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PERFORATING THE PULMONARY VALVE WITH A GUIDE WIRE IN PULMONARY ATRESIA WITH INTACT INTERVENTRICULAR SEPTUM: TECHNICAL TIPS

By Bharat Dalvi, MD, DM; Robin Pinto, MD, DM

Pulmonary atresia with intact interventricular septum (PAIVS) is a heterogenous condition with a wide morphological spectrum and variable prognosis. At one end of the spectrum are those with near normal right ventricle and mildly hypoplastic tricuspid valve annulus, whereas at the other end are children with severe hypoplasia of the tricuspid valve annulus and the right ventricular patients with a hypoplastic but patent tricuspid valve may have communications between the right ventricle and coronary arteries through the coronary sinusoids. Those with coronary sinusoids feeding the coronary arteries are associated with stenosis of the epicardial coronary arteries. Under these circumstances, decompressing the right ventricle would result in left ventricular ischemia and dysfunction. Therefore, the management strategy for PAIVS is largely determined by the status of the coronary circulation and severity of the right ventricular hypoplasia. Most often the coronary abnormalities are associated with the smallest TV annuli and right ventricular volumes. Those with two or more epicardial coronary arteries supplied by sinusoids (RV dependent coronary circulation – RVDCC) are usually condemned to univentricular repair, whereas those with none or one epicardial coronary artery supplied through the right ventricular sinusoids can be considered for right ventricular decompression with a view to have two ventricular circulation in future.[1]

Cardiac catheterization is performed in all patients with PAIVS with the aim of defining the coronary anatomy and determining the extent of coronary involvement. Patients with isolated valve atresia, well developed RV infundibulum, a relatively good sized TV annulus (Z score of > -3) and absence of RVDCC are candidates for transcatheter treatment.

Currently, most of the centers use radiofrequency (RF) energy to perforate the atretic valve. In emerging countries, the investment (approximately 2 million Indian Rupees) on a commercially available RF energy delivery system is considered exorbitant. In addition, the cost of the guide catheter, RF wire and multiple balloons makes this procedure beyond the financial abilities of most of the institutes. Only one centre in India, a nation with a billion-plus population can boast of possessing the RF system. Most are left with no choice but to consider guide wire perforation of the atretic valve. In addition, all the centers including those with pediatric cardiology programs work with a monoplane catheterization laboratory. We describe our experience with nine cases using hard end of the coronary guide wire to perforate the atretic pulmonary valve.

> ***"In emerging countries, the investment (approximately 2 million Indian Rupees) on a commercially available RF energy delivery system is considered exorbitant."***

All the babies were stabilized in the intensive care unit prior to being taken for the

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procedure. They were catheterized in a monoplane catheterisation laboratory under GA with intermittent positive pressure respiration. The arterial pressure was monitored throughout the procedure using a 20 gauge cannula. Most of the procedure was done in the lateral projection and only rarely was the image intensifier brought in the PA projection to confirm the lie of the guide wire with respect to the branch pulmonary arteries. Right femoral vein was cannulated using a 6F hemaquit. 100 i.u./kg of heparin was injected. A right ventricular angiogram was performed in lateral projection to define the coronary sinusoids, if any, and to delineate the lie of the right ventricular outflow tract and the atretic pulmonary valve (Figure 1A). A 4F/5F Judkins right coronary catheter was positioned just below the pulmonary valve and the position was confirmed with a test angiogram (Figure 2A). The proximal hub of the catheter was connected to a Tohey-Borst adaptor (Y connector) to enable scout angiograms throughout the procedure. Through the other end of the Y connector, the hard end of a 0.014" coronary angioplasty guide wire was passed. The distal end of the wire was given a gentle bend, so that it pointed posteriorly during the time of perforation. One of the major problems with the hard end of the guide wire (if not given a bend) is that it tends to straighten the guide catheter when it reaches its tip and any attempt at perforation in this position, invariably results in the perforation of the roof of the right ventricular outflow tract. On the other hand, a very acute bend could result in perforating the posterior wall of the outflow tract. Another manoeuvre found to be very useful during perforation was to have the guide catheter held firmly against the pulmonary valve so that the hard end of the guide wire had no place to go except in the direction of the valve (Figure 2B). In our experience, this manoeuvre, therefore, requires two operators; one to hold the catheter firmly against the valve and the other to jab and perforate the valve with the hard end of the guide wire bent appropriately so as to look posteriorly in the direction of the atretic pulmonary valve. The smoothness with which the wire moved to and fro and its lie with respect to the atretic valve on the check angiogram (Figure 1B) were the only two markers to know that the wire had gone the right way. Having an echo machine in the cath lab can help confirm the position of the wire. Unfortunately, this luxury was not available during these cases. Due to the small weight of the neonates and infants there were limitations on the volume of contrast used during the procedure. We preferred to dilute the non-ionic contrast three times so as to be able to make angiograms more liberally since that was crucial for accurate positioning of the catheter just prior to jabbing the guidewire. For the same reason, we used diagnostic catheter rather than a guide catheter at the time of perforation since the latter requires larger quantity of contrast for opacification.

"...the cost of the guide catheter, RF wire and multiple balloons makes this procedure beyond the financial abilities of most of the [emerging countries] institutes."

Once the hard end of the guidewire was just inside the main pulmonary artery (MPA), the diagnostic catheter was changed over to a 5F/6F Judkin's right guide catheter (Figure 2C). It was possible to exchange the catheters in all the cases over a 0.014" guide wire with only a couple of centimeters or so of the hard end inside the MPA. Once the guide catheter was positioned just below the atretic valve, a 1.5 mm Maverik (Boston Scientific) balloon was tracked over the wire through the guide catheter and was inflated across the pulmonary valve (Figure 2D). After this, the hard end of the wire was removed from the MPA and was replaced by the floppy end with the guide wire being parked into the descending aorta through the PDA or in the distal part of the RPA/LPA. Subsequently, 2 (Figure 1C), 2.5, 3, 6 (Figure 1D), and 7 (Figure 2E) mm balloons were passed serially and inflated across the pulmonary valve till the waist disappeared either fully or in some cases even partly. The highest diameter of the balloon used did not exceed 140% of the pulmonary annulus. A post dilatation angiogram was done to confirm adequacy of the antegrade flow (Figures 1E and 2F).

All the babies were electively ventilated for at least 12 hours and were then gradually weaned depending on their hemodynamics and ventillatory parameters. Attempts to wean the child off PGE1 were started after 48 hours and the doses were titrated depending upon the oxygenation. All except one could be weaned off the PG support in about 72 hours while one patient needed support for seven days. One of the patients despite PG infusion had persistent hypoxia 24 hours after the procedure and was subjected to a BT shunt. Another strategy that has been suggested is to stent the PDA electively after balloon dilation of the valve to ensure more reliable pulmonary blood flow. However, we have not used this strategy so far.

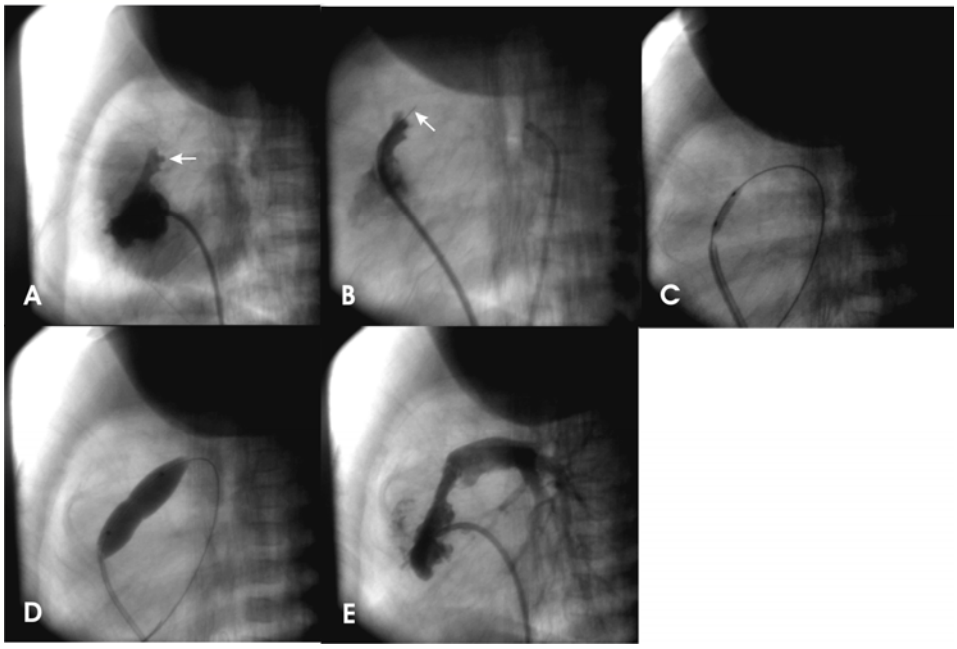

Figure 1. (A) Right ventricular angiogram in lateral projection showing atretic pulmonary valve (arrow); (B) Right ventricular check angiogram in lateral projection after perforating the atretic valve with the hard end of the guide wire (arrow) to confirm the position of the wire; (C) 2 mm angioplasty balloon inflated across the pulmonary valve till the waist disappeared; (D) 6 mm Tyshak II balloon dilated across the pulmonary valve at 3.5 atmospheres. There was a mild residual waist. (E) Final right ventricular angiogram showing adequate antegrade flow through the pulmonary valve.

