PEDIATRIC CARDIOLOGY TODAY

RELIABLE INFORMATION IN PEDIATRIC CARDIOLOGY

VOLUME 3, ISSUE 3 | WWW.PEDIATRICCARDIOLOGYTODAY.COM | MARCH 2005

PEDIATRIC CARDIOLOGY TODAY BECOMES CONGENITAL CARDIOLOGY TODAY

INSIDE THIS ISSUE

DEPARTMENTS

PEDIATRIC CARDIOLOGY TODAY

9008 Copenhaver Drive, Ste. M
Potomac, MD 20854 USA
www.PediatricCardiologyToday.com

What's in a name? Just a few words but a lot of meaning!

As of the April issue, Pediatric Cardiology Today will become Congenital Cardiology Today. The name change accompanies an expansion of the newsletter from a print publication distributed only in North America to an international print and electronic publication. There will be two editions each month. North American readers will continue to receive the monthly printed newsletter in their regular mail boxes. International readers will receive the Table of Contents of the newsletter at their work or personal email accounts from which they can then go to the specific issue, and read it electronically in a PDF file. In addition, the scope and focus of the publication will shift from issues primarily of interest to North Americans, to issues of interest to the wider international audience as well as an expanded group of North American readers. While most of the content will be shared between the North American and International versions, each will have selected news and information with a regional significance.

"As of the April issue, Pediatric Cardiology Today will become Congenital Cardiology Today."

In much of the world, patients of all ages with congenital heart disease are treated by a single cardiologist. Most patients are children, however largely because of the success of modern treatment modalities, an increasing percentage are adults. This is also true to a considerable extent in U.S., Canada and other countries, where the physicians are designated "pediatric cardiologists."

The name change signifies the expanding scope of the newsletter to include issues of adults as well as children with congenital heart disease, and the widening focus of the letter relating to interests of an international audience in addition to an expanded North American audience. In the United States and Canada, and a few other countries, a new specialty focusing solely on the adult age patient with congenital heart disease has arisen. The newsletter seeks to include these physicians who specialize in adult congenital heart disease among its readership.

CONGENITAL
CARDIOLOGY TODAY

Figure 1. The new name and logo starting with the April 2005 issue.

A sampling of readers and Board Members of Pediatric Cardiology Today supports the name change: Michael Slack, MD of Children's National Medical Center in Washington, DC likes the idea because he says many "adult" cardiologists refer their adult patients with congenital heart disease to him. Gil Wernovsky, MD of The Children's Hospital of Philadelphia stated that he was contemplating changing his title to "Congenital Cardiologist." And Ziyad Hijazi, MD, MPH actually suggested the name change. We suspect that most North American readers will understand and support the change.

At the same time, congenital cardiology is more recognizable and acceptable to many of our international colleagues. After all, what's the difference between a 15 year old and a 30 year old with Tricuspid Atresia? Congenital Cardiology Today will deal with the issues of both patients all around the world.

"The name change signifies the expanding scope of the newsletter to include issues of adults as well as children with congenital heart disease."

The editorial board has expanded to include physicians from all parts of the world including Argentina, Australia, Brazil, Brunei, Canada, Chile, Germany, India, Japan, Lebanon, Malaysia, Mexico, Saudi Arabia, Taiwan, United Kingdom, and the United States. Below is the expanded list of editorial board members for Congenital Cardiology Today (in alphabetical order):

To Contact an Editorial Board Member

Send your e-mail to:
NAME@CongenitalCardiologyToday.com

Place the Board Member's last name before the @. For example, to send an email to Dr. Moore, you would send it to Moore@CongenitalCardiologyToday.com

Your email will be forwarded to the appropriate person

AN UPDATE ON INFORMATION TECHNOLOGY IN CARDIAC MEDICINE

By Geoffrey L. Bird, MD

Does the fact that I own a 40GB iPod mean that I shouldn't buy one of the new iPod Shuffles? Don't I owe it to my 5 year old son to boost his chances at getting into college with an iMac? These and other "important" questions are the ones I'm pondering from today's USA Today in my hotel room in Houston. The reason I'm here is kind of neat, but more about that later. First I wanted to discuss an approach to another hot topic in medical information technology circles – the hand held computer. Admittedly, I am a gadget lover. I'm the kind of guy who doesn't get upset if his PDA gets dropped or broken. Why? It's the opportunity to get a new one! My geekness is all well and good on a personal level, but I think there's an important lesson to be learned in approaching technology as a healthcare provider.

Medicine is still falling in love with the PDA, long after business has decided that it needs a different solution to its problems. But, for technology in general, that's a tired tale. Many have realized for some time that information technology trends show up earlier in the business world than in medicine.

"It isn't fear that drives clinician restraint with technology. It's the lives of our patients."

It's a basis for physicians and other clinicians often being maligned as technophobes. But, how could you look at the daily life of a laparoscopic surgeon, cardiac perfusionist, or cardiac intensive care nurse and accuse clinicians of being technophobes?

It isn't fear that drives clinician restraint with technology. It's the lives of our patients. When the new suite of PDAs at the car dealership goes wrong, the sales staff might have to revert back to paper day-runners and contact lists. The biggest cost might be that a car goes unsold. When the new PACS angiography system of a cardiology department goes down from an unforeseen bug, delays in interpretation and diagnosis could cost lives. We clinicians know this, and we've known it for years. That's what makes us move so slow in the minds of business and information technology (IT) intelligentsia. We don't fear the technology; we love the technology. We just don't want it to kill our patients.

PDAs are coming into vogue

Literature describes that PDA use in medicine has evolved over time. That use has matured into a tighter and more seamless assimilation. When McLeod et al.[1] sent surveys to the 867 physician members of the Mayo Clinic's Department of Internal Medicine in Rochester, Minnesota, they received 473 responses. 46% of the responders reported use of a PDA, with extremes ranging from 68% of trainee residents to 37% for attendings. Ninety percent chose handhelds based on the

"We don't fear the technology; we love the technology. We just don't want it to kill our patients."

Palm operating system, whereas the 10% remainder worked with Microsoft's Pocket PC operating system. Residents used the handhelds mostly in hospital settings for direct patient care, like drug information programs, medical references, and medical calculators. Attending physicians used them more in administrative settings and for scheduling/calendar applications.

There have been several other survey based reports of handheld usage patterns in medicine. There results are pretty much in line with what you'd find walking down the hallway of any hospital. Handhelds have arrived; they're being used by many clinicians in many different productive ways, but many clinicians are still getting along fine without them.

Why isn't their use more universal and widespread? It's been nearly 10 years since the earliest descriptions of handhelds in medicine were published in the Paleozoic era of the Apple Newton in 1995(2). One of the unfortunate facts about handhelds is that there have been few, if any, outcome studies concerning their introduction or ongoing use.

Some of the people behind Isabel, a

medical knowledgebase and decision support system in the UK (www.isabel.org.uk), organized a conversion of access methodology from desktop to handheld computers with wireless Internet access. After enabling access via wireless Internet handhelds, the frequency of Isabel queries among house staff at four London hospital units increased by over 400%.[3] What they and others have yet to show is that their patients fared better and/or left hospital sooner. That being said, it is probably a good thing that clinicians checked into their available knowledgebase more frequently.

In this era of increased attention to the prevalence of medical errors, it's almost become assumed that the absence of error implies the presence of quality. While there's reason to debate that the two are so closely related, Grasso et al.[4] used a handheld solution to decrease the rate of medication transcription errors on discharge forms from 22% to 8% in back to back four month periods. As mentioned above, while there was no follow-on discussion about improved patient outcomes, this powerful reduction of error is absolutely a good thing. While their impression was that the "PDA was inexpensive and simple to use,"(p1326) the implementation and change was clearly driven by motivated investigators and a significant period of training time for the institution's staff.

In the world of cardiology, evidence of a PDA's role in care improvement are slowly coming to light. Pettis, et al.[5] and Leibrandt, et al.[6] showed that cardiologists were as facile reading electrocardiograms on the LCD screens of PDAs and cellular telephones, as they were on paper. The natural subsequent effect on care is already taking place. Paramedics in the field are transmitting ECG images of chest pain patients to the PDAs and smartphones of cardiologists at receiving hospitals. The result? Certain patients with particular subtypes of myocardial infarction are being diverted from wasted minutes being triaged in the ED directly to a fully prepped and waiting cardiac catheterization lab for intervention.

