in the field of congenital heart disease. Allen played a vital role in manufacturing catheters/balloons and stents specifically designed for children. The award was given during the Gala dinner, which was held at Sea World.

PICS is the only course of its kind dedicated to the field of intervention for congenital heart disease in children and adults in the USA. This year, a new area was added to cover the new field of Hybrid surgery where surgeons and cardiologists work hand in hand to help patients with cardiac defects.

The entire program can be seen at: www.picsymposium.com

Next year's PICS will take place September 19-22, 2004 in Chicago, IL. For more details, please visit PICS website.

~PCT~



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# PEDIATRIC CARDIOVASCULAR DRUGS: A SMALL MARKET INHIBITS DEVELOPMENT

***By Steven Heffner, Acquisitions Editor, Kalorama Information***

Although it may seem odd to read a piece about the market for pharmaceutical products in a predominantly clinical publication, in some instances the dedicated clinician needs to understand how the effective treatments of tomorrow are being affected by larger market dynamics. In the case of pediatric cardiology, the facts on the ground in the marketplace do not bode well.

We'll start with these facts: The market for pediatric cardiovascular (CV) pharmaceuticals is the smallest therapeutic segment of the $30 billion worldwide pediatric drug market, and the outlook for significantly increased revenues is not rosy (Figure 1). CV drugs for the pediatric population currently represent about 1.5% of the pediatric pharmaceutical market and that portion will drop to about 1.2% or lower by 2007. The market is growing, but pediatric CV drugs are only progressing at the well-below-average pace of about 3% per year, slower than any other pediatric segment. In fact, the sales of Pfizer's Viagra alone this year will more than quadruple the entire worldwide pediatric CV drug market.

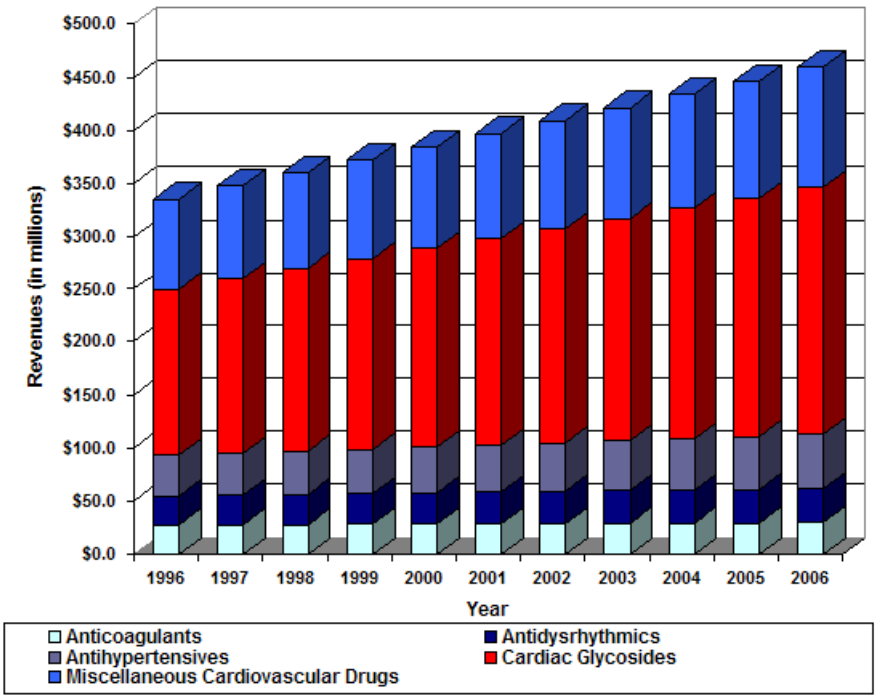


*Figure 1: World Market for Pediatric Cardiovascular Drugs by Type 1996-2006*

There are a number of reasons for this depressing revenue outlook for makers of pediatric CV drugs. First and foremost is the relatively small prevalence of pediatric CV conditions. Congenital heart conditions and hypertension are the two CV conditions with the highest prevalence in children. Worldwide, approximately 11.1 million children are affected by congenital heart abnormalities, and approximately 15 million children have hypertension. From a human suffering point of view, these are large numbers; from a drug marketer's point of view, these numbers are small—very small. In addition, congenital problems often indicate surgery not pharmacologic treatment, and hypertension is often not treated at all in this population—two more reasons that these are not attractive therapeutic areas for drug marketers.

