

# MHIF Research Highlights: OCTOBER 2019

## CONGRATULATIONS!!

### Dr. Paul Sorajja and Sara Olson

Congratulations on first enrollment in the Tendyne MAC with Clip study!

### Dr. Traverse and team

Proud to see *JACC* publication of porcine ECM study; MHIF was key enroller in first-in-human, FDA-approved Phase I trial for VentriGel (to repair damage after heart attack)!

### Dr. Sharkey and team

Congratulations on publication of largest study for STEMI-SCAD in *JACC*; results showed PCI is successful in most STEMI-SCAD patients, with low 3-year mortality!

## FEATURED MHIF STUDIES

*Open for Enrollment and Referrals!*

**OPTION** comparison of anticoagulation with left atrial appendage closure after AF ablation  
CONTACT: Jacob Cohen, 612-863-4022

**SPYRAL-HTN** renal denervation for patients with uncontrolled hypertension  
CONTACT: Carina Benson, 612-863-6288

**Heart EXPAND CAP** extended criteria donor hearts for transplantation  
CONTACTS: Kari Thomas, 612-863-7493 or Kari Williams, 612-863-0027

## WAY TO GO CHRISTINE MAJESKI

Recipient of *Mpls. St. Paul Magazine's* 2019 Outstanding Nurses Award for Research!

## MARK YOUR CALENDARS

**Complex Cardiovascular Imaging:**  
Multimodality Imaging Education for Technologists, Technicians and Nurses

**Sat., Oct. 26, Delta Hotels  
Minneapolis**



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## Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

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**Title:** Engaging MHIF Research: Structural Heart, EP and CCAD

**Speakers:** Current CCAD Studies

**Emmanouil S. Brilakis, MD, PhD**

Director, Center for Complex Coronary Artery Disease,  
Minneapolis Heart Institute® at Abbott Northwestern Hospital  
Adjunct Professor of Medicine,  
University of Texas Southwestern Medical School

**Cardiac Electrophysiology Beyond Tomorrow**

**Jay Sengupta, MD**

Cardiac Electrophysiologist  
Director, Genetic Arrhythmia Center  
Director, Electrophysiology Research  
Co-director, Cardiac Device Clinic  
Minneapolis Heart Institute® at Abbott Northwestern Hospital

**Structural Heart Update 2019**

**Paul Sorajja, MD**

Roger L. and Lynn C. Headrick Family Chair for Valve Science Research, Valve Science Center  
at Minneapolis Heart Institute Foundation  
Director, Center of Valve and Structural Heart Disease, Minneapolis Heart Institute  
Foundation  
Cardiologist, Minneapolis Heart Institute® at Abbott Northwestern Hospital

**Date:** October 14, 2019

**Time:** 7:00 – 8:00 AM

**Location:** Minneapolis Heart Institute Building, Suite 100, Learning Center

### OBJECTIVES

At the completion of this activity, the participants should be able to:

1. Recall research occurring at MHIF in the cardiovascular areas of structural heart, electrophysiology and complex coronary artery disease.
2. Describe research studies occurring at MHIF that give patients treatment options not available at other cardiovascular clinics and hospitals.
3. Identify patients that possibly qualify for MHIF research studies.

### DISCLOSURE POLICY & STATEMENTS

Allina Health, Learning & Development intends to provide balance, independence, objectivity and scientific rigor in all of its sponsored educational activities. All speakers and planning committee members participating in sponsored activities and their spouse/partner are required to disclose to the activity audience any real or apparent conflict(s) of interest related to the content of this conference.

The **ACCME defines a commercial interest** as “any entity” producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

#### Moderator(s)/Speaker(s)

Dr. Emmanouil Brilakis had disclosed the following relationships: Regeneron, Siemens: Grant/Research Support; Abbott Vascular, Biotronic, Boston Scientific, CSI, GE Healthcare, Infraredx, Medtronic: Speakers Bureau; MHI Ventures: Stock Shareholder; Elsevier: Royalties

Dr. Sengupta, MD has disclosed that he DOES NOT have any real or apparent conflicts with any commercial interest as it relates to presenting the content in this activity/course.

Dr. Paul Sorajja has disclosed the following relationships: Abbott Vascular, Boston Scientific, Medtronic: Grant/Research support, Consultant, Speaker’s Bureau

#### Planning Committee

Dr. Alex Campbell, Jake Cohen, Jane Fox, Dr. Kevin Harris, Dr. Kasia Hryniewicz, Rebecca Lindberg, Amy McMeans, Dr. Michael Miedema, Dr. JoEllyn Moore, Pamela Morley, Dr. Scott Sharkey, Maia Hendel and Jolene Bell Makowsky have disclosed that they DO NOT have any real or apparent conflicts with any commercial interest as it relates to the planning of this activity/course. Dr. Mario Gössl has disclosed the following relationships – Edwards Life Sciences: Grant/Research Support; Abbott Vascular, Caisson: Consultant; Speaker’s Bureau: Edwards Lifesciences. Dr. David Hurrell has disclosed the following relationship –Boston Scientific: Chair, Clinical Events Committee.

#### **NON-ENDORSEMENT OF COMMERCIAL PRODUCTS AND/OR SERVICES**

We would like to thank the following company for exhibiting at our activity.

**Actelion Pharmaceutical Companies  
of Johnson & Johnson**

**Pfizer, Inc**

Accreditation of this educational activity by Allina Health does not imply endorsement by Allina Learning & Development of any commercial products displayed in conjunction with an activity.

A reminder for Allina employees and staff, the Allina Policy on Ethical Relationship with Industry prohibits taking back to your place of work, any items received at this activity with branded and or product information from our exhibitors.

## EP Beyond Tomorrow

Jay D. Sengupta, MD, FACC, FHRS

Cardiac Electrophysiology

Director, Electrophysiology Research

Director, Genetic Arrhythmia Center

Co-director, Cardiac Device Clinic at Minneapolis Heart  
Institute and Abbott Northwestern Hospital



### Disclosures

- None
- The Genetic Arrhythmia Center is supported by the Minneapolis Heart Institute Foundation. Clinical research is funded in part by a grant from Medtronic



## Objectives

- How do we advance the field of Cardiac Electrophysiology at Minneapolis Heart Institute?
  - ◆ Mix of industry and investigator-initiated studies
  - ◆ Large volume of complex clinical electrophysiology management matched with extraordinary research support and staff
- Complex Arrhythmia and Ablation
- Device Science and Safety
- Device Therapy Innovation
- Genetic Arrhythmia Center



## Atrial Fibrillation: Scope of the problem

- Up to 6 million individuals in U.S. with atrial fibrillation
  - ◆ Estimated to be 12 million by 2030
- 9% of people ages 65 and older in the U.S. have atrial fibrillation
  
- Centers for Disease Control and Prevention (CDC) Worldwide Epidemiology of Atrial Fibrillation, A Global Burden of Disease 2010 study, Citation 2013



## Atrial Fibrillation: Goals

- Improve ablation safety and efficacy
  - ◆ Understand atrial fibrillation mechanisms
  - ◆ Prevent recurrent atrial arrhythmias
  - ◆ Expand the pool of ablation candidates
- Identify patients at risk and reduce morbidity and mortality



## Atrial Fibrillation: Mechanisms

Received: 20 March 2019 | Revised: 1 July 2019 | Accepted: 17 July 2019  
DOI: 10.1111/jce.14092

ORIGINAL ARTICLE

WILEY

### Outcomes following persistent atrial fibrillation ablation using localized sources identified with Ripple map

Daniel P. Melby MD<sup>1</sup> | Charles Gornick MD<sup>1</sup> | Raed Abdelhadi MD<sup>1</sup> | Jay Sengupta MD<sup>1</sup> | Manju Pai MD<sup>1</sup> | John S. Zakaib MD<sup>1</sup> | JoElynn Moore MD<sup>1</sup>

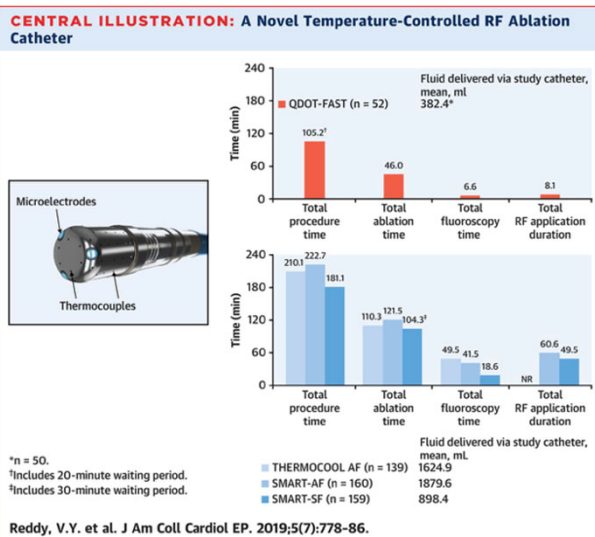


## Atrial Fibrillation: Innovation

- Use the next generation of ablation catheters and devices
- Beta-test and develop the software for mapping with the industry leaders
- Paroxysmal atrial fibrillation
  - ◆ Currently high success rate
  - ◆ Innovating to reduce procedure time, improve safety, and prevent recurrence
- Persistent atrial fibrillation
  - ◆ Identify rhythm drivers to improve long-term success rate
  - ◆ Reduce frequency of complex recurrent atrial tachyarrhythmias
  - ◆ Improve understanding of atrial cardiomyopathy



## Atrial Fibrillation: High power short duration ablation



Qdot study  
 PI Dan Melby

→ Evaluate safety and effectiveness with pulmonary vein Isolation in paroxysmal atrial fibrillation



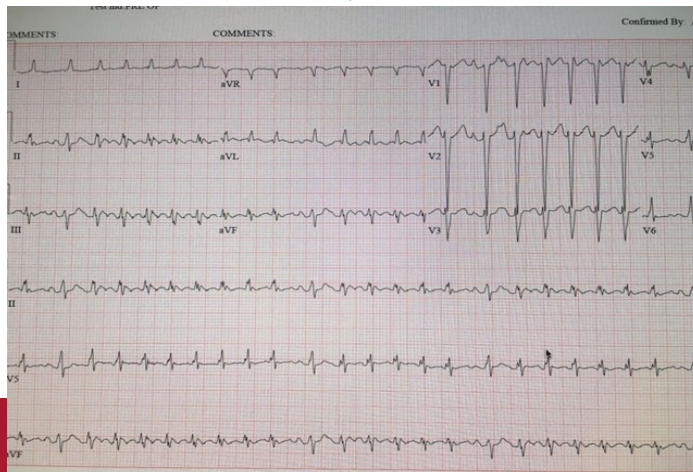
## Complex Arrhythmia Case

- 58 year old female with non-ischemic cardiomyopathy attributed to adriamycin therapy +/- tachycardia, NYHA class III (HFrEF) with LVEF 25% and worsening severe mitral regurgitation presents with rapid SVT, likely atrial flutter with 1:1 conduction at times.
- She has had 2 prior catheter ablations (2017 for atrial fibrillation and a second one in the same year for atypical left atrial flutter); LVEF previously improved from 35% to 43% (MR was moderate).
- She is relatively frail and decompensated. History of NHL, Hypertension, CVA. Recently cardioverted and optimized with medical therapy.
- Now presents with symptomatic, paroxysmal episodes of narrow complex tachycardia with rates up to 190 bpm



## Next step?

- A. Repeat catheter ablation
- B. AVJ ablation and pacing
- C. Mitra-clip
- D. Advanced heart failure options





### Complex atypical atrial flutter

The image displays the Biosense CARTO v7 mapping system. The top left shows a 3D map of the left atrium with a complex, multi-colored activation sequence. The bottom left shows ECG traces with a heart rate of 190 BPM and a cycle length of 315 msec. The right side shows a 3D map of the right atrium with a similar complex activation sequence. The text 'Biosense CARTO v7' is visible at the bottom left, and the Minneapolis Heart Institute Foundation logo is at the bottom right.

