



SCAD

Spontaneous Coronary Artery Dissection
Research Program Stewardship Update

December 2014

SCAD Research Program Stewardship Update

Background

The Mayo Clinic Spontaneous Coronary Artery Dissection (SCAD) Research Program is a multidisciplinary collaborative research and clinical practice initiative formed in 2010. The goal of the initiative is to advance the understanding of the underlying causes and risk factors for SCAD and develop solutions for its optimal diagnosis, treatment and prevention. **Your gifts to the SCAD Research Program help make this work a reality.**

SCAD is an uncommon, typically sporadic disorder most often occurring in young, otherwise healthy women. Men also experience SCAD and it affects teenagers through the eighth decade of life. This disorder creates an acute coronary artery tear that disrupts vital blood supply to the heart, which can result in myocardial infarction (heart attack), congestive heart failure and sudden death. It is the most common cause of heart attack during pregnancy and in women under the age of 45. The 10-year recurrence rate has been reported as high as 17 percent. Unlike coronary artery disease due to atherosclerosis, there are no known modifiable risk factors for SCAD or treatments to prevent it.

There is little evidence available to guide health care teams caring for patients with SCAD, and even fewer accessible and reliable sources of information available to patients and families. Our team is committed to change this through our novel approach to patient-initiated, rare-disease research using registries; comprehensive review of available data; genetic analyses; advanced medical imaging; and other collaborative investigations involving research colleagues from across Mayo and at select outside organizations.

Our project originated from activism by engaged patients who initiated what is now a multidisciplinary collaborative research network. It began when a group of women who had experienced this life-threatening condition found each other at the online community WomenHeart (www.WomenHeart.org) and organized to form an online support group. Two highly motivated women with SCAD ultimately reached out to Mayo Clinic, encouraging us to advance the understanding of SCAD through research. Recognizing this unique and unusual opportunity, we have spent the last four years endeavoring to advance not only the science and health care of women and men with SCAD, but also exploring the novel role of social media in health care and research studies.

From a clinical perspective, we have developed a formal multidisciplinary “SCAD Clinic.” Partly due to our research efforts, our team is currently seeing about 10 new patients with SCAD each month (>160 total). This contrasts with our previous experience of seeing fewer than 10 patients per year from 1993 to 2010. We are learning much from these patients that will provide insight for our future research. Our clinical work is complementary and amplifies and informs our research efforts.

In close collaboration with our patients and research participants, our team hopes to generate new knowledge that will provide patients with SCAD, their families, and their health care providers with answers to fundamental and critical questions that must be addressed. These answers will allow us to confidently guide decisions and deliver optimal health care.

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Key SCAD Research Program Personnel

Principal/Lead Investigators

Sharonne N. Hayes,
M.D. *Cardiovascular Diseases*

Rajiv Gulati, M.D., Ph.D.,
Interventional Cardiology

Timothy M. Olson, M.D.,
Cardiovascular Genetics

Staff Collaborators

Terri J. Vrtiska, M.D.,
Radiology

Patricia J.M. Best, M.D.,
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Sharon L. Mulvagh, M.D.,
Women's Heart Clinic

Shawna L. Ehlers, M.D.,
Psychology and Psychiatry

Carl H. Rose, M.D., *Obstetrics
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Trainee Contributors

