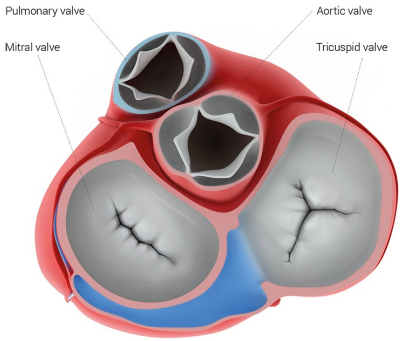
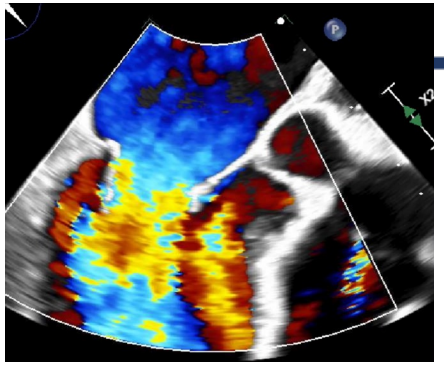
Indiana-ACC 2022 Annual Meeting

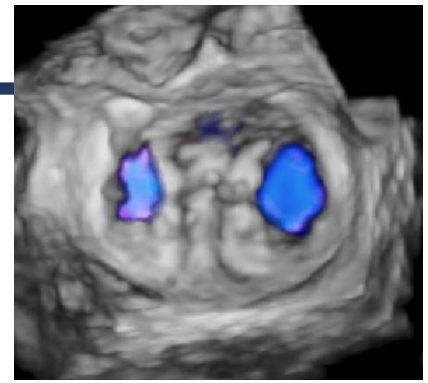
Friday, Sept 10th, 2022
11:30 – 12:15 AM



Structural Heart Intervention: Present and Future



James B. Hermiller, MD, MSCAI, FACC
Ascension Medical Group
Ascension St Vincent Heart Center of Indiana
Indianapolis, IN



American College of Cardiology | Indiana Chapter

Ascension St. Vincent

Disclosures

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

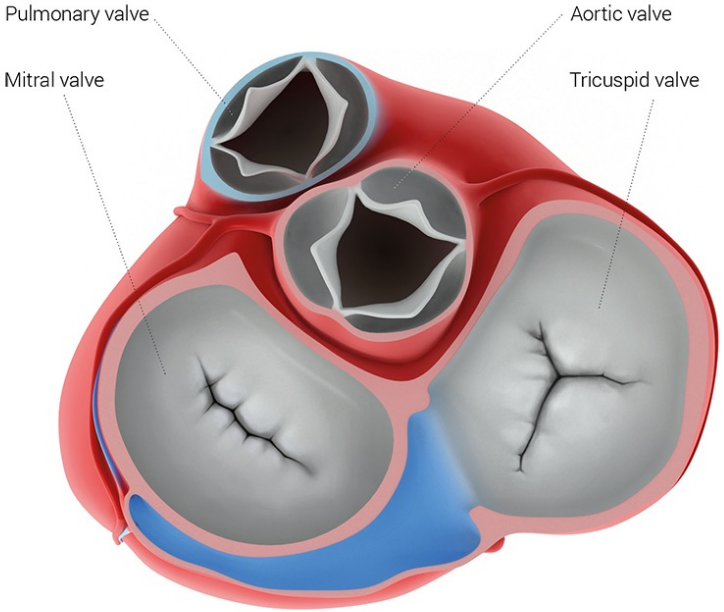
Affiliation/Financial Relationship	Company
• Grant/Research Support	• Abbott, BSC, Edwards, Medtronic
• Consulting Fees/Honoraria	• Medtronic, Edwards, Abbott, BSC

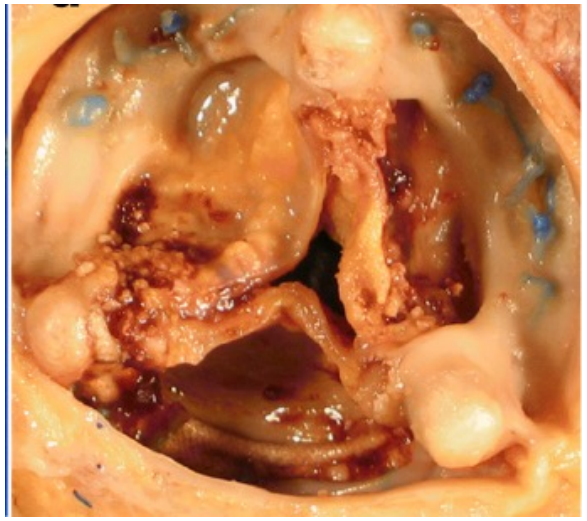
Outline

- Introduction: How did we get here?
- Transcatheter Valve Intervention
  - TAVR, TEER, TMVR, TTVR
- Stroke Prevention
- Conclusion

The SHD Journey: Hyper-Innovation

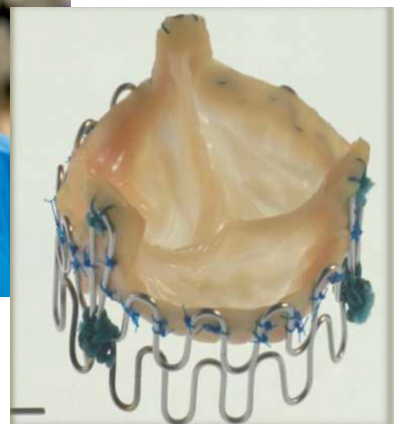
The SHD Journey



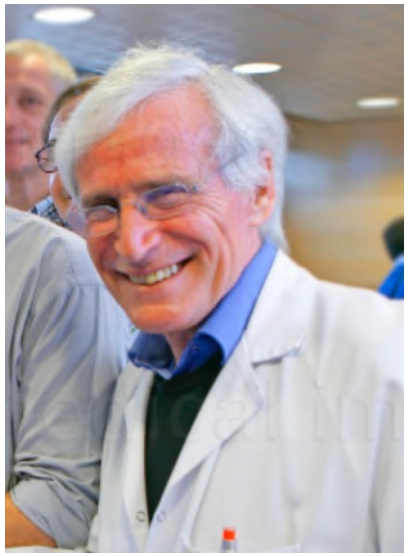


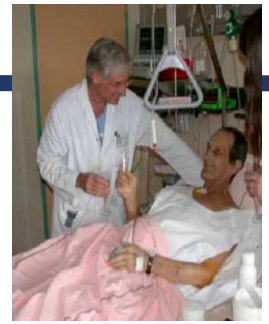
TAVR

Henning Anderson 1992:
First Description of Valve Sutured in Stent
Porcine Model



Alain Cribier April 16, 2002:
First Description of Valve Sutured in Stent
Porcine Model

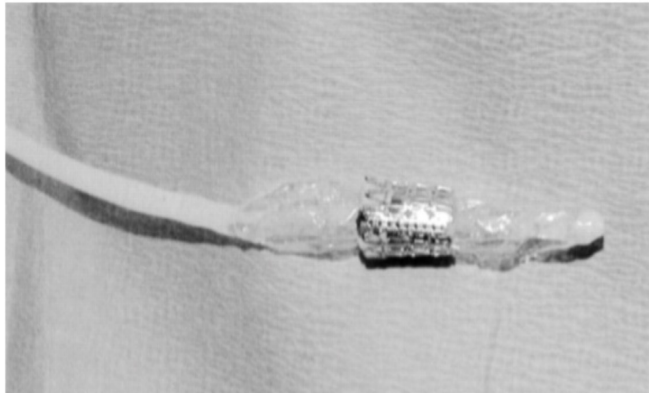




Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

Alain Cribier, Helene Eltchaninoff, Assaf Bash, Nicolas Borenstein, Christophe Tron, Fabrice Bauer, Genevieve Derumeaux, Frederic Anselme, François Laborde, and Martin B. Leon

Circulation, Volume 106(24):3006-3008 December 10, 2002



Big Bang

TAVR

John Webb 2005
Successful TF TAVR

Circulation. 2006;113:842–850

Eberhart Grube 2005
Self-Expanding TAVR

Circulation. 2006;114:1616–1624

Off to The Races

101-Year-Old Becomes World Record Holder in 100-Meter Dash: 'I Missed My Nap For This'

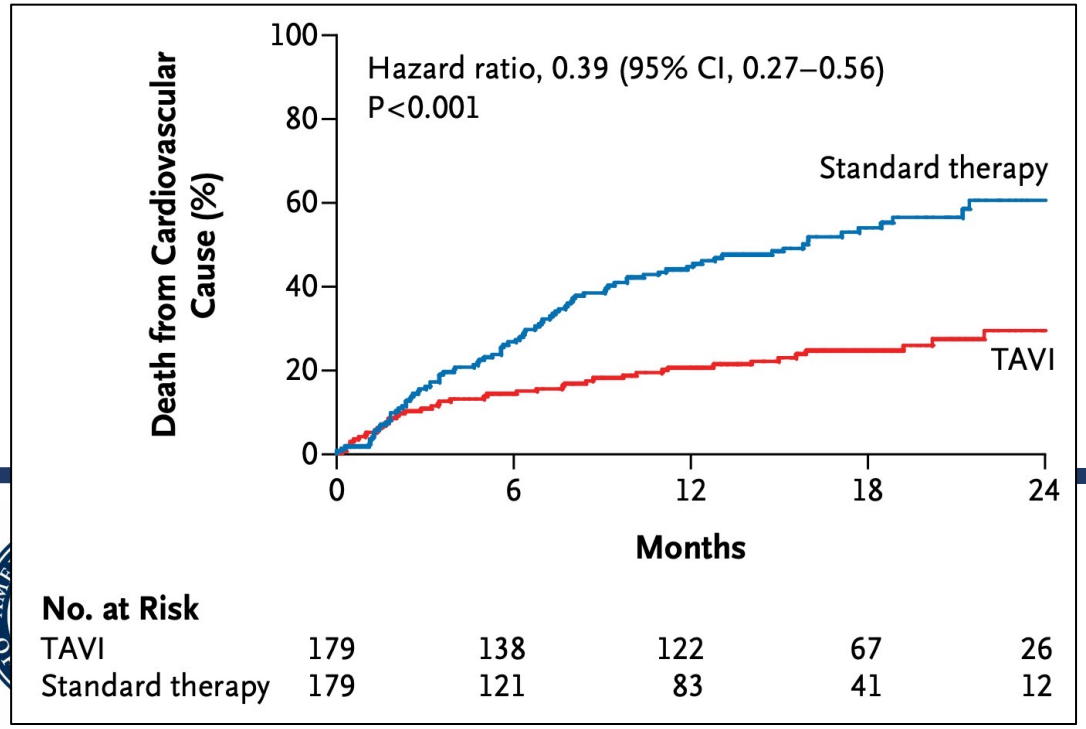
TAVR – Cadence of Innovation and Science

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

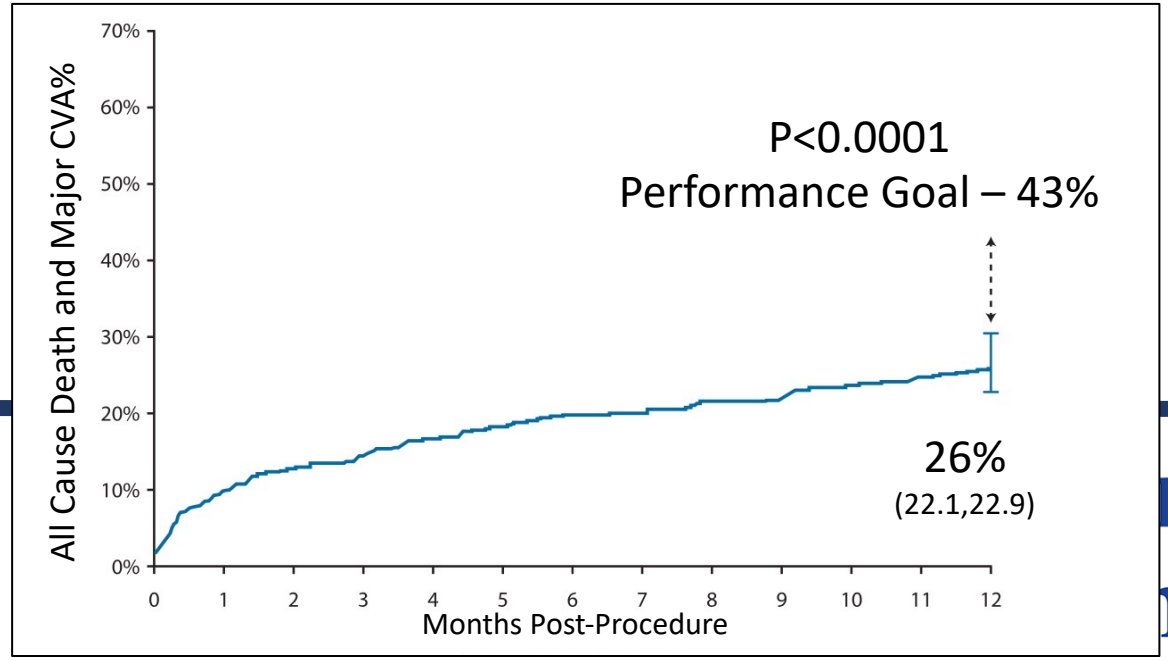
Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*



Transcatheter Aortic Valve Replacement Using a Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis at Extreme Risk for Surgery

J Am Coll Cardiol 2014;63:1972–81

Jeffrey J. Popma, MD,* David H. Adams, MD,† Michael J. Reardon, MD,‡ Steven J. Yakubov, MD,§ Neal S. Kleiman, MD,‡ David Heimansohn, MD,‖ James Hermiller, JR, MD,‖ G. Chad Hughes, MD,¶ J. Kevin Harrison, MD,¶ Joseph Coselli, MD,# Jose Diez, MD,# Ali Kafi, MD,** Theodore Schreiber, MD,** Thomas G. Gleason, MD,†† John Conte, MD,‡‡ Maurice Buchbinder, MD,§§ G. Michael Deeb, MD,‖‖ Blasé Carabello, MD,¶¶ Patrick W. Serruys, MD, PHD,## Sharla Chenoweth, MS,*** Jae K. Oh, MD,††† for the CoreValve United States Clinical Investigators



