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Syncope and Adolescent Dysautonomia

Claire R. Galvin, HBSc; Kathryn R. Armstrong, MB, ChB; Shubhayan Sanatani, MD, FRCP

Introduction

Syncope is defined as a transient loss of consciousness associated with an inability to maintain postural tone which is followed by a spontaneous or rapid recovery.^{1,2} The cumulative incidence of syncope by 60 years of age is reported to be 30%-40%.^{2,3} Incidence of syncope increases in adolescence.⁴ The age of first faint is typically reported to be around 13 years of age.⁵ In children and adolescents, the most common form of syncope is called vasovagal syncope (VVS) due to a transient dysfunction of the autonomic nervous system (ANS).²

While VVS is the most common form of syncope in children and adolescents, it is important to evaluate whether there are any underlying features that would indicate the presence of a cardiac cause.⁶ Cardiac or neurologic syncope have more serious implications for patient health and outcomes. Cardiac syncope is caused by heart conditions including conditions categorized by electrical disturbances or structural heart disease.⁶ Classification of cardiac causes are found in **Table 1**. Neurologic syncope causes include seizures and narcolepsy.⁶

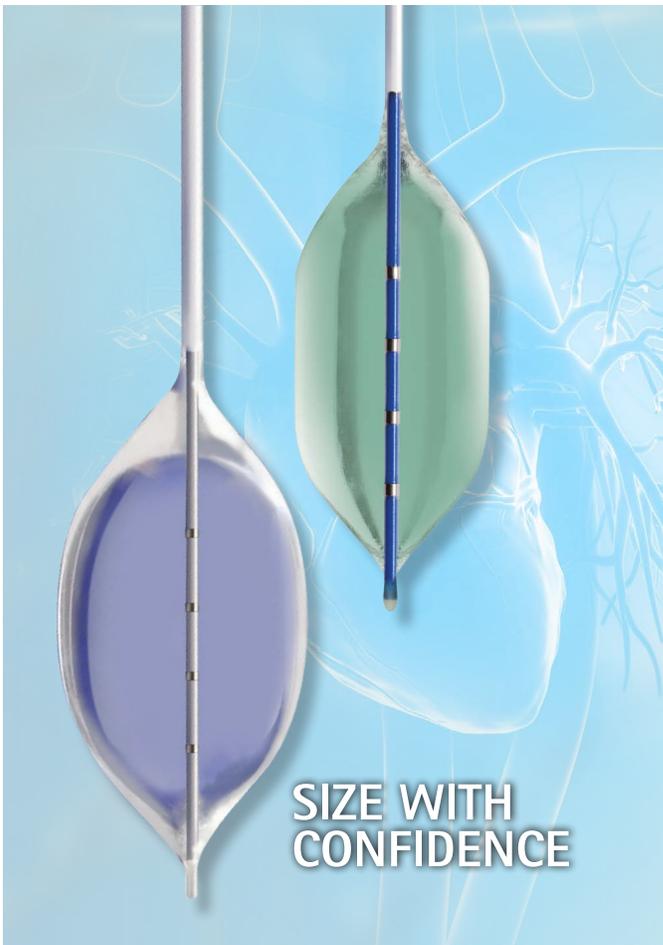
TABLE 1 Examples of Cardiac Causes of Syncope⁵

Cardiac Causes of Syncope	Examples
Arrhythmia	Long QT Syndrome
	Short QT Syndrome
	Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT)
	Burgada Syndrome
	Wolff-Parkinson-White Syndrome
Structural	Hypertrophic Cardiomyopathy
	Acute Myocarditis
	Arrhythmogenic Right Ventricular Cardiomyopathy
	Coronary Artery Anomalies
	Valvular Aortic Stenosis
	Pulmonary Hypertension

The most important diagnostic tool for syncope evaluation is patient history. The presence of a prodrome such as vision change, clammy skin, and dizziness as well as an unremarkable physical exam and family history suggest VVS with no further investigations needed.⁶ The absence of a prodrome prompts further clinical evaluation as it is an indication of cardiac causes. A patient with a family history of sudden death, arrhythmias, seizures, structural heart disease, or an abnormal

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TABLE 2 Syncope Diagnostic Tools

	Vasovagal Syncope	Concerning Features - Suggestive of Cardiac Causes
Prodrome	Present	Absent
Triggering Event	Inadequate hydration, overexertion without proper nutrition, environment (warm, crowded), phlebotomy	Swimming, physical exertion, loud noise, no potential triggering event
Loss of Consciousness	< 1-2 minutes	> 5 minutes
Supine or Standing Prior to Event	Standing	Supine or standing
Physical Exam	Unremarkable	Abnormal cardiac exam
Family History	Unremarkable	Family history of sudden death, structural heart disease, arrhythmias, seizures

cardiac examination should prompt further investigations by a syncope specialist.⁶ While these types of syncope are less common, they are important to distinguish from VVS as they may represent an underlying cardiac or neurologic cause. The underlying cause of VVS is due to a transient dysfunction of the ANS. Heart rate and blood pressure regulated by the ANS decreases suddenly, which causes a reduction in blood flow to the brain leading to loss of consciousness. Loss of consciousness can be mediated with patient education on presyncopal prodromes as well as potential triggers, and adequate hydration.^{6,7} A concise list of important factors in syncopal evaluation is found in **Table 2**.

