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INSIDE THIS ISSUE

TRANSCATHETER CLOSURE OF MULTI-FENESTRATED ATRIAL SEPTAL DEFECTS USING THE NEW AMPLATZER CRIBRIFORM DEVICE

By Ziyad M. Hijazi, MD, MPH, FACC, FSCAI and Qi-Ling Cao, MD

Introduction

The use of the Amplatzer device for transcatheter closure (TCC) of single secundum ASD is associated with high and complete closure rate (1, 2) and has become an accepted alternative to surgical repair (3). However, in about 10% of patients with atrial level shunt, the fossa ovalis may contain more than one fenestration with different sizes (4). If the defects are separated by 7mm or more of tissue, two Amplatzer devices can be used to close such defects sequentially with good results (5, 6). However, on occasions the fossa may contain many fenestrations "Swiss cheese type" that are close to each other. Using the Amplatzer septal occluder to close such defects may not achieve the desired result. In this article, we describe a patient who had multiple atrial defects of the Swiss cheese type that underwent successful complete closure using a new device designed specifically for closure of the multi-fenestrated atrial defects.

Figure 1: See Figure Legend, page 4

Device: Similar to all Amplatzer family of devices, the cribriform device (AGA Medical Corporation, Golden Valley, MN) is a self-expandable, double disc device made of Nitinol wire mesh. The two equal size discs are connected together by a short (3-mm) connecting waist (Figure 1). The device is available in 3 sizes, the 18, 25 and 35-mm. An 8-9 Fr delivery sheath is required for deployment.

Case

EN is a 37-year young lady presented with increasing symptoms of fatigue. Transthoracic echocardiogram (TTE) demonstrated the presence of left-to-right shunt at the atrial level with mild enlargement of the right atrium and ventricle. She underwent transesophageal echocardiography (TEE) that revealed the presence of multiple atrial defects (Swiss cheese type) in the posterior inferior part of the septum in addition to at least two defects in the superior anterior part of the septum (fossa ovalis location). The patient was referred for device closure. Under conscious sedation, she underwent cardiac catheterization using two separate sheaths in the right femoral vein. A 9 Fr sheath for device placement and an 11 Fr sheath for the use of the AcuNav catheter (Acuson Corporation, A Siemens company, Mountain View, CA) for continu-

