

Future of Evidence Generation – Patient-centered, patient-initiated

The iSCAD Registry: A Case Study

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No Disclosures

Objectives

- Introduce the iSCAD Registry as a case study in patient-initiated, patient-centered research
- Discuss the lessons learned in working with patients as research partners
- Summarize considerations when considering patient-centered research (beyond PED/PROs)

The iSCAD Registry

Esther S.H. Kim, MD, MPH

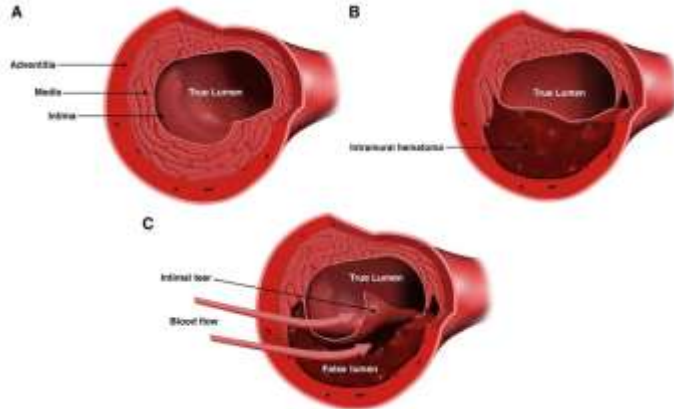
Associate Professor of Medicine

Cardiovascular Medicine

Vanderbilt University Medical Center

*I think this talk is the
reason I was invited
today (thank you!)*

Spontaneous Coronary Artery Dissection

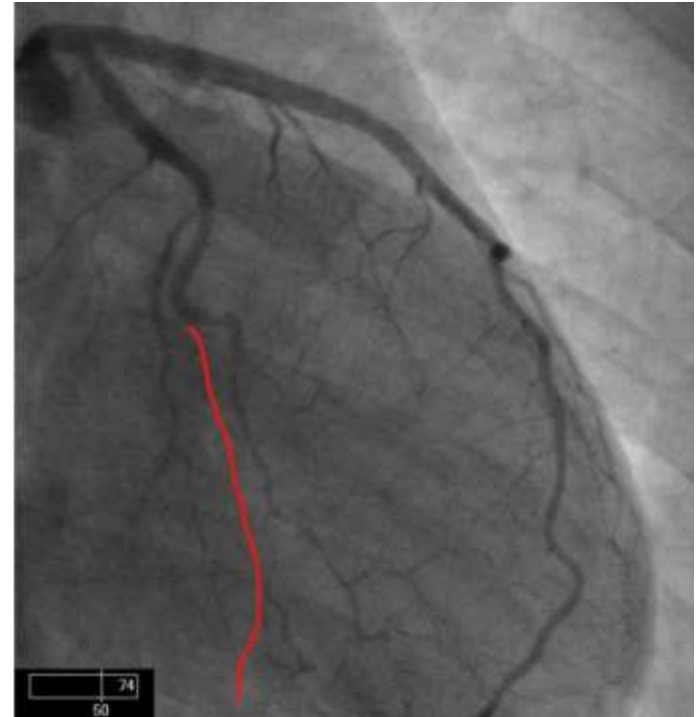


Nontraumatic, noniatrogenic, non-atherosclerotic separation of the coronary arterial wall by intramural hemorrhage creating a false lumen, **with or without** an intimal tear.