Clinical and hemodynamic parameters of the patients are summarized in the Table.

Of nine infants, one died after right ventricular angiogram without any attempt at pulmonary valve perforation. This was due to progressive ischemic LV dysfunction not responding to routine measures to support circulation. The cause of ischemia remained undetermined. Another patient died 5 days after the procedure of a primary ventricular arrhythmia resistant to conventional treatment. Prior to this he was completely stable, was weaned off PG and was on

"In conclusion, guide wire perforation of the atretic pulmonary valve is feasible and is probably the only option for the majority of patients in resource restricted situations. Patient selection is the most important criterion for success."

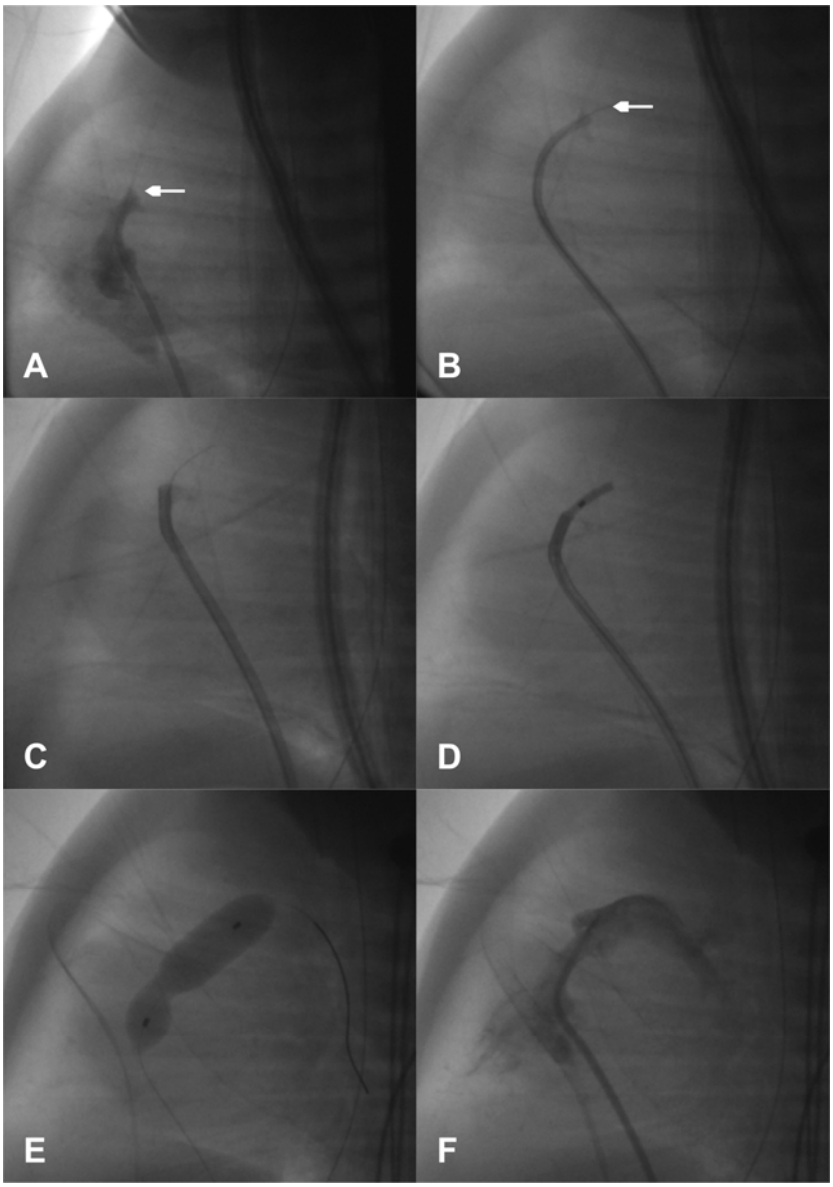

Figure 2. (A) Right ventricular angiogram in lateral projection just below the atretic pulmonary valve (arrow) just prior to perforating with the guide wire; (B) Plane lateral projection immediately after perforating the atretic valve with the hard end of the guide wire (arrow); (C) Judkins right guide catheter exchanged for a diagnostic catheter over a small length of the hard end of the 0.014 guide wire placed in the proximal MPA; (D) 1.5 mm Maverik (Boston Scientific) balloon passed over the hard end of the guide wire and dilated across the pulmonary valve; (E) 7 mm Tyshak II balloon dilated across the pulmonary valve at 3.5 atmospheres. There was a residual waist; (F) Final right ventricular angiogram showing adequate antegrade flow through the pulmonary valve.

minimum ventilatory support. His metabolic parameters had not revealed any abnormality and he was maintaining the O2 saturations in high 80s. In yet another patient, there was a failure of the procedure with inability to perforate the valve due to unusual lie of the RVOT and inability to park the guide catheter just proximal to the pulmonary valve. This child had a severely dysplastic and atretic pulmonary valve with moderate TR and dilated RV with impaired contractility. This child underwent successful pulmonary balloon valvuloplasty as a hybrid procedure in the operating room in another centre.

Six patients were discharged from the hospital. Amongst these, one had to be subjected to one and a half ventricular repair and five others had a potential for two ventricular circulation. All of them had oxygen saturation in the range of high 80s to low 90s at the time of their last follow up. RV development as evident from TV annulus Z-score was marginal. None of them have undergone ASD closure so far.

Transcatheter perforation of pulmonary valve, as a palliative procedure in PAIVS, was performed for the first time by Qureshi et al in 1991.[2] Subsequently many other groups have successfully performed this procedure in favourable forms of PAIVS using laser, hard end of the guidewire or more recently with radiofrequency wire.[3,4,5] Recently, Agnoletti et al have reported a success rate of 85% with a procedural mortality of 5% and morbidity of 12%[6] Almost everybody accepts that success of the procedure to a very large extent depends upon the patient selection and to some extent on the technical expertise. Some children despite an adequate antegrade flow require an additional BT shunt or a right ventricular outflow patch because the impaired right ventricular compliance and a high pulmonary vascular resistance prevents maintenance of adequate systemic saturations. In such a

Sr No	Age in days	SaO2 in% on admission	TV annulus Z score	TR	Pre RV pressure	Post SaO2 in %	PostRV pressure	Outcome at final FU
1	88	42	-2.4	Trivial	106	90	50	2 ventricles
2	175	70	-3.4	Mild	150	88	40	S/P Glenn
3	10	65	-2.7	Mild	142	86	55	Died after 5 days
4	3	76	-2.6	Mild	134	92	60	2 ventricles
5	26	63	-2.8	Trivial	156	87	52	2 ventricles
6	6	55	-2.2	Mild	140	84	48	2 ventricles
7	28	66	-1.1	Moderate	132		-	Failure to perforate
8	8	48	-2.6	Mild	128	95	64	2 ventricles
9	30	68	-3	Trivial	130	-	-	Died after angiogram

Table 1. Patient clinical and hemodynamic parameters.

situation, ductal stenting is performed as an alternative palliative procedure with satisfactory results.[7]

In conclusion, guide wire perforation of the atretic pulmonary valve is feasible and is probably the only option for the majority of patients in resource restricted situations. Patient selection is the most important criterion for success. The procedure is technically demanding and has a definite learning curve. Periprocedural management is as important for determining the ultimate outcome.

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INAUGURAL MEETING OF THE ACC CONGENITAL HEART DISEASE AND PEDIATRIC CARDIOLOGY SECTION

By Gerard R. Martin, MD

The inaugural meeting of American College of Cardiology's Congenital Heart Disease and Pediatric Cardiology Section was held on Sunday March 6, 2005 at the American College of Cardiology Scientific Session in Orlando, Florida. Launched in January of 2005 to all ACC members with an interest in congenital heart disease, the Section has received a tremendous response with 450 members enrolled and 150 members attending the inaugural event.

