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

WAY TO GO CHRISTINE MAJESKI
Recipient of Mpls. St. Paul Magazine’s 2019 Outstanding Nurses Award for Research!
Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

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.

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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 Makowesky 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

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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

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

Daniel P. Melby MD, Charles Gornick MD, Raed Abdelhadi MD, Jay Sengupta MD, Manju Pai MD, John S. Zakaib MD, JoElyn Moore MD
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

Atrial Fibrillation: Stroke Risk in Subclinical AF

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

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
</tr>
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<tbody>
<tr>
<td>1. Permanent pacemaker or defibrillator (with or without resynchronization) or insertable cardiac monitor capable of detecting SCAF</td>
</tr>
<tr>
<td>2. At least one episode of device-detected SCAF ≥ 6 minutes in duration, but no single episode &gt; 24 hours in duration at any time prior to enrollment. Avg atrial high rate episode with average &gt; 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 ≥ 6 hours in duration</td>
</tr>
<tr>
<td>3. Age ≥ 55 years</td>
</tr>
<tr>
<td>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</td>
</tr>
</tbody>
</table>

Other risk factors are:
- hypertension
- CVA
- diabetes
- vascular disease (i.e. CAD, PAD or Aortic Plaque)
- female
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, MS1,2,3, Santiago Garcia, MD1,2, Lucille E. Axia, BS1, Pamela Morley, RN1, Ros Garberich, MS1, Charles C. Gornick, MD1,2, John Lesser, MD1,2, Paul Song, MD1,2, Mario Gösal, MD, PhD1,2, Jay Sengupta, MD1,2

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 A. Almquist, MD, Charles Gornick, MD, William T. Katschidanilo, 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 McGiff, 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 A. Almquist, MD, Barry J. Rosen, 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. Schnitz, MD, FHRS, Larissa L. Standberg, PhD, Moses K. Wanam, MD, Raed Abdelhadi, MD, FHRS

From the: “Minneapolis Heart Institute Foundation, Minneapolis, Minnesota, and The Clinic 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: Dorsal lead showing location of an insulation breach under the proximal superior vena cava (arrow). The cable in the distal right ventricular shocking coil has abraded through the inner silicone from the inside-out and with a traumatic laceration 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,1,2 Katelyn Storey BA,1 Susan Casey RN,1 Lena Trager BA,1 Melissa Buescher MPH,1 Mark Horning RN,2 Charles Gornick MD,1,2 Raed Abdelhadi MD,1,2 Chuen Tang MD,1,2 Suzanne Brill RN,2 Laura Ashbach RN,2 Robert G. Hauser, MD1

1Minneapolis Heart Institute Foundation, Minneapolis, MN, USA
2Minneapolis 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
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 CV Grand Rounds – Oct. 14, 2019

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

MHIF Grand Rounds 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
“You can’t think big enough”
- Robert Van Tassel, MD

80 year-old woman with severe dyspnea, normal EF, moderate MR
Simultaneous VO$_2$, echo

Dyspnea Evaluation
PCWP

Patient 1

Patient 2

Resting

Exercise

Cardiac

Non-cardiac
REDUCE-LAP Study

Atrial Shunting for Heart Failure
Alt-FLOW Early Feasibility Study
Multicenter Study of ROOT Device
National Principal Investigator: Paul Sorajja, MD

- Ambulatory HFpEF 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

Sleeve curves rotated 90°
TRILUMINATE CE Mark/EFS
Symptoms and QOL Changes

NYHA class

Baseline 30-day

KCCQ score

Baseline 30 d

p<0.001

p<0.0001

Nickenig G, et al. PCR London Valves 2018

Minneapolis Heart Institute Foundation

Creating a world without heart and vascular disease
TRILUMINATE PIVOTAL TRIAL

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

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

80 study sites worldwide

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

First 3 Patients Worldwide Here
August 28, 2019
84 year-old woman with severe TR and not candidate for surgery or TriClip
4Tech TriCinch Coil

