Structural Heart Innovation: Barriers and Opportunities

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Disclosure Statement of Financial Interest

- I am a full-time employee of the Cardiovascular Research Foundation, which organizes and operates Transcatheter Cardiovascular Therapeutics and which has received educational and research grants from some of the companies developing TMVR devices

- I am a co-founder and co-inventor of Cephea Valve Technologies

Why is the structural heart field important?

All structural heart conditions present or evolve into heart failure!

Technology Trends in Mitral Innovation

Making a Case for Transcatheter Replacement: Not All MR Patients are Suitable for TEER

Anatomies associated with stenosis with TEER[1]

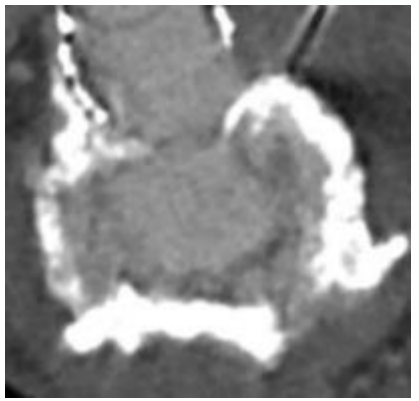
- Severe MAC with MS
- Calcified Leaflets

Anatomies associated with inadequate MR reduction with TEER[1]

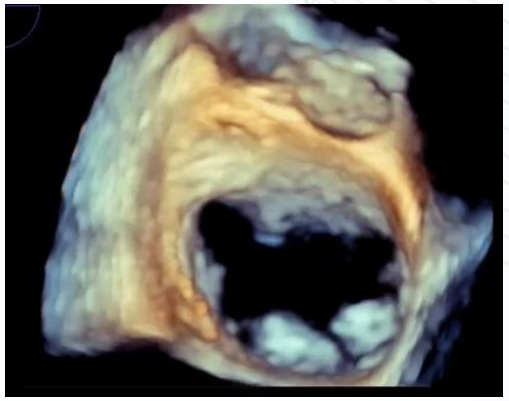
- Multiple regurgitation jets
- Extreme valve complexity
- Cleft leaflets
- Short posterior leaflet, unlikely to be graspable
- Tethered leaflets
- Large coaptation gaps

Other anatomic limitations that may preclude from performing TEER[1]

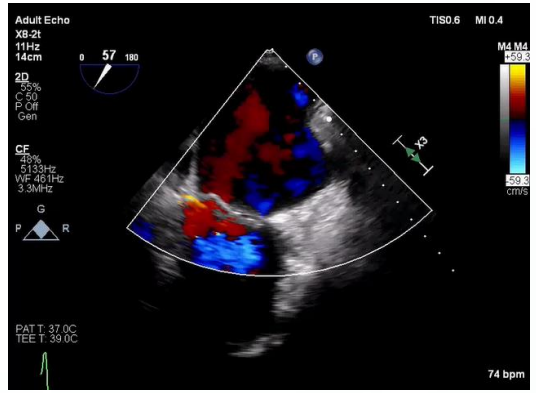
- Inability to obtain views on TEE



MAC



Multiple Cleft Leaflets



Multiple Regurgitant Jets

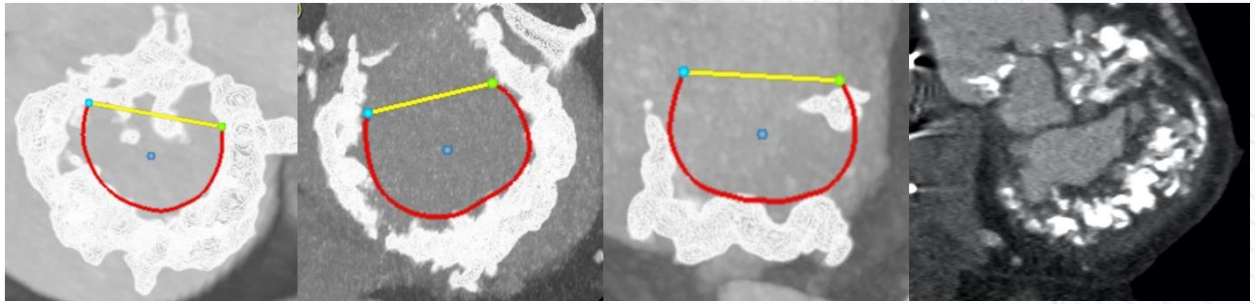
[1]Lim, et. al. Structural Heart. 2021;5(3):227-233

