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Descriptive Analysis of Structural and Process Characteristics of Pediatric Cardiac Surgery Centers

By Jason M. Kane, MD, MS

Introduction

More than 4 million patients are admitted to an Intensive Care Unit (ICU) each year in the United States. Research has demonstrated that cohorting patients with respect to their disease process in separate ICUs results in significantly improved clinical outcomes including ICU length of stay and overall mortality. The first description of a Cardiac Intensive Care Unit (CICU) was presented to the British Thoracic Society in 1961.¹ Soon thereafter, reports of improved outcomes were published demonstrating how the cohorting and empowerment of nursing staff dramatically improved patient mortality, which decreased from 26% for patients on the regular ward to 7% in patients treated in the CICU model.²

In the early years of development of congenital heart surgery, pediatric cardiac surgeons have been primarily responsible for postoperative intensive care. Over the past three decades, other pediatric professionals including intensivists, cardiologists, critical care nurses, and cardiac anesthesiologists have started to contribute increasingly to the care of these patients.³ In a study evaluating the practice patterns of delivery of care of children undergoing congenital heart surgery in the United States, Burstein and colleagues found that a combination of cardiologists and/or critical care physicians were primarily responsible for postoperative management (47%), and trainee involvement in

direct patient care was high including critical care fellows (53%), cardiology fellows (47%), and pediatric residents (53%).⁴ It is unclear what models currently exist with respect to team leadership, multidisciplinary team composition and specific responsibility, as well as accountability for patient care for patients who have undergone congenital cardiac surgery.

The purpose of this study was to evaluate the contemporary models of intensive care delivery used by medical centers where congenital cardiac surgery is performed. Specifically, the goal of this study was to elucidate the pattern of leadership structure, care providers, and team dynamics associated with the care of critically ill patients following congenital heart surgery.

Methods

Study Design

This cross-sectional evaluation used an internet-based, non-validated survey construct with commercially available software (www.surveymonkey.com). The survey was distributed in October 2010 to members of the following groups and list-servs: Pediatric Cardiac Intensive Care Unit Practitioners Group on Facebook (www.facebook.com), and PediHeartnet (www.pediheart.net), and PICUList (www.vpicu.org). Survey items included questions on: hospital and practice demographics; available training programs; characteristics of post-operative care and caregiver demographics; administrative information on general structure

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and process of care including daily rounds and staffing patterns and two clinical scenarios. Where appropriate, a 4 point Likert scale was used to gauge agreement. No personal identifier information was collected as part of the survey. The IRB at Rush University Medical Center approved this study.

Analysis

Summary statistics were performed. In cases where multiple responses from a single center were received, the average Likert Score was calculated and used to represent that center's response and dichotomous values were verified by direct contact or publicly available data. Formal statistical comparisons were not performed given the descriptive nature of the study.

Results

A total of 84 respondents representing 43 uniquely identified and 17 unidentified institutions participated in the study. There were 6 institutions with multiple responders. After averaging responses from identical institutions, a total of 60 responses were used for analysis.

Hospital Demographics

Geographic location favored the United States with 89% of those responding. Free-standing children's hospitals (47%) and 'hospitals-within-a-hospital'(47%) represented nearly the entire sample with an additional 6% providing pediatric services within an adult facility. A total of 88% of organizations were either university hospitals, or university affiliated-hospitals. Surgical volume varied with 21 centers (35%) performing greater than 300 open-heart surgical procedures per year, 17 (28%) performing between 201 and 300, 19 (32%) performing between 101 and 200, and 3 (5%) performing less than 100. Pediatric residency programs were present at 90% of the hospitals, and pediatric critical care and pediatric cardiology fellowships were present in 70% and 62% of reporting centers. Additional CICU-focused 4th year training was available at 25% of the centers. Attending physicians were present on site for 24/7 coverage in 59% of the centers responding. The highest level of care in-house at night was a resident physician in 9% of reporting centers, and a fellow in 28% of reporting centers.

Cardiac Surgery Processes of Care

Following pediatric cardiac surgery, patients were most often admitted to the pediatric ICU (40%) or to a geographically separate CICU (40%). An additional 18% of centers contained a CICU geographically incorporated within a pediatric ICU. The cardiac surgeon was the attending physician of record 58% of the time, compared to an intensivist 32% of the time, and a cardiologist 5% of the time. Front-line medical providers that were identified as sometimes or always responsible for responding to patient needs and carrying out daily patient management included pediatric critical care fellows (68% of the time), cardiology fellows (61% of the time), APN/PNP (72% of the time), attending physician (91% of the time), cardiac surgeon (54% of the time). Of note, pediatric residents were identified as front line providers only 38% of the time.

With respect to directing and coordinating the daily management, physicians board-eligible or certified in pediatric critical care medicine most frequently led rounds (Figure 1). In addition, there was variability in the presence of different caregivers participating in daily rounds (Figure

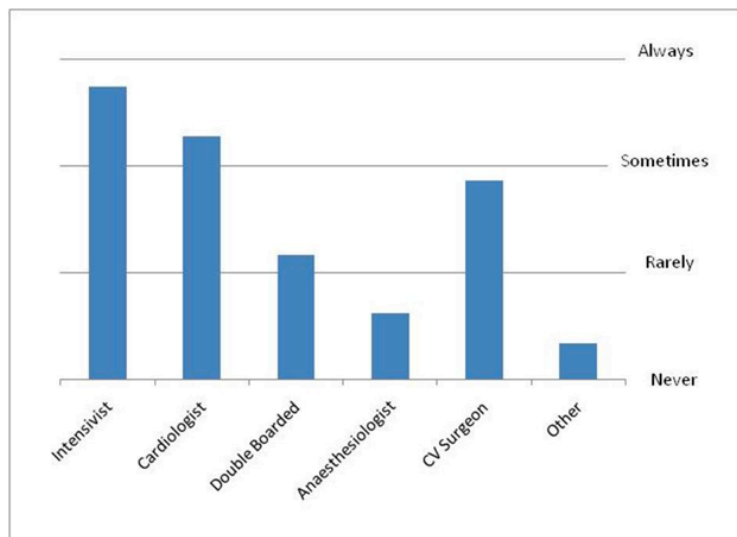


Figure 1. Frequency of specific physician responsible for directing rounds (Likert score 1-4; 1=never, 2= rarely, 3=sometimes, 4=often) .