The goal of this first meeting was to provide Section members with the background on ACC's decision to establish member sections, to discuss the opportunities that a section could provide and to invite member participation in establishing Section objectives. Dr. David Sahn, MD, MACC, Chair of the ACC Congenital Heart Disease and Pediatric Cardiology Committee (CHDPC), directed the meeting. Perspectives from College leadership were provided by Pamela S. Douglas, MD, FACC, President-Elect of the College and from James Fasules, MD, FACC, Chair of the ACC Board of Governors and member of the Board of Trustees. Dr. Sahn commented, "This new Section within the ACC centralizes the interests and endeavors of all components of the congenital heart disease community, including pediatric cardiologists, heart surgeons, adult congenital heart disease specialists and non-physician allied health associates. No where else among the cardiovascular or subspecialty organizations does this complete spectrum of our community come together."

The CHDPC Section and the Women in Cardiology Section are two-year pilot projects started by the College to model the establishment of member sections. The Women in Cardiology began their pilot in 2004 and have over 500 members to date. Mary Norine Walsh, MD, FACC, chair of the Women in Cardiology Section, spoke to the members on the objectives of their section and early activities to date. Their section has focused on attracting more women into the field of cardiology and has begun a "virtual" mentoring program for medical students, residents and fellows.

During a fall meeting in New Orleans, the CHDPC committee and senior advisors from the congenital heart disease community drafted objectives for the section. At this meeting, Carole Warnes, MD, FACC presented these draft section objectives for discussion and received good feedback from the attendees.

Representatives from other national organizations were in attendance to offer support and advice. Robyn J. Barst, MD, FACC reported that the AHA Council on Cardiovascular Disease in the Young was very enthusiastic about the opportunities provided by ACC's new section. Thomas S. Klitzner, MD, FACC, represented the Joint Council on Congenital Heart Disease and the American Academy of Pediatrics and Michael Gatzoulis, MD, FACC represented the International Society of Adult Congenital Heart Disease. Each had excellent ideas on how the section could work with their respective organizations in advocating for congenital heart disease.

Figure 1. Dr. Carole Warnes presenting on potential Section objectives.

Amy Verstappen of the Adult Congenital Heart Association commented that her organization would like to see the section succeed and is interested in partnering with the section to advocate for improved training of providers for the growing population of survivors of congenital heart disease.

Dr. Sahn introduced Gerard R. Martin, MD, FACC as the incoming chair of the committee and newly formed section for a discussion of next steps. These included formal adoption of section objectives, review of current committee structure and establishing a process to ensure the section's success, and communication of the objectives to the CHDPC community. Members attending the meeting filled out questionnaires, provided suggestions for new objectives and ultimately ranked the objectives. They were also asked to indicate their willingness to participate on work groups that would be developed based on the objectives of the section. The meeting adjourned with two cannons of confetti being exploded over the participants by Dr. Sahn.

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Ranking	Section Objectives
1	Advocacy for CHD related specialties and their role in patient care; advocacy to improve access and reimbursement for care.
2	Document training requirements and manpower needs for Adult CHD specialty care.
3	Develop a visiting professor program.
4	Fund travel awards for fellows to attend the ACC annual meeting or ACC courses.
5	Develop a mentoring program.

Table 1. Section Objectives: Ranking by Members.

Work on developing the section continued at the Congenital Heart Disease and Pediatric Cardiology Committee meeting on March 8 in Orlando. Committee members, senior advisors from the congenital heart disease community, liaisons from other organizations and ACC staff discussed the inaugural meeting and the recommendations from the section members for activities going forward. The objectives rankings are shown in the accompanying table.

The committee identified the need to gather more input from membership. A follow-up survey is being developed to gain consensus on objectives for the section and a mission statement is also being drafted for the section. The mission will parallel the mission of the ACC but will relate specifically to the CHD/PC constituency.

The Committee is also interested in developing stronger relationships and involvement with the membership of other organizations, such as the Society of Thoracic Surgeons, Congenital Heart Surgeons Society, International Society of Adult Congenital Heart Disease, and the European Society of Cardiology.

Gerard Martin commented, "I am excited to be a part of this new section launch. The section provides us with a framework to work together to achieve objectives of high interest and value to our community, and it will increase the visibility of congenital heart disease issues within the College."

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HIGHLIGHTS FROM THE FOURTH MINI-SYMPOSIUM ON CONGENITAL HEART DISEASE

By Girish Shirali, MD

The Children's Heart Program of South Carolina hosted the Fourth Charleston Mini-Symposium on Congenital Heart Disease from February 25 to 27, 2005, at the Medical University of South Carolina in Charleston, SC. The symposium has evolved into a format that features in-depth presentations that include cardiac development, morphology, imaging and management of selected congenital heart defects. It provides exposure to renowned guest faculty, local experts in cardiac development from MUSC's Cardiovascular Developmental Biology Center and local clinical faculty. This year, erudite guest faculty consisting of Prof. Robert Anderson from Great Ormond Street Hospital, London, UK, Dr. Emile Bacha from the University of Chicago, Chicago, IL, and Diane Spicer from the University of Florida, Gainesville, FL, joined outstanding host faculty in putting together a wonderful, interactive educational program. Half-day sessions were assigned to each of two topics: Atrioventricular Septal Defect and Transposition of the Great Arteries; an entire day was devoted to a session on Hypoplastic Left Heart.

Highlights of the Symposium included three scholarly discourses by Prof. Anderson and hands-on demonstrations of morphology by Diane Spicer, featuring specimens from the Van Mierop collection of hearts. Dr. David Sedmera presented a fascinating discussion of experimental models of Hypoplastic Left Heart. Dr. Tim McQuinn gave an astounding demonstration of echocardiographic videos that he has performed on early-gestation mouse and quail embryos. The surgical talks included Dr. Bacha's presentation on Hybrid Approaches to Hypoplastic Left Heart, Dr. Scott Bradley's discussion of Modifications of the Norwood procedure, and Dr. Fred Crawford's analysis of his 20-year experience with surgery for Atrioventricular Septal Defect. Dr. Girish Shirali presented talks on the echocardiographic approach to each of the three defect complexes under study. The session on Hypoplastic Left Heart proved to be fertile ground for extended discussions on various aspects of clinical management. Following Dr. Andrew Atz's insights into perioperative management principles in Hypoplastic Left Heart, Dr. Eric Graham presented illustrative clinical cases to highlight these principles. Dr. Geoffrey Forbus shared his experience and ongoing research studies on post-Norwood echocardiography in these patients. Dr. Varsha Bandisode presented her experience with interventional approaches preceding and following the Norwood procedure. Dr. Andrew Blaufox reviewed dysrhythmias in this condition.

> ***"The symposium has evolved into a format that features in-depth presentations that include cardiac development, morphology, imaging and management of selected congenital heart defects."***

The Symposium is an excellent educational opportunity for students of congenital heart disease. We encourage fellows and practicing pediatric cardiologists as well as pediatric cardiology nurses and sonographers to come to the next symposium. Check future issues of this journal for more information.

Email comments on this article to: MAYGS@CongenitalCardiologyToday.com

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HIGHLIGHTS FROM THE TENTH VAIL SYMPOSIUM ON PEDIATRIC CARDIAC DISEASES

By D. Dunbar Ivy, MD

The Tenth Vail Symposium on Pediatric Cardiac Diseases was held in Vail, Colorado from March 13th to 16th 2005, and was sponsored by The Children's Hospital Heart Institute of Denver. This three-day symposium brought many leading cardiology and cardiac surgery programs together. The main sessions involved medical, nursing, and surgical aspects of conotruncal abnormalities and hypoplastic left heart syndrome. Other sessions were held, including interventional cardiology, cardiac nursing, transplantation, adult congenital heart disease, and pulmonary artery hypertension. The Nastar course was the site of spectacular crashes and amazing race times. Mike Flanagan and his daughter, Chelsea, had the fastest times, while Neil Wilson and his wife Meredith were the fastest couple on the course.

