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Isolated Congenital Right Ventricular Aneurysm and Successful Non-Surgical Device Closure in a Pediatric Patient

By Howard S. Weber, MD; Athira Nair, MD; Sunil Patel, MD; Jason R. Imundo, MD

Legend

RVA - Right ventricular aneurysm
TTE - Transthoracic echocardiogram
TEE - Transesophageal echocardiogram
CCAM - Congenital cystic adenomatoid malformation
ASO - Amplatzer occluder device

CASE REPORT

Introduction

The incidence of congenital ventricular aneurysms is estimated at 0.5 per 100,000 live births[1] with equal male and female distribution.[2] Left ventricular aneurysms are more common than RVAs. They are typically located apically (51%), on the ventricular wall (41%) and septal (8%).[3] Postulated theories include in utero myocardial ischemia and infarction, inherited intrinsic embryologic disruption of myocardium which produces a weakened dysplastic myocardium and congenital viral infection.[4, 5]

A RVA is defined as a broad-based outpouching of the ventricular cavity containing dysplastic myocardium and fibrous tissue.[6] Contraction is typically paradoxical when compared to the normal right ventricular myocardium (filling during systole and emptying in diastole). This is differentiated from a diverticulum which usually has a narrow neck with all 3 components, including endocardium, mesocardium and pericardium with hypokinetic wall movement, which is concordant with ventricular myocardial contraction.

The differential diagnosis includes ventricular diverticulum, which is usually associated with: midline defects of the fetal thorax and abdomen (i.e. Pentology of Cantrell, omphalocele and ectopia cardis), Uhl's anomaly, cardiomyopathy and epicardial cyst. Reported prenatal complications include arrhythmias,[7, 8] pericardial effusion which may lead to fetal hydrops[6, 9, 10, 11] and pulmonary hypoplasia. There may also be thrombi formation within the aneurysm. Isolated cases of spontaneous rupture have been reported,[12, 13] and there is a theoretical risk of endocarditis, although spontaneous resolution may also occur.[14]

In an asymptomatic patient, the management of RVAs is controversial; although surgical ligation via a sternotomy incision without the use of cardiopulmonary bypass has been advocated, especially if the RVA is expanding.

We present an 8-year-old boy with a presumed prenatal diagnosis of a congenital cystic

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- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22-Fr size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

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Potential device-related adverse events that may occur following device implantation include: stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, and hemolysis.

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adenomatoid malformation (CCAM) which postnatally was determined to be an isolated congenital RVA that progressively became larger. The RVA was successfully occluded in the catheterization laboratory utilizing a 10 mm ASO.

Case Presentation

An 8-year-old male was born at term to a 34-year-old, G2P1, with an uncomplicated pregnancy except for Lexapro exposure during the first trimester. Prenatal ultrasounds were suspicious for a CCAM and macrosomia. Prenatal serology and TORCH titers were negative. There was no apparent history of intrauterine hypoxic events or viral infections in the mother and the family history was negative for congenital heart disease or cardiomyopathy.

Postnatally, a transthoracic echocardiogram (TTE) demonstrated an apical RVA. Electrocardiography demonstrated normal sinus rhythm with right axis deviation and non- specific T wave changes. A cardiac MRI at 3 days and 1 month of age confirmed the presence of an apical RVA measuring 11x 15 mm in diameter with a narrow neck and no thrombus formation. The child remained asymptomatic and was followed on an annual basis. Repeat cardiac MRI at 33 months of age demonstrated that the RVA had increased in size (13mm x 18mm) with no evidence of a pericardial effusion, normal right ventricular end diastolic volume and no thrombus formation within the aneurysm. Subsequent yearly TTEs were unchanged and 24-hour Holter monitoring was unremarkable. A maximal exercise treadmill stress test at 8 years of age demonstrated a normal exercise capacity and no ventricular ectopy. He was not placed on prophylactic antiplatelet therapy.

A follow-up cardiac MRI at 7 years of age demonstrated that the RVA had further increased in diameter (26 x 20 mm) with stable dimensions the following year (Figure 1). Following a discussion with the family pertaining to continued observation vs intervention, they decided to proceed with closure of the aneurysm. This was based on the child's desire to participate in competitive sports, the increasing size of the RVA and the theoretical risks for thrombosis, arrhythmias or spontaneous rupture.