Marysia S. Tweet, M.D.,
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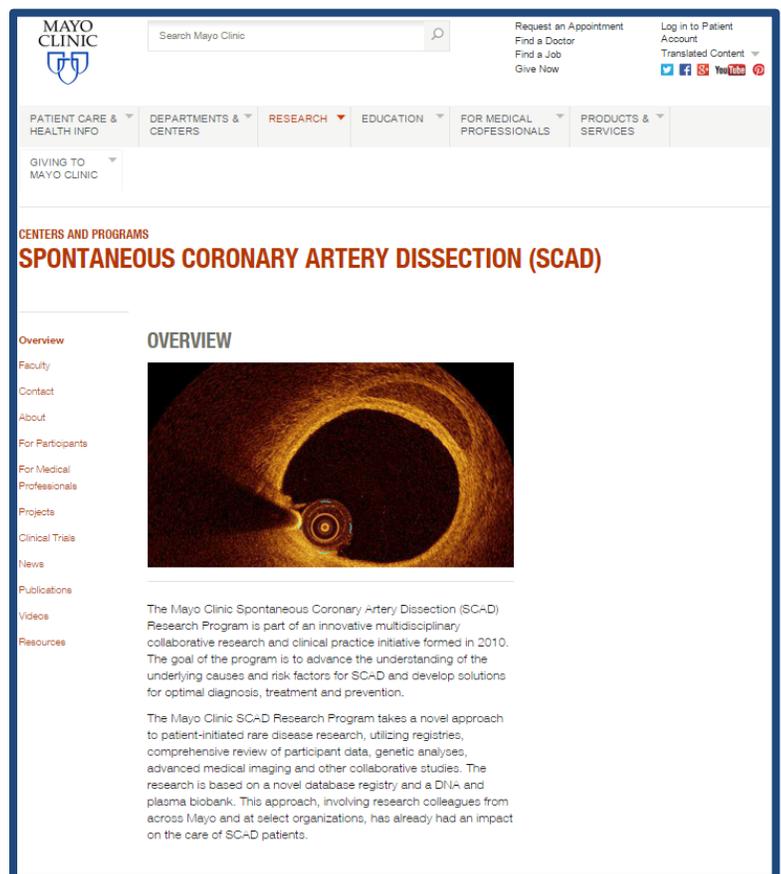
Mackram F. Eleid, M.D.,
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Jeanne L. Theis, Ph.D.,
Cardiovascular Genetics

Website

The Mayo Clinic Spontaneous Coronary Artery Dissection (SCAD) Research Program created a website with resources for patients, research program participants and medical professionals.

<http://www.mayo.edu/research/SCAD>

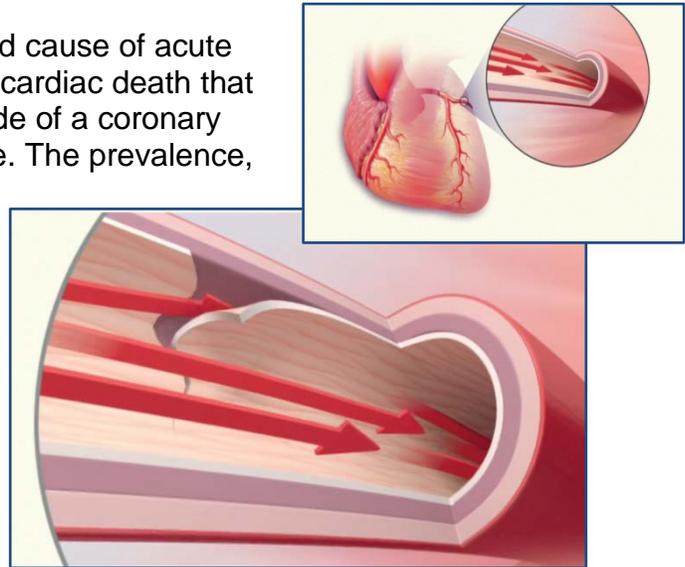


The screenshot shows the Mayo Clinic website for the Spontaneous Coronary Artery Dissection (SCAD) Research Program. The top navigation bar includes 'PATIENT CARE & HEALTH INFO', 'DEPARTMENTS & CENTERS', 'RESEARCH', 'EDUCATION', 'FOR MEDICAL PROFESSIONALS', and 'PRODUCTS & SERVICES'. The 'RESEARCH' menu is expanded. Below the navigation is a search bar and a 'GIVING TO MAYO CLINIC' link. The main content area is titled 'CENTERS AND PROGRAMS' and features the heading 'SPONTANEOUS CORONARY ARTERY DISSECTION (SCAD)'. Underneath, there is an 'OVERVIEW' section with a list of links: Overview, Faculty, Contact, About, For Participants, For Medical Professionals, Projects, Clinical Trials, News, Publications, Videos, and Resources. A large image of a coronary artery cross-section showing a dissection is displayed. Below the image, the text reads: 'The Mayo Clinic Spontaneous Coronary Artery Dissection (SCAD) Research Program is part of an innovative multidisciplinary collaborative research and clinical practice initiative formed in 2010. The goal of the program is to advance the understanding of the underlying causes and risk factors for SCAD and develop solutions for optimal diagnosis, treatment and prevention. The Mayo Clinic SCAD Research Program takes a novel approach to patient-initiated rare disease research, utilizing registries, comprehensive review of participant data, genetic analyses, advanced medical imaging and other collaborative studies. The research is based on a novel database registry and a DNA and plasma biobank. This approach, involving research colleagues from across Mayo and at select organizations, has already had an impact on the care of SCAD patients.'

