

Percutaneous technologies to correct TR :
Myth or Reality ?



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Disclosures

- Ownership Interest: Millipede and Pipeline

TR is BAD

Decreased CO

Fatigue, decreased exercise tolerance

“Right-sided” Heart Failure

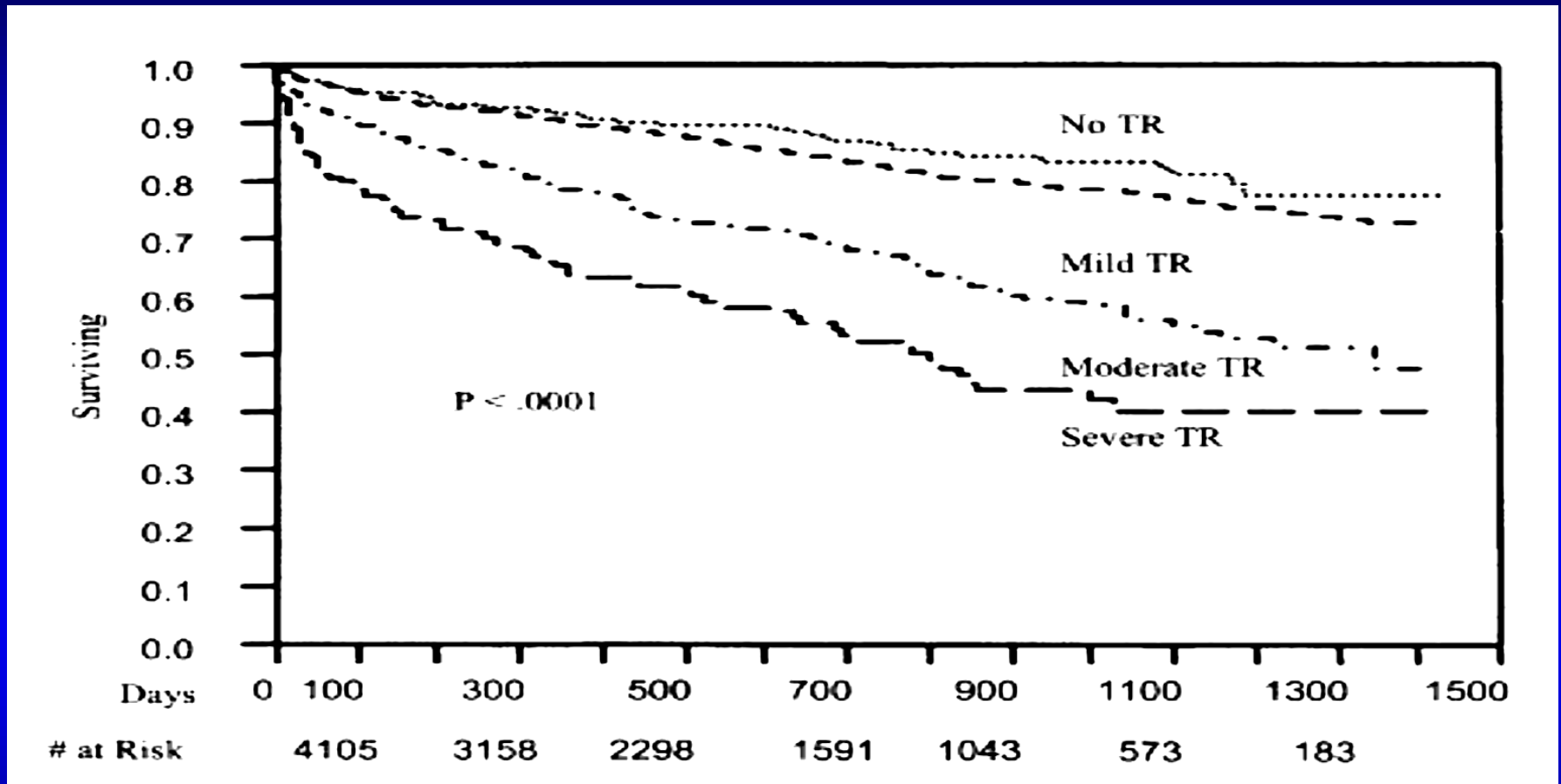
Ascites, edema, decreased appetite, fullness

FTR - feel terrible

Valve repair for functional tricuspid valve regurgitation:
anatomical and surgical considerations

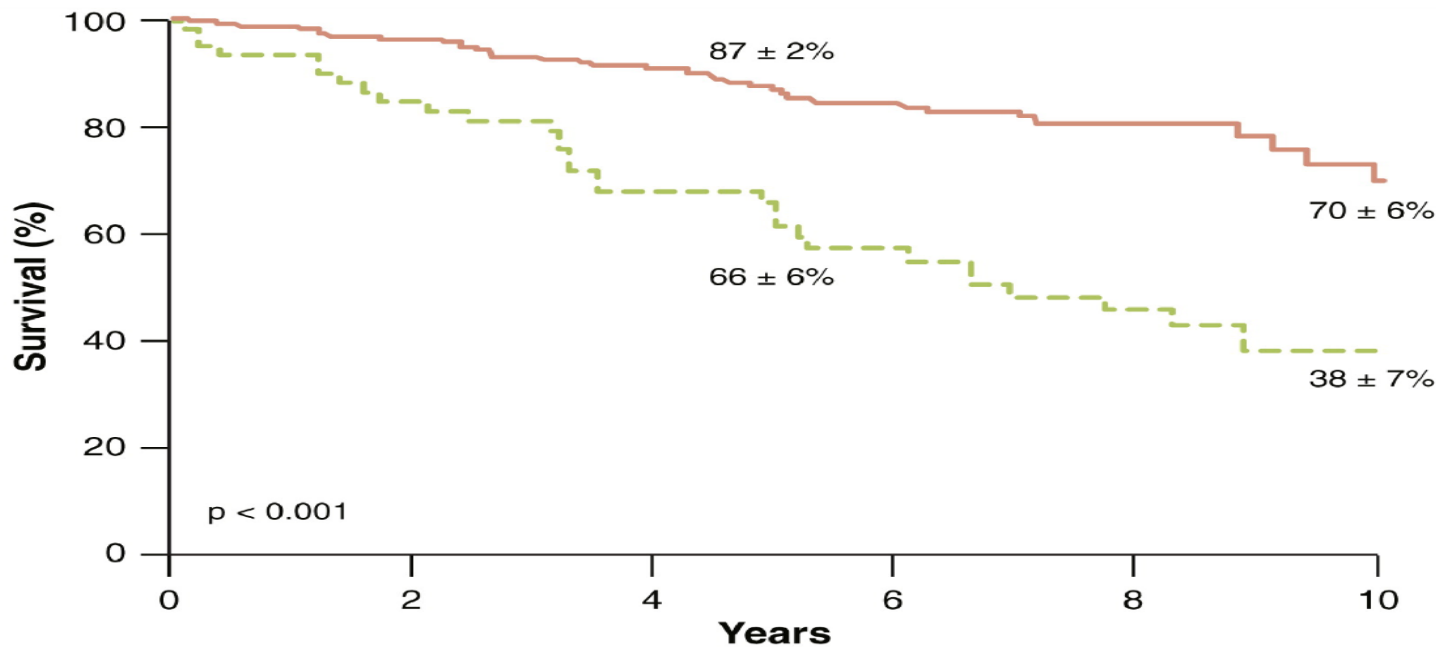
Rogers JH Bolling SF Semin Thorac Cardiovasc Surg. 2010 ;22(1):84-9

FTR increases Mortality



Severe and **MODERATE** TR increase mortality
independent of PASP, LVEF, IVC size, RV size/ function, 5223 pts

Severe and MODERATE TR decreases survival



Number at Risk

Total	353	308	252	194	70	31
ERO <math>< 40</math>	285	253	210	163	46	23
ERO <math>\ge 40</math>	68	55	42	31	24	8

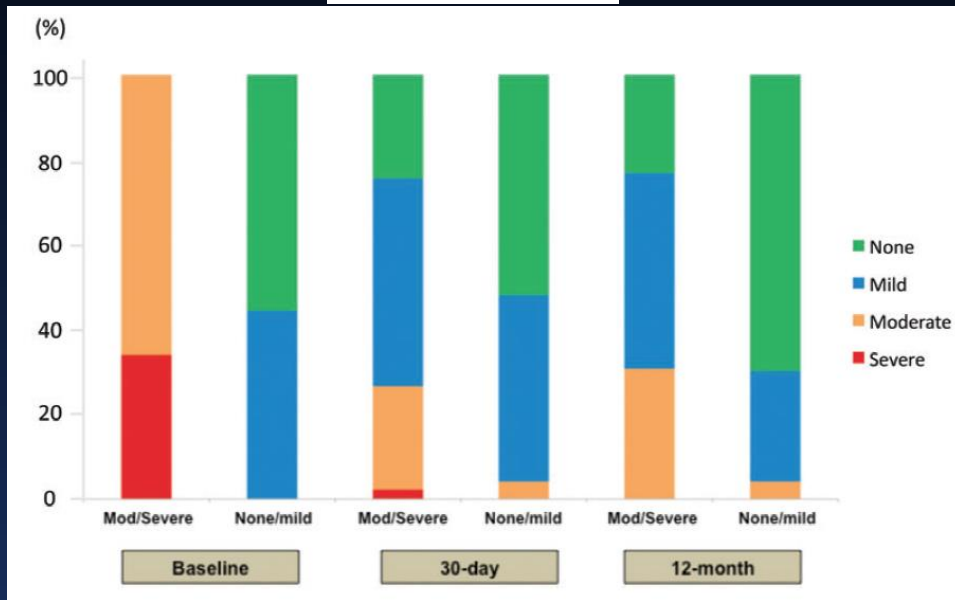
— ERO $\ge 40 \text{ mm}^2$ — ERO $< 40 \text{ mm}^2$

Topilsky. JACC 2014.

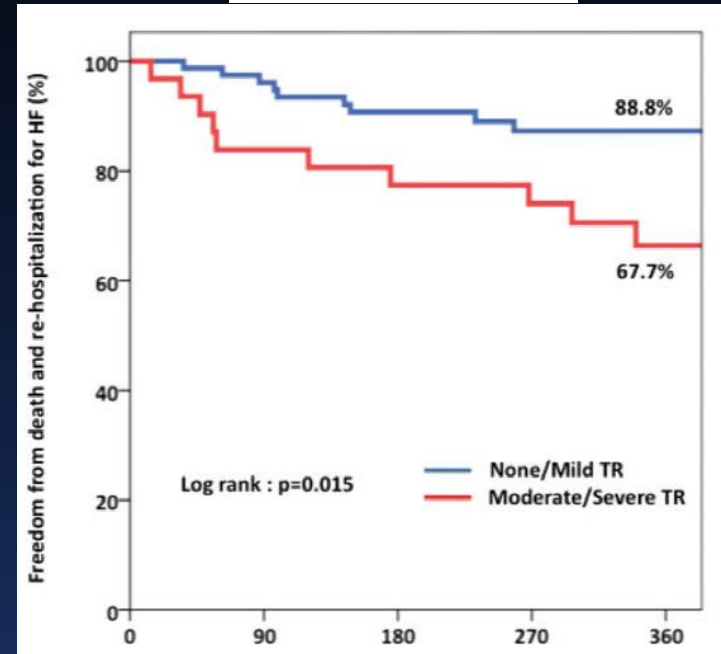
Having TR is BAD!

TR after MitraClip for FMR

TR Severity



Death/Rehosp



Ohno et al. EHJ 2014;15:1246.