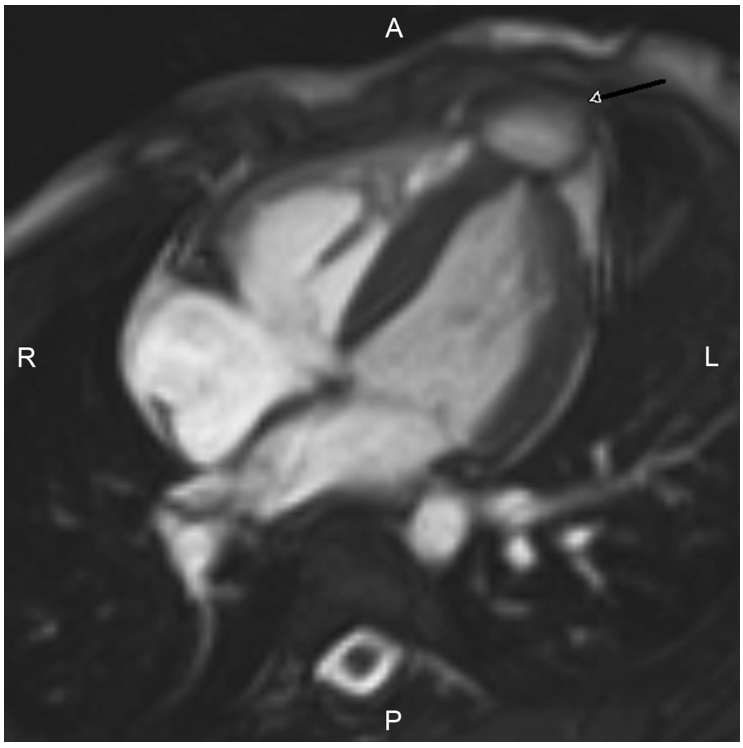

Figure 1. Cardiac MRI demonstrating the right ventricular aneurysm. Arrow denotes right ventricular aneurysm at right ventricular apex.

The patient underwent cardiac catheterization under general anesthesia and all hemodynamic measurements were normal. Angiography demonstrated an apical RV aneurysm with a minimal and maximal diameter of 6.9 and 8.5mm respectively, at its communication with the right ventricular cavity (Figure 2). The RVA contracted paradoxically with the right ventricle myocardium. TTE was also utilized during closure

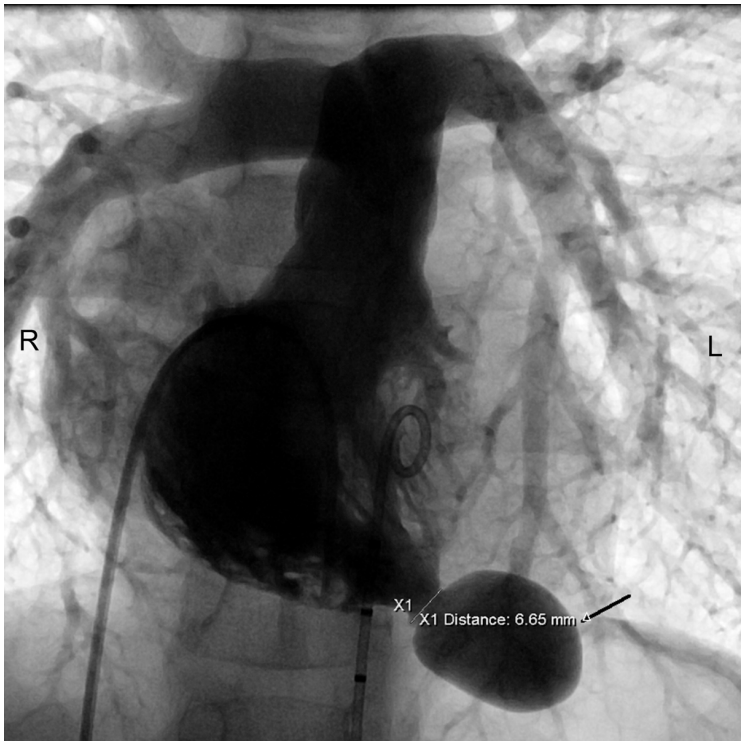

Figure 2. Right ventricular angiography illustrates the narrow mouth (X1) of the apical right ventricular aneurysm. Arrow denotes right ventricular aneurysm at right ventricular apex during systole.

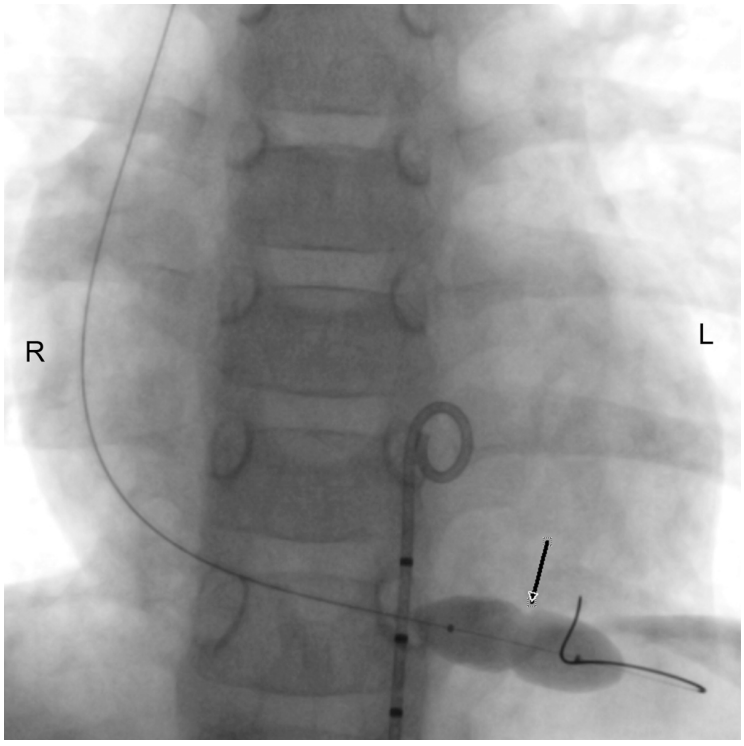

Figure 3. Compliant Tyshak II 12mm diameter balloon catheter inflated at the mouth (arrow) of the right ventricular aneurysm with temporary complete closure.

since TEE imaging was unable to visualize the aneurysm at the right ventricular apex.

