The Evolution of Mitral and Tricuspid Valve Interventions: What is it and Where it needs to go?

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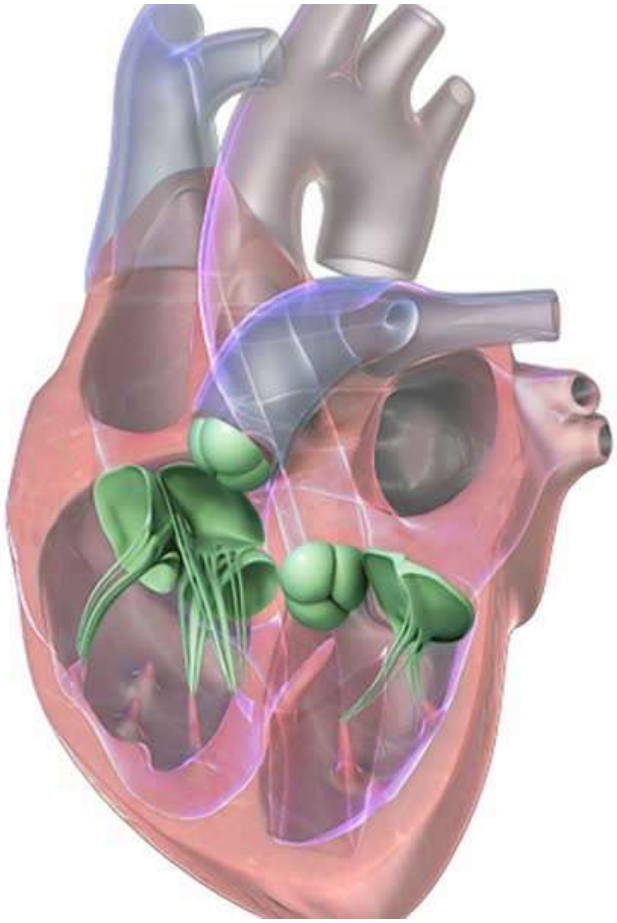
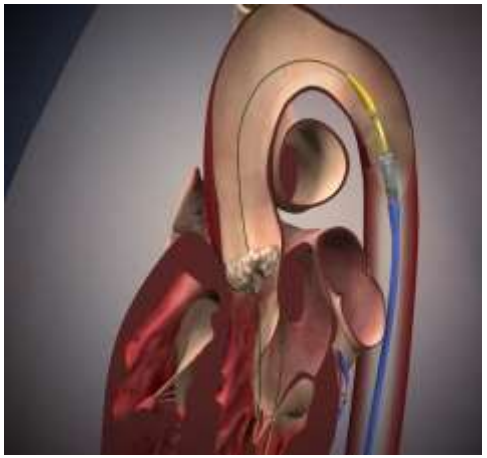
Disclosure Statement of Financial Interest

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

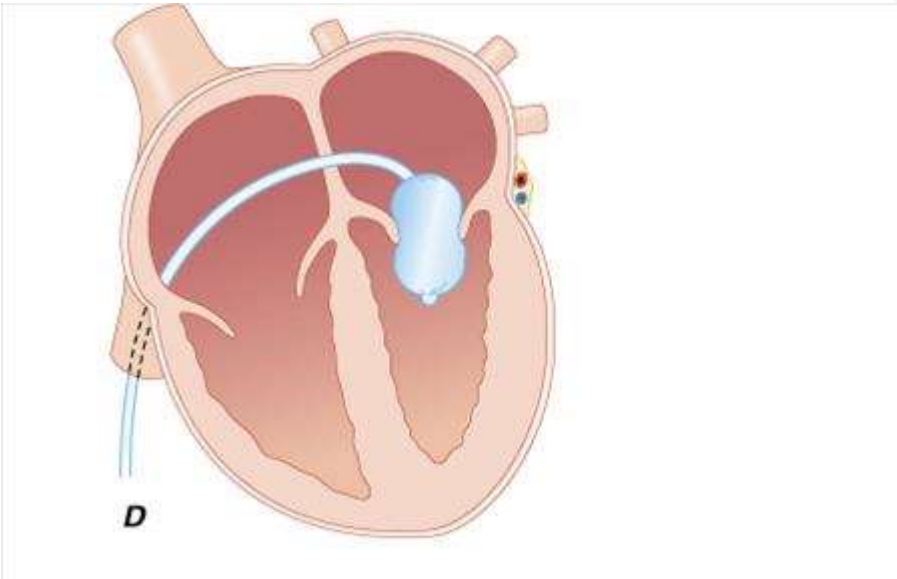
Affiliation/Financial Relationship	Company
• Grant/Research Support	• Edwards Lifesciences, Abbott
• Scientific Advisory Board	• Medtronic, Abbott
• Executive Physician Council	• Boston Scientific Corp