More TR at baseline - worse outcome

Moderate or Severe TR is BAD

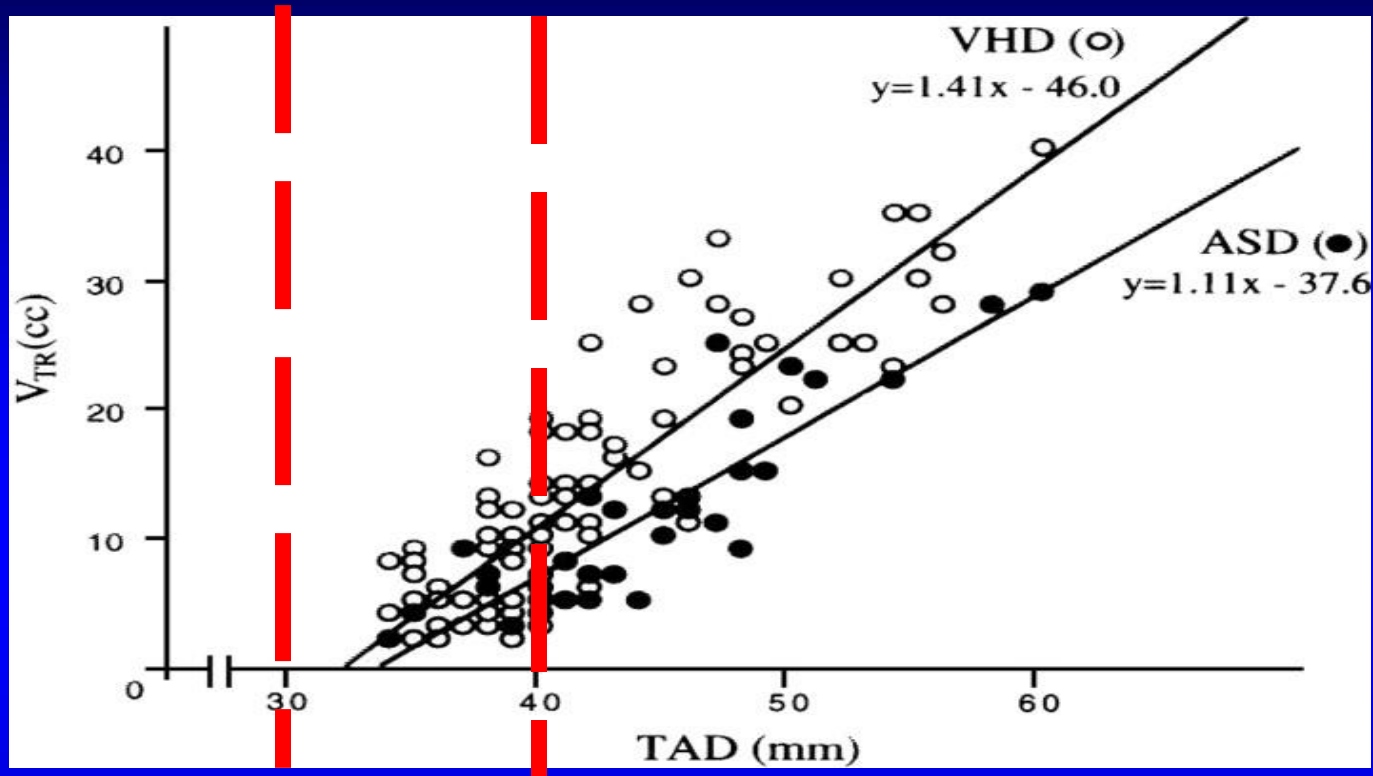
...even percutaneously !

FTR : *Reality*

Mod /severe TR - BAD

Pathophysiology of Functional / Secondary TR

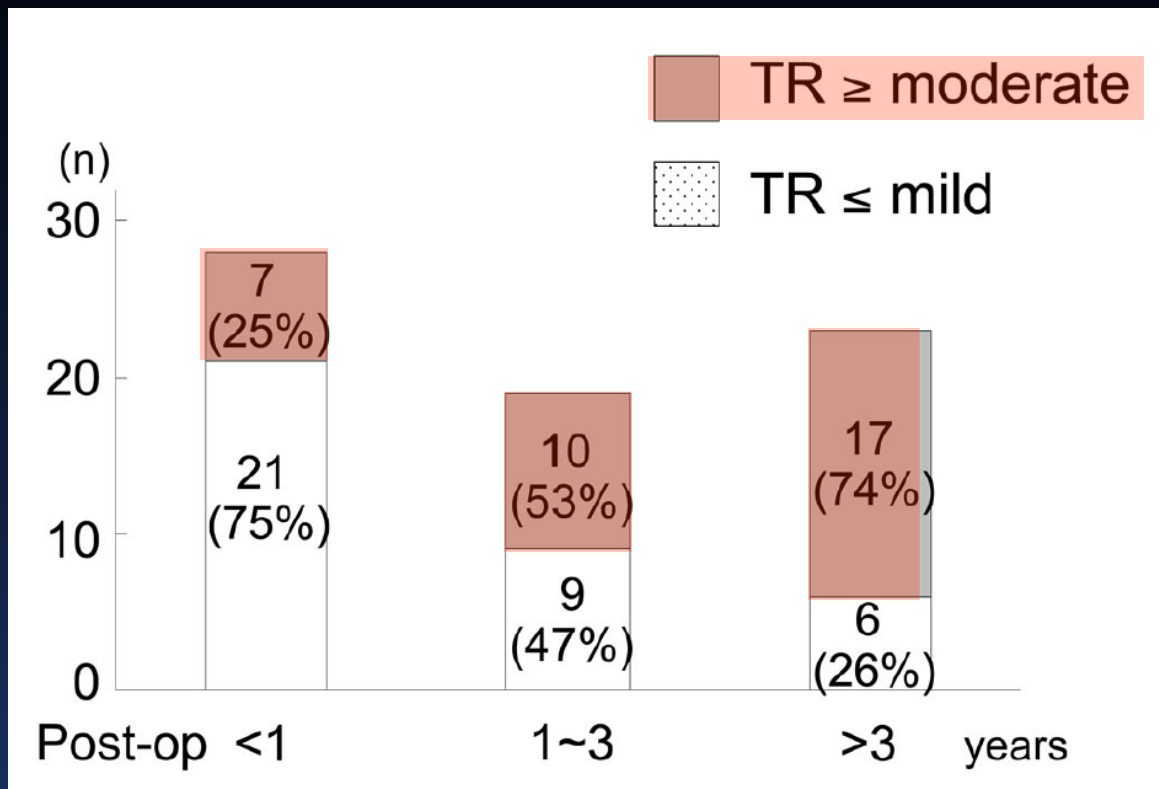
What size?



NORMAL TRICUSPID ANNULAR DIMENSION

2.8 \pm 0.5 cm !

Late TR after Functional MR Surgery



Matsunaga, Duran. Circulation 2005.

More TR with ↑ TV annulus size

FTR: *Reality*

Mod /severe TR - Bad

Dilated annulus - Bad

Tricuspid Valve Repair- *Does it matter ?*

Secondary Tricuspid Regurgitation or Dilatation: Which Should Be the Criteria for Surgical Repair?

Gilles D. Dreyfus, MD, Pierre J. Corbi, MD, K. M. John Chan, AFRCs, and

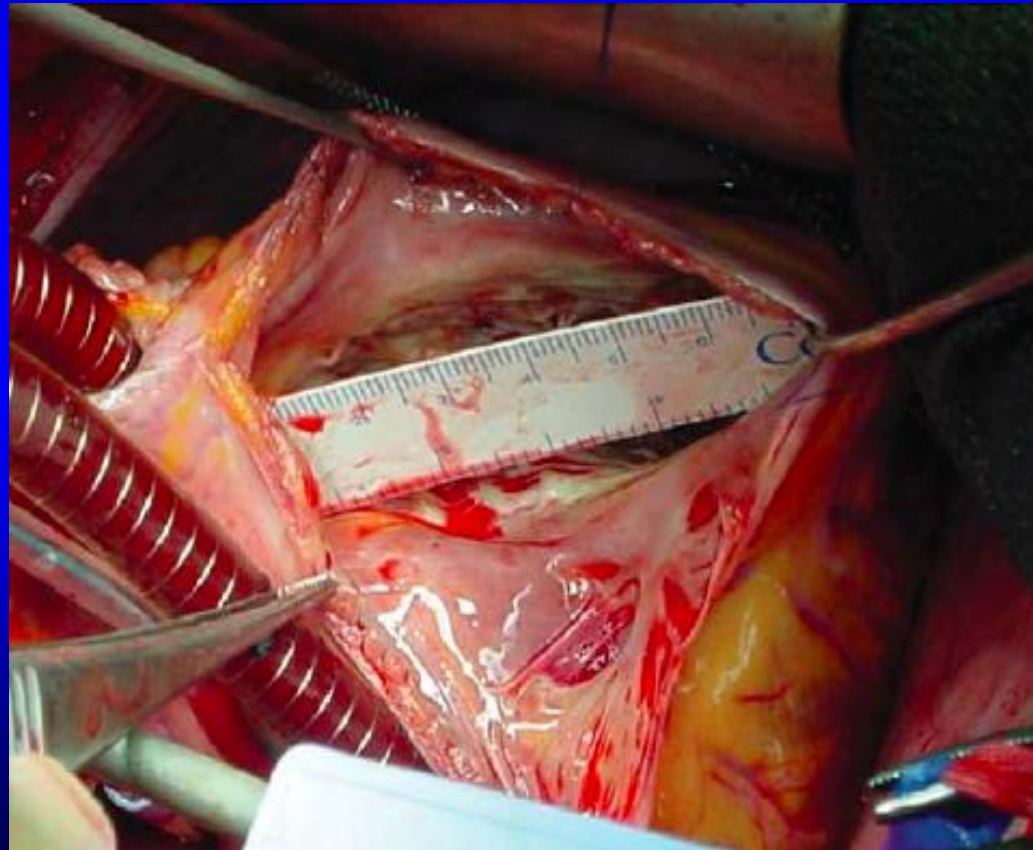
311 Patients MV Repair

Preop TR 0.7 – 0.9

93 % no/trace/mild

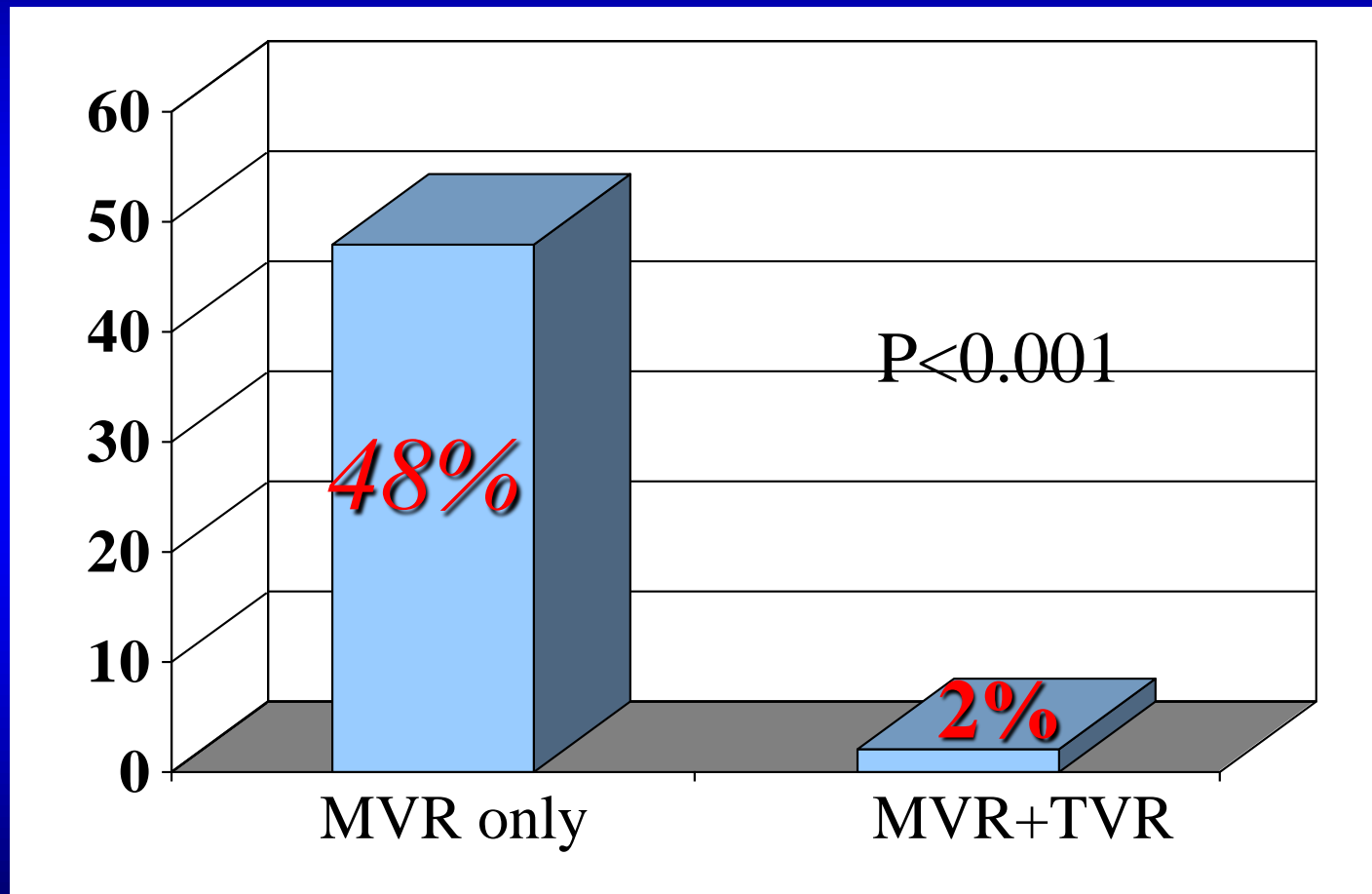
7 % moderate

NONE Severe !



