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## Developing a Congenital Heart Surgery Program in Ho Chi Minh City, Vietnam: A Five Year Retrospective and Lessons Learned

By Casey B. Culbertson, MD; Nguyen Kinh Bang, MD; Vu Minh Phuc, MD

### Introduction

Efforts to develop sustainable congenital heart disease surgical programs in developing (3rd World) countries have been previously described in the literature.

In 2006, the Socialist Republic of Vietnam determined that the Children's Hospital (Nhi Dong #1) in Ho Chi Minh City (HCMC), formerly known as Saigon, should develop a Congenital Heart Disease (CHD) surgical program with the goal of beginning surgical repair of the most common forms of CHD in 2007. Nhi Dong #1 (ND #1) is a 1200 bed Children's Hospital serving primarily the 31 surrounding provinces of HCMC with a population of approximately 40 million. The Cardiology Ward has 55 beds with 70-80 admitted patients on a typical day. The cardiology and cardiovascular (CV) surgical "team" at ND #1 consists of 3 CV surgeons, 4 CV anesthesiologists, 9 CVICU doctors and 14 cardiologists (6 of which would be considered "attendings" in the American medical system; the rest are "trainees"). There is no formal "fellowship" training for Pediatric Cardiology in Vietnam.

*"In 2006, the Socialist Republic of Vietnam determined that the Children's Hospital (Nhi Dong #1) in Ho Chi Minh City (HCMC), formerly known as Saigon, should develop a Congenital Heart Disease (CHD) surgical program with the goal of beginning surgical repair of the most common forms of CHD...."*

There was a waiting list of approximately 6000 children who needed CHD surgery when this program was conceived in 2006. The cost of surgical repair of CHD for Vietnamese children is between \$2500-3000 USD. At the program's inception, children less than 6 years of age



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had 100% of the surgical cost paid for by the government. In 2009, the government of Vietnam bought all the insurance programs being offered to Vietnamese families. Currently, a child under 6 years of age with CHD has 80% of the surgical costs paid for by insurance (i.e. the government) with the family being responsible for the remaining 20%. For a child over 6 years of age with CHD, if the family bought insurance, the insurance pays for 60% of the surgical charges and the family is responsible for the other 40%. If the family has no insurance, they are responsible for 100% of the surgical charges. As many Vietnamese families make less than \$10 USD a month; non-government organizations (NGO's) such as the "East Meets West" Foundation and other charitable organizations have been instrumental in helping Vietnamese families obtain CHD surgery.

## Background

Prior to starting this program, several on-site meetings were held between the ND#1 cardiologists, CV surgeons, the leadership of ND#1 and their "Western" colleagues. Several *'tenets'* were agreed upon and developed from these meetings and have been rigidly held to by all participants.

Accurate diagnosis of patients with CHD. This required both financial and intellectual investment from the Vietnamese doctors and their "Western" colleagues. "Up-to-date" echocardiography equipment (HP/Phillips Sonos 5500 ultrasound machines) was obtained from Assist International. More formal echocardiography training was done either during on-site visits (primarily by teams from the United States and Singapore) or by sending the ND#1 cardiologists abroad (primarily to Malaysia) as supported by Children's Heartlink International. This extensive echocardiography training was felt to be a priority prior to starting the surgical program. Since early 2007, every child presenting for cardiac evaluation at ND #1 receives a complete history and physical exam, ECG and when indicated, a full echocardiogram (as defined by ASC standards) performed by a ND #1 cardiologist.

**Best hemodynamic repair possible in the operating room.** A pediatric trans-esophageal echo (TEE) probe is used during every cardiac bypass (CPB) case done at ND #1. Before separating from CPB, every patient is evaluated by a ND #1 cardiologist with a post operative TEE to confirm the adequacy of the repair and that there are no significant residual lesions. Any concerns about residual lesions found results in an immediate discussion in the OR with the CV surgeon and (usually) results in a 2nd CPB "run" to correct the residual lesion.

**Aggressive post operative care.** Multiple evidence-based protocols were developed for the cardiovascular ICU (CVICU) for the management of "straightforward" lesions (such as atrial septal defects, ventricular septal defects, atrioventricular canal defects, etc). These are subject daily to clinical evaluation or re-evaluation of each patient by the CVICU doctors. These protocols include management of inotropic support, ventilator support, fluid and electrolyte management etc. Special emphasis has been placed on concerns about post-operative Nosocomial infections in the CVICU and the Cardiology Ward. ND #1 actively participates in and contributes CHD surgical data to the "International Quality Improvement Collaborative" (IQIC-for CHD Surgery in Developing Countries) which was developed and is maintained at Boston Children's Hospital and from which ND#1 receives quarterly progress reports.

## Other Considerations

It must be noted that prostaglandin E1 (PGE1) is not available in Vietnam. Therefore, ductal dependent lesions often die after presentation to provincial hospitals that refer patients to ND #1, or

arrive at ND #1 in extremis, even if significant CHD is recognize outside of ND #1. Unfortunately, this 'skews' the data presented in this article about PDA-dependent lesions. Since 2010, an effort has been made to place percutaneous stents in the PDA of ductal-dependent lesions of patients presenting to ND #1, and if reasonable, to allow for further evaluation and surgical treatment of these patients if possible.

Given the financial constraints of the Vietnamese medical system and Vietnamese families, it was decided at the inception of this program that single ventricle patients would only be offered palliative care or, if reasonable, a palliative surgery (such as BT shunts). Further, at the inception of the program, it was also decided that no Vietnamese patient admitted to ND#1 for evaluation would be sent abroad for surgery unless the family had both that wish and the financial means to support their child. To-date, every child presenting to ND #1 with CHD for surgery has been operated on at ND #1.

