GRAND ROUNDS

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Demographic and Clinical Characteristics of Patients Enrolled in a Non-Academic Multidisciplinary Cardio-Obstetrics Program

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Disclosures

- None

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Background

- Cardiovascular disease (CVD) is the leading cause of maternal death. Maternal mortality has steadily increased in the US. More than 60% of deaths due to CVD are preventable.

- Due to both maternal and fetal risk, it is recommended for women with CVD to be treated in specialized cardio-obstetrics (CVOB) teams.

- In 2018, a non-academic multidisciplinary cardio-obstetrics program was formed at a Midwest hospital system.

- We describe the demographic and clinical characteristics of patients enrolled in a non-academic multidisciplinary CVOB specialty program compared to standard of care.

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Cardio-Obstetrics Program

- Cardiologists and Maternal Fetal Medicine (MFM) specialists work together to provide evidence-based care to pregnant women with new or pre-existing CVD or CVD symptoms.
- All patients have an RN Care Coordinator; most visits are conducted with multi-disciplinary providers (e.g., cardiology, perinatology, pharmacy).
- Program components: Preconception counseling, risk stratification, prenatal care, development of a collaborative individualized pregnancy and birth plan, and coordinated postpartum care.
- All cases are presented at conference prior to delivery and postpartum planning.

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Hypothesis

Women seen by the CVOB program will have higher CVD risk profiles compared to pre-program controls

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Methods

- A retrospective chart review was conducted of 113 patients who received care from the CVOB program in 2018/2019 as well as 338 pregnant women seen by cardiology in 2016/2017 prior to the program's inception.
- Data on demographics, cardiovascular disease status/co-morbidities, risk predictor scores, tobacco and substance use, and medication use were collected.
- CVD risk profile was measured using the CARPREG2 risk index, and the modified World Health Organization (mWHO) classification system for pregnant women.

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Demographics and clinical characteristics of women enrolled in the CVOB program and historical comparisons

	CVOB 2018-2019 (n=113)	Comparison 2016-2017 (n=338)
mWHO, n (%)*		
none	10 (9)	156 (46)
I	15 (13)	67 (20)
II	24 (21)	59 (17)
II-III	37 (33)	29 (9)
III	22 (19)	19 (6)
IV	5 (5)	8 (2)
Carpreg2, n (%)*		
0	56 (49)	218 (65)
1	0	22 (7)
2	12 (11)	11 (3)
3	38 (34)	69 (21)
4+	7 (6)	16 (4)
Missing	0	2

$* p < 0.01, ** p < 0.05$

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Demographics and clinical characteristics of women enrolled in the CVOB program and historical comparisons

	CVOB 2018-2019 (n=113)	Comparison 2016-2017 (n=338)
Comorbidities, n (%)		
CAD	2 (2)	5 (2)
HTN	21 (19)	40 (12)
Hyperlipidemia	4 (4)	6 (2)
Cerebrovascular disease	3 (3)	5 (2)
Renal Disease**	4 (4)	1 (0.3)
Pulmonary HTN	0	0
Heart Failure	3 (3)	3 (1)
Cardiac Arrest	1 (1)	4 (1)
Aortic Dissection	1 (1)	0
Cardiac Valve Insufficiency*	17 (15)	13 (4)
Cardiac Valve Stenosis*	14 (12)	13 (4)

* p < 0.01, ** p <0.05

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Demographics and clinical characteristics of women enrolled in the CVOB program and historical comparisons

	CVOB 2018-2019 (n=113)	Comparison 2016-2017 (n=338)
Parity, n (%)		
0	41 (36)	126 (38)
1	41 (36)	98 (29)
2+	31 (28)	114 (33)
Age, mean(SD)	30.0 (5.5)	30.6 (5.3)
Race, n (%)**		
American Indian	2 (2)	2 (1)
Asian	5 (5)	14 (4)
Black or African American	21 (19)	57 (17)
Multiracial	9 (8)	7 (2)
White	73 (66)	254 (76)
Missing	3	4
Ethnicity, % Hispanic	6 (5)	15 (4)

* p < 0.01, ** p <0.05

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Demographics and clinical characteristics of women enrolled in the CVOB program and historical comparisons

	CVOB 2018-2019 (n=113)	Comparison 2016-2017 (n=338)
Medications prior to pregnancy, n (%)		
Anticoagulation	8 (7)	10 (3)
Anti-cholesterol	1 (0.9)	7 (2.1)
Anti-platelet	8 (7)	21 (6)
Anti-hypertensive	24 (21)	72 (21)
Antiarrhythmic	4 (3.5)	5 (1.5)
Antidepressant	22 (19)	57 (17)
Medications during pregnancy, n (%)		
Anticoagulation	6 (5)	9 (3)
Anti-cholesterol	0	3 (0.9)
Anti-platelet*	30 (27)	29 (9)
Anti-hypertensive*	40 (35)	61 (18)
Antiarrhythmic	5 (4.4)	6 (1.8)
Antidepressant	19 (17)	43 (13)

* $p < 0.01$, ** $p < 0.05$

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Results

- CVOB patients were more racially diverse (34% nonwhite vs 24% in the comparison group)
- There was no difference with regard to parity, age, or Hispanic ethnicity.
- CVOB group had higher rates of valvular heart disease (27% vs 8%)
- CVOB patients had higher CVD risk scores based on mWHO and CARPREG2
- Antiplatelet and antihypertensive use was higher during pregnancy among CVOB patients

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Conclusions

- Guidelines recommend multidisciplinary CVOB management for women with heart disease and pregnancy
- The CVOB group referral was less than ½ of the prior year's referral to cardiology in pregnancy.
- The CVOB group patients were those who were at higher risk, however, utilization of the program could be increased in all risk categories as a CVOB program model may have the potential to improve health related outcomes.

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Changes in Clinical Outcomes for Patients Enrolled in a Non-Academic Multidisciplinary Cardio-Obstetrics Program

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Results

Women who received care in the CVOB program:

- Had more cardiology tests during pregnancy relative to pre-program controls (median of 8 tests vs 5; $p < 0.001$).
- Experienced ½ day longer LOS (median of 2.66 vs 2.13 days; $p = 0.006$) for vaginal deliveries.
- Had more telemetry during pregnancy and were more likely to see a perinatologist postpartum.
- Were less likely to have inpatient or ED visits in the 6 months postpartum (34% vs 71%; $p < 0.001$).

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Conclusions

- CVOB patients were more closely monitored by cardiology and MFM during pregnancy as well as postpartum (i.e. more tests, telemetry, longer LOS).
- In a multidisciplinary, non-academic CVOB program, coordination of care and monitoring during pregnancy may have contributed to fewer postpartum emergency visits and readmissions.

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Adverse Events Associated with AV Node Ablation in Patients with an Implanted Leadless Pacemaker

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Disclosures

Robert G. Hauser MD: Cardiac Insight Inc, Scientific Advisory Board

Susan A. Casey RN: None

Elizabeth A. Steele MS: None

Jay D. Sengupta MD: None

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Introduction

- AV node ablation (AVA) is performed in 5-10% of patients who have or are undergoing leadless pacemaker (LPM) implantation.

- Data from the Micra™ Transcatheter Pacing (IDE) Study, Continued Access study, and Post-Approval Registry showed that concomitant AVA + LPM implantation is feasible, but the risk of major complications and need for system revision was higher than with LPM implantation alone.

- Recently, we reported our analysis of adverse events (AE) associated with Micra LPM implantation based on information obtained from the Food and Drug Administration (FDA) Manufacturers and User Facility Device Experience (MAUDE) database. Included were AEs that occurred during concomitant or staged AVA and LPM implantation.

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His bundle recording/RF ablation | Complete heart block/Micra pacing RV

Ho & Prutkin HRJ 2017
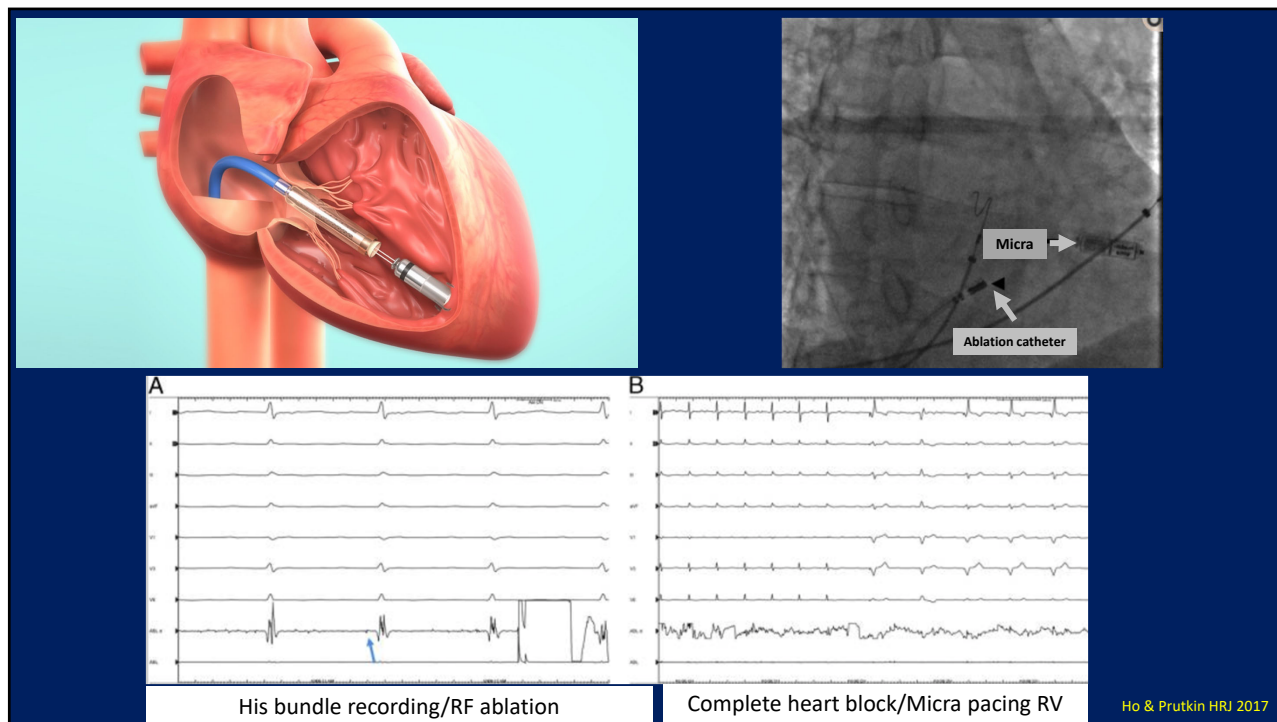
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Hypothesis