Through a right-internal jugular venous approach, a 12mm diameter (2cm long) low pressure compliant Tyshak II balloon was placed across the mouth of the RVA and manually inflated until a waist was appreciated, consistent with a minimal occlusive diameter of 8.4mm (Figure 3). A #7-French long sheath was then advanced into the RVA over a floppy tipped 0.035" Magic Torque wire through which a 10 mm diameter ASO was introduced and placed successfully across the mouth of the RVA. Repeat hemodynamics, angiography and TTE demonstrated complete closure of the RVA and stable device positioning (Figure 4). The device was released from the delivery cable without difficulty and maintained appropriate positioning. No ventricular ectopy was noted during or after device implantation. TTE the following day demonstrated complete occlusion of the RVA, appropriate device position and no pericardial effusion. At 6 months follow-up post implantation, the patient continues to do well with no cardiovascular symptoms or abnormal findings on ancillary testing.

Discussion

The incidence of congenital RVA is rare and the etiology is unclear. Most are appreciated incidentally on fetal ultrasounds when there is distortion of the 4 chamber anatomy, the presence of fetal arrhythmias or a pericardial effusion. There are rare reports of pulmonary hypoplasia as a direct result of compression from the aneurysm or associated pericardial effusion. Poor fetal prognostic factors include detection at an early gestational age, increasing size of the aneurysm throughout gestation, or fetal hydrops. Postnatally, there have been reports of ventricular ectopy and progressive enlargement of RVAs which has resulted in surgical ligation.[15]

There is ample literature in the adult population regarding device closure of right and left ventricular aneurysms, the most common etiology being secondary to myocardial infarction and subsequent rupture. There is no available literature regarding catheter-based device closure of congenital RVAs in the pediatric population. Our patient was ideal for device closure secondary to a distinct neck of the aneurysm and sufficient space within the aneurysmal sac for the larger ASO left atrial disc. The theoretical indications for closure are the potential for endocarditis, thrombus formation and pulmonary emboli, spontaneous rupture and patient preference. Whether these patients have an increased risk of

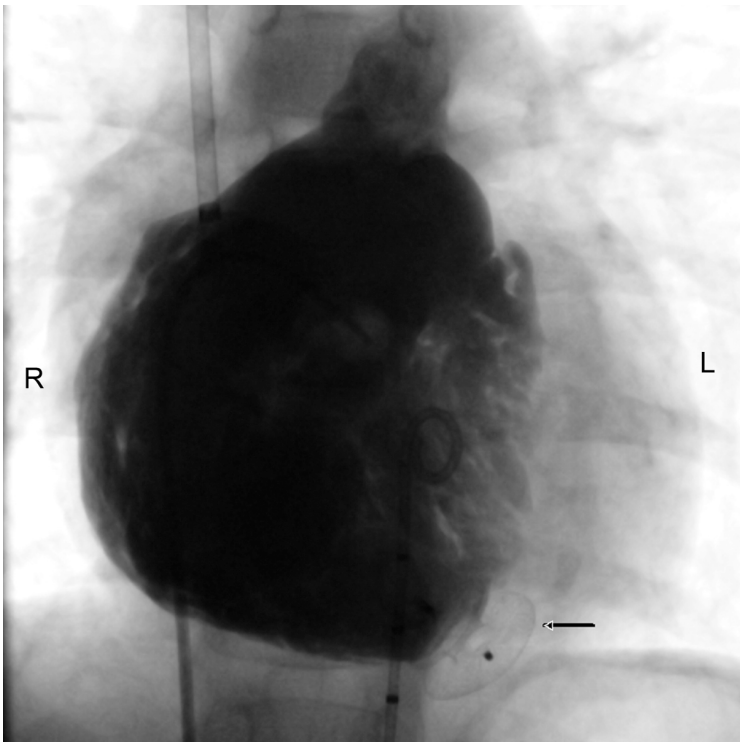

Figure 4. Right ventricular angiography post Amplatzer septal occluder placement and release from the delivery cable. Right ventricular aneurysm is occluded and the proximal atrial disc is in contact with the right ventricular endocardium. Arrow denotes the distal atrial disc within the right ventricular aneurysm.

unexplained sudden death and should be restricted from contact sports or strenuous physical activity if the aneurysm is not addressed, is unknown.

Challenges to device closure of RVAs may be suboptimal imaging during the procedure as TEE may not visualize the RV apex sufficiently, although the procedure can be performed with TTE and fluoroscopic guidance. A RVA with a wide mouth may present a further challenge due to difficulty in positioning an occluder device. Potential complications of device closure may include rupture due to device erosion, embolization of the occluder device and ventricular ectopy. Despite these challenges, catheter-based device closure of RVAs appears to be a safe acceptable alternative to surgical repair in the pediatric population.

Conclusion

In select cases, catheter-based device closure of RVAs appears to be a safe acceptable alternative to surgical repair in the pediatric population although long-term follow-up is also necessary.

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Brief Introduction of Principal Author

Howard Weber, MD is a Professor of Pediatrics at the Penn State Hershey Children's Hospital and Director of the Pediatric Catheterization Lab. He completed his fellowship at Yale New Haven Hospital in 1989, and is a fellow of the American Academy of Pediatrics and the Society for Cardiac Angiography and Intervention.