The regulatory environment for pediatric drugs has also undergone significant changes in recent years. Despite the FDA's addition of the so-called pediatric extension (The

Best Pharmaceuticals for Children Act) which offers drug companies six months of additional patent protection on drugs that have been approved for children), few pharmaceutical manufacturers have been willing to undergo another round of costly clinical trials for their established cardiology drugs. Pediatric studies are more costly than the already expensive adult studies. Most companies have been content with the rampant "off-label" prescribing.

It has been estimated that about four out of five drugs used to treat conditions in children have never been tested in children. This startling statistic convinced the FDA to pass regulations in the late 1990s that require pharmaceutical companies to conduct clinical trials on all new drugs that will be or could be used to treat children. The 1997 FDA Modernization Act and the 1998 FDA Pediatric Rule, both of which have provisions aimed at stemming the tide by various mechanisms of potentially dangerous off-label prescribing in the pediatric population.

These actions will undoubtedly have an effect on more appropriate labeling and formulations. However, it is doubtful that the CV population will be the one that benefits the most. Only 3 of the 96 most prominent drugs coming through clinical development for a pediatric indication have any CV application whatsoever. To put that in perspective, that's fewer than the number of drugs for ADHD alone. These low numbers persist despite the fact that on the Center for Drug Evaluation and Research's (CDER) list of approved prescription drugs for which additional pediatric information may produce health benefits in the pediatric population, almost 25% are CV drugs, a number that doesn't even include therapeutics for related conditions such as diabetes and obesity. These drugs have been pegged by the CDER as almost certainly worth studying on children, and yet they are for mostly market reasons, languishing in the adult world.

***"...estimated that about four out of five drugs used to treat conditions in children have never been tested in children."***

Although CV drugs are vital to the few children that require them, the outlook for new products catering to the pediatrics population is depressing. The frequency of CV conditions in children and the cost of developing a drug for pediatric use will continue to make new drug approvals sparse if not nonexistent in the next few years. New drug availability will only come when primary patents are exhausted and the pediatric exclusivity of an additional six months may be beneficial to retaining revenues. From this market perspective, we can only conclude that the clinician will have to be content with his or her current arsenal of products for the foreseeable future.

**References:**

Kalorama Information. *The Worldwide Market for Prescription Pediatric Drugs.* New York: October 2002.

~~PCT~

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Kalorama Information is a leader in worldwide business intelligence and syndicated market research in life sciences. Kalorama studies provide timely, high-quality research to decision makers in the pharmaceutical, biotechnology, medical device, and diagnostics sectors. Recent titles in cardiology include:

- *Drug-Eluting Stents: Markets and Technologies* - April 2003
- *Congestive Heart Failure: Worldwide Drug and Medical Device Markets*- March 2002
- *Trends in the Early Diagnosis of Cardiovascular Disease: Worldwide Market Opportunities* - October 2001

# PRODUCT SHOWCASE

### AGA Medical Corporation's Amplatzer® Duct Occluder for Treating Congenital Heart Defect

AGA's Amplatzer Duct Occluder is a less-invasive alternative to cardiac surgery for closing patent ductus arteriosus (PDA), a common and potentially fatal congenital heart defect.

The Amplatzer Duct Occluder is the first device of its kind approved by the FDA for treatment of PDA. Since 1998 the device has been implanted in thousands of patients worldwide. The FDA approved the device after reviewing results of a clinical trial involving 435 implanted patients at 24 U.S. hospitals and clinics. Based on one-year follow-ups of 227 patients who received the implant, the device was 100 percent effective in closing the PDA.

The Amplatzer Duct Occluder was designed to address ease of placement and higher rates of occlusion for all sizes and types of PDAs. Clinical results using the Amplatzer Duct Occluder demonstrated low rates of dislodgment and extremely high occlusion rates with a single device and procedure.

The Amplatzer Duct Occluder is a self-expandable device made from a Nitinol wire mesh. A retention skirt on the aortic side provides secure positioning in the ampulla of the ductus. As the occluder is implanted, it expands outward and the wires push against the wall of the ductus. Polyester fabric is sewn into the occluder with polyester thread. The fabric induces thrombosis that closes the communication.