JACC REVIEW TOPIC OF THE WEEK

Mitral Valve Dysfunction in Patients With Annular Calcification

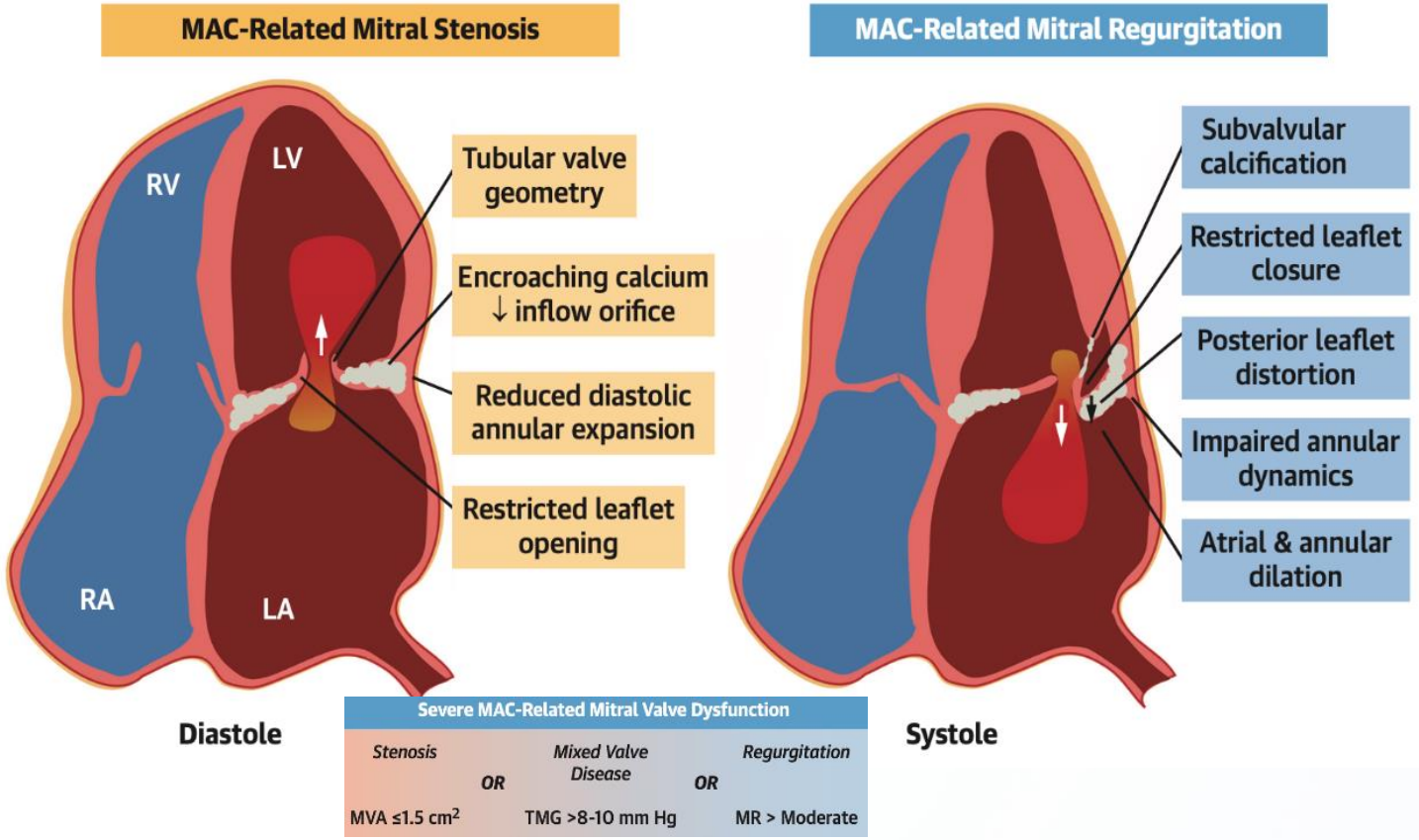
JACC Review Topic of the Week

Timothy W. Churchill, MD,[a] Evin Yucel, MD,[a] Sébastien Deferm, MD, PhD,[b,c] Robert A. Levine, MD,[a] Judy Hung, MD,[a] Philippe B. Bertrand, MD, PhD[a,b,c]