- Uncommon, <5% all ACS but >1/3 ACS in women <50 years
- ~90% cases in women; mean age dx early 50s
- Primarily presents as troponin+ ACS
- Underlying vasculopathy (FMD) in >50%

Spontaneous Coronary Artery Dissection

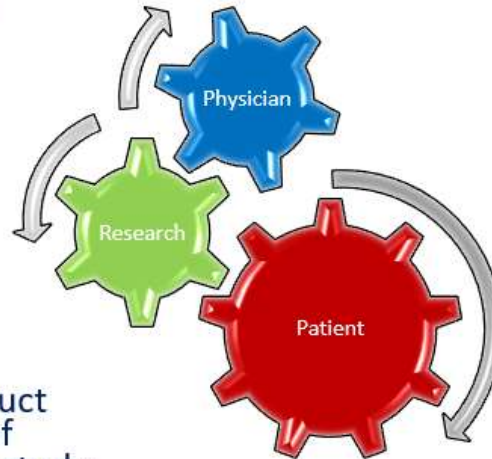
- Diagnosis is both relieving and devastating
- Majority of patients are healthy women otherwise at low risk for cardiac conditions
- Evidence for treatment is lacking → no RCTs
- Recurrence rate is unclear
- Cardiac outcomes are only part of the picture: $>1/3$ patients meet criteria for PTSD but $<1/2$ receive tx for PTSD



The Challenges of Studying Rare Disease

Barriers to Advancement of Science for Rare Diseases

- Small patient populations
- Geographic dispersion of patients
- Expertise limited to
 - Few individuals
 - Tertiary academic institutions
- Lack of funding
 - Generalizability for population at large
 - Small market for product development → lack of financial incentive for study by industry



Drivers of Advancement of Science for Rare Diseases

- Disease Champions
 - Patient champion
 - Physician champion
- Collaboration
 - Physician-Physician
 - Patient-Physician
 - Social media
 - Patient advocacy groups
- Mechanism for Research Funding

Organizational Structure

Registry Centers



Site DATA

- Institutional IRB
- Data Use Agreement

\$



PERFUSE



iSCAD DATA

Publications Committee

Steering Committee

Presentations/
Publications



Chair, Steering Committee

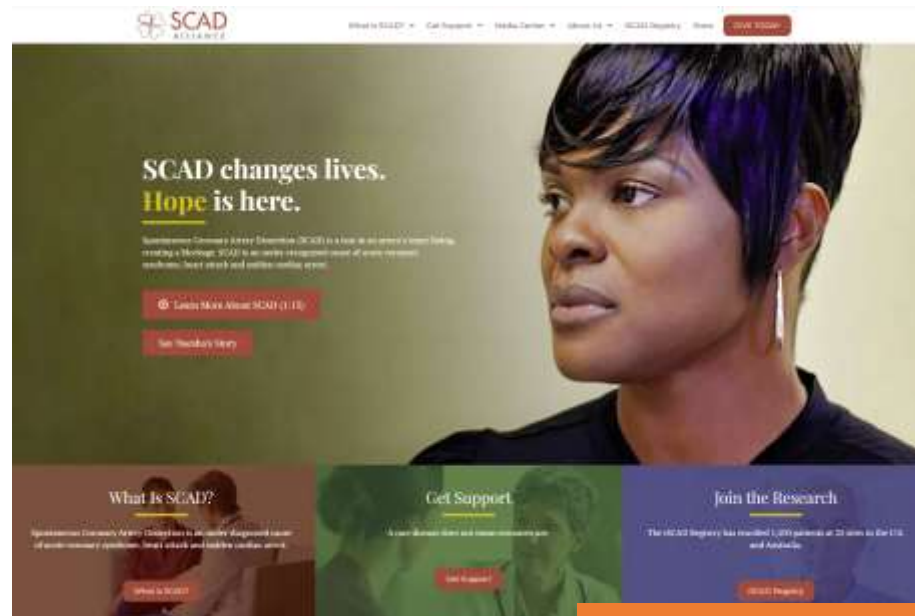


Director, PERFUSE



Mission

The mission of the International Spontaneous Coronary Artery Dissection (iSCAD) registry is to develop and maintain an independent, quality data repository to advance the pace and breadth of SCAD research around the world, toward the common goals of improving patient diagnosis and outcomes and accelerating scientific discovery.

