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Retained Adherent Intravascular Catheter: What to Do?

By Preston Boyer, MD; Philippe Mercier, MD; Anne Gildehaus, CPNP-AC; Saadeh Jureidini, MD

Introduction

Transcatheter snare-assisted retrieval of retained intravascular catheter fragments is now the method of choice for removal of these fragments.[1] This technique may not be successful if both ends of the catheter fragment are well-adherent to the vessel wall and/or cardiac chambers. Review of the literature reveals no uniform recommendation for such a condition. We present, herewith, a case report where both ends of a ventriculo-atrial (VA) shunt catheter fragment were ahered to vascular tissues, and not responsive to snare removal. We discuss our rationale for the treatment choice we made in this case based on our experience and literature review, as well as long-term follow-up of this patient.

Case Report

The interventional cardiology service was consulted by the neurosurgical team on a 5-year-old male patient with a malfunctioning VA shunt. The patient had an extensive medical history, including: neurofibromatosis, prematurity, intraventricular hemorrhage, post-hemorrhagic hydrocephalus, ventriculitis, and cerebral palsy. He had three previous ventriculo-peritoneal (VP) shunts placed as an infant which failed. As a result of numerous bowel surgeries, the infant had a hostile abdomen so, after his third VP shunt failed at 11 months of age, he underwent placement of a VA shunt in lieu of another VP shunt. Yearly follow-up for four years with neurosurgery showed continued patency and function of the shunt. Eleven months after his most recent follow-up, he presented with increased lethargy and vomiting, and was found to have VA shunt fracture at the level of the left clavicle. He underwent placement of another VP shunt, and during the same procedure, an attempt was made to surgically remove the VA shunt fragment. The cephalic end of the catheter fragment was shown by x-ray to be in the left subclavian vein region (Figure 1), but it could not be directly visualized during surgery, and was feared to be intraluminal. The extraction

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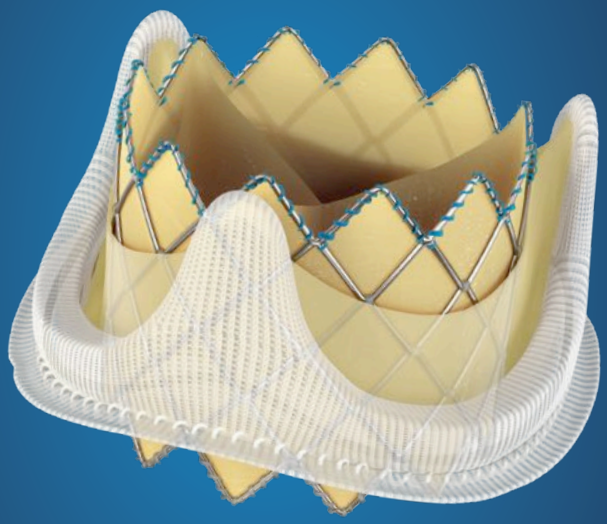

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attempt was abandoned. Because it had been several years since a VP shunt was attempted, the shunt was revised to a VP shunt with the assistance of general surgery to lyse adhesions and place the abdominal catheter. Following that, the decision was made to attempt to retrieve the shunt catheter by snare in the cardiac catheterization laboratory. At the time of cardiac catheterization, fluoroscopy demonstrated the cardiac end of the shunt catheter was likely in the right ventricle (Figure 2), while the distal end was seen in the area of the left subclavian vein. The right femoral vein was cannulated and a 7-French sheath was inserted. Since neither end of the shunt catheter fragment was accessible to loop the snare, attempts were made to free the cardiac end into the inferior vena cava in order to retrieve it with the snare. Initially a J-wire was used to loop around the catheter fragment, but this was unable to pull either end free. Next, a pigtail catheter was used to loop around the shunt fragment, which enabled slightly better traction, but that had no better result. A multipurpose catheter with a 0.025" tip deflector (Cook Medical, Bloomington, IN), which could be looped over the shunt catheter fragment, was then used, which provided still better traction, but could not dislodge the end of the shunt catheter fragment. Lastly, a tip deflector was used with the tip hand-bent into a U shape, which created a complete circle, and was advanced within the multipurpose 5-French catheter. This was looped around the shunt catheter fragment with good success and, as a result, a large amount of traction was able to be placed on the shunt catheter fragment, but neither end of the fragment was able to be dislodged (Figure 3). Echocardiography at this time confirmed location of the cardiac end in the right ventricle surrounded by dense tissue and calcification (Figure 4). It was felt that using increased force would be harmful to the adhered structures, so the retrieval attempt was abandoned. Cardiothoracic surgery was consulted, and the decision was made to leave the shunt catheter in place for the time being as the risks of an open heart procedure would outweigh the risks of the retained intracardiac shunt. The patient was placed on 5mg/kg aspirin therapy for anticoagulation and followed regularly by the cardiology service. At follow-up visits one, eight, and 12 months after the procedure, the patient had no signs of complications from the retained intracardiac shunt. Repeat echocardiograms remained unchanged with no evidence of thrombus or fragment migration.

Discussion

Since the development of the Spitz-Holter and the Pudenz valves in the mid-20th century, ventricular shunting has become the definitive management for hydrocephalus. Initially most shunting systems were directed at vascular drainage, but the VP shunt has since become the most widely used shunt as it is associated with less complications.[2] VA shunts are still in use, though predominantly for patients in whom a VP shunt is contraindicated, such as those with a hostile abdomen.[3]

Unfortunately, all intravascular catheters intended for chronic use, such as a VA shunt or total parenteral nutrition, have the potential to fracture, migrate, or become adherent to vascular tissue.[4,5,6,7] In the literature, trans-catheter snare removal of fragmented

