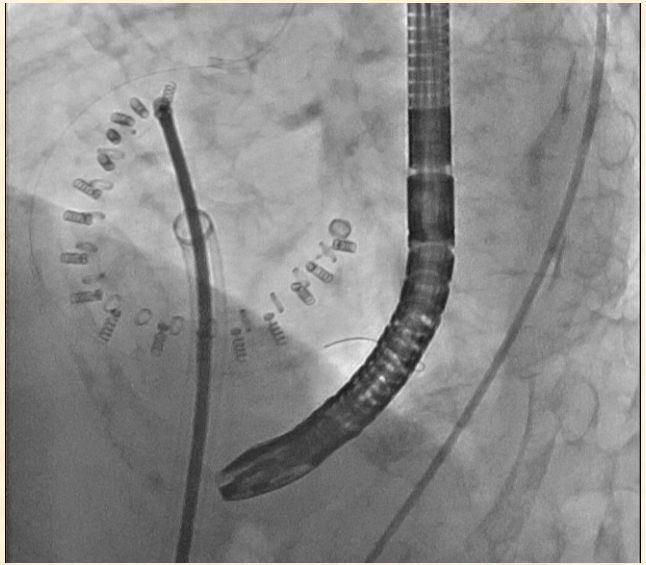
Transcatheter Tricuspid Annuloplasty

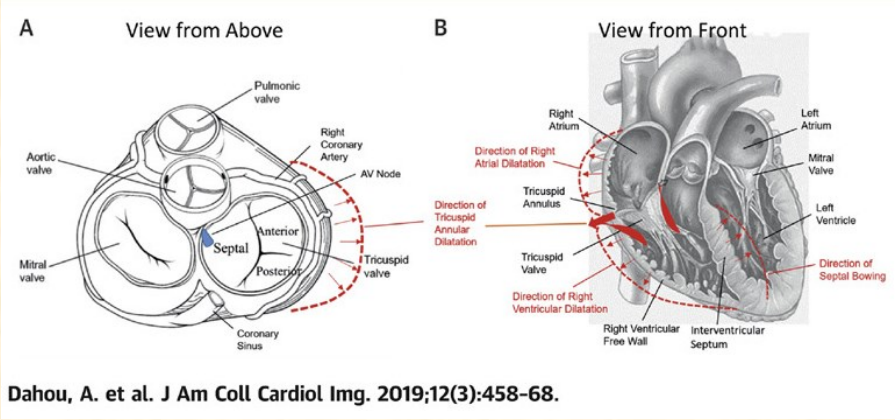
Cardioband TR case in Israel



המרכז הרפואי קפלן
יש על מי לסמוך
מקבוצת כללית
מסונף לבי"ס לרפואה של האוניברסיטה העברית

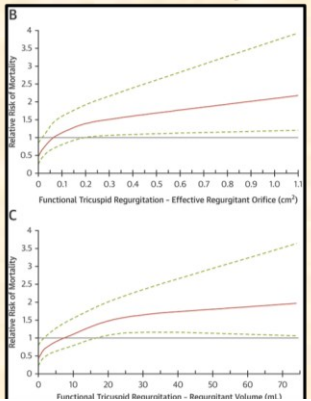
Dan Haberman

TV Pathophysiology and challenges

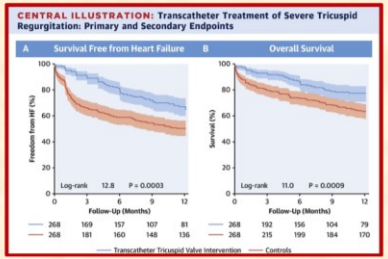


Dahou, A. et al. J Am Coll Cardiol Img. 2019;12(3):458-68.

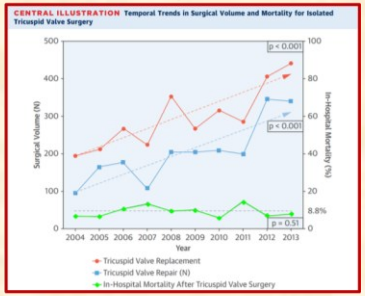
Mortality Increases with TR Severity



Outcomes with medical…



…and surgical therapies are suboptimal



Bartko PE et al. JACC Cardiovasc Imaging. 2019 Mar;12(3):389-397.

Taramasso M et al. JACC. 2019;74(24):2998-3008.

Zack CJ et al. JACC. 2017;70(24):2953-2960.

TR challenges

Real world treated population

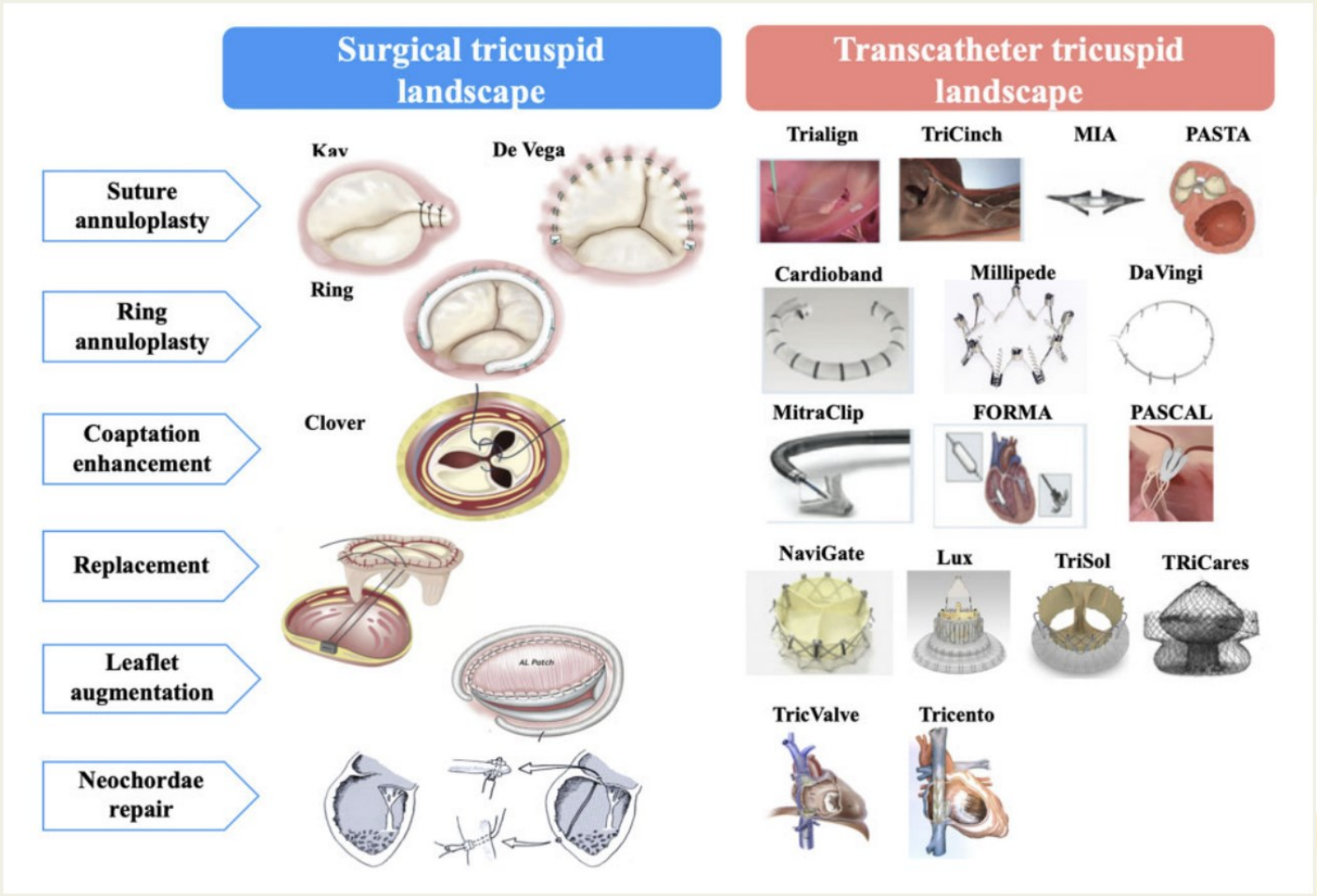
CHARACTERISTIC	TRILUMINATE PILOT [1] N = 85	BRIGHT [2] N=300	CLASP TR [3] N= 54	Surgery [4] N =466
Age, Mean (years)	78 ± 8	78.5 ± 7.6	80 ± 6	60 ± 16
Atrial Fibrillation	92%	85.0%	96%	39%
Prior Cardiac Surgery	33%	36 %	36%	24 %
NYHA III-IV	75%	79%	77%	47%
Renal Failure	33%	40.7%	55%	7%
Euroscore II /STS score	8.6% /-		-/ 9.0 %	2.7%/-