Although vasovagal syncope is a transient occurrence, some children and adolescents will progress to a condition termed Dysautonomia of Adolescence (DAOA). DAOA is a dysregulation of the ANS that primarily affects adolescents during the pubertal growth and development period. Syncope is one of many symptoms experienced by children and adolescents caused by ANS dysfunction. The mechanism for ANS dysfunction is unknown but may be associated with hormonal changes, stress, illness or trauma (such as concussions).⁸ In addition to syncope and presyncope, adolescents may present with symptoms such as dizziness, palpitations, musculoskeletal pain, gastrointestinal pain, headaches, fatigue, and nausea. A hallmark of DAOA is the pervasive nature of the symptoms.

TABLE 3 Common Reported DAOA Symptoms

Symptom Categories	Commonly Reported
Cardiac	Palpitations, chest pain or tightness
Neurologic	Syncope, presyncope, brain fog
Musculoskeletal	Aches and pains, painful trigger points
Gastrointestinal	Nausea, vomiting, constipation
Skin	Cold extremities, heat or cold intolerance
Energy/Activity	Fatigue, sleep disturbance, exercise intolerance

While DAOA is a transient condition typically improving as adolescents complete the rapid growth phase of their pubertal years, it is important to support those affected as symptoms can be so debilitating adolescents withdraw from school, sport, and social activities, which may lead to a low quality of life and social isolation.^{9,10}

Diagnosis of DAOA

Characteristics of DAOA may typically present around the onset of puberty, and have overlapping features of conditions such as fibromyalgia, chronic fatigue syndrome, postural orthostatic intolerance, and orthostatic intolerance. Typical symptoms reported by adolescents are found in **Table 3**. Similar to a syncopal diagnosis, a thorough patient history is the best diagnostic criteria for DAOA. In addition to a comprehensive history of the patient, the DAOA diagnosis is made on the basis of (i) no underlying pathological disease to account for symptoms; (ii) symptoms affecting at least two or more organ systems; and (iii) significant interference with the activities of daily living including poor school attendance and withdrawal from sports participation.⁹

The Dysautonomia Clinic at British Columbia Children’s Hospital (BCCH) was established to provide care to the pediatric dysautonomia population. The Clinic is supported by a multi-disciplinary team which includes: a pediatric cardiologist, nurse clinician, clinical exercise physiologist, and clinical psychologist. Each clinic appointment consists of a physical exam and comprehensive history, and an exercise stress test with 12-lead ECG¹¹ including a consultation with the clinical exercise physiologist. The exercise stress test is used to measure exercise capacity as well as rule out underlying cardiac conditions. Unless otherwise indicated by the exercise stress test, an echocardiogram is not performed. If necessary, adolescents participate in a session with the clinical psychologist as part of their clinical care.

Consistent with our population, previous studies report many adolescents with ANS dysfunctions see multiple specialists before their diagnosis is made, and undergo a variety of unnecessary tests due to the wide range of symptoms experienced in multiple organ

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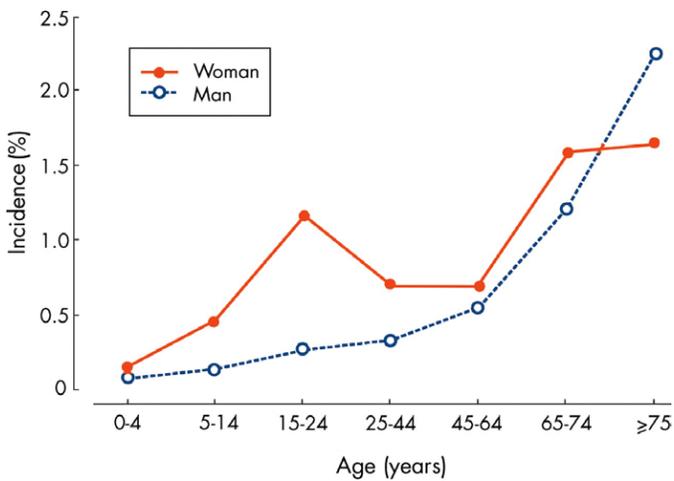


FIGURE 1 Prevalence of syncope-related health care visits.⁴
 Image obtained from: <https://europe.medtronic.com/content/dam/medtronic-com/xd-en/hcp/documents/Diagnostics/syncope-therapy-awareness-presentation.pdf>

systems.¹² The average age of adolescents diagnosed with DAOA in the clinic is 15.7 years, with adolescents reporting a mean symptom duration of two years prior to receiving their diagnosis. Contributing factors such as hormones, growth, and stress are prevalent during this time in adolescents development and have been linked to increased susceptibility to ANS dysfunction.¹³