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Third International Conference on Cardiomyopathy in Children - May 15th-16th

By Gina M. Peattie, MPA; Lisa Yue

The Third International Scientific Conference on Cardiomyopathy in Children took place on May 15th-16th in Bethesda, MD and brought together more than 60 leading researchers and clinicians to exchange ideas and discuss research direction on cardiomyopathies in children. Hosted by the Children's Cardiomyopathy Foundation (CCF) and co-chaired by Steven Lipshultz, MD of Wayne State University School of Medicine and James Wilkinson, MD, MPH of Children's Hospital of Michigan, the conference covered a wide range of topics on cardiomyopathy, heart failure and heart transplantation in children.

Dr. Jeffrey Towbin, Chair of Pediatric Cardiology and Cardiac Research at Cincinnati Children's Hospital Medical Center, presenting on left ventricular non-compaction.

CCF Founder and Executive Director, Lisa Yue, with Conference Chairperson, Dr. Steven Lipshultz, Chair of Pediatrics at Wayne State University School of Medicine.

With the goal of creating a new pediatric cardiomyopathy research agenda, speakers and panelists from across the U.S., Canada, Europe and Australia shared study findings, identified research gaps and evaluated new approaches and technologies for improving patient outcomes. Representatives from the National Heart, Lung, and Blood Institute (NHLBI) also participated in the discussions.

From left to right: Drs. Stephanie Ware (Indiana University School of Medicine), Daniel Bernstein (Stanford University), Paul Kantor (Stollery Children's Hospital), and Steven Webber (Children's Hospital at Vanderbilt) during a panel discussion on Advances in Personalized Medicine Relevant to Pediatric Cardiomyopathy and Heart Transplant.

The conference covered the following topics:

- Genetic and Molecular Mechanisms in Pediatric Cardiomyopathy - *Session Leaders: Wendy Chung, MD, PhD of Columbia University Medical Center and Jeffrey Towbin, MD of Cincinnati Children's Hospital Medicine Center*
- Heart Transplantation and Pre-Transplant Device Support for Pediatric Cardiomyopathy - *Session Leader: Charles Canter, MD of Washington University School of Medicine in St. Louis*
- Advances in Pediatric Heart Failure Research and Treatment - *Session Leaders: John Lynn Jefferies, MD, MPH of Cincinnati Children's Hospital Medical Center and Joseph Rossano, MD of The Children's Hospital of Philadelphia*
- Advances in Cardiac Imaging in Pediatric Cardiomyopathy - *Session Leader: Steven Colan, MD of Boston Children's Hospital*
- Advances in Personalized Medicine Relevant to Pediatric Cardiomyopathy and Heart Transplant - *Session Leaders: Paul Kantor, MBBCh, DCH of Stollery Children's Hospital and Steven Webber, MBChB, MRCP of Children's Hospital at Vanderbilt*
- Interventional Studies in Pediatric Cardiomyopathy - *Session Leader: Daphne Hsu, MD of Children's Hospital at Montefiore*

"The medical issues and research discussed were extremely valuable, but the bottom line for all of us is finding ways to answer: How do we get to the best quality of life for children with cardiomyopathy and for their families?" said conference Co-Chair Dr. Steven Lipshultz.

Session leaders will now finalize the research agenda and form working groups to address the research priorities derived from the meeting. Conference proceedings will be published in three dedicated issues of *Progress in Pediatric Cardiology*.

Other conference sponsors included: Global Productivity Solutions, Macquarie Group Foundation, National Heart, Lung, and Blood Institute, MyoKardia, Berlin Heart and Children's Hospital of Pittsburgh.

The Children's Cardiomyopathy Foundation is a national organization focused on all forms of cardiomyopathy affecting children. In addition to its commitment to research and education, CCF spearheads several advocacy and awareness initiatives, develops and distributes educational materials, and offers various support services and resources for children and families affected by cardiomyopathy. For additional information, visit www.childrenscardiomyopathy.org, or call 866-808-CURE.

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24th Annual International Course on Congenital Heart Disease in the Adult

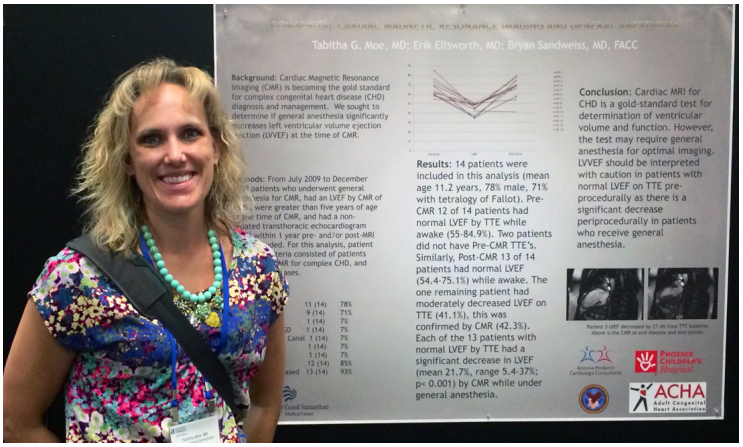
By Tabitha G. Moe, MD

The *24th Annual International Course on Congenital Heart Disease in the Adult* was held at the Hilton Netherland Plaza in Cincinnati, Ohio, from June 10th-13th. The location is an historic national landmark paying homage to 1920's era French Art Deco architecture. Cincinnati Children's Heart Institute, anchored by Dr. Gary Webb, hosted the landmark meeting. There was an excellent multinational attendance including teams from: Belgium, Switzerland, Toronto, Montreal, and others.