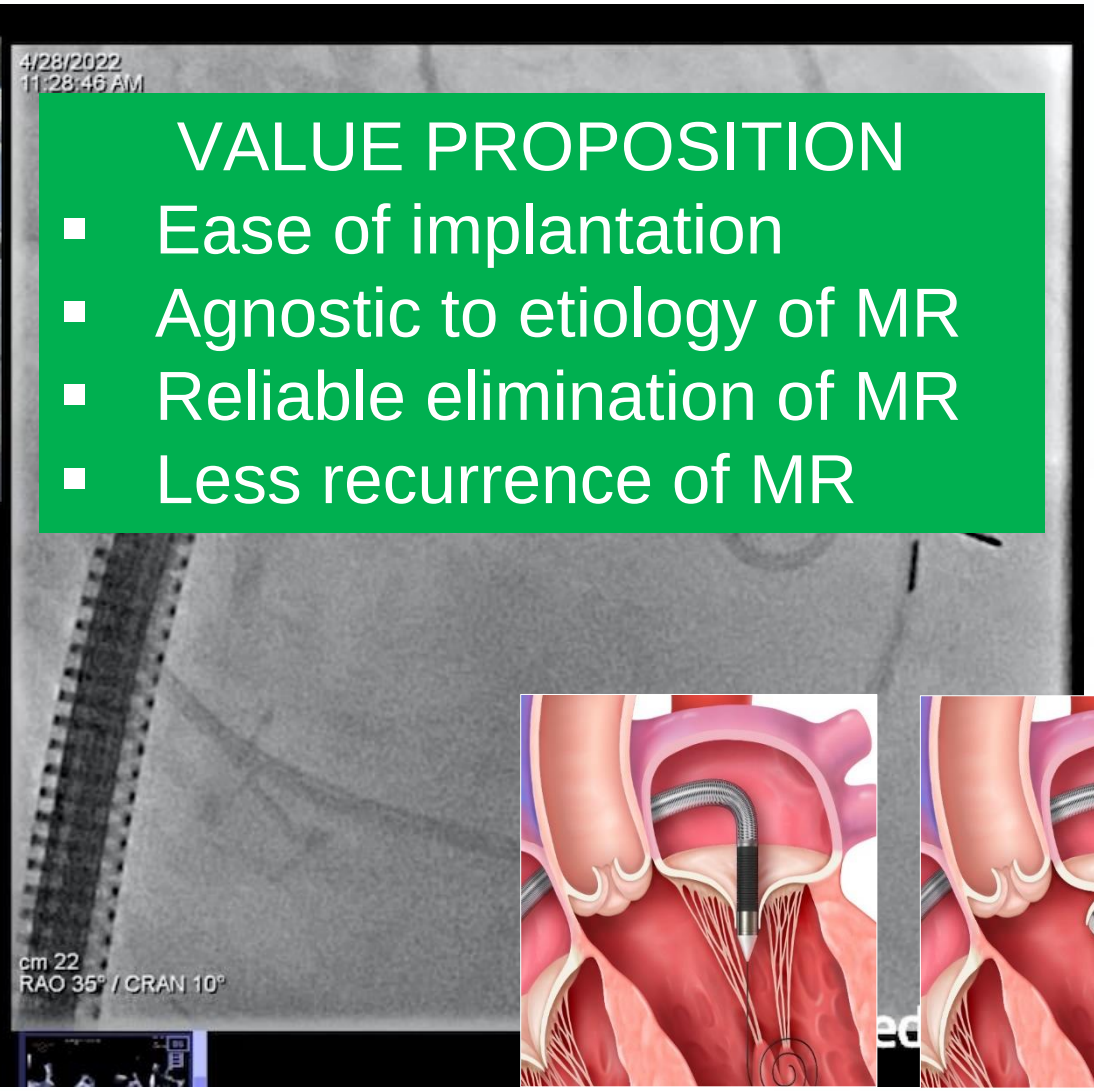
MAC-Related MV Dysfunction

The high-surgical risk MAC-MR population represents a big opportunity for catheter-based mitral innovation!



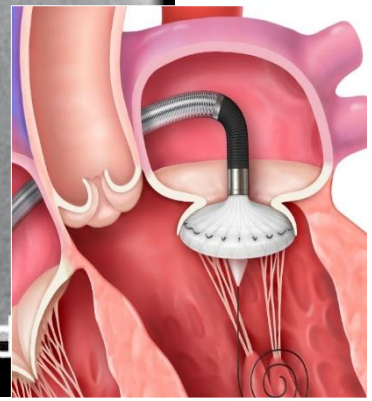
Churchill TW. J Am Coll Cardiol 2022;80:739–751

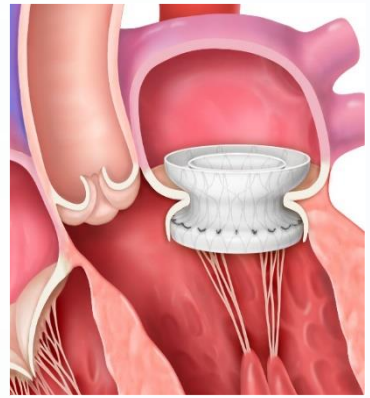
CEPHEA (Abbott) TMVR System



VALUE PROPOSITION

- Ease of implantation
- Agnostic to etiology of MR
- Reliable elimination of MR
- Less recurrence of MR





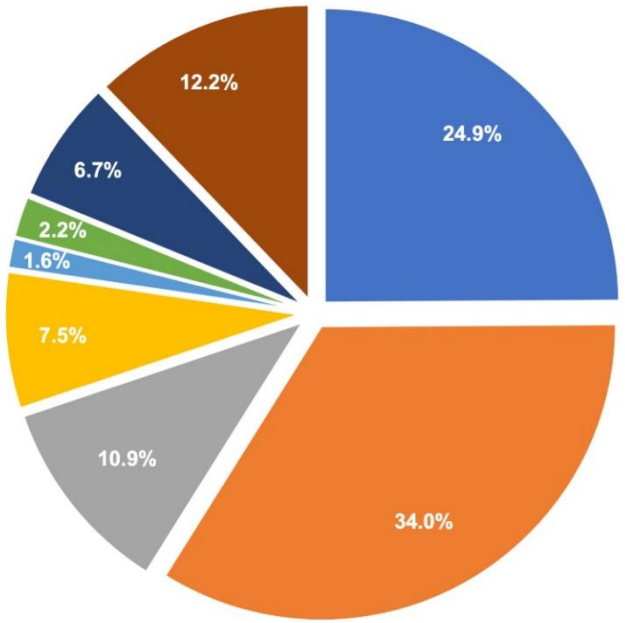
- 36-mm valve
- Single step
- Over the wire
- No pacing needed

First US EFS Case. Vinod Thourani, TVT2022

Anatomical Reasons for Screen Failure in "Real-World Patients" Referred for TMVR

ESC European Society of Cardiology
European Journal of Heart Failure (2022)
doi:10.1002/ejhf.2492
RESEARCH ARTICLE

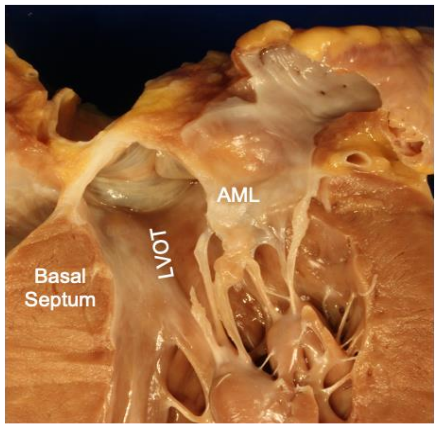
Characteristics and outcomes of patients screened for transcatheter mitral valve implantation: 1-year results from the CHOICE-MI registry



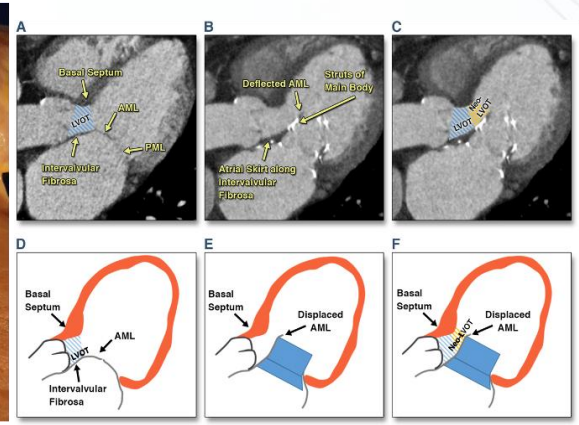
- Risk of LVOT obstruction
- Annulus size
- Small LV size
- MAC
- Leaflet morphology
- LV function
- Comorbidities
- Other = Trans-septal delivery