TR Does Not Just “Go Away” After MVr

311 undergoing MVr, mostly degenerative, all with dilated TV annulus
TR Worsening by > 2 Grades



“Undersized” TV repair for FTR

Undersized Tricuspid Annuloplasty Rings Optimally Treat Functional Tricuspid Regurgitation

Mehrdad Ghoreishi, MD, Jamie M. Brown, MD, Craig E. Stauffer, BS, Cindi A. Young, Mary J. Byron, PA-C, Bartley P. Griffith, MD, and James S. Gammie, MD

Division of Cardiac Surgery, University of Maryland Medical Center, Baltimore, Maryland

Background. In contrast to mitral valve repair, residual and recurrent regurgitation after tricuspid valve (TV) repair for functional tricuspid regurgitation (TR) is common. We have systematically used undersized, rigid 3-dimensional annuloplasty rings to treat functional TR.

Methods. From March 2006 to October 2009, 101 consecutive patients with moderate or greater functional TR underwent TV repair with an undersized rigid 3-dimensional annuloplasty ring. All patients had a pre-discharge echocardiography evaluation in a core echocardiography laboratory. Follow-up echocardiography was available for 96% of surviving patients. Mean follow-up was 17 ± 9 months.

Results. Twenty-nine percent of patients had undergone previous cardiac operations, 74% were in New York Heart Association functional class III or IV, and 48% had atrial fibrillation. Mitral valve operations were performed in 93 patients, aortic valve operations in 17,

coronary artery bypass grafting in 21, and CryoMaze procedures in 40. Size 26 or 28 rigid tricuspid annuloplasty rings were used in 88% of patients, and no ring larger than a 28 has been used since November 2008. The operative mortality rate was 6% ($n = 6$). Freedom from significant TR (TR > moderate) at hospital discharge, as assessed by the clinical core laboratory, was 97%. Only 3% of patients had TR greater than moderate during follow-up. No patient required TV reoperation. New postoperative permanent pacemakers were inserted in 3 patients.

Conclusions. Tricuspid valve repair with an undersized (size 26 or 28) rigid 3-dimensional annuloplasty ring is the method of choice for reliable and durable treatment of functional TR.

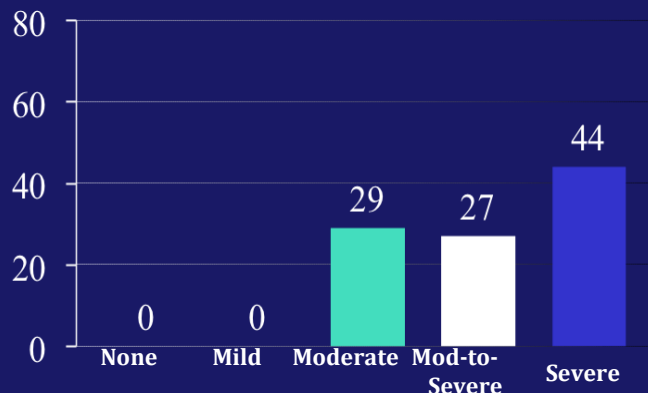
(Ann Thorac Surg 2011;92:89–96)

© 2011 by The Society of Thoracic Surgeons

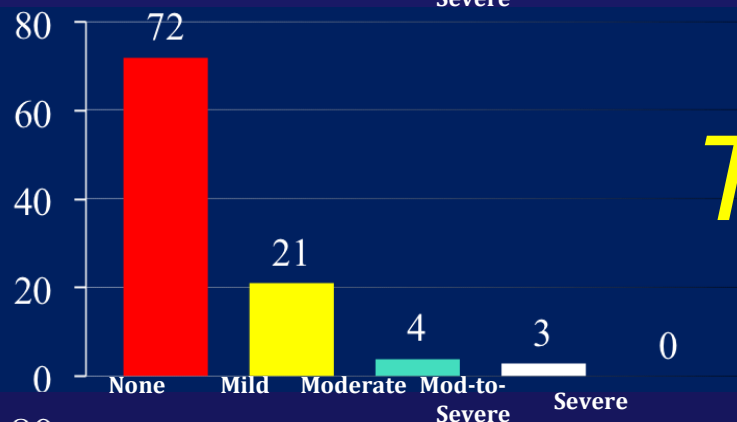
Actually Re-NORMAL size !

“Undersized” TV repair for FTR

Preoperative

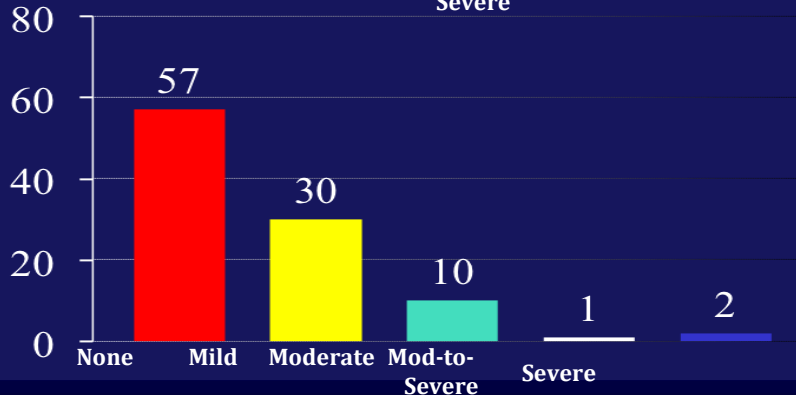


Predischarge



TR Grade

**Follow-up
(mean = 1 yr)**



Impact of TVr in 645 patients

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<http://dx.doi.org/10.1016/j.jacc.2015.01.059>

Impact of Concomitant Tricuspid Annuloplasty on Tricuspid Regurgitation, Right Ventricular Function, and Pulmonary Artery Hypertension After Repair of Mitral Valve Prolapse

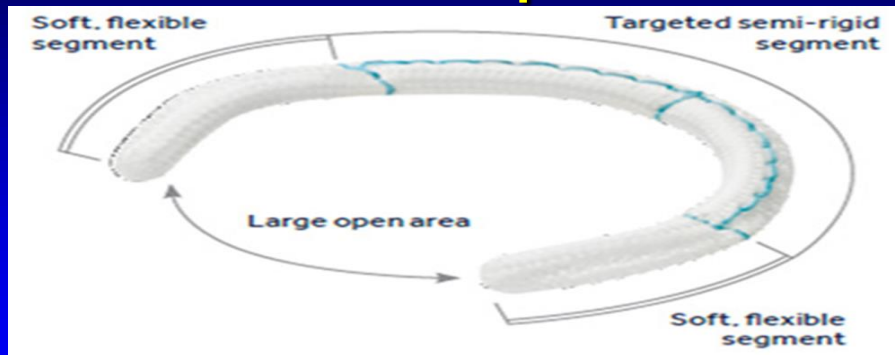


Joanna Chikwe, MD, Shinobu Itagaki, MD, Anelechi Anyanwu, MD, David H. Adams, MD

CONCLUSIONS In patients with moderate TR or tricuspid annular dilation who were undergoing degenerative mitral repair, concomitant tricuspid annuloplasty is safe, effective, and associated with improved long-term right-sided remodeling. Routine treatment of moderate TR or tricuspid annular dilation at the time of MV repair appears to be beneficial. (J Am Coll Cardiol 2015;65:1931-8) © 2015 by the American College of Cardiology Foundation.

*Far less TR, better RV
NO ↑ mortality or PPM*

Outcomes of Guideline directed repair of FTR performed during MV surgery



Ward, Romano, Bolling : JTCVS 2018

262 pts TVr, mod or \leq mod TR, 26/28/30 ring

No mortality, No TS, RV improved

1% progression to severe TR,

2.6 % de novo PPM rate

FTR : *Reality*

Mod/severe TR - BAD

TR ring - GOOD

Do many patients have TR ?

STS Database: 58,000 Patients Isolated MR

Moderate TR: 12.4%

Severe TR: 7.1%

Moderate or Severe 19.5%

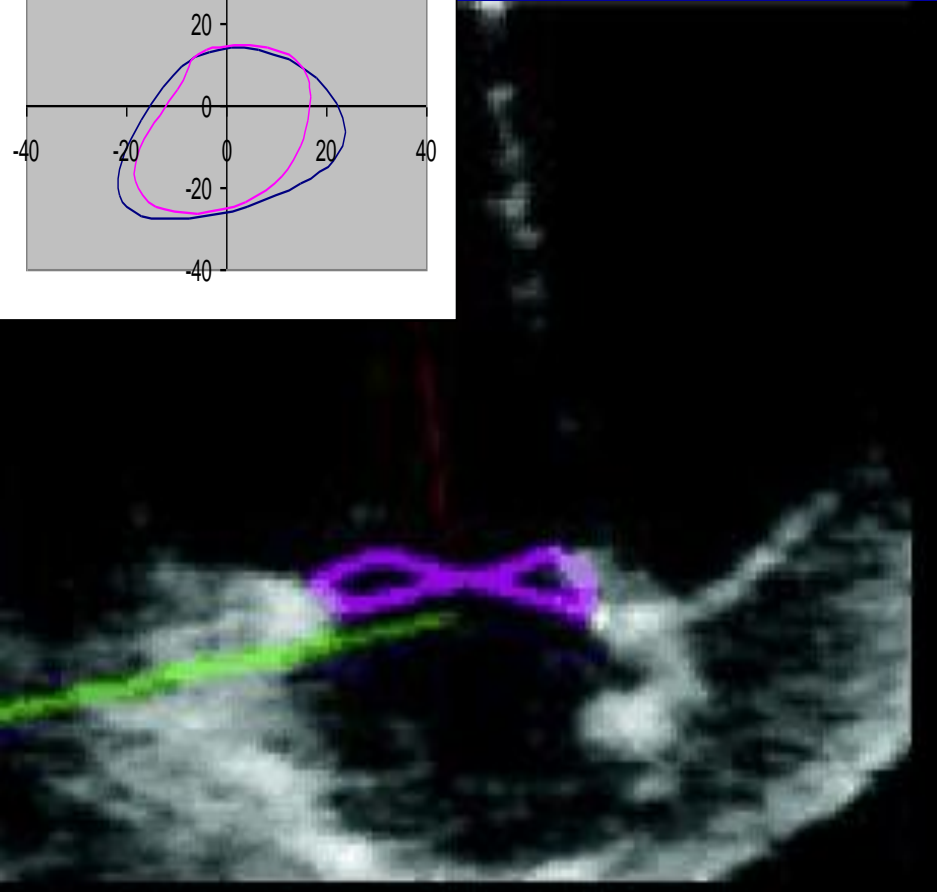
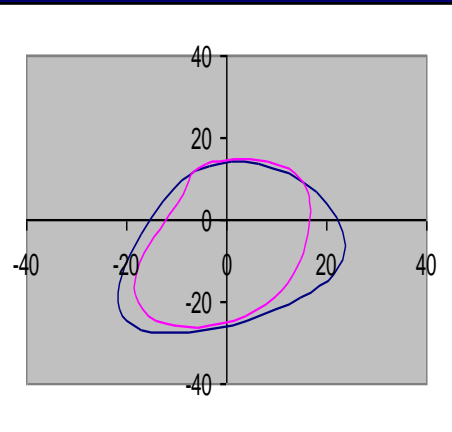
LOTS!