Challenges beyond the Semilunar Valves





Closed Commissurotomy

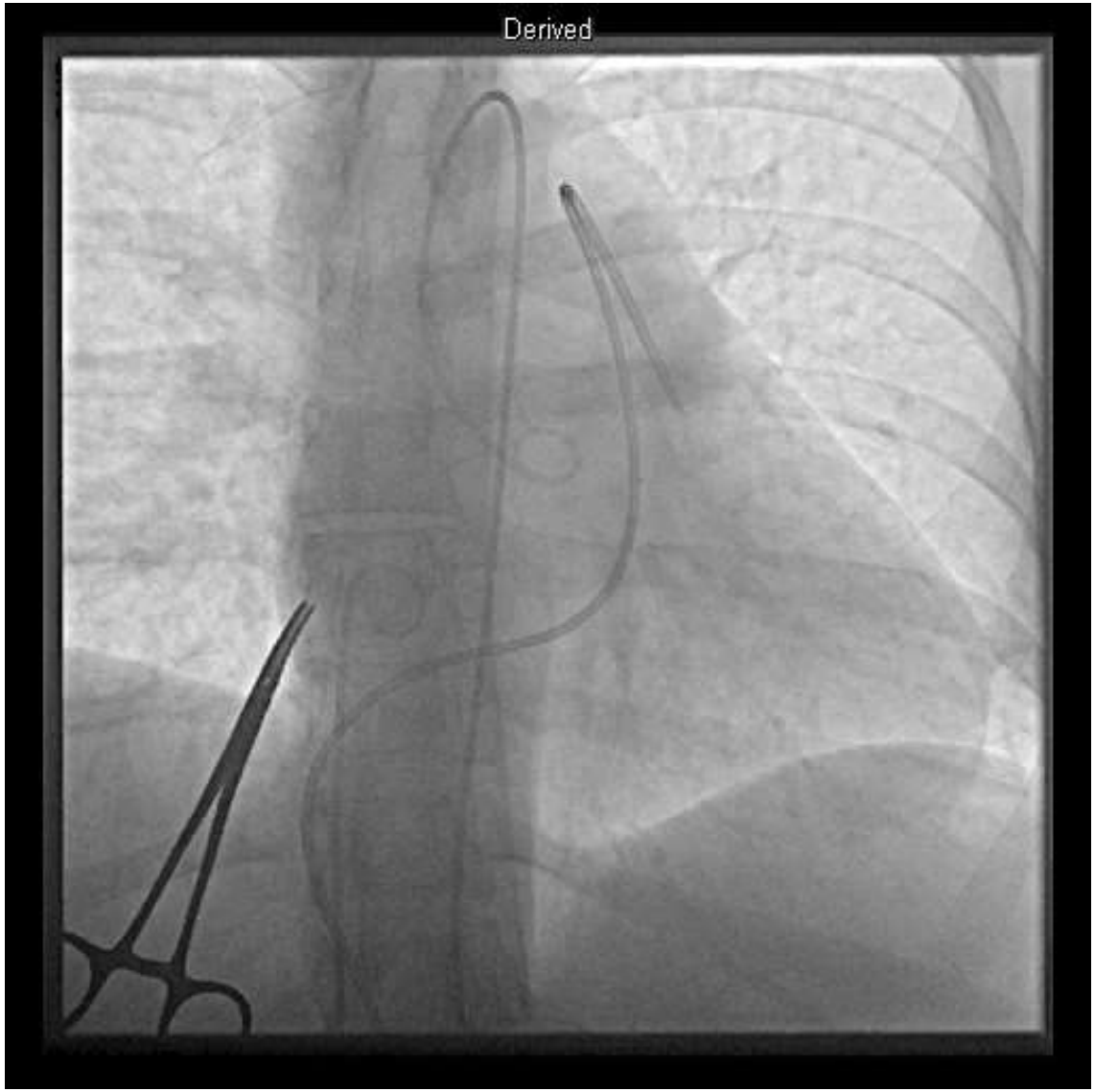


Source: Fauci AS, Kasper DL, Braunwald E, Hauser SL, Longo DL, Jameson JL, Losca
Harrison's Principles of Internal Medicine, 17th Edition: http://www.accessmedicine.com

Mitral Stenosis in Pregnancy

- 32 y/o G2P1 Caucasian Female 26 wks pregnant with severe rheumatic mitral stenosis c/b severe PH and RV dysfunction
- Invasive Hemodynamics

