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By Bennett P. Samuel, MHA, BSN, RN; Yasser Al-Khatib, MD; Cynthia E. L. Peacock-McKenzie, MD; Reda E. Girgis, MD; Joseph J. Vettukattil, MBBS, MD, DNB, CCST, FRCPCH, FRSM, FRCP ~Page 1

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Use of Occlutech® Fenestrated Atrial Septal Defect Occluder in ASD-Associated Pulmonary Arterial Hypertension

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*Presented at the 2016 Pediatric Academic Societies Annual Conference, Baltimore, MD USA

Keywords: Atrial Septal Defect, Pulmonary Arterial Hypertension, Right-Sided Heart Failure (Right-Heart Failure).

Introduction

Pulmonary Arterial Hypertension (PAH) is a chronic disease with progressively increasing right ventricular (RV) pressure, Right-Heart Failure (HF), and death.1 An association between PAH and secundrum-type Atrial Septal Defect (ASD) is observed in 9 to 35% of patients, especially in females. It is speculated that ASD-Associated PAH resolves after intervention and rarely progresses especially with early intervention. 2-4 However, as most of these patients are left with untreated ASDs, there is a dearth of information. Fenestrated ASD closure is preferable in patients with moderate to severe PAH. A restricted interatrial shunt in these patients can enhance systemic ventricular output at the expense of desaturation if shunt reversal occurs when

progressive PAH ensues. Maintaining a sustainable restricted interatrial communication is challenging without the use of a dedicated device such as the Occlutech® Fenestrated Atrial Septal Defect (FASD) occluder (Figure 1). We describe compassionate use of the FASD Occluder with optimal outcomes in a 56-year-old female with ASD-Associated PAH.

Case Report

A 56-year-old female with progressive PAH was referred to the Congenital Heart Center for evaluation and management. She was receiving combination medical therapy with



Figure 1: Occlutech® Fenestrated Atrial Septal Defect Occluder.

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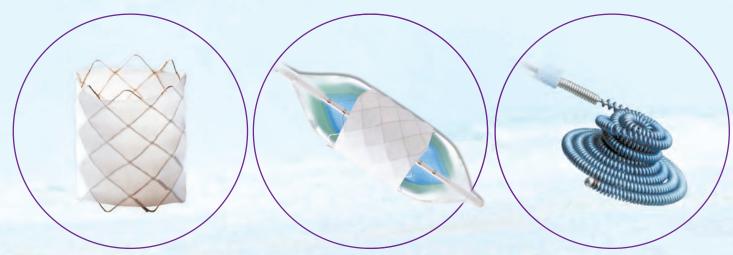
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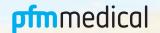
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Refer to the Instructions for Use for complete indications, relevant warnings, precautions, complications, and contraindications

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macitentan and tadalafil. However, she continued to experience dyspnea when attempting to climb a flight of stairs and had bilateral lower extremity edema.

At the age of 48 years, she did not fully recover from bronchitis with symptoms including orthopnea, paroxysmal nocturnal dyspnea, dyspnea on exertion, fatigue, wheezing, cough, near-syncope, and nausea, which was later diagnosed as severe PAH with moderately elevated Pulmonary Vascular Resistance (PVR). Right ventricular (RV) systolic pressure was 95 mmHg, pulmonary artery (PA) pressure was 95/30 (53) mmHg with systemic blood pressure of 112/66 (81) mmHg. Cardiac output was 3.87 L/min (Fick method).

She had a 27 mm ostium secundum ASD. A three-dimensional transesophageal (3DTEE) echocardiogram showed predominantly left-to-right shunt with some flow reversal. Her six-minute walk test distance dropped from 1580 to 1400 feet in a span of three months. As a result of worsening PAH on maximal medical therapy, a decision was made by a multidisciplinary team including pulmonologist and lung transplant director, and congenital heart specialists to close the defect with a fenestrated device. The Occlutech® FASD Occluder was selected for use under the U.S. Food and Drug Administration's compassionate use guidance. The patient was given comprehensive education on the risks and benefits of the procedure, including complications of general anesthesia, TEE, cardiac catheterization and the occluder itself. The potential intraprocedural and postprocedural risks including air embolus, allergic reaction to nickel, arrhythmia, bleeding, injury to blood vessels, device embolization and migration, and thromboembolic events were also discussed. The patient signed the compassionate use informed consent form after all questions were addressed to her satisfaction prior to the procedure.