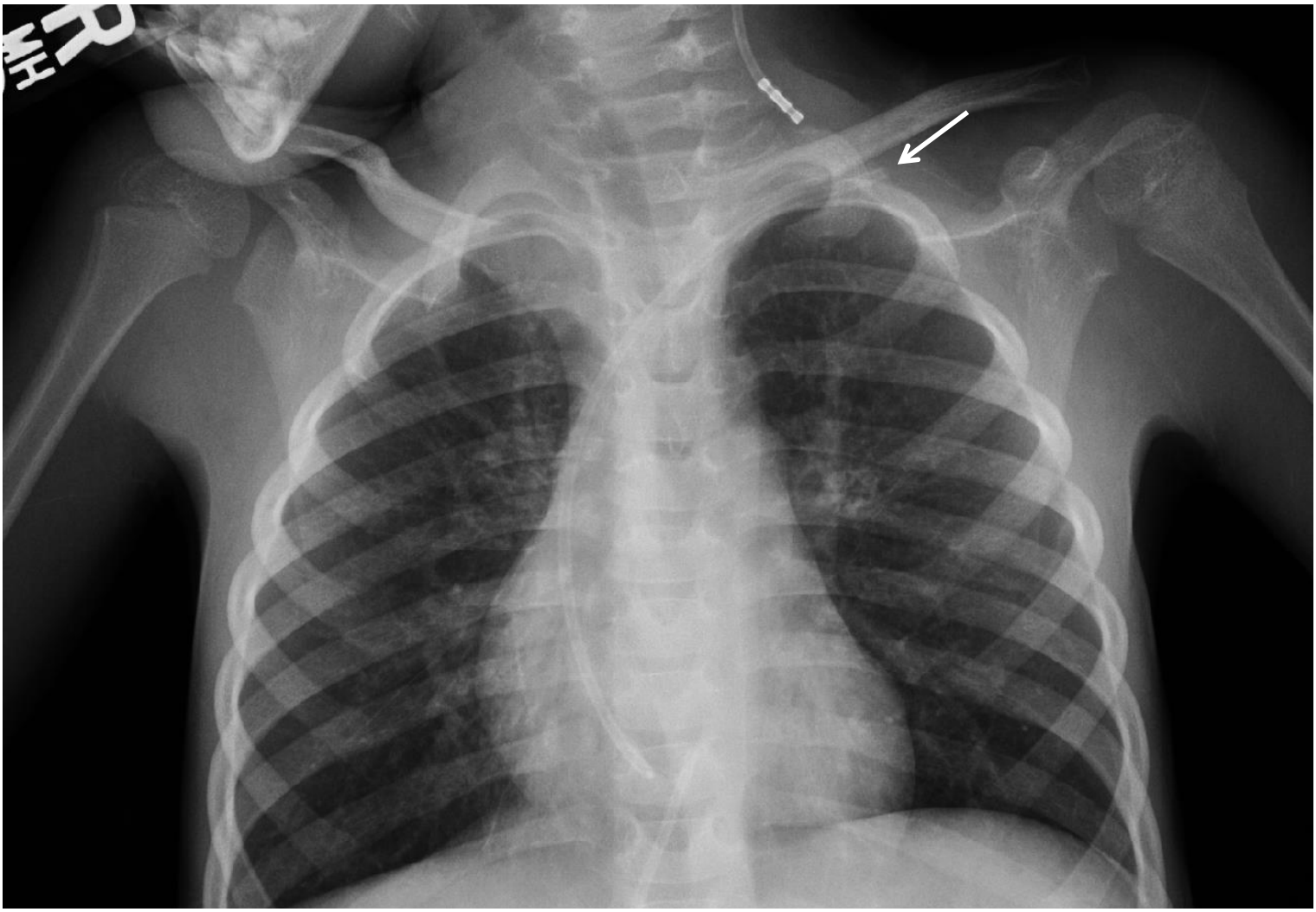

Figure 1. AP radiograph demonstrating the fractured VA shunt. Arrow indicates the cephalic end of the catheter fragment in the left subclavian vein region.

intravascular catheters is the most common practice. However, for cases in which adherence prevents successful snare retrieval, some authors have argued for surgical removal[8,9,10] while others advocate leaving the catheter in place.[11,12,13,14] No large studies have compared these two treatment options for any type of adhered intracardiac catheter fragment. At least two case series, however, do suggest the incidence of complications caused by retained and fixed intravascular foreign bodies is low, though it is unclear whether anticoagulation was used in these patients long-term.[13,15] An additional part of the rationale to leave the shunt fragment in place is our experience with retained pacemaker leads. These are often left in-situ with minimal long-term complications.[16,17,18,19] There still is insufficient data to accurately predict the risk of having a retained shunt. Thus, no uniform recommendations exist for the management of such cases.

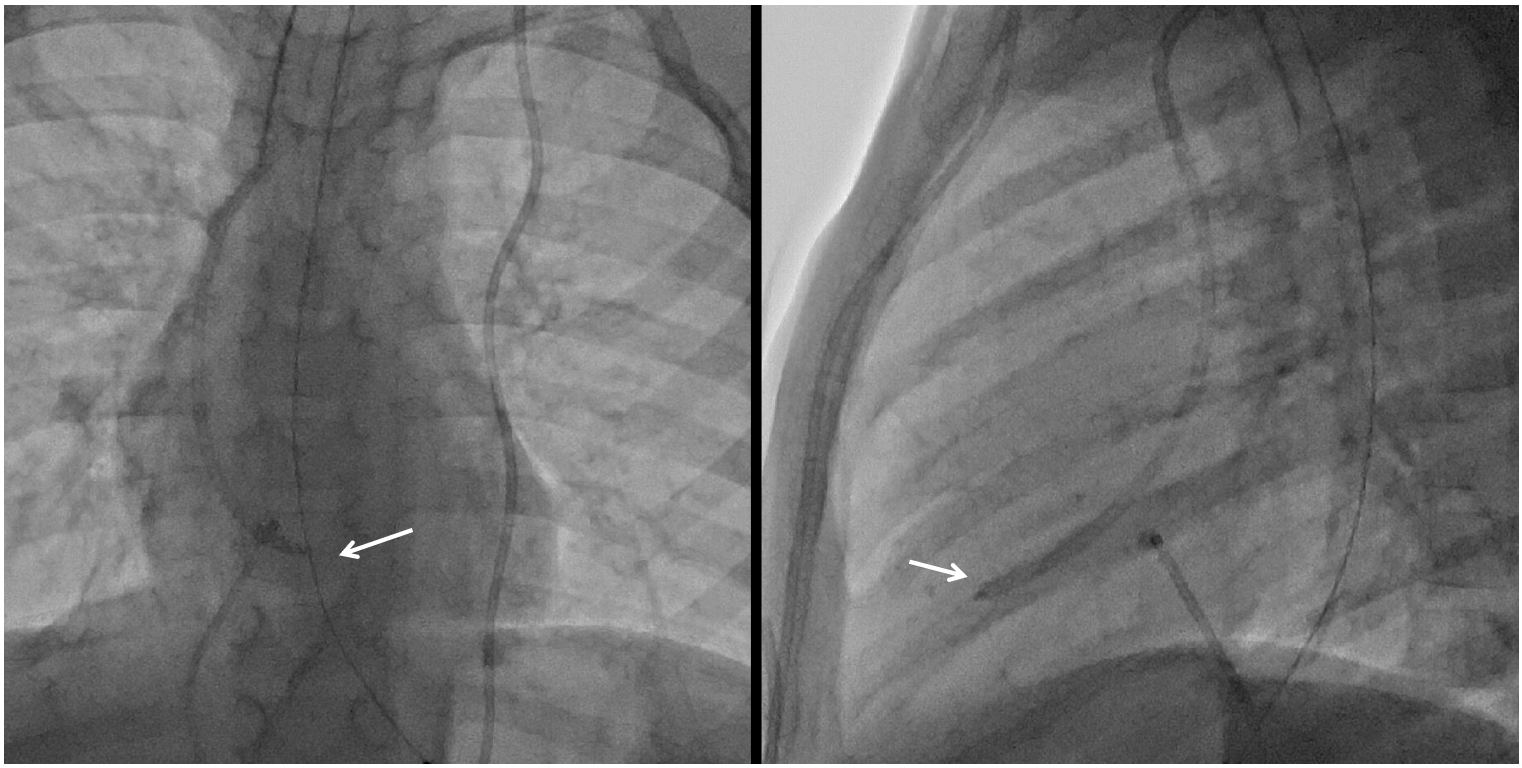

Figure 2. Intraprocedural AP and lateral fluoroscopy images demonstrate the tip of the shunt catheter fragment within the right ventricle.