Implantation success >95%, MAE 30 d <3%

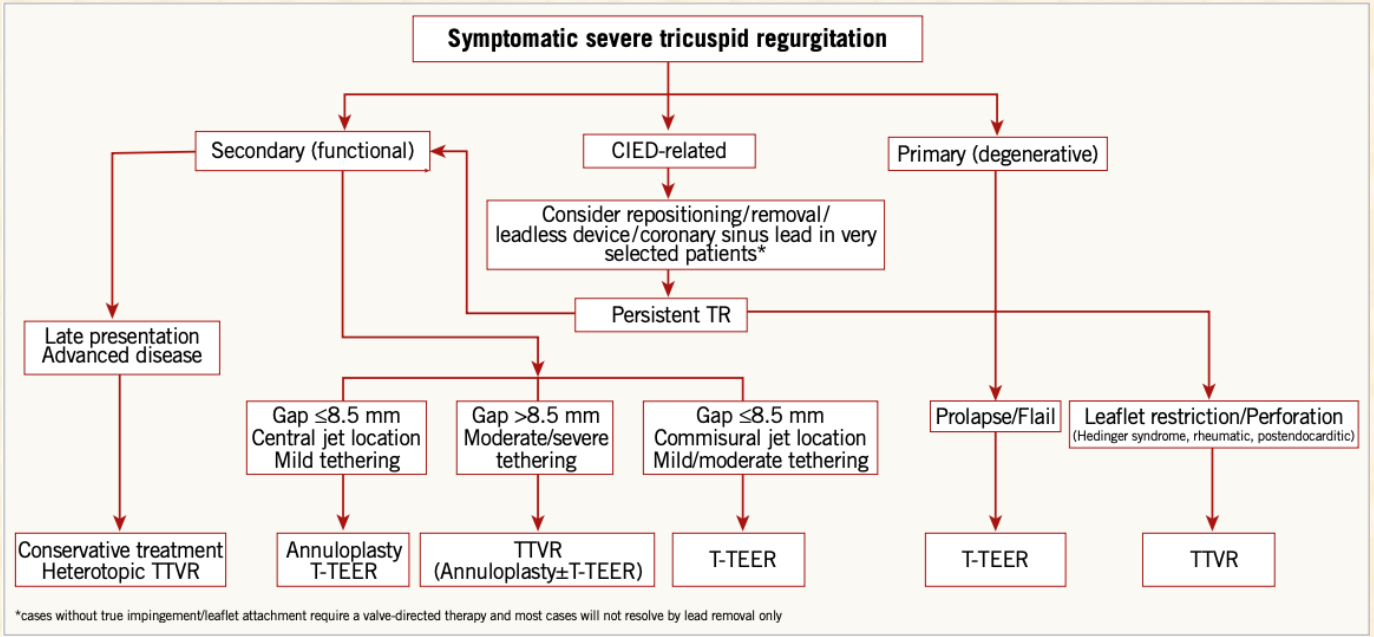
1. *Triluminate. Lancet* 2019; 394: 2002–11
2. *Lurz P et al. EuroPCR 2022*
3. *Baldus S et al. EuroPCR 2022*
4. *Dreyfus J et al. Eur Heart J 2022;43: 654-62*

Sitges M. Transcatheter tricuspid valve intervention - Real world data. PCR London Valves 2022

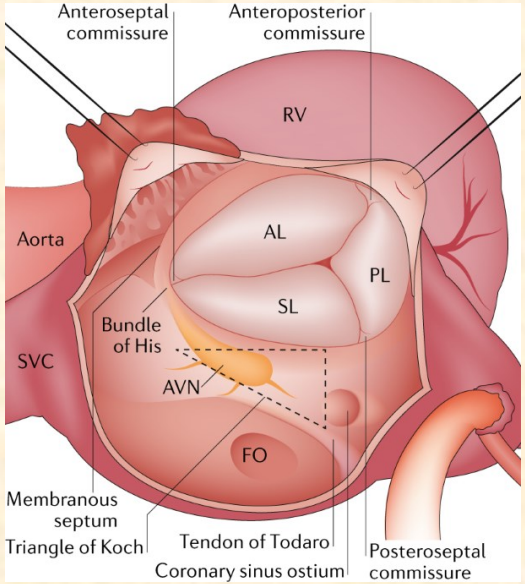
“Current” TTVi Toolbox



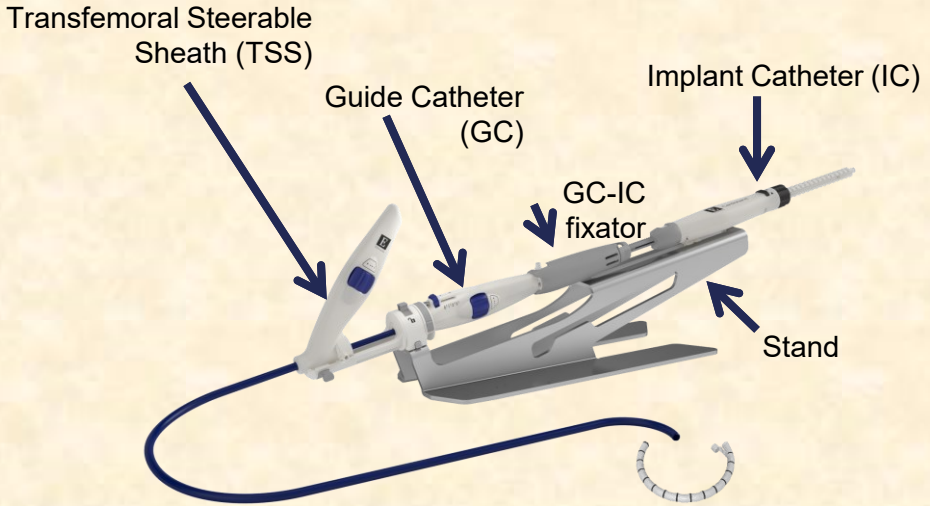
TTVi selection?



Cardioband Tricuspid System



Implant delivery system (IDS) = GC+IC



Asmarats L, Taramasso M, Rodés-Cabau J. Tricuspid valve disease: diagnosis, prognosis and management of a rapidly evolving field. Nat Rev Cardiol. 2019 Sep;16(9):538-554.

Cardioband Tricuspid Valve Reconstruction System

Safely and effectively reduce TR through annular reduction

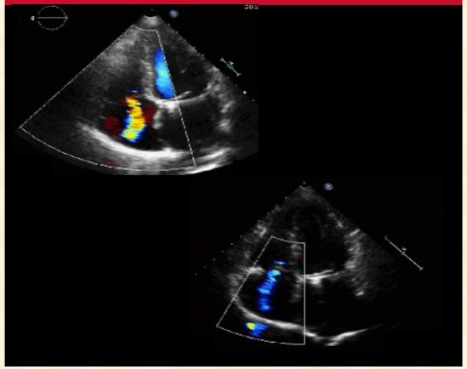
Annular reduction

Restores valve to a more functional state – facilitating **leaflet coaptation**

Adjustable implantation

Enables **annular reduction** through a standardized procedure based on each **patient's anatomy**

Real – time confirmation



Supports real-time annular adjustment and confirmation of procedural results through **echocardiography**

Nickenig G. et al. EuroIntervention 2021;16:e1264-e1271. DOI: 10.4244/EIJ-D-20-01107

GZ, 81 Y/O Female

- 81 years old female (Known to EP and HF clinic since 2011)
  - C/C – Weakness and Effort Dyspnea (NYHA 3)
  - PMH –Dyslipidemia, Recurrent paroxysmal A.Fib,
  - S/P CVI AFL Ablation 2015, recurrent DCCV

  - HFpEF, LVEF – 50-55%, Severe TR, sPAP 45-50 mmhg
    - Recent need for daycare IV Fusid q2 a month
    - SAT 99% RA, RR 18 bmp, HR 70 bpm, BP 123/61
    - Phys: JVP ++, Leg edema ++
    - Labs: Hgb 10-12, Renal ~70 / 1.3, K 4.5 - 5

GZ, Medical Treatment

- Medical treatment
  - P.O Fusid 100 mg / day (+ Day care)
  - Aldactone 25 mg / day
  - Cardiloc 2.5 mg 1X1 / day
  - Procor 100 mg 1X1 / day
  - Eliquis 2.5 mg 1X2 /day (S.C Bleeding)
  - Atozet 10/10 mg 1X1 /day
  - Euthyrox ~400 mcg / week