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Significant Findings

SCAD is an uncommon and poorly understood cause of acute coronary syndrome, heart attack and sudden cardiac death that occurs as a result of a sudden tear in the inside of a coronary artery, blocking blood flow to the heart muscle. The prevalence, causes, prognosis, recurrence rate, and optimal management of SCAD are unknown, and there are currently no guidelines for acute and chronic management. The demographics of SCAD differ markedly from that of typical atherosclerotic heart attacks; most SCAD patients are young women who do not have risk factors for atherosclerosis (plaque). SCAD may also occur in the postpartum period. There appear to be differences between men and women in causes, recurrence risk and associated conditions.



Since its inception in 2010, our team has gained new insights into associated conditions and treatment approaches. Highlights and significant findings include:

- Identifying a high rate of abnormalities in non-coronary blood vessels in patients with SCAD. These include fibromuscular dysplasia (FMD), aneurysms, and additional dissections. Patients with these findings may need additional imaging and follow-up, and may be at higher risk for recurrence.
- We have found significantly lower success rates and higher complication rates when coronary artery stenting or ballooning is used to open artery blockages due to SCAD, compared to patients with typical heart attacks. This has implications for early decision making for treatment and highlights the need for an accurate diagnosis.
- A significant rate of spontaneous healing of SCAD-damaged arteries without specific intervention (medical treatment only). This has led to a change in practice whereby in select patients we do not intervene, but instead give their artery time to heal on its own.
- Identifying a potential association between statin use and recurrent SCAD. Since there is no evidence of benefit, and a possible harm, statins should not be routinely given to patients with SCAD.
- Discovering that SCAD incidence is not as rare as previously believed and may be the major cause of heart attack in women under the age of 45. Defining the role and value of specialized imaging of the inside of the coronary artery at the time of SCAD to make an accurate diagnosis and guide treatment. SCAD is often missed if only standard coronary angiography is used.
- We have demonstrated that advanced imaging techniques such as IVUS (intravascular ultrasound) and OCT (optical coherence tomography) can not only enhance diagnostic accuracy, but also guide treatment in the crucial early minutes of a heart attack.

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Current Research

We continue recruitment of patients with SCAD to our registries. Early findings from our research and clinical care of these patients have generated several hypotheses and sub-studies, currently underway or proposed. With additional resources, we hope to continue exploring new aspects of SCAD in order to better understand how to diagnose, treat, identify risk and, ultimately, to prevent this disorder.

2014 SCAD PROGRAM FOCUS AREAS

Ongoing recruitment, data abstraction, reporting

We have had a gratifying, overwhelming and unexpectedly robust response to our research by both patients and physicians. As such, we have accelerated our research activities to try to meet current response — engaging new research personnel and collaborators at Mayo and beyond. We have more than 350 patients who have been screened, had their SCAD diagnosis confirmed, and formally consented to participate in the study. This includes items that must be completed by participants themselves and by their health care providers/hospitals. Completing the collection of individual participant data is critical to proceeding with data abstraction and analysis and will require additional dedicated personnel.

DNA investigations

During the second quarter of 2013 we performed DNA exome sequencing on 73 probands (patients with SCAD) and both of their parents (trios), comprising 14 families. Funds for this project came from the Mayo Clinic Center for Individualized Medicine. Analysis of those samples is ongoing and we have identified at least three genes that may be related to SCAD. We have also modified our biobank participation criteria to include collection of DNA and pathology specimens from individuals who have died of SCAD. As of December 2014 the DNA biobank is comprised of more than 600 samples from patients with SCAD and their parents. Additional funding would allow for further DNA sequencing and analysis, and development of an animal model of SCAD.