## Atrial Fibrillation: Stroke Risk in Subclinical AF

- ARTESIA: PI Dr. JoEllyn Moore
- Apixaban for the Reduction of Thrombo-Embolism in Patients with Device-detected Subclinical Atrial Fibrillation

Inclusion Criteria	Criteria
	1. Permanent pacemaker or defibrillator (with or without resynchronization) or insertable cardiac monitor capable of detecting SCAF
	2. At least one episode of device-detected SCAF $\geq$ 6 minutes in duration but no single episode $>$ 24 hours in duration at any time prior to enrollment. <u>Any</u> atrial high rate episode with average $>$ 175 beats/min will be considered as SCAF. No distinction will be made between atrial fibrillation and atrial flutter. SCAF requires electrogram confirmation (at least one episode) unless $\geq$ 6 hours in duration
	3. Age $\geq$ 55 years
	4. Risk Factor(s) for Stroke: Previous stroke, TIA or systemic arterial embolism OR Age at least 75 OR Age 65-74 with at least 2 other risk factors OR Age 55-64 with at least 3 other risk factors  Other risk factors are: • hypertension • CHF • diabetes • vascular disease (i.e. CAD, PAD or Aortic Plaque) • female

The Minneapolis Heart Institute Foundation logo is located at the bottom right of the slide.

## Atrial Fibrillation: Populations at Risk

### Detection of Atrial Fibrillation and Atrial Flutter by Pacemaker Device Interrogation After Transcatheter Aortic Valve Replacement (TAVR): Implications for Management

Michael Megaly, MD, MS<sup>1,2,3</sup>; Santiago Garcia, MD<sup>1,3</sup>; Lucille E. Anzia, BS<sup>3</sup>; Pamela Morley, RN<sup>3</sup>; Ross Garberich, MS<sup>3</sup>; Charles C. Gornick, MD<sup>1,3</sup>; John Lesser, MD<sup>1,3</sup>; Paul Sorajja, MD<sup>1,3</sup>; Mario Gössl, MD, PhD<sup>1,3</sup>; Jay Sengupta, MD<sup>1,3</sup>

J Invasive Cardiol. 2019 Jul;31(7):E177-E183.

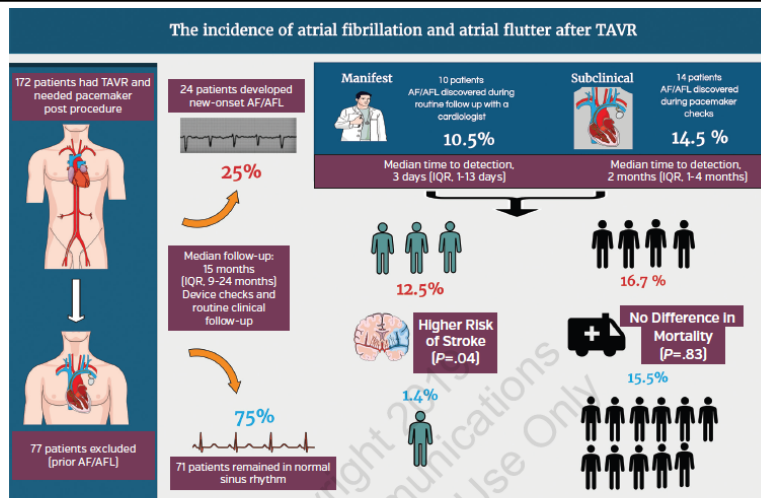


FIGURE 3. Summary of the study results. AF/AFL = atrial fibrillation or atrial flutter; IQR = interquartile range; TAVR = transcatheter aortic valve replacement.

J Invasive Cardiol. 2019 Jul;31(7):E177-E183.



## CIED and Patient Safety

- Long history of focus on patient safety with implantable devices at MHI thanks to Drs. Hauser, Gornick, Almquist, Abdelhadi and best device clinic nurses in the country

### Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead

Robert G. Hauser, MD, Linda M. Kallinen, BS, Adrian K. Almquist, MD, Charles C. Gornick, MD, William T. Katsiyiannis, MD

*From the Minneapolis Heart Institute Foundation, Minneapolis, Minnesota.*

### Deaths caused by the failure of Riata and Riata ST implantable cardioverter-defibrillator leads

Robert G. Hauser, MD, FHRS, Raed Abdelhadi, MD, Deepa McGriff, BS, Linda Kallinen Retel, BS, FHRS

*From the Minneapolis Heart Institute Foundation, Minneapolis, Minnesota.*

### FDA Calls Class 1 Recall For Riata, Riata ST Defibrillation Leads

### Unpredictable implantable cardioverter-defibrillator pulse generator failure due to electrical overstress causing sudden death in a young high-risk patient with hypertrophic cardiomyopathy

Charles C. Gornick, MD, Robert G. Hauser, MD, Adrian K. Almquist, MD, Barry J. Maron, MD



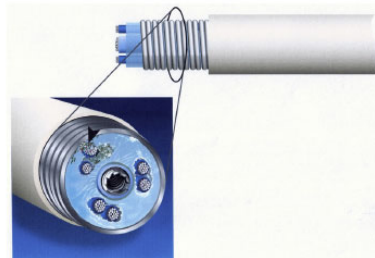
## Patient CIED Safety

### Internal insulation breaches in an implantable cardioverter-defibrillator lead with redundant conductors

Robert G. Hauser, MD, FHRS,\* Jay Sengupta, MD, FHRS,\* Edward J. Schloss, MD, FHRS,<sup>†</sup> Larissa I. Stanberry, PhD,\* Moses K. Wananu, MD,\* Raed Abdelhadi, MD, FHRS\*

*From the \*Minneapolis Heart Institute Foundation, Minneapolis, Minnesota, and <sup>†</sup>The Christ Hospital/The Ohio Heart & Vascular Center, Cincinnati, Ohio.*

(Heart Rhythm 2019;16:1215–1222) © 2019 The Authors. Published by Elsevier Inc. on behalf of Heart Rhythm Society. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).



**Figure 2** Durata lead showing location of an insulation breach under the proximal superior vena coil (arrow). The cable to the distal right ventricular shocking coil has abraded through the inner silicone from the inside-out and ethylene tetrafluoroethylene has been damaged, allowing the cable to short to the underside of the shocking coil.



## Patient CIED Safety

### Outcomes Before and After the Recall of a Heart Failure Pacemaker

Jay Sengupta MD,<sup>1,2</sup> Katelyn Storey BA,<sup>1</sup> Susan Casey RN,<sup>1</sup> Lena Trager BA,<sup>1</sup> Melissa Buescher MPH,<sup>1</sup> Mark Horning RN,<sup>2</sup> Charles Gornick MD,<sup>1,2</sup> Raed Abdelhadi MD,<sup>1,2</sup> Chuen Tang MD,<sup>1,2</sup> Suzanne Brill RN,<sup>2</sup> Laura Ashbach RN,<sup>2</sup> Robert G. Hauser, MD<sup>1</sup>

<sup>1</sup>Minneapolis Heart Institute Foundation, Minneapolis, MN, USA

<sup>2</sup>Minneapolis Heart Institute at Abbott Northwestern Hospital, Minneapolis, MN,



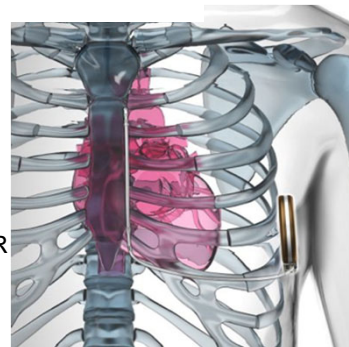
## Cardiac device clinic

- Forefront of identifying patient device safety issues
- Transitioning to electronic database with the goal of partnering with HDI to leverage large volume device data (approx 25,000 patient visits annually) to advance patient care and help with early recognition of device safety concerns
- Revolutionize the identification and risk stratification of patients with implantable devices at risk of malfunction/failure and in need of issuance of a safety advisory
- Large volume of patients with high percentage of follow-up throughout Minnesota and upper Midwest Region (Iowa, North Dakota, Wisconsin)



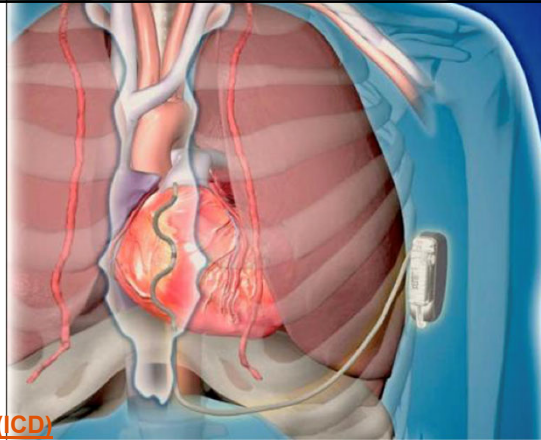
## Device Innovation

- Leverage expertise to be on the forefront of new device technology
- Quality of program attracts industry studies and innovative technology so that we are involved early



Lifesaver doesn't touch the heart  
A Farmington man became the first in the state to receive Boston Scientific's new S-ICD.  
By James Walsh Star Tribune NOVEMBER 27, 2012 — 9:28PM





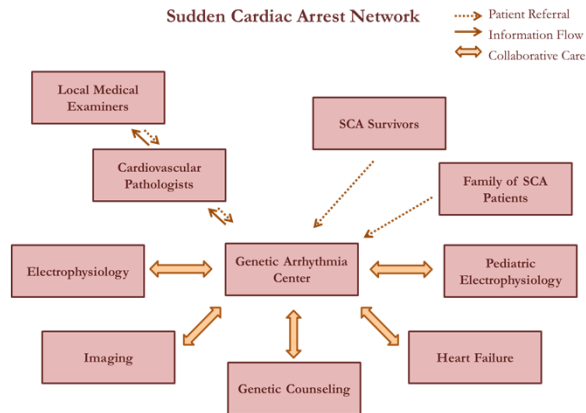
**NEWS | IMPLANTABLE  
CARDIOVERTER DEFIBRILLATOR (ICD)  
OCTOBER 11, 2019**

**Medtronic Initiates Worldwide Pivotal Study of Extravascular Implantable Cardioverter Defibrillator**

Study to evaluate novel ICD system with a lead placed outside the heart and veins



**Patient and data flow within the Sudden Cardiac Arrest Network**



CLINICAL REPORT

Autosomal-dominant biventricular arrhythmogenic cardiomyopathy in a large family with a novel in-frame DSP nonsense mutation

Sajya M. Singh Susan A. Casey Allison A. Berg Raed H. Abdelhadi William T. Katsiyannis Mosi K. Bennett Shannon Mackey-Bojack Emily R. Duncanson Jay D. Sengupta

First published: 16 July 2018 <https://doi.org/10.1002/ajmg.a.38719> Cited by: 1

Funding information: Minneapolis Heart Institute Foundation; Medtronic

- Identifying and characterizing novel genetic mutations
- Optimize risk-stratification and management for entire families with conditions predisposing to sudden cardiac death
- Maintain clinical registry to follow patients with rare heritable cardiac conditions
  - ◆ Long QT Syndrome
  - ◆ Catecholaminergic Polymorphic VT
  - ◆ Brugada syndrome
  - ◆ Arrhythmogenic cardiomyopathy
  - ◆ Left ventricular non-compaction
  - ◆ Other channelopathies and hereditary cardiomyopathies



## Genetic Arrhythmia Syndromes

- Develop the network of healthcare professionals to care for families with genetic arrhythmia and cardiomyopathy syndromes
- On the forefront of rare conditions that we need to know more about:
  - ◆ Arrhythmogenic cardiomyopathy
  - ◆ Malignant Early Repolarization Syndrome
  - ◆ Malignant Mitral Valve Prolapse Syndrome

[Minn. Researchers Look to Genetic Code for Answers Behind Sudden Cardiac Death](#)

Sudden cardiac arrest in young athletes is something Dr. Jay Sengupta with the Minneapolis Heart Institute says researchers are learning more about everyday ...