Treatment Recommendations

Pharmacological treatments for symptoms associated with DAOA have mixed evidence of symptom relief and are difficult to prescribe for this population because of the variety of symptoms caused by ANS dysfunction.^{10,14,15} The approach to DAOA treatment is holistic and includes multidisciplinary lifestyle changes. Fluctuations in symptoms over time are common, thus it is essential for patients to maintain stable and consistent lifestyle habits to avoid unnecessary symptom flair-ups. Through consistent lifestyle changes, the holistic approach allows patients to learn to manage their symptoms. Recommendations for children and adolescents affected by DAOA include drinking 2-3L of fluid per day, increasing salt intake to ½ teaspoon per day, participating in a lower-body strength training program,⁹ and supporting the patient's mental health as they navigate through their adolescent years into adulthood. In addition, advice is given on sleep hygiene and food intake.

Syncope and dizziness are common complaints among the DAOA population. Increasing fluid and salt is essential for these patients as it has previously been shown to decrease recurrent syncopal episodes as well as aid in improving volume dysregulation.¹⁶⁻¹⁹ The inclusion of lower-body strength training helps a patient's increase blood volume, hemoglobin mass, and has been shown to improve QoL and improve exercise performance.^{20,21} Exercises recommended to DAOA patients include isometric and isotonic movements, specifically step-ups, planks, squats, and forward lunges.⁹ The Dysautonomia Clinic has previously demonstrated the inclusion of these exercises in the form of an eight-week strength

training program reducing symptom burden and significantly improves QoL of patients.⁹ Psychological support for DAOA patients is essential to improve overall well-being and mental health. Adolescents with symptoms present with low QoL, high symptom burdens, and may experience isolation in the form of low school attendance and sport participation.^{9,10,22} Common symptoms experienced by patients have been shown to negatively affect depression levels, anxiety levels, QoL, and increase distress.^{23,24} Sleep and sleep quality may also be affected by high symptom burdens. Thus, advice is given to adolescents to maintain healthy sleep patterns, such as consistent bedtimes and wake-up times to form a regular sleep cycle, and allow them to function normally throughout the day, eventually leading to increased school attendance. Many DAOA patients report symptoms of nausea and vomiting, especially in the morning. Our group advises patients to have smaller, more frequent meals throughout the day in an effort to decrease nausea while maintaining proper nutrition.

Syncope may be one of the first presenting symptoms for adolescents and further appraisal of non-syncope related symptoms may help make a patient's dysautonomia diagnosis earlier.¹² It is important for those caring for patients with syncope and presyncope to carefully consider if this transient loss of consciousness is vasovagal in nature, has a cardiac or neurologic cause, or whether the patient is experiencing DAOA in order to provide the best possible care.

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Cardiovascular Magnetic Resonance in Myocarditis Related to Multisystem Inflammatory Syndrome in Children Associated with COVID-19

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Cardiac involvement, including myocarditis, has been reported in patients with Multisystem Inflammatory Syndrome in Children (MIS-C) temporally associated with the Coronavirus Disease 2019 (COVID-19).¹ The pathophysiology of myocarditis in these children remains unclear. Cardiovascular magnetic resonance (CMR) has the unique potential to evaluate tissue changes in these patients, but scheduling a CMR examination in the acute phase of the illness with the risk of unnecessary exposure to others is often challenging. CMR data on these children is, hence, limited so far.² We performed CMR examinations in children with MIS-C associated with COVID-19 by following a specific protocol that enabled us to obtain important CMR findings.

Between April 20th and June 20th, 2020, 32 children were diagnosed with MIS-C at Maria Fareri Children's Hospital at Westchester Medical Center, a Level 1 Trauma and Tertiary Care Center, in Westchester County, New York. Nine children and adolescents were identified to have clinically suspected myocarditis based on their clinical presentation, abnormal cardiac enzymes and evidence of ventricular dysfunction on echocardiogram. Five of these patients, who were older and were assessed to not require sedation, had CMR examination to confirm the diagnosis. Following the infection control guidelines of our hospital, we developed a specific protocol, which involved performing CMR examinations on these patients as the last case of the day, typically at night, with only the pediatric CMR physician and the technologist being present for the study. Studies were performed using a 1.5T CMR system (Philips Achieva). The CMR protocol included: balanced steady-state free precession (SSFP) cine imaging, T2-weighted short tau inversion recovery (T2-STIR), native T1 mapping, T2 mapping, First-pass perfusion imaging (FPP), T1-weighted imaging precontrast and postcontrast for early gadolinium enhancement (EGE) and

late gadolinium enhancement (LGE) imaging 10 minutes after gadolinium administration. Two experienced CMR physicians reviewed the CMR findings on the five patients independently. This report was granted an exemption status by the Institutional Independent Review Board (IRB).