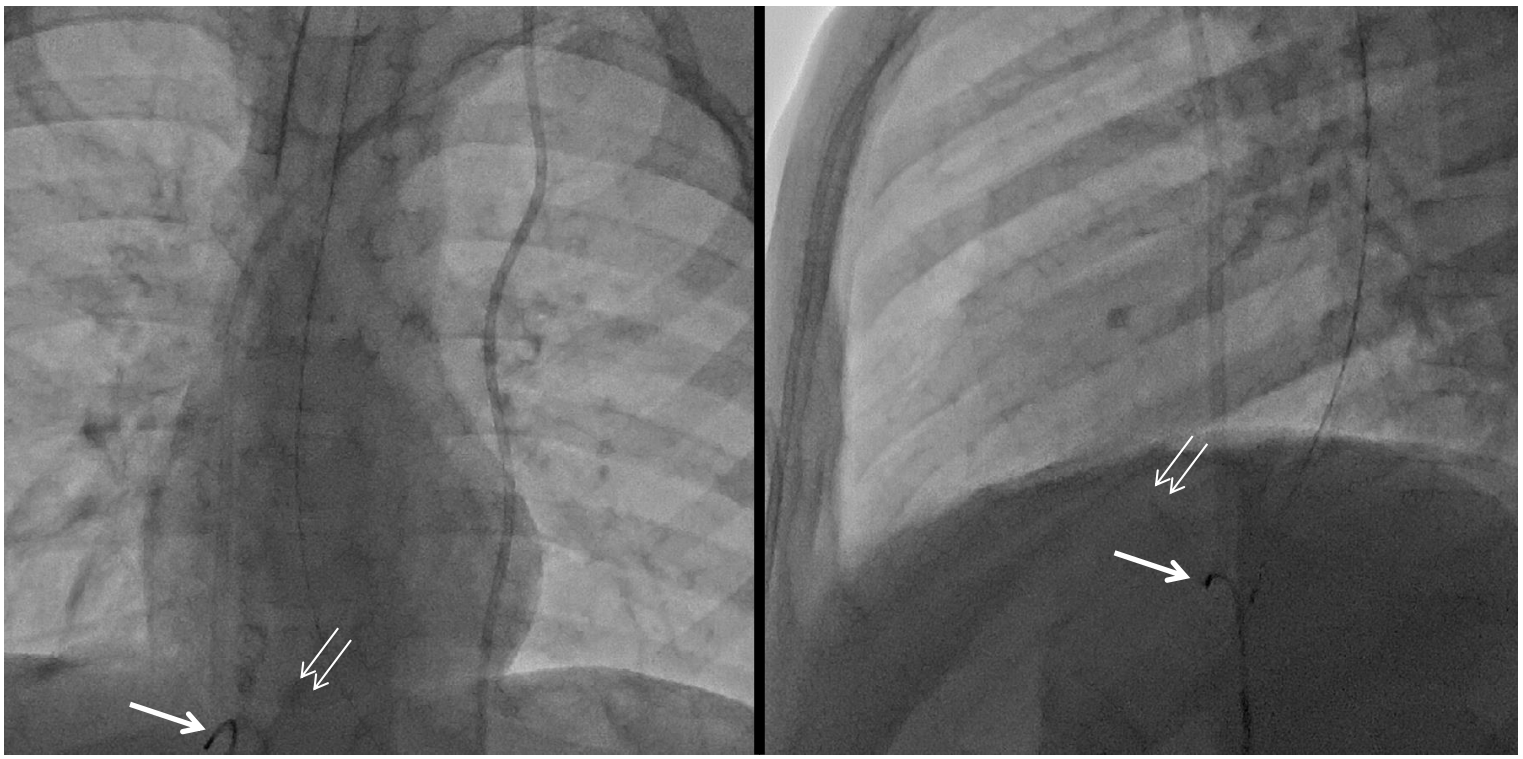

Figure 3. Intra-procedural AP and lateral fluoroscopy images showing the tip deflector (single arrow) looped over the catheter fragment and a large amount of traction being placed on the fragment. The cardiac end of the shunt fragment (double arrow) remains fixed in the right ventricle.

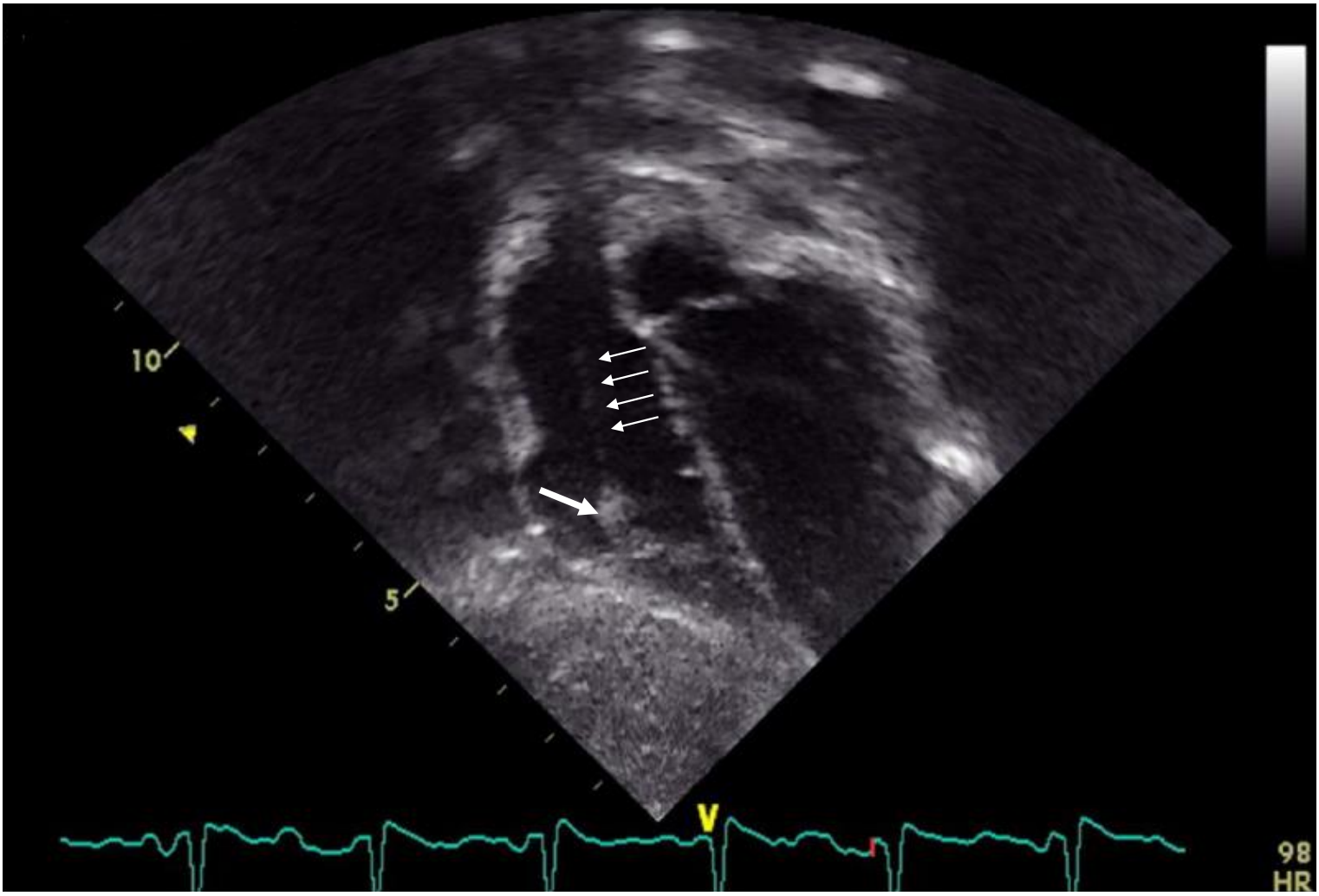

Figure 4. Intra-procedural echocardiography, modified four chamber subcostal view showing the course of the shunt fragment through the right ventricle (small arrows) and dense tissue at the end of the fragment (large arrow).

This study provides a unique perspective in that a broken, migrated, and adhered intracardiac VA shunt fragment is a rare complication of a seldom-used cephalic shunt. We recommend minimally invasive methods to attempt extraction of an intracardiac catheter fragment, but when unsuccessful, to leave the fragment in place, maintaining the patient on aspirin for anticoagulation, and ensuring routine follow-up with echocardiographic imaging to monitor for complications.

Conclusion

Our case report and review of the literature suggest that retained, but well adherent intravascular and/or intracardiac catheter fragments may be left in-situ with potentially minimal risk of complication. We recommend aspirin therapy for thrombotic prophylaxis and regular follow-up with echocardiography.

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Principal Author

Preston Boyer, MD
The University of Arizona
Department of Pediatrics
1501 N. Campbell Ave.
P.O. Box 245073
Tucson, AZ 85724 USA
Tel: 520.626.7944; Fax: 520.626.5652
prestonboyer3@gmail.com

Brief Biographical Sketch of Principal Author:

Principal author, Dr. Preston Boyer is a recent graduate of St. Louis University School of Medicine in St. Louis, USA. He is now a resident in Pediatrics at the University of Arizona in Tucson, AZ and plans to pursue a career in pediatric cardiology. He is a member of the American Medical Association and the American Academy of Pediatrics.