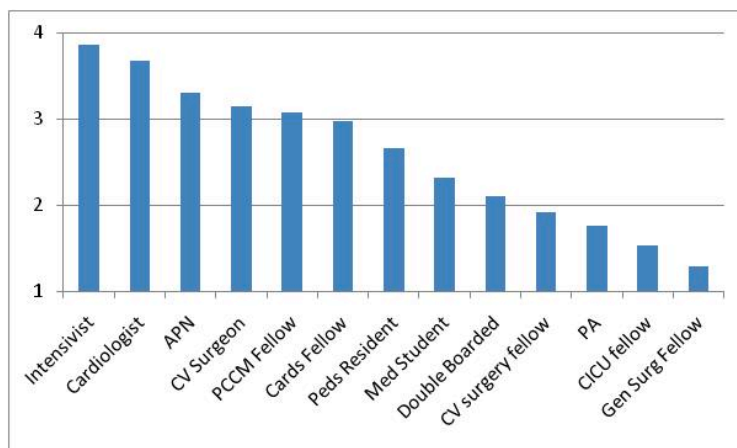


Figure 2. Frequency of caregiver present on daily rounds (Likert score 1-4; 1=never, 2= rarely, 3=sometimes, 4=often).

2). Patient discussions on rounds were considered multi-disciplinary, where clinical issues are discussed and plan of care is reached by team consensus 68% of the time compared to other models where either the intensivist, cardiologist, or surgeon decide the plan of care. When lack of consensus did occur, the cardiac surgeon was identified as the ultimate decision maker 57% of the time whether or not present on rounds, compared to the intensivist on rounds (29%) or the cardiologist on rounds (5%).

Clinical Scenarios

When asked to provide the admission location of a 4-month-old with unrepaired Tetralogy of Fallot with a concurrent diagnosis of acute RSV bronchiolitis requiring oxygen therapy, 32% responded that the patient would be admitted to a general medical-surgical pediatric ICU,



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“The purpose of this study was to evaluate the contemporary models of intensive care delivery used by medical centers where congenital cardiac surgery is performed. Specifically, the goal of this study was to elucidate the pattern of leadership structure, care providers, and team dynamics associated with the care of critically ill patients following congenital heart surgery.”

compared to 20% CICU, and 23% cardiac telemetry general floor bed. When asked for the admission location of a newborn with a pre-natal diagnosis of Hypoplastic Left Heart Syndrome who was awaiting palliative surgery, 45% indicated CICU, 39% Neonatal ICU (NICU), and 3.9% pediatric ICU.

Discussion

There are multiple models of care utilized by hospitals for pediatric cardiac surgery patients including: geographic cohorting, team leadership and decision making, caregiver training and exposure, and staffing. Unlike prior work, this study is the first to examine the processes of care and the dynamics of team leadership and models of care for this high-risk population.

Current trends in pediatric cardiac intensive care include the creation of dedicated, geographically separate, pediatric CICUs designed to exclusively care for postoperative pediatric cardiac surgery patients. A survey of 55 international centers that perform the most complex congenital cardiac surgery cases revealed wide variation in care models.⁵ Approximately half of the centers provided postoperative care in units specifically designated for pediatric cardiac intensive care and half in multidisciplinary pediatric ICUs. The most common model was for preoperative and postoperative care to be given in a pediatric CICU, followed by preoperative care in a neonatal intensive care unit and postoperative care in a multidisciplinary pediatric ICU. The results of this study revealed similar results suggesting that the trends described in prior work have continued.

Previous data have suggested that an intensivist-led team may improve outcomes in

children with congenital cardiac disease.⁶ It is unclear however, whether this model is well accepted among medical centers where congenital cardiac surgery is currently performed. The specific geographical cohorting of patients seems to be less important than the leadership and team structure of the caregivers involved.

Structural and process variability in the care of cardiac surgery patients may signal a change in the overall administrative management of these patients. For example, nearly 60% of centers surveyed now provide attending physician coverage in-house and around the clock. This staffing model is in contrast to care-models where trainees, namely fellow-level providers, are available on-site and attending physicians are only available off site on-call. Additionally, in stark contrast, in nearly 10% of the hospitals sampled, the highest level of in-house nighttime coverage was a pediatric resident. This finding is consistent with that of previous work noting that pediatric residents were only involved in the care of pediatric cardiac surgery patients in the CICU 31% of the time compared to fellows 69% of the time.⁴ The role, scope of practice, and effective function of pediatric residents with this complex patient population continues to come into question.

Limitations

The limitations of this study are related to the voluntary nature of the survey and the

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“The role of senior, skilled providers on the continuous direct care of these patients [pediatric patients who undergo cardiac surgery] is noteworthy, and the participation of less experienced trainees is now infrequent.”

validation of the data. First, the sample size of responding institutions is small. Although the survey successfully obtained responses from nearly half of the 122 US-based centers performing pediatric cardiac surgery, there was a large degree of variation between the demographic characteristics of responding centers. Also, it is possible that a selection bias occurred. Given the self-reporting nature of the survey, all responses were treated as accurate and responses were not independently validated. As evidenced by the variability of multiple responders from a single center, there may be differences in perception affecting the responses. Averaging Likert scores should have mitigated variation of multiple responders from the same institution. Although the goal of this study was to identify

patterns of leadership structure, care providers, and team dynamics, there are likely many other factors involved that affect the clinical outcomes of these complex patients.

Conclusions

This study describes multiple variations in the structure and process of care provided to pediatric patients who undergo cardiac surgery in the United States. The role of senior, skilled providers on the continuous direct care of these patients is noteworthy, and the participation of less-experienced trainees is now infrequent.

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Infective Endocarditis: Four Years' Experience at a Tertiary Care Hospital in Sudan

By Samia H. Osman, MD; Ghada Sh. Mohamed, MD

Abstract

Background: Infective endocarditis in children, although uncommon, but has serious potential for morbidity and mortality.

Methods: We reviewed retrospectively the records of patients admitted at Gafaar Ibn Auf specialized hospital, a central referral hospital in Khartoum, Sudan with the diagnosis of infective endocarditis based on Duke's criteria from January 2006 to July 2010.

Results: Thirty-six patients were seen: 20 (58%) were males and 16 (42%) were females. The underline cardiac conditions were Rheumatic Heart Disease (RHD) in 14 (40%) of the cases, Congenital Heart Disease (CHD) in 16 (44%), combined RHD and CHD in 2 (5%), post surgery in 3 (8%) and one patient (3%) had a normal heart. In cases with RHD, the mitral valve was the most affected valve, while in CHD, Tetralogy of Fallot and ventricular septal defect were the dominating lesions. Fever, hepatomegaly, splenomegaly, clubbing and cough were the major clinical findings. Major complications were heart failure in 14 (40%), renal failure in 14 (40%), pericardial effusion in 5 (15 %), cardiogenic shock in 3 (10%) and cardiovascular accident in 2 (5%). All the patients had vegetations. The sites were on the mitral valve in 16 patients (45%), pulmonary valve in 7 (20%), tricuspid valve in 7 (20%) and on multiple valves in 2 (5%). Twenty-nine (80%) of the patients were cured, and 7 (20%) died. The causes of death were ruptured aortic valve cusp, very large vegetations and massive intracranial hemorrhage.