A screenshot of the SCAD Alliance website. The top navigation bar includes the SCAD Alliance logo, a search bar, and links for "What is SCAD?", "Call Register", "Media Center", "About Us", "iSCAD Registry", and "Join Us". The main content area features a large image of a woman with short dark hair and purple highlights, looking thoughtfully to the side. Overlaid on the image is the text "SCAD changes lives. Hope is here." in white and yellow. Below this is a paragraph of text and two red buttons: "Learn More About SCAD (1/1)" and "See Research Here". At the bottom of the page, there are three smaller sections: "What is SCAD?", "Get Support", and "Join the Research", each with a red button.

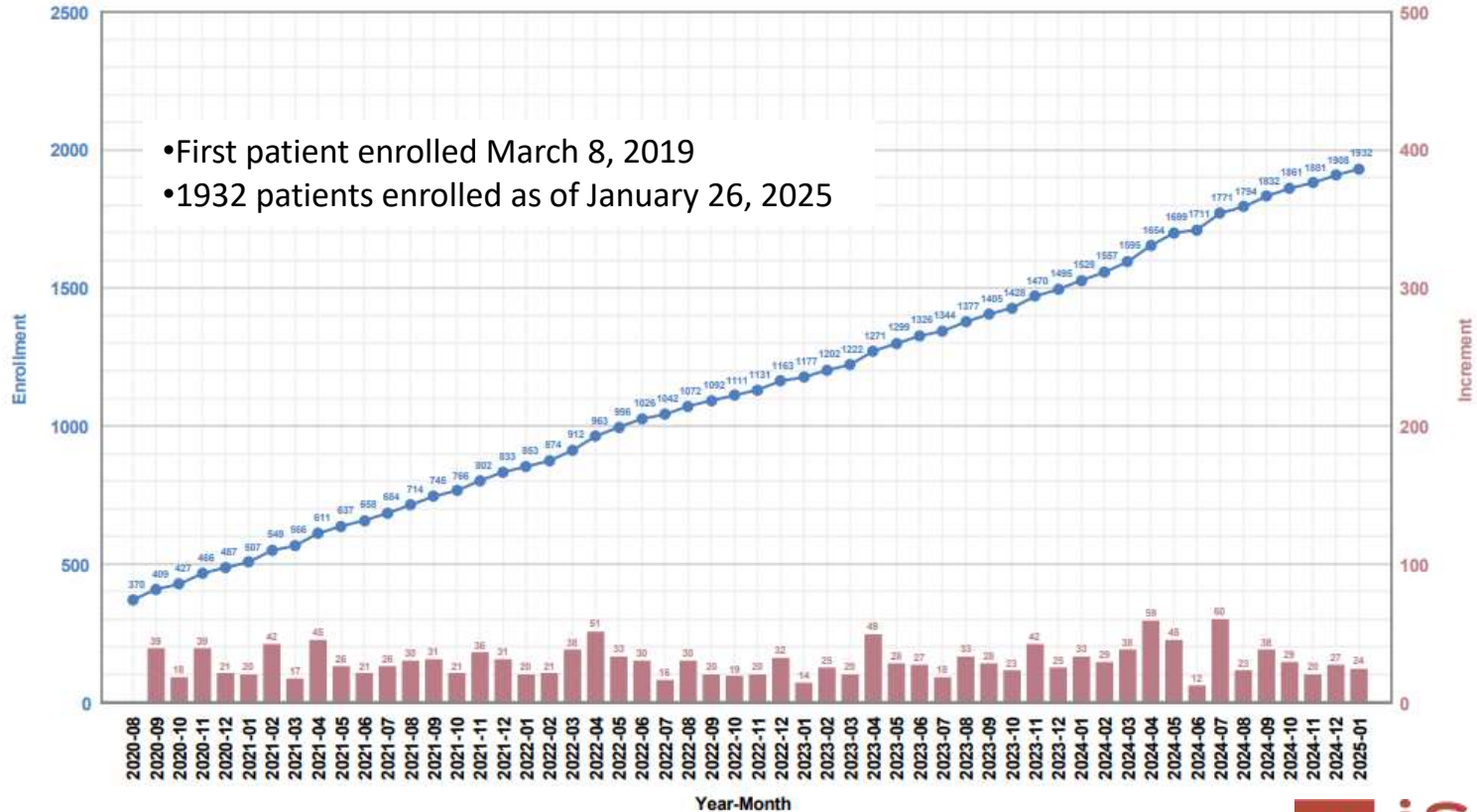
scadalliance.org

Enrolling Sites (n=29)