Two teams from abroad (the United States and Singapore) have made a significant investment in this program from its inception. These teams try to alternate visits to ND#1 every 6 months, if possible, to support the program. The Singaporean CV surgeon also routinely makes visits (usually monthly) for a day to assist the ND #1 CV surgeons on complex CHD patients. These two teams have also made a significant effort to address and concentrate teaching on specific cardiac lesions during each visit (such as atrioventricular canal, Tetralogy of Fallot, and transposition physiology-primarily d-TGA) in order to maximize effective learning.

## Presentation

Children presenting to ND#1 with CHD have a high incidence of pneumonia (13.6%), malnutrition (58.6%) based on body weight for age and general appearance on presentation, and cyanosis (21.7%), primarily in children presenting with d-TGA, TOF and TAPVR. This data is summarized in Chart I.

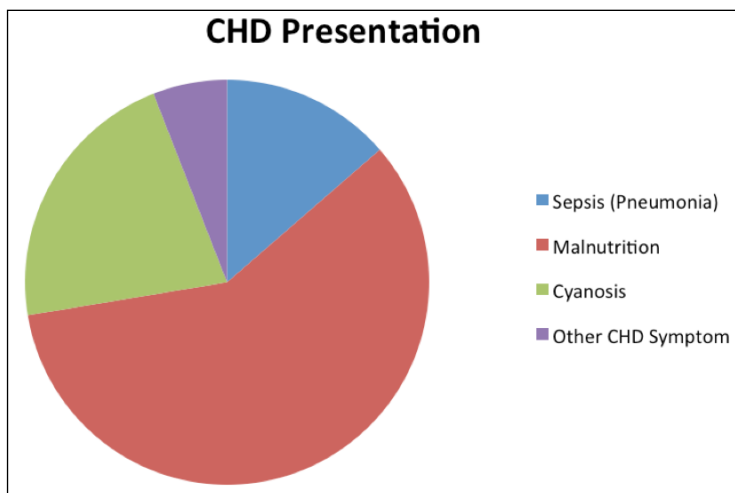


Chart I

## Overall Results

The CV surgical database maintained at ND#1 was retrospectively analyzed from inception of the surgical program (June 30, 2007) until July 31, 2011. Six-hundred and thirty-three children received operations during that time period with an overall mortality of 0.94% (6/633). This mortality data represents all CHD surgical



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deaths < 30 days post surgery and include: 1 intra operative death and 5 CVICU deaths. Median age and median weight of this group was 28 months (range <1 week to 165 months) and 9.2Kg (range 2.6 Kg to 47 Kg) respectively. There has been a definite trend in the last 2 years to operate on both younger and smaller patients with more complex lesions (d-TGA, total anomalous pulmonary venous return, etc.). One hundred percent of CHD surgery patients received complete pre-operative transthoracic (TTE)

echocardiograms, while only 5.9% of CHD patients received a cardiac catheterization prior to surgery.

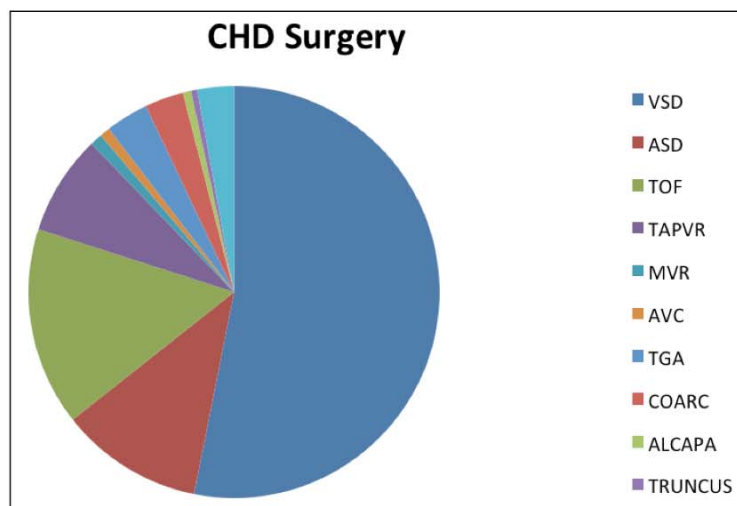


Chart II

The major types of CHD operations done at ND #1 are listed in Chart II.

As seen in Chart II, ND #1 is presented with a large spectrum of CHD for surgical repair. The majority of surgeries performed at ND #1 are complete repairs on CPB (98%), with only 2% of the cardiac surgeries being palliative repairs (primarily modified BT shunts) or non-CPB surgeries (i.e. PDA ligations). The majority of CHD surgical repairs performed at ND #1 in this report were VSD's (53.1%), ASD's (11.24%) and TOF (15.3%). Since the initiation of cardiac catheterization interventions at ND #1 in 11/2009, the number of surgical PDA ligations and ASD closures has dropped dramatically. To date, the cardiac catheterization laboratory at ND #1 has performed over 1000 cases, all primarily interventional.

The CV surgeons at ND#1 have been well supported by "outside" CV surgeons and the ND#1 CV surgeons are "scrubbed in" on 100% of all CV surgical cases done when there is a visiting CV surgeon. The visiting CV surgeon from the United States has assisted with 2.6% of all surgeries; the visiting CV surgeon from Singapore has assisted with 6.3% of all surgeries, and a senior CV surgeon from a large heart center in HCMC has assisted with 6.7% of all CHD surgeries performed at ND#1. The remaining 84.4% of CHD surgeries have all been performed by the 3 ND #1 CV surgeons and they divide the cardiac surgeries performed equally so no one CV surgeon has more "experience" than the other. Analysis of mortality shows no one ND #1 CV surgeon as having poorer surgical outcomes than his or her colleagues.