TAVR – Cadence of Device Improvement

Miniaturization

PV Leak Solutions

Improved Imaging

Take A Mulligan:
Recapture and reposition

TAVR

Low Risk

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 2, 2019 VOL. 380 NO. 18

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

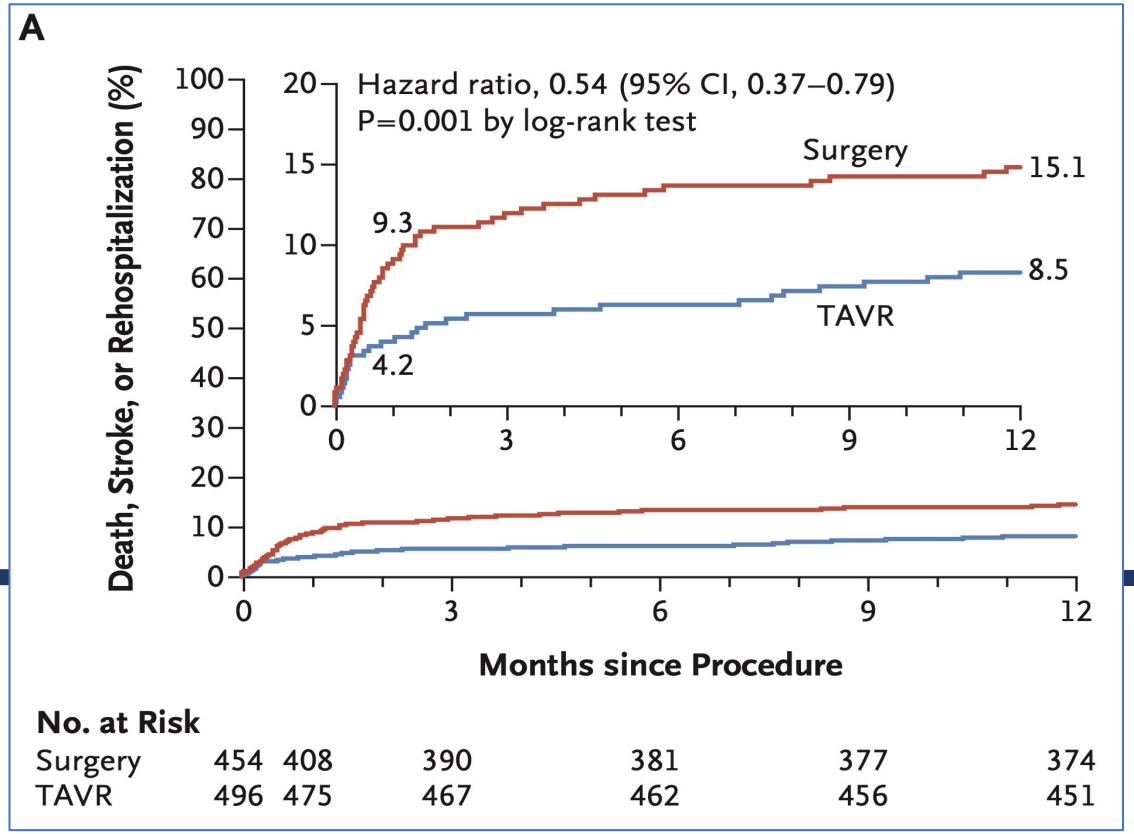
M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*

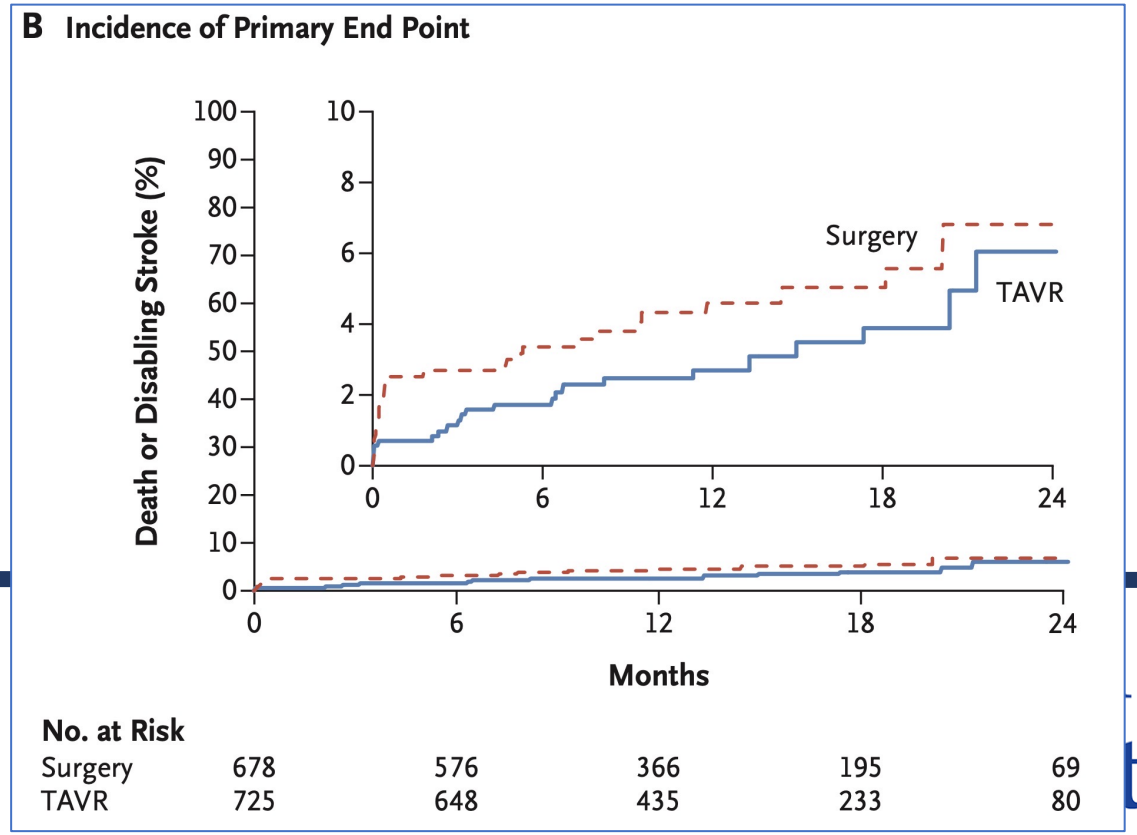
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

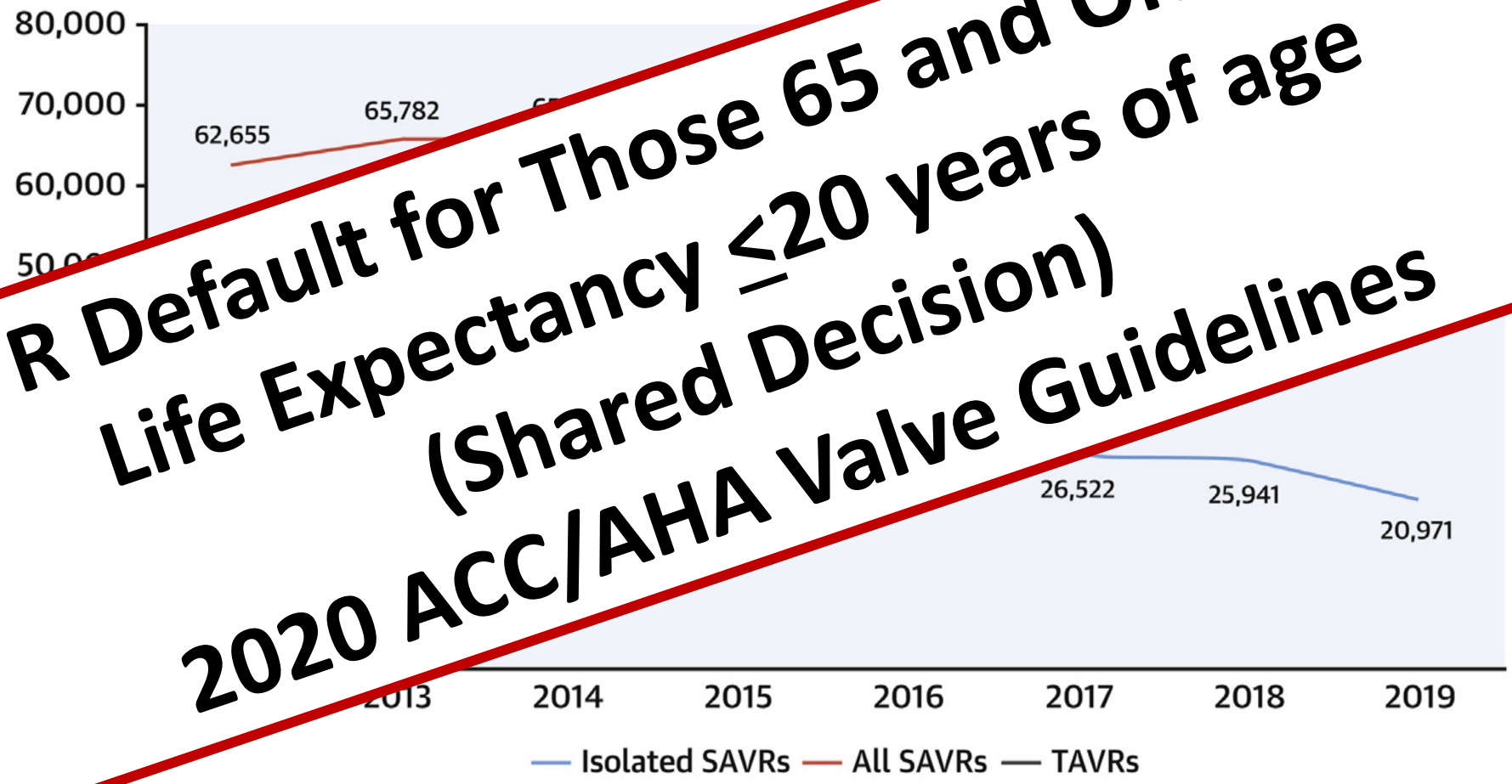
Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D.,





Annual volumes of TAVR a



TAVR Default for Those 65 and Older With Life Expectancy ≤20 years of age (Shared Decision)

2020 ACC/AHA Valve Guidelines

Ann Thorac Surg 2020;-:--- ! 2020 by The Society of Thoracic Surgeons and the American College of Cardiology Foundation

Indiana CHAPTER

Ascension St. Vincent

TAVR – Unmet Challenges

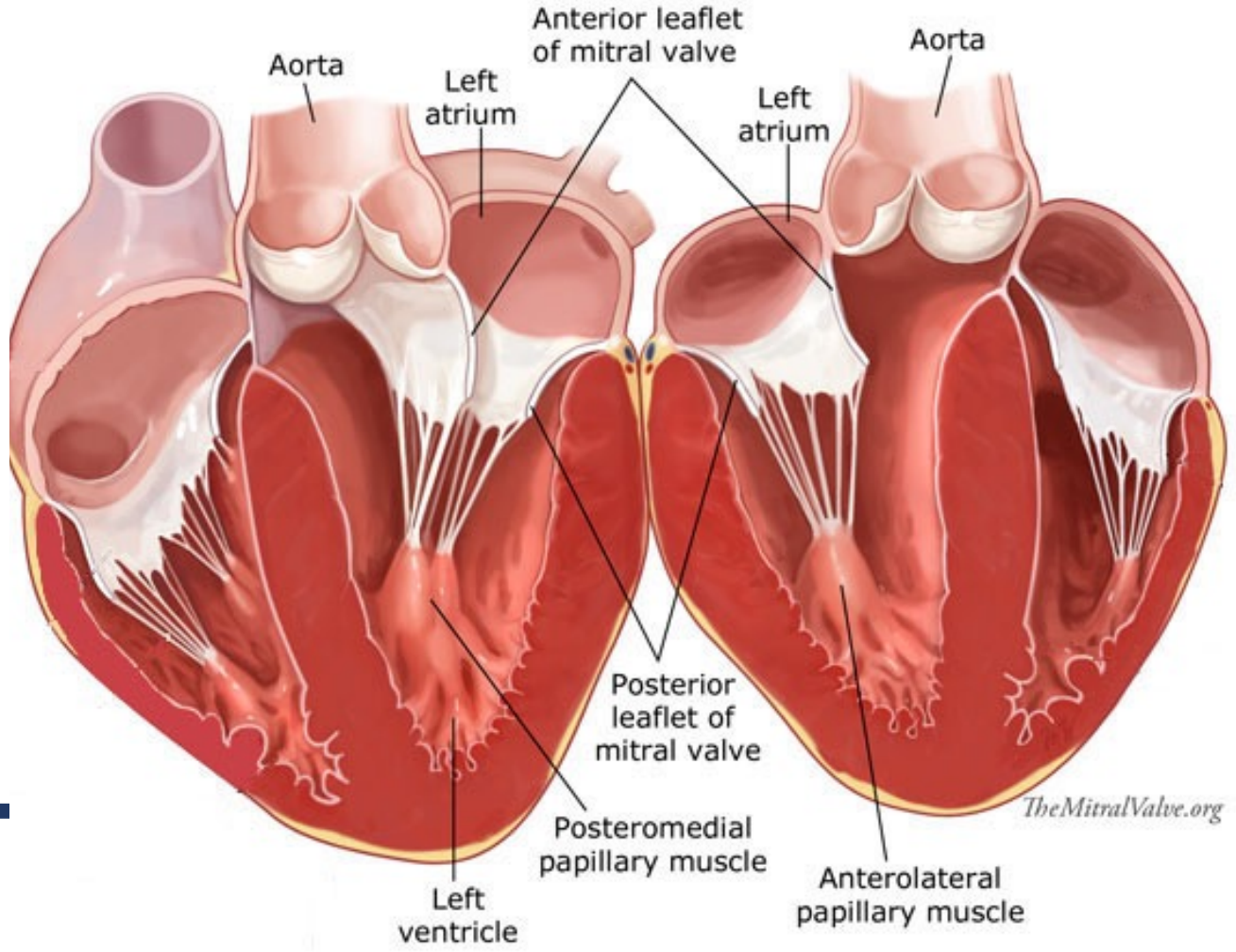
- Valve Durability
- Valve in Valve – TAV in SAV and TAV in TAV
  - Commissural Alignment, Leaflet Modification
- Embolic Protection
- Pure Aortic Insufficiency
- New Indications – Moderate AS, Asymptomatic
- Life-Long Management