Concomitant or staged Micra™ LPM implantation and AVA may result in serious adverse events or malfunctions due to increased pacing thresholds, exit block, or interference with the pacemaker's electronics.
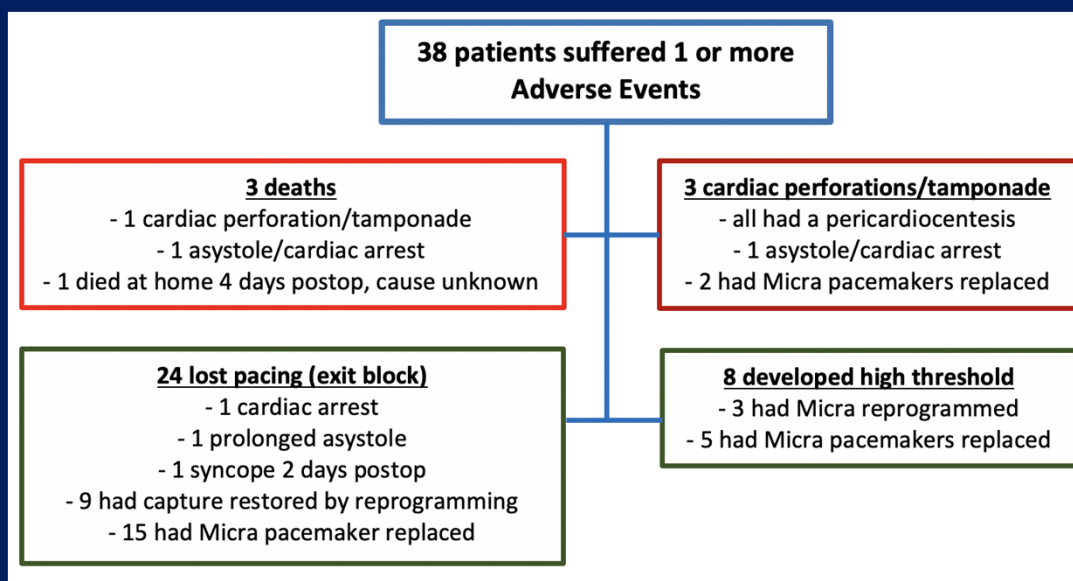
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Methods

- The FDA MAUDE database was searched for "Micra and ablation" adverse events from 2016-October 2021 using Basil Systems software.

- Duplicate reports and reports from sources other than the manufacturer were excluded.

- Data were extracted from event descriptions and the manufacturer's narratives.

- 28 patients had AV node ablation at the time of Micra implant, and 15 patients had ablation done 1-2 days after implant.

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Results

38 patients suffered 1 or more Adverse Events

3 deaths
- 1 cardiac perforation/tamponade
- 1 asystole/cardiac arrest
- 1 died at home 4 days postop, cause unknown

3 cardiac perforations/tamponade
- all had a pericardiocentesis
- 1 asystole/cardiac arrest
- 2 had Micra pacemakers replaced

24 lost pacing (exit block)
- 1 cardiac arrest
- 1 prolonged asystole
- 1 syncope 2 days postop
- 9 had capture restored by reprogramming
- 15 had Micra pacemaker replaced

8 developed high threshold
- 3 had Micra reprogrammed
- 5 had Micra pacemakers replaced

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Results 3

- <u>4</u> Micras could not be interrogated temporarily, including one where electromagnetic interference (EMI) from the ablation system appeared to be the cause.

- <u>1</u> Micra's automatic threshold test feature malfunctioned.

- <u>No</u> permanent Micra malfunctions or damage were identified.

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Conclusions

1. AV node ablation during or shortly after leadless pacemaker implantation may cause exit block or high thresholds, and result in serious adverse events and need for pacemaker replacement.
2. While ablation may not cause permanent leadless pacemaker damage, it may temporarily interfere with pulse generator communication and diagnostics.
3. The incidence of complications in patients undergoing concomitant or staged leadless pacemaker and AV node ablation is unknown; studies are needed to determine when and how ablation can be performed safely.

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Use Of Mechanical Circulatory Support In Chronic Total Occlusion Percutaneous Coronary Intervention: Insights From The PROGRESS-CTO Registry

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Disclosures

I, **Judit Karacsonyi** DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

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Background

The use of mechanical circulatory support (MCS) in complex percutaneous coronary intervention (PCI) is the subject of ongoing investigation, but the role of MCS in chronic total occlusion (CTO) PCI is not well studied

Danek et al. : Elective MCS in 4% of CTO-PCI, in high-risk patients is associated with similar technical and procedural success rates, but higher risk of complications
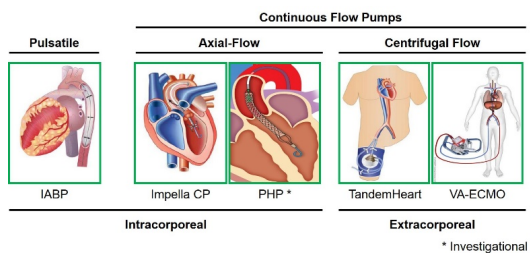
J Invasive Cardiol 2018 Mar;30(3):81-87
Interventional Cardiology Review 2017;12(1 Suppl 1):10-13.

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Goals

- To examine the frequency, outcomes and predictors of mechanical circulatory support (MCS) in chronic total occlusion (CTO) percutaneous coronary intervention (PCI)

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Methods

- **DESIGN**: Prospective, multi-center observational registry

  PROGRESS CTO registry

- **STUDY POPULATION**: 8718 patients enrolled between 2012 and 2020 in 35 international centers

- **ANALYSES PLANNED**:
  - Determine the frequency, outcomes and predictors of MCS
  - Compare baseline clinical, angiographic characteristics and clinical outcomes of cases with MCS to cases without MCS

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Statistical analyses

- **Categorical variables were expressed as percentages and were compared using Pearson's chi-square test or the Fisher exact test. Continuous variables are presented as mean ± SD or as median (interquartile range [IQR]) and were compared using the Student's t-test and the Wilcoxon rank sum test and as appropriate.**

- **All statistical analyses were performed using JMP version 13.0 (SAS Institute, Cary, NorthCarolina).**

- **A 2- sided p value of 0.05 was considered to indicate statistical significance.**

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Results

8718 patients enrolled between 2012 and 2020 in 35 international centers

1,795 cases excluded with no information on MCS use

7,171 CTO PCIs with information on MCS use

310 cases (4.32%) with MCS use

6861 cases (95.68%) with no MCS not used
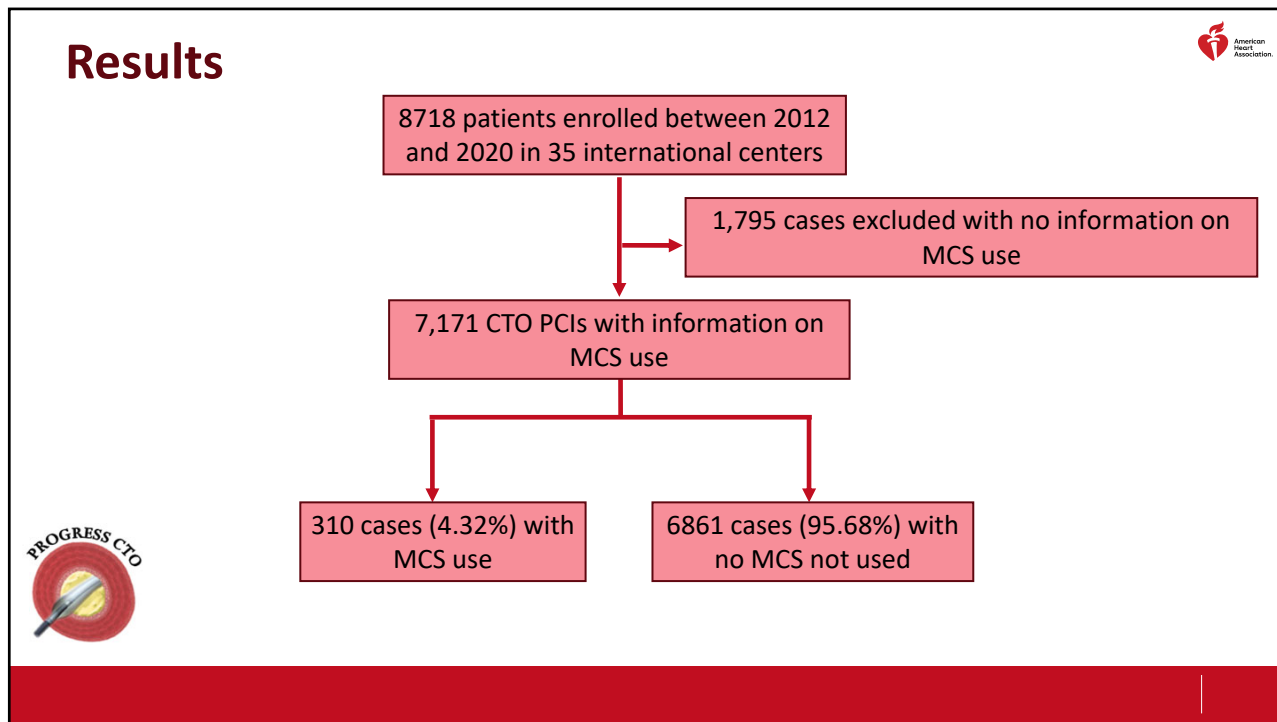
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Results: Baseline clinical characteristics I.