Conclusion: RHD remains a common underlying cardiac condition. Late presentation and inability to offer emergency surgery increased morbidity and mortality.

Introduction

Infective Endocarditis, IE, first described by Osler in the 19th century, is an infection caused by microorganism bacteria or fungi involving either the heart or the great vessels. The prevalence in children worldwide is 0.5-1/1000 hospital admission.^{1,2} It has significant morbidity and mortality as it carries the risk of potential complications from embolic and immunological phenomena.^{3,4,5} The need for prolonged hospital admission and parenteral antibiotic treatment causes psychosocial impact on the child and his family.⁶ Infective endocarditis in developing countries has a special pattern, as patients are referred late, there is low yield of blood cultures and incidence of rheumatic heart disease is still high.⁷

Methods

All records of children (<18 years old) admitted at our hospital with IE from January 2006 to July 2010 were collected and analyzed retrospectively. The demographic details, clinical, microbiological, echocardiography data, treatment and outcomes were reviewed. Diagnosis of IE was based on Duke's criteria established by the Duke Endocarditis Service⁸ (Duke University, Durham, North Carolina, USA).

The major criteria were:

1. Positive Echocardiogram:
 - a. Oscillating intracardiac mass on valve or supporting structures in the path of regurgitant jets or on implanted material in the absence of an alternative anatomic explanation.
 - b. Intramural abscess.
 - c. New partial dehiscence of a prosthetic valve.
 Echocardiography was performed using Easote MyLab™ 30 echocardiography machine equipped with 2.5–5.0 MHz transducer.
2. Positive blood cultures in two samples for typical organism (streptococcus Viridians, Streptococcus bovis, or HACEK group, Staphylococcus aureus or enterococci). In all cases, three blood samples were collected under aseptic conditions and inoculated in aerobic and anaerobic environments. The samples were then incubated at 37 degrees C and tested with the VITEC SYSTEM automatized system (BIOLAB).

Minor criteria:

1. Predisposing heart condition or IV drug use.
2. Fever.
3. Vascular phenomena: major arterial emboli, septic pulmonary infarcts, mycotic aneurysm, intracranial hemorrhage, conjunctival hemorrhages and Janeway lesions.
4. Immunologic phenomena: glomerulonephritis, Osler nodes, Roth's spots and positive rheumatoid factor.
5. Microbiological evidence: positive blood culture, but does not meet a major criterion.

Table 1: Underline cardiac lesion in the cases of infective endocarditis (n=35).

Underline cardiac lesion	No. of patients
RHD	14
MR+AR	7
MR	4
Multiple lesions	3
CHD	16
TOF	5
VSD	5
Complex lesions	4
AVSD	1
PDA	1
Post surgery	3
RHD+CHD	2
Total	65

RHD=Rheumatic heart disease; MR=mitral regurgitation; AR=aortic regurgitation; CHD=congenital heart disease; TOF=Tetralogy of Fallot; VSD=ventricular septal defect; AVSD=atrioventricular septal defect; PDA=patent ductus arteriosus.

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Fig 1 clinical presentation of the cases

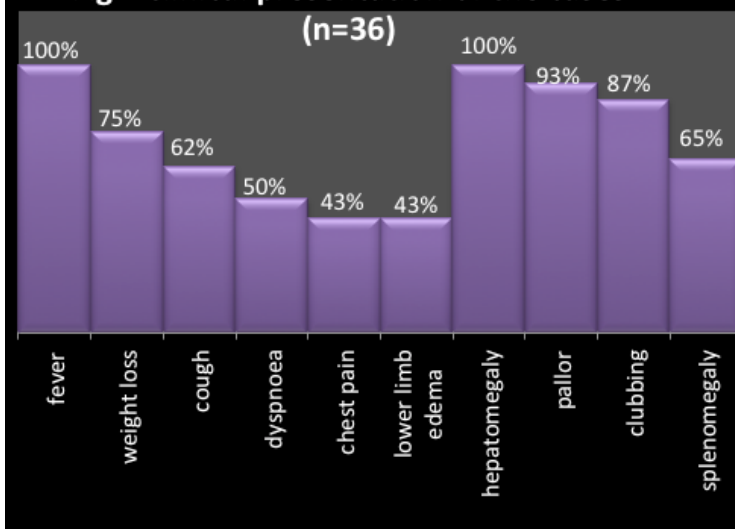


Figure 1. Clinical presentation of the cases of infective endocarditis (n=36).

Fig. 2 Laboratory findings in the cases of infective endocarditis (n=36)

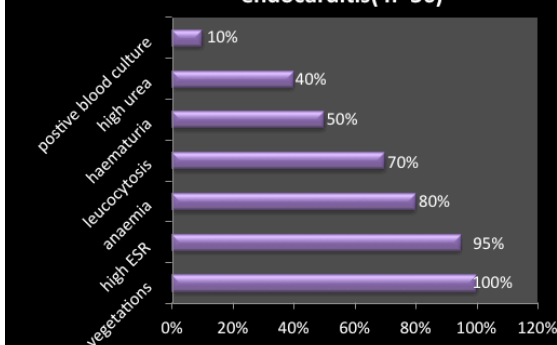


Figure 2. Laboratory findings in the cases of infective endocarditis (n=36).

Two major criteria or 1 major criterion + 3 minors, or 5 minor criteria were used to diagnose IE.

Results

During the study period 36 patients with IE were seen. Fifty-eight percent were males and 42% were females. The age was below five years in 16%; from 6-10 years in 39% and above ten years in 45%. Most of the cases (85%) came from rural and peri-urban areas, while only 15% came from urban areas. Table 1 shows the underline cardiac lesion. RHD was found in 14 patients and the mitral valve (MV) was the most affected valve while Tetralogy of Fallot and ventricular septal defects dominated the CHD.

Figure 1 shows the clinical presentation of the cases fever and hepatomegaly were found in all the cases. Pallor, weight loss,

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splenomegaly, clubbing and cough were found in more than two third of the cases. Dyspnoea, lower limb swelling and chest pain were found in almost half of the cases.

The complications developed were heart failure in 14 patients (40%), renal failure in 14 (40%), pericardial effusion in five (15%), cardiogenic shock in three (10%) and cardiovascular accident in two (5%).