Mayo: 115/699 16% Mod/Sev TR

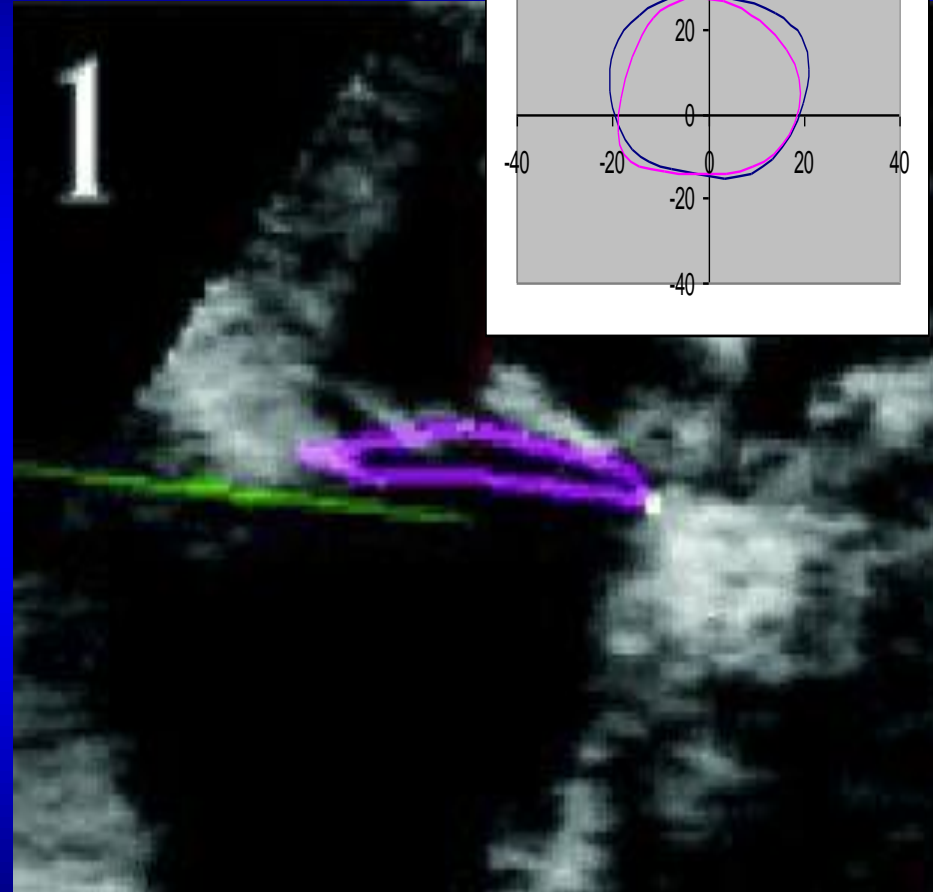
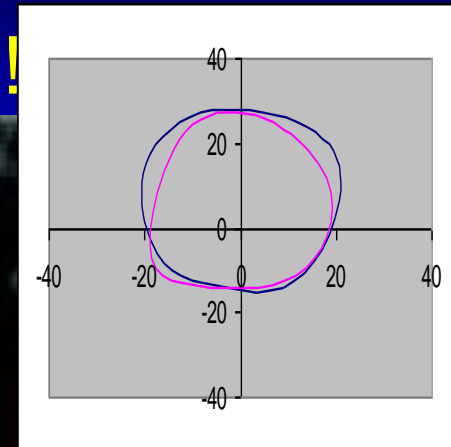
Matsuyama et al. 46/174 26% Mod + TR

Annular Dilation / Shape Change of FTR :

75%- all cases of MR !

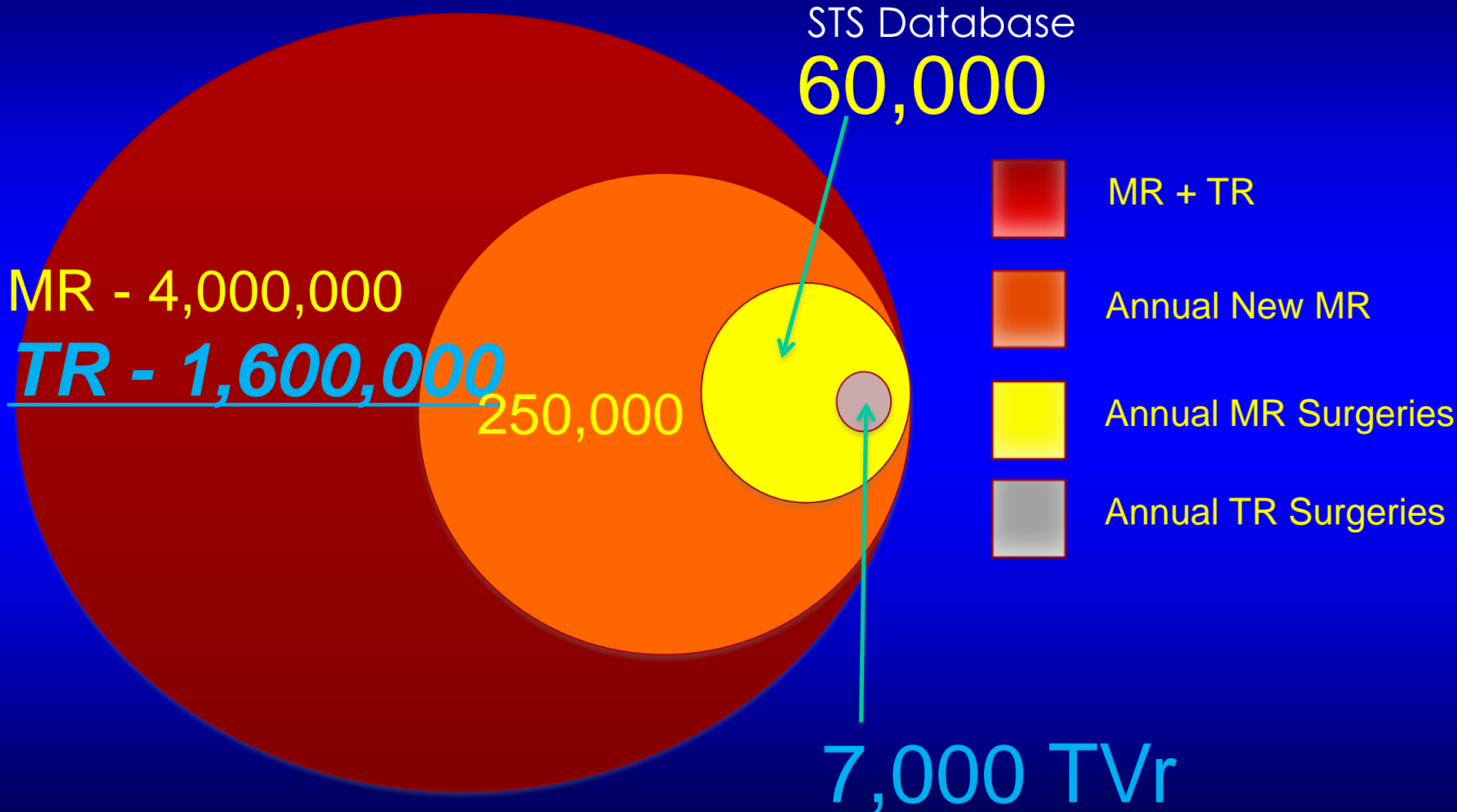


Normal Tricuspid Annulus

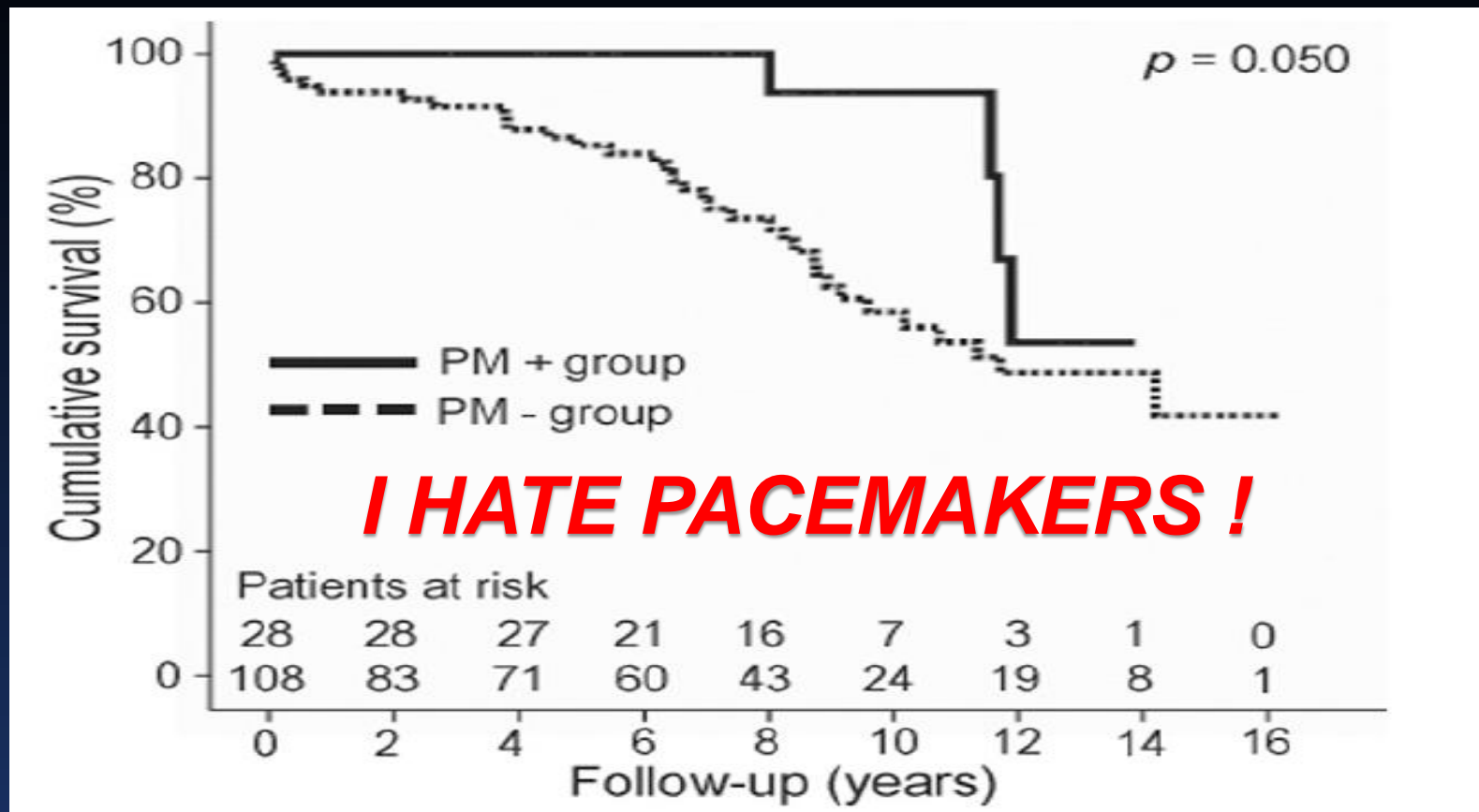


Tricuspid Annulus with Functional TR

TR is ignored !

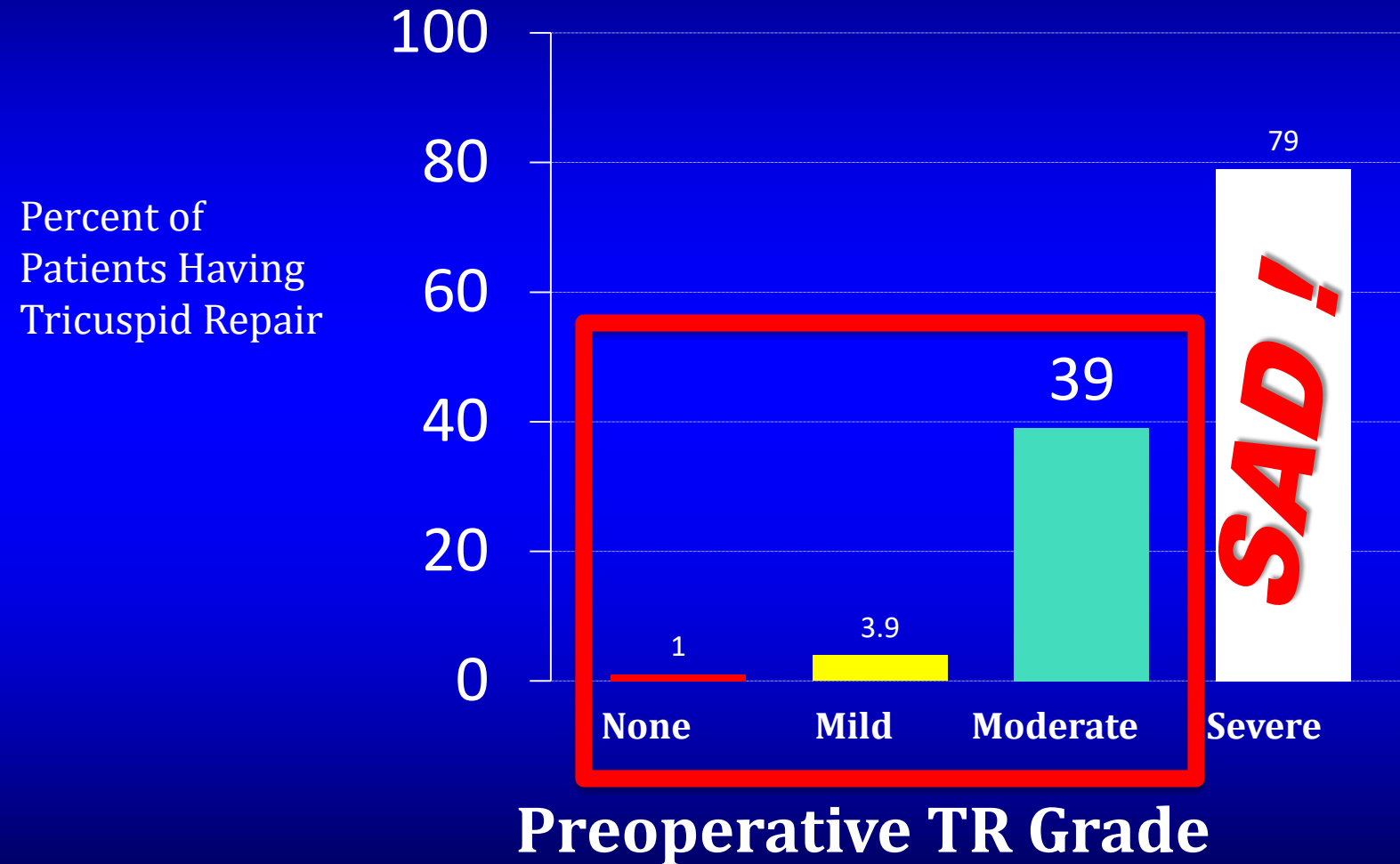


Why Not Fix TR at Surgery ?