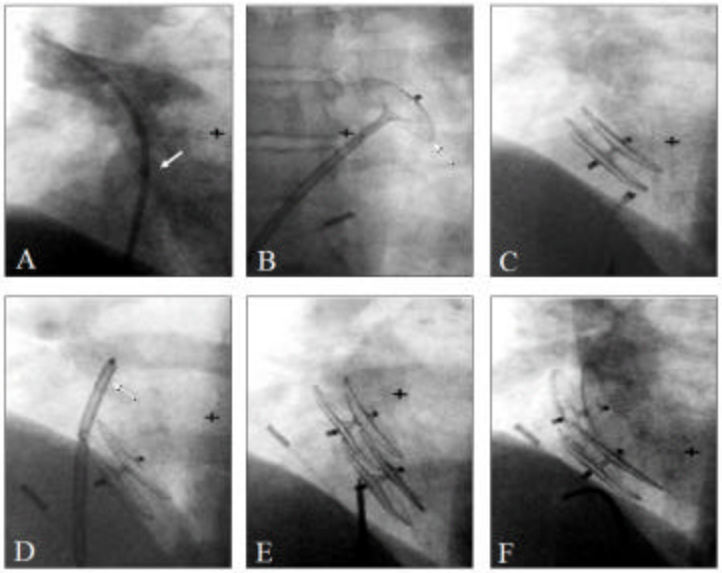

Figure 2: See Figure Legend, page 4

ous intracardiac echocardiographic (ICE) guidance. Her right heart pressures were remarkable for mild pulmonary artery hypertension (Main pulmonary artery pressure: systolic 55; diastolic 25 and mean 36 mm Hg) and her left ventricle pressure was 148/15. The Qp/Qs ratio was calculated to be 1.6:1. Angiography was performed in the right upper pulmonary vein in the hepatoclavicular projection. This revealed the presence of multiple atrial level shunts (Figure 2A). ICE evaluation confirmed the presence of many defects with left-to-right shunt (Figures 3A, B). Short rims of tissue less than 7-mm separated the defects. The atrial septum was crossed through the central most defect (Figure 3C). A 35-mm Amplatzer cribriform device was loaded into a 9 Fr delivery sheath (AGA Medical Corporation, Golden valley, MN). The device was deployed and released under fluoroscopic and ICE guidance similar to the deployment of the Amplatzer septal occluder (Figures 2B, C, 3C, D). Repeat assessment by ICE revealed the presence of residual shunt arising from the superior anterior aspect of the septum (Figures 3D, E). Therefore, the atrial septum was recrossed superior and anterior to the first device using a multipurpose catheter. Another 35-mm Amplatzer cribriform device was deployed and released similar to the first device (figures 2D, E, 3F, G). Repeat angiogram in the right atrium with pulmonary levophase and ICE evaluation demonstrated complete closure of the defects. The two devices were overlapping and aligning the septum (Figures 2F, 3H). The total fluoroscopy time was 13.3 minutes and the total procedure time was 55 minutes.

The following day, repeat TTE demonstrated good devices position and no residual shunt. The patient was discharged home on 81 mg aspirin per day and to observe subacute bacterial endocarditis prophylaxis for six months.

Discussion

Since the approval of the Amplatzer septal occluder in December 2001, TCC of single secundum ASD has become an accepted modality of treatment worldwide. This device has all the characteristics required for a device to be widely used: user and patient friendly, the operator has the ability to retrieve and reposition the device prior to release and the success rate achieved is high. However, a potential limitation of the septal occluder is the inability to effectively close multiple defects of the Swiss cheese type. This is due to the design of the septal occluder with a thick connecting waist used to plug larger atrial defects. The new device (cribriform) is designed to overcome such limitations. In addition to the above ideal features that the septal occluder has, it can be used effectively to close multiple defects that are very close to each other. This device is currently undergoing clinical trials to assess its safety and effectiveness in patients with the following conditions:

1. Fenestrated secundum atrial septal defects: two or more defects in the region of the septum primum with volume overload of the right ventricle.

2. Non-fenestrated atrial septal aneurysm: the aneurysm has to extend more than 10 mm into the

right or left atrium. This may be associated with a patent foramen, secundum ASD or no defect at all.

3. Fenestrated atrial septal aneurysm: aneurysm with multiple defects and right ventricle volume overload or paradoxical embolism.

4. Patent foramen ovale: single defect (1-20 mm) that allows right-to-left shunt at rest or with provocative maneuvers.

When attempting to close an ASD, it is important to have an accurate evaluation of the atrial septum to rule in or out the possibility of multiple defects. This is done by careful interrogation of the atrial septum by color Doppler echocardiography, preferably by TEE or ICE at the time of catheterization. During measurement of the stretched balloon diameter of any defect, color flow mapping should be applied to the septum to rule this possibility in or out.

When using two Amplatzer septal occluders to close two or more defects, it is recommended that the two delivery sheaths be in the left atrium simultaneously. This is done to avoid crossing the septum with the possibility of dislodgment of the first device. However, using the new cribriform device instead provides the operator a better sense of security. As we demonstrated in our patient, we were able to re-cross the septum safely after we deployed the first device. The dislodgment chances of the first device would have been very small