Variable	MCS used (n= 310)	MCS not used (n= 6861)	P value
Age (years)[a]	66.7 ± 10	64.4 ± 10	<.0001
Men	263 (85.4%)	5538 (81.3%)	0.069
BMI (kg/m2)[a]	29.4 ± 6	30.6 ± 8	0.002
Diabetes Mellitus	153 (51.0%)	2837 (42.4%)	0.003
Hypertension	267 (87.5%)	6048 (90.0%)	0.174
Dyslipidemia	286 (93.8%)	5871 (87.2%)	0.001
LVEF (%)[a]	34.0 ± 15	51.0 ± 12	<.0001
Family History of CAD	75 (31.8%)	1900 (31.9%)	0.981
Congestive Heart Failure	183 (60.6%)	1835 (27.9%)	<.0001
Prior Myocardial Infarction	151 (52.3%)	2923 (45.3%)	0.020

a: mean ± standard deviation; b: median (interquartile ranges), BMI: Body Mass Index, LVEF: Left Ventricular Ejection Fraction, CAD: Coronary Artery Disease

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Results: Baseline clinical characteristics II.

Variable	MCS used (n= 310)	MCS not used (n= 6861)	P value
Prior CABG	108 (35.3%)	1947 (29.1%)	0.020
Prior CVD	46 (15.2%)	669 (10.1%)	0.004
Prior PVD	53 (17.4%)	919 (13.8%)	0.076
Clinical presentation			
▪ Stable angina	146 (48.7%)	4474 (67.4%)	<0.001
▪ Unstable angina	61 (20.3%)	994 (15.0%)	
▪ NSTEMI	64 (21.3%)	528 (8.0%)	
▪ STEMI	10 (3.3%)	81 (1.2%)	
▪ Non-ischemic symptoms	6 (2.0%)	167 (2.5%)	
▪ No symptoms	13 (4.3%)	398 (6.0%)	

CABG: Coronary Artery Bypass Graft Surgery, CVD: Cerebrovascular Disease, PVD: Peripheral Vascular Disease, NSTEMI: non ST Segment Elevation Myocardial Infarction

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Angiographic characteristics I.

Variable	MCS used (n= 310)	MCS not used (n= 6861)	P value
CTO Target Vessel			
▪ RCA	35 (58.3%)	3456 (52.8%)	
▪ LAD	11 (18.3%)	1705 (26.0%)	
▪ Left Circumflex Coronary	12 (20.0%)	1264 (19.3%)	0.525
▪ LM	0 (0%)	7 (0.1%)	
▪ Other	1 (1.7%)	26 (0.4%)	
J-CTO score [a]	3.50 ± 0.90	2.39 ± 1.27	<0.001
Progress CTO score [a]	1.53 ± 1.10	1.18 ± 1.00	0.014

a: mean±standard deviation, RCA: Right Coronary Artery, LAD: Left Anterior Descending Coronary Artery, LCX: Left Circumflex Coronary, LM: Left Main, J-CTO: Japan CTO score

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Angiographic characteristics II.

Variable	MCS used (n= 310)	MCS not used (n= 6861)	P value
Calcification (moderate/severe)	218 (70.3%)	3028 (44.1%)	<0.001
Proximal vessel tortuosity (moderate/severe)	123 (39.7%)	1898 (27.7%)	<0.001
Proximal cap ambiguity	134 (45.7%)	2196 (34.0%)	<0.001
In-stent restenosis	10 (17.5%)	1093 (16.8%)	0.882
Side branch at the proximal cap	29 (9.97%)	1093 (16.8%)	0.002
Vessel diameter (mm)[b]	3.0 (2.5, 3.5)	3.0 (2.5, 3.0)	0.057
Occlusion length (mm)[b]	30 (20, 50)	25 (15, 40)	<0.001
Number of stents used	2.8 ± 1.2	2.3 ± 1.1	<0.001

b: median (interquartile ranges)

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Procedural characteristics

Variable	MCS used (n= 310)	MCS not used (n= 6861)	P value
Successful Crossing Strategy			
▪ Antegrade wiring	123 (39.9%)	3778 (55.3%)	
▪ Retrograde	111 (36.0%)	1228 (18.0%)	<.0001
▪ Antegrade dissection and re-entry	36 (11.7%)	916 (13.4%)	
▪ None	38 (12.3%)	907 (13.3%)	
First Crossing Strategy			
▪ Antegrade wiring	213 (68.9%)	5734 (83.9%)	
▪ Retrograde	83 (26.9%)	770 (11.3%)	<.0001
▪ Antegrade dissection and re-entry	12 (3.9%)	269 (3.9%)	
Retrograde crossing strategy	161 (51.9%)	2058 (30.0%)	<.0001
ADR crossing strategy	76 (24.5%)	1502 (21.9%)	0.275

ADR: Antegrade Dissection and Reentry

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Procedural outcomes

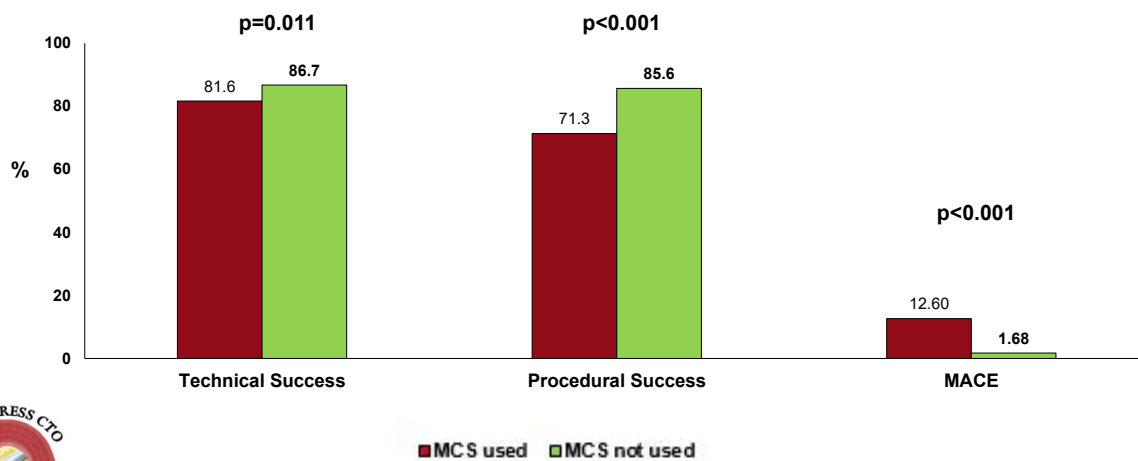| Variable	MCS used (n= 310)	MCS not used (n= 6861)	P value
Technical Success	253 (81.6%)	5945 (86.7%)	0.011
Procedural Success	221 (71.3%)	5870 (85.6%)	<.0001
MACE	39 (12.6%)	115 (1.68%)	<.0001
Procedural Success	221 (71.3%)	5870 (85.6%)	<.0001
Procedure time (min)[b]	212 (157, 270)	113 (74, 167)	<.0001
Fluoroscopy time (min) [b]	71 (52, 105)	41 (25, 67)	<.0001
Air kerma radiation dose (Gray) [b]	2.96 (1.67, 4.50)	2.24 (1.26, 3.72)	<.0001
Contrast volume[b]	230 (160, 300)	212 (150, 300)	0.281

b: median (interquartile ranges), MACE: Major Adverse Cardiac Events

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Procedural outcomes

Technical, procedural success and major cardiac events (MACE) among study procedures classified according to mechanical circulatory support (MCS) use

