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Timely News & Information for Congenital/Structural Cardiologists & Cardiothoracic Surgeons Worldwide
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Risk of Cancer in Young and Older Patients with Congenital Heart Disease and the Excess Risk of Cancer by Syndromes, Organ Transplantation and Cardiac Surgery: Swedish Health Registry Study (1930-2017)

Venu Amula, MD

Commentary from Dr. Venu Amula (Salt Lake City, UT, USA) on the following article: Risk of Cancer in Young and Older Patients with Congenital Heart Disease and the Excess Risk of Cancer by Syndromes, Organ Transplantation and Cardiac Surgery: Swedish Health Registry Study (1930-2017)
Christina Karazisi, Mikael Dellborg, Karin Mellgren, Kok Wai Giang, Kristofer Skoglund, Peter Eriksson, Zacharias Mandalenakis. Lancet Reg Health Eur. 2022 May 29;18:100407. doi: 10.1016/j.lanepe.2022.100407. eCollection 2022 Jul. PMID: 35663362

Take-Home Points

1. There is a 23% increased risk of cancer in young and older patients with Congenital Heart Disease when compared to matched controls without Congenital Heart Disease (CHD).
2. The risk is higher in children and those who were born in later birth cohorts.
3. The risk remains elevated after excluding patients with genetic syndromes and transplant recipients.

Overall, congenital cardiac surgery was not associated with an increased risk of cancer except in children who underwent cardiac surgery during the first year of life.

Karazasi et al. performed an observational case-control study using the Swedish health registry to investigate the risk of cancer in young and older patients with CHD and to evaluate the excess risk of cancer by syndromes, organ transplantation, and cardiac surgery. With the increasing survival of patients with congenital heart disease, they are at risk of acquired cardiovascular conditions and other diseases such as cancer. However, limited studies exist quantifying such a risk in patients with congenital heart disease compared to the general population.

The authors of this study used data from the Swedish National Inpatient Register, the Swedish National Outpatient Register, and the Swedish Cause of Death Register. Inclusion criteria included patients born between 1930 and 2017 with a diagnosis of CHD. ICD codes were used for diagnosis. Each patient with CHD was matched by sex and birth year with ten controls without CHD from the general population, identified from the Swedish Total Population Register. Follow-up times for CHD and control populations were

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estimated from birth until the event (cancer), death, or the end of the study period (31, December 2017), whichever occurred first. Incidence rates were reported as per 10,000 person-years and were estimated as the number of events divided by the total follow-up time of the population. Incidence rate ratio (IRR) was defined as the relative difference between CHD and the control population, with 95% confidence intervals (CI) Cox proportional hazard regression models used to obtain hazard ratios (HR) with 95% CIs. For all models, the control population was considered the reference population.

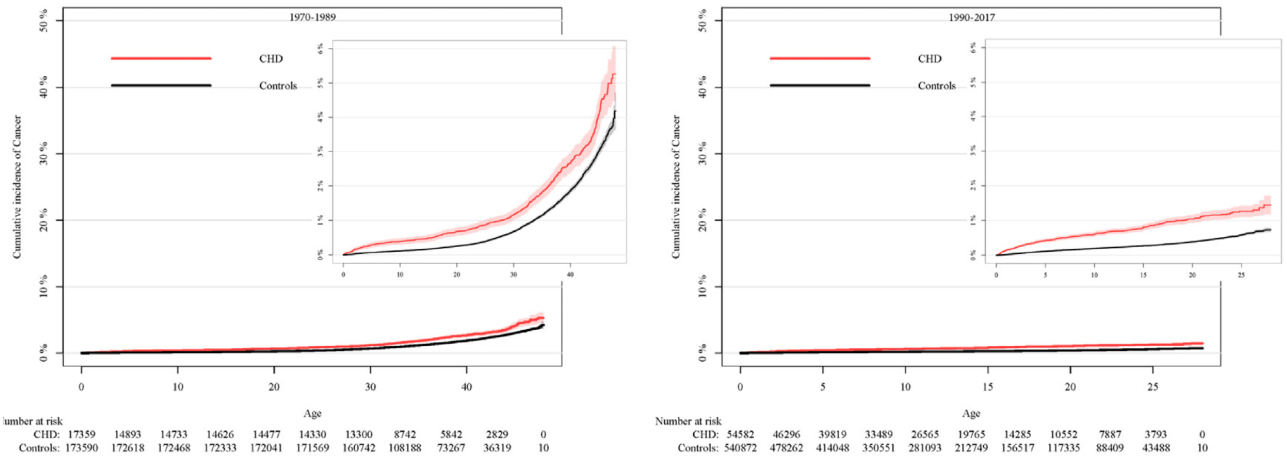
The authors identified 89,542 patients born between 1930 and 2017 who were registered with the diagnosis of CHD and 890,472 controls who were matched by birth year and sex. As noted in the table below, the baseline characteristics were similar in cases and controls. After a median follow-up time of 58.8 years for CHD patients and 61.3 years for controls, 4.5% of patients with CHD and 4.0% of the control population developed cancer. The cancer risk was 23% more in patients with CHD than in controls. The increased risk was maintained after excluding patients with syndromes and organ transplant recipients. When studying the cumulative incidence of cancer according to the birth cohort, the incidence of cancer was significantly higher in the CHD population from the youngest birth cohorts.

Characteristic	CHD	Controls
All patients, No (%)	89,542 (9·1%)	890,472 (90·9%)
Male	45,372 (50·7%)	453,720 (51·0%)
Female	44,170 (49·3%)	436,752 (49·0%)
Birth cohort		
1930–1949	7026 (7·8%)	70,260 (7·9%)
1950–1969	10,575 (11·8%)	105,750 (11·9%)
1970–1989	17,359 (19·4%)	173,590 (19·5%)
1990–2017	54,582 (61·0%)	540,872 (60·7%)
Age at event*		
Mean, years (SD)	52·6±22·1	57·4±17·6
Median, years (IQR)	58·8 (42·4–69·0)	61·3 (49·0–69·8)

***Table 1*: Characteristics of the study population.**
*cancer, death or end of the study period (31 December 2017).
CHD = congenital heart disease. SD = standard deviation. IQR = interquartile range.

	HR (95% CI)		p-value
	All patients	Excluding patients with syndromes and organ transplant recipients	(all vs excluded patients)
Study population	1·23 (1·19–1·27)	1·18 (1·14–1·22)	<0·001 / <0·001
Age group			
0–17 years	3·21 (2·90–3·56)	2·42 (2·15–2·73)	<0·001 / <0·001
18–39 years	1·34 (1·21–1·48)	1·24 (1·12–1·38)	<0·001 / <0·001
40+ years	1·11 (1·07–1·15)	1·11 (1·07–1·15)	<0·001 / <0·001
Birth cohort			
1930–1949	1·03 (0·98–1·08)	1·03 (0·98–1·08)	0·20 / 0·25
1950–1969	1·33 (1·25–1·42)	1·32 (1·24–1·40)	<0·001 / <0·001
1970–1989	1·76 (1·59–1·96)	1·62 (1·45–1·81)	<0·001 / <0·001
1990–2017	2·88 (2·57–3·22)	2·16 (1·89–2·47)	<0·001 / <0·001

***Table 2*: Cancer risk in patients with congenital heart disease compared with matched controls, according to age and birth cohort.**
HR = hazard ratio. CI = confidence interval.