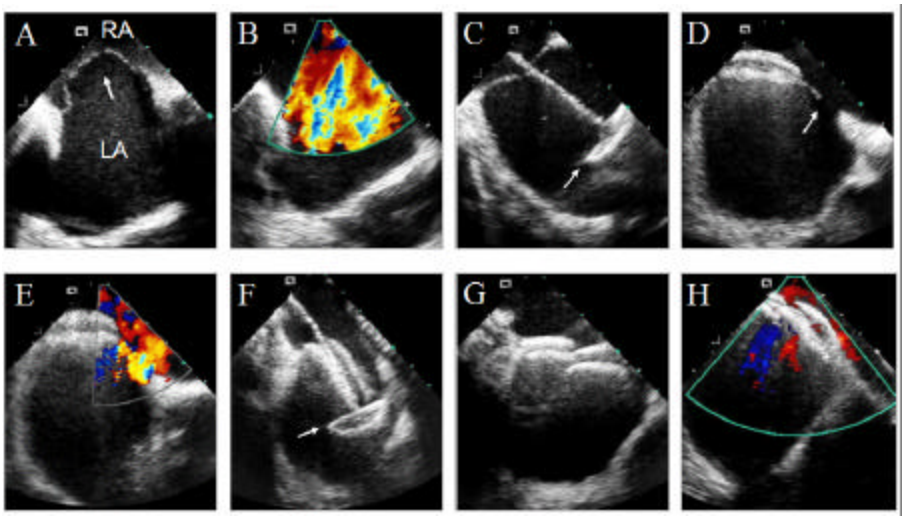

Figure 3: See Figure Legend, page 4

due to the large disc and small connecting waist.

In conclusion, this new device was used effectively to close and completely repair the atrial septum in this patient with a complex atrial septum. The two devices used in this case were overlapping and their profile was rather thin. Therefore, the addition of this device to our armamentarium of devices will certainly enable us to close more defects.

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Figure Legend

Figure 1: The Amplatzer cribriform device. Note the two equal discs.

Figure 2: Cine angiographic images during closure. A, angiogram in the right upper pulmonary vein in the 35° LAO/35° cranial projection demonstrating left-to-right shunt at the atrial level (arrow).B, cine image in the frontal projection after the left atrial disc (arrow) of a 35-mm Amplatzer cribriform occluder has been deployed. C, cine image in the same projection as A, demonstrating good device alignment with the septum. D, cine image as in the previous projection demonstrating the 9 Fr delivery sheath with the second 35-mm cribriform device at the tip of the sheath (arrow). Note, the sheath has crossed the septum superior to the first device. E, cine image after the second device has been released demonstrating the overlap between the two devices and alignment with the septum. F, cineangiogram of the pulmonary levophase after injection in the right atrium. This demonstrates good devices position and no residual shunt.

Figure 3: Intracardiac echocardiographic images demonstrating steps of closure. A, Septal view demonstrating presence of multiple defects in the septum (arrow). B, same view with color Doppler demonstrating the left-to-right shunt. C, deployment of the left atrial disc (arrow) of the 35-mm cribriform device. D, after the first device has been released demonstrating the presence of a residual defect superior/anterior (arrow) to the first device. E, with color Doppler demonstrating the left-to-right shunts. F, deployment of the left disc (arrow) of the second device. G, after the second device has been released demonstrating overlapping between the two devices. H, with color Doppler demonstrating no residual shunt.

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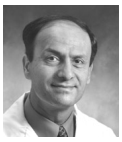

Ziyad M. Hijazi, MD, MPH, FACC, FSCAI

zhijazi@peds.bsd.uchicago.edu

Section of Pediatric Cardiology, Department of Pediatrics, The University of Chicago Children's Hospital and The Pritzker School of Medicine

Qi-Ling Cao, MD

Assist. Professor of Pediatrics, Section of Pediatric Cardiology, The University of Chicago Children's Hospital

USEFUL WEB LINKS

Congenital Heart Information Network

C.H.I.N. is an international organization that provides information, support services and resources to families of children and adults with congenital heart defects and acquired heart disease, and the professionals who work with them.
www.tchin.org/

3-D Visualization of Congenital Heart Disease

everst.radiology.uiowa.edu/nlm/app/cnjheart/cnjheart.html

Coe Point Foundation

Univ. of VA Children's Heart Center Patient education for congenital Heart disease.
www.PtEd.org

Congenital Heart Surgeons Society

CHSS is a group of 70 pediatric heart surgeons who meet once a year to discuss problems of mutual interest in patient management.
www.chssdc.org

The Society for Cardiac Angiography and Interventions

The Society promotes excellence in invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care.
www.scai.org/public/pages/index.cfm?pageid=1