Each of these PDA interventions had a clear and present effect on a surrogate marker for patient outcome; knowledgebase consultation, error frequency, and time delay to definitive therapy. Until more outcome studies are described, we'll take these findings for the positive indicators that they are.

"Information technology is seen as one of the cornerstones of patient safety, error reduction, and improved outcomes. What is less clear are the ways in which handhelds and other technology implementations might contribute to medical error."

At that same time, we have to remember that no one is publishing results of their handheld interventions that went wrong. How many old Palm "Professionals" and "Palm VII's" are sitting unused in desks? They were, no doubt, bought or donated with noble intentions, but the pace of computer technical progress is far greater than our own pace at assimilating new technology into clinical practice.

Information technology is seen as one of the cornerstones of patient safety, error reduction, and improved outcomes. What is less clear are the ways in which handhelds and other technology implementations might contribute to medical error. Thankfully, this issue is being looked into, addressed, and described in the literature.[7] Ash et al. have taken things a long way toward a better understanding of the epidemiology of technology-induced medical error.

As for failed implementations, there's not just the blistering pace of technological progress to blame. Rather, in some cases it seems that certain handheld proponents, largely trade writers and technology vendors, have almost magical thinking regarding the capabilities of handhelds in medicine. Handhelds are very good at storing, transmitting, and recalling units of information that could fit on an index card. As such, they fit very well into certain medical work styles, i.e. that of a medical trainee. If, for hundreds of years, the job of a medical trainee has involved "index cards," it stands to reason that handhelds can probably help to do the job better.

Handhelds, however, do not provide every solution for medical workflow inefficiencies and care deficiencies. The cardiac ICU clinician that needs to view a large amount of simultaneous graphical waveform data might do better with a wireless tablet PC or laptop, rather than a handheld computer. The cardiologist in private practice that wants to view their patient's angiograms and radiographs would currently be better off viewing these images on a device that's just plain bigger than a handheld. In contrast, the business people and general public that are making cell phones and smartphones fly off the shelves, need less screen space than many clinicians trying to make decision on graphical data.

"But neither we, nor our patients, will be better off, if we try to justify an investment in the expense and effort of bringing PDAs further into our practices with the "Wow! Factor" and "Think of the potentials!"

In the medical world, PDAs are not dead. With lots of unsuccessful fits and starts hiding in the closet, handheld computers have finally gained enough ground in medicine to start showing up more frequently in the literature. There, they are clearly shown as having an important role for aspects of our medical work for the near future. But, handhelds cannot do everything. If we understand what they are, and what they are not, we'll be better off. If we understand and share descriptions of how they are successfully (and unsuccessfully) incorporated into the jobs we do, we'll be better off.

But neither we, nor our patients, will be better off, if we try to justify an investment in the expense and effort of bringing PDAs further into our practices with the "Wow! Factor" and "Think of the potentials!"

Now what about the Houston hotel room? I'll give you a hint, but then you'll have to come back to a future issue of this journal (if the editors will have me!). A group of pediatric cardiovascular professionals are trying a new approach for getting more of what we want from one of our software vendors. It starts with "C" and ends with "ooperation," and the multi-institutional involvement looks like it could be good for us, good for the vendor (which is also good for us), but, most importantly, it'll be good for our patients… Please stay tuned!

The reader is referred to Fischer et al.[8] for a comprehensive and well-written review and compendium of resources concerning handheld computers in medicine.

When Geoffrey Bird isn't busy trying to rationalize the purchase of a new electronic gadget, he continues in his role as one of the staff cardiac intensivists at The Children's Hospital of Philadelphia. Comments, scathing critique, and unfettered praise are all warmly received at bird@email.chop.edu.

Reference List

1. McLeod TG, Ebbert JO, Lymp JF. *Survey assessment of personal digital assistant use among trainees and attending physicians*. J Am Med Inform Assoc 2003; 10: 605-607.

2. Labkoff SE, Shah S, Bormel J, Yee Y, Greenes RA. *The Constellation project: experience and evaluation of personal digital assistants in the clinical environment.* Proc Annu Symp Comput Appl Med Care 1995; 678-682.

3. Ramnarayan P. *Personal communication: Isabel User Survey* May 2003.2004.

4. Grasso BC, Genest R, Yung K, Arnold C. *Reducing errors in discharge medication lists by using personal digital assistants*. Psychiatr Serv 2002; 53: 1325-1326.

5. Pettis KS, Savona MR, Leibrandt PN et al. *Evaluation of the efficacy of hand-held computer screens for cardiologists' interpretation of 12-lead electrocardiograms.* Am Heart J 1999; 138: 765-770.

6. Leibrandt PN, Bell SJ, Savona MR et al. *Validation of cardiologists' decisions to initiate reperfusion therapy for acute myocardial infarction with electrocardiograms viewed on liquid crystal displays of cellular telephones*. Am Heart J 2000; 140: 747-752.

7. Ash JS, Berg M, Coiera E. *Some unintended consequences of information technology in health care: the nature of patient care information system related errors.* J Am Med Inform Assoc 2004;

8. Fischer S, Stewart TE, Mehta S, Wax R, Lapinsky SE. *Handheld computing in medicine*. J Am Med Inform Assoc 2003; 10: 139-149.

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

~PCT~

Geoffrey L. Bird, MD, FAAP
Staff Cardiac Intensivist
Assistant Professor of Anesthesiology & Pediatrics
University of Pennsylvania
The Children's Hospital of Philadelphia
Philadelphia, PA

bird@email.chop.edu

This article is an expansion of one written by Dr. Bird for the American Heart Association's (AHA) Spring 2004 edition of the Council Connections Newsletter– A Quarterly Communication of the AHA/ASA, Vol. 2, No. 1, "Whither the hype: An update on personal digital assistants in cardiac medicine." For more information: www.americanheart.org

PFM DEVICE CLOSES PERIMEMBRANOUS VSDS

By John W. Moore, MD

Closure of the perimembranous VSD is the latest challenge for transcatheter devices. To date, the Amplatzer Perimembranous VSD Occluder (Amplatzer Medical Corporation, Golden Valley, MN) has been the only device available. Recent events in Brazil appear to have opened up the field.

In Rio de Janeiro, on January 15th and 16th Dr. Trong Phi-Le and Dr. Luis Carlos Simoes implanted some of the first pfm (Productke fur die Medicine, Cologne, Germany) devices designed to close perimembranous VSDs. In Rio de Janeiro, six patients were catheterized. Their defects were all restrictive but hemodynamically significant. The defects ranged from 4 mm to 8 mm minimum diameter, most with some aneurysm formation. None had aortic cusp prolapse or aortic insufficiency. The distance from the superior rim of the defects to the aortic valve annulus ranged from 2 to 4 mm. These VSDs were similar to those reported in Amplatzer closures.[1-3]

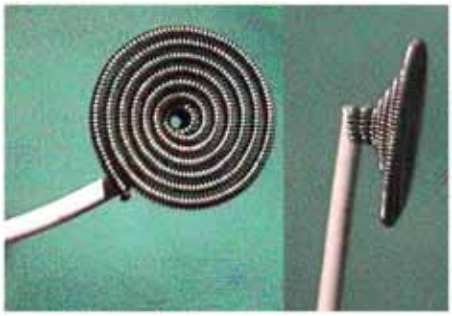


Figure 1. Nit-Occlud PDA Occluder. Photograph courtesy of Dr. Le.

Dr. Le has a track record in closing VSDs using the pfm Nit-Occlud device. The Nit-Occlud device is a nitinol coil with a cone-in-cone configuration, designed for PDA closure. It is available in most of the world without restrictions, and it is currently finishing a Phase 2 FDA clinical trial in the United States. Dr. Le has performed closure of perimembranous and muscular VSDs using the Nit-Occlud coil with surprisingly good results: achieving greater than 90% complete closure in muscular VSDs, and almost 80% in perimembranous defects by 6 months after implant. Furthermore, in more than 40 patients there have been no deaths and no major complications. Dr. Le expects that the modified Nit-Occlud device will perform better.

"Certainly, these anecdotal results look promising. We should look forward to Dr. Le's data from the first series of pfm Nit-Occlud VSD device implants."