Figure 2 shows the laboratory investigations in the cases; all the patients had vegetations, 95% had high ESR, 28 (80%) had anemia 70% had leucocytosis, 18 (50%) had haematuria, 14 (40%) had high blood urea and 4 (10%) had positive blood BC culture. The site of vegetations was on the mitral valve in 16 patients (45%), the pulmonary valve in seven (20%), tricuspid valve in seven (20%) and on the three valves mitral, pulmonary and aortic in two (5%). Twenty-nine patients (80%) were cured and seven (20%) died. The cause of death was very large vegetation in 50%, ruptured AV cusp in 25% and CVA with massive intracranial hemorrhage in 25%.

Figure 3 shows echocardiogram of a seven-year-old boy with combined rheumatic mitral regurgitation and unoperated VSD. The vegetation appears on both tricuspid and mitral valve.

Figure 4 shows echocardiogram of a ten year old boy with normal heart anatomy, the vegetation appears on the tricuspid valve.

“Infective endocarditis presented with wide range of non-specific symptoms and classical signs were not detected, so it should be excluded in any febrile child with cardiac lesion and antibiotics should be postponed until samples for BC are taken to improve the yield of the blood culture results.”

Discussion

The profile of IE in our study revealed late presentation as the majority (85%) of the cases came from rural and peri-urban areas. RHD was still a common underlying cardiac condition, as it was found in 45% of patients, either alone or combined with CHD. Similar results were obtained from other developing countries; in India (42-46%), Pakistan (53%) and Nigeria (66%).^{6, 9,10,11} This had led to the presence of the vegetations mainly on the MV, as MR was the common valvular lesion encountered in our study in contrast to the described pattern in developed countries where RHD is rarely found and facilities for intervention for CHD where either through catheterization or surgical repair and the vegetations were mainly on the conduit and prosthetic material.^{12,13,14,15,16,17,18}

Pediatric Cardiology Opportunities

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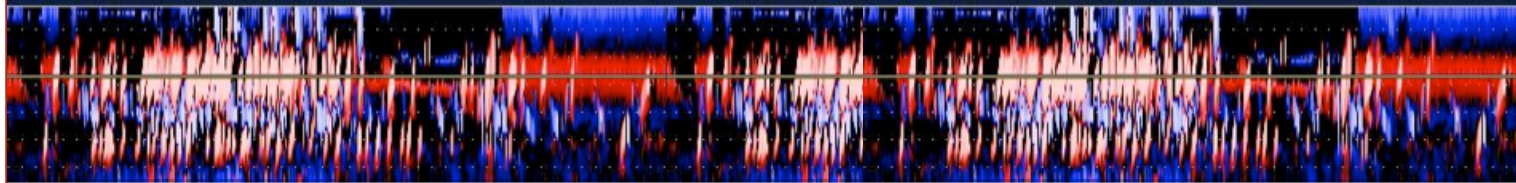
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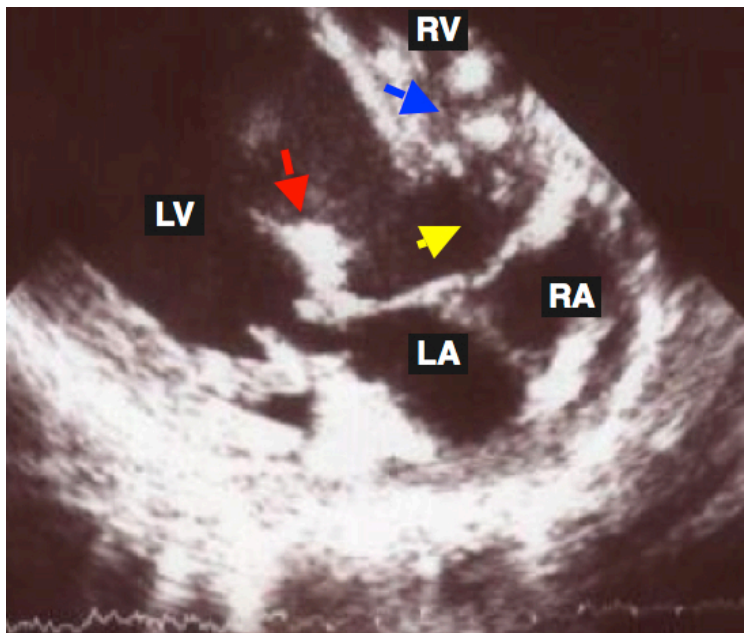


Figure 3. Echocardiogram of a seven-year-old child with rheumatic mitral regurgitation and ventricular septal defect. The red arrow points to the vegetation on the mitral valve, blue arrow points to the vegetation on the tricuspid valve, and the yellow to the ventricular septal defect. LA=left atrium, RA=right atrium, LV=left ventricle RV=right ventricle.

This late presentation with antecedent antibiotic use in the peripheral health centers before coming to our centre led to a high percentage of negative BC result (90%), unlike developed countries where patients presented earlier, but unsatisfactory laboratory services might be a contributory factor to this very high percentage.^{19, 20}

The mortality was 20%. The causes of death were very large vegetations, massive intracranial hemorrhage, cardiogenic shock and rupture of valve supporting structures. In all the deaths surgery was indicated but was not done because of limited surgical facilities, so it might have been life-saving as surgery even during the acute febrile stage is well-practiced in many countries.^{21,22}

Conclusion

Infective endocarditis presented with a wide range of non-specific symptoms and classical signs were not detected, so it should be excluded in any febrile child with cardiac lesion; antibiotics should be postponed until samples for BC is taken to improve the yield of the blood culture results.

The fact that inability to offer emergency surgery had increased the morbidity and mortality stresses the need of improvement and extension of cardio thoracic surgery services.



Pediatric Cardiologist

The Division of Pediatric Cardiology at the University Of Utah School Of Medicine is recruiting a pediatric cardiologist with a major interest in **Adult Congenital Heart Disease**. The candidate should have a strong clinical background in all areas of pediatric cardiology with expertise in caring for adults with congenital heart disease. The candidate will be joining a 24-member division of Pediatric Cardiology including one pediatric cardiologist currently running the Adult Congenital Heart Disease Program. The Division has a very active clinical program, currently seeing a large volume of adults with congenital heart disease. The Division also has a very active clinical research program and is one of the participating centers in the Pediatric Heart Disease Clinical Research Network funded by the NIH. There will be protected time for clinical research with mentoring available within the Division for clinical research studies. This faculty position will be involved in a very active academic teaching program.

The successful candidate will receive a faculty appointment at the University of Utah. The Pediatric Cardiology Division is based at Primary Children's Medical Center, a tertiary referral center for a three-state area located on the hills overlooking Salt Lake City. Adults with congenital heart disease are seen at the children's hospital and at nearby 'adult' hospitals. The area offers an excellent quality of life with immense cultural and recreational opportunities close and available.

