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Why Low-Field Imaging is Expected to Boost Interventional CMR Procedures

Aimee K. Armstrong, MD; Orlando P. Simonetti, PhD; Paul J.A. Borm, PhD

Despite the numerous drawbacks to x-ray fluoroscopy for cardiac catheterization, including poor soft tissue visualization, need for repeated injections of iodinated contrast to depict the anatomy, inability to visualize the anatomy during interventions, harmful effects of radiation, and the need for lead protection that can induce orthopedic injuries, it continues to be the mainstay for catheterization imaging. The adverse effects of radiation are even worse in children, as tissue in growing children is particularly sensitive to the detrimental effects of radiation because of greater mitotic activity. In addition, congenital heart disease (CHD) patients need repeated cardiac catheterizations and radiation-based imaging throughout their lives, sometimes receiving accumulated lifetime doses that are associated with a detectable increased risk of cancer.^{1,2} Children also have longer lifespans than adults, thereby having more time to develop radiation-induced cancer.

With its exceptional soft tissue imaging in multiplanar views in arbitrary directions and dynamic imaging of cardiac function, cardiac magnetic resonance (CMR) eliminates all the disadvantages of x-ray, but it comes with its own challenges for real-time interventional imaging. The field of interventional CMR (ICMR) has been slow to progress, due to radiofrequency-induced heating of catheterization equipment during scanning, inability to see standard catheters with MR, and large metallic artifacts from interventional wires that obstruct the imaging. The many faults of x-ray imaging, however, continue to be the impetus behind pursuing ways to overcome these limitations in the field of ICMR.

To date, the vast majority of the ICMR work has been performed in 1.5 Tesla scanners. Clinician investigators at the National Institutes of Health used real-time MR guidance to perform right heart catheterizations (RHC) in adults,³ and Ratnayaka and colleagues were the first to move ICMR into the pediatric hospital on a large scale, reporting 50/50 successful RHC in children.⁴ As the field progressed, specific MR equipment was developed for catheterization to make wires and catheters conspicuous. Nano4Imaging (Dusseldorf, Germany) has been a leader in this field and produced the first FDA-approved guidewire (EmeryGlide MRWire) for ICMR by placing passive markers on the distal tip of the wire, which is made of glass fibers and polymers and protected by a high-strength aramid fiber mantle covered with a Teflon sleeve. The markers create signal voids in MR, which provide their visibility, and they are also seen on x-ray, which allows for use in both settings. This technology helped to bring ICMR to CHD, allowing the successful completion of right or left heart catheterization (LHC) in 23/25 patients with CHD, to measure pressure gradients across stenoses with MR guidance,⁵ and in 31/34 children and adults with CHD, including for Fontan fenestration test occlusion.⁶

While diagnostic catheterizations with MR guidance are being performed on a regular basis at some institutions, interventional procedures, such as angioplasty, stenting, and septal defect closures, are not part of clinical practice today, due to the lack of equipment that is both visible and safe in the MR environment, the absence of supporting software, and uncertainty about reimbursement. Early work is pointing to low-field (0.55T) MR scanners having great potential to overcome some of these long-standing problems,

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LOW-FIELD IMAGING TO BOOST INTERVENTIONAL CMR PROCEDURES

however. They may allow the use of commercially available catheterization equipment since radiofrequency-induced heating of interventional devices is reduced at low field strength (theoretical 7.5-fold difference in heating between 0.55T and 1.5T).⁷ Campbell-Washburn and colleagues showed that two types of nitinol non-exchange length glidewires and two types of stainless-steel braided catheters were safe at 0.55 T (<1°C heating) during two minutes of continuous scanning.⁷ They then performed low field MR-guided RHC successfully in 7/7



FIGURE 1 CMR still frame from a realtime interactive scan showing CO2-filled wedge catheter balloon in IVC after 2 mg/kg ferumoxytol (red arrow).



FIGURE 2 CMR still frame showing platinumiridium covered CP stent (red thin arrow) implanted in proximal IVC, causing significant artifact, and a 316L stainless steel 36 mm long Mega LD stent crimped on a 20 mm x 3 cm Z-Med balloon with 1 mm MagnaFy® MRI markers (stent edge cannot be distinguished from markers) (red thick arrow) over EmeryGlide® guidewire (white arrow shows EmeryGlide MR markers)

patients using a commercially available nitinol glidewire (180 cm 0.035" Micro J-tip Glidewire, Terumo, Tokyo, Japan) without complication or evidence of heating.⁷ These studies were performed on an investigational, modified commercial MRI system (1.5T MAGNETOM Aera; Siemens Healthineers, Erlangen, Germany) that operated at 0.55 T but retained the gradient performance of the original 1.5T system (maximum gradient amplitude 45 mT/m, maximum slew rate 200 T/m/sec).

Since these studies were performed, a lowfield scanner has become commercially available (0.55T MAGNETOM FREE. Max MRI System, Siemens Healthineers, Erlangen, Germany), but it has limited gradient performance (maximum gradient amplitude 26 mT/m, maximum slew rate 45 mT/m/ms), which requires compromises in spatial resolution and frame rates. Stronger, faster gradient performance would come at a significantly higher cost due to the large 80 cm diameter bore of this system. The wide bore is ideal for patients with large body habitus and for adults and children who have claustrophobia and offers greater patient access for in-magnet procedures. The system is more affordable than high Tesla scanners, as it is less expensive to manufacture, transport, install, and operate. Susceptibility artifacts are reduced at lower field, and thus this system can provide improved imaging at the air-tissue boundaries like in the lungs and sinuses. Most importantly for interventionalists, it may be the breakthrough that is needed to allow MR-guided interventional procedures, because of the decreased RFinduced heating that can allow the use of standard equipment, improved access to the patient in the wider bore, and multiple simpler safety and maintenance features. With FDA approval of the MAGNETOM Free.Max and multiple installations around the world, there seems to be a renewed energy in ICMR by clinicians and industry alike, which was clearly visible during a live case at the Pediatric Interventional Cardiac Symposium (PICS) in Chicago in September 2022.⁸ The current platform still needs considerable development, such as imaging techniques and pulse sequences required for cardiovascular imaging, but is expected to make the difference for interventional MRI in cardiology and interventional radiology.