The Nit-Occlud VDS device, like the PDA device, is made of nitinol coils and has a cone-in-cone configuration. The device has been modified by adding additional larger, reinforced coil loops on both the left ventricular and the right ventricular ends of the coil. Perhaps more importantly, polyester fibers have been added to the left ventricular cone. The fibers are placed between the tightly spaced primary coils of the device, much like the synthetic fibers in a standard Cook Gianturco coil. Several prototype devices have been built, the largest being the 14 x 8 device. (The device nomenclature refers to the sizes of the largest diameter left ventricular coil, followed by the largest diameter right ventricular coil.) The 14 x 8 device has a maximum left ventricular coil diameter of 14 mm and a maximum right ventricular coil diameter of 8 mm.

Figure 2. Nit-Occlud Perimembraneous VSD Occluder . Photograph courtesy of Dr. Le.

Drs. Le and Simoes implanted the Nit-Occlud VSD devices using techniques similar to those employed for the Amplatzer device. Typically, the VSD was assessed by transesophageal echocardiography and long axis oblique angiography. The defect was crossed retrograde using a Judkins right coronary catheter and a floppy wire. The wire was advanced into the pulmonary artery, with care to avoid the moderator band and the tricuspid apparatus. The wire tip was snared in the pulmonary artery by a loop snare introduced in the

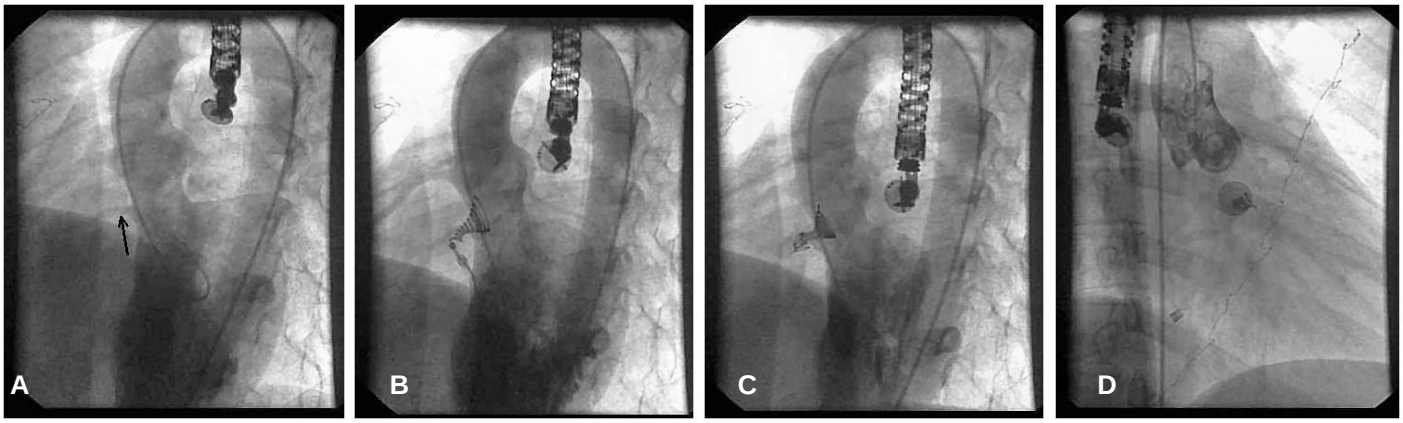


Figure 3 (A-D). (A) VSD prior to device closure; (B) Nit-Occluder device in VSD prior to release; (C) Nit-Occluder device in VSD after release; (D) Nit-Occluder device does not interfere with aortic valve function. Courtesy of Dr. Simones.

femoral vein. The wire end was externalized and a "rail" established. The Judkins catheter was advanced through the VSD along the rail into the inferior vena cava. A 7 French long sheath (Cook Flexor or Cordis Brite Tip) was introduced into the femoral vein, and advanced on the rail until the dilator "docked" with the tip of the Judkins catheter introduced in the femoral artery. Clamps were attached to both ends of the wire securing a tight docking of dilator and Judkins catheter. The sheath was advanced as the Judkins was withdrawn, until the sheath passed through the VSD and was comfortably into the ascending aorta. The Judkins catheter was removed and a pigtail catheter was advanced from the femoral artery along the wire until it met the dilator. Subsequently, the dilator was removed and the pigtail catheter was advanced into the sheath to the level of the hepatic portion of the IVC, this maneuver to prevent sheath kinking. The Nit-Occlud delivery catheter was introduced into the sheath and advanced to the tip of the pigtail catheter. The delivery catheter was further advanced into the ascending aorta as the pigtail catheter was withdrawn from the sheath. The delivery catheter was extended outside the long sheath, and the distal cone of the device was formed by pushing the coil outside the catheter. The distal cone was gently pulled to the level of the aortic sinuses and allowed to fall through the aortic valve into the left ventricular outflow tract. Once in the outflow tract, the distal coil cone was gently pulled into the VSD, guided by echocardiography and fluoroscopy. The largest one or two loops remain opposed to the left ventricular rims of the defect. The remainder of the coil cone is within the defect. Finally, the reverse cone of the device is developed to anchor the device. This is done carefully in order to avoid entrapping tricuspid valve structures. Angiography and echocardiography are employed to verify good device position, and the device is detached.

Figure 4. Drs. Simoes and Le confer prior to VSD Closure.

Of the six procedures performed in Rio de Janeiro, five were successful with 4 patients achieving total occlusion prior to departing from the catheterization laboratory. One patient had good device position, but had a small amount of leaking at the time of the last angiogram. The unsuccessful patient interestingly

Figure 5. Dr. Le and Dr. Simoes perform a VSD Closure.

had the smallest defect (4 mm) and the least aortic side rim (about 2 mm). Dr. Le felt that an 8 mm maximum aortic coil diameter was appropriate. The smallest available device had a 10 mm coil diameter. Closure with a smaller Nit-Occlud PDA device was attempted, without success. This coil was removed. There were no complications in these six patients. Early follow up shows that all five with device implants were totally closed at their first follow up echocardiograms.

Dr. Le later traveled on to Puerto Alegre and Sao Paulo, and the Rio de Janeiro experience was repeated in the labs of Dr. Raul Rossi Filho and Dr. Carlos Pedra. From there he traveled to Vietnam, presumable to implant additional devices.

Certainly, these anecdotal results look promising. We should look forward to Dr. Le's data from the first series of pfm Nit-Occlud VSD device implants. Many of our colleagues will get to observe the procedure soon because Dr. Carlos Pedra is planning to perform a live case demonstration at PICS in Buenos Aires this September. Stay tuned!

References:

1. Hijazi ZM, Hakim F, Haweleh AA, Madani A, Tarawna W, Hiari A, Cao QL. *Catheter closure of perimembranous ventricular septal defects using the new Amplatzer membranous VSD occluder: initial clinical experience*. Catheter Cardiovasc Interv 2002;56:508-515.

2. Thanopoulos BD, Tsaousis GS, Karanasios E, Eleftherakis NG, Paphitis C. *Transcatheter closure of perimembranous ventricular septal defects with the Amplatzer asymmetric ventricular septal defect occluder: preliminary experience in children*. Heart 2003;89:918-922.

3. Pedra CA, Pedra SR, Esteves CA, Pontes SC, Braga SL, Arrieta SR, Santana MV, Fontes VF, Masura J. *Percutaneous closure of perimembranous ventricular septal defects with the Amplatzer device: technical and morphological considerations*. Catheter Cardiovasc Interv 2004;61:403-410.

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

~PCT~

John W. Moore, MD, MPH, FACC
Director of the Pediatric Cardiac Catheterization Laboratory
Mattel Children's Hospital at UCLA

jwmoore@mednet.ucla.edu

Ask the Editorial Board

Do you have a question about a procedure, technology or product that you would like to ask the Editorial Board's opinion? e-mail your question to:

ASK@PediatricCardiologyToday.com

Selected questions and answers may be published in upcoming issues. Names will be withheld upon request.