  Pre-valvuloplasty
  - RA 12, RV 79/15, PA 79/41/56, PCWP 29, SBP 90/60
  - LA 30 (post-transeptal puncture), MV mean gradient 25
  - CO/CI 5.9/3.2
  - LVG: Mild to Moderate MR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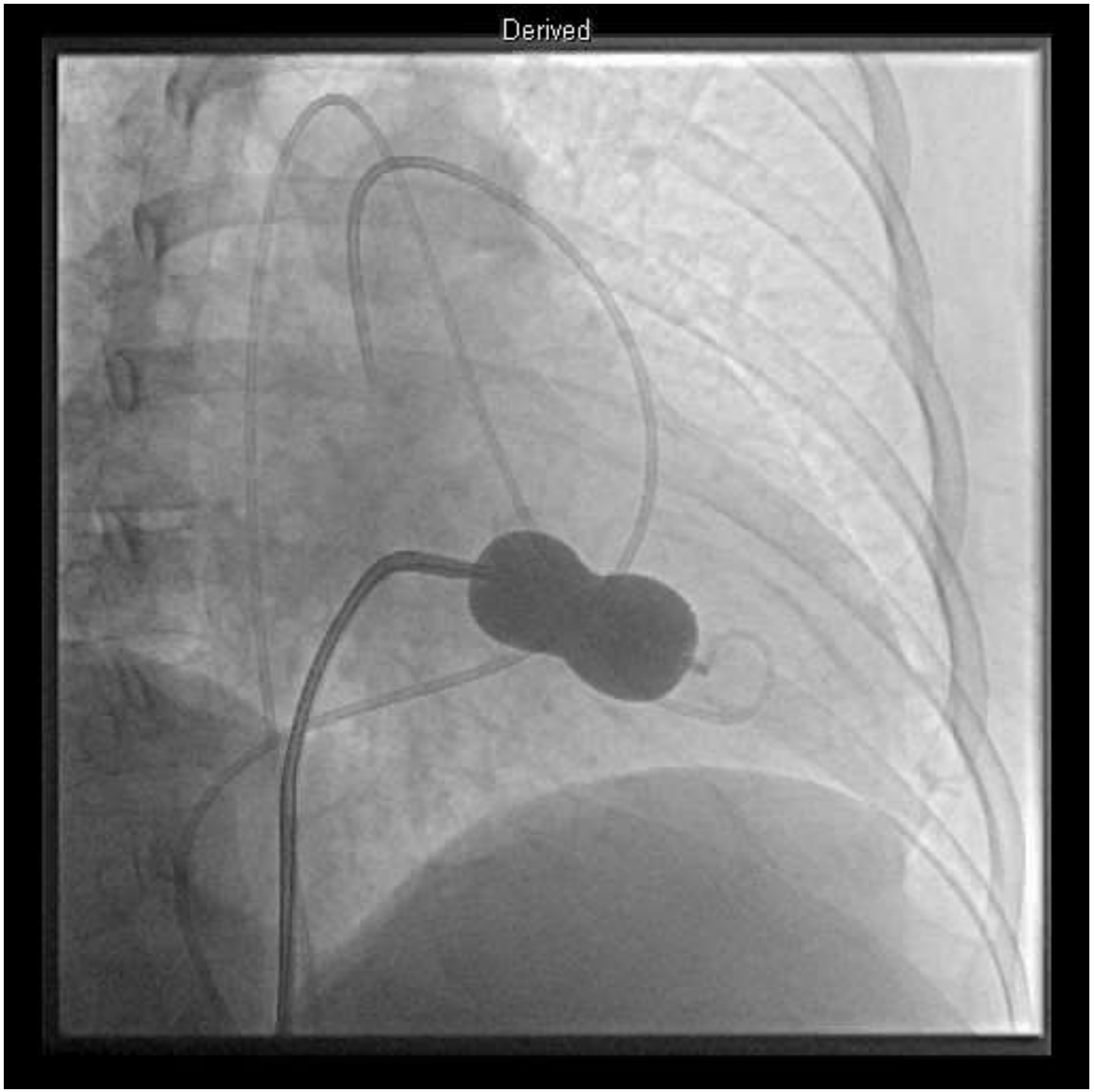
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Mitral Stenosis in Pregnancy (2)

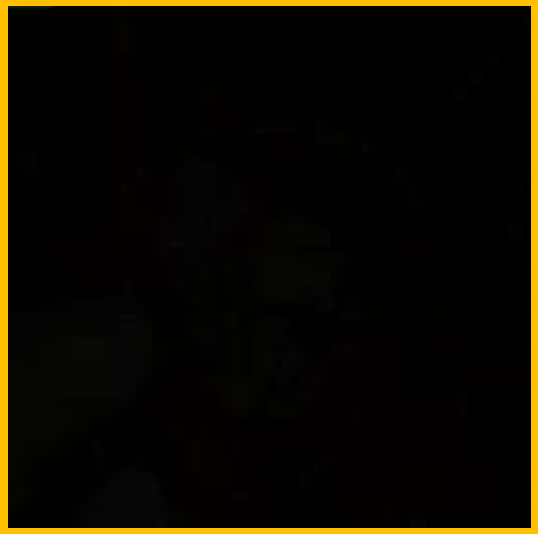
- Invasive Hemodynamics

  Post-valvuloplasty (serial balloon inflations up to 26mm)
  - PA 65/30/41
  - MV mean gradient 6 (25 pre)
  - CO/CI 7.7/4.2
  - LVG Mild to Moderate MR