Armstrong, Simonetti, and colleagues were the first to test the feasibility of performing R&LHC, inferior vena cava (IVC) angioplasty, and IVC stenting with realtime imaging in the 0.55T MAGNETOM Free.Max. While many types of standard catheterization equipment can be used safely at low field, they need to be made conspicuous, and this can be done by adding MR-visible markers to the standard equipment. Three different sizes of proprietary MagnaFy MR-visible markers (Nano4Imaging GmbH, Dusseldorf, Germany) were evaluated on Z-Med balloons (NuMED Inc., Hopkinton, NY) in nine juvenile Yorkshire pigs (62.4 ± 9.5 kg).8



FIGURE 3 CMR still frame showing 20 mm x 3 cm Z-Med balloon from Figure 2 inflated with 1% gadolinium provided with 1 mm MagnaFy® MRI markers (white arrow) well distinguished from implanted Mega LD stent (red arrow)



FIGURE 4 CMR still frame showing implanted platinum-iridium stent with significant artifact (red thin arrow) and implanted 316L stainless steel Mega LD stent with good wall apposition demonstrated (red thick arrow)



One of these cases was performed during a live case for PICS 2022. The pigs were under general anesthesia and had sheaths placed in the femoral vein and artery via cutdown. Arrow balloon wedge catheters (Teleflex, Wayne, PA) with CO2- or airfilled balloons were used for RHC, and Judkins Right catheters (Cook Medical, Bloomington, IN) were used for LHC. The 0.035" EmeryGlide® guidewires were used for both R&LHC. The first three pigs were imaged before and after infusing varying doses of ferumoxytol. Subsequent pigs were imaged after infusing 2 mg/kg ferumoxytol over 20 minutes to enhance blood pool signal and visualization of markers. Trade-offs between temporal and spatial resolution were investigated using the following spoiled gradient echo MRI sequences for real-time visualization of devices: high temporal resolution: 7 frames/sec, TE/TR = 2.8ms/6.0ms, Rate 3 GRAPPA, 3.5 x 3.5 x 10mm voxels; high spatial resolution: 2.2 frames/sec, TE/TR = 2.8 ms/6.2 ms, Rate 2 GRAPPA, 1.8 x 1.8 x 9.5mm voxels. In seven pigs, IVC angioplasty and/or stenting was performed using 20 mm x 3 cm Z-Med balloons with two MR markers of varying widths (0.25 mm, 0.5 mm, 1 mm) and 1% gadolinium in the balloon. Mega and Max LD 316L stainless steel stents (Medtronic, Dublin, Ireland) were deployed on Z-Med balloons, and a Covered Mounted CP stent (NuMED) was deployed in the IVC. In three of the stenting procedures, a custom-made 14French Flexor[®] sheath with proprietary markers on the tip of the dilator and sheath (Cook Medical) was used.

Yorkshire swine have known sensitivity to ferumoxytol; one pig expired during infusion, but catheterization was still performed. RHC was successful in all pigs with the balloon tip seen well in all MRI sequences (Figure 1). LHC was attempted and successful in two pigs; the EmeryGlide guidewire entered the left ventricle retrograde easily. IVC angioplasty was attempted in four pigs and was successful in all. Implantation of seven stainless steel stents and one platinum-iridium stent was attempted and successful in all (Figures 2 & 3). MagnaFy® MR markers were finetuned by different width and number of layers (Figure 2 & 3) on the Z-Med balloons. The 0.5 mm- and 1 mmwide were more easily seen than 0.25 mm-wide markers. The platinum-iridium

stent caused significant artifact, leading to inability to assess wall apposition (Figure 4). The 316L stainless steel Mega and Max LD stents were seen well, however, before and after deployment, and wall apposition was assessed (Figure 4). Markers placed at the ends of the tapered tips of the balloons were more easily distinguished from the stent compared to the typical marker location on the shoulders of the balloons (Figure 5). The markers on the Flexor® dilator and sheath were well seen in all cases and allowed proper placement of the sheath in relationship to the stent during implantation. Ferumoxytol 2 mg/kg led to superior imaging of all MR markers, balloons, and stents, compared to no contrast and to 1 mg/kg. Balancing spatial and temporal resolution for the anatomy and intervention was important. For IVC stenting, a higher resolution (144/192 matrix) lower frame rate (~5/2 fps) image yielded optimal visualization.

If low-field MRI is going to be used for ICMR in the future, cardiovascular imaging needs optimization under the conditions of low signal-to-noise ratio and limited gradient performance. Fortunately, pre-clinical and clinical testing has demonstrated that a comprehensive CMR imaging protocol is feasible, including compressed-sensing 2D phasecontrast cine, dynamic contrast-enhanced imaging for myocardial perfusion, 3D MR angiography, and late gadoliniumenhanced tissue characterization.⁹



FIGURE 5 CMR still frame showing 0.5 mm MagnaFy ®markers (white arrows) placed at the ends of the tapered tips of the 20 mm x 3 cm Z-Med balloon well distinguished from ends of crimped 26 mm long Mega LD stent (red arrows) compared to markers on the shoulders of the balloons, which are not well distinguished, seen in Figure 2

The past 12 months have shown how a dedicated collaboration of clinical and industry partners is able to make big steps forward in bringing low-field MRI to the interventional space. The Ohio State University functioned as a field-lab to bring in devices and software from Siemens Healthineers, Nano4Imaging, Cook Medical, and NuMED to start performing the pre-clinical work necessary to bring interventional procedures with real-time MR-guidance to the bedside. Future studies will further optimize tools, software, and contrast to close the gap to routine clinical applications.