Procedure

Under general anesthesia, 3DTEE confirmed the presence of a significant atrial communication with persistent left-to-right shunt. A detailed right-heart catheterization was performed under aseptic precautions with stepwise oximetry

and hemodynamics. The patient's RA pressure was 12/7 (9) mmHg, PA pressure was 80/29 (47) mmHg with systemic blood pressure of 100/50 (67) mmHg. Oximetry in 30% oxygen included superior vena cava (SVC) 78%, inferior vena cava (IVC) 75%, RA 80%, RV 81%, PA 80%, and LA 92%. Although the pre-procedure calculated Qp:Qs was 0.91 suggesting a net right-to-left shunt through the ASD, the pulmonary reactivity testing showed Qp:Qs of 1.5: 1 on 100% oxygen and nitric oxide. A balloon occlusion test showed no hemodynamic instability on complete occlusion. Cardiac output was 3.81 L/min (Fick method).

A 0.035-inch extra-stiff guidewire was placed into the pulmonary vein and a 14F Mullins sheath was advanced over the guidewire and positioned into the uppper-left pulmonary vein. A 27 mm FASD occluder with 6 mm fenestration was loaded on the delivery cable system and advanced in through the sheath. The LA disk was deployed followed by deployment of the RA disk under fluoroscopic and

3DTEE guidance. After confirming secure deployment of the FASD occluder on 3D TEE (Figures 2 and 3), hemodynamic

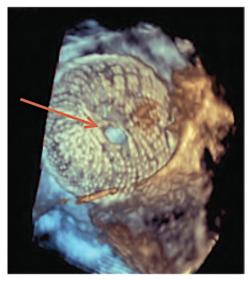


Figure 2: Post-deployment 3DTEE shows a well-seated FASD. The red arrow shows the 6 mm fenestration in the occluder.

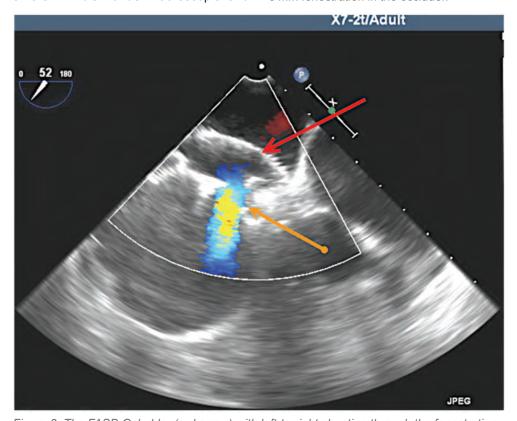


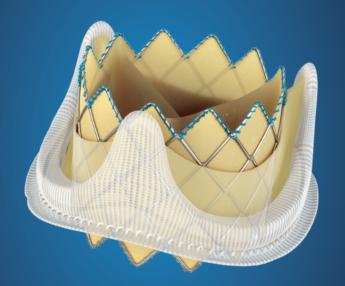
Figure 3: The FASD Ocludder (red arrow) with left-to-right shunting through the fenestration (orange arrow) on two-dimensional TEE post deployment.



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*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

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measurements were repeated. The patient's RA pressure was 10/8 (8) mmHg, PA pressure was 72/26 (43) mmHg with systemic blood pressure of 139/68 (94) mmHg. Cardiac output improved to 5.97 L/m (Fick Method) with no significant demonstration of left-to-right shunt post device deployment. The delivery cable was then released from the device and withdrawn.

The patient's hemodynamics were stable throughout the procedure and there were no arrhythmias or other complications. She was also extubated without any complications and discharged home the next day. As PAH warrants anticoagulation therapy; the patient's anticoagulation regimen (clopidogrel and aspirin) was continued after the deployment of the device.