- Non invasive Hemodynamics
  - MV mean gradient 23 (HR 69) → 12 (HR 76) with stable mild-mod MR
  - Estimated RVSP 99 → 67 + JVP with improved RV function

Mitral Regurgitation : Repair

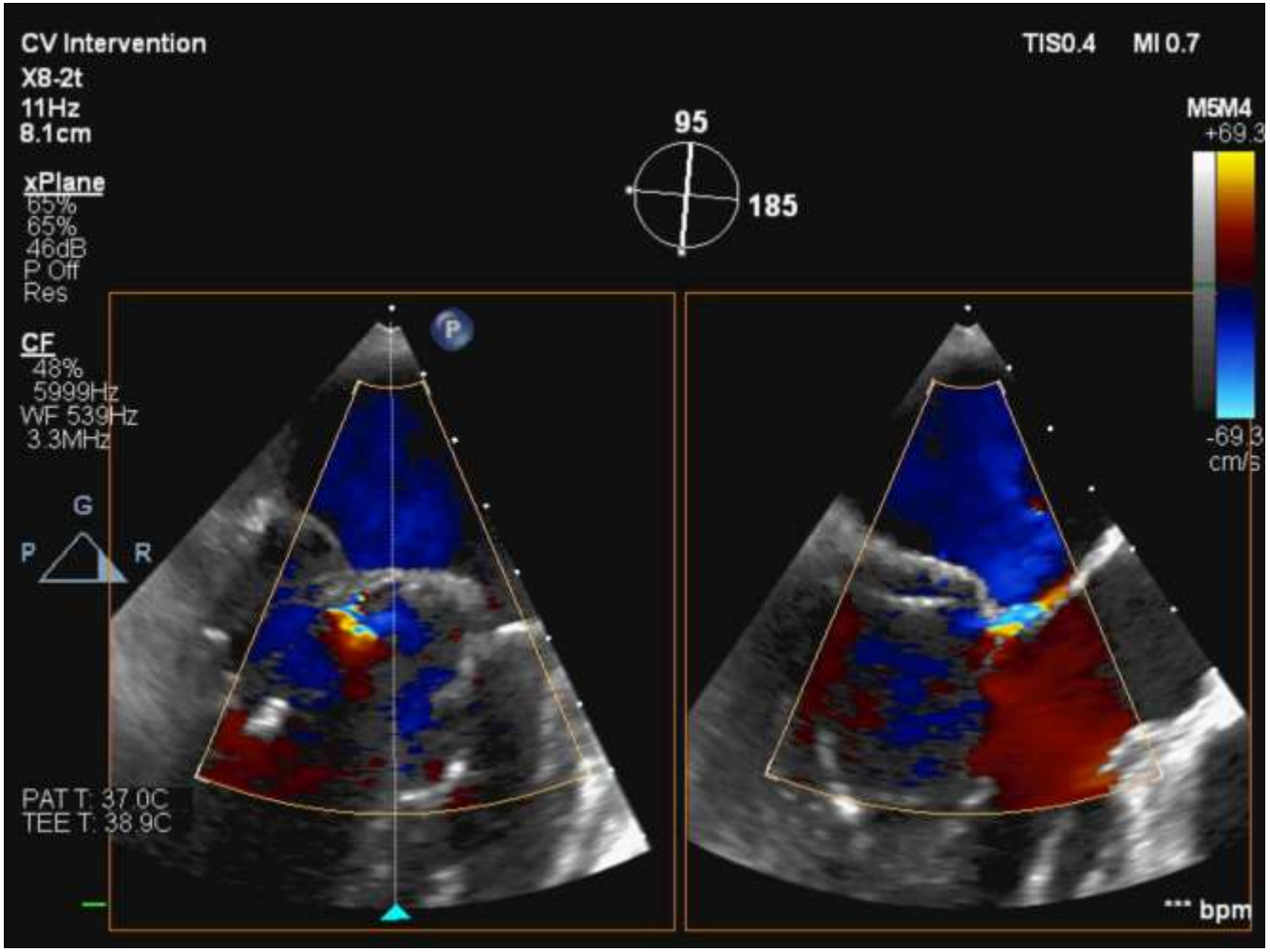
Alfieri Stitch