References

- Writing Committee Members, et al., 2018 ACC/HRS/NASCI/ SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging-Best Practices for Safety and Effectiveness, Part 2: Radiological Equipment Operation, Dose-Sparing Methodologies, Patient and Medical Personnel Protection. Catheter Cardiovasc Interv, 2018. 92(2): p. 222-246. PMID: 30160013.
- Stern H, Seidenbusch M, Hapfelmeier A, Meierhofer C, Naumann S, Schmid I, Spix C, Ewert P. Increased Cancer Incidence Following up to 15 Years after Cardiac Catheterization in Infants under One Year between 1980 and 1998-A Single Center Observational Study. J Clin Med. 2020 Jan 22;9(2):315. doi: 10.3390/ jcm9020315. PMID: 31979109.
- Rogers T, et al. CMR fluoroscopy right heart catheterization for cardiac output and pulmonary vascular resistance: results in 102 patients. Journal of Cardiovascular Magnetic Resonance 2017;19:54. PMID 28750642.
- Ratnayaka K, et al. Radiation-free CMR diagnostic heart catheterization in children. J Cardiovasc Magn Reason. 2017 Sep 6;19(1):65. PMID 28874164.
- Meierhofer C et al. Real-time CMR guidance for intracardiac and great vessel pressure mapping in patients with congenital heart disease using an MR conditional guidewire—results of 25 patients. *Cardiovasc Diagn Ther* 2021;11(6):1356-1366. PMID 35070804.
- 6. Reddy SRV, Arar Y, Zahr RA, et al. Invasive cardiovascular magnetic

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resonance (iCMR) for diagnostic right and left heart catheterization using an MR-conditional guidewire and passive visualization in congenital heart disease. J Cardiovasc Magn Reason 2020 Mar 26;22(1):20. PMID 32213193.

- Campbell-Washburn A, Ramaswamy R, Restivo MC, et al. Opportunities in Interventional and Diagnostic Imaging by Using High-Performance Low-Field-Strength MRI. Radiology 2019 Nov;293(2):384-393. PMID 31573398.
- Armstrong A, Krishnamurthy R, Swinning J, Liu Y, Joseph M, Simonetti O. Feasibility of MRI-Guided Cardiac Catheterization, Angioplasty, and Stenting in a 0.55T Scanner with Limited Gradient Performance. PICS-AICS 2022, Chicago, IL, September 2022. Selected Abstracts from the PICS Society Symposium 2022 Marriott Chicago Downtown September 7–10, 2022. Pediatr Cardiol 43, 1934–2029 (2022). https://doi.org/10.1007/s00246-022-02969-y.
- Varghese J, Jin N, Giese D, et al. Building a comprehensive cardiovascular magnetic resonance exam on a commercial 0.55T system: A pictorial essay on potential applications. Frontiers in Cardiovascular Medicine 01 March 2023. doi: 10.3389/fcvm.2023.1120982.



AIMEE K. ARMSTRONG, MD, FAAP, FACC, FSCAI, FPICS

Director, Cardiac Catheterization and Interventional Therapies The Heart Center, Nationwide Children's Hospital Professor of Pediatrics, The Ohio State University College of Medicine Chair, PICS Early Career Development

Committee Columbus, Ohio, USA



ORLANDO P. SIMONETTI, PHD, MSCMR, FISMRM, FAHA

John W. Wolfe Professor in Cardiovascular Research Research Director, Advanced Cardiovascular Imaging Professor of Internal Medicine and Radiology The Ohio State University Columbus, Ohio, USA



PAUL J.A. BORM, PHD

CTO and Co-founder of Nano4Imaging GmbH Professor of Toxicology, Heinrich Heine University (HHU) Dusseldorf Staff Member Radiology HHU Dusseldorf, Germany

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Leadership and the Female Interventional Cardiologist on behalf of the Lead Skirts

Shabana Shahanavaz, MD; Laurie Armsby, MD; Holly Bauser-Heaton, MD-PhD; Audrey C. Marshall, MD, MPH; Jaqueline Kreutzer, MD, FACC, FSCAI; Sarah Badran, MBBCh, MACM, FSCAI, FPICCS; Howaida El-Said, MD, PhD, FPICS; Sara M. Trucco, MD, FSCAI, FACC, FPICS

Introduction

In recent years, significant strides have been made in diversifying the medical field, with more women pursuing careers in various specialties. However, despite these advancements, female pediatric interventional cardiologists continue to face a concerning lack of leadership representation within their field. This article aims to shed light on the issue and explore potential solutions to promote gender equality and empower women in pediatric interventional cardiology.

The Gender Disparity

Pediatric interventional cardiology, a highly specialized branch of medicine, focuses on diagnosing and treating heart conditions in children with heart disease as well as adults with Congenital Heart Disease using minimally invasive procedures. While an increasing number of women are entering the field, they often encounter significant barriers when it comes to advancing their careers into leadership roles. Approximately half of firstyear pediatric cardiology trainees in 2020 were women, a substantial increase from the past decade (53.4% women [n=163] in 2020 versus 39% [n=119] in 2007–2008).¹ The increased percentage of women in pediatric cardiology training reflects the overall field of pediatrics (72.3% pediatrics versus 42.3% in Internal Medicine).^{1,2} Despite this positive trend, the gender disparity becomes evident in the post-training career in various aspects, including research opportunities, committee memberships, and administrative positions. Even with half of the pediatric cardiology trainees being female, only 17% of division chiefs and 19% of editorial board members are women.³ Although there has been an increase in the number of women recognized as subspecialty directors, this has not translated to an increase in representation at national meetings and committees with differences being more pronounced for high-profile talks (as defined by conference organizers) among invasive specialties.⁴

