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THE CHANGING MANAGEMENT OF RIGHT VENTRICULAR OUTFLOW TRACT DYSFUNCTION

IMPACT OF PERCUTANEOUS PULMONARY VALVE IMPLANTATION

By Philipp Lurz; Twin-Yen Lee; Louise Coats, MRCP; Johannes Nordmeyer; Philipp Bonhoeffer, MD

### Introduction

Advances in cardiac surgery, intensive care and non-invasive imaging, over the last fifty years, have led to a substantial increase in life expectancy for many patients with congenital heart disease. Currently, more than 85% of children born with morphological or functional cardiovascular anomalies reach adulthood and it is likely that this will increase further over the coming decades [1].

One of the major problems for adults and children with repaired congenital heart is dysfunction of the right ventricular outflow tract (RVOT) either manifesting as an obstructive lesion or as pulmonary regurgitation.

Whilst for some time it was believed that these residual lesions were well tolerated, it is now increasingly clear that they are associated with right ventricular dysfunction, reduced exercise capacity and an increase in arrhythmia potential.

### Conventional Management of RVOT Dysfunction

Growing evidence of the detrimental consequences of RVOT dysfunction have led to a strategy of re-operation designed to restore valvar competency and relieve residual obstruction. Importantly, surgical pulmonary valve replacement has been shown to halt, or in some cases, reverse this functional deterioration [2]. Homografts have gained in popularity as the optimal conduit for this purpose because of

their superior longevity. However, repeat operations are associated with increased risk, and some investigators have found that subsequent conduits do not last as long. Increasingly, the timing of intervention to the RVOT is being called into question. There is some evidence to suggest that we are intervening too late, beyond the point at which right ventricular function is recoverable. Thus, whilst early interven-

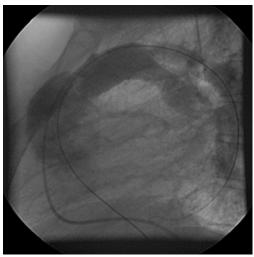


Figure 1. Lateral angiogram before PPVI shows moderate pulmonary requrgitation.

tion seems to be crucial to preserve right ventricular function, the decision to reoperate must balance this ideal against the risks of repeated surgery and the limited longevity of newly implanted conduits.

### Percutaneous Pulmonary Valve Implantation (PPVI)

In 2000, the first implantation of a transcatheter pulmonary valve was reported by us [3]. This new technological approach to the treatment of RVOT dysfunction is likely

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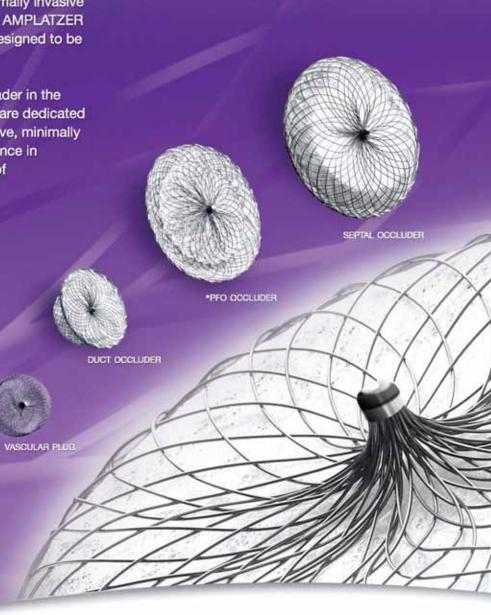
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to have important consequences for the management of this condition.

Composed of a bovine jugular venous valve, sewn into a balloon-expandable platinum iridium stent, the device is delivered by a catheter via the venous circulation under general anaesthesia. The size of the delivery system limits the procedure to those older than 5 years and greater than 20 kilograms in weight. The valved stent is deployed within the existing degenerated conduit and acts both to relieve obstruction and restore a competent pulmonary valve.

