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Exploring Resilience in Adult Congenital Heart Disease

Jill M. Steiner, MD, MS; J. Randall Curtis, MD, MPH; Abby R. Rosenberg, MD, MS, MA

Major medical and surgical treatment successes in Congenital Heart Disease have increased life expectancy and, in some populations, decreased the physical impacts of the underlying disease. Yet patients with Adult Congenital Heart Disease (ACHD) live daily with a lifelong chronic illness. Emotional and psychosocial impacts of this illness are known to adversely affect quality of life. Contributing factors include physical and cognitive limitations, altered familial and social relationships, prognostic uncertainty, and the presence of mood and anxiety disorders.[1–3] Patients report feeling inadequately equipped to effectively cope with their illness, navigate healthcare decisions, and plan for the possibility of early mortality.[4,5]

Early in the history of ACHD clinical care, clinicians and researchers focused on physical health problems in order to improve longevity and decrease physical morbidity. Now that we have made progress in addressing these physical health needs, it is time to address the high prevalence of emotional distress and other mental health issues in this patient group.

Tools to Address the Emotional Wellbeing of Patients with ACHD: Resilience, Sense of Coherence, and Palliative Care

In the moment, life's challenges can be stressful and initially perceived as negative experiences. However, such experiences may provide opportunity for people to evaluate their perspectives and learn over time. This includes managing a chronic illness like ACHD. Resilience is the process of harnessing personal resources to sustain physical and emotional well-being in the face of stress.[6,7] While some level of resilience is generally innately present, resilience can be developed and strengthened, through experience or targeted intervention.[8,9] Indeed, several "resilience resources" have been associated with improved quality of life among patients with chronic diseases. These tend to fall into three reproducible categories: internal characteristics (i.e., stress-management skills), external characteristics (i.e., social supports), and existential characteristics (i.e., spirituality or meaning-making skills).[6,10] Different resources work better for different people in different situations, such as whether someone prefers to use internal skills in stress management versus external reliance on family support or versus existential processes of meaning making.

An overlapping but distinct concept from resilience is sense of coherence (SOC). In the 1980s, Antonovsky described his salutogenic theory, which involved focusing on resources and capacities rather than disease.[11] SOC is a major component of this theory, the idea that people can develop internal and external resources and experience life events that allow them to better cope with stress. In turn, they may have better quality of life and clinical outcomes. In this manner, SOC seems to be one of the key personal resources for fostering resilience among patients with serious illness.[12–14]

People with a strong SOC perceive the world as comprehensible, manageable, and meaningful. In 2006, Moons et al proposed SOC as a pathway to improving quality of life in ACHD.[15] They provided examples of how parents and clinicians can help patients with ACHD develop SOC. Education about their heart condition could alleviate uncertainty and enhance comprehensibility; provision of support from the challenges of living with ACHD could create manageability through balance

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between stressors and perceived resources; and including the patient in decisions about their care and addressing existential issues could help life make sense, fostering meaningfulness.

Other studies of SOC in ACHD have shown that SOC is positively associated with perceived physical and psychosocial health and quality of life, and that degree of personal control is a major determinant in developing SOC.[14,16] In some ACHD studies, increased SOC has been associated with increased age, education, and employment, as well as partnered status, better heart failure functional class, and higher ACHD severity. SOC is thought to be a universal concept, but intercountry variability in SOC has been described, characterized at least partially by degree of cultural individualism.[17]

Encompassing both the broader process of resilience and specific individual resources like SOC is the practice of palliative care. The goal of palliative care is to alleviate suffering and improve quality of life for patients with serious illness and their families.[18,19] As resilience and SOC can both help achieve this goal, both have been adopted as targets for palliative care intervention and support. However, while the idea has been raised that promoting resilience may have promise in ACHD, to our knowledge, it has not yet been widely studied in this population. In adolescents[20] and adults[21] with CHD, pilot interventions targeting psychological distress and resilience have been found to be feasible, however no single intervention has been proven effective. In addition, these programs were delivered in group format, which may be undesirable for patients who are less comfortable sharing personal information. There are not studies defining the relationships between resilience and key psychosocial outcomes in ACHD that might explain how best to approach these issues. We therefore proposed to evaluate in further depth the concept of resilience in ACHD, including the application of a proven, one-on-one resilience intervention.