RECOGNITION OF THE ROLE OF ELECTROPHYSIOLOGIC-HEMODYNAMIC INTERACTIONS

By James C. Perry, MD

There is a growing body of literature in the realm of management of severe ventricular dysfunction and congestive heart failure in adult patients that supports the premise that ventricular activation sequences are important determinants of ventricular function. This concept, that the electrophysiologic control of cardiac activation can have profound implications on functional status, has wide applications to other conditions in children and adults. Biventricular pacing in older patients with left bundle branch block and forms of intraventricular conduction delay has been shown to improve left ventricular ejection fraction and reduce symptomatology in a significant number of patients. While there has been some debate on the topic, optimization from a wide QRS toward a narrow QRS complex tends to achieve improved hemodynamic status in many patients. In other pacing modalities that clearly influence hemodynamics, interventricular septal pacing in patients with obstructive forms of cardiomyopathy can reduce left ventricular outflow tract gradients and eliminate or postpone the need for surgical myectomy.

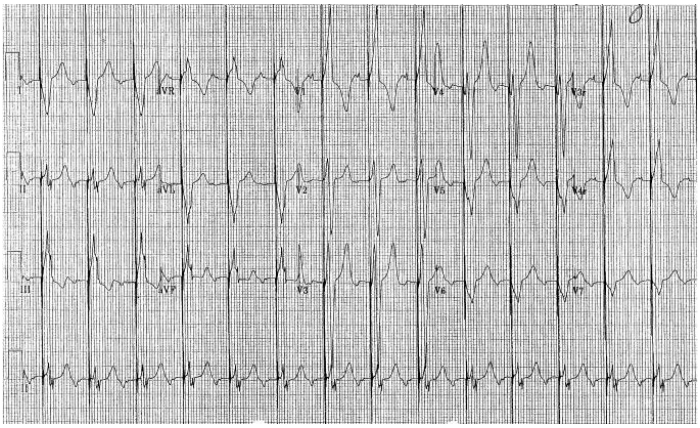

Figure 1a: Electrocardiogram during atrial sensed and ventricular paced rhythm via a single ventricular lead system

Do any of these principles apply to pediatric patients, especially those with structural congenital heart disease? There is good evidence in the immediate post-operative period that "resynchronization" of ventricular activation in patients with right bundle branch block (RBBB) can improve hemodynamics, increase arterial pressure and cardiac output and reduce some of the need for inotropic and ventilatory support. This is achieved by pacing the right ventricle after a properly timed AV interval to produce a fusion complex of intrinsic left ventricular activation with paced right ventricular (RV) activation. This can be particularly helpful in young patients with fast heart rates where late right ventricular contraction due to RBBB nearly coincides with right atrial contraction of the next beat. This can produce atrial contraction against a closed or partially closed AV valve, poor RV filling and elevation of the CVP with cannon waves on the pressure tracing. Earlier activation of the RV by resynchronization eliminates this relationship, resulting in improved flow across the tricuspid valve in diastole. Recognition of this pacing modality should be the standard of care for postoperative congenital heart patients.

"The next several years should prove exciting for research efforts in clinical and animal models of pacing and hemodynamics through collaborative, multicenter studies."

Assessment of the role of electrophysiologic-hemodynamic interactions may prove helpful in other