- 136 pts, mostly TV repair
- 8 yr follow up, **PPM in 21%,**

Tricuspid Repair Rate when fixing MR *Based on Preop TR Grade*



FTR: *Reality*

Mod/severe TR - Bad

TR ring - Good

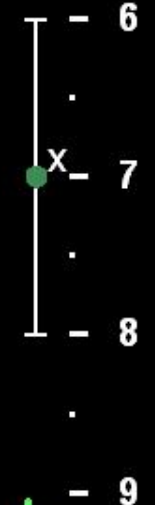
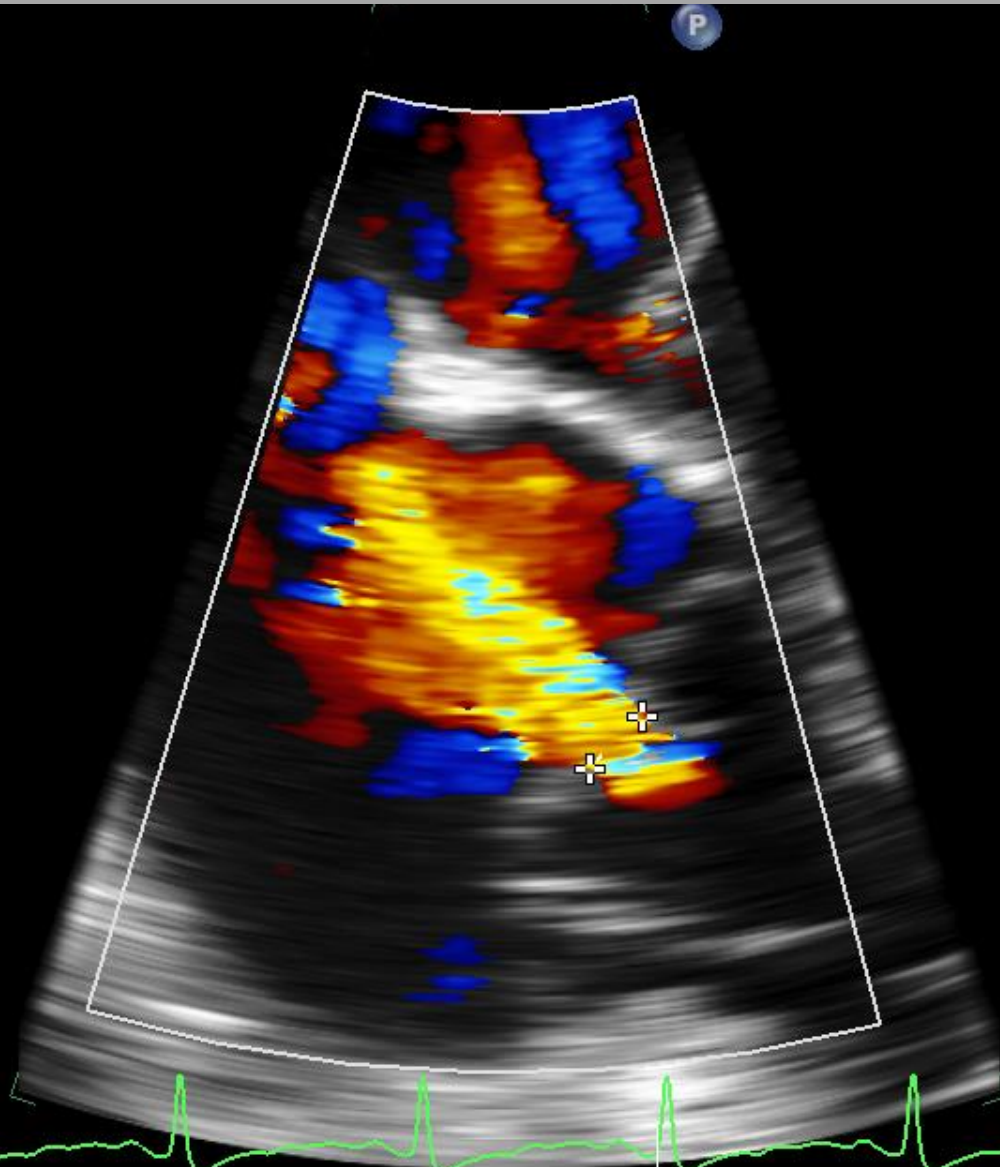
TVR - Sad

Percutaneous Implications for TR

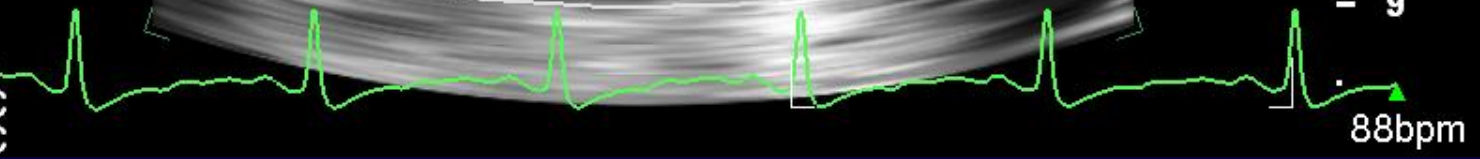
2D
64%
C 50
P Off
Gen



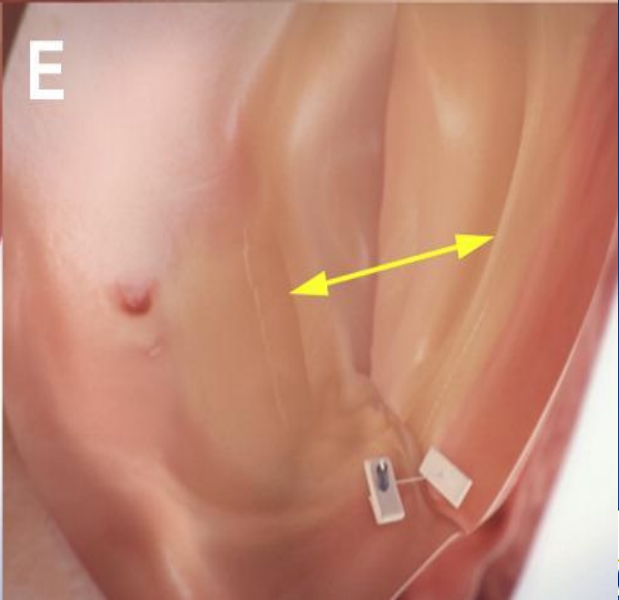
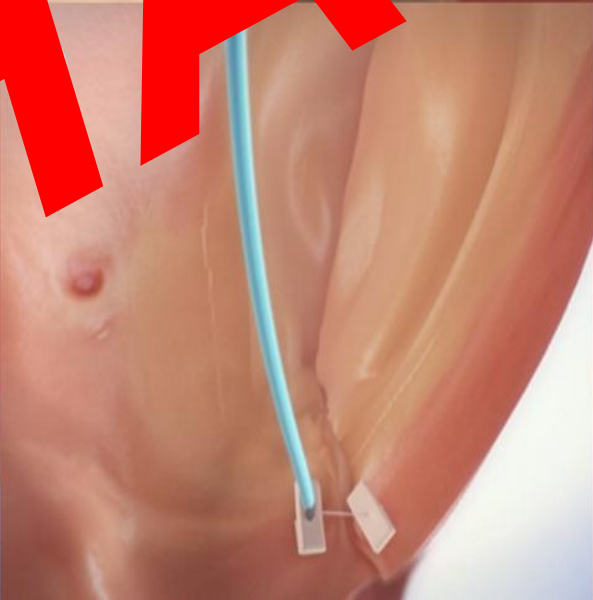
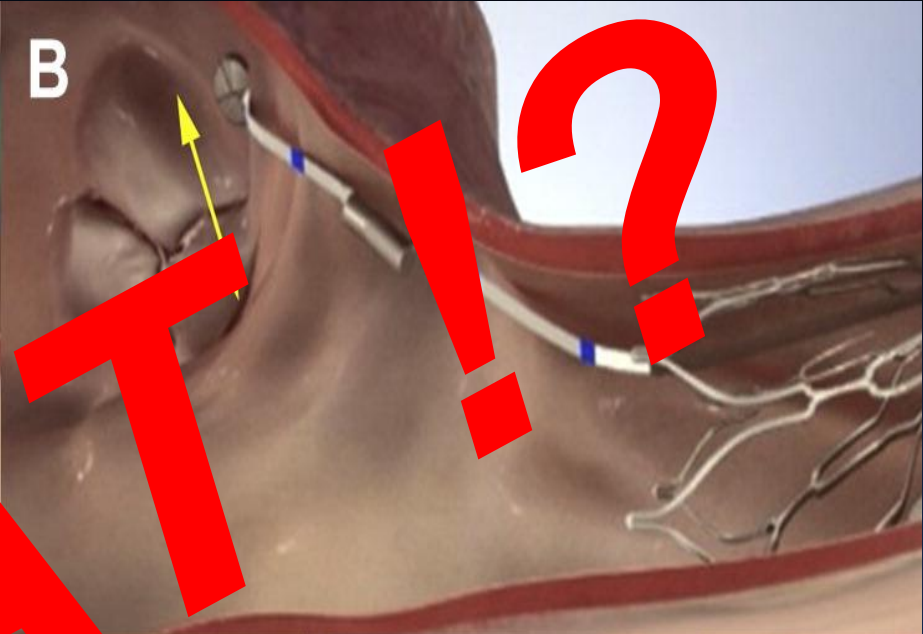
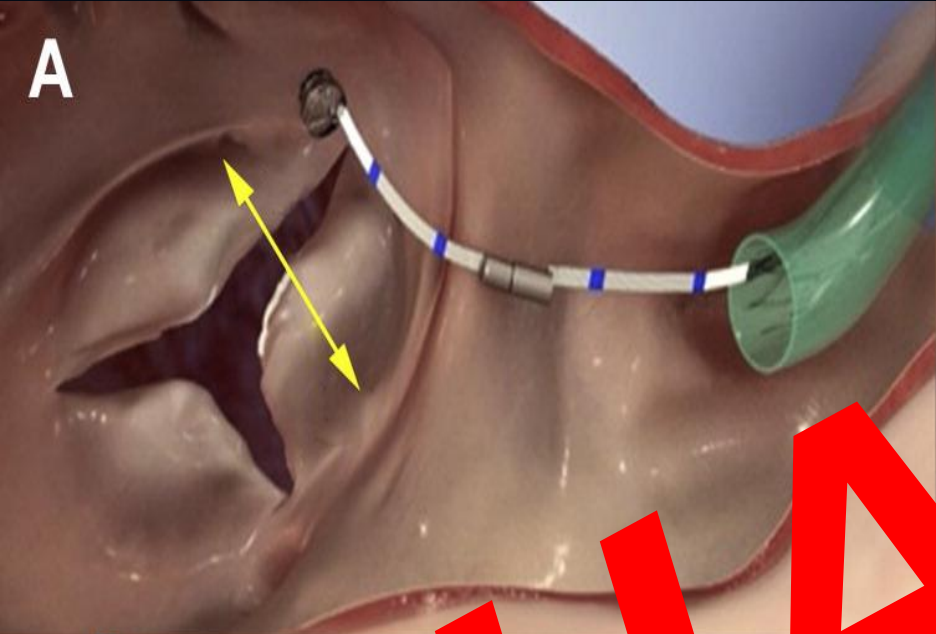
CF
59%
4.4MHz
WF High
Med



+ Dist 0.470 cm
Area 0.174 cm²



FTR: Percutaneous “Not” Rings

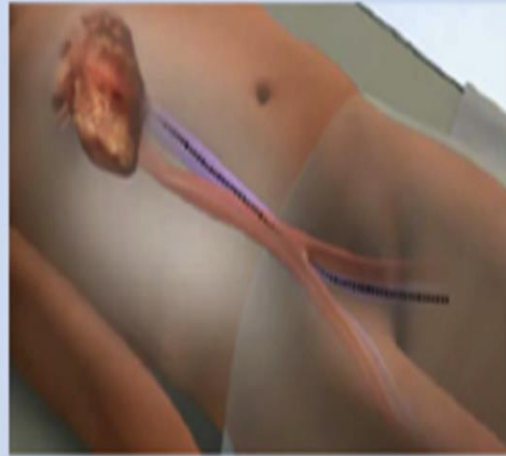


?

