Triscuspid Regurgitation: Clinical Relevance and Treatment Options in Contempoary Practice

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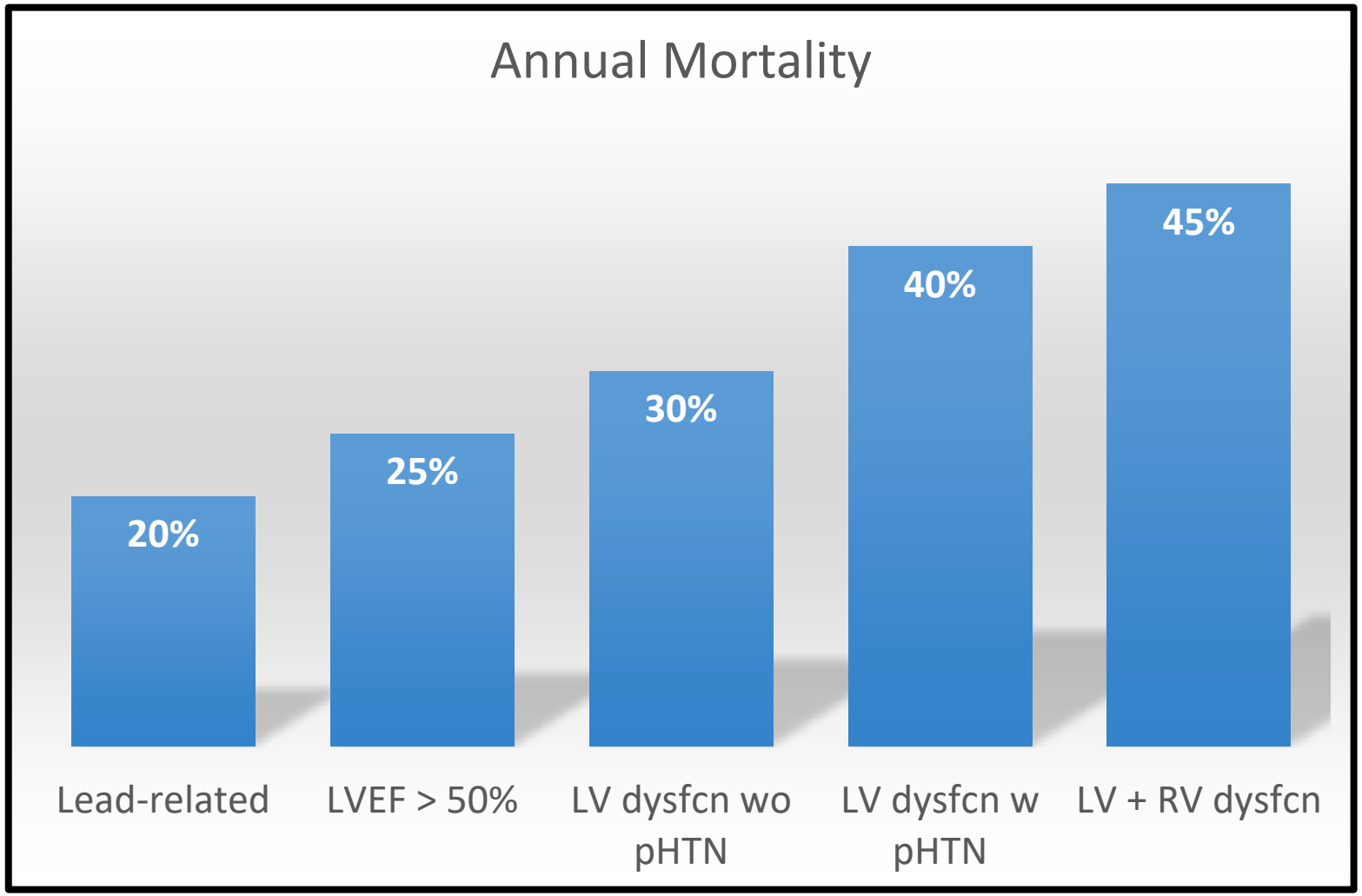
Outline

- Epidemiology of TR
- Relationship of electrophysiology and TR
- Treatment options and outcomes for patients with TR

TR is Common & Associated with Poor Survival

Prevalence:
2.4 million

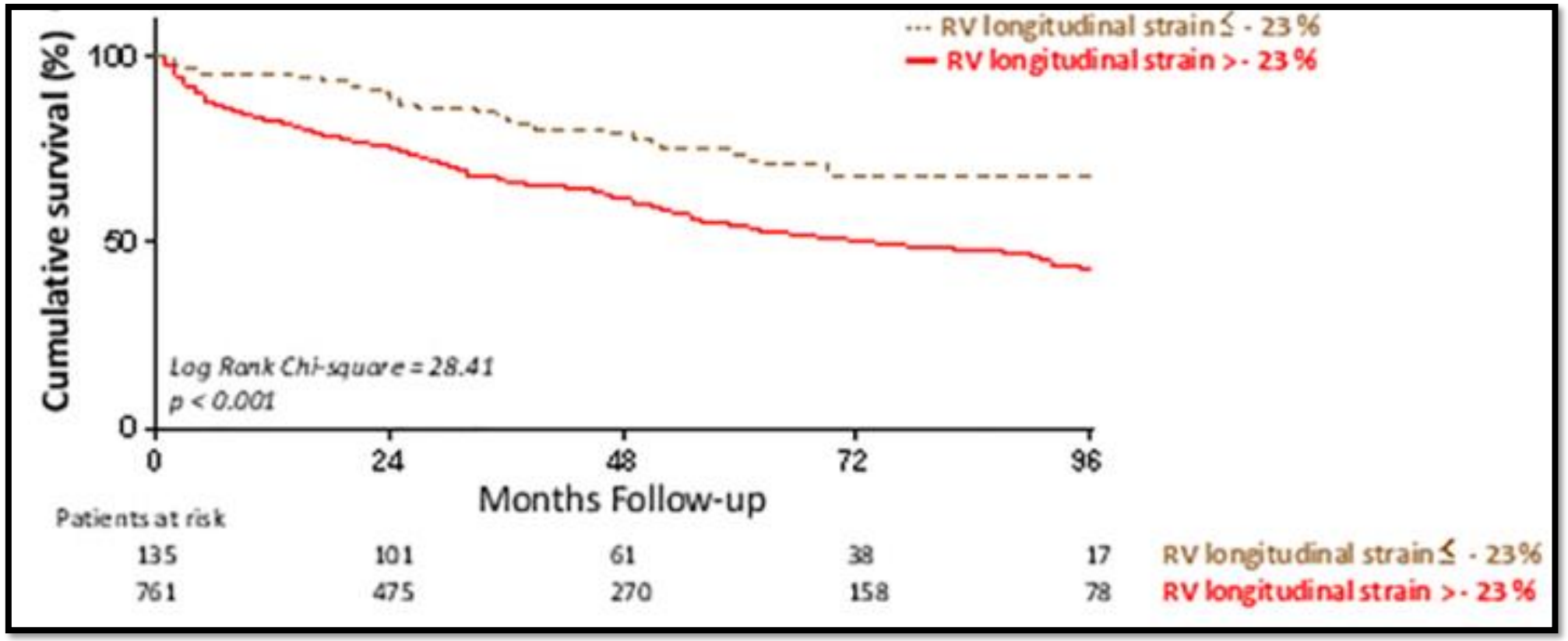
10,000 TR
surgeries/year



Zahr F et al. Catheter Cardiovasc Interv 2022;1–16

Enriquez-Sarano et al., 2019 - Tricuspid regurgitation is a public health crisis

Prognosis of TR is Worse as RV Function Declines



Prihadi et al. Circ CV Imaging 2018

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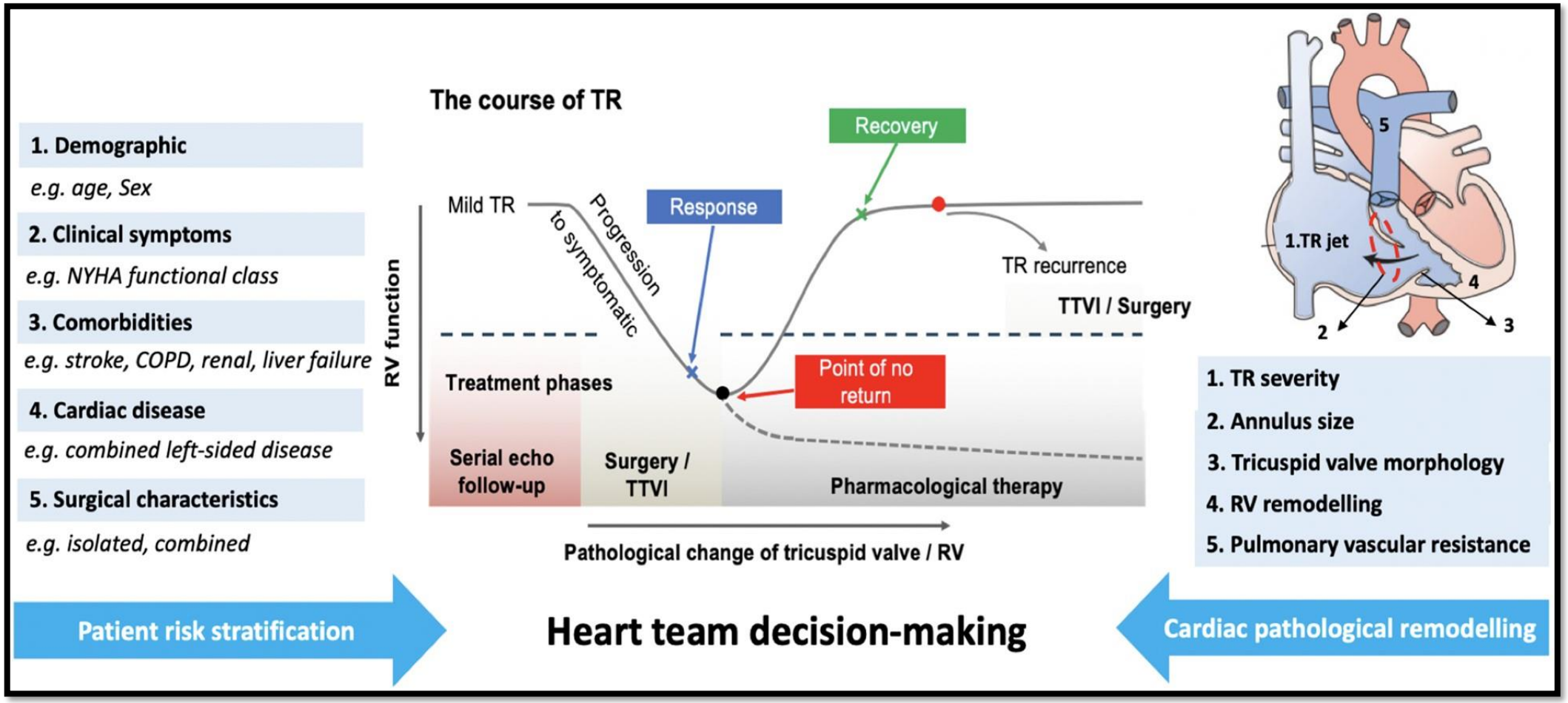
Decision on Timing of TV Therapy is Complex



Chang CC et al EHJ 2020;41(20):1932

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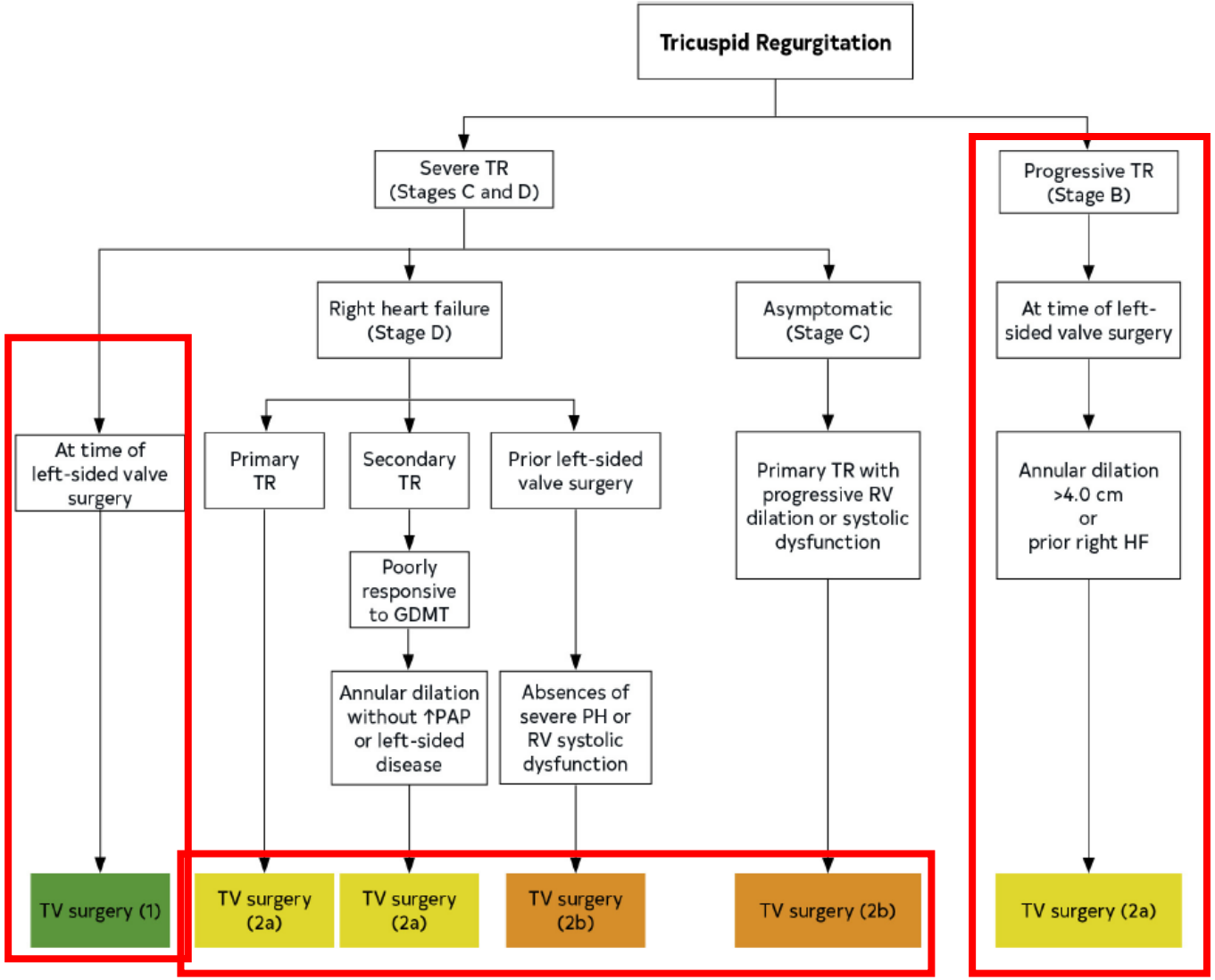
Guidelines: Only Class I is for Severe TR at the Time of Left-sided Valve Surgery



Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology (JACC)*. 2021;77(4):e25-e197.