*Last Updated 2017-10-12 23:00*



## A word of thanks

- All members of the Electrophysiology Section and Device Clinic
- Sue Casey, Christine Majeski, Jacob Cohen, Andrew Nauertz
- Michael Megaly
- Ross Garberich, Larissa Stanberry
- Minneapolis Heart Institute Foundation and Summer Internship Program





MHIF Grand Rounds 2019

## Structural Heart Disease Update

### 5 Patients, 4 Messages

**Paul Sorajja, MD**  
Roger L. and Lynn C. Headrick Family Chair  
Valve Science Center  
Minneapolis Heart Institute Foundation  
Abbott Northwestern Hospital



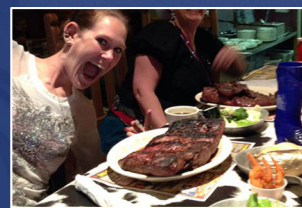
## Disclosures

- **Consulting or Advisory Board:** Abbott Structural, Admedus, Boston Scientific, Edwards Lifesciences, Medtronic, Gore
- **Research:** Abbott Structural, Boston Scientific, Edwards Lifesciences, Medtronic
- **Speaking:** Abbott Structural, Boston Scientific, Edwards Lifesciences, Medtronic
- **National P.I.:** Tendyne in MAC, Alt-FLOW, TRILUMINATE II Pivotal



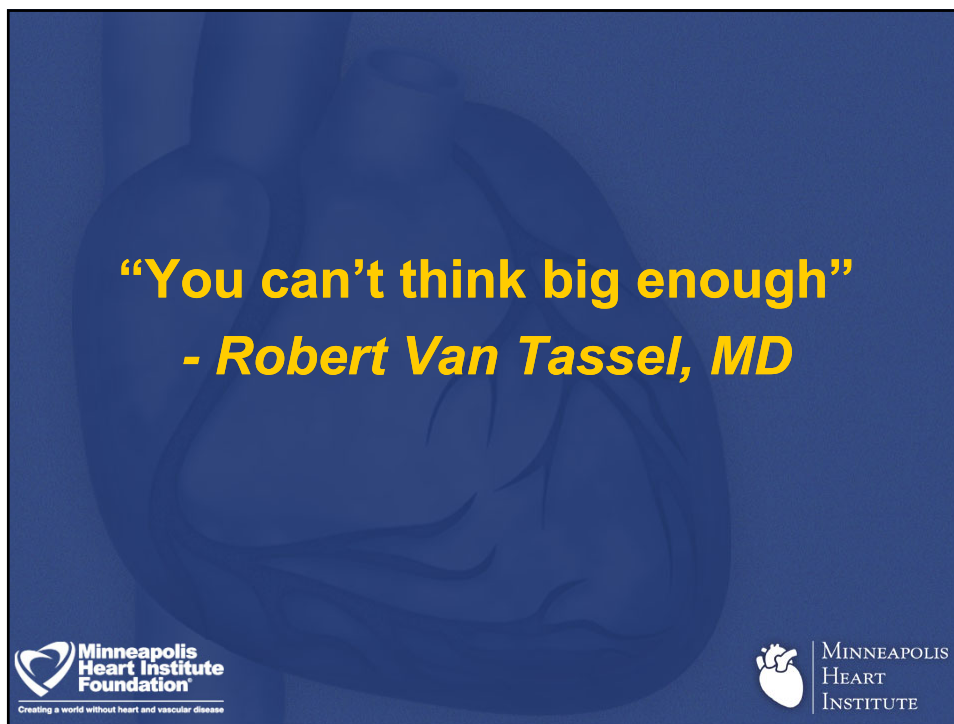
## Key Points

- Diagnose and treat dyspnea in new ways
- Catheter-based TR options available
- TMVR for MAC works in selected pts
- Transcatheter mitral rx will be complementary repair and replacement





Everything is big in my home





**“You can’t think big enough”**  
**- Robert Van Tassel, MD**

 **Minneapolis  
Heart Institute  
Foundation**  
Creating a world without heart and vascular disease

 **MINNEAPOLIS  
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**80 year-old woman with  
severe dyspnea, normal EF,  
moderate MR**

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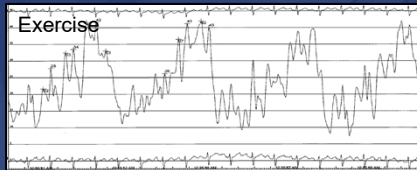
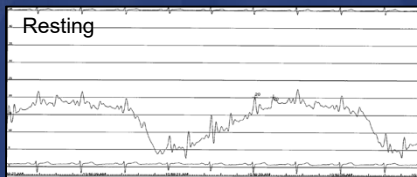
## Simultaneous VO<sub>2</sub>, echo



## Dyspnea Evaluation

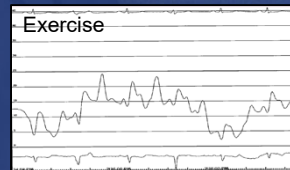
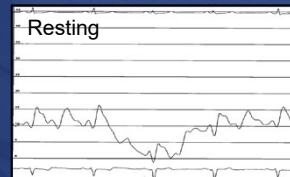
### PCWP

#### Patient 1



**Cardiac**

#### Patient 2



**Non-cardiac**



# REDUCE-LAP Study

## Transcatheter Interatrial Shunt Device for the Treatment of Heart Failure With Preserved Ejection Fraction (REDUCE LAP-HF I [Reduce Elevated Left Atrial Pressure in Patients With Heart Failure])

### A Phase 2, Randomized, Sham-Controlled Trial

**BACKGROUND:** In nonrandomized, open-label studies, a transcatheter interatrial shunt device (IASD, Corvia Medical) was associated with lower pulmonary capillary wedge pressure (PCWP), fewer symptoms, and greater quality of life and exercise capacity in patients with heart failure (HF) and midrange or preserved ejection fraction (EF ≥40%). We conducted the first randomized sham-controlled trial to evaluate the IASD in HF with EF ≥40%.

**METHODS:** REDUCE LAP-HF I (Reduce Elevated Left Atrial Pressure in Patients With Heart Failure) was a phase 2, randomized, parallel-group, blinded multicenter trial in patients with New York Heart Association class II or ambulatory class III HF, EF ≥40%, exercise PCWP ≥25 mmHg, and PCWP-right atrial pressure gradient ≥5 mmHg. Participants were randomized 1:1 to the IASD versus a sham procedure (internal atrial access with intracardiac echocardiography but no IASD placement). The participants and investigators assessing the participants during follow-up were blinded to treatment assignment. The primary effectiveness end point was exercise PCWP at 1 month. The primary safety end point was major adverse cardiac, cerebrovascular, and renal events at 1 month. PCWP during exercise was compared between treatment groups using a mixed-effects repeated measures model analysis of covariance that included data from all available stages of exercise.

**RESULTS:** A total of 56 patients were enrolled, of whom 44 met inclusion/exclusion criteria and were randomized to the IASD (n=22) and control (n=22) groups. Mean age was 70(±9) years, and 50% were female. At 1 month, the IASD resulted in a greater reduction in PCWP compared with sham control (14.1±2.8 mmHg) for all stages of exercise. Peak PCWP decreased by 3.5±4.4 mmHg in the treatment group versus 0.5±5.0 mmHg in the control group (P=0.14). There were no periprocedural or 1-month major adverse cardiac, cerebrovascular, and renal events in the IASD group and 1 event (worsening renal function) in the control group (P=1.0).

**CONCLUSIONS:** In patients with HF and EF ≥40%, IASD treatment reduces PCWP during exercise. Whether this mechanistic effect will translate into sustained improvements in symptoms and outcomes requires further evaluation.

**CLINICAL TRIAL REGISTRATION:** URL: <https://clinicaltrials.gov>. Unique identifier: NCT02600234.

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Christopher D. Nielsen, MD  
Scott Lilly, MD, PhD  
Joseph B. Manemann, PhD  
Daniel Burkhardt, MD, PhD  
Sergio J. Shah, MD  
On behalf of the REDUCE LAP-HF Investigators and Study Coordinators

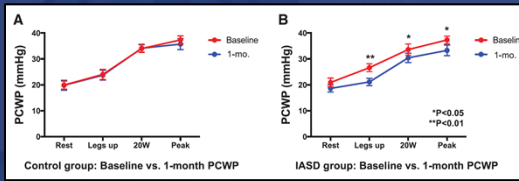
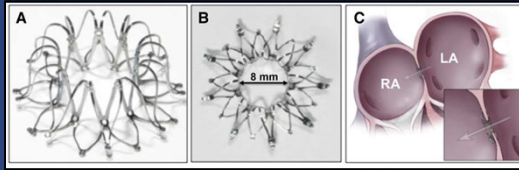
\*See below and above for disclosures.

Correspondence to: Sergio J. Shah, MD, Department of Medicine, Feinberg School of Medicine, Northwestern University, 630 North Dearborn Street, Suite 500, Chicago, IL 60611. E-mail: [shah@northwestern.edu](mailto:shah@northwestern.edu)

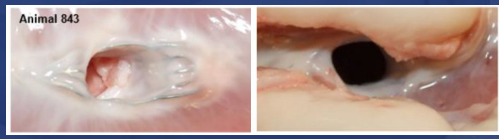
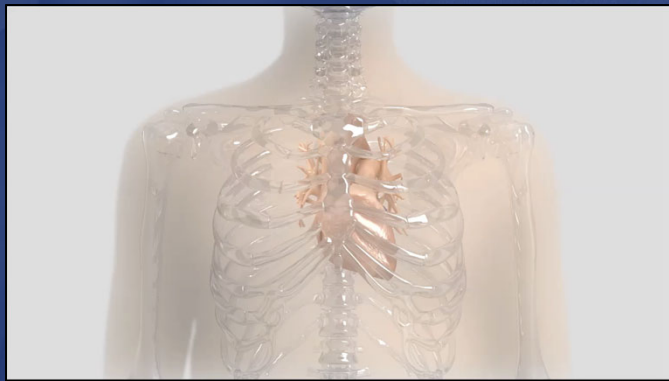
Source of funding: see page 214

Key Words: atrial heart failure • hemodynamics • interatrial shunt • randomized controlled trial

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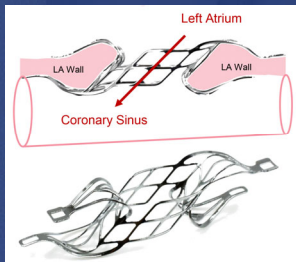
# Atrial Shunting for Heart Failure





## Alt-FLOW Early Feasibility Study

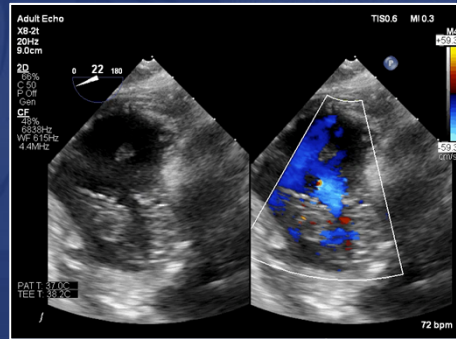
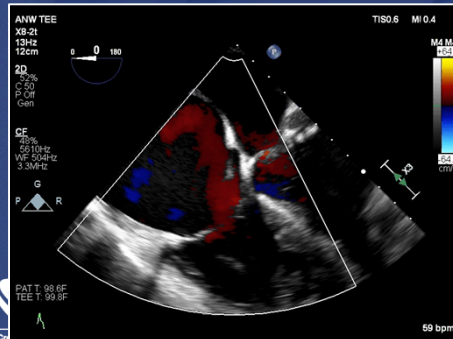
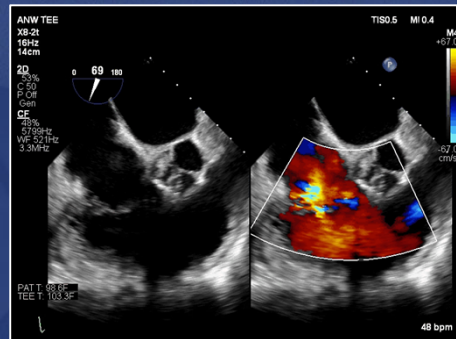
Multicenter Study of ROOT Device  
National Principal Investigator: Paul Sorajja, MD