#### ICU Outcomes

The CVICU at ND #1 is a 6-bed unit with 3 primarily more senior CVICU doctors and 6 "junior" doctors who also cover the CVICU. Several of these doctors have been trained in cardiac critical care outside of Vietnam (primarily in Malaysia) and a significant effort has been made by visiting teams to further train the CVICU doctors on site. Both foreign training and on-site training have added to the overall success of the CVICU. The ND #1 cardiologists are also involved and round daily in the CVICU. All the CVICU doctors have been trained to perform basic TTE echo studies for urgent hemodynamic evaluations in the CVICU.



Of note, a significant effort has also been made in the training of the CVICU nursing staff by visiting teams (which have included critical care nurses). A critical care nurse from Singapore makes frequent visits to ND #1 for training and several of the ND#1 CVICU nurses have also been able to go to Singapore for further training. This CVICU nursing training component (both on-site and abroad) has made a significant contribution to the overall success of the CHD program at ND #1.

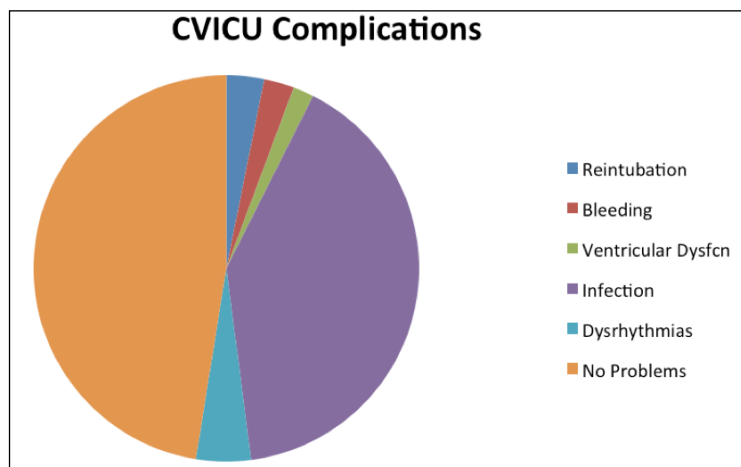


Chart III

Chart III shows the post-operative complications reported in the CVICU.

The majority of the mortality we report for the ND#1 CV surgical program has occurred in the CVICU. Of the 5 CVICU deaths, 3 patients had d-TGA status post arterial switch operation (1 thought to be due to an anaphylactic protamine reaction; 1 due to ventricular



Post operative VSD patient.



Drs. Trang, Minh, Thien and Phuc in the CVICU



The 'Emergency Room' on the Cardiology Ward at Nhi Dong #1.

tachycardia, and 1 with LV dysfunction possibly secondary to a coronary injury). The final 2 deaths were patients status post complete- TOF repairs (one due to bleeding and one due to uncontrolled junctional ectopic tachycardia and RV dysfunction).

Database review of the CVICU complications excluding mortality demonstrates low rates of re-intubation (3.2%), dysrhythmias (4.7%) and post-operative bleeding (2.6%). However, review of the ND #1 database also demonstrates a post-operative CVICU infection rate reported at 41.1%, all primarily listed as "pneumonia." In one author's experience (CBC) working with the CVICU doctors, a post-operative temperature of 38°C was considered a post-operative fever and / or an "abnormal" chest X-ray (even with no positive blood or sputum cultures and no elevation in the white blood count) often resulting in initiation of

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empiric antibiotics (usually Rocephin® and often Vancomycin) and a diagnosis of “pneumonia.” Thus, most likely the 41.1% infection rate reported in their database is an exaggeration of the true incidence of infection in the CVICU.

Further, when reviewing the ND #1 database for blood, urine or sputum culture with positive infections or clear evidence of post-surgical wound infections (as rigidly required for the IQIC reports vs. the reported “pneumonias”), the incidence of post-operative infections appears to be quite low. At the last ND #1 visit, the criteria for diagnosis of post-operative infections, appropriate diagnostic testing and appropriate use of antibiotics was completely reviewed by the visiting ICU cardiologist (CBC) with the CVICU physicians.

## Summary

The CHD Open Heart Surgical Program at ND#1 has evolved over the past 5 years into an outstanding center based on the hard work of the ND #1 cardiology and CV surgical “team” and their “Western” counterparts. A surgical operative mortality rate of essentially 1% is certainly envious, even for their “Western” colleagues who support the program. Indeed, other South East Asian countries (such as Cambodia) now send their CV surgery teams to learn from the CV surgery program at ND #1. Upon reflection, the three ‘tenets’ of this program developed in 2006 (accurate ECHO diagnosis, best intra-operative hemodynamic repair possible, and aggressive postoperative care) have laid the foundation for a successful CHD surgical program at ND #1.

## Challenges

Many challenges remain to continue to expand the CHD surgical program at ND #1. The government clearly wants this program to grow and has made plans to build a separate (300+ bed) pediatric cardiac hospital dedicated to patients with CHD. Indeed, they see ND#1 as the leader in pediatric cardiology and CHD surgery for HCMC and the surrounding provinces. However, surgical capacity, manpower, and CVICU bed space currently remain significant “roadblocks” for the ND #1 CHD “team” and the delivery of proper evaluations and treatment for thousands of children with CHD in HCMC and the surrounding provinces. Infections (both pre- and post-

***“There is an additional (essentially unspoken) problem which also threatens the expansion of CHD surgical care in Vietnam. Physicians who come from abroad to work with the Vietnamese cardiologists and CV surgeons know the problem as ‘brain drain.’”***

operative) and pre-operative malnutrition preoperative remain as significant challenges that threaten the surgical outcomes for children in Vietnam with CHD.