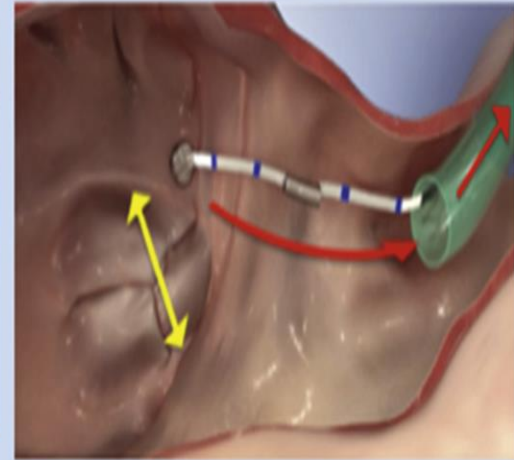
WHYAT!



Tricuspid Regurgitation 4-TECH



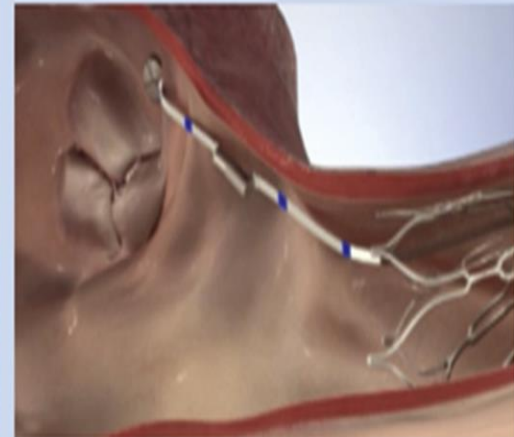
Step 1: Access via Inferior Vena Cava



Step 3: Implant the anchor on the annulus



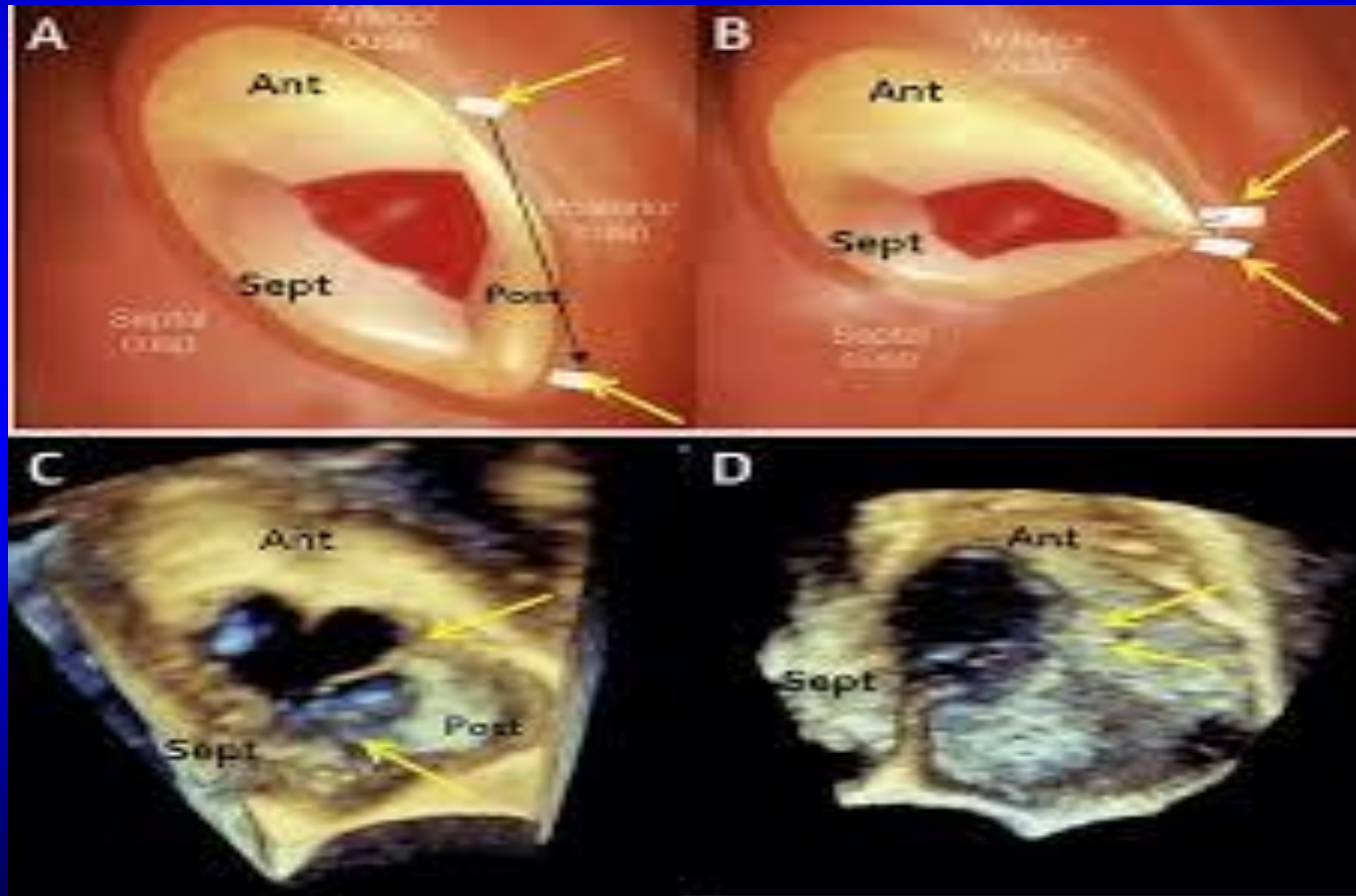
Step 2: Aim at the anterior annulus



Step 4: Pull tension, check, secure.

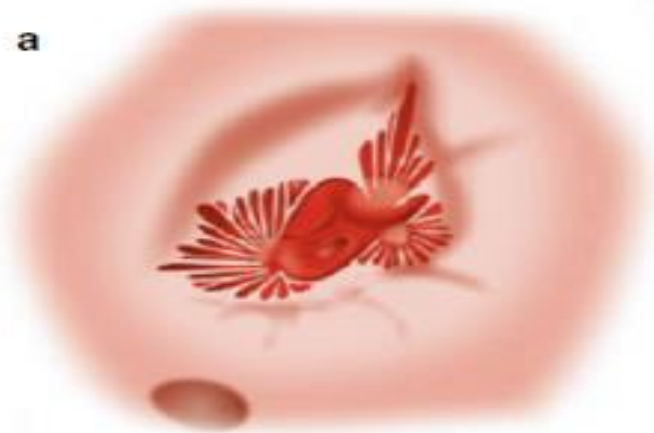
Tricuspid Regurgitation

Mitralign... Trialign

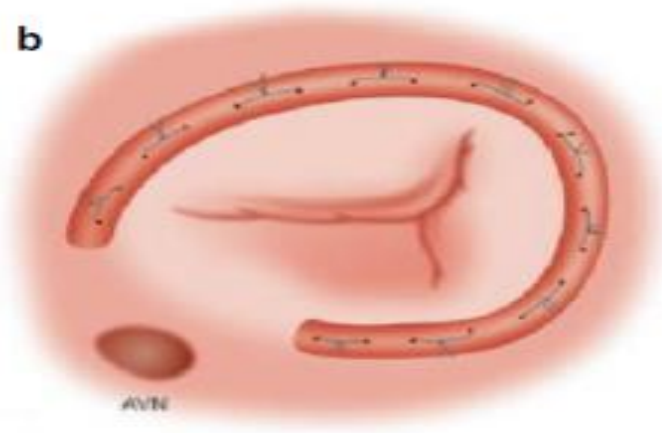


FTR: Perc McKay ?

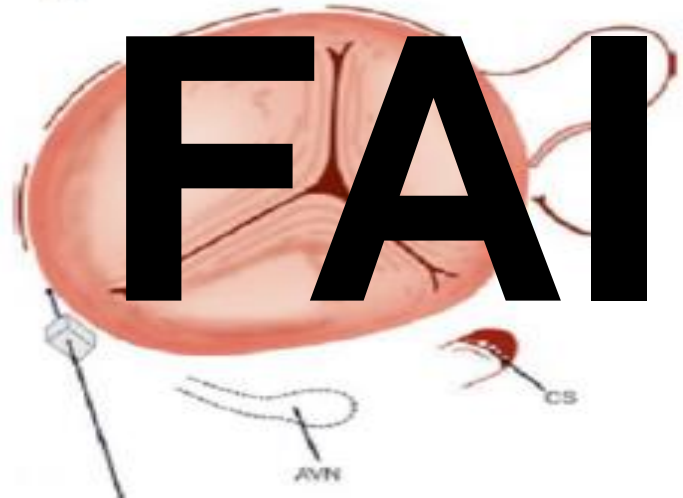
a



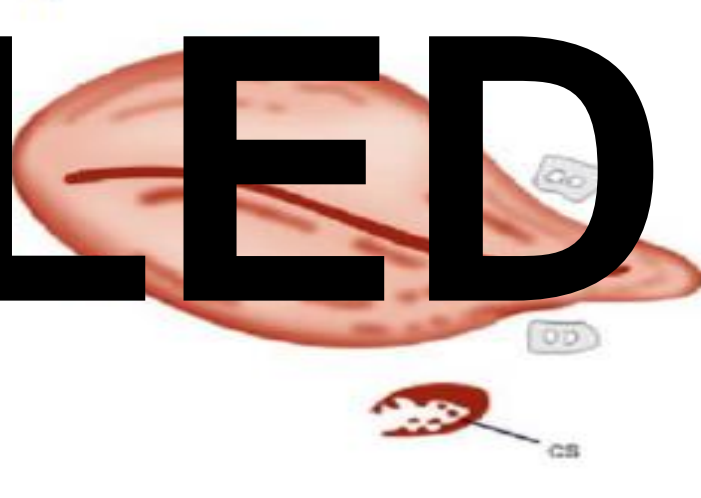
b



c

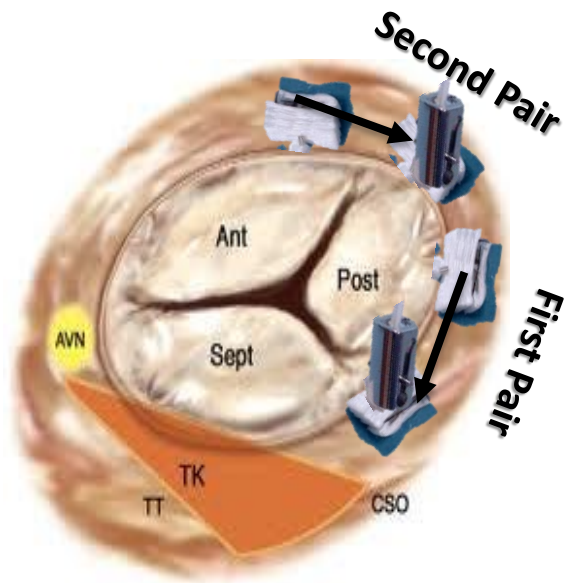


d



FAILED

Additional Pledget Pair Configuration



2 Pair

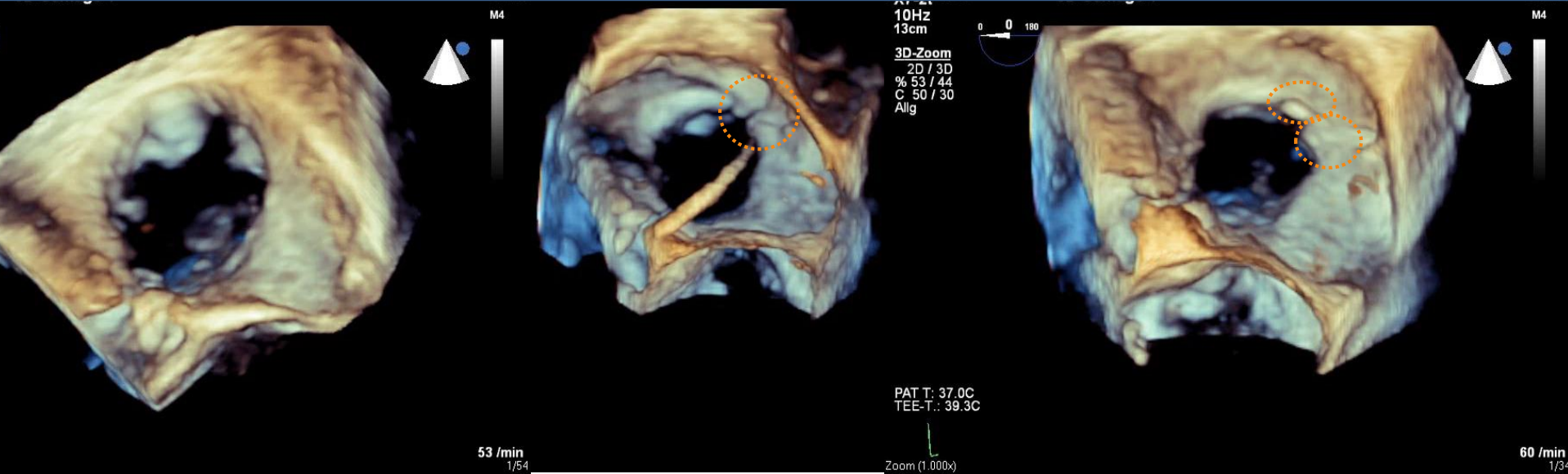
- 4 pledgets
- 2 Locks
- Target: Full Posterior Annulus