TAVR – Heart Team

Indiana CHAPTER

Mitral: Holiest of Valves

Andreas Vesalius 1543 - Mitre



The Mitral Valve Complex: It's a House of Cards

Surgical Mitral Intervention

Transcatheter Mitral Intervention

Mitral Intervention: Imitate Alfieri

How Dr. Oz Kick-Started a Groundbreaking Device for Patients with Heart Failure

SEPTEMBER 26, 2018 – 7:00 AM – 0 COMMENTS

11

By CHRISTINE COPELAN

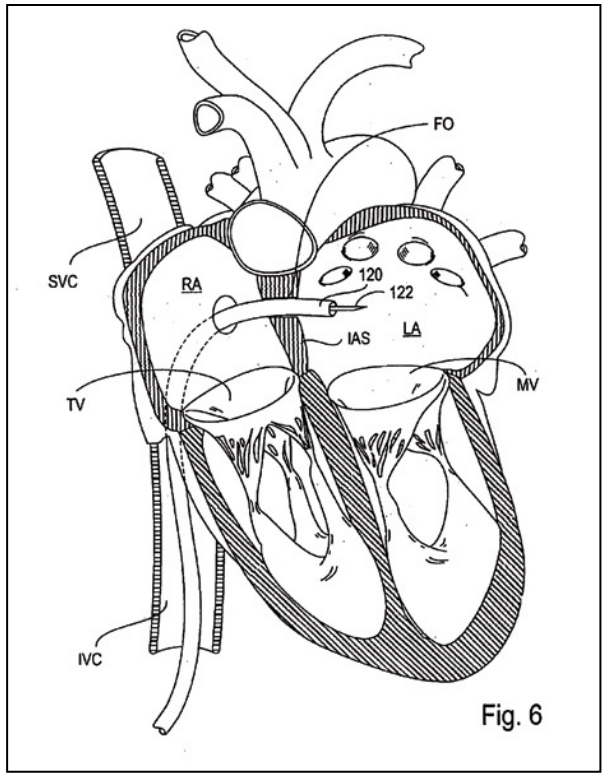


Fig. 6

American College of Cardiology | Indiana Chapter

Ascension St. Vincent

Mitral Intervention

MITRACLIP
The Beginning

P. P. Rubens, Daniel in the Lion s Den. - Peter Paul Rubens

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2011 VOL. 364 NO. 15

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

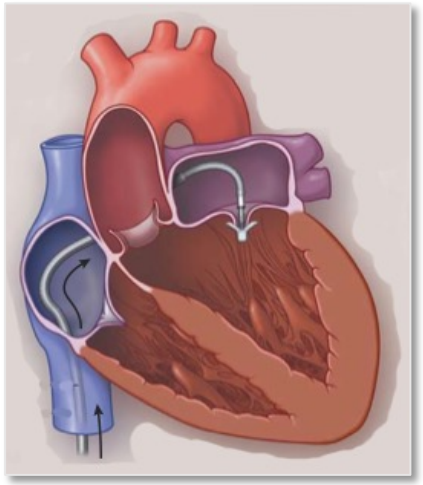
BACKGROUND

Mitral-valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.

of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral-valve dysfunction, 20% versus 2%; and grade 3+ or 4+ mitral regurgitation, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days ($P<0.001$). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with baseline.

CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)



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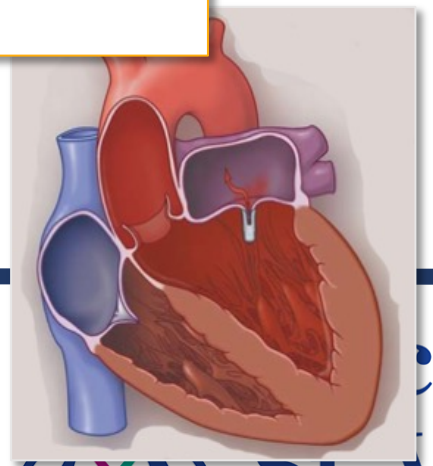
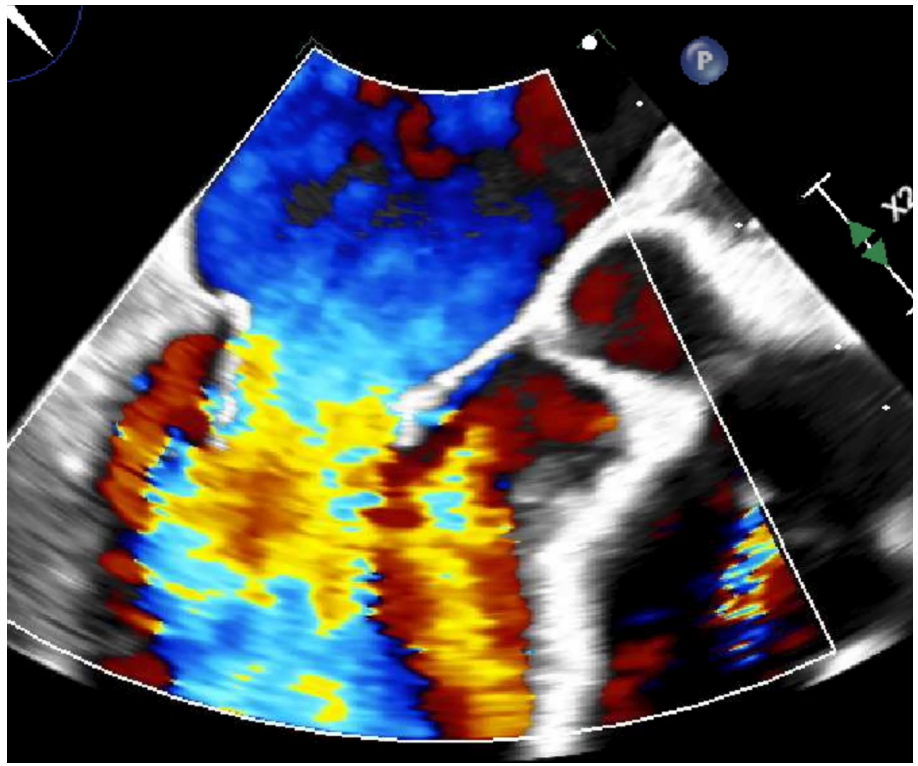
Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.

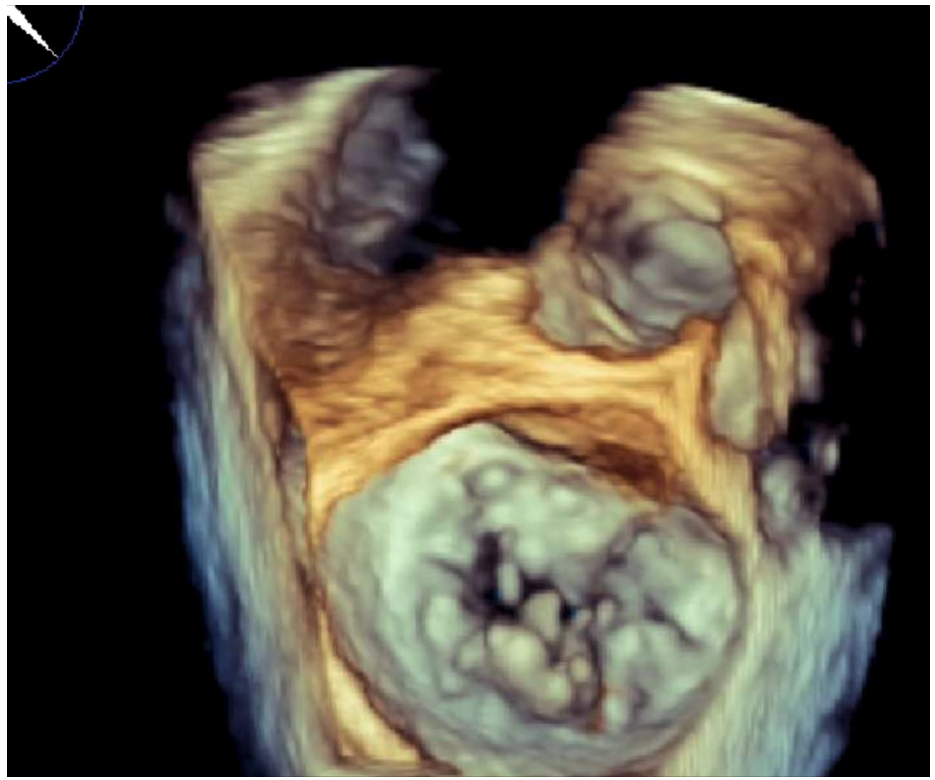


Indiana CHAPTER

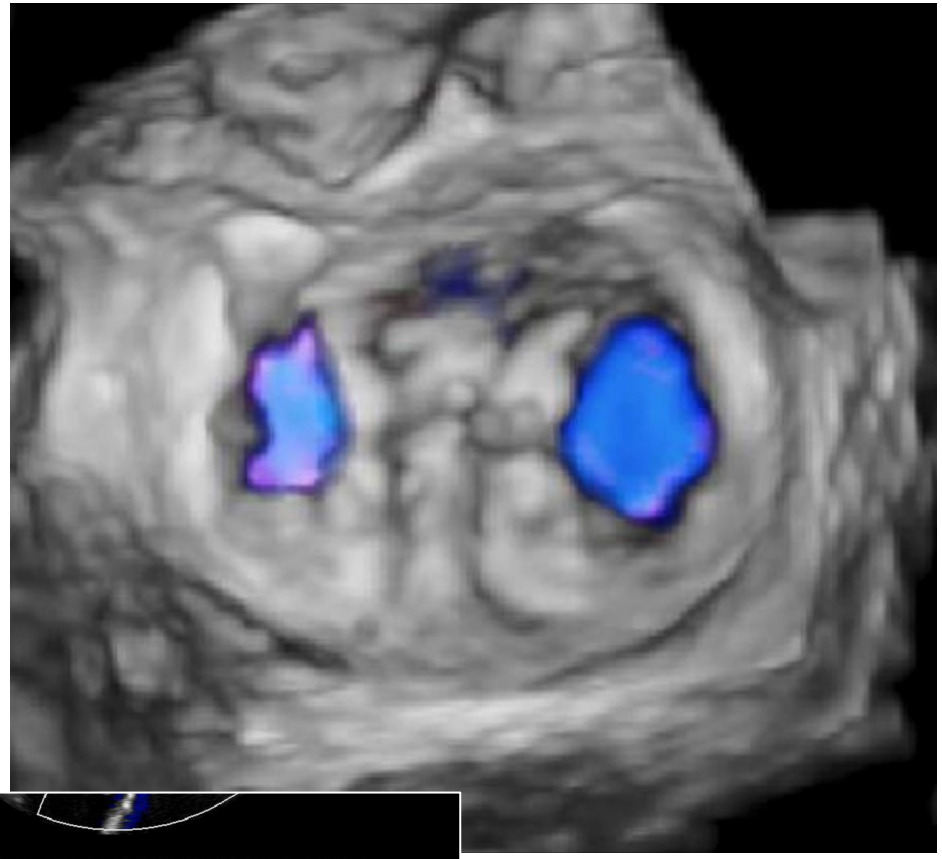
ension St. Vincent

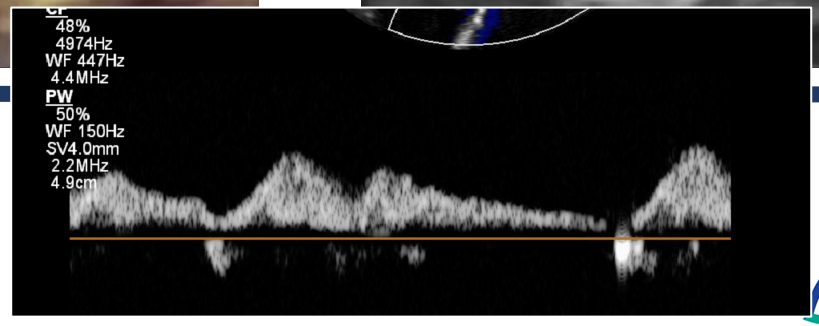
Mitral Intervention



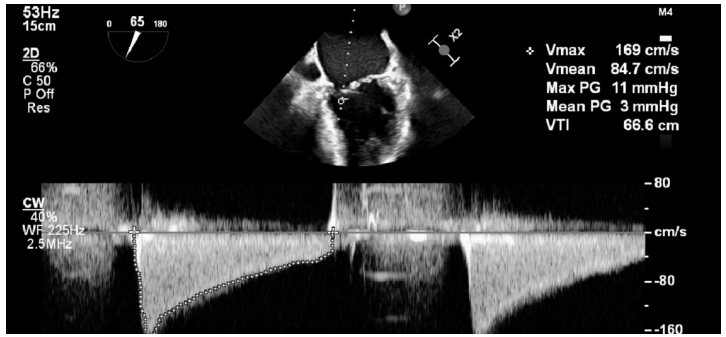


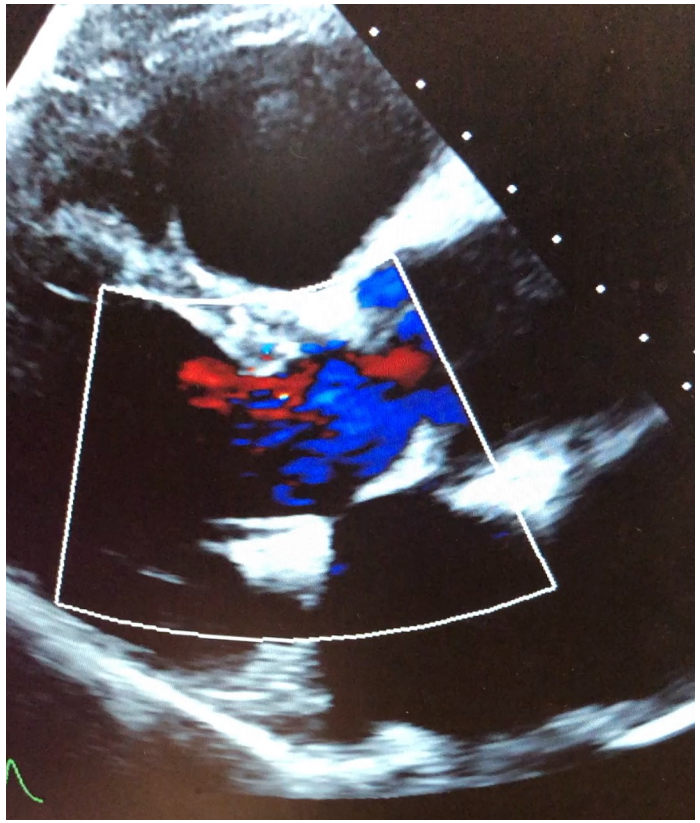
Mitral Intervention





Mitral Intervention





Mitral Intervention

Does Reducing MR Mechanically Matter in FMR?