APRIL CONFERENCE FOCUS

2nd Annual Symposium on New Interventions in Transcatheter Valve Techniques

April 28-29, 2005
Hyatt Regency Chicago, Chicago, IL
www.tvsymposium.com

This 2nd symposium has been created by course organizers, Carlos Ruiz, MD, PhD; Philipp Bonhoeffer MD; Carlos Duran, MD, PhD; and Sir Magdi Yacoub, MD. In addition, faculty members include Drs. Mark Galantowicz, of Columbus, USA; Ziyad Hijazi, of Chicago, USA; Peter Kleine, Frankfurt, Germany; Andrew Redington, Toronto, Canada; Jose Antonio Condado, Caracas, Venezuela; Alain Cribier, Rouen, France; Jacques Seguin, Créteil, France; Patrick Serruys, Rotterdam, Netherlands; Steven Oesterle, Minneapolis, USA; Robert Lederman, Washington, DC USA; Jan Harnek, Lund, Sweden; Howard Herrmann, Philadelphia, USA; and Martin Elliott, London, UK to name a few.

The symposium will be broken into major sections:

- BACK TO SCHOOL (Chairs: Drs. P. Bonhoeffer & M. Yacoub)
- IMAGING (Chairs: Drs. C. Ruiz & P. Serruys)
- TRANSCATHETER TECHNOLOGIES (Chairs: Drs. C. Duran & Z. Hijazi)
- THE SURGEON'S PERSPECTIVE (Chairs: Drs. V. Fuster & M. Leon)
- CROSS FIRE SESSION (Chairs: Drs. P. McCarthy & C. Ruiz)
- WHAT HAVE WE LEARNED FROM THE COMPLICATIONS? (Chairs: Drs. A. Cribier & J. Cox)
- OVERCOMING ROADBLOCKS (Chairs: Drs. A. Redington & W. O'Neill)
- STATE OF THE ART SURGICAL VALVE PROCEDURES (Chairs: Drs. P. Bonhoeffer & C Duran)

TRANSCATHETER CARDIAC VALVE IMPLANTATION

By Carlos E. Ruiz, MD

Introduction

The management of valvular heart disease remains one of the major challenges to contemporary medicine. It involves the choice of the most appropriate medical regimens, the right timing for intervening, choosing the right procedure and certainly the most appropriate prosthesis, when a new valve implant is considered.

Operative cardiac valve intervention is actually almost a century old and was first pioneered by Theodore Tuffier (1857-1929) who successfully attempted the first operative treatment of a patient with aortic stenosis on July 13, 1912 with a finger-dilatation. However, the first human implant of a prosthetic ball-valve was done on September 11, 1952 by Charles A. Hufnagel (1916-1989) in a patient with severe aortic insufficiency that was implanted in the descending aorta. The first successful aortic valve replacement in the subcoronary position was performed by Dr. Dwight Harken and colleagues[1] and caged ball valve was also used. The first conference on prosthetic heart valves was held in September of 1960. Since then a periodic assessment of the many undertakings to develop valve substitutes and their experimental an clinical evaluation have made possible a tremendous advance in this field. This progress has not been easy or free of serious disappointments. The mortality in the early experiments was extremely high, greater than 40%. Yet, as was prophetically pointed out by Dr. K.A. Merendino, another pioneer in valve surgery, "…one should not have been totally discouraged by the failures, but rather encouraged by the limited success." We must not forget those early results of prosthetic valve implantation and objectively keep it in mind when we are ready to evaluate today's results with the new transcatheter technologies.

Transcatheter Pulmonary Valve Implantation

The first transcatheter cardiac valve implanted in humans was performed by Dr. Philipp Bonhoeffer and was reported in Lancet October 21, 2000.[2] Bonhoeffer used a clinically available preserved bovine jugular vein valve sutured to a Nu-Med CP stent and crimped on a balloon catheter (Figure 1).

In the past 5 years he has implanted more than 81 valves in 75 patients with 98% success rate. The majority of patients were post repair of tetralogy of Fallot, pulmonary atresia-VSD, d-TGA, truncus arteriosus, s/p Ross procedure etc. and the great majority have had more than one thoracotomy performed in the past. They all experienced a significant decrease in the existing transvalvular gradient from 39 mmHg to 21 mmHg ($p<0.001$). However, the most impressive parameter is the resolution of the pulmonary insufficiency causing an immediate decrease in the right ventricular end-diastolic volume, with a concomitant increase in the left ventricular end-diastolic volume MRI. These immediate hemodynamic changes translated into a significant improvement of the patient metabolic exercise testing, increasing the peak oxygen consumption from 24.4+1.5 ml/kg/min to 26.3+1.6 ml/kg/min ($p=0.009$). The median age is 16 (9-44) years and the median number of previous cardiac surgeries was three.[2,3]

There have been few device failures, which include the so-called "Hammock Effect" that has been resolved by re-engineering the suture of the valve on the stent and also there have been several stent fractures.

Procedural complications occurred in four patients and were life-threatening in two. Freedom from surgical re-

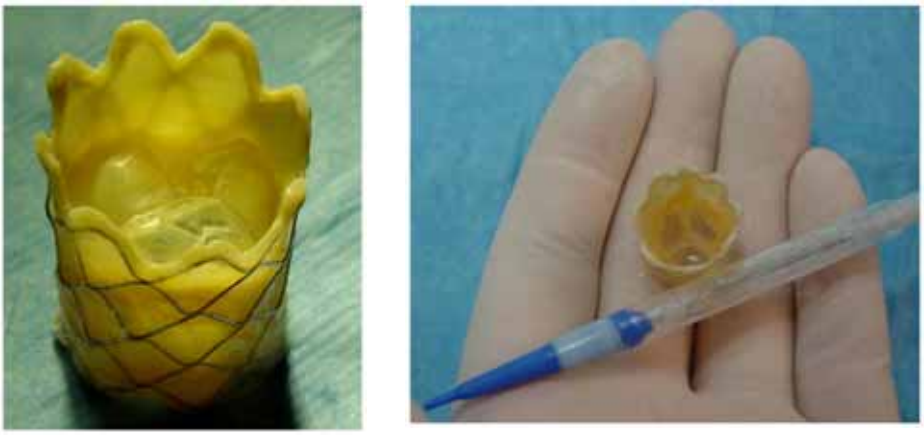


Figure 1. Bonhoeffer 's pulmonary valve. Courtesy of Dr. P. Bonhoeffer.

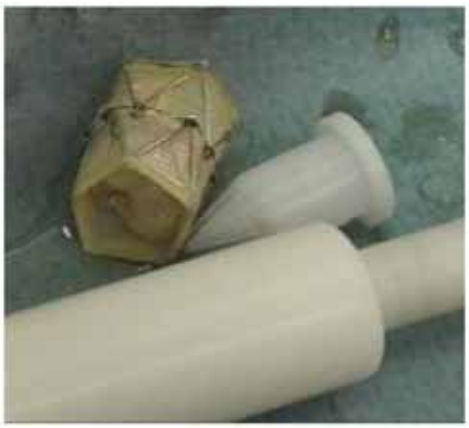


Figure 2. Amin's valve. Courtesy of Dr. Z. Amin.

intervention at 1 year was 91.7% with the current design. There have been other complications reported, such as three cases of late endocarditis and one case of intravascular hemolysis. Surgery post percutaneous valve implant was never due to pulmonary insufficiency. Surgery was necessary in a subgroup of five patients because of residual stenosis non-responsive to stent. Perhaps, though, the most important parameter is that there has been no acute or late mortality.

Based on the current device design, the selection of patients is limited to patients older than 5 years and weight larger than 20 Kg, with significant pulmonary insufficiency with increasing RV dilatation and/or impaired exercise tolerance, as well as those with RV outflow tract obstruction with RV pressures greater than 2/3 systemic.

There is no question that, in part, the great success achieved by Bonhoeffer and collaborators is due to the intelligent and cautious approach in patient selection.[3] Rather than attempting implantation of the valve in native structures, they elected to choose patients with conduits in whom the detailed anatomy is better known. Furthermore, the pulmonary valve location does not have the same adjacent vulnerable structures as the aortic valve and therefore there is no risk of device failure that can be catastrophic. Finally, all these patients are destined to undergo re-operations, thus making it easier to justify this approach to minimize the number of thoracotomies.

There are other transcatheter cardiac valve prosthesis that are currently in the animal investigational phase. Perhaps, the one that seems to be closer to human experimental implant, is the transcatheter valve developed by PVT-Edwards, modified for the pulmonary valve position and that is also balloon expandable (detailed explanation will follow under the aortic valve implants). So far there have been no reports on animal or human experimentation of this valve.

Also, Dr. Zahid Amin has experimented with the Shelhigh No-React porcine pulmonary valve mounted on Gianturco-Rosch Z-stents and delivered by direct access of the free wall of the RV through a purse-string suture (Figure 2).