Barriers and Challenges

Several factors contribute to the lack of female representation in pediatric interventional cardiology leadership roles. One major challenge is the prevailing unconscious biases that permeate the medical profession.⁵ These biases can manifest in subtle ways, such as underestimating a woman's capabilities or assuming traditional gender roles.⁶ Such biases may affect decisions related to promotions, committee appointments, and research funding, hindering women from reaching leadership positions.⁷ ⁸ Bumenthal et al studied adult female cardiologists in 2014 and found that women faculty were younger than men (mean age, 48.3 years versus 53.5 years, P<0.001), had fewer total publications (mean number: 16.5 publications versus 25.2 publications; P<0.001), were similarly likely to have National Institutes of Health funding (proportion with at least one National Institutes of Health award, 10.8% versus 10.4%; P=0.77), and were less likely to have a registered clinical trial (percentage with at least one clinical trial, 8.9% versus 11.1%; P=0.10).⁹

Given the data above along with stereotypic assumptions of leaders within society, it is not surprising to find that there is deficient

mentorship and sponsorship. Mentorship plays a vital role in career advancement--providing guidance, support, and opportunities for professional growth. Female pediatric interventional cardiologists often struggle to identify mentors and particularly, sponsors, to help them navigate the complex landscape of academic medicine and advocate for their career development, promoting them to achieve higher goals.^{10,11}

Despite the challenges, there have been female interventional cardiologists who have successfully navigated the challenges and have conquered different leadership positions. Below is their perspective within academic leadership positions.

Leadership in National Organizations

One of the most rewarding aspects of my career has been the opportunity to serve in leadership positions within national organizations. In many ways the work is similar to leadership within your institution; it involves creating a vision, developing a team, supporting the team members, cultivating a culture, accomplishing goals, and managing communication. But for me there have been additional, unique aspects to leading at a national level that have yielded significant rewards. It has been energizing to look up from the intensity of direct patient care to work on issues that shape the field and impact patients, providers and systems. In addition, I have loved the opportunity to either reconnect or maintain connections with peers or mentors that I became close to during training or early in my career. These renewed or enriched friendships over the span of my career epitomize the sense of pediatric cardiology as a relatively small, cohesive and supportive community. In addition, working at a national level offers a chance to get to know and work with some of the most inspiring, productive and creative leaders in pediatric cardiology. Once I gained leadership positions myself I was able to provide opportunities to junior colleagues, and experience the immeasurable rewards that come from supporting the career development of others. Finally, these opportunities are extremely important in supporting one's own professional goals. Work at a national level is a requirement in most institutions to achieve academic promotion to the level of professor.

So how do you get involved in this? One pathway to leadership at a national level (such as AAP-SOCCS, AHA, ACC, ABP, ACGME), is to first get involved at the committee level. Once there, it is important that you do the work that supports and expands the committee. If you earn the reputation as someone who is reliable, engaged and adds value, you will eventually be given an opportunity to rise to leadership positions on those committees. In person meetings are still priceless, but the movement toward virtual meetings in the current era have significantly enhanced the frequency, engagement and productivity of national committees. I've found that this has made the work not only more successful, but more enjoyable as well.

Finally, I have found this work to be extremely rewarding, however like all things, it comes at a cost. The work takes time, requires your best efforts, and supplementary resources. In following this path you'll need to volunteer for work and complete it quickly and well. Because these activities don't directly serve your institution, you will do much of the work after normal work hours. To meet people and participate in key meetings you will still need to attend the national conferences. Your CME funds will likely not cover all your expenses. However, in my experience the cost pales in comparison to the enjoyment, impact and reward that these opportunities have yielded.

Leadership in the Catheterization Lab

Leadership experiences come in infinite varieties. Often, what comes to mind is a person, usually male, sitting commandingly at the head of a table in a board room, or maybe a brilliant individual, again often male, rapidly devouring the data at a lab meeting. One of my favorite leadership experiences is getting a cath lab team through a difficult and rapidly moving case in the lab. Each member of the team comes into the case with their own expectations, variable experience, and level of comfort with others on the team. Some may be anticipating the most stressful three hours of the week, while others may simply be expecting an unremarkable last case before the start of a long weekend. When everyone starts to share the feeling that this is not just going to be "a routine diagnostic cath," but instead, that the patient may be unstable, or the intervention may be very high risk, you feel the team respond to the tension by upping their performance level. At this point, when uncertainty begins to permeate the room, a team-leader dynamic starts to take shape amongst a group of coworkers. As the primary operator, I love helping to orchestrate this transition. Acknowledging anticipatory moves by the techs, communicating with the anesthesiologists, and calling out events and orders that the team members will expertly respond to, can be such a rewarding experience. Engendering confidence in my leadership by providing my own best technical performance and judgement, I can appreciate the bilateral nature of this type of leadership experience. It doesn't escape my notice that often, in the cath lab, much of the team is female. While we've had a few great male nurses and techs, the teams in both cath labs I've led have been largely dominated by X chromosomes. My experience has been that female leaders with predominantly female teams seem to get to the "shared mental model" in a unique way. The camaraderie that we share in the locker room, the break room, makes leading easier and more intuitive. When sinus rhythm is re-established, or the device slips right into place, we share equally in the sense of a job well-done. I quietly savor the satisfaction leading a group of highly skilled women, and I hope they also take pride in being part of the female-led team.