GRAPHS *Cumulative incidence of cancer risk by birth cohort: Birth cohorts 1970–1989 and 1990-2017. This study is of utmost importance and raises several important questions. The reasons for such an increased cancer risk remain elusive, but several are plausible. Genetic predisposition, increased exposure to low ionizing radiation as a part of diagnostic and therapeutic procedures, and early thymectomy with immune dysregulation are possible explanations without any direct evidence incriminating them. The association of higher cancer risk with younger birth cohorts does follow the increased surgical and catheter-based intervention trends in recent periods. Longitudinal studies involving large populations may provide more insight, but in the meanwhile, cardiologists should be aware of this higher risk and engage in heightened surveillance of young patients.*

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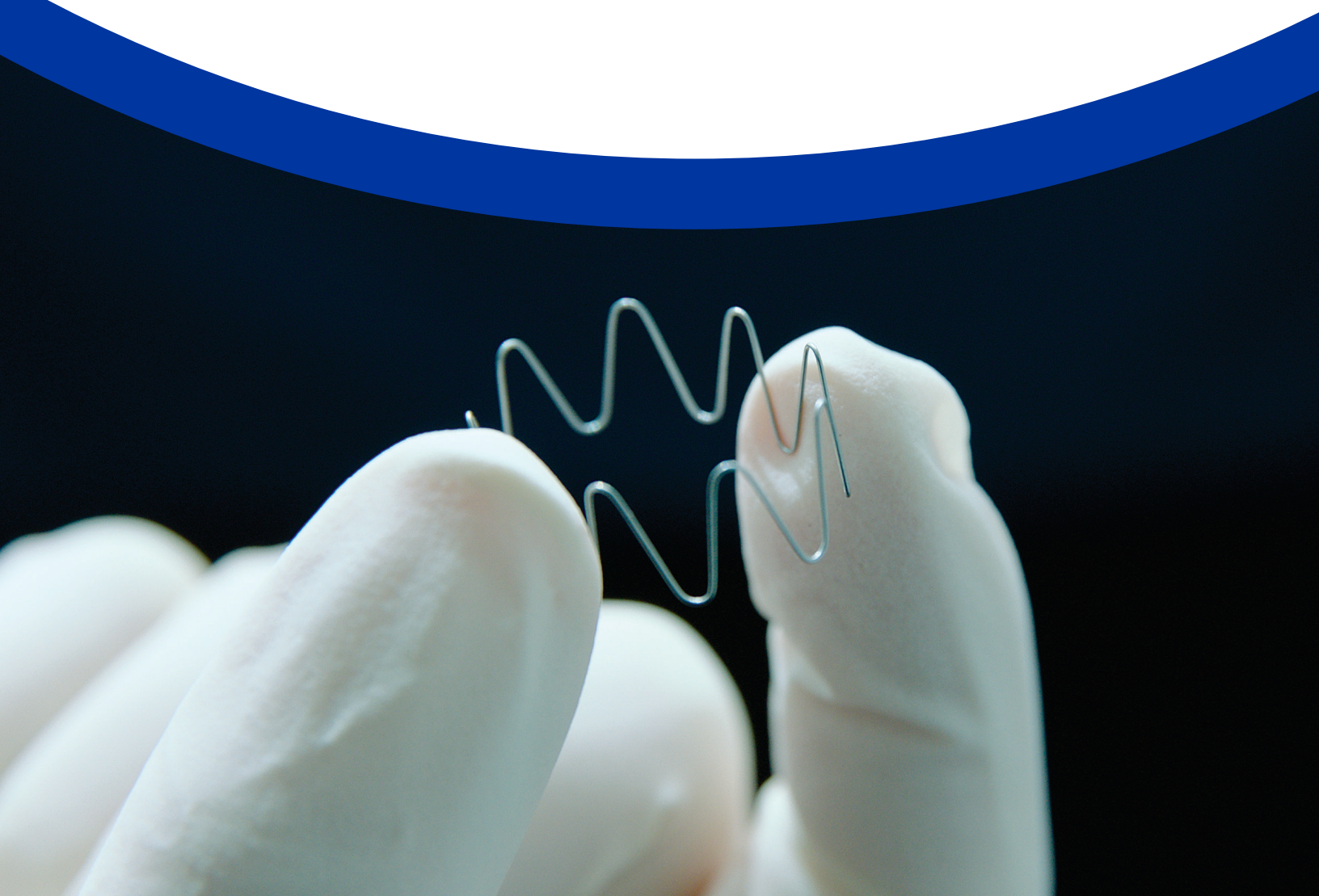

Indications
The Harmony™ transcatheter pulmonary valve (TPV) system is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction ≥ 30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

Contraindications
The following are contraindications for the use of this device: active bacterial endocarditis or other active infections, known intolerance to Nitinol (titanium or nickel), or an anticoagulation/antiplatelet regimen.

Warnings
General: Implantation of the Harmony TPV system should be performed only by physicians who have received Harmony TPV system training. The transcatheter pulmonary valve (TPV) is to be used only in conjunction with the Harmony delivery catheter system (DCS). This procedure should only be performed where emergency pulmonary valve surgery can be performed promptly. Do not use any of the Harmony TPV system components if any of the following has occurred: it has been dropped, damaged, or mishandled in any way, or if the use-by date has elapsed.

Transcatheter pulmonary valve (TPV): This device was designed for single use only. Do not reuse, reprocess, or resterilize the TPV. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not resterilize the TPV by any method. Exposure of the device and container to irradiation, steam, ethylene oxide, or other chemical sterilants renders the device unfit for use. The device is packaged with a temperature sensor. Do not freeze the device. Do not expose the device to extreme temperatures. Do not use the device if the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded. Do not use the device if any of the following have occurred: the tamper-evident seal is broken, the serial number tag does not match the container label, the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded, or the device is not completely covered by the storage solution. Do not contact any of the Harmony TPV system components with cotton or cotton swabs. Do not expose any of the Harmony TPV system components to organic solvents, such as alcohol. Do not introduce air into the catheter. Do not expose the device to solutions other than the storage and rinse solutions. Do not add or apply antibiotics to the device, the storage solution, or the rinse solution. Do not allow the device to dry. Maintain tissue moisture with irrigation or immersion. Do not attempt to repair a damaged device. Do not handle the valve leaflet tissue or use forceps to manipulate the valve leaflet tissue. Do not attempt to recapture the device once deployment has begun. Do not attempt to retrieve the TPV if any one of the outflow TPV struts is protruding from the capsule. If any one of the outflow TPV struts has deployed from the capsule, the TPV must be released from the catheter before the catheter can be withdrawn. Do not attempt post-implant balloon dilatation (PID) of the TPV during the procedure, which may cause damage to or failure of the TPV leading to injury to the patient resulting in reintervention.

Delivery catheter system (DCS): This device was designed for single use only. Do not reuse, reprocess, or resterilize the DCS. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not reuse or resterilize the DCS. If resistance is met, do not advance the guidewire, DCS, or any other component without first determining the cause and taking remedial action. Do not remove the guidewire from the DCS at any time during the procedure.

Precautions
General: Clinical long-term durability has not been established for the Harmony TPV. Evaluate the TPV performance as needed during patient follow-up. The safety and effectiveness of Harmony TPV implantation in patients with pre-existing prosthetic heart valve or prosthetic ring in any position has not been demonstrated. The Harmony TPV system has not been studied in female patients of child-bearing potential with positive pregnancy.

Before use: Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the chemical vapor. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water (for a minimum of 15 minutes) and seek medical attention immediately. The TPV and the glutaraldehyde storage solution are sterile. The outside of the TPV container is nonsterile and must not be placed in the sterile field. The TPV and DCS should be used only in a sterile catheterization laboratory (cath lab) environment. Ensure that sterile technique is used at all times. Strictly follow the TPV rinsing procedure. For TPV 25: Ensure that all green sutures have been removed from the attachment suture loops on the TPV before loading onto the DCS. Prevent contamination of the TPV, its storage solution, and the DCS with glove powder. Verify the orientation of the TPV before loading it onto the DCS. The inflow end of the TPV with attachment suture loops must be loaded first. Do not place excessive pressure on the TPV during loading. Inspect the sealed DCS packaging before opening. If the seal is broken or the packaging has been damaged, sterility cannot be assured. Proper functioning of the DCS depends on its integrity. Use caution when handling the DCS. Damage may result from kinking, stretching, or forceful wiping of the DCS. This DCS is not recommended to be used for pressure measurement or delivery of fluids. Carefully flush the DCS and maintain tight DCS connections to avoid the introduction of air bubbles.