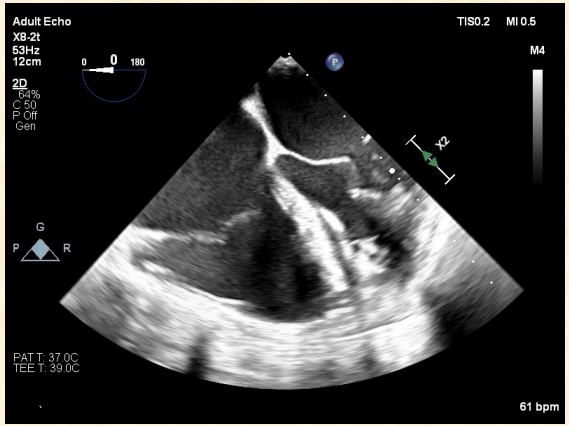
GZ, Echocardiography

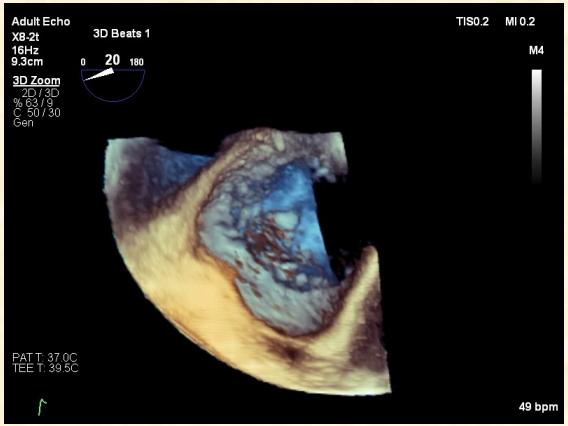
- Bi-Atrial enlargement (~60cm)
- LVEDD 43 mm
- Muscle, 8 / 8mm
- LVEF = 50%
- Diastolic dysfunction gr. 1

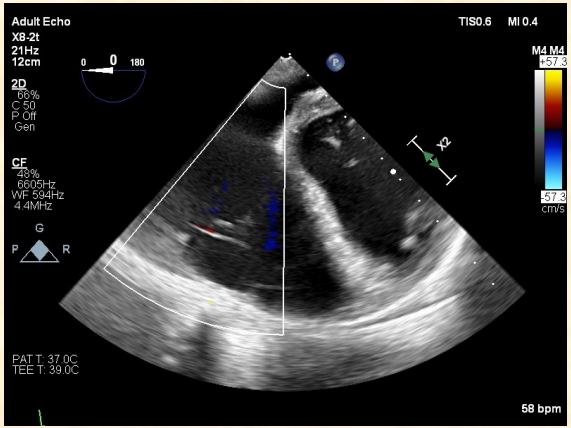
- RV chamber, Mild enlargement
- RVEF – Mildly reduced

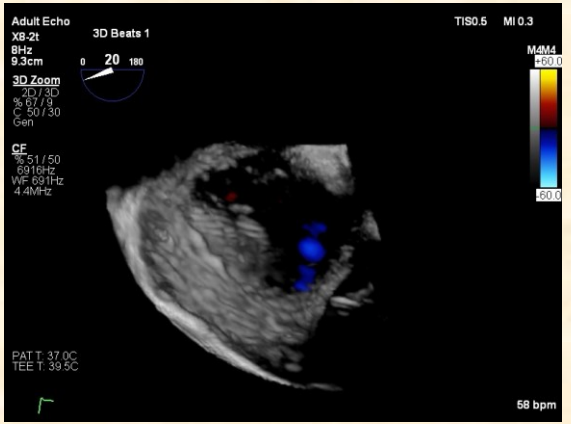
- Mild MR, Severe TR (Torrential)
  Secondary