On echocardiogram at presentation, the patients had severe-mild left ventricular dysfunction (EF: 25%-50%). They all had evidence of current/recent Severe Acute Respiratory Syndrome coronavirus 2 (SARS-COV-2) infection/exposure (three patients were both nasopharyngeal SARS-COV-2 RT PCR + and serum IgG +, while two were serum IgG +). They had elevated acute inflammatory markers including C-reactive protein, erythrocyte sedimentation rate (ESR), ferritin, procalcitonin, interleukin-6 and D-dimer. Troponin and B-type natriuretic peptide were elevated in all. They required inotropic support in the Intensive Critical Care Unit, including one child requiring extracorporeal membrane oxygenation. With immunomodulatory treatment and heart failure management, the ventricular dysfunction resolved in all children prior to discharge. CMR was performed on four children during the initial hospitalization and after discharge on one. Using the recommended Lake Louise diagnostic CMR imaging criteria for patients with suspected myocarditis,³ tissue-based CMR markers consisting of T2-weighted ratio, EGE and LGE were evaluated to assess for myocardial edema, hyperemia/capillary leak and fibrosis/necrosis, respectively (**Figure 1**). Based on the myocardial signal intensity increase in T2-weighted images (T2 STIR), myocardial edema was diagnosed in four patients. Three patients had evidence of early gadolinium enhancement and in two patients, a small focal area of late gadolinium enhancement was noted in the inferolateral segment of the subepicardial region of the left ventricle (**Figure 1**). Newer parametric imaging techniques such as native T1 and T2 mapping done in a few patients were

supportive of myocardial inflammation.^{4,5} FPP imaging was normal in all.

CMR findings in our patients confirm that children with MIS-C associated with COVID-19 can have evidence of myocardial inflammation, which include not only myocardial edema and hyperemia/capillary leak, but also myocardial necrosis/fibrosis. While a post-infectious immune response triggered by SARS-COV-2 infection is the most likely suspected reason for the cardiac findings, a direct complication secondary to SARS-COV-2 infection cannot be ruled out. The limitations include absence of histopathological confirmation and follow up CMR data at this time. In conclusion, CMR can be done safely following infection control precautions in patients with MIS-C associated with COVID-19 during the acute phase of illness, by adopting a specific protocol. CMR has a role in the management of children with myocarditis related to MIS-C associated with COVID-19, in establishing the diagnosis, assessing its prognosis and for the long-term follow-up of these children.

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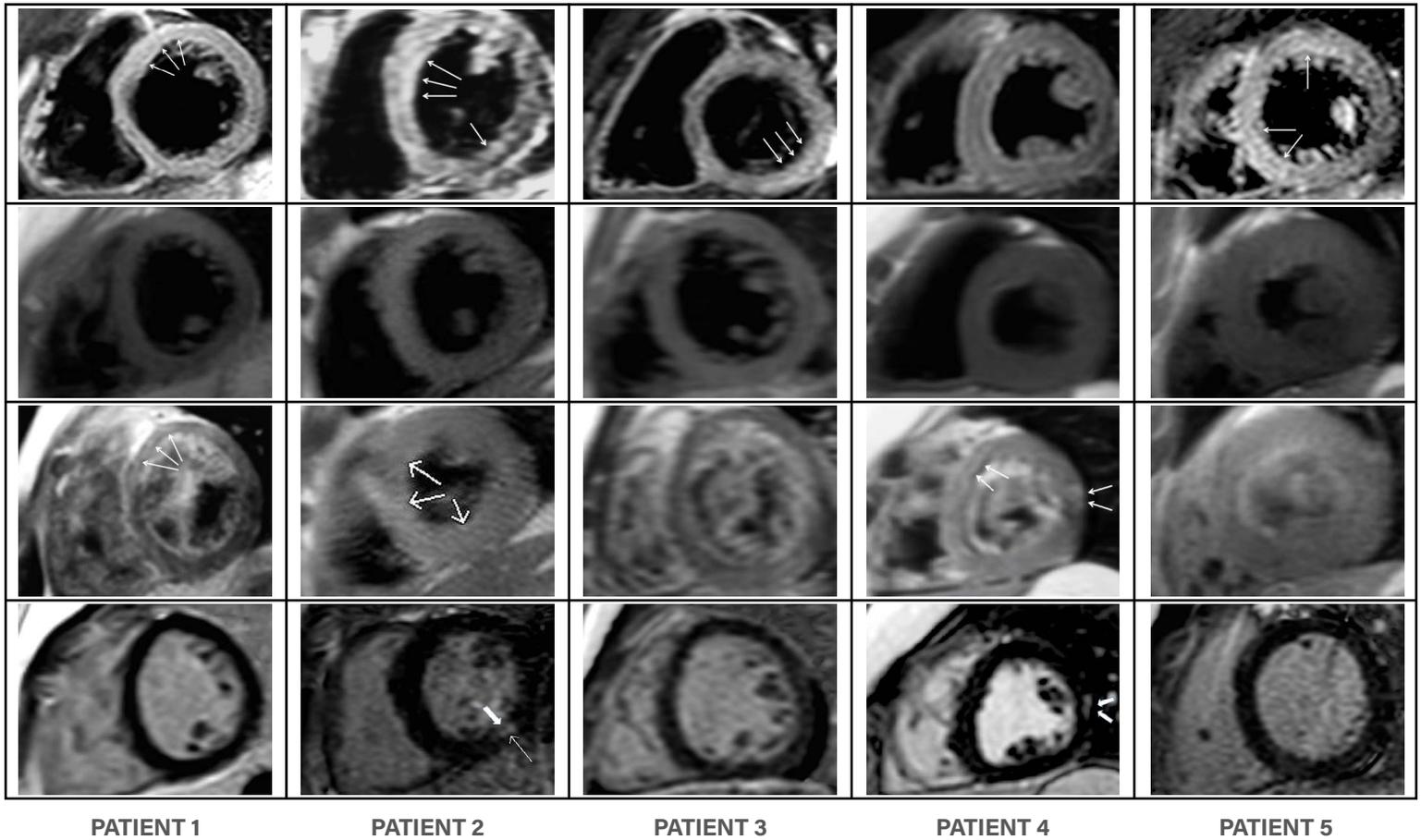