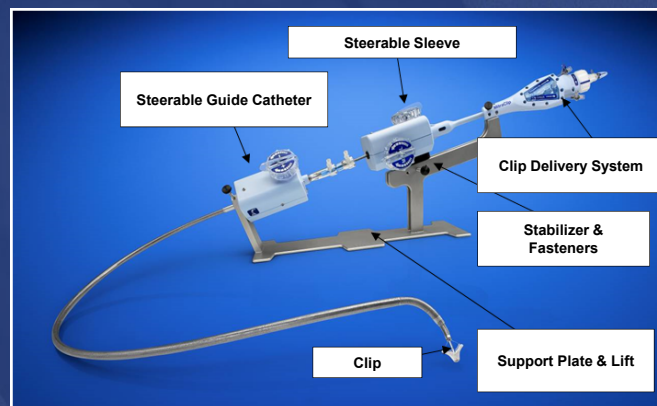
- Ambulatory HFpFEF or HFrEF
- PCWP >15 at rest or >25 at exer.
- Stable GDMT >4 weeks
- No significant valve disease

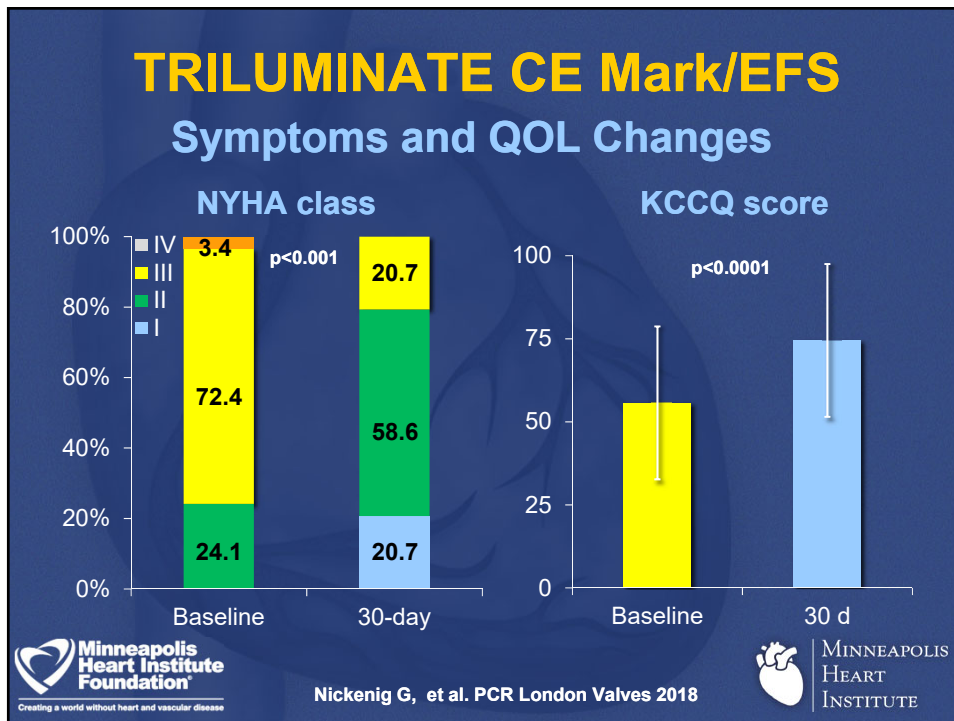
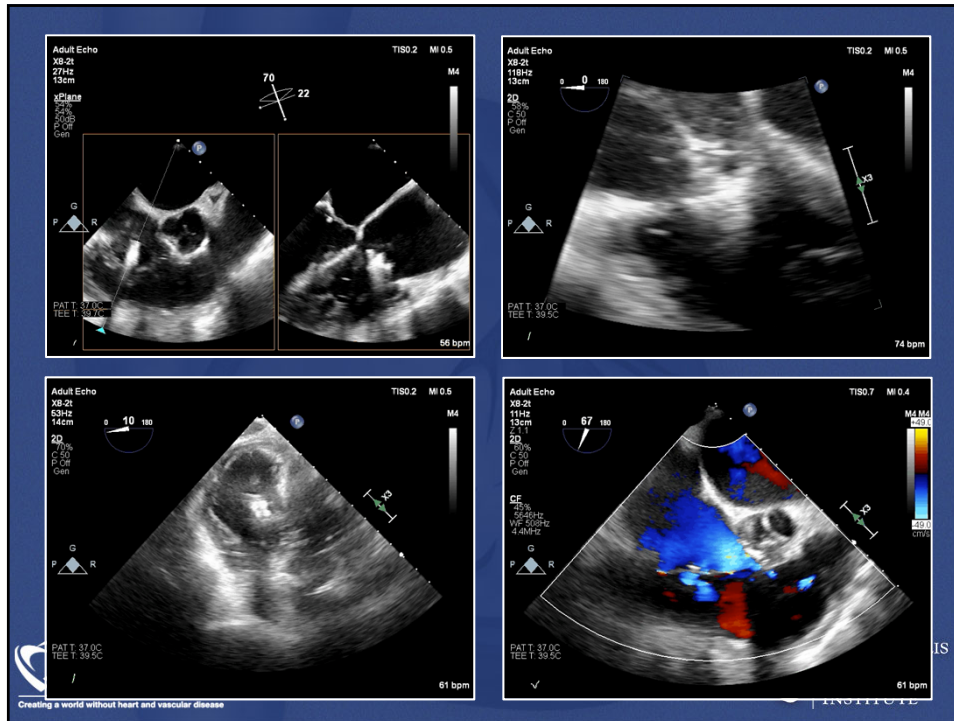
*Do you have a patient with dyspnea?*

## 74 year-old woman with fatigue and edema




## Tricuspid Valve Repair System Specifically Designed for TV









**Subject Selection**  
Subject has symptomatic, severe TR and is at intermediate or greater risk of mortality with TV surgery

Ability to reduce TR to Moderate or less?

Yes → **Randomize 1:1 (N=450)**

No → **Single Arm (N=100)**



Randomized groups: **TriClip Device** vs **Medical Therapy**

Single Arm group: **TriClip Device**

**80 study sites worldwide**

**P.I's**  
**David Adams, MD,**  
**Paul Sorajja, MD**

**Primary Endpoint: 1-yr death, HF hosp., TV surgery, QOL**

## First 3 Patients Worldwide Here

### August 28, 2019







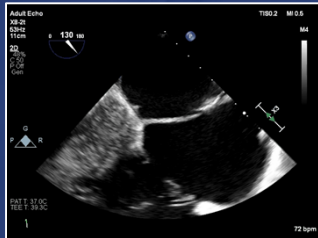




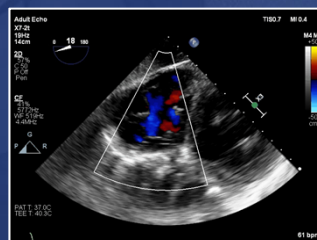
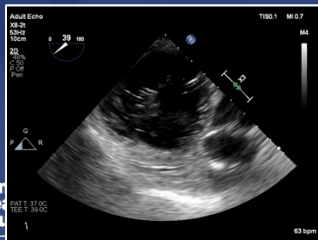
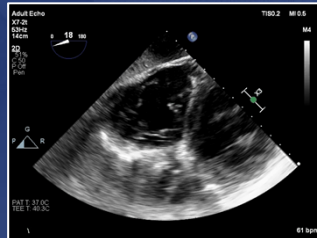


## TriClip Candidacy

### Appropriate



### More Difficult

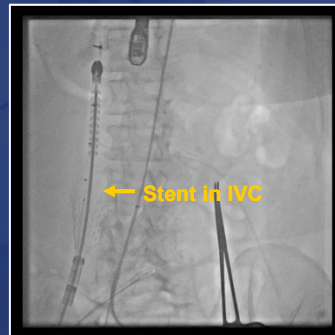
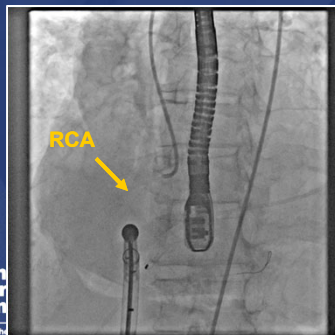
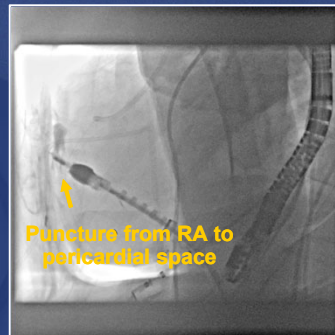
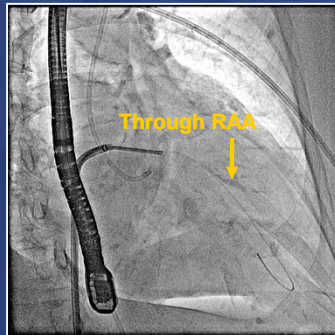
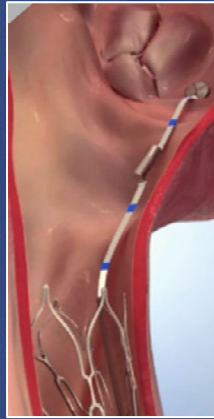


MINNEAPOLIS  
HEART  
INSTITUTE

**84 year-old woman with  
severe TR and not candidate  
for surgery or TriClip**



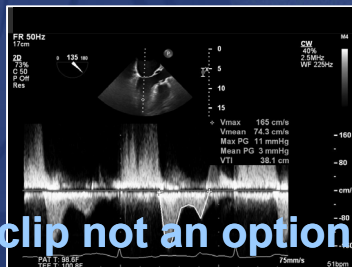
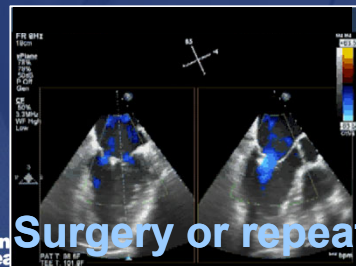
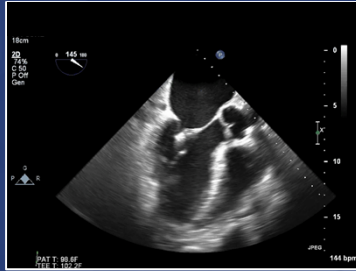
# 4Tech TriCinch Coil







## 80 year-old man with severe HF

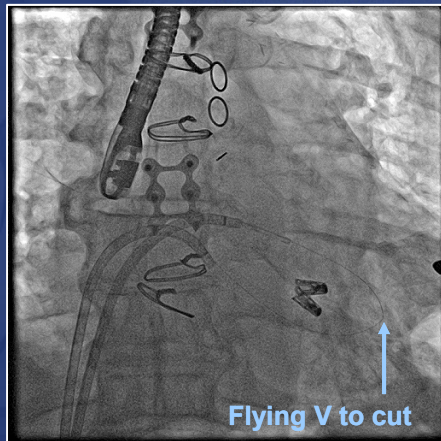
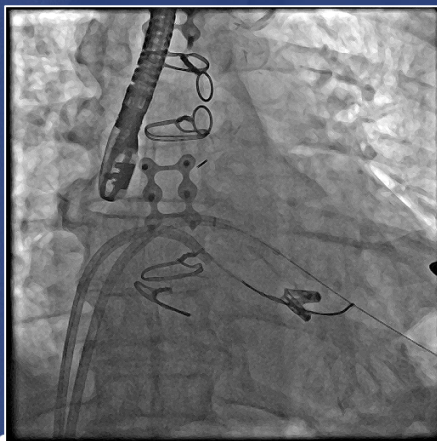


Surgery or repeat clip not an option.