Evaluation of EVA in patients with SCAD

EVAs (extracoronary vascular abnormalities), including fibromuscular dysplasia, aneurysms, dissections, and tortuosity, have been discovered on physical exam or incidentally with medical imaging performed for another purpose on patients in the SCAD Clinic. Our team described iliac artery FMD in half of patients (8 of 16) who had limited femoral angiography incidental to coronary angiography; other centers have similarly found this association. As a result, we advise patients to undergo vascular imaging to identify clinically or prognostically important vascular conditions as part of their medical evaluation. We developed a unique CT protocol which minimizes contrast, radiation, time and cost and enhances convenience for patients. Our team is evaluating these studies retrospectively — whether performed at Mayo or elsewhere — to help better understand the cause of SCAD, inform patient follow-up, and determine how these abnormalities impact outcomes. With additional funding, future studies could focus on determining the best imaging modality to identify these abnormalities — balancing risks (radiation, contrast), accuracy and cost.

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Current Research (continued)

Coronary artery imaging evaluations

Our team has the world's greatest experience in interpreting coronary artery imaging in patients with SCAD. Our clinical findings have led us to hypothesize that patients with SCAD have abnormalities in their underlying coronary architecture (perhaps similar to FMD) that predispose them to vessel wall dissection. We also hypothesize that characterizing these abnormalities will provide clues to the underlying mechanism, and may identify those at higher risk for recurrent events.

Additional funding would provide us the opportunity to proceed with retrospective and prospective studies re-analyzing SCAD angiograms quantitatively and characterize the unique angiographic features of SCAD. Our goal would be determining whether these features have prognostic relevance, based on our preliminary observations of severe symmetric tortuosity of branch coronary vessels. A second potential study is to use state-of-the-art intravascular imaging technologies (OCT and Near-SPECT IVUS) to characterize vessel wall architecture in patients with prior or acute SCAD. We would perform multimodality intravascular coronary imaging at the time of clinically indicated coronary angiography to determine an optimal imaging technique and better understand the pathophysiology.

SCAD and mental health concerns

Depression and anxiety symptoms commonly occur after a heart attack, associated with an increased risk of subsequent cardiac events and adversely affecting quality of life. We are collecting self-reported measures of the presence and severity of these conditions from study participants. We hypothesize that anxiety and PTSD are more common among patients with SCAD than patients without heart disease, as well as those who have heart attacks due to atherosclerosis (for which there are far more known and many proven treatment options). Earlier and more effective recognition and treatment of these conditions may provide for improved quality of life and outcomes.

Actively Recruiting Mayo Clinic SCAD Registries

"Virtual" Multicenter SCAD Registry (IRB # 11-001852)

<http://clinicaltrials.gov/ct2/show/NCT01429727>

This is a retrospective and prospective study of men and women with SCAD. Accurate case ascertainment requires angiographic review prior to enrollment into the study. Confirmed cases are sent additional documents including the consent form, recruitment letter and supplementary questionnaires. We plan to accrue a sample size of 200 participants, which matches that of the Genetic Investigations in Spontaneous Coronary Artery Dissection study (IRB# 11-000160) and will ensure that participants are aware of both ongoing studies.

Genetic Investigations in SCAD (IRB # 11-000160)

<http://clinicaltrials.gov/ct2/show/NCT01427179>

This exploratory case/family study is designed to discover mutations that underlie SCAD and will enroll up to 200 adult subjects with SCAD and up to 400 of their parents. For the initial two years of the study, the primary focus will be on developing a DNA and plasma biobank for subjects with SCAD. Once established, genes responsible for SCAD will be identified by two general strategies: 1) whole-exome sequencing of a defined subset of proband/parent triads, utilizing the Mayo Clinic Advanced Technologies Genomics Center and Bioinformatics Core; 2) high-throughput heteroduplex mutational scanning of the entire cohort of SCAD probands, targeting candidate genes uncovered by exome sequencing. Testing parental DNA samples for identified, potentially pathogenic mutations will enable the mode of inheritance to be established.