~50%

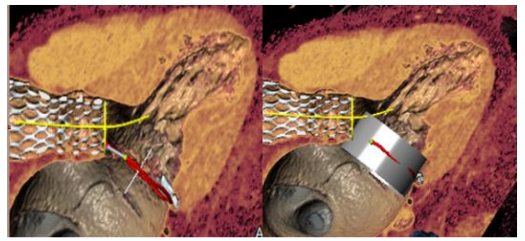
LVOT Obstruction: A multi-factorial problem not completely solved by improved valve frame design



Anatomical Factors



Contributing Device Design Features



TAVR Interaction

Ben Ali W, Ludwig S…et al. Eur J Heart Fail. 2022 May;24(5):887-898

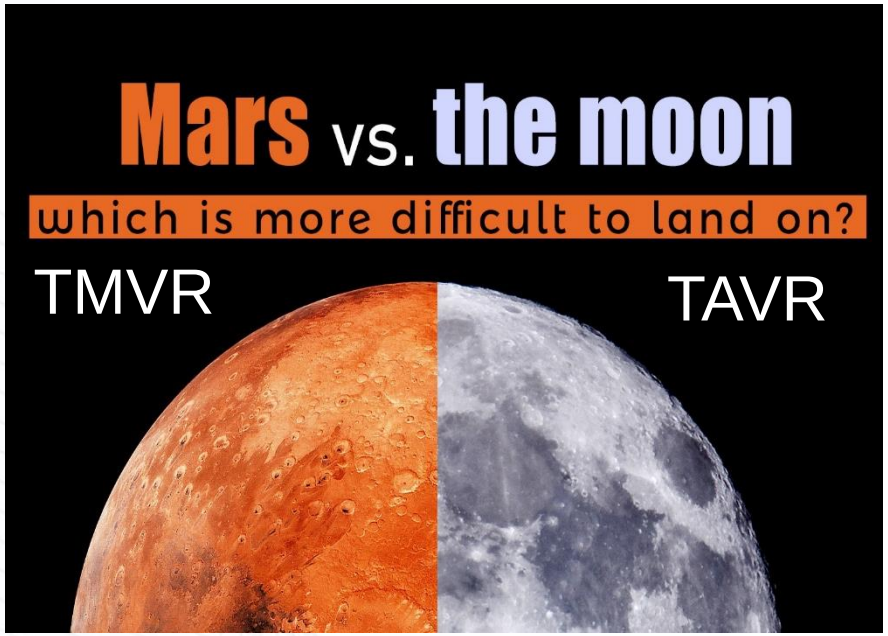
HIGHLIFE TMVR Multi-Step System

- Transseptal delivery
- 18F shaft and 29F capsule
- >70 Patients treated
    - 7 EFS, 60 EU, 5 China

Next Generation Highlife Valve (Clarity) Open Frame Design

Nico Piazza, TVT2022

How To Re-Define the Path Forward in the TMVR Field



Redefine target population & anatomical requirements

Designs adaptable to annular size & anatomical variability

Final Goal = Trans-Septal TMVR Delivery

Mechanical performance in real-world anatomy (i.e., MAC)

"Low profile" high performance delivery systems

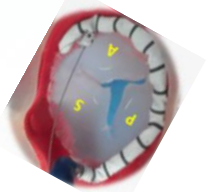
Technology Trends in Tricuspid Innovation