Philippe Mercier, MD
Saint Louis University School of Medicine
Department of Neurosurgery
Division of Pediatric Neurosurgery
3635 Vista Ave., 5th Floor FDT
St. Louis, MO 63110 USA
mercierpj@slu.edu

Anne Gildehaus, CPNP-AC
Saint Louis University School of Medicine
Department of Neurosurgery
Division of Pediatric Neurosurgery
3635 Vista Ave., 5th Floor FDT
St. Louis, MO 63110 USA
anne.gildehaus@ssmhealth.com

Corresponding Author

Saadeh Jureidini, MD
Saint Louis University School of Medicine
Department of Pediatrics
Division of Cardiology
1465 S. Grand Blvd.
St. Louis, MO 63104 USA
Tel: 314.577.5633
jureidsb@slu.edu

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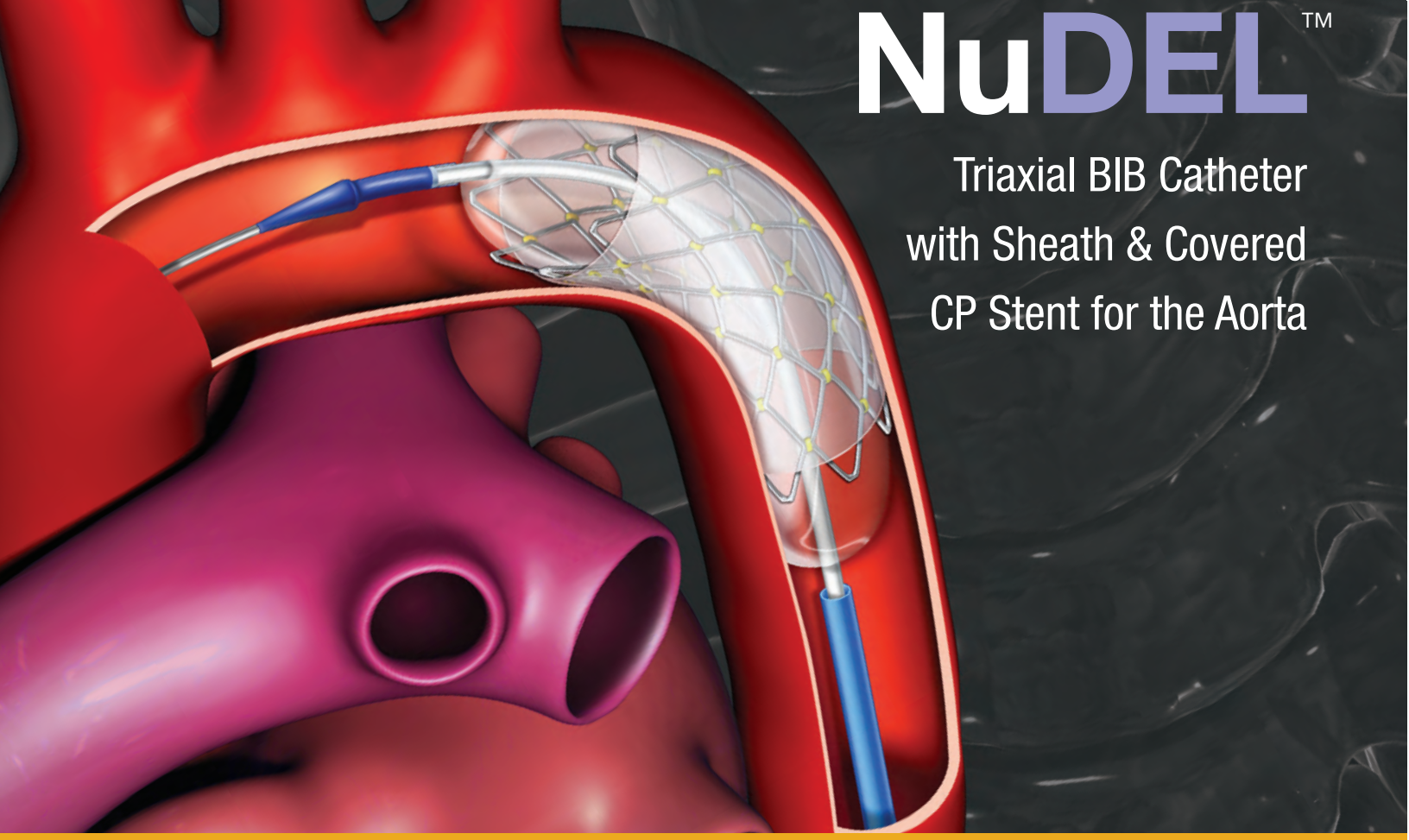

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Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

Cardiac Cell Therapy Safely Improves Heart Function, Upper Limb Strength in Duchenne Muscular Dystrophy Patients: Phase I/II-A Clinical Trial Results Could Help Lead to Treatment for Fatal, Incurable Disease

After boys and young men with Duchenne Muscular Dystrophy received cardiac progenitor cell infusions, medical tests indicated that the patients' hearts appeared improved, results from a new study show. Patients in the study also scored higher on arm strength tests after receiving the cell infusions.

Results from the HOPE Duchenne randomized clinical trial of 25 patients were presented today at the American Heart Association Scientific Sessions in Anaheim. The cardiac progenitor cells administered to the patients were contained in CAP-1002, the lead investigational therapy under development at Capricor Therapeutics, Inc.

"This is the first trial to test cell therapy to treat Heart Disease in patients with Duchenne Muscular Dystrophy," said Ronald G. Victor, MD, Associate Director of the Cedars-Sinai Heart Institute and one of the clinical trial's primary investigators. "These early results show that further research is warranted and, in fact, is being planned."

Affecting one in 3,600 boys, Duchenne Muscular Dystrophy is a neuromuscular disease caused by an absence of a key muscle protein called dystrophin, which leads to progressive muscle degeneration. Most Duchenne patients lose their ability to walk between ages 12 and 15. Average life expectancy is about 25 years.

"The need is great because there is no current treatment to address heart failure in these patients," said Eduardo Marbán, MD, PhD, Director of the Cedars-Sinai Heart Institute and the researcher who developed the cardiosphere-derived cell (CDC) technology used in the study. "Generally, the primary cause of death in these patients is heart failure. If we can slow or reverse heart failure in Duchenne patients, it will be a step forward."

In the study, 25 patients ages 12 to 22 were treated at the Cedars-Sinai Heart Institute, University of Florida Health or Cincinnati Children's. Twelve patients were randomly assigned to receive standard care consisting of prescription medications. The remaining 13 patients received the standard medications and also underwent a minimally invasive procedure during which a catheter was threaded up into each patient's three main coronary arteries before releasing 75 million CDCs grown from donor hearts.

Results show:

- As measured by MRI, the patients who received the progenitor cells experienced a 7% reduction in the area of the heart scarred by cardiomyopathy. Patients who had the usual regimen saw an increase in their heart scars.
- Among the subgroup of patients with the most advanced impairment of arm function, one year after treatment, eight out of nine patients who received the CDCs experienced improved skeletal muscle function in the hands and forearms. Their arm strength was measured by the Performance of the Upper Limb (PUL) test. The test assesses patient's ability to perform the arm tasks associated with daily living arm strength, as well as the ability to perform a variety of movements, such as picking up coins, removing a container lid and lifting light weights. At that time, none of the patients who received standard medical therapy experienced improved arm strength and function.
- Five of the 13 patients who received cells experienced temporary atrial fibrillation, an irregular and often rapid heart rate that can increase the risk of complications such as stroke and heart failure. Temporary atrial fibrillation is known to occur during cardiac catheterization in patients of this age range.