3D

Pre Procedure

Post 1st Pair

Post 2nd Pair



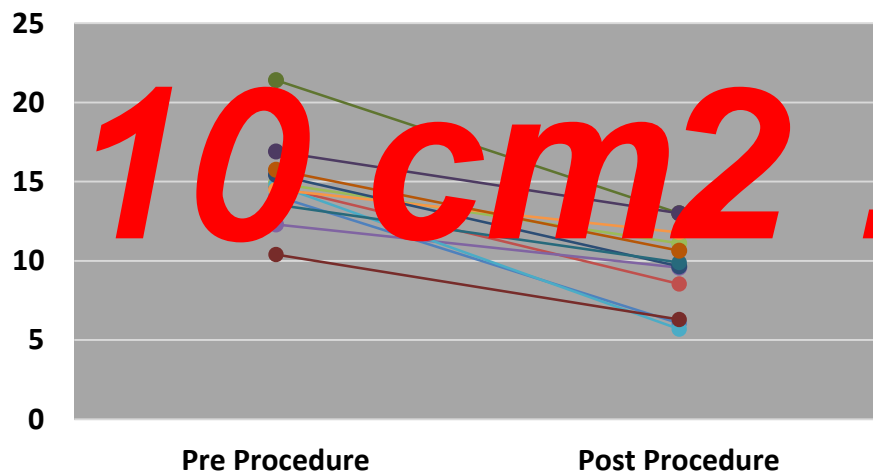
Perc De Vega ?

Trialign Compassionate Use

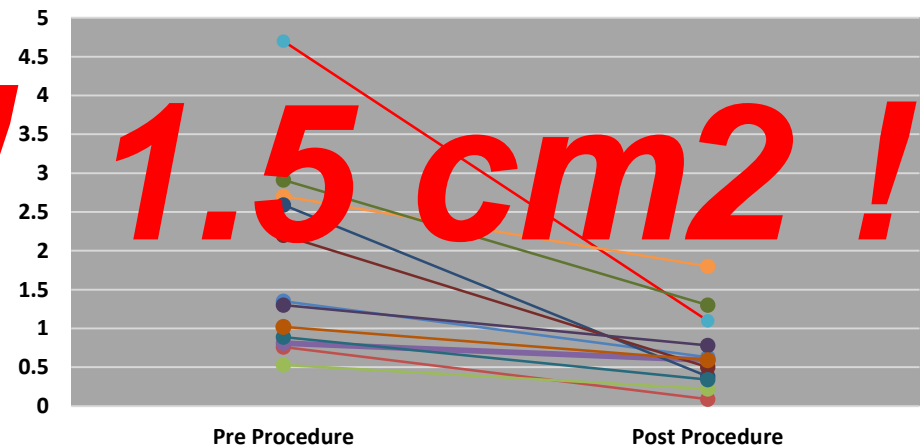
Acute Reduction: *Goal accomplished*

- 12/14 patients received one pair of implants
- Average annular reduction – **35%**
- Average EROA reduction – **58%**
- Adverse event – **1 access complication**

Annular Area cm²



EROA cm²



Tricuspid Percutaneous - *Myth*

TR goal is different..

TR grades 1- 4 and...

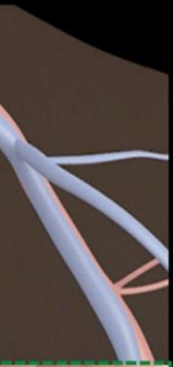
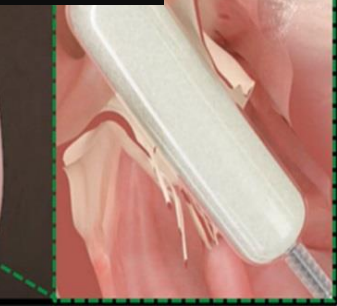
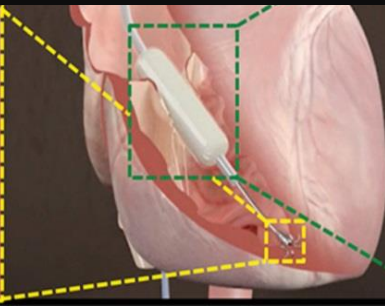
5+ “massive”

6+ “torrential”

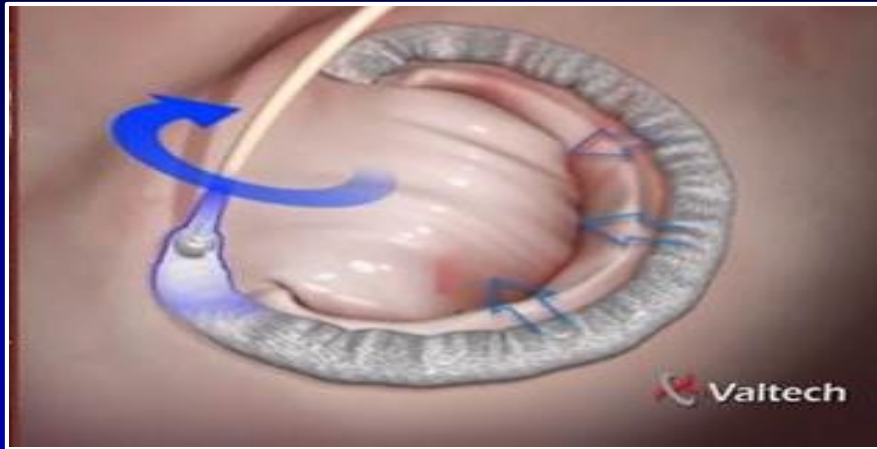
FTR: Percutaneous “other things”

Remain calm!

Carry on!



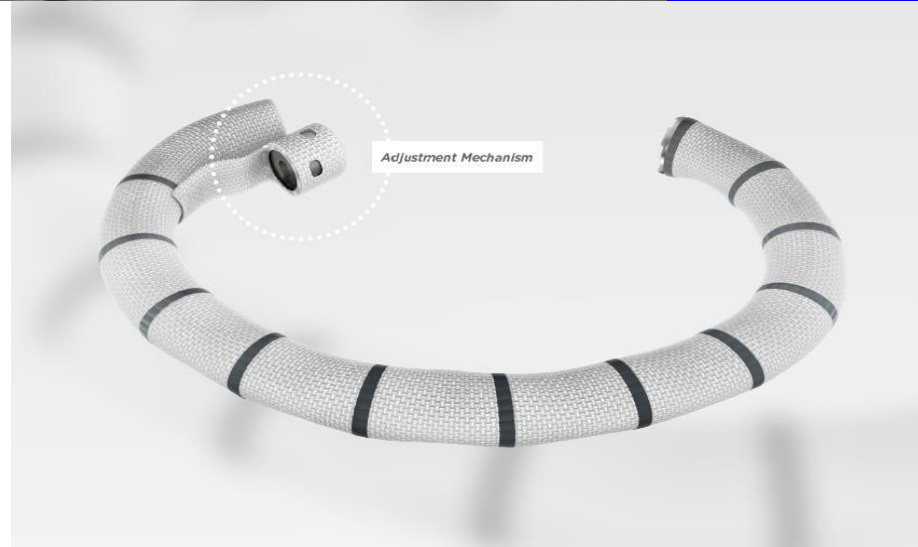
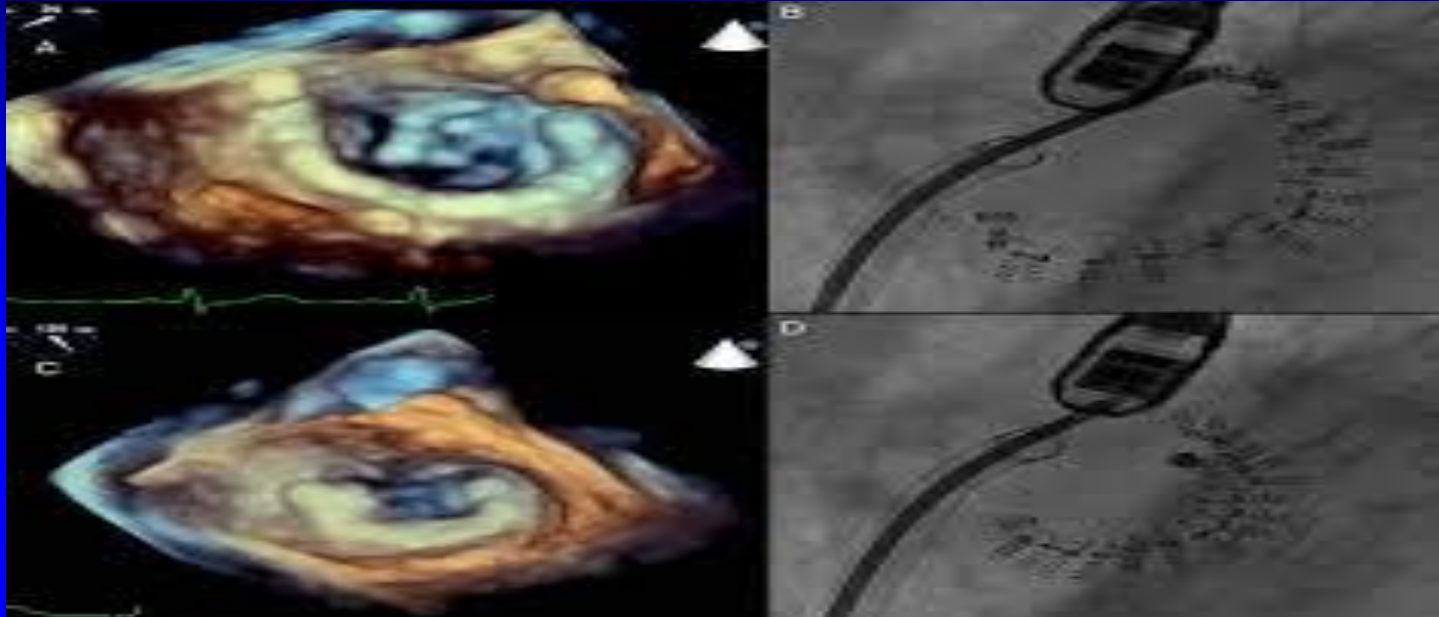
FTR Surgery : Percutaneous Implications