PRISM

The Promoting Resilience in Stress Management, or PRISM, intervention is built on the foundations of Resilience and Stress-and-Coping Theories.[22] The latter posits that personal appraisals of stress influence emotional, physical, and functional outcomes. PRISM's overarching hypothesis is that resilience works similarly: if someone believes they have the resources to be resilient, perhaps they will experience better health and psychosocial outcomes. Thus, PRISM was designed as a reproducible, skills-based training program that teaches common resilience resources endorsed by adolescents and young adults with serious illness and caregivers of patients with serious illness: skills in stress-management, goal-setting, positive reframing, and meaning-making.

PRISM was created using the ORBIT model for translating behavioral and social science theory to health-related interventions.[23,24] It was initially developed by and for adolescents and young adults with cancer,[9] and in efficacy studies found to improve resilience, hope, psychological distress, and quality of life compared to usual care. It was iteratively adapted for patients with type 1 diabetes[25] and cystic fibrosis,[26] as well as parents of children with cancer.[27] Each adaptation process again followed ORBIT guidelines to hone intervention language, timing, and approach for use in different patient groups. Additionally, modules were added based on specific patient population needs. For example, a module on advance care planning, the process of considering future healthcare preferences in the event the patient is unable to make their own decisions, was added at the request of patients with CF and advanced cancer.[28]

Evaluating and Building Resilience in ACHD

We had previously been studying palliative care in ACHD, with the stance that tailored palliative care interventions may address unmet psychosocial needs by both increasing sense of control and decreasing psychological distress. We found that patients were interested in participating in advance care planning and learning more about palliative care, however there were also a number of barriers to incorporating this into regular ACHD care, including not feeling sick enough to discuss care during serious illness and uncertainty about what their preferences might be if sicker.[29] In addition to systems-level issues, we identified several patient-level factors. Specifically, patients were not sure how or when advance care planning would apply to them personally, and there seemed to be substantial concerns around lack of skills to cope with chronic illness and to manage uncertainty.[30,31] This led to the idea of exploring the role of resilience in addressing these concerns.

The foundation of PRISM is not disease specific, so we hypothesized that a tailored approach might be useful in ACHD, as it has been in other disease groups. One major difference is that our patients are slightly older and perhaps in a different stage of life than the young patients for which PRISM had been designed. At the same time, we recognized that some patients with ACHD have lower psychosocial maturity than their physical age due to the challenges they have faced, and we were encouraged by findings that PRISM was also impactful in parents of ill children.

With research funding from the Adult Congenital Heart Association, we began by interviewing patients with ACHD, asking about their ways of coping with heart-related stress and experiences with resilience. We also asked how they felt about a program like PRISM, specifically eliciting feedback on acceptability, appropriateness, and suggestions for revisions. We used purposive sampling to ensure a diverse group based on key characteristics, such as age, sex, race, ethnicity, and severity of ACHD. We then analyzed all interview transcripts using qualitative methods. Specifically, we developed a codebook and performed inductive coding to identify recurrent themes and the relationships among them in an iterative fashion. After 15 interviews, we noticed few to no new themes from patient interviews and thus concluded we had gathered adequately representative patient perspectives about PRISM. Currently, we are continuing interviews to more deeply explore the concepts of coping and resilience from the patient perspective; this second phase of analysis will help us determine if patients with ACHD would like additional components in their PRISM than the standard core modules.

Interview participants were overwhelmingly interested in participating in PRISM or a program like it, if offered the opportunity. Some specifically asked us to contact them if the opportunity arose. Participants reported feeling that anyone with ACHD could benefit from participating (14/15 participants), and that people most likely to benefit may be younger adults who have yet to develop similar life-skills (6/15), those who are struggling with management of their ACHD (8/15), or those with newly-recognized life- or illness-related challenges (3/15). Participants also identified several facilitators and barriers to participation **(Table).**

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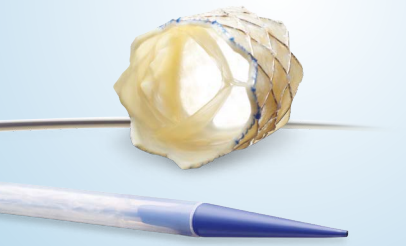