- IVC, Mild Dilatation
- sPAP 45-50 mmHg

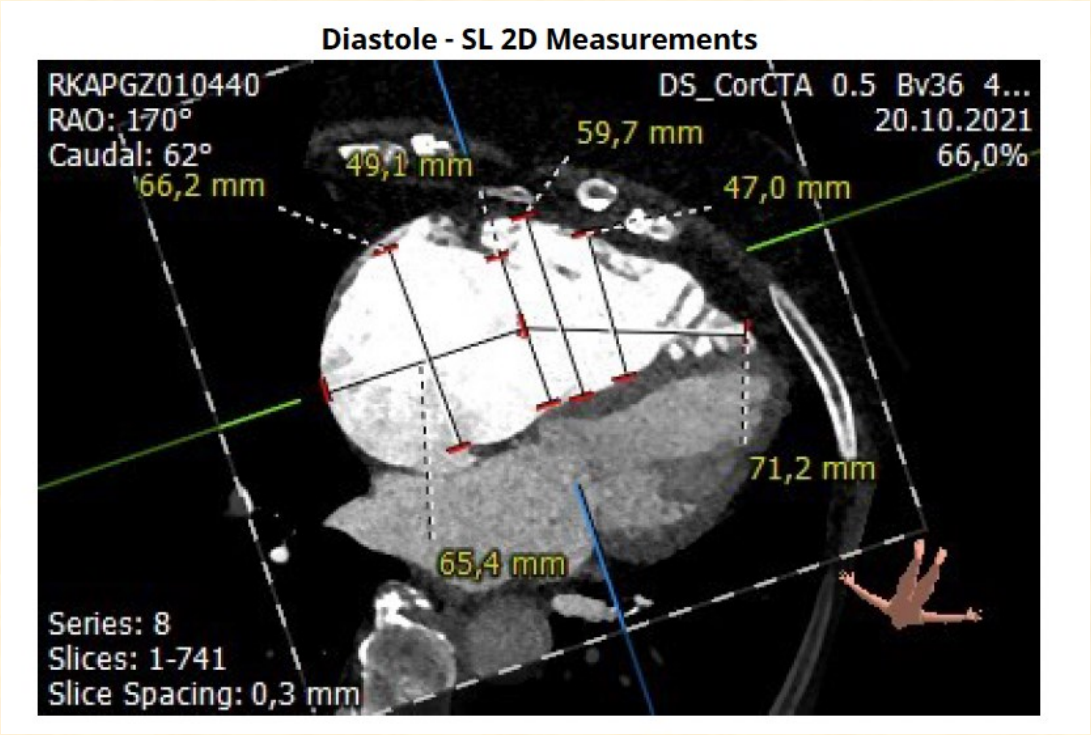


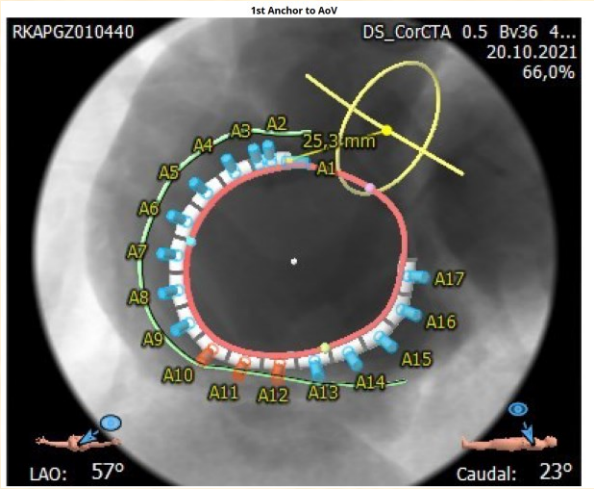


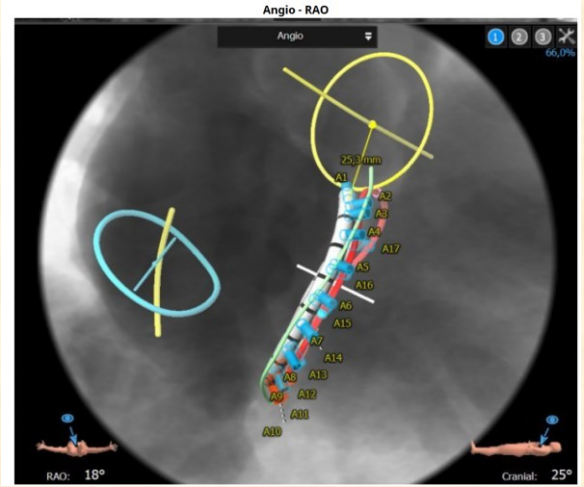




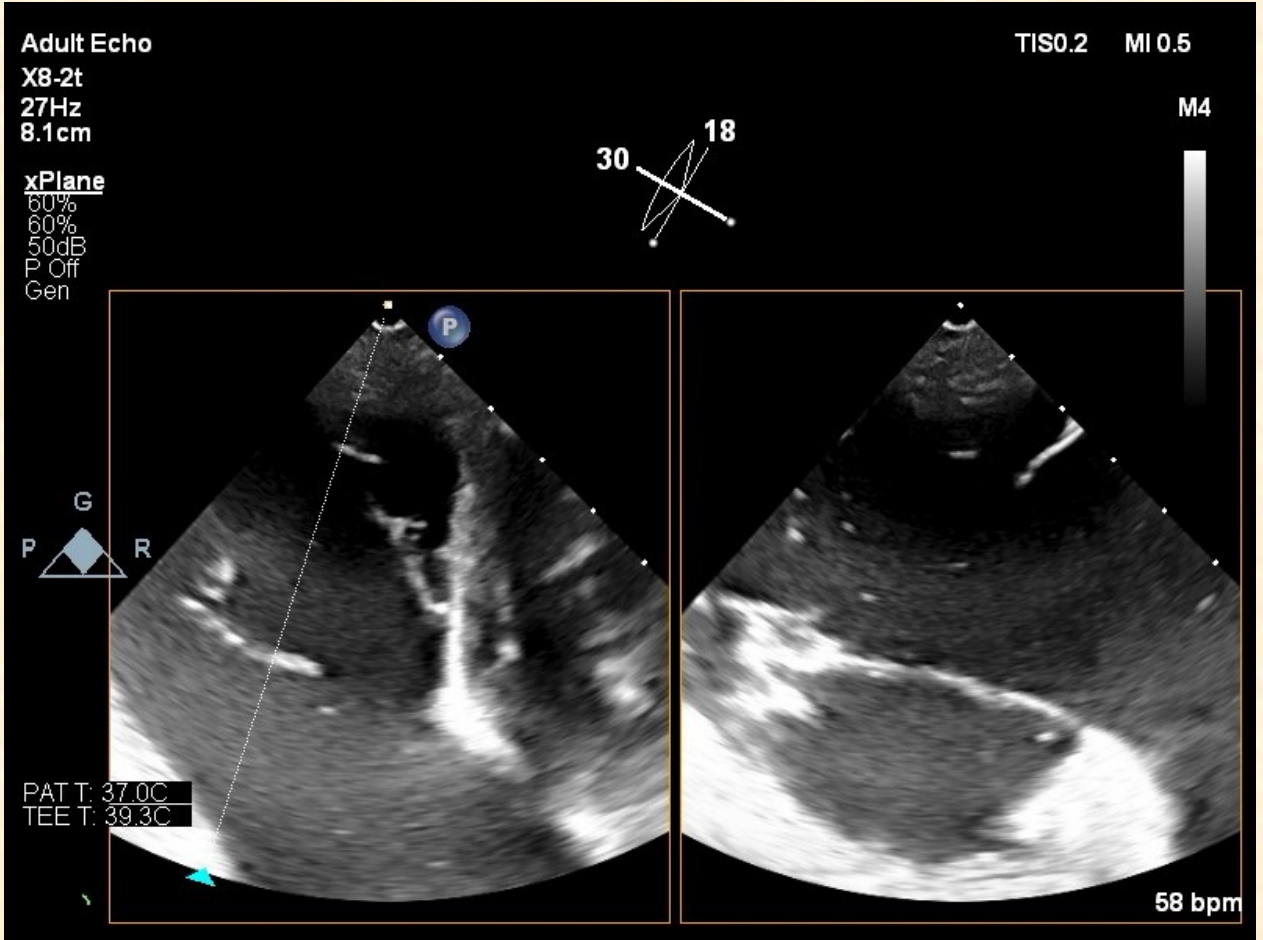
GZ, Procedure planning



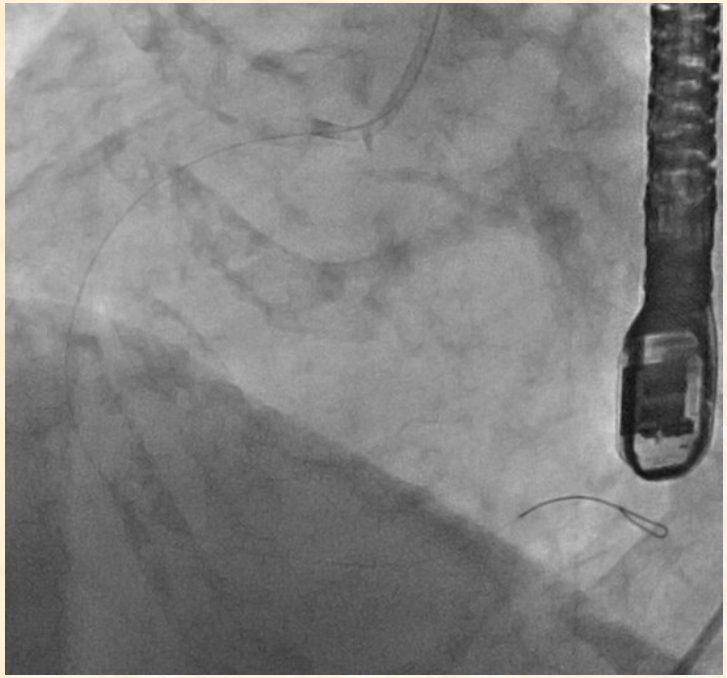


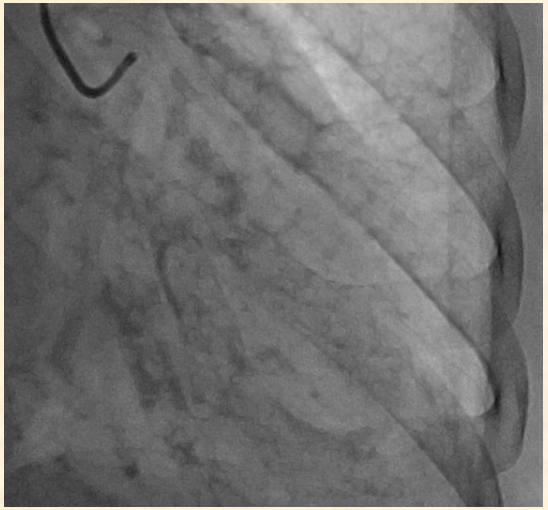


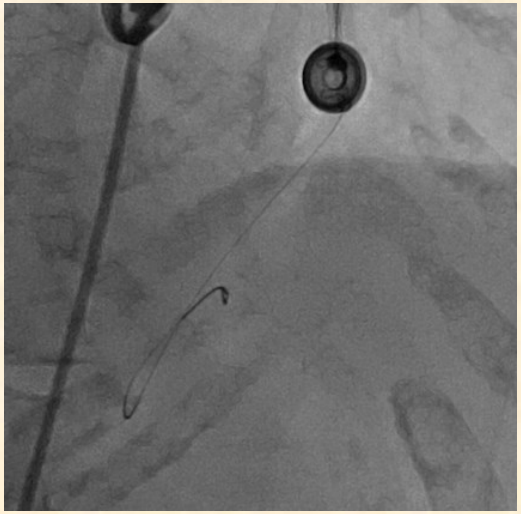
GZ, Procedure Day