Sorajja P, et al. J Am Coll Cardiol 2019



## Complementary Transcatheter Repair and Replacement First-in-human Experience



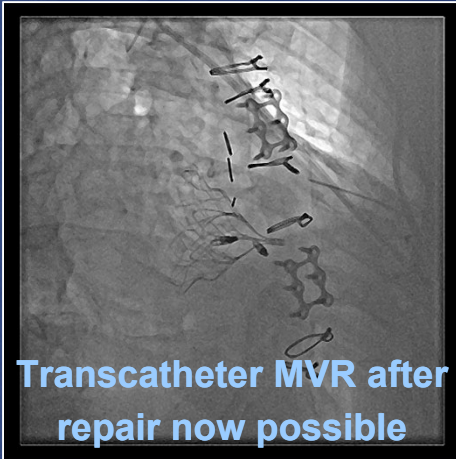
Sorajja P, et al. J Am Coll Cardiol 2019



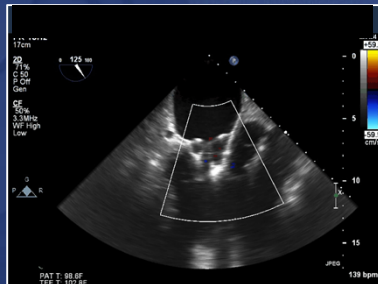
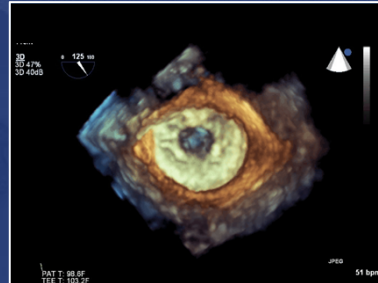
## First-in-human Experience



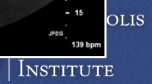
## First-in-human Experience



Transcatheter MVR after repair now possible



Sorajja P, et al. J Am Coll Cardiol 2019



## Key Points

- Diagnose and treat dyspnea in new ways
- Catheter-based TR options available
- TMVR for MAC works in selected pts
- Transcatheter mitral rx will be complementary repair and replacement



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2020  
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**Denver, Colorado**

**MASTERS' APPROACH TO CRITICAL LIMB ISCHEMIA**  
**COMPLEX HIGH-RISK PCI**  
**FRONTIERS IN STRUCTURAL HEART DISEASE**

**COMPLICATIONS COURSE**

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[www.cvinnovations.org](http://www.cvinnovations.org)

*This activity has been approved for AMA PRA Category 1 Credit™.*

The background of the slide is a scenic photograph of snow-capped mountains under a clear blue sky, with a dense forest of evergreen trees in the foreground.



**Thank you!**

**paul.sorajja@allina.com**

**507-513-1357**

**@psorajja**

 **Minneapolis  
Heart Institute  
Foundation**  
Creating a world without heart and vascular disease

 **MINNEAPOLIS  
HEART  
INSTITUTE**

Making the impossible possible through innovative research and education around treatment approaches for the most complex of coronary artery disease cases.

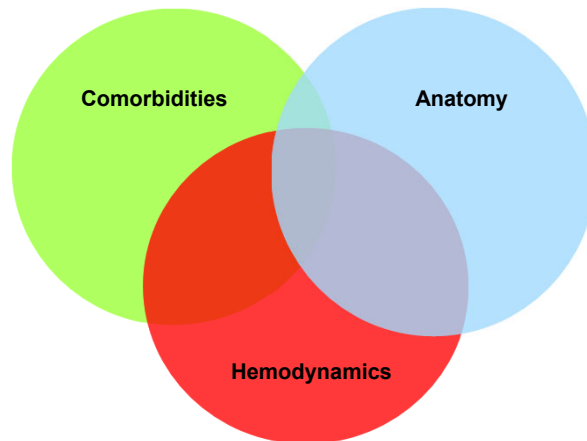
## Science Center for Coronary Artery Disease (CCAD)

Emmanouil S. Brilakis, MD, PhD



### What is “Complex”?

1. Acute coronary syndrome
2. Prior CABG
3. Heart failure
4. Atrial fibrillation
5. Advanced age
6. Diabetes
7. Renal failure
8. COPD
9. Peripheral vascular disease
10. High bleeding risk
11. Frailty

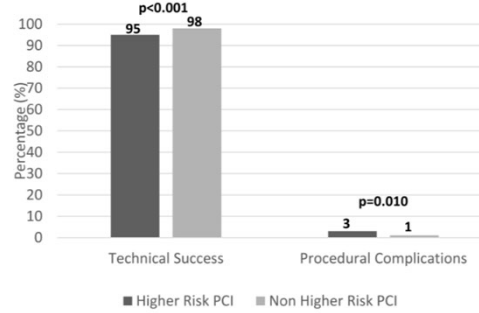
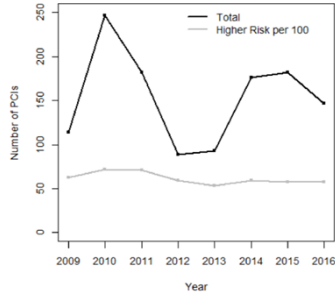


1. CTO
2. Bifurcation
3. Left Main
4. SVG
5. Thrombus
6. Calcification
7. Ostial lesions
8. Multi-vessel disease
9. Small vessel
10. Diffuse disease

1. Low ejection fraction
2. High filling pressures

## Frequency of Complex PCI at MHI

**Overall Frequency= 62% (1230 out of 1975)**



- **Unprotected left main coronary artery lesion**
- **Chronic total occlusion**
- **Procedure requiring atherectomy**
- **Multivessel PCI**
- **Bifurcation PCI**
- **Patient with prior coronary artery bypass graft surgery**
- **Pre-PCI left ventricular ejection fraction ≤30%**
- **Use of intra-aortic balloon pump or hemodynamic support**

Iverson et al. *Cardiovasc Revasc Med*. 2018



## Complex Coronary Artery Disease Science Center

### Interventionalists



Kenneth W. Baran, MD



Nicholas Burke, MD



Ivan G. Chavez, MD



Santiago Garcia, MD



Mario Goessl, MD, PhD



Michael R. Mooney, MD



Anil Poulouse, MD



Paul Sorajja, MD



Jay Travers, MD



Yale L. Wang, MD

## Complex Coronary Artery Disease Science Center

### Surgeons



Judah Askew, MD



Frazier Eales, MD



Thomas F. Flavin, MD



Karol Mudy, MD



Bassam Shukrallah,  
MD



Ben Sun, MD



Robert Steffen, MD

## Complex Coronary Artery Disease

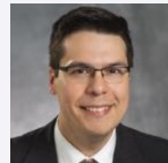
### Non-Invasive



Richard Bae, MD



Steven Bradley, MD,  
MPH



Joao Cavalcante, MD



Thomas Knickelbine,  
MD



John Lesser, MD



Michael Miedema, MD, MPH



Retu Saxena, MD









Scott Sharkey, MD



Greg Strauss, MD, MPH


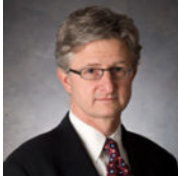





**Complex Coronary Artery Disease  
Science Center**

Heart Failure

					
Mosi Bennett, MD, PhD	Barry Cabuay, MD	Peter Eckman, MD	Kasia Hryniewicz, MD	Peter Zimbwa, MD, PhD	Michael Samara, MD

**Complex Coronary Artery Disease  
Science Center**

**Operations team**

			
Emmanouil Brilakis, MD, PhD Chairman	M. Nicholas Burke, MD Co-Chairman	Bavana V. Rangan, BDS, MPH Program Director	
			
Pamela Morley, RN, BSN Research Nurse	Iosif Xenogiannis, MD Sr. Research Scholar/ Fellow	Evangelia Vemmu, MD Research Scholar/ Fellow	Ilias Nikolakopoulos, MD Research Scholar/ Fellow

**Complex Coronary Artery Disease  
Science Center**

*Making the impossible possible*

**Research** ↔ **Clinical Practice** ↔ **Education**

↙ ↘  
*Patients*      *Providers*

**ASAP-SVG**

**www.ctomanual.org**  
**www.pcimanual.org**

**Complex Coronary Artery Disease  
Science Center**

*Making the impossible possible*

**Research**

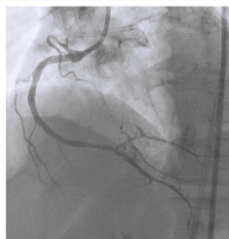
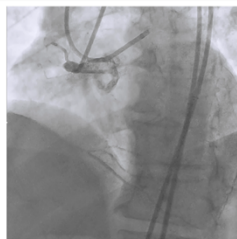
# RESEARCH

Ongoing	Startup	Future
Progress CTO	Progress-bifurcation	
ASAP-SVG	CLEAR-CTO	Revive-CTO
SHINE-CTO	NASA: native vs. SVG intervention	
Rebirth		



HOME INVESTIGATORS PUBLICATIONS NEWS RESOURCES JOIN FOR INVESTIGATORS ONLY

**PROGRESS-CTO**  
Prospective Global Registry for the Study of Chronic Total Occlusion Intervention



Online CTO Score Calculator [here](#)

Summary of PROGRESS CTO Results



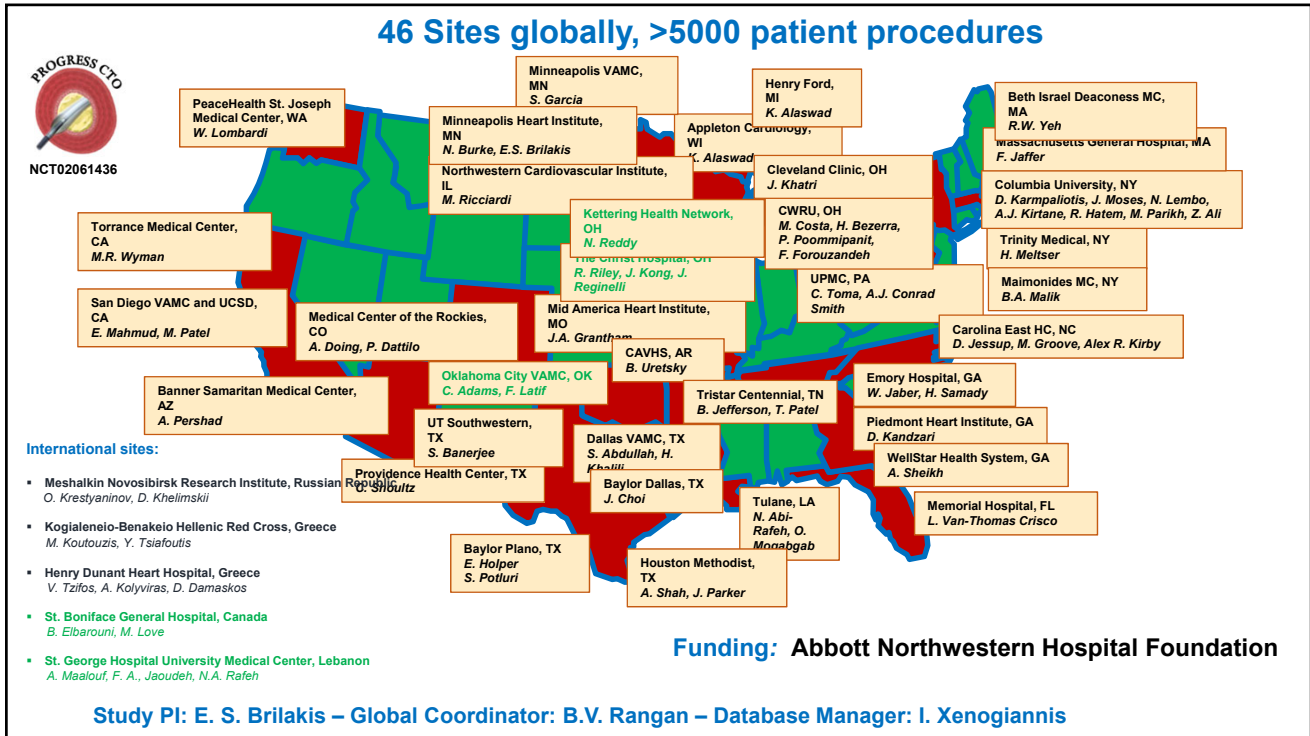
**ABOUT US**

PROGRESS-CTO is a contemporary, multi-center registry of chronic total occlusion percutaneous coronary interventions.

**OUR GOAL**

Our goal is to help advance the field of CTO PCI through rigorous study of techniques and outcomes across a varied group of operators and medical practices.