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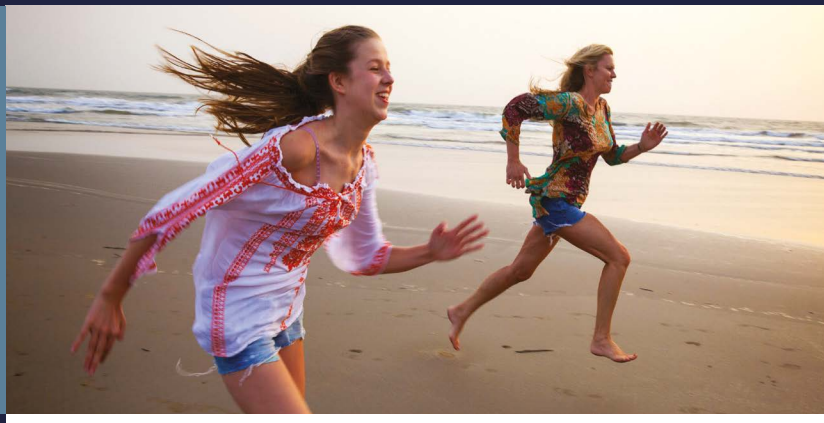

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TABLE *Facilitators and Barriers to Participation in a Program Like PRISM*

Facilitators to Participation	Barriers to Participation
• Flexibility of the intervention (length, format, location) • Comforting environment, support for participants to say what they need to say • Check-ins between modules to make sure they understand the skills • Knowing they are not alone in needing help • Having awareness of some of these skills, wanting to develop more • Free coaching opportunity • Positive prior experiences with healthcare	• If program is too fast-paced or too demanding on time, too much "homework" • If participants must travel far • Hard to find ACHD-related examples (i.e., finding meaning in going to doctor visits) • Hard to engage people not focused on these issues, especially if too young • If people don't recognize they need this or that these skills could help them • If people feel like they are already so positive/resilient this is not needed

When asked about delivery preferences, participants preferred in-person sessions, feeling the program would be more personal and they could feel more engaged. However, they found the option of virtual sessions appealing because of the flexibility this provided. A few stated they were recently more comfortable with the idea of a virtual format, having had virtual medical visits during the COVID-19 pandemic. Interestingly, no one specifically stated they preferred one-to-one format over a group setting, and some participants (6/15) wished there would be a group component of the program. Participants also asked whether the instructor could be someone with ACHD (3/15). For both of these suggestions, participants cited a desire to connect with other people with ACHD, who shared similar experiences.

With regard to content, the module including relaxation and meditation skills was most appealing, and no module was identified as undesirable. There seemed to be some equipoise about the advance care planning module, with some participants concerned it could carry a negative connotation. Suggestions for additional sessions included mental health and "healthy habits" like nutrition and exercise.

Using This Information to Plan Next Steps

Participants' interest in PRISM, appraisal of the modules, and suggestions for new material will allow us to move forward with plans for tailoring and testing the program in ACHD. It is exciting to support positive psychology and mental health, and to holistically improve the patient experience while considering these palliative care and quality-of-life goals. In line with our anticipated findings, participants were interested in a program that was supportive in addressing their emotional concerns yet flexible enough to fit their schedules. The appeal of an opportunity to connect with other patients reflects their expressed desire to feel less alone in uncertainty. We will partner with patients to identify the ideal program format, including how much out-of-session practice will be recommended and how a group component may be offered. These interviews also provided insight into a potential need to develop ACHD-specific examples for some of the modules. Questions remain about how best to engage patients who are less aware of their needs or the role of resilience in supporting psychosocial health - which we will explore further in other concurrent studies.

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ACHA Debuts New Website, Mission, and 13th Edition of the ACHD Travel Directory

We are thrilled to share our updated website today, which has been refreshed with usability and simplicity in mind for our supporters and the greater Congenital Heart Disease (CHD) community. We know that people across the country are accessing our website for a wealth of information, but especially in some key areas—such as defect-specific educational resources and the ACHD Clinic Directory. With that in mind, we have made these areas and other priority program content the core of our homepage, and easily accessible with fewer clicks.

We heard your feedback on our educational webinars, and have made this area of our website searchable (by keyword, category, or date) so you can easily find presentations in our library. The website also has been refreshed with a new, clean look and is much simpler to use on a mobile device or tablet than ever before.

"One of the pillars that ACHA was founded on was being a source of easy to access, credible information for all people living with CHD," said President and CEO Mark Roeder. "With enhanced navigation and resources on our website, we've now made it easier than ever for patients and medical providers to locate the information they need."

Alongside the website launch, we are also debuting our new ACHA logo today. As you'll see, along with our Walk for 1 in 100 logo, this now completes an overall refreshed look of ACHA.