"One of the major problems for adults and children with repaired congenital heart is dysfunction of the right ventricular outflow tract (RVOT) either manifesting as an obstructive lesion or as pulmonary regurgitation."

Clinical experience now exists in over 140 patients (age 7-58 years, UK and Canada), most of whom have undergone two or more surgical interventions in the past. The relief of right ventricular volume and pressure overload in these patients is associated with improved cardiac performance and an increase in objectively measured exercise capacity. The procedural complication rate is 5% and includes homograft rupture, device instability, coronary artery compression and branch pulmonary obstruction. Death occurred only in the critically ill patients and was not device- or procedure-related. One patient died of pulmonary oedema related to a concomitant

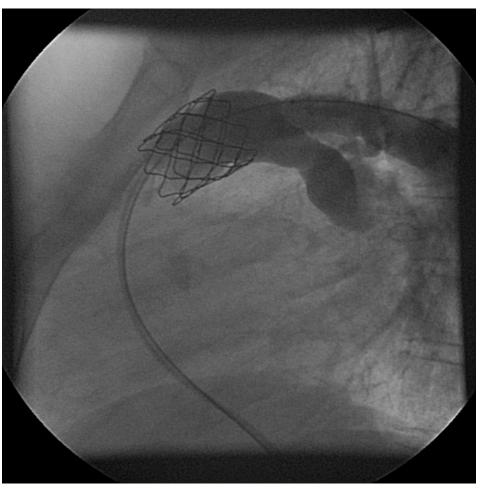


Figure 2. Lateral angiogram after PPVI shows well seated device in RVOT with trivial pulmonary regurgitation.

left-sided problem also treated during the same procedure. The other died 6 weeks after the valve implantation due to sepsis in the context of a failed defibrillator implant. The majority of patients were discharged home the following day with no requirement for intensive care. Few complications occur during follow-up, with the most evident being stent fracture, which if detected early can be treated with a second interventional procedure.

Percutaneous pulmonary valve replacement therefore, provides a new approach for the management of RVOT dysfunction. It is minimally invasive, patients recover rapidly and there is low morbidity and mortality. The impact of this new procedure on the conventional surgical strategy is beginning to emerge.

### Impact of PPVI on the Conventional Management of RVOT Dysfunction

PPVI should not be seen as an alternative to surgery, rather as a complemen-

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"PPVI should not be seen as an alternative to surgery, rather as a complementary treatment that can be used to prolong conduit life and reduce the number of reoperations a patient may require during a lifetime."

tary treatment that can be used to prolong conduit life and reduce the number of re-operations a patient may require during a lifetime. With this aim, lower device durability may be acceptable, particularly in view of the success of repeat PPVI (stent-instent), if the negative effects of cardiopulmonary bypass are avoided,

Furthermore, a less invasive approach could allow earlier intervention to the RVOT satisfying current clinical inclination to preserve right ventricular function. In addition, patients who are conventionally considered too high risk for surgery could benefit from intervention.

At present, a major limitation for PPVI is the size of the RVOT as bovine jugular venous valves are only available up to 22 mm in diameter. Implantation in humans is therefore limited to those patients with an RVOT that does not exceed that maximum diameter and preferably exhibits some degree of circumferential calcification as this promotes device stability. Unfortunately, the most common group of patients requiring pulmonary valve replacement are children and adults who underwent surgery for tetralogy of Fallot during infancy and had patch augmentation of their RVOTs. The consequence of this repair is free pulmonary regurgitation and an aneurysmal RVOT that is unsuitable for PPVI.

The availability of PPVI is, therefore,

now influencing the initial strategy for primary repair in patients with congenital heart disease. Surgeons are increasingly placing smaller patches or, where possible, suitably sized homograft conduits that prepare the patient for a future percutaneous approach when RVOT dysfunction ensues. A novel approach, which so far has only been tested in the experimental setting, is the implantation of an expandable-valved conduit that can be sequentially dilated by balloon angioplasty as the patient grows. When valvar incompetence occurs a percutaneous pulmonary valve can be implanted into the conduit [4]. If this strategy can be translated to the clinical setting, it could have a major impact on patients with congenital heart disease perhaps bringing to an end repeated open heart surgery altogether.