The first day of the conference was a 1-day *Symposium on Transitions*. Excellent take-home points included the concept that transition of care does not dictate the timeline for a definitive event in transfer of care. Transitioning is a mindset and a culture, allowing the patient to transition from a passive recipient of care to an active participant, and then an advocate in his/her own care. This cultural change may take place within a Pediatric Cardiology based-clinic, a primary care based-clinic, a Transitional Cardiology Clinic, or even an Adult Congenital Cardiology Clinic. Allowing patients to accept and maintain a developmentally appropriate level of responsibility for their care, is the goal of transitions. Dr. Towbin touted the benefit of developing programs for adult care systems for adolescent and adult survivors of pediatric disease. Sick Kids in Toronto offered the Good2Go website (www.sickkids.ca/good2go/) as a disease-generic transition program in a system where there is a designated age for transfer of care. An interesting smart device application (available on iPad/iPhone and Android), Heart Compass, is being utilized in the Swiss program that has opportunities for French and German speakers. Dr. Schwerzmann is guiding the translation into other languages for broader appeal. There is now a certification available from the University of Florida in Health Care Transition: http://education.ufl.edu/education-healthcare-transition/, and coming soon from a Toronto-based platform - iHeartChange. Day 1 concluded with a well-attended reception in the Hall of Mirrors.

Day 2 generated interest in invasive cardiopulmonary exercise testing, as Dr. David Systrom, a pulmonologist from Boston, demonstrated applications for exercise-induced pulmonary hypertension, myopathy involvement in pulmonary hypertension, and other diagnostic conundrums elucidated including: exercise-induced heart failure with preserved ejection fraction. Dr. Stuart challenged us as practitioners to not only encourage our patients to exercise, but to not hesitate to write exercise prescriptions. Notably, one of the winning abstracts demonstrated the high likelihood of the development of diabetes mellitus in Congenital Heart Disease, Dr. Madsen's data would suggest that as providers, we should be not only urging, but prescribing ability appropriate exercise. That exercise regimen may be as simple as walking for 10 min. three times weekly, and gradually working up to 30 minutes most days. Day 2 concluded with an adventure to the Great American Ballpark to cheer on the Cincinnati Reds.

Day 3 highlighted the challenges in arrhythmia management and the newly released 2014 guidelines for pharmacotherapeutics, and device implantation. The only Class I indication for Cardiac Resynchronization Therapy includes a systemic left ventricular ejection fraction <35%, sinus rhythm, complete left bundle branch block with a QRS complex >150 ms (spontaneous or paced), and NYHA class II-IV symptoms (Level of Evidence: B). Patients with a systemic right ventricle may be considered for CRT as a Class IIB indication, and Tetralogy patients with a complete right bundle branch block, also fall into the IIB category. Drs. Mitchell Cohen, Louise Harris, and Paul Khairy all agreed on reading and referring to the new guideline document: http://hrsonline.org/Practice-Guidance/Clinical-Guidelines-Documents/2014. Catheter-based interventions, including the transcatheter pulmonic valve, and a myriad of complications were reviewed in detail. Notably, a novel therapy for



pulmonary hypertension in patients who are not transplant candidates, was introduced by the Boston team represented by Dr. Audrey Marshall, with the concept of a transcatheter "Potts" shunt procedure and stenting from the left pulmonary artery to the descending aorta. Their initial experience was published in the April 2013 edition of the *Journal of Heart and Lung Transplantation*.

Day 4 brought all of our expectations home in a session on Pregnancy in the Adult Congenital patient. The new ZAHARA-II data gave us a sneak peek into what Dr. Pieper and her team have been up to, and is soon to be published. All of the session moderators exhorted involvement in and contributing to the Registry of Pregnancy and Cardiac disease (ROPAC) registry, as well as pointing towards the international standard of the World Health Organization (WHO) classifications for preconception counseling, and pregnancy risk stratification. To get involved in the *EURObservational Research Programme Registry of Pregnancy and Cardiac Disease*, email: eorp@escardio.org.

As we have come to expect, Dr. Gary Webb offered an excellent meeting, with cutting-edge clinical care, and world-renowned experts in Adult Congenital Cardiology. The *25th Annual International Adult Congenital Heart Disease Symposium* will be next June 2015 in Toronto, Canada. For more information, contact the Continuing Medical Education office at: cme@cchmc.org.

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Balancing the Clinical and Administrative Operation of a Cardiology Group

By Alan S. Weisman, MA, FACHE

When I joined Children's National Health System in Washington, DC, I was the first administrator for the Cardiology group. As the Administrator, I was responsible for General Cardiology, Echocardiography, Cath Lab, Electrophysiology, and Cardiovascular Surgery. I worked very closely with the program directors of each specialty, regarding their budgets, staffing, outpatient and inpatient volumes and the other intricacies related to the respective specialty. I was completely interactive with them, as well as all of the providers. In addition, I provided and supervised administrative support for the 36 cardiologists and 3 cardiac surgeons. This included maintaining multi-state licenses, hospital privileges, CMEs, board certifications, and any other requirements for all providers. I monitored the financial performance of the Heart Institute and Nephrology, and prepared monthly financial reports for presentation to hospital leadership.