- ♥ Allegheny Singer Research Institute
- ♥ Atrium Health
- ♥ Case Western/University Hospitals
- ♥ Cedars- Sinai
- ♥ Catholic Medical Center
- ♥ Columbia
- ♥ Cornell
- ♥ Dartmouth
- ♥ Emory
- ♥ Hartford Hospital
- ♥ Inova
- ♥ Intermountain
- ♥ Johns Hopkins
- ♥ Kaiser Permanente
- ♥ Massachusetts General Hospital
- ♥ Mount Sinai
- ♥ Oklahoma Heart
- ♥ Providence
- ♥ St. Luke's Mid America
- ♥ UCLA
- ♥ University of Colorado
- ♥ University of Pennsylvania
- ♥ University of South Florida
- ♥ University of Virginia
- ♥ University of Washington
- ♥ UPMC
- ♥ UT Southwestern
- ♥ Vanderbilt
- ♥ Victor Chang Clinical Research Institute

iSCAD Patient Enrollment



We Don't Know What We Don't Know – So We Should Ask...

MD priorities:

- DAPT duration?
- Beta blocker?
- Etiology?
- Recurrence?
- Angiographic healing?
- LV recovery?

Your Thoughts



List the top 3 challenges you have faced as a result of SCAD

- The unknown – recurrence, answers to questions
- Loss of prior ability to exercise/activity
- Lifestyle change/slowing down
- Finding local doctors who know SCAD
- Fear/anxiety/PTSD in me and my family and friends
- Ongoing pain/fatigue/foggy brain
- Not knowing if another SCAD or panic attack
- Preparing my family for potential sudden death
- People assume SCAD MI was an ASO MI
- Putting myself/health first
- No information on SCAD when I had mine
- What to take for migraines
- Realistic expectations of recovery/recurrence
- Not knowing if the meds help or harm
- Weight gain
- Parenting while recovering from SCAD
- Finding my normal

We Don't Know What We Don't Know

Exercise post-SCAD



What cardiologists imagine you're doing when you ask about exercise...



What cardiologists hope you're doing when you ask about exercise...

can be used to assign provisional diagnoses of PTSD, and is more feasible for use in clinical settings.^{18,19} Research with gold-standard clinical interviews to determine full diagnostic criteria is needed. By focusing on assessing symptoms of SCAD-induced PTSD, we also were unable to determine whether patients had a history of PTSD symptoms that developed in response to other types of traumatic experiences as well. Despite these limitations, this largest study analyzing SCAD-induced PTSD conducted to date has several unique strengths, including (1) integrating patients from multiple clinics, (2) incorporating information from patients and provider site investigators, (3) assessing lifetime and past-month probable diagnoses of SCAD-induced PTSD, and (4) investigating associations between SCAD-induced PTSD and a range of health-relevant correlates.

CONCLUSIONS

Our investigation of >800 patients with SCAD suggests that SCAD-induced PTSD symptoms are a common mental health consequence for these patients. Furthermore, these symptoms are linked to clinical characteristics that are relevant to the course of disease, including adverse health behaviors and disease-specific health status. Moreover, nearly half of patients who developed probable SCAD-induced PTSD reported never receiving trauma-related treatment. The high prevalence of SCAD-induced PTSD symptoms and this treatment gap are particularly notable given that a lack of mental health resources after SCAD is a leading concern for patients.¹² Efforts to support screening for PTSD symptoms after SCAD and connecting those patients experiencing distress postevent with empirically supported treatments are critical next steps.