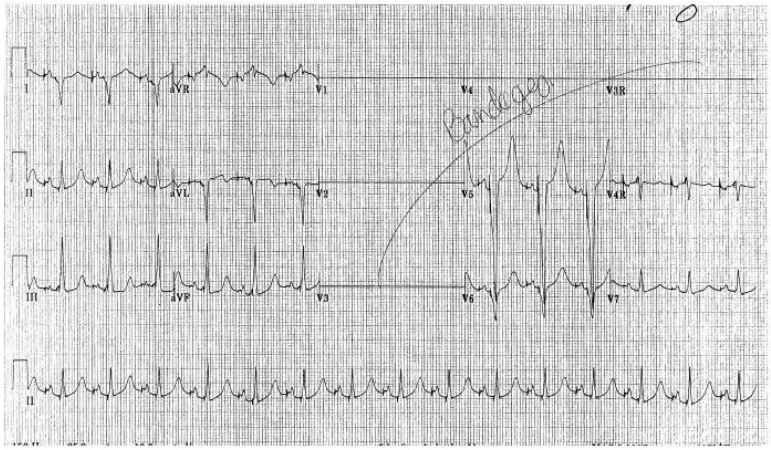

Figure 1b: Change at time of battery depletion

paced rhythm via a single ventricular lead system. Figure 1b shows the change, at the time of battery depletion, to a biventricular configuration with reduction in the QRS duration and improved hemodynamics. The double ventricular spike (V-V delay of 36 msec) can be seen in lead III. In these cases, functional myocardial improvement may have much to do with ventricular morphology and the placement of atrial and ventricular leads in specific locations. Atrial events must trigger, through the sensed or paced AV interval, proper timing for appropriate ventricular activation. Ventricular lead placement strategies may need to consider activation of the ventricle underlying the AV valve to promote diastolic ventricular filling. New biventricular pacing systems allow programmable timing of pacing for the ventricles. This feature should allow timing sequences to be programmed that result in optimal cardiac output, whether by simple QRS optimization or by echocardiographic determinants of ventricular contraction sequences and filling. Several pacemaker manufacturers have or are developing biventricular pacing devices.

clinical settings on our field. Congenital complete AV block often requires pacing in very young patients. Are these patients best served by a single ventricular lead, resulting in asynchronous ventricular activation or might they be better off with a biventricular pacing system? Studies have indicated that chronic RV pacing can result in long-term adverse functional consequences, so the potential benefits of biventricular pacing from the outset demand investigation. Most of the single ventricle population can be looked upon as existing in various states of compensated (or uncompensated) congestive heart failure. Are these patients a prospective group to benefit from biventricular pacing strategies or resynchronization therapies? The figure shows a patient with single ventricle physiology and congenital AV block. Figure 1a is the electrocrdiogram during atrial sensed and ventricular

The next several years should prove exciting for research efforts in clinical and animal models of pacing and hemodynamics through collaborative, multicenter studies. There are certainly many opportunities for investigation and improving patient care. Once we have clear evidence of these new benefits in the not-too-distant future, it should become obvious that we will need to revise the current "indications" for pacing, above and beyond the standard indications related to bradycardia and complete AV block.

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James C. Perry, MD, FACC

jperry@chsd.org

Co-Director of Cardiology, Director Electrophysiology, Children's Hospital - San Diego; Children's Specialists Medical Group, San Diego, California; Associate Clinical Professor of Pediatrics, University of California San Diego and University of California Irvine; Consultant in Pediatric Cardiology & Electrophysiology; Children's Hospital Orange County; Children's Heart Institute

Nit-Occlud Device Enters FDA Trial

Study to determine the Nit-Occuld device's efficacy and safety in closing small to moderate patent ductus arteriosus.

By John W. Moore, MD

Pfm Medical Corporation (Oceanside, CA) announced that the Nit-Occlud Device entered a sentinel FDA clinical trial. The purpose of the study is to determine the device's efficacy and safety in closing small to moderate patent ductus arteriosus. The initial implants were performed in November 2002 at Columbus Children's Hospital in Ohio by Dr. John Cheatham and at Valley Children's Hospital in Fresno, California by Doctors Carl Owada and John Coulson. Additional Centers in Texas, California, Illinois, Delaware, and the District of Columbia have subsequently begun enrolling patients and implanting devices.

The Nit-Occlud Device is the latest modification of a previous Pfm device call the Duct-Occlud. The Device was designed specifically for occlusion of patent ductus arteriosus. It is a coil type device made of nitinol. The device has a compact cone-in-cone configuration and comes in 9 sizes. The larger sizes are reinforced because they are made of thicker wire and also have a core wire which further stiffens the device. Nit-Occlud has a controlled delivery system which allows operators to accurately position devices, and which significantly reduces the chance of device embolization during or after implant. Unlike Cook's Gianturco coils, the Nit-Occlud Device does not have Dacron feathers imbedded along its length.

"The trial is being conducted at 20 U.S. Medical centers and will enroll 340 patients in primary study group."

