





1

Appropriate Utilization of Novel Medications to
Reduce CVD risk in Individuals with Type 2 Diabetes

Abdul Gamam, MD



PREVENTION: Nolan Family Center for Cardiovascular Health



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An Increasing Prevalence of Diabetes

Year	Diabetes and CVD	CVD only	Diabetes only
1994	3.8	2.2	2.1
1999	3.6	2.1	2.0
2004	3.4	2.0	1.8
2009	3.1	2.0	1.7
2014	3.2	2.1	1.6

- In 2019, 11% of the US population had diabetes compared to 6.9% 10 years prior.
- 45% of those with diabetes had established CVD
- Intensive glucose therapy alone does not decrease CV mortality

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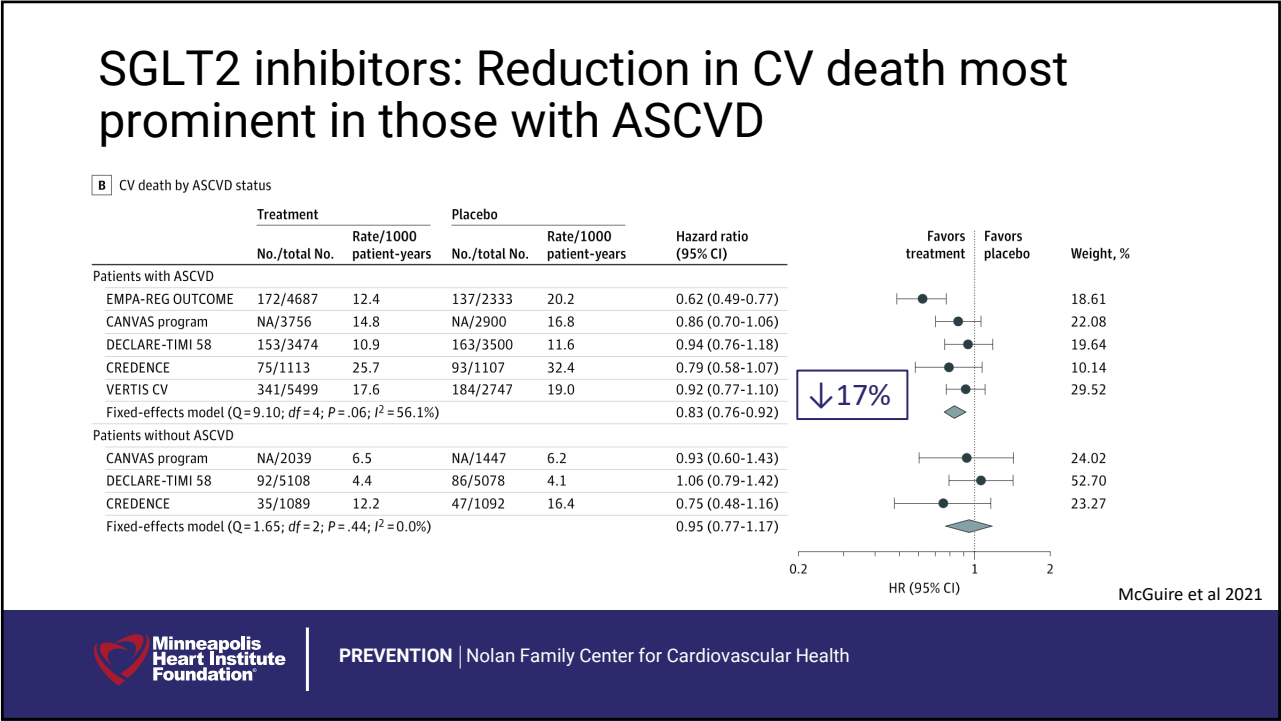
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Timeline of GLP-1 and SGLT2 Cardiovascular outcome Trials

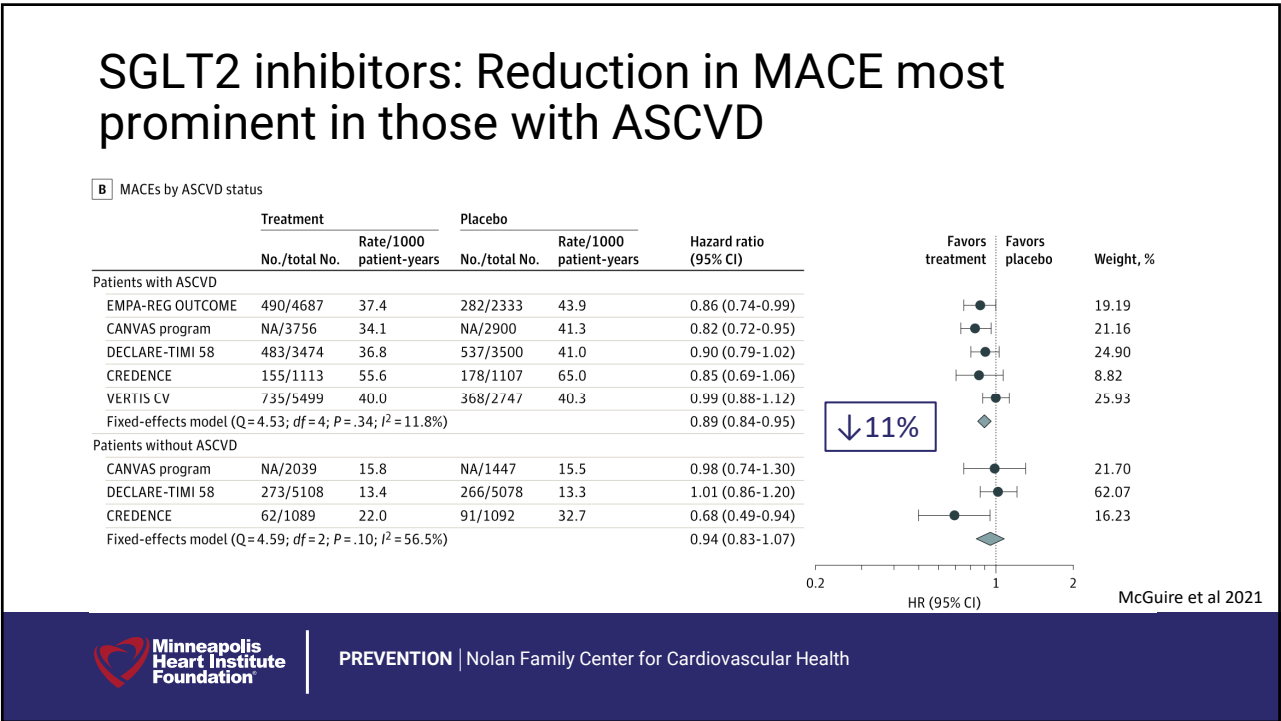
Year	GLP-1 Trials	SGLT2 Trials
2015	Empagliflozin	Lixisenatide
2016		Liraglutide
2017	Canagliflozin	Exenatide
2018	Dapagliflozin	Albiglutide*
2019		Semaglutide (SC)
2020	Ertugliflozin	Dulaglutide
2021		Semaglutide oral

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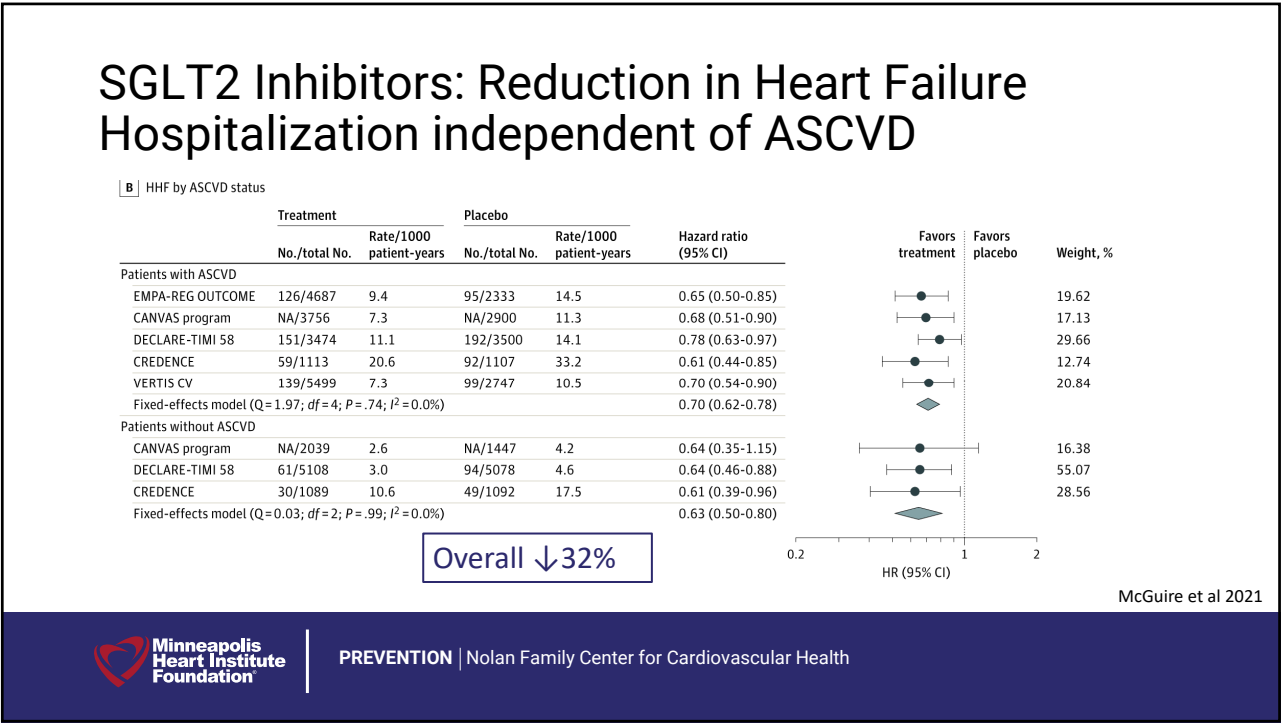
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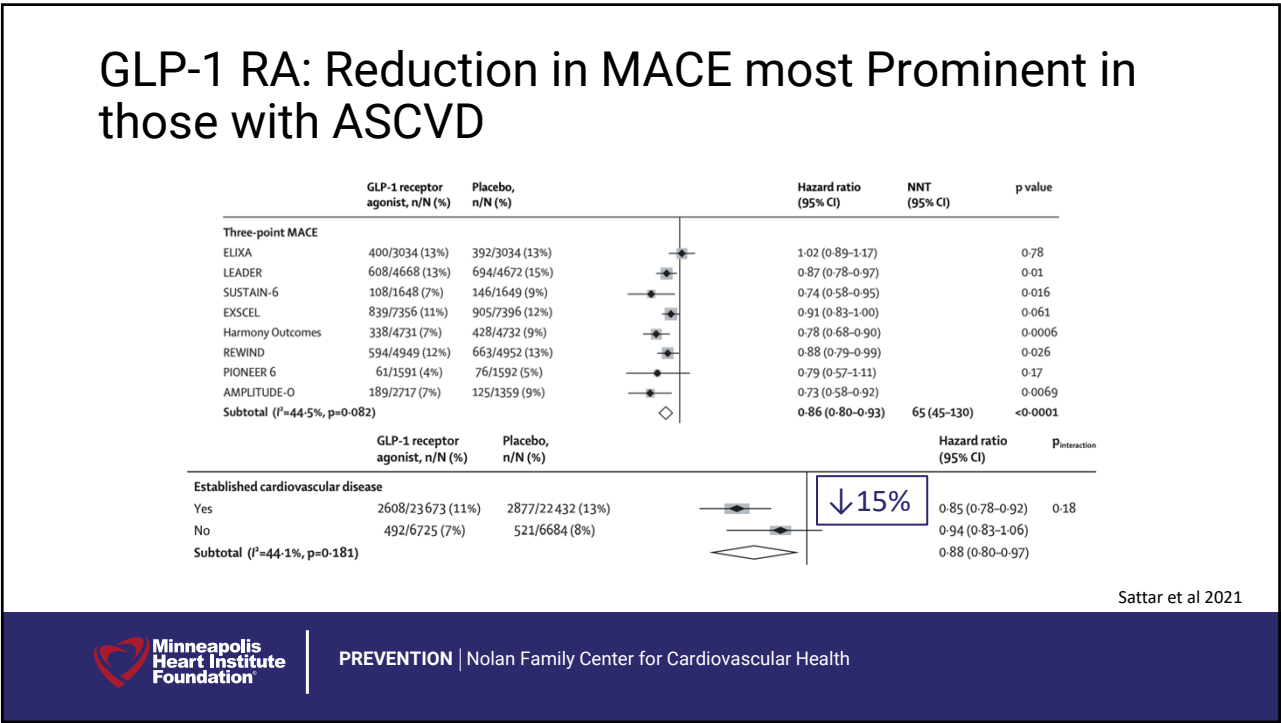
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8

Summary: SGLT2 inhibitor vs GLP-1RA

Consider SGLT2 inhibitor first	Consider GLP-1RA first
Reduces MACE & CV death	Reduces MACE & CV death
Reduction heart failure hospitalization	No proven reduction in heart failure hospitalization
Reduction in creatinine doubling and albuminuria progression	Reduction in albuminuria progression
	Substantial weight loss



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Current recommendations on novel therapies for CVD risk reduction in patients with T2D

Committee	Selected Recommendations for patients with T2D
ADA 2023	Consider SGLT-2 inhibitor and/or GLP-1 receptor agonists in those with established ASCVD or at high risk for ASCVD independent of hemoglobin A1c
ESC 2021	Consider SGLT-2 inhibitor or GLP-1 receptor agonist in those with established ASCVD or target organ damage independent of hemoglobin A1c
ACC 2020	For patients with clinical ASCVD consider an SGLT-2 inhibitor or GLP-1 RA with proven CV benefit.