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Complications

| Variable	MCS used (n= 310)	MCS not used (n= 6861)	P value
MACE	39 (12.6%)	115 (1.68%)	<.0001
Death	18 (5.81%)	18 (0.3%)	<.0001
Acute Myocardial Infarction	11 (3.55%)	36 (0.52%)	<.0001
Re-PCI	4 (1.29%)	10 (1.29%)	<.0001
Stroke	3 (0.97%)	11 (0.16%)	0.002
Emergency CABG	1 (0.32%)	5 (0.07%)	0.137
Pericardiocentesis	13 (4.19%)	52 (0.76%)	<.0001
Perforation	36 (11.61%)	315 (4.59%)	<.0001
Tamponade	8 (2.58%)	42 (0.61%)	<.0001
Dissection/Thrombus of Donor Artery	12 (3.87%)	47 (0.69%)	<.0001
Vascular Access Site Complication	10 (3.23%)	77 (1.12%)	0.001

MACE: Major Adverse Cardiac Events, PCI: Percutaneous Coronary Intervention, CABG: Coronary Artery Bypass Graft Surgery
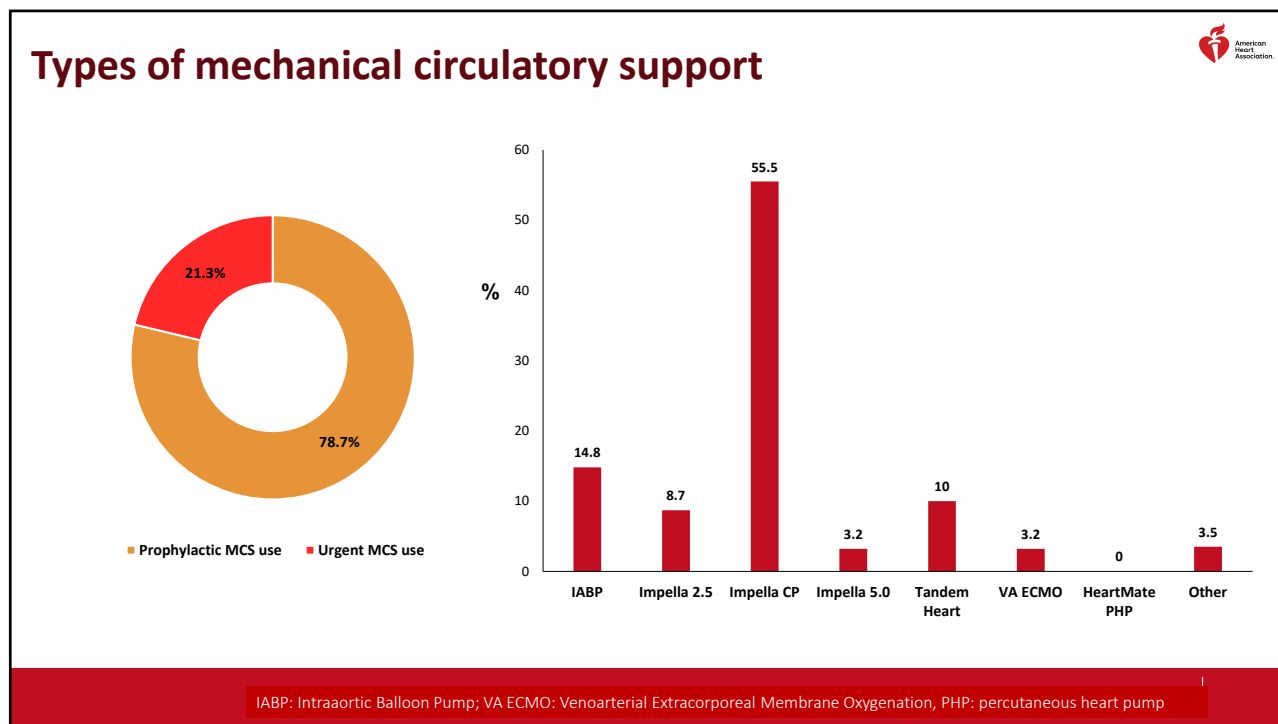
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Complications

Procedural complications classified according to mechanical circulatory support use
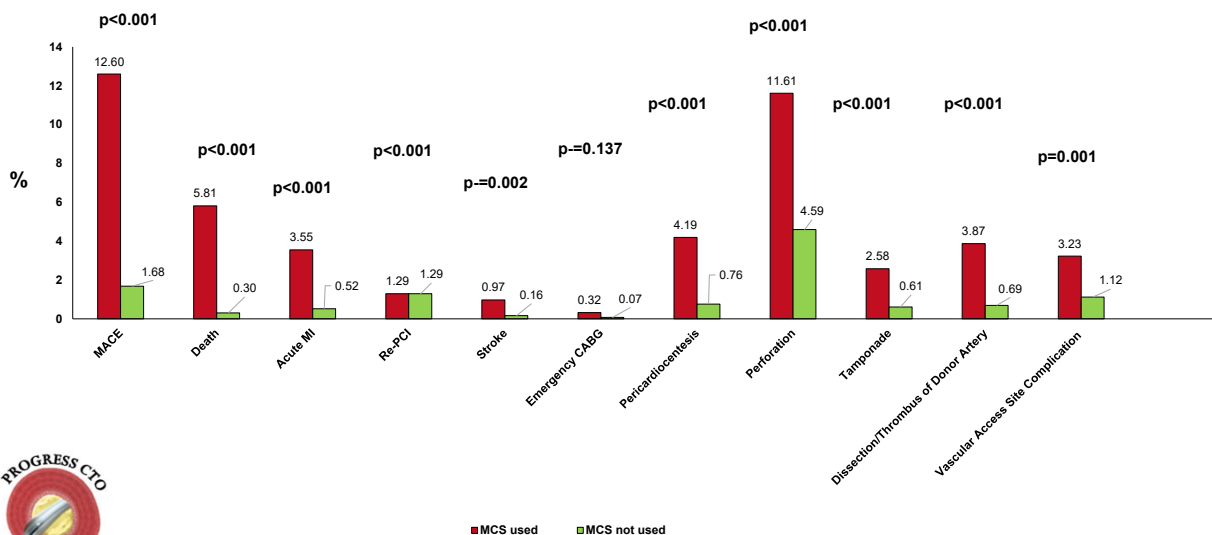
MACE: Major Cardiac Adverse Events; MI: Myocardial Infarction, PCI: Percutaneous Coronary Intervention, CABG: Coronary Artery Bypass Grafting

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Types of mechanical circulatory support

IABP: Intraaortic Balloon Pump; VA ECMO: Venoarterial Extracorporeal Membrane Oxygenation, PHP: percutaneous heart pump

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Conclusions

- In a contemporary, multicenter registry mechanical circulatory support was used in **4.3% of CTO PCI**

- **Urgent MCS was associated with lower technical and procedural success and higher major complication rates**

- Further investigation is required to see if elective use of MCS can improve outcomes in patients with increased comorbidities and higher lesion complexity.

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THANK YOU

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Clinical Impact of Hypoattenuating Leaflet Thickening (HALT) After Transcatheter Aortic Valve Replacement

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CRF
TCT

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Grant/Research Support	Edwards Lifesciences, BSCI, Abbott, Medtronic
Consulting Fees/Honoraria	Edwards Lifesciences, BSCI, Medtronic
Major Stock Shareholder/Equity	NA
Royalty Income	NA
Ownership/Founder	NA
Intellectual Property Rights	NA
Other Financial Benefit	Proctor Edwards Lifesciences

Faculty disclosure information can be found on the app

CRF TCT

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**Thrombus Formation Following Transcatheter Aortic Valve Replacement**

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Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

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Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: an observational study

Tarun Chakravarty, Lars Søndergaard, John Friedman, Ole De Backer, Daniel Berman, Klaus F Kofoed, Hasan Jilaihawi, Takahiro Shiota, Yigal Abromowitz, Troels H Jørgensen, Tanya Rami, Sharjeel Israr, Gregory Fontana, Martina de Knegt, Andreas Fuchs, Patrick Lyden, Alfredo Trento, Deepak L Bhatt, Martin B Leon, Raj R Makkar, on behalf of the RESOLVE and SAVORY Investigators*
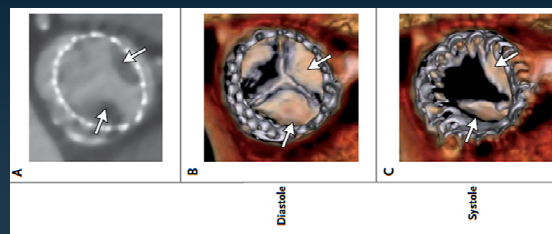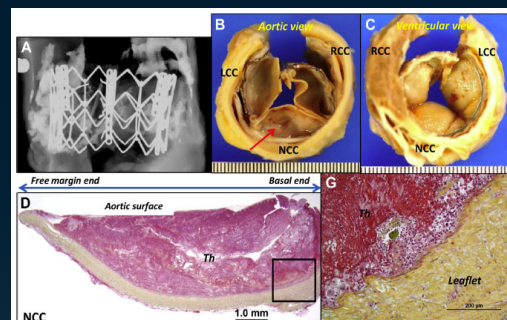
CRF TCT *Makkar NEJM 2015, De Marchena J Am Coll Cardiol Intv 2015; 8: 728-39*

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## Methods: Study Design

- In July 2015, the Minneapolis Heart Institute (MHI) adopted a strategy of routine screening for HALT after TAVR with cardiac CT performed 30-days post-procedure

- Patients with evidence of HALT were recommended to initiate anticoagulation for 3-6 months with an oral vitamin K antagonist (VKA), irrespective of HALT or RELM severity