"In patients with ASD-Associated PAH, the unrestricted shunting can lead to severe symptoms and progressive PAH. A fenestrated device must be considered in these patients to restrict significant left-to-right shunting, but simultaneously allow for any necessary overflow if and when right HF develops in the future....

The significant symptomatic improvements and the sustained atrial communication four months after implantation of the FASD Occluder in our patient shows that it may be a useful closure device in patients with ASD-Associated PAH."

Following discharge, the patient developed a right pseudoaneurysm with an arteriovenous fistula at the catheterization site requiring two thrombin injections. The complication resolved over time and was determined to be unrelated to the FASD occluder.

At her one-month follow-up visit, the patient reported significant improvement in her exercise tolerance and she had more energy with recorded resting saturation of 99%. Her six-minute walk test distance was relativity unchanged at 1430 feet. She remained without pedal edema on the same diuretic therapy. An echocardiogram demonstrated good device placement, improved RV pressures, and continuous left-to-right shunt across the FASD Occluder at rest.

Four months after the procedure, the patient reported feeling very well with significant improvement in her stamina and exercise tolerance. An echocardiogram demonstrated improved RV

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pressures with continuous left-to-right shunt across the FASD Occluder at rest. Her six-minute walk test distance significantly improved to 1520 feet.

Discussion

The association between PAH and ASD in young adults, especially in females is well recognized. It is typically independent of the degree of shunting and increased pulmonary blood flow through the ASD.²⁻⁴ Although it can be slow in becoming symptomatic, these patients can develop progressive PAH. It is critical to appreciate the difference between this group of patients from those who do not develop mild PAH with large ASDs. In the latter group, it can resolve after intervention, especially when performed early and rarely do patients develop progressive PAH. When considering our patient's clinical presentation and cardiac catheterization findings at the time of ASD closure, she is likely to have had ASD-Associated PAH.

Patients who develop PAH immediately or several months or years after ASD closure have poorer prognosis when compared to Congenial Heart Disease (CHD) patients with PAH.⁵⁻⁷ As such, a fenestrated ASD closure is preferred in patients with ASD and moderate-to-severe PAH to decrease significant left-to-right shunting, but allow possible overflow for right HF in the future.⁷ Creating a restricted and sustainable atrial communication can be challenging and compelled us to use the FASD Occluder that can maintain a fenestration. However, spontaneous closure can occur in fenestrated devices.⁷⁻⁹

Conclusion

In patients with ASD-Associated PAH, the unrestricted shunting can lead to severe symptoms and progressive PAH. A fenestrated device must be considered in these patients to restrict significant left-toright shunting, but simultaneously allow for any necessary overflow, if and when right HF develops in the future. It is desirable to achieve higher systemic ventricular output with marginal increase in cyanosis in these patients with an optimal saturation range of 87-90% at rest. The significant symptomatic improvements and the sustained atrial communi cat ion four months after implantation of the FASD occluder in our patient shows that it may be a useful closure device in patients with ASD associated PAH.

References

- Micheletti A, Hislop AA, Lammers A, Bonhoeffer P, Derrick G, Rees P, Haworth SG. Role of atrial septostomy in the treatment of children with pulmonary arterial hypertension. Heart. 2006;92:969-972.
- Post MC. Association between pulmonary hypertension and an atrial septal defect. Neth Heart J. 2013;21:331-332.
- Vogel M, Berger F, Kramer A, Alexi-Meshkishvili V, Lange PE. Incidence of secondary pulmonary hypertension in adults with atrial septal or sinus venosus defects. Heart. 1999;82:30– 33
- Engelfriet P, Meijboom F, Boersma E, Tijssen J, Mulder B. Repaired and open atrial septal defects type II in adulthood: an epidemiological study of a large European cohort. Int J Cardiol. 2008;126:379–385.
- D'Alto M, Romeo E, Argiento P, Correra A, Santoro G, Gaio G, Sarubbi B, Calabrò, Russo MG. Hemodynamics of patients developing pulmonary arterial hypertension after shunt closure. Int J Cardiol. 2013;168:3797-3801.
- van Loon RL, Roofthooft MT, Hillege HL, ten Harkel AD, van Osch-Gevers M, Delhaas T, Kapusta L, Strengers JL, Rammeloo L, Clur SA, Mulder BJ, Berger RM. Pediatric pulmonary hypertension in the Netherlands: Epidemiology and characterization during the period 1991 to 2005. Circulation. 2011;124:1755-1764.
- 7. Patel MB, Samuel BP, Girgis RE, Parlmer MA, Vettukattil JJ. Implantable atrial flow regulator for severe, irreversible pulmonary arterial hypertension. EuroIntervention. 2015;11:70-709.
- Stümper O, Gewillig M, Vettukattil J, Budts W, Chessa M, Chaudhari M, Wright JGC. Modified technique of stent fenestration of the atrial septum. Heart. 2003;89:1227-1230.
- Sivaprakasam M, Kiesewetter C, Veldtman GR, Salmon AP, Vettukattil J. New technique for fenestration of the interatrial septum. J Interv Cardiol. 2006;19:334-336.