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Project background and Objective

- Despite CV benefit, nationwide cohort studies estimate that **less than 15% of those with T2D and CVD** are on an SGLT2 inhibitor or GLP-1RA.
- The purpose of this study was to:
 - determine uptake of these novel agents in the Allina Health System and
 - Identify potential barriers to access



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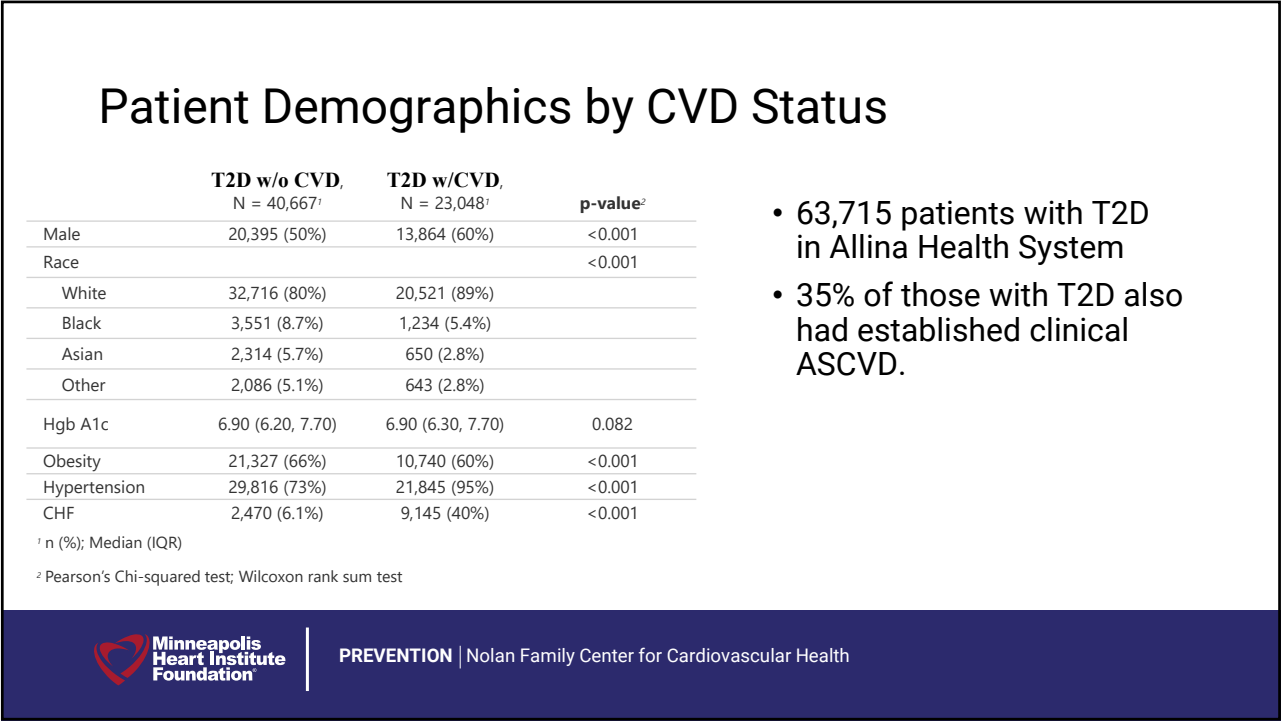
Methods

- Data was obtained through Allina Health's Electronic Data Warehouse
- We identified patients who received care from the Allina Health System between October 1, 2021, and October 1, 2022
- Medical and procedure history was obtained through ICD-10 codes

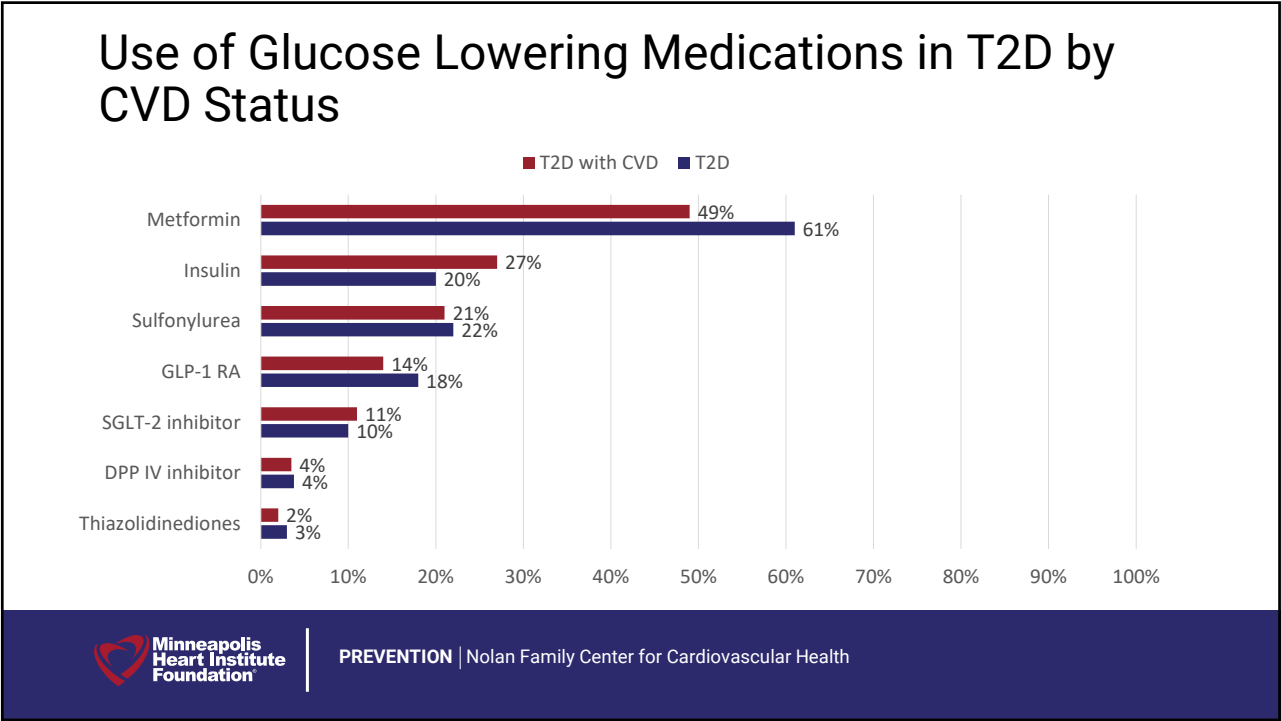


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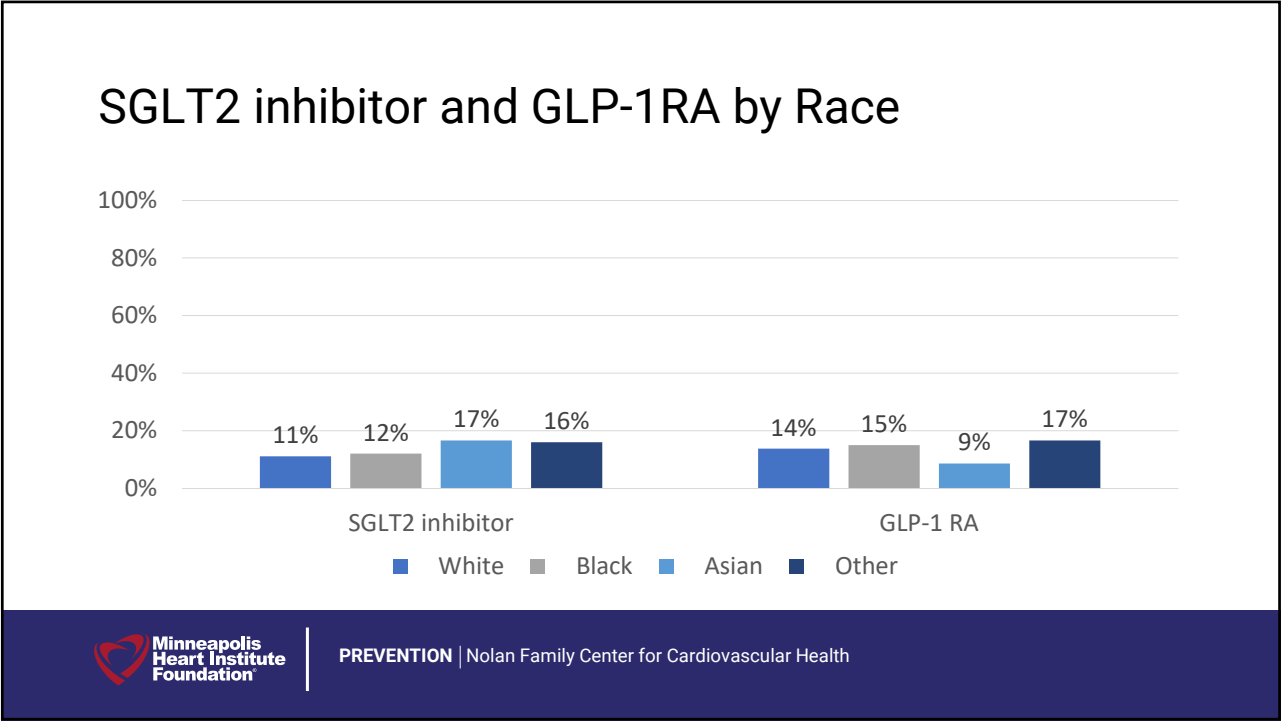
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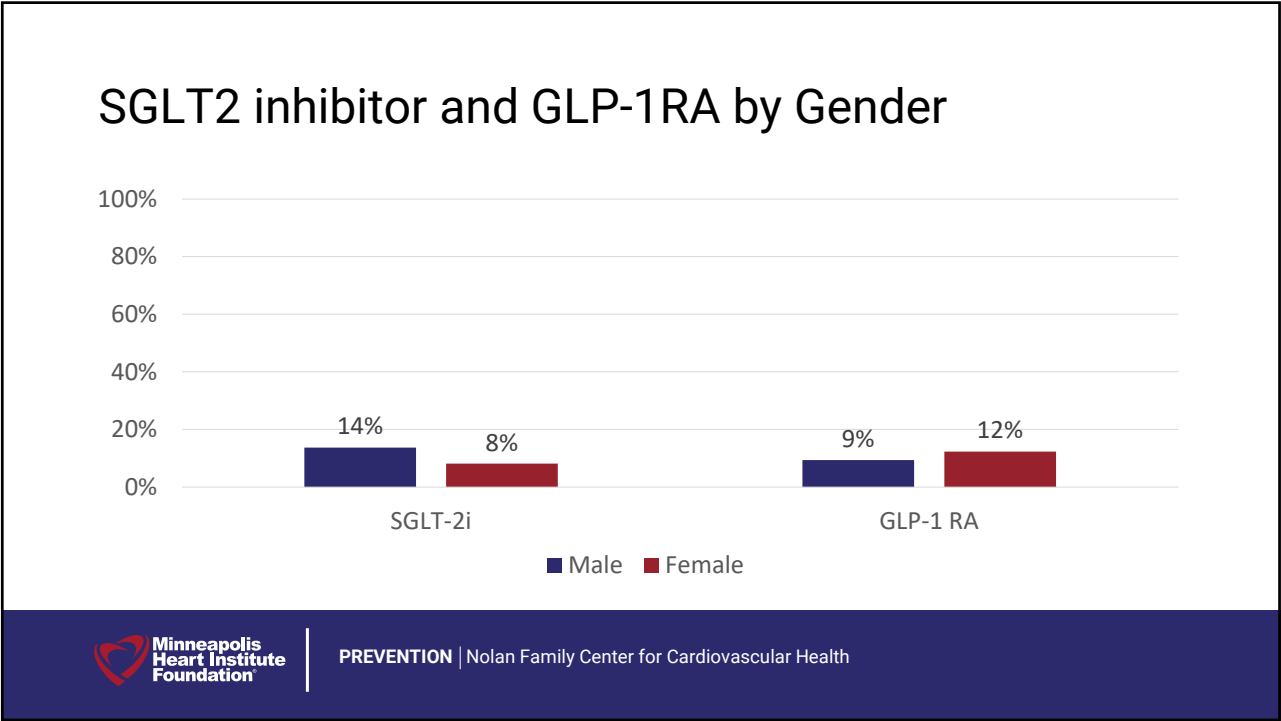
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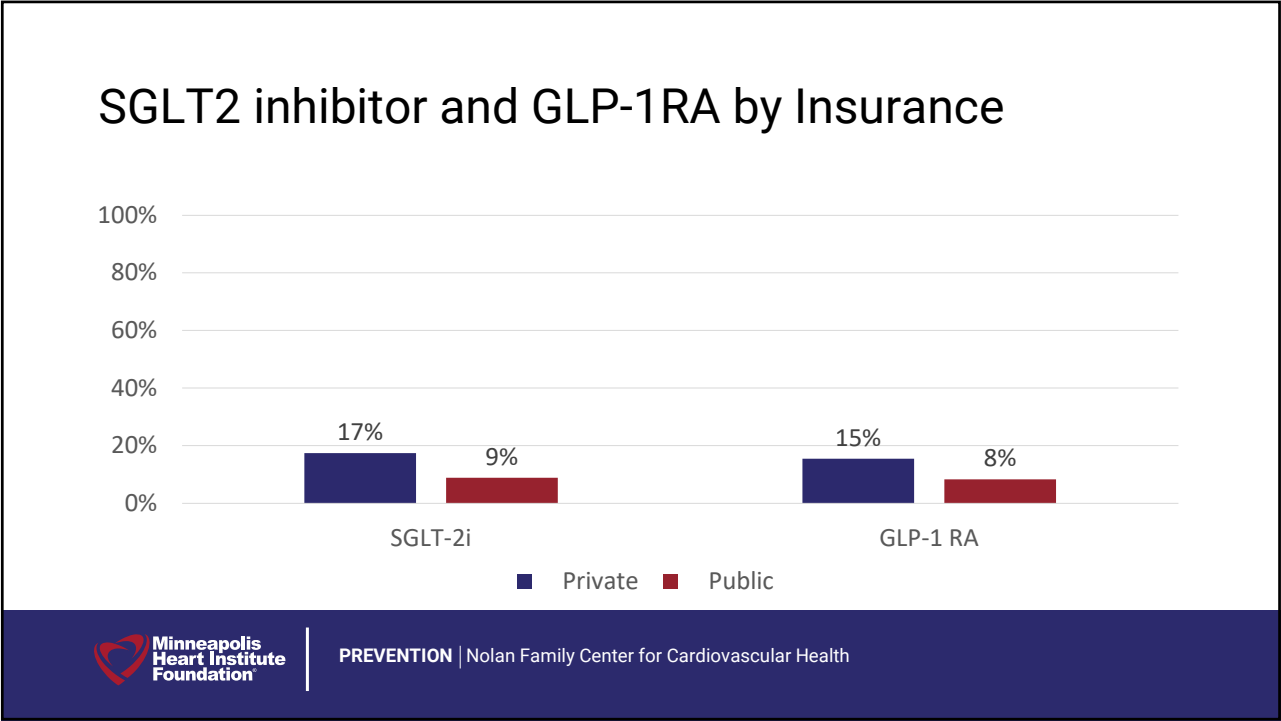
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Discussion

- The use of SGLT2 inhibitors and GLP-1RA in T2D with ASCVD in our cohort was low at less than 15%, this is comparable to nationwide estimates
- The use of these novel agents was similar between those with and without ASCVD.
- Although there was a statistically significant differences in use of SGLT2 inhibitors and GLP-1RA across gender, race, insurance type, and history of ASCVD

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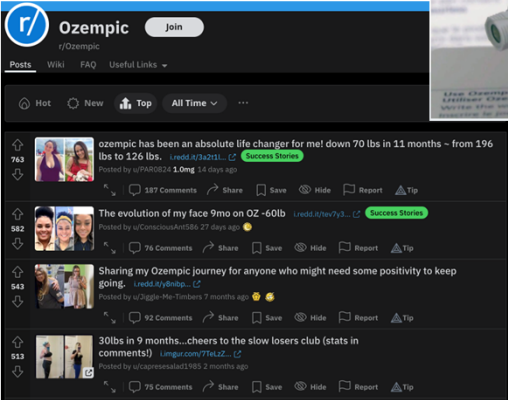




Illustration by Varitika Sharma; Getty Images

Those Weight Loss Drugs
May Do a Number on Your
Face



Canada's health minister calls mass exports
of Ozempic to U.S. an 'outrageous' abuse






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Proposed GLP-1RA project

- Physician orders GLP-1RA
- Pharmacist starts prior-authorization process and titrates medication
- Follow up scheduled in 3 months with APP




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Thank you!

Mike Miedema, Gretchen Benson, Evan Walser-Kuntz, Larissa Stanberry



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Questions?




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Advances and Future of Cardiovascular Computed Tomography


Amr Idris, MD
Advanced Cardiovascular Imaging Fellow
Minneapolis Heart Institute at Abbott Northwestern Hospital

5/8/2023

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History of CT Scan (1971)

The idea of “looking inside a box without opening it.”



British engineer sir Godfrey Hounsfield introduced the first CT scanner



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History of CT Scanner


Technology Milestone	Year
Electron-beam CT	1990
Twin-slice CT	1991
Electron-beam CT angiography	
16-slice CT	2000
64-slice CT	
ECG tube current modulation	
100-kVp tube voltage	2004
Dual-source CT 64-slice	2005
Prospectively ECG-triggered CT	2006
Wide-area detectors (256-slice)	2008
High-pitch helical CT	2009
Iterative reconstruction	
Dual-source CT 128-slice	2011

Allen Taylor. Cardiac Computed Tomography. Thoracic key.

