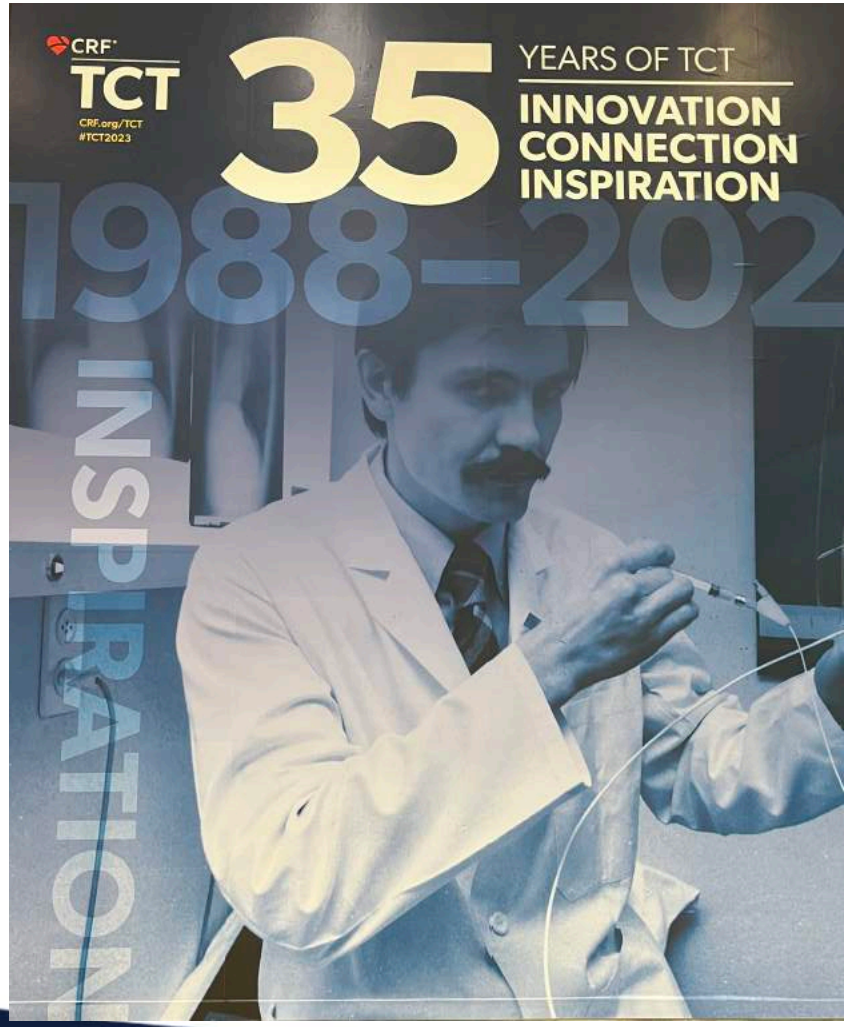
Update TCT Higlights 2023

TS.BS. Nguyễn Quốc Thái, FAsCC, FSCAI
Viện Tim Mạch Việt Nam- Bệnh viện Bạch Mai


CRF
TCT
CRF.org/TCT
#TCT2023
35
YEARS OF TCT
INNOVATION
CONNECTION
INSPIRATION
1988–202
INSPIRATION

Abbott

Một số nghiên cứu nổi bật về can thiệp tim cấu trúc

The JenaValve Trilogy™ Heart Valve System in High Surgical Risk Patients with Symptomatic, Severe Aortic Regurgitation: The ALIGN AR Trial

Vinod H. Thourani, MD and
Torsten P. Vahl, MD

On Behalf of the ALIGN AR Investigators

CRF TCT

The Trilogy THV System is for Investigational Use Only in the United States and is Limited by Federal (or United States) law for this use.

THE ALIGN AR TRIAL

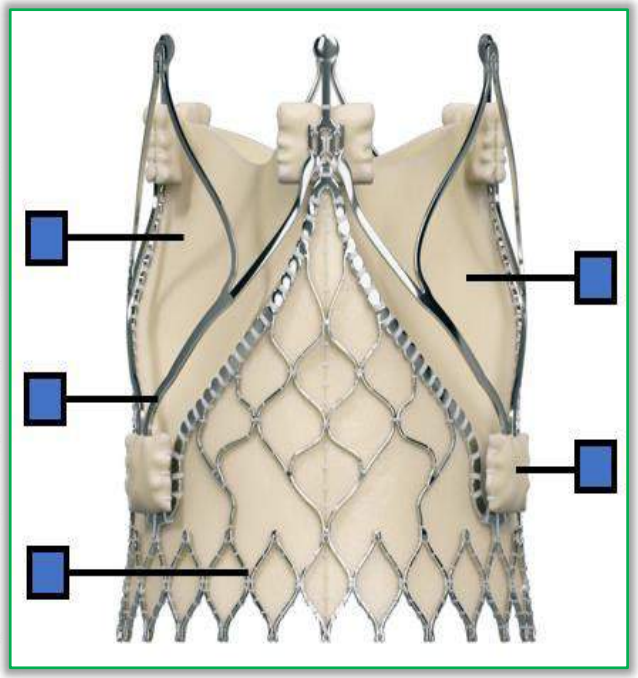
Trilogy THV System for Aortic Regurgitation

Available in 3 sizes with a perimeter rang from 66-90mm

27-31 French Open Cell

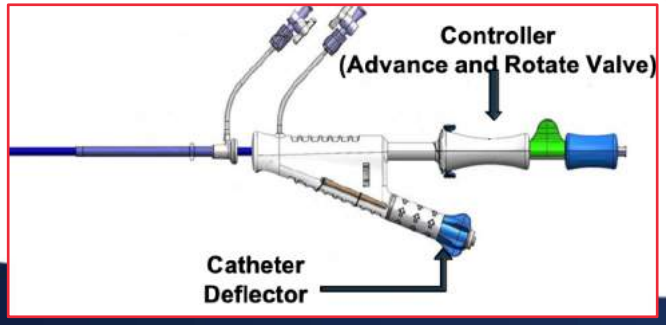
Nitinol Frame

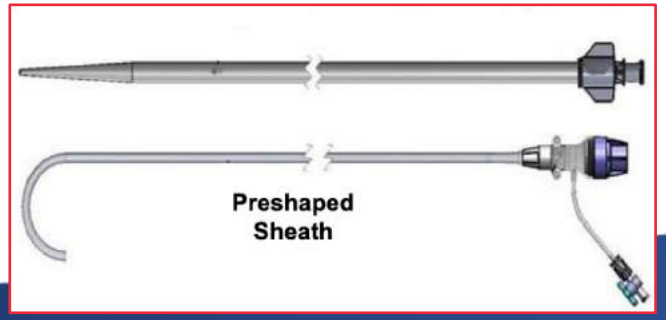
Flared Sealing Skirt



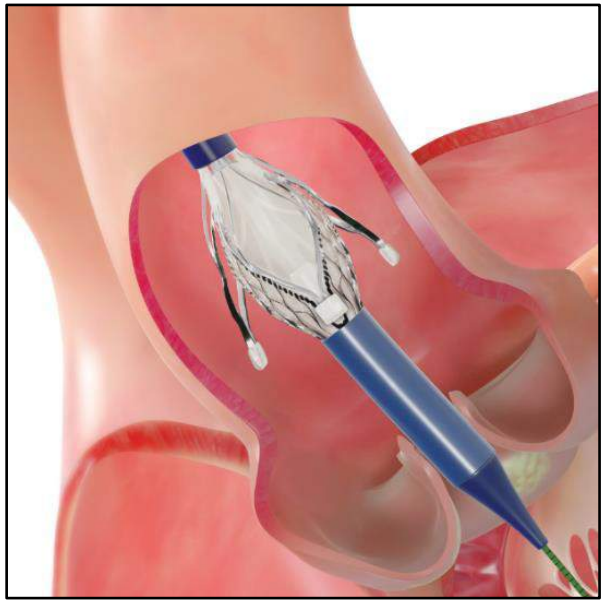
Porcine Pericardial Tissue

Locator



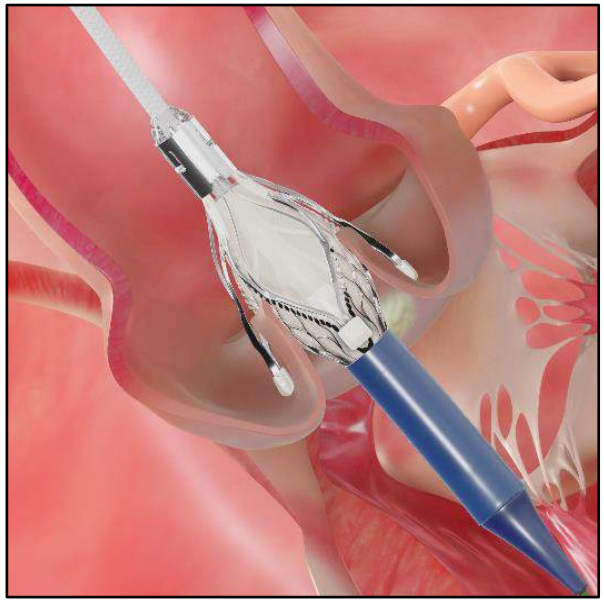


Trilogy THV in AR Anatomy



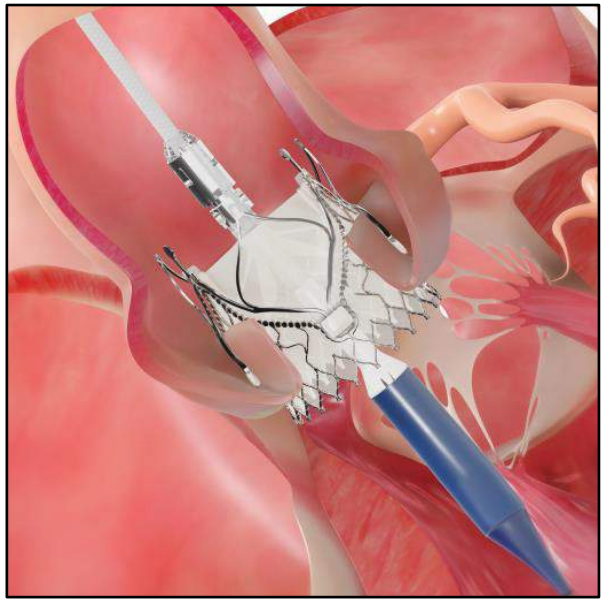
Alignment

- Aligns THV with native cusps



Positioning/Anchoring

- Locators “clip” onto native leaflets forming a natural seal and stable securement



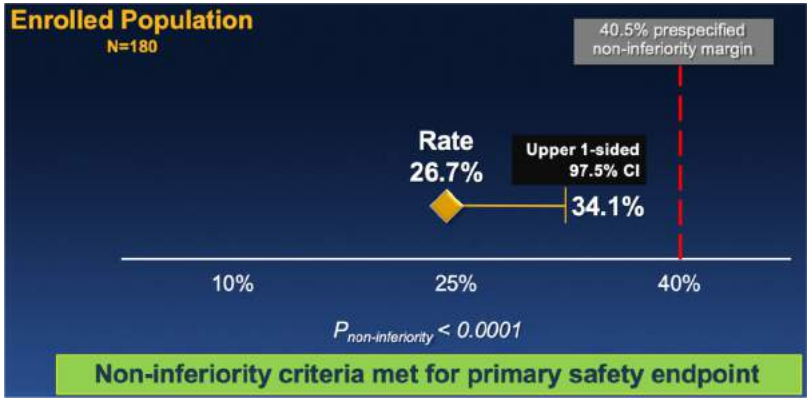
Deployment

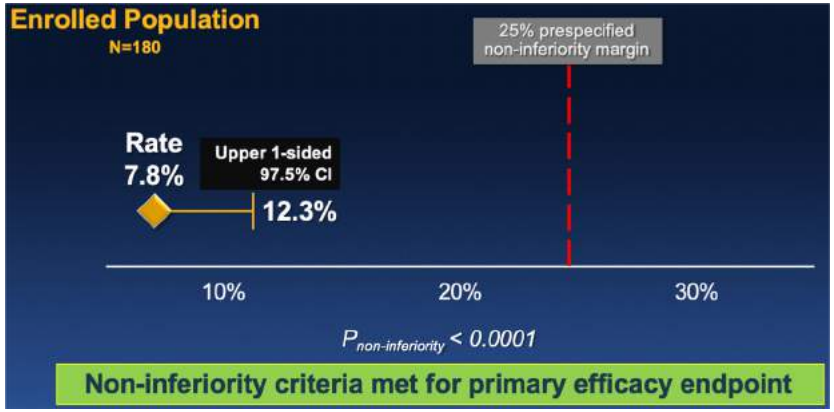
- Large open cells provide access to low coronaries
- Flared sealing ring conforms to annulus