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Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

EchoPixel Announces Progress in the Clinical Adoption of Interactive Virtual Reality for Pediatric Surgery

(Marketwired - - EchoPixel announced in March progress in the clinical adoption of its True 3D Viewer Software for pediatric surgical procedures that allows clinicians to use real patient image data in a desktop virtualreality environment. At several leading clinical sites, surgeons and radiologists are adopting the True 3D Viewer Software, powered by innovative HP displays, to develop surgical plans, effectively communicate in a common 3D language, and assist in challenging procedures. EchoPixel's True 3D Viewer Software translates DICOM image data into life size virtual-reality objects, allowing physicians to move, turn, dissect, and closely examine patient-specific anatomy.

At Lucile Packard Children's Hospital Stanford, doctors have used EchoPixel's True 3D Viewer Software — in conjunction with the HP Zvr virtual reality Display and HP Z440 Workstation — to assist in a number of surgical procedures. In December, doctors used EchoPixel's technology to assist with a groundbreaking seventeen-hour surgery that successfully separated twin girls who were conjoined from the sternum down. True 3D's unique interactive 3D views helped doctors gain a more complete understanding of the unique anatomy prior to, and during, the operation.

At Cook Children's Medical Center in Fort Worth, Texas, physicians have incorporated EchoPixel's True 3D Viewer Software into an integrated 3D lab, with the goal of establishing 3D technology as a diagnostic tool. The center has focused on using interactive virtual reality to better differentiate certain vascular anomalies in Congenital Heart Disease.

"We're excited to establish 3D virtual viewing as part of our 3D program," said Steve Muyskens, MD, cardiologist at Cook Children's Medical Center in Fort Worth, Texas. "Having this technology, in addition to 3D printing capabilities, allows Cook Children's cardiologists and cardiothoracic surgeons to improve the planning of complex procedures and surgeries. We believe this approach will eventually lead to less time in the operating room and fewer complications."

In addition to Packard Children's and Cook Children's, pediatric sites, including: Nicklaus Children's Hospital in Miami and Sick Kids Hospital in Toronto, are also embracing EchoPixel's technology. Building on success in clinical uses, the company is looking to expand the role of interactive virtual reality in Pediatrics.

"Our True 3D Viewer Software has demonstrated significant results in a range of applications, from septal defects to cardiac valve defects, this is why we're particularly excited about our progress in Pediatric Cardiology," said Ron Schilling, CEO of EchoPixel. "We're honored to play a role in the success of these complex and difficult operations, and to assist physicians in understanding and working with patient anatomy."

Collaboration with HP

"Our customers rely on HP to help transform lives through innovative solutions," said Reid Oakes, Senior Director, Worldwide Healthcare, $\,$

HP Inc. "We've seen the value in EchoPixel's technology and our collaborative approach, and we're excited about virtual reality's ability to change the face of healthcare. The success of the EchoPixel True 3D powered by HP system in pediatrics really validates this as a gamechanging tool for doctors."