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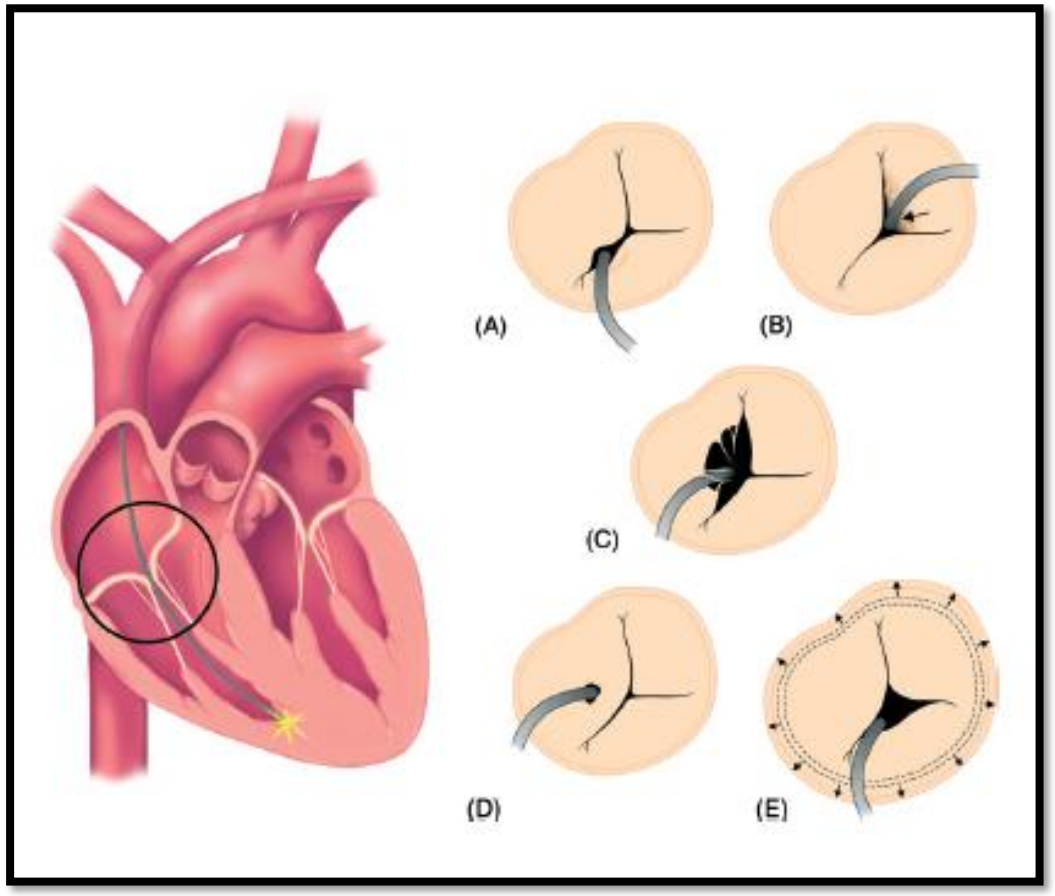
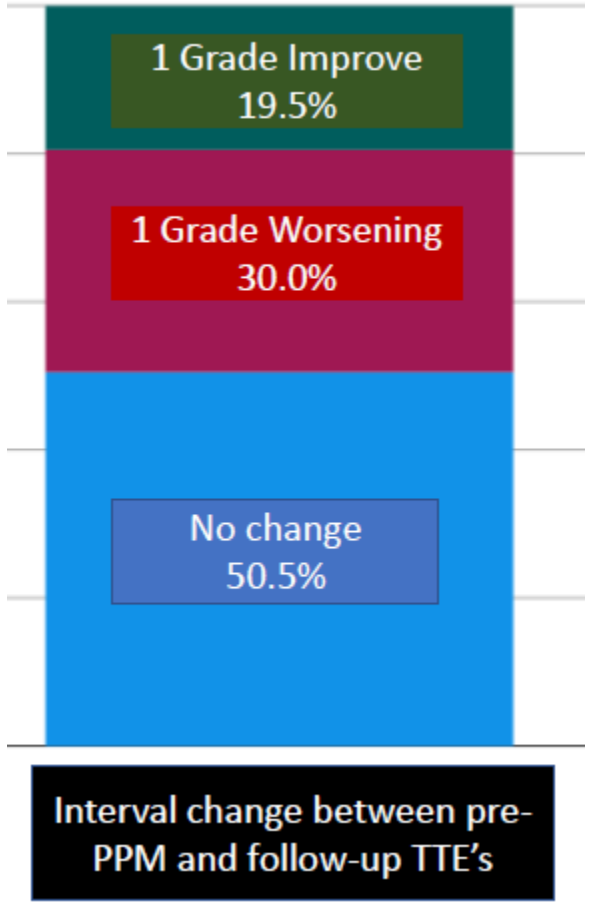
Implanted Rhythm Devices are An Important Cause of TR



Al-Bawardy R et al Clin. Cardiol 2013



Allard-Ratick M et al TVT 2022

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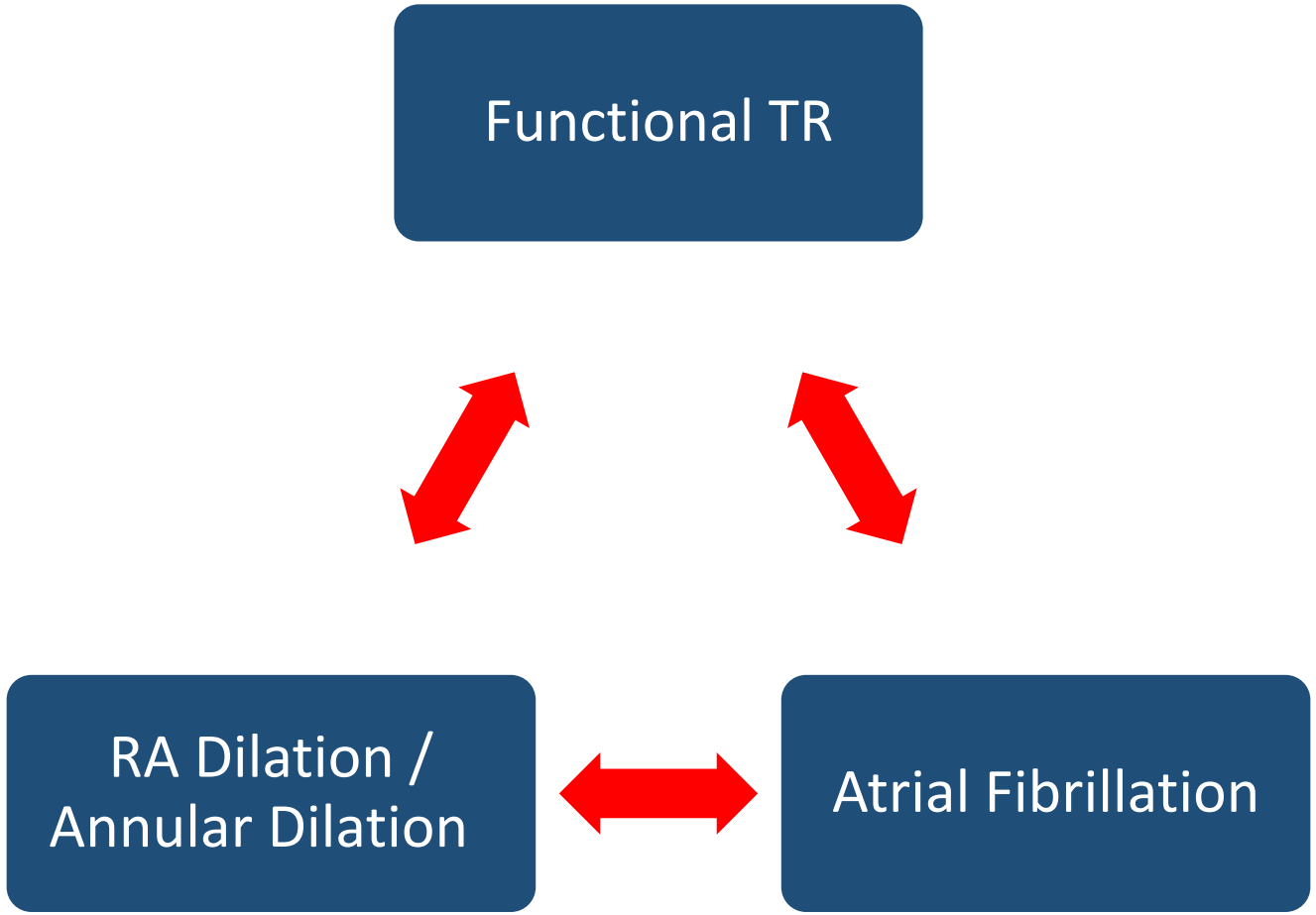
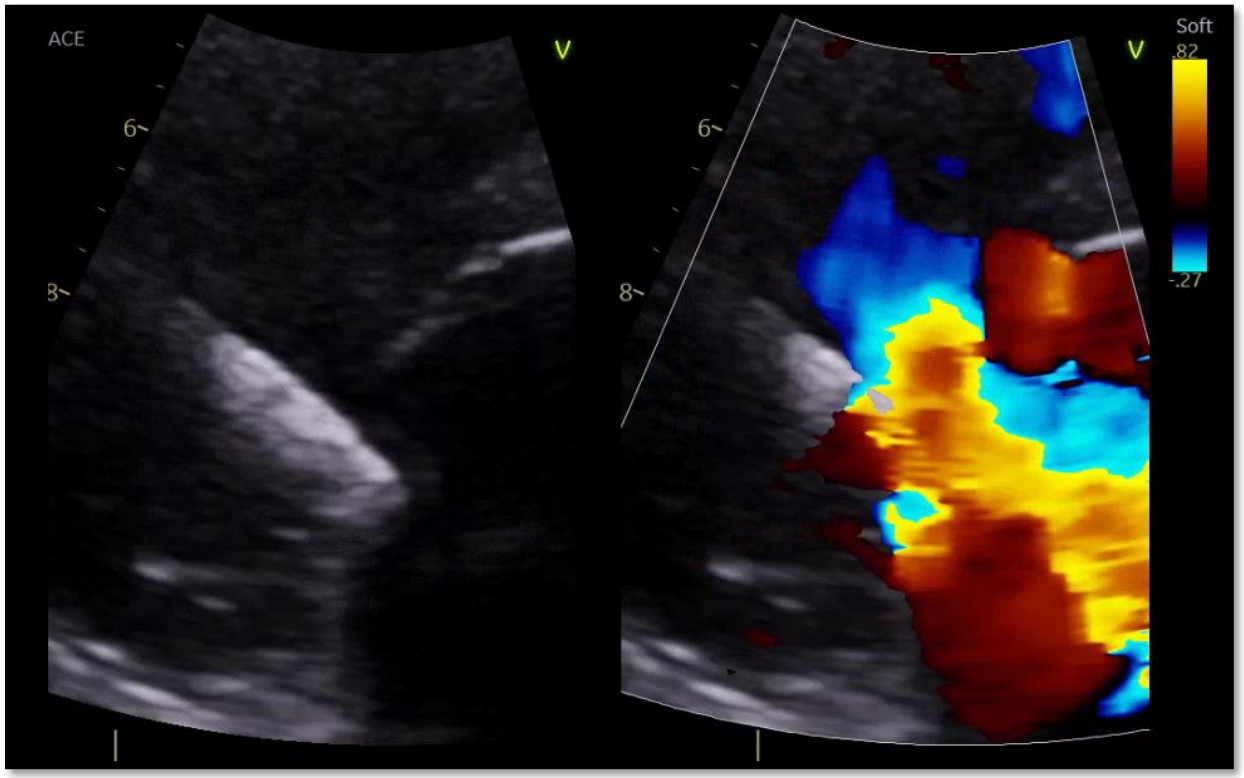
Atrial Fibrillation and TR are a Complex Interplay



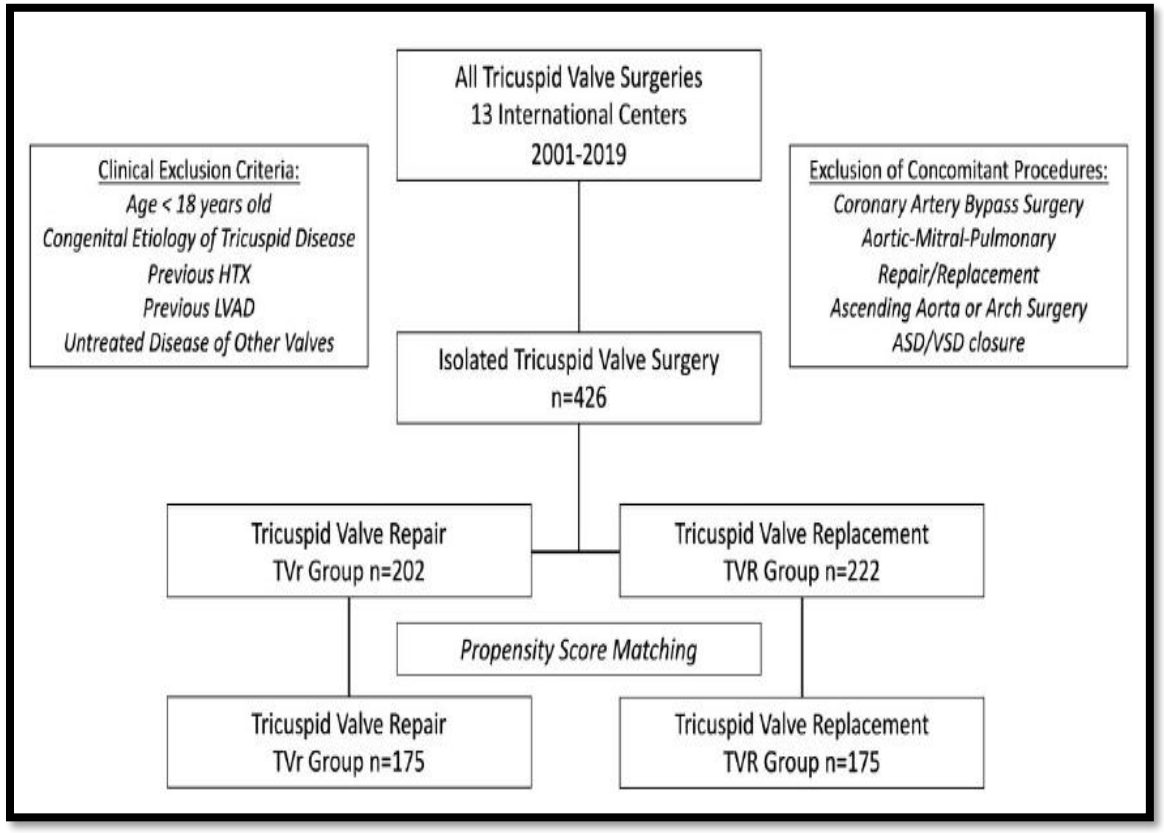
Case 1

- 68yo woman
- PMHx:
  Afib
  2001: 1st OHS (MVRe)
  2014: 2nd OHS (MVR)
  2018: ICD (VT secondary to Tikosyn)
- Now w torrential TR
  Exertional dyspnea/fatigue
  Combination of RA enlargement and ICD
- Normal LVEF and well-functioning MVR