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Methods: HALT Definition and Grading
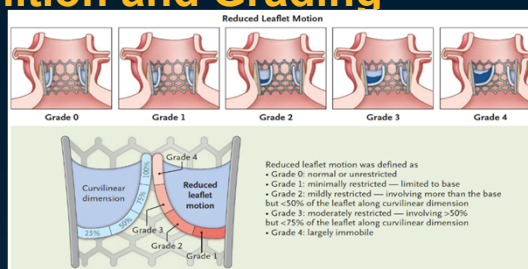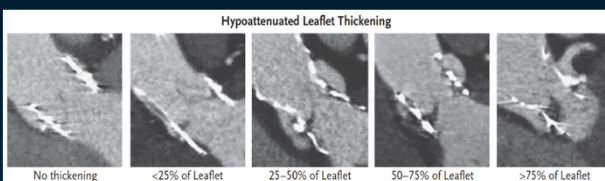
- HALT was defined as increased leaflet thickness with typical meniscal appearance in at least 2 different multiplanar projections and present on at least 2 different reconstruction time intervals
- The extent of leaflet thickening and leaflet motion was classified using a 5-grade system with higher grades indicating more severe cases
- All HALT + were reviewed by 2 independent readers

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Blanke JACC Imaging 2019 and Ole de Backer et at. NEJM 2019

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Methods: Clinical Outcomes

- Echocardiographic, ischemic, and bleeding outcomes were compared between HALT + and HALT – patients
- Survival rates were compared between HALT + and HALT – patients using log-rank test
- Cox regression analysis used to identify variables independently associated with long-term death landmarked at time of CTA
- This analysis included patients treated from July 1st 2015 to October 31st 2019

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Results

856 Patients underwent commercial TAVR (2015-2019)

No CTA at 30 days (25%)
- *CKD, n=83 (39%)*
- *Distance from TAVR hospital ≥ 2 hours, n=24 (11%)*
- *Hospitalization within 30 days, n=25 (12%)*
- *Contrast allergy, n=3 (1%)*
- *No show, n=28 (13%)*
- *Miscellaneous/Declined, n=52 (24%)*

638 (75%) CTA at 30-days

12 % HALT + (n=79)

88 % HALT - (n=558)

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Baseline Characteristics

	HALT- n = 558	HALT + n = 79	P-value
Male (%)	302 (54%)	50 (63%)	0.16
Age- years (IQR)	81 (76, 86)	83 (80, 87)	0.025
Body Mass Index (kg/m²)	29 (25, 33)	29 (26, 32)	0.94
Current Smoker	24 (4.3%)	4 (5.1%)	0.77
Arterial Hypertension	484 (87%)	64 (81%)	0.23
Diabetes Mellitus	171 (31%)	16 (20%)	0.077
Prior Stroke or TIA	90 (16%)	10 (13%)	0.53
Atrial Fibrillation/Flutter	199 (36%)	25 (32%)	0.57
Coronary Artery Disease	296 (53%)	36 (46%)	0.26
STS PROM Score (%)	3.29 (2.13, 5.15)	3.12 (2.58, 4.30)	0.87
Warfarin (%)	129 (23%)	11 (14%)	0.089
NOAC (%)	49 (8.8%)	1 (1.3%)	0.036

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Baseline Echocardiographic Characteristics

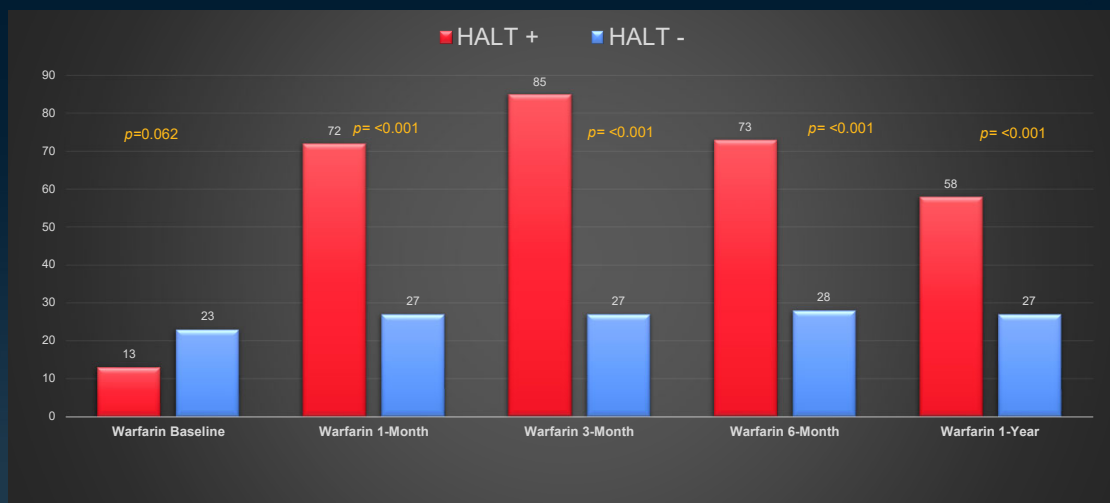|	HALT- n = 558	HALT + n = 79	P-value
LVEF (%)	60 (55, 65)	60 (54, 66)	0.63
End-Diastolic Dimension (mm)	45 (40, 50)	44 (40, 49)	0.6
End-Systolic Dimension (mm)	29 (25, 35)	29 (25, 34)	0.82
Peak Aortic Velocity (m/sec)	4.10 (3.70, 4.40)	3.90 (3.50, 4.30)	0.036
Mean Gradient (mmHg)	40 (32, 47)	36 (29, 42)	0.014
Dimensionless Index	0.22 (0.19, 0.25)	0.22 (0.20, 0.26)	0.49
≥ Moderate MR (%)	110 (20%)	11 (14%)	0.28
≥Moderate TR (%)	92 (16%)	12 (15%)	0.9

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CT and Procedural Characteristics

	HALT- n = 558	HALT + n = 79	P-value
Annulus Area (mm2)	478 (411, 552)	478 (428, 552)	0.69
Annulus Perimeter (mm)	79 (73, 85)	79 (75, 84)	0.7
Minimal Diameter (mm)	22.0 (21.0, 24.5)	22.0 (21.0, 24.0)	0.72
Maximal Diameter (mm)	27.0 (25.0, 29.0)	27.0 (25.0, 29.0)	0.65
AV Calcium Score (AU)	2,397 (1,661, 3,140)	2,384 (1,565, 3,435)	0.62
Transfemoral Access – no. (%)	532 (95%)	76 (96%)	0.69
Balloon Expandable Valves	343 (61%)	55 (70%)	0.2

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VKA Utilization post-CTA

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Echocardiographic Gradients

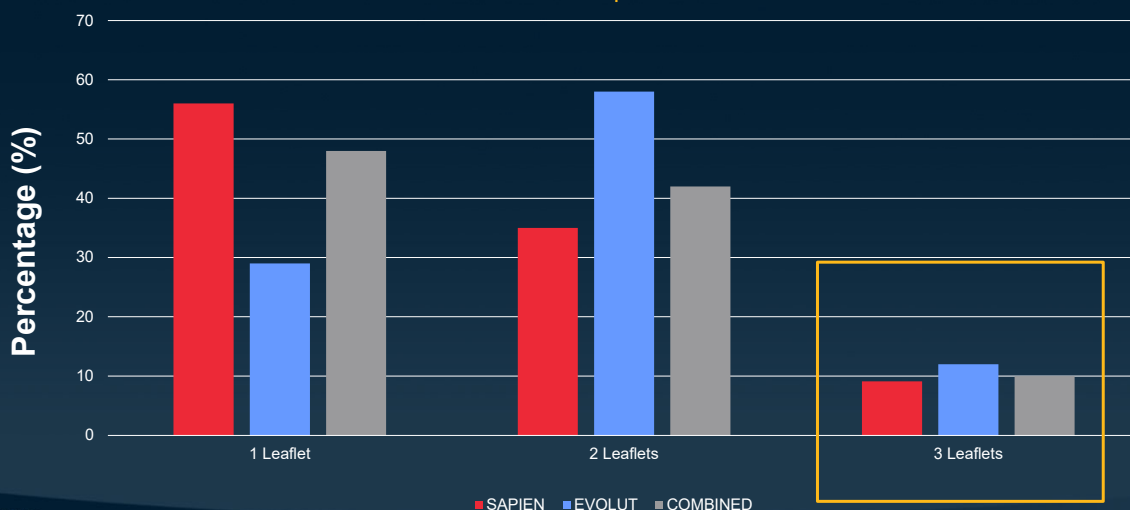|	HALT – (n=558)	HALT + (n=79)	P value
Mean Gradient ≥ 20 mmHg at 1-Month	10/558 (1.8%)	3/79 (3.8%)	0.21
Mean Gradient ≥ 20 mmHg at 1-Year (*)	10/343 (2.9 %)	1/48 (2.1%)	0.99