During use: The TPV segment is rigid and may make navigation through vessels difficult. Do not advance any portion of the DCS under resistance. Identify the cause of resistance using fluoroscopy and take appropriate action to remedy the problem before continuing to advance the DCS. Careful management of the guidewire is recommended to avoid dislodgement of the TPV during DCS removal. Once deployment is initiated, retrieval of the TPV from the patient is not recommended. Retrieval of a partially deployed valve may cause mechanical failure of the delivery catheter system or may cause injury to the patient. Refer to the section below for a list of potential adverse events associated with Harmony TPV implantation. During deployment, the DCS can be advanced or withdrawn prior to the outflow struts protruding from the capsule. Once the TPV struts contact the anatomy during deployment, it is not recommended to reposition the device. Advancing the catheter forward once the TPV struts make contact with the anatomy may lead to an undesired deployment or may cause damage to or failure of the TPV and injury to the patient. Refer to the section below for a list of potential adverse events associated with the Harmony TPV implantation. Physicians should use judgment when considering repositioning of the TPV (for example, using a snare or forceps) once deployment is complete. Repositioning the bioprosthesis is not recommended, except in cases where imminent serious harm or death is possible (for example, occlusion of the main, left, or right pulmonary artery). Repositioning of a deployed valve may cause damage to or failure of the TPV and injury to the patient. Refer to the section below for a list of potential adverse events associated with the Harmony TPV implantation. Ensure the capsule is closed before DCS removal. If increased resistance is encountered when removing the DCS through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and harm to the patient. If the cause of resistance cannot be determined or corrected, remove the DCS and introducer sheath as a single unit over the guidewire, and inspect the DCS and confirm that it is complete. If there is a risk of coronary artery compression, assess the risk and take the necessary precautions. Endocarditis is a potential adverse event associated with all bioprosthetic valves. Patients should make their healthcare providers aware that they have a bioprosthetic valve before any procedure. Post-procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. Prophylactic antibiotic therapy is recommended for patients receiving a TPV before undergoing dental procedures. Post-procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment and/or institutional protocol. Excessive contrast media may cause renal failure. Preprocedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long term.

Potential Adverse Events
Potential risks associated with the implantation of the Harmony TPV may include, but are not limited to, the following: • death • valve dysfunction • tissue deterioration • hematoma • heart failure • cerebrovascular incident • perforation • rupture of the right ventricular outflow tract (RVOT) • compression of the aortic root • compression of the coronary arteries • sepsis • pseudoaneurysm • erosion • stent fracture • arrhythmias • device embolization or migration • pulmonary embolism • occlusion of a pulmonary artery • laceration or rupture of blood vessels • device misorientation or misplacement • valve deterioration • regurgitation through an incompetent valve • physical or chemical implant deterioration • paravalvular leak • valve dysfunction leading to hemodynamic compromise • residual or increasing transvalvular gradients • progressive stenosis and obstruction of the implant • hemorrhage • endocarditis • thromboembolism • thrombosis • thrombus • intrinsic and extrinsic calcification • bleeding • bleeding diathesis due to anticoagulant use • fever • pain at the catheterization site • allergic reaction to contrast agents • infection • progressive pulmonary hypertension • progressive neointimal thickening and peeling • leaflet thickening • hemolysis. General surgical risks applicable to transcatheter pulmonary valve implantation: • abnormal lab values (including electrolyte imbalance and elevated creatinine) • allergic reaction to antiplatelet agents, contrast medium, or anesthesia • exposure to radiation through fluoroscopy and angiography • permanent disability.

Please reference the Harmony TPV system instructions for use for more information regarding indications, warnings, precautions, and potential adverse events.

CAUTION: Federal law (USA) restricts these devices to the sale by or on the order of a physician.

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VENU AMULA, MD
Section Editor
Pediatric & Fetal Cardiology Journal Watch
The CHiP Network
Salt Lake City, UT, USA

Short- and Medium-Term Outcomes for Patent Ductus Arteriosus Stenting in Neonates ≤2.5 Kg with Duct-Dependent Pulmonary Circulation

Konstantin Averin, MD

Commentary from Dr. Konstantin Averin (Glen Oaks, NY, USA) on the following article:
Short- and Medium-Term Outcomes for Patent Ductus Arteriosus Stenting in Neonates ≤2.5 kg with Duct-Dependent Pulmonary Circulation
Nasef MA, Shahbah DA, Batlivala SP, Darwich R, Qureshi AM, Breatnach CR, Linnane N, Walsh KP, Oslizlok P, McCrossan B, Momenah T, Alshahri A, Abdulhamed J, Arafat A, Tamimi OA, Diraneyya OM, Goldstein BH, Kenny D. Catheter Cardiovasc Interv. 2022 Oct;100(4):596-605. doi: 10.1002/ccd.30351. Epub 2022 Jul 29.PMID: 35904221

Take-Home Points

- Stenting the patent ductus arteriosus in infants ≤ 2.5 kg with DDPBF is technically feasible and achieves short-term outcomes comparable to or better than surgical systemic-to-pulmonary shunting.
- There is a relatively high incidence of morbidity with this procedure, especially related to arterial access.

Stenting of the patent ductus arteriosus (PDA) has become an accepted alternative to a surgical systemic-to-pulmonary shunting (SPS) in patients with ductal dependent pulmonary blood flow (DDPBF). Infants who are ≤ 2.5 kg are at highest risk for SPS, so PDA stenting is an attractive option in this patient population. The authors sought to assess procedural and short-term outcomes in infants ≤ 2.5 kg undergoing PDA stenting for DDPBF using data from four large cardiac centers.

FIGURE 1

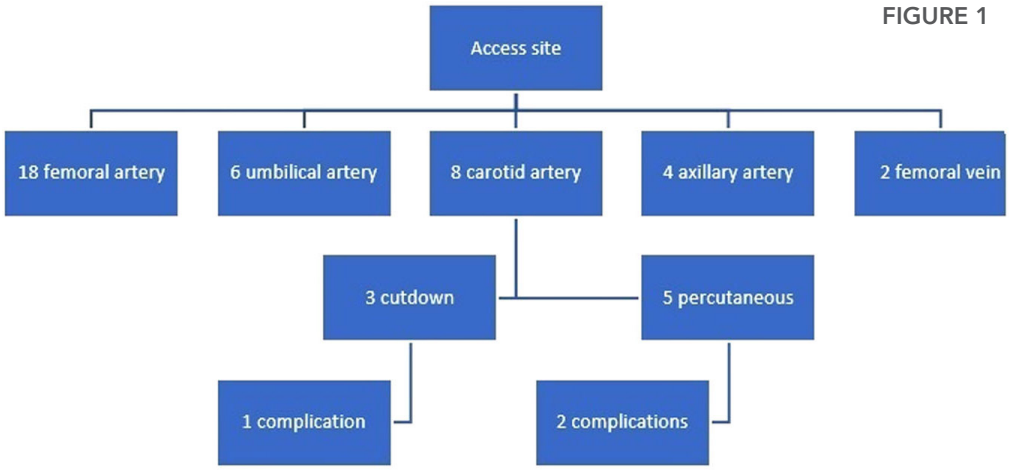
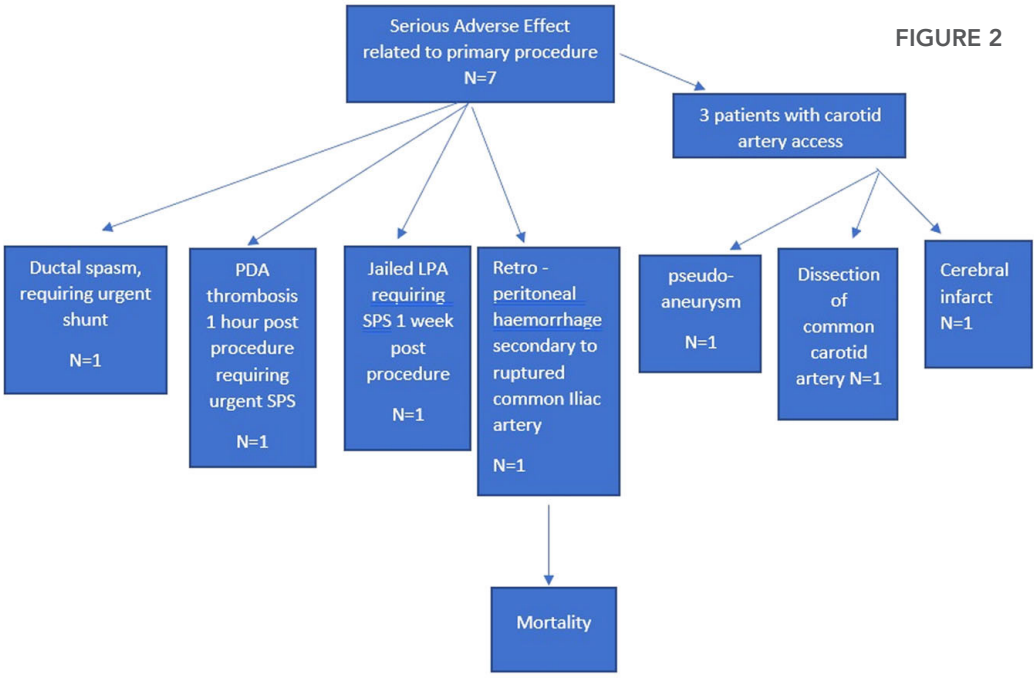