-> Isolated TV repair + epicardial coil; home after 6 days. Thrilled with her outcome

Isolated TR Surgery Patients are Generally High Risk



Variable	Whole population (*n* = 426)	After matching			
		Replacement (*n* = 175)	Repair (*n* = 175)	SMD[a]	*P*-Value
Age, year, mean (SD)[b]	57 (18)	54 (16)	56 (16)	-0.15	0.9
Male sex, *n* (%)	189 (44)	74 (42)	81 (46)	-0.08	0.4
Diabetes, *n* (%)	61 (15)	21 (12)	27 (15)	-0.10	0.3
NYHA[c] III–IV, *n* (%)	212 (49)	100 (57)	86 (47)	0.17	0.06
Previous stroke, *n* (%)	26 (6)	8 (5)	10 (6)	-0.05	0.62
Dialysis, *n* (%)	14 (3)	8 (5)	5 (3)	0.09	0.39
COPD[d] *n* (%)	57 (13)	27 (15)	23 (13)	0.06	0.54
LV ejection fraction, %	56 (9)	56 (9)	57 (9)	-0.13	0.84
Previous cardiac surgery, *n* (%)	181 (53)	83 (47)	65 (37)	0.19	0.06
Endocarditis, *n* (%)	115 (27)	55 (31)	41 (23)	0.17	0.09
EuroSCORE II, (SD)	4.8 (6.0)	5.5 (6.1)	4.2 (5.5)	0.20	0.07
CRS[e] score, *n* (SD)	4.2 (2.7)	4.1 (2.7)	4.5 (2.8)	0.12	0.07
Urgency/emergency, *n* (%)	90 (21)	41 (23)	36 (21)	0.07	0.51
Median sternotomy, *n* (%)	353 (82)	147 (83)	147 (84)	0.02	0.1
CPB[f] time, min (SD[b])	97 (51)	103 (55)	92 (55)	0.13	0.2
Beating heart, *n* (%)	157 (37)	75 (43)	60 (34)	0.19	0.08

Russo M et al EJCTS 2022; vol 62

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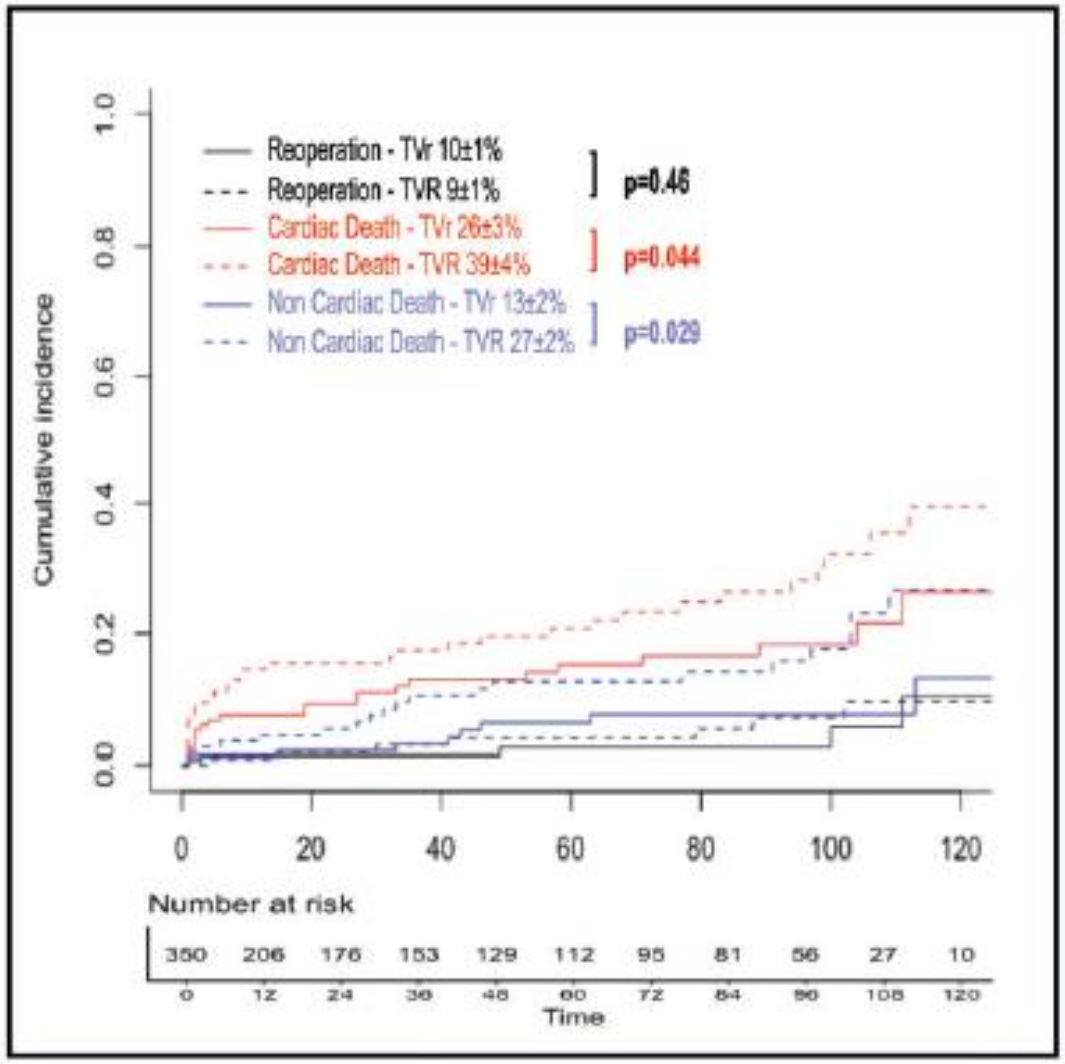
Outcomes of Isolated TV Surgery are Cautionary



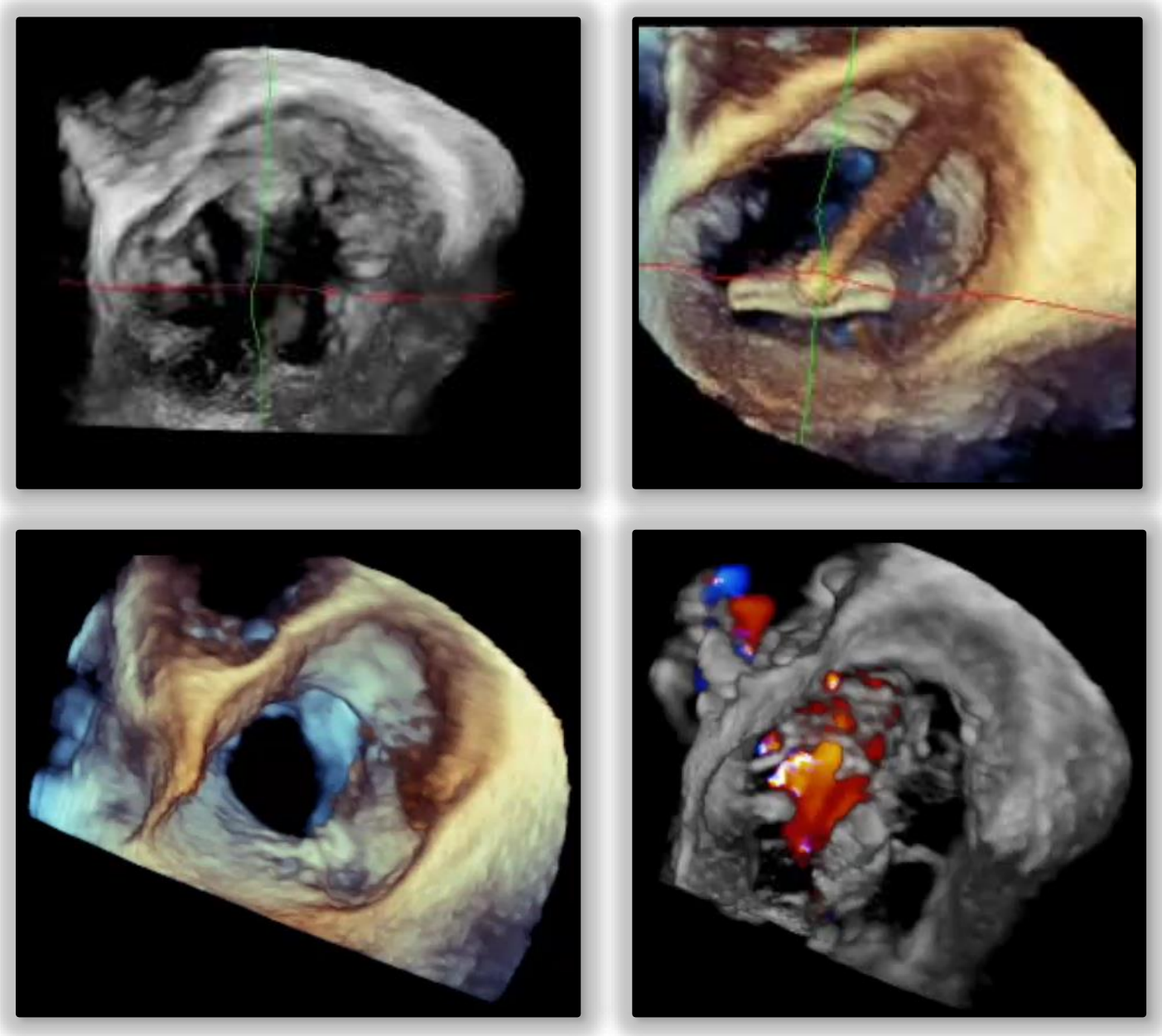
30-day Mortality:
P=NS **TVR: 8%**
TVr: 4%