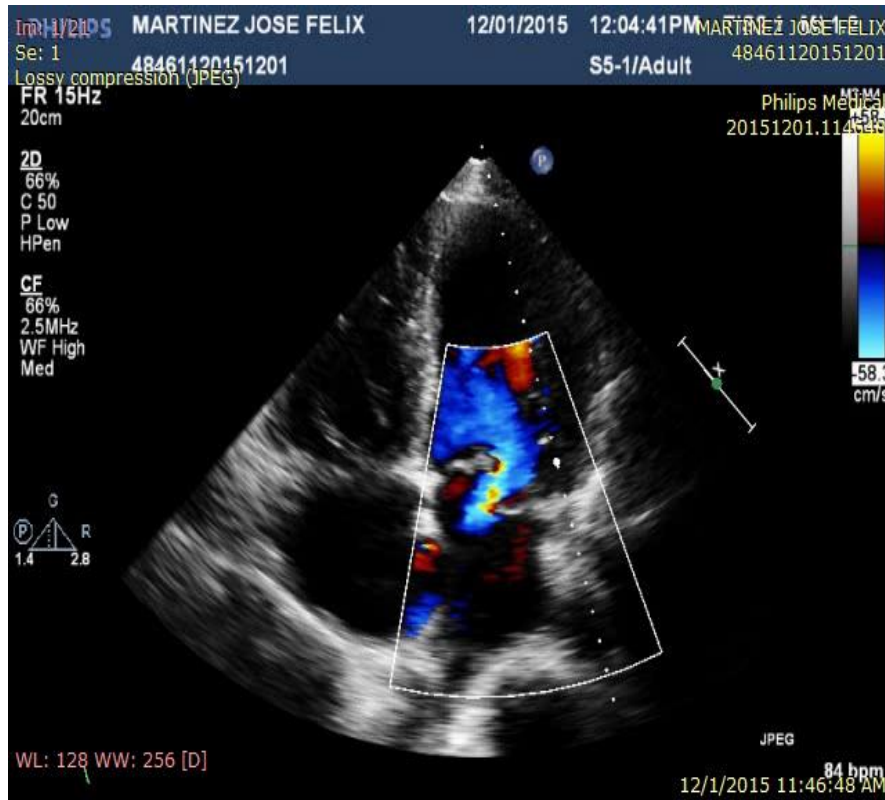
***TV Perc
Rings !***



Tricuspid Regurgitation Cardioband



Pre-op Echo : 4+ MR, 3-4+ TR

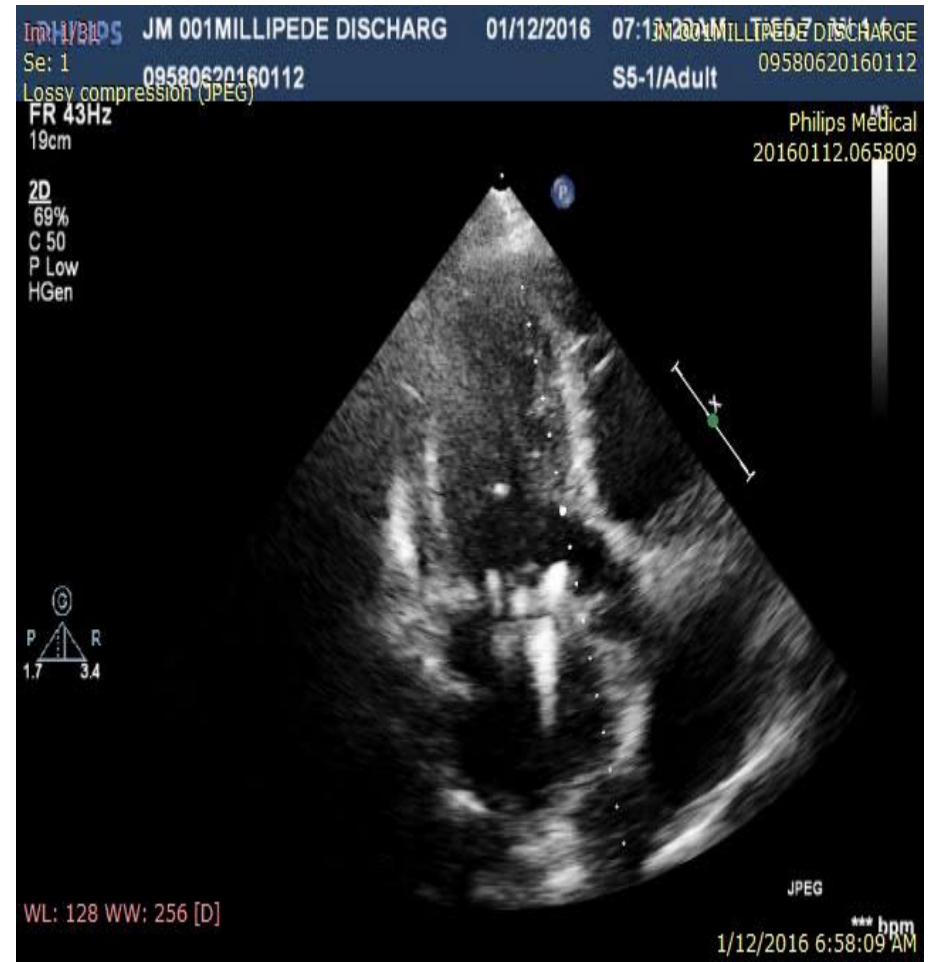
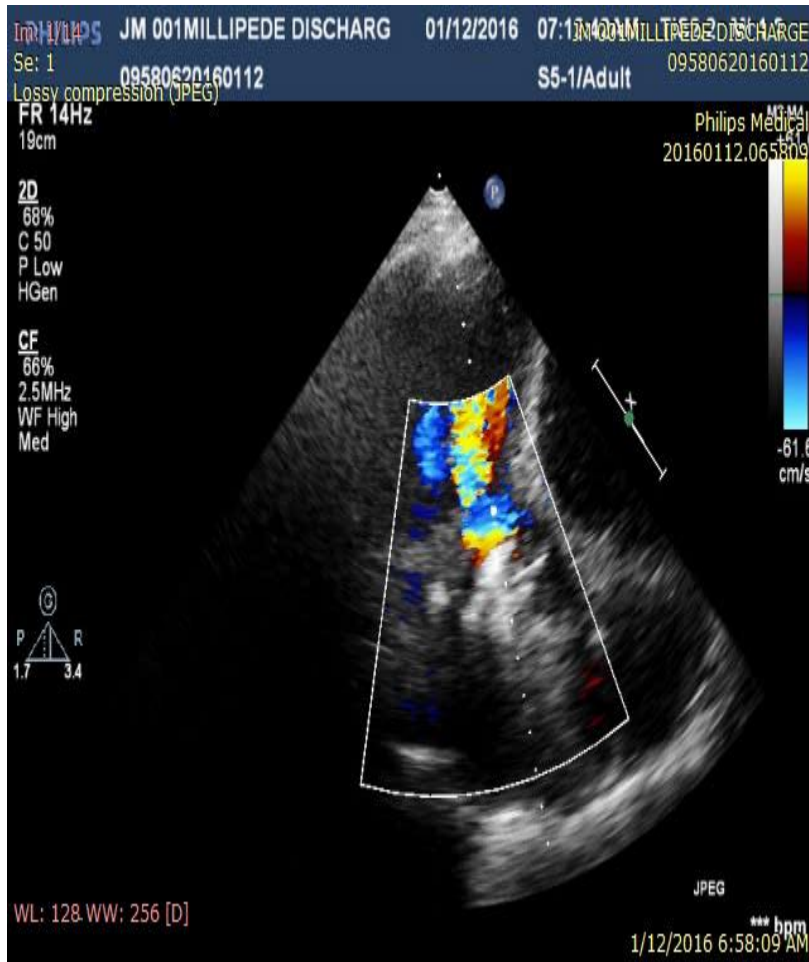


Millipede

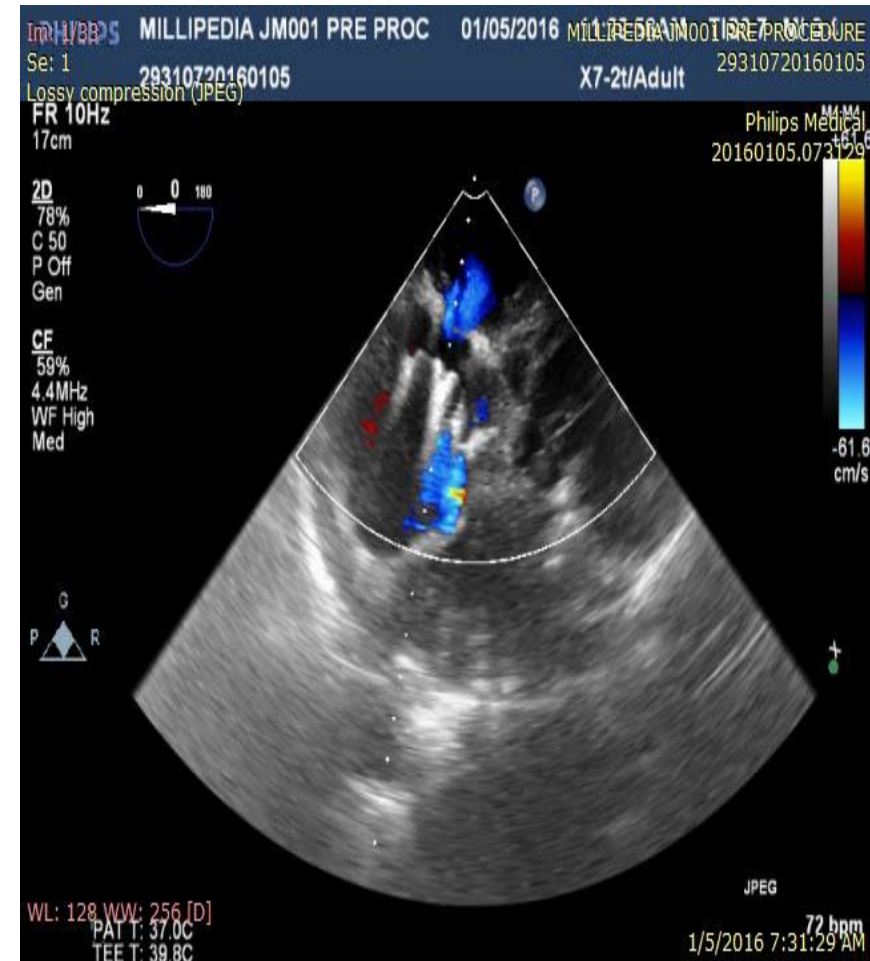
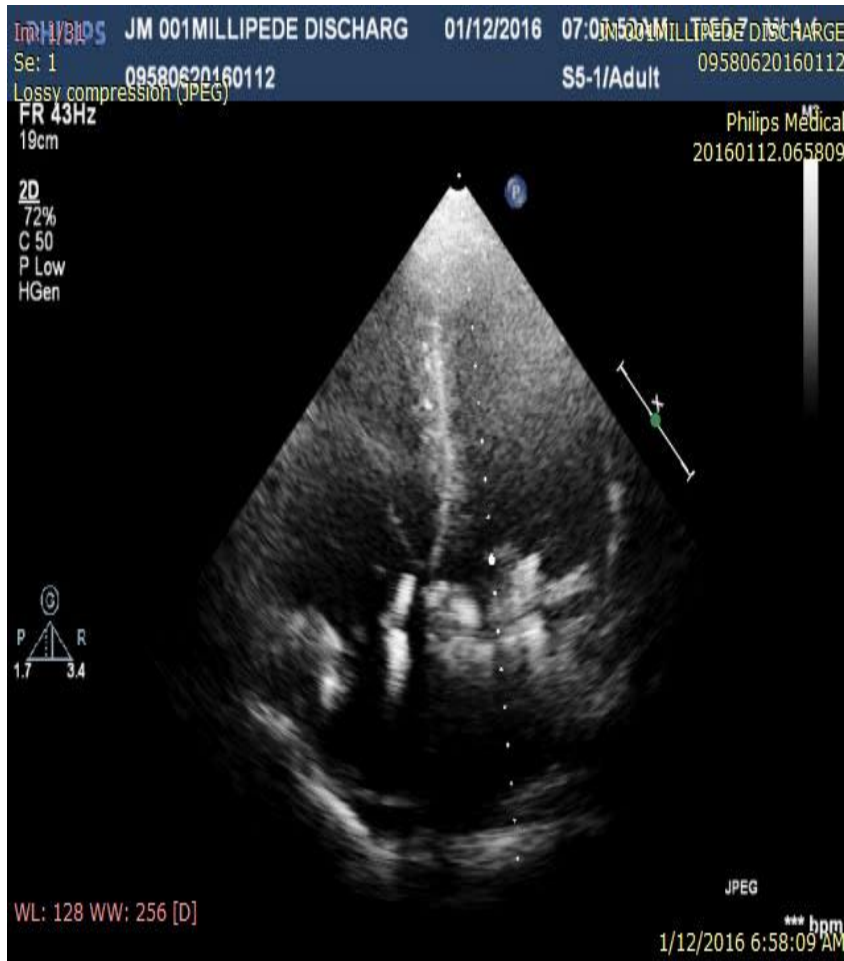
Post MVR / TVR Millipede FLUORO



24 month Post MVR / TVR Millipede TTE



24 month Post MVR / TVR Millipede TTE



Tricuspid Regurgitation - *Reality*

TR is BAD

*“The biology of TR will not change
with the method of therapy”*

*A new grading method
will not “fool” nature*

TR severity - *reality*

*Sustained, meaningful
reduction of TR*

TR Percutaneous : *Myth and reality*

Less impact...Earlier intervention

Best TR is zero

Good enough ? 1-2+TR

Reality : Huge market - \$\$

Patients want it...it will happen