### **Future Directions**

PPVI is now on the threshold of wider clinical use. The challenge remains to adapt this approach to all RVOT sizes and morphologies. Development of new devices that can downsize the RVOT or hybrid approaches incorporating minimally invasive surgery without cardio-pulmonary bypass may provide potential options [5]. Close cooperation between cardiologists, surgeons, imaging specialists and biomedical engineers is needed to bring these ideas forward; the management of RVOT dysfunction will continue to evolve.

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### LEVERAGING TECHNOLOGY FOR IMPROVED SUPPLY AND DEVICE MANAGEMENT

By Ziyad M. Hijazi, MD, MPH

### Introduction

Medical device and supply utilization has become a critical part of effectively treating congenital heart problems and other cardiovascular conditions in the pediatric environment and elsewhere. With the advancements in therapeutic catheterization devices and supplies such as drug-eluting stents, we have made tremendous strides in improving the outcomes of the patients that receive treatment through percutaneous coronary interventional procedures.

While the growth of percutaneous coronary interventional procedures has been prolific, having doubled over the past ten years, it pales in comparison to the growth rate for the utilization of certain devices and supplies to support those procedures [1]. Specifically, the utilization of coronary stents has increased by more than seven times since their initial introduction in 1995. As highlighted in a report from the Society for Cardiovascu-Angiography and Interventions (SCAI), approximately 800,000 stents were estimated to be used in procedures performed during 2004 [2]. Given the two-year latency in the estimate, it is safe to assume this number has continued to rapidly increase.

As the utilization of devices such as drug-eluting stents has increased, they have also assumed a growing presence in the revenue and cost structures of most cardiovascular service lines. Per data provided by a 2005 study conducted by Goodroe Health Solutions, the

average cost of a procedure utilizing coronary stents was \$4,500 with an average of 1.63 stents used per case [3]. In further looking at the role of the stents in the cost structure, consulting firm KPMG reported that the average cost of a stent is \$2,400 [4].

would represent \$29.5 million to the healthcare organization.

### Challenges Emerge with the Increased Role of Device Utilization

Given the significant presence these devices are playing in the economic



Figure 1. Mobile Aspect's iRISupply.

For an organization that annually performs 5,000 catheterization procedures in which stents are used, the cost incurred by the provider organization to acquire and stock these devices would total \$19.7 million annually. In addition, assuming a charge markup of 200% and an average reimbursement rate of 50% for billed charges, the revenues derived from these devices

structure of cardiovascular services, it is imperative that operational processes are followed that will mitigate the risk of unnecessarily adding costs or missing opportunities to document their utilization and in turn, capture the charges incurred. Sadly, it is quite common for organizations to follow less than optimal processes, often



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leading to the emergence of problems in two principal areas.

The first area of concern is with regard to the charges captured for the use of devices and supplies during a procedure. Many organizations employ manual, paper-based documentation processes to support the charge capture process. Often, this is augmented by the application of stickers to the paper documentation to provide more thorough information. Due to the realities of our busy clinical environments, many times the documentation of the charges for device and supply utilization are missed. Some sources have estimated the incidence of missed charges to range from ten to twenty percent. Using the example above, this represents between \$5.9 to \$11.8 million of missed charges.

The second area of concern deals with the ability to effectively manage the quantity and quality of the device and supply inventories. Unfortunately, health care organizations may lack the data to perform retrospective and prospective analysis of their device and supply utilization patterns to guide their inventory levels. For example, most organizations stock an unnecessarily wide variety of stent sizes when practice patterns would reveal that certain sizes are most commonly used, and others very seldom, if ever used. As such, most organizations use arcane estimating methodologies to determine how much stock to carry on their shelves, usually resulting in high volumes of inventory for certain items and low volumes or unavailable items for others. With a carrying cost to the organization of 25% for each stocked item, this ties up capital resources that could be deployed towards other areas of patient care delivery [5].