EchoPixel (www.echopixeltech.com) is building a new world of patient care with its groundbreaking medical visualization software. The company's FDA-cleared True 3D Viewer Software uses existing medical image datasets to create virtual reality environments of patient-specific anatomy, allowing physicians to view and dissect images just as they would real, physical objects. The technology's goal is to make reading medical images more intuitive, help physicians reach a diagnosis, and assist in surgical planning. Leading institutions, including the University of California, San Francisco, the Cleveland Clinic, the Lahey Clinic, and others are using True 3D Viewer Software in clinical and research applications. EchoPixel is a privately held, venture backed company located in Mountain View, CA.

Dr. Mary Norine Walsh Assumes American College of Cardiology Presidency

Mary Norine Walsh, MD, FACC, became President of the American College of Cardiology during the Convocation Ceremony - March 9th, 2017 held in conjunction with the *ACC's* 66th Annual Scientific Session in Washington.

Walsh is the Director of the Heart Failure and Cardiac Transplantation Programs and Director of Nuclear Cardiology at St. Vincent Heart Center in Indianapolis. In her 25 years of membership in the ACC, she has been active both locally and nationally, serving as president of the Indiana Chapter and serving on and chairing multiple committees.

"Volunteering as a member of the ACC has

been a very important part of my life. I realized early on that the mission and vision of the College meshed with my own and I really found a 'home' at ACC," Walsh said. "To succeed the many gifted leaders who are past presidents of the College is truly a dream come true for me. I am so inspired by the dedication of so many of our staff and members who contribute their talents to make our organization better. It is truly my honor to take the helm and lead this year."

As president, Walsh plans to focus on equipping ACC members to navigate the changing health care environment as it moves from being volume-driven to valuedriven.

"Team-based care has been a passion of mine in my own practice and the College will continue to have a focus on this in the next few years to come," Walsh said. "Working in teams will allow us to better serve the populations of patients whose care we undertake."

She also hopes to engage more members in advocacy efforts.

"We need to make our voices heard on Capitol Hill and at our state houses by advocating for patient access, quality care and even public health issues that result in a decrease in cardiovascular morbidity and



For more information:
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Dear Colleagues,

The Organizing Committee is pleased to announce the **7**th **World Congress of Pediatric Cardiology and Cardiac Surgery (WCPCCS)**, which will take place on July 16 - 21, 2017, in the Centre Convencions Internacional de Barcelona (CCIB), Barcelona, Spain.

The aim of WCPCCS is to bring together all professionals involved in the care of children's heart disease and congenital heart disease of all ages, from the fetus to the aged. The Congress will provide a unique opportunity to meet the leaders of specialties worldwide; to learn about the latest innovations and the results of procedures; and to contribute to the discussions, debates and plenary sessions with renowned speakers.

The central philosophy of the Congress is "bridging together" all major specialties in the field. Accordingly, the scientific program is carefully planned to address all interests and expertise with concentration streams on pediatric cardiology, pediatric cardiac surgery, adult congenital heart diseases, anesthesia, intensive care and nursing.

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mortality," Walsh said. "Being an advocacy leader can be a goal for all of our members and I hope to help foster that leadership."

Walsh earned both her undergraduate and medical degrees from the University of Minnesota. She completed her internship and residency at the University of Texas Southwestern and her cardiology fellowship at Washington University School of Medicine. She then served as an Assistant Professor of Medicine in the Division of Cardiology, as well as an Assistant Professor of Radiology at the Hospital of the University of Pennsylvania.

Walsh serves on the editorial board of the *Journal of Cardiac Failure* and as an editorial consultant for JACC: Heart Failure. She is a reviewer for multiple other journals and has authored more than 80 articles and book chapters. Previously, Walsh has served as an associate editor of HeartWatch, a publication of the Massachusetts Medical Society.

She is actively involved in clinical research in heart failure, nuclear cardiology and systems approaches for quality initiatives in the practice setting. She is the 2014 recipient of the Wenger Award for Medical Leadership and has been elected by her peers for inclusion in Best Doctors in America annually since 2005.

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The American College of Cardiology is a 52,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and to improve heart health. For more information, visit acc.org.

Moderate Exercise May be Beneficial for HCM Patients

As one of the most common causes of Sudden Cardiac Death (SCD) in young people, a diagnosis of Hypertrophic Cardiomyopathy (HCM) can push patients into sedentary lifestyles.