However there have been no human implant attempts of this device thus far.

Another type of pulmonary valve that is in the animal experimentation phase, is the Cook-SIS self expandable valve. This valve is a modified venous valve that was initially developed by Dusan Pavcnik from the Dotter Interventional Institute of the University of Oregon. This valve utilizes a biomaterial called SIS, which is derived from the small intestinal (jejunum) submucosa of the pig. This biomaterial is basically an acellular matrix mostly composed of type-I and some type III and IV collagen that contains other extracellular matrix molecules such as fibronectin, hyaluronic acid, chondroitin sulfate A and B, heparin, heparan sulfate and some growth factors such as basic Fibroblast Growth Factor-2 (FGF-2), Transforming Growth Factor β (TGF-β) and Vascular Endothelial Growth Factor (VEGF). The SIS is mounted on a very low profile, self-expandable stent that was based on the earlier square design of the venous valve,[4] and the newer designs are self-centering and self-aligning. (Figure 3).

The one year follow-up study post implantation performed in a swine model with RV failure showed that the valve was successful in controlling pulmonary insufficiency and reversing the RV failure, and the SIS tissue underwent progressive and extensive remodeling with neovascularization and complete endothelization after the first 3 months.[5] However, there was an excessive remodeling noted mainly at the base of the leaflets, with some foreshortening; therefore, the use of SIS as a cardiac valve tissue, needs further and longer animal studies

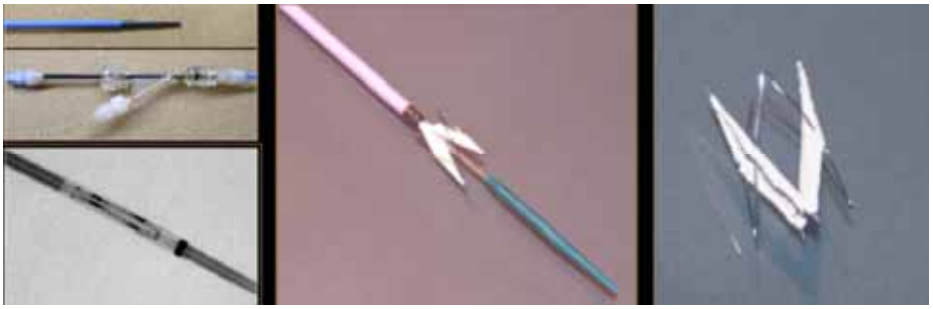


Figure 3. Cook-SIS valve.

before any attempts to human implantation can be contemplated.

Transcatheter Aortic Valve Implantation

The concept of percutaneous intervention for patients with severe aortic stenosis was first introduced in 1986 by Cribier and Letac[6] when they first performed aortic balloon valvuloplasty in patients with severe calcific aortic stenosis. However, the initial success was very short lived, and quickly it became obvious that the valvuloplasty procedure could not be an alternative to valve replacement, but could be used as a bridge to valve replacement in special circumstances.

Highly stimulated by the poor long-term results obtained with balloon valvuloplasty in calcific aortic stenosis,[7] Alain Cribier started to contemplate the possibility of mounting a biological valve in a large stent and placed across the calcified valve. He first conducted some cadaver studies and determined the length of the stent that would be needed to effectively hold a valve and not to interfere with the coronary blood flow. Based on the Henning R. Anderson patent from February 2000, Percutaneous Valve Technologies (PVT) developed the first balloon expandable stented valve that could be delivered by a catheter across the aortic valve. In April 2002, Alain Cribier and colleagues successfully implanted the first transcatheter aortic valve prosthesis in a patient with severely calcified aortic stenosis.[8] The current valve is constructed from equine pericardium and mounted on a 14 mm long x 23 mm diameter, highly resistant stainless steel balloon expandable stent that is mechanically crimped on a 23 mm Z-Med II balloon valvuloplasty catheter. The mounted stented valve can be introduced through a Fr. #24 sheath. (Figure 4)

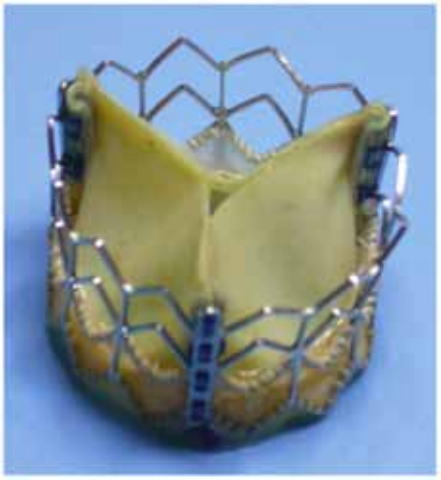


Figure 4. Cribier's aortic valve. Courtesy of Percutaneous Valve Technologies-Edwards LifeScience.

Because the delivery system lacks a cover sheath to protect the stent, it would be very hard to get across the heavily calcified aortic valves and therefore the majority of the implantations had to be done in an anterograde approach, transseptally, although they have also implanted in a retrograde approach. There have been more than 20 valves implanted and all patients were deemed inoperable by at least two cardiothoracic surgical teams. Obviously, this kind of patient selection for the transcatheter implant of aortic valve prosthesis tilts the balance toward having much higher risks for fatal complications, and therefore when analyzing the result one has to keep in mind this very important factor. Nevertheless, significant para-valvular regurgitation and early mortality characterize their experience thus far.[9]

Another pioneering work in the field of transcatheter aortic valve prosthesis has been briefly reported by Paniagua and collaborators,[10] there has been only one successful human implant of this lower-profile transcatheter valve prosthesis. This prosthesis is built from porcine pericardium treated by a proprietary physico-chemical process technology that produces a 40 µm thick biologically inactive membrane with a smooth blood-surface contact and great strength. It is highly resistant to calcification in animal models at a relatively long-term implantation. This material is tailored in a tubular fashion and sutured to either a balloon expandable (stainless steel) stent with an introducible diameter of Fr. #14 or to a self-expandable (nitinol) stent with an introducible diameter of Fr. #11.[9] (Figure 5).

There is another transcatheter aortic valve prosthesis that has recently entered into phase one clinical trials, the CoreValve. This prosthesis is made of a self-expandable nitinol stent 50 mm long and with variable diameters, it has a commercially available bovine pericardial valve sutured into the stent. The stent has a very high radial force and is able to effectively crush the native valvular calcifications (Figure 6).

The delivery catheter requires a Fr. #24 introducer, and currently all human implants have been done under fem-fem by-pass with a membrane oxygenator.

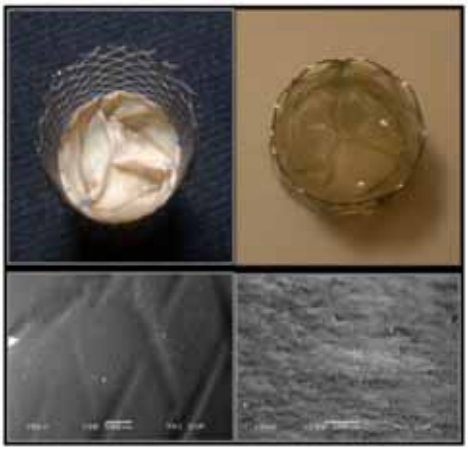


Figure 5. Paniagua's valve. Courtesy of Dr. David Paniagua

Figure 7. Intracardiac echocardiogram guiding placement of CoreValve.

The delivery of the prosthesis in some instances were guided by intracardiac echocardiogram (ICE) using a Siemens AcuNav System (Figure 7).

There have been very few human implants done with this valve to the best of my knowledge and their results have not yet been published, but their pilot study protocol is aimed at patients that are good surgical candidates for valve replacement.

There are other transcatheter aortic valve prosthesis being developed and at different investigational stages, but without any human implantation experience, so far reported, such as the self expandable nitinol stent with active fixation barbs that uses either porcine aortic valve or porcine pericardium (Figure 8), that was developed and reported by Lutter G, et al.[11]

Figure 6. The CoreValve. Courtesy of CoreValve.

The stent is 21 to 28 mm in length and they have valves from 15 to 23 mm in diameter and it requires a Fr. #22 introducer.