Mitral Intervention - COAPT

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*

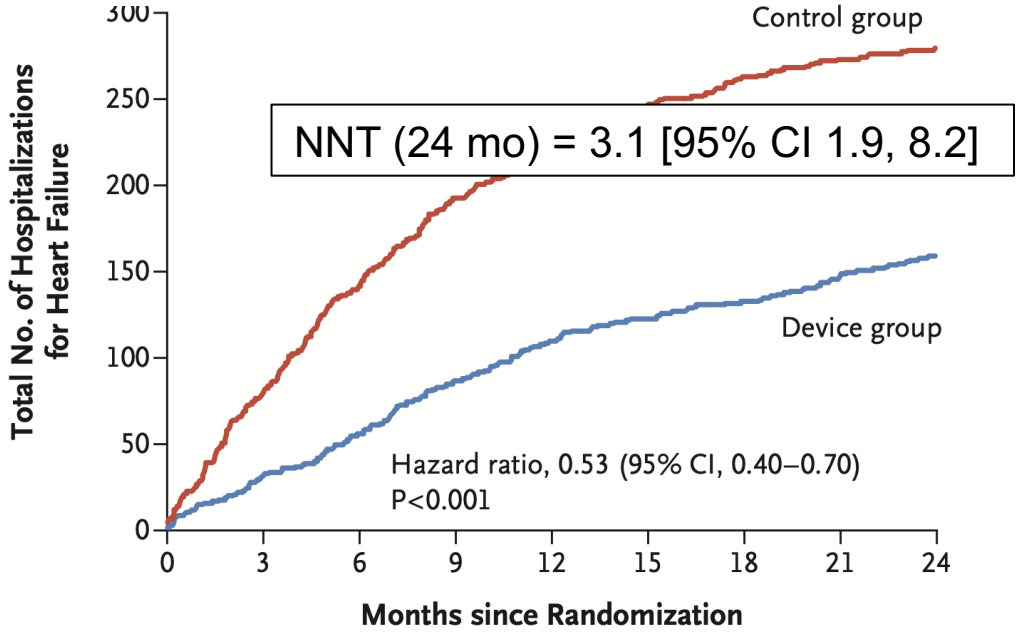
N Engl J Med 2018;379:2307-18.

Indiana CHAPTER

Ascension St. Vincent

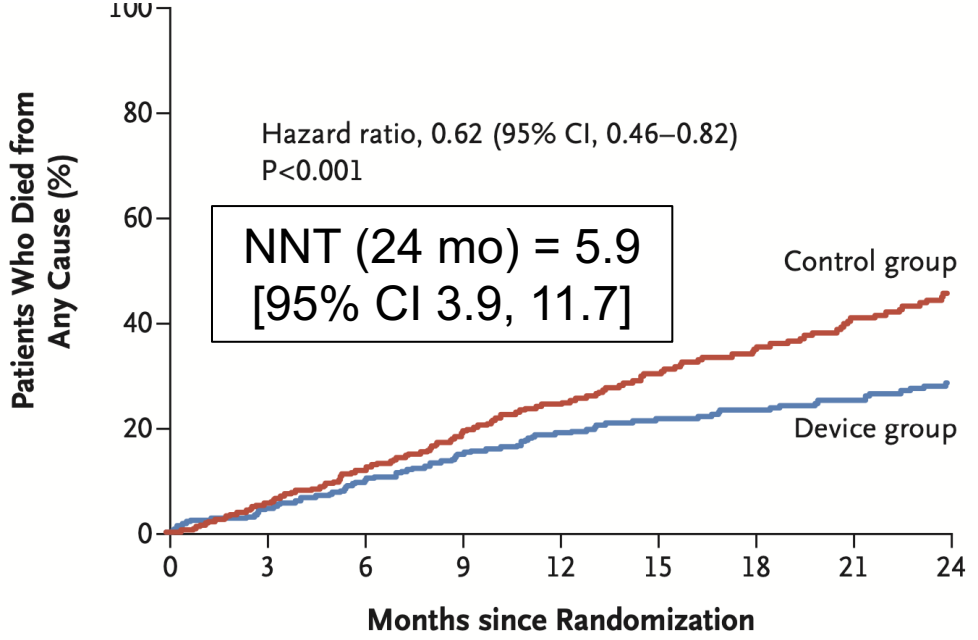
Mitral Intervention - COAPT

Hospitalization for Heart Failure



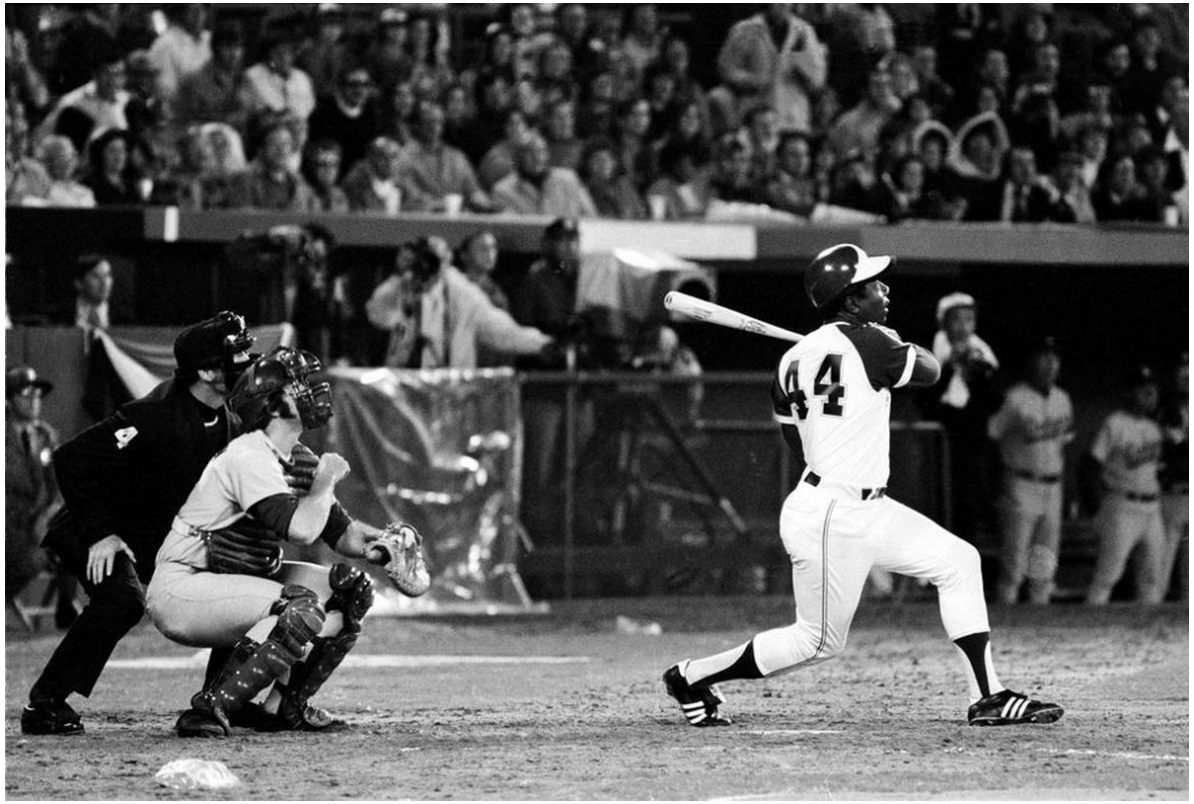
No. at Risk									
Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124

Death from Any Cause



No. at Risk									
Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124

Mitral Intervention - COAPT



Mitral Intervention – MITRA-FR

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 13, 2018 VOL. 379 NO. 24

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*

N Engl J Med 2018;379:2297-306.

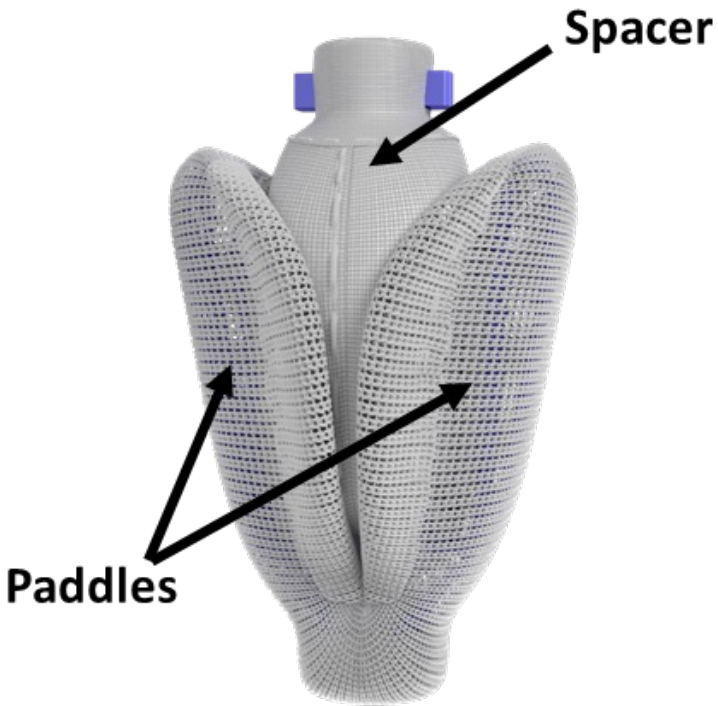
Indiana CHAPTER

Ascension St. Vincent

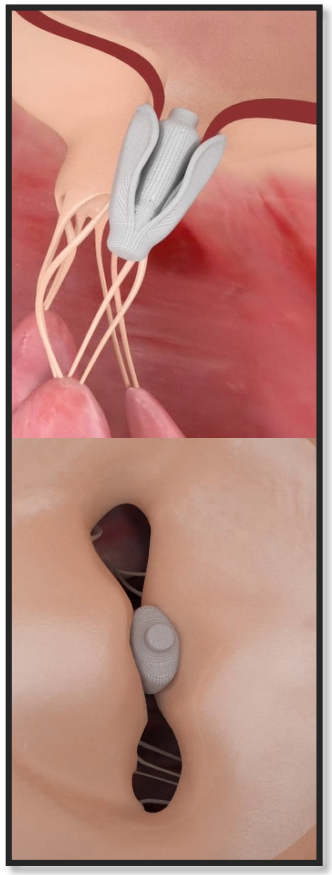
Mitral Intervention – Medical Rx

Mitral Innovation: New Mousetraps

TMvR Device Innovation – Leaflet Directed



PASCAL Transcatheter Valve Repair System

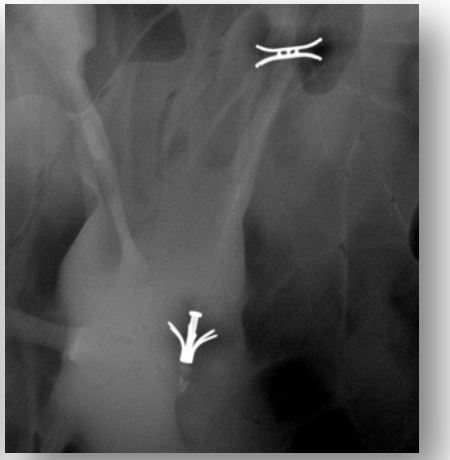


CoreMedic - ChordArt TMCI

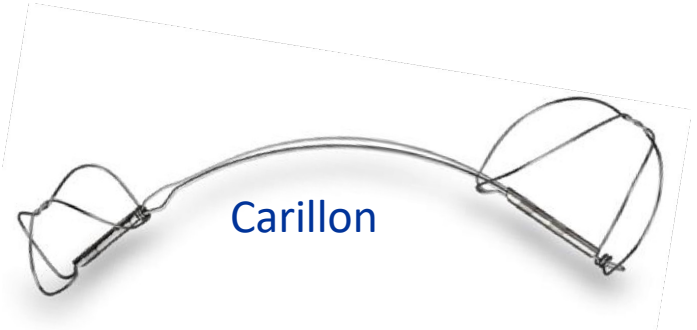
Transcatheter Mitral Chords Implantation