Patient Perspective

As a survivor who has journeyed through the challenges of SCAD, I am thankful for the ongoing research dedicated to understanding the intricate connection between SCAD and PTSD. I think it is incredibly important that those engaged in post-SCAD care recognize that the emotional aftermath of SCAD can be just as, if not more, stressful than the event itself. SCAD survivors require not only medical support but also emotional support to truly heal after facing SCAD.

As a patient diagnosed with a rare disease, it is important to acknowledge the additional emotional aspect that is required in the healing process. The diagnosis of a rare condition, where even medical professionals have limited information, increased my anxiety and uncertainty surrounding its cause and likelihood of recurrence. Although the initial heart attack

and hospitalization were emotionally challenging for me, the period following my discharge from the hospital proved even more challenging. The uncertainty took a toll on my emotional healing and perspective for my future health.

During my time in the hospital, although I experienced moments of anxiety, it was when I was discharged that my anxiety seemed to intensify. Losing the comforting presence of medical professionals and the reassuring presence of the machines that monitored my heart's every beat left me feeling vulnerable and uncertain about the path ahead.

I vividly recall the realization that, with SCAD, life could slip away in the blink of an eye, with no warning, no chance to seek help. Faced with this unsettling uncertainty and the gravity of SCAD's potential impact, adapting to a sense of "normalcy" was a challenge. With time, I found strength through cardiac rehabilitation, where I learned to trust my healing heart once more and the fearful moments gradually gave way to a newfound sense of confidence. The journey after my discharge was undeniably stressful, but it also carried the precious gift of a second chance at life.

It was not until the 1-year mark of my SCAD journey that I found myself grappling with PTSD. The moment arrived unexpectedly, as my spouse and I were leaving a restaurant. I glanced at my watch and realized it was the exact time we had dialed 911 a year earlier. Just then, an ambulance rushed past us, heading in the direction of my home, the same path it had taken that day. At that moment, I was overwhelmed with anxiety. Later that evening, as I lay in bed, the memories flooded back as I recalled the smell of the hospital sheets, the hospital machines beeping, and the profound fear that gripped me during my hospital stay. These recollections weighed heavily on my already anxious heart, and it became apparent that I needed help. I made an appointment with my cardiologist, as well as my physician, and was diagnosed with PTSD.

Twelve years have passed since my diagnosis of PTSD, and although my life has returned to normal, there are moments when my PTSD resurfaces. Whenever my heart flutters or the mere thought of something resembling the feeling of my SCAD experiences, anxiety instantaneously takes over me. External triggers, like appointments with physicians, the wailing sirens of ambulances, or the hospital environment, cause me to have anxiety. Even my annual cardiology appointment fills me with anxiety. The fear of discovering something awry and facing hospitalization looms over me. This anxiety extends to my visits to the primary doctor and dentist as well. These settings take me back to those moments of crippling fear and uncertainty.

PTSD is another aspect of SCAD that SCAD survivors are faced with. There is an urgent need for health