**AGA Medical Corporation**

**+1.952.298.9814**

**www.amplatzer.com**

### The New ACUSON Sequoia ™ C512 Echocardiography System

The new ACUSON Sequoia™ C512 echocardiography system builds on the foundation of renowned Sequoia system technology to elevate the acoustic basis of ultrasound performance. In fact, through Sequoia™ matched response technology with the programmable waveform generator, the Sequoia C512 system overcomes acoustic challenges and maximizes performance. From the most difficult-to-image patient to the tiniest mouse heart investigation, the Sequoia C512 system is driven to deliver greater depth, detail and diagnostic dependability.

**Siemens Medical Solutions**

**Ultrasound Division**

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**www.siemens.com/ultrasound**

### NuMED's X-Line Catheters

NuMed has a line of balloon catheters. These catheters utilize a newly designed braided shaft. This new "X-Line" of catheters has several unique characteristics that enhance the catheter operation and allow for more trouble-free operation. These new catheters are offered in addition to the standard Tyshak, Z-MED, Z-MED II and Mullins Catheters.

The new braided inner tubing increases the pushability of the catheter and eliminates the kinking and buckling associated with tough vasculature. It also eliminates any binding on the guidewire during a tough catheter removal. This tubing does not stretch. The guidewire

can be moved in the catheter even while the balloon is inflated. There is no constriction or collapse of the inner tubing. Guidewire movement is greatly improved even in a tortuous passage. This inner tubing is radiopaque. Inflation deflation is virtually unchanged from the previous design.

**NuMED, Inc.**

**+1.315.328.4491**

**numed@slic.com**

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**Tyshak® Balloon Catheters for Angioplasty Procedures**


A low profile reduces sheath size and entry site complications.

Tyshak® II catheters are designed with a low profile that delivers high performance. Manufactured from a microthin, non-compliant balloon material, these innovative balloon catheters let you use the smallest introducers possible. The reduced sheath size helps minimize vessel trauma and entry site complications.

Short, flexible distal tip gives you superior maneuverability.

With well-defined shoulders and minimum balloon tapers, Tyshak® II glides easily through smaller and difficult to negotiate vessels. Additional Tyshak® II features include exceptionally low deflated profiles and a coaxial shaft designed to provide columnar strength and enhance pushability.

**B. Braun Medical, Inc.**

**1.800.BBRAUN2 (227.2862)**

**www.bbraunusa.com**

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**New Medtronic Electrodes Allow Infants And Children To Be Saved From Cardiac Arrest With Automated External Defibrillators**

Sudden cardiac arrest (SCA) can strike anyone – including children – at any time. Until now, however, it has been difficult to deliver appropriate therapy to younger, smaller patients. Medtronic Physio-Control has a FDA approved infant/child electrode for use with automated external defibrillators (AEDs) for children younger than 8 years old.

The Medtronic Physio-Control infant/child electrodes reduce the energy to appropriate levels to use on infants and children under the age of 8. The new electrodes also allow pediatric patients to benefit from an escalating energy protocol in the AED, meaning that the device first uses a small shock and then uses larger shocks only if the smaller shocks are ineffective. The new infant/child electrodes can be used with Medtronic Physio-Control's biphasic LIFEPAK® 500 AEDs and all LIFEPAK CR Plus AEDs.

**Medtronic, Inc.**

**+1.763.514.4000**

**www.medtronic.com**

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DECEMBER

CONFERENCE HIGHLIGHT

**The First International Conference on Heart Failure in Children and Young Adults: From Molecular Mechanisms to Medical Surgical Strategies**

*Presented by Baylor College of Medicine and Texas Children's Hospital.*

*December 3-6, 2003, Inter Continental Hotel, Houston, TX*

The conference brings together the world's leading experts in pediatric and adult cardiology and cardiac surgery, as well as cardiac anesthesiologists and health care professionals in the fields of intensive care, perfusion and nursing.

Almost 50 of the leading experts will give presentations at the conference. Among them are Dr. Michael E. DeBakey, Dr. Denton A. Cooley, Dr. James T. Willerson, Dr. O. Howard Frazier, Dr. George Noon, Dr. Charles Fraser Jr., Dr. Leonard L. Bailey, Dr. J. Timothy Bricker, Dr. Douglas L. Mann and Dr. Jeffrey A. Towbin.

Dr. Anthony C. Chang, associate professor of pediatric cardiology at Baylor and director of the Pediatric Cardiac Intensive Care Unit at Texas Children's Hospital, is the program director of the conference.

For more information:

Claudia Garnica, *Office of CME*
Baylor College of Medicine

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www.heartfailureinchildren.org

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