The ALIGN AR Trial: Kết quả chính

Outcome	% (n)
In-procedural Death	0
Annular Rupture	0
Ventricular Perforation	0
Coronary Obstruction	0
Valve Embolization	2.2% (4)
Aortic Dissection	0.6% (1)
Femoral Access Site Intervention	2.2% (4)
Success	
Technical Success	95.0% (171)
Device Success	96.7% (174)
Procedure Success	92.8% (167)

Variable	% (n)
All Cause Mortality	2.2% (4)
Cardiovascular Mortality	2.2% (4)
Any Stroke	2.2% (4)
Disabling Stroke	1.1% (2)
Nondisabling Stroke	1.1% (2)
Major/Life Threatening Bleeding	4.4% (8)
Major Vascular Complication	3.9% (7)
Acute Kidney Injury Stage 2 or 3 or Dialysis (7 Days)	1.1% (2)
Surgery/Intervention Related to the Device	2.8% (5)
New Pacemaker Implantation	24.0% (36)
Pre-existing PPM	16.7% (30)
≥ Moderate Paravalvular Regurgitation	0.6% (1)
Total	26.7% (48)



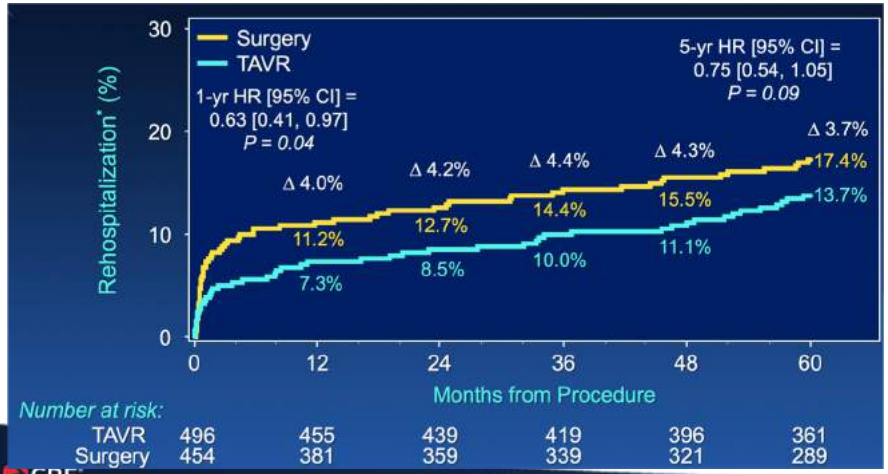


THE PARTNER 3 TRIAL

Five-year Clinical And Echocardiographic Outcomes From The PARTNER 3 Low-risk Randomized Trial

Martin B. Leon, MD &
Michael J. Mack, MD
on behalf of the PARTNER 3 Trial Investigators

The PARTNER 3 trial: 5 years Outcomes



Endpoints	0 – 5 Years			
	TAVR	Surgery	HR [95% CI]	*P-value*
Aortic valve reintervention	2.6% (12)	3.0% (12)	0.86 [0.39, 1.92]	0.72
Endocarditis	1.3% (6)	2.0% (8)	0.65 [0.23, 1.87]	0.42
Valve thrombosis (VARC-3)	2.5% (12)	0.2% (1)	10.52 [1.37, 80.93]	< 0.01
New-onset atrial fibrillation*	13.7% (55)	42.4% (155)	0.25 [0.19, 0.34]	< 0.0001
New pacemaker	13.5% (63)	10.4% (43)	1.33 [0.90, 1.96]	0.15
MI*	2.1% (10)	4.4% (18)	0.48 [0.22, 1.05]	0.06
Serious bleeding*	10.2% (49)	14.8% (64)	0.65 [0.45, 0.95]	0.02
Revascularization*	3.7% (17)	6.0% (25)	0.59 [0.32, 1.09]	0.09

Clinical Implications

The 5-year follow-up findings from the PARTNER 3 trial reaffirm the clinical and echocardiographic benefits of SAPIEN 3 TAVR as a meaningful alternative to surgical therapy for low-risk severe, symptomatic AS patients!

Four-Year Outcomes from the Evolut Low Risk Trial

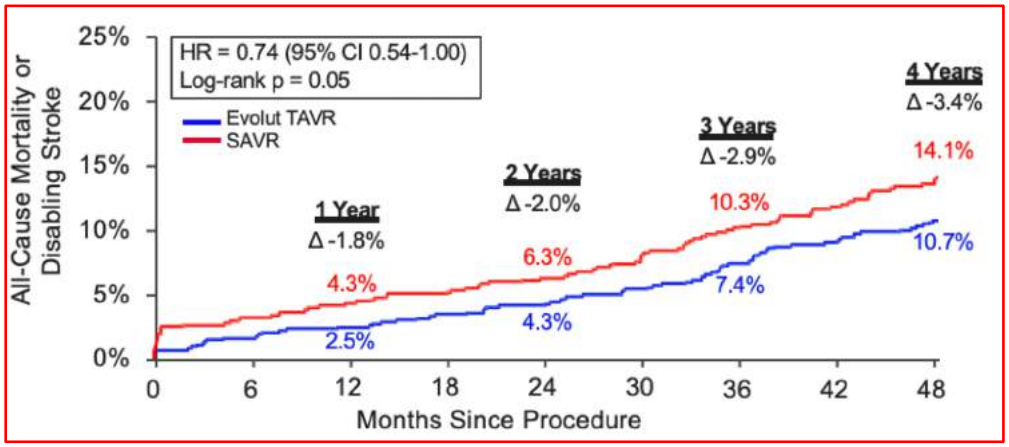
Michael J. Reardon, MD

Methodist DeBakey Heart and Vascular Center, Houston, TX On behalf of the Evolut Low Risk Trial Investigators

EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

Evolut™ Low Risk Trial

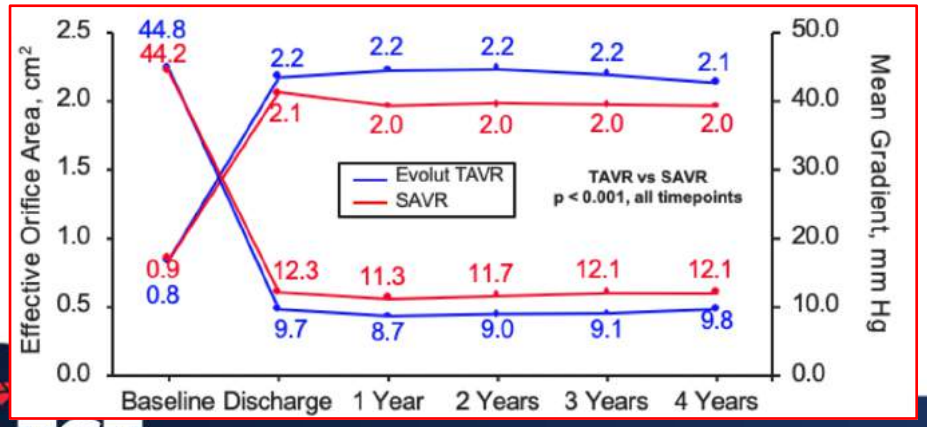
Primary Endpoints: All-Cause Mortality, Disabling Stroke or AV Rehospitalization



Secondary Endpoints at 4 Years

Secondary Endpoint	Evolut TAVR	SAVR	P Value
All-cause mortality, %	9.0 (64)	12.1 (76)	0.07
Cardiovascular mortality, %	5.3 (37)	7.3 (46)	0.12
Disabling stroke, %	2.9 (20)	3.8 (24)	0.32
AV hospitalization[a], %	10.3 (71)	12.1 (75)	0.27
All-cause mortality, disabling stroke, or AV rehospitalization	18.0 (128)	22.4 (144)	0.04
Myocardial infarction, %	4.8 (33)	2.6 (17)	0.06
Permanent pacemaker implant[b], %	24.6 (171)	9.9 (62)	<0.001
Permanent pacemaker implant[c], %	23.8 (171)	9.7 (63)	<0.001
Atrial fibrillation, %	14.0 (100)	40.8 (276)	<0.001
Reintervention, %	1.3 (9)	1.7 (10)	0.63

Comparative Hemodynamics



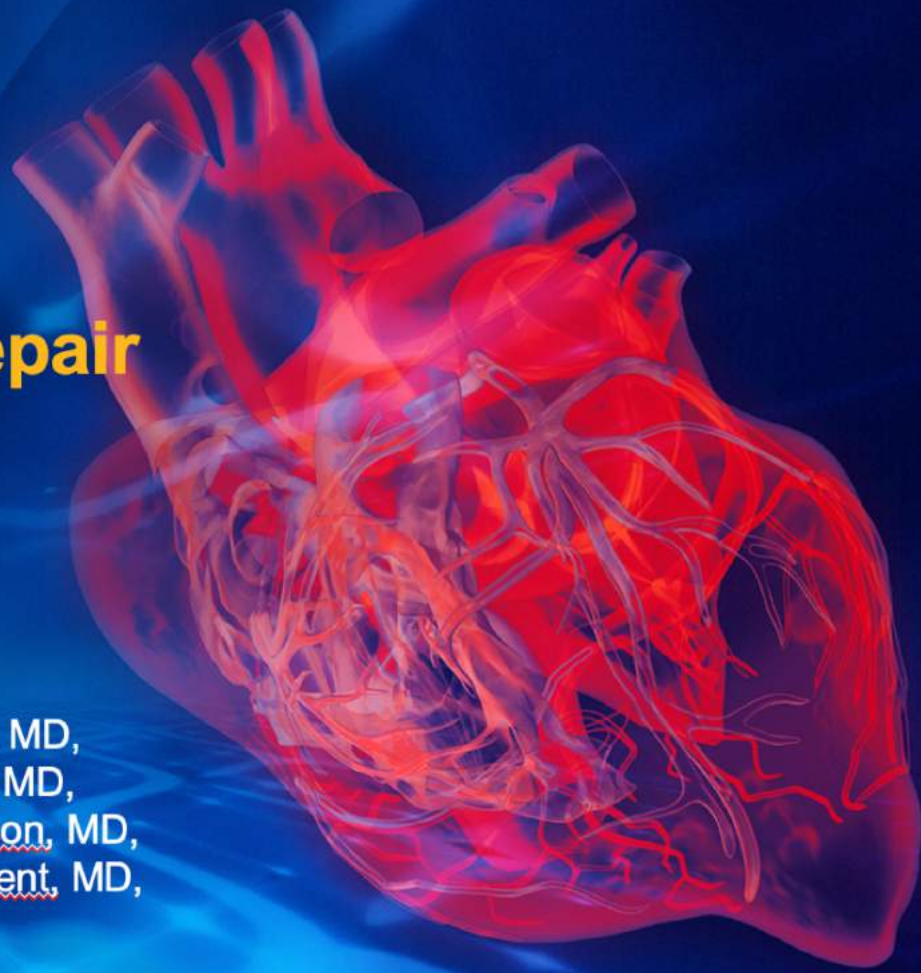
Clinical Implications

In low-risk patients, the Evolut platform is the THV of first choice due to valve performance and associated excellent clinical outcomes:

- Evolut has reported lower rates of death or disabling stroke versus state-of-the- art surgery that are diverging each year to 4 years[1]
- Evolut shows superior hemodynamics over SAVR at all time points tested[1]
- Evolut has shown significantly lower rates of structural valve deterioration, which result in lower death and hospitalization for AV or HF at 5 years[2]
- Evolut has shown significantly better valve performance, which also improves late clinical outcomes

TCT

One-Year Outcomes with the Fourth-Generation Mitral Valve Transcatheter Edge-to-Edge Repair (MitraClip G4 System) from the EXPAND G4 Study



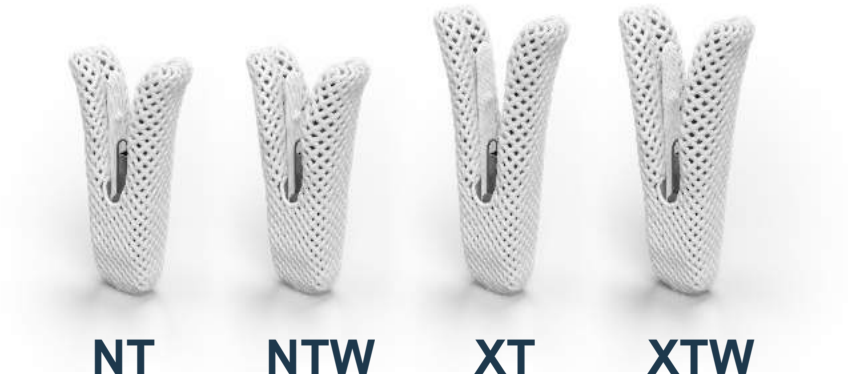
Ralph Stephan von Bardeleben

Paul Mahoney, MD, M. Andrew Morse, MD, Matthew J. Price, MD, Paolo Denti, MD, Francesco Maisano, MD, Jason H. Rogers, MD, Michael Rinaldi, MD, Federico De Marco, MD, William Rollefson, MD, Bassem Chehab, MD, Mathew Williams, MD, Guillaume Leurent, MD, Federico M. Asch, MD, Evelio Rodriguez, MD
on behalf of EXPAND G4 Investigators

CRF TCT

Background

- With 20 years of development, the **4th-generation MitraClip G4 System** builds on previous generations with two wider clip sizes (NTW and XTW), an independent grasping feature, and an improved clip deployment sequence allowing **tailored treatment of mitral regurgitation (MR)** to a broad range of anatomies.