There is an additional (essentially unspoken) problem which also threatens the expansion of CHD surgical care in Vietnam. Physicians who come from abroad to work with the Vietnamese cardiologists and CV surgeons know the problem as “brain drain.” Most ND #1 cardiologists and CV surgeons make less than \$70 USD a month which means that many are “literally” running out the door at 4p.m. (when not on call) to staff their private clinics for which they can make 2-3 times the income of that at ND #1. Most of the ND #1 physicians are young and have young families which they need to support. The pressure to go out into “private” practice and make much more money than at ND #1 is enormous. This is a problem that the government of Vietnam needs to address in order to expand congenital heart surgery in HCMC. It should be noted that none of the ND #1 physicians have left the CHD program to pursue “easier” or more financially rewarding positions. They have taken “ownership” of the ND #1 CHD cardiac program, and they seem happy to work harder at night when not on call to support their families than to abandon “their” program which is providing superior cardiac care to the children of Vietnam with CHD.

*Special thanks to Jay Yeh, MD for reviewing this manuscript.*

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# Holmes Heart with Left Atrioventricular Valve Atresia: Case Report with Fetal Diagnosis

By Karim A. Diab, MD; Hyehyun Reynolds, BS, RDCS, MLS; Randy Richardson, MD; and Ernerio T. Alboliras, MD

## Introduction

Univentricular hearts represent a rare congenital cardiac anomaly characterized by both atria being related to a functionally single ventricle either through two separate or a common atrioventricular valve. Single double-inlet left ventricle (DILV) belongs to this category and accounts for about 1 % of all congenital heart malformation.<sup>1</sup> In this report, we present a case of single DILV with normally related great arteries (Holmes heart) and left AV-valve atresia diagnosed prenatally. We also present the associated findings on post-natal cardiac computed tomography (CT). To our knowledge this is the first report of fetal diagnosis of this lesion in the literature.

## Case report

A 42 year-old mother was referred to our center at 30 weeks of gestation due to suspected congenital heart disease on obstetrical ultrasound screening. The mother had a history of previous twin demise at 23 weeks and her current pregnancy was conceived through in vitro fertilization. The fetal echocardiogram showed normal viscerotransverse situs, levocardia, normal systemic and pulmonary venous return and double inlet left ventricle with atresia of the left atrioventricular valve (Figure 1). There was a large ventricular septal defect between the large left ventricle and the rudimentary right ventricular outflow chamber or bulboventricular foramen with no obstruction. The great vessels were normally related with the main pulmonary artery arising from the outlet chamber and coursing in a normal pulmonary arterial relationship.

The patient was born at 39 weeks gestation via C-section. Postnatal echocardiogram confirmed the diagnosis of single double inlet left ventricle with left atrioventricular valve atresia and normally related great arteries (Holmes heart) with a moderate ASD and a large VSD. Upon delivery, the baby was stable and was admitted to the NICU for further management. At two days of age a cardiac CT was performed with 3-D reconstruction using an electrocardiographic (EKG)-gated multidetector. The CT angiogram demonstrated a single double inlet left ventricle with a hypoplastic right ventricle and normally related great arteries and normal anatomy of the coronary arteries (Figure 2). Additional work-up included a karyotype which was normal and FISH for 22q11 deletion which was negative.

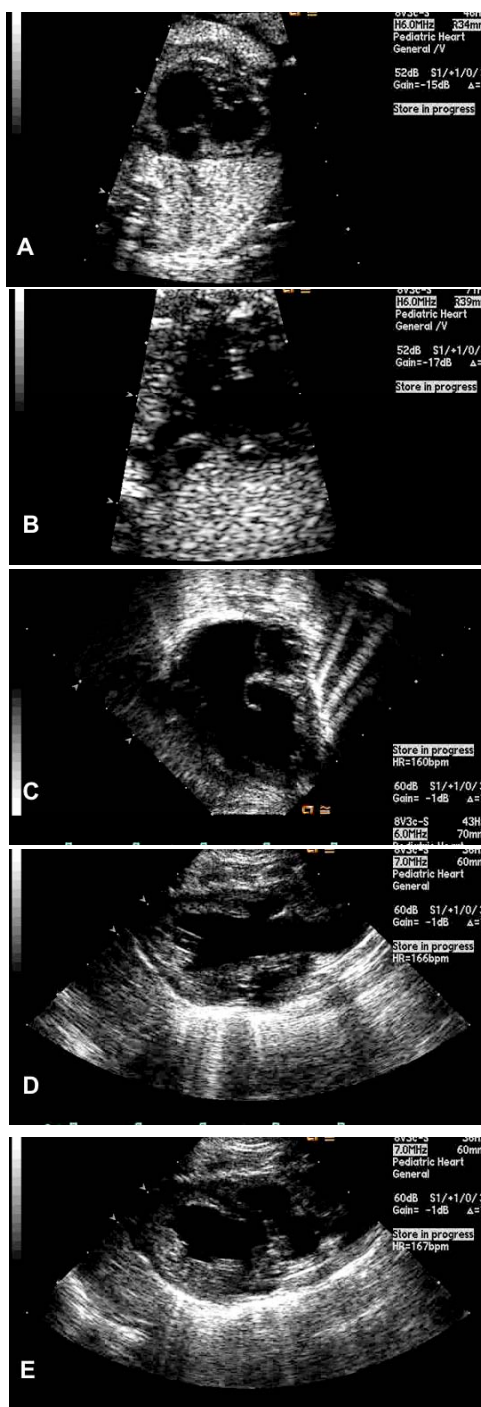


Figure 1. Fetal (A and B) and postnatal (C, D and E) echocardiographic views showing the double-inlet LV with both atria connected to the same ventricle with left atrioventricular valve atresia. The modified parasternal views show the relationship of the great arteries: the aorta originates from the posterior LV and the pulmonary artery comes off from a rudimentary anterior outlet chamber.