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Interested individuals should send or email a cover letter and curriculum vitae to:

Lloyd Y. Tani, M.D.
Chief, Division of Pediatric Cardiology
University of Utah School of Medicine
100 N. Mario Capecchi Drive
Salt Lake City, UT 84113
Email: lloyd.tani@imail.org



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Applications will continue to be received until the position is filled. Academic rank and salary will be commensurate with qualifications.

Interested applicants should forward letter of intent, curriculum vitae, and three letters of recommendation to:

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Professor and Associate Chairman
Search Committee Chairman
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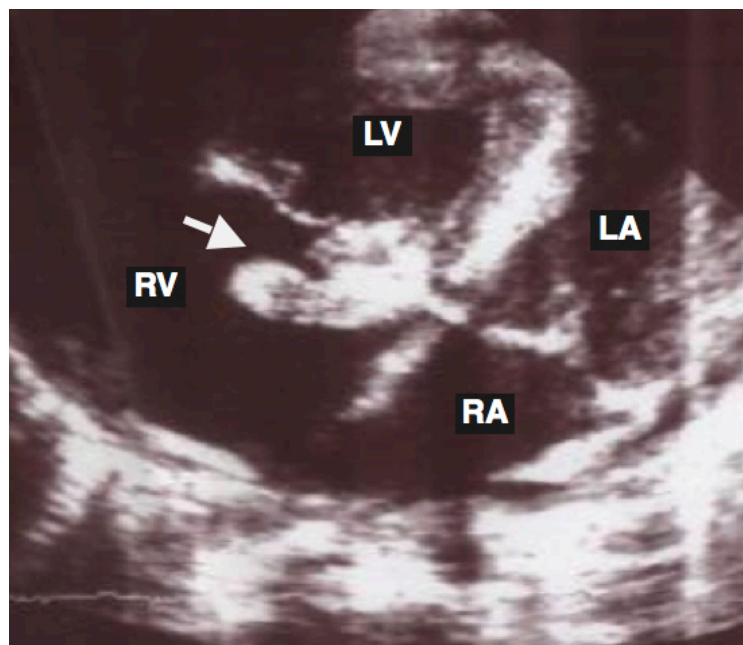


Figure 4. Echocardiogram of a child with normal heart anatomy and infective endocarditis. Vegetations on the tricuspid valve in a ten years old boy with normal heart anatomy LA=left atrium, RA=right atrium, LV=left ventricle RV=right ventricle. White arrow points to tricuspid valve vegetation.

Acknowledgement

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Also, thanks to the staff at the Medical Records Storage Service at Gafaar Ibn Auf Specialized Hospital- Khartoum for their dedication.

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Highlights from The Congenital Heart Disease Symposium at SCAI 2011 Scientific Sessions

Frank F. Ing, MD, FSCAI

The Congenital Heart Disease Symposium at SCAI 2011 Scientific Sessions won accolades from attendees, who praised its educational value regarding congenital and structural interventions. On average, attendees scored the congenital heart disease presentations at 3.6 out of a possible 4.0. Of all the sessions offered during the 2½ days of lectures, case reviews, interactive discussions, taped case presentations, and workshops, the ever-popular “I Blew It” sessions received the highest rating, an amazing 3.9.

Cases Scratch Attendees’ Brains

The ‘I Blew It’ sessions are always a valuable opportunity for discussion of interventional complications in a non-intimidating atmosphere that promotes both teaching and learning. Of course, it is always fun to crown the ‘I Blew It’ king or queen, based on the participants’ votes for overall best case; this year the honor went to Mark Hoyer, MD, FSCAI, for his case on occlusion of a giant LV aneurysm.

Back by popular demand, and in keeping with attendees’ enthusiasm for case-based sessions, the “Brain Scratchers” session featured five taped conundrum cases focusing on unusual diagnostic or interventional mysteries. Each of these cases included much discussion between the audience, moderators, and faculty, and concluded with clear teaching points that attendees can take home to their own practices.

Another popular feature of the congenital heart disease program is the annual debate, this time between Jonathan J. Rome, MD, and Phillip Moore, MD, who faced off over the pros and cons of balloon atrial septostomy for infants with d-transposition of the great arteries. It was interesting to see these two senior pediatric interventional “warriors” who were trained at the same center at around the same time but now live on opposite coasts as they battled it out. The results? A deadlock tie.

Mullins Lecturer Outlines a Bright Future

Mullins Keynote Lecturer John Cheatham, MD, FSCAI, presented “The Past, Present, and Future of Hybrid Procedures.” A pioneer of this new technique, Dr. Cheatham took attendees through the history of hybrid procedures and emphasized the importance of collaboration between cardiovascular interventionalists and surgeons. He showed us the future is certainly bright for us as the cath lab transforms into the hybrid suite and new innovative procedures are limited only by our own creativity.

Sessions Highlight Ongoing Challenges, New Advances

While the case-based sessions were back, new sessions also provided opportunities for cross-pollination of ideas. The new workshop on “Diagnosis and Treatment of Thrombosis in the Pediatric Patient,” for example, included pediatric hematologists Marilyn Manco-Johnson, MD, and Leo Brando, MD. This was the first time the SCAI program has included pediatric subspecialists outside of cardiology. They shared their expertise on the work-up, treatment, and predisposing factors for cardiovascular thrombosis in pediatric patients.

“The Congenital Heart Disease Symposium at SCAI 2011 Scientific Sessions won accolades from attendees, who praised its educational value regarding congenital and structural interventions. On average, attendees scored the congenital heart disease presentations at 3.6 out of a possible 4.0.”

Also new to the program was the “Late-Breaking Pediatric Clinical Trials” session, where Richard Ringel, MD, FSCAI, gave an update on the Coarctation of the Aorta Stent Trial (COAST). It was exciting to hear the results of the only FDA-sponsored trial on the use of stents in congenital heart disease.

Among new advances highlighted during the congenital and structural heart disease program were presentations on the recently approved Melody valve for the pulmonary position and the development of bioabsorbable stents and the transcatheter Colibri valve for the aortic position. These and other presentations were part of sessions titled “Dress for Success: Anticipation, Preparation, and Prevention” and “The Role of the Interventionalist in Genetic Research.”





With its focus on complications of various interventions, "Dress for Success" also featured discussions on stenting the pulmonary artery, using radiofrequency wires for perforation



across atretic valves and vessels, the "hybrid Norwood" procedure, and covered stents for coarctations of the aorta.

Not Just for Children's Cardiologists

As SCAI's congenital heart disease program expands and its therapies become increasingly effective, the curriculum is also becoming more relevant for adult interventionalists. Just as cardiovascular thrombosis is a topic that should be of interest to all cardiologists, we

created sessions of broad interest such as "The Adult with the Single Ventricle."