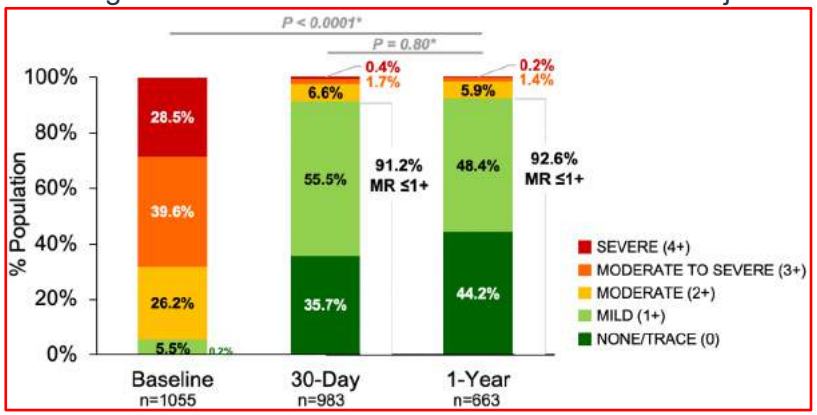
- The **EXPAND G4 study** was designed to confirm the safety and effectiveness of the MitraClip G4 System in a contemporary, real-world setting.

- Previously, the **30-day safety and effectiveness was demonstrated** for the MitraClip G4 System.[1]

[1]von Bardeleben et al, *JACC Cardiovasc Interv.* 2023;16(12):1463-73.

EXPAND G4 study: Real world

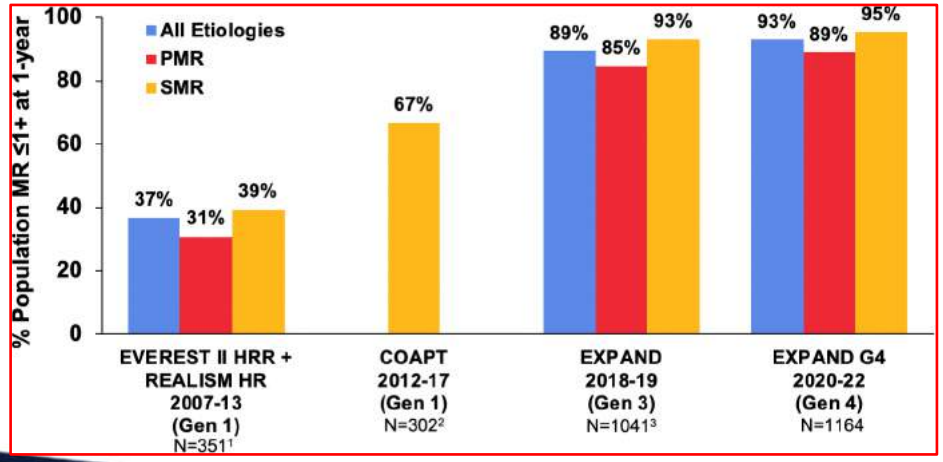
Significant and Durable MR Reduction in All Subjects



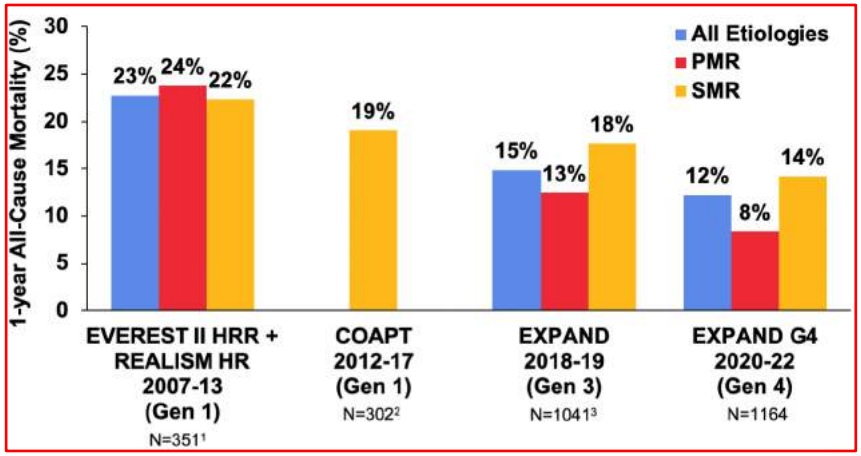
Major Adverse Events

Major Adverse Events (MAE) and Leaflet Adverse Events (LAE)	Through 1 Year	Through 30 Days[1]
All-cause Mortality	12.3% (128)†	1.3% (15)
Myocardial Infarction	1.2% (14)	0.2% (2)
Stroke	1.8% (20)	0.5% (6)
Mitral Valve Surgical Reintervention	1.9% (23)	0.9% (10)
SLDA	1.6% (17)	1.1% (12)
Leaflet damage	0.2% (2)	0.2% (2)

1-Year MR Reduction to ≤1+ Over Time with the MitraClip System



1-Year Mortality Over Time with the MitraClip System



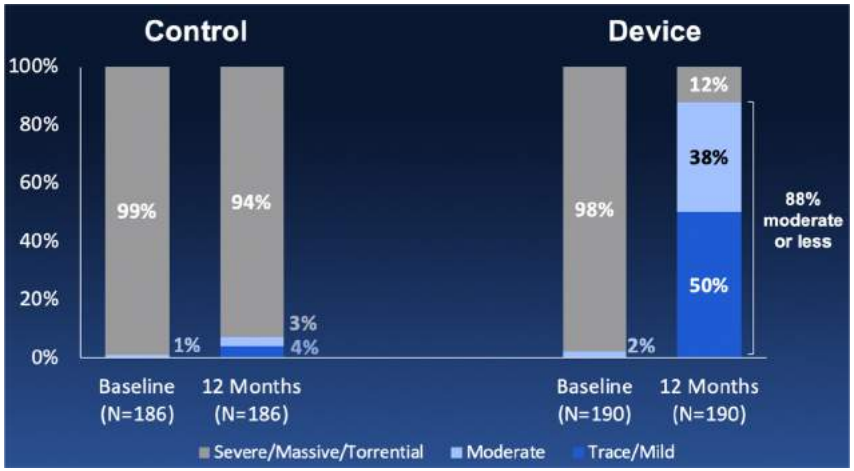
TRILUMINATE Pivotal: Outcomes of All Randomized and the Single-arm Subjects with Transcatheter Tricuspid Valve Edge-to-Edge Repair for Tricuspid Regurgitation

David H. Adams, MD,
and Paul Sorajja, MD,
on behalf of the TRILUMINATE investigators

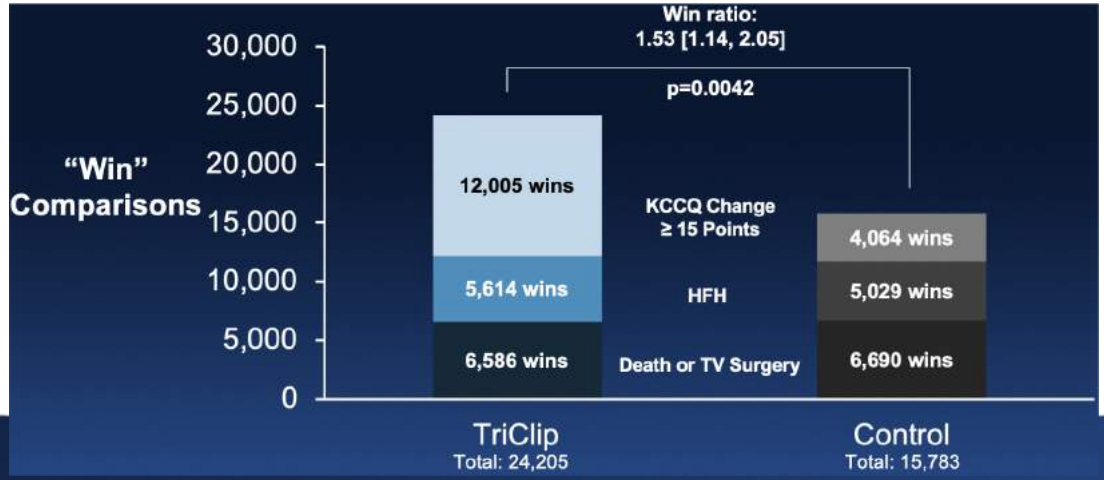
CRF TCT

Randomized Cohort of TRILUMINATE Pivotal

Patient Population	Ability to reduce TR to moderate or less
Randomization	1:1 TriClip: Control (Medical Therapy)
Endpoint	Hierarchical composite of all-cause mortality or tricuspid valve surgery, HFH, and KCCQ improvement ≥ 15 points at 12 months
Primary Analysis (adaptive design)	350
Total Enrolled (Treated)	589 (572)*

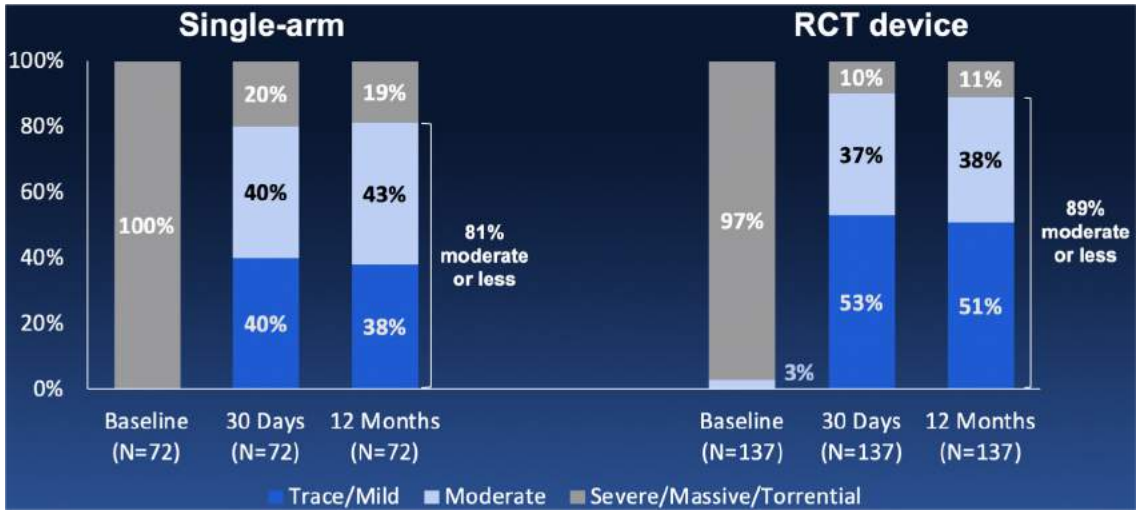


Primary Endpoint in All Randomized Subjects



Single-arm Cohort of TRILUMINATE Pivotal

Patient Population	Low likelihood of achieving moderate or less, with ability to reduce TR by 1 grade, considering factors such as: • TR severity • Presence and location of pacing lead • Coaptation gap size
Randomization	TriClip Only
Endpoint	Survival through 12 months with KCCQ improvement ≥ 10 points compared to baseline
Primary Analysis	100



Single-arm	Estimate*	Lower 98.75% CI	Performance Goal	P value
Primary endpoint	46.2% (42/91)	34.3%	30%	0.0008

*Nine subjects excluded from analysis: Missing KCCQ score (n=6), COVID related death/hospitalization prior to 12 months (n=2), withdrew prior to 12 months (n=1).