"We are now planning our Phase II Trial, which will be a bit different," Victor said. "Instead of a one-time infusion during a cath lab procedure, the patients will receive the CDCs in an intravenous drip, and will receive multiple treatments spaced over several months."

Pending FDA approval, Victor said, the Phase II Trial could begin in early-2018.

Disclosure: The Cardiac Derived Cells (CDCs) used in the Phase I/II HOPE Trial were derived from donor hearts and provided by Capricor Therapeutics. Marbán developed the process to grow CDCs when he was on the faculty of Johns Hopkins University; the process was further developed at Cedars-Sinai. Capricor has licensed the process from Johns Hopkins and from Cedars-Sinai for clinical and commercial development. Capricor has licensed additional intellectual property from Cedars-Sinai and the University of Rome. Cedars-Sinai and Marbán have financial interests in Capricor. Victor has been a consultant to the company, but was not paid by the company for his work on this study.

The Duchenne Muscular Dystrophy study was funded in part by a grant from the California Institute for Regenerative Medicine to Capricor. Coalition Duchenne, CureDuchenne and Parent Project Muscular Dystrophy also provided support or guidance.

The Cedars-Sinai Heart Institute is internationally recognized for outstanding heart care built on decades of innovation and leading edge research.

The Medical Director of Cardiology at Florida Medical Center Is Elected President of the Florida Chapter of the American College of Cardiology and to the Board of Governors for the National American College of Cardiology

Florida Medical Center Medical Director, David Perloff, MD, FACC, FACP, a board-certified cardiologist, was elected President of the Florida Chapter of the American College of Cardiology (ACC) and placed on the Board of Governors for the National American

College of Cardiology. A practicing physician in South Florida since 1991, his three-year term will start in August of 2018.

The American College of Cardiology is a close to 50-thousand member non-profit medical society that is dedicated to enhancing the lives of cardiovascular patients. It bestows credentials upon cardiovascular specialists who meet its qualifications. Education is a core component of the College, which is also active in the formulation of health policy and the support of cardiovascular research.

"These leadership positions with both the state and national ACC are prestigious for both Florida Medical Center, and our parent company, Tenet Healthcare, and I wholeheartedly congratulate Dr. Perloff," said Trey Abshier, Florida Medical Center CEO. "Additional resources from the ACC will help us further elevate our prestigious cardiac program and allow patients to get better access to some of the most up-to-date treatment options."

The Heart Institute of Florida at Florida Medical Center performed the first open heart surgery in Broward County, and continues to offer a complete range of heart and vascular treatments. The hospital recently opened an electrophysiology lab, and is also home to a Hybrid Operating Suite, an accredited Chest Pain Center, and cardiac catheterization labs.

Florida Medical Center, a campus on North Shore is a 459-bed acute care hospital founded in 1973. Located at 5000 West Oakland Park Boulevard in Fort Lauderdale, Fla., Florida Medical Center is the home of The Heart Institute of Florida, the hospital's center for cardiac services which offers a Hybrid Operating Suite, Heart Valve Clinic, Chest Pain Center and the Aortic Disease Institute of Florida.

The hospital is one of the only Comprehensive Stroke Centers in Western Broward County as designated by the Florida Agency for Healthcare Administration, allowing physicians and staff to offer a higher level of stroke care to its patients.

Florida Medical Center received the following awards from Healthgrades, the leading online resource that helps consumers search, compare and connect with physicians and hospitals: ranked among the top 10% in the nation for cardiology services and coronary interventional procedures in 2014, five-star recipient for Coronary Intervention Procedures for 3 years in a row (2013-2015), five-star recipient for coronary interventional procedures for three years in a row (2013-2015), and five-star recipient for the treatment of heart failure (2014-2015 and 2017).

Florida Medical Center has also received recognition from the American Heart Association's "Get With The Guidelines Gold Plus Performance Achievement Award" in stroke care and the target stroke honor roll, the highest distinction awarded for stroke care. To learn more about Florida Medical Center, visit www.FloridaMedCtr.com.

TAVR Found To Be Cost-Effective Compared with SAVR in Intermediate Risk Patients with Aortic Stenosis

Newswise — Analysis of the PARTNER 2A Trial and the SAPIEN-3 Intermediate Risk Registry found Transcatheter Aortic Valve Replacement (TAVR) to be highly cost-effective compared with Surgical Aortic Valve Replacement (SAVR) in intermediate surgical-risk patients with aortic stenosis.

Findings were reported in October at the *29th Annual Transcatheter Cardiovascular Therapeutics (TCT) Scientific Symposium*. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

Researchers led by Dr. David J. Cohen (Saint Luke's Mid America Heart Institute, Kansas City, MO) used data from the PARTNER 2A Randomized Trial and the SAPIEN-3 Intermediate Risk Registry to perform a formal, patient-level economic analysis comparing TAVR using either the SAPIEN XT valve (XT-TAVR) or the SAPIEN-3 valve (S3-TAVR) with SAVR. The comparison between XT-TAVR and SAVR was based upon randomized assignment within PARTNER 2A; the comparison between S3-TAVR and SAVR was not randomized. Procedural costs were assessed based on measured resource utilization and all other costs were assessed by linking trial data with Medicare claims for the index hospitalization and follow-up period or by piecewise regression models for the remaining patients.

PARTNER 2A

In the trial, XT-TAVR led to significant reductions in procedure duration compared with SAVR (102±46 vs. 236±83, P<0.001) and hospital length of stay (6.4±5.5 vs. 10.9±7.6, P<0.001). Although procedural costs were $22,083 higher with XT-TAVR than SAVR (reflecting the higher cost of the transcatheter valve), most of this higher cost was offset by reduced costs related to length of stay and in-hospital complications such that total costs for the index hospitalization were only ~$2,900 higher with TAVR ($61,433 vs. $58,545; P=0.014). Over the following 24 months, follow-up costs were substantially lower with XT-TAVR (by $9,303 per patient) such that total medical care costs were lower with TAVR than SAVR two-year follow-up ($107,716 vs. $114,132, P=0.014). When the trial results were projected over a lifetime horizon, XT-TAVR was projected to result in both cost savings of $7,949 and greater quality-adjusted life expectancy (by 0.15 years).

SAPIEN 3

When performance of S3-TAVR in the S3i registry was compared with SAVR within PARTNER 2A, the reductions in procedure duration (84±38 vs. 236±83, P<0.001) and length of stay (4.6±5.7 vs. 10.9±7.6, P<0.001) were even greater than in the randomized trial. As a result, despite the higher cost of the transcatheter valve, total costs for the index hospitalization were lower with S3-TAVR than SAVR ($54,256 vs. $58,410, P=0.014). Over the first year of follow-up, S3-TAVR resulted in additional cost savings of nearly $11,000/patient. When these in-trial results (including improved survival at two years) were projected over a lifetime horizon, S3 TAVR was projected to yield lifetime cost savings of $9,692 per patient and a significant gain in quality adjusted life-years (0.27 years)—an economically dominant strategy.

"For patients with severe aortic stenosis and intermediate surgical risk similar to those enrolled in the PARTNER 2 Trial, these results, demonstrating substantial cost savings and improved quality-adjusted life expectancy, indicate that transcatheter aortic valve replacement should be considered the preferred strategy based on

both clinical and economic considerations," said David J. Cohen, MD, MSc, Director of Cardiovascular Research at Saint Luke's Mid America Heart Institute in Kansas City, MO.