FIGURE 2



From March 2007 to February 2020, 38 patients – median age at procedure 10 days (IQR 6-15), median procedural weight 2.2 kg (IQR 2-2.4 kg) (11 under 2.0kg) – underwent PDA stenting. There were a variety of diagnoses, but a majority had pulmonary atresia or pulmonary stenosis (71%). A majority (79%) of the PDA's had complex anatomy with a tortuosity index of II or III. In 47% of patients, the procedure was performed via the femoral artery, while the carotid artery was used in eight (21%), umbilical artery in six, axillary artery in four, and femoral vein in two **(Figure 1)**.

Patient outcomes are summarized in **Figure 3**. Successful stent implant was achieved in 92% of initial procedures (35/38) with no procedural deaths. There was a high incidence (18%, 7/38) of serious adverse events related to the primary procedure **(Figure 2)** – most commonly related to carotid and femoral artery access. The thirty-day survival for the entire cohort was 97%. Twenty patients required reintervention.

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- St. Peters Pediatric Cardiologist /Attending Physician
- Provide patient care at CHOP Satellite locations of St. Peters University Hospital and Princeton offices
- St. Peters University Hospital and Princeton Specialty Care Satellite
- As a Pediatric Cardiologist/Attending physician at St. Peters University Hospital and Princeton
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The authors conclude that PDA stenting in infants ≤ 2.5 kg is feasible and effective. The authors should be commended for providing important data on a challenging procedure in a very challenging patient population. Despite the relatively high risk of access-related complications, it is interesting that none of the patients who underwent axillary artery access had any complications related to this. Recognizing that this was one of the access sites used least frequently, further investigation as to whether the axillary artery may be a safer approach for this procedure is warranted. This study highlights the need for additional data to inform decision making around PDA stenting.

This article was originally published by The CHiP Network and can be view on the following site:

https://thechipnetwork.org/short-and-medium-term-outcomes-for-patent-ductus-arteriosus-stenting-in-neonates-%e2%89%a42-5-kg-with-duct-dependent-pulmonary-circulation/

KONSTANTIN AVERIN, MD
Catheterization Section Editor
Pediatric Cardiology Journal Watch
The CHiP Network
Glen Oaks, NY, USA

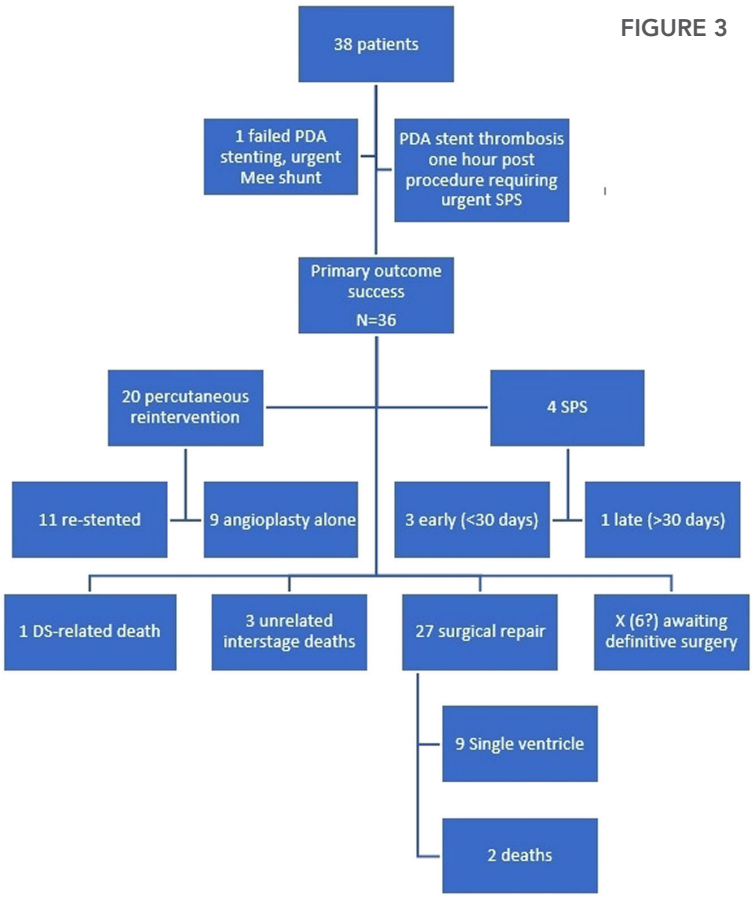

FIGURE 3

MaineHealth
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The Congenital Heart Program at Maine Medical Center provides comprehensive services including congenital heart surgery, interventional cardiology and invasive electrophysiology. Maine Medical Center has provided surgical care in the state for over 25 years and congenital interventional services for over 20 years. The Congenital Heart Program currently participates in STS, PC4, PAC3, CNOC, VPS, and IMPACT registries. Integrated across both the Pediatric and Cardiovascular Services Lines at the Barbara Bush Children's Hospital and Maine Medical Center, the Congenital Heart Program provides cohesive care across disciplines and collaborates closely with both pediatric and adult subspecialists.

Maine Medical Partners is Maine's largest multi-specialty medical group serving the healthcare needs of patients locally and throughout northern New England. This high quality team of 600+ physicians and 350+ advanced practice professionals provides a wide range of hospital based, primary, specialty, and sub-specialty adult and pediatric care delivered throughout a network of 54 locations across the State and acts as a regional referral network. Maine Medical Center has 700 licensed beds and is the state's leading tertiary care hospital and Level One Trauma Center, with a full complement of Residencies and Fellowships and an integral part of Tufts University Medical School.

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gina.mallozzi@mainehealth.org

Peak Oxygen Uptake on Cardiopulmonary Exercise Test is a Predictor for Severe Arrhythmic Events During Three-Year Follow-Up in Patients with Complex Congenital Heart Disease

Timothy Roberts, MD

Commentary from Dr. Timothy Roberts (Melbourne, Australia) on the following article:
Peak Oxygen Uptake on Cardiopulmonary Exercise Test Is a Predictor for Severe Arrhythmic Events during Three-Year Follow-Up in Patients with Complex Congenital Heart Disease
Von Sanden F, Ptushkina S, Hock J, Fritz C, Hörer J, Hessling G, Ewert P, Hager A, Wolf CM.J Cardiovasc Dev Dis. 2022 Jul 4;9(7):215. doi: 10.3390/jcdd9070215. PMID: 35877577

Take-Home Points

- Risk stratification for sudden cardiac death (SCD) and primary prevention ICD therapy in patients with complex Congenital Heart Disease is challenging.
- This single-centre retrospective study of 1194 patients with complex CHD evaluated the ability of a range of measurements collected during routine cardiopulmonary exercise testing (CPET) to aid in the risk assessment of SCD over a three-year follow-up period.
- Severe arrhythmia was documented in 97 patients (8.1 %/3 years), with independent risk factors being older age and low peak oxygen uptake (VO2peak) on multivariate analysis.
- The authors, thus, suggest considering age and VO2peak in the risk stratification of SCD and the individualized decision for primary prevention ICD implantation in patients with complex CHD.
- The data from this study has a number of limitations and will not result in a significant change in clinical practice, however it does endorse the large body of literature supporting the use of CPET in the overall risk stratification of patients with CHD.