Non-Traditional Leadership

In addition to conventional leadership roles (Division Chief, Subsection Director, Department Chair, Hospital Administrator) there are many nontraditional forms of leadership. These positions may or may not come with an official title and include roles that are appointed in addition to those that one more naturally falls into. Unlike positions of formal power, non-traditional leadership roles often arise when an interest becomes a passion, or an innate talent is brought to light. One can be an expert in a particular area, the authority in a specific niche, rendering them the leader in that field. Another might be exceptionally skilled in performing a procedure, which over time yields to a large referral base. An individual who is an enthusiastic and effective teacher, may be asked to direct a course or design a curriculum. A person that can build meaningful rapport and form positive connections, could ultimately start an organization or form a collaborative. There are those who carefully assess situations, determine the fundamental problems, and thereby guide effective programmatic change. These are just some examples of forms of nontraditional leadership, as the range is so vast a complete list would be impossible to generate.

Although men and women can equally fill such roles, it is where these endeavors eventually lead that often differs by gender. All these tasks require time and effort; not always do they generate payment or advancement. Where historically women may have been satisfied with just the knowledge of having done a job well, men are more likely to seek acknowledgement and payment for their efforts. Women in medicine, just as in any other professional career, need to be confident in their worth, and advocate for appropriate recognition and compensation.

Women in Research

The field of cardiology has several areas of disparate inclusion of women in research. It is well known that clinical trials are highly weighed toward male involvement as patients, but in addition, there have been no major clinical trials run by a women primary investigator. In this regard, representation does matter for recruitment and the women-led clinical trial must be a goal for improved equity. We have been quite fortunate to have strong leaders in outcomes research that are women, but this has yet to proven fruitful in other areas. Our research in basic science continues to reveal significant areas of improvement in equity. While much of our research falls into the realm of biomedical engineering, the base representation of females is guite poor in academic positions. Public funding continues to be discrepant as well with only 31% of grantees being women. We are aware female applicants receive less funding than males, often due to differences in amounts requested by males versus females. Despite achieving parity in biomedical degrees, we see that in recent years there has been a decline in percentage of females receiving R01 and renewal grants. It remains no mystery, therefore, that women representation in leadership in basic science continues to be few and far between. As others have pointed out, the role of editor of major journals continues to be held mostly by males, creating a bias for published science. As we continue to investigate the role of women leaders in our field, we continue to uncover the bias that exists at a leadership level in research. At every turn, recruitment, retention, and promotion of women within the research arena is anemic. Despite our gains in representation of females in pediatric cardiology, we do not see promotion of women to pursue these much-needed academic efforts within research. Protection of time and encouragement of women in these fields of research is paramount to increased success and to avoid attrition throughout one's career. It remains unclear in current research the cause for the discrepancies noted above, however, as research is often noted in our field to be an additional task without time provided in many circumstances, the additional burdens placed on women may prevent continuation in this arena. With fewer academic appointments, lower rates of funding applications, decreased awarded dollar amounts and the recent decline of females receiving high level public funding, leadership will continue to suffer in this research arena.

Leadership Training and Support

Throughout my career I had the opportunity to receive formal leadership training several times. These were most valuable programs, which helped me learn about group dynamics, biases, negotiation, conflict resolution and much more. Certainly, such training is most advisable and helpful. However, I recognize that every time I had to make a major decision with regards to undertaking a significant new leadership role, I felt very much alone and unprepared. I did not know how much to ask, how demanding to be, what I deserved, what was reasonable or what would be regarded as crazy. It was thanks to the generosity of two other successful women leaders who provided guidance and advice, that I could develop the strength to advocate for myself as they had done. The lesson to all of us is that we should lean on each other and seek advice from those who have already driven the same road.

Concluding Remarks

There is still work to be done both on a systematic basis within academic institutions and, importantly, within society to bring about consistent change within leadership positions for females. Institutions will need to work on the professional development of women cardiologists, flexible work pathways, provide interim gap funding for research, and offer sponsorship to professional societies. Professional societies' journals should ensure a better balance in editorial boards and better representation among their invited speakers to improve the visibility of women in cardiology.

Lean into yourself and lead with kindness.

To emulate a respected leader, don't simply copy their behaviors without considering the impact. It may result in feeling uncertain, unworthy, or experiencing imposter syndrome. Instead, take a step back and observe the leader's unique beliefs and attitudes, which, combined with their circumstances, skills, and timing, manifest as specific behaviors. By understanding the various paths between beliefs and achievements, you can confidently forge your own authentic path. Don't suppress parts of yourself in the professional realm. Embrace your heart, personality, skills, abilities, and preferences. Identify what makes you uncomfortable, acknowledge your limitations, and seek out multiple avenues of fulfillment. Be proud of your unique style, whether it's enjoying diverse interests or pursuing traditionally gendered activities. Remember, you can't compete with compassion if you are trying to imitate someone else. Find many happy places and figure out how YOU can get there without being shamed into trying to out-man the men. Revel shamelessly in the style that is uniquely yours, from bars to breast feeding, baseball to ballet. You can't compete compassionately as anyone else.

References

- Accreditation Council for Graduate Medical Education. Data resource book. 2018. https://www.acgme.org/About-Us/ Publications-and-Resources/Graduate-Medical-Education-Data-Resource-Book.
- Khan MS, Mahmood S, Khan SU, Fatima K, Khosa F, Sharma G, Michos ED. Women Training in Cardiology and Its Subspecialties in the United States: A Decade of Little Progress in Representation. Circulation. 2020 Feb 18;141(7):609-611. doi: 10.1161/CIRCULATIONAHA.119.044693.
- 3. Balasubramanian S, Pasquali SK, Cousino MK, Lowery RE, Les AS, Yu S, McCormick AD, West CL, Fifer CG, Goldberg CS, Romano JC, Owens ST. Representation of Women and Minority Faculty and Fellows in Academic Pediatric Cardiology Training Programs. J Am Coll Cardiol. 2023 Mar 28;81(12):1181-1188.
- Yong CM, Balasubramanian S, Douglas PS, Agarwal P, Birgersdotter-Green U, Gummidipundi S, Batchelor W, Duvernoy CS, Harrington RA, Mehran R. Temporal Trends in the Proportion of Women Physician Speakers at Major Cardiovascular Conferences. Circulation. 2021 Feb 16;143(7):755-757. doi: 10.1161/CIRCULATIONAHA.120.052663.
- Lau ES, Wood MJ. How do we attract and retain women in cardiology? Clin Cardiol. 2018 Feb;41(2):264-268. doi: 10.1002/ clc.22921. Epub 2018 Feb 26. PMID: 29480589; PMCID: PMC6490032.
- Jolly S, Griffith KA, DeCastro R, Stewart A, Ubel P, Jagsi R. Gender differences in time spent on parenting and domestic responsibilities by high-achieving young physician-researchers. Ann Intern Med. 2014; 160: 344– 353.
- 7. Lewis SJ, Mehta LS, Douglas PS, et al. Changes in the professional lives of cardiologists over 2 decades. J Am