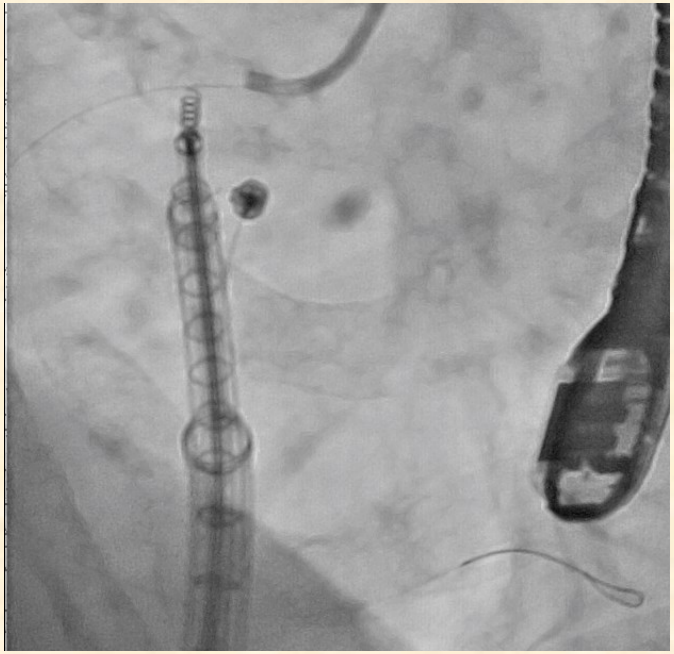
Coronary Angiography
RCA Wire

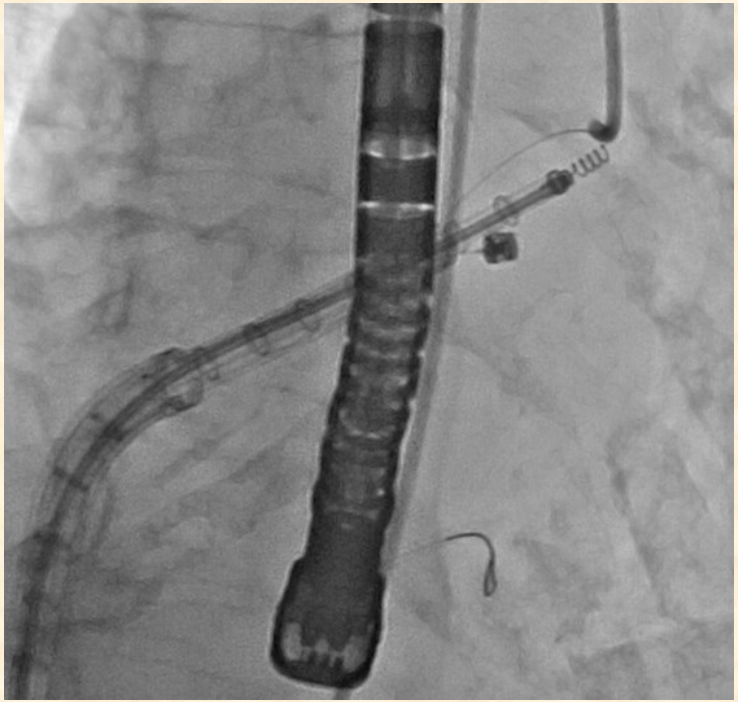




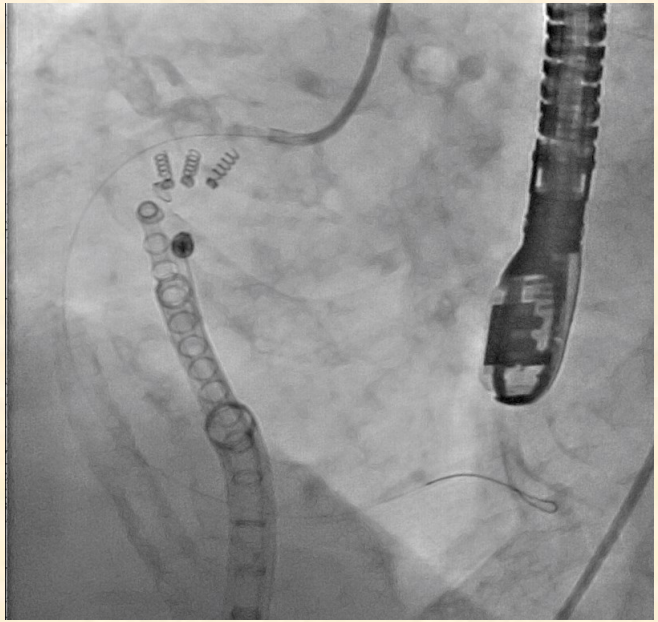


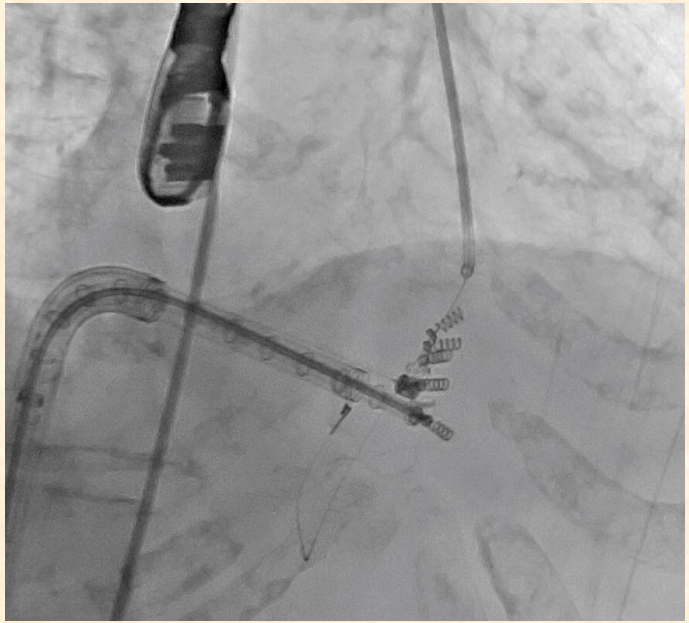
Procedure – First Anchor



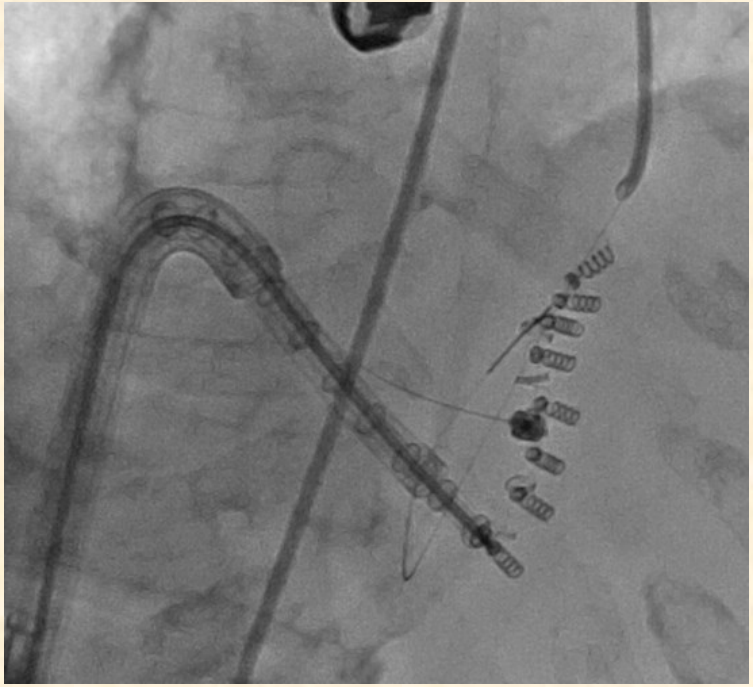


Procedure - A3-A5 – Anchors

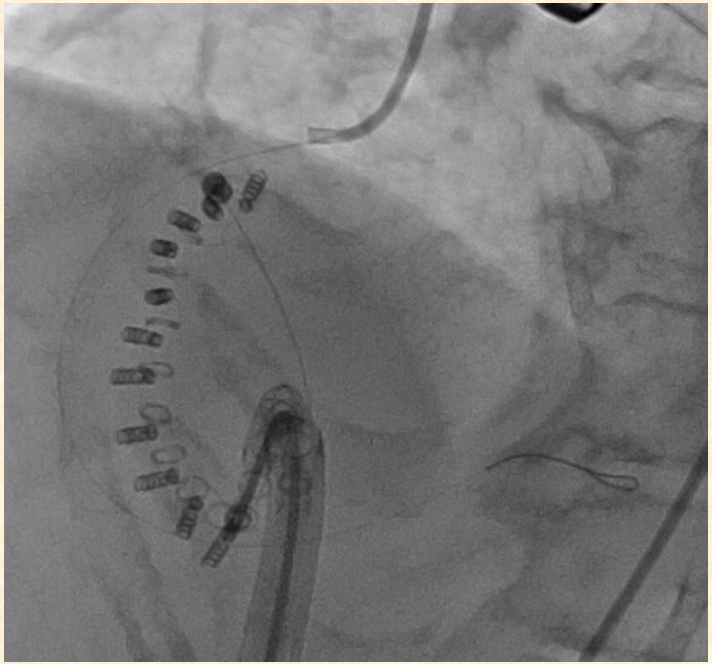


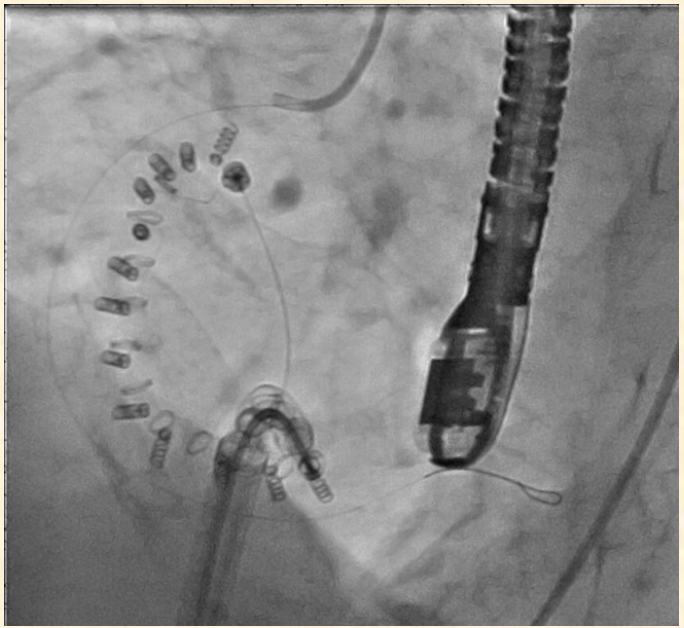


“Pull Test”