"We're an organization that is about connecting people," said Roeder. "We are proud to be represented by an identifier for our organization that encompasses this notion, as well as CHD care across the lifespan."

Finally, ACHA Board of Directors, Medical Advisory Board, and staff came together earlier this year to review our current mission and where ACHA's work has taken us since we last updated this important, fundamental purpose of our organization. With our updated website and new look, we are excited to debut ACHA's vision, as well as an updated mission, that incorporates our value of lifelong care for CHD and our more than 20 years of work in the CHD field and support to patients, family members, and medical providers.

Our Vision: Every adult with Congenital Heart Disease receives specialized cardiac care.

Our Mission: To empower the Congenital Heart Disease community by advancing access to resources and specialized care that improve patient-centered outcomes.

The 13th Edition ACHD Travel Directory is free for ACHA members! If you're planning a trip or going away to college, this resource can help you find specialized Adult Congenital Heart Disease care in an emergency. The directory includes Adult Congenital Heart Disease (ACHD) programs across the globe and lists each clinic's name, location, and contact information.

If you would like one of these resources for your personal use, please email orders@achaheart.org with your name and mailing address. Or click download a printer-friendly PDF version from the website: https://www.achaheart.org/media/3080/traveldirectory13thedition.pdf?bblinkid=252555521&bbemailid=32515012&bbejrid=2023546307.

If you are a medical professional and would like to order multiple copies for your patients, please visit https://shop.achaheart.org/products/achd-travel-directory?bblinkid=252545967&bbemailid=32515012&bbejrid=2023546307.

New Heart Regeneration Study Provides Never-Before-Described Process

There is a ground breaking study, https://www.pubstemcell.com/epub/uploads/0160103000010EPA121120.pdf, that could speed up the effort to defeat heart disease, a major health epidemic that kills over 650,000 Americans each year, and that continues to increase because of COVID-19.

The peer-reviewed study written by Dr. Ian White, President and CSO of regenerative medicine researchers Neobiosis, https://neobiosis.com/, explains how a never-before-described process may be used to help regenerate damaged human hearts.

Dr. White and colleagues from the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine said the research can be especially useful to those stricken by COVID-19.

The virus is known to cause inflammation in the heart. That poses health risks for so called "long-haulers", who have not fully recovered from COVID-19 weeks or even months after first experiencing symptoms. Among many other applications, the research could be a long-term solution to study the cardiovascular effects of COVID in a way never possible before.

The Study

- The scientists studied neonatal mouse hearts in a petri dish.
- Most mammalian hearts have between one and seven days where they retain primordial regenerative abilities.
- In a controlled environment, the team extended that period for a month.
- This gave them time to learn how different therapies or drugs can repair or regenerate the damaged organ.

"We took a neonatal heart from a baby mouse and studied it in a petri dish. We studied it under a controlled environment and designed a method to keep the heart alive and keep the regenerative process active long enough to study the biology behind it." This work is unprecedented as it has not been possible, until now, for scientists to keep a whole heart alive long enough in the lab to make significant scientific discoveries about the regenerative process" — Dr. Ian White, President and CSO of Neobiosis

White's paper explains that neonatal cardiac repair is mediated by the epicardium, which is a single layer of cells that covers the heart. The cells activate in response to injury by proliferating before actively migrating to the site of damage.

It is the first demonstration that whole, intact mammalian hearts can be cultured long-term without coagulative necrosis and that the innate regenerative mechanisms remain intact when afforded a conducive environment.

Dr. Keith March, Professor of Medicine and Director of the Center for Regenerative Medicine at the University of Florida, emphasized the major clinical implications of prolonging the viability of hearts in the absence of blood flow, such as is experienced by donor hearts on the way to transplantation.

"We have been excited to discover that novel biological therapies from adult stem cell secretome could markedly improve cardiac transplantation, and Dr. White's new finding could amplify this therapeutic benefit. We would be interested in testing this concept together with Dr. White's team," said Dr. Keith March.

"This study gives us an unprecedented window on how hearts heal and how we can enhance their regeneration," said Dr. Anthony Atala, Director of the Wake Forest Institute for Regenerative Medicine. "The insights from this work will have a major and lasting impact in the development of new therapies for patients with heart disease."