Primary Endpoint

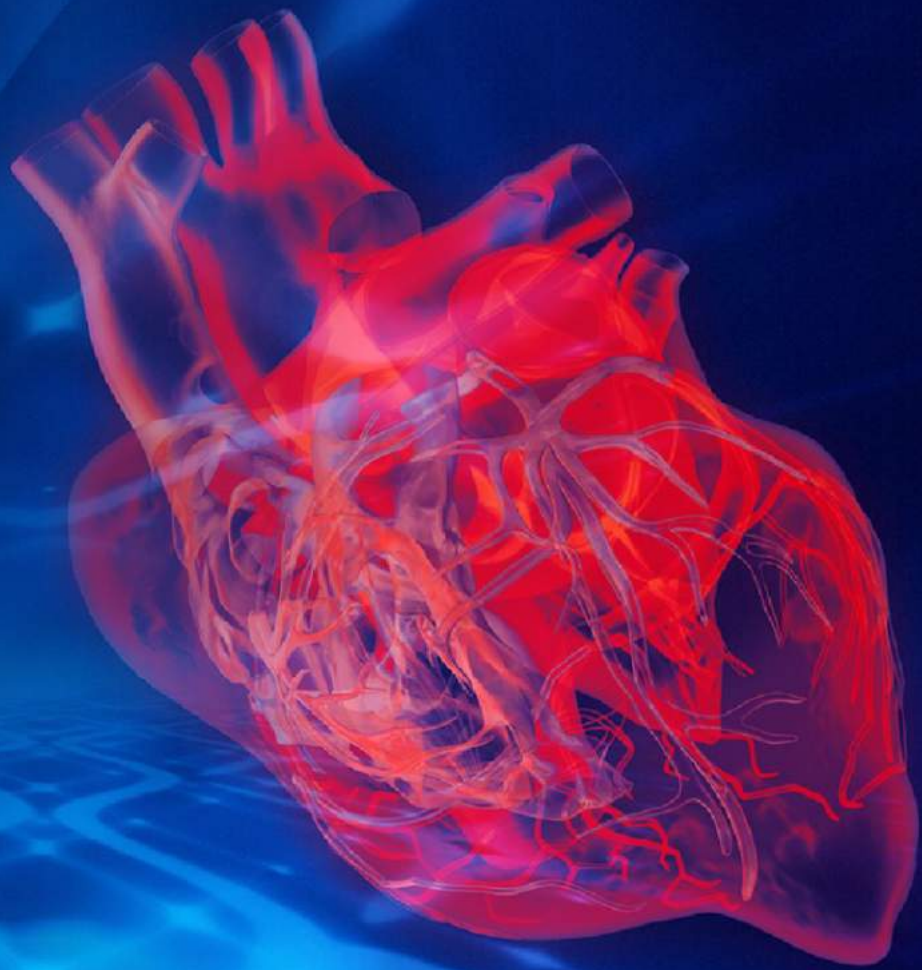
Survival through 12 months with a quality-of-life improvement (assessed using KCCQ overall score) of at least 10 points compared to baseline (performance goal of 30%).

✓ **Primary endpoint met despite more anatomically complex patients.**

Conclusions

- Data from all randomized subjects in the TRILUMINATE Pivotal trial strengthen the conclusions of the previously reported primary cohort analysis.
- Despite the complex anatomies present in the single-arm cohort, outcomes between single-arm and randomized cohorts were comparable, including 30-day safety, sustained TR reduction, and 12-month change in KCCQ-OS.

TRISCEND II Trial: A Randomized Trial of Transcatheter Tricuspid Valve Replacement in Patients with Severe Tricuspid Regurgitation



Susheel Kodali, MD
Columbia University Irving Medical Center, New York, New York, USA

on behalf of the **TRISCEND II Trial** investigators

THE TRISCEND II PIVOTAL TRIAL

CRF TCT

EVOQUE Transcatheter Tricuspid Valve Replacement System

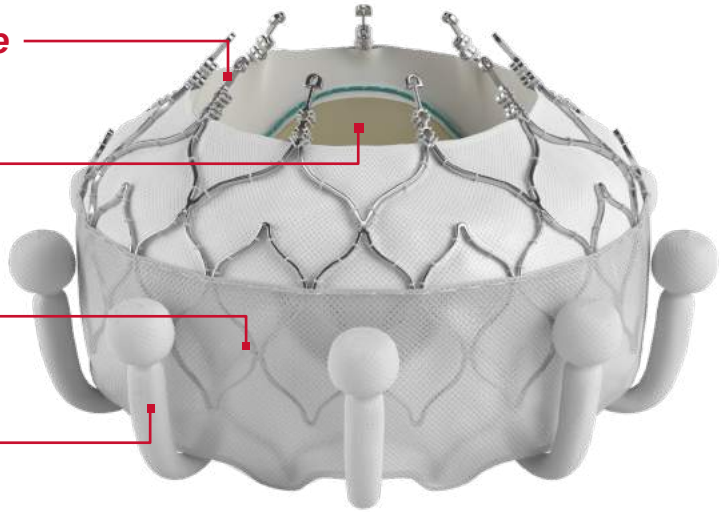
EVOQUE Valve

Nitinol self-expanding frame

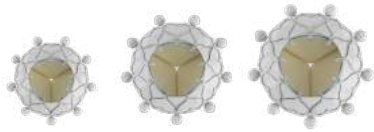
Bovine pericardial tissue

Intra-annular sealing skirt

9 ventricular anchors



Available in three sizes



44 mm *48 mm* *52 mm*

EVOQUE Delivery System

Transfemoral

28 Fr *outer diameter*

3 planes of movement

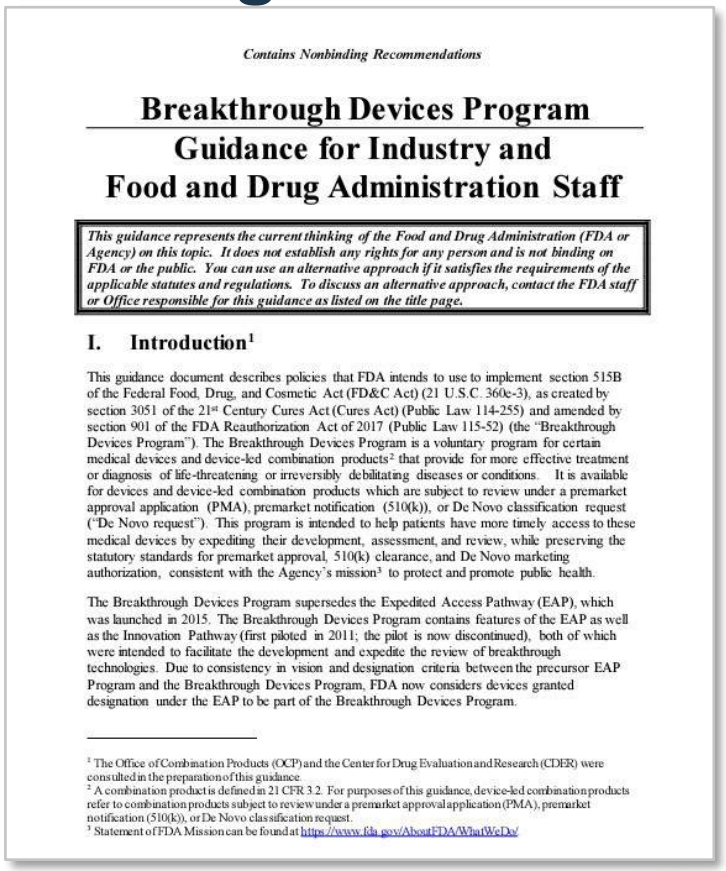
CRF TCT

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

EVOQUE Tricuspid Valve Replacement System Received FDA Breakthrough Designation

FDA Breakthrough Designation

- ***Designed to provide patients with timely access to new devices for life-threatening or irreversibly debilitating conditions***
- ***May accept greater uncertainty if probable benefits outweigh probable risk of harm***



Contains Nonbinding Recommendations

Breakthrough Devices Program
Guidance for Industry and
Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction[1]

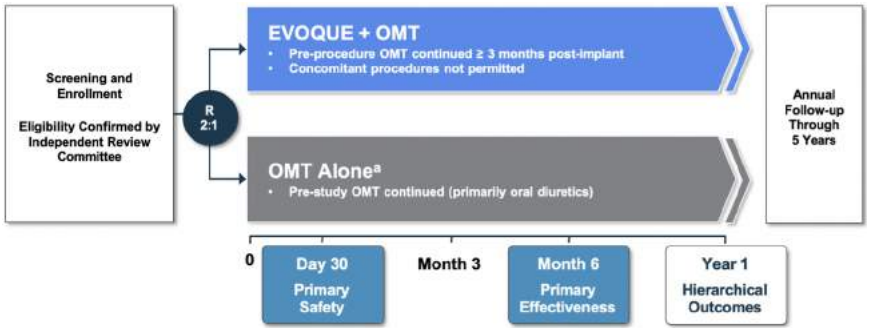
This guidance document describes policies that FDA intends to use to implement section 515B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e-3), as created by section 3051 of the 21st Century Cures Act (Cures Act) (Public Law 114-255) and amended by section 901 of the FDA Reauthorization Act of 2017 (Public Law 115-52) (the "Breakthrough Devices Program"). The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products[2] that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products which are subject to review under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request ("De Novo request"). This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission[3] to protect and promote public health.

The Breakthrough Devices Program supersedes the Expedited Access Pathway (EAP), which was launched in 2015. The Breakthrough Devices Program contains features of the EAP as well as the Innovation Pathway (first piloted in 2011; the pilot is now discontinued), both of which were intended to facilitate the development and expedite the review of breakthrough technologies. Due to consistency in vision and designation criteria between the precursor EAP Program and the Breakthrough Devices Program, FDA now considers devices granted designation under the EAP to be part of the Breakthrough Devices Program.

[1] The Office of Combination Products (OCP) and the Center for Drug Evaluation and Research (CDER) were consulted in the preparation of this guidance.
[2] A combination product is defined in 21 CFR 3.2. For purposes of this guidance, device-led combination products refer to combination products subject to review under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request.
[3] Statement of FDA Mission can be found at https://www.fda.gov/AboutFDA/WhatWeDo/

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

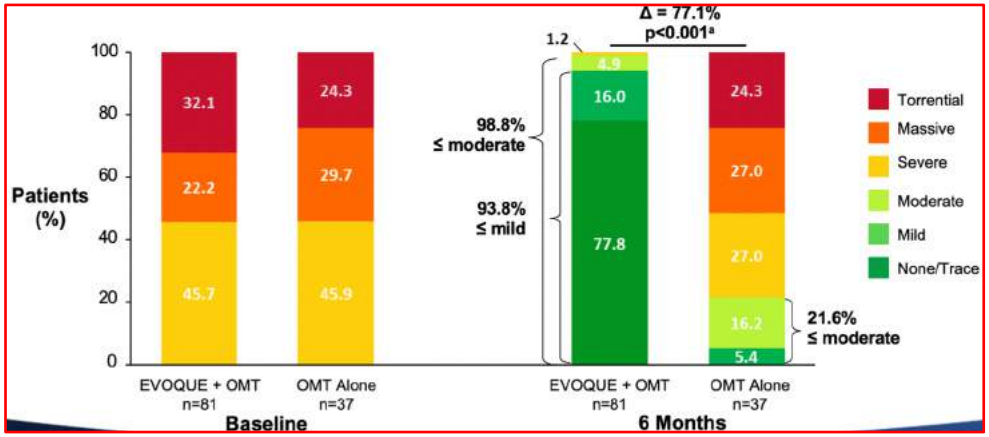
TRISCEND II study: Kết quả ban đầu



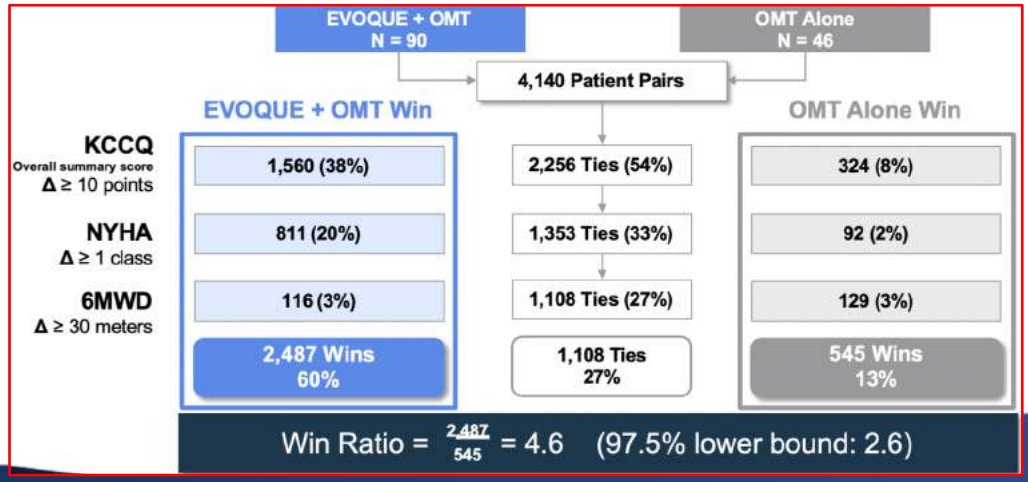
CEC-Adjudicated Major Adverse Events	EVOQUE + OMT N=95 % (n)
Cardiovascular mortality	3.2 (3)
Myocardial infarction	1.1 (1)
Stroke	0.0 (0)
New need for renal replacement therapy	1.1 (1)
Severe bleeding[a]	10.5 (10)
Non-elective TV re-intervention	0.0 (0)
Major access site and vascular complication	3.2 (3)
Major cardiac structural complication	2.1 (2)
Device-related pulmonary embolism	1.1 (1)
Arrhythmia and conduction disorder requiring permanent pacing	14.7 (14)
Composite MAE Rate[b]	27.4 (26)