Patients with complex CHD carry a lifetime elevated risk for severe arrhythmia and sudden cardiac death (SCD), with up to 26% of CHD deaths attributed to SCD. International guidelines specific to CHD patients and indications for primary prevention ICD are limited, and improving the risk stratification process is desperately needed.

Cardiopulmonary exercise testing (CPET) provides a well-established marker of cardiopulmonary function in children and adults with CHD and has not been mentioned in 2015 and 2020 guidelines as a tool for SCD risk stratification. The aim of this study was to evaluate measurements obtained during CPET as predictors for the occurrence of severe arrhythmias during a three-year follow-up.

The study design was that of a single-centre retrospective analysis of patients with complex CHD (univentricular heart, Ebstein's anomaly, Tetralogy of Fallot, truncus arteriosus communis, and transposition of the great arteries post arterial switch operation or Senning/Mustard procedure) undergoing CPET between 2009 and 2014. A symptom-limited customized ramped upright bicycle CPET protocol was used until exhaustion (respiratory exchange ratio > 1.0). The highest 30-second interval of oxygen uptake during exercise was defined as peak oxygen uptake (VO2peak). Data collected on the date of CPET were: demographics (age, gender, body mass index), VO2peak, anaerobic threshold (VO2at), ventilatory efficiency (VE/VCO2 slope), respiratory exchange ratio at peak exercise, and pulse oximetric saturation at peak exercise (SpO2max). Medical charts and available Holter recordings, ICD-, pacemaker- and event-recorder readings were reviewed within a follow-up time of three years after CPET. Systemic ventricular function by transthoracic echocardiography was added to the analysis if assessed within 12 months of the index CPET. Primary endpoint was survival without severe arrhythmia events (SAE), chiefly SCD, aborted SCD, appropriate ICD discharge, ICD anti-tachycardia pacing for VT, hospital admission for acute ventricular arrhythmia, cardiac syncope caused by ventricular arrhythmia, and the occurrence of non-sustained VT on Holter, event-recorder, pacemaker, or ICD recordings. Data analyses were performed using SPSS with appropriate statistical considerations. Univariate and backwards stepwise multivariable logistic regression models were used to identify parameters associated with SAE within three years. Time-to-event analysis was conducted via univariable and backwards stepwise multivariable Cox regression analysis. Receiver operating characteristic (ROC) analysis was used to evaluate the diagnostic ability of VO2peak to predict SAE.

In total, 1,194 patients (663 male) were included in the study. Median age was 25.9 years (IQR 17.4–34.6 years), median BMI was 22.4 (IQR 19.8–25.6) kg/m2. Underlying diagnosis was:

- Univentricular heart (UVH) in 205
- Ebstein's anomaly (EBS) in 135
- Tetralogy of Fallot (TOF) in 469
- Truncus arteriosus communis (TAC) in 51
- Transposition of the great arteries, arterial switch operation (TGA ASO) in 149
- Transposition of the great arteries, Senning/Mustard procedure (TGA SM) in 185

Transthoracic echocardiogram was available in 1,148 patients. Peak performance was reached by 1,075 patients during CPET. Three years of follow-up were completed in 1,101 patients (92.2 %). Holter recordings were available in 445 patients (38.1 %). During follow-up, ICD's were present in 42 patients, 145 patients had a pacemaker, and event-recorders were used in three patients; of these totals, 27 pacemakers and 17 ICDs were implanted during follow-up, including five ICD-upgrades to preexisting pacemakers. Twenty-seven patients (2.3 %) died during follow-up:

- SCD diagnosed in 2 patients
- Non-SCD in 16
- Unclear cause of death in 9

Severe arrhythmic events occurred in 97 of 1,194 patients (8.1 %), with no statistically significant differences found between the distinct anatomical groups. Non-sustained VT was the most frequent SAE, while sustained VT was documented in eight patients (**Table 2**).

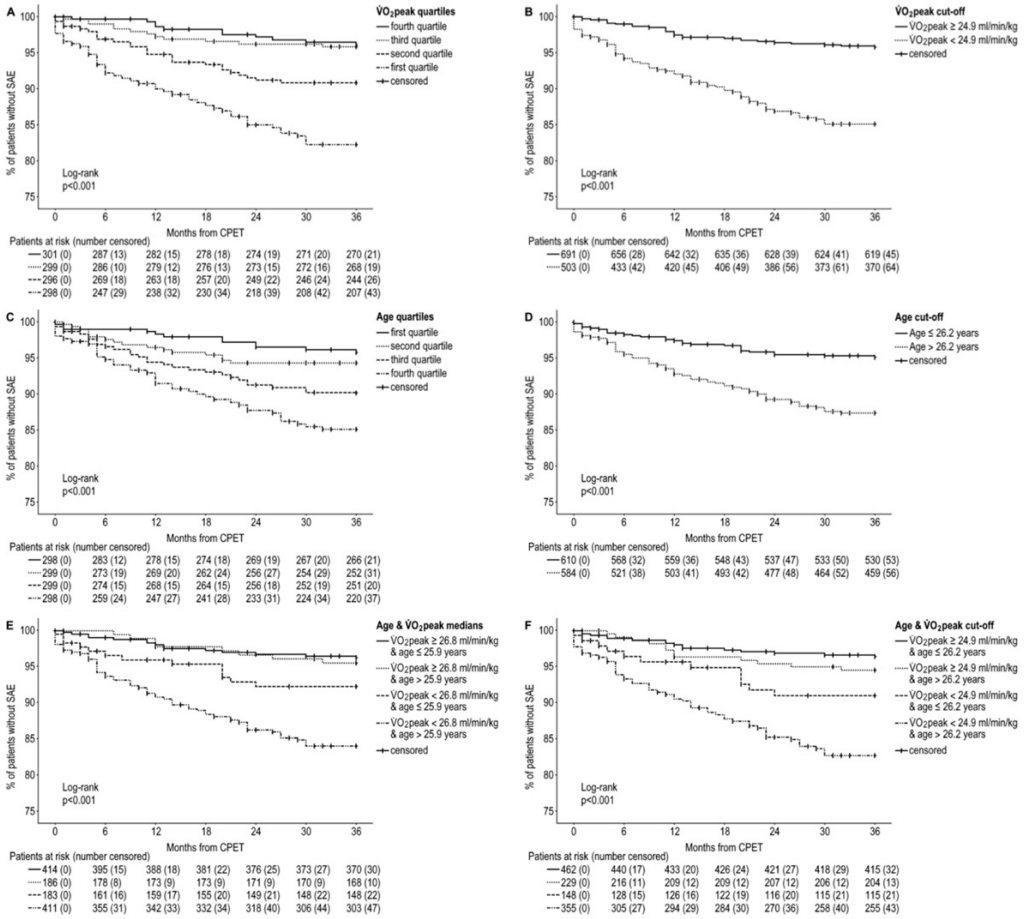

Figure 1. Kaplan–Meier SAE-free survival for $\dot{V}O_2$peak and age. (**A**) Kaplan–Meier SAE-free survival for quartiles of $\dot{V}O_2$peak, (**B**) Kaplan–Meier SAE-free survival for patients reaching or failing the ROC cut-off value for $\dot{V}O_2$peak (24.9 mL/min/kg), (**C**) Kaplan–Meier SAE-free survival for quartiles of age at CPET, (**D**) Kaplan–Meier SAE-free survival for patients exceeding or not exceeding the ROC cut-off value for age (26.2 years) at CPET, (**E**) Kaplan–Meier SAE-free survival separated by medians of age and $\dot{V}O_2$peak, (**F**) Kaplan–Meier SAE-free survival separated by ROC cut-off values for age at CPET (26.2 years) and $\dot{V}O_2$peak (24.9 mL/min/kg); SAE: Severe arrhythmic event, $\dot{V}O_2$peak: Peak oxygen uptake, ROC: Receiver operating characteristic, CPET: Cardiopulmonary exercise testing.