*All patients had a post-procedure echocardiogram at 1-month. Numbers listed as (X/XX) show X as number of patients with increased gradients, and XX as total number of patients who had an echo at that time point. *Only those patients surviving 12 months were included.*
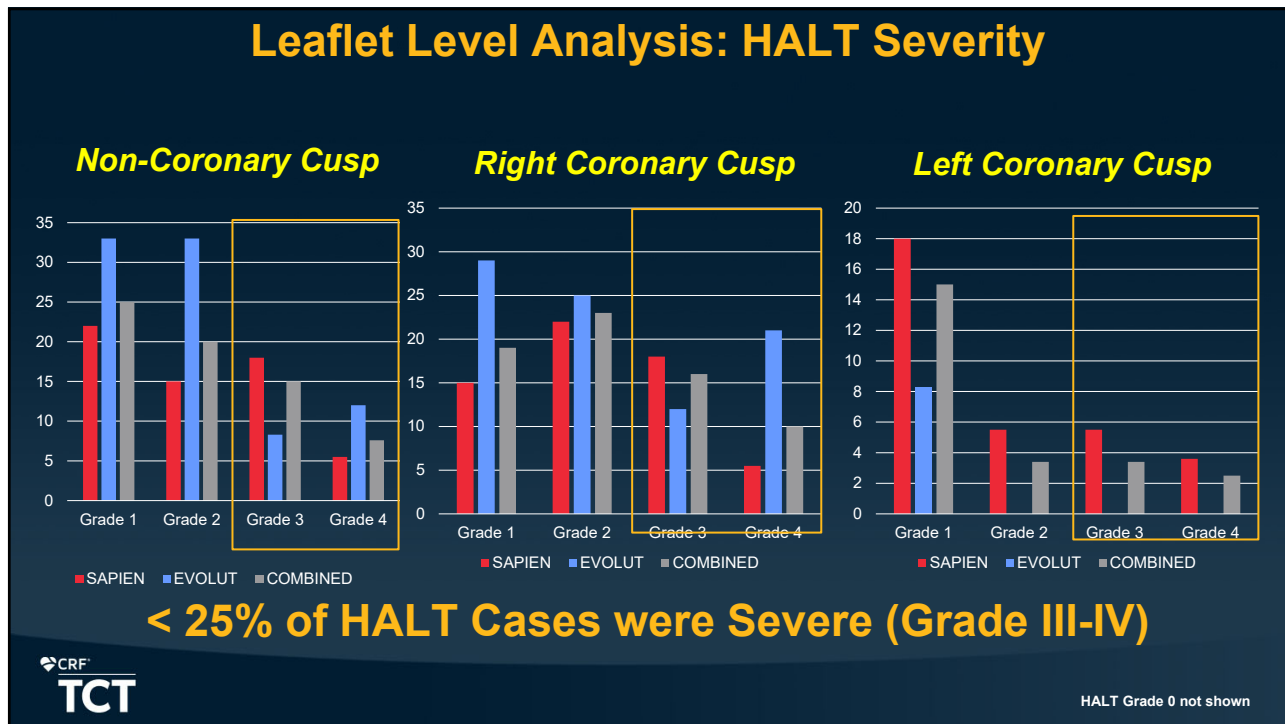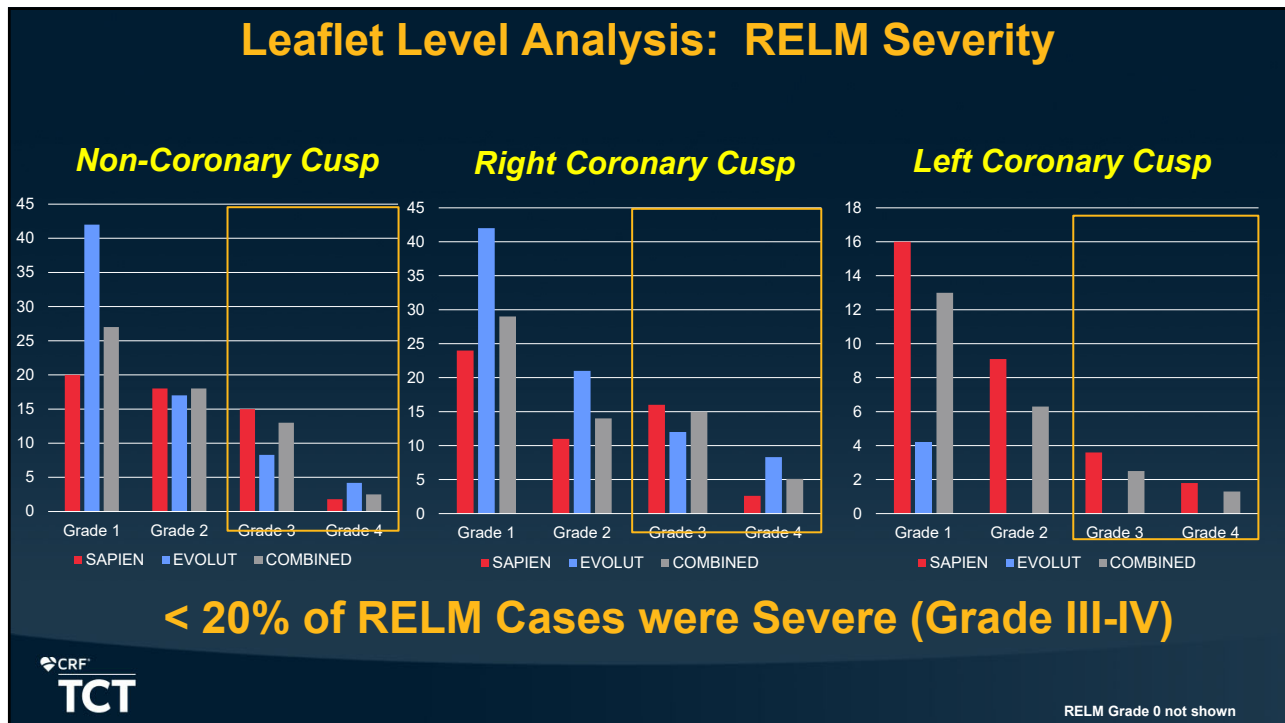
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HALT Severity

of Leaflets with HALT p=0.064

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Clinical Outcomes:
Bleeding events (VARC-2) landmarked at the time of CT according to HALT status

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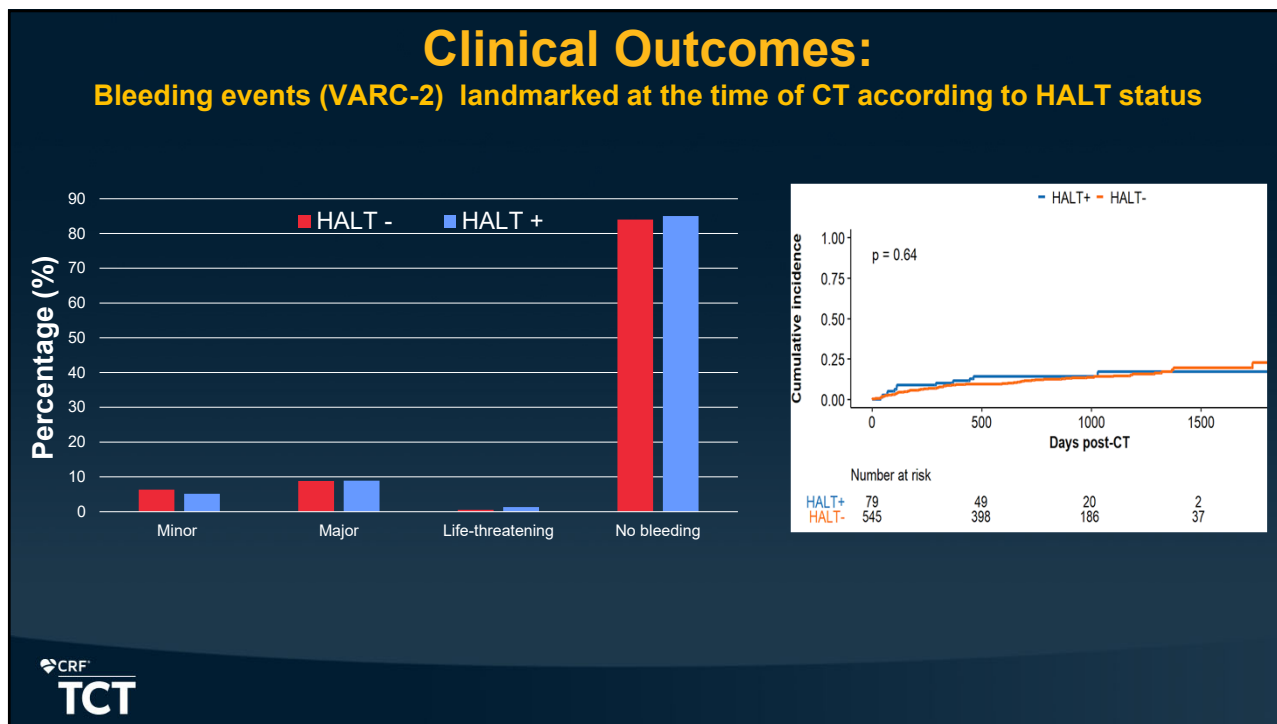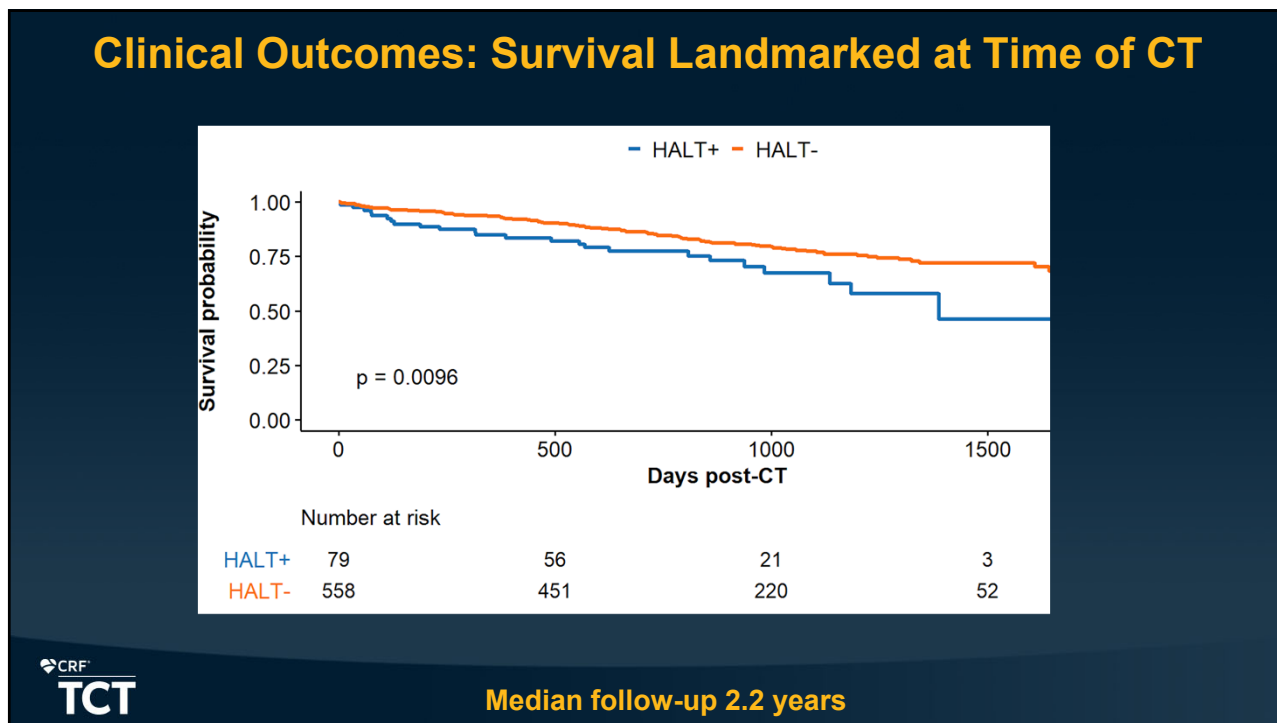Clinical Outcomes: Survival Landmarked at Time of CT