Through RA

Puncture from RA to pericardial space

RCA

Start in IVC
Transcatheter TriCinch

Before

15.8 mm²
4.5 cm

After

12.5 mm²
3.8 cm

75 year-old woman with severe MR and heart failure
TMVR for Severe MAC

16 patients treated worldwide

STS = 7.4 ± 3.8%
MAC vol = 3,953 mm³
No 30-day deaths; 1 late death
No MR

Now in pivotal trial
80 year-old man with severe HF

Surgery or repeat clip not an option

Complementary Transcatheter Repair and Replacement
First-in-human Experience

Flying V to cut
First-in-human Experience

Transcatheter MVR after repair now possible

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
Thank you!
paul.sorajja@allina.com
507-513-1357
@psorajja
Science Center for Coronary Artery Disease (CCAD)

Emmanouil S. Brilakis, MD, PhD

What is “Complex”?

Comorbidities
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

Anatomy
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

Hemodynamics
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

Making the impossible possible

Research ↔ Clinical Practice ↔ Education

Patients ↔ Providers

www.progresscto.org

SHINE-CTO
SHam-controlled INEvntion to improve QOL in CTOs

ASAP-SVG

www.ctomanual.org
www.pcimanual.org

Research
# RESEARCH

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<th>Startup</th>
<th>Future</th>
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<td>Progress-bifurcation</td>
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<td>CLEAR-CTO</td>
<td>Revive-CTO</td>
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<td>SHINE-CTO</td>
<td>NASA: native vs. SVG intervention</td>
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<tr>
<td>Rebirth</td>
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**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, multicenter registry of chronic total occlusion (CTO) interventions across various techniques and operators.

**OUR GOAL**

Our goal is to advance the field of CTO PCI through rigorous study of techniques and outcomes across a varied group of operators and clinical practices.
46 Sites globally, >5000 patient procedures

Funding: Abbott Northwestern Hospital Foundation

Study PI: E. S. Brilakis – Global Coordinator: B.V. Rangan – Database Manager: I. Xenogiannis

PROGRESS-CTO Registry Expansion

- India (Arun Kalyanasundaram, MD)
- MENATA (Nidal Abi-Rafeh, MD [Lebanon]/ Omer Goktekin[Turkey])
- Pakistan
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
**Alirocumab for Stopping Atherosclerosis Progression in Saphenous Vein Grafts (ASAP-SVG) Pilot Trial**

Patients with intermediate SVG lesion (30%-60% stenosis) → SVG-angiography + IVUS

- **Alirocumab**
- **Clinical FU**

* Last dose of alirocumab

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

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

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

**Screening of eligible patients (before or after surgery)**
- Scheduled to undergo coronary artery bypass graft (CABG) and procedure included/planned to include at least two saphenous vein grafts
- On a moderate to high intensity statin therapy

*Defined as atorvastatin 60 mg daily, rosuvastatin 40 mg daily, simvastatin 80 mg daily, pravastatin 40 mg daily, or any other statin or non-statin therapy clinically justified.

**Clinical, Biochemical, Lipid Assessments, SAEs etc.**
- Evolocumab 140mg/1ml SC Q2W
  - 383 subjects
- Placebo 1 mL SC Q2W
  - 383 subjects

**Primary Outcome:** proportion of vein grafts with significant stenosis or total occlusion (≥50%) on CTA 24 months post CABG.