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Acute chest pain studies

Journal of the American College of Cardiology
© 2011 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 58, No. 14, 2011
ISSN 0735-1097/\$36.00

CLINICAL RESEARCH

The CT-STAT (Catheterization Trial in ST-Segment Elevation Myocardial Infarction) Study

James A. Goldstein, MD,*
Stephan Achenbach, MD,†
John R. Lesser, MD,‡
Michael Y. H. Shen, MD,§
for the CT-STAT Investigators
Royal Oak and Detroit, Michigan
Boston, Massachusetts; Minneapolis, Minnesota

CT-STAT 2011

The NEW JOURNAL

ESTABLISHED IN 1812

Coronary CT Angiography Versus Radionuclide Myocardial Perfusion Imaging in Patients With Chest Pain Admitted to Telemetry Units: A Randomized Trial

UDOPAC-2012

ROMICAT-II 2012

The Annals of Internal Medicine®

LATEST ISSUES IN THE CLINIC JOURNAL CLUB MULTIMEDIA CME / MOC AUTHORS / SUBMIT

Original Research | 4 August 2015

Coronary Computed Tomography Angiography Versus Radionuclide Myocardial Perfusion Imaging in Patients With Chest Pain Admitted to Telemetry Units: A Randomized Trial

Harold I. Litt, M.D.
Harjit Singh, M.D.
James M. Leaming

ACRIN-PA 2012

Prospect 2015

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Stable chest pain studies

<p>The NEW ENGLAND JOURNAL OF MEDICINE</p> <p>ESTABLISHED IN 1812</p> <p>Calcium imaging tomography functional test artery disease CRESCENT</p> <p>Pamela S. Douglas, M.D., Udo Hoerig, Hussein R. Al-Khalidi, Ph.D., Christopher B. Fordyce, M.D., Mey Mitchell W. Krucoff, M.D., V. Eric J. Velazquez, M.D., En</p> <p>PROMISE 2015</p>	<p>The LANCET</p> <p>JACC: CARDIOVASCULAR IMAGING PUBLISHED BY ELSEVIER ON BEHALF OF COLLEGE OF RADIOLOGY FOUNDATION</p> <p>ORIGINAL RESEARCH</p> <p>Selective Reperfusion Direct Referral for Invasive Coronary Intervention for Suspected Myocardial Infarction: A Randomized, Controlled Trial</p> <p>Hyoek-Jae Chang, MD, PhD,*†, Ravi Bathina, MD,* Andrea B. Jung-Hyun Choi, MD,* So-Young Sang-Sin Ha, MD,* Ae-Young J. Sang-Wook Kim, MD,* Woon-Yao Lu, MS,* Amit Kumar, M. Sang-Bum Lee, MD,* Ji Hyun Joseph Zullo, BA,* Lealee J. S.</p> <p>CORONARY CT ANGIOGRAPHY PROMISE 2015</p>	<p>The NEW ENGLAND JOURNAL OF MEDICINE</p> <p>ESTABLISHED IN 1812 APRIL 9, 2020 VOL. 382 NO. 15</p> <p>Initial Invasive or Conservative Strategy for Stable Coronary Disease</p> <p>D.J. Maron, J.S. Hochman, H.R. Reynolds, S. Bangalore, S.M. O'Brien, W.E. Boden, B.R. Chaitman, R. Senior, J. López-Sendón, K.P. Alexander, R.D. Lopes, L.J. Shaw, J.S. Berger, J.D. Newman, M.S. Sidhu, S.G. Goodman, W. Ruzyllo, G. Gosselin, A.P. Maggioni, H.D. White, B. Bhargava, J.K. Min, G.B.J. Mancini, D.S. Berman, M.H. Picard, R.Y. Kwong, Z.A. Ali, D.B. Mark, J.A. Spertus, M.N. Krishnan, A. Elghamazy, N. Moorthy, W.A. Hueb, M. Demkow, K. Mavromatis, O. Boekenja, J. Petreio, T.D. Miller, R. Szwed, R. Doerr, M. Keltai, J.B. Selvanayagam, P.G. Steg, C. Held, S. Kohsaka, S. Mavromichalis, R. Kirby, N.O. Jeffries, F.E. Harrell Jr., F.W. Rockhold, S. Broderick, T.B. Ferguson Jr., D.O. Williams, R.A. Harrington, G.W. Stone, and Y. Rosenberg, for the ISCHEMIA Research Group*</p> <p>ISCHEMIA 2020</p>
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2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

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Sankey W. Williams, MD†¶

*Writing committee members are required to recuse themselves from voting on sections to which their specific relationship could apply as Appendix 1 for detailed information. †ACCF Representative; ‡ACC/AHA Representative; §PCNA Representative; ¶BCN Representative; **Clinical non-voting expert; ††Society Representative; †††Society Representative; ††††ACCF/AHA Task Force on Practice Guidelines Liaison; †††††ACCF/AHA Task Force on Performance Measures Liaison.

AHA/ACC CLINICAL PRACTICE GUIDELINE

2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Writing Committee Members*

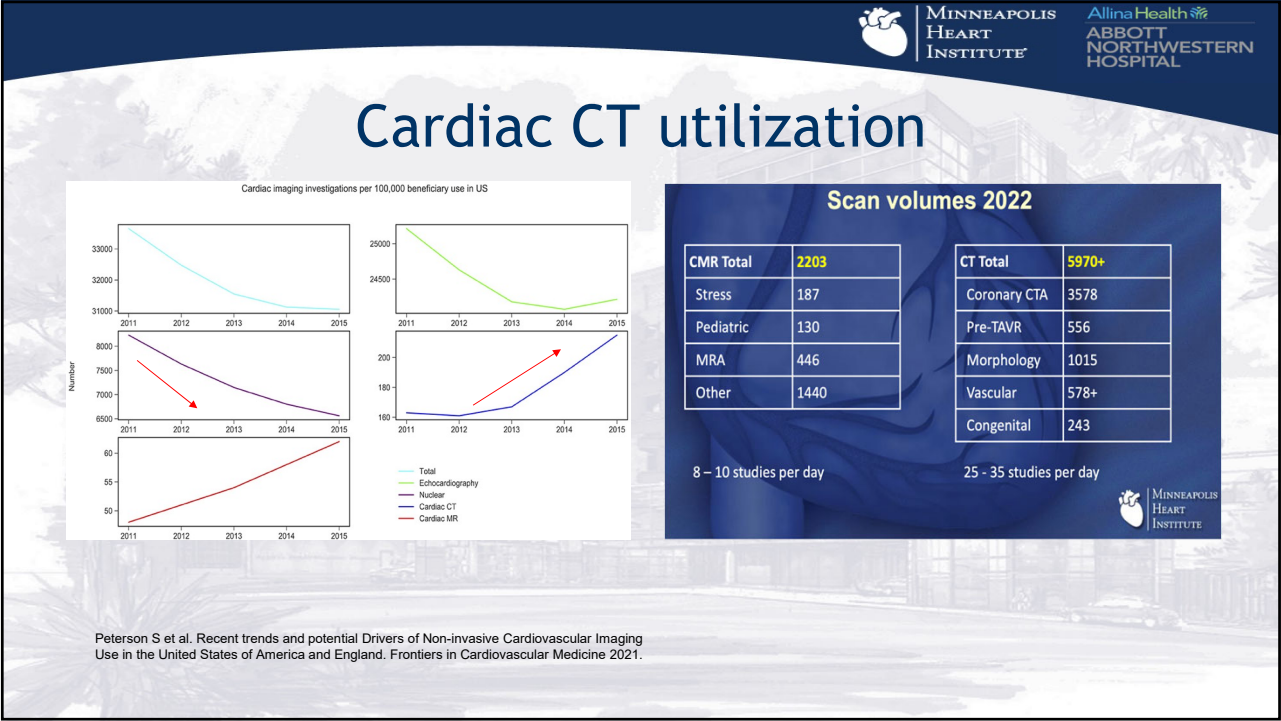
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1	A	1. For intermediate-high risk patients with stable chest pain and no known CAD, CCTA is effective for diagnosis of CAD, for risk stratification, and for guiding treatment decisions. ¹⁻¹²
1	A	1. For intermediate-risk patients with acute chest pain and no known CAD eligible for diagnostic testing after a negative or inconclusive evaluation for ACS, CCTA is useful for exclusion of atherosclerotic plaque and obstructive CAD. ¹⁻¹¹

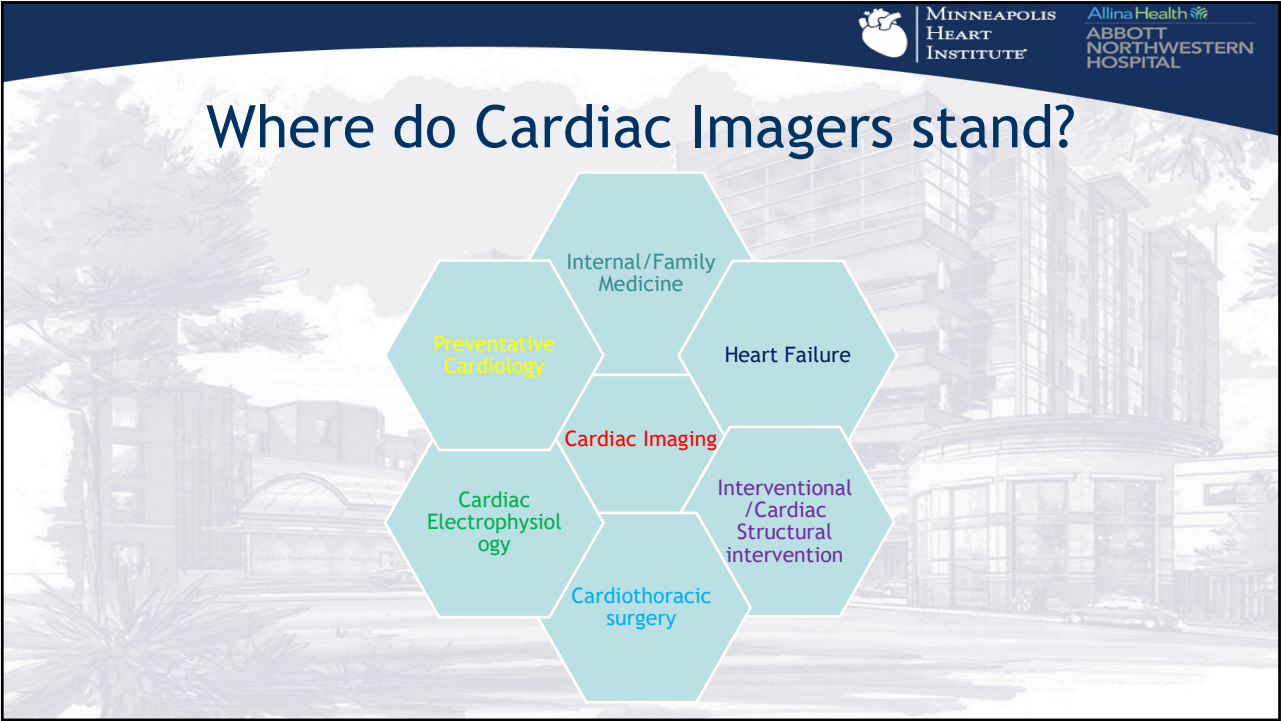
Table 11. Stress Testing and Advanced Imaging for Initial Diagnosis in Patients With Suspected SIHD Who Require Noninvasive Testing

Exercise ECG	X		X		X	I
Exercise with nuclear MPI or Echo	X			X	X	I
CCTA	X		Any		X	Iib


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Evaluate coronary arteries




Normal anatomy

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Anomalous Coronary artery




Anomalous LCx from RCA

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Anomalous LAD from right coronary cusp

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Invasive FFR



Shah et al. CT Coronary Angiography Fractional Flow Reserve: New Advances in the Diagnosis and Treatment of Coronary Artery Disease. Current Problems in Diagnostic Radiology

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CT-FFR

A CCTA

B Anatomic 3D model

C Physiology model

Q_c^{rest}
 M_{myo}^B

$R_{myo} \propto d^k$

D Computation of coronary blood flow

$\rho \vec{v}_t + \rho \vec{v} \cdot \nabla \vec{v} = -\nabla p + \nabla \cdot \tau$
 $\nabla \cdot \vec{v} = 0$

E Color-coded 3D mesh of FFR_{CT}

0.95, 0.87, 0.65

1.00 0.90 0.80 0.70 0.60 0.50

FFR_{CT}

Tesche et al. Coronary CT Angiography-derived Fractional Flow Reserve. Radiology 2017

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FFR-CT vs. Invasive FFR correlation

Scatter plot showing the correlation between FFR-CT (Y-axis) and Invasive FFR (X-axis). The correlation coefficient is $R = 0.72$ and the p-value is $p < 0.001$.

Correlates well

ROC curves comparing FFR-CT (solid blue line) and CCTA (dashed red line) for diagnosing intermediate lesions.

- ROC Per Vessel:** FFR-CT, AUC=0.90; CCTA, AUC=0.75
- ROC Per Patient:** FFR-CT, AUC=0.92; CCTA, AUC=0.70


Improves diagnostic accuracy of CTA alone in intermediate lesions

Discover-Flow 2011


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Normal CT FFR case (Normal anatomy)




Proximal LAD lesion




CT-FFR insignificant at 0.86

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Abnormal CT FFR case (Normal anatomy)

56 y.o. male with ESRD, DM2, tobacco use disorder who presents with chest pain.



Distal left main/proximal LAD lesion



CT-FFR significant at 0.66

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Anomalous Coronary artery with positive FFR

The figure consists of two panels. The left panel is a CT scan of the chest, showing the heart and major vessels. A blue circle highlights the anomalous RCA. The right panel is a 3D CT-FRR reconstruction of the coronary arteries. The anomalous RCA is highlighted in red, indicating a positive FFR value of 0.54. The main RCA is highlighted in blue, indicating a positive FFR value of 0.88. A color scale at the bottom indicates FFR values from 0.00 (red) to 1.00 (blue).

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J-CTO

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J-CTO

CTO Planning

J-CTO 2.

1. Tapering of the cap
2. No calcification
3. angulation < 45 degrees
4. CTO length of 28 mm.
5. Re-try lesion

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J-CTO

J-CTO SCORE SHEET

Version 1.0

Variables and definitions		
Tapered 	Blunt 	Entry shape <input type="checkbox"/> Tapered (0) <input type="checkbox"/> Blunt (1) point
Calcification 	Regardless of severity, 1 point is assigned if any evident calcification is detected within the CTO segment.	Calcification <input type="checkbox"/> Absence (0) <input type="checkbox"/> Presence (1) point
Bending > 45degrees 	One point is assigned if bending > 45 degrees is detected within the CTO segment. Any tortuosity separated from the CTO segment is excluded from this assessment.	Bending > 45° <input type="checkbox"/> Absence (0) <input type="checkbox"/> Presence (1) point
Occlusion length 	Using good collateral images, try to measure "true" distance of occlusion, which tends to be shorter than the first impression.	Occl.Length <input type="checkbox"/> <20mm (0) <input type="checkbox"/> ≥20mm (1) point
Re-try lesion Is this Re-try (2 nd attempt) lesion ? (previously attempted but failed)		Re-try lesion <input type="checkbox"/> No (0) <input type="checkbox"/> Yes (1) point
Category of difficulty (total point) <input type="checkbox"/> easy (0) <input type="checkbox"/> Intermediate (1) <input type="checkbox"/> difficult (2) <input type="checkbox"/> very difficult (≥3)		Total points

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The figure is a composite of medical imaging used for TAVR planning. It includes:


- Annulus size:** Two axial CT slices of the aortic annulus. The left slice shows a circular measurement with a diameter of 20 mm. The right slice shows a more complex, irregular shape with a diameter of 18 mm.
- Severe AV calcification:** A cross-sectional CT scan of the aortic valve showing significant calcification (bright white areas) on the leaflets.
- ECV screening:** A cross-sectional CT scan of the aortic valve showing the left ventricular outflow tract (LVOT) area, labeled as 26%.
- TAVR Access:** A 3D reconstruction of the aorta and iliofemoral arteries, showing the path for catheter access.