	Total Events (N)	EVOQUE + OMT Patients (%) N=96[a]	One-Sided 97.5% Upper Confidence Bound
Composite MAE at 30 days	36	26 (27.4%)	36.9%

Significant Reductions in TR Grade with EVOQUE System at 6 Months



Superior QoL Outcomes



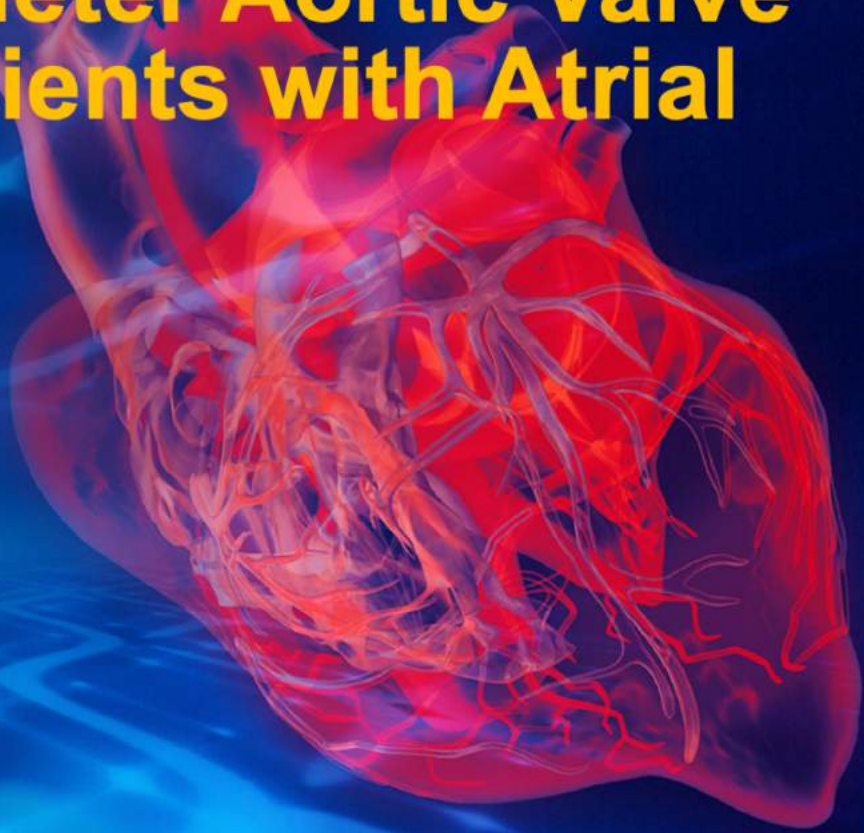
Conclusions

- ***TRISCEND II has demonstrated that transcatheter tricuspid valve replacement (TTVR) with the EVOQUE system is feasible with an acceptable safety profile in a highly comorbid patient population***
  - ***MAE rate of 27.4% is less than the expected MAE rate of 43.8%***
- ***TTVR with the EVOQUE system effectively eliminates TR in a vast majority of patients despite the presence of massive or torrential at baseline in more than 50% of population***
  - ***Mild or less in 93.8%***
  - ***None/trace in 77.8%***
- ***Treatment of severe TR with the EVOQUE system resulted in meaningful improvements in functional status and symptoms at 6 months***

MAE, major adverse event; TR, tricuspid regurgitation

Concomitant Left Atrial Appendage Occlusion and Transcatheter Aortic Valve Replacement Among Patients with Atrial Fibrillation

WATCH-TAVR Trial

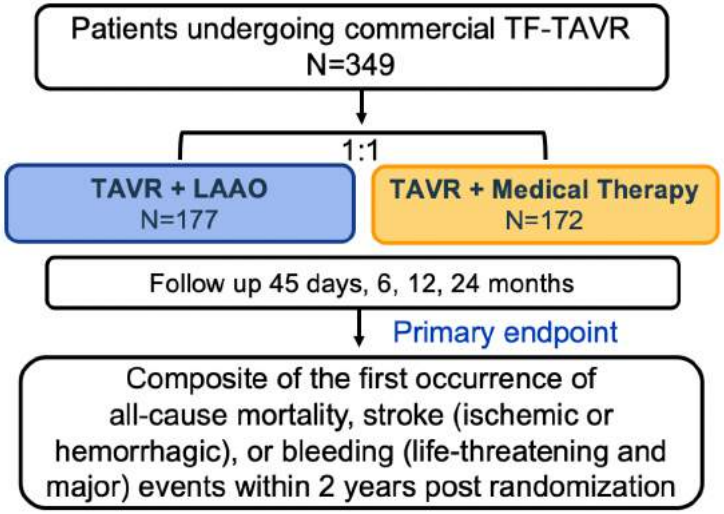


Samir R Kapadia, MD
Chairman, Cardiovascular Medicine

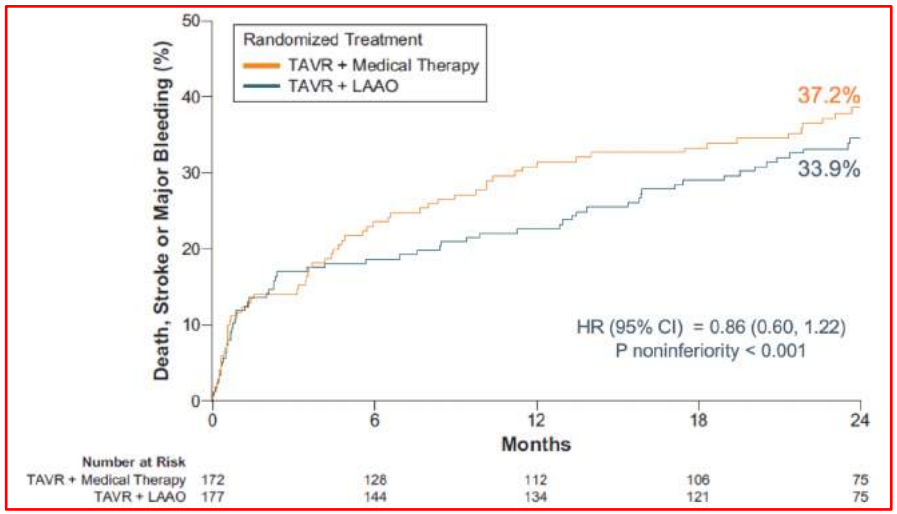
Cleveland Clinic

CRF TCT

WATCH-TAVR Trial



Primary Outcome



Secondary Outcome

	TAVR + LAAO (N=177) n(%)	TAVR + Medical Therapy (N=172) n (%)	TAVR + LAAO vs TAVR + Medical Therapy Hazard Ratio (95% CI)
All-cause mortality	37 (20.9)	39 (22.7)	0.86 (0.55, 1.34)
Stroke	10 (5.7)	12 (7.0)	0.76 (0.33, 1.77)
Major/life-threatening bleeding	35 (19.8)	30 (17.4)	1.10 (0.67, 1.79)
Cardiovascular death	20 (11.3)	22 (12.8)	0.82 (0.45, 1.51)
Ischemic stroke	10 (5.7)	11 (6.4)	0.83 (0.35, 1.96)
Hemorrhagic stroke	0 (0.0)	1 (0.6)	..
Arterial or venous thrombosis or embolism	16 (9.0)	3 (1.7)	5.03 (1.47,17.26)
Rehospitalization	18 (10.2)	22 (12.8)	0.76 (0.41, 1.42)

Conclusions

- LAAO with the WATCHMAN 2.5 device at time of TAVR is non-inferior to contemporary medical therapy for the primary composite endpoint of all-cause mortality, stroke, and major bleeding at 2 years in patients with AF and severe symptomatic AS.
- Cardiovascular mortality, stroke, and rehospitalization due to WATCHMAN device or procedure were similar between groups. Arterial and venous thromboembolism was more frequent in patients undergoing TAVR + LAAO compared to TAVR + medical therapy.
- In-hospital mortality was low (0.6%) in both groups with similar length of stay and AKI. Pericardial effusion occurred in 2.4% of combined procedures compared to 0.5% in TAVR alone.
- Almost one third of the patients randomized to TAVR + medical therapy were not taking anticoagulants at 2 year follow up.

Một số nghiên cứu nổi bật về can thiệp ĐMV

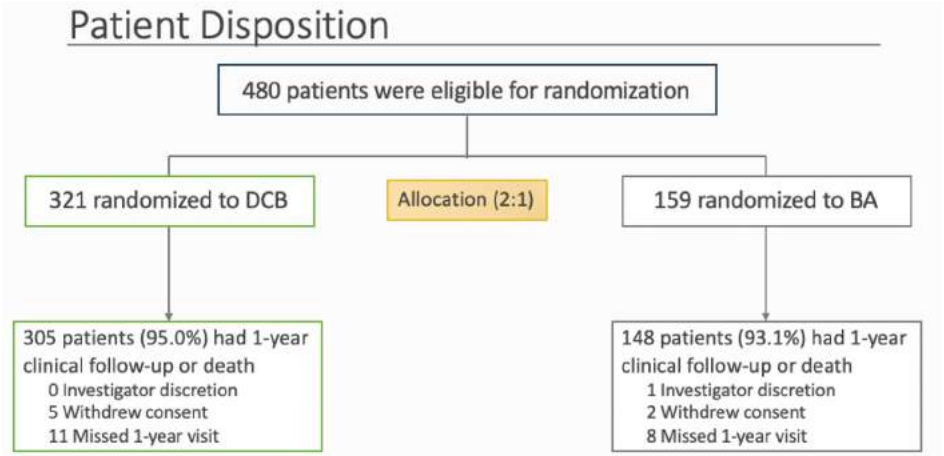
Primary Outcomes of a Pivotal Multicenter Randomized Trial Comparing the AGENT Paclitaxel-Coated Balloon with Conventional Balloon Angioplasty for In-Stent Restenosis

Robert W. Yeh, MD

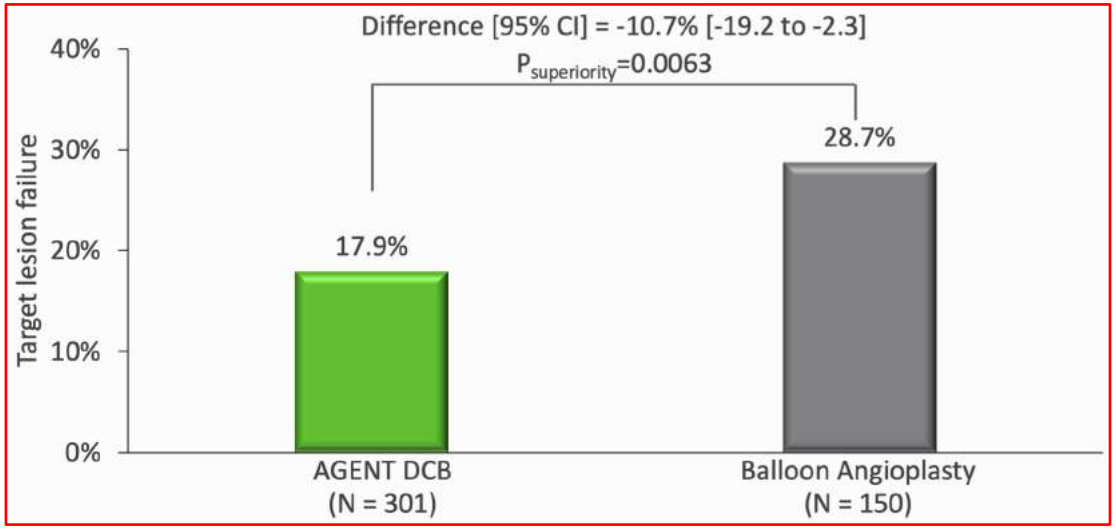
Beth Israel Deaconess Medical Center, Boston, MA