Patient Involvement in iSCAD -

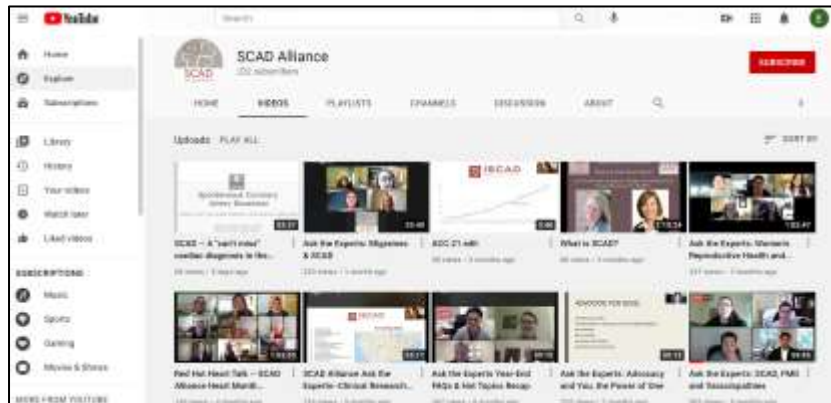
Acknowledgments

The iSCAD Registry was developed in partnership with patients with SCAD who recognized the need for a collaborative international research model accessible to patients and investigators. Patients simultaneously raised funds to support the registry, answered surveys to develop the study questions, and generously shared their medical and personal information as active enrolled participants in the registry. The authors would like to acknowledge these patients; this work would not have been possible without their time, effort, generosity, and dedication. The authors would also like to acknowledge the many coinvestigators and research staff at the enrolling sites who volunteered their time to complete this work.

“Importance of Clinical Studies”



“When thinking about SCAD, which of the following topics are most important to you?” n=421 respondents



<https://www.youtube.com/c/SCADAlliance>

Sanger SCAD Patient Symposium



Spontaneous coronary artery dissection (SCAD) is an increasingly recognized cause of heart attack, particularly in women. There has been incredible progress made in the understanding of SCAD, and this symposium will provide an update about SCAD to an audience of patients and their loved ones.

Date: Saturday, April 22, 2023

Venue: Sanger Heart & Vascular Institute – 1237 Harding Place, Charlotte, NC

Time: 8:00am – 5:00pm

Registration fee: \$25.00

Topics will include a review of the anatomy and physiology of the heart and arteries, a description of common cardiology tests and procedures and why they are performed, and a review of why SCAD may happen and how SCAD heart attacks are treated.

A highlight of this meeting will be **special breakout sessions** that will allow patients to interact in smaller groups to discuss important topics such as developing coping methods after SCAD, finding ways to help others who have experienced a SCAD, and defining strategies for caregivers to cope after their loved ones have suffered a SCAD heart attack. There will also be talks on mental health, physical activity, and reproductive health considerations after a SCAD heart attack.

Early Bird Hotel Registration Discount for Out of Town Guests

The first 10 patients who register for hotel accommodation at the **Hampton Inn Charlotte-Uptown** will receive a discount if they use the link below: [Discount at Hampton Inn](https://www.charlotteahc.org/event/70708)

Kindly register using the website link or QR Code

<https://www.charlotteahc.org/event/70708>



STATE-OF-THE-ART REVIEW

Spontaneous Coronary Artery Dissection

Current Knowledge, Research Gaps, and Innovative Research Initiatives: JACC Advances Expert Panel

Daniela Cruz-Uribe, MD,^{1,2} Aray Sarma, MD,^{1,3} Malissa Wood, MD,⁴ Sagar Nalluri, MD, MPH,⁵ Catherine Lanoie, MD,⁶ Michael Gibson, MD,⁷ Aaron Aday, MD, MS,⁸ Anna Grodzinsky, MD, MS,⁹ Kathy Hurl, BA,¹⁰ Jason C. Kossack, MD, PhD,¹¹ Mark E. Lindsay, MD, PhD,¹² Dermot Phelan, MD, PhD,¹³ Patricia F. Rodriguez-Lorenzo, MD, MS,¹⁴ Handika S. Scott, MD,¹⁵ Markus Scherer, MD,¹⁶ Aditya Sharma, MD,¹⁷ Surya Sweta, MD,¹⁸ Jennifer A. Stamer, PhD,¹⁹ Esther S.H. Kim, MD, MPH²⁰

ABSTRACT

Despite needed advancements in the recognition and diagnosis of spontaneous coronary artery dissection (SCAD) over the past decade, knowledge of the basic pathophysiologic mechanisms of disease, contributing factors, and treatment continues to be poorly understood. We describe significant research gaps in our knowledge of SCAD and introduce strategies including the role of patient advocacy, independent registries, and creation of diverse centers of excellence to bridge the gap in clinical care, research, and outcomes. Lastly, we introduce an innovative patient-centered clinical care and research framework established through the SCAD Alliance and International Spontaneous Coronary Artery Dissection registry as a model for advancing knowledge of SCAD. (JACC Adv. 2024;3:101385) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