The Benefits of Regenerative Therapy

Regenerative medicine has the potential to fight disease and revolutionize healthcare, https://neobiosis.com/about-neobiosis/. The therapies center on treatments that support the body in repairing, regenerating and restoring itself. Some of these benefits include:

- Delivering biochemical instructions and raw biomaterials to damaged tissues and organs stimulating the body's own repair mechanisms to functionally heal previously irreparable tissues or organs.
- Modulating inflammation to facilitate recovery and tissue repair.
- Treating injuries and disease naturally without surgery and opioids.

Dr. White is eager to share his work with the world. He has called on colleagues to use the same neonatal heart preservation method for their own experiments. The sharing of this research is one example of how Neobiosis leads the way in the field of regenerative science.

"Now other scientists can use our methods to employ these technologies and use it for drug interactions and studying COVID in the heart. The more minds on this subject the better. Others can use this tool, apply their own specialties to further the knowledge of the mechanisms of cardiac regeneration to reduce the impact of heart diseases." – Dr. Ian White

Dr. Ian White can speak to the following:

- How regenerative medicine is advancing studies in cardiology
- How he and his team were able to regenerate cardiac tissue in a neonatal mouse heart and what that means for human beings.
- How these findings help people suffering from COVID-19 and for the "long-haulers" still battling the after-effects.
- How COVID-19 damages the heart.
- How regenerative medicine works.

About Neobiosis

Neobiosis, LLC is a clinical-stage contract development and manufacturing organization (CDMO) run by scientists focused on the science of regenerative medicine. They produce regenerative medicines from perinatal tissues, cells and extracellular vesicles (EVs) for research and clinical trials. Regenerative medicine taps into the body's innate ability to heal itself relieving pain without opioids, being more cost effective and safer than many surgical alternatives. Neobiosis is an FDA-registered CDMO operating under current Good Manufacturing Practice (cGMP) standards with cleanroom laboratories located in Alachua and Gainesville. Visit https://neobiosis.com/.

Biosense Webster Announces Completion of Atrial Fibrillation Cases Using Novel HELIOSTAR™ Balloon Ablation Catheter

HELIOSTAR™ Balloon Ablation Catheter is the First-Ever Radiofrequency Balloon Ablation Catheter and Supports More Efficient Cardiac Arrhythmia Ablation Procedures

Biosense Webster, Inc., part of the Johnson & Johnson Medical Devices Companies[1] today announced post-approval procedures were successfully performed with the first-ever radiofrequency balloon ablation catheter at sites across Europe with Biosense Webster's HELIOSTAR™ Balloon Ablation Catheter. In Europe, the HELIOSTAR Balloon Catheter is indicated for use in catheter-based cardiac electrophysiological mapping of the atria and for cardiac ablation.

Europe is home to more than 11 million people living with atrial fibrillation (AF), and estimates state that by 2030 the number of people with AF is projected to increase by up to 70%.[i,ii] In Europe, catheter ablation is a recommended first-line treatment option[2,13] and is associated with a significant improvement in quality of life and significant reductions in AF burden and AF-related complications.[iii,iv,v]

The HELIOSTAR Balloon Ablation Catheter, with the LASSOSTAR™ Catheter and CARTO® 3 System, allows physicians to provide more efficient ablation procedures, with lower procedure times and reduced fluoroscopy time and exposure[3], potentially benefitting both the patient and physician.[vi,vii,viii] Shorter procedure time may require less anesthesia and radiation and may result in less nursing and facility time. These time savings may also enable more procedures per day facilitating patient access.[ix,x]

The novel HELIOSTAR Balloon Ablation Catheter features ten gold-plated, irrigated electrodes that can be tailored based on anatomical location and known tissue thickness[4] enabling personalized ablation procedures for unique patient anatomies and arrhythmias.[xi] The amount of power delivered to each electrode can be controlled independently to provide electrophysiologists with greater customization, control and the ability to achieve pulmonary vein (PV) isolation in approximately ten seconds.*

"Pulmonary vein isolation is a technically complex and time-consuming procedure so it's important that advancements in balloon ablation systems help electrophysiologists quickly and easily isolate the pulmonary veins, while maintaining safety," said Ahmed Abdelaal, Senior R&D Director and HELIOSTAR Project Leader at Biosense Webster. "The HELIOSTAR Balloon Ablation Catheter was developed with electrophysiologists in mind giving them the ability to perform personalized ablation procedures to better meet patient's needs."