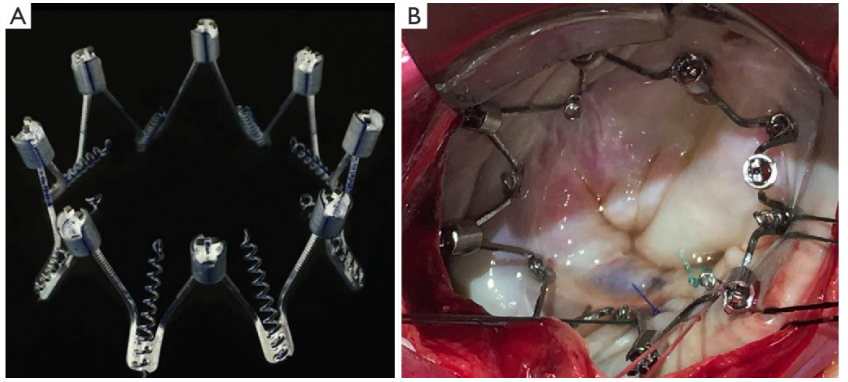
- Unique Implant design:

  papillary muscle anchor + suture + leaflet anchor

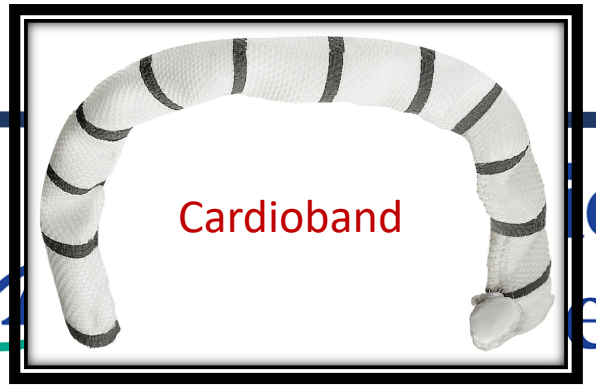


TMVr Device Innovation - Annuloplasty





IRIS mitral annuloplasty

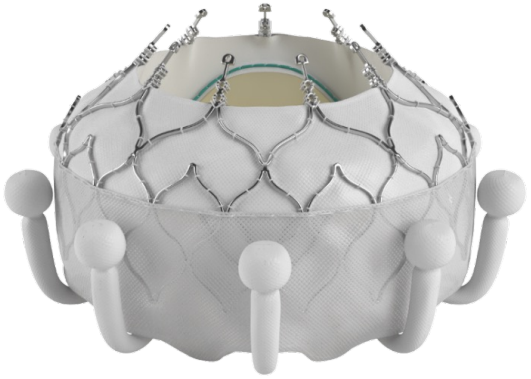


Mitral Intervention – TMVR

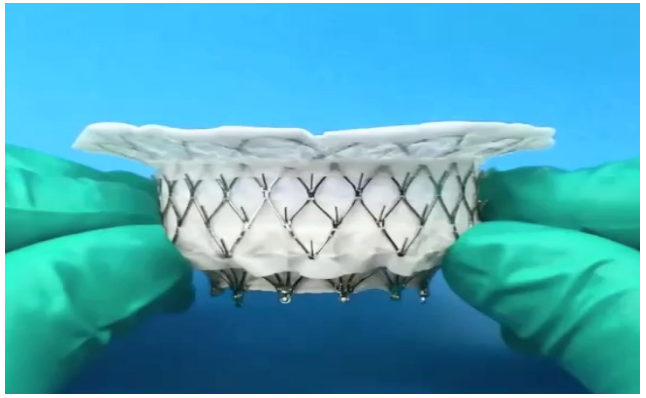
Mitral Intervention – Transseptal TMVR

- Complex curve from IVC to mitral valve
- To be orthogonal to valve plane, not a single angle, but rather two 90+ degree bends
- Delivery of large valve around curves (think of a BUS)
- Device may have to be unique design
  - Single device vs. multiple steps
- Iatrogenic ASD

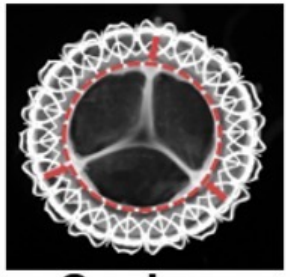
Mitral Intervention – Transseptal TMVR



Edwards EVOQUE



Medtronic Intrepid



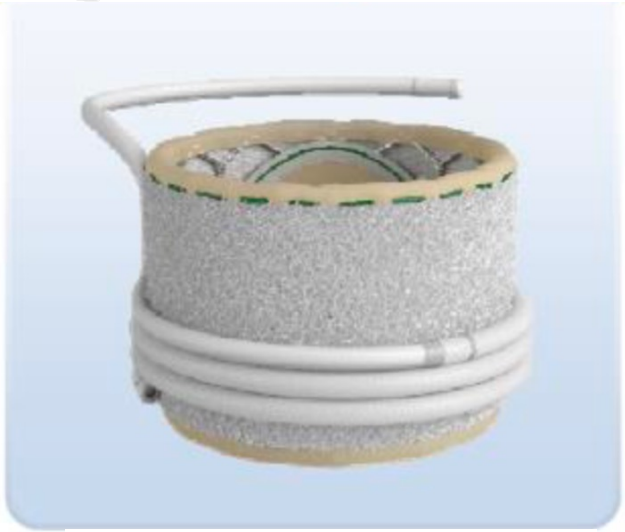
Cephea

AltaValve

POLARES

M3 Dock

SAPIEN M3 Valve



SAPIEN M3 System

Mitral Intervention – TMVR vs TMVr

- Clinical Need for TMVR (Reversibility of TEER)
  - Fewer anatomic exclusions
  - Potentially simpler procedure and less variable result
- Designs are converging
  - Transseptal
  - LVOT obstruction
- However, mitral valve anatomy and disease is complex – Valve thrombosis
  - "One size fits all" transcatheter valve replacement therapy unlikely
- Evidence: Specter of TEER safety vs improved MR reduction – "jury out"

Tricuspid Valve – Forgotten No More

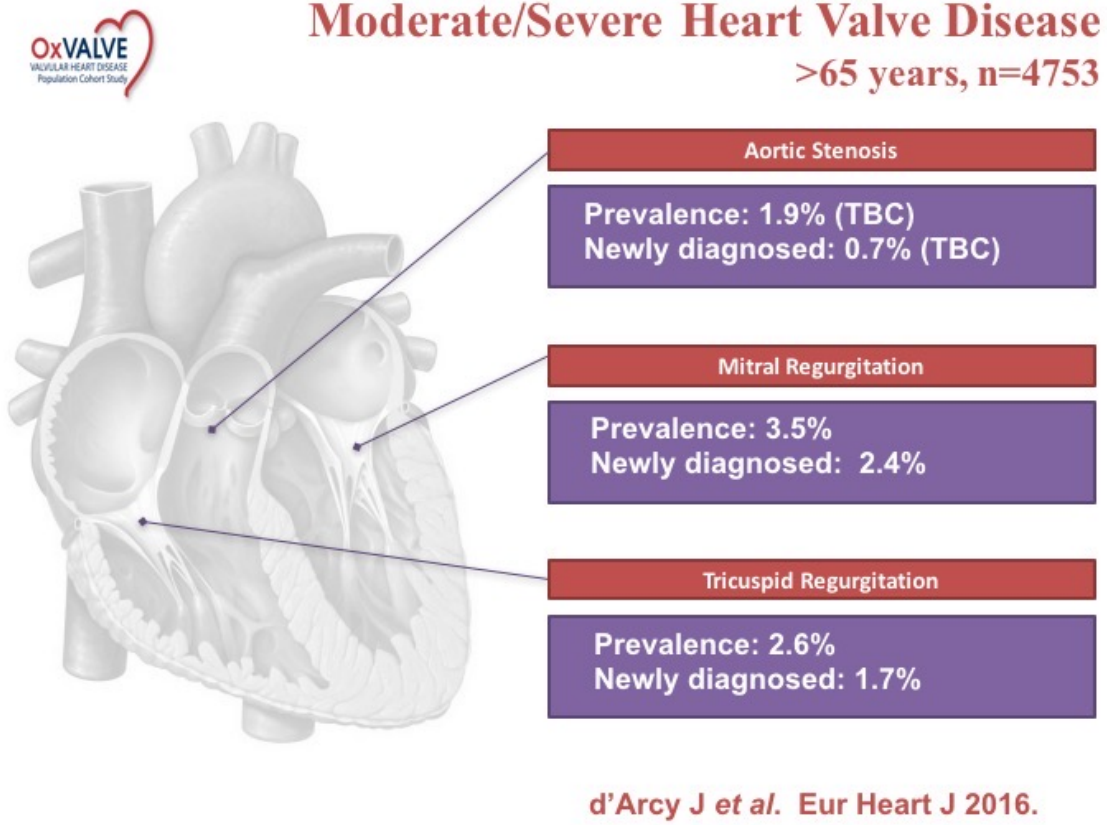
Conservative Management of Tricuspid Regurgitation in Patients Undergoing Mitral Valve Replacement

By Nina S. Braunwald, M.D., John Ross, Jr., M.D., and Andrew G. Morrow, M.D.

Summary:

In many patients with advanced mitral valve disease, associated tricuspid regurgitation is of a functional nature and secondary to right ventricular hypertension and dilatation of the tricuspid annulus. The present results indicate that in such patients tricuspid regurgitation will improve or disappear after mitral replacement and that tricuspid valve replacement is seldom necessary.

Circulation 1967;35:I-63



d'Arcy J *et al.* Eur Heart J 2016.

Tricuspid Valve – Forgotten No More

Unmet need for transcatheter solution

1.6M

People in the US Suffer from TR

Only 8,000 Procedures

Tricuspid surgical procedures performed annually in the US

~500

Isolated TV surgeries annually

High Mortality Rates

9% **Isolated TV surgery**

11% **Concomitant TV surgery**

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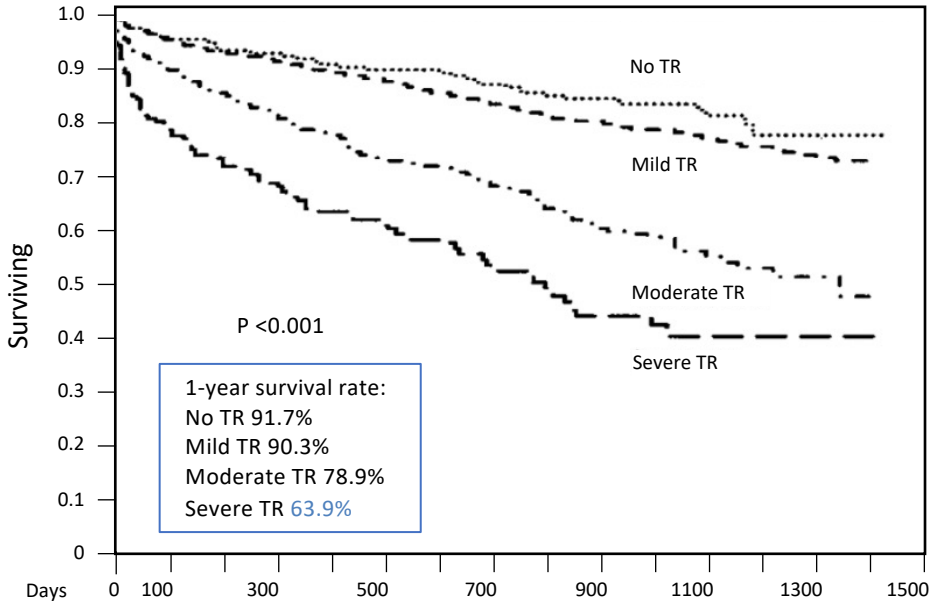
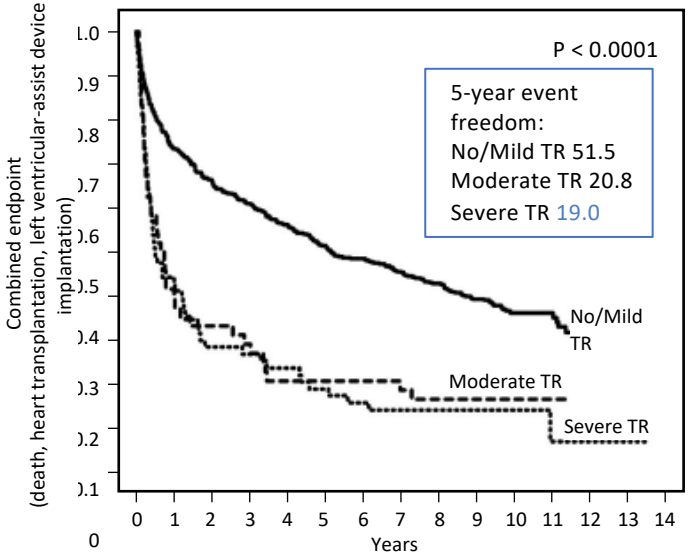
Tricuspid Valve – TR is BAD

Retrospective analysis of 5,223 patients (age 66.5 ± 12.8 years) adjusted for age, LVEF, inferior vena cava size, and RV size and function



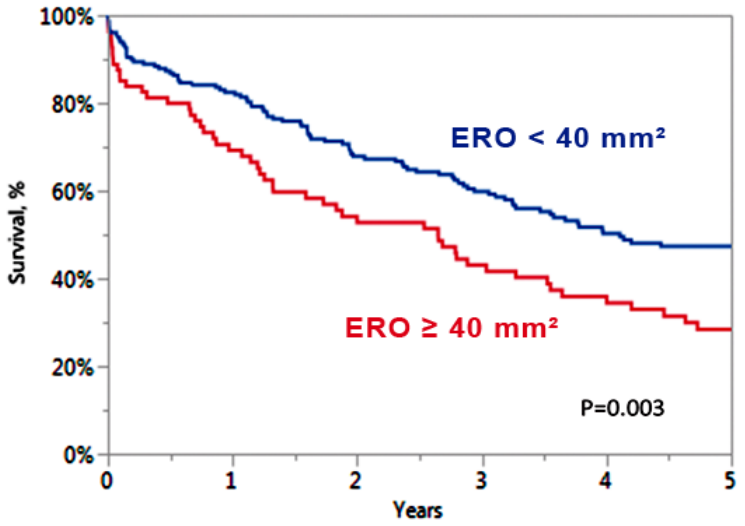
Nath et al. J Am Coll Cardiol 2004;43:405–09