Reoperation:
TVR: 13%
TVr: 7%

LoS:
TVR: 13 days
TVr: 9 days

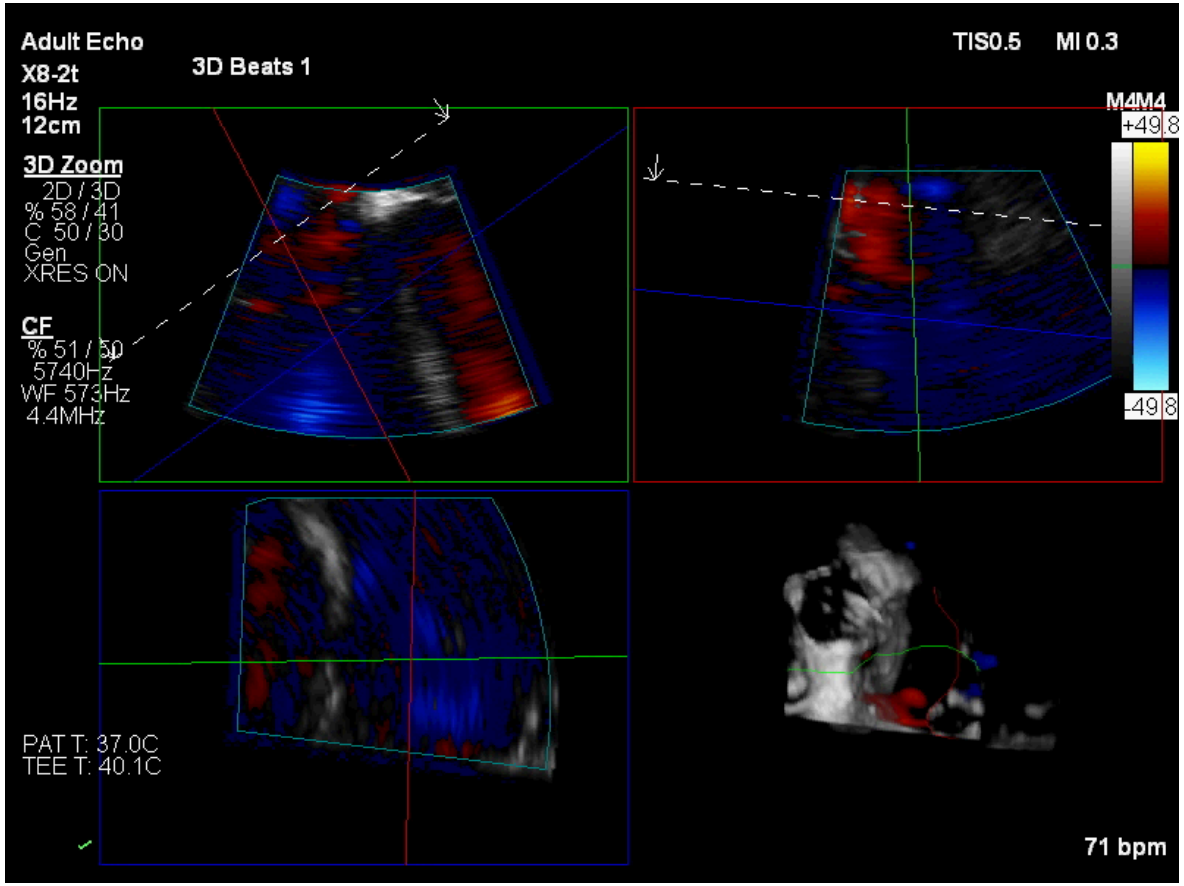
New PPM:
TVR: 12%
TVr: 5%

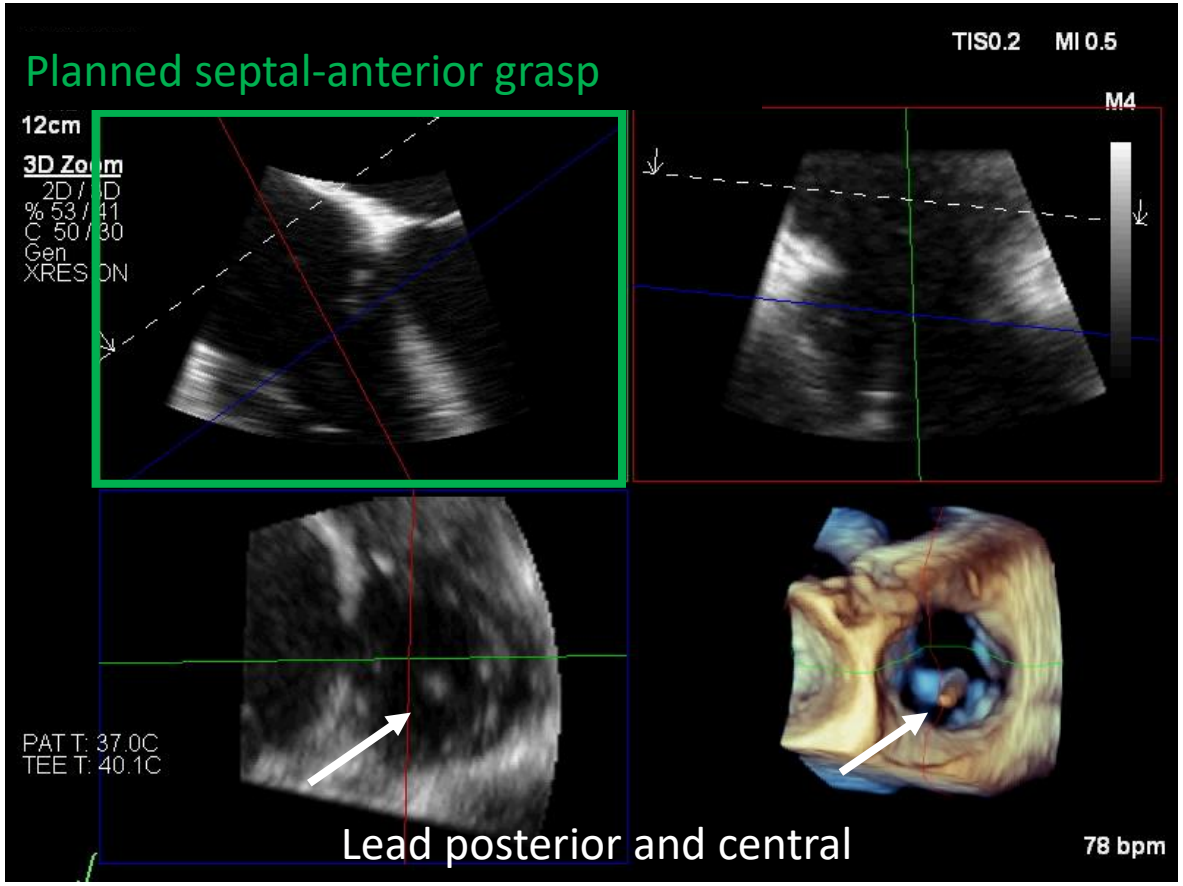
83yo Woman with Symptomatic TR



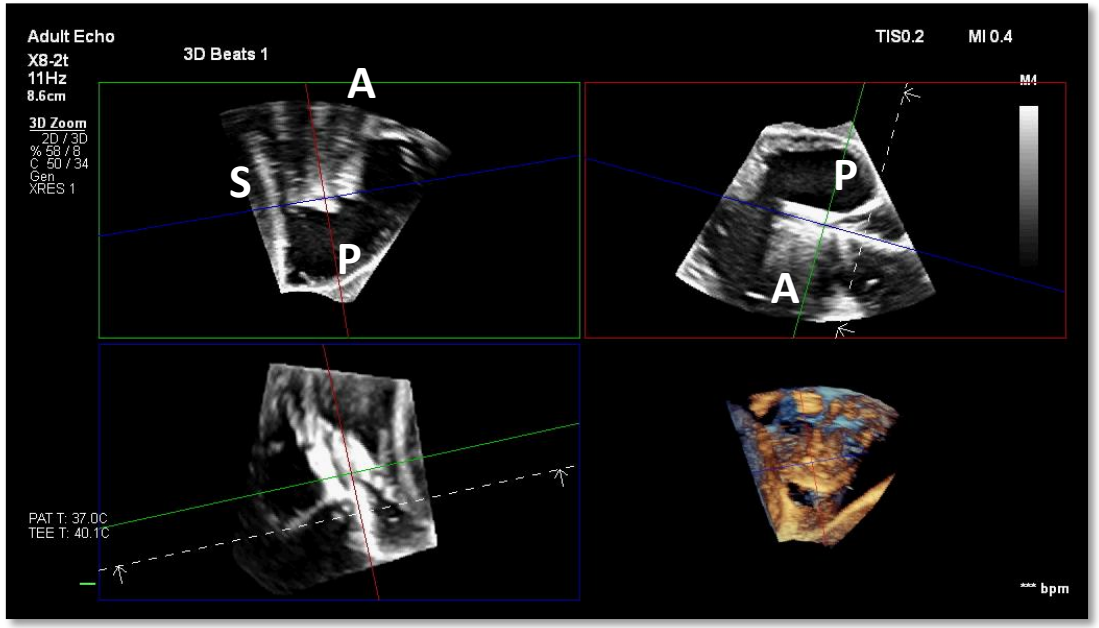
56 yo with NICM (EF 30%), with severe symptomatic MR and TR. Presents for MV/TV clips.

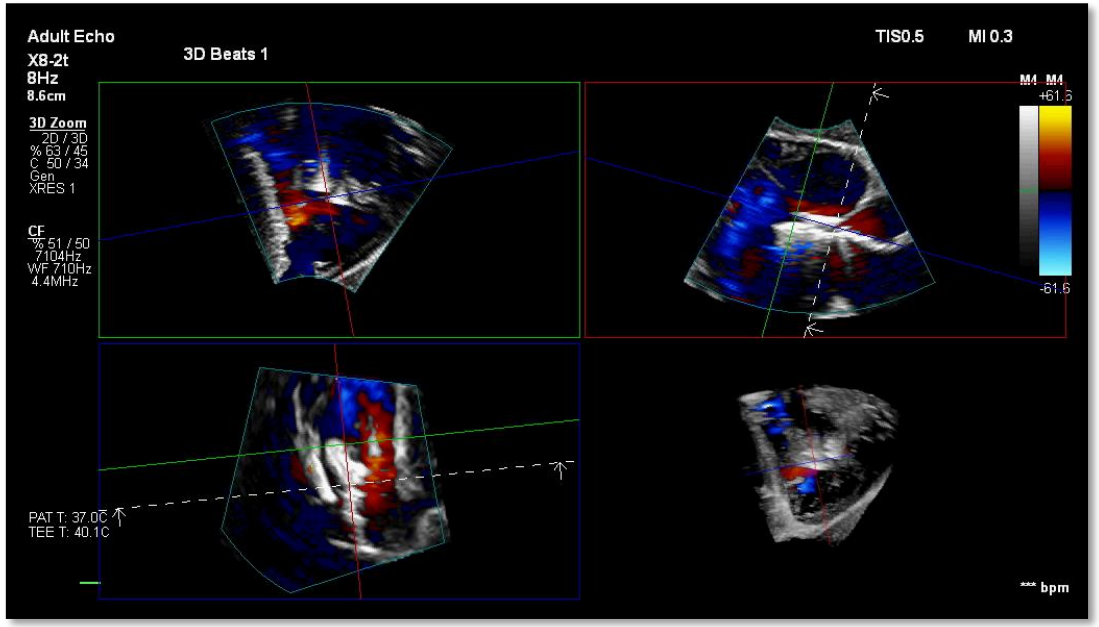
Preprocedural TV clip planning

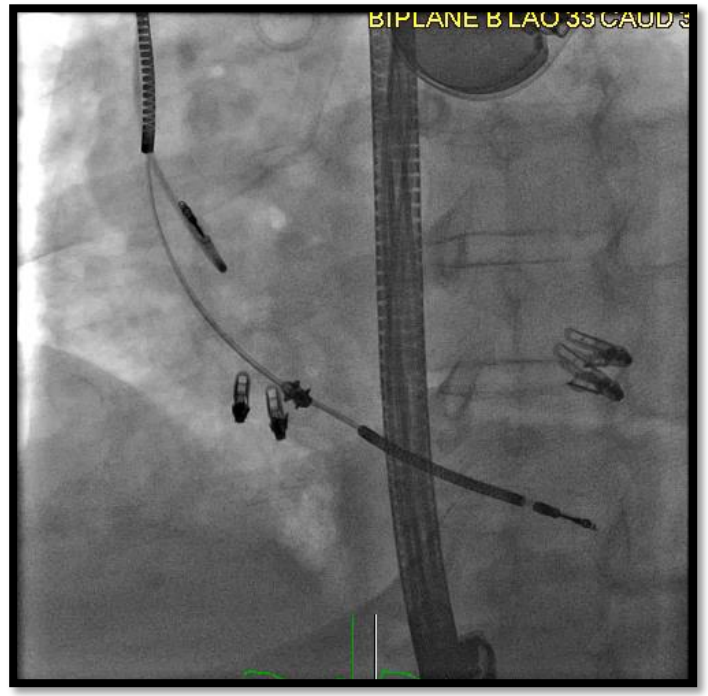




Tip 9: Fluoroscopic Spatial Resolution Can Be More Accurate







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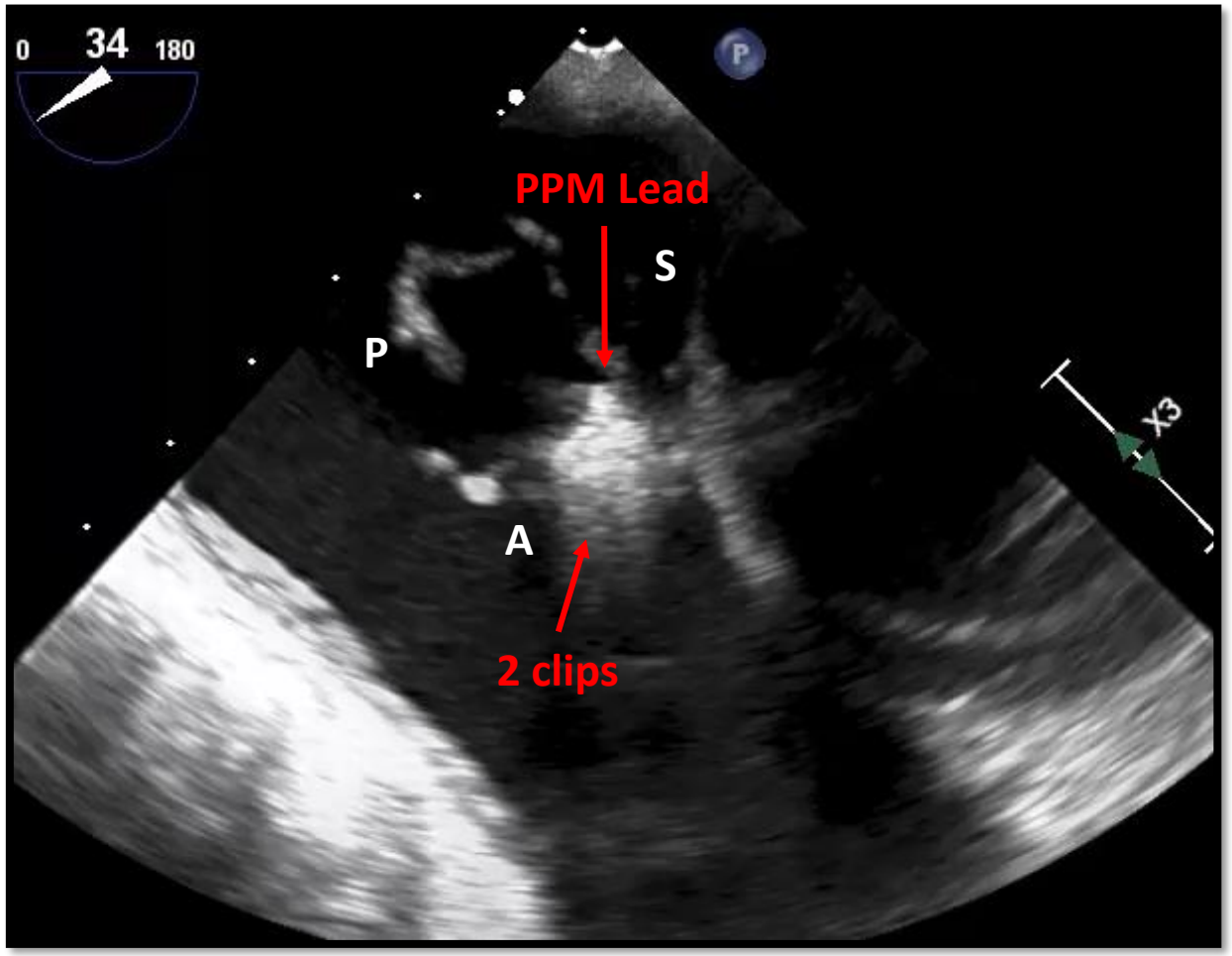
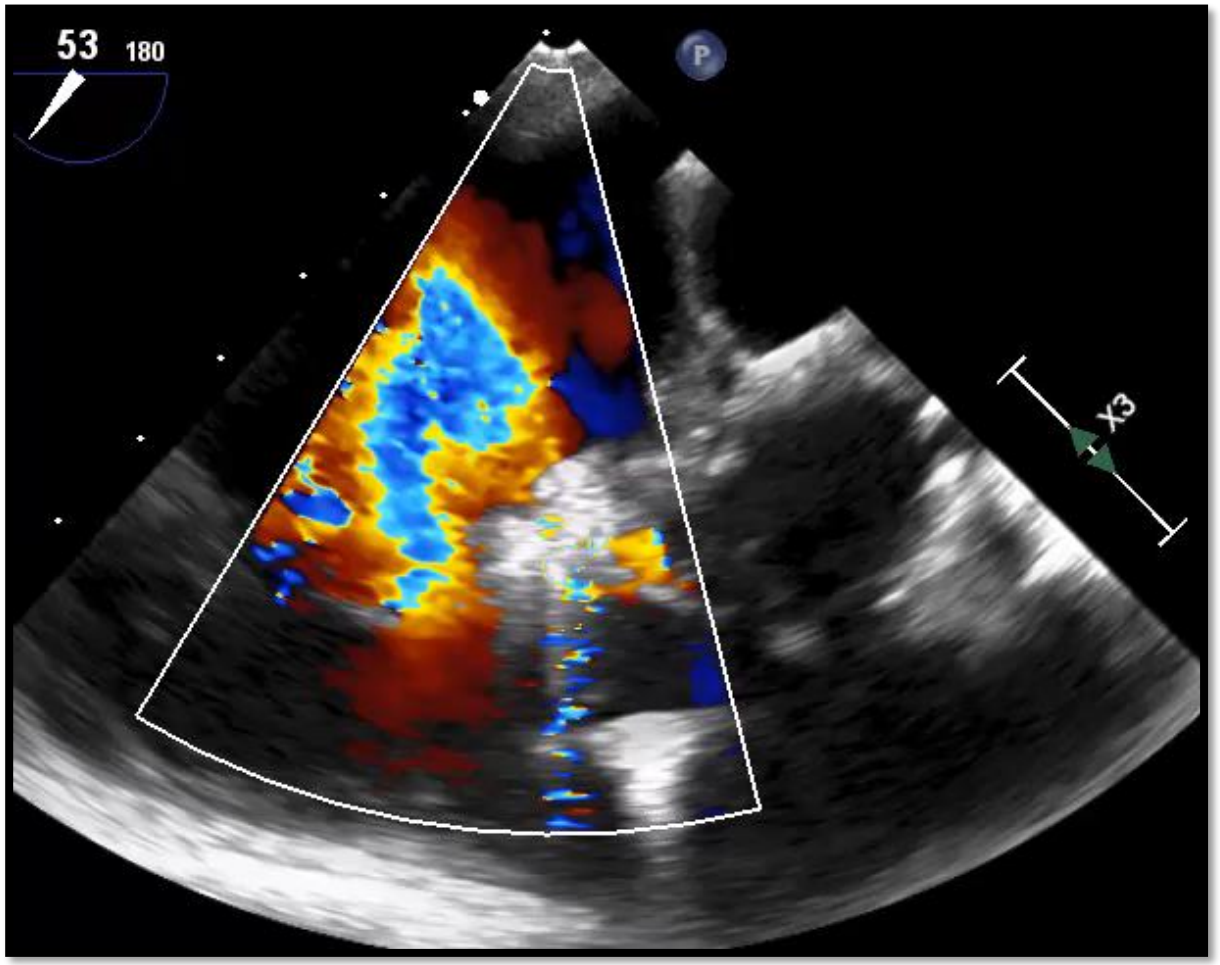
Sometimes Moving the RV Lead Is Necessary