My Executive Director, Bill McMahon, FACHE, had recruited me to administer Cardiology, the largest group of our Center of Excellence, Heart, Lung and Kidney Diseases. My job was to ensure that the leadership of the group and the faculty had an administrator who would oversee the business side of the practice, along with making certain every need of the department was addressed. I worked alongside the Nursing Director, Jeanne Ricks, RN, who was the most professional and effective nursing director I had ever encountered, to assure the clinics were operated efficiently and effectively, with adequate nurse staffing in not only the hospital clinics, but in the 10 regional outpatient centers as well. Jeanne and I worked closely with Dr. Charles Berul, Chief of Cardiology, to staff these clinics and centers, keeping in mind the 36 providers who were assigned to these areas, who often changed schedules. What kept this process going was our persistent commitment to making sure that patient care was not compromised. I focused my attention on quality of the practice, i.e., ensuring that the physicians were providing quality care to our patients, through training of management principles, safety, and service excellence. My intention was not to offer advice on the practice of clinical medicine, but to assist the faculty in the hospital goals and objectives. If I had to state my primary role, it would be as the "go-to guy" for the department to satisfy any needs and wants the faculty might have. This is the first thing an administrator should do as he/she begins the job.

My group of 36 cardiologists, with many differing personalities (but all committed to exceptional patient care), were somewhat of a challenge for me early on. There needed to be on-going management training for the group, especially for CPT and ICD coding. To that end, I hired a certified coding analyst who led training sessions on coding. Another challenging aspect was to assure that multi-state licenses, hospital privileges and board certifications were kept current. I did additional training with the administrative office staff to ensure that they kept impeccable records to avoid expiration of licenses and hospital privileges. This allowed the faculty to spend more time to take care of patients. Things as trivial as "my cell phone doesn't work, and I am on call tonight" is an example of issues I handled for the faculty. Another more extreme example was the provider, whose patient was scheduled for surgery in two days, and the insurance was not valid, even though it had been authorized previously. The provider came to me to resolve the problem, so that the surgery would not be cancelled. The physician leadership and I worked in harmony to meet the established goals and objectives. They provided full support regarding provider issues that needed to be addressed, which was critical. My recommendation for any administrator is to develop a good working relationship with the physician leaders. They will provide the clinical guidance for faculty, and act as the liaison for you and the faculty on administrative matters.

One of the most rewarding facets of my job was to be the designated UNOS (United Network for Organ Sharing) transplant administrator for the heart transplant program. In this capacity, I worked very closely with the Chief of Cardiac Surgery, Dr. Richard Jonas and the Sr. VP of Heart, Lung and Kidney Diseases, Dr. Gerard Martin. A notable milestone in my career was to be a primary player in the reactivation of the Heart Transplant Program at Children's in 2011, after it was deactivated in 2006 due to the absence of a UNOS-certified heart transplant surgeon, who had left the facility. Along with Drs. Jonas and Martin, I worked to form a collaborative effort between Children's National and the Washington Hospital Center to reactivate the program. After 18 months of negotiating and completing the required UNOS documents, not to mention a hearing with UNOS in Chicago, the program was approved by UNOS on December 8th, 2011. We now had a program eliminating the need to refer patients and families to facilities in other cities, which uprooted families in order to receive a transplant.

Every administrator should be very visible to all faculty and hospital leadership. I learned so much about cardiology and cardiovascular surgery from the department leadership and the faculty in my 8-year tenure, that I now teach it to my Health Management students at a local university. I encourage any administrator who is thinking about working in this specialty, or who already does so, to focus on building relationships with faculty and other support staff. Positive results will be derived as long as everyone works together for the same goal.

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- "Walking in Physician Shoes," Healthcare Executive (American College of Healthcare Executives); Volume 29 Number 5 May/June 2014 pp.86-87.

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Medical News, Products & Information

Vital Connect HealthPatch™ MD Biosensor Receives FDA Clearance

Vital Connect, an industry pioneer of wearable biosensor technology, has announced that its HealthPatch™ MD biosensor has received FDA clearance. The HealthPatch™ MD is capable of capturing clinical-grade biometric measurements and is the first FDA cleared medical device that includes a fall detection feature. It is designed to support the treatment of a range of diseases and conditions, is a versatile and comprehensive biosensor solution that may be used by healthcare professionals to provide 24-hour, real-time, unattended monitoring of patients' physiological data or vital signs.

Encapsulated within the HealthPatch™ MD are cutting-edge sensor and electronics technologies. Combined with Vital Connect's proprietary algorithms, these technologies enable the device to provide clinical-grade measurements of the following core health metrics: single lead ECG, heart rate, heart rate variability, respiratory rate, skin temperature, posture including fall detection and severity, and steps. The HealthPatch™ MD leverages on-board intelligence to perform sophisticated, proprietary SensorFusion algorithms, which process thousands of data points per minute to produce accurate robust measurements.