## PROGRESS-CTO Registry Expansion




- India (Arun Kalyanasundaram, MD)
- MENATA (Nidal Abi-Rafeh, MD [Lebanon]/ Omer Goktekin[Turkey])
- Pakistan

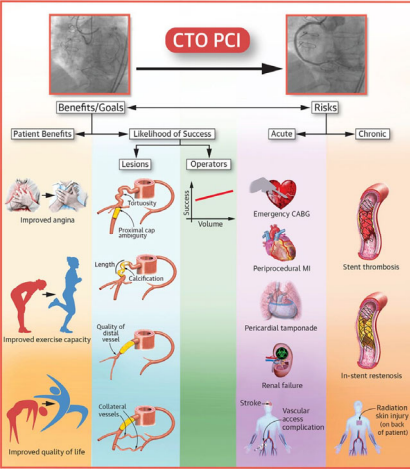




**PROSpective Global REGiStry for the Study of CTO interventions**

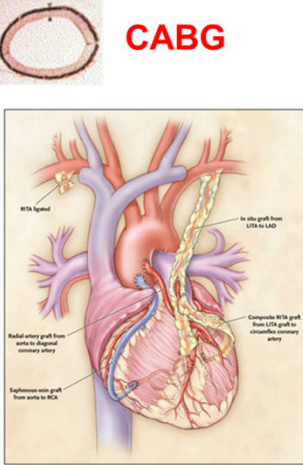
[www.progresscto.org](http://www.progresscto.org)



1. Application and outcomes of the hybrid approach
2. Comparison with other studies
3. Target vessel and outcomes
4. Mode of failure
5. Prior CABG
6. Radial approach
7. J-CTO score validation
8. PROGRESS-CTO score
9. In-stent restenosis
10. Impact of prior failed CTO PCI
11. Side-branch loss
12. Antegrade dissection/re-entry outcomes
13. Guidewire utilization in AWE
14. Contrast utilization
15. Proximal cap ambiguity
16. Retrograde outcomes
17. Impact of lesion age
18. Use of SVGs for retrograde approach
19. Use of intravascular imaging
20. Balloon uncrossable occlusions
21. CTO scores comparative analysis
22. PROGRESS-CTO Complications score
23. Impact of age and sex
24. Impact of diabetes
25. Approaches to RCA occlusions
26. Spatial distribution of CTOs
27. Radiation exposure
28. Further validation of hybrid algorithm
29. Effect of proximal vessel tortuosity
30. Effect of calcification
31. Perforation incidence treatment and outcomes
32. Retrograde CTO PCI via LIMA
33. Balloon undilatable CTOs
34. Mechanical cardiac support
35. >1 CTO PCI during the same procedure
36. Hybrid Approach for CTO PCI – Update
37. CTO PCI in patients with CKD
38. Ostial CTO PCI
39. Use of guide catheter extension in rCAR
40. CTO PCI via radial approach
41. Ad hoc vs planned CTO PCI
42. Atherectomy in CTO PCI
43. CTO PCI in prior CABG patients
44. Left main CTO PCI
45. Concomitant non-CTO PCI
46. Dyevert in CTO PCI
47. Retrograde via SVG

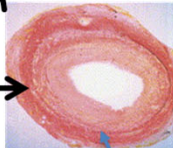
## Natural history of saphenous vein grafts



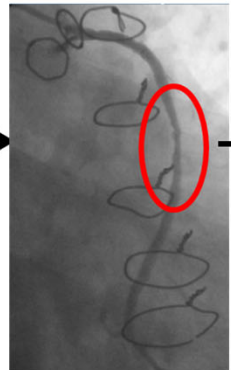
**CABG**

**Early remodeling**

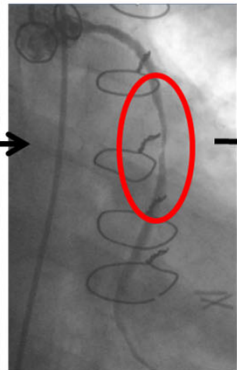
**Early occlusion**



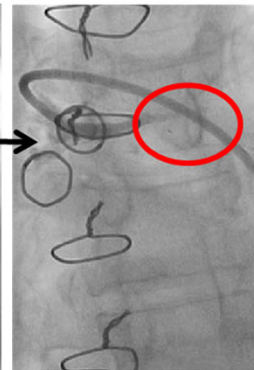
**Intermediate lesions**



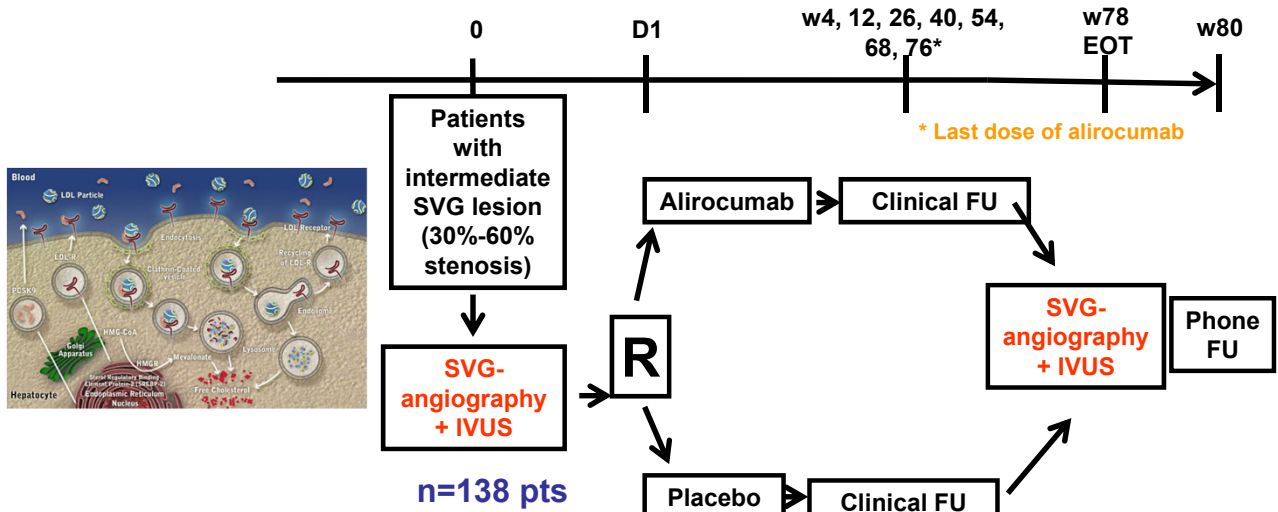
**Severe lesions**



**Occlusion**



## Alirocumab for Stopping Atherosclerosis Progression in Saphenous Vein Grafts (ASAP-SVG) Pilot Trial



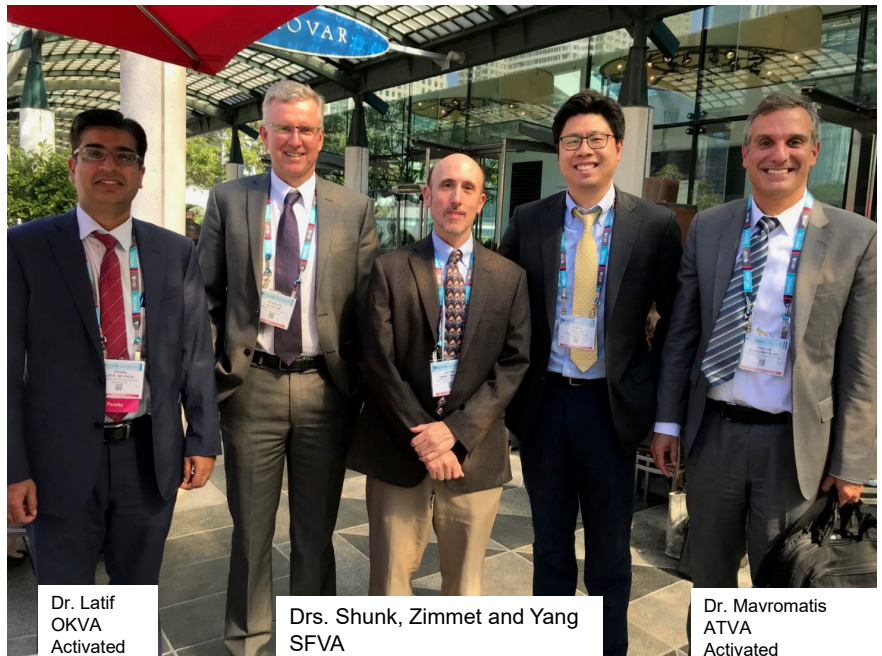
### TCT 2019: ASAP-SVG Investigators Meeting

**Overall Trial Enrollment:**  
30/138

Trial start at MHIF 8/2018,  
participating centers activated  
06/2019

**Enrollment Standings:**  
MHIF= 13,  
ATVA= 11  
SFVA= 5  
OKVA= 1

Upcoming Trial Status/  
Milestone Review with  
Sponsor (Regeneron):  
AHA 2019



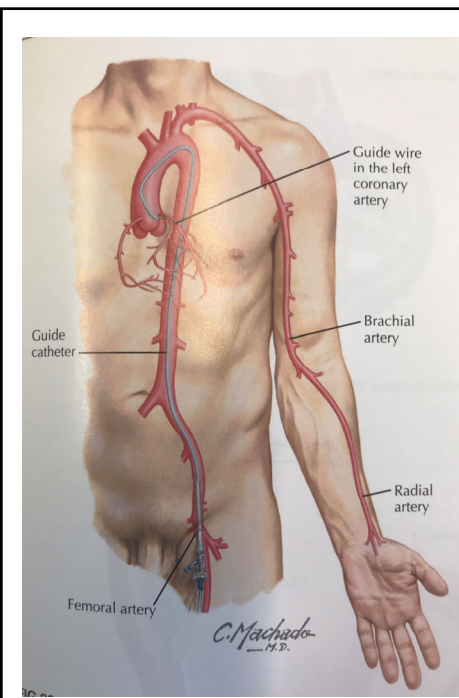
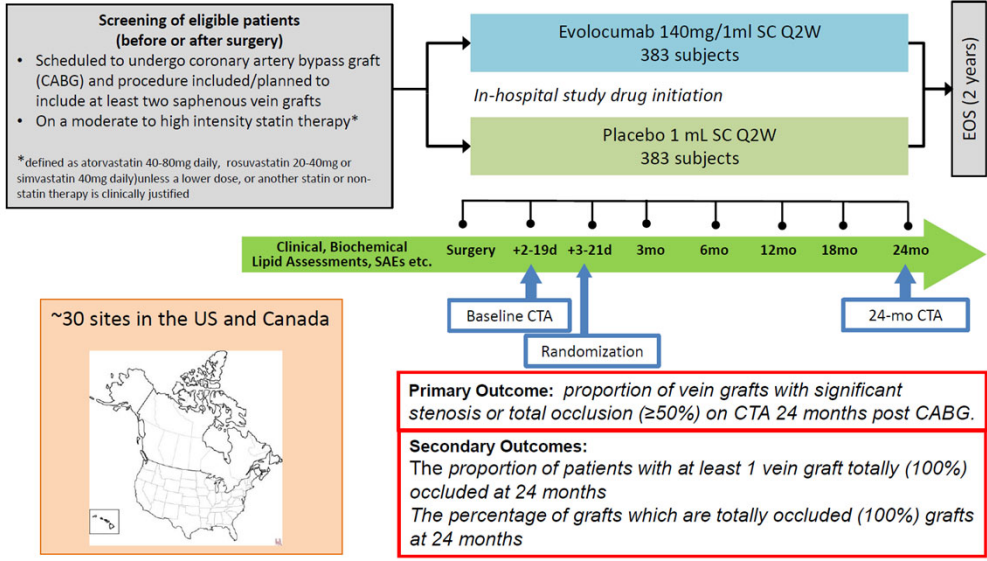
Dr. Latif  
OKVA  
Activated  
06/07/2019

Drs. Shunk, Zimmet and Yang  
SFVA  
Activated 06/12/2019

Dr. Mavromatis  
ATVA  
Activated  
06/07/2019

## A randomized trial of evolocumab on saphenous vein graft patency following coronary artery bypass surgery (NEWTON-CABG)