Transcatheter Tricuspid Landscape

Annuloplasty

Trialign

Cardioband

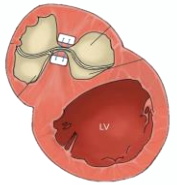


TriCinch

Millipede

MIA

PASTA



DaVingi

Coaptation Enhancement

Edge-to-Edge

TriClip

Pascal

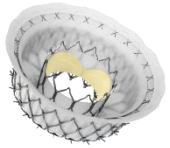
Dragonfly

Mitralix

Orthotopic Replacement

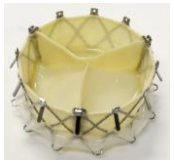
Evoque

Intrepid



V-Dyne

Navigate



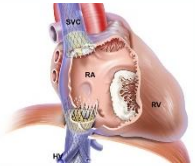
Trisol

Lux

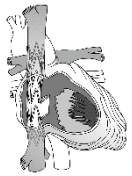
Topaz

Heterotopic Replacement

TricValve



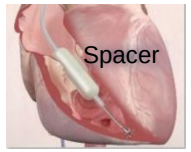
TriCento



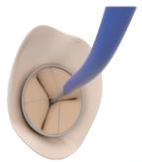
Trillium

Spacers

Forma



Croi

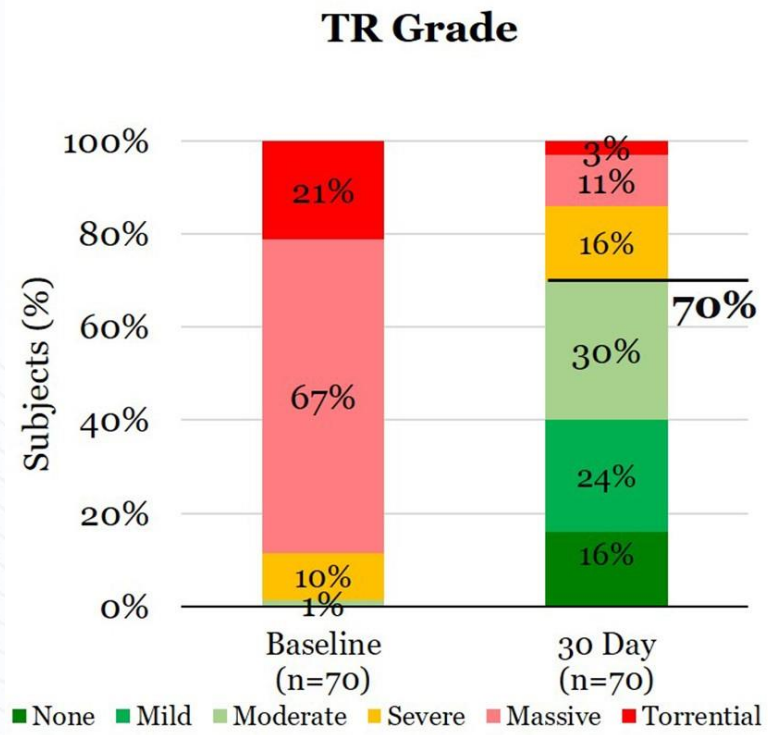


Coramaze

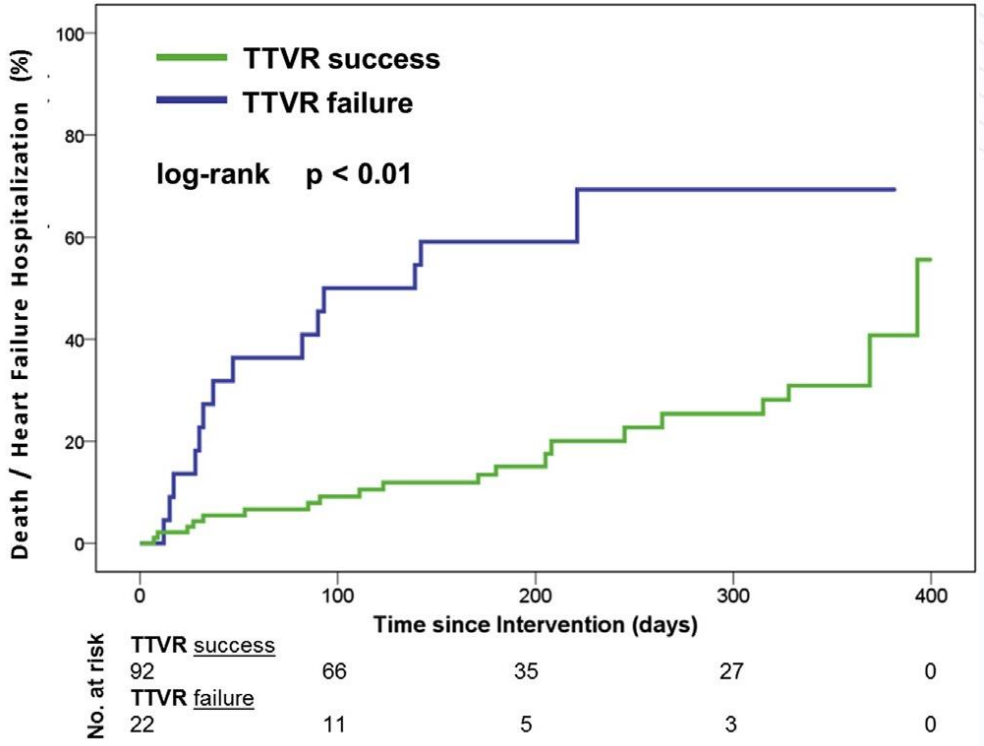
Tri-Flow

TR Resolution After T-TEER
~60% Remain with >Moderate TR

TR Grade Following T-TEER (bRIGHT study)

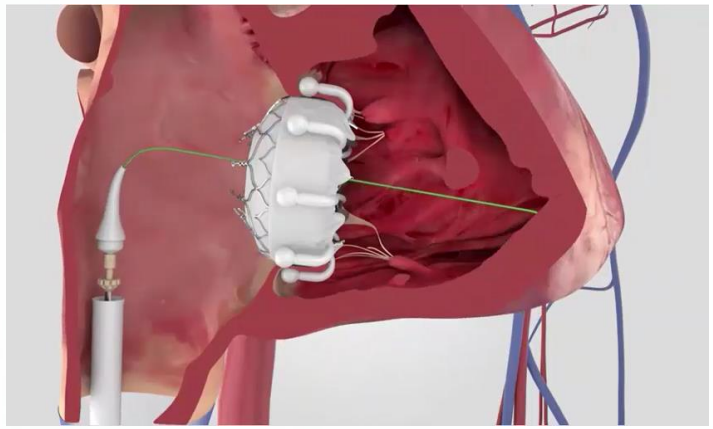


Donal et al. EHJ CV Imaging 2022



Besler et al. JACC CV Interv 2018

Transcatheter Tricuspid Valve Replacement Device Related Complications a Major Risk



NEW RESEARCH PAPERS

STRUCTURAL

Transfemoral Tricuspid Valve Replacement in Patients With Tricuspid Regurgitation

TRISCEND Study 30-Day Results

Susheel Kodali, MD,[a] Rebecca T. Hahn, MD,[a,b] Isaac George, MD,[a] Charles J. Davidson, MD,[c] Akhil Narang, MD,[c] Firas Zahr, MD,[d] Scott Chadderdon, MD,[d] Robert Smith, MD,[e] Paul A. Grayburn, MD,[e] William W. O'Neill, MD,[f] Dee Dee Wang, MD,[f] Howard Herrmann, MD,[g] Frank Silvestry, MD,[g] Sammy Elmariah, MD,[h] Ignacio Inglessis, MD,[h] Jonathan Passeri, MD,[h] D. Scott Lim, MD,[i] Michael Salerno, MD,[i] Moody Makar, MD,[j] Michael J. Mack, MD,[e] Martin B. Leon, MD,[a] Raj Makkar, MD,[j] on behalf the TRISCEND Investigators

TABLE 4 Clinical Events Committee-Adjudicated Safety Events at 30 Days (N = 56)

Cardiovascular mortality	1 (1.8)[a]
Myocardial infarction	0
Stroke	0
Renal complications requiring dialysis or renal replacement therapy	0
New need for renal replacement therapy	0
Severe bleeding[b]	15 (26.8)
Major cardiac structural complications	0
Device-related pulmonary embolism	0
Composite MAE rate	15 (26.8)

Values are as n (%) or n. [a]All-cause mortality included 1 cardiovascular and 1 noncardiovascular death. [b]Severe bleeding is defined as major, extensive, life-threatening, or fatal bleeding per Mitral Valve Academic Research Consortium criteria.