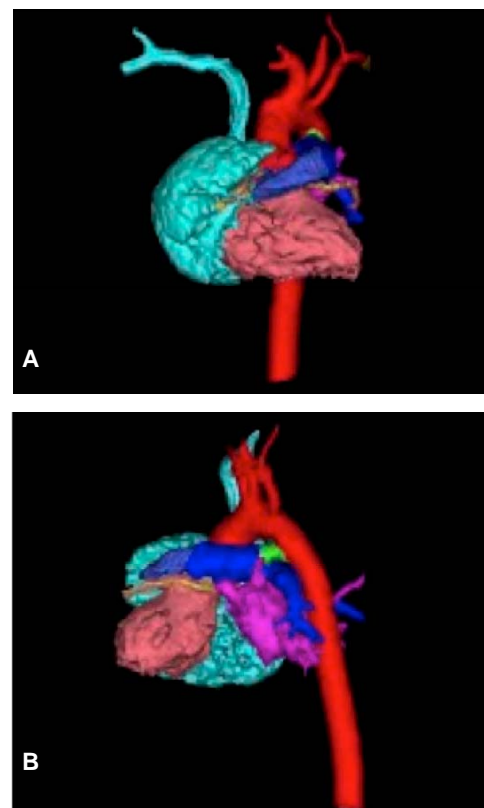


Figure 2 (A and B). CT angiographic images with 3-dimensional reconstruction demonstrating an enlarged right atrium (teal) with adjacent left ventricle (light red) and the rudimentary right outlet chamber (dark blue) superior and anterior to the left ventricle, the pulmonary artery (blue) is seen originating from the rudimentary outlet chamber. A PDA is seen as well (green).

At one month of age, the patient underwent balloon atrial septostomy and at the age of five months she successfully underwent a Damus-Kaye-Stansel operation and bidirectional Glenn shunting. The patient was discharged home one week after her operation and is still thriving well.

## Discussion

Single ventricle lesions account for about 2-3 % of congenital heart malformations and can be divided into four types (A-D) based on the absence of the right or left ventricular sinus, both, or absence of the sinus portion of ventricular septum (2). They can also be more simply divided into types A and C based on the presence or absence of an outflow chamber. They are further subdivided based on the position of the great arteries: subtype I, where the great arteries are normally related i.e. the aorta is posterior and to the right of the pulmonary artery at the level of the semilunar

valves; subtype II, where the aorta is anterior and rightward to the PA; subtype III, with the aorta leftward and subtype IV with the aorta inverted in a posterior and leftward orientation.<sup>2</sup> Those with normally related great arteries account for about 10-15 % of cases of univentricular hearts.<sup>3</sup> In 1824, Holmes described the first such case of single ventricle with a DILV with normally related great arteries in a 21-year-old man, which was documented at autopsy.<sup>4</sup> Given the rarity of this case, M. Abbott republished it in 1901.<sup>5</sup> This particular lesion consists of a single double inlet morphological LV, rudimentary RV, a small infundibular outlet chamber and normally related great arteries with the pulmonary artery arising from the outlet chamber and the aorta from the LV and coursing posterior and to the right of the pulmonary artery. Typically, there is absence of the sinus or body of the right ventricle.

In about 50% of cases, Holmes heart is associated with pulmonary stenosis which is usually subpulmonary.<sup>6</sup> Other possible associated lesions include ASD, common atrium, anomalous pulmonary venous return, and PDA. The association of left AV valve atresia with Holmes heart -as is the case in our patient- is a rare finding and has been reported previously in a 3-month-old infant and documented on autopsy.<sup>7</sup> In such cases, it is preferable to use the term left or right AV valves rather than mitral or tricuspid since these valves are often bicuspid and hence it is hard to differentiate which valve is on which side.

Survival of patients with DILV is still poor. Franklin et al. found that the survival rate of infants with this lesion was 57% and 42% at 1 and 10 years of age respectively.<sup>1</sup> Although survival was better for those deemed suitable for surgical repair, the rate was still poor (68% at one year).<sup>8</sup> Similarly, Moodie et al. found that, among a large series of patients with unoperated univentricular hearts, those who have type A have a survival rate of only 30 % at 16 years and that the presence of pulmonary stenosis does not affect the overall survival.<sup>9</sup> Amongst those who underwent palliative repair, the 5-year survival rate was 70% for those with type A.<sup>10</sup> The oldest reported patient with Holmes heart is a 59 year-old man who developed Eisenmenger's syndrome and was diagnosed by trans-esophageal echocardiography.<sup>11</sup>

Fetal diagnosis of this lesion is important in order to avoid delayed recognition of this lesion since patients can present with heart failure (with excessive unobstructed pulmonary flow) or significant cyanosis (with obstruction of the VSD or bulboventricular foramen or pulmonary stenosis). In our case, the patient was stable and required a balloon septostomy to open the atrial septum at the age of 1 month followed by DKS anatomosis and Glenn shunt at 5 months of age with good results. The use of cardiac CT with 3-D reconstruction was helpful in further delineating the anatomy and planning the survival intervention in our case.

Although many questions about the best surgical therapies remain in these cases, providing prenatal diagnosis would allow for better planning of delivery, for timely post-natal management and would possibly help achieve a better outcome.