Richard Shlofmitz, Jeffrey Moses, William Bachinsky, Suhail Dohad, Steven Rudick, Robert Stoler, Brian K. Jefferson, William Nicholson, John Altman, Cinthia Bateman, Amar Krishnaswamy, J. Aaron Grantham, Francis J. Zidar, Jennifer A. Tremmel, Cindy Grines, Mustafa I. Ahmed, Azeem Latib, Behnam Tehrani, J. Dawn Abbott, Wayne Batchelor, Paul Underwood, Dominic J. Allocco, Ajay J. Kirtane

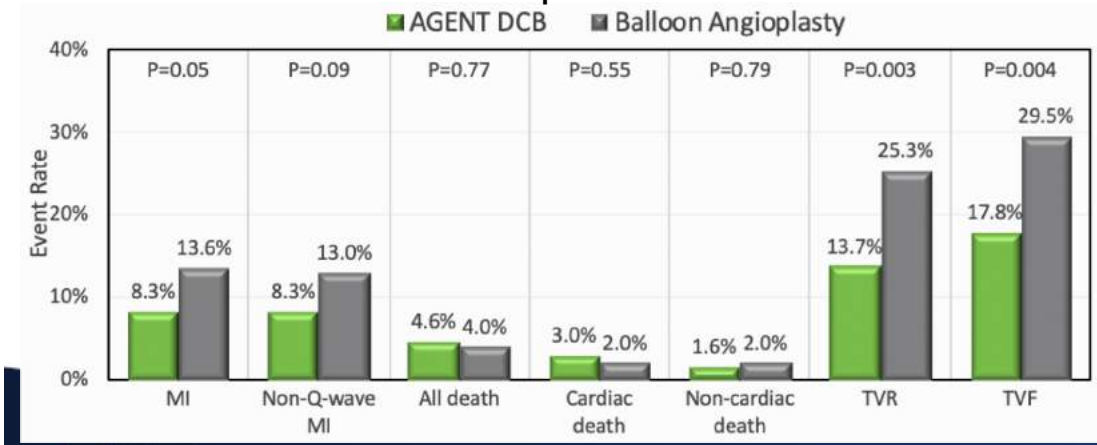
AGENT IDE trial: Kết quả chính



Primary Endpoint: TLF at 1-Year



Additional Endpoints at 1-Year



Conclusions

- AGENT IDE is the first RCT conducted in the US examining the efficacy and safety of DCB in patients with coronary ISR
- AGENT DCB was superior to conventional balloon angioplasty for the primary endpoint of TLF at 1-year (17.9% vs. 28.7%; P=0.006)
  - These differences were driven by ~50% reductions in rates of TLR and TV-MI after treatment with AGENT DCB compared with BA
- No thromboses occured in the AGENT arm (0.0% vs. 3.9%; P=0.001)
- These data support the use of AGENT DCB for the treatment of coronary in-stent restenosis

Drug-Coated Balloon for Acute Coronary Syndromes: A Multicenter Randomized Non-inferiority Trial (DCB-ACS)

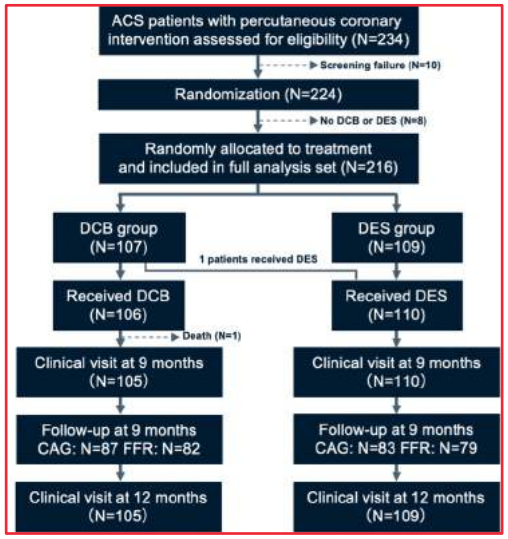
Haibo Jia, Bo Yu

The 2nd Affiliated Hospital of Harbin Medical University, Harbin, China

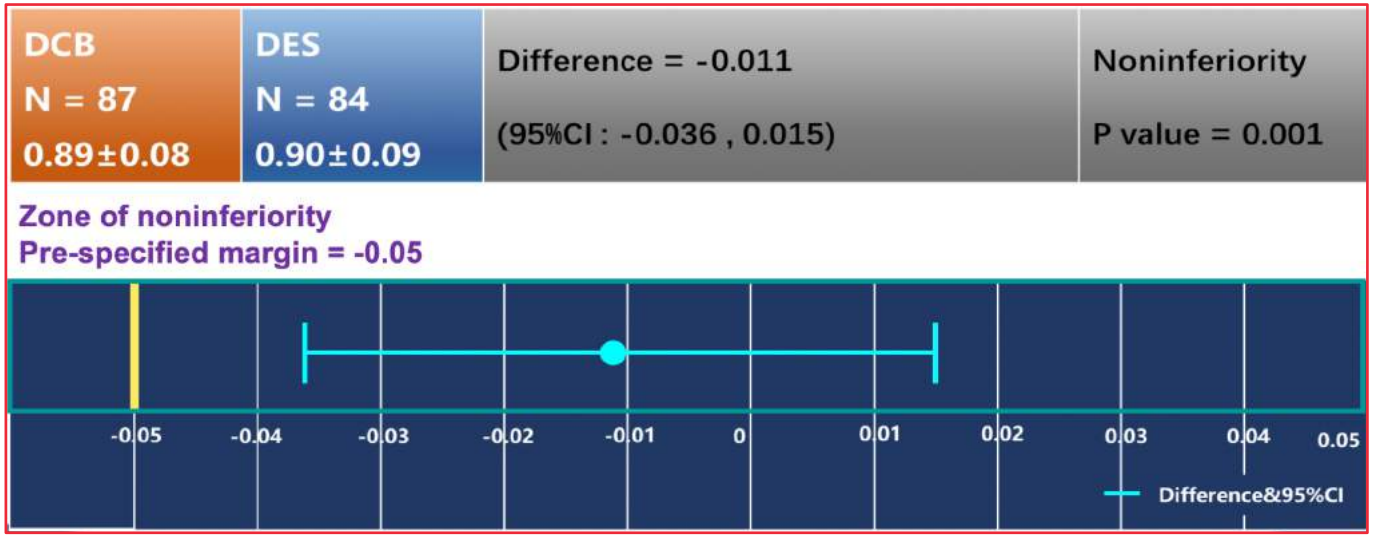
On behalf of the DCB-ACS trial investigators

DCB-ACS trial: Kết quả chính

Study flow chart



Primary endpoint: FFR at 9 months



Secondary endpoints --- 9 months angiographic findings

	DCB n = 93	DES n = 89	*P* Value
Late lumen loss, mm			
- In-segment	**0.14 ± 0.46**	**0.18 ± 0.55**	**0.56**
- In-device	**0.15 ± 0.48**	**0.20 ± 0.57**	**0.54**
Binary restenosis			
- In-segment	13 (14.0)	9 (10.1)	0.42
- In-device	13 (14.0)	7 (7.9)	0.19
Diameter stenosis, %			
- In-segment	32.1 ± 16.8	22.6 ± 20.5	<0.001
- In-device	31.8 ± 17.3	18.6 ± 20.7	<0.001

Secondary endpoints --- 12 months clinical events

	DCB n = 107	DES n = 109	*P* Value
Target lesion failure	6 (5.6)	11 (10.1)	0.22
- Cardiac death	1 (0.9)	0 (0.0)	0.50
- Target vessel-related myocardial infarction	0 (0.0)	1 (0.9)	1.00
- Target lesion revascularization	5 (4.7)	11 (10.1)	0.13
Patient-oriented composite endpoint	9 (8.4)	15 (13.8)	0.21
- Death	1 (0.9)	0 (0.0)	0.50
- Myocardial infarction	1 (0.9)	1 (0.9)	1.00
- Revascularization	7 (6.5)	15 (13.8)	0.08
Definite and possible thrombotic events	0 (0.0)	0 (0.0)	1.00
Major bleeding	2 (1.9)	2 (1.8)	1.00
Rehospitalization due to angina	2 (1.9)	5 (4.6)	0.26
Stroke	2 (1.9)	5 (4.6)	0.26

Conclusions

- DCB was non-inferior to DES for treating de novo lesions of ACS patients in terms of physiologic endpoint at 9 months.
- DCB treatment is an option for ACS patients.
- In the future, a larger randomized controlled trial will be required to compare DCB with DES for de novo lesions in ACS patients in terms of clinical adverse outcomes.

TCT

Sirolimus-Coated Balloon Versus Paclitaxel-Coated Balloon Angioplasty for the Treatment of Drug-Eluting Stent In-Stent Restenosis: a Prospective, Multicenter, Randomized Trial

NCT04240444

PI: Yaling Han, MD

on Behalf of All Investigators

CRF TCT

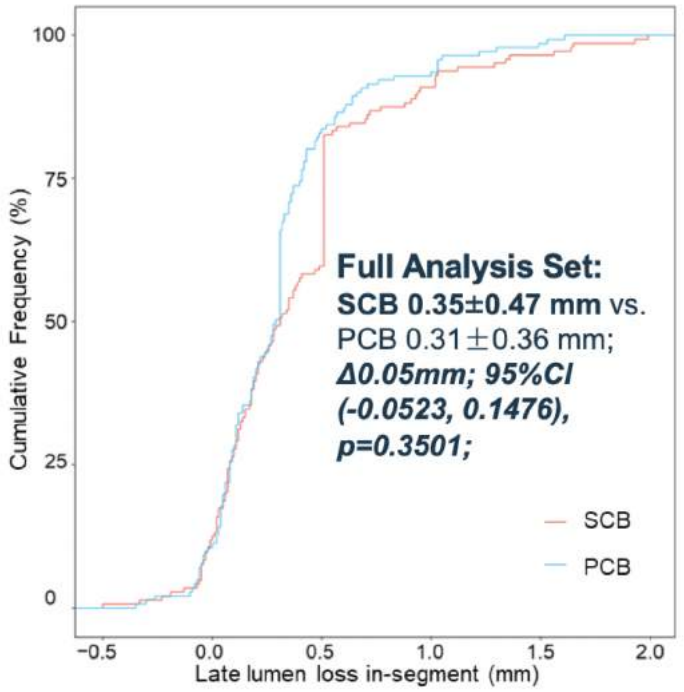
SCB vs. PCB in DES in-stent restenosis

Study Flow chart

Clinical Outcome at 12 months

	SCB Group (n=130 Patients)	PCB Group (n=127 Patients)	p
TLF, n (%)	17(13.1)	14 (11.0)	0.61
Cardiac Death	1(0.8)	1 (0.8)	1.00
Target Vessel MI	1 (0.8)	0	1.00
Clinically-driven TLR	15 (11.5)	13 (10.2)	0.74
PoCE, n (%)	28 (21.5)	26 (20.5)	0.83
All-cause Mortality	1 (0.8)	2 (1.6)	0.62
Any MI	2 (1.5)	1 (0.8)	1.00
Any Revascularization	26 (20.0)	23 (18.1)	0.70

Primary Outcome



Conclusions

- This trial, conducted at 16-Chinese centers, for the first demonstrates that a novel SCB with a dose of 4 mg/mm^2 is non-inferior to a clinically-proven PCB in terms of late lumen loss at 9-month follow-up for patients with DES-ISR.
- Further clinical trial is warranted to identify the improvement in clinical events by SCB for patients with DES-ISR.