For updates on the exciting program that Program Chair Dr. Daniel S. Levi is developing along with Program Co-chair Thomas E. Fagan, MD, FSCAI, for 2012, please be sure to visit www.SCAI.org/SCAI2012.

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Laboratories
Co-Chair, SCAI 2011
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Helping Families Access Fetal Cardiac Intervention to Interrupt Evolving HLHS and HRHS

By Brita Dietzel

Elliana Grace Foundation (EGF) provides financial, logistical and emotional support to families traveling for Fetal Cardiac Intervention and follow-up care.

The journey of a child born with a single-ventricle anatomy is uncertain. Nearly all these children face enormous challenges. These challenges begin shortly after birth, and continue throughout their lives. In recent decades, doctors learned to perform palliative surgeries that allow children to live with a single-ventricle circulation. However, the long-term future for these children remains largely unknown. As a result, a team at Children's Hospital Boston and Brigham and Women's Hospital initiated Fetal Cardiac Intervention in 2000. To date, 140 Fetal Cardiac Interventions have been performed in Boston. The goal of the Fetal Cardiac Intervention is to interrupt the progression of HLHS and HRHS and give children the chance of a two ventricle circulation. While there are varying outcomes, it is this hope that brings families from all corners of the country to Boston.

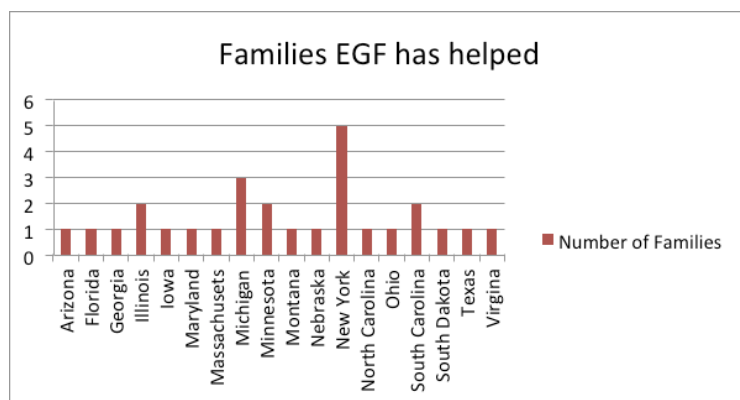
Elliana Grace Foundation is a non-profit organization that assists families with the financial, logistical and emotional needs required to travel for the Fetal Cardiac Intervention (FCI). The organization was founded in late 2008 by two mothers, Brita Dietzel and Jessica Lindberg, who both underwent Fetal Cardiac Interventions. Their families traveled from their homes in the Midwest to Boston for their children, Ellianna and Ethan in 2004 and 2005 respectively.

For Ellianna, the Fetal Cardiac Intervention prevented Hypoplastic Left Heart Syndrome. At just under twenty weeks gestation, Ellianna was diagnosed with critical aortic stenosis with evolving Hypoplastic Left Heart Syndrome and an intact atrial septum. At this time, she presented with a dilated LV, restricted aortic valve, restricted atrial septum, and retrograde flow through the aortic arch. Within a few days of diagnosis, Ellianna and Brita underwent the FCI. Ellianna experienced bradycardia in which the doctors needed to administer atropine intramuscularly. She also developed a pericardial effusion that was drained prior to ending the procedure and monitored for the next 48 hours. Ellianna and Brita had a stable recovery and returned to Minnesota two days post-procedure. Throughout the rest of the pregnancy, Ellianna was monitored with monthly fetal echocardiograms in Minneapolis. Brita was able to return back to work after two weeks.

Ellianna's fetal echoes showed continued improvement in LV growth and function and her dilated aortic valve remained open. In January 2005, Ellianna was born with adequate LV size and function and was discharged from the hospital without any further cardiac procedures. At the time of discharge, she had mild mitral stenosis and known endocardial fibroelastosis (EFE). At four months of age, Ellianna's stiff left ventricle was causing increase in pressures in her left atrium and lungs. At this time, she underwent an EFE resection in her left ventricle and a mitral valvuloplasty. This surgery proved to be a

success as she thrived at home until she died in a car related accident at 18 months of age.

Ethan also underwent a Fetal Cardiac Intervention to treat his aortic stenosis and evolving Hypoplastic Left Heart Syndrome. His Fetal Cardiac Intervention was technically successful, and he was monitored by fetal echo bi-weekly until his birth. During the remainder of Jessica's pregnancy, Ethan's left ventricle continued to grow though it was quite stiff. Ethan was born in Boston in May of 2005 and underwent a modified Norwood with EFE resection of his left ventricle and aortic and mitral valvuloplasty. Ethan continued down the single ventricle path having his Fontan at 2 years of age. However, his left ventricle continued to grow and his surgeon continued to repair his mitral and aortic valves and resect EFE from his left ventricle. Today at 6 years of age, Ethan is in the hospital recovering from a mitral valve replacement, aortic valvuloplasty, and restriction of his atrial septum to push more blood into his LV. He has a normal LV size and function. His cardiac team has decided to proceed with a two ventricle repair in the near future.



Both children have had challenges in life, but have been greatly helped by undergoing the Fetal Cardiac Intervention. In Ethan's case, the support given to his LV in the early years to encourage growth and function has become a life-saving option today. For Ellianna, she was spared a single ventricle diagnosis after opening her aortic valve as a fetus.

After making many trips to Boston for surgeries and follow-up care, Brita and Jessica wanted to find a way to help other families access the same care their children had received. In the spirit of thanksgiving and hope, they founded Ellianna Grace Foundation to help other families access Fetal Cardiac Intervention. Once confirmed as a candidate, a family may access Fetal Cardiac Intervention in the following cases:

- 1) Critical aortic stenosis with evolving HLHS,
- 2) Pulmonary atresia with an intact ventricular septum and evolving HRHS, and
- 3) Established HLHS with an intact or highly restrictive atrial septum.



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Elliana Grace Foundation awards grants to families to assist with costs associated with traveling for a Fetal Cardiac Intervention and follow-up care. The grants help pay for airfare, lodging, meals, and/or transportation. Since December of 2008, \$22,000 in aid has been given to families across the country (below).

“If you are caring for a family who may be a candidate for Fetal Cardiac Intervention, Ellianna Grace Foundation wants to help. Please refer families to email the foundation directly....”

More than 90% of the patients who were treated with the FCI lived outside Boston and the surrounding areas.¹ Thankfully, in recent years, the FCI has become more accepted therapy both nationally and internationally as more institutions are initiating Fetal Cardiac Intervention programs. In the US, the University of Michigan and University of California, San Francisco are also gaining experience with FCI. However, for majority of families, the travel requirements will remain significant financial drain. In addition to financial assistance, Ellianna Grace Foundation provides *Parent-to-Parent Connections* where families can speak directly with others who have gone through Fetal Cardiac Intervention.