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# Medical News Products and Information

## Royal Sussex County Hospital First in the UK to Enroll a Patient in the Gore REDUCE Clinical Study for the Indication of Patent Foramen Ovale (PFO) Closure

*International study to demonstrate safety, effectiveness of GORE® HELEX® Septal Occluder for PFO closure in patients with a history of cryptogenic stroke*

W. L. Gore & Associates (Gore) announced that Royal Sussex County Hospital in Brighton, is the first medical center in the UK to enroll a patient in the Gore REDUCE Clinical Study. The study is an FDA approved prospective, randomized, multi-center, international trial designed to demonstrate safety and effectiveness of the GORE HELEX Septal Occluder for PFO closure in patients with a history of cryptogenic stroke or imaging-confirmed transient ischemic attack (TIA). The unique study includes up to fifty investigational sites in the US and Europe. Today's milestone was achieved by the site's study investigator, David Hildick-Smith, MD, Director of Cardiac Research Unit, Brighton and Sussex University Hospitals.

"We are committed to reducing incidences of stroke. The enrollment of the first UK patient in the Gore REDUCE Clinical Study is a step in the right direction. The "Royal Sussex County Hospital is honored to take part in this international trial with the hope of advancing treatment options for patients suffering from a history of cryptogenic strokes," said Dr. Hildick-Smith.

Patients in the Gore REDUCE Clinical Study are randomized to one of two treatment arms, either anti-platelet medical management alone or device closure of the PFO in conjunction with anti-platelet medical management. The primary endpoint is freedom from recurrent ischemic stroke, imaging confirmed TIA, or death due to stroke through 24 months post-randomization.

The US Food and Drug Administration (FDA) approved the GORE HELEX Septal Occluder for treatment of atrial septal defect (ASD), a congenital heart defect, in 2006. The device received CE Mark for ASD and PFO closure in 1999. Participation in the Gore REDUCE Clinical Study by centers in the UK and Nordic countries is helping to drive enrollment in this pivotal trial.

The GORE HELEX Septal Occluder is composed of ePTFE material supported by a single wire nitinol frame. Over the course of several weeks to months following implantation of the device, cells begin to infiltrate and grow over the ePTFE material, aiding in the successful closure of the defect.

"We are committed to reducing incidences of stroke. The enrollment of the first UK patient in the Gore REDUCE Clinical Study is a step in the right direction," said Stuart Broyles, PhD, Associate with the Gore Medical Division Stroke Business. "Due to our European experience regarding the clinical performance of the GORE HELEX Septal Occluder and our unique study design, we are confident in the completion of this study and the pursuit of an FDA indication for PFO closure and the prevention of recurrent stroke."

Gore was recently named one of the best companies to work for by Fortune magazine for the 14th consecutive year. [www.goremedical.com](http://www.goremedical.com). Products listed may not be available in all markets. GORE®, HELEX®, and designs are trademarks of W. L. Gore & Associates.

## Kawasaki Disease Linked to Wind Currents

First evidence that long-range wind transport of an infectious agent might result in human disease

Kawasaki Disease (KD) is a severe childhood disease that many parents, even some doctors, mistake for an inconsequential viral infection. In fact, if not diagnosed or treated in time, it can lead to irreversible heart damage. After 50 years of research, including genetic studies, scientists have been unable to pinpoint the cause of the disease.

Now, surprising findings of an international team of scientists organized by Jane C. Burns, MD, Professor and Chief, Division of Allergy, Immunology, and Rheumatology at the University of California, San Diego School of Medicine's Department of Pediatrics and Rady Children's Hospital-San Diego, suggest that KD cases are linked to large-scale wind currents that track from Asia to Japan and also traverse the North Pacific.

"Our findings suggest an environmental trigger for Kawasaki Disease that could be wind-borne," Burns said.

Signs of KD include prolonged fever associated with rash, red eyes, mouth, lips and tongue, and swollen hands and feet with peeling skin. The disease causes damage to the coronary arteries in a quarter of untreated children and may lead to serious heart problems in early adulthood. There is no diagnostic test for Kawasaki Disease, and current treatment fails to prevent coronary artery damage in at least one in 10 to 20 children and death in one in 1,000 children.

While seasonality of the disease has been noted in many regions – particularly in Japan, the country of highest incidence for KD – the search for factors that might contribute to epidemics and fluctuations in KD occurrence has been elusive. A study of KD cases in Japan since 1970 showed three dramatic nationwide epidemics, each lasting several months and peaking in April 1979 (6,700 cases), May 1982 (16,100 cases) and March 1986 (14,700 cases). These three peaks represent the largest KD epidemic events ever recorded in the world.

To investigate a possible influence from large-scale environmental factors, researchers including Daniel R. Cayan, Climate Atmospheric Science and Physical Oceanography (CASPO) at Scripps Institution of Oceanography in La Jolla, and Xavier Rodo and Joan Ballester, of the Institut Català de Ciències del Clima and the Institut Català de Recerca (IC3) in Barcelona, Spain, investigated a set of atmospheric and oceanographic measures, which revealed a link to pressure patterns and associated wind flow from the surface to mid-tropospheric atmospheric levels during the summer months prior to onset of the epidemics.

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"The Japanese dataset revealed that a low number of KD cases were reported prior to the epidemics, a period coinciding with southerly winds which blew across Japan from the Pacific Ocean during the summer months," said Rodo, the study's first author. "However, the numbers rapidly mounted all over Japan when winds turned and blew in a southwesterly direction. After the peaks, the winds again shifted, blowing from the south when the number of cases again decreased."

"Importantly, subsequent to the three epidemics, years with increased numbers of Kawasaki Disease cases in Japan were significantly associated with enhanced local northwesterly winds, as a result of low pressure centered to the north," said Cayan.

To assess whether such variations in wind patterns were associated with KD case fluctuations on the other side of the North Pacific, similar analyses were conducted for San Diego. According to the scientists, the atmospheric connection from continental Asia to Japan and San Diego is intermittent and can take different routes. However, it was possible from their analysis to identify the major anomalous yearly peaks of KD cases occurring in San Diego from 1994 to 2008 as belonging to two main atmospheric configurations.