Figure 1: Nit-Occlud Device

Devices are usually implanted via the venous system through the right heart, but may be implanted retrograde via the aorta in very small patent ductus arteriosus which are difficult to cross antegrade. Four or Five French Sheaths are required to accommodate the device and delivery system. The delivery catheter is placed in the descending aorta via the patent ductus arteriosus. The first coil cone is configured and the device is pulled into the aortic ampulla of the ductus. The second coil cone is configured in the ductus and a single coil loop is pulled across the narrowing of the ducts to the pulmonary side. The device is released if optimal position is attained, or it may be drawn back into the delivery catheter for a second attempt. Occlusion of the ductus is caused by the compact mass of coil loops in the ductus lumen and by the mechanical properties of the nitinol device's configuration, which tends to kink the ductus. Animal studies have shown that thrombosis and subsequent endothelialization occur within a few weeks causing definitive ductus occlusion and permanent device

"The Nit-Occlud Device is the latest modification of a previous Pfm device…."

CONFERENCES

7th Annual Pediatric Interventional Cardiac Symposium (PICS-VII)

Sep. 21-24, 2003, Orlando, FL

www.picsymposium.com

Fourth International Cardiovascular Symposium: Heart Failure in Pediatrics

Oct. 10-12, 2003, Atlanta, GA

www.choa.org/professionals/conference/fourthinterpedi/general.shtml

Scientific Meeting of the Section on Cardiology and Cardiac Surgery, AAP (American Academy of Pediatrics)

Oct. 31-Nov. 2, 2003, New Orleans, LA

www.aap.org/

American Academy of Pediatrics New Orleans 2003

Nov 1-5, 2003, New Orleans, LA

www.aap.org

American Heart Association Meeting

Nov. 9-12, 2003, Orlando, FL

www.scientificsessions.org/portal/scientificsessions/ss/

fixation.

The Trial will test the Nit-Occlud Device in patent ductus arteriosus with minimum angiographic diameter of 4 mm and smaller in patients 21 years old or younger. There are Registries for older patients and for patients with minimum ductus diameters larger than 4 mm. The trial is being conducted at 20 U.S. medical centers and will enroll 340 patients in the primary study group. Performance criteria derived from historical control data will be used in lieu of a prospectively enrolled control group. The criteria regarding safety require serious complication rates to be lower than 1 % and echocardiographic complete occlusion rates to be higher than 85% with clinical closure (by auscultation) higher than 95%. These criteria were agreed to by the FDA because the current widespread off label use of Gianturco coils for occlusion of small patent ductus arteriosus makes design of an acceptable control group impossible.

Based on current clinical experience with the Device in Europe, Asia and South America, Pfm expressed confidence that the Nit-Occlud will have a successful Trial and eventually achieve FDA approval. The company estimates that the Trial will achieve full enrollment in 18 to 24 months. The Study Design requires one year follow up of patients prior to submission of the PreMarket Approval Application to the FDA. Thus, FDA approval is expected by late 2005 or 2006.

References

Additional information regarding the Nit-Occlud Device or the FDA Trial may be obtained from Pfm Medical Corporation (phone 760-758-8749). Also see: (1) Moore JW, DiMeglio D, Javois AP, Takahashi M, Berdjis F, Cheatham JP. *Results of the Phase I Food and Drug Administration Clinical Trial of Duct-Occlud Device Occlusion of Patent Ductus Arteriosus*. Cathet Cardiovasc Intervent 2001;52:74-78. (2) Le TP, Moore JW, Neuss MB, Freudenthal F. *Duct-Occlud for Occlusion of Patent Ductus Arteriosus*. Current Interventional Cardiology Reports 2001;3:165-173.

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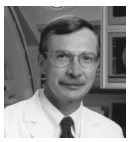

John W. Moore, MD, MPH, FACC

jwmoore@mednet.ucla.edu

Director of the Pediatric Cardiac Catheterization Laboratory, Mattel Children's Hospital at UCLA; Chairman of American Academy of Pediatrics Executive Committee, Section of Cardiology and Cardiac Surgery.

THE REAL DEAL: REAL-TIME 3-D ECHOCARDIOGRAPHY in Congenital Heart Disease

By Gerald R. Marx, MD

A number of innovative advances have occurred in pediatric echocardiography including utilization of harmonics to improve border detection, contrast agents to enhance chamber imaging and Doppler interrogation of jets, and Doppler tissue velocimetry to glean an enhanced understanding of both ventricular function but also atrial and ventricular conduction. However, a most recent advance, which has also has important application for day to day clinical care, is real-time three-dimensional echocardiography.