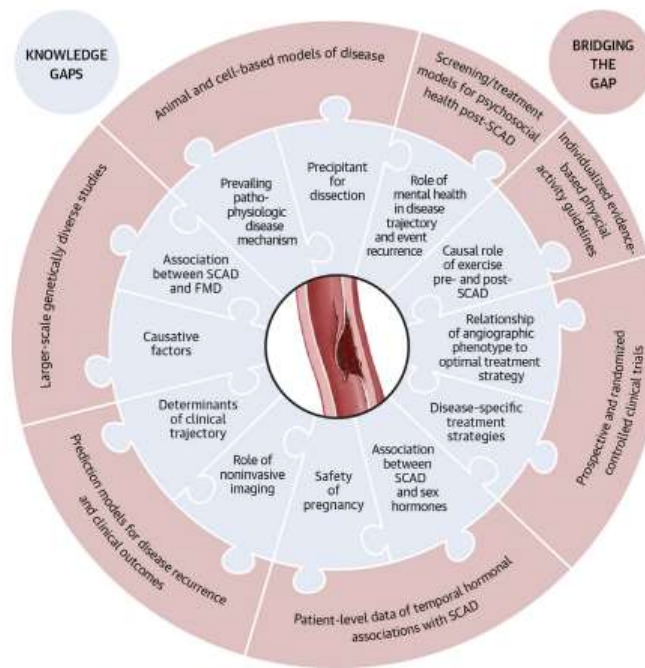
Women remain underrepresented in cardiovascular research, limiting our understanding of sex-specific differences and contributing to inequalities in care.¹ This underrepresentation is perpetuated by low perceived risk of disease among patients and clinicians, exclusion of pregnant and childbearing age people from research, and disparities in referrals of women to

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The authors state they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the author center.

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CENTRAL ILLUSTRATION Current Knowledge, Gaps, and Research Priorities in SCAD



Crousillat D, et al. JACC Adv. 2024;3(12):101385.

Significant knowledge gaps in our understanding of spontaneous coronary artery dissection (SCAD) and suggested future research initiatives to bridge the gaps.

FIGURE 1 Founding Principles of the iSCAD Registry


DEMOCRATIZATION	DECENTRALIZATION	PATIENT VOICE	INNOVATION	DIVERSITY	EQUITY
Independent data coordinating center	Data ownership by SCAD Alliance, non-profit patient organization	Patient representation on Steering and Publications Committees	Novel multidisciplinary and patient-centered research framework	International, multicenter referral centers of excellence	Equal opportunity for engagement including publications

iSCAD = International Spontaneous Coronary Artery Dissection.

Lessons learned...

- Be humble
- Re-learn how to listen
- We know research, but patients live with the disease so don't assume to know
- Don't underestimate patient input
- Be patient

Looking ahead...

- **MACE** is an important outcome, but we must not “kill the patient” to “save the heart” – i.e. how many would take a medication if it made them feel lousy, even if it prevented recurrence?
- Patients and physicians may have **similar questions** but for different reasons: ex – virtual cardiac rehab (MDs: convenience, compliance, efficacy; patients: empowerment, regain control “it would feel like my own workout instead a hospital treatment and help me feel not as “sick””)
- **Patient input** can be and should be incorporated into virtually every step of the study design and execution process. Research is done on behalf of the patients – it would be strange to not include the patient voice
- Patients want to share their data – Apple watches, Oura ring outputs, genetics – how to accept this data as outcomes but also how to use it to generate **novel questions**
- Patient organizations are important **collaborators/mediators**; direct to “consumer” outreach may not be as effective

* Special thanks to Katherine Leon for her thoughts on this slide

Thank you