"We are very proud and excited that the HealthPatch™ MD has received FDA clearance and can now be sold in the United States for medical use," said Vital Connect CEO Nersi Nazari. "Together with our partners, we cannot wait to begin implementing solutions using the HealthPatch™ MD to optimize the way healthcare is delivered in the U.S."

Healthcare professionals will be able to use the HealthPatch™ MD to collect patient data on-demand and may be notified when physiological data falls outside selected parameters. It is intended to be less obtrusive than other sensors, can be customized for data reporting, operates on Bluetooth 4.0 and provides HIPPA-compliant cloud-based storage and connectivity.

The HealthPatch™ MD has received regulatory approval (CE Mark) for distribution in the EU, and is licensed and registered by Health Canada for distribution in Canada. For more information, visit: www.vitalconnect.com.

Study Examines Variation in Cardiology Practice Guidelines Over Time

Newswise — An analysis of more than 600 Class I (procedure/treatment should be performed/administered) American College of Cardiology/American Heart Association guideline recommendations published or revised since 1998 finds that about 80% were retained at the time of the next guideline revision, and that recommendations not supported by multiple randomized studies were more likely to be downgraded, reversed, or omitted, according to a study in the May 28th issue of *JAMA*.

As adherence to recommended clinical practice guidelines increasingly is used to measure performance, guidelines play a major role in policy efforts to improve the quality and cost-effectiveness of care. Past research has established the importance of revising guidelines over time to address advances in research and population-level changes in health risks. Nonetheless, unwarranted variability across guidelines can reduce trust in guideline processes and complicate efforts to promote consistent use of evidence-based practices. Moreover, policies based on recommendations that prematurely endorse practices subsequently found to be ineffective can lead to waste and potential harm. Little is known regarding the degree to which individual guideline recommendations endure or change over time, according to background information in the article.

Mark D. Neuman, MD, MSc, of the Perelman School of Medicine at the University of Pennsylvania, Philadelphia, and colleagues analyzed variations in Class I American College of Cardiology/American Heart Association (ACC/AHA) guidelines (n = 11) published between 1998 and 2007 and revised between 2006 and 2013. The researchers reviewed and recorded all Class I recommendations from the first of the 2 most recent versions of each guideline and identified corresponding recommendations in the subsequent version. Recommendations replaced by less determinate or contrary recommendations were classified as having been downgraded or reversed; recommendations for which no corresponding item could be identified were classified as having been omitted.

Out of 619 index recommendations, 495 (80.0%) were retained in the subsequent version; 8.9% were downgraded, 0.3% were reversed, and 10.8% were omitted. The percentage of recommendations retained varied across guidelines from 15.4% to 94.1%.

Among recommendations with available information on level of evidence, 90.5% of recommendations supported by multiple randomized studies were retained, vs 81.0% of recommendations supported by 1 randomized trial or observational data and 73.7% of recommendations supported by opinion. After accounting for guideline-level factors, the odds of a downgrade, reversal, or omission were more than 3 times greater for recommendations based on a single trial, observational data, consensus opinion, or standard of care than for recommendations based on multiple randomized trials.

"… our results may have important implications for health policy and medical practice. The categorization of medical evidence, through guidelines, into stronger and weaker recommendations, influences definitions of good medical practice and informs efforts to measure the quality of care on a large scale. Our findings stress the need for frequent re-evaluation of practices and policies based on guideline recommendations, particularly in cases where such recommendations rely primarily on expert opinion or limited clinical evidence," the authors write.

"Moreover, our results suggest that the effectiveness of clinical practice guidelines as a mechanism for quality improvement may be aided by systematically identifying and reducing unwarranted variability in recommendations. Finally, our work emphasizes the importance of greater efforts on the part of guideline-producing organizations to communicate the reasons that specific recommendations are downgraded, reversed, or omitted over time."

In an accompanying editorial, Paul G. Shekelle, MD, PhD, of the VA West Los Angeles Medical Center, Los Angeles, and RAND Corporation, Santa Monica, discusses the importance of keeping clinical practice guideline recommendations up-to-date.

"The need for surveillance and updating of practice guidelines is increasingly gaining attention. To meet the need, guideline development organizations need to change their focus. This change is not easy. It is not just a matter of resources, although guideline organizations are going to have to devote more resources to active surveillance and maintenance of their guidelines than most probably do at present. It also has to be a change to the mindset, recognizing that keeping existing guidelines up-to-date in a timely way is an important goal for good patient care."

Surgical Safety Program Greatly Reduces Surgical Site Infections for Heart Operations

A common postoperative complication after open heart operations—infection at the surgical site—has been reduced by 77% at a Canadian hospital through its participation in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP®), according to a new case study presented at the *2014 ACS NSQIP National Conference*, in July.

Vancouver General Hospital in Vancouver, British Columbia, reportedly reduced its rate of cardiac surgical site infections (SSIs) using a "best practices bundle," or combination of scientifically proven, up-to-date methods for reducing these potentially serious infections. The hospital's new surgical patient safety program, which aligned with NSQIP best practices, quickly resulted in "a dramatic reduction" of SSIs, said Rael Klein, MD, FRCP, a study coauthor and an anesthesiologist at the University of British Columbia, Vancouver.