Prospective analysis of 576 consecutive patients with CHF (age 56.4+ 11.2 years)



Neuhold et al. Eur Heart J 2013;34:844–52

Retrospective analysis of 291 patients with LVEF<50% and Functional TR (age 70 ± 12 yrs; EF 31±10%)



Topilsky et al. Eur Heart J Eur Heart J. 2018 Jul 27

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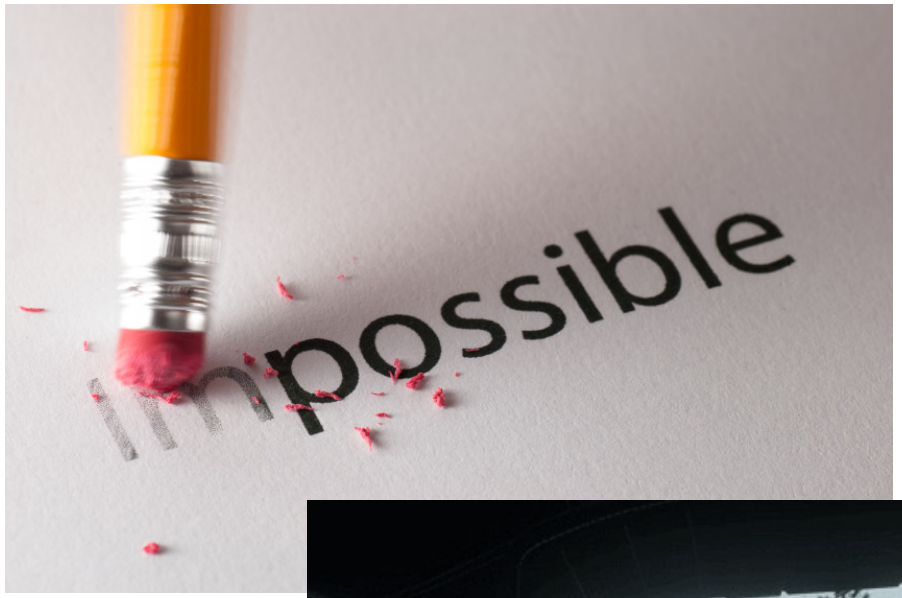
Tricuspid Intervention



- Poor definition of TV leaflet body due to thin leaflets
- Off-plane position of esophagus in relation to TV annulus limiting structural definition
- Acoustic shadowing or reverberation in the far field can mask the distal TV
  - Anterior structure close to chest wall
  - Further away from esophagus

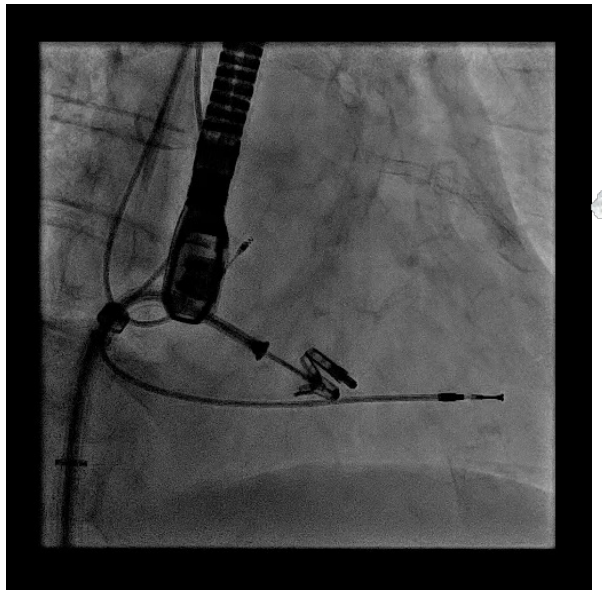
Tricuspid Intervention

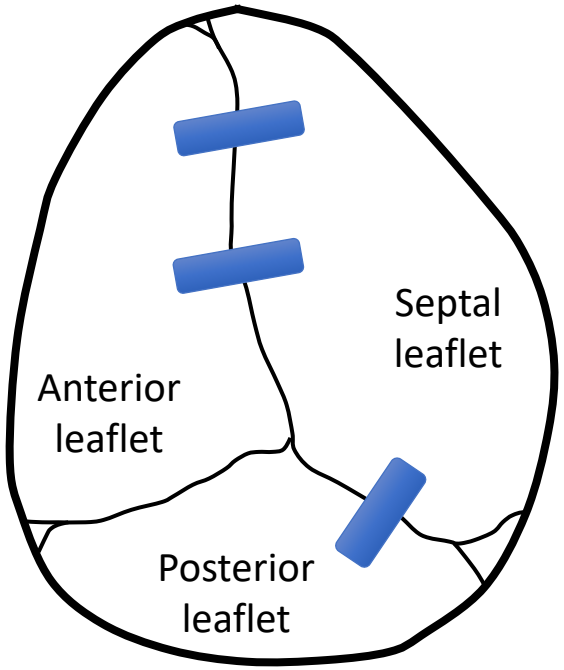
Circulation

ORIGINAL RESEARCH ARTICLE

Transcatheter Treatment of Severe Tricuspid Regurgitation With the Edge-to-Edge MitraClip Technique

Georg Nickenig, Marek Kowalski, Jörg Hausleiter, Daniel Braun, Joachim Schofer, Ermela Yzeiraj, Volker Rudolph, Kai Friedrichs, Francesco Maisano, Maurizio Taramasso, Neil Fam, Giovanni Bianchi, Francesco Bedogni, Paolo Denti, Ottavio Alfieri, Azeem Latib, Antonio Colombo, Christoph Hammerstingl, Robert Schueler





Tricuspid Clip

- ~2000 cases worldwide
- Transfemoral
- Antero-septal or postero-septal commissure
- TRILUMINATE CE-study completed
- TRILUMINATE PIVOTAL started

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TRILUMINATE Pivotal Study Design

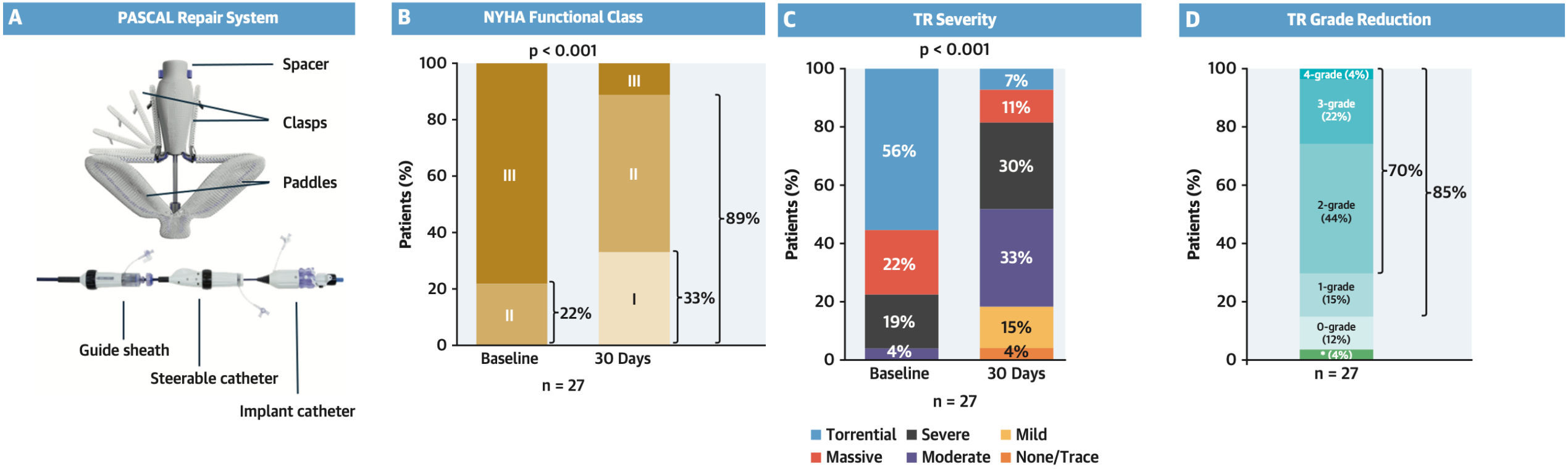
TRILUMINATE
PIVOTAL TRIAL

TRIAL DESIGN	• Prospective, randomized, controlled, multi-center trial
	• **450** subjects enrolled at up to 80 sites in the US, Canada, Europe
	  • Primary endpoint to be assessed after 350 subjects reach 12 month follow-up
	  • Adaptive design incorporated, in case study is under-powered to show a difference
	• ***Principal Investigator:*** *Dr. David Adams (Mt. Sinai), Dr. Paul Sorajja (Abbott Northwestern)*
	• ***Core lab:*** *Dr. Rebecca Hahn (CRF)*

SCIENTI-FIC OBJECTIVE	• To evaluate the safety and effectiveness of the TriClip device in improving clinical outcomes in symptomatic patients with severe tricuspid regurgitation (TR) who have been determined by the site's local heart team to be at intermediate or greater estimated risk for mortality with tricuspid valve surgery
PRIMARY ENDPOINT	**Randomized Arm** A composite of mortality or tricuspid valve surgery, heart failure hospitalizations, and quality of life improvement assessed using the Kansas City Cardiomyopathy Questionnaire (KCCQ), evaluated at 12 months in a hierarchical fashion using the Finkelstein-Schoenfeld methodology **Single Arm:** Survival and quality of life improvement (assessed using KCCQ) at 12 months compared to baseline. In this cohort of sick patients in which it is believed TR cannot be reduced to moderate or less, it is expected that there will be significant improvement in quality of life at 12 months post enrollment

TTVr - PASCAL

CENTRAL ILLUSTRATION The PASCAL Transcatheter Valve Repair System



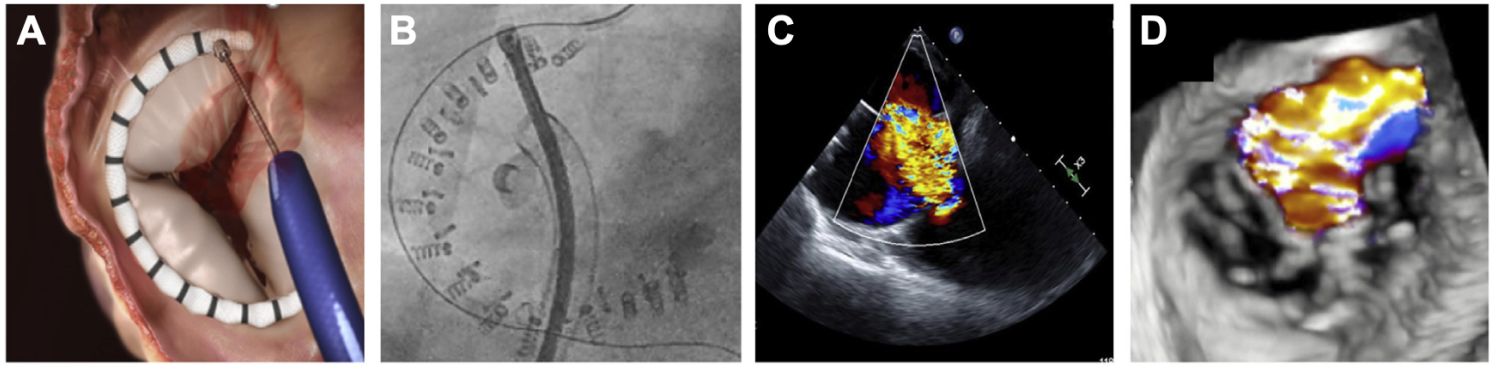
Kodali, S. et al. J Am Coll Cardiol. 2021;77(4):345–56.

TTVr - Annuloplasty

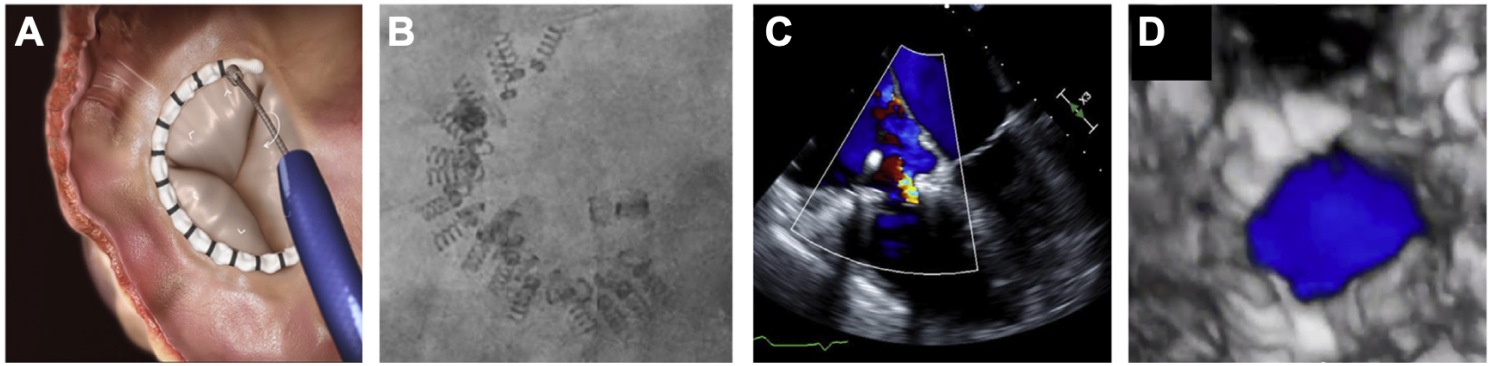
CENTRAL ILLUSTRATION Transcatheter Cardioband Tricuspid Valve Reconstruction System

First U.S. Cardioband Feasibility Study (N=30)

Pre-contraction



Post-contraction

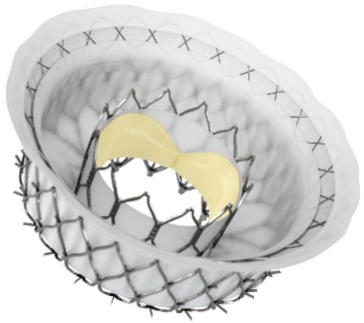


Davidson, C.J. et al. J Am Coll Cardiol Intv. 2021;14(1):41-50.