PI – Drs S Verma and CD Mazer



## REBIRTH Getting to the heart

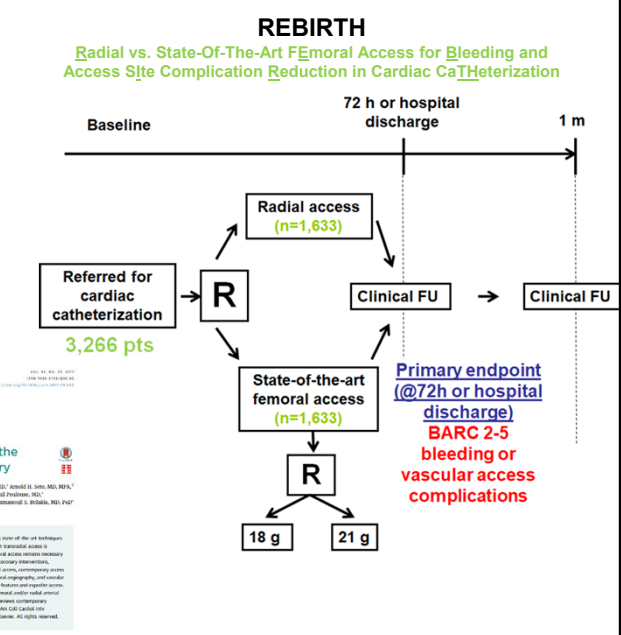
**CENTRAL ILLUSTRATION** Contemporary State-of-the-Art Femoral Arterial Access

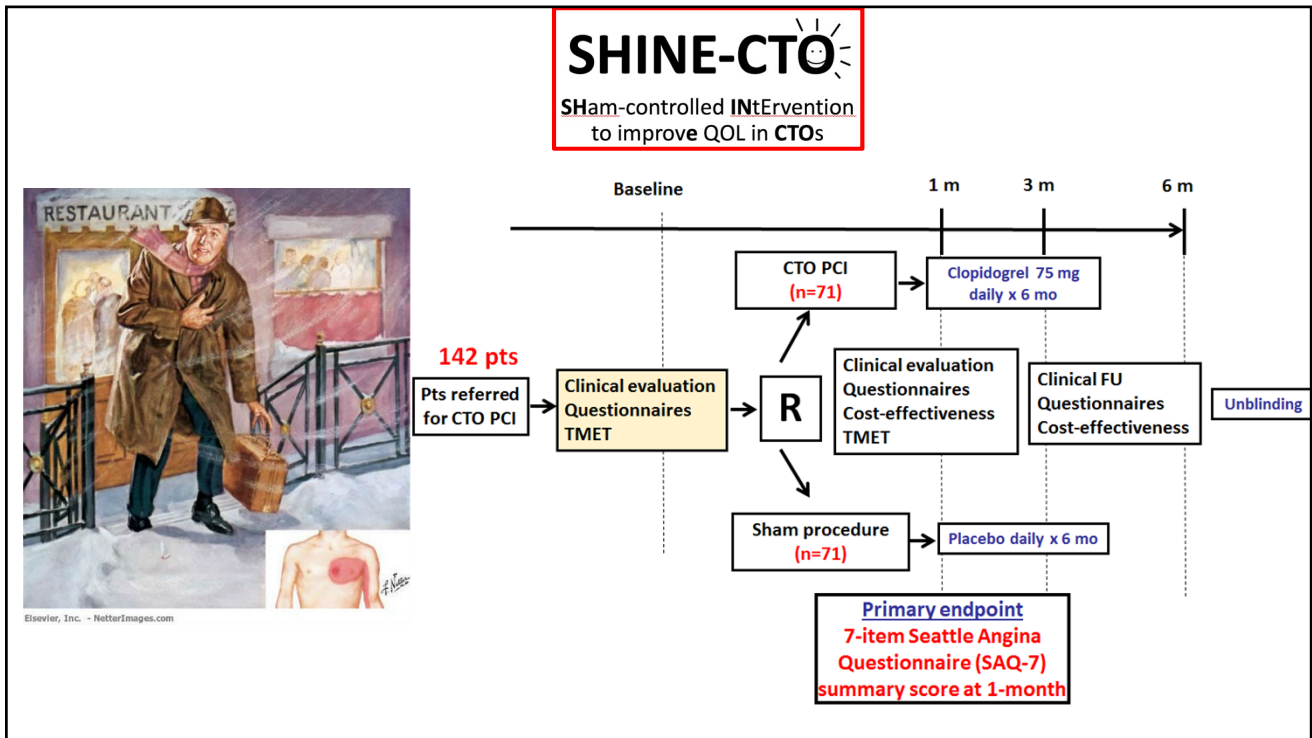
**STATE-OF-THE-ART REVIEW**

**Contemporary Arterial Access in the Cardiac Catheterization Laboratory**

Yadav S, et al. *Journal of Intensive Care Medicine*. 2017;32(10):1000-1008.

**ABSTRACT**  
 Identifying femoral and radial arterial access in the cardiac catheterization laboratory using one of the two techniques is essential to optimize outcomes, patient satisfaction, and procedural efficiency. Although femoral access is increasingly used for coronary angiography and percutaneous coronary interventions, radial access offers numerous advantages for numerous procedures, with the exception of large-bore access, including: smaller high-risk coronary interventions, decreased pain, and patient comfort. Radial access is preferred for all other procedures. The femoral artery, contemporary access techniques should consider the use of femoral, retrograde, microcatheter needles, femoral angiography, and central venous catheterization. The radial artery, retrograde approach may require additional needles and equipment. Despite continued evidence supporting the use of radial retrograde approach for femoral artery radial arterial access, additional details continue to be published. Contemporary techniques in cardiac catheterization laboratory. © An CAD Catheter 2017. DOI:10.1177/0885066617700000. Published by Sage. All rights reserved.



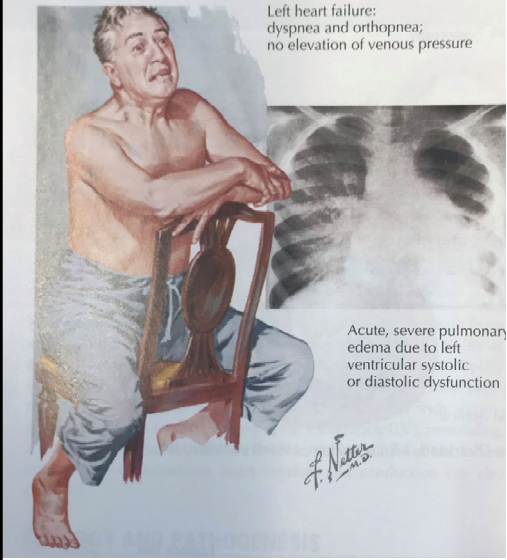


## New studies



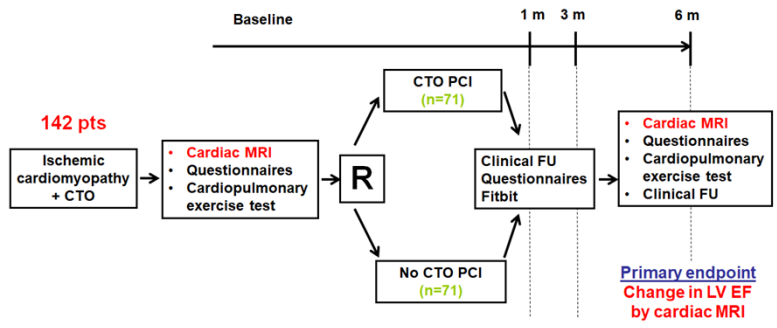
### REVIVE-CTO

#### REvascularization to Improve Left VEntricular function in Chronic Total Occlusions



Left heart failure:  
dyspnea and orthopnea;  
no elevation of venous pressure

Acute, severe pulmonary  
edema due to left  
ventricular systolic  
or diastolic dysfunction



**142 pts**

Ischemic cardiomyopathy + CTO

• Cardiac MRI  
• Questionnaires  
• Cardiopulmonary exercise test

**R**

CTO PCI (n=71)

No CTO PCI (n=71)

Clinical FU  
Questionnaires  
Fitbit

• Cardiac MRI  
• Questionnaires  
• Cardiopulmonary exercise test  
• Clinical FU

**Primary endpoint**  
Change in LV EF  
by cardiac MRI

Timeline: Baseline, 1 m, 3 m, 6 m

## Upcoming techniques/devices

### Guidance – CLEAR CTO



CT01  
1011841566  
Fluoro CTA 0.6 Bv49 6...  
\*1/11/1957  
# 0014378948  
CT  
1/14/2015  
2:05:11 PM

Uni Erlangen Kardiologie  
SOMATOM Force  
syngo CT VAS3A  
HFS

5 cm

<Plan>  
MIP  
0/0

W 1388  
C 358

### Penetration

**IMAGES IN INTERVENTION**

**E-CART (ElectroCautery-Assisted Re-enTry) of an Aorto-Ostial Right Coronary Artery Chronic Total Occlusion**

First-in-Man

William Nicholson, MD,<sup>1,2</sup> James Harvey, MD, MSc,<sup>1,2</sup> Rajiv Dhawan, MD<sup>1</sup>



Distal crossing tip of the guidewire was engaged in cutting mode at 50 W for a 1-s burst, with immediate unimpeded crossing into the lumen of the aorta.

### Soundbite system



Wire connector

### PlasmaWire System



Retrovascular, Inc.

- The PlasmaWire System consists of an RF Generator (RFG), Connector Cable and two 0.014" RF wires (PlasmaWire).
- Two, independently steerable PlasmaWires act as electrodes to form a bipolar arrangement for precise directional ablation.

**2018: 87**

THE LANCET

ARTICLES | VOLUME 391, ISSUE 10134, P1397-2007, MAY 19, 2018

**Drug-eluting stents versus bare-metal stents in saphenous vein grafts: a double-blind, randomised trial**

Prof Emmanouil S Brilakis, MD, Robert Edson, MA, Prof Deepak L Bhatt, MD, Prof Steven Goldman, MD, Prof David R Holmes Jr, MD, Sunil V Rao, MD, Prof Kendrick Shunk, MD, Barava V Rangan, MPH, Kriston Mavromatis, MD, Kodangudi Ramanathan, MD, Anthony A Bary, MD, Santiago Garcia, MD, Faisal Latif, MD, Ebrin Armstrong, MD, Hans Jneid, MD, Todd A Conner, PharmD, Todd Wagner, PhD, Jozsef Karsosy, MD

JACC: Cardiovascular Interventions  
Volume 11, Issue 3, 12 February 2018, Pages 225-233

JACC: Cardiovascular Interventions  
Volume 12, Issue 4, 25 February 2019, Pages 346-358

Focus on CTO

**Randomized Comparison of a CrossBoss First Versus Standard Wire Escalation Strategy for Crossing Coronary Chronic Total Occlusions: The CrossBoss First Trial**

Jozsef Karsosy MD, Peter Taji MD, Barava V Rangan BDS, MPH, Sean C Halligan MD, Raymond H. White MD, William J. Nicholson MD, James E. Haney MD, MSc, Anthony J. Speedy MD, Farouc A. Jaffer MD, PhD, Aaron Grantham MD, Adam Salisbury MD, Anthony J. Hart MD, David M. Saffey MD, William L. Lombardi MD, Ravi Hira MD, Craigton Don MD, James M. McCabe MD, M. Nicholas Burke MD, Emmanouil S. Brilakis MD, PhD

**Procedural Outcomes of Percutaneous Coronary Interventions for Chronic Total Occlusions Via The Radial Approach: Insights From an International Chronic Total Occlusion Registry**

Peter Taji MD, Khalidun Alswad MD, Dimitri Kampalotis MD, PhD, Farouc A. Jaffer MD, Robert W. Yeh MD, Mital Patel MD, Ehtisham Mahmood MD, James W. Choi MD, M. Nicholas Burke MD, Anthony H. Doong MD, Phil Daniels MD, Catalin Toma MD, A.J. Conrad Smith MD, Barry F. Uretsky MD, Elizabeth Holper MD, Srinivasa Pulluri MD, R. Michael Wyman MD, David E. Kandari MD, Santiago Garcia MD, Oleg Krestyaninov MD, Dmitrii Khelimiaki MD, Michaila Koutouzis MD, Ioannis Tsifoutsis MD, Jakub Jan Klatni MD, Wissam Jaber MD, Habi Samady MD, Brian Jefferson MD, Taral Patel MD, Shuaib Abdullah MD, Jeffrey W. Moses MD, Nicholas J. Lembo MD, Manish Parikh MD, Ajay J. Kirtane MD, Ziad A. Ali MD, Danish Doshi MD, Israf Xenogiannis MD, Larissa I. Stanberry PhD, Barava V. Rangan BDS, MPH, Imre Ugras MD, PhD, Subhash Banerjee MD, Emmanouil S. Brilakis MD, PhD