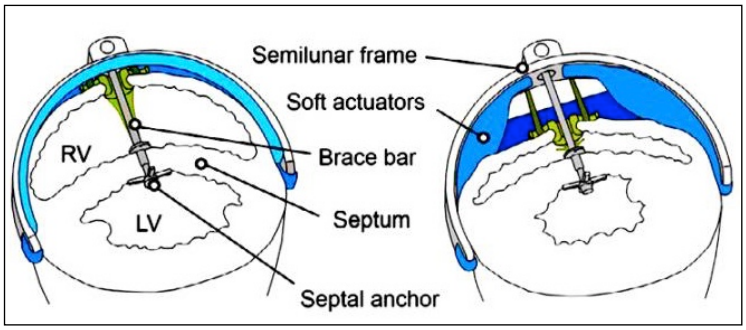
The PARTNER 2A and SAPIEN 3 Cost-effectiveness Trial was funded by Edwards Lifesciences. Dr. Cohen reported receiving research grant support from Edwards Lifesciences, Medtronic, Boston Scientific, and Abbott Vascular, as well as consulting income from Edwards Lifesciences and Medtronic.

The Cardiovascular Research Foundation (CRF) is a nonprofit research and educational organization dedicated to helping doctors improve survival and quality of life for people suffering from heart and vascular disease. For over 25 years, CRF has helped pioneer innovations in interventional cardiology and educate doctors on the latest treatments for heart disease.

Transcatheter Cardiovascular Therapeutics (TCT) is the annual scientific symposium of CRF and the world's premier educational meeting specializing in interventional cardiovascular medicine.

For more information, visit www.crf.org and www.tctconference.com.

A 'Half-Hearted' Solution to One-Sided Heart Failure
Soft Robotic System Can Provide Isolated Support to the Right or Left Ventricle



This is an illustration showing sectional view of a heart with the soft robotic system helping to draw blood into (left) and pump blood out (right) of the heart's right ventricle.
CREDIT: Boston Children's Hospital

Boston Children's Hospital - Soft robotic actuators, which are pneumatic artificial muscles designed and programmed to perform lifelike motions, have recently emerged as an attractive alternative to more rigid components that have conventionally been used in biomedical devices. In fact, earlier this year, a Boston Children's Hospital team revealed a proof-of-concept soft robotic sleeve that could support the function of a failing heart.

Despite this promising innovation, the team recognized that many pediatric heart patients have more one-sided heart conditions. These patients are not experiencing failure of the entire heart -- instead, congenital conditions have caused disease in either the heart's right or left ventricle, but not both.

"We set out to develop new technology that would help one diseased ventricle, when the patient is in isolated left or right heart failure, pull blood into the chamber and then effectively pump it into the circulatory system," says Nikolay Vasilyev, MD, a researcher in cardiac surgery at Boston Children's.

Now, Vasilyev and his collaborators -- including researchers from Boston Children's, the Harvard John A. Paulson School of Engineering and Applied Sciences and the Wyss Institute for Biologically Inspired Engineering at Harvard University -- have revealed their soft robotic solution. They describe their system in a paper published online in *Science Robotics*.

Getting to the Heart of the Challenge

Although other existing mechanical pumps can help propel blood through the heart, they are designed so that blood must run through the pump itself, exposing blood to its unnatural surface.

"Running blood through a pump always requires a patient to be placed -- permanently -- on anticoagulant medication to prevent blood clotting," Vasilyev says, who is a co-senior author on the paper. "It can be very difficult to keep the right balance of medication, especially in pediatric patients, who are therefore at risk of excessive bleeding or dangerous clotting."

So, using external actuators to help squeeze blood through the heart's own chamber, the team has designed a system that could theoretically work with minimal use of anticoagulants.

"We've combined rigid bracing with soft robotic actuators to gently but sturdily help a diseased heart chamber pump blood effectively," Vasilyev says.

The rigid brace component is deployed via a needle into the heart's intraventricular septum, the wall of tissue between the heart's chambers, to prevent the septum from shifting under the pressure of the artificial "muscle" of the soft actuator.

"With the use of classic left Ventricular Assist Devices (VAD), there are patients who experience a septum-shift towards the right side and subsequent ballooning of the right ventricle, which can cause secondary right heart failure," Vasilyev says. "Here, the rigid brace keeps the septum in its original position, protecting the healthy right side of the heart from the mechanical load of the left ventricular assistance."

In contrast, existing Ventricular Assist Devices don't involve the septum at all.

Tailoring the Concept for Future Translation

Altogether, the system involves a septal anchor, a bracing bar and sealing sleeve that pass through the ventricle wall, and a frame embedded with soft actuators that is mounted around the ventricle. The researchers designed two distinct versions of the system for the right and left ventricle.

In animal studies, the soft robotic system contributed significantly to the diseased ventricle's ability to eject blood. The researchers speculate that the system's effectiveness is due in part, to its

integration with the septum, which plays a key role in the heart's ability to pump blood.

The system also made significant improvement in its ability to draw blood into the ventricles, which is just as important as the heart's ability to pump it out.

"As the actuators relax, specially-designed elastic bands help return the heart's wall to its original position, filling the chamber sufficiently with blood," Vasilyev says.

Based on these initial proof-of-concept results, Vasilyev and his team are working on key design modifications that can bring this system closer to use in humans, such as portability and miniaturization of the components. They also need to do longer tests in animals to see how the system impacts the heart over prolonged periods of time.

In addition to Vasilyev, additional authors on the paper are: Christopher Payne, Isaac Wamala, Daniel Bautista-Salinas, Mossab Saeed, David Van Story, Thomas Thalhofer, Markus Horvath, Colette Abah, Pedro del Nido and Conor Walsh (co-senior author).

This work was supported by the U.S. Department of Defense Directed Medical Research Programs Discovery Award (W81XWH-15-1-0248), the Wyss Institute and Harvard SEAS.

Materialise and Siemens Healthineers syngo.via Partner to Bring 3D Printing to Hospitals Worldwide

Materialise NV, a leading provider of 3D printing services and software solutions, and Siemens Healthineers, a leading medical technology company announced late November that they are joining forces to bring Materialise Mimics inPrint software to hospitals around the world. 3D printing technology is growing rapidly in the medical field, and soon it will be even more mainstream as 3D printing software becomes more accessible in hospitals. The partnership, announced at the *2017 Radiological Society of North America (RSNA) Annual Meeting,* makes Materialise Mimics inPrint software, a dedicated solution for printing anatomical models in hospitals, available to radiologists through the Siemens Healthineers syngo.via open app platform.

Adopting virtual 3D anatomical models facilitates surgical planning and collaboration between radiologists and surgical teams. 3D-printed anatomical models improve patient communication, training and education surrounding anatomically complex pathologies.

“We believe 3D printing is going to revolutionize the medical industry and we are always looking for ways to improve accessibility of our 3D printing software to more patients and hospitals,” said Brigitte de Vet, VP of Medical at Materialise. “By partnering with other global healthcare leaders like Siemens Healthineers, we can do just that, and more importantly, we can further contribute to a better and healthier world.”

By integrating the software into syngo.via, Mimics inPrint is directly incorporated into the standard hospital workflow. This allows for safe and easy access to in-house and Materialise-powered 3D printing services. This will facilitate the integration of 3D printing within clinical environments, contributing to higher quality, cost-efficient care for patients and hospitals. Each patient will now have access to more personalized care through Materialise's patient-specific anatomical models.

"By incorporating 3D technology into syngo.via, we jointly support the entire workflow from patient diagnosis to therapy planning," said Valentin Ziebandt, Head of Marketing at the Syngo Business Line at Siemens Healthineers. "This is a cost-effective way to increase the clinical capabilities of syngo.via and an important step towards achieving personalized care and precision medicine."

For more information on this partnership and the Materialise Mimics inPrint software, visit www.materialise.com/en/medical/3d-printing-introduced-into-your-workflow.

Three Weeks in Beautiful Yunnan Province, China - China California Heart Watch Requests Volunteer Pediatric Cardiologists

China California Heart Watch (www.chinacal.org), a California State and Yunnan Province, China based not for profit public charity is soliciting for volunteer Pediatric Cardiologists from the Untied States and other countries to spend 3 weeks during the months of July, August or December, 2018 in Yunnan Province, China.