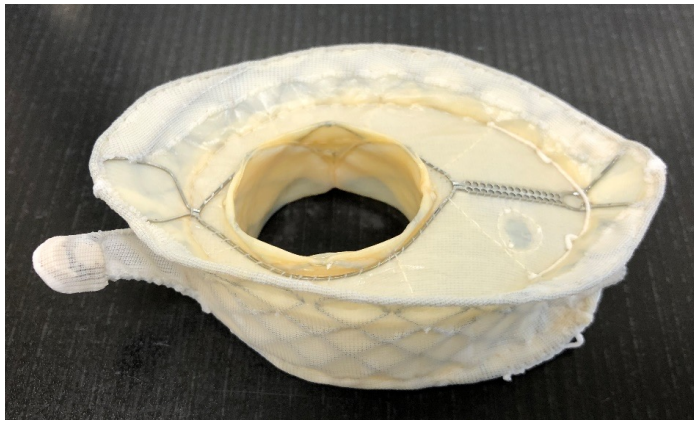
TTVR

Evoque

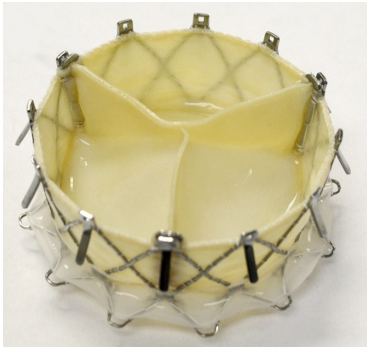
Intrepid



V-Dyne



Navigate



TC repair data shows residual TR and long procedure times TriClip[1]

- 34% ≥ severe residual TR
- Procedure Time 153 min
- Majority excluded

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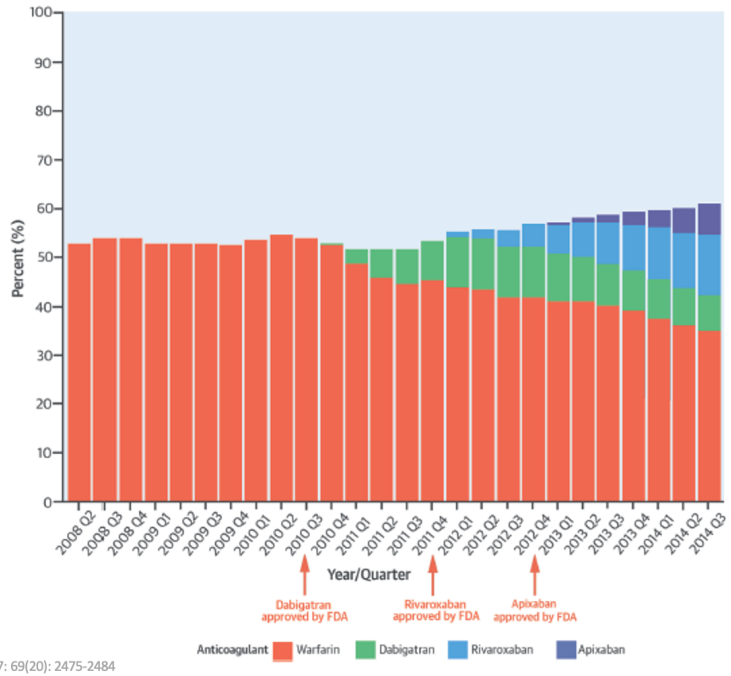
Outline

- Introduction: How did we get here?
- Transcatheter Valve Intervention
- Stroke Prevention
- Advanced Heart Failure Therapy
- SCAI's Role in Advancing the Field
- Conclusion

Atrial Fib and Anticoagulant Compliance

Despite Increasing Usage of DOACs, Gaps in Care Remain



Marzec et al. JACC 2017: 69(20): 2475-2484

Data from the NCDR PINNACLE Registry shows that the rate of overall OAC use increased from 52.4% to 60.7% with the introduction of DOACs

Still, nearly **40%** of OAC-eligible patients are not taking OAC therapy.

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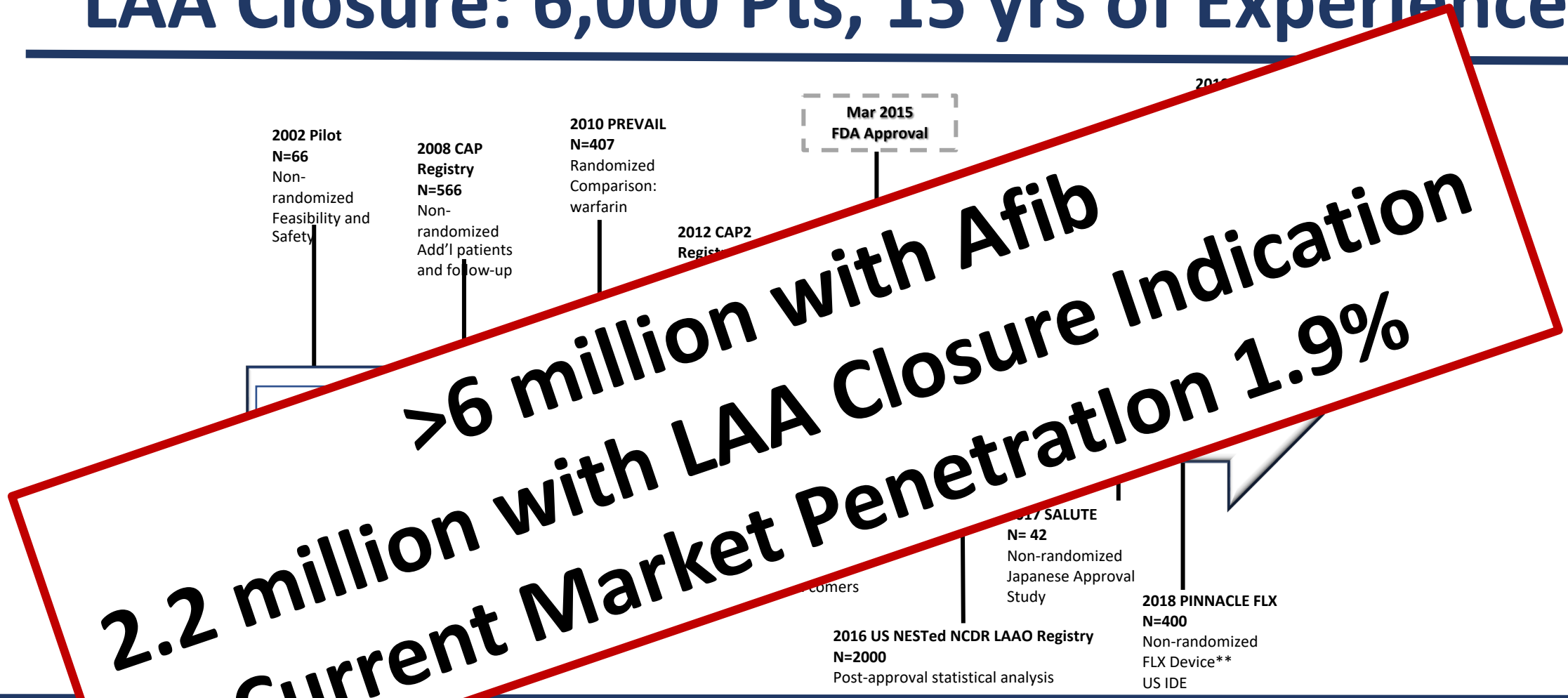
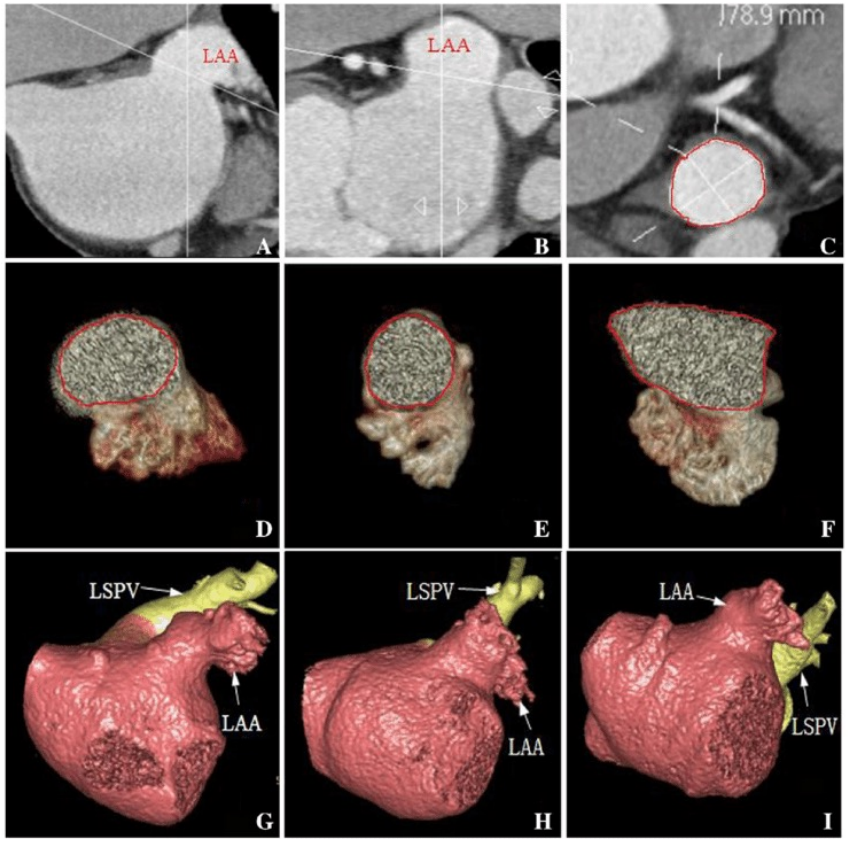
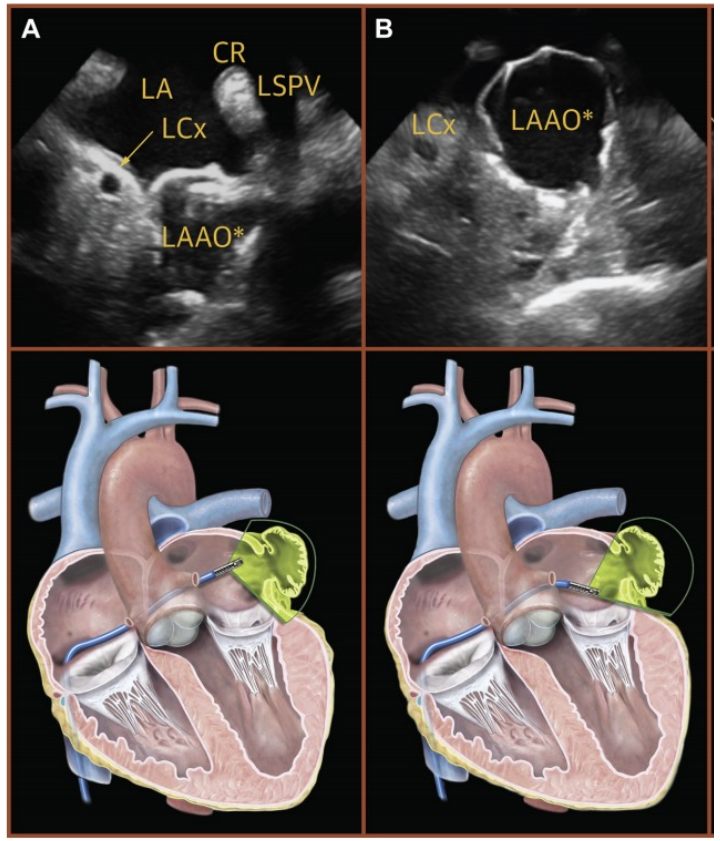
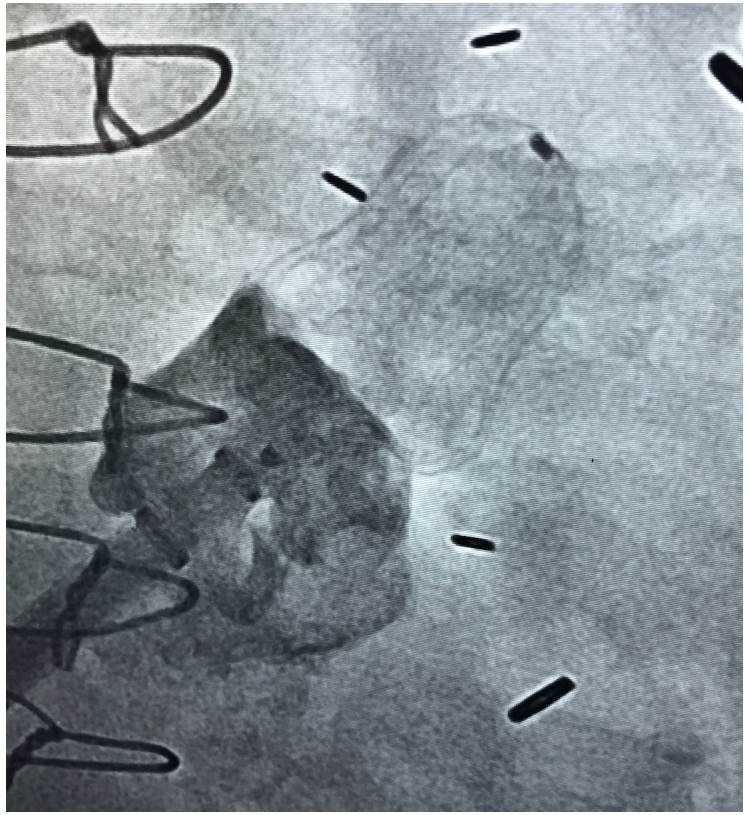
LAA Closure: 6,000 Pts, 15 yrs of Experience