Prenatal diagnosis remains the cornerstone of the Fetal Cardiac Intervention option. Early detection and diagnosis not only makes the FCI a possibility, but there is also a direct correlation to positive outcomes for the baby.² Ellianna Grace Foundation strives to educate expecting mothers to ask their obstetricians these three questions during their mid-gestation routine ultrasounds:

1. Can you see four chambers in the heart?
2. Can you see two valves entering the heart and two valves leaving the heart?
3. Are the great arteries of the heart crossing each other?

Lastly, the many families who travel to Boston for Fetal Cardiac Intervention need the

support, guidance and great care of their local pediatric cardiologists. Good communication is essential. The best-case scenario happens when the local cardiologist works hand-in-hand with the team in Boston. The team in Boston is readily accessible and dedicated to each of these children. Ethan and Ellianna received superb care from doctors at Children's Hospital of Wisconsin and of Minnesota. The sharing of information between doctors has allowed for the best plan of care for these children.

If you are caring for a family who may be a candidate for Fetal Cardiac Intervention, Ellianna Grace Foundation wants to help. Please refer families to email the foundation directly at: info@elliannagrcefoundation.org or call 952.484.6196. In addition, the staff at Children's Hospital Boston and Brigham and Women's Hospital can assist in facilitating aid from Ellianna Grace Foundation.

To learn more please visit www.elliannagrce.org.

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NOVEMBER MEDICAL MEETING FOCUS

3rd Annual Phoenix Fetal Cardiology Symposium

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Hospital Clinicians Can Now View Up-to-the-Moment ECG Data on iPads, iPhones

GE Healthcare teams with AirStrip Technologies to enable continuous, near real-time access to diagnostic cardiology data; interactive touch-enabled displays support clinical decision making anytime, anywhere



GE Healthcare and AirStrip Technologies has announced a secure mobile app empowering clinicians with access to precise, near real-time cardiac information. Data from the GE Healthcare MUSE® Cardiology Information System is now available on iPhones® and iPads,™ via AirStrip Cardiology.™ This enables a continuous flow of electrocardiograph (ECG) data and interactive historical data access, helping mobile clinicians make more informed care decisions. Cedars-Sinai Medical Center in Los Angeles, Texas Health Resources and several other large hospitals and healthcare systems will soon be live with AirStrip Cardiology.

Today, remote physicians commonly view ECG data from static scanned images, which require computer access and easily distort upon zooming. ECGs measure electrical cardiac activities, such as ST elevation, an indication of heart attack risk. Remote ECG measurements are challenging because changes as small as 0.5 millimeters can indicate the presence of a serious or emergency heart condition. AirStrip Cardiology's high resolution can detect such small differences through

completely interactive iPad or iPhone views. Unlike traditional remote diagnostics, zooming in on waveforms does not affect visual clarity. With AirStrip Cardiology, clinical information is available from 12- and 15-lead ECGs, supporting high precision levels. Clinicians can view current data and historical tests conducted up to one year ago, in ten-second increments.

Regardless of where remote cardiologists are when a critical decision is needed, they can leverage AirStrip Cardiology to quickly determine the best treatment paths for their patients. This may reduce the need to return to the hospital or access a computer connected to the hospital network. A remote cardiologist can now use AirStrip Cardiology to precisely measure ECG waveforms, helping on-site ED clinicians determine, for example, if a patient requires cath lab intervention.

"When I am on call, I need instant access to clinical data to help make informed treatment decisions," said Mark Peterman, MD, an interventional cardiologist on the medical staff at Texas Health Presbyterian Hospital Plano, one of Texas Health Resources' 16 acute-care hospitals. "Traditionally, off-site cardiologists must rely on caregiver descriptions and incomplete information, such as a faxed ECG. Viewing near real-time ECG data from any location, as well as a complete database of prior ECGs, is an incredibly powerful way to increase accuracy of diagnosis."

Clinicians are early adopters of many wireless devices like smartphones and tablets. According to Spyglass Consulting Group, 94% of US physicians are using smartphones to communicate, manage workflows and access medical information.

"Among physicians, there is incredible demand for enterprise medical information on iPhones and iPads," said Darren Dworkin, CIO at Cedars-Sinai Medical Center. "This new application introduces secure cardiology decision making anywhere and anytime. The interactive functionality is more advanced than anything else available today and pushes the path toward a day when all clinical hospital information will be available on a mobile platform."

Based on a GE Healthcare and AirStrip global alliance for in-hospital cardiac diagnostics, U.S. hospitals can now purchase AirStrip Cardiology through GE Healthcare. The technology directly links to the GE Healthcare MUSE Cardiology

Information System, a central cardiac repository that facilitates ECG analysis, supporting informed clinical decisions. AirStrip Cardiology is an initial step in the collaboration and an important milestone in advancing GE Healthcare's Clinical Information Logistics vision, which reflects the company's commitment to deliver actionable clinical intelligence at the right time and place, supporting quality of care and patient safety.

"Working with mobile health pioneer AirStrip, GE Healthcare is now bringing its unique cardiology heritage and innovation to the iPad and iPhone," said David Ataide, VP & GM of Patient Care Solutions, GE Healthcare. "To make efficient clinical decisions, caregivers need access to clinical intelligence across and beyond hospital boundaries. Offering highly accurate cardiac data on mobile devices supports our commitment to deliver comprehensive clinical information wherever it is needed."

"Our vision is to eliminate geographic and logistical barriers associated with clinical care," said Cameron Powell, MD, President and Chief Medical Officer, AirStrip. "GE Healthcare's global presence and cardiac innovations will help us expand our powerful mobile apps to cardiologists worldwide."

A native application, AirStrip Cardiology is specifically designed for iPad and iPhone screens, functionality and mobile environments. Instead of clicking through each step with a mouse or keyboard, clinicians can use their fingers and touch to quickly zoom and switch between viewing formats.

In 2010, the FDA cleared the platform behind AirStrip Cardiology. This technology is HIPAA compliant and uses state-of-the-art security protocols and cloud computing to securely transmit information rather than allowing data to reside on the mobile device, thereby enhancing privacy protections.

To learn more about AirStrip Cardiology, visit www.airstriptechnology.com/ or its iTunes store listing at <http://itunes.apple.com/us/app/airstrip-cardiology/id415432331?mt=8>.

Drug Can Reverse Overgrown Hearts to Help Prevent Heart Failure

A promising cancer treatment drug can restore function of a heart en route to failure from high blood pressure,

researchers at UT Southwestern Medical Center have found.