Coll Cardiol. 201 Yong CM, Balasubramanian S, Douglas PS, Agarwal P, Birgersdotter-Green U, Gummidipundi S, Batchelor W, Duvernoy CS, Harrington RA, Mehran R. Temporal Trends in the Proportion of Women Physician Speakers at Major Cardiovascular Conferences. Circulation. 2021 Feb 16;143(7):755-757. doi: 10.1161/ CIRCULATIONAHA.120.0526637; 69: 452– 462.

- 8. Carnes M, Bairey Merz CN. Women Are Less Likely Than Men to Be Full Professors in Cardiology: Why Does This Happen and How Can We Fix It? Circulation. 2017 Feb 7;135(6):518-520. doi: 10.1161/CIRCULATIONAHA.116.026671.
- Blumenthal DM, Olenski AR, Yeh RW, DeFaria Yeh D, Sarma A, Stefanescu Schmidt AC, Wood MJ, Jena AB. Sex Differences in Faculty Rank Among Academic Cardiologists in the United States. Circulation. 2017 Feb 7;135(6):506-517. doi: 10.1161/ CIRCULATIONAHA.116.023520. PMID: 28153987.
- Eshtehardi P, Bullock-Palmer RP, Bravo-Jaimes K, Bozkurt B, Dorbala S, Gillam LD, Grines CL, Mehran R, Mieres JH, Singh T, Wenger NK. Women leaders: transforming the culture in cardiology. Open Heart. 2022 Feb;9(1):e001967. doi: 10.1136/ openhrt-2022-001967. PMID: 35228269.
- October TW (2022) Why women say no to leadership positions. Front. Pediatr. 10:1027295. doi: 10.3389/fped.2022.1027295.



SHABANA SHAHANAVAZ, MD

Director Cardiac Catheterization Laboratory Cincinnati Children's Hospital Medical Center Cincinnati, Ohio, USA



LAURIE ARMSBY, MD

Professor of Pediatrics Division of Pediatric Cardiology Oregon Health Sciences University Portland, Oregon, USA



HOLLY BAUSER-HEATON, MD-PHD

Associate Professor of Pediatrics Children's Healthcare of Atlanta, Division of Cardiology Atlanta, Georgia, USA



MEETING CALENDAR



AUDREY C. MARSHALL, MD, MPH

Section Head, Interventional Cardiology Hospital for Sick Children Toronto, Ontario, Canada

JAQUELINE KREUTZER, MD, FACC, FSCAI

Division Chief, Pediatric Cardiology Professor, Department of Pediatrics, University of Pittsburgh School of Medicine Peter and Ada Rossin Endowed Chair in Pediatric Cardiology Co-Director, Heart Institute UPMC Children's Hospital of Pittsburgh Pittsburgh, Pennsylvania, USA



SARAH BADRAN, MBBCH, MACM, FSCAI, FPICCS

Professor of Pediatrics College of Human Medicine, Michigan State University Division Chief, Pediatric and Congenital Cardiology Helen Devos Children's Hospital Grand Rapids, Michigan, USA



HOWAIDA EL-SAID, MD, PHD, FPICS

Professor of Pediatric Cardiology University of California San Diego Director of Cardiac Cath Lab Rady Children's Hospital Adult Congenital Heart Disease Certified San Diego, California, USA

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SARA TRUCCO, MD, FSCAI, FACC, FPICS Associate Professor of Pediatric Cardiology Associate Director, Cardiac Cath Lab Director, Quality Improvement for Cardiac Catheterization UPMC Children's Hospital of Pittsburgh Pittsburgh, Pennsylvania, USA sara.trucco@chp.edu

Heart of a Champion Day Offers Life-Saving Screening for Student Athletes

Atrium Health Partnered with the Carolina Panthers to Provide Free Sports Physicals at Bank of America Stadium





Atrium Health

Atrium Health partnered with the Carolina Panthers and hosted Heart of a Champion Day at Bank of America Stadium in Charlotte, North Carolina. The event provided student-athletes with a free general sports screening, musculoskeletal check and a vision examination. Unlike typical athletic screenings, Heart of a Champion Day also included electrocardiograms to detect genetic heart abnormalities that could lead to sudden cardiac arrest during competition – a rare, but catastrophic event. Heart of a Champion Day began in 2008 with the goal of ensuring high school athletes could safely compete in sports. The program has since expanded and now screens thousands of students at more than 90 schools across the Carolinas. Volunteers completed more than 1,000 screenings throughout this year's event.

Some of the volunteers were: Dr. David Price, Sports Medicine Physician with Atrium Health Musculoskeletal Institute and a founding member of Heart of a Champion Day; Dr. Gonzalo Wallis, Interim Chief of Pediatric Cardiology with Atrium Health Levine Children's; and Kenny Moore, Carolina Panthers legend and Butler High School alumni.