FIGURE 1 CMR images in five children with clinical diagnosis of myocarditis associated with Multisystem Inflammatory Syndrome in Children (MIS-C) related to COVID-19. The top panel shows T2- weighted images (T2 STIR) which demonstrate areas of high signal intensity (arrows) with average ratios of myocardium over skeletal muscle > 2 denoting myocardial edema in patients 1, 2, 3 and 5. The second and third panel shows T1-weighted images before and shortly after gadolinium administration, respectively. In patients 1, 2 and 4, there is evidence of early gadolinium enhancement (arrows) with calculated myocardial early gadolinium enhancement ratio between myocardium and skeletal muscle >4 in patients 1, 2 and absolute myocardial enhancement >45% in patient 4. The bottom panel demonstrates late gadolinium enhancement in patients 2 and 4 as a small focal lesion in the inferolateral segment of the sub-epicardial region of the left ventricle (arrows).

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The SCAI Congenital Heart Disease 2020 Program

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In July 2019, Julie Vincent, MD, Dan Gruenstein, MD and I were tasked to develop the SCAI-CHD track for the May 2020 Annual Scientific Sessions. We met shortly after the 2019 Las Vegas meeting in Washington, DC. With the support of the SCAI Programming Committee (in particular Rachel Pham, Robert Bartel and John Breinholt, MD, who represented the CME Oversight Committee), we created a program to examine complications during interventional procedures: how to anticipate problems, how to avoid them and how to deal with them when they occurred. The program took shape very quickly, and by the end of the year the invitations had gone out and we had the framework of the program set. In addition to the overarching complications theme, the highlights included the Mullins' Lecture, the 'I Blew It' session and a dedicated Congenital Heart Disease live case, to be broadcast from Rady Children's Hospital. Little could we anticipate the global crisis just a few months away. With the reality of the global pandemic, the decision to cancel the in-person meeting was made in March-April by the SCAI Executive Committee and planning for a virtual on-line program began. We knew this would be difficult, but everyone involved accepted the challenge of developing an educational program that would be of interest to our community, based on the structure of our original program. I was reminded what Winston Churchill said of addressing difficulties: "A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty." And so, our on-line virtual program was developed.

The first session was on Friday, May 15th and included the CHD Community Forum chaired by Frank Ing, MD. Here a timely review of resource allocation for pediatric catheterizations during COVID-19 was presented by Shyam Sathanandam, MD; followed by a discussion of CPT coding for

'ACHD Starts Young: My six-year old soccer playing niece has a fenestrated Fontan: should it be closed? What could happen down the road?' by Dan Levi, MD, UCLA Medical Center, Los Angeles, CA

CHD catheterizations by Sergio Bartakian, MD; and updates on the Online Learning Working Group by Nasser Moiduddin, MD; the activities of the PICES group by Ryan Callahan, MD; the Adult Congenital Heart Disease Work Group by Howaida El-Said, MD; and the AngioAtlas by Renelle George, MD. The Mullins' Lecture was given by Shakeel Qureshi, MD, from Evelina Children's Hospital, titled 'Interventional Catheter Laboratories in Developing Countries: Open Mind and Supportive Philosophy, reviewing the needed resources for advanced cardiac care and the work he and colleagues have been doing to support developing programs around the world. Dr. Mullins was able to attend from his home in Texas, and we were all glad to see him. Jacqueline Kreutzer, MD, Julie Vincent, MD, Frank Ing, MD and Shak Qureshi, MD moderated a session on 'Late Breaking Science', with presentations on outcomes of the Harmony percutaneous valve implant study by John Cheatham, MD, the long-term (10-year) outcomes from the Melody valve IDE cohort by Tom Jones, MD, and the one-year results from the Compassion 3 Sapien 3 valve study by Vasilis Babaliaros, MD. The session was closed with the presentation