China Cal is offering $1,000 toward round trip airfare to Dali, China and room, board and local transportation support.

Volunteer work will include physical and ultrasound diagnosis of children (newborn to 18 years) suspected of having congenital heart disease and recommendation for clinical management. Work will also include teaching of USA and Chinese university and high school level students regarding Congenital Heart Disease.

Our team will include a Chinese physician sonographer, who is especially trained in pediatric cardiac sonography, bilingual translators and experienced administrative support.

We will be working in destinations such as Li Jiang, Xi Shuang Ban Na and Yu Xi. There will be time for sightseeing at these destinations. For more information, please visit the website www.chinacal.org, or email Dr. Robert Detrano at robert@chinacal.org.

Families of Survivors of ECMO for Heart Conditions Report Favorable Quality of Life

One of the few large studies to report long-term outcomes in cardiac patients treated in childhood with extracorporeal membrane oxygenation (ECMO) has found overall favorable outcomes among survivors, as reported by families. ECMO provides short-term breathing and heart support for critically ill children while doctors treat the underlying illness.

Matthew D. Elias, MD, is a Pediatric Cardiologist at Children's Hospital of Philadelphia.
CREDIT
Children's Hospital of Philadelphia

A research team from Children's Hospital of Philadelphia (CHOP) published the ECMO study in the August 2017 issue of *Pediatric Critical Care Medicine*.

The team analyzed a cohort of 396 patients with cardiac disease treated with ECMO at CHOP from 1995 to 2012. Overall mortality was 66% at a median follow-up of 6 years after ECMO therapy, which remains consistent with outcomes seen in previous decades.

In phone surveys or written surveys among the families of survivors, a majority reported positive outcomes regarding health and physical limitations. Over 90% of families reported good or excellent health, and approximately 86% reported no or mild physical limitations.

However, the authors noted a discrepancy between family-reported favorable outcomes and a relatively high rate of medical and behavioral issues revealed by more detailed questioning. Almost 25% of patients had below-average school performance and required special education, and almost 50% had parental-reported learning disabilities. These results may help families define realistic expectations regarding long-term outcomes for children supported with ECMO due to an underlying cardiac condition.

Matthew D. Elias, MD, a Pediatric Cardiologist at CHOP and first author of the study, noted that ECMO use in children with Congenital Heart Disease (CHD) has increased markedly over the past several decades, as increased experience in Pediatric Cardiology and Cardiac Surgery has allowed ECMO use to expand to more complex patients. Senior author Matthew J. O'Connor, MD, also a CHOP Pediatric Cardiologist, added that "several factors have potentially improved long-term outcomes, such as increasing experience with ECMO and CHD in general. But the inclusion of a more medically complex population in the recent era may mitigate these improvements in outcomes, accounting for the fact that overall mortality rates haven't changed much."

Although this single-center study represents one of the largest cohorts of ECMO patients undergoing detailed assessments of outcomes and quality of life, Elias said that further research in larger, multicenter studies should further investigate family experiences and long-term patient outcomes. He added, "In the meantime, our findings should allow for improved family counseling in discussing long-term quality-of-life for children with heart disease."

The ECMO Center at Children's Hospital of Philadelphia recently received the "Platinum Level ELSO Award for Excellence in Life

Support" from the Extracorporeal Life Support Organization (ELSO), an international consortium of centers offering ECMO (extracorporeal membrane oxygenation) for support of failing organ systems in infants, children and adults. CHOP's ECMO Center has been recognized as an ELSO Center of Excellence since 2008. The Platinum Level is the highest awarded honor, and is rarely achieved by ELSO member institutions, especially pediatric centers. The ECMO Center at CHOP is the only ECMO center in the Philadelphia region designated by ELSO as a Platinum Center of Excellence, and is one of the most active in the country. It has supported more than 1,300 patients since it was established in 1990. The program's multidisciplinary team is comprised of pediatric surgeons, neonatologists, intensivists, anesthesiologists, perfusionists, specially trained nurses and respiratory therapists.

Matthew D. Elias, et al. "Long-Term Outcomes of Pediatric Cardiac Patients Supported by Extracorporeal Membrane Oxygenation," Pediatric Critical Care Medicine, August 2017. http://doi.org/10.1097/PCC.0000000000001227

Children's Hospital of Philadelphia was founded in 1855 as the nation's first pediatric hospital. For more information, visit www.chop.edu.

Newborns with Trisomy 13 or 18 Benefit from Heart Surgery, Study Finds

Heart surgery significantly decreases in-hospital mortality among infants with either of two genetic disorders that cause severe physical and intellectual disabilities, according to a new study by a researcher at the Stanford University School of Medicine and his colleagues at the University of Arkansas for Medical Sciences.

Trisomy 13 and 18, which result from having extra chromosomes, often cause heart defects. Infants with the conditions generally die within their first year. Many die within weeks, if not days, of being born.

Due to these infants' short life expectancy, their heart conditions are often treated with standard medical care -- blood pressure medication, ventilators and intravenous fluids -- but not surgery. Many hospitals rarely give parents the option of surgery for their child. "The thought has been it doesn't make sense to undertake a major heart surgery if the patient's death within a few months is a near certainty," said Thomas Collins, MD, Clinical Associate Professor of Pediatric Cardiology at the Stanford University School of Medicine.

But Collins and his co-authors at the University of Arkansas for Medical Sciences analyzed the outcomes of the 100 babies with Trisomy 13 or 18 in the study who had received heart surgery, and recorded the health impacts. What they found was that patients who underwent heart surgery had a significant decrease in mortality, and that the impact lasted for the next two years. "We thought we'd show no difference in survival, but it turns out there's a marked one," Collins said.

A study describing the team's findings was published online Oct. 17 in *Pediatrics*. Collins, the senior author, was on the faculty of the University of Arkansas for Medical Sciences when much of the work was done. The lead author is Katherine Kosiv, MD, a cardiology fellow at the university.

Largest Study of its Kind

Using data gathered from 44 children's hospitals across the United States between 2004 and 2015, the researchers reported outcomes for nearly 1,600 patients, the largest study ever of infants with Trisomy 13, also known as Patau Syndrome, or Trisomy 18, also known as Edwards Syndrome, Collins said.

The researchers found that heart surgery increased survival and hospital discharge on average from 33% to approximately 67% for these patients, and that this benefit lasted through two years of follow-up. "When we analyzed the survival curves, the data spoke for themselves," Collins said. "Especially for Trisomy 18, the number of babies that survive more than doubles after surgery."

Most infants in the study were admitted at less than a day old, and 51% of infants in the study who had Congenital Heart Defects died in the hospital or were discharged to hospice. The researchers also found that in-hospital mortality decreased in infants who were older at their admission date, heavier and female, corroborating previous findings.

Challenging the Narrative

Collins said his goal is to challenge the narrative surrounding these two conditions, much like how the story of Trisomy 21, or Down Syndrome, has changed in the last 40 years.

"Back in 1975, folks would've said there's nothing we can do to help those babies," he said. "But now people have proven if you do heart surgery early, patients with Down Syndrome can live to adulthood and be active members of their community. The difference it makes for them is tremendous." Forty percent of people with Down Syndrome have Congenital Heart Disease, Collins said. And unlike cases of Trisomy 13 and 18, it is now standard-of-care to operate on children with Down Syndrome.

Scientists aren't sure why Trisomy 13 and 18 are associated with higher rates of congenital heart disease than trisomy 21, and why patient death rates are so much higher.

Collins is certain, however, that Trisomy 13 and 18 patients have far more neurological and developmental issues than those with Down syndrome, and is unsurprised at hospitals' attitudes that surgery is considered a big risk to take with patients who have a low likelihood of survival anyway.