Also Dr. Philipp Bonhoeffer has reported[11] an ingenious self-centering and self-orienting transcatheter aortic valve prosthesis using a combination of a self-expandable nitinol stent to orient and align and a balloon expandable stent to fix the valve without obstructing the coronary artery ostiums. (Figure 9).

In addition of the above mentioned transcatheter aortic valve prosthesis, there are many other start-up companies that are actively pursuing this new technology in response to what promises to be a very exciting future. The majority of the efforts are being focused on developing biological prosthesis; these include finding the right biomaterial. There are many fascinating projects in the works including the use of biologically inactive scaffolds that can be reabsorbed or remodeled in combination with tissue-engineered valves as pioneered by Dr. John Mayer from Harvard of Boston, and Sir Magdi Yacoub from the Imperial College of London.

Certainly, we cannot complete this brief review on transcatheter valve technologies without mentioning the efforts in developing mechanical, non-biological prosthetic valves. The pioneering effort began with Dusan Pavcnik when he developed a transcatheter cage-ball valve using modified Gianturco Z-stents and an inflatable ball[12] – Figure 10. However, one of the most exciting technologies using nanotechnology is the initial work being

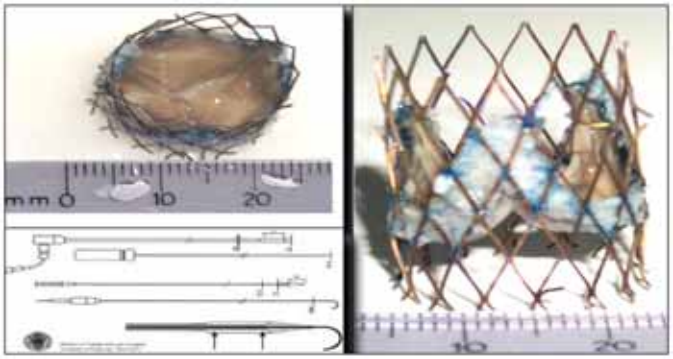


Figure 8. Lutter's valve. Courtesy of Dr. G. Lutter.

done by Dr. Steven Bailey from the University of Texas in San Antonio. At our First Transcatheter Valve Symposium celebrated in London in March of 2004, he reported that using a vacuum deposition developmental system, a 3D-Spluttering Magnetron, basically they would load it with metals in their pure state, and by using a chamber pressurized at 10^{12} Atm. In the presence of an anode and a cathode, specific ions are driven to the center where there is a mold, that can perform 3D stereometric assembly. This, allows them to control the thickness of the material down to 4µm, therefore omitting the need for thinning the metal. Furthermore, this allows them also to control the expansion characteristic or elasticity of the new metal. Using this technology they have been able to develop metallic membranes that have been used as vascular graft as well as developing valve leaflets (Figure 11).

He reported the successful transcatheter implant of this mechanical valve in the animal model with a very high rate of success and minimal complications in the mid-term follow-up.

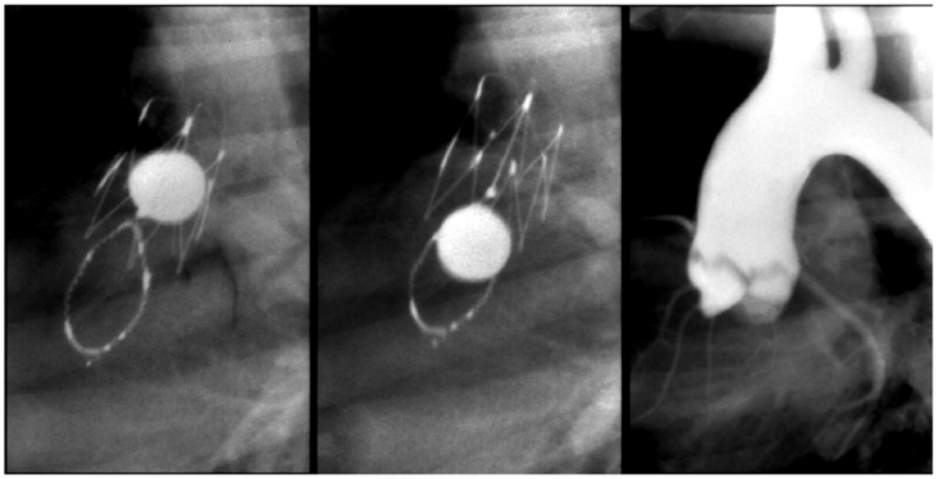


Figure 10. Pavcnik's valve. Courtesy of Dr. D. Pavcnik.

Transcatheter cardiac valve prosthesis is an emerging technology with a phenomenal potential for providing patients with less invasive means of treating valvular heart disease. In this manuscript we briefly commented on the outflow cardiac valves, pulmonic and aortic, however it will not be long before the firsts reports appear on the efforts that many of us are developing to construct a feasible and safe transcatheter in-flow cardiac valve, i.e., mitral and tricuspid. Aside from these galloping technologies there will be other crucial issues that will need to be addressed before the use of these technologies can be offered as a true therapeutic alternative for some patients. First, we need to really convince ourselves and the regulatory agencies throughout the world that these devices are equivalent to the ones that are in use today. However, durability of the prosthesis will need to be put in perspective depending on the intended use of the device. But what is certain in my view is that these procedures should be "safer" than the current surgical techniques, with less co-morbidity and mortality for this technology before they have a chance to become the gold standard.

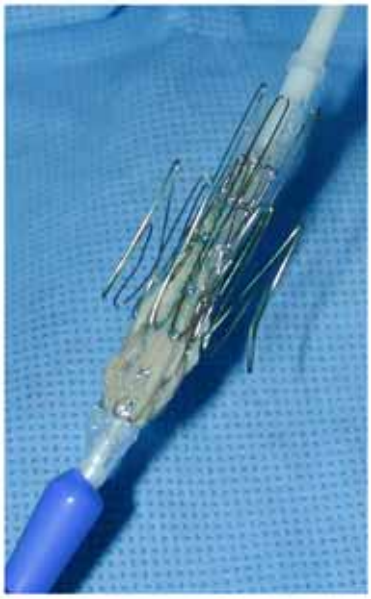


Figure 9. Bonhoeffer's aortic valve. Courtesy of Dr. P. Bonhoeffer.

Therefore, we will need a true collabo-

Figure 11. Bailey's valve. Courtesy of Dr. S. Bailey.

ration among cardiac surgeons, cardiologist, engineers, basic scientists, etc. when trying to prove the safety and efficacy of these devices. Trial design, control groups, end-points for assessment, investigator and institutional requirements, as well as specific safety issues are going to be crucial. This will need to be put in the perspective that, for almost all patients open cardiac surgical valve replacement is the gold standard, and the few considered inoperable, will need to be well defined with a unified rigorous criteria for "non-operable" across the board.

Finally, I think that perhaps one of the main handicaps to the advancement of these technologies is due to the lack of optimal imaging technology. The surgeons in the operating theater have indeed the ultimate imaging technology, their own eyes, with or without magnifying lenses. There is no question in my mind, after having implanted many transcatheter valve prosthesis, mostly in animals and a few in humans, that in order to make these procedures safe and effective we must also partner with the leaders in imaging industry, to develop better and more realistic imaging modalities.

References

1. Harken DE, Soroff HS, Taylor WJ, et al: *Partial and complete prostheses in aortic insufficiency*. J Thorac Cardiovasc Surg 1960; 40: 744.

2. Bonhoeffer P, Younes B, Zakhia S, et al: *Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction*. Lancet 356: 1403-1405, 2000.

3. Bonhoeffer P, Boudjemline Y, Qureshi SA, et al.: *Percutaneous insertion of the pulmonary valve*. J Am Coll Cardiol 39:1664-1669, 2002.

4. Pavcnik D. Uchida BT. Timmermans H. et al.: *The square stent-based large vessel occluder: an experimental pilot study.* Journal of Vascular & Interventional Radiology. 11(9):1227-34, 2000.

5. Ruiz CE, ……..

6. Cribier A, Savin T, Saoudi N, et al.: *Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: An alternative to valve replacement?* Lancet 1:63-67, 1986.

7. O'Neil WWand *Mansfield Scientific Aortic Valvuloplasty Regestry Investigators.: Predictors of long term survival after percutaneous aortic valvuloplasty: Report of the Mansfield Scientific Aortic Valvuloplasty Regestry*. J Am Coll Cardiol 17:909-913, 1991.