of 10 abstracts focused on procedures and imaging involving the arterial duct in premature newborns chaired by Evan Zahn, MD and Shyam Sathanandam, MD. While all the presentations were outstanding and the presenters were applauded for their work, the winner of the best (of the best) abstract was Hitesh Agrawal, MD, presenting 'Transcatheter Closure of PDA Compared to Surgical Ligation in Premature Neonates: Clinical Outcomes and Cost Comparison's from the University of Tennessee/Le Bonheur Children's Medical Center... congratulations! This session is available for review on the SCAI website 'On-Demand' under 'Virtual Congenital Heart Disease.' Please take advantage of seeing the session at your leisure.

Beginning each Monday in June, at 6pm, a 90-minute session was developed from the original SCAI-CHD track. As is often a highlight of the annual meeting, the 'I Blew It Session' was chaired by Frank Ing, MD and Tom Fagan, MD. This year the voting was tight! All four presenters were rewarded the trophy, to be shared by each for three months and returned to the annual meeting for next year's competition.



Congratulations to Drs. Bauser-Heaton, Bansal, Grunstein and Taylor! Included were sessions on: 'Oops! How to Stay Out of Trouble: A Primer on Complications,' a PICES supported session: 'Planning Complicated Interventions and Dealing with Unpredictable Complications: How to Expect the Unexpected,' and the debate 'ACHD Starts Young: My six-year old soccer playing niece has a fenestrated Fontan: should it be closed? What could happen down the road?' and a very informative and lighthearted debate by Dan Levi, MD and Mike Seckler, MD. These and additional pre-recorded sessions from the original program are available 'On-Demand' on the SCAI website under the heading 'Congenital Heart Disease.'

We are very grateful to all the presenters, moderators and participants in the webinars...the average interest rating was 84%, with more than half of the registered viewers attending the sessions. Finally, we want to thank the SCAI staff for the support, long hours and perseverance to help create this series. After all..."Kites rise highest against the wind, not with it," Winston Churchill.



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Learnings from Pandemic & Practice: A Gore Webinar Series for Medical Professionals

In response to COVID-19, Gore Medical produced a free four-part series, <https://www.goremedical.com/COVID-19-response/webinars>, on lessons learned by medical professionals amid the pandemic. The webinars, moderated by Darren Schneider, MD, of New York-Presbyterian, feature learnings from medical professionals from around the globe and cover how physicians are working, and working together, to apply these learnings to improve protocols, approaches and teamwork within cardiovascular practices.

Summaries of the latest sessions follow, and a condensed Q&A of Session One, "Considerations in Resuming Cardiovascular Procedures," is available in the June 2020 edition, https://www.congenitalcardiologytoday.com/index_files/CCT-JUN20-NA.pdf, of *Congenital Cardiology Today*.

Soft Skills Considerations for Hard Conversations with Cardiovascular Patients

Cardiovascular physicians weighed in on how COVID-19 has changed patient concerns and conversations, and how they have adapted their softer skill sets to manage patient expectations and anxieties. The panelists included: Gareth Morgan, MD, Denver, Colorado, Prabir Roy-Chaudhury, MD, PhD, Durham, North Carolina, and George Adams, MD, Raleigh, North Carolina.

One of the top concerns cited was patients delaying or even skipping appointments for essential treatment because of fears that the hospital is unsafe. In many cases, panelists noted in the May 6th session, standard scheduling conversations with patients have evolved into emotional discussions about reassurance and explanations of protocols that have been put in place to facilitate their safety.

Still, there is optimism that telemedicine has been helping to at least maintain touchpoints and connection with patients. However, no



panelists felt it was a substitute for physical presence during difficult conversations, especially while many patients are dealing with the additional stress of being physically isolated from their traditional social support groups.

Supporting Physician Wellness in Support of Patient Outcomes

Physician advocates in both clinical and administrative positions discussed: physician peer support and the role of physician wellness in patient safety and outcomes, practice stability and practitioner resilience, and how COVID-19 impacted their wellness priorities and approaches. The May 13th panelists included: Albert Wu, MD, Baltimore, Maryland, Nimesh Desai, MD, Philadelphia, Pennsylvania, George Everly, PhD, Baltimore, Maryland, and William Cobb, MD, FACS, Greenville, South Carolina.

During the panel, attendees were asked about what was most impacting their mental health or wellness during the pandemic, with 41% identifying a poor work/life balance and limited physical activity as main drivers. Half of those polled identified colleague connection or support as being most helpful to mental health challenges. While most respondents agreed or somewhat agreed that they had adequate access to mental

health resources, only 34% fully agreed with the statement, suggesting hospitals have room for improvement.