**Secondary Outcomes:**
- The proportion of patients with at least 1 vein graft totally (100%) occluded at 24 months
- The percentage of grafts which are totally occluded (100%) grafts at 24 months

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**Getting to the heart**

**REBIRTH**
Radial vs. State-Of-The-Art Femoral Access for Bleeding and Access Site Complication Reduction in Cardiac Catheterization

- Baseline
- 72 h or hospital discharge
- 1 m

- Radial access
  - (n=1,833)

- Referred for cardiac catheterization

- Clinical FU

- Clinical FU

- State-of-the-art femoral access
  - (n=1,833)

- Primary endpoint (@72h or hospital discharge)
  - BARC 2-5 bleeding or vascular access complications

- 3,256 pts
New studies
Patients with CTO and proximal cap ambiguity undergoing CTO PCI

202 pts

CTO PCI with CTA guidance (n=101)

CTO PCI without CTA guidance (matched by J-CTO score) (n=101)

Primary endpoint: antegrade proximal cap crossing success

Secondary endpoints:
1. Technical and procedural success
2. Time needed to cross CTO
3. Total procedure time
4. Fluoroscopy time
5. Total air kerma radiation dose
6. Total contrast volume
7. Incidence of complications
8. Use of retrograde crossing
9. Final successful crossing strategy
10. Number of wires, microcatheters, balloons, and coronary stents used.
11. Operator perception regarding the safety of CTO crossing

Native Coronary Artery Instead of SAnphenous Vein Graft Intervention for Treatment of Significant Saphenous Vein Graft Lesions (“NASA”)

Baseline 12 m 12-36 m

Native coronary PCI

SVG with 50-99% stenosis

Clinical FU

SVG PCI
REVIVE-CTO
REVascularization to Improve Left VEntricular function in Chronic Total Occlusions

Baseline

142 pts

- Ischemic cardiomyopathy + CTO
- Cardiac MRI
- Questionnaires
- Cardiopulmonary exercise test

CTO PCI (n=71)

R

Clinical FU

- Questionnaires
- Clinical FU

No CTO PCI (n=71)

Primary endpoint
Change in LV EF by cardiac MRI

Upcoming techniques/devices

Guidance – CLEAR CTO

Penetration

Soundbite system
Presentations

Univ. of Manitoba, Winnipeg, Canada, October 2018
AHA Chicago, USA, Nov. 2018
TCT San Diego, USA, Sept. 2018
PCI Masters Boston, USA, August 2018
SCAI Shock Boston, USA, September 2018
TOB Venice, Italy, October 2018
EURO CTO Club Toulous, France, Sept. 2018
TCT Tuni, Tunisia, April 2019
Endog CTO revascularization course Budapest, Hungary, April 2019
SIC Middle East CTO summit Jordan, South Arabia, January 2019

Live cases: Abbott NW Hospital (MN) – ACC 2018 + SCAI 2018
Bad Krozingen (Germany) – MLCTO 2018
Novosibirsk (Russia) – Meshalkin CTO

Complex Coronary Artery Disease Science Center

Making the impossible possible

Education
MHIF CV Grand Rounds – Oct. 14, 2019

Complex Coronary Artery Disease Science Center

Education

Patients

Providers

Live cases

Society for Cardiovascular Angiography & Interventions

SIF2019

AMERICAN COLLEGE OF CARDIOLOGY

CTO courses

Visiting MDs

CHIP fellow 2018-19

Allison Hall, MD

Global cardiovascular education

CCAD YouTube channel

Views ▲ 476.1K

Watch time (minutes) ▲ 2.0M

Subscribers ▲ +4.1K

Updated Oct 10, 2019, 2:00 AM
Complex Coronary Artery Disease Science Center

Education - future

Patients

Providers

Life after CABG

www.pcimanual.org

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PCI: the process

1. Preparation

4. Access

5. Engagement

6. Angiography

7. Determine target lesion(s)

8. Guidewire

9. Lesion Preparation

10. Stent(s)

11. Closure

12. Physiology

13. Imaging

14. Hemodynamic support

*2. Monitoring

*3 Pharmacology

Balloon angioplasty
Orbital atherectomy
Rotational atherectomy
Laser
Thrombectomy

Orbital atherectomy
Rotational atherectomy
Laser
Thrombectomy

www.pcimanual.org