SSIs affect 2% to 20% of coronary artery bypass graft (CABG) procedures.[1] CABG is the most common type of open heart procedure performed in the United States, with nearly 159,000 CABG procedures performed in 2013,[2] according to the Society of Thoracic Surgeons Adult Cardiac Surgery Database. An infection can develop in the surgical wound of either the patient's sternum (chest) or leg if a vein was harvested from the leg for the bypass.

"Sternal infections can be devastating for the patient because it is close to vital structures such as the heart," Dr. Klein said. "Reducing the SSI rate means fewer postoperative complications and a reduced length of stay in the hospital."

Dr. Klein and other members of Vancouver General's multidisciplinary cardiac surgery quality improvement team led the SSI reduction effort after finding that their average cardiac NSQIP SSI rate was 7%, about twice that of other comparable hospitals that participate in ACS NSQIP. The NSQIP database is the leading nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care in hospitals.

The project's goal was to reduce the cardiac NSQIP SSI rate to 2%, according to lead author Barbara A. Drake, RN, Clinical Quality and Safety Coordinator for Vancouver General Hospital. The team succeeded in lowering the infection rate to a NSQIP average of 1.6% in the nine months after fully instituting the surgical best practices bundle in July 2013.

Ms. Drake attributed their success to involving all health care disciplines that care for cardiac surgical patients. The quality improvement team included: surgeons, anesthesiologists, nurse practitioner, an infection control specialist, quality coordinators, pharmacists, educators, nurse leaders, and staff nurses who championed the changes with their peers. After querying frontline providers and searching published best practices, the team identified several areas needing improvement.

Specifically, the group improved guidelines for prophylactic antibiotic use so that providers routinely administered the proper, weight-based intravenous dose of antibiotic at the best time and gave the patient a second dose if needed during long surgical procedures. In addition, patients received new types of wound dressings designed to reduce the chance of infection. The nurse practitioner led the team in standardizing the postoperative wound care of the surgical sites.

Another change involved active warming of patients to normal body temperature once they were taken off the cardiac surgery bypass machine. Patients are deliberately cooled when on the cardiac bypass machine, but warming the patients as soon as possible can help reduce the chance of infection. Cold constricts blood vessels, hindering oxygen needed for healing, Ms. Drake explained.

OSF HEALTHCARE

BC/BE Noninvasive Pediatric Cardiologist

The Congenital Heart Center (CHC) at the Children's Hospital of Illinois is seeking a BC/BE noninvasive pediatric cardiologist to join 2 well established pediatric cardiologists in the Rockford branch of the CHC system. The practice has been a stable source of quality pediatric cardiology care in the community for more than 20 years.

The candidate should be skilled in all facets of echocardiography. Skills in fetal cardiology are desirable. The qualified individual will be part of the Congenital Heart Center which includes an additional 8 cardiologists at the Peoria campus. There is a direct clinical and academic relationship between the two groups.

Professional efforts will be bolstered by the support of 2 pediatric cardiovascular surgeons and a fully staffed cardiac intensive care unit with cardiac intensivists at the Children's Hospital of Illinois, located in Peoria.

Please contact or send CV to:
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She said many of the new improvements came from information obtained from Safer Health Care Now, a program of the Canadian Patient Safety Institute in collaboration with other organizations.

The team called the SSI reduction program CLEAN, an acronym that stood for the collected best practices, both existing and new:

C: **C**lean hands before touching the dressing, chlorhexidine wipes applied to the body before surgery, clippers used for hair removal instead of shaving, and nasal decolonization (disinfecting the nostrils with ultraviolet light) performed
L: **L**eave the dressing on for 72 hours postoperatively, and leave the pink chlorhexidine disinfectant on the skin for 6 hours after the operation
E: **E**ngage patients and staff on best practices for SSI prevention
A: **A**ppropriately use antibiotics
N: **N**ormothermia (normal body temperature), normal blood glucose (sugar), nutritious meals, and no smoking for patients

Using the ACS NSQIP data sampling of 12 to 16 cardiac surgery cases a month, which is 20% of the surgical volume, the number of SSIs was tracked. From January 2012 to June 2013 the NSQIP SSI rate was 7%. Once the CLEAN protocol was fully implemented in July 2013, the SSI rate fell to 1.6% by the end of March 2014.

Our infection control practitioner monitors all cardiac inpatients who receive cardiac bypass and/or valve surgery for 90 days. An average of one sternal infection a month was reported. Since July 2013, only two sternal infections have been recorded. No sternal infection was observed for eight consecutive months from July 2013.

At an approximate cost of $30,000 to treat a sternal infection, she estimated that the hospital saved $300,000 in the past year. The new dressings cost $35,000 per year.

"This project," Dr. Klein said, "shows it is possible to really improve patient outcomes and obtain excellent compliance from physicians in changing clinical practice."

The other study authors were: Peter L. Skarsgard, MD; Wendy Bowles, NP; Rita Dekleer, ICP; Jennifer Kelly, RN; Howard Paje, RN; Jessie Rodrigue, RN; Emily Trew, RN; Tina Oye, RN; and Markus Zurberg, RN.

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[1] Swenne CL, et al. "Surgical-site infections within 60 days of coronary artery by-pass graft surgery." J Hosp Infect 2004;57(1):14-24.
[2] Society of Thoracic Surgeons. Adult Cardiac Surgery Database Executive Summary.

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