The first session opened with a description of logical analysis of the ventricular outflow tracts by Professor Robert Anderson. Professor Anderson pointed out the difficulties in the use of the terms conotruncal abnormalities, as there is no overall agreement as to which part of the developing outflow tract is the conus and which is the truncus. Professor Anderson suggested that it is preferable to analyze the lesions that can be produced by abnormalities within the pathways than using the term 'conotruncal abnormality'. Dr. Ruchira Garg described the use of MRI and evaluation of this group of lesions and emphasized the importance of a systematic and complete evaluation. Dr. Paul Grossfeld presented an update on the genetics of DiGeorge syndrome with an emphasis on clinical implications. François Lacour-Gayet described a uniform approach to treatment of complex coronary arterial anatomy associated with the arterial switch procedure. This lecture was followed by a presentation by Dr. Tom Spray describing the surgical options and outcomes for surgery for transposition of the great arteries and left ventricular outflow tract obstruction. Dr. Edward Bové presented the options for surgical treatment of the Taussig Bing anomaly. The next speaker was Dr. François Lacour-Gayet, who presented surgical treatment options for double outlet right ventricle with non-committed ventricular septal defect and pointed out that many of these patients are candidates for a biventricular repair rather than a Fontan type of repair. Dr. Tom Karl presented the current challenges in repair of interrupted aortic arch with left ventricular outflow tract obstruction. The final speaker in the first session was Dr. Edward Bové, who presented data on timing of repair for truncus arteriosus and concluded in general that the majority of these patients are candidates for surgery within the first month of life.

The afternoon session was a provocative session describing an update on interventional cardiology. Dr. Evan Zahn provided a review of the importance of a hybrid approach between the interventional cardiologist and surgeon to achieve optimal outcomes. Dr. Neil Wilson presented the Great Ormond Street experience with transcutaneous pulmonary valve replacement. This was followed by a description of PDA stenting for a ductal dependent systemic and pulmonary circulation in which Dr. Mark Boucek described his experience with hypoplastic left heart syndrome, emphasizing the importance of the anatomy of the arterial duct for successful stent placement. Dr. Ziyad Hijazi updated the group on the device closure of ventricular septal defects, concentrating on muscular ventricular septal defects, the percutaneous closure protocol, and perimembranous and membranous ventricular septal defect closure. The evening nursing session provided updates on heterotaxy syndrome by Catherine Dodds of Children's Hospital of Philadelphia and cath lab palliation of hypoplastic left heart syndrome by Christine Mashburn of Denver Children's Hospital.

Figure 1. Dr. François Lacour-Gayet (left) and Dr. Dunbar Ivy (right).

The second day provided a lively discussion with regard to treatment of hypoplastic left heart syndrome. Professor Anderson began the session with review of the anatomy. This was followed by a discussion of the genetics of hypoplastic left heart syndrome by Dr. Paul

Figure 2. Vail Pass: left to right Dr. and Mrs. Robert Anderson and Dr. and Mrs. Chen-Chan.

Grossfeld and pointed to the evidence for evaluation of a causative gene or group of genes that may underlie the development of hypoplastic left heart syndrome, and pointed to his studies on Jacobson syndrome. This talk was followed by a discussion of antenatal evaluation by Dr. Curt DeGroff as well as antenatal intervention for hypoplastic left heart syndrome and severe aortic stenosis by Dr. Audrey Marshall. The second session was opened by Dr. Spray, who presented the current results for the stage I Norwood by The Children's Hospital of Philadelphia group. He emphasized similar survival using a right ventricle to pulmonary artery conduit and Blalock-Taussig shunt at their institution. Furthermore, he pointed to an increase in morbidity and mortality in high-risk patients with hypoplastic left heart syndrome irrespective of surgical approach. The next several speakers focused on palliation by catheterization in surgery for hypoplastic left heart syndrome. Dr. Kak-Chen Chan presented the Denver approach. This was followed by a discussion of combined surgery and catheterization for patients with hypoplastic left heart syndrome by Dr. Christian Pizzaro. Dr. Pizzaro described the initial ten patients who were treated under combined interventional protocol consisting of stenting of the patent ductus arteriosus with surgical pulmonary artery bands followed by a subsequent combined stage I and II procedure in some. Dr. Mel Almodovar presented the pre-and postoperative management strategies and treatment of patients with single ventricle physiology, including hypoplastic left heart syndrome. The final talk presented a perspective of "long-term" results of hypoplastic left heart syndrome staged reconstruction by Dr. Spray.

A cardiac nursing luncheon panel was held discussing family coping strategies in the Intensive Care Unit. The evening session provided an update on heart transplantation with the possibility of heart transplantation by Dr. David Campbell and Dr. Max Mitchell. Dr. Bill Pietra provided animal data with regard to the possibility of immune intolerance induction and possible means to achieve this. The final evening nursing session was a description of care for patients with single ventricle by Julie Ann Koehler of Denver Children's Hospital and the adult congenital heart disease experience in the pediatric setting by Catherine Madigan of the University of North Carolina. The final morning session provided interesting data on the current problems in adult congenital heart disease. An overview was provided by Dr. Joe Kay with a discussion following by Dr. Andrew Redington with regard to the right ventricle as the systemic ventricle in corrected transposition of the great arteries or following the Senning or Mustard repair. Dr. Anji Yetman provided novel data with regard to the incidence and mechanisms of aortic root dilatation in patients with bicuspid aortic valve. This was followed by a description of modifications of the Ross procedure with outcomes by the group from the Oregon Health and Science University. The final session described novel therapies for pulmonary hypertension by Dunbar Ivy. This was followed by a discussion of the risks and benefits of sildenafil therapy by Dr. Andrew Redington. Dr. Max Mitchell presented data on patients who had a failing Fontan circulation and were later found to have pulmonary vascular disease. The final two talks were more basic in nature and described non-invasive evaluation of pulmonary hypertension by Dr. Robin Shandas as well as potential for stem cell treatment of pulmonary hypertension by Dr. Neil Davie.

Overall, the conference was quite fun with good scientific presentation. We look forward to the next Vail meeting in March 2007.

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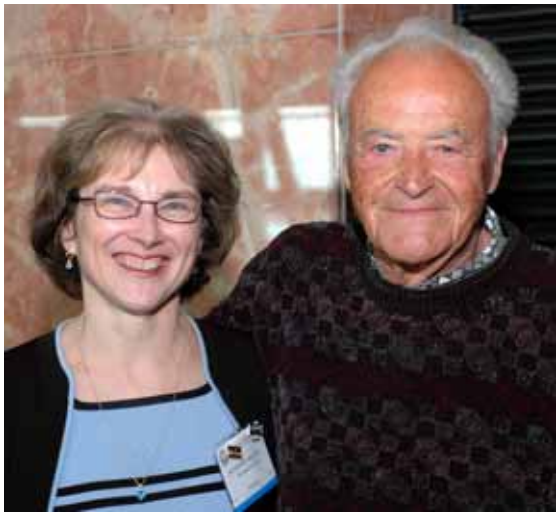
MEDICAL NEWS AND INFORMATION

AGA Medical Founder and AMPLATZER® Vascular Plug to Share Innovation Spotlight at SIR´s Annual Scientific Meeting

MINNEAPOLIS, March 23, 2005; - Dr. Kurt Amplatz, the founder of AGA Medical Corporation, received the Leaders in Innovation Award from the Society of Interventional Radiology (SIR) Foundation during the SIR's 30th Annual Scientific Meeting March 31 - April 5 in New Orleans, LA, USA.

SIR Foundation Chairman Dr. Joseph Boon presented Dr. Amplatz with the award during the SIR Plenary Session April 4 in the Ernest N. Morial Convention Center auditorium. The



Dr. Katharine L. Krol, MD (Incoming 2006 SIR President) and Dr. Kurt Amplatz.

"Leaders in Innovation" award recognizes an individual who has conceptualized and implemented an idea -- a device, technique, approach, a clinical practice model -- having a significant improvement on the quality of patient care or economics of interventional radiology.

One of Dr. Amplatz's innovations highlighted at SIR was the AMPLATZER® Vascular Plug, a unique implantable occlusion device that gives physicians a minimally invasive alternative for correcting an array of common vascular disorders. Besides being featured during the Leaders in Innovation award ceremony, the device will be showcased throughout the SIR meeting via a special SIR New Product Showcase.™

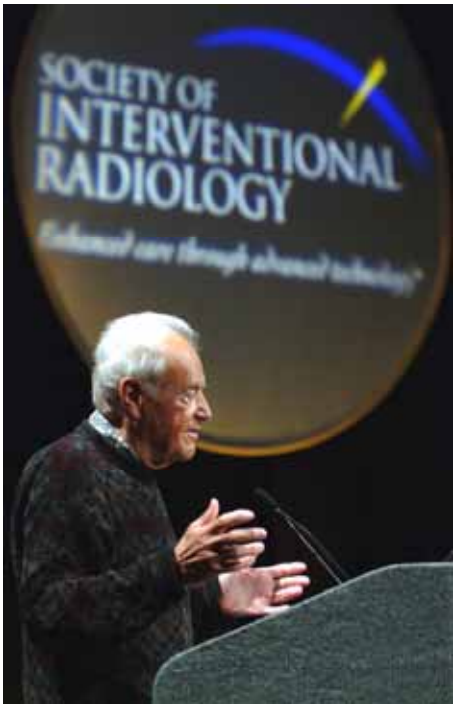
About Dr. Amplatz:

Dr. Amplatz, a longtime SIR member, is widely regarded as a pioneer in interventional radiology. His inventions encompass many of the field's fundamental tools, including several models of guidewires, renal dilators and sheaths, thrombectomy devices, goose-neck snares and vena cava filters.

Born in Weistrach, Austria, in 1924, Amplatz attended medical school at the University of Innsbruck. For much of his career he was a professor of radiology at the University of Minnesota Hospitals, where he retired in 1999. Dr. Amplatz has been awarded gold medals for distinguished service to radiology by the American College of Radiology, the European Congress of Radiology, and the American Roentgen Ray Society.

In founding AGA Medical Corporation in 1995, Dr. Amplatz launched what has since become the world's leading manufacturer of transcatheter occlusion devices for treating cardiac and vascular defects. *About the AMPLATZER Vascular Plug:*

The AMPLATZER Vascular Plug is one in a growing family of minimally invasive, implantable occlusion devices developed and manufactured by AGA Medical, and the company's first device intended for implantation within the radiology lab, by interventional radiologists.



Dr. Kurt Amplatz at the SIR podium.

In 2004 the U.S. Food and Drug Administration granted clearance of the AMPLATZER Vascular Plug for arterial and venous embolizations in the peripheral vasculature. Previously, the two most common treatments for peripheral vascular disorders had been surgery or implantable coils, which are designed to induce blood clotting. The AMPLATZER Vascular Plug may be used to treat: Aortopulmonary Collaterals, Arteriovenous Malformation, Surgical Aortopulmonary Shunts, Anomalous Venovenous Connections, Arteriovenous Fistulas, Peripheral Vessels.

Unlike some coil technologies, which are embolized (released into the blood vessel) in a less-controlled fashion, the AMPLATZER Vascular Plug can be placed, repositioned if necessary, and finally released in a precise and controlled manner.

Director of Transesophageal and Interventional Echocardiography

The Heart Center at Columbus Children's Hospital, the pediatric teaching facility for the Ohio State University, is seeking a board certified or board eligible pediatric cardiologist to be Director of Transesophageal and Interventional Echocardiography. This exciting position teams the candidate with colleagues in cardiothoracic surgery and interventional catheterization who perform state-of-the-art procedures including Hybrid procedures. The candidate should be experienced in all areas of congenital heart echocardiography (e.g. transthoracic, transesophageal, 3D-, fetal, intravascular, intracardiac imaging) in which he/she will participate. In addition, the candidate should be experienced in echocardiography assistance in placing a variety of transcatheter devices including patent foramen ovale, atrial and ventricular occluding devices. The candidate will also participate in other pediatric cardiology duties such as night call, a regular clinic and ward attending. **Candidates are encouraged to submit their curriculum vitae to Timothy F. Feltes, MD, Chief of Pediatric Cardiology, The Heart Center, 700 Children's Drive, Columbus, OH 43205, PH: 614 722-2565 or e-mail tfeltes@chi.osu.edu.**

The Ohio State University is an Equal Opportunity, Affirmative Action Employer. Women, minorities, veterans, and individuals with disabilities are encouraged to apply.

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The self-expandable, cylindrical device is made of Nitinol-wire mesh and is available in diameters ranging from 4 mm to 16 mm. Nitinol's superelastic properties allow the device to compress inside a catheter, then spring back to full size once situated within the blood vessel. The device's Nitinol-wire frame provides strong radial traction that holds it securely within a vessel wall. The device is also nonmagnetic, and therefore compatible with magnetic resonance imaging (MRI) technology.

For more information:
www.amplatzer.com

Funding Available for Biomedical Research on Pediatric Cardiomyopathy (Dilated, Hypertrophic, Restrictive or Arrhythmogenic Right Ventricular Cardiomyopathy)

The Children's Cardiomyopathy Foundation (CCF) announces the availability of funding ($25,000-$50,000 Research Award) for research on pediatric cardiomyopathy. The purpose of the award is to promote understanding of the basic mechanism and improve current therapies related to cardiomyopathy in children.

Types of Proposals Sought:

The Children's Cardiomyopathy Foundation (CCF) accepts grant proposals on an annual basis for innovative basic, clinical or translational research relevant to the cause or treatment of cardiomyopathy in children under the age of 18 years. CCF's grant program is designed to provide seed funding to investigators for the testing of initial hypotheses and collecting of preliminary data to help secure long-term funding by the National Institute of Health and other major granting institutions.

Funding is available in the range of USD $25,000 to USD $50,000 for total direct costs only. For grant re-

Congratulations to Dr. Kurt Amplatz on the Society of Interventional Radiology (SIR) Foundation's Leaders in Innovation Award

"On behalf of all my colleagues in Congenital Heart Disease, we would like to congratulate Dr. Amplatz on receiving the Leaders in Innovation Award from the Society of Interventional Radiology (SIR) Foundation. Kurt Amplatz is a pioneer, visionary and a great human being. His ingenuity has paved the way for all of us and made our lives much easier with his innovations. Thousands, if not millions benefited and will benefit from this great man's innovations. Keep up the excellent work Kurt and congratulations and well deserved."

~Ziyad M. Hijazi, MD, MPH

"Kurt Amplatz recently received a very deserving and distinguished award as a Leader in Innovation at the recent Society of Interventional Radiology (SIR) Foundation meeting in New Orleans. All of us dedicated to the transcatheter therapy for Congenital Heart Disease have benefited from Kurt's ingenuity and creativity over the past two decades. Moreover, countless numbers of our patients all over the world have been recipients of this great man's dedication to this cause, while others have ventured into more "profitable" endeavors of acquired cardiac disease. I am reminded of a time when I presented Kurt with a reason to design a device that would be perfect for a very select number of children and adults with a specific form of congenital heart disease and clearly there would be little if any profit for his company, AGA Medical, Corp. However, Kurt, in his typical no-nonsense manner clearly indicated that if it was for "the betterment of mankind," then he would begin production of the device, regardless of the financial implications.

This spirit of doing what is right, what makes one feel good inside at the end of the day, is what separates Kurt from his peers...if he has any peers. I just want to thank you, Kurt, for your dedication, your genius, your humanity, and most of all for your friendship in helping us treat our patients in the way that we would like for our own family members to be treated."

~ John P. Cheatham, M.D.

newals, CCF funding is limited to two years (consecutive or otherwise) of support.

Eligibility Requirements:

Principal investigators must hold a MD, PhD or equivalent degree and reside in the United States. The investigator must have a faculty appointment at an accredited U.S. institution and have the proven ability to pursue independent research as evidenced by original research in peer-reviewed journals.

Review Process & Timing:

Grant award decisions are made through a careful and detailed peer-review selection process by CCF's Medical Advisors and Board of Directors. Scientific excellence and relevance to pediatric cardiomyopathy are the basic criteria for selecting supported research projects. The 2005 deadline for grant submissions is October 3, 2005 with final award decisions made in early December. There are no extensions to this deadline. Disbursement of funds would be made before December 31, 2005. For grant guidelines, application information: www.childrenscardiomyopathy.org or contact Lisa Yue, President of the Children's Cardiomyopathy Foundation; PO Box547; Tenafly, NJ 07670 USA; Tel: 201-227-8852; grants@childrenscardiomyopathy.org.

Funding Available From the Children's Heart Foundation for Research on Congenital Heart Disease

The Children's Heart Foundation, which support research toward discovering the cause and improving the methods for diagnosing, treating and preventing congenital heart defects, calls upon all investigators to submit clinical research proposals on congenital heart disease by June 3, 2005.

The Medical Advisory Board of The Children's Heart Foundation will review these proposals in late Fall 2005. Those recommended will receive funding in December 2005.

Investigators should contact The Children's Heart Foundation for an application, or download an application from the website. Thirty-five copies of each grant with an abbreviated CV are required, including any published work in the research proposal area. For additional informa-

tion on the research awards, contact: The Children's Heart Foundation; Phone (847) 634-6474; Fax: (847) 634-4988; www.childrensheartfoundation.org.

'Heart Attack Gene' Discovered at Cleveland Clinic; Exists in 1-2% of U.S. Heart Attack, Coronary Artery Disease Patients

In November 2003, Cleveland Clinic researchers announced the discovery of the first gene confirmed as a cause of coronary heart disease in humans. Less than a year later, their studies indicate this "heart attack gene" is more prevalent among Americans than expected.

According to their findings, as many as 1 - 2 % of all U.S. heart attack and coronary artery disease patients may carry mutations of the MEF2A gene. Cleveland Clinic researchers discovered this gene by methodically studying the genetic makeup of 21 members of an Iowa family plagued for generations by clogged arteries and heart attacks.

When researchers initially discovered an MEF2A deletion mutation in the Iowa family, they acknowledged it was unlikely that the exact genetic mutation would be found in other people. Instead, they began to search for smaller mutations involving the same gene, and they found just that.

The latest mutation involves three novel mutations in exon 7, rather than exon 11 as in the original MEF2A mutation. The new mutations also involve one base pair point change, instead of a 21 base pair deletion. The full study is posted online in the journal, Human Molecular Genetics.

The MEF2A gene makes a protein that controls the expression of hundreds or even thousands of other genes in the endothelium, the barrier between blood vessels and blood elements. Cleveland Clinic scientists suspect the resulting genetic changes weaken the endothelium, making it more susceptible to invasions and attacks by monocytes and macrophages, which drive inflammation in the artery wall. These attacks allow atherosclerotic plaques to form. Once the integrity of the arterial wall is lost and blockages have occurred, unstable angina, heart attack or sudden cardiac death can result.

For more information: www.clevelandclinic.org.

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Would you like to ask the Editorial Board's opinion about a procedure, technology or product?
Email your question to: ASK@CongenitalCardiologyToday.com

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

THE EMERGING ROLE OF THE CUTTING BALLOON IN CONGENITAL INTERVENTIONAL THERAPY

By Michael C. Slack, MD

Introduction

The concept of using micro-surgical dilation devices in catheter based cardiovascular interventions began in the early 1990s with the introduction of the "Barath cutting balloon."[1] This novel modification of the standard coronary angioplasty balloon introduced a whole new potential strategy for the ablation of the difficult atheromatous plaque in resistant coronary artery lesions. Initial reports suggested

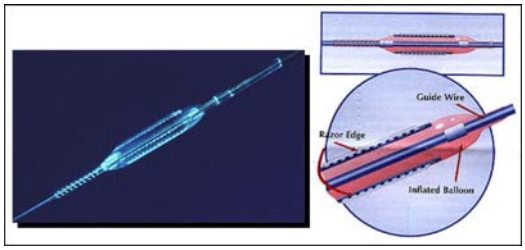

Figure 1. Cutting Balloon Detail (Boston Scientific, Natick, MA).

that the microtomes of the cutting balloon reduced barotrauma and caused a more discrete histologic post-dilation lesion than conventional balloons,[2] and that when compared to conventional coronary angioplasty balloon results, the cutting balloon produced a lower incidence of dissection with comparable minimum luminal diameter (MLD) and restenosis rates.[3] More recently a meta-analysis of the combined results of percutaneous coronary interventions from sixteen randomized clinical trials including over nine thousand patients, failed to demonstrate any measurable benefit from the use of the cutting balloon in either clinical or angiographic outcomes.[4] Now, with the near universal use of primary stenting in the treatment of atherosclerotic coronary artery disease, instent restenosis has become an important clinical problem. The use of the cutting balloon was heralded as having potential advantages in treating this common stent related problem. Results from a recent multi-center clinical trail (RESCUT Trial) showed that, although the cutting balloon did not reduce instent restenosis or major clinical event end-points compared to conventional balloon, it did offer some significant procedural advantages such as fewer balloons used, less balloon slippage, and reduced need for additional stent implantation.[5]

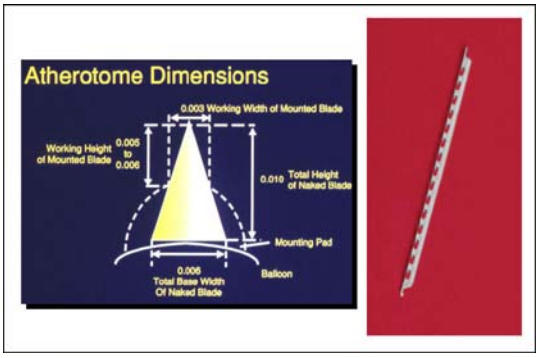

Figure 2. Microtome Detail.

Most recently, the cutting balloon has been applied to lesions found in notoriously difficult to treat peripheral vascular disease. New larger diameter cutting balloons have very recently become available and have been used to treat complex vessel obstruction in the lower limbs of adults. A recent study using the cutting balloon angioplasty (CBA) for percutaneous revascularization in peripheral vascular disease showed that almost 90% of threatened limbs could be salvaged after a mean follow-up of one year.[6] To date, no randomized clinical trials comparing the results of the cutting balloons to other catheter-based modalities in the treatment of peripheral vascular disease have been reported.

The Cutting Balloon

The cutting balloon combines the standard shaped angioplasty balloon, with the addition of three to four razor sharp thin microtome blades (Figure 1) attached to the balloon surface and extending along the working length of the balloon. The microtomes are said to be up to 5 times sharper than a scalpel blade. Although the total height of the blades is 0.010 inch, the working cutting height of the blades is approximately 0.006 inch (Figure 2). The blade, therefore, could be expected to make at least a 0.2 mm deep cut in the tissue it comes in contact with. In the un-expanded balloon, the microtomes are folded and protected by the balloon material (Figure 3). With balloon expansion, the microtomes protrude out at a 90 degree angle to the balloon surface, thus contacting the vessel wall (Figure 4). If the tissue or lesion is compressed against the extended blade, it is likely that the depth of the cut may be greater than 0.2 mm. Calculations based on the contact surface area of the blades estimate the force exerted on the lesion or tissue could be as high as 157,000 times that of a standard balloon.[7]

The first generation cutting balloon, devel-

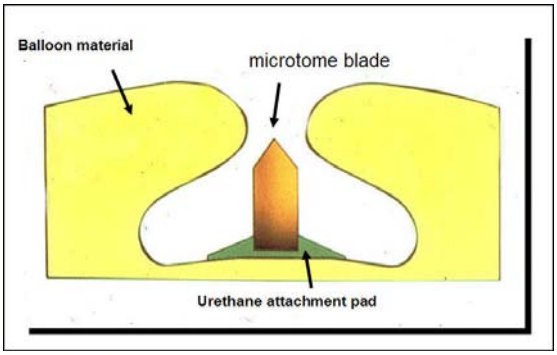

Figure 3. Magnified view of microtome attached to balloon material and folded into unexpanded balloon.

MEDICAL CONFERENCES

European Heart Network Annual Workshop
May 18-20, 2005; Madrid, Spain
www.ehnheart.org/content/default.asp

AEPC 40th Annual General Meeting
May 18-20, 2005; Copenhagen, Denmark
www.aepc2005.dk/

The 1st Annual Toronto Symposium: Contemporary Questions In Congenital Heart Disease 2005
May 29-31, 2005: Toronto, Canada
www.sickkids.ca/cardiology

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Morphology@rbh.nthames.nhs.uk

14th Parma Int. Echo Meeting
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June 8-11, 2005; Shanghai, China
www.congenitalcardiology.com/2005-ICU-Shanghai.pdf

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

ASE 16th Annual Scientific Sessions
June 15-18, 2005; Boston, MA, USA
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 Congenital Heart Disease from Infancy to Adulthood
June 23-26, 2005; Amelia Island, FL, USA
www.choa.org

12th World Congress on Heart Disease
July 16-19, 2005; Vancouver, Canada
www.cardiologyonline.com

SIS (Summer in Seattle) 2005
July 19 - 23, 2005; Seattle, WA, USA
www.summerinseattle.com

oped by Interventional Technologies, Inc. (IVT), was approved by the FDA in April 2000. Initial uses were fibro-calcific atheromatous coronary lesions resistant to conventional balloon, ostial coronary lesions, and dilation of in-stent restenosis. Following the acquisition of IVT, by Boston Scientific Corporation in early 2000, a refined version of the cutting balloon called the Ultra 2 (Boston Scientific Corp., Natick, MA) was introduced and approved by the FDA in April of 2003 (Figure 5). The blades are mounted to a non-compliant balloon coated with a hydrophilic material for enhanced vessel passage. An improved microtome design gives improved blade flexibility to enhance advancing the balloon to the target lesion. The microtomes are mounted on urethane pads which are bonded to the balloon material. The end result of this secure attachment is a blade to balloon bond strength that makes it more likely that the blades would fracture rather than being torn off the balloon. The Ultra 2 coronary cutting balloon is available in diameters ranging from 2.0 to 4.0 mm in 0.25 mm increments and lengths ranging from 6 to 15 mm. More recently, larger diameter cutting balloons based on the Ultra 2 designed for the catheter-based treatment of peripheral vascular disease were FDA approved (510k) in July 2004. These balloons are currently available in the U.S. in diameters ranging from 5.0 mm to 8.0 mm with lengths of 1.0 and 2.0 cm. The recommended maximum inflation pressure is not to exceed 10 atms.

Cutting Balloon in Congenital Heart Interventions

Like many of the new technologies developed for the catheter-based treatment of adult cardiovascular disease, congenital interventional cardiologists have taken an interest in the potential uses for microsurgical dilation devices. The cutting balloon was employed in an animal feasibility study by Coe and associates, using the first generation coronary cutting balloon to create atrial septal defects (ASD) in piglets.[8] In six animals, after a transseptal puncture, they perform initial dilation with a 4 mm cutting balloon followed by static

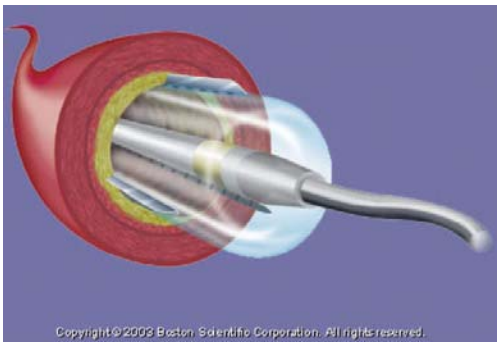


Figure 4. Cutting balloon expanded with microtomes in contact with vessel wall.

dilation with an 8mm standard dilation balloon. The results in these animals showed that the static balloon tore the atrial septum cleanly along the lines of the cuts made by the initial cutting balloon even when the initial transseptal was across a more muscular portion of the septum. There was no evidence of tissue fraying or clot formation. The potential clinical advantages were apparent that up to four simultaneous equally spaced cuts in the atrial septum could be safely made instead of only one with each use of the Park blade.

Later Latson and associates used the coronary cutting balloon in four patients (age 3-4 years) in seven lesions, both small-vessel native pulmonary artery branch stenosis and stenosed unifocalized

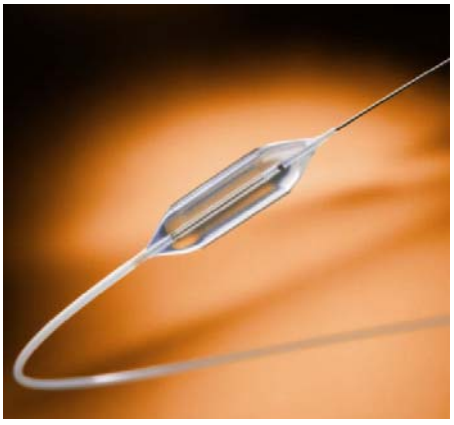


Figure 5. New Ultra 2 Cutting Balloon (courtesy of Boston Scientific Corp.).

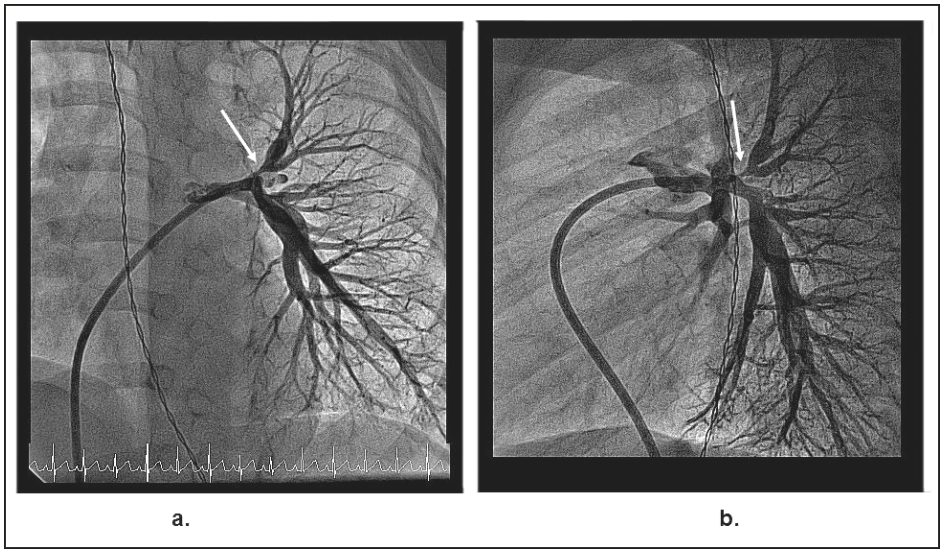


Figure 6. Left anterior oblique view (a) and straight lateral view; (b) of left pulmonary artery showing severe discrete stenosis at the origin of the upper lobe branch (white arrows).

MAPCAs, that were resistant to standard balloon angioplasty.[9] Final vessel MLDs were increased over initial by nearly two fold compared to 'no significant response' of the lesions to standard balloons. On final angiography, no intimal tears or flaps, aneurysm, or significant luminal irregularity was seen. At repeat catheterization with a median of 14 months follow-up, no vascular complications were identified and late luminal loss was minimal at just over half a millimeter. Similarly, Bergersen et al,[10] reported the use of the cutting balloon as either primary angioplasty or as an augmentation to high pressure balloon angioplasty in pulmonary artery branch stenosis in twelve patients (age 0.5 - 10.8 years) with a combined experience of 38 vessel lesions. Defining successful dilation as an increase in MLD of >50%, procedural success was 92% (35/38 vessels). Twenty-nine of 38 vessels which did not initially respond to high pressure balloon dilation, did subsequently respond with elimination of the waist after pre-treatment with a cutting balloon diameter chosen as a mean of 1.1mm larger than the diameter of the residual waist which formed in the conventional balloon. Complications were reported, consisting of one unconfined tear caused by an adjacent catheter, rather than the cutting balloon, resulting in significant hemoptysis requiring coil closure of the distal pulmonary vascular segment. One confined tear was encountered at the cutting balloon dilation site which was stabilized with placement of three uncovered stents and maintenance of the vessel lumen integrity. There was one cutting balloon rupture encountered, but without removal difficulty. Interestingly, 35% of their catheterization procedures required transfusions for blood loss. No peri-procedural deaths were encountered.

Children's National Medical Center Experience

In early 2002, we began using the cutting balloon at the Children's National Heart Institute for selected indications following training obtained from experienced adult coronary interventionalists. These indications have included, small vessel (second and third order) pulmonary artery branch stenosis that is unresponsive to high pressure balloon dilation, controlled creation of ASDs in symptomatic patients with severe pulmonary artery hypertension, creation of fenestrations in the prosthetic material of lateral intra-cardiac baffles in patients with failing Fontan physiology, creation of ASDs in newborn infants with severely restrictive foramen ovale in hypoplastic left heart syndrome, and in-stent restenosis in renal artery stenosis post pediatric renal transplantation. To illustrate the usefulness of the cutting balloon in the treatment of congenital heart disease, two selected cases are presented.

Case # 1

A 22 month old infant with Williams Syndrome and severe bilateral branch pulmonary artery hypoplasia presented to the catheterization suite for pulmonary artery rehabilitation. Long segment supravalvar aortic narrowing with a diffusely hypoplastic aorta down to the iliac bifurcation was also present. The right ventricular pressure ratio was approximately 60% systemic. At the initial procedure, balloon angioplasty therapy was directed at the left pulmonary artery branches. High pressure balloon dilation of the proximal, mid and left lower lobe branches was successfully performed. A severe discrete stenosis at the origin of the left upper lobe branch was also noted on angiography (Figures 5a & 5b) The left upper lobe branch was completely resistant to high pressure with the high pressure balloon and formed a dramatic waist despite dilation to 20 atmospheres (Figure 6a). A 4 mm x 1.0 cm cutting balloon was employed at the site of the waist with full expansion of the cutting balloon at 10 atmospheres on the first inflation (Figure 6b). Angiography of the left upper lobe branch demonstrated a nearly four fold increase in the MLD with minimal distal vessel irregularity (Figures 7a & 7b). Follow-up angiography at catheterization eight months later, for rehabilitation of the right pulmonary artery branch, showed not only no interval late luminal loss, but a slight increase in the MLD of the left upper lobe vessel presumably from growth.

Case #2

A full term 3 kilogram newborn infant with a prenatal diagnosis of hypoplastic

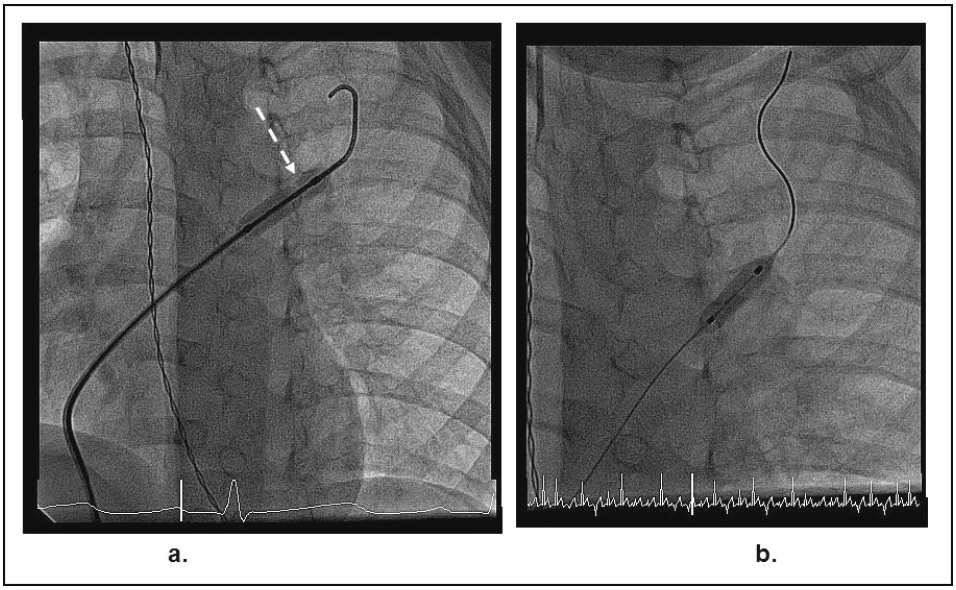


Figure 7. (a) High pressure conventional balloon angioplasty of left upper lobe branch with severe residual "waist" (dashed white arrow); (b) Cutting balloon angioplasty with complete resolution of balloon waist at 10 atms pressure.

left heart syndrome (HLHS) with a severely restrictive foramen ovale was born by planned C-section at our institution. A variant of HLHS and a large patent ductus arteriosus with bidirectional flow was confirmed by echocardiogram. The infant was initially relatively hemodynamically stable with an oxygen saturation of 70% on blow by oxygen. Intravenous prostaglandin infusion was immediately begun. After placement of umbilical lines, the infant was transported directly to the cardiac catheterization suite. The left atrium was quite small and there was a very tiny hole in the area of the foramen ovale. The atrial septum was bulging towards the right atrium and there was minimal flow visible across the thickened septum. Initial attempts to pass a standard septostomy balloon across the tiny hole were unsuccessful. Neither the 5 French nor the 4 French Braun (B Braun, Bethlehem, PA) low profile septostomy balloons would come close to passing into the left atrium even utilizing a wire. At this point a 0.014 coronary wire was advanced through a 4 French angled glide catheter (Boston Scientific, Natick, MA) into the left atrium. A conventional 4mm x 8 mm non-compliant coronary angioplasty balloon was then advanced over the wire and through the foramen then statically dilated. Immediately following this, another attempt was made to advance the 4 French low profile septostomy catheter, this time over the coronary wire placed in the left pulmonary vein, but still it would not cross the foramen. Next, a 4 mm x 10 mm Ultra 2 cutting balloon (Boston Scientific, Natick, MA) was advanced over the coronary wire, through the foramen and dilated three times (Figures 8a & 8b). During the final inflation, the cutting balloon was gently pulled over the wire into the right atrium then deflated. Finally, a dynamic atrial septostomy was easily performed using the 4 French Braun septostomy catheter with echocardiographic imaging demonstrating the creation of a 3.5 - 4.0 mm atrial septal defect and laminar color flow into the right atrium. Systemic arterial saturations increased to 90 percent.

Summary

The cutting balloon has demonstrated a role in the catheter-based treatment of atherosclerotic coronary artery disease, however, its benefit may yet to be precisely defined. The tremendous force that can be applied to the tissue has made it a useful tool in pre-dilating the tenacious fibro-calcific ostial coronary lesions prior to

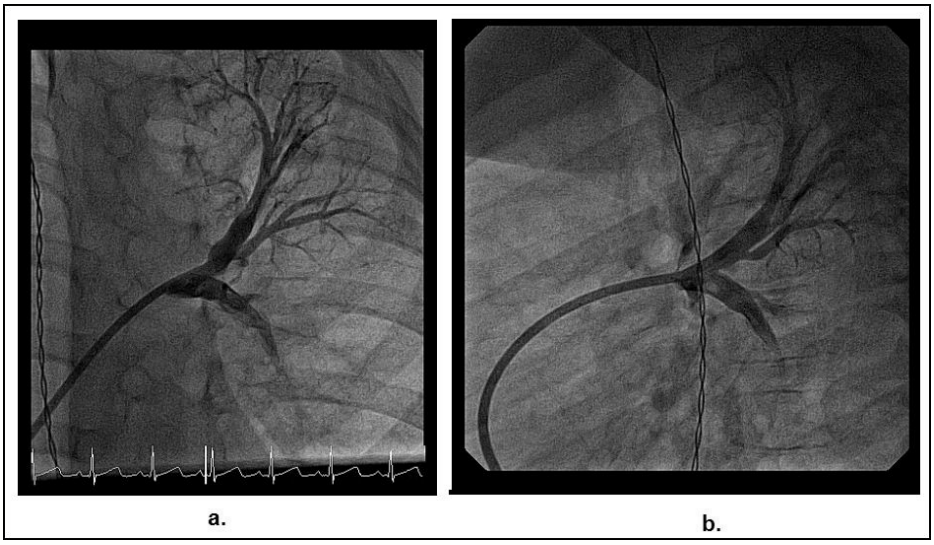
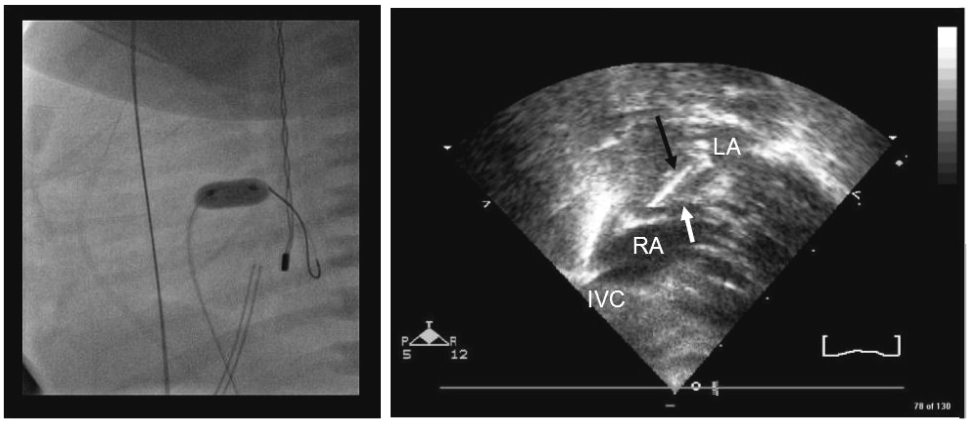


Figure 8. LAO/cranial view (a) and straight lateral (b) of left upper lobe branch following cutting balloon angioplasty. Note the marked increase in flow to the distal vascular bed.

stenting. In peripheral vascular disease the cutting balloon shows promise, but has yet to be compared rigorously in randomized clinical trials to other catheter-based treatment modalities.

In congenital heart disease, the use of the cutting balloon has resulted in some dramatic benefits in a limited number of cases. The combination of animal feasibility studies showing a favorable mechanism of action with some favorable early clinical experience in the treatment of high pressure balloon resistant pulmonary artery stenosis is encouraging. Also, with few significant peri-procedural complications encountered thus far, the use of the cutting balloon may become more widespread. Furthermore, the potential for creating more effective and potentially longer lasting atrial septal defects with less procedural morbidity and the ability to open high pressure resistant branch pulmonary artery stenosis is quite promising. This early congenital heart experience warrants further investigation in the form of larger clinical trials. Clearly, micro-surgical dilation devices are an intriguing new technology that, particularly now with a broader range of available balloon diameters, may play an increasingly important role in the catheter-based treatment of congenital heart disease.



a. b.

Figure 9. (a) Lateral fluoroscopic view of cutting balloon fully inflated in the atrial septum; (b) companion echocardiographic view showing balloon in atrial septum (white arrow). Note echogenic bright microtome visible along length of balloon (solid black arrow).

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