The feelings of loss of connection between colleagues was especially prominent during the discussion, with several panelists noting that the breakdown of teams and daily interactions has affected physician mental health. Panelists also expressed concerns about feelings of disillusionment and a possible spike in suicides, indicating that we are at a point where we should anticipate that people need help to recover, or to recover faster.

In terms of resources available to support physician mental health, panelists focused on four key areas to support the mental health of physicians and their peers, including: a peer support program, psychological first aid training, crisis leadership and management training, and promoting self-care principles. Self-care principles were cited as being especially valuable because they could serve to help physicians regain a sense of control during an uncertain time.

Four Pandemic Pivots Medical Professionals May Want to Keep

Physicians from around the world shared department, device, patient and personal



pivots they made recently that they think are worth carrying forward post-pandemic. The May 21 panelists included: Prof. Santi Trimarchi, Milano, Italy, Prof. Vicente Rimbau, Barcelona, Spain, Weiwei Wu, MD, Beijing, China, and Erik B. Wilson, MD, FACS, Houston, Texas.

In terms of department changes, panelists noted that their practices had to adjust to support colleagues on the front line of the pandemic – anesthesiologists, pneumologists, and nurses, in particular. One panelist revealed that the physicians in his hospital often left the vascular surgery area and spent nights in the emergency department while another mentioned that his region had tried to turn hotels into hospitals.

Both telemedicine and new conference formats ranked high on the list of changes anticipated to continue post-pandemic. Although most panelists expected telemedicine to continue even in the wake of the pandemic and cited its recent adoption and expansion by their own health systems as evidence, not all were in favor of its growth, with one panelist remarking that telemedicine can negatively affect the relationship between physician and patient.

To limit social distancing, the panelists also expected a rise in the use of virtual platforms to replace conferences and other in-person events. These new, virtual events will serve to limit exposure to COVID-19, lower costs, and address physicians' limited availability to attend events due to their busy procedure schedules.

Full recordings of all four sessions are available at Gore's website, www.PandemicAndPractice.com.



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The Children's Cardiomyopathy Foundation and Kyle John Rymiszewski Research Scholarship in Pediatric Cardiomyopathy

The Department of Pediatrics at The Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo and John R. Oishei Children's Hospital, in partnership with the Children's Cardiomyopathy Foundation and the Kyle John Rymiszewski Foundation, is pleased to announce the third annual Children's Cardiomyopathy Foundation and Kyle John Rymiszewski Research Scholarship in Pediatric Cardiomyopathy. This partnership was formed to nurture the next generation of researchers to address the specialized needs of children affected by cardiomyopathy and their families.

The program provides support to a high-achieving clinical researcher in the early stages of his/her career to promote their development. This is a 12-month research scholar position at the University at Buffalo working with the Pediatric Cardiomyopathy Registry. This is a mentored research experience focused on pediatric hypertrophic cardiomyopathy. A scholarship of \$50,000 to support research under the terms of the program will be provided as well as research space and support.

Background

The Children's Cardiomyopathy Foundation (CCF) is a national organization focused on funding research and educational initiatives, providing family support, and increasing awareness and advocacy on all forms of cardiomyopathy affecting children. Cardiomyopathy is the leading cause of heart transplants and sudden cardiac arrest in children 18 and younger. In 2016, the CCF approached the Kyle John Rymiszewski Foundation to establish the Pediatric Cardiomyopathy Research Scholar position. The scholarship honors Kyle Rymiszewski, a teenager diagnosed with hypertrophic cardiomyopathy, who died in 2009 following a cardiac arrest. His namesake foundation supports and collaborates with the CCF on research projects with the objective to improve outcomes for children afflicted with hypertrophic cardiomyopathy.

The Pediatric Cardiomyopathy Registry (PCMR) is a patient clinical database established in 1994 by the National Heart, Lung, and Blood Institute to describe the epidemiologic features and clinical course of cardiomyopathies in children aged 18 years or younger. Data from more than 3,500 children with cardiomyopathy from 100 medical centers across the United States, Canada, and Puerto Rico is included in the registry. Through its many publications, the PCMR provides the most in-depth illustration of this disease regarding: its etiology, clinical course, associated risk factors, and patient outcomes. Data from the registry has helped guide the clinical management of cardiomyopathy in children under 18 years of age.

Eligibility Requirements

Eligible applicants include persons with experience or a demonstrated interest in developing a clinical research career in pediatric heart disease focused on cardiomyopathy and heart failure. Such candidates may include

physicians, epidemiologists, geneticists, or those from related health fields. The Candidate will hold a MD, PhD, DO, DVM, MPH or equivalent degree at the time of award activation and be able to fulfill the position requirements and conduct the research at The University at Buffalo, Department of Pediatrics.