In a multicenter single-arm study, SHINE, the HELIOSTAR™ Balloon Ablation Catheter was an effective treatment for paroxysmal atrial fibrillation (AF) and electrophysiologists isolated targeted pulmonary veins (PV) in 98.8% of patients without the need for focal touch-up.[5] On average, time to isolation of the pulmonary vein was approximately ten seconds, total procedure time was less than 90 minutes and dwell time was less than 40 minutes.*[6]

"HELIOSTAR™ Balloon Ablation Catheter reaffirms our commitment to partnering with physicians to advance the practice of electrophysiology and to help change the lives of patients suffering from atrial fibrillation," said Uri Yaron, Worldwide President of Biosense Webster, Inc. "With CE mark approval and the first commercial procedures completed, we have made significant progress in providing electrophysiologists with another novel option for the safe and efficient treatment of this burdensome disease."

In Europe, full commercial availability is expected in 2022. In the United States, HELIOSTAR is an investigational device and is not approved by the U.S. Food & Drug Administration.

About Biosense Webster

Biosense Webster is the global market leader in the science and technology behind the diagnosis and treatment of cardiac arrhythmias. Part of the Johnson & Johnson Family of Companies, the specialized medical-technology company is headquartered in Irvine, Calif., and works across the world to advance the tools and solutions that help electrophysiologists identify, treat, and deliver care. Learn more at www.biosensewebster.com and connect on LinkedIn www.linkedin.com/company/biosense-webster/ and Twitter https://twitter.com/biosensewebster.

About Johnson & Johnson Medical Devices Companies

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people's healthcare experiences. In surgery, orthopaedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere. For more information, visit www.jnjmedicaldevices.com.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding HELIOSTAR Balloon Ablation Catheter. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Biosense Webster, any of the other Johnson & Johnson Medical Devices Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products

and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Johnson & Johnson Medical Devices Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

1. The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson's Medical Devices segment
2. Recommended first-line treatment for patients with symptomatic Paroxysmal AF episodes or persistent AF without major risk factors for AF recurrence, of as an alternative to AAD class I or III, considering patient choice, benefit, and risk.
3. In a multicenter single-arm study, SHINE (n=95), fluoroscopy time was 10.9 ± 9.1 minutes in per-protocol population while in a multicenter single-arm study RADIANCE (n=40), fluoroscopy time was 17.4 ± 10.1 minutes without using LASSOSTAR™ Diagnostic Catheter.
4. Tissue thickness is known per anatomical location or measured via intracardiac echocardiography.
5. This data is based on 7 operators. PV isolation is defined as sustained PV entrance block on adenosine/ isoproterenol challenge. PV isolation is defined as sustained PV entrance block on adenosine/isoproterenol.
6. SHINE study (n = 95, roll-ins = 8 patients). Per SHINE protocol, a roll-in phase of up to 3 patients per physician was implemented. Total procedure time: 87.6 ± 22.25 min. and dwell time: 40.3 ± 16.69 min.

*In a multicenter single-arm study (SHINE, n=95), pure single shot isolation was achieved by one initial RF application (regardless of the duration of ablation). Time to isolation (mean ± SD, sec) was 9.0 ± 6.46 (LIPV), 12.0 ± 11.58, (LSPV), 9.1 ± 4.95 (RIPV), 8.9 ± 6.22 (RSPV).

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Hackensack University Medical Center Heart Doctors are First in New Jersey to Perform Innovative Heart Failure Treatment

Promising Therapy is Offered Through Multicenter International Study

Interventional cardiologists and heart surgeons at Hackensack University Medical Center were the first in New Jersey to treat a patient with heart failure after a heart attack using a unique device that makes a weak, enlarged heart smaller — enabling it to pump blood more efficiently, relieving heart failure symptoms, and improving quality of life. The procedure is being evaluated through a clinical trial called ALIVE (American Less Invasive Ventricular Enhancement). Hackensack University Medical Center is participating in this study and is now enrolling eligible patients with heart failure and left ventricular scars and/or aneurysms.

Heart failure occurs when the heart becomes inefficient and weak, making it difficult for organs throughout the body to receive enough oxygenated blood to work effectively. Patients may experience shortness of breath, fatigue easily, have swelling in their legs, and develop other symptoms. When someone has had a major heart attack that causes scarring of tissue in the left ventricle of the heart (the chamber responsible for propelling freshly oxygenated blood out of the heart), the ventricle can become enlarged. An aneurysm can result, where part of the ventricle wall bulges out. In both cases, it becomes very difficult for the ailing heart to do its job.