Current guidelines recommend people with HCM, the most common genetic cardiovascular disease, limit intense exercise because of concerns over triggering ventricular arrhythmias. But new Michigan Medicine research finds there may be reason to re-evaluate the guidelines.

"We are challenging the idea that exercise is dangerous for these patients," says senior author Sharlene Day, MD, a Michigan Medicine cardiologist and Associate Professor. "And we show that it can actually be beneficial."

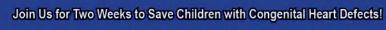
University of Michigan researchers collaborated with colleagues at Stanford University and the VA Palo Alto Health Care System for the new study released in *JAMA* and presented as a latebreaking clinical trial at the *American College of Cardiology's Annual Scientific Session*. The preliminary study announced a small, but statistically significant increase in exercise capacity in HCM patients who underwent moderate-intensity exercise training.

Questioning Guidelines

The general population is encouraged to stay active to maintain good health and reduce the risk of cardiovascular events. Yet because of the risk of sudden cardiac death, people with HCM are told not to participate in competitive sports.

But there isn't a global consensus on whether it's safe for those with HCM to participate in recreational activities, such as jogging. Surveys have revealed most patients with HCM reduce their activity levels after diagnosis, becoming less active than the general population.

First author Sara Saberi, MD, says providers need data to guide their recommendations, so they don't become colored by emotion.



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"We have those images entrenched in our brains of young, healthy athletes collapsing suddenly in the middle of a competition, and these devastating events trigger a visceral response," says Saberi, a Michigan Medicine cardiologist and Assistant Professor. "But by limiting exercise, we're creating another set of health problems that stem from obesity, such as: Coronary Heart Disease, diabetes, obstructive sleep apnea, depression and anxiety."

Increasing Exercise Capacity

Saberi's team studied 136 patients with HCM between the ages of 18 and 80. For 16 weeks, members of one group were told to continue with their usual level of physical activity, while the other group members were given individualized exercise plans the researchers created.

The exercises were moderate, including walking, using an elliptical, jogging or biking, and excluding intervals or weight training. The participants began week one working out at least three times each week for 20 minutes. By the end of the program, they were working out four to seven times per week for up to an hour.

The exercise group participants experienced a small, but statistically significant increase in peak VO_2 max, a measure of exercise capability, after the 16 weeks. Reduced peak VO_2 is common in HCM patients, and it correlates with mortality in HCM.

"The findings show patients that follow-up an exercise prescription can actually train and improve their functional capacity," Saberi says.

In this preliminary study, neither group experienced any major adverse effects, such as death, appropriate ICD shocks or sustained ventricular tachycardia.

Of note, there was also a statistically significant improvement in self-reported physical functioning in the exercise group as compared with the usual-activity group.

Establishing Safety

The long-term safety of exercise in the HCM population remains to be established, but the researchers call this study an important first step.

Because adverse events like sustained ventricular tachycardia are exceedingly rare in HCM patients, Saberi says a clinical trial designed to address safety of exercise in terms of dangerous heart rhythms and sudden cardiac death would require a larger number of patients with longer follow up. In the meantime, an observational study called LIVE-HCM is ongoing and will address the benefits and safety of exercise at many levels, including vigorous recreational exercise and competitive sports participation.

Michigan is One of Three Leading Sites for this Registry

Day, a Taubman Scholar, and Saberi say they approach their patients with HCM differently than many physicians. They strongly encourage some physical activity at least three days each week, preferably with an exercise partner and at a level at which they feel comfortable. They give individual recommendations to each patient they see in their clinics.

"I tell my patients not to let HCM prevent them from keeping in shape," Saberi says. "Exercise training has shown improvements in outcomes in terms of mortality, including in patients with chronic heart failure, and we think it's likely to have the same benefits in HCM patients."

Funding: Michigan Institute for Clinical & Health Research (grant UL1TR000433), University of Michigan Frankel Cardiovascular Center's McKay Research Grant, University of Michigan Frankel Cardiovascular Center Inaugural Grant and an anonymous donor.