Case c/o Jamie McCabe, University of Washington, Seattle USA

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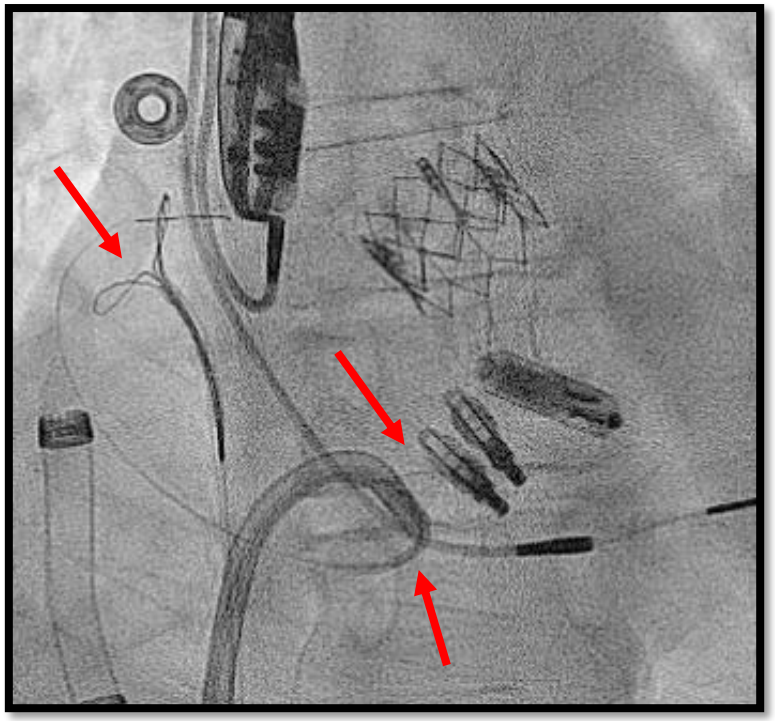
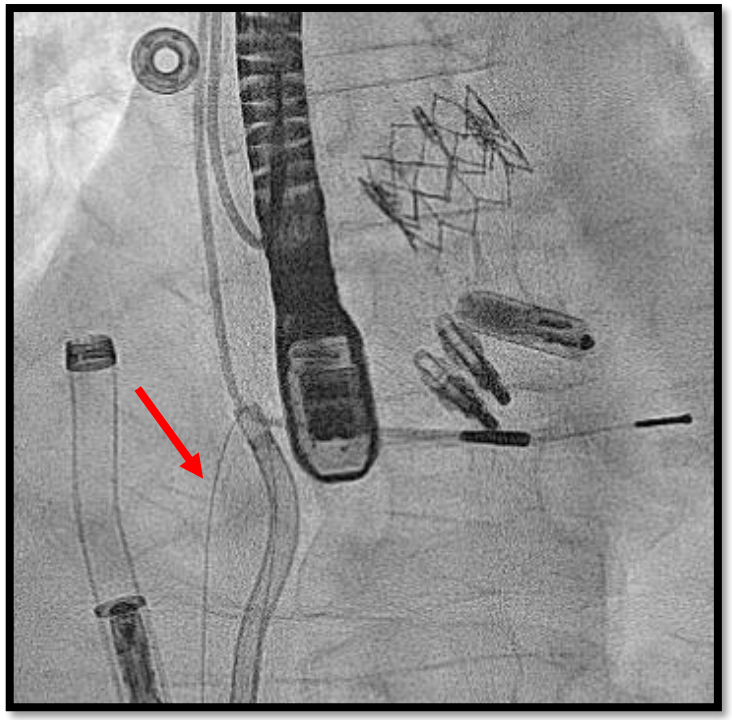
Sometimes Moving the RV Lead Is Necessary

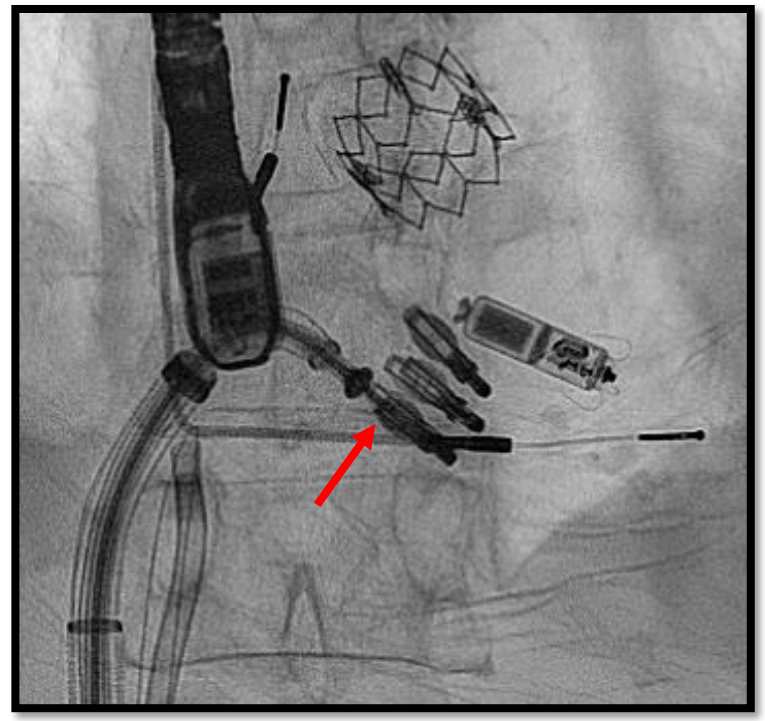
Lead Captured in the RA (steerable catheter / wire)



Wire Snared to Provide Ability For Careful Lead Manipulation



3rd Clip Placed Posterior to the First 2 Clips



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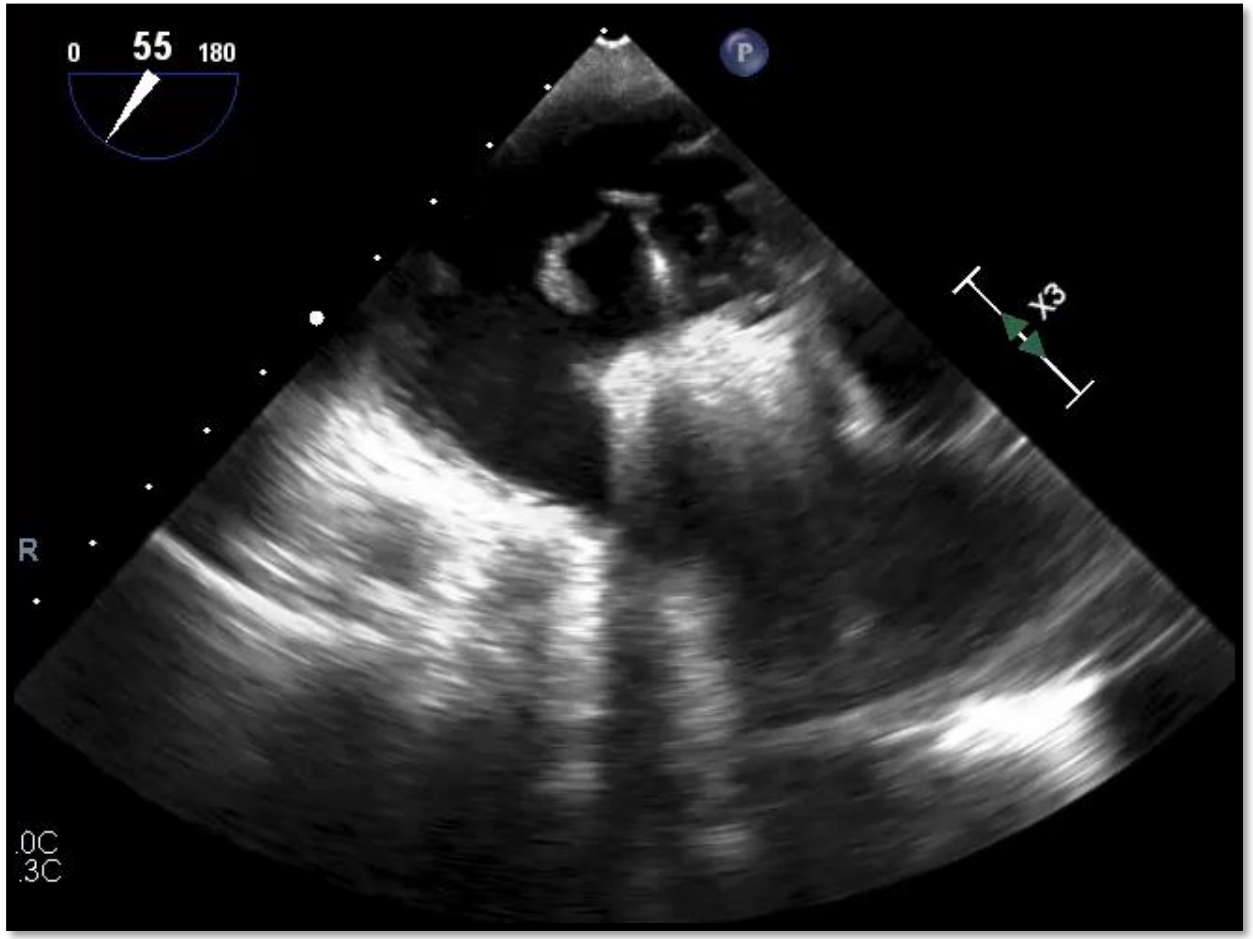

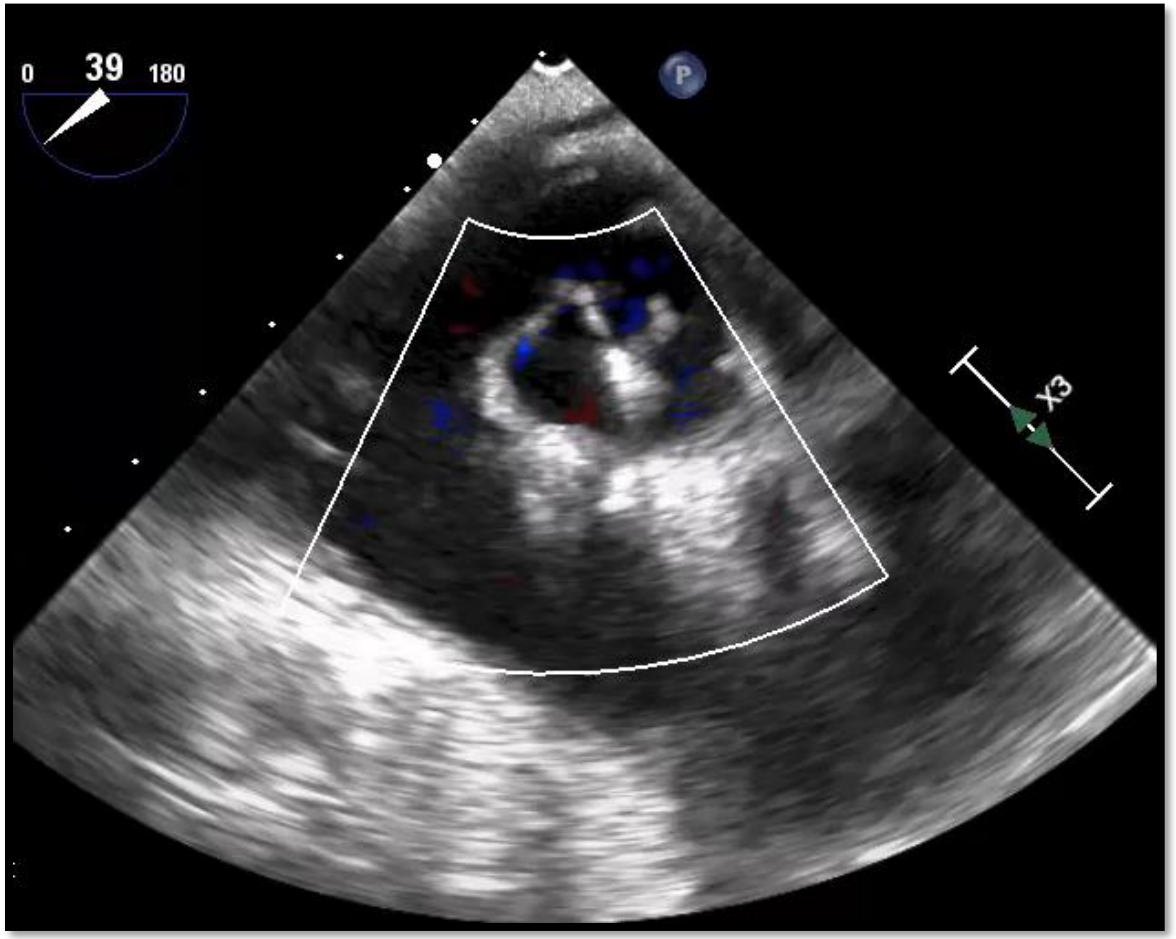

Case c/o Jamie McCabe, University of Washington, Seattle USA

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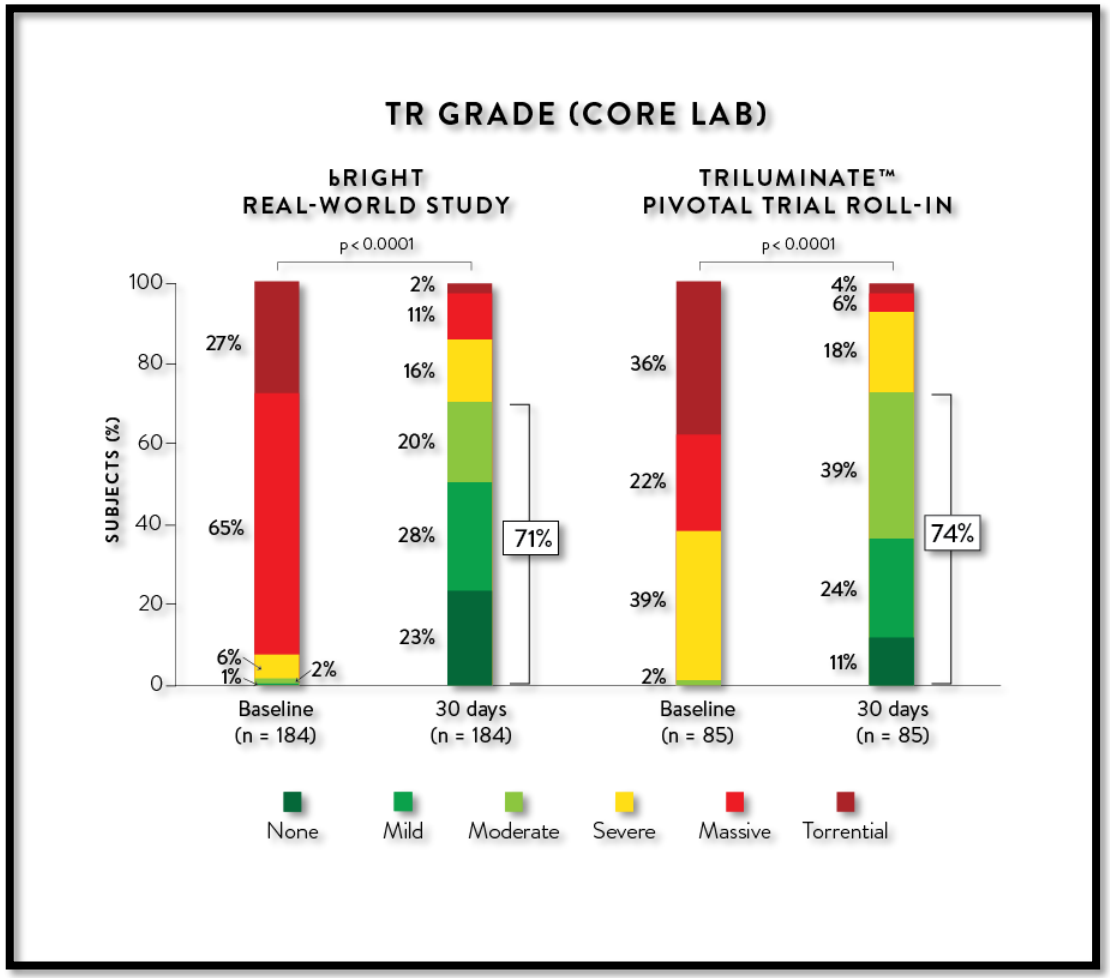
TV Clipping Patients Are Elderly and Comorbid