TABLE 2 *Clinical variables associated with SAE in multivariable analysis were age at CPET (OR, 1.029; 95 % CI, 1.00901.049; p=0.004) and VO2peak (OR, 0.951; 95 % CI, 0.921-0.982; p=0.002). VE/VCO2 slope, RERmax, SpO2max, gender, and type of CHD did not correlate significantly in the logistic regression model.*

ROC curve analysis identified VO2peak (AUC, 0.687; 95 % CI, 0.631-0.743; p < 0.001) and age (AUC, 0.659; 95 % CI, 0.602-0.715; p < 0.001) as independent predictors for SAE in CHD patients, with potential cut-off values for VO2peak at 24.9 ml/min/mg (Youden's Index, 0.318; sensitivity 0.702; specificity 0.616) and age at 26.2 years (YI, 0.242; sensitivity 0.711; specificity 0.531). Lower VO2peak values in the second and first quartiles were associated with a decrease in SAE-free survival (90.7% and 82.2%). Patients with VO2peak above the cut-off value of 24.9 ml/min/kg presented with more frequent 3-year survival without SAE than patients with lower VO2peak than cut-off (95.8% vs. 85.1%). Age above the cutoff value of 26.2 years led to less frequent 3-year survival without SAE (87.4% vs. 95.1%).

Table 2. Occurrence of severe arrhythmic events (total and separated in CHD groups).

[n/N[%]]	Total	UVH	EBS	TOF	TAC	TGA ASO	TGA SM	*p*-Value
Severe arrhythmic event	97/1194(8.1)	18/205(8.8)	15/135(11.1)	41/469(8.7)	1/51(2.0)	8/149(5.4)	14/185(7.6)	0.291 [χ^2]
SCD equivalent	15/1194(1.3)	2/205(1.0)	3/135(2.2)	8/469(1.7)	0/51(0.0)	1/149(0.7)	1/185(0.5)	0.588 [χ^2]
SCD	2/1194(0.2)	0/205(0.0)	1/135(0.7)	1/469(0.2)	0/51(0.0)	0/148(0.0)	0/186(0.0)	0.593 [χ^2]
Aborted SCD	6/1194(0.5)	1/205(0.5)	1/135(0.7)	2/169(0.4)	0/51(0.0)	1/149(0.7)	1/185(0.5)	0.990 [χ^2]
ICD-ATP	8/1194(0.7)	2/205(1.0)	1/135(0.7)	5/469(1.1)	0/51(0.0)	0/149(0.0)	0/185(0.0)	0.549 [χ^2]
Appropriate ICD-discharge	6/1194(0.5)	1/205(0.5)	1/135(0.7)	4/469(0.9)	0/51(0.0)	0/149(0.0)	0/185(0.0)	0.661 [χ^2]
Hospitalisation/Syncope	21/1194(1.8)	2/205(1.0)	2/135(1.5)	13/469(2.8)	0/51(0.0)	2/149(1.3)	2/185(1.1)	0.400 [χ^2]
Hospitalisation	11/1194(0.9)	1/205(0.5)	1/135(0.7)	7/469(1.5)	0/51(0.0)	1/149(0.7)	1/185(0.5)	0.697 [χ^2]
Syncope	14/1194(1.2)	1/205(0.5)	2/135(1.5)	8/469(1.7)	0/51(0.0)	1/149(0.7)	2/185(1.1)	0.695 [χ^2]
sVT/nsVT in device	83/1194(7.0)	17/205(8.3)	12/135(8.9)	33/469(7.0)	1/51(2.0)	7/149(4.7)	13/185(7.0)	0.481 [χ^2]
sVT in device	8/1194(0.7)	2/205(1.0)	1/135(0.7)	4/469(0.9)	0/51(0.0)	0/149(0.0)	1/185(0.5)	0.859 [χ^2]
nsVT in device	82/1194(6.9)	17/205(8.3)	12/135(8.9)	32/469(6.8)	1/51(2.0)	7/149(4.7)	13/185(7.0)	0.475 [χ^2]

CHD: Congenital heart disease, UVH: Univentricular heart, EBS: Ebstein's disease, TOF: Tetralogy of Fallot, TAC: Truncus arteriosus communis, TGA: Transposition of the great arteries, ASO: Arterial switch operation, SM: Senning/Mustard, SCD: Sudden cardiac death, ICD: Implantable cardioverter defibrillator, ATP: Antitachycardia pacing, sVT: Sustained Ventricular Tachycardia, nsVT: Non-sustained ventricular Tachycardia, device:

This article was originally published by The CHiP Network and can be view on the following site:
https://thechipnetwork.org/peak-oxygen-uptake-on-cardiopulmonary-exercise-test-is-a-predictor-for-severe-arrhythmic-events-during-three-year-follow-up-in-patients-with-complex-congenital-heart-disease/

TIMOTHY ROBERTS, MD
Section Editor
ACHD Journal Watch
The CHiP Network
Melbourne, Australia

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Congenital Heart Surgeon

Primary Purpose of Organizational Unit
The UNC School of Medicine has a rich tradition of excellence and care. Our mission is to improve the health and wellbeing of North Carolinians, and others whom we serve. We accomplish this by providing leadership and excellence in the interrelated areas of patient care, education, and research. We strive to promote faculty, staff, and learner development in a diverse, respectful environment where our colleagues demonstrate professionalism, enhance learning, and create personal and professional sustainability. We optimize our partnership with the UNC Health System through close collaboration and commitment to service.

OUR VISION
Our vision is to be the nation's leading public school of medicine. We are ranked 2nd in primary care education among all US schools of medicine and 5th among public peers in NIH research funding. Our Allied Health Department is home to five top-ranked divisions, and we are home to 18 top-ranked clinical and basic science departments in NIH research funding.

OUR MISSION
Our mission is to improve the health and well-being of North Carolinians and others whom we serve. We accomplish this by providing leadership and excellence in the interrelated areas of patient care, education, and research.

> ***Patient Care:*** We will promote health and provide superb clinical care while maintaining our strong tradition of reaching underserved populations and reducing health disparities across North Carolina and beyond.
>
> ***Education:*** We will prepare tomorrow's health care professionals and biomedical researchers by facilitating learning within innovative curricula and team-oriented interprofessional education. We will cultivate outstanding teaching and research faculty, and we will recruit outstanding students and trainees from highly diverse backgrounds to create a socially responsible, highly skilled workforce.
>
> ***Research:*** We will develop and support a rich array of outstanding health sciences research programs, centers, and resources. We will provide infrastructure and opportunities for collaboration among disciplines throughout and beyond our University to support outstanding research. We will foster programs in the areas of basic, translational, mechanistic, and population research.

Position Summary
The Department of Surgery at The University of North Carolina is seeking applications for a full-time academic congenital heart surgeon to join our Division of Cardiothoracic Surgery. The Division of Cardiothoracic Surgery is among 9 clinical Divisions in the Department of Surgery. The Division currently includes 7 faculty members that provide exceptional care to patients from across the state of North Carolina. Academic appointment will be commensurate with the candidate's experience.

The ideal candidate will be mid to late career with a proven track record and requisite experience in all aspects of congenital cardiac surgery. The chosen candidate will be expected to work closely with the current Section Chief of Congenital Cardiac Surgery. The breadth of responsibilities will include neonatal cardiac surgery, pediatric heart failure, transplantation, ECMO, and adult congenital surgery. Preference will be given to individuals who bring unique skills, interests or qualifications to the current faculty in a complementary fashion. Individuals with a strong interest in research are encouraged to apply. Faculty members within the Division of Cardiothoracic Surgery must possess a desire to commit to all three mission of the department and school of medicine, including the clinical, education, and research missions. Regarding the education mission, faculty members are expected to regularly participate in the education of medical students, residents, and fellows. Regarding research, a commitment to any one of a broad array of research interests is desirable, including but not limited to clinical, outcomes, health services, basic science, translational, ethics, education, or global surgery research. Regarding the clinical mission, faculty members must be committed to delivering high quality clinical care that is of value to the patients of UNC. Selected candidate must be team-oriented and have the ability to interact well with colleagues inside and out of the Division.