The drug, a type of histone deacetylase (HDAC) inhibitor being evaluated in numerous ongoing clinical trials, has been shown to reverse the harmful effects of autophagy in heart muscle cells of mice. Autophagy is a natural process by which cells eat their own proteins to provide needed resources in times of stress. The new study appears in *Proceedings of the National Academy of Sciences*.

"This opens the way for a new therapeutic strategy in hypertensive heart disease, one we can test for potential to promote regression of heart disease," said Dr. Joseph Hill, Chief of Cardiology and Director of the Harry S. Moss Heart Center at UT Southwestern.

Dr. Hill, senior author of the study, and other researchers have shown previously that all forms of heart disease involve either too much or too little autophagy, normally an adaptive process. For example, in the presence of high blood pressure, the heart enlarges, or hypertrophies, and autophagy is turned on. Ultimately, the hypertension-stressed heart can go into failure.

Prior research from Dr. Hill's laboratory has shown that HDAC inhibitors blunt disease-associated heart growth, so researchers designed this study to determine what impact a particular type of HDAC inhibitor had on autophagy.

The researchers engineered mice with overactive autophagy and induced hypertrophy leading to heart failure. Scientists then gave the mice an HDAC inhibitor known to limit autophagy.

"The heart decreased back to near its normal size, and heart function that had previously been declining went back to normal," Dr. Hill said. "That is a powerful observation where disease regression, not just disease prevention, was seen."

Dr. Hill noted that the research that led to this finding started decades ago and included studies led by Dr. Kern Wildenthal, former President of UT Southwestern and now President of Southwestern Medical Foundation.

"This is one of those exciting, but rare, examples where an important finding made originally in yeast moved into mouse models and is soon moving to humans," Dr. Hill said. "That's the Holy Grail for a physician-scientist – to translate those sorts of fundamental molecular discoveries through preclinical studies and ultimately in humans."

Other UT Southwestern researchers involved in the study were Dr. Dian Cao, postdoctoral trainee in internal medicine; Dr. Zhao Wang, postdoctoral researcher in internal medicine; Dr. Pavan Battiprolu, postdoctoral researcher in internal medicine; Nan Jiang, research associate in internal medicine; Cyndi Morales, student research assistant in internal medicine; Yongli Kong, Research scientist in internal medicine; and Drs. Beverly Rothermel and Thomas Gillette, both assistant professors of internal medicine.

The study was funded by the National Institutes of Health, American Heart Association, American Diabetes Association and the AHA-Jon Holden DeHaan Foundation.

PEDIATRIC HEART FAILURE/ TRANSPLANT CARDIOLOGIST OPPORTUNITY



The Departments of Pediatrics at the University of Louisville School of Medicine and Kosair Children's Hospital are recruiting for a medical director of heart failure and cardiac transplantation for the Congenital Heart Center at Kosair Children's Hospital in Louisville, Ky.

The primary responsibilities for this position focus on directing and expanding current clinical programs in pediatric heart failure and transplantation to include collaborating with very successful clinical programs in adult heart failure, mechanical assist devices and transplantation. The Kosair Charities Pediatric Heart Research Program at the Cardiovascular Innovation Institute in Louisville and a broad array of basic science research programs at the University of Louisville provide outstanding research infrastructure and collaborative opportunities, with active programs in basic science and translational research involving tissue engineering, stem cells and ventricular assist devices.

An excellent multi-year compensation package is available, commensurate with expertise. Contact Christopher L. Johnsrude, M.D., chief of pediatric cardiology, at cljohn02@louisville.edu or (502) 852-3876, or Amanda R. Bailey, physician recruitment manager, Norton Physician Services, at (502) 439-5144 or amanda.bailey@nortonhealthcare.org.



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Simple Surgical Procedure May Help Prevent Heart Damage in Children

Removing enlarged tonsils and adenoids may help prevent high blood pressure and heart damage in children who suffer from obstructive sleep apnea (OSA), according to a study conducted at Cincinnati Children's Hospital Medical Center. In some children with OSA, adenotonsillectomy can result in significantly lower blood pressure within 24 months of the procedure.

The results were presented at the ATS 2011 International Conference in Denver.

Children with enlarged tonsils and adenoids are particularly prone to developing OSA, said study lead author Lisa Burns, MD, (Pulmonary Fellow at Cincinnati Children's Hospital Medical Center). And, in children and adults, OSA has been linked with elevations in both daytime and nighttime blood pressure. OSA can also interfere with the normal "dip" in blood pressure levels that occur during sleep. Persistent elevations in blood pressure can result in organ damage, including heart damage.

"Our study emphasizes the importance of treating severe sleep apnea in order to prevent persistent elevation in blood pressure and end-organ damage," Dr. Burns said. "We also show that during sleep, diastolic blood pressure, the measurement of your blood pressure when the heart is relaxing, is more sensitive to the effects of sleep apnea than other measures of blood pressure."

Dr. Burns and colleagues evaluated 115 children between the ages of 7 and 13 years, including 28 patients with mild OSA, 27 with severe OSA and 60 healthy controls. The subjects were evaluated for level of OSA using polysomnography, a diagnostic test used to measure breathing during periods of sleep. All OSA subjects had enlarged adenoids and tonsils and underwent adenotonsillectomy. Blood pressure, rest and activity levels, and heart size were measured at the

beginning of the study and during follow-up at 12 to 24 months.

At follow-up, researchers found blood pressure levels during sleep decreased following adenotonsillectomy when compared with measurements at baseline. The procedure also restored the normal nighttime "dip" in blood pressure relative to daytime blood pressure, Dr. Burns said.

In addition, in a subset of children with moderate to severe sleep apnea, there was a decrease in heart size after adenotonsillectomy.

Dr. Burns said the results are similar to those obtained from studies of adults with OSA.

"We expected to see changes based on what we know about adults with sleep apnea and its effect on blood pressure," she said. "We know that children with sleep apnea tend to have higher blood pressures than children without sleep apnea, even if these elevations still fall within a normal range. However this is the first study to evaluate how treatment of sleep apnea impacts blood pressure and heart size in a pediatric population who are free from other diseases, which may also contribute to elevations in blood pressure."

Treating OSA in childhood is especially critical, Dr. Burns noted. "Children who have elevated blood pressure throughout childhood will often go on to develop high blood pressure in adulthood," she said. "Adults with high blood pressure are at risk for other cardiovascular diseases, such as heart attacks, stroke, and heart failure. By identifying and treating elevations in blood pressure at an earlier age through treatment of OSA, we hope to prevent development of cardiovascular disease in childhood and later in life."

Future studies should investigate the mechanisms leading to blood pressure changes with sleep apnea, she added.

Please note that numbers in this release may differ slightly from those in the abstract. Many of these investigations are ongoing; the release represents the most up-to-date data available at press time.

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