Logos for **MINNEAPOLIS HEART INSTITUTE** and **Abbott Northwestern Hospital** are visible in the top right corner.


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Bicuspid AV

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Post TAVR CT




Post TAVR
HALT




4 Months on warfarin
HALT resolved

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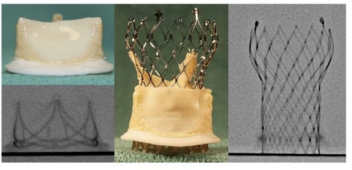
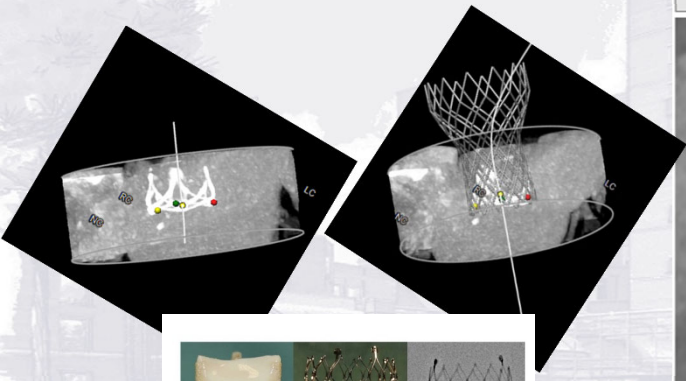


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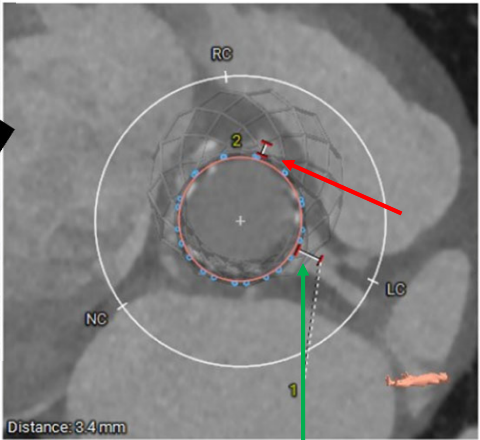


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ViV Planning Coronary obstruction (VTC)



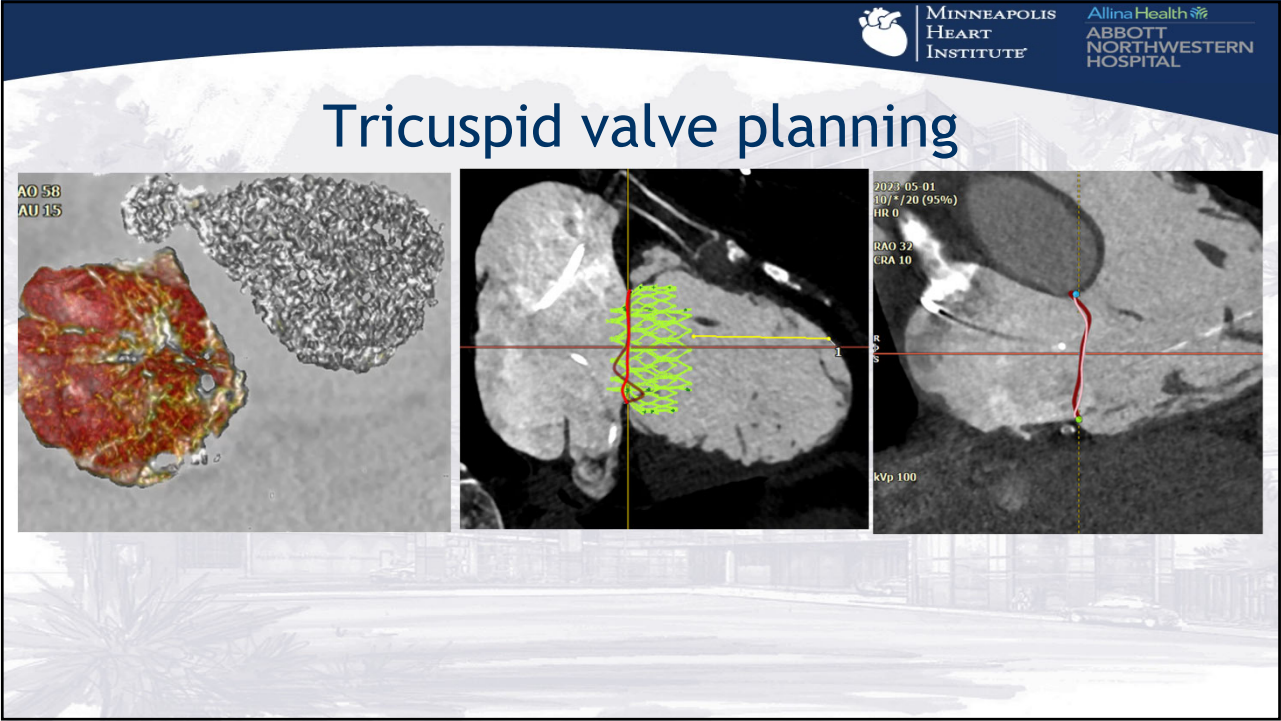
Valve to LCA and RCA Distance



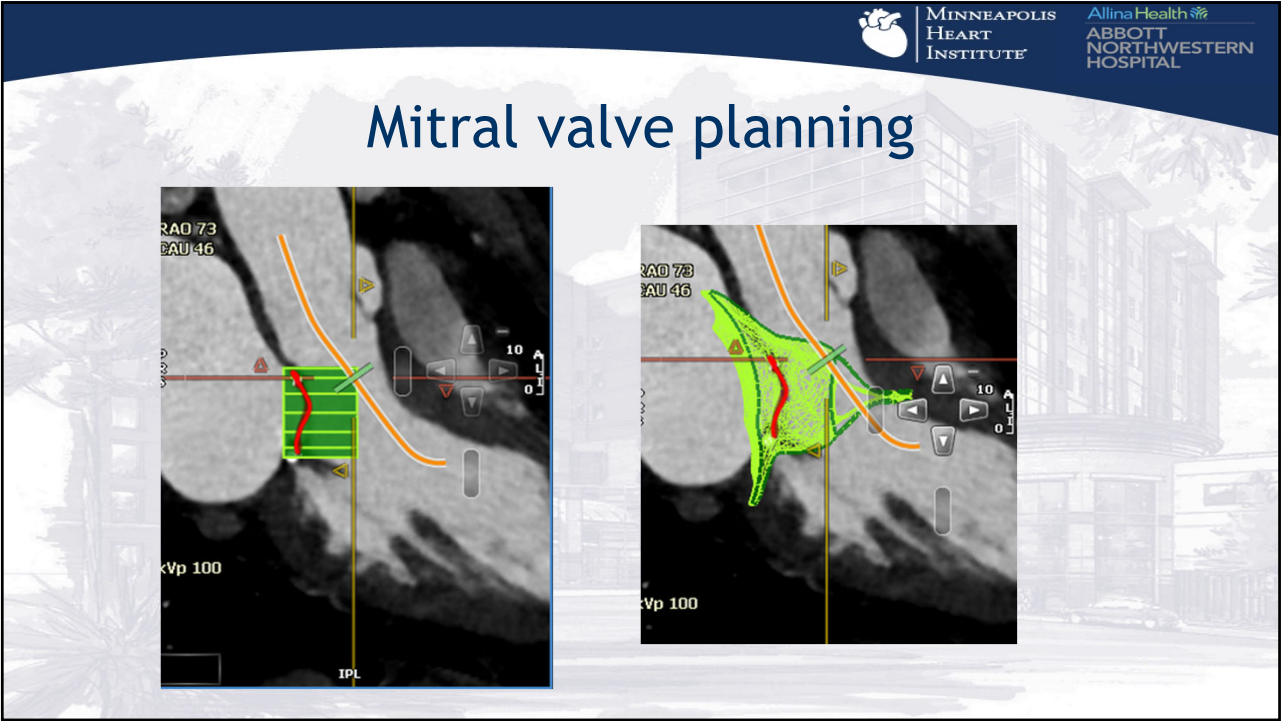
Distance: 3.4 mm

ID Type	Label	Value
1	Diameter Valve To LCA Distance	4.3 mm
2	Diameter Valve To RCA Distance	2.2 mm

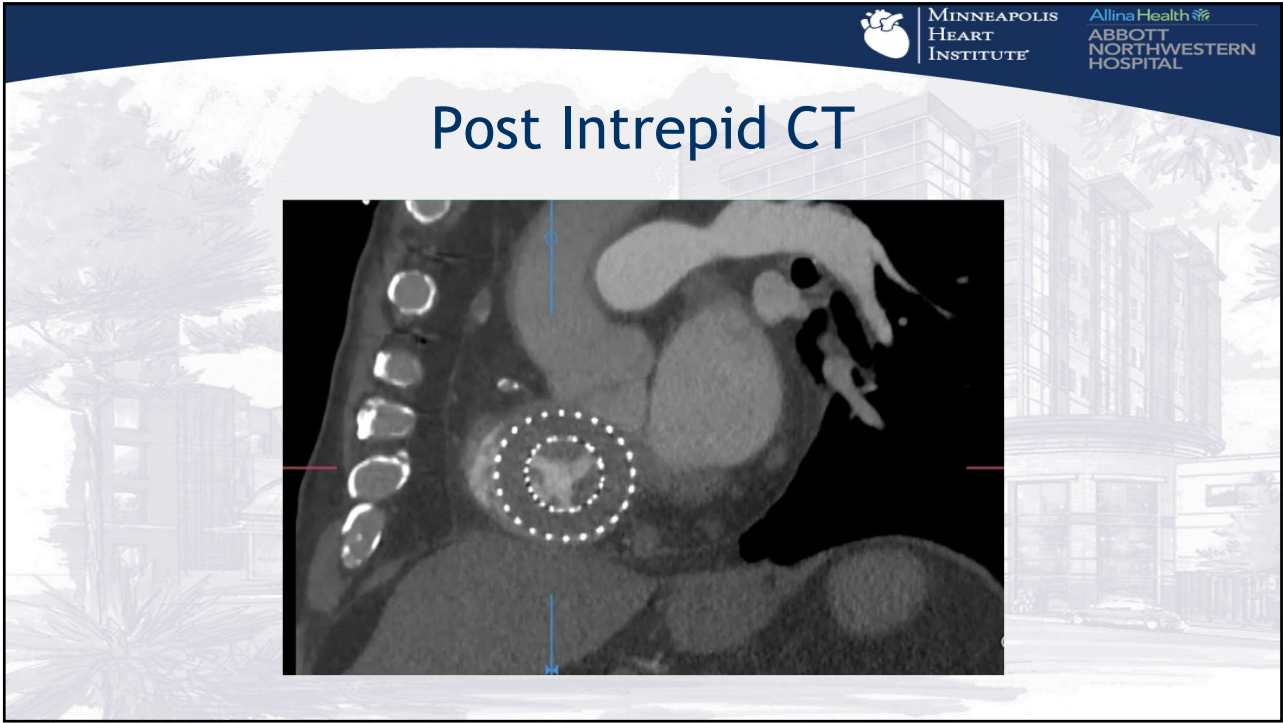
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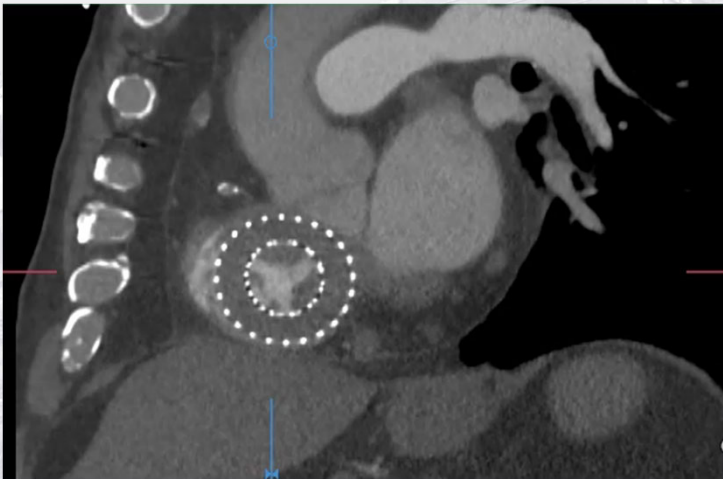
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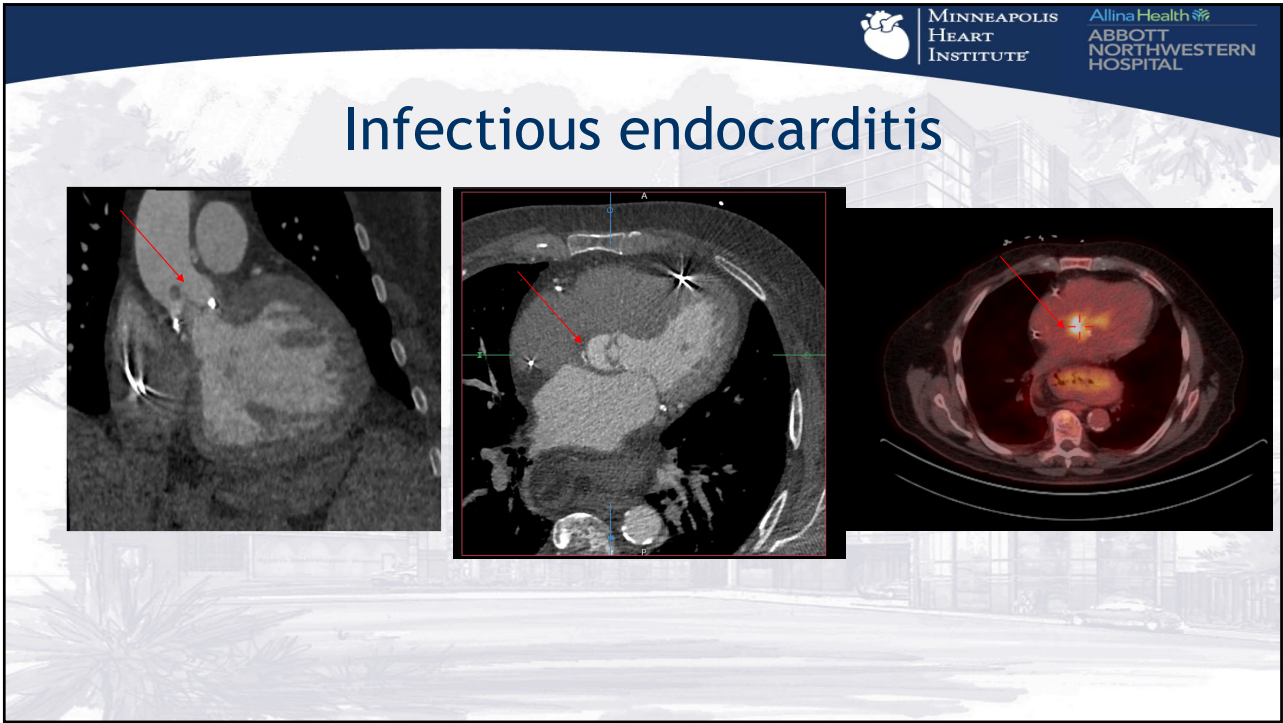
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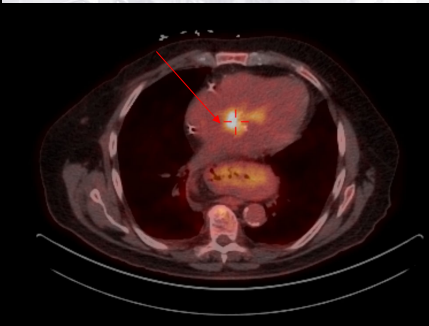
Post Intrepid CT