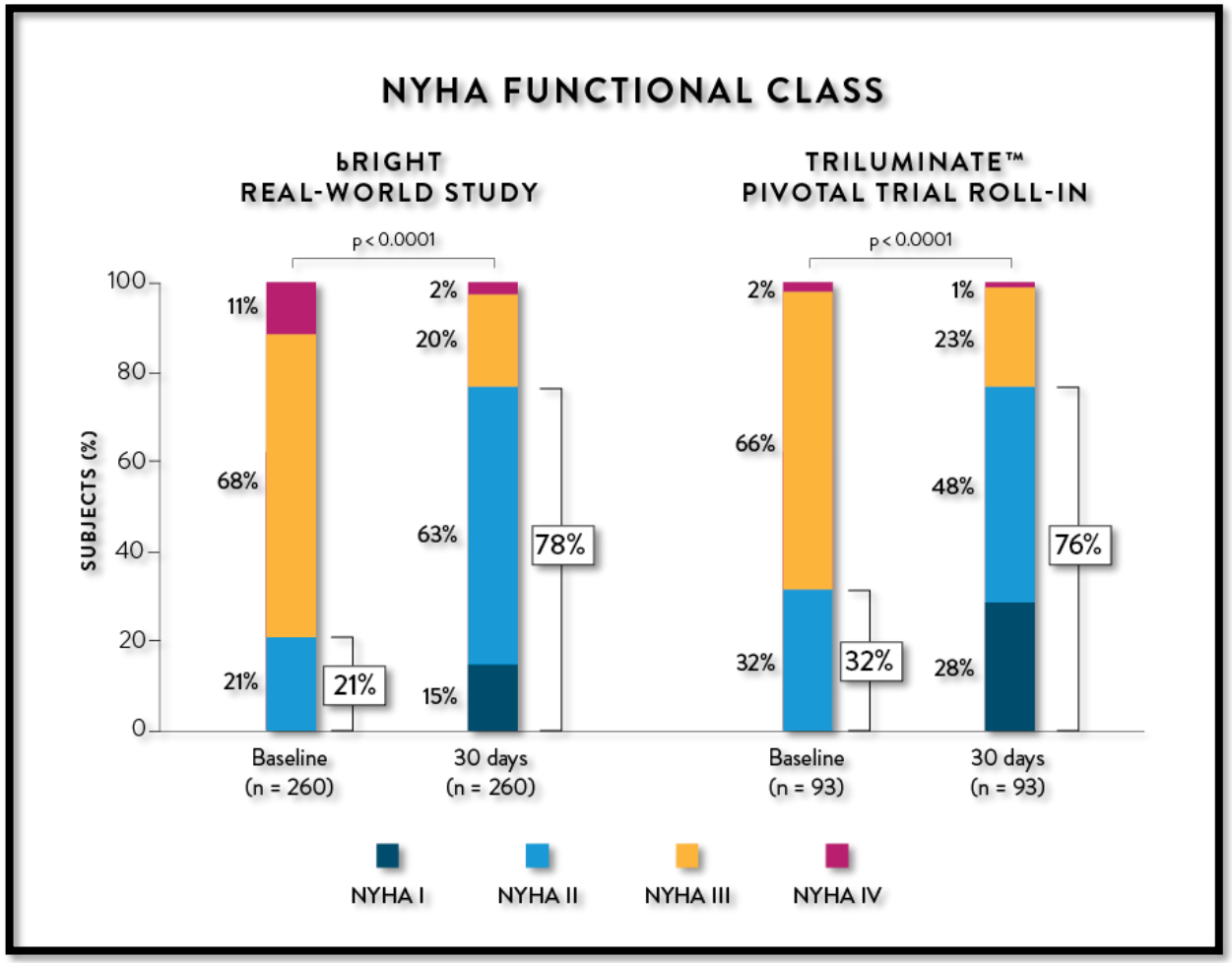
Characteristics	bRIGHT Real-world Study (n=300)	TRILUMINATE™ Pivotal Trial Roll-in Patients (n=97)
Age, Mean (years)	**78.5** ± 7.6	**79** ± 9
Male / Female (%)	47% / **53%**	**62%** / 38%
Hypertension	84.7%	80%
Atrial Fibrillation	**85.0%**	**90%**
Prior Left-sided Intervention	35.7%	39%
Diabetes	22.3%	25%
Renal Disease	**40.7%**	27%
NYHA Functional Class III/IV	**79%**	**68%**
KCCQ Score	**44** ± 23	**55.3** ± 21.5
LVEF	55.2 ± 11.2%	59.8 ± 10.2

R-S von Bardaleben TCT 2022

TV Clipping Results in Substantial TR Reduction & Improvement in Functional Class

- Procedural success 98-99%





R-S von Bardaleben TCT 2022

TV Clipping Is Very Safe

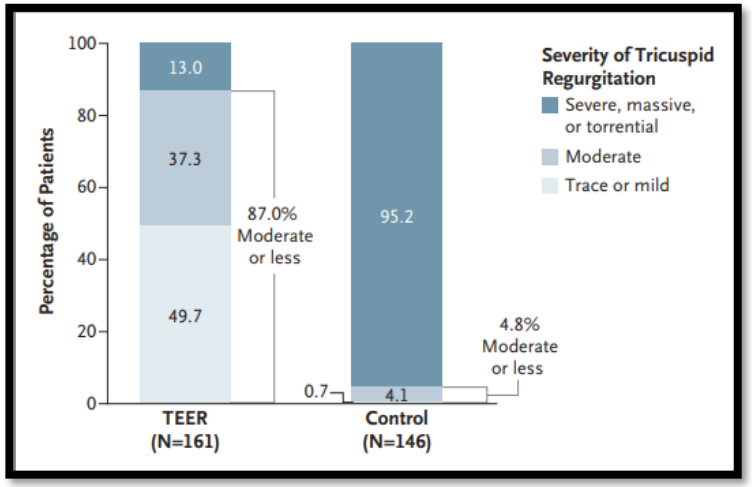
Event	bRIGHT Real-world Study (n=300)	TRILUMINATE™ Pivotal Trial Roll-in (n=97)
Major Adverse Event (MAE) Through 30-days	**1.0% (3)**	**1.0% (1)**
- Cardiovascular Mortality	**0.3%** (1)	**1.0%** (1)
- Stroke	0.3% (1)	0% (0)
- New Onset Renal Failure	0.3% (1)	1.0% (1)
- Non-elective CV Surgery, TVRS Device-related AE	0.3% (1)	0% (0)
Other Clinical Safety Endpoints Through 30-days		
- All-cause Mortality	**0.3%** (1)	**1%** (1)
- Tricuspid Valve Re-intervention or Re-operation	1.3% (4)	1% (1)
- Major Bleeding	6.7% (20)	7.2% (7)
- Single Leaflet Device Attachment (SLDA)	3.7% (11)	7.2% (7)
- Embolization	0% (0)	0% (0)

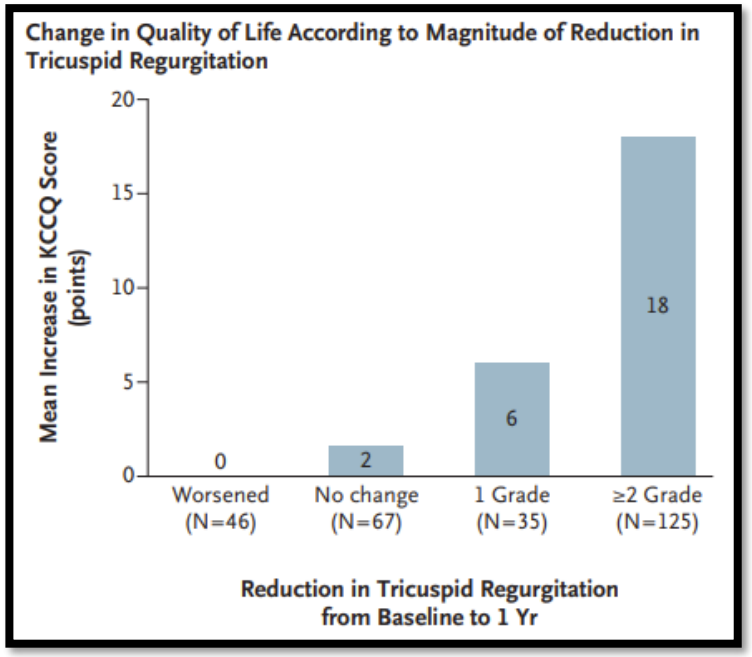
Triluminate Demonstrated Improvements in TR and QoL

Transcatheter Repair for Patients with Tricuspid Regurgitation

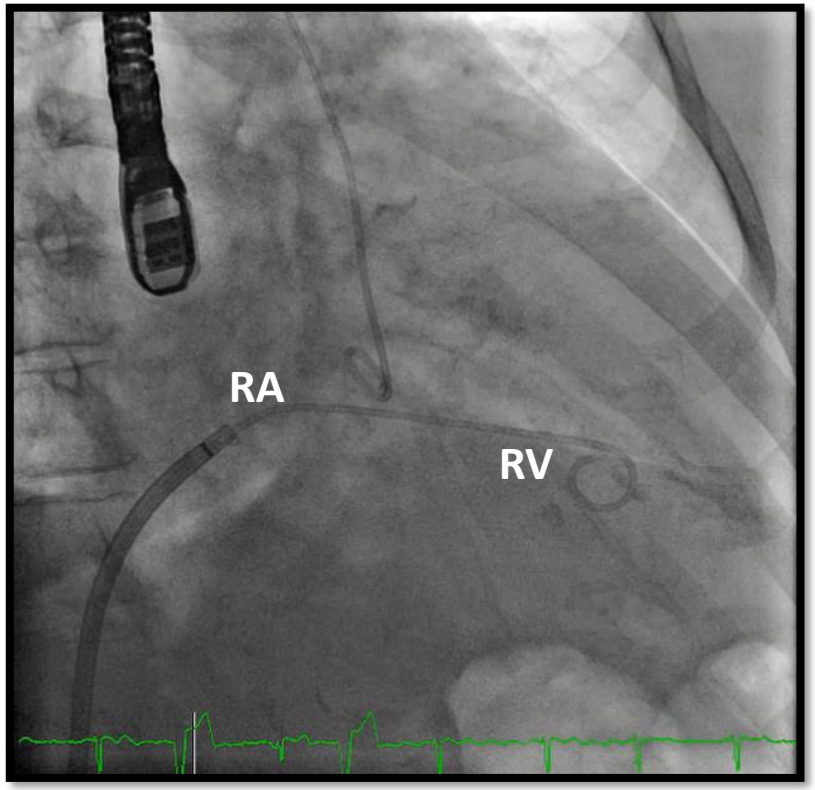
Paul Sorajja, M.D., Brian Whisenant, M.D., Nadira Hamid, M.D., Hursh Naik, M.D., Raj Makkar, M.D., Peter Tadros, M.D., Matthew J. Price, M.D., Gagan Singh, M.D., Neil Fam, M.D., Saibal Kar, M.D., Jonathan G. Schwartz, M.D., Shamir Mehta, M.D., Richard Bae, M.D., Nishant Sekaran, M.D., Travis Warner, M.D., Moody Makar, M.D., George Zorn, M.D., Erin M. Spinner, Ph.D., Phillip M. Trusty, Ph.D., Raymond Benza, M.D., Ulrich Jorde, M.D., Patrick McCarthy, M.D., Vinod Thourani, M.D., Gilbert H.L. Tang, M.D., Rebecca T. Hahn, M.D., and David H. Adams, M.D., for the TRILUMINATE Pivotal Investigators*

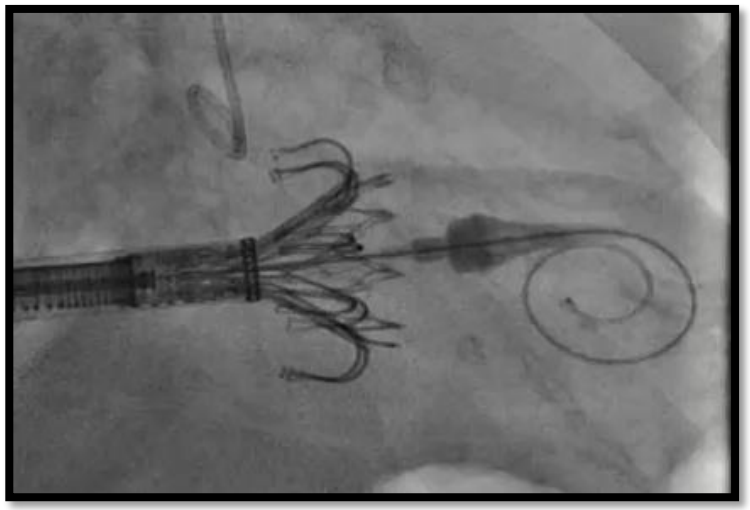
- 350 patients with severe TR
- Randomized to continued medical mgmt. vs TV clipping