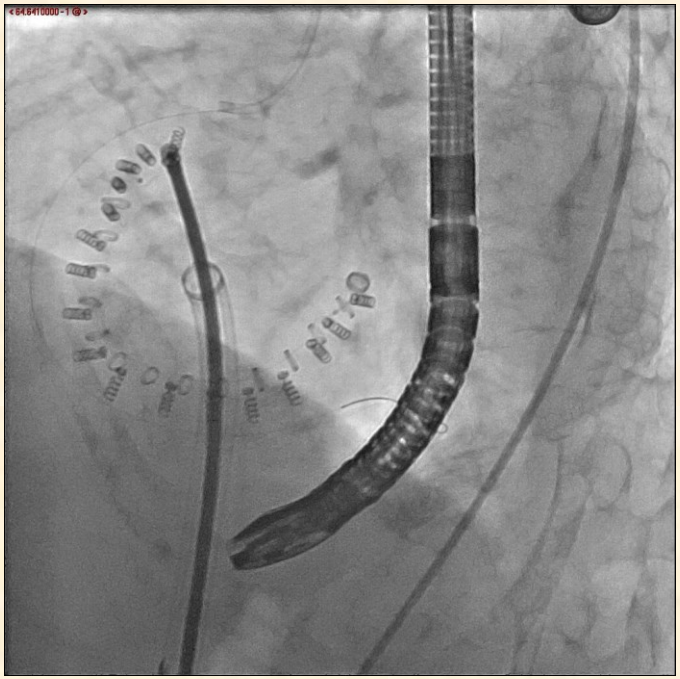


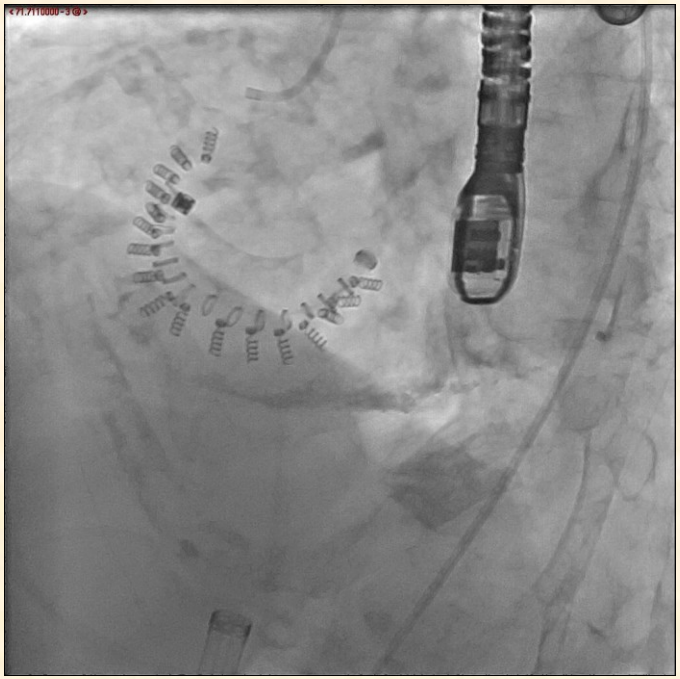
A12 - RCA Spasm, Resolved





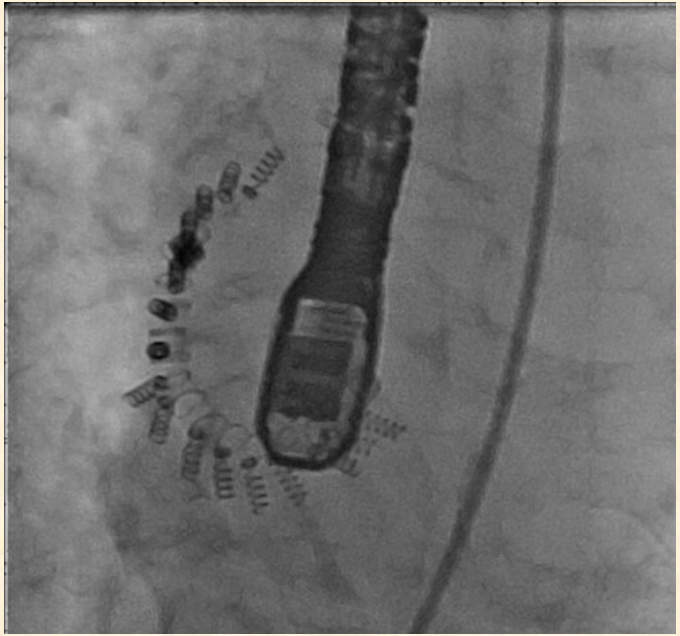
Pre – Post sinching (En-face)

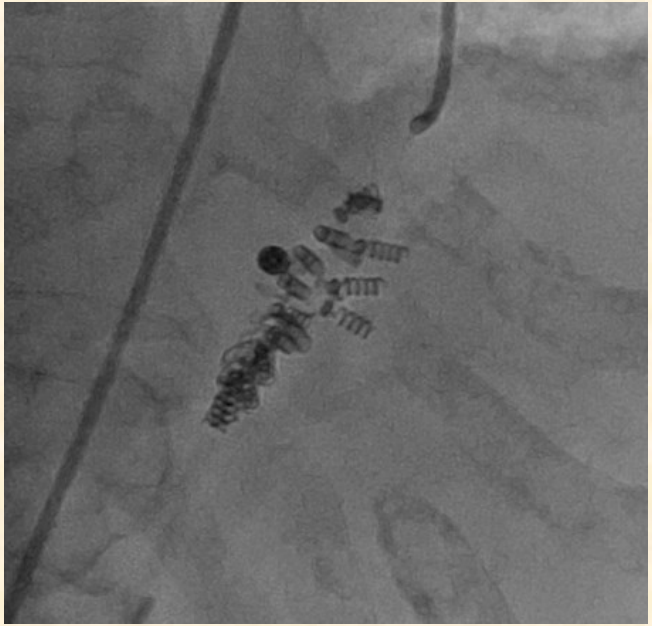




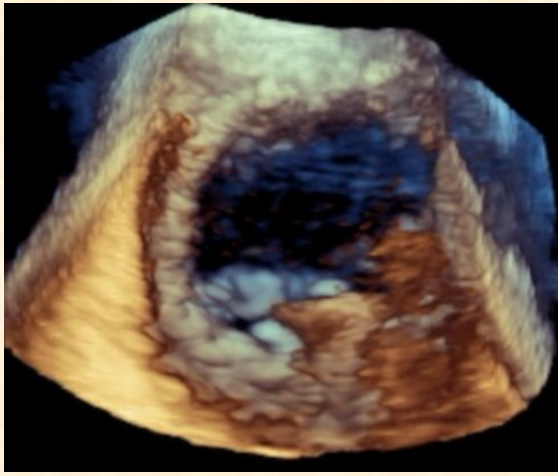
Pre – Post sinching (RAO)