Minimum Education and Experience Requirements
Prospective candidates must be Board Certified/Board Eligible or Equivalent in Thoracic Surgery and in Congenital Cardiac Surgery.

Preferred Qualifications, Competencies, and Experience
Completion of an ACGME approved Cardiothoracic Surgery Residency and Congenital Cardiac Surgery fellowship is preferred. Chosen candidate should either have a current North Carolina Medical License or be eligible for application.

Please apply online at https://unc.peopleadmin.com/postings/234256

The University of North Carolina at Chapel Hill is an equal opportunity and affirmative action employer. All qualified applicants will receive consideration for employment without regard to age, color, disability, gender, gender expression, gender identity, genetic information, national origin, race, religion, sex, sexual orientation, or status as a protected veteran.

Res Cordis et Mentis: Peccatum Omissionis

Neil Wilson, MBBS, DCH, FRCPCH, FSCAI

In 1995, perhaps, 1996, at the Royal Hospital For Sick Children in Glasgow, Scotland. An interesting name for a hospital as an American friend once teased me. "So, do you have hospitals for well children in Scotland too"? Good point.

Wednesday morning outpatient clinic was quite busy with 18 patients booked. No fellow, third-year medical student. We'd been enjoying the clinical signs and repartee, and with plenty of outstanding experienced echo tech support, things were moving smoothly. It's about 9.30am. In comes Jamie, a chubby nine-month-old baby boy, accompanied by his mom.

I had seen Jamie three months earlier. He was referred then by his family practitioner because of a heart murmur and some (insignificant as I thought) episodes of pallor and screaming. He was pink, and too lively to tolerate the pulse oximeter for a meaningful reading. I wasn't concerned about a cyanotic lesion. Sure enough, he had widespread systolic murmurs throughout the precordium and well heard into the back. EKG wasn't the best quality, perhaps debatable right ventricular hypertrophy with a splintered rSr pattern. Echo, well, no way was Jamie going to entertain that notion though we did see enough to confirm normal situs and connections and no major structural intracardiac lesions. Main pulmonary artery debatably small. I settled on a clinical diagnosis of bilateral branch pulmonary artery stenosis. He was indisputably well. Growth well up the centile charts. I wasn't going to sedate him, but was confident we'd get better pictures in a few months time. So here we are…

Jamie, still chubby, now nine-months-old. Mom still relating these episodes of him becoming upset, pale and then settling down in a matter of minutes. He's in great shape sitting on mom's knee, very cooperative, clinical signs pink with saturations 94-95%. Active precordium, perhaps I could convince myself of a precordial heave, but we'll see. Widespread systolic murmurs as before. He's engaging and cooperative and in good shape for an EKG which unequivocally shows right axis deviation. Echo, he's a sweetheart on mom's lap. Excellent pictures. Right atrium and ventricle are unequivocally dilated, atrial septum is intact; in fact, I'd say a whiff of right to left through a PFO. Main pulmonary artery is small, we can see small branches too and the colour Doppler signal lights up with aliasing flow like the lungs are on fire. Tricuspid regurgitation is trivial to mild, not the best waveform but Doppler predicts more than 4 m/sec. I am immediately concerned about the episodes of pallor and screaming he'd had, which I had not hitherto felt relevant. I'm thinking RV ischaemia. Now longish chat with mom, complete with a hasty pencil sketch of a normal heart and side by side a drawing of what I thought was going on in Jamie's. I explain the rationale for admission right now and procedure of cardiac catheterisation the following day, "To get some more information about how severe these lung artery narrowings are." "Will he need an operation doctor?" asks mom. "Possibly," I responded, "but we'll have a better idea after the catheter test tomorrow."

Jamie and mom head directly from outpatients to the ward with Kate, the specialist cardiac nurse. I carry on with the clinic, dictate the letters and helped my student carry the enormous pile of 18 case notes to the secretary office. We walk up the five flights of stairs to the ward (it was in my running days). And there's Jamie on his mom's knee hoovering down an off yellow sludge of banana something. Both look settled and happy. I reward the student with lunch and spend the afternoon fiddling about with a presentation I am due to give at the Scottish Cardiac Society the coming weekend. I've got Jamie on my mind, he's fourth on the list tomorrow. I go down to the echo department and review the images of the following day's catheter cases. I can't see anything different with Jamie's pictures, but start thinking he might be a candidate for stents which are just beginning to take off in the congenital heart intervention armamentarium. I had done a handful of cases of branch pulmonary artery stents but in much bigger patients.

Sign out round about 6:15pm. Jamie is sitting in his cot chewing at a blue and red plastic toy. Happy enough, nothing to report. No mom to be seen. Nurse says "Mom left just after admission, I suppose she's gone home to see Jamie's older sister say hello and explain things to dad". Fair enough, understandable, she'll no doubt be back.

Not sure what I had for dinner that evening. I spent the post-prandial time irritating the kids about homework, pleading them to tidy bedrooms, the usual stuff.

9.15pm, the phone rings. "Dr. Wilson, the baby you admitted from outpatients has arrested, the crash team (code team) are with him." I'm in the car speeding and feeling sick, "What the hell is going on, what have I done wrong?" Twenty minutes later I'm at the bedside. He's intubated, pulse oximeter is not reading. CPR looks effective though Jamie's body is grey, white, monitor shows electrical asystole. Empty glass ampoules of various drugs litter the mattress. We carry on with the CPR, more adrenaline, calcium etc, etc. We get an agonal rhythm eventually but can't get output. Forty minutes on I ask, "Where's mom?" "She's in the parent room at the end of the ward, she was with him when he started to get agitated and went pale and arrested." Another ten minutes, no output, back to asystole on EKG. Pupils are enormous and unresponsive. These are the days before available resuscitative ECMO. The anaesthesiologist eyes me and looks away. I read her mind, and indeed the minds of the rest of the team. "I think we should stop. OK? He's not coming back." I ask the team to continue CPR and I peel off to speak to mom adding that we'll stop after I had spoken to her. I get about halfway to the parent room from which I can hear loud distressed crying. A nurse hurries up from behind me. "Doctor Wilson, you probably ought to know, Mom's dad had a heart attack and died in the Western Infirmary (Adult hospital 400 yards across the road) this afternoon." Oh hell. Mom knows what's coming. Second time today. I can hardly get my words out. She's

now on the floor, face down distraught and almost screaming her tears. A slightly younger looking woman is beside her, kneeling, sobbing too and trying to get her arms round her sister. I can't stop saying, "I am so sorry, I am so sorry," though I am sure my words can't be heard through the crying. You can imagine what's going through my mind. Why didn't I sedate him for echo when I saw him for the first time three months ago? If I had, I might have catheterised him then, organised treatment and saved his life. Why did I ignore the potential significance of the episodes of agitations, crying, etc? Find me a six-month-old baby who doesn't appear to get upset for no reason… I am trying to rationalise to make myself feel better, but it doesn't work. After about 30 minutes, Mom and sister leave the parent room and come into the ward. More intense crying, then a moment of silence from both. Mom reaches into the cot and picks up her baby, her tears dropping on to her son's face as she rocks him, "Oh mah wee man, whit's all this aboot? First yer grandad now you…"

Post Script

Jamie's post mortem showed severe dilation and hypertrophy of the right ventricle with evidence of subendocardial ischaemia. He had a small main pulmonary artery with extensive bilateral branch pulmonary artery narrowings well beyond the hila, some arteries almost atretic. Liver normal macro and microscopically. Chromosomes…Normal.