Recurrent Revascularization After Treatment Of Drug-Eluting Stent Restenosis With Plain Balloon, Drug-Coated Balloon Or Drug-Eluting Stent

10-Year Results From the Randomized ISAR-DESIRE 3 Trial

Tobias Koch, MD

On behalf of the ISAR-DESIRE 3 investigators

October 26th, 2023

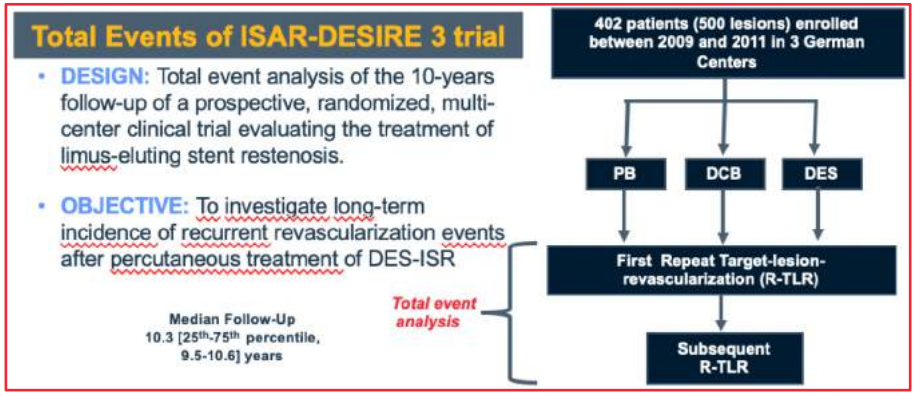
CRF TCT

Technische Universität München

Deutsches Herzzentrum München

10-Year Results From the Randomized ISAR-DESIRE 3 Trial

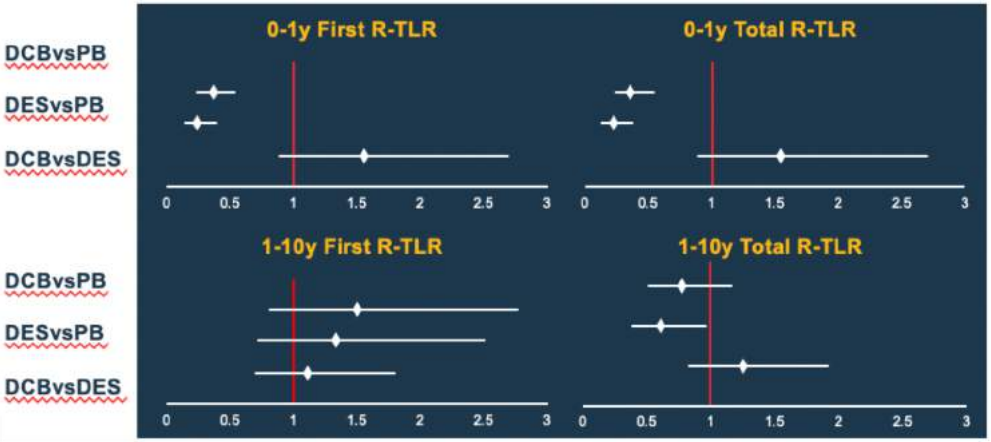
Study Flow



Results According to Randomized Treatment Group

	Lesions, No. (%)			
	PB (n=160)	DCB (n=172)	DES (n=168)	p-Value
Frequency of R-TLR				0.003
No R-TLR	78 (48.8)	102 (59.3)	116 (69.0)	
Single R-TLR	47 (29.4)	47 (27.3)	34 (20.2)	
Multiple R-TLR	35 (21.9)	23 (13.4)	18 (10.7)	

Results of the Lesion-based Analysis of the Effect of Treatment Arm on First and Total R-TLR



Conclusions

- In patients undergoing percutaneous treatment of DES-ISR, recurrent restenosis occurred in one third of cases.
- 45% of R-TLR were subsequent recurrent events, not displayed in conventional time-to-first-event analyses
- DCB and in particular DES are able reduce the need of both, first and recurrent revascularizations as compared with PB
- Addition of total R-TLR in the analysis enabled capturing of treatment effects over the entire 10-year follow-up that were not observable in the analysis confined to first R-TLR only

Long-term Outcomes with Biodegradable Polymer Sirolimus- eluting Stents versus Durable Polymer Everolimus-eluting Stents in ST-segment Elevation Myocardial Infarction: 5-year follow-up of the BIOSTEMI randomized trial

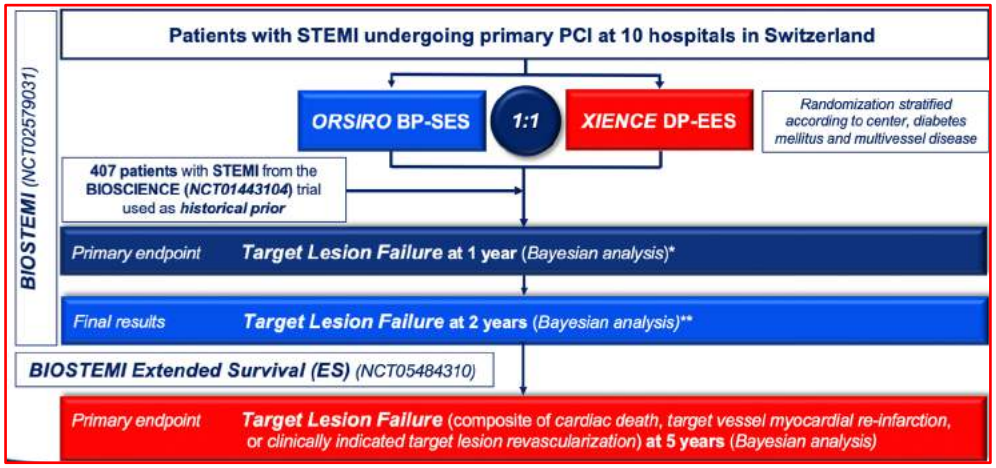
***Juan F. Iglesias**, MD FESC FACC*

Geneva University Hospitals

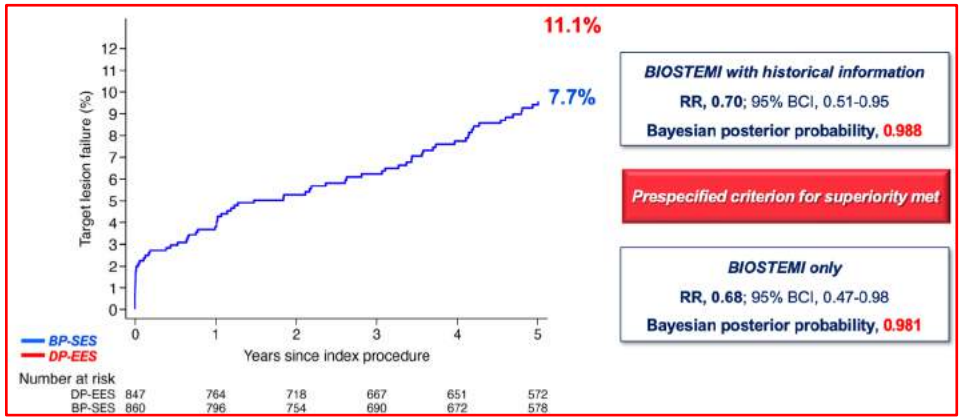
Switzerland

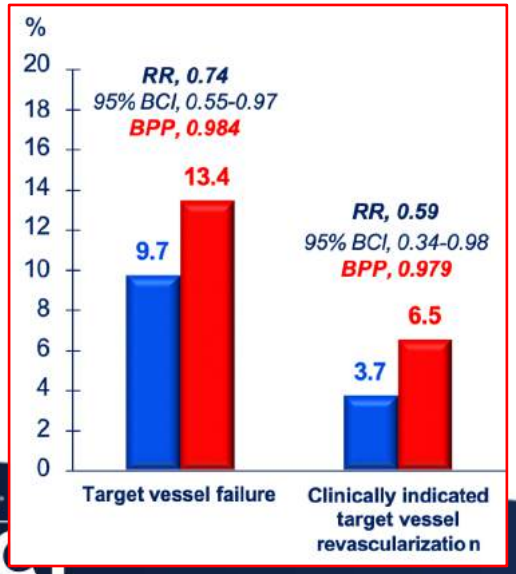
On behalf of the BIOSTEMI Extended Survival (ES) investigators

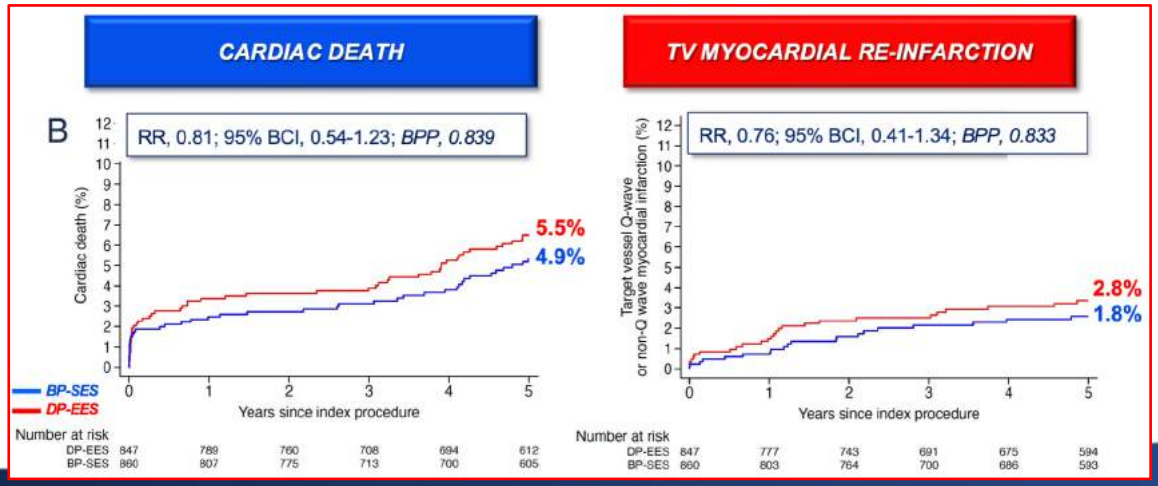
5-year follow-up of the BIOSTEMI randomized trial



Primary endpoint: Target lesion failure @ 5 years







Một số nghiên cứu về các lĩnh vực khác

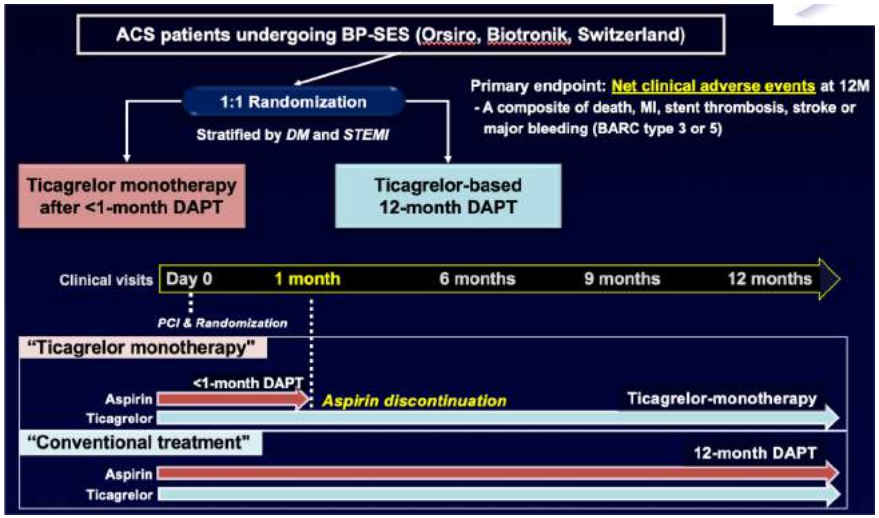
Less than 1-month dual anti-platelet therapy followed by ticagrelor monotherapy after coronary drug-eluting stent implantation for acute coronary syndrome: A randomized T-PASS trial

Myeong-Ki Hong, MD

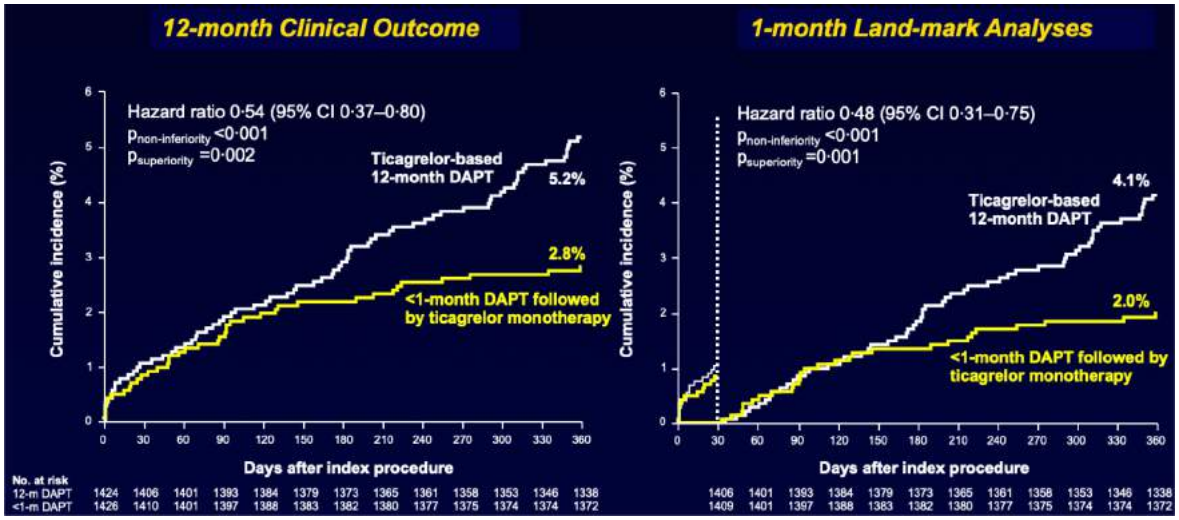
on behalf of the T-PASS trial investigators