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Future of SCAD Research at Mayo Clinic

The greater-than-expected patient identification and recruitment has challenged our study team. We have enrolled **more than 5 times** our original estimated number of participants, which had been based on historical prevalence data. We have accelerated our research activities to try to meet current response and need. Early findings from our clinical care of patients with SCAD have generated several sub-studies to study fibromuscular dysplasia in patients with SCAD; optimal imaging of extracoronary blood vessels; blood markers of SCAD risk; and exome evaluation of our DNA samples. We have engaged additional study personnel and team members (including Mayo Clinic radiologists, internal medicine and cardiology trainees, psychologists, ob/gyns, and geneticists) and expanded collaboration to include other Mayo Clinic sites. If we are successful in obtaining additional funding, our goal is to develop and lead a multicenter prospective trial to better understand optimal acute treatment (at the time of the initial heart attack). Our team's early observations raised many new questions and set the stage for numerous retrospective, prospective, clinical and genetic studies; only a fraction of these are outlined above.

SCAD Research Program: Future Goals and Areas of Exploration

- SCAD Registry Expansion
- Angiographic Features of SCAD
- Recurrent SCAD
- Noninvasive imaging of SCAD
- Genetics of SCAD
- Pathology of SCAD
- Extracoronary Findings of SCAD
- Psychology of SCAD
- Pregnancy/peripartum and SCAD
- Social media and SCAD
- Cardiac rehabilitation and SCAD
- Prospective SCAD evaluations
- Further develop SCAD Clinic and patient resources

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Patient Story

DISSECTING A RARE HEART CONDITION

At 35, Ana Gregg never imagined she'd have a heart attack at such a young age. Or that her doctors would initially miss the signs. Now, Gregg is participating in a research study at Mayo Clinic in Rochester that she hopes will help researchers better understand the mysterious medical condition called spontaneous coronary artery dissection or SCAD, which caused her to have two heart attacks.



It all started one night shortly after she had put her two young sons to bed. After the boys fell asleep, she decided to take advantage of some "me time" by exercising. When she finished 45 minutes later, she says she began feeling warm, and then felt pressure building in her chest. "At first, I thought I had worked out too soon after dinner," she told the Twin Cities Heart Foundation in a video created for the Go Red campaign to help raise awareness of heart disease in women.

"I thought maybe it would just go away," she says. But, instead, things got worse. "I was having a hard time breathing ... I looked in the mirror, and I was gray." At that point, Gregg says she knew something was seriously wrong and went to a local hospital. An EKG initially showed she was having a heart attack. "I was shocked," she says. Almost as shocked as she was a few minutes later when another doctor came in and told her he didn't believe she was having a heart attack. Instead, Gregg says that while her initial EKG results were "abnormal," the doctor told her "that could be my normal." So, she was sent home and told she had acid reflux.

Nine months later, however, it happened again. And Gregg told Mayo Clinic News Network that it was after this second go-around that her doctors realized what was going on: She had suffered SCAD. "I couldn't believe it," she says. Fortunately, Gregg has since become part of the aforementioned research study led by Mayo's Sharonne Hayes, M.D., who's doing all she can to solve the SCAD puzzle.

Dr. Hayes says what makes SCAD so hard to understand is that it's not your typical heart attack. "Instead of plaque building up, the artery splits," she says. And, when it does, that initial tear allows blood flow to split the artery wall, creating a "loose flap of tissue" on the inside of the artery that can then restrict blood flow to the heart. While there's still much to be learned, research by Dr. Hayes and her team has helped shed some light on the condition. That includes indications that angiograms could make the problem worse by lengthening the tear, that patients with SCAD are at a higher than expected rate of having an artery condition called fibromuscular dysplasia, and that recurrence is not as rare as once thought.

Ana Gregg is thankful her condition was caught when it was and is hoping the seven stents she now has placed in her chest will help reduce further risk by keeping her arteries open. "Every day I think God has given me a new day," she says.

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Select Mayo Clinic SCAD publications

We continue to share our findings with other scientists, clinicians and patients. Our team has published numerous scientific abstracts, invited presentations, scientific posters, peer-reviewed publications, and received generous media coverage. A partial list of publications is shared here.