Investigators have been actively involved in the development of three-dimensional echocardiography for over two decades (1). Studies have shown, in both in-vitro, in-vivo and human clinical studies the advantages of three-dimensional echocardiography over two-dimensional echocardiography for ventricular volumes, mass and ejection fraction calculations (2). This application is intuitive, in that two-dimensional echocardiography relied on assumptions of ventricular shapes to apply mathematic models for volume measurement. Many of these initial studies relied on surface rendered images that could portray the endo and epicardial surfaces, but could not delineate the anatomic details of pathologic disease. In the last decade, volume rendered three-dimensional imaging came to the forefront and excellent three-dimensional echocardiographic displays could be realized (3). Unique imaging planes and projections were rendered, providing detailed anatomic definition of anatomy and pathology that was not possible with two-dimensional echocardiographic images. Yet despite a myriad of reports, and on-going research studies, three-dimensional echocardiography was not accepted into the clinical care setting (4). This paradox is best attributed to the difficulties with the acquisition, post-processing and rendering phases of the three-dimensional echocardiographic studies. First, the acquisition phase, or the attainment of the echocardiographic images was slow and difficult, and often associated with imaging artifacts. The processing phase, i.e. conversion of echocardiographic information to a digital volume data set was slow, and essentially off-line. Initially, the post-processing phase could take several hours. Even with significant advances, with the time reduced to several minutes, this did not allow for on-line clinical decision making. Finally, the rendering phase did not provide immediate display and feedback, and was more of a trial and error format. The placement of the cutting or crop planes within the data set was not readily apparent, and this phase was difficult to learn. Moreover, replication of three-dimensional echocardiographic images was difficult to accomplish on a reliable basis. In essence, despite great potential, the increased time, difficulty, necessity of additional personnel and inher-

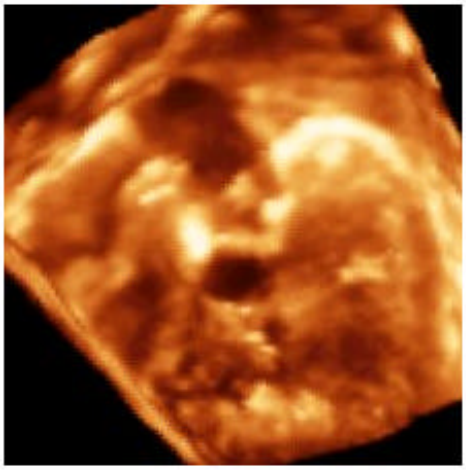

Figure 1: En-face view sub-pulmonic VSD in infant with LTGA. Note the smooth walled left ventricular septal surface

ent imaging artifacts impeded the clinical application of three-dimensional echocardiography.

Real-time three-dimensional echocardiography (Philips Medical, Andover Mass) has essentially circumvented the difficulties previously encountered for the clinical application in pediatric patients with acquired and congenital heart disease (5). A number of technological advances have allowed for this development to occur, both in transducer design, advances in high speed digital scan conversion, and software computing. In brief, the transducer is a "matrix array" with approximately 3000 transducer elements, each transmitting and receiving ultrasound signals. This transducer, although larger than standard pediatric transducers, can comfortably be placed and held in the sub-costal position in even the smallest of infants. Digital scan conversion and beam forming now occur within the transducer itself, and with complex and intricate circuitry, the information digitally processed to a digital volume data set within milli-seconds. In fact, with the flip of a singular switch a three-dimensional echocardiographic image can immediately be displayed on the monitor. Although this display is somewhat restricted by the size of the echocardiographic information that can be projected, a track ball on the echocardiographic machine allows the operator to turn and rotate the three-dimensional image in any direction deemed necessary. The importance is that even in the smallest of babies, a three-dimensional echocardiographic image can be displayed instantaneously. This 'live" imaging format provides excellent depiction of select pathologies such as en-face views of the aortic or mitral valve, or left ventricular outflow tract.