MAE = major adverse event(s).

were taking warfarin. Of 36 patients without a pacemaker prior to enrollment, 4 (11.1%) developed new conduction disturbances requiring permanent pacemaker implantation (site reported).

Kodali S, JACC Interv. 2022

Percutaneous Treatment of Heart Failure (A New Field Now So-Called “Interventional Heart Failure”)

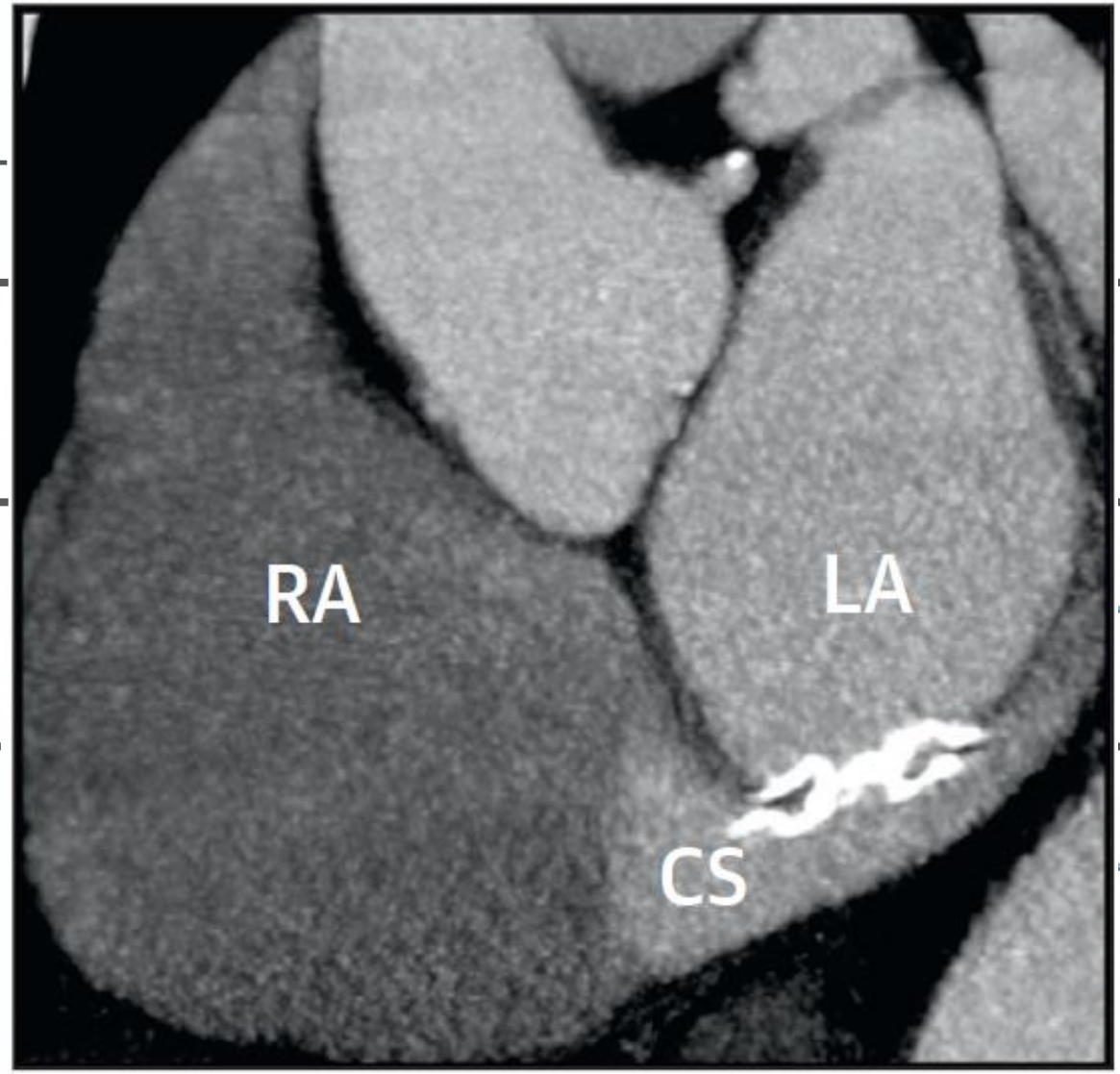
Edwards APTURE Transcatheter Shunt System