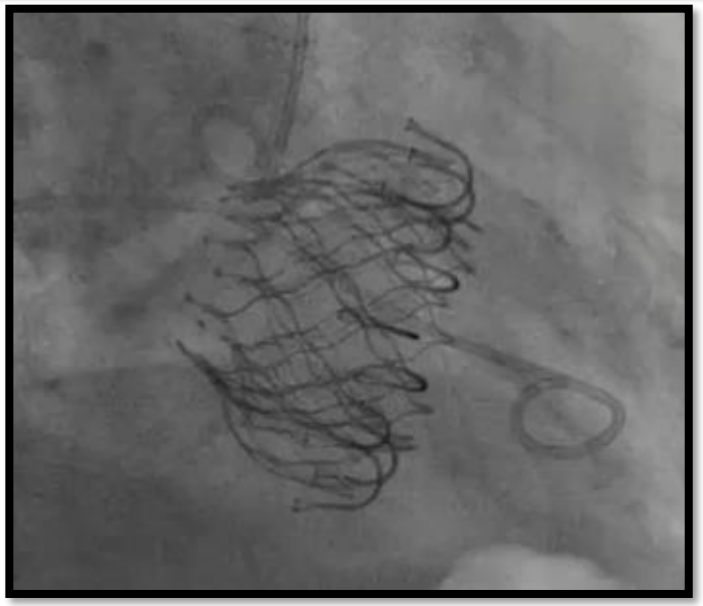


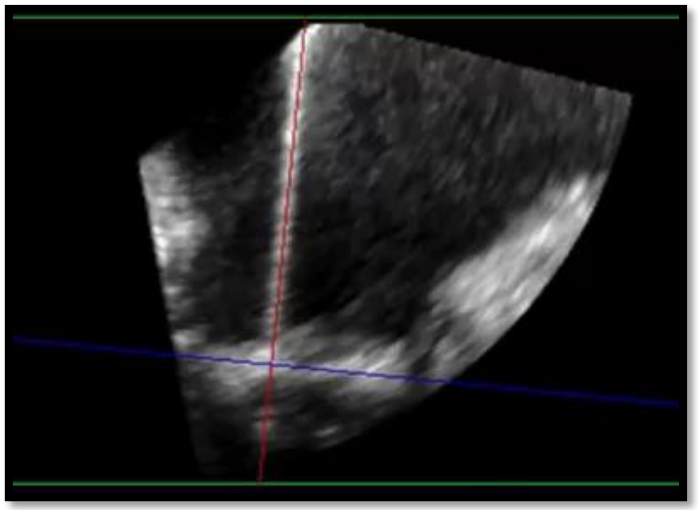


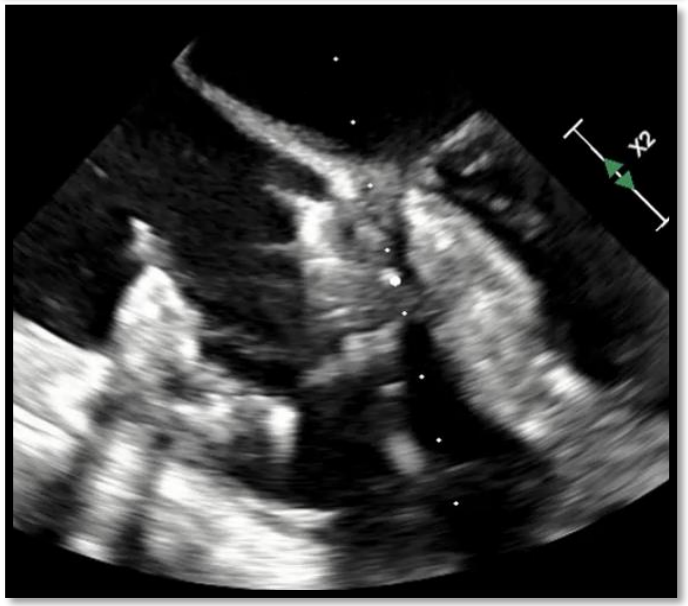
87yo with Septal Leaflet Flail / Infeasible for Clipping







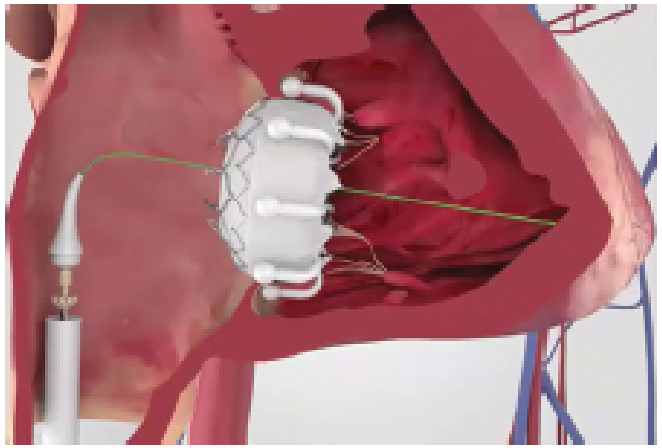




Percutaneous TV Replacement is Promising

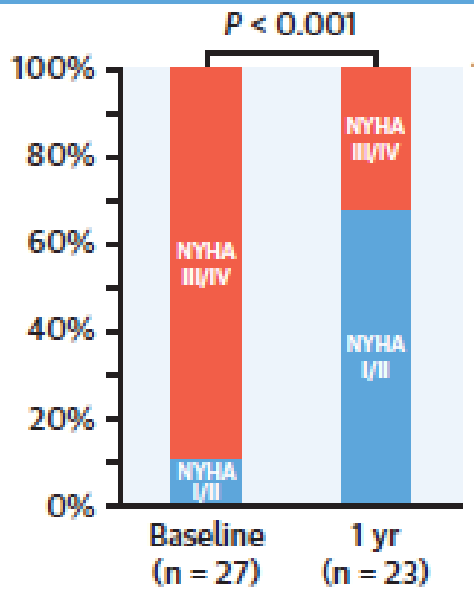
EVOQUE Transfemoral Tricuspid Replacement

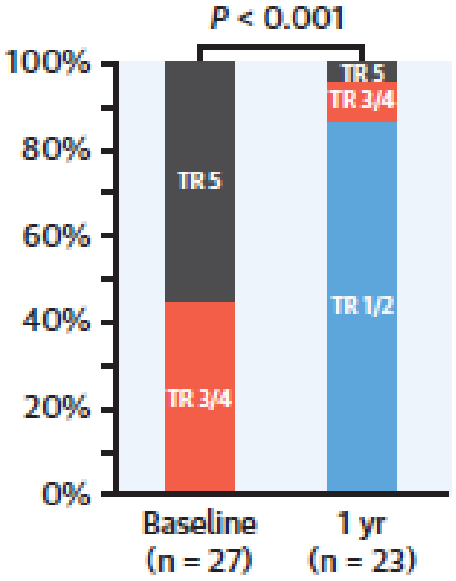
1-Year Clinical and Echocardiographic Outcomes



1-Year Follow-Up

30-D Mortality: 0





27 patients with severe TR
treated with the EVOQUE system
7 sites (Canada, Europe, U.S.)
May 2019 to July 2020

All-cause mortality: 7%
HF hospitalization: 7%
New pacemaker: 7% within 30 days,
4% beyond 30 days

Sustained improvement in NYHA functional class as well as improvement in TR degree suggesting that the EVOQUE System is a promising treatment option for this population

Webb, J.G. et al. J Am Coll Cardiol Intv. 2022;15(5):481-491.

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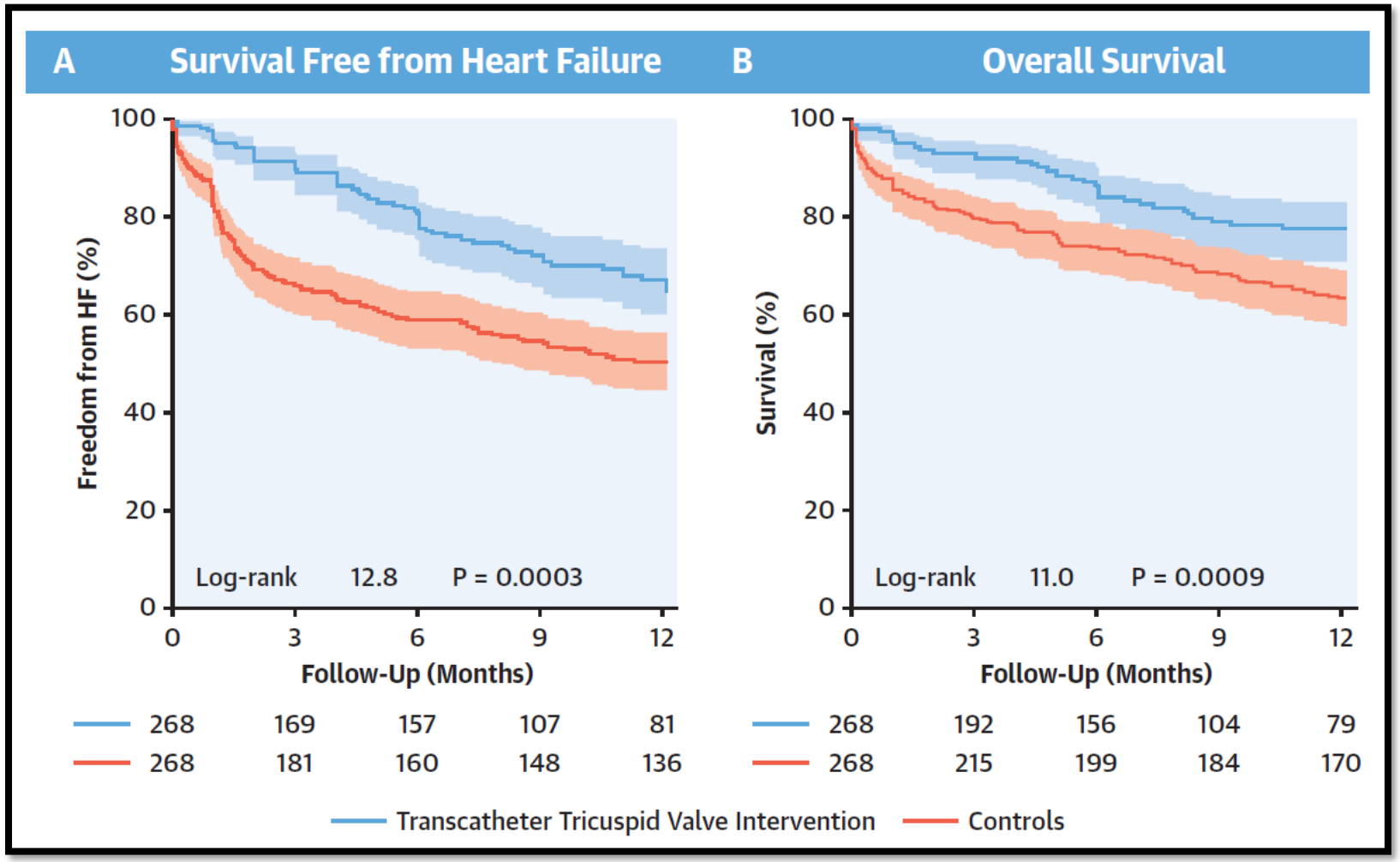
Considerations for Percutaneous TVR with PPM/ICD

- Enough “slack” in the RV lead to prevent dislodgement
- Theoretic risk of future lead/pocket infection (~1 % / yr)
  - Prophylactic lead extraction?
    - SQ ICD
    - CS lead vs leadless PPM
  - No lead extraction given patient / procedural risks

Transcatheter TV Interventions May Improve Survival



Tamasso M. et al J Am Coll Cardiol 2019 Dec 17;74(24):2998-3008

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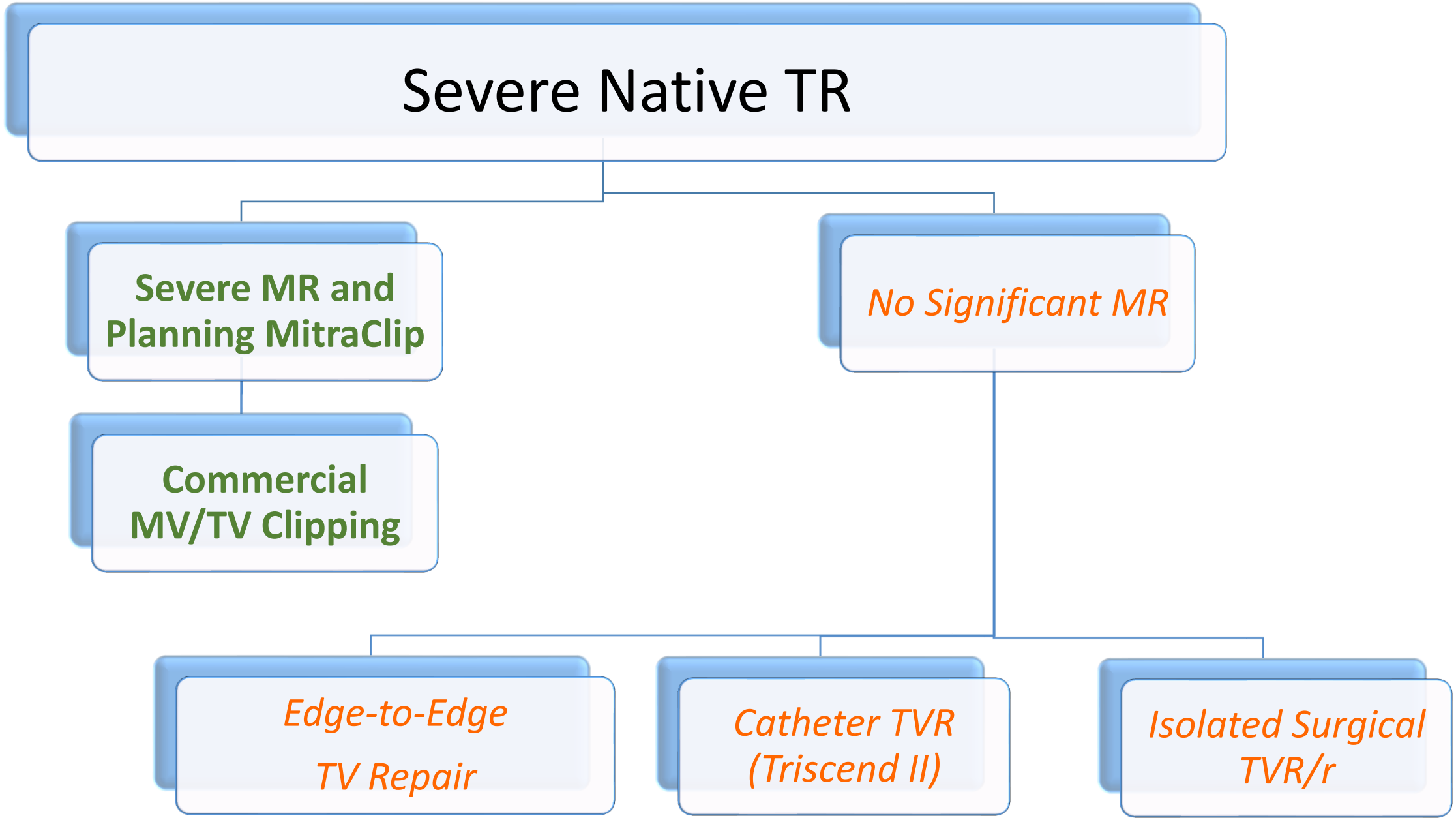