**2019: 54**

**Circulation**

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**Guiding Principles for Chronic Total Occlusion Percutaneous Coronary Intervention**

A Global Expert Consensus Document

Emmanouil S. Brilakis, Kamalis Meshayekh, Etsuo Tsuchikane, Nidal Abi Rafeh, Khalidun Alswad, Mario Araya, Alexandre Arvan, Lorenzo Azzaletti, Armand M. Balounashvili, Balaiah Bayaril, Ravivay Bhandi, Nicolas Bouillon, Marouane Bouabrit, Nensad Z. Buljovic, Lavek Brynski, Alexander Bule, Christopher E. Buller, M. Nicholas Burke, Heide Joachim Buttner, Show all Authors

Originally published 29 Jul 2019 | <https://doi.org/10.1161/CIRCULATIONAHA.119.039791> | Circulation. 2019;140:425-433

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**In-Hospital Outcomes of Chronic Total Occlusion Percutaneous Coronary Interventions in Patients With Prior Coronary Artery Bypass Graft Surgery**

Insights From an International Multicenter Chronic Total Occlusion Registry

Peter Taji, Dimitri Kampalotis, Khalidun Alswad, Farouc A. Jaffer, Robert W. Yeh, Mital Patel, Ehtisham Mahmood, James W. Choi, M. Nicholas Burke, Anthony H. Doong, Phil Daniels, Catalin Toma, A. J. Conrad Smith, Barry Uretsky, Elizabeth Holper, R. Michael Wyman, David E. Kandari, Santiago Garcia, Oleg Krestyaninov, Dmitrii Khelimiaki, Show all Authors

Originally published 15 Mar 2019 | <https://doi.org/10.1161/CIRCINTERVENTIONS.118.007303> | Circulation: Cardiovascular Interventions. 2019;12:e007303

**Jump to**

Abstract

**WHAT IS KNOWN**

**WHAT THE STUDY ADDS**

Introduction

Methods

Results

Discussion

Acknowledgments

Sources of Funding

**Abstract**

**Background:** We examined the procedural outcomes of chronic total occlusions (CTO) percutaneous coronary interventions in patients with prior coronary artery bypass graft surgery (CABG).

**Methods and Results:** We compared the clinical, angiographic, characteristics and outcomes of 3406 CTO interventions performed in patients with (n=1191) and without (n=2217) prior CABG at 21 centers. Prior CABG patients (32% of total cohort) were older (67.9 versus 63.10 years, P<0.001) and had more comorbidities and lower left ventricular ejection fraction (50% [40-58] versus 55% [45-60], P<0.001). The CTO target vessel in prior CABG patients was the right coronary artery (50%), circumflex (20%), and left anterior descending artery (17%). The mean J-CTO II 2.61.2 versus 2.2±1.3, P<0.001 and PROGRESS-CTO (Prospective Global Registry for the Study of Chronic Total Occlusion Intervention, 1.5±1.1 versus 1.2±1.0, P<0.001) score was higher in prior CABG patients. Retrograde (53% versus 30%, P<0.001) and antegrade

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**Innovations in Radiation Safety During Cardiovascular Catheterization**

Emmanouil S. Brilakis

Originally published 27 Mar 2018 | <https://doi.org/10.1161/CIRCULATIONAHA.117.020868> | Circulation. 2018;137:1317-1319





## Complex Coronary Artery Disease Science Center

*Making the impossible possible*


# Education



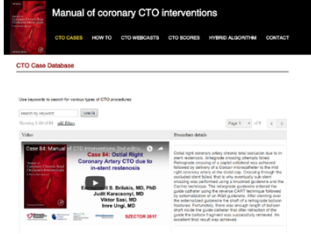
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### Education


Patients




Providers




**Live cases**



**SCAI**  
Society for Cardiovascular  
Angiography & Interventions



**SIF2019**  
SCOTTSDALE INTERVENTIONAL FORUM




**AMERICAN COLLEGE of  
CARDIOLOGY**

**CTO courses**  
**Visiting MDs**

**www.ctomanual.org**

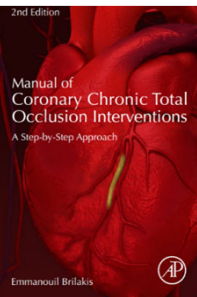
**CHIP fellow 2018-19**  
**Allison Hall, MD**

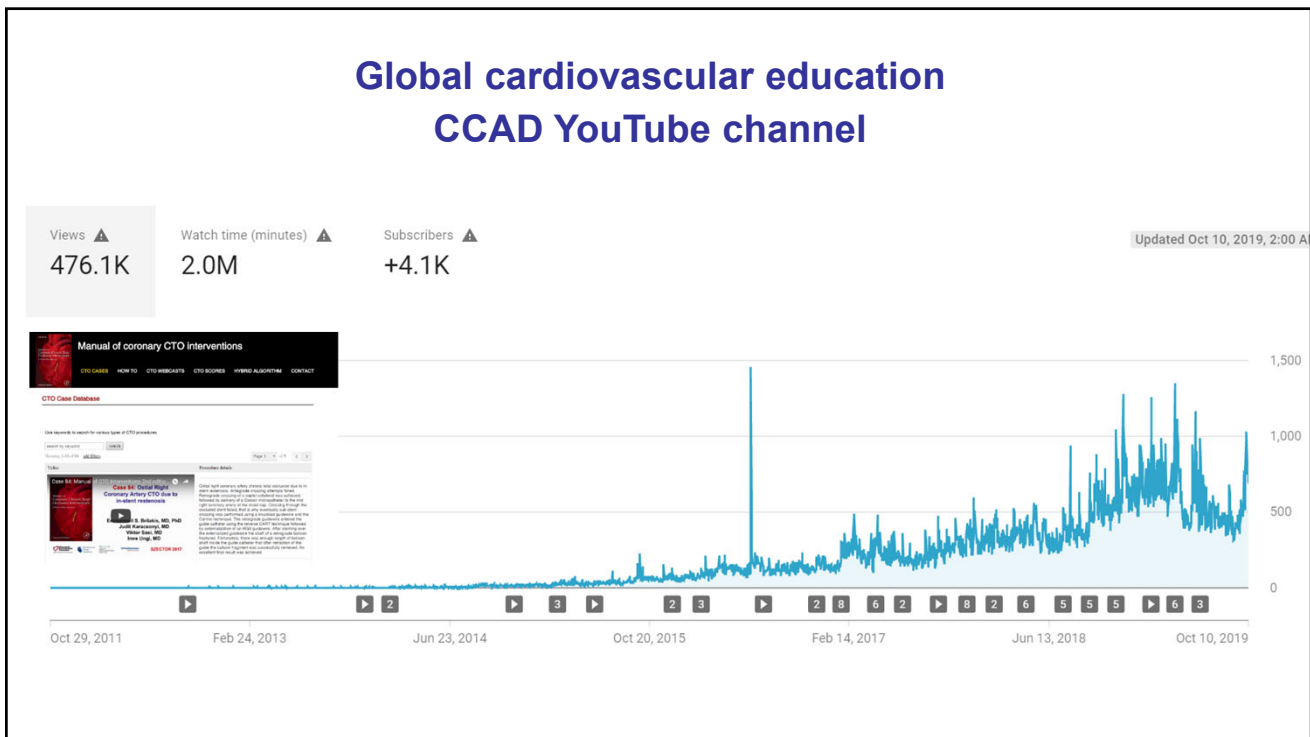


2nd Edition

**Manual of  
Coronary Chronic Total  
Occlusion Interventions**  
A Step-by-Step Approach

Emmanouil Briaklis





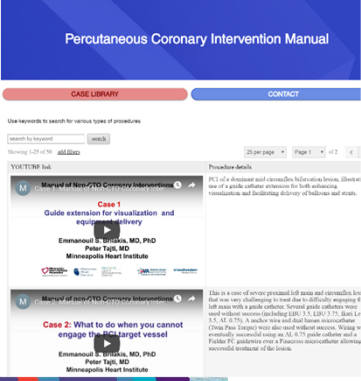
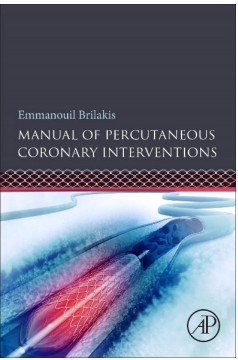
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### Education - future

Patients

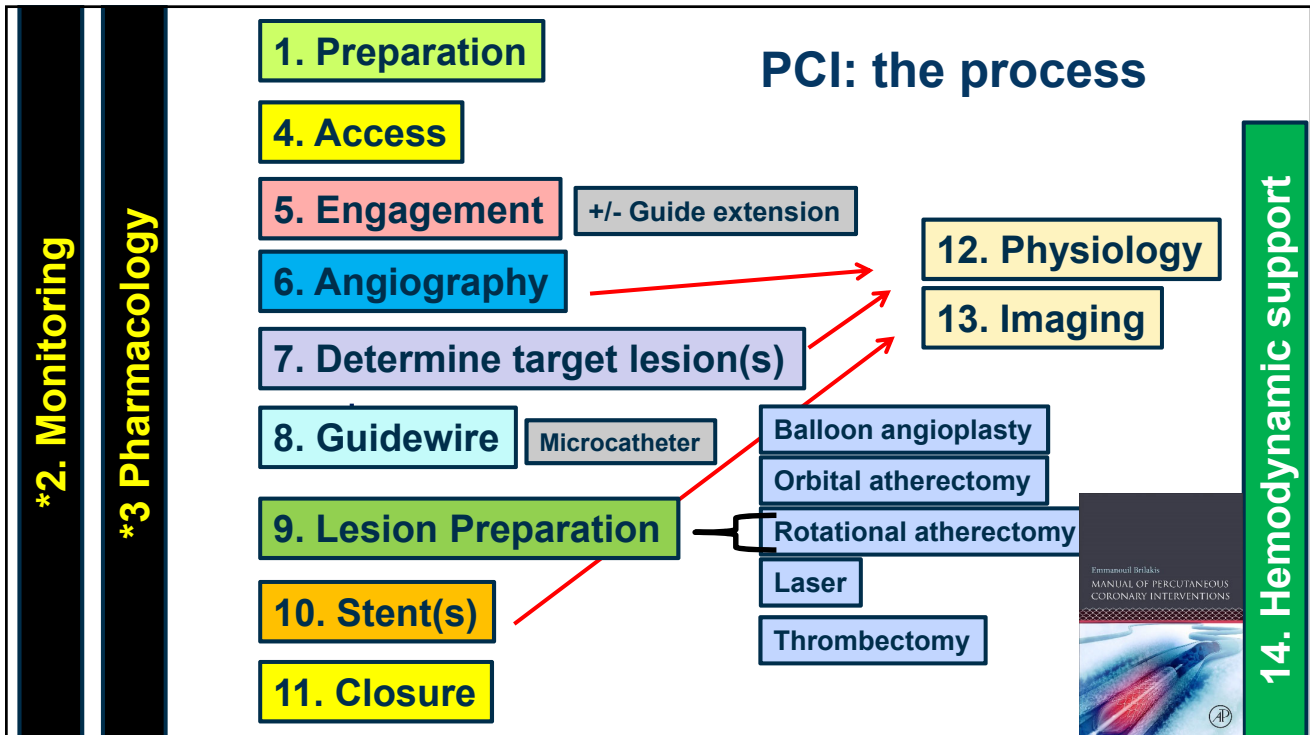
Life after CABG

Providers



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*Making the impossible possible*

**Research** ↔ **Clinical Practice** ↔ **Education**

↙ ↘  
*Patients*      *Providers*





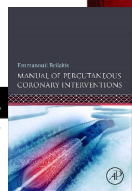
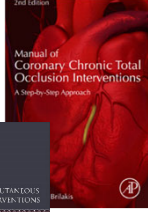

[www.progresscto.org](http://www.progresscto.org)



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**REBIRTH**





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