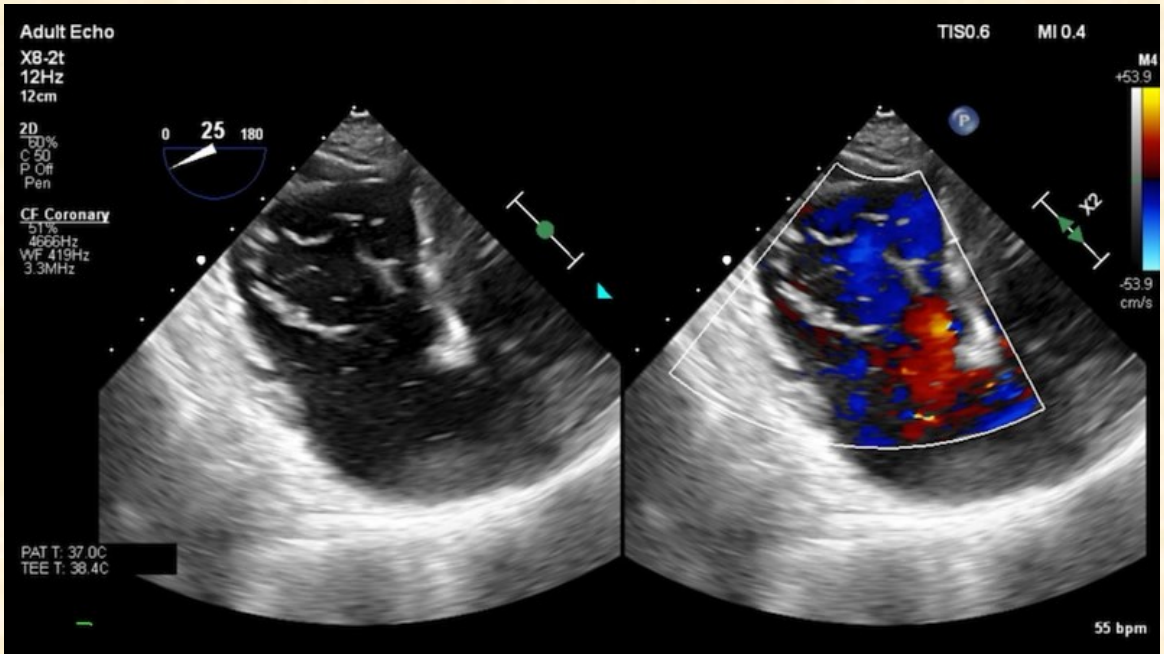
Final Fluro, Post sinch

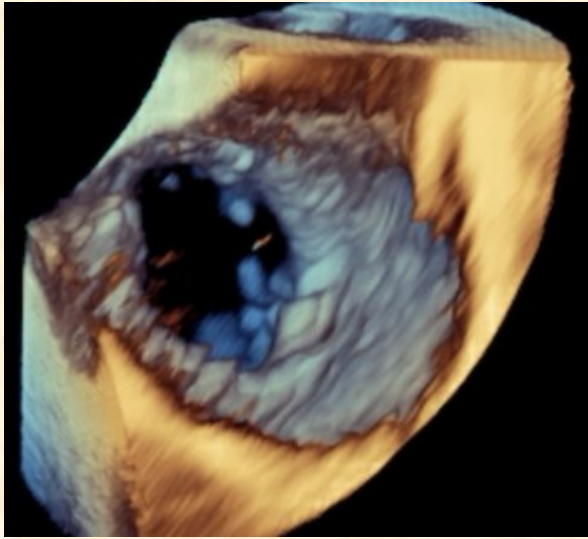




Acute Result

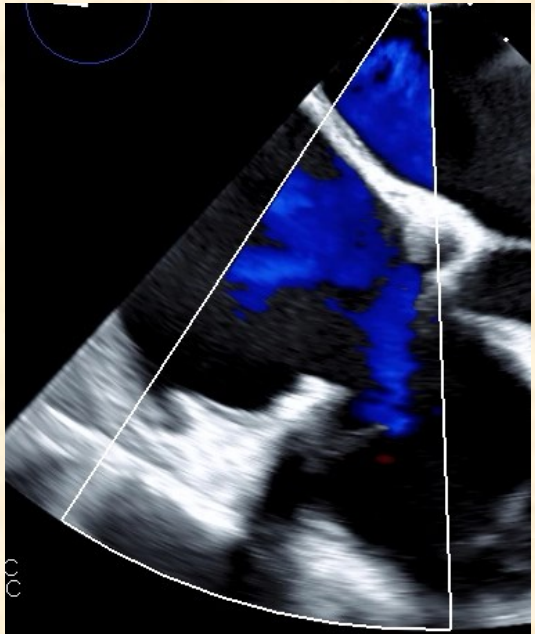




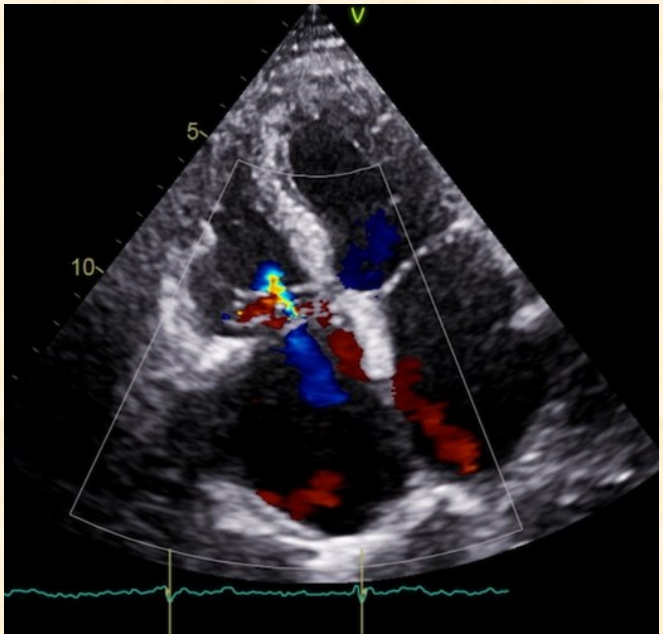


Follow-up

2 Weeks



2 Month

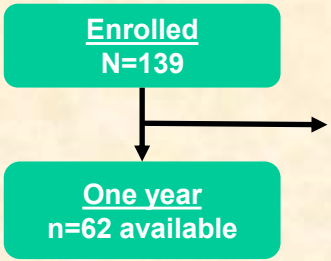


Baseline Characteristics and Device Success

Baseline Characteristics	N=139 % or mean ± SD
Age	79 ± 6.3
Female	76%
STS score (MV replacement), %	6.8 ± 4.6*
EuroSCORE II, %	5.3 ± 4.5^
NYHA class III-IV	85%
LVEF, %	53 ± 8.4¶
Atrial fibrillation	94%^
Pulmonary hypertension	55%
Renal disease	48%
Stroke	11%†
Myocardial infarction	10%‡
PCI/stent	21%
Pacemaker	14%
Aortic valve procedure/surgery	11%
Mitral valve procedure/surgery	20%

Index procedure	%, mean ± SD, or median (IQR)
Device success[a]	93%^
Time for implant delivery system insertion to removal, mins	147 ± 49§
Length of hospital stay, days	5 (4,7)^
Discharge to home	89%^

Patients available at one-year follow-up



Visit not due: 48
Pending visit: 11
Withdrew: 7
Death: 8
Exited for other reasons: 3

[a]Device deployed and delivery system retrieved as intended by patient's exit from catheterization laboratory. *n=136, ^n=138, ¶n=126, †n=131, ‡n=133, §n=130.
IQR, interquartile range; *LVEF*, left ventricular ejection fraction; *MV*, mitral valve; *NYHA*, New York Heart Association, *PCI*, percutaneous coronary intervention; *STS*, Society of Thoracic Surgeons

Favorable Clinical Outcomes to 1 Year

CEC-adjudicated MAEs (N=139)	30 days % (n)	1 year % (n)
Cardiovascular mortality	0% (0)	2.9% (4)
Myocardial infarction	1.4% (2)	1.4% (2)
Stroke	0% (0)	0.7% (1)
Coronary artery injury requiring intervention	5.8% (8)	5.8% (8)
Major cardiac structural complications	0% (0)	0% (0)
Nonelective tricuspid valve reintervention	0% (0)	0.7% (1)
Arrhythmia and conduction disorders requiring permanent pacing	2.9% (4)	3.6% (5)
New need for renal replacement therapy	2.2% (3)	4.3% (6)
Severe bleeding[a]	9.4% (13)	11.5% (16)[b]
Pericardial effusion requiring intervention	2.9% (4)	3.6% (5)
Major access site and vascular complications	2.9% (4)	2.9% (4)
Composite MAEs	**16.5% (23)**	**20.9% (29)**

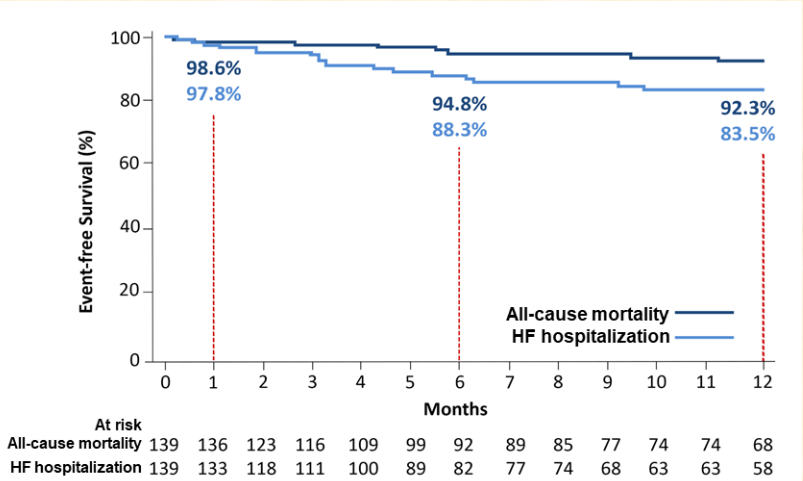
Other events (N=139)	30 days % (n)	1 year % (n)
All-cause mortality	1.4% (2)	5.8% (8)
At least one HFH	2.2% (3)	12.9% (18)
Anchor detachment/dislodgment	2.9% (4)	2.9% (4)