Mayo Clinic Researchers Demonstrate Value of Second Opinions

Newswise — Many patients come to Mayo Clinic for a second opinion or diagnosis confirmation before treatment for a complex condition. In a new study, Mayo Clinic reports that as many as 88 percent of those patients go home with a new or refined diagnosis — changing their care plan and potentially their lives. Conversely, only 12% receive confirmation that the original diagnosis was complete and correct.

These findings were published online March 30th in the *Journal of Evaluation in Clinical*

Practice. The research team was led by James Naessens, ScD, a health care policy researcher at Mayo Clinic.

Why Get a Second Opinion?

When people are sick, they look to their doctor to find solutions. However, physicians don't always have the answers. Often, because of the unusual nature of the symptoms or complexity of the condition, the physician will recommend a second opinion. Other times, the patient will ask for one.

This second opinion could lead to quicker access to lifesaving treatment or stopping unnecessary treatments. And a second opinion may reduce stress in a patient's extended family, when they learn the new diagnosis does not carry dire genetic implications. These scenarios can result from diagnostic error.

Good the Diagnosis Will be Adjusted

To determine the extent of diagnostic error, the researchers examined the records of 286 patients referred from primary care providers to Mayo Clinic's General Internal Medicine Division in Rochester over a twoyear period (Jan. 1, 2009, to Dec. 31, 2010). This group of referrals was previously studied for a related topic. It consisted of all patients referred by nurse practitioners and physician assistants, along with an equal number of randomly selected physician referrals.

The team compared the referring diagnosis to the final diagnosis to determine the level of consistency between the two and, thus, the level of diagnostic error. In only 12% of the cases was the diagnosis confirmed.

In 21% of the cases, the diagnosis was completely changed; and 66 percent of patients received a refined or redefined diagnosis. There were no significant differences between provider types.

"Effective and efficient treatment depends on the right diagnosis," says Dr. Naessens. "Knowing that more than 1 out of every 5 referral patients may be completely [and] incorrectly diagnosed is troubling — not only because of the safety risks for these patients prior to correct diagnosis, but also because of the patients we assume are not being referred at all."

The ACHA website offers resources for ACHD professionals as well as for patients and family members.

Explore our website to discover what ACHA can offer you. www.achaheart.org/home/professional-membership-account.aspx



Upcoming Medical Meetings

Society for Cardiovascular Angiography and Interventions (SCAI) May 10-13, 2017; New Orleans, LA USA www.scai.org/SCAI2017/Default.aspx

2017 Heart Rhythm Society Annual Meeting

May 10-13, 2017; Chicago, IL USA www.hrsonline.org/Education-Meetings/Scientific-Sessions#axzz3hsLSBDcN

28th Annual Conference of The Western Society of Pediatric Cardiology / 6th Annual Congenital/Fetal Imaging Conference

May 19-21, 2017; Seattle, WA, USA http://wsopc.org/annual-meeting-savethe-date/

Catheter Interventions in Congenital, Structural & Valvular Heart Disease Jun. 28 - Jul. 1, 2017; Frankfurt, Germany csi-congress.org

7th World Congress of Pediatric Cardiology & Cardiac Surgery Jul. 16 - 21, 2017; Barcelona, Spain wcpccs2017.org/en

CSI-UCSF

Sep. 8 - 9, 2017; San Francisco, USA www.csi-congress.org/csi-ucsf.php

27th International Symposium on Adult Congenital Heart Disease Sep. 14-16, 2017; Cincinnati, OH USA www.cincinnatichildrens.org/ ACHDsymposium

8th Phoenix Fetal Cardiology Symposium

Oct. 27-31, 2017; Phoenix, AZ USA www.fetalcardio.com

LAA 2017

Nov. 17–18, 2017; Frankfurt, Germany www.csi-congress.org/laa-workshop. php?qo=0

Devices for Heart FailureDec. 15-16, 2017: Berlin, Germany
www.csi-congress.org/dhf.php?go=0

Risks of Cost Containment

To manage costs in a health care environment with ever-increasing costs, health insurers often limit access to care outside their network, effectively limiting referrals. Further, primary care providers may be more confident in their diagnostic expertise than warranted in a particular case, or patients may lack the knowledge or assertiveness to request a referral.