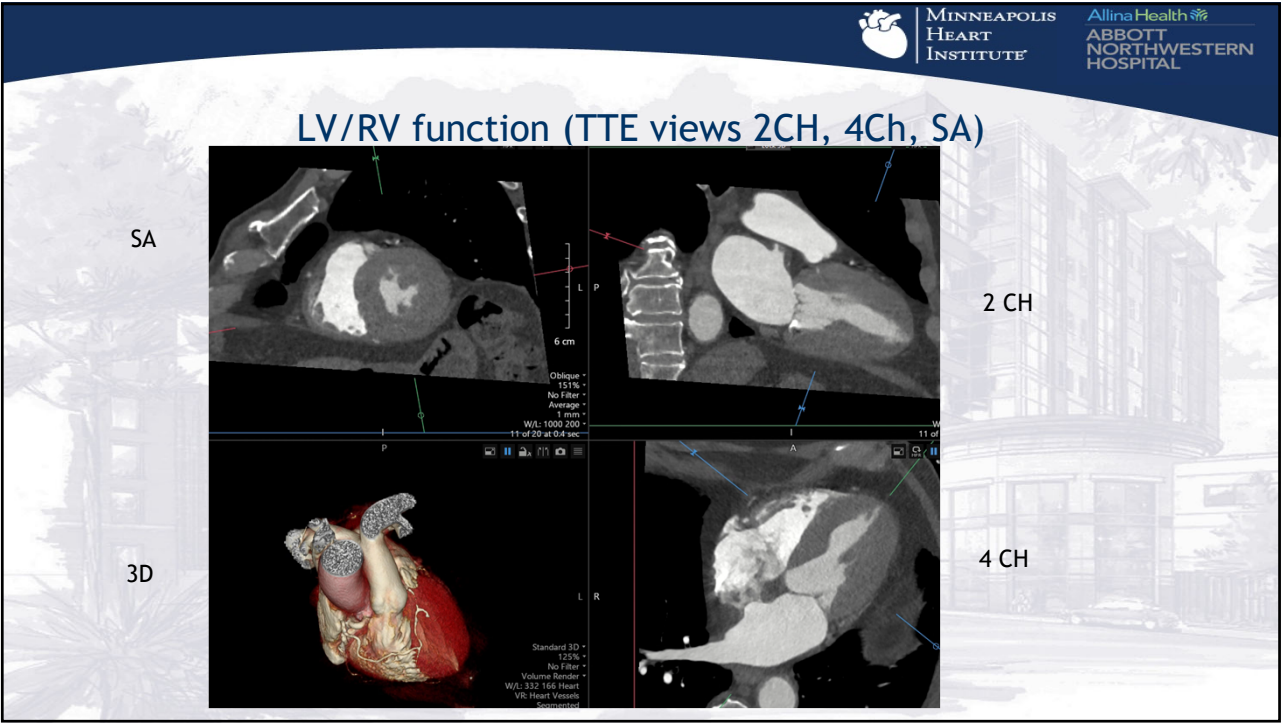
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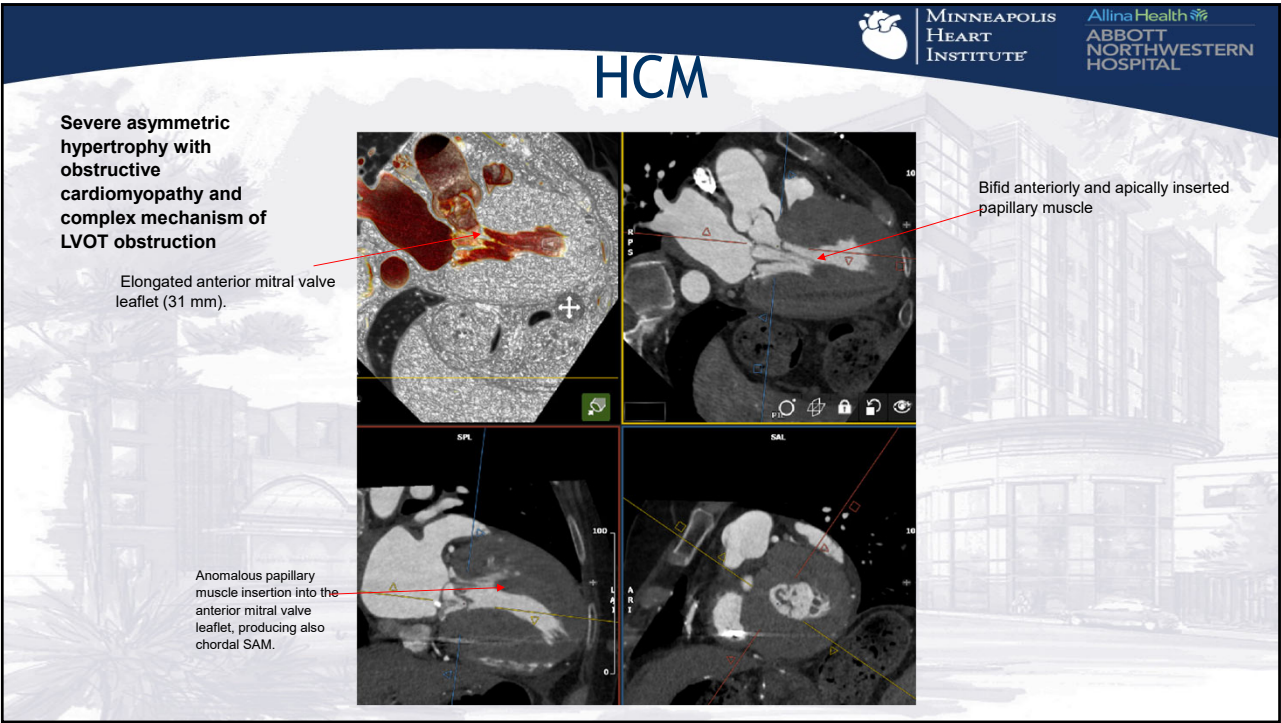
Infectious endocarditis



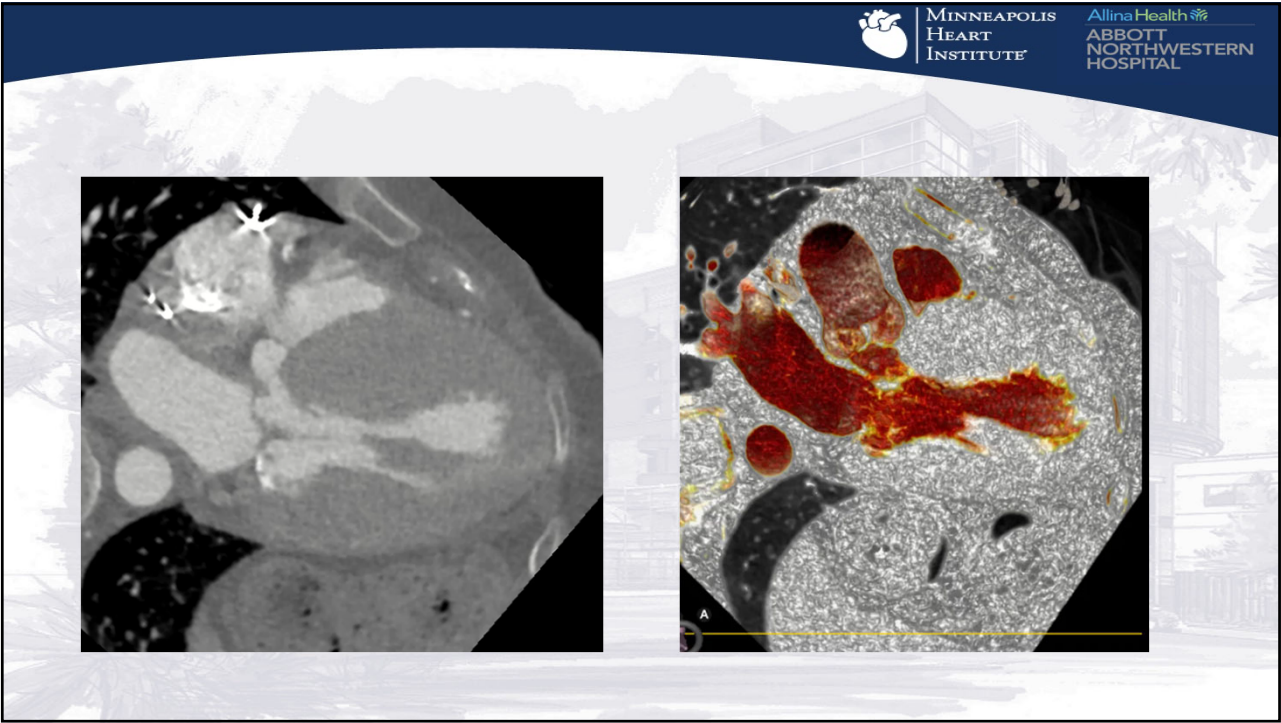
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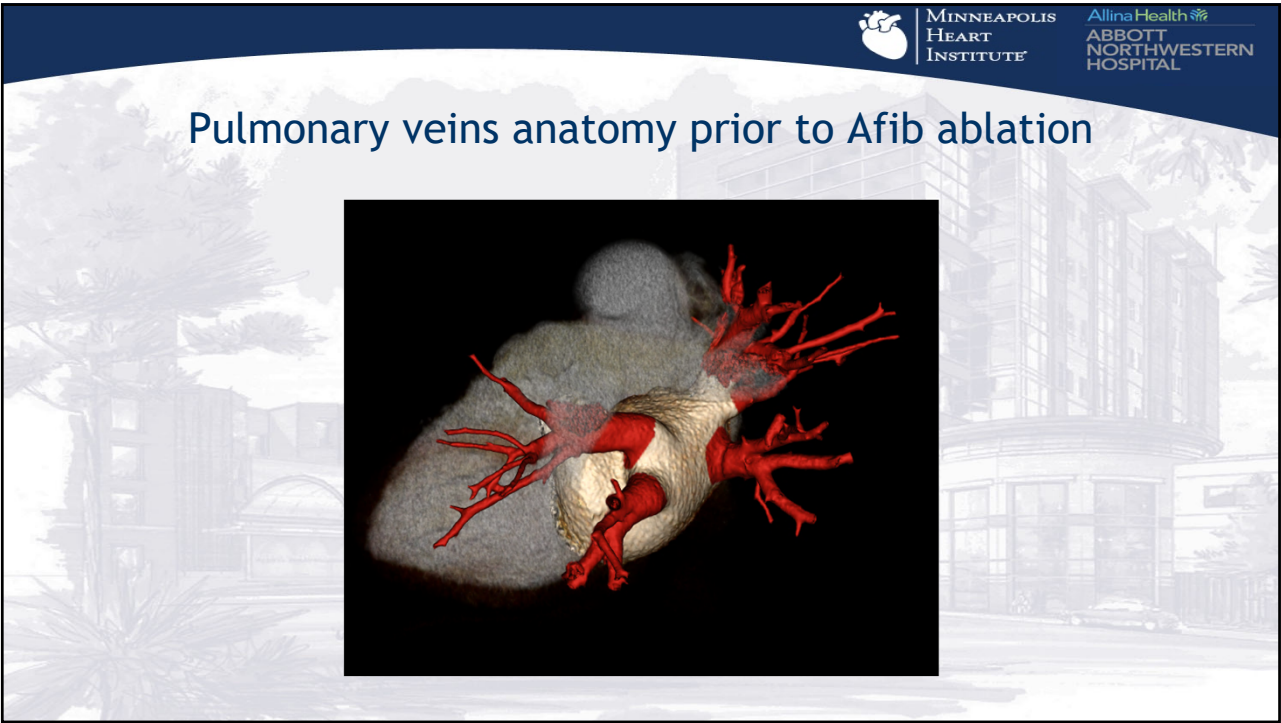
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Left atrial appendage anatomy




Evaluated left atrial appendage morphology




Evaluate left atrial appendage thrombus

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CT vs. TEE to rule out thrombus (Metanalysis)

Cardiac Computed Tomography Versus Transesophageal Echocardiography for the Detection of Left Atrial Appendage Thrombus: A Systemic Review and Meta-Analysis

Shandong Yu, Heping Zhang  and Hongwei Li 

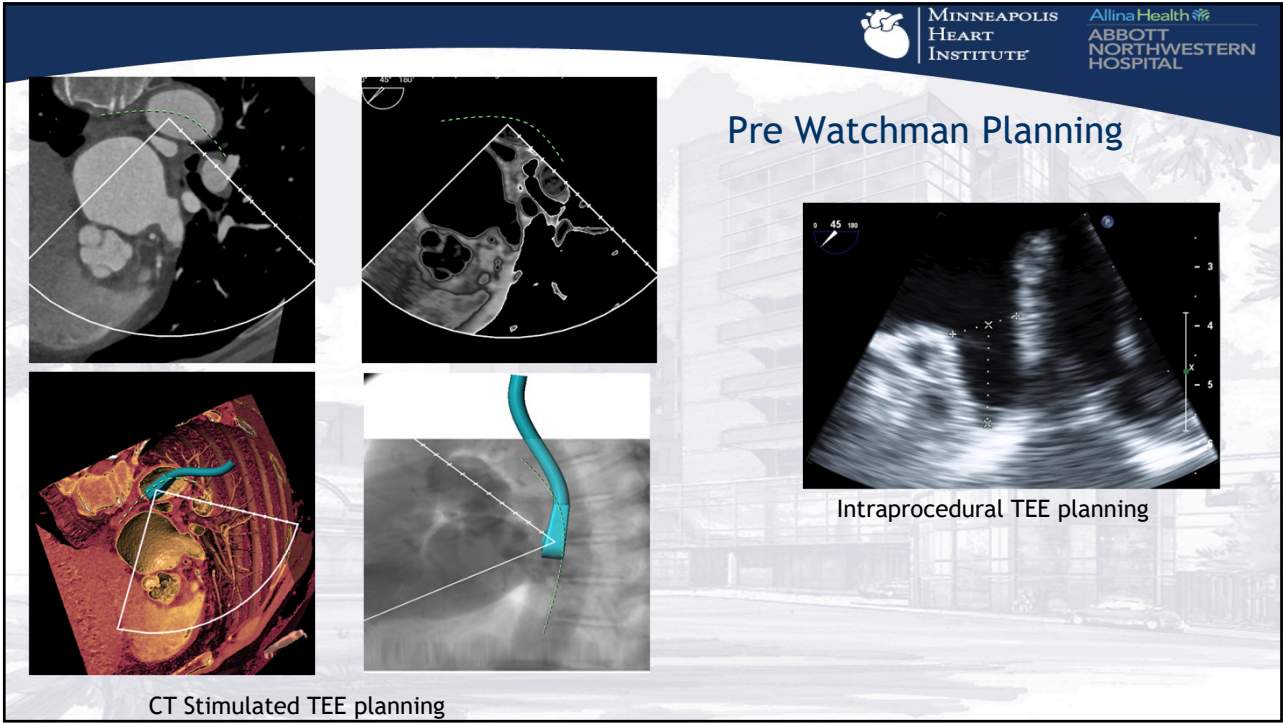
Originally published 19 Nov 2021 | <https://doi.org/10.1161/JAHA.121.022505> | Journal of the American Heart Association. 2021;10:e022505