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CHIP NETWORK CONGENITAL HEART INTERNATIONAL PROFESSIONALS



ACTION Develops Registry to Close Gaps Amongst the Pediatric Heart Failure Patient Population

A leading pediatric heart failure organization ACTION, the Advanced Cardiac Therapies Improving Outcomes Network (Cincinnati, OH), has developed a registry to close gaps amongst the pediatric heart failure patient population.

Background

ACTION started with a focus on patients supported with a Ventricular Assist Device (VAD), and while ACTION's efforts were very successful for improving access to and outcomes for children on a VAD, the group observed a lack of data about the use of heart failure medications in children. This is an important opportunity to improve outcomes for all children at risk for or living with heart failure.

"Now is the time to improve outcomes for children with heart failure," said Joseph Spinner, MD, Texas Children's Hospital. "ACTION has the experience and success with our VAD registry to lead the way and take on this very important problem affecting children. Through the ACTION HF registry, we now have the infrastructure to learn from one another and rapidly acquire and disseminate information to improve outcomes for children with heart failure."

HF Registry

The Heart Failure database began with limited patient data entry. ACTION's intent was to analyze and share the findings from learning and implementing quality improvement strategies to enhance care practices. Initiatives derived from data learnings required additional data entry to substantially support findings, which led to database



expansion and to the HF Registry. The registry is designed as a single-entry point to optimize and increase the data entry volume and efficiency. The innovative centralized structure allows for new initiatives to be rapidly added with limited data burden.

HF Registry Initiatives

Its initial pilot ACTION HF database and the feedback it received helped ACTION identify several initiatives to focus its efforts on: 1). an inpatient acute decompensated heart failure registry; 2). standardization of heart failure medication usage and dose titration; 3). understanding the use and side effect profile of Sodium-glucose Cotransporter-2 (SGLT2) inhibitors; 4). determining the feasibility of using Apple wearables for real time data and tracking; and 5). understanding the use and safety of CardioMEMS in children and adults with congenital heart disease with heart failure. There are many medications and advanced therapies which have been studied for adults with heart failure, but ACTION does not have evidence for them in its pediatric heart failure patients --- the HF registry aims to close those gaps.

1. Inpatient Acute Decompensated Heart Failure Registry Acute decompensated heart failure in children is associated with significant morbidity, mortality, and resource utilization. However, previous attempts to better characterize pediatric heart failure hospitalizations are limited by an inability to capture accurate underlying diagnoses and long-term outcomes, and granular data pertaining to heart failure medication usage are lacking. The ACTION Inpatient Acute Decompensated Heart Failure Registry will better characterize all pediatric heart failure hospitalizations, including among children with congenital heart disease, and better capture granular heart failure medication use to help ACTION better understand if and how heart failure medications are associated with pediatric heart failure short-term and longer-term outcomes.

2. Meds Titration The pediatric heart failure population has considerably fewer drug studies to support medication usage than the adult heart failure population. Thus, heart failure medication options for children are limited, and decisions on how to use and adjust medications are less well-informed. The medication titration initiative aims to facilitate titration of heart failure medication doses among ACTION center patients using telephone, telehealth, and in-person visits. The HF registry collects information illustrating what medicines are being used and at what time points to develop consensus-driven medical therapies amongst pediatric heart failure providers. The ability to deliver care in accessible ways and

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MEDICAL NEWS



understand the use of consensus driven medical therapies may be an ideal advancement to improve the care of this pediatric population.

3. SGLT2*i* The SGLT2*i* study is an example of a new project that needed specific data entry in addition to the Meds Titration project. The use of SGLT2*i* in children is based on very little pediatric data, though literature strongly supports the use of SGLT2*i* in adults with heart failure. ACTION hope to understand how SGLT2*i* medications are used in pediatric centers and rapidly disseminate data in order to potentially add these medications as potential therapies for children with diastolic or systolic heart failure.

4. Wearables In addition to the lack of data supporting pediatric heart failure therapies is the lack of remote monitoring and assessment tools available for children with heart failure. Adult heart failure assessments are supported by studies that have demonstrated that biomarkers received through technology have been useful to identify signs and allow for early treatment of heart failure symptoms. ACTION does not yet know if technology can be utilized to improve heart failure care in pediatric populations. The wearables project aims to understand the usefulness of collecting real time biometric health data in pediatrics by using Apple technology.

5. CardioMEMS[™] Implantable hemodynamic monitors (IHMs) have been utilized to measure pulmonary artery pressures to provide earlier and more accurate detection of filling pressures and volume status to help clinical management of adults with heart failure. The existing CardioMEMS[™] HF System trials excluded patients with Congenital Heart Disease (CHD) and of pediatric

age. This prospective registry will collect use and safety data of CardioMEMS[™] device implantations in children or adults with CHD and heart failure who meet the appropriate indications. This study aims to understand the feasibility of implantation, safety, and clinical outcomes of CardioMEMS[™] in pediatric heart failure patients and will ultimately allow for additional indications and benefit a larger patient population.

"ACTION is trying to use the very latest technology such as sensors and wearables to improve our understanding, treatment, and outcomes in heart failure," said David Peng, MD, CS Mott Children's Hospital. "We can only do this because of our community's extraordinary collaboration, open-mindedness, and commitment."

Goals and Next Steps

The heart failure registry expansion launched in July 2022 within ACTION. As of May 2023, 156 patients from 13 pediatric centers have been enrolled into the registry. ACTION plans to include as many pediatric heart failure patients and centers as possible to best understand variability and feasibility of its studied initiatives. ACTION strives to get new therapies approved and guidelines developed to ultimately improve outcomes for pediatric heart failure patients.

To learn more about ACTION and how to join its efforts, please visit: www.actionlearningnetwork.org.