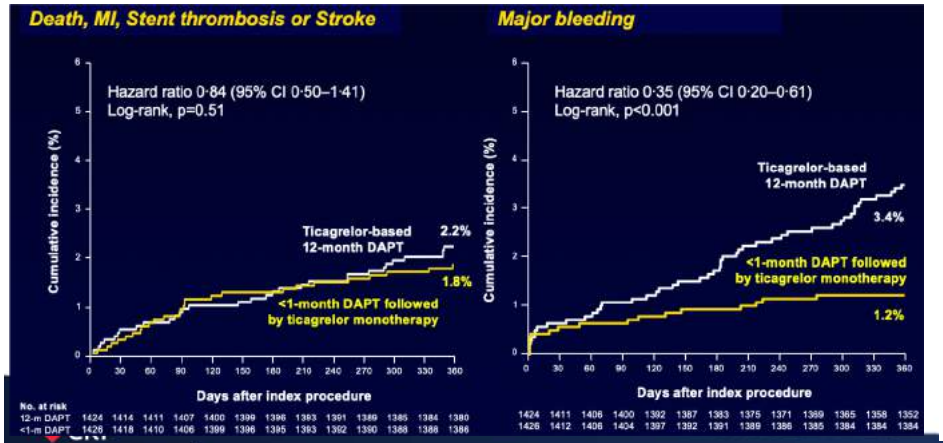
Professor, Yonsei University College of Medicine,
Severance Hospital, Seoul, Korea

T-PASS trial: Kết quả chính



Primary Outcome (NACE)





Conclusions

Among patients treated with ultrathin biodegradable polymer sirolimus eluting stents for ACS,

- <1 month of DAPT followed by ticagrelor monotherapy met a noninferiority threshold and provided evidence of superiority to 12 months of ticagrelor-based DAPT for a 1-year composite outcome of death, myocardial infarction, stent thrombosis, stroke, and major bleeding, primarily due to a significant reduction in bleeding events.
- This study provides evidence that stopping aspirin within 1 month after implantation of drug-eluting stents for ticagrelor monotherapy is a reasonable alternative to 12-month DAPT as for adverse cardiovascular and bleeding events.

TCT

Individual Patient-Data Pooled Analysis of Endovascular Ultrasound Renal Denervation or a Sham Procedure at 6 Months in the RADIANCE Clinical Trial Program

Ajay J. Kirtane, MD, SM
Columbia University Irving Medical Center
NewYork-Presbyterian Hospital

on behalf of Michel Azizi and the RADIANCE Investigators

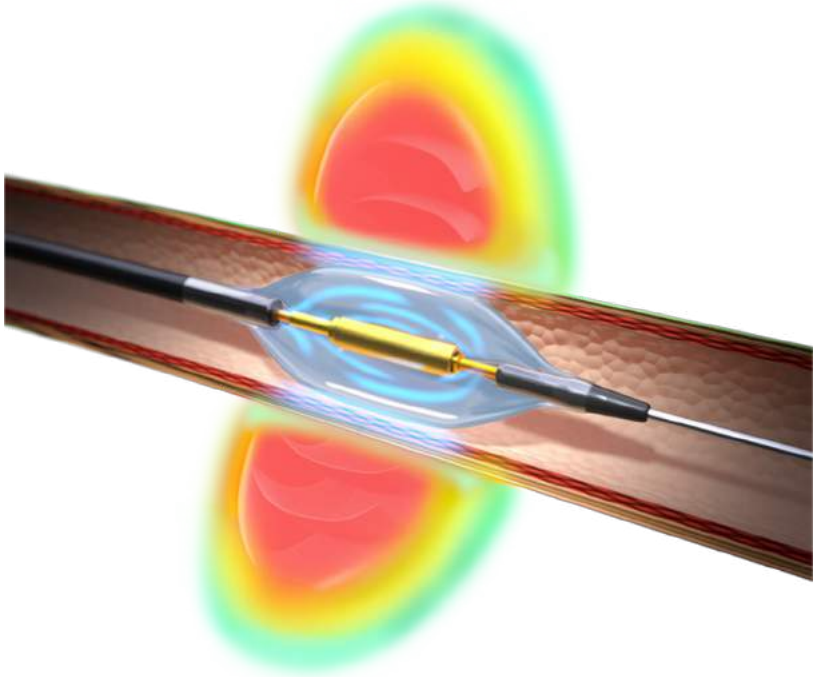
CRF TCT

Paradise Ultrasound Renal Denervation System

- Circumferential ring of ablative energy (depth of 1-6 mm) to interrupt renal nerve signaling
- Arterial wall protected by water circulating through balloon
- 2-3 sonications each lasting 7 seconds are delivered to appropriately sized renal arteries

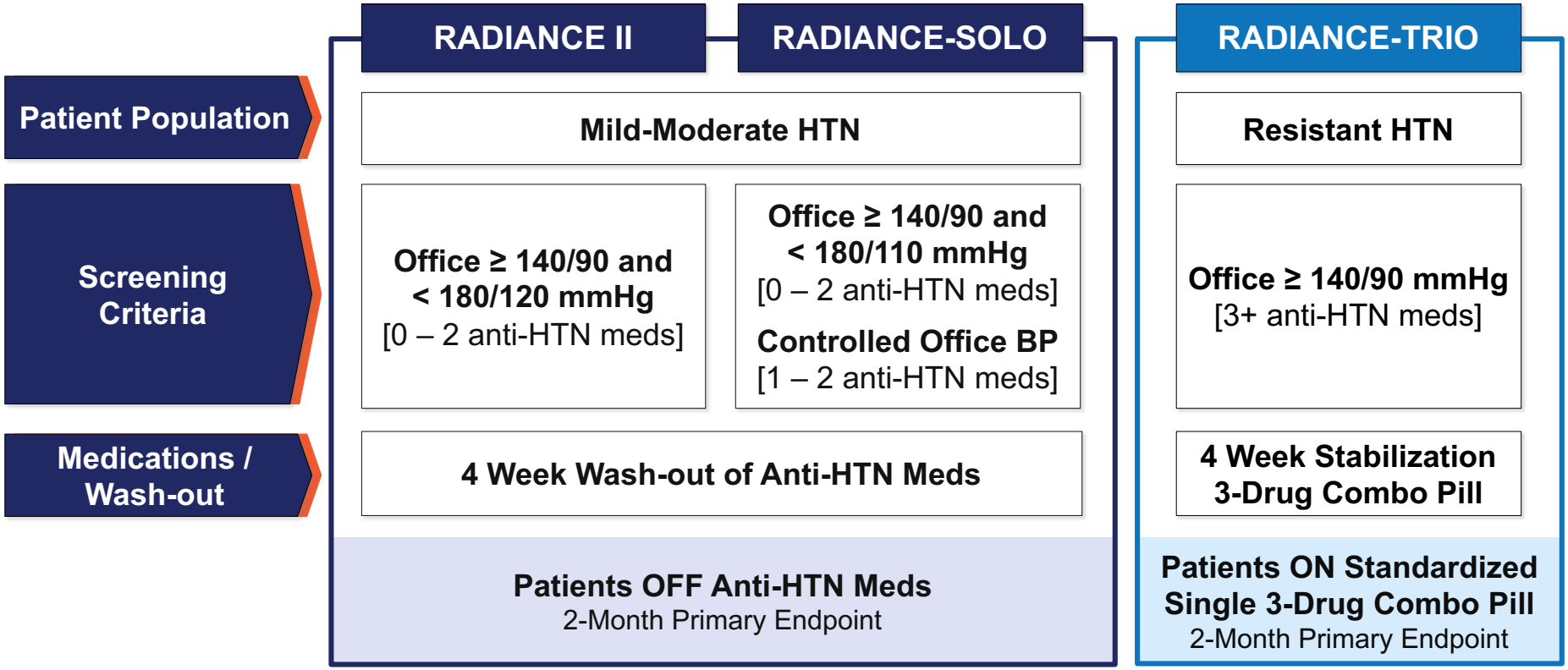
Thermal Profile

Ultrasonic Heating + Water Cooling

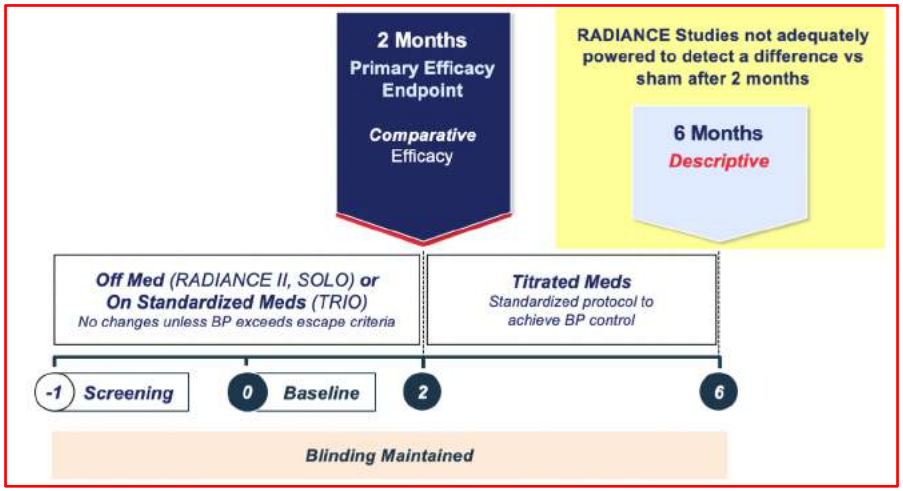


RADIANCE Study Designs (RADIANCE II, SOLO, and TRIO)

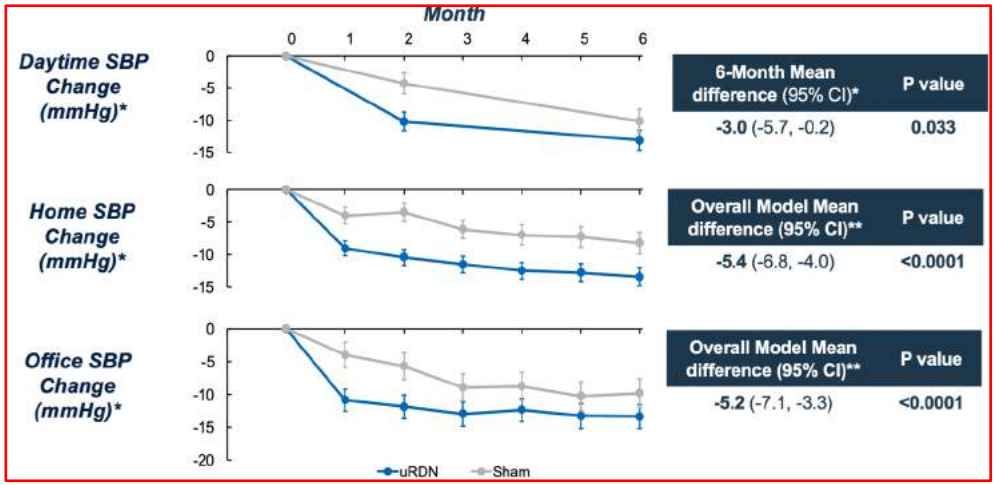
Blinded, Sham-Controlled, Individually Powered Trials to Demonstrate BP Lowering



RADIANCE Pooled Analysis



Baseline-adjusted SBP over Time (adjusting for medications)



Medication Changes at 6M in Patients with Drop in Home SBP ≥ 10 mmHg

Characteristic, mean ± SD	uRDN N = 203	Sham N = 113	P value*
Change in Number of anti-HTN meds at 6 Months from Baseline	+1.2	+1.7	<0.0001
Change in Medication dose burden at 6 Months from Baseline			
Change in Defined Daily Dose	+1.5	+2.2	<0.0001
Change in Antihypertensive medication load index	+0.6	+0.9	<0.0001

Conclusions

- Each of the three independently powered trials of the RADIANCE-HTN program previously showed that uRDN with the Paradise system safely reduced BP at 2 months vs. a sham procedure in patients with mild to moderate hypertension off-medications or with resistant hypertension on triple-drug fixed dose combination therapy
- The present individual patient data analysis demonstrates that after initiating standardized medication regimen for hypertension control from the 2nd month post-procedure onwards, there was less addition of these medications in the uRDN group compared with sham, and after adjustment for this difference, the BP lowering effect of uRDN vs. sham was maintained throughout the 6-month follow-up

Save The Date for TCT 2024

October 27–30, 2024

The Global Forum for Interventional Cardiology Is in Washington, D.C.!