In fact, the major fluctuations in KD case numbers in Japan, Hawaii and San Diego were linked to a seasonal shift in winds that exposed Japan to air masses from Central Asia. One key pattern simultaneously exposed Hawaii and California to air masses from the western North Pacific.

"The linkage to the wind currents, which can cross the Pacific in less than one week, may explain why KD case numbers recorded in Japan, San Diego and Hawaii show a nearly synchronized seasonal peak in disease activity from November through March," Rodo said.

Burns reports that the findings could be significant in efforts to isolate the cause of this devastating childhood disease. "It could be that an infectious agent is transported across the ocean by strong air currents developing in the upper troposphere," she said, adding that while this would seem the most plausible explanation for the findings, the role of pollutants or other inert particles must be considered.

These hypotheses are currently being investigated. A research aircraft carrying an engineer from the Catalan team used a custom-built air sampling apparatus to collect tropospheric air samples from over Japan in March 2011, and the entire biome of the tropospheric dust collection is being sequenced in the laboratory of W.Ian Lipkin, MD, at Columbia University in New York City. Lipkin is one of the leading "molecular detectives" who uses sequencing to find new infectious agents. On the other side of the U.S., teams of pediatric doctors from hospitals from California to Alaska and Hawaii have initiated real-time reporting of KD cases to Scripps Institution of Oceanography via the Web. There, Cayan and his team are analyzing cases in relation to regional climate and tropospheric wind patterns.

While links between human respiratory disease and large-scale dust transport are well-documented, to date there has been no evidence of long-range wind transport of an infectious agent causing human disease.

Additional contributors to the study include Marian E. Melish, John A. Burns School of Medicine, Kapiolani Medical Center, Honolulu, Hawaii; Yoshikazu Nakamura and Ritei Uehara, Jichi Medical School, Japan.

Funding for the study was provided in part by a grant from the National Heart, Lung and Blood Institute, part of the National Institutes of Health, by the NOAA Regional Integrated Sciences and Assessments program, and by a grant to Rodo from La Marató de TV3 Foundation.

#### **Gore Receives FDA Approval for Conformable GORE® TAG® Thoracic Endoprosthesis**

W. L. Gore & Associates, Inc. (Gore) announced that it has received approval from the US Food and Drug Administration (FDA) to market the Conformable GORE® TAG® Thoracic Endoprosthesis as a minimally invasive treatment for patients suffering from thoracic aortic aneurysms (TAAs). Today's announcement came at the VEITH Symposium 2011 Conference in New York. The device is the only FDA approved ePTFE thoracic endoprosthesis designed for endovascular repair of the descending thoracic aorta that offers conformability and ease of use, while accommodating tapered anatomy and resisting compression. The

broad oversizing window for the device ranges from 6-33%, allowing physicians to choose the appropriate oversizing for the patient anatomy.

William Jordan, MD, Chief of Vascular Surgery at the University of Alabama, Birmingham, served as national principal investigator for the Conformable GORE TAG Device in the Thoracic Aortic Aneurysm Trial (Gore TAG 08-03) over the past two years. According to Dr. Jordan, "This new device represents a substantial product improvement brought to us by a company that was already leading the market in aneurysm devices. Gore evaluated the real world results of the first generation endograft and engineered improvements so that the device can be used across a wider range of aortic diameters with stronger radial force to resist compression. These modifications are intended to improve the lives of our patients and provide better outcomes for challenging clinical problems."

The following physicians completed successful procedures using the Conformable GORE TAG Thoracic Endoprosthesis during the first week of release:

- William McMillan, MD – Vascular Surgeon at Minneapolis Vascular Physicians
- Robert Mitchell, MD – Thoracic Surgeon at Central Baptist Hospital, Lexington, Kentucky
- Brian Peterson, MD – Vascular Surgeon in the Department of Surgery at Saint Louis University
- Robert Rhee, MD - Associate Professor of Surgery at the University of Pittsburgh Medical Center

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#### **Update in Congenital Heart Management**

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- Joshua Rovin, MD - Cardiovascular Surgeon at Bayfront Medical Center, St. Petersburg, Florida
- Daniel Watson, MD – Director of Endovascular Surgery at Riverside Methodist Hospital, Columbus, Ohio

The device is available in diameters of 21-45 mm, allowing for the treatment of patients with aortic diameters of 16-42 mm. Tapered device configurations are also available.

TAAAs are a serious health risk because they can burst or rupture with little or no symptoms after developing over years. A ruptured aneurysm can cause severe internal bleeding, which can rapidly lead to shock or death. Thoracic aneurysms affect approximately 15,000 people in the US each year. Some patients may have more than one TAA or may also have an aneurysm of the abdominal aorta. Due to the high mortality risk associated with undetected and untreated TAAAs, it is critical to get screened for aneurysm risk and seek early treatment if detected.

"The GORE TAG Device has been a leading endovascular treatment option for safely and effectively treating patients with aneurysms of the descending thoracic aorta. The device is backed by a proven safety record with more than 50,000 devices distributed worldwide and a decade of worldwide clinical data," said David Abeyta, Gore Aortic Business Leader. "Now featuring design enhancements such as a modified stent frame, optimized graft film layers, enhanced conformability, and expanded oversizing ranges, the Conformable GORE TAG Device provides an optimal fit and maximum conformability for each patient's anatomy without compromising conformability."

For more information, visit [www.goremedical.com](http://www.goremedical.com).

#### **Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S.**

Edwards Lifesciences Corporation (NYSE: *EW*), the global leader in the science of heart valves and hemodynamic monitoring, today announced that it has received approval from the United States Food and Drug Administration (FDA) for the transfemoral delivery of the Edwards SAPIEN transcatheter aortic heart valve for the treatment of inoperable patients with severe symptomatic aortic stenosis. This is the first U.S. commercial approval for a transcatheter device enabling aortic valve replacement without the need for open-heart surgery.