8. Cribier A, Eltchaninoff H, Bash A, et al.: *Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis. First human case description.* Circulation 106:3006-3008, 2002.

9. Paniagua D, Induni E, Ortiz C, et al.: *Percutaneous Heart Valve in the Chronic In Vitro Testing Model*. Circulation 106: 51–52, 2002.

10. Lutter G, Kuklinski D, Berg G, et al.: *Percutaneous aortic valve replacement: An experimental study. I. Studies on implantation. Journal of Thoracic & Cardiovascular Surgery*. 123(4):768-776, 2002.

11. Cribier A, Eltchaninoff H, Tron C, et al.: *Early experience with percutaneous transcatheter implantation of heart valve prosthesis for the treatment of end-stage inoperable patients with calcific aortic stenosis*. J Am Coll Cardiol 43:698-703, 2004.

12. Pavcnik D. Wright KC. Wallace S.: *Development and initial experimental evaluation of a prosthetic aortic valve for transcatheter placement. Work in progress*. Radiology. 183(1):151-4, 1992.

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

~PCT~

Carlos E. Ruiz, MD, PhD
Professor and Chief
Division of Pediatric Cardiology
University of Illinois at Chicago

cruizmd@uic.edu

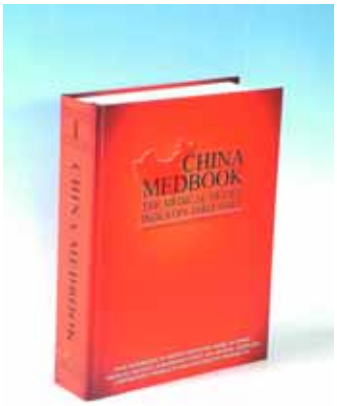
MEDICAL NEWS AND INFORMATION

China's Medical Device Industry Forecasted to Become the Worlds Largest

(PRWEB) - The medical device industry in China is growing at 17% per year and forecasted to continue this incredible growth rate for the next 10 years. China Medbook, a new directory and industry reports from Life Sciences Publishing (LSP) provides complete information on the industry and profiles 9,000 manufacturers. Manufacturers in China are expanding rapidly in size and in their numbers. There are now over 9,000 device firms in China and this number will soon pass the United States. They are not only meeting the needs of China's massive market, but export sales of medical devices are growing at 25% a year as shown in a report from China Customs. To facilitate global trade with China's explosive medical device industry Life Sciences Publishing announces the launch of China Medbook, the world's first medical device industry directory for China. China Medbook provides complete information on the industry with in-depth profiles of 9,000 manufacturers. Information provided by China Customs Department illustrates that it is manufacturers in the United States and Europe who are getting the most benefit from this growth with China imports of medical devices up by an astounding 34% as of the September 30th, 2004. China's State Food and Drug Administration has recently mandated Good Manufacturing Practices for all medical device manufacturers which is expected to increase the quality and reliability of medical devices made in China and allow them to compete globally. This will only enhance the dramatic growth already underway.

China Medbook contains accurate and detailed information on all firms in both Mainland China (8,000), Taiwan & Hong Kong (1,000). Information provided includes phone, fax, e-mail and postal addresses. Also included are key personnel, number of employees and registered capital. The directory has 3 sections: the 1st section sorts manufacturers by over 200 different categories allowing users to find companies by product. The 2nd sorts companies geographically and the 3rd is organized by company profile.

A detailed verification process undertaken by LSP's professional bilingual staff of software engineers, information specialists, and data entry specialists ensures that the data found in China Medbook is accurate. A team of Medical Doctors reviewed each manufacturer's products to ensure accuracy in the placement of products into categories.



China Medbook from Life Science Publishing

Bill Goodwin, Publisher of China Medbook says, "This project, which has taken over 2 years and 40,000 man-hours, will increase and facilitate 2-way trade with China, a vital market for the world's major medical device firms. Lack of quality information is an obstacle for western firms who want to do business in China. China Medbook will save users hundreds of hours in sourcing made in china medical devices, equipment, dental supplies, laboratory products and diagnostic products".

Included in China Medbook is a market research report with pertinent industry and marketing data. Tradeshows across China are included along with a list of all relevant organizations and agencies involved in the development of medical standards. Current import and export data are in separate tables. A list of all trade publications and journals is included along with contact details. Purchasers of China Medbook who cannot locate a particular product or company can obtain free assistance from LSP staff for 1 year after date of purchase.

For more information: www.lifesciencespublishing.com

Elizabeth G. Nabel, MD, Named New Director of the National Heart, Lung, and Blood Institute

Dr. Nabel, whose appointment began on February 1, 2005, will oversee an annual budget of almost $3 billion and a staff of approximately 850 Federal employees. The Institute provides leadership for a national research program on heart, lung, blood, and sleep diseases and disorders. Since 1993, the Institute has been the home of the National Center on Sleep Disorders Research and, since 1998, it has had responsibility for the NIH Women's Health Initiative. Institute-funded research is conducted in Bethesda, Maryland in the NHLBI's intramural laboratories and throughout the country

by institutions and individuals supported by research grants and contracts. In addition, the NHLBI conducts educational activities, including the development and dissemination of materials for health professionals, patients, and the general public, with a strong emphasis on prevention.

Dr. Nabel has received numerous awards, including the Distinguished Achievement Award from the Basic Cardiovascular Sciences Council of the American Heart Association and the Amgen-Scientific Achievement Award from the American Society for Biochemistry and Molecular Biology. She is an elected member of the American Society of Clinical Investigation, the Association of American Physicians, and the Institute of Medicine of the National Academy of Sciences. In 2001, Dr. Nabel received an honorary doctoral degree from the University of Leuven in Belgium.

Dr. Nabel is an editorial board member of The New England Journal of Medicine. She has been a reviewing editor for Science and an editorial board member of the Journal of Clinical Investigation. She also served as a consulting editor for Circulation, Circulation Research, and Arteriosclerosis, Thrombosis, and Vascular Biology.

Dr. Nabel has served on American Heart Association committees including: the Board of Directors; the Scientific Publishing Committee (Chair); the Atherosclerosis, Thrombosis and Vascular Biology Council (Chair); the executive committee of the Basic Cardiovascular Sciences Council, and the Science Advisory and Coordinating Committee. Other national and international leadership roles include President of the North American Vascular Biology Organization, Councilor of the American Society of Clinical Investigation, member of the Board of Directors for the Keystone Symposium, member of the Scientific Advisory Board of The Stanley J. Sarnoff Endowment for Cardiovascular Science, and as a member of the membership committee of the Institutes of Medicine. She has also served on international advisory committees including the Center for Transgene Technology and Gene Therapy and the Center for Molecular and Vascular Biology at the University! of Leuven, and the International Vascular Biology Organization.

For more information: www.nih.gov

Edwards Launches ThermaFix Tissue Process on PERIMOUNT Magna Heart Valves at STS 2005

(PRNewswire). Edwards Corporation (NYSE: EW), a leader

Ask the Editorial Board

Do you have a question about a procedure, technology or product that you would like to ask the Editorial Board's opinion? e-mail your question to: ASK@PediatricCardiologyToday.com

Selected questions and answers may be published in upcoming issues. Names will be withheld upon request.

in heart valve technologies, at its annual meeting in January Edwards announced the U.S. launch of its ThermaFix advanced tissue treatment process, which will now be available on the company's Carpentier-Edwards PERIMOUNT Magna replacement tissue heart valves. The new combination of technologies was formally unveiled at the 41st annual scientific meeting of the Society of Thoracic Surgeons (STS) in Tampa, FL, January 24 - 26.

Edwards co-developed the ThermaFix process with biochemist Sophie Carpentier, PhD, and her husband Prof. Alain Carpentier, chairman of the Department of Cardiovascular Surgery at the Hopital Europeen Georges Pompidou in Paris. Laboratory studies have demonstrated that, when compared to Edwards' current market-leading tissue treatment, the ThermaFix process significantly reduces leaflet calcification, which is one of the primary causes of tissue valve deterioration.

"Although pericardial valves have demonstrated decades of reliable performance, mitigating the calcification of a tissue valve's leaftlets has been a focus of research and development since their introduction," said Albert Starr, MD, medical director of the Providence Heart and Vascular Institute in Oregon, and co-inventor of the Starr-Edwards heart valve, the first commercially available artificial heart valve in the world. "By coupling the PERIMOUNT Magna valve's improved hemodynamic performance with the ThermaFix process, Edwards is providing patients with the confidence that they are getting the best technology there is to offer."