MEDICAL NEWS

Coronary Bioresorbable Scaffolds Nearly as Safe and Effective as Conventional Metal Stents for Heart Disease Patients

First-generation bioresorbable vascular scaffolds (BVS) may be just as effective as drug-eluting metallic stents, which are currently the standard treatment for heart disease patients undergoing Percutaneous Coronary Intervention (PCI).

These are significant findings from a global clinical trial led by a researcher from the Icahn School of Medicine at Mount Sinai. The work could lead to advancements and improvements in new BVS technology and future clinical use among interventional cardiologists across the United States.

This multi-center trial is the largest trial to examine the long-term safety and effectiveness of PCI using Abbott's "Absorb BVS," a novel stent made of absorbable polymer (plastic-like material). It shows this treatment option, when properly implanted, may lead to long-term outcomes for heart disease patients that are similar to conventional treatment with metallic drug-eluting stents.

The five-year results from the "ABSORB IV" trial were announced Wednesday, May 17th, in a Late Breaking Clinical Trials/Hotline session at the EuroPCR meeting in Paris, the official annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), and simultaneously published in the Journal of the American College of Cardiology.

"In this study, the largest ever of BVS in patients with coronary artery disease, the absorbable scaffold, when implanted with optimal technique, resulted in similar five-year rates of patient-oriented adverse events, quality of life, and recurrent angina as the standard metallic drug-eluting stent," says lead author Gregg W. Stone, MD, Director of Academic Affairs for the Mount Sinai Health System and Professor of Medicine (Cardiology), and Population Health Science and Policy, at Icahn Mount Sinai. "Some adverse events with this thick strut first-generation scaffold were more common within the first three years, prior to its complete bioresorption. Thereafter, event rates were nearly identical with BVS and metallic stents. The early excess risk could likely be eliminated with an improved thinner next-generation scaffold and its implantation with intravascular imaging guidance, affording long-term restoration of the coronary artery to its original native state without a permanent implant."

Dr. Stone adds, "There is a real desire among patients and their doctors for an absorbable stent which is present early while it is needed and then completely disappears. The favorable long-term results from this study emphasize the fact that this novel technology, which was voluntarily withdrawn from the market by the manufacturer due to lower-than-expected market adoption, should not be abandoned."

Patients with coronary artery disease-plague buildup inside the arteries that leads to chest pain, shortness of breath, and heart attackoften undergo PCI, a non-surgical procedure in which interventional cardiologists use a catheter to place stents in the blocked coronary arteries to restore blood flow. The standard treatment uses a metallic drug-eluting stent, and the permanent metallic implant effectively opens the artery. However, the permanent metallic cage may be responsible for the roughly 2% per year rate of adverse events that arise from the lesion every year for the life of the patient. Some of these events, known as stent thrombosis events, can cause a fatal heart attack in about 20% of cases.

For decades, manufacturers have been working on BVS made of a polymer (a type of plastic) as an alternative. These scaffolds open the blocked artery and then over a three-year period are safely absorbed into the bloodstream, where they are metabolized into carbon dioxide and water. The Food and Drug Administration approved Abbott's "Absorb BVS" in 2016—the most widely used device of its kind—but the company voluntarily stopped manufacturing and sales.

The ABSORB IV clinical trial compared Abbott's polymeric everolimus-eluting BVS, implanted with improved technique compared to prior studies, with Abbott's cobalt chromium everolimus-eluting stents (CoCr-EES) to assess safety and outcomes over the course of five years following the procedure. Researchers randomized 2,604 patients at 147 sites with stable or acute coronary syndromes to receive either BVS with improved technique or CoCr-EES. Patients did not know which stent they received.

At the five-year mark, 17.5% of patients with BVS had target lesion failure (cardiac death, heart attack, or repeat intervention linked to the treated device or vessel), compared with

14.5% of patients treated with metallic stents-a 3% difference. Twenty-one BVS patients had thrombosis (blood clot) linked to the device, compared with 13 metallic stent patients, a 62% difference. The risk period for increased cardiac events was within the first three years, before the complete scaffold was absorbed into the bloodstream, but the rates of these cardiac events were similar between both groups from three to five years after implantation. At five years, there was no significant difference between the two groups in death or overall cardiac events, both groups had a similar guality of life (which was measured continually through the five year study period with the Seattle Angina Questionnaire (SAQ)-7 and the EuroQOL-5D Visual Analog Scale (EQ-5D VAS)) and there was no difference in chest pain symptoms.

A unique aspect of the study involved an indepth look at recurring angina—chest pain that is often the reason that patients undergo stent implantation. Around 5-8% of PCI patients typically report this symptom to their cardiologist at any given follow-up time. However, in this trial, researchers had patients in both groups answer detailed questions to characterize their chest pain symptoms continuously for up to five years post-PCI. The descriptions of these symptoms were reviewed by an independent committee to determine whether they were truly angina. This analysis showed 53% of patients in both groups (BVS and metallic stent) had recurring angina at some point within five years. This rate, much higher than previously appreciated, may give new insights into the burden of angina on patients and raises questions about the causes of angina.

"The fact than angina recurred so frequently was unexpected, and much higher than we would have anticipated given the fact that the patients and lesions treated in this study were not overly complex. This suggests that there may be causes of angina other than obstructive epicardial coronary artery disease, such as microvascular disease and vasospasm, that require different treatments than stents if we are to further improve patient's symptoms," says Dr. Stone.

This study was funded by Abbott.

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PO Box 52316 Sarasota, FL 34232 USA

CORPORATE TEAM

PUBLISHER & EDITOR-IN-CHIEF Kate Baldwin kate.f.baldwin@gmail.com

FOUNDER & SENIOR EDITOR Tony Carlson tcarlsonmd@gmail.com CO-FOUNDER & MEDICAL EDITOR John W. Moore, MD, MPH jwmmoore1950@gmail.com

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