As another byproduct of the lack of detailed data for product inventories, often

the processes of managing those devices that are time-sensitive to expiration, such as drug-eluting stents, becomes a very manual, time-intensive exercise which is often prone to error. Catheterization laboratory staff, materials management staff, or other individuals spend several hours manually reviewing each item located on the shelves, seeking out product types, serial numbers, lot numbers or manufacturer's date ranges to identify expired items. Due to the potential oversight errors that can occur, many times items on the shelves are missed, leading to the expiration and disposal of the item. In turn, a sunk cost to the organization is realized. In the scenario above, if only one percent of the stents purchased by the organization result in expiration and waste, it will cost the healthcare organization nearly \$200,000 annually.

### Finding Assistance through Technology

Due to our innovative and leading edge pursuits in interventional procedures, the University of Chicago Section of Pediatric Cardiology acknowledged the prevalence of our use of devices and supplies in our procedures and the problems related to our ability to effectively manage that utilization. In 2004, the Section sought to find a solution to the challenges of improving charge capture and better managing our device and supply storage and tracking. In addition to these areas of focus, there was importance in process improvement as we were opening a new facility on campus while continuing to perform procedures in our old location as well. At the time, all technicians were responsible for the management and replenishment of catheter lab inventory. Upon opening the new facility, the team's responsibilities would become more complex as

they managed inventory between two separate buildings.

"As the innovative developments in medical devices and supplies continue, it is likely we will see corresponding increases in the costs to purchase these critical items. As such, we look forward to leveraging technology to assist us in our efforts to continue providing world class pediatric care while demonstrating optimized financial and operational practices towards the utilization and management of these important devices and supplies."

To address our needs, the Section engaged Mobile Aspects, a Pittsburgh, PA, based vendor that specializes in clinical resource management solutions for the cardiac catheterization laboratory environment. The vendor designs and installs cabinet-based storage systems (see Figure 1) that use radio frequency identification (RFID) technologies to automate the processes associated with managing and tracking medical devices and supplies. Items such as stents, balloons, guide-wires, catheters, and implantable devices such as ASD, PDA, VSD, and pacemakers are affixed with an RFID tag and then stored in the cabinets.

The system then tracks each individual



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item, and when the item is taken from the cabinet, it is automatically recorded without needing manual interaction such as pushing buttons or scanning bar codes. At the end of the procedure, any returned items are reconciled within the cabinet, and all items used during the procedure are detected to allow for charges to be captured and inventory levels to be appropriately decreased.

#### Results

To assess the results of implementing this technology in pursuit of our goals, the Section initially focused on improvements seen in our charge capture processes. We conducted an internal analysis related to the charges captured for cardiac catheterization procedures addressing Atrial Septal Defect (ASD) device closure. Over two eight-month time periods, one prior to implementing the system and one after implementing the system, we examined the charge capture levels associated with these cases. As illustrated in the chart summary above, by combining the implementation of the system with additional process changes for our staff, the Section realized a 30% increase in captured charges per case, or over \$5,600 of charges billed per case (see Table A).

With these results, it's become clearly apparent that the introduction of this technology to automate our medical de-

vice and supply utilization processes has been extremely beneficial. Moving forward, we intend to leverage the data available within the system to analyze for optimal par levels of inventory based on our practice patterns. We anticipate that this will add to the benefits we' have experienced in using this technology.

#### Conclusion

As the innovative developments in medical devices and supplies continue, it is likely we will see corresponding increases in the costs to purchase these critical items. As such, we look forward to leveraging technology to assist us in our efforts to continue providing world class pediatric care while demonstrating optimized financial and operational practices towards the utilization and management of these important devices and supplies.