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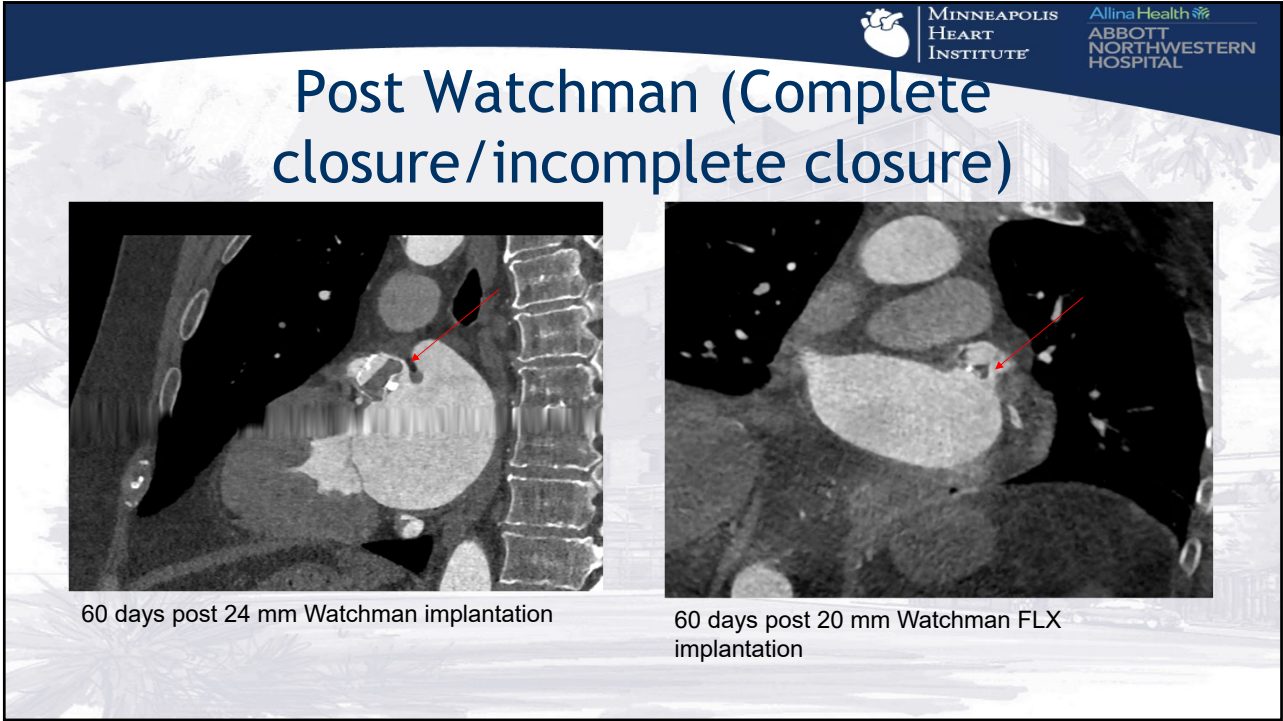
Conclusions

Cardiac computed tomography with a delayed imaging is a reliable alternative to TEE. It may save the patient and health care from an excess TEE.

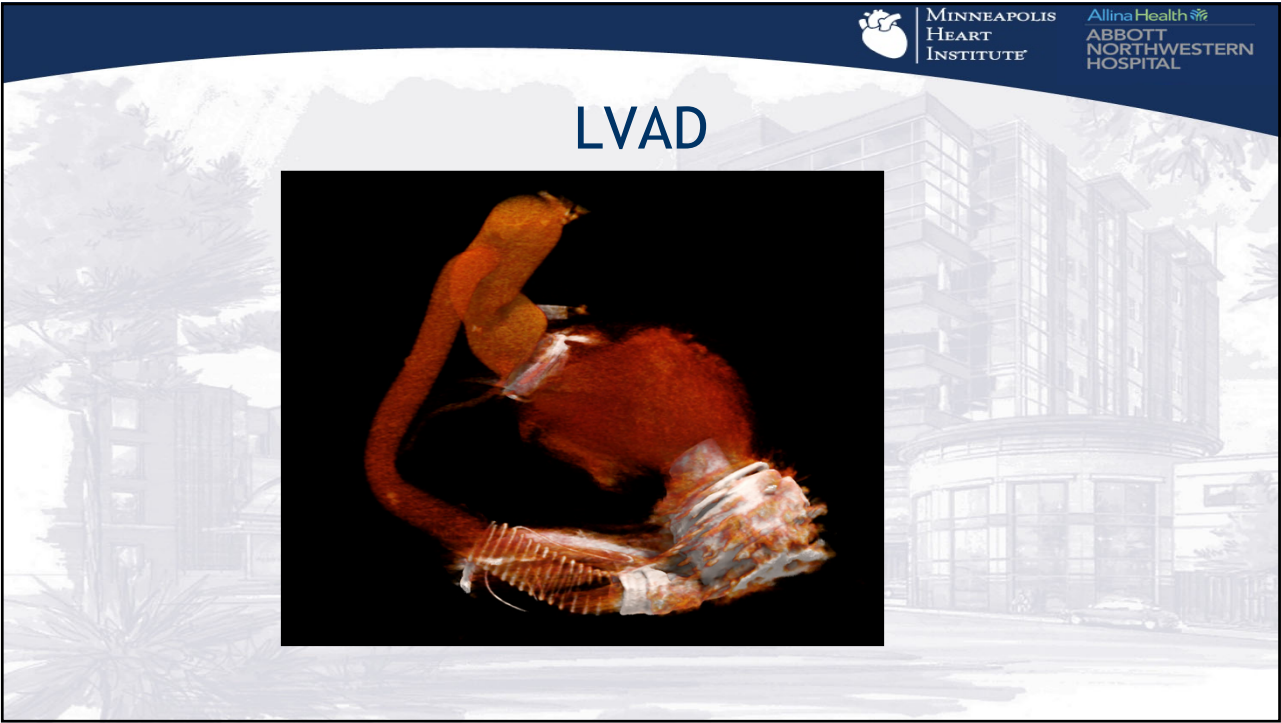
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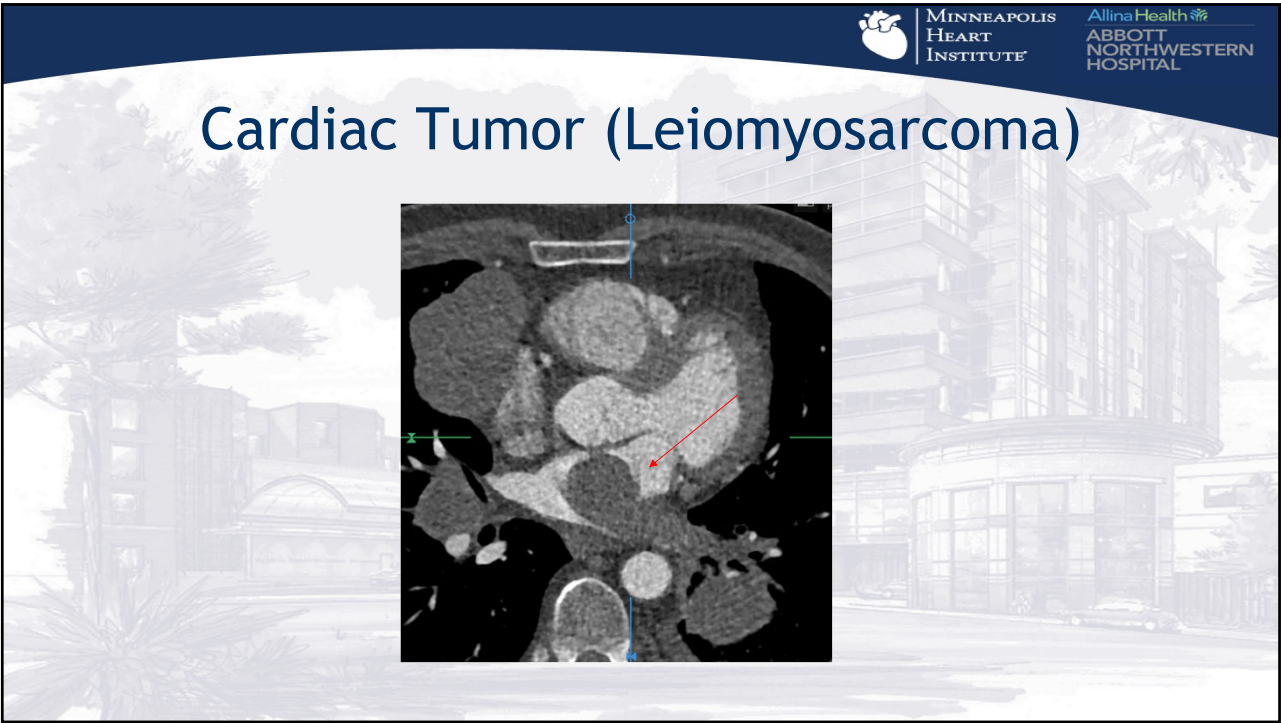
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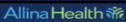
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Peripheral arterial disease



Severe peripheral arterial disease




EVAR




Subclavian artery stenosis

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New Scanners





Smaller detector pixels



Elimination of electronic noise



Intrinsic spectral sensitivity




Equal contribution of lower energy quanta




[NAEOTOM Alpha photon-counting CT scanner - Siemens Healthineers \(siemens-healthineers.com\)](https://www.siemens-healthineers.com)

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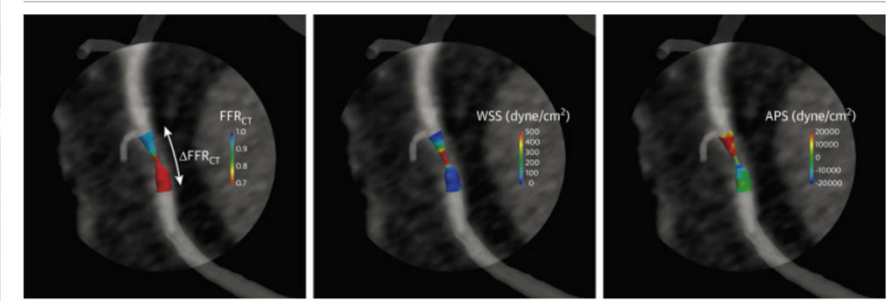


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Novel Applications




Beyond traditional coronary CFD parameters, EMERALD trial introduced additional CFD parameters for CT for the evaluation of coronary plaque and risk including: Delta fractional flow reserve computed tomography, Wall shear stress (WSS), Axial plaque stress (APS)

Nicole et al. The Future of Cardiovascular Computed Tomography. JACC Cardio Imag 2019
Lee et al. Identification of High-Risk Plaques Destined to Cause Acute Coronary Syndrome Using Coronary Computed Tomographic Angiography and Computational Fluid Dynamics. JACC Cardio Imag 2018

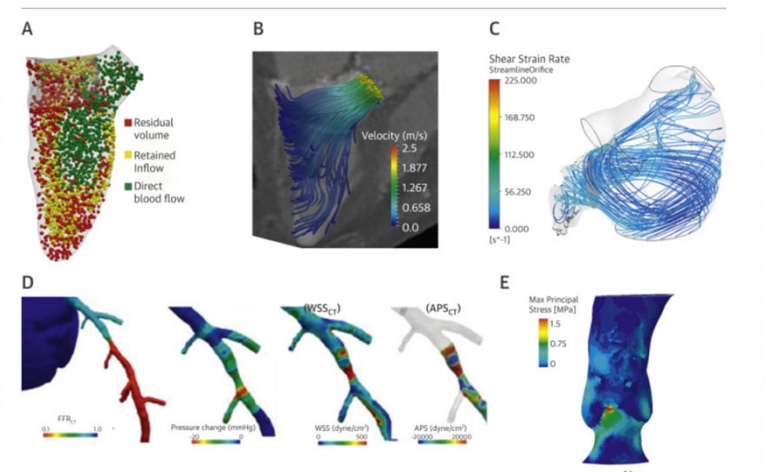
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Blood stasis analysis in the left ventricle post-TMVR with associated flow modelling
Left atrial computational flow dynamics used in modelling of LAA thrombus risk
Shear stress applications in the coronary arteries
Shear stress post TAVR in the aortic root

Lee et al. Identification of High-Risk Plaques Destined to Cause Acute Coronary Syndrome Using Coronary Computed Tomographic Angiography and Computational Fluid Dynamics. JACC Cardio Imag 2018

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Curved multiplanar reconstruction with a partially calcified plaque in the LAD. Radiomic analysis, voxels containing plaque are extracted from the image which are analyzed using novel analytic techniques, such as machine learning.

Lee et al. Identification of High-Risk Plaques Destined to Cause Acute Coronary Syndrome Using Coronary Computed Tomographic Angiography and Computational Fluid Dynamics. JACC Cardio Imag 2018

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A

Template LVED Point Cloud

Target LV Point Cloud, Later in RR cycle

Point Cloud matching by Coherent Point Drift yields Displacement Field and Strains

B

SQUEEZ Value

1.2

1.1

1.0

0.9

0.8

0.7

0% of RR End Diastole

15% of RR Mid Systole

35% of RR End Systole

A(0,0)

A(2,0)

A(1,35)

A(2,35)

$\frac{SQUEEZ(1,35)}{\sqrt{A(1,0)}} = 0.6$

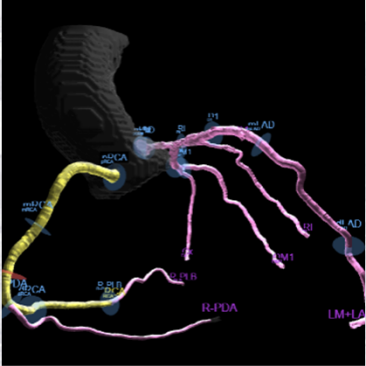
$\frac{SQUEEZ(2,35)}{\sqrt{A(2,0)}} = 1.0$

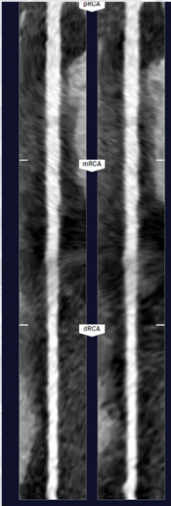
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Figure 6. Advanced Image Analyses Enabling Strain Analysis With CT

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AI plaque quantification

Clearly labs

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Our research on AI plaque analysis

Summary:
Control/Tracking Number: 2023-A-695-SCCT
Activity: Abstract
Current Date/Time: 4/29/2023 12:35:37 AM

Experienced Reader And Artificial-Intelligence Quantitative Computed Tomographic Differentiation Of Normal Coronary Arteries And Minimal Coronary Atherosclerosis: An Early Real-world Compatibility Study:

Author Block: Amr Idris, MD¹, Mahdi Hurreh, BS¹, Thomas Knickelbine, MD¹, James Earls, M¹, Melissa Aquino, MS¹, Victor Y. Cheng, MD¹,
¹Minneapolis Heart Institute, Minneapolis, MN, USA, ²George Washington Univ. School² Washington, DC, USA, ³Clearly Inc., Denver, CO, USA.