Conclusions

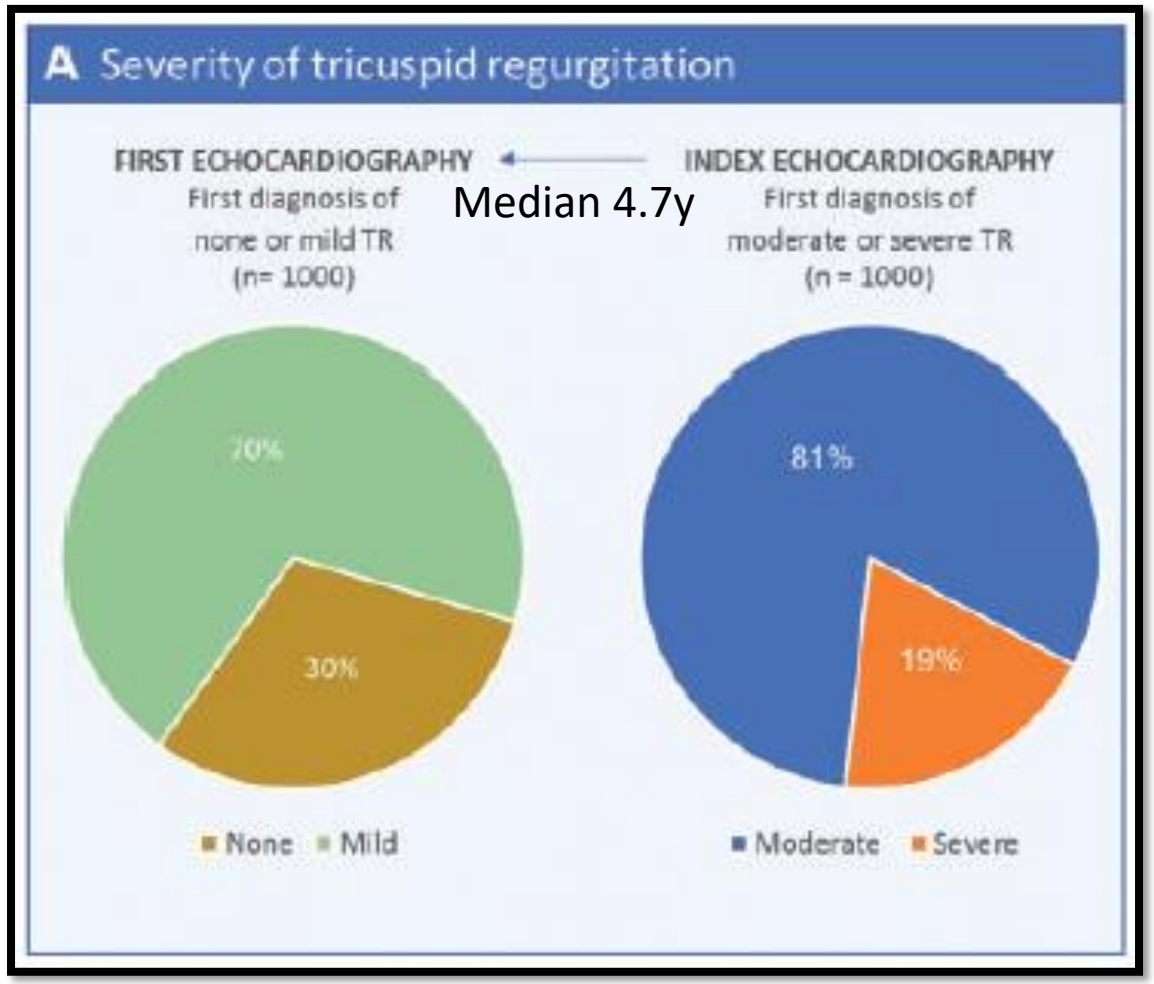
- TR is a common condition, and CIEDs are commonly in place in patients w TR
- Significant TR is independently associated with mortality
- Isolated TV surgery can be helpful; but patient selection is critical
- Percutaneous TV therapies are promising
  - Safety is high, efficacy is excellent, and functional benefits are robust
  - Results of randomized trials (vs medical therapy alone) are eagerly anticipated
- Management of leads may be relevant:
  - TV clipping can usually be performed without involvement with the leads
  - Transcatheter TV replacement can be performed even with leads in place
  - Whether prophylactic lead extraction should be performed before percutaneous TV replacement will be an important point of conversation moving forward

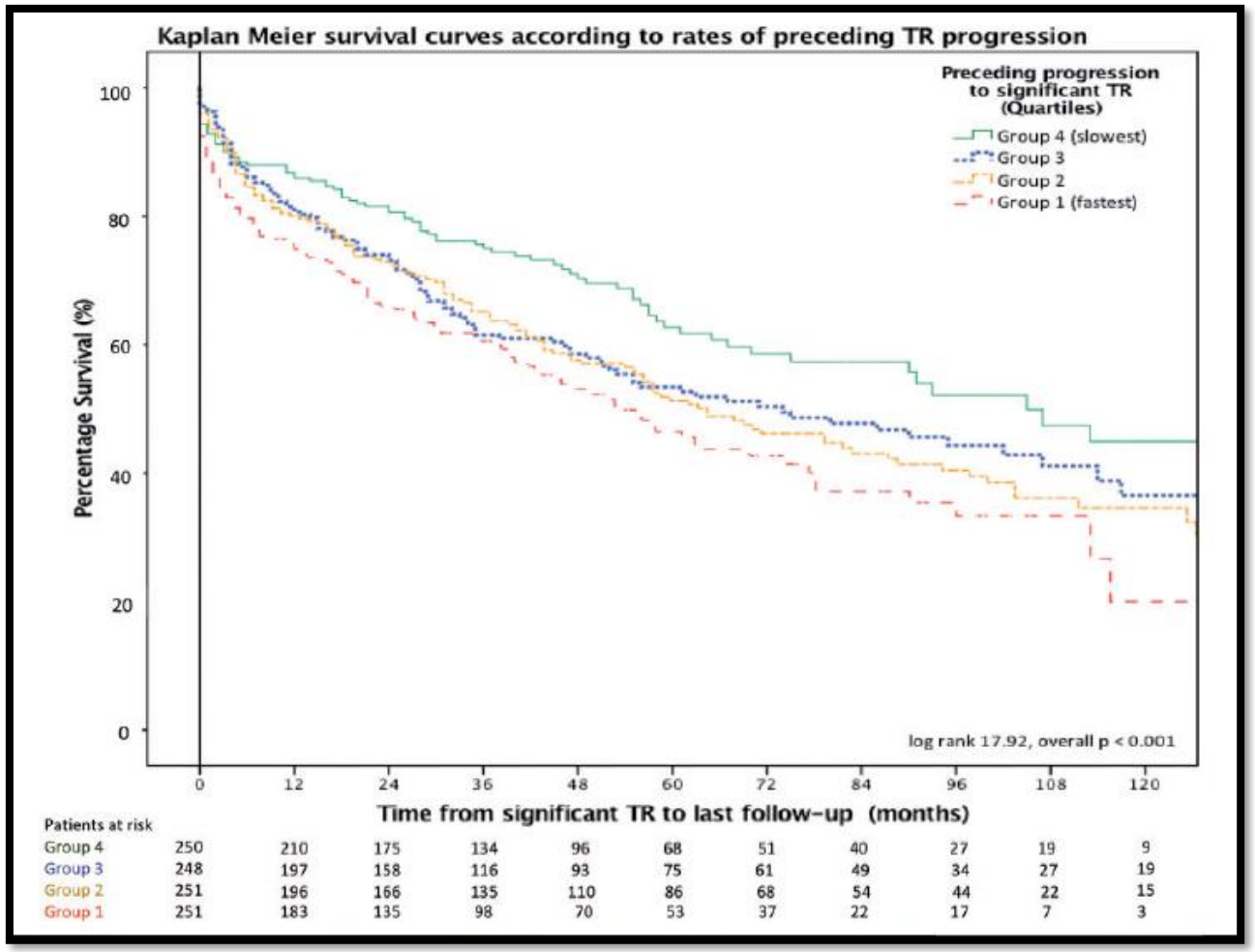
Thank You!

Krishna2@ccf.org

Unused Slides

More Rapid TR Progression = Worse Prognosis

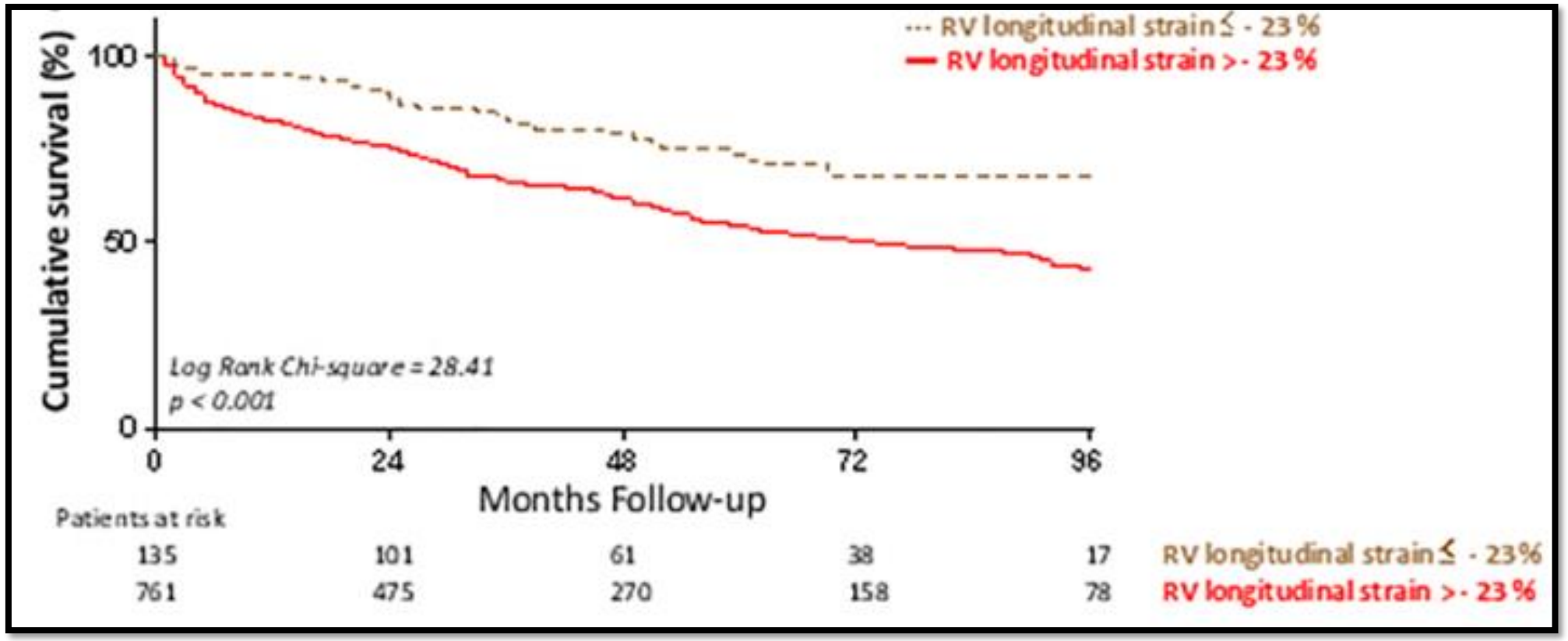




Prihadi et al. Eur Heart J 2018

Cleveland Clinic

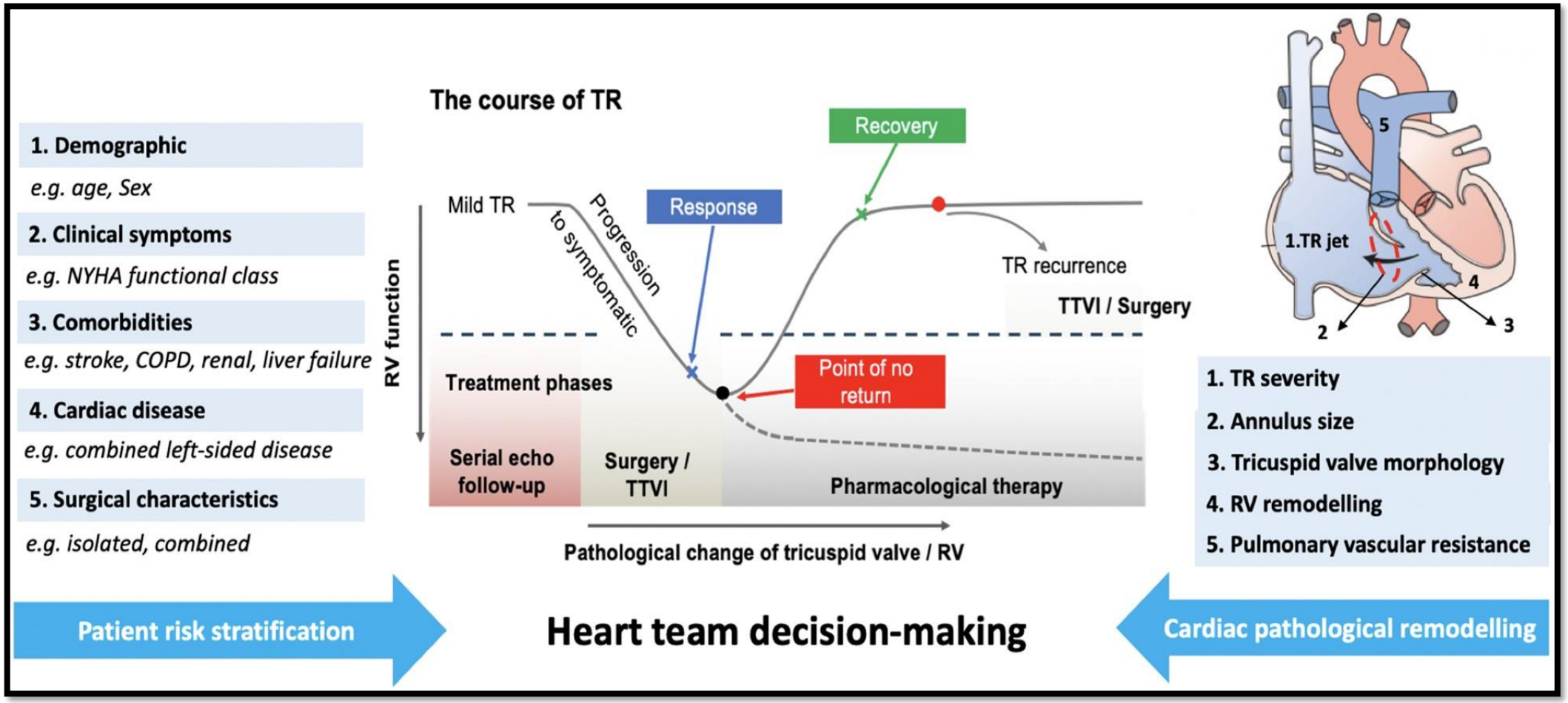
Prognosis of TR is Worse as RV Function Declines



Prihadi et al. Circ CV Imaging 2018

Cleveland Clinic

Decision on Timing of TV Therapy is Complex



Chang CC et al EHJ 2020;41(20):1932

Cleveland Clinic