The ALIVE study is evaluating the LIVE procedure (left invasive ventricular enhancement) in patients with heart failure who have left ventricular scars or aneurysms on the front of the heart and whose symptoms are not responding well to medical treatment. An interventional cardiologist and surgeon work together, taking a hybrid approach to implant the device components through a catheter threaded into the heart via a vein in the neck and a probe inserted through a 1-inch incision in the chest. Multiple anchors inserted into the heart pinch the area of dead tissue closed, excluding the non-functioning scar tissue from the rest of the heart and reshaping the healthy part of the heart to a more normal size.

This procedure is a promising alternative to traditional open-heart surgery to remove scarred heart tissue, which requires a large incision in the chest, attachment to a heart-lung machine, and a two-week hospital stay. "With the LIVE procedure, there is just a one-inch chest incision and the patient stays in the hospital for only two days," noted cardiologist Joseph E. Parrillo, MD, chair of the Heart and Vascular Hospital at Hackensack University Medical Center. "If successful, the patient experiences a relief of heart failure symptoms."

The LIVE device was approved in Europe and has been shown to improve function, such as a better ability to walk. At Hackensack University Medical Center, doctors performed the procedure in July 2021 in a 63-year-old man, reducing the volume of his left ventricle by 30% to a more normal size and already relieving his shortness of breath. Tests also showed that his heart is beating more effectively and that his ejection fraction (a measure of the strength of the left ventricle) has improved, too.

"This approach is very promising. It is not for everyone with heart failure, but for those with scar tissue in the heart, it offers another option," explained Tilak K.R. Pasala, MD, interim director, Structural and Congenital Heart Program and the structural interventional cardiologist involved in the first LIVE procedure at Hackensack University Medical Center.

"This minimally-invasive procedure has the potential to treat heart failure patients whose disease is beyond medications but not severe enough for heart transplant or implantation of an external left ventricle assist device," added Mark B. Anderson, MD, the cardiac surgeon who participated in the groundbreaking LIVE procedure.

The ALIVE study is recruiting patients who:

- Have symptomatic heart failure (New York Heart Association functional class III or ambulatory class IV)
- Are referred for treatment of left ventricular scars/aneurysms on the front of the heart that are contiguous
- Have a left ventricular ejection fraction under 45%
- For more information or to inquire about being considered for this study, please contact 551.996.2136 or email **Ann.TownsendSolis@hackensackmeridian.org**

About Hackensack University Medical Center

Hackensack University Medical Center, a 771-bed nonprofit teaching and research hospital located in Bergen County, is the largest provider of inpatient and outpatient services in New Jersey. Founded in 1888, it was the county's first hospital. It was the first hospital in New Jersey and second in the nation to become a Magnet®-recognized hospital for nursing excellence, receiving its sixth consecutive designation in 2019 from the American Nurses Credentialing Center. The academic flagship of the Hackensack Meridian *Health* network, Hackensack University Medical Center ranked #1 in New Jersey and #7 in the New York metro area by *U.S. News & World Report's* 2021-2022 "Best Hospitals" Honor Roll. Hackensack University Medical Center is also rated as High Performing in 14 procedures and conditions, and sets the standard for all New Jersey hospitals in several specialties including New Jersey's only nationally-ranked Neurology & Neurosurgery and Urology programs; ranked nationally in Cardiology & Heart Surgery; New Jersey's Best Urology and Neurology & Neurosurgery programs since 2013; with Cardiology & Heart Surgery, Gastroenterology & GI Surgery, Geriatrics and Orthopedics ranked among the top in New Jersey. This award-winning care is provided on a campus that is home to facilities such as John Theurer Cancer Center, a consortium member of the NCI-designated Georgetown Lombardi Comprehensive Cancer Center and recognized as the #1 hospital for cancer care in New Jersey by *U.S. News & World Report's* 2021-22 "Best Hospitals" Honor Roll; the Heart & Vascular Hospital; and the Sarkis and Siran Gabrellian Women's and Children's Pavilion, which houses the Joseph M. Sanzari Children's Hospital and Donna A. Sanzari Women's Hospital, recognized as being in the top 1% of children's hospitals in the nation and #1 children's hospital in New Jersey by *U.S. News & World Report's* 2021-22 "Best Hospitals" Honor Roll; as well as the Deirdre Imus Environmental Health Center. Hackensack University Medical Center is listed on the Green Guide's list of Top 10 Green Hospitals in the U.S. Our comprehensive clinical research portfolio includes studies focused on precision medicine, translational medicine, immunotherapy, cell therapy, and vaccine development. The hospital has embarked on the largest healthcare expansion project ever approved by the state: construction of the Helena Theurer Pavilion, a 530,000-sq.-ft., nine-story building, which began in 2019. A $714.2 million endeavor, the pavilion is one the largest healthcare capital projects in New Jersey and will house 24 state-of-the-art operating rooms with intraoperative MRI capability, 50 ICU beds, and 150 private patient rooms, including a dedicated 50-bed Orthopedic Institute.