A second real-time three-dimensional echocardiographic format, is to acquire gated images over four heart beats, allowing the compilation of four quadrant screens of digital information. In the smallest of babies, with the probe placed in the sub-costal position, an entire data set of information can be obtained which encompasses the entire heart. The acquisition is approximately four seconds in duration. The post-processing is instantaneous, culminating in a volumetric data set that can then be rendered on-line. Importantly, cut planes can be placed, rotated and images rendered, allowing for immediate feedback and visualization of three-dimensional spatial projections. This technique is revolutionary in providing anatomic display such as the relationships of ventricular septal defects to the great arteries in complex pathology (Figure 1).

"The importance is that even in the smallest of babies, a three- dimensional echocardiographic image can be displayed instantaneously."

The potential for real time three-dimensional echocardiography seem unbounded in the display and understanding of acquired and congenital heart disease. However, this technology also allows for three-dimensional echocardiographic analysis of left, right and singular ventricular volume and mass calculation. The entire ventricle can be scanned within seconds and the digital information processed with dedicated software (TOMTEC, Munich Germany) for more expedient calculation of ventricular volumes than ever before.

Recent real time three-dimensional echocardiographic advances have included the potential application to fetal echocardiography, and more recently three-dimensional color flow Doppler. The latter presently allows for the depiction of the shape, direction and propagation of color flow jets in three-dimensions for analysis of ventricular septal defects, valvar and subvalvar stenosis, regurgitant jets, etc. Importantly, this technology will allow for the analysis of blood velocity across the entire lumen of the vessel, potentially allowing for accurate calculation of flow and hence determination of cardiac output, regurgitant fractions, and shunt magnitude.

Although, three-dimensional echo-

cardiographic images can be instantaneously displayed and projected, the information can also be stored digitally and the images instantly retrieved. Equally important is that the entire data set is available for subsequent analysis and rendering to analyze information not realized at the time of the study. In the future, the volumetric data sets will be available for the surgeon to render the imaging cut planes and projections to plan surgical procedures.

The applications of real time three-dimensional echocardiography appear limitless. This images are presently shown to the surgeons in pre-planning of operative procedures. Three-dimensional echocardiographic images are extraordinary in the educational value to the patients and parents. On many occasions parents have remarked that they can understand their child's cardiac defect much better than ever before. The display of complex congenital heart disease in three-dimensional reality, similar to holding a pathologic specimen in one's hands, will fundamentally change the aspects of teaching cardiac anatomy and pathology to medical students, residents, and fellows Presently, a highly trained and experienced sonographer not only acquires, but also renders the three-dimensional echocardiographic images. Such expert personnel can learn to scan the heart in real time three-dimensional echocardiographic display. This may aid in the more reliable diagnosis of common cardiac malformations such as mitral valve prolapse, bicuspid aortic valves, or membranous sub aortic stenosis.

Certainly the present and future application of real-time three-dimensional echocardiography to the clinical management of pediatric patients with congenital heart disease is very promising. However, this is not to imply that real time three-dimensional echocardiography will replace two-dimensional imaging. Rather, real-time three dimensional echocardiography will be an very important addition to the non-invasive imaging of acquired and congenital heart disease in the pediatric patient. Real-time three-dimensional echocardiography is the real deal.

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Gerald R. Marx, MD, FACC

marx@cardio.tch.harvard.edu

Associate Professor Pediatrics, Harvard School of Medicine; Senior Associate Cardiology, Boston Children's Hospital

FACT OF THE MONTH

"***Cardiomyopathy is the number one reason for heart transplants in children....***"

Source:

Children's Cardiomyopathy Foundation

Tel: 201-227-7016

www.childrenscardiomyopathy.org

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9008 Copenhaver Drive, Suite M
Potomac, MD 20854 U.S.A.

Article Submission

Article@PediatricCardiologyToday.com

Production

Prod@PediatricCardiologyToday.com

Marketing and Sponsorships

Tony Carlson, Founder
Tel: 301.279.2005
Fax: 240.465.0692
TCarlson@PediatricCardiologyToday.com

Publishing Management

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

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9008 Copenhaver Drive, Suite M

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