Transcatheter aortic valve replacement (TAVR) with the Edwards SAPIEN valve enables multi-disciplinary heart teams to replace a patient's diseased aortic valve without traditional open-heart surgery and while the heart continues to beat -- avoiding the need for cardiopulmonary bypass.

"This day marks an important milestone for inoperable American patients who have long been awaiting a therapeutic option for the often debilitating symptoms associated with severe aortic stenosis," said Michael A. Mussallam, Edwards' chairman and CEO. "We are extremely proud of the dedication of the heart teams and the patients involved in the clinical trial for this therapy, who have paved the way for this therapy to help even more people around the world."

In performing the TAVR procedure, the valve is crimped onto the catheter-based transfemoral delivery system, which is inserted into the body through a small cut in the leg. Once delivered to the site of the patient's diseased valve, the Edwards SAPIEN valve is expanded with a balloon and immediately functions in place of the patient's native valve.

The Edwards SAPIEN valve is indicated for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.

The safety and effectiveness of the Edwards SAPIEN transcatheter valve were evaluated in a randomized, controlled pivotal study called The PARTNER Trial. The name of the trial signifies the important partnership between cardiac surgeons and interventional cardiologists, who were brought together to collaborate in patient evaluation, treatment and follow-up. Additional analyses of data from The PARTNER Trial demonstrated that patients receiving the SAPIEN valve experienced substantially better quality of life as compared to the control group patients, and also that TAVR was cost effective.

As part of this approval, FDA has requested the implementation of two substantial post-approval studies. One study will follow patients already enrolled in The PARTNER Trial, and the second study will track new US patients. The company anticipates the second study will be incorporated into a new national patient registry.

Additional company information and its products can be found at [www.edwards.com](http://www.edwards.com).

#### **Study Demonstrates Detection of Acute Kidney Injury Possible Within Hours of Cardiopulmonary Bypass**

Up to 40% of adults and children who have cardiac surgery develop acute kidney injury (AKI), often with deadly consequences. That's partially because it takes several days to determine if the test used to diagnose AKI for 50 years is abnormal – too late to prevent kidney failure.

A new study, however, shows that a panel of biomarkers can be used to detect AKI just hours after initiation of cardiopulmonary bypass – allowing physicians to pinpoint timing of kidney injury and potentially initiate therapy earlier than ever before.

The study, conducted by Catherine Krawczeski, MD, a pediatric cardiologist at Cincinnati Children's Hospital Medical Center, was published online Nov. 15th in the *Journal of the American College of Cardiology*. Publication of the study coincided with her presentation of the data on the same date at the annual meeting of the American Heart Association in Orlando, FL.

"These biomarkers not only enhance the potential for appropriately timed therapy but also offer severity and prognostic information at early time points," says Dr. Krawczeski. "Concentrations of one biomarker in urine, NGAL, increased earliest – as little as two hours after bypass – and were most predictive of AKI."

The Cincinnati Children's researchers studied 220 children and adolescents who went on cardiopulmonary bypass. Urine samples were obtained before bypass and at regular intervals afterward. AKI, an acute loss of kidney function, occurred in 27% of patients. Urine NGAL increased significantly at two hours post-bypass. Three other biomarkers (IL-18, L-FABP and KIM-1) rose significantly at later points.

The study marks the first time researchers have studied all four of these biomarkers together in one group of patients and described "their exact temporal evolution," says Dr. Krawczeski. "Biomarkers, especially when used in combination, like a panel, give us the strongest predictive ability – better than using just clinical data and better than just NGAL alone. NGAL provides the earliest information, but the others add predictive ability."

The best test for kidney injury currently available measures creatinine, a waste product. A high level of creatinine in the blood means the kidney is unable to filter out the chemical. The standard of care is to wait until creatinine rises before diagnosing and treating AKI. Unfortunately, it may take days for the creatinine level to rise after the kidney is injured. By the time the creatinine test shows kidney injury, the child or adult may already have lost up to 50% of kidney function.

It isn't only cardiopulmonary bypass that raises the risk of AKI. As many as one of three critically ill patients develop AKI as a consequence of

shock, infection, trauma, surgery, medications or procedures that are toxic to the kidney. Patients may need to spend extra days in the ICU on a ventilator, need dialysis or even need a kidney transplant. AKI is the number one predictor of death in critically ill patients.

Because of the urgent need for a better diagnostic tool, Prasad Devarajan, MD, Director of Nephrology and Hypertension at Cincinnati Children's and a co-author of Dr. Krawczeski's study, went to the laboratory and discovered that NGAL was a useful biomarker, secreted into the blood and urine and thus allowing for it to be measured non-invasively.

To build on this research, Cincinnati Children's established the Center for Acute Care Nephrology in 2010. This center brings together a unique team: nephrologists who are pioneering leaders in laboratory and clinical research, working in an unusually collaborative relationship with experts in cardiac and pediatric intensive care. The center is directed by Stuart Goldstein, MD, who collaborated with Dr. Devarajan in 2007 on an earlier NGAL study and is also a co-author of Dr. Krawczeski's study. Dr. Krawczeski co-directs the center with Dr. Goldstein.

Cincinnati Children's is now launching "proof of concept" studies in the Pediatric Intensive Care Unit to determine whether physicians can make more timely care decisions by relying on the NGAL test.

Cincinnati Children's has also been funded by the National Institutes of Health as one of only nine Pediatric Heart Network core sites in the United States and Canada. As a member of the consortium, Cincinnati Children's has proposed studying whether early treatment of AKI with sodium bicarbonate and N-acetylcysteine, an antioxidant, will improve outcomes following cardiopulmonary bypass.

## CONGENITAL CARDIOLOGY TODAY

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