Abstract:
Introduction: Reader differentiation of normal from minimally diseased CTA is valuable, as the former portends very low coronary artery event risk. Artificial intelligence quantitative computed tomographic (AIQCT) prior to coronary artery plaque not achievable by manual means. When determined normal coronary arteries from minimally diseased arteries. We identified 503 consecutive patients (mean age 64.4, 49% women) without coronary artery stent or bypass graft who underwent coronary CT angiography (CCTA). AIQCT plaque analysis with reader-determined normal coronary arteries (P reader CAD-RADS 0) and minimal coronary artery stenosis (CAD-RADS 1) and 1 compared AIQCT results between R_{QCT} and AIQCT. Area-under-curve (AUC) analysis to derive a threshold for AIQCT to differentiate the 2 groups. **Results:** There were 116 R_{QCT} and 25 R_{AIQCT} cases. Mean plaque volume (mean 30.75 mm³ vs. 8.88 mm³ in R_{QCT} and 24.67 mm³ vs. 7.81 mm³ in R_{AIQCT}). AIQCT found 27/116 cases (23.3%) with AIQCT total plaque volume threshold was 15.3 mm³ with an AUC of 0.85. AIQCT identified 96/116 (82.8%) of R_{QCT} cases and ≥ 15.3 mm³ of R_{AIQCT} cases (Figure). **Conclusions:** AIQCT finds substantially higher total plaque volume in real-world minimally diseased coronary arteries compared to normal coronary arteries, promising compatibility with reader interpretation. Our exploratory analysis suggests AIQCT total plaque volume of < 15.3 mm³ may be consistent with reader-determined normal coronary arteries.

with atherosclerosis has been established as a standard for coronary artery disease (CAD) diagnosis. Artificial intelligence (AI) analysis automatically identifies higher segmental and artery atherosclerosis burden. We aimed to evaluate whether and to what extent AIQCT could be used in a single center clinical setting. We evaluated 503 consecutive patients (mean age 64, 49% women) without coronary artery stent or bypass graft who underwent coronary CT angiography (CCTA). AIQCT plaque analysis with reader-determined normal coronary arteries (P reader CAD-RADS 0) and minimal coronary artery stenosis (CAD-RADS 1) and 1 compared AIQCT results between R_{QCT} and AIQCT. An SIS score of > 4 was considered increased risk. AIQCT detected higher mean SIS (4.8 vs 3.8, p < 0.0001) than the clinical reader. SIS was consistent both when reader SIS was 0 (AIQCT 1.83) and when reader SIS was > 4 (AIQCT 5.78). AIQCT interpretation reclassified 70/503 (14.7%) of patients into a higher risk category. In patients in whom the reader found nonobstructive disease (n = 10/96 (10.4%)) in whom the reader found obstructive disease (≥ 1 segment with ≥ 50% diameter stenosis). **Conclusions:** AIQCT identifies higher plaque burden when using the conventional marker of SIS. This lead to a significant up re-classification of patient risk compared to conventional reader interpretation, with the effect most prominent in those with nonobstructive coronary arteries. The clinical implication of this difference needs further systematic evaluation.

Table 1: Comparison of AIQCT vs reader determined plaque and presence of obstructive disease

Reader determined	NONOBSTRUCTIVE				OBSTRUCTIVE			
	AIQCT determined segments with plaque				AIQCT determined segments with plaque			
	0	1 or 2	3 or 4	> 4	0	1 or 2	3 or 4	> 4
0	34	52	38	6	0	0	0	0
1 or 2	2	35	42	11	0	1	2	1
3 or 4	0	9	36	11	0	1	1	1
> 4	0	1	11	11	0	0	3	11

Reclassification Rate: 100% (24/24) 100% (24/24)

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Italian astronaut Luca Parmitano stands beside his space suit sitting under a medical imaging scanner

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MHI IMAGING!

- John Lesser
- Victor Cheng
- Joao Cavalcante
- Marc Newell
- Michael Miedema
- Thomas Knickelbine
- David Lin
- Erik Schelbert
- Jonathan Urbach

- David Caye
- Jana Lindberg
- Lynn Klitzke
- Tanya Owens
- Deanna Knutsen
- John Rosbolt
- Antonia Sylva
- Tara Schell
- Denise Hauptert
- Brad Adamski
- Rachel Copple
- Jenice Wirth

- Kristin Lambrecht
- Miho Fukui
- Hideki Koike

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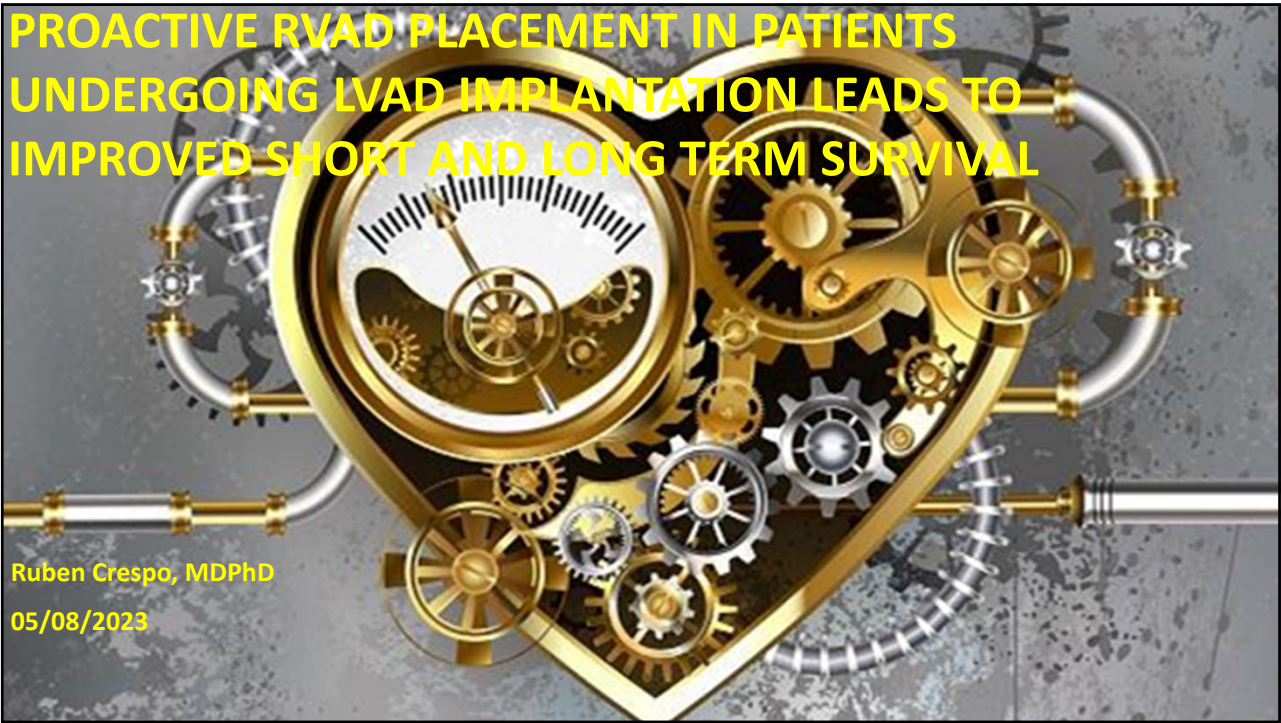
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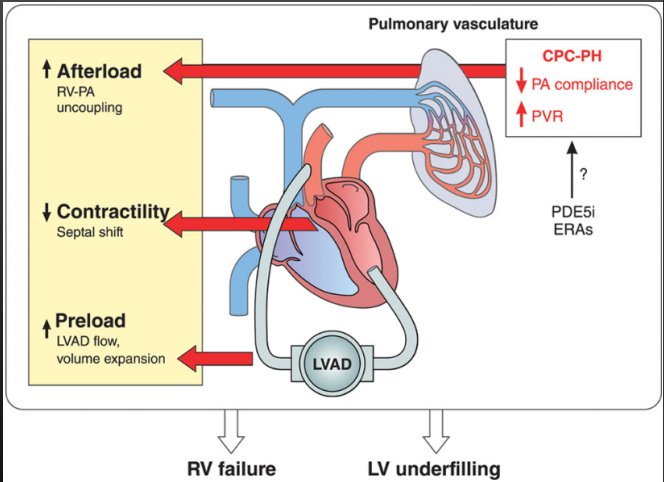
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INTRODUCTION

- Right Ventricular failure (RVF) occurs in approximately 20-40% of patients early after LVAD implantation
- In turn RVADs in this setting are required in 5-10% and 15-20% pts will still need inotropic therapies for RV failure following LVAD implantation
- The mechanisms of RV failure are multifaceted (figure on right)
- Risk scores and prediction models are unable to mitigate the need for RVAD following LVAD implantation



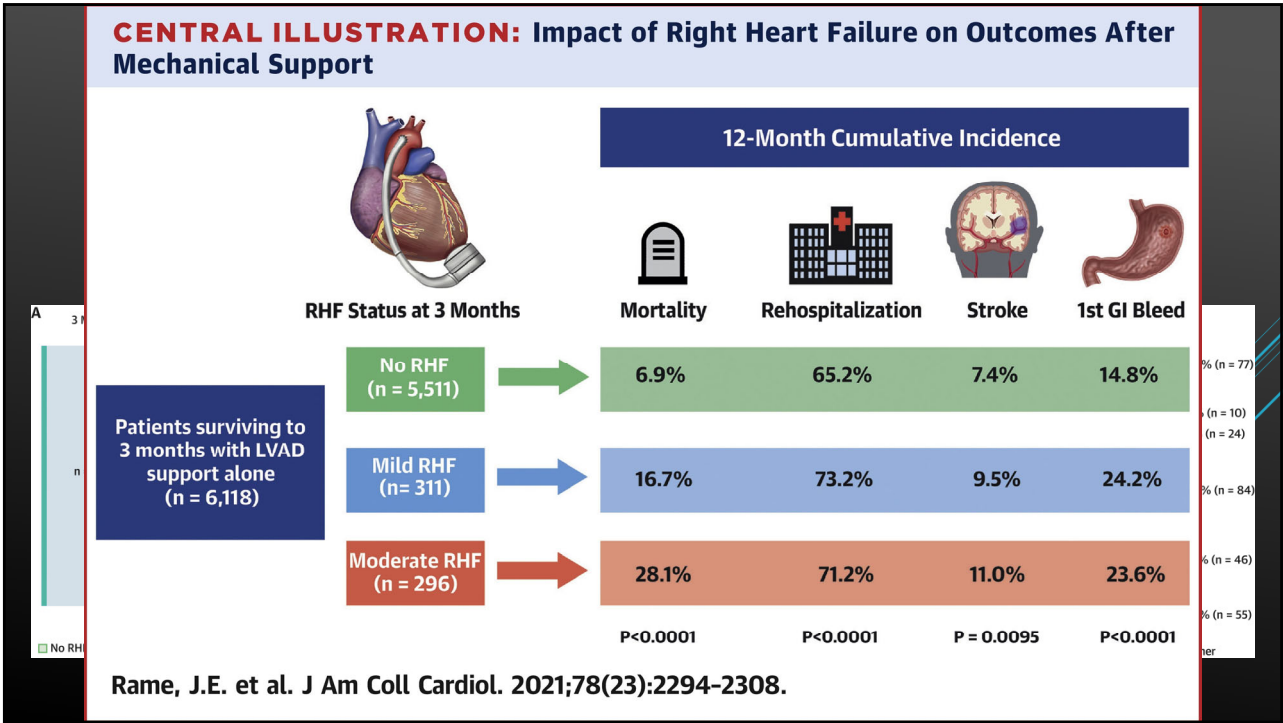
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INTERMACS (2015)	Definition	Must meet criteria 1 and 2						
		Criteria 1. Elevated CVP: CVP >16 mmHg OR dilated and fixed IVC OR JVP at half neck in upright position Criteria 2. Symptoms: peripheral edema ≥2+ OR ascites OR hepatomegaly OR bilirubin >2 mg/dl OR creatinine > 2 mg/dl						
	Severity	Mild		Moderate		Severe		Severe-acute
		Implant	Follow-up	Implant	Follow-up	Implant	Follow-up	Implant
		Inotropes, iNO or IV vasodilators <7 days	No readmissions AND no inotropes	Inotropes, iNO or IV vasodilators 7-14 days	1 readmission for IV diuretics or vasodilators AND no inotropes	Inotropes, iNO or IV vasodilators >14 days AND CVP >16 mmHg	Use of inotropes OR RVAD OR ≥2 readmissions for IV diuretics or vasodilators OR death due to RVF	CVP >16 mmHg AND RVAD use OR death due to RVF
MCS-ARC INTERMACS (2021)	Definition	At least 2: peripheral edema ≥2+ OR ascites OR JVP at half neck in upright position OR CVP >16 mmHg OR at least 1: bilirubin >2 mg/dl OR AST/ALT x2 ULN OR creatinine x2 baseline OR Svo2 <50% OR CI <2.2 l/min/m2 OR lactate >3 mmol/l OR drop >30% in pump flow						
	Timing	Early acute		Early		Late		
		Need for temporary or durable RVAD (or ECMO) implanted in the operating room		1) Need for RVAD within 30 days 2) Failure to wean from inotropes, vasopressors or iNO for >14 days during the initial 30 days 3) Death within 14 days while on inotropes or pressors in patients who have not received RVAD		1) Need for RVAD 30 days after LVAD implant 2) Admission at least 30 days after LVAD implant requiring IV diuretics or inotropes for >72h		

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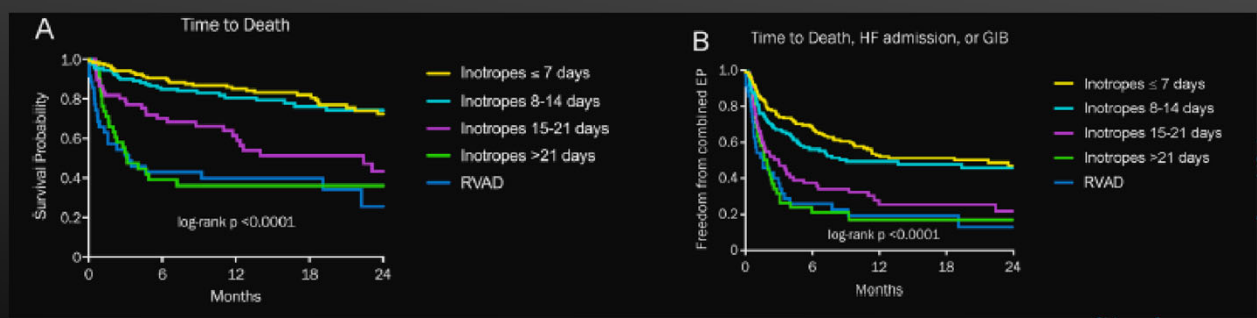


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CLINICAL OUTCOMES ASSOCIATED WITH INTERMACS-DEFINED RIGHT HEART FAILURE AFTER LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION



Larue JHLT 2017

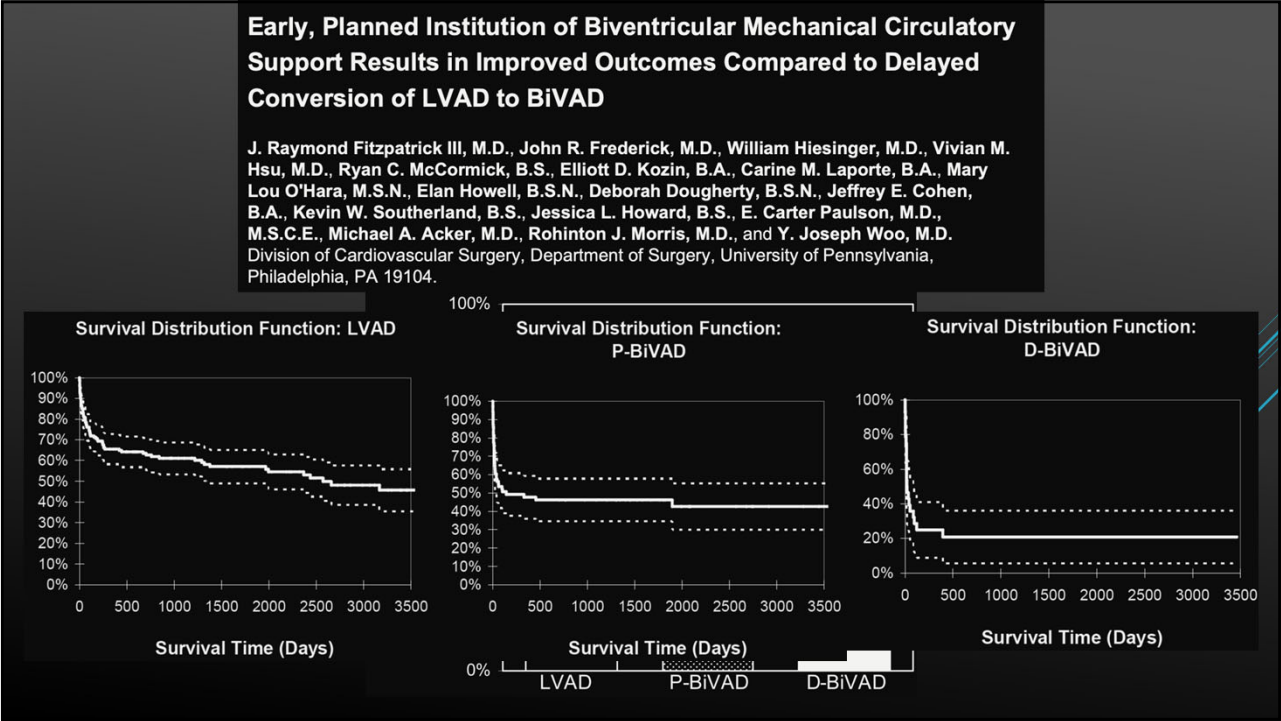
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2019 EACTS Expert Consensus on long-term mechanical circulatory support

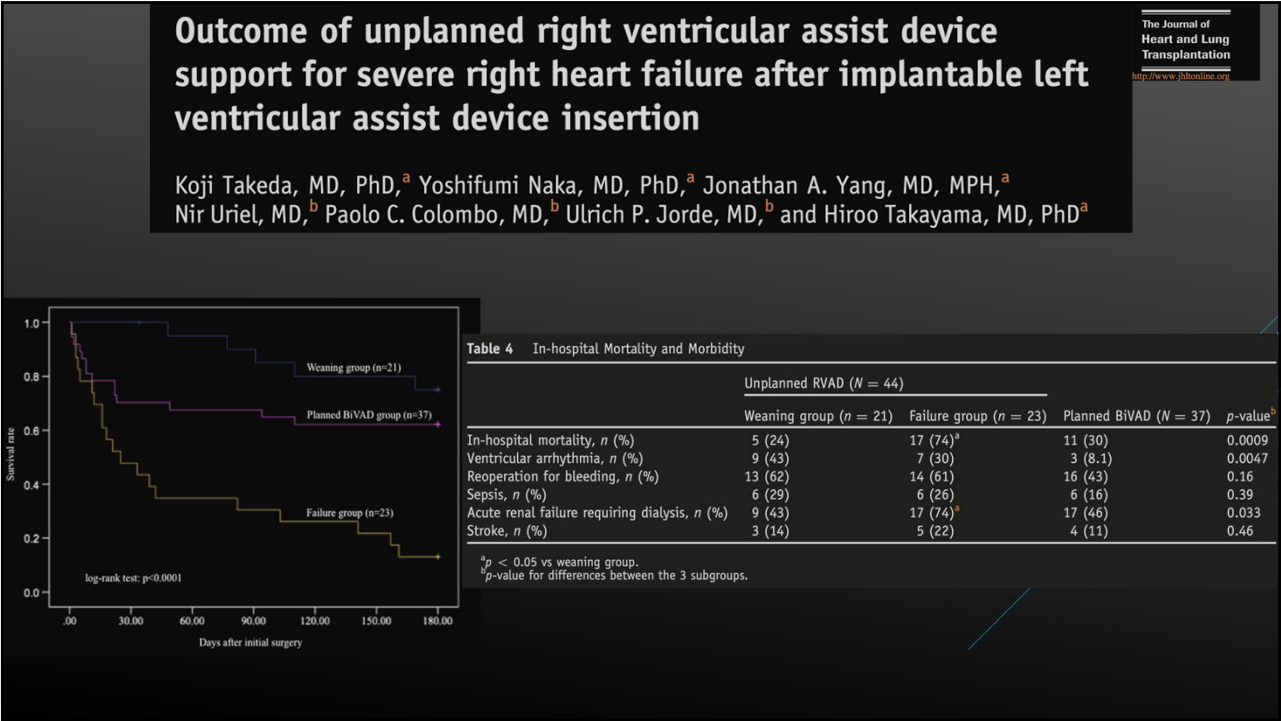
Evgenij V. Potapov^{a,*†} (EACTS Chairperson), Christiaan Antonides^{b,†},
Maria G. Crespo-Leiro^c, Alain Combes^{d,e}, Gloria Färber^f, Margaret M. Hannan^g, Marian Kukucka^h,
Nicolaas de Jongeⁱ, Antonio Loforte^j, Lars H. Lund^k, Paul Mohacsi^l, Michiel Morshuis^m, Ivan Netukaⁿ,
Mustafa Özbaran^o, Federico Pappalardo^p, Anna Mara Scandroglio^q,
Martin Schweiger^r, Steven Tsui^s, Daniel Zimpfer^t and Finn Gustafsson^{u,*} (EACTS Chairperson),
The Task Force on Long-Term Mechanical Circulatory Support of the EACTS

Recommendation	Class	Level	References
For predicting right heart failure, the use of clinical, haemodynamic, echocardiographic and biochemical parameters should be considered.	IIa	C	[170–174]
In patients with refractory right heart failure after implantation of an LVAD, early implantation of a temporary RVAD should be considered.	IIa	C	[147, 168, 169, 171, 179]
Early RVAD implantation in case of right heart failure to decrease morbidity and mortality should be considered.	IIa	C	[147, 168, 169, 171, 179, 186]

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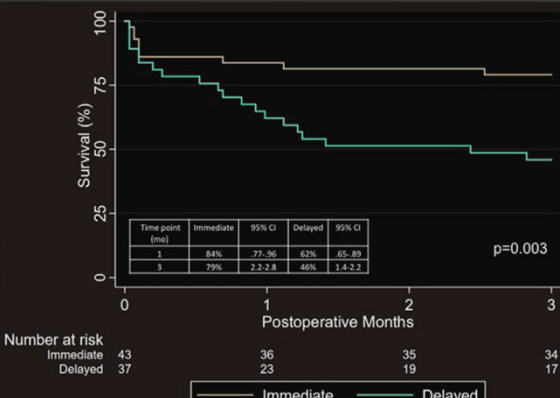
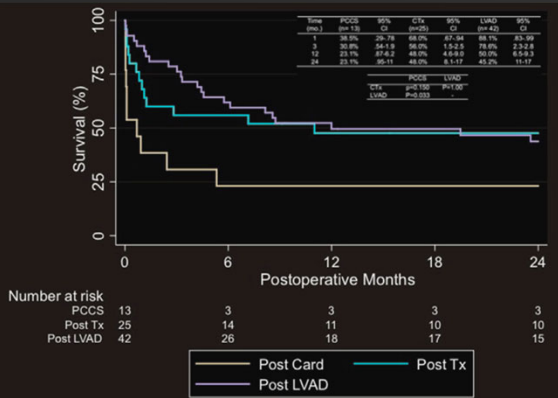
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Clinical experience with temporary right ventricular mechanical circulatory support

Jay K. Bhamra, MD,^a Utsav Bansal, BS,^b Daniel G. Winger, MS,^c Jeffrey J. Teuteberg, MD,^d Christian Bermudez, MD,^c Robert L. Kormos, MD,^d and Aditya Bansal, MD^f



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Inhaled nitric oxide after left ventricular assist device implantation: A prospective, randomized, double-blind, multicenter, placebo-controlled trial

105 patients randomized to receive 40ppm NO vs placebo at time of weaning from bypass

Use of iNO at 40 ppm given before separation from CPB did not reach statistical significance for the primary end point of reduction in RVD incidence. No statistically significant difference was found for secondary variables, including time on mechanical ventilation, ICU or hospital stay, and the need for RVAD after LVAD placement.

Table 5 Primary and Secondary Outcome Measures in the Intent-to-Treat Population			
Outcome Measure	iNO	Placebo	p-value
Patients meeting RVD criteria ≤48 hours			0.330
No. of total (%)	7/73 (9.6)	12/77 (15.6)	
95% CI	2.8-16.3	7.5-23.7	
Males, No. (%)	7/64 (10.9)	7/65 (10.8)	>0.99
Females, No. (%)	0/9 (0.0)	5/12 (41.7)	0.045
PVRI <270.5 dyne/sec/cm ⁻⁵	6/51 (11.8)	6/48 (12.5)	>0.99
PVRI ≥270.5 dyne/sec/cm ⁻⁵	1/7 (14.3)	5/7 (71.4)	0.103
Days on mechanical ventilation ^a	70	67	0.077
Mean (SD)	5.37 (7.72)	11.10 (24.81)	
Median (range)	2.0 (1-30)	3.0 (0-160)	
No. of ICU days ^b	60	58	0.630
Mean (SD)	20.52 (32.31)	19.90 (24.38)	
Median (range)	11.0 (3-194)	9.0 (3-115)	
No. of total hospital days ^c	58	58	0.979
Mean (SD)	40.57 (32.19)	40.76 (29.41)	
Median (range)	32.0 (11-194)	31.5 (10-156)	
Quantity of blood products used	73	77	
Mean, ml (SD)	4,232 (4675)	4,885 (7760)	0.226
Patients requiring RRT, No. (%) ^d	10/71 (14.1)	8/70 (11.4)	0.622
Non-survival at Day 28, No. (%)	8/71 (11.3)	8/70 (11.4)	0.924
Patients needing RVAD by Day 28, No. (%)	4/71 (5.6)	7/70 (10.0)	0.468

J Heart Lung Transplant 2011;30:870-8

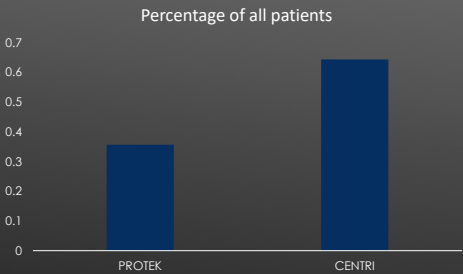
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OUR CENTER DATA

- ▶ Retrospectively evaluated 75 adult patients underwent LVAD and temporary RVAD insertion
- ▶ RVAD was either a planned procedure during LVAD surgery or a bailout strategy after LVAD placement (patient left the OR)
- ▶ Evaluated several factors such as: presence of temporary mechanical support (MCS) prior to LVAD insertion, echocardiography-based RV function and invasive hemodynamic data
- ▶ Patient demographics and clinical characteristics were compared along with 3-month, 6-month and 1-year survival.

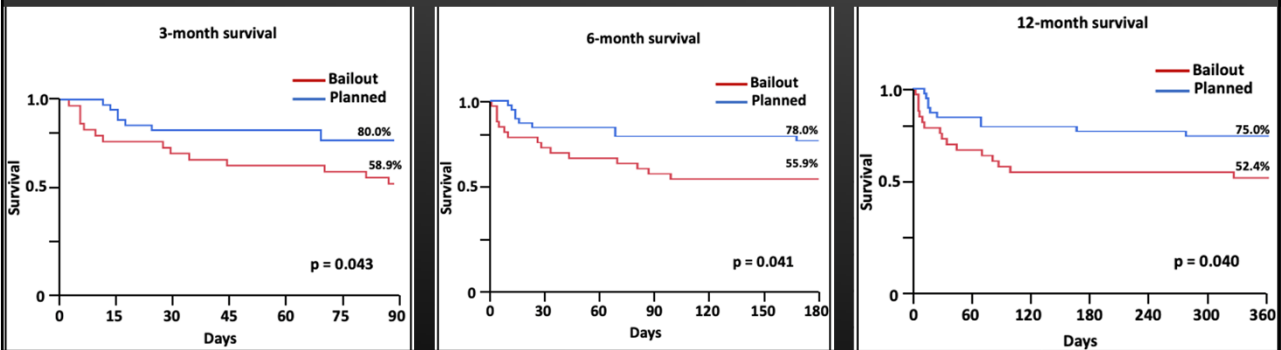
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Characteristic	Bailout (n=35)	Planned (n=40)	p
Age, (years)	57.5 ± 21.2	59.8 ± 19.4	0.67
Male, (%)	67.7	75	0.50
Female, (%)	32.3	25	
BMI, (kg/m ²)	31.0 ± 9.46	30.4 ± 10.6	0.34
CKD, (%)	58.9	52.5	0.44
DM, (%)	32.4	42.5	0.37
CAD, (%)	61.8	70.0	0.46
INTERMACS, (%)			
1-2	64.7	90.0	0.02*
3-5	32.4	10	
6-7	2.94	0	
Pre-LVAD MCS, (%)	58.2	80.0	0.047*
ICM, (%)	38.2	40.0	0.37
NICM, (%)	52.9	42.5	
Mixed, (%)	8.82	17.5	
LVEF, (%)	18.1 ± 8.7	14.4 ± 8.7	0.03*
LVIDd, (cm)	6.90 ± 1.17	6.29 ± 1.47	0.13
Visual RV function, (%)			0.007*
Normal	34.4	10.3	
Mildly reduced	40.6	23.1	
Moderately reduced	18.8	33.3	
Severely reduced	6.20	33.3	
TAPSE, (cm)	1.52 ± 0.58	1.44 ± 0.67	0.38
PAPi score	1.29 ± 1.46	1.7 ± 1.32	0.68
RVAD duration, (days)	10.0 ± 9.50	10.0 ± 10.0	0.72
Days of intubation	19.8 ± 16.2	16.8 ± 14.4	0.53
ICU stay, (days)	28.4 ± 17.1	25.5 ± 12.5	0.69



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OUTCOMES



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RESULTS

- ▶ Baseline characteristics were not significantly different between bailout versus planned RVAD strategy
- ▶ Patients with a planned RVAD had lower INTERMACS score and a higher proportion of temporary MCS preoperatively
- ▶ Although the Tricuspid Annular Plane Systolic Excursion (TAPSE), there was an increased percentage of patients with visually moderate to severe RV dysfunction in the planned RVAD group
- ▶ Invasive hemodynamic comparison between the groups were not statistically significant
- ▶ Length of RVAD duration, Intensive Care Unit (ICU) stay and intubation time were also not different
- ▶ Survival was greater at 3-month, 6-month and 12-months when RVAD placement was planned instead of bailout (right panel).

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Percutaneous RVAD to Preemptively Treat Right Heart Failure Post-LVAD

Protocol 2020P000422 / NCT04458103



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III. SPECIFIC AIMS

The purpose of this study is to compare clinical outcomes of standard of care treatment versus preemptive percutaneous right ventricular assist device (RVAD) placement surrounding left ventricular assist device (LVAD) implantation. We hypothesize that the use of the RVAD will mitigate need for inotropic support, reducing the vasoactive-inotrope score (VIS) by 50%, and will improve end organ function in patients compared to standard of care.

IV. SUBJECT SELECTION

This trial will include both a prospective interventional cohort and a retrospective control cohort. The prospective interventional cohort will consist of patients undergoing LVAD implantation at Massachusetts General Hospital. These patients will receive an RVAD (either the ProtekDuo or Impella RP) prior to or during LVAD implantation. The historical control cohort will consist of retrospective data collection on patients who have undergone LVAD implantation in the past. This group will be age and sex matched with the enrolled prospective interventional patients.

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THANK YOU

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