Still, he suspects that the results of this study might shift the paradigm of how babies with Trisomy 13 and 18 are cared for. "Surgery gives parents the option to say, 'We're going to do everything we can for our baby,'" said Collins. "And, now we've shown that heart surgeries could allow parents to take their babies home from the hospital, and have them for two years or beyond, as opposed to two weeks."

Collins also said that taking care of the patients' heart problems early on could enable caregivers to then properly analyze other health issues and perform follow-up procedures, such as tracheotomies, to improve the infants' respiration. His next study, in fact, is looking at all the risk factors other than heart disease in more than 3,000 Trisomy 13 and 18 patients and analyzing how their collective health problems fit together. Collins hopes eventually to create a guideline for pediatric caregivers to determine which problems to treat in which order.

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His work teasing out the most effective treatments for these babies ties into Stanford Medicine's focus on precision health, the goal of which is to anticipate and prevent disease in the healthy and precisely diagnose and treat disease in the ill.

Two researchers at the University of Arkansas for Medical Sciences are also co-authors.

The research did not receive external funding. The data were acquired from the Pediatric Health Information System as part of the use agreement with participating hospitals.

Excel Medical's WAVE Clinical Platform Receives FDA Clearance - The Patient Surveillance and Predictive Algorithm Platform is the First of Its Kind to Be Cleared by the FDA

Excel Medical launched the first FDA-cleared patient surveillance system. The WAVE Clinical Platform is the first of its kind cleared for marketing.

The WAVE Clinical Platform is an always-on remote monitoring platform that displays near real-time clinical views of physiologic and medically relevant data including waveforms and alarms for at-risk patients across hospital workstations, mobile devices and inside electronic medical records. WAVE automatically calculates risk, giving an at-a-glance early warning of patient deterioration up to six hours in advance of when clinicians would otherwise notice —and while there is still time to prevent further deterioration. In fact, while using the Visensia Safety Index, WAVE's first FDA-cleared predictive algorithm, UPMC went from six unexpected deaths in their control group to zero. *

"Everything we do as an organization aligns toward and supports the goal of eradicating unexpected deaths in hospitals," says Lance Burton, General Manager of Excel Medical. "People may say zero unexpected deaths is unattainable. We say anything other than zero is unconscionable."

For more than a decade, Excel Medical's products have been battle-tested in over 80% of the top academic medical centers, as well as by researchers and innovation partners. Now, with the clearance of the WAVE Clinical Platform, the company sits on the edge of a major opportunity to fulfill the promise of predictive healthcare. "We look forward to bringing other revolutionary predictive algorithms to the WAVE platform soon, many of which are currently under development," adds Burton.

Excel Medical's technologies were designed with one goal in mind-—to eradicate unexpected deaths in hospitals. There are more than 400,000 unexpected deaths in U.S. hospitals annually making it the nation's third-leading category of death—behind heart disease and cancer. Excel Medical's "True North" is to make predictive analytics an actionable process, "predicting the preventable™," making it possible to achieve zero unexpected hospital deaths. Excel Medical was founded in 1995, and its products/services are used by more than 80% of the top academic medical centers and children's hospitals in the United States.

Excel Medical Electronics, LLC, has multiple high-profile partners including IBM Watson, OBS Medical and EPIC. It is a privately-held company headquartered in Jupiter, FL, with customers throughout North America, Europe, Australia and Asia. www.Excel-Medical.com.

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**Study available upon request: "Cardiorespiratory instability before and after implementing an integrated monitoring system," by 6 authors including Marilyn Hravnak, University of Pittsburgh and Michael A. Devita, New York City Health and Hospitals Corporation.*

FDA Clears First Medical Device Accessory for Apple Watch® - AliveCor's KardiaBand™ Allows Users to Take a 30 Second EKG Right on the Wrist

AliveCor, the leader in FDA-cleared personal electrocardiogram (EKG) technology, announced in November FDA clearance of KardiaBand in the U.S., allowing Apple Watch users to discreetly capture their EKG anytime, anywhere in order to quickly detect normal sinus heart rhythms and atrial fibrillation (AFib), the most common heart arrhythmia. The first FDA-cleared medical device accessory for Apple Watch, KardiaBand can record an EKG in 30 seconds with just a touch of its integrated sensor. Results from the Kardia App are displayed on the face of Apple Watch.

The first of its kind, FDA-cleared, clinical grade wearable EKG replaces your original Apple Watch® band providing access to a 30-second EKG anytime, anywhere. KardiaBand requires Premium membership.

AliveCor is also introducing SmartRhythm, a new feature within the Kardia app for Apple Watch. SmartRhythm uses artificial intelligence in concert with inputs from Apple Watch's heart rate and activity sensors to continuously evaluate the correlation between heart activity and physical activity. When SmartRhythm detects that heart rate and activity are out of sync, the device notifies users to capture an EKG with KardiaBand, or with KardiaMobile, AliveCor's popular, portable EKG reader.

"KardiaBand paired with SmartRhythm technology will be life-changing for people who are serious about heart health," said Vic Gundotra, CEO, AliveCor. "These capabilities will allow people to easily and discreetly check their heart rhythms when they may be abnormal, capturing essential information to help doctors identify the issue and inform a clear path of care to help manage AFib, a leading cause of stroke, and other serious conditions."

Atrial Fibrillation (AFib), is the most common heart arrhythmia, and a leading cause of stroke. AFib affects more than 30 million people worldwide, and one in four people over the age of 40 are at risk for developing it. Millions of people around the world are unknowingly living with AFib. Yet, two out of three strokes are preventable when AFib is detected and treated appropriately.

"This is a paradigm shift for cardiac care as well as an important advance in healthcare," said Dr. Ronald P. Karlsberg, MD FACC, Board Certified Cardiologist and Clinical Professor of Medicine, Cedars Sinai Heart Institute and David Geffen School of Medicine UCLA. "Today, EKGs are available only in offices and hospitals, using complex equipment, and usually only after a life threatening event, for example a stroke. With an EKG device on the wrist, AFib can be detected wherever the patient is, 24 hours a day. In randomized research trials, KardiaMobile, the first AliveCor EKG device, proved to be superior to routine care provided by physicians. Today, KardiaBand is a giant leap in personalized health care"

As a medtech leader, AliveCor uses advanced artificial intelligence, mobile, cloud and micro-electrode technology to change the dynamic in cardiac care. AliveCor empowers people worldwide to proactively manage heart health and to vastly improve the quality of care in the fight against heart disease. AliveCor's KardiaMobile and KardiaBand enable people and their care teams to easily, quickly and inexpensively detect and manage possible abnormal heart rhythms.

KardiaBand is available for $199 and requires subscription to AliveCor's Premium service for $99 a year. The combined system includes SmartRhythm notifications on Apple Watch; unlimited EKG recordings; automatic detection of Atrial Fibrillation or normal sinus rhythm; the unlimited ability to send EKG readings to anyone via email; unlimited cloud history and reporting of all EKGs ever taken; weight and medication tracking; and a mailed monthly paper report on readings taken each calendar month.

The FDA-cleared KardiaMobile is the most clinically validated mobile EKG solution on the market. It is recommended by leading cardiologists and used by people worldwide for accurate EKG recordings. KardiaMobile, and KardiaBand, when paired with the Kardia app provide instant analysis for detecting atrial fibrillation (AF) and normal sinus rhythm in an EKG. Kardia is the first A.I. enabled platform to help clinicians manage patients for the early detection of atrial fibrillation, the most common cardiac arrhythmia and one that leads to a five times greater risk of stroke. KardiaBand is the first FDA-cleared medical device accessory for Apple Watch. For more information, please visit alivecor.com.

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Publication Company Address:
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[1] "International Multicentre Clinical Device Investigation on Safety and Effectiveness of the Nit-Occlud® Lê VSD Spiral Coil System for VSD Occlusion" (clinicatrials.gov identifier NCT00390702).

[2] "The Nit-Occlud® Lê VSD Registry", publication in preparation.

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