Median follow-up 2.2 years

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Clinical Outcomes Landmarked at the Time of Post-TAVR CT According to HALT Status

	HALT – (n=558)	HALT + (n=79)	P-value
Death	112 (20%)	24 (30%)	0.0096
Myocardial Infarction	25 (4.5%)	3 (3.8%)	0.87
Hemorrhagic Stroke	1 (0.2%)	1 (1.3%)	0.11
Ischemic Stroke	24 (4.3%)	4 (5.1%)	0.57
Transient ischemic attack	8 (1.4%)	0	-
Cardiovascular Surgery	18 (3.2%)	2 (2.5%)	0.76

Outcomes are to the end of follow-up and were compared using log-rank test
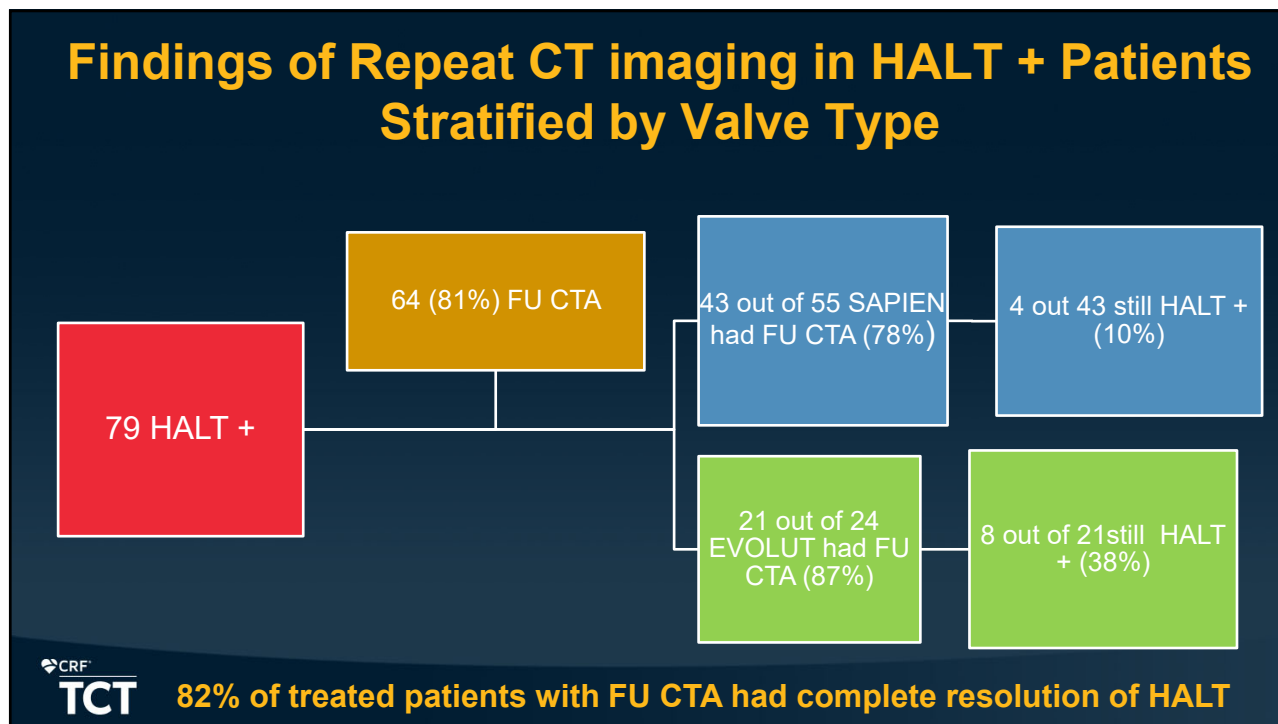
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Cox Proportional Hazard Regression Analysis for Long-Term Mortality Landmarked at the Time of CTA

Variable	Hazard ratio	95% CI	p-value
Age, per 10 years	1.23	(0.97, 1.55)	0.088
Male Gender	1.64	(1.15, 2.34)	0.007
Warfarin Use 1 mo. Post-Op	0.87	(0.58, 1.31)	0.52
Self-Expanding Valve	1.18	(0.83, 1.66)	0.36
Atrial Fibrillation	1.14	(0.96, 2.09)	0.079
TF Access	0.49	(0.26, 0.95)	0.034
HALT+	1.83	(1.13, 2.97)	0.014

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Findings of Repeat CT imaging in HALT + Patients Stratified by Valve Type

79 HALT +

64 (81%) FU CTA

43 out of 55 SAPIEN had FU CTA (78%)

4 out 43 still HALT + (10%)

21 out of 24 EVOLUT had FU CTA (87%)

8 out of 21 still HALT + (38%)

82% of treated patients with FU CTA had complete resolution of HALT

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Limitations

- Observational study, hence findings should be considered hypothesis-generating rather than confirmatory
- Role of routine screening for HALT in asymptomatic patients without elevated gradients is controversial
- It is not clear if all patients with HALT, irrespective of severity or gradients, require treatment with anticoagulation
- One treatment arm with no control group of untreated HALT patients
- Single-center design limits the generalizability of our findings
- Time in the therapeutic range (TTR) not reported

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Conclusions

- Screening for HALT is feasible in most (74%) patients undergoing commercial TAVR
- HALT is present in 12% of patients at 30-days
- Treatment with VKA was associated with resolution of HALT in 82% of patients with FU CT and low transvalvular gradients

- HALT at 30-days was associated with increased mortality during long-term follow-up
- The value of routine screening for HALT and treatment of asymptomatic patients with normal valvular gradients remains unproven and cannot be recommended
- Further studies are needed

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Clinical Impact of Hypoattenuating Leaflet Thickening (HALT) after Transcatheter Aortic Valve Replacement

Santiago Garcia, MD

Minneapolis Heart Institute

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Previous HALT CT Studies (total HALT n=93)

Study Title	Publication	Sample Size	Incidence of HALT	HALT +	Mean Age	Follow-up time	Findings
PARTNER 3 HALT Sub-study	Makkar et al. JACC 2020	435	10% at 30 d 24% at 1 year	n=35	72	1 year	• Increased gradients at 1 year • No difference in clinical outcomes
Low risk TAVR trial (Washington hospital Center)	J. Khan Circ CV Int 2019	170	16%	N= 27	75	1 year	• No difference in gradients or clinical outcomes • HALT + had lower DI at 30-days but not 1 year
EVOLUT Low-Risk Trial	Blanke et al. JACC 2020	197	17% for pts. Not on OAC	N=31	74	1 year	• No correlation with valve hemodynamics