Peer-Reviewed Articles

1. Tweet MS, Gulati R, Aase LA, Hayes SN. *Spontaneous coronary artery dissection: a disease-specific, social networking community-initiated study*. Mayo Clin Proc. 2011 Sep; 86(9):845-50
2. Hardegree EL, Tweet MS, Hayes SN, Gulati R, Kane GC. *Multivessel spontaneous coronary artery dissection associated with hormonal infertility therapy in a 39-year-old female*. Journal of Cardiology Cases. 2012; 5(2):e69-72.
3. Tweet MS, Hayes SN, Pitta SR, Simari RD, Lerman A, Lennon RJ, Gersh BJ, Khambatta S, Best PJ, Rihal CS, Gulati R. *Clinical features, management, and prognosis of spontaneous coronary artery dissection*. Circulation. 2012 Jul 31;126(5):579-88.
4. Liang JJ, Skalski JH, Mankad R. *Spontaneous coronary artery dissection: is there a metabolic association?* Perfusion. 2013 Sep;28(5):457-8.
5. Mir MA, Patnaik MM, Herrmann J. *Spontaneous coronary artery dissection during hematopoietic stem cell infusion*. Blood. 2013 Nov 7;122(19):3388-9.
6. Liang JJ, Tweet MS, Hayes SE, Gulati R, Hayes SN. *Prevalence and predictors of depression and anxiety among survivors of myocardial infarction due to spontaneous coronary artery dissection*. J Cardiopulm Rehabil Prev. 2014 Mar-Apr; 34(2):138-42.
7. Liang JJ, Prasad M, Tweet MS, Hayes SN, Gulati R, Breen JF, Leng S, Vrtiska TJ. *A novel application of CT angiography to detect extracoronary vascular abnormalities in patients with spontaneous coronary artery dissection*. J Cardiovasc Comput Tomogr. 2014 May-Jun; 8(3):189-97.
8. Hayes S, Tweet M, Hayes S, Gulati R, Ehlers S. *Quality of life and depression in women with SCAD*. J Women's Health. 2014 Apr 1; 23(4):8.
9. Hayes SN. *Spontaneous Coronary Artery Dissection (SCAD): New Insights into This Not-So-Rare Condition*. Tex Heart Inst J. 2014 Jun; 41(3):295-8.
10. Eleid M, Guddeti R, Tweet R, Lerman A, Singh M, Best P, Vrtiska T, Prasad M, Rihal C, Hayes S, Gulati R. *Coronary Artery Tortuosity in Spontaneous Coronary Artery Dissection: Angiographic Characteristics and Clinical Implications*. Circ Cardiovasc Interv. 2014; CIRCINTERVENTIONS.114.001676 published online before print August 19 2014.
11. Alfonso F, Bastante T, Rivero F, Cuesta J, Benedicto A, Saw J, Gulati R. *Spontaneous Coronary Artery Dissection*. Jpn Circ J. 2014 Aug 25;78(9):2099-110.
12. Tweet MS, Eleid MF, Best PJ, Lennon RJ, Lerman A, Rihal CS, Holmes DR Jr, Hayes SN, Gulati R. *Spontaneous Coronary Artery Dissection: Revascularization Versus Conservative Therapy*. Circ Cardiovasc Interv. 2014 Nov 18. pii: CIRCINTERVENTIONS.114.001659. [Epub ahead of print]
13. Eleid MF, Guddeti RR, Tweet MS, Lerman A, Singh M, Best PJ, Vrtiska TJ, Prasad M, Rihal CS, Hayes SN, Gulati R. *Coronary artery tortuosity in spontaneous coronary artery dissection: angiographic characteristics and clinical implications*. Circ Cardiovasc Interv. 2014 Oct;7(5):656-62. doi: 10.1161/CIRCINTERVENTIONS.114.001676. Epub 2014 Aug 19.