[a]Severe bleeding as defined by Mitral Valve Academic Research Consortium. [b]No fatal bleeding events up to one year. Patients may have experienced more than one event.
CEC, clinical events committee*; MAE*, major adverse events; *HFH*, heart failure hospitalization

High Survival and Low HF Hospitalization at 1 Year

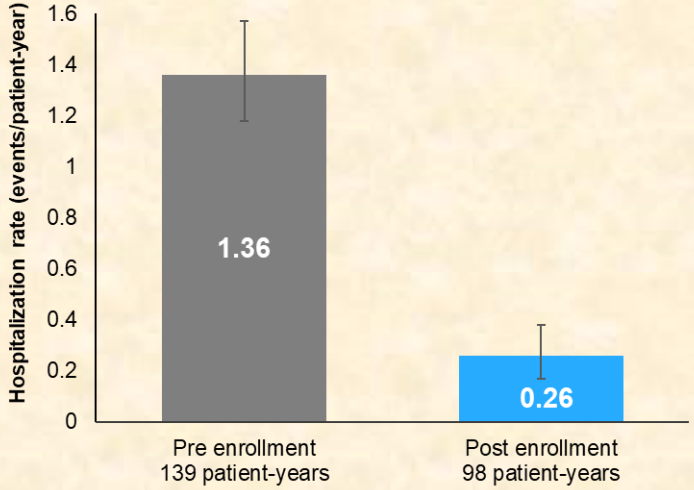
Kaplan-Meier Estimates

92% survival and 84% freedom from HF hospitalization at 1 year



Annualized HF Hospitalization

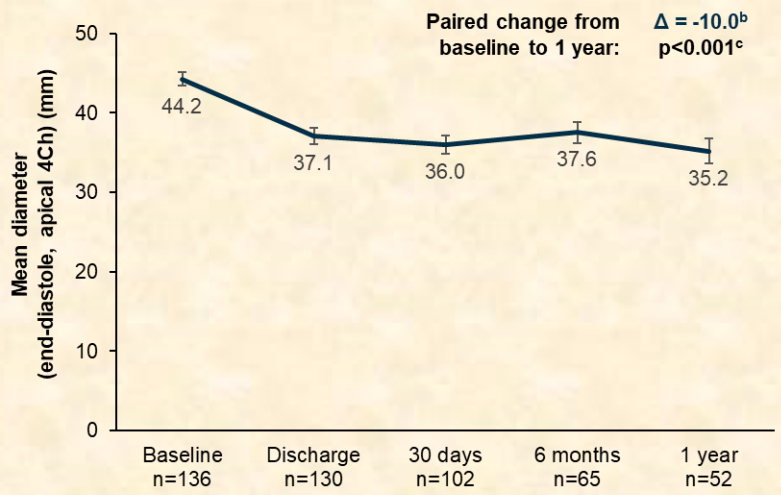
81.2% Relative reduction in hospitalization
p<0.001[a]



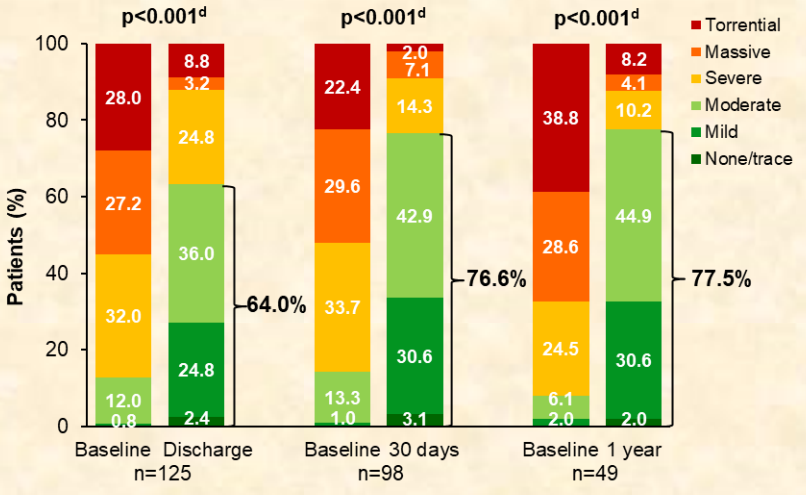
[a]P-value from log-linked model on incidence rate reduction. Error bars represent 95% confidence interval. *HF*, heart failure

Sustained Annular and Tricuspid Regurgitation Grade Reductions by Core Lab[a] at 1 Year

Tricuspid Annulus Diameter



Tricuspid Regurgitation Grade

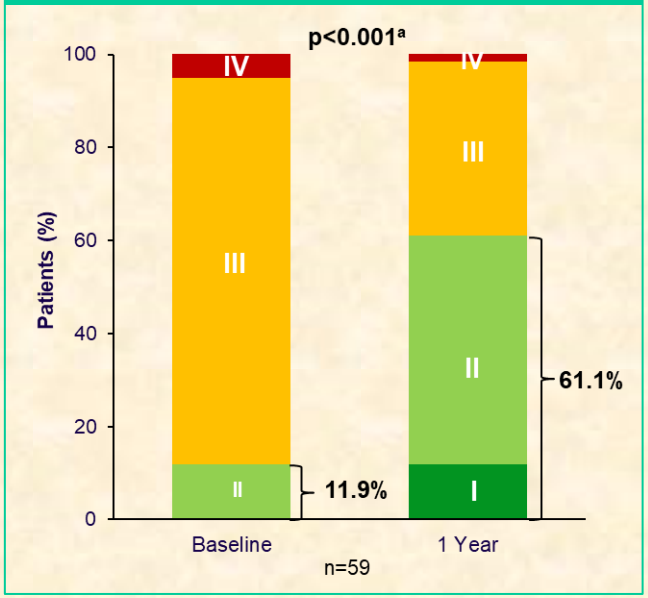


At 1 year, TV annulus diameter decreased by 22%,[b] 86% of patients achieved ≥ 1 TR grade reduction, and 67% achieved ≥ 2 grade reductions

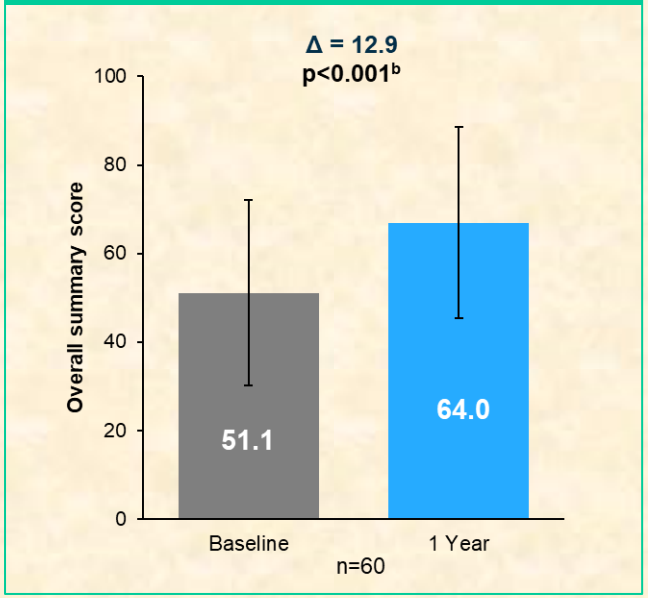
Tricuspid annulus diameter graph shows unpaired data. TR graph shows paired data. [a]Cardiovascular Research Foundation. [b]Decrease from 45.3mm to 35.3mm on paired analysis, n=50. [c]Paired t-test. Error bars represent 95% confidence interval. [d]Wilcoxon signed-rank test.

Significant Functional and Quality-of-Life Improvements at 1 Year

NYHA Class



KCCQ Score



At 1 year, 32% of patients improved ≥ 20 points in KCCQ and 18% improved 10-19 points

[a]Paired t-test. [b]Wilcoxon signed-rank test. Error bars represent standard deviation. *KCCQ*, Kansas City Cardiomyopathy Questionnaire; *NYHA*, New York Heart Association