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### HIGHLIGHTS FROM THE 15TH INTERNATIONAL PARMA ECHO MEETING

By Sommi Marcello, MD

In late June, between 28th and 30th, the Section of Pediatric Cardiology of Parma University, hosted the 15th International Parma Echo Meeting, at the University campus in Parma (Italy).

Over a hundred professionals in neonatal and pediatric cardiovascular disease from over sixteen different countries attended the Meeting.

Different sessions were held reviewing the echocardiographic assessment of the cardiac function including some new techniques such as the strain and strain rate imaging, the evaluation of the Fontain patient and the assessment of the valvular lesions with the traditional 2D echo, but also with the new 3D echo imaging.

Some lectures were dedicated to specific subjects such as, ARVD, Perinatal cardiology, Sudden death in the young, and the

"Dr. Nava updated the audience on the new concepts of the genetic contribution about ARVD (Arrhythmogenic Right Ventricular Dysplasia). He made a convincing argument for the clinical diagnosis and assessment of the 1st degree relative of a proband, in a fashion similar to the Long Qt syndrome."



The Nativity by William G. Congdon – The cover of the Program.

Cardiac Stem cells and myocardial regeneration.

Dr. Coleman and Dr. Sanders opened the meeting discussing the Conventional methods for the assessment of Ventricular systolic and diastolic function, and the methods for measuring and evaluating the ventricular size and volume. These two lectures and the related discussions pointed out the importance of evaluating diastolic function, not only in adult patients, but also, in children as the routine echocardiographic examination. Other lectures were given by Dr. Mertens who reviewed the "Strain and Strain Rate Imaging in Assessing Systolic Function," and during the morning session of the 2nd day, the "Doppler Tissue Imaging and Strain Rate Imaging in Assessment of Diastolic Function," relatively new techniques which offer a very complex, but complete data about both ventricular movements and function, globally but particularly in segments. The data offered by these techniques allow us to study the complex systolic movement of the two ventricles, evaluating the shortening/ lengthening movement, the thinning/thicking movement and the twist/untwist movement which compose the systole and diastole of the cardiac cycle.

In the morning session of the 2nd day, the "Assessment of Diastolic Function Using Doppler Methods" was reviewed by Dr. Hagler, who presented the traditional way for evaluating diastolic function with Doppler, and also explained how all these parameters change with the worsening of the ventricular diastolic function. He later also reviewed the Diastolic stress testing, and its possible clinical application. Later, during the morning session Dr. Hagler discussed the methods for the assessment of the left atrium and their echocardiographic uses. Dr. Coleman updated the attendees about the echo evaluation and clinical treatment of Dilated Cardiomyopathy and Myocarditis with great echo video clips and images in his lecture.

During the afternoon session Dr. Sanders and Dr. Mertens reviewed the evaluation of the Fontan patient preoperative and postoperative, but also the clinical management and strategies in patients who present a failing Fontan.

In the morning session of the last day a very complete review of the echo assessment of the valvular heart lesions was given by Dr. Sanders. An innovative way for studying these kind of diseases is 3D echocardiography presented also by Dr. Sanders who discussed the possibilities of this technique which offers a wide range of post-processing the imaging obtained from the examination.

Dr. Hagler then updated the attendees on the clinical application and uses of intraoperative TEE field aiming to reduce



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the complications and reoperations particularly in children.

Dr. Galal reviewed his personal experience in Jeddah about congenital heart disease in adults proposing a number of cases with related discussion with the attendees.



Prof. Umberto Squarcia, Director of the Meeting.

In the afternoon session, before abstract and case presentations, Dr. Vogel presented the assessment of VSD with 3D echo, a technique which offers images and also clips of high definition.