AngelMed Announces FDA Approval of Enhanced Real-Time Cardiac Detection Monitor

Monitor for Acute Coronary Syndrome (ACS) Events, AngelMed Guardian® System, Prompts High-Risk ACS Patients to Seek Medical Care

Angel Medical Systems, Inc., (dba AngelMed) a proactive diagnostics company focused on the advancement of long-term management of high-risk coronary disease, announced today the FDA approval of the second-generation AngelMed Guardian® device. The AngelMed Guardian System is the world's first implantable cardiac detection monitor and patient-warning system for acute coronary syndrome (ACS) events, including silent heart attacks. The new, second-generation device is enhanced with ease-of-use adaptations and an updated, long life battery that could potentially double the life of the implanted device.

The AngelMed Guardian device is implanted subcutaneously by a cardiologist during a low-risk, outpatient surgical procedure. Using a patented algorithm, the AngelMed Guardian continuously records the heart's electrical activity, 24 hours a day, monitoring for electrical changes that can indicate an impending ACS event. The AngelMed Guardian device provides a more effective diagnosis of a life-threatening condition when compared to patient symptoms alone.[1]

"Patients who have had a prior ACS event often remain at high-risk for a recurrent event. Even those patients who are on alert for another potential cardiac event may delay seeking treatment," said Dr. C. Michael Gibson, MD, Boston Clinical Research Institute. "The AngelMed Guardian System has demonstrated the ability to identify the earliest signs of an ACS event, including heart attacks, more effectively than patients' symptoms alone, and in patients who do not experience symptoms at all."

"The improved AngelMed Guardian device will have a meaningful effect on the current standard of patient cardiology care for ACS events. Our dedicated team and supporting physicians have worked tirelessly to bring this disruptive technology to market," said AngelMed Chief Executive Officer, Brad Snow. "As the first real-time detection device for high-risk heart attack patients, the AngelMed Guardian System provides critical data at the point of care, along with peace of mind for physicians and patients alike."

"Our key learnings based on hundreds of thousands of hours of clinical monitoring data for many ambulatory patients with cardiovascular disease provides a technology platform for future offerings. Our patient-centric approach will drive our research and development," said Dave Keenan, AngelMed chief operating officer.

Every 40 seconds, someone in the U.S. suffers a myocardial infarction or heart attack.[2] The most important risk factors for another cardiovascular event in post-heart attack patients are age, medical history, comorbidities, and the severity of their first ACS event.[3] Despite proactive ongoing efforts over the last decade from the medical community to better educate the public on signs and symptoms of a heart attack, the time from symptom onset to arrival at a hospital remains static at eight hours.[4]

For more important safety information, please visit: www.angel-med.com/.

About Angel Medical Systems, Inc.

Angel Medical Systems, Inc., is a proactive diagnostics company committed to advancing life-sustaining, personalized patient care, including the long-term management of high-risk coronary disease. Angel Medical Systems maintains a robust portfolio of U.S. patents relating to detecting cardiac events, including silent heart attacks.

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DECEMBER

03-04

CSI America 2021
Denver, Colorado
https://www.csi-congress.org/america

05-07

ICI for All 21 – Innovation in Cardiovascular Interventions Award
Tel Aviv, Israel
https://icimed.org/ici-award/

06-09

Echo on Marco Island: Case-Based Approach
Marco Island, Florida
https://cveducation.mayo.edu/store/echo-on-marco-island-case-based-approach

FEBRUARY

17-19

CATCH: Caring for Adults and Teens with Congenital Heart Disease
Oahu, Hawaii
https://www.hawaiipacifichealth.org/CATCH

Hospital Directory 2021-2022

Published Mid-August

- Hospitals that Offer Open Heart Surgery for Children in North America
- Contact information at each hospital for Chief of Pediatric Cardiology & Fellowship Director
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- Lists Pediatric Cardiology Fellowships
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- Electronic version available on CCT's website: www.congenitalcardiologytoday.com

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