APT

Edwards Stabilizer

Guidewire Delivery Catheter

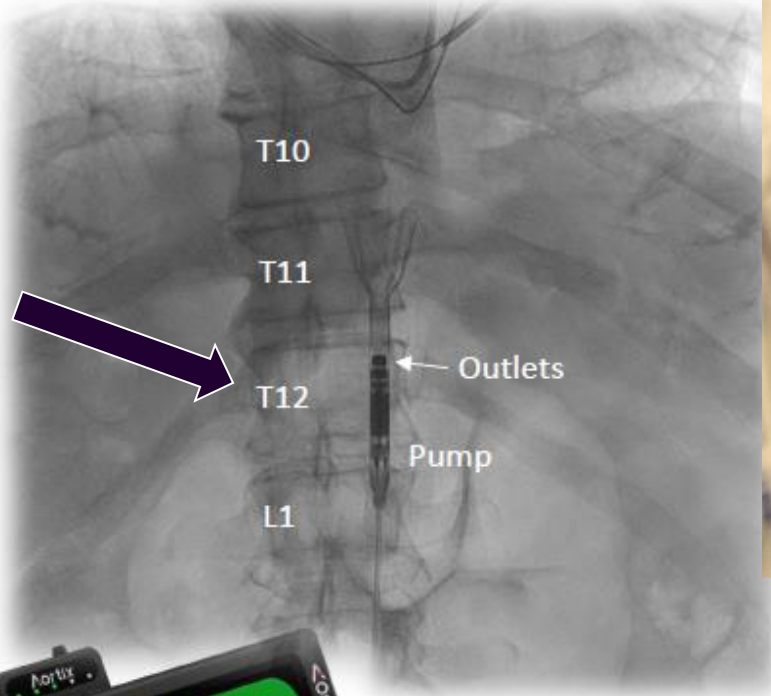
Atrial Shunt Delivery Catheter

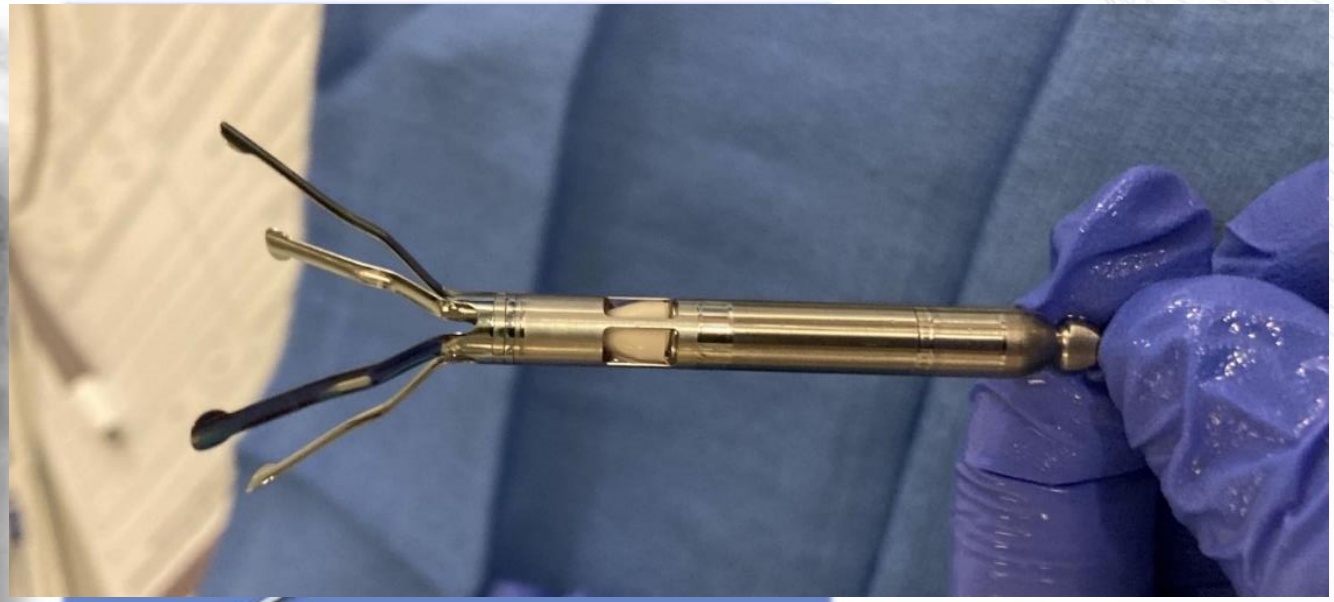


William Gray, THT2023

The Aortix System in Patients with Decompensated Heart Failure and Cardiorenal Syndrome