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ORIGINAL ARTICLE

A Controlled Trial of Rivaroxaban after Transcatheter Aortic-Valve Replacement

G.D. Dangas, J.G.P. Tijssen, J. Wöhrle, L. Søndergaard, M. Gilard, H. Möllmann,

Surrogate Marker

Clinical End-Point

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G. Dangas et al. NEJM 2019

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NOAC Trials in TAVR

Trial	NCT #	N	AFib	Test arm	Control Arm	Duration	Endpoint
POPular TAVI	2247128	1,000	Yes, cohort B	**Cohort A:** Clopidogrel for 3 months **Cohort B:** OAC	**Cohort A:** Clopidogrel for 3 months + ASA 100 mg for 1 year **Cohort B:** OAC + ASA 100 mg	12 months	Freedom from non-procedure-related bleeding at 1 year
GALILEO	2556203	1,644	No	Rivaroxaban 10 mg + ASA for 3 months followed by rivaroxaban alone	ASA long term + Clopidogrel for 3 months	25 months	Composite of death, stroke, systemic embolism, MI, PE, DVT and valve thrombosis
ATLANTIS	2664649	1,510	Yes	**Stratum 1 and 2:** Apixaban 5 mg bid	**Stratum 1:** VKA **Stratum 2:** Antiplatelet Rx	13 months	Composite of death, MI, systemic embolism, DVT, PE, major bleeding, valve thrombosis
ENVISAGE	02943785	1,400	Yes	Endoxaban	VKA	36 months	Composite of death, MI, stroke, systemic embolism and valve thrombosis

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Deformation of Transcatheter Aortic Valve Prostheses: Implications for Hypo-Attenuating Leaflet Thickening

Miho Fukui, MD, PhD

Research Scholar, Minneapolis Heart Institute Foundation

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Deformation of Transcatheter Aortic Valve Prostheses: Implications for Hypo-Attenuating Leaflet Thickening

Miho Fukui, Vinayak N. Bapat, Santiago Garcia, Marshall W. Dworak, Go Hashimoto, Hirotomo Sato, Maurice Enriquez-Sarano, John R. Lesser, João L. Cavalcante, and Paul Sorajja.
Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, Minneapolis, Minnesota, USA
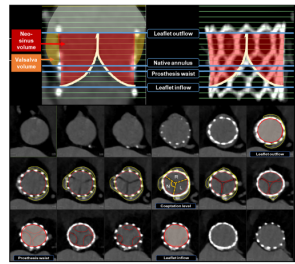
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Background

- While transcatheter aortic valve replacement (TAVR) therapy continues to grow, there have been concerns regarding the occurrence of hypo-attenuating leaflet thickening (HALT), which may affect prosthesis function or durability. Insight into causative factors for HALT remains limited.
- This study sought to examine the occurrence of non-uniform expansion of TAVR prostheses and correlate its extent to the frequency of HALT.
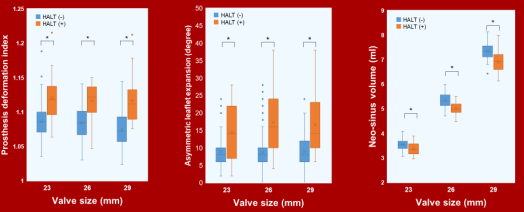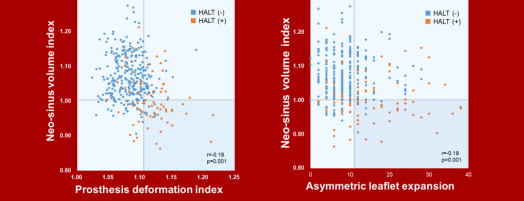
Methods

- We prospectively examined 352 patients with severe native aortic stenosis who underwent cardiac CT screening for HALT at 30-day following balloon-expandable TAVR with 23, 26, or 29 mm SAPIEN 3 prostheses. Study exclusions were valve-in-valve procedure, inadequate image quality for transcatheter heart valve (THV).
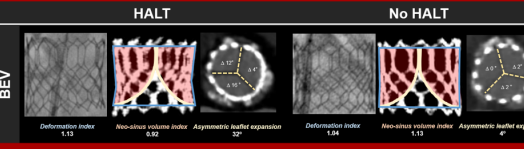
- *Prosthesis deformation index* = (area at leaflet outflow + area at leaflet inflow) / (2 × area at prosthesis waist)
- *Asymmetric leaflet expansion* = sum of the difference between 120° and each angle formed by each prosthetic leaflet
- *Neo-sinus volume* was measured as the volume above the THV leaflets within the THV frame.

TAVR prosthesis deformation and HALT

Tables

Overall, HALT occurs 21% (73 of 352 patients).
(19% for 23mm, 19% for 26mm, and 25% for 29mm; p=0.23)

Table 1. Baseline Patient Characteristics

	All patients (n=352)	HALT (n=73)	No HALT (n=279)	p
Age (years)	82 (76-87)	83 (78-87)	81 (76-86)	0.23
Male – no. (%)	217 (62%)	48 (66%)	169 (61%)	0.42
Body mass index (kg/m²)	28 (25-32)	29 (25-32)	28 (25-32)	0.94
Diabetes mellitus – no. (%)	108 (31%)	20 (27%)	88 (32%)	0.50
Hypertension – no. (%)	303 (86%)	63 (86%)	240 (86%)	0.95
Atrial fibrillation/flutter – no. (%)	133 (38%)	20 (27%)	113 (41%)	0.04
eGFR (mL/min/1.73 m²)	65 (54-78)	65 (52-77)	65 (54-78)	0.95
LV ejection fraction (%)	60 (53-66)	58 (48-66)	60 (55-66)	0.19
Aortic valve area index (cm²/m²)	0.39 (0.33-0.46)	0.41 (0.34-0.47)	0.39 (0.33-0.47)	0.33
STS-PROM score (%)	3.1 (2.1-4.6)	3.1 (2.5-4.1)	3.1 (2.1-4.7)	0.97
Baseline CT variables				
Bicuspid aortic valve – no. (%)	18 (5%)	3 (4%)	15 (5%)	0.66
Aortic valve calcium score (AU)	2445 (1691-3336)	2339 (1601-3478)	2454 (1691-3319)	0.96
Oversizing (%)	5.0 (-0.4 to11.6)	7.5 (0.2 to 11.8)	4.4 (-0.8 to 11.5)	0.13
TAVR procedure				
Transfemoral Access – no. (%)	338 (96%)	71 (97%)	267 (96%)	0.54
Valve size (#23/26/29)	97/157/98	18/30/25	79/127/73	0.23
Pre-dilatation – no. (%)	302 (86)	238 (85)	64 (88)	0.61
Balloon filling (under/nominal/over)† -no.	22/296/34	4/66/3	18/230/31	0.24
Post-dilatation – no. (%)	5 (1%)	3 (4%)	2 (1%)	0.03
Medications at discharge				
Antiplatelet therapy – no. (%)	350 (99%)	73 (100%)	277 (99%)	0.47
Anticoagulant therapy – no. (%)	125 (36%)	14 (19%)	111 (40%)	0.001

Table 2. Post-procedure Cardiac CT

	All patients (n=352)	HALT (n=73)	HALT (n=279)	p
Expansion (%)				
Leaflet outflow	84 (82-87)	86 (82-88)	84 (82-86)	0.03
Prosthesis waist	76 (74-78)	75 (73-77)	76 (74-79)	0.01
Leaflet inflow	81 (78-84)	82 (79-84)	80 (78-83)	0.03
Eccentricity				
Prosthesis waist	0.34 (0.30-0.38)	0.34 (0.29-0.38)	0.34 (0.30-0.38)	0.58
Leaflet inflow	0.34 (0.29-0.38)	0.34 (0.30-0.38)	0.33 (0.28-0.38)	0.45
Prosthesis deformation index	1.09 (1.07 to 1.10)	1.12 (1.10 to 1.13)	1.08 (1.06 to 1.10)	<0.001
Asymmetric leaflet expansion (degree)	8 (6-12)	14 (10-22)	8 (6-10)	<0.001
Implant depth (mm)	3.8 (2.5-5.3)	4.8 (2.8-6.3)	3.5 (2.3-5.1)	0.004
Canting (mm)	2.1 (1.2-3.3)	2.7 (1.2-3.9)	2.1 (1.2-3.2)	0.06
Commissure malalignment				
Right coronary	2 (1%)	0 (0%)	2 (1%)	0.47
Left coronary	12 (3%)	4 (6%)	8 (3%)	0.27
LV SV index (ml/m²)	47 (39-52)	44 (37-50)	47 (40 to 53)	0.02

Table 3. Multivariable regression analysis for HALT.

	OR (95% CI)	p-Value
Anticoagulant therapy	0.21 (0.08-0.56)	0.002
Implant depth (per 1-mm)	1.17 (0.99-1.38)	0.07
Canting (per 1-mm)	0.99 (0.76-1.28)	0.91
LV stroke volume index (per 5-ml/m²)	0.65 (0.52-0.82)	<0.001
Prosthesis deformation index (per 0.05)	16.0 (6.21-41.2)	<0.001
Asymmetric leaflet expansion (per 1-degree)	1.22 (1.14-1.31)	<0.001
Neo-sinus volume index (per 0.1)	0.23 (0.11-0.46)	<0.001

<Disclosures> The authors have no disclosures related to this study to report.

HALT   No HALT

✓ TAVR prosthesis deformation (i.e., Frame deformation; asymmetric leaflet expansion; neo-sinus volume) might explain HALT occurrence following balloon-expandable TAVR prosthesis.
✓ These data may have implications for both design and deployment techniques to improve clinical outcomes with TAVR.

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