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Select Mayo Clinic SCAD publications

Abstracts and Posters

1. Tweet M, Kumar G, Gulati R, Hayes S. *Spontaneous coronary artery dissection in women*. (Poster) 7th Annual Women's Health Research Conference, September 2010, University of MN, Minneapolis, Minnesota
2. Tweet M, Gulati R, Hayes S. *Internet networking to propel the research of rare diseases: Our experience with spontaneous coronary artery dissection*. (Poster) Awarded second place at the ACC Controversies in Cardiovascular Disease Fellows in Training Poster Competition, May 2011, St. Paul, Minnesota.
3. Tweet M, Gulati R, Hayes S. *Internet networking to propel the research of rare diseases: Our experience with spontaneous coronary artery dissection*. (Poster) 8th Annual Women's Health Research Conference, September 2011, Minneapolis, Minnesota.
4. Tweet MS, Hayes SN, Pitta S, et al. *Outcomes after Spontaneous Coronary Artery Dissection: A Long-Term Single Center Experience*. *Circulation*. 2011; 124:A14504
5. Chandra, SM, Fenstad ER, Nyguen D, Hayes SN, *Déjà Vu All Over Again: Recurrent Spontaneous Coronary Artery Dissection Presenting as Acute Coronary Syndrome*, AMA Poster session Honolulu, HI, November 2012 (Poster)
6. Tweet M, Hayes SN, Lerman A, Rihal C, Gulati R *Percutaneous Coronary Intervention for Acute Spontaneous Coronary Artery Dissection is Associated with Reduced Rates of Technical Success*. *Circulation*. 2012; 126:A17969. (Oral abstract presentation)
7. Prasad M, Liang J, Tweet M, Hayes S, Gulati R, Vrtiska T. *Spontaneous coronary artery dissection and fibromuscular dysplasia--A prospective consecutive series with extracoronary vascular imaging*. National ACP, San Francisco, CA, 2013 (Poster)
8. Liang J, Prasad M, Tweet M, Hayes SN, Gulati R, Breen JF, Vrtiska TJ. *A novel and comprehensive CT angiography protocol to detect extracoronary vascular lesions in patients with spontaneous coronary artery dissection*. 2013 Society for Cardiovascular Angiography and Interventions Scientific Sessions, Orlando, FL, 2013 (Poster)
9. Tweet M, Hayes SN, Lerman A, Lennon R, Holmes, DR, Rihal CS, Gulati R., *Percutaneous Coronary Intervention versus Conservative Therapy for Acute Management of Spontaneous Coronary Artery Dissection*. *Circulation*. 2013; 128:22 A18315 (Poster)
10. Tweet M, Hayes S, Rihal C, Gulati R. *Percutaneous coronary intervention for acute spontaneous coronary artery dissection is associated with reduced rates of technical success*. ACC Controversies in Cardiovascular Disease Fellows in Training Poster Competition (2nd place), Minneapolis, MN, 2013 (Poster, 2nd place)
11. Liang J, Prasad M, Tweet M, Hayes S, Gulati R, Breen J and Vrtiska T. *A novel and comprehensive CT angiography protocol to detect extracoronary vascular lesions in patients with spontaneous coronary artery dissection*. Society for Cardiovascular Angiography and Interventions 2013 Scientific Sessions, Orlando, FL, 2013 (Poster) and ACC Controversies in Cardiovascular Disease Fellows in Training Poster Competition, Minneapolis, MN, 2013 (Poster)
12. Prasad M, Liang J, Tweet M, Gulati R, Vrtiska T, and Hayes S. *Spontaneous coronary artery disease and fibromuscular dysplasia--a prospective consecutive series with extracoronary vascular imaging*. National ACP conference, San Francisco, CA, 2013 (Poster)
13. Hayes S, Tweet M, Hayes S, Gulati R, Ehlers S. *Quality of life and depression in women with spontaneous coronary artery dissection*. Women's Health 2014 Congress Scientific Poster Session, Washington, DC, April 2014 (Poster)
14. Prasad M, Tweet M, Liang J, Hayes S, Breen J, Gulati R, Vrtiska T. *Extracoronary Abnormalities are Common in Patients with Spontaneous Coronary Artery Dissection: Analysis of 72 Patients at a Tertiary Referral Center*. *J Am Coll Cardiol*. 2014; 63(12S) (Poster)
15. Tweet MS, Hayes SN, Gulati R, Best PB. *The Risk of Pregnancy after Spontaneous Coronary Artery Dissection*. *J Am Coll Cardiol*. 2014;63 (12_S) (Moderated Poster)