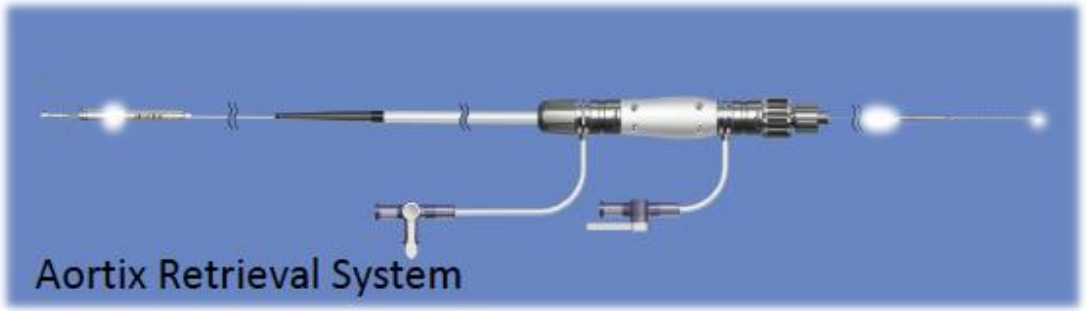
Placed at T10 to T12, perirenal





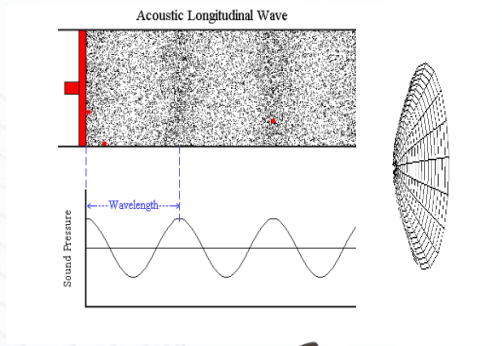

Aortix Delivery System

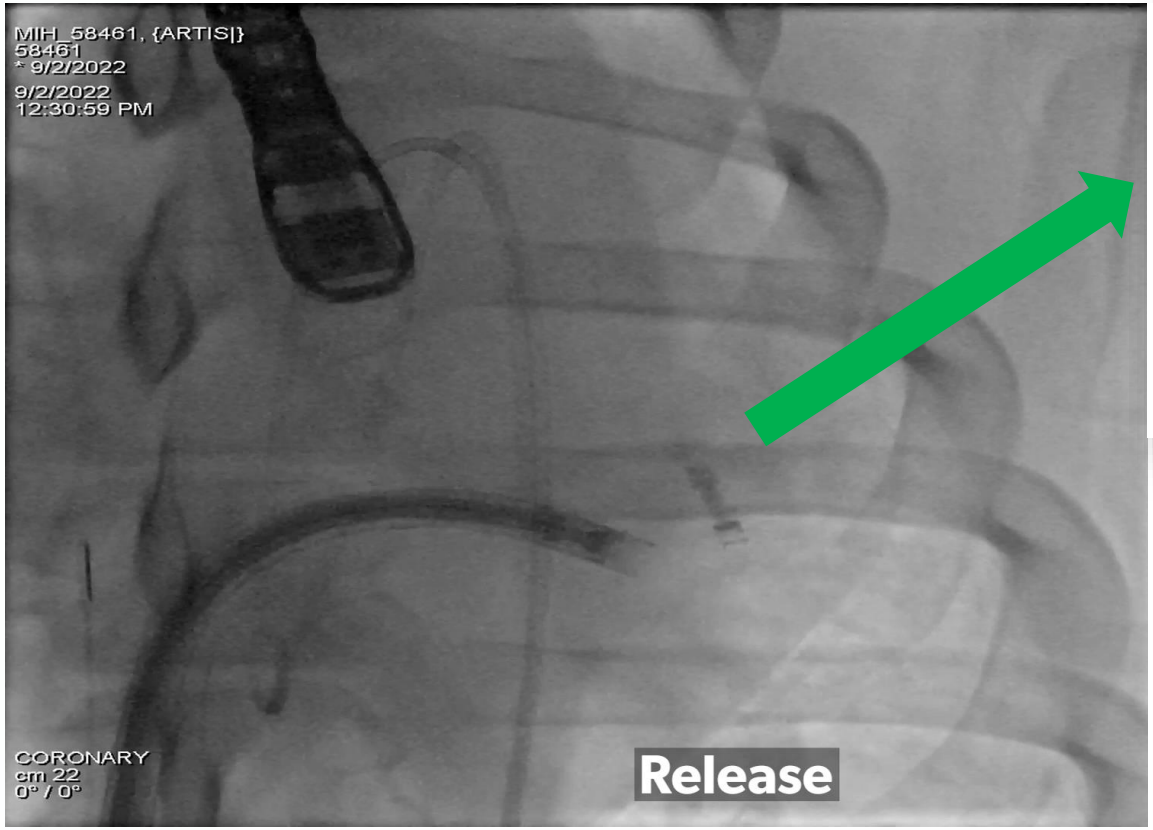
Aortix Control System

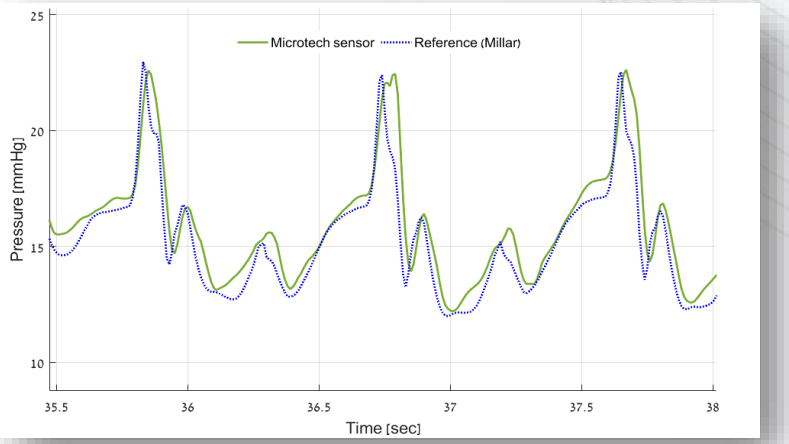

Aortix Retrieval System

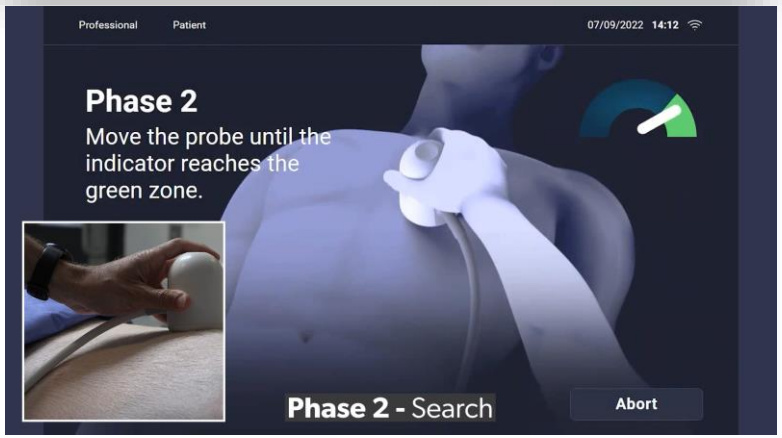
Jennifer Cowger, THT2023

Microsensors: Turning Implantable Devices Into Real-Time Physiologic Monitors









Yoram Richter. TCT Innovation Forum 2022

There Has Never Been a Better Time To Be An Interventional Cardiologist!