"This may prevent identification of diagnostic error, and could lead treatment delays, complications lead to more costly treatments, or even patient harm or death," says Dr. Naessens. "We want to encourage second opinions when the provider is not certain."

The National Academy of Medicine cites diagnostic error as an important component in determining the quality of health care in its new publication, *Improving Diagnosis in Health Care*. Despite the pervasiveness of diagnostic errors and the risk for serious patient harm, diagnostic errors have been largely unappreciated within the quality and patient safety movements in health care. Without a dedicated focus on improving diagnosis, these errors will likely worsen as the delivery of health care and the diagnostic process continue to increase in complexity.

"Referrals to advanced specialty care for undifferentiated problems are an essential component of patient care," Dr. Naessens says. "Without adequate resources to handle undifferentiated diagnoses, a potential unintended consequence is misdiagnosis, resulting in treatment delays and complications, and leading to more costly treatments."

There searchers identified costs associated with second opinions, and Dr. Naessens notes, "Total diagnostic costs for cases resulting in a different final diagnosis were significantly higher than those for confirmed or refined diagnoses, but the alternative could be deadly."

He says that he and his team are pleased by the National Academy of Medicine's call for dedicated federal funding for improved diagnostic processes and error reduction. They also plan further research on diagnostic errors and hope to identify ways to improve the process. Dr. Naessens leads quality and safety research initiatives within the Office of Health Care Practice and Policy in the Mayo Clinic Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery. He is also the Scientific Director for the Florida team within the center.

Mayo Clinic is a nonprofit organization committed to clinical practice, education and research, providing expert, wholeperson care to everyone who needs healing. For more information, visit http://www.mayoclinic.org/about-mayo-clinic or http://newsnetwork.mayoclinic.org/.

Edwards' Advanced Hemodynamic Monitoring Platform Receives FDA Clearance



Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, has received FDA clearance for its HemoSphere advanced monitoring platform. This technology provides clinicians with exceptional clarity on a patient's hemodynamics, or the factors that manage blood flow, to help them make proactive, timely clinical decisions. It's also a scalable platform that can be tailored to meet the needs of each patient and clinician.

"The HemoSphere advanced monitor enables simplified visual clinical support, which is particularly important in the care of our most complex, critically ill patients," said Davinder Ramsingh, MD, director of Clinical Research and Perioperative Ultrasound and associate professor, Department of



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Anesthesiology, Loma Linda University Medical Center. "Clinicians can choose the clinical support screens that best suit their needs and monitor the pressures and blood flow of the right heart as conditions change, informing potentially life-saving decisions on behalf of their patients."

generation Representing the next of monitoring. hemodynamic the HemoSphere advanced monitor is wireless-enabled and allows clinicians to collect a patient's hemodynamic data, which they can evaluate to improve patient care. The platform incorporates highquality, visual clinical support screens and an intuitive touchscreen, and clinical teams can adapt the system to meet the needs of their care environment. The HemoSphere advanced monitor is currently compatible with the Edwards Swan-Ganz pulmonary artery catheter and Oximetry catheters.

"The HemoSphere advanced monitor builds on Edwards' more than 50 years of experience in providing clinicians with technology and education to help improve patient care and lays the foundation for future advancements in hemodynamic monitoring," said Catherine M. Szyman, Edwards' corporate vice president, critical care.

Hemodynamic monitoring is the measurement of blood circulation and cardiac function that allows clinicians to evaluate whether enough oxygen is being delivered to a patient's organs and tissues. Healthcare providers use this information to detect changes or problems in a patient's health, which allows for more informed, immediate treatment decisions.

The HemoSphere advanced monitor is also approved for commercial use in Europe, Japan, Australia and New Zealand.

Edwards Lifesciences, based in Irvine, Calif., is the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, the company collaborates with the world's leading clinicians and researchers to address unmet healthcare needs, working to improve patient outcomes and enhance lives. For more information, visit www.edwards.com.

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