The PERIMOUNT Magna valve, an aortic replacement tissue heart valve constructed of bovine pericardium, is designed specifically to optimize patient blood flow and facilitates placement above the patient's native valve opening, which may allow surgeons to implant a valve that is larger than other conventional tissue valves. Surgeons generally prefer valves that can provide optimal blood flow for their patients, and Edwards' PERIMOUNT valve line has been shown to provide greater valve opening areas to facilitate that blood flow, according to an article published by Thomas Walther, MD and colleagues in the September, 2004 issue of Circulation.

Edwards Lifesciences is a leader in advanced cardiovascular disease treatments, focusing on four main cardiovascular disease states: heart valve disease, coronary artery disease, peripheral vascular disease and congestive heart failure.

For more information: www.edwards.com.

Long-Term Treatment with Bosentan Improves Outcomes in Pulmonary Arterial Hypertension, European Respiratory Journal

Pulmonary arterial hypertension (PAH) is a devastating disease that carries a poor prognosis. Untreated, about half of patients die within two years.

Only recently have specific medicines for this disease become available. While effective, the first available therapy, epoprostenol, proved difficult for patients to use because it is delivered on a continuous intravenous basis rather than in a pill form.

Bosentan, a dual endothelin receptor antagonist, is the first approved oral treatment for PAH. In short-term (12-16 week) trials, bosentan has demonstrated improvements in how far patients can walk and how they feel.

This improvement, combined with the convenience of an oral therapy provides a valuable treatment option for patients.

In order to assess the long-term benefit of bosentan, a recent analysis of long-term data was performed. Vallerie McLaughlin (University of Michigan, Ann Arbor, USA) and her American and European colleagues compared the survival in bosentan-treated patients to the survival that would have been predicted based on past clinical experience.

Survival in the treated patients was 96% at one year and 89% at two years. In comparison, the expected survival without treatment was 67% at one year and 58% at two years. After two years of follow-up, 70% of patients were still on bosentan alone, without the need for additional therapies. Although treatment with bosentan was well tolerated, it was associated with a 10% incidence of elevated liver enzymes thereby requiring monthly liver enzyme monitoring by a simple blood test. In summary, bosentan, an oral treatment of pulmonary hypertension, improves how patients feel and how long they live.

This is a press release from the European Respiratory Journal (ERJ), Vol. 25, No 2.

For more information: http://erj.ersjournals.com/

EDITORIAL COMMENT FOR MARCH

The February Issue of Pediatric Cardiology Today published a survey submitted by readers who were concerned about the recent increase in the annual dues of the American College of Cardiology. In retrospect, this survey should have addressed various associations' membership dues, not specifically the American College of Cardiology. It did not frame the larger issue, which in my view is the total burden of memberships, dues and fees upon Pediatric Cardiology Today's readers, related to the large number of organizations claiming their allegiance. Many pediatric cardiologists are members of the American College of Cardiology, the American Academy of Pediatrics, the American Heart Association, a sub-specialty society (e.g. the Society of Cardiac Angiography and Intervention), and a regional society (e.g. the Western Society of Pediatric Cardiology). Each of these organizations requires annual dues and charges fees related to attending meetings. To further burden our readers their charges have gradually been increasing in recent years. The over all financial burdens on individual pediatric cardiologists may be substantial.

> ***"Each of the professional societies ...offering membership to pediatric cardiologists needs to address the reasons for and benefits of membership for the pediatric cardiologist."***

In addition, many academic divisions no longer provide funding for memberships in professional societies or for attending meetings. This benefit has in many cases disappeared or been significantly reduced as a cost cutting measure. Thus many pediatric cardiologists must fund memberships, dues and fees out-of-pocket. Clearly, in this environment, choices must be made and cost-benefit needs to be considered. Each of the professional societies and organizations offering membership to pediatric cardiologists needs to address the reasons for and benefits of membership for the pediatric cardiologist.

The survey responses were generally positive about membership in the American College of Cardiology. In addition, there is much interest in participating in a number of additional associations. Moreover, the respondents confirm that the financial burden of membership in multiple organizations in an environment of limited funding is significant.

It seems apparent that Pediatric Cardiology Today's readers value membership and participation in multiple professional societies and organizations. In order to assist readers in their membership evaluations, Pediatric Cardiology Today will solicit statements from various societies and organizations describing the benefits of membership and participation for pediatric cardiologists.

John W. Moore, MD, MPH
Editorial Board
Pediatric Cardiology Today

MARED@PediatricCardiologyToday.com

~PCT~

MEDICAL CONFERENCES

International Workshop on Interventional Pediatric Cardiology
March 31-April 2, 2005; Milan, Italy
www.workshopIPC.com

2005 SIR 30th Annual Scientific Meeting
March 31-April 5, 2005; New Orleans, LA
www.sirweb.org

The 2005 Symposium on Advanced Pediatric Cardiovascular MR
April 2-3, 2005; Toronto, Canada
www.nasci.org

AATS 85th Annual Meeting
April 10-13, 2005; San Francisco, CA
www.aats.org/annualmeeting/

2nd Annual Symposium on New Interventions in Transcatheter Valve Techniques
April 28-29, 2005; Chicago, IL
www.tvsymposium.com

3rd Charleston Symposium on Interventional Pediatric Electrophysiology
May 1-3, 2005; Kiawah Island, SC
www.pediatrics.musc.edu/pedscard/

SCAI's 28th Annual Scientific Sessions
May 4-7, 2005; Ponte Vedra Beach, FL
www.scai.org

2005 PAS Annual Meeting
May 14-17, 2005; Washington, DC
www.pas-meeting.org

14th Parma Int. Echo Meeting
June 6-8, 2005; Parma, Italy
www.unipr.it/arpa/echomeet/

PEDIRHYTHM-2
June 15-18, 2005; Antalya, Turkey
www.pedirhythm.org

ASE 16th Annual Scientific Sessions
June 15-18, 2005; Boston, MA
www.asecho.org

8th International Workshop Catheter Interventions in Congenital Heart Disease
June 16-18, 2005; Frankfurt, Germany
www.chd-workshop.org

5th International Pediatric Cardiovascular Symposium: Management of Complex CHD from Infancy to Adulthood
June 23-26, 2005; Amelia Island, FL
www.choa.org

PEDIATRIC CARDIOLOGY TODAY ®
9008 Copenhaver Drive, Suite M
Potomac, MD 20854 USA

Your *FREE* *March* Issue of PEDIATRIC CARDIOLOGY TODAY

PEDIATRIC CARDIOLOGY TODAY®

RELIABLE INFORMATION IN PEDIATRIC CARDIOLOGY™

New Product Submission
PR@PediatricCardiologyToday.com

FREE Subscription
Pediatric Cardiology Today ® is published monthly and FREE to qualified professionals in pediatric cardiology and related fields in the U.S. and Canada. To subscribe send an email with name, title, phone, e-mail and address to:
Subs@PediatricCardiologyToday.com

Or fax your request to 240.465.0692

Article Submission
Article@PediatricCardiologyToday.com

Production
Prod@PediatricCardiologyToday.com

Letters to the Editor
Letters@PediatricCardiologyToday.com

Sales & Marketing
Sales@PediatricCardiologyToday.com

Reprints
Reprint@PediatricCardiologyToday.com

Publishing Management
Tony Carlson, Founder & VP of Marketing
Tel: 301.279.2005; Fax: 240.465.0692
TonyC@PediatricCardiologyToday.com

Richard Koulbanis, Editor & Publisher
Tel: 240.988.4390; Fax: 240.465.0692
RichardK@PediatricCardiologyToday.com

Virginia Dematatis, Editorial Consultant
VirginiaD@PediatricCardiologyToday.com

Loraine Watts, Editorial Assistant

Caryl Cornell, Editorial Assistant

Sales Offices
PEDIATRIC CARDIOLOGY TODAY
9008 Copenhaver Drive, Suite M
Potomac, MD 20854 USA

Editorial Offices
PEDIATRIC CARDIOLOGY TODAY
19509 Pine Cone Court, Suite 100
Gaithersburg, MD 20879 USA

www.PediatricCardiologyToday.com