LAA Closure – What's New







CTA

ICE Guidance

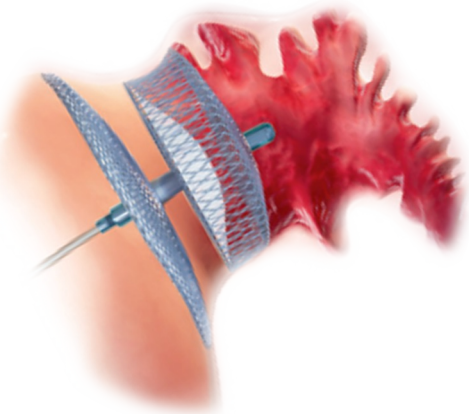
Watchman FLX

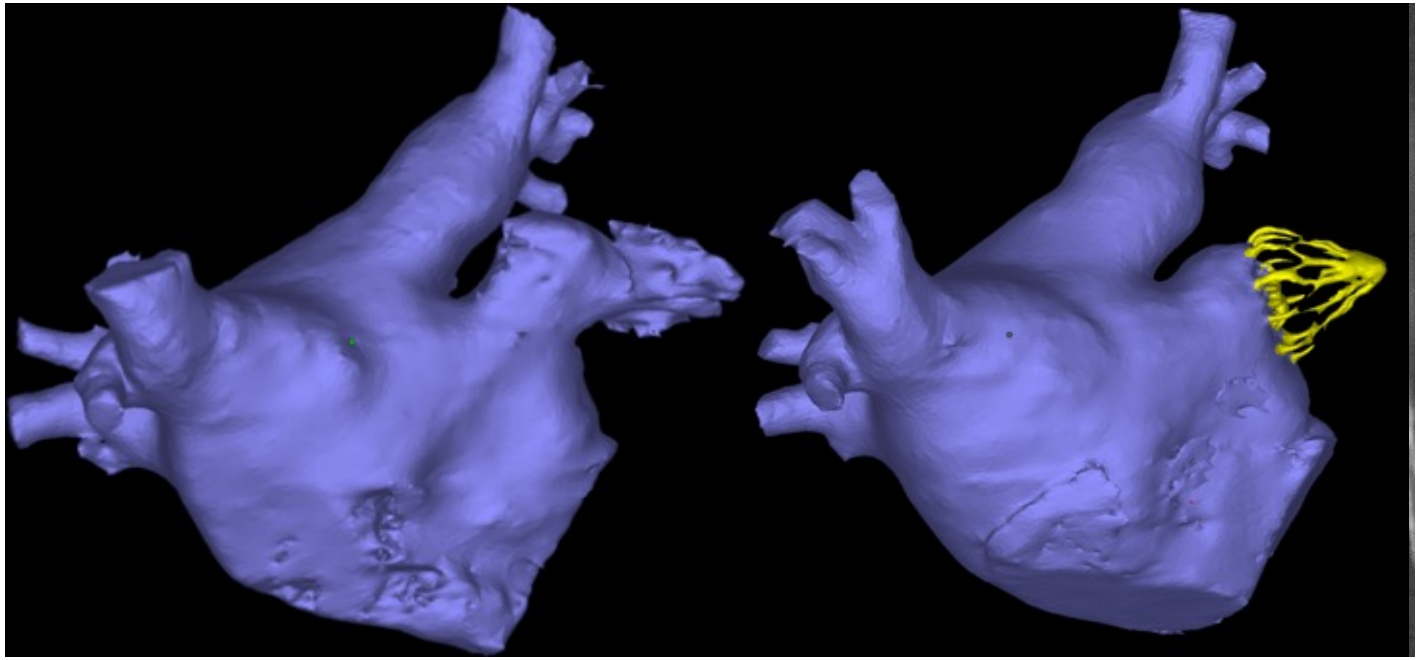
Alkhouli et al. JACC: Cardiovasc Interv 2018

LAA Closure – What's Ahead?

Watchman → FLX

Amulet

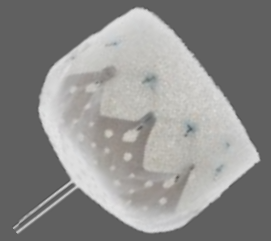




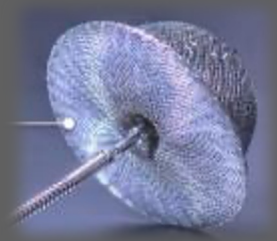
Wavecrest

Lambre

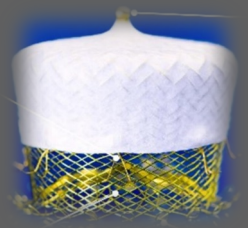
Conformal



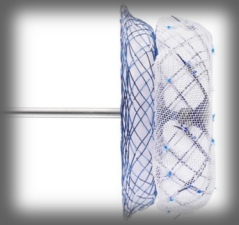
Omega



Occlutech+



SeaLA

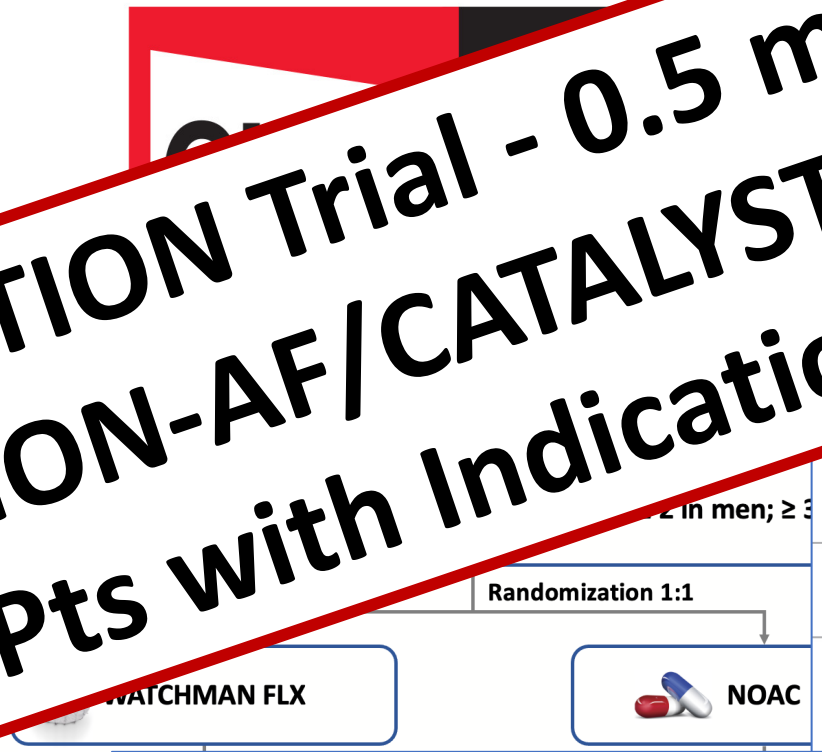


UltraSeal

Lariat

LAA Closure – What's Abo

OPTION Trial - 0.5 million
CHAMPION-AF/CATALYST - >3 million
More Pts with Indications for LAAC



U.S. National Library of Medicine
ClinicalTrials.gov

Home > Search Results > Study Record Detail

Amplatzer Amulet LAAO vs. NOAC (CATALYST)

ELIGIBLE PATIENTS

- A documented history of non-valvular atrial fibrillation
- CHA_2DS_2-VASc score ≥ 3
- Eligible for long-term NOAC therapy

AF Ablation* + WA
O

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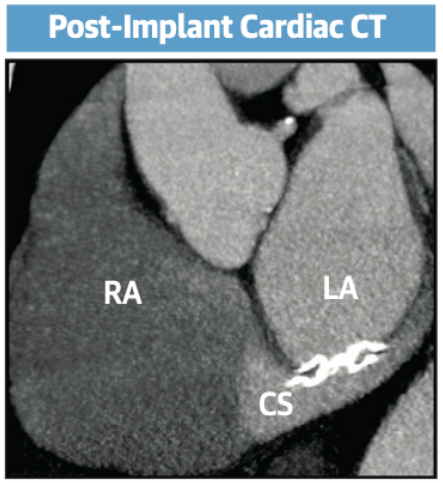
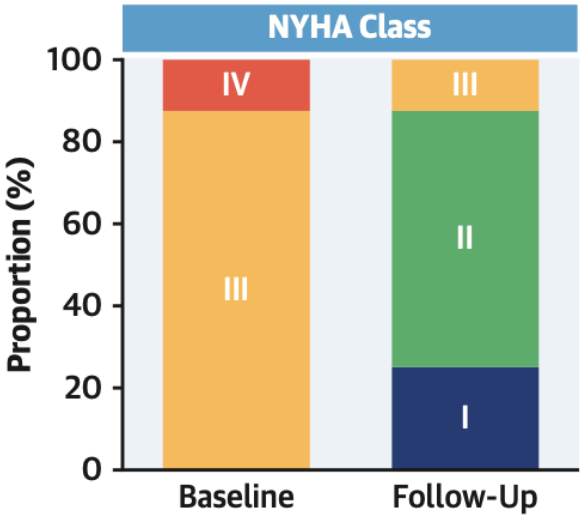
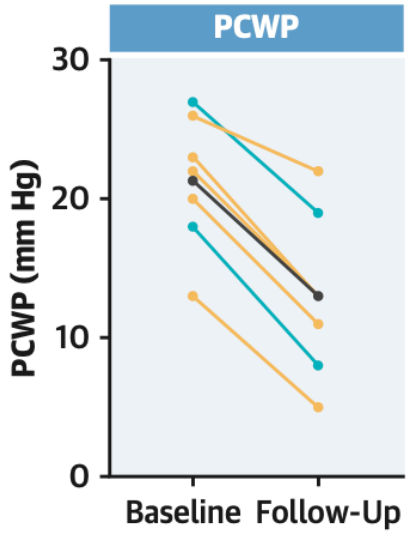
Percutaneous Atriotomy for Levoatrial–to–Coronary Sinus Shunting in Symptomatic Heart Failure

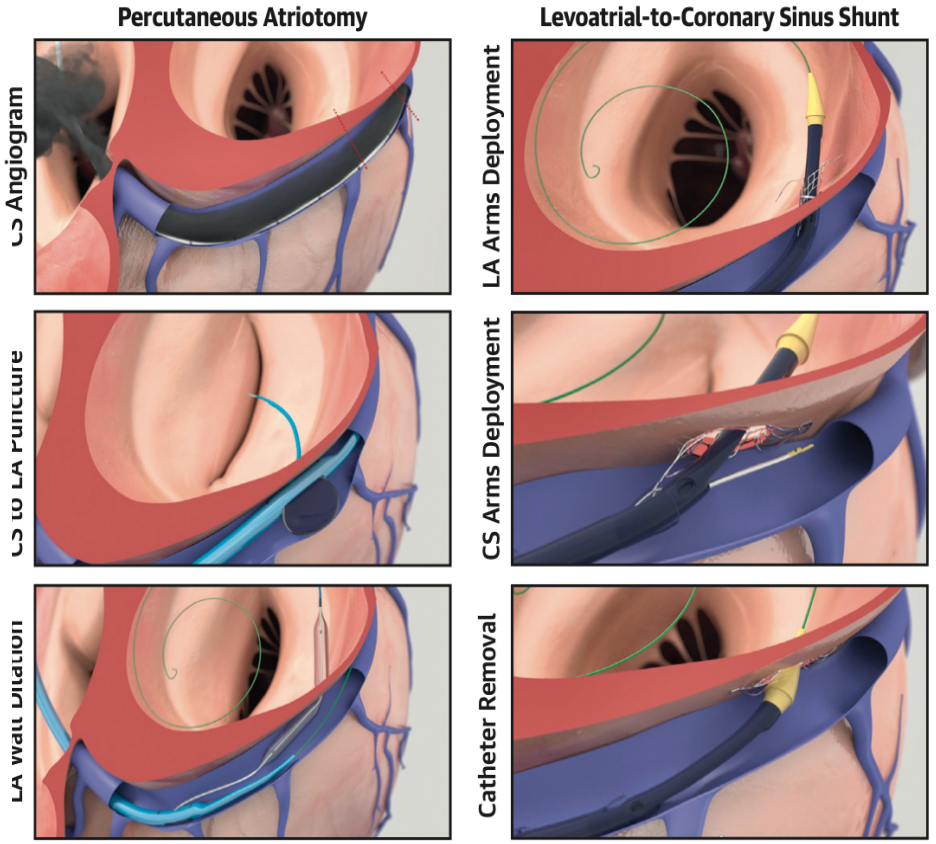
First-in-Human Experience

Trevor Simard, MD,[a,b] Marino Labinaz, MD,[a] Firas Zahr, MD,[c] Babak Nazer, MD,[c] William Gray, MD,[d] James Hermiller, MD,[e] Sunit-Preet Chaudhry, MD,[e] Leonardo Guimaraes, MD,[f] François Philippon, MD,[f] Peter Eckman, MD,[g] Josep Rodés-Cabau, MD,[f] Paul Sorajja, MD,[g] Benjamin Hibbert, MD PhD[a,b]









Simard, T. et al. J Am Coll Cardiol Intv. 2020;13(10):1236–47.

Summary: The SHD Journey

Thanks for your attention!