NEIL WILSON, MBBS, DCH, FRCPCH, FSCAI
Formerly Professor of Pediatrics
University of Colorado School of Medicine
Formerly Director Cardiac Catheter Laboratory
Children's Hospital Colorado
Colorado, USA

SEPTEMBER

08TH - 09TH

2023WPC – 2023 World Pediatric Conference
Singapore
https://pediatrics.episirus.org/

21ST- 23RD

2023 Midwest Pediatric Cardiology Society Meeting and CV Ultrasound Conference
Cincinnati, Ohio, USA
book.passkey.com/event/50489874/owner/1475/home?utm_source=MC&utm_medium=email&utm_campaign=

25TH - 26TH

CME HeartCare and Cardiovascular Medicine Cardiac Surgery
Paris, France
https://heart.plenareno.com/

OCTOBER

06TH - 08TH

CSI Asia-Pacific 2023
Bangkok, Thailand
https://www.csi-congress.org/asia-pacific

28TH

13th Annual UCLA Fetal Echocardiography Symposium
Westwood, California, USA
https://events.medschool.ucla.edu/event/fetalcardiac23

COLUMBIA UNIVERSITY

Pediatric Cardiologist – Noninvasive Imaging
Assistant Professor

THE OPPORTUNITY

This opportunity to join the **Department of Pediatrics at the Vagelos College of Physicians and Surgeons** at the rank of **Assistant Professor** is an exciting one. Columbia University Irving Medical Center, one of the nation's foremost academic health science centers working together with one of the nation's premier health systems, New York-Presbyterian Hospital. **https://www.pediatrics.columbia.edu/**

The Division of Pediatric Cardiology at the Columbia University Irving Medical Center and Morgan Stanley Children's Hospital of New York-Presbyterian seeks a full-time pediatric cardiologist to serve as Noninvasive Imaging Cardiologist. The successful applicant will become a full-time faculty in the Department of Pediatrics at the academic rank of Assistant Professor. Proposed academic rank will be commensurate with training and experience. The desired candidate has clinical and research experience in 2D/3D echocardiography, procedural imaging, advanced functional analysis and quality improvement to lead a high-volume academic noninvasive imaging laboratory. Expertise in fetal echocardiography and/or cardiac MR/CT is desirable but not a pre-requisite. Candidates must be board certified or eligible in Pediatric Cardiology.

The New York Presbyterian Pediatric Heart Program (joint with Cornell University) is ranked among the nation's top cardiology & heart surgery programs by US News & World Report. Our training program includes 15 general cardiology fellows and 2 advanced training fellows with plans for a permanent 4th year advanced imaging position. Our combined surgical program treats patients with the highest disease complexity.

The Pediatric Non-Invasive Imaging Laboratory at Columbia University Irving Medical center is one of the largest imaging programs for children with congenital heart disease in the United States, with over 15,000 echocardiograms performed annually. The section includes 11 full-time and 7 part-time pediatric cardiologist imagers. Activities include fetal cardiology, transesophageal echocardiography, cardiac magnetic resonance and cardiac computed tomography.

KEY RESPONSIBILITIES

Responsibilities include fetal echocardiography in addition to reading transthoracic echoes and performing/reading transesophageal studies. Provides all aspects of care and consultation, direct and indirect, to this complex patient population. Attend patient rounds and complete consultation and inpatient notes as well as conference preparation and on-call duties. Engage with referring providers and families to assure that the needs of patients and families are being met. Serve as a role model to trainees, colleagues and staff, and provide behavioral based feedback to team members as needed.

Additional clinical responsibilities the appropriate coordination and integration with other services in the care of their patients. Seek opportunities to become actively involved in scientific investigation. Participate and contribute to quality improvement projects and/or curriculum development. Support cardiac clinical educational programs for nursing, medical students, residents, fellows, ancillary staff, and ARNPs, etc.

PROFESSIONAL EXPERIENCE/QUALIFICATIONS

- Must have a MD or DO degree and an active NYS Medical License
- Must be Board certification in Pediatric Cardiology or an equivalent board certification with a fourth-year additional training at an accredited ACGME institution in Non-Invasive Imaging

COMPENSATION

Compensation arrangements are competitive and commensurate with both experience and achievement.

COMMITMENT OF DIVERSITY

Columbia University is an Equal Opportunity/Affirmative Action Employer and Educator. The University is dedicated to the goal of building a culturally diverse and pluralistic faculty and staff committed to teaching and working in a diverse environment, and strongly encourages applications from women, minorities, individuals with disabilities, and veterans.

Columbia University welcomes applications from individuals who may have had nontraditional career paths, or who may have taken time off for family reasons (e.g. children, caring for disabled or elderly family), or who have achieved excellence in careers outside of academia (e.g., in professional or industry service). The University is responsive to the needs of dual career couples and is committed to supporting the work-life balance of its faculty. We are interested in candidates who have a record of success advising and mentoring individuals from groups underrepresented in higher education and is particularly interested in candidates who have research interests in subjects that will contribute to the understanding of diversity and equal opportunity.

To apply, please visit: http://apply.interfolio.com/130680

CareDx's HeartCare Multimodality Service Receives Medicare Coverage for Heart Transplant Surveillance

HeartCare Combines Testing Using Both AlloMap Gene Expression Profiling and AlloSure Donor-Derived Cell-Free DNA

CareDx, Inc. (Nasdaq: CDNA), a leading precision medicine company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers – today announced Medicare coverage for HeartCare, a multimodality testing service that includes both AlloMap® Heart and AlloSure® Heart, in a given patient encounter, for heart transplant surveillance. Coverage is effective April 1, 2023. AlloMap Heart and AlloSure Heart are also covered by Medicare individually.

"Today is a major milestone for heart transplant care and for the use of multimodality technologies to improve patient outcomes with HeartCare," said Reg Seeto, CEO and President of CareDx. "I could not be prouder of our organization's unwavering commitment to serving patients and leading transplant innovation. I want to thank MolDX for recognizing the critical clinical value of multimodality in heart transplant surveillance."

"Medicare's coverage of HeartCare reflects the growing scientific evidence supporting its use for routine graft surveillance in lieu of a biopsy. We have witnessed a significant reduction in the need for endomyocardial biopsies in our clinical practice by incorporating paired testing with AlloMap and AlloSure, which provides complementary information about allograft health," said Jeffrey Teuteberg, MD, Professor of Medicine, Section Chief of Heart Failure, Cardiac Transplantation, and Mechanical Circulatory Support, Stanford University.

Studies showed that multimodal testing with HeartCare, including both AlloMap and AlloSure, dramatically reduced dependency on endomyocardial biopsies (EMBs).[1,2] These publications showed a reduction in biopsies with HeartCare when compared to prior use of an AlloMap-only protocol, without impacting outcomes.[1,2] These studies also showed that when using HeartCare, a negative AlloMap result that accompanied a positive AlloSure result was associated with fewer biopsies than if every AlloSure result above threshold led to a biopsy.[1,2] When both tests were negative, 99.5% of biopsies were deferred.[1,2]

"Since the introductions of AlloMap gene expression profiling and AlloSure donor-derived cell-free DNA, followed by their subsequent incorporation in ISHLT guidelines, we've seen widespread adoption of these noninvasive testing services at leading heart transplant centers in the U.S.," said Eugene DePasquale, MD, Medical Director, Heart Transplant Program, Keck Medicine, USC. "The additive value of both biomarkers will lead to a new standard of care, from routine endomyocardial biopsies to noninvasive surveillance, using HeartCare as a robust strategy for the surveillance of heart transplant recipients."

The use of HeartCare has been supported by the new International Society for Heart and Lung Transplantation (ISHLT) guidelines recommending the use of AlloMap gene expression profiling (GEP) and donor-derived cell-free DNA (dd-cfDNA), as in AlloSure, in routine heart transplant surveillance: AlloMap has been in the ISHLT guidelines since 2010 and both in the 2022 update.[3] In a guide published in the Journal of the American College of Cardiology: Heart Failure, the transition from routine invasive EMBs to a less invasive acute rejection monitoring protocol was described for clinicians.[4]

AlloMap became commercially available in 2005 and has the distinction of being the only gene expression profiling test that has been FDA cleared for use in heart transplant patients.[5] In 2020, CareDx launched HeartCare, which includes both AlloMap GEP and AlloSure dd-cfDNA, to provide a comprehensive view of organ rejection by assessing immune quiescence and graft injury. HeartCare is currently used in over one in two newly-transplanted patients and in over 90% of heart transplant centers in the U.S.[5]

AlloMap Heart, AlloSure Heart, and HeartCare are covered by Medicare under MolDX LCD L38568 and will be listed on the Palmetto GBA Dex Exchange. HeartCare is covered for the first year, starting two months post-transplant.

For more information, please visit: CareDx.com.

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