Scholar Requirements

The Research Scholar is expected to accomplish the following during the one (1) year award period:

- Complete at least one original research project on pediatric hypertrophic cardiomyopathy and submit a scientific meeting abstract(s) and at least one manuscript for publication in a peer-reviewed medical journal
- Collaborate on other scholarly works (review articles, textbook chapters) related to pediatric cardiomyopathy and heart failure
- Attend University at Buffalo's Department of Pediatrics educational activities
- Attend at least one national cardiology meeting

Selection Criteria

Applicants will be asked to submit a current CV and at least one (1) letter of reference from a supervisor. All candidates will have an initial telephone or in-person interview with the Presidents of both sponsoring Foundations and Dr. Steven Lipshultz from the University at Buffalo. The awardee will be notified after approval from the two sponsoring foundations.

Application Deadline September 1, 2020

Contact

To apply or make inquiries, please contact Miriam Mestre at mamestre@buffalo.edu

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Carag Receives US FDA IDE Approval to Conduct Clinical Study of First Transcatheter Septal Occluder with Bioresorbable, Metal-Free Framework

The US Trial for CE-Marked CBSO is Designed to Enroll Up to 250 Patients in a Staged Study Approach

Baar, SWITZERLAND – July 1, 2020

CARAG AG, a privately-held Swiss medical device development company, today announced receiving U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) approval for its Carag Bioresorbable Septal Occluder (CBSO). The CE-marked CBSO is the first-ever transcatheter septal occluder with bioresorbable, metal-free framework. Carag's first US trial is designed to enroll up to 250 patients in a staged study approach, the largest clinical trial for the company to date.

Atrial Septal Defects (ASD) are currently treated with transcatheter implants with a metal framework that permanently clamps the septum. The long-term presence of metal in the heart can lead to rare but severe complications, such as erosion, arrhythmia and thrombus formation. Moreover, current devices limit treatment options for future heart interventions requiring septum crossing, such as mitral valve repair or replacement, left atrial appendage and ablation.

"Based on the data seen so far, we are very hopeful that a metal-free bioresorbable framework has the potential to reduce the risk of late complications for patients," explained Larry Latson, MD, pediatric cardiologist and specialist in Adult Congenital Heart Disease at Joe DiMaggio Children's Hospital (FL) and who, along with Saibal Kar, MD (Los Robles Medical Center, CA), is the national co-Principal Investigator for the Carag US trial. "With heart procedures requiring septal crossing on the rise, a framework that dissolves when no longer needed would improve future treatment options. Both benefits would represent major advancements in ASD treatment," he added.

Results from Carag's first-in-human trial¹ conducted in Germany demonstrated that CBSO is easy to use, with excellent closure results at procedure and at two year follow-up, with no serious device-related complications reported. CBSO is CE-marked for use in the European Union and it is currently being implanted as part of a post-market registry in selected centers in Germany and Switzerland.

The prospective, multi-center, US clinical trial is designed to enroll up to 250 patients in a staged study approach to evaluate the safety and efficacy of the CBSO in patients with clinically significant ASD.

"We designed the CBSO to achieve a more natural intact septum by eliminating the metal framework, which has no purpose once the septum is healed. Our novel approach enables pediatric and adult cardiologists to perform transcatheter septal occlusions today that will not undermine future left-sided interventional procedures requiring transeptal access," explained Jérôme Bernhard, Carag CEO. "We are looking forward to offering eligible patients a novel treatment approach for septal occlusion," he stated. Carag expects trial enrollment to begin in late 2020.

Patients with ASD have an opening in the septum between the atria that allows blood to return from the left to the right side of the heart. The excess of blood in the right ventricle and lungs may cause: enlargement of the right ventricle, shortness of breath, fatigue and palpitations. These openings in the heart are either due to a congenital heart defect, affecting nearly six in 10,000 births, or to a cardiac procedure during which a physician crossed the septum to carry out an intervention on the left side of the heart, such as mitral valve repair.

About Carag

CARAG AG is a privately-held Swiss medical device development company and an innovation think-tank for the medtech industry. As a leading Swiss engineering company, Carag is a point of contact for physicians and medtech companies developing high-quality products for cutting-edge medical applications. Carag has an experienced, performance-driven, interdisciplinary team of engineers, physicians, medical and electronic technicians, and software developers. The company offers a broad range of services, from technical feasibility assessments to complex product development and market approvals, in addition to developing its own technologies and products.

Reference

1. Söderberg B, Vaskelyte L, Gafoor S, Hofmann I, Mellmann A, Bernhard J, Sievert H. Prospective single center First in Human (FIH) clinical trial to evaluate the safety and effectiveness of a septal occluder with bioresorbable framework in patients with clinically significant atrial septum defect (ASD) or patent foramen ovale (PFO). *Journal of the American College of Cardiology*, Vol 68, No 18, Suppl B, 2016.



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27-29

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<https://www.epicsec.org/>

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11-13

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21-22

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05-10

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<https://www.cincyhearteducationseries.org/achdsymposium>

10

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https://www.cme.ucla.edu/courses/event-description?registration_id=533268&client_view_p=f

16-17

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27-30

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