During the three-day meeting among the lectures scheduled some magistral lectures were given, particularly Dr. Nava updated the audience on the new concepts of the genetic contribution about ARVD (Arrhythmogenic Right Ventricular Dysplasia). He made a convincing argument for the clinical diagnosis and assessment of the 1st degree relative of a proband, in a fashion similar to the Long Qt syndrome.

Dr. Huhta talked about his personal experience in perinatal cardiology presenting also some interventional techniques such as valvuloplasty in the newborn with very interesting iconography and real time imaging.

Two lectures were given by Prof. Thiene who presented the discovery of blood circulation during the opening ceremony at the suggestive Aula Magna, and also discussed the sudden death in the young, updating all of us on the genes which seem to be involved in the inheritance of this disease condition.

The last Magistral Lecture was given by Prof. Quaini, who updated the audience on the uses of cardiac stem cells for myocardial regeneration and for possible future treatment of congenital heart disease.

Two session were held to discuss clinical trials, research and cases studied, in addition to the display of five posters by physician, residents and nurses from around the world.

Some cases were then examined live with echocardiographic complete examination and discussed together in the tradition of our Parma Echo Meeting.

The Organizing Committee is already actively planning the 16th International Parma Echo Meeting for next year, which will be held on the 27th, 28th and 29th of June 2007.

You may look at the "Echoes" from the past editions of the Meeting at our web site http://www.unipr.it/arpa/echomeet.

Additional ideas, or advices for the next meeting can be sent to umberto.squarcia@unipr.it. We hope to see you next year in Parma!

~CCT~

Sommi Marcello, MD Resident in Pediatric Cardiology U.O. of Pediatric Cardiology Department of Pediatrics University of Parma

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By Bistra Zhelev

For 37 years, Children's HeartLink has been dedicated to the mobilization of global resources to prevent, treat and cure children's heart disease – a major health issue in developing countries around the world. We provide a combination of lifesaving treatment, advanced training, and technical assistance through medical missions to our international partner sites. As a result, we bring both immediate relief and a long-term solution intended to help build sustainable, quality cardiac services for all children in need.

We seek not just to save the lives of children suffering from heart disease, but also to develop the knowledge, skills and technologies of health sectors in developing countries. Children's HeartLink currently has partner hospital programs in Malaysia, India, China, Ukraine and Kenya and programs of assistance in Ecuador and South Africa

Pediatric heart disease kills and weakens the growth and future performance potential of millions of children throughout the developed and developing world. Children's Heart Link is committed to providing the world's health sector and political leaders with information to attack and

resolve this important health risk and is launching the second installment of a research series into factors related to global advances in pediatric heart health in developing countries. The study will be conducted in cooperation with the World Health Organization, University of Minnesota and the World Heart Foundation, with completion date set for May 2007.

This year's focus will build on the past investigation of the incidence and prevalence of congenital and acquired heart disease in children in the developing world, but now will also highlight trends and issues in the attraction and retention of specially trained nurses and physicians into the pediatric heart health arena. This study is designed to explore the state of children's heart disease and to identify organizations and strategies across the globe that are successfully responding to the causes and consequences of children's heart disease.

The report will be presented at the Third Global Humanitarian Forum on Humanitarian Medicine in Cardiology and Cardiac Surgery in Geneva in May 2007

An Editorial Board consisting of global leaders in pediatric cardiac care will review and determine publication of the submitted data. The Editorial Board will be chaired by Joseph A.

Dearani, MD, cardiovascular surgeon at Mayo Clinic, Rochester, Minnesota and Children's HeartLink Medical Director.

All persons interested in participating in this study, or in receiving copies of the final report should contact B is tra Zheleva at bistra@childrensheartlink.org.

Copy of the first study published in 2005 can be viewed at Children's Heart Link's website at www.childrensheartlink.org/articles/Childrens\_Heartlink\_Study.pdf

Please refer to our website for additional information about our work and international network of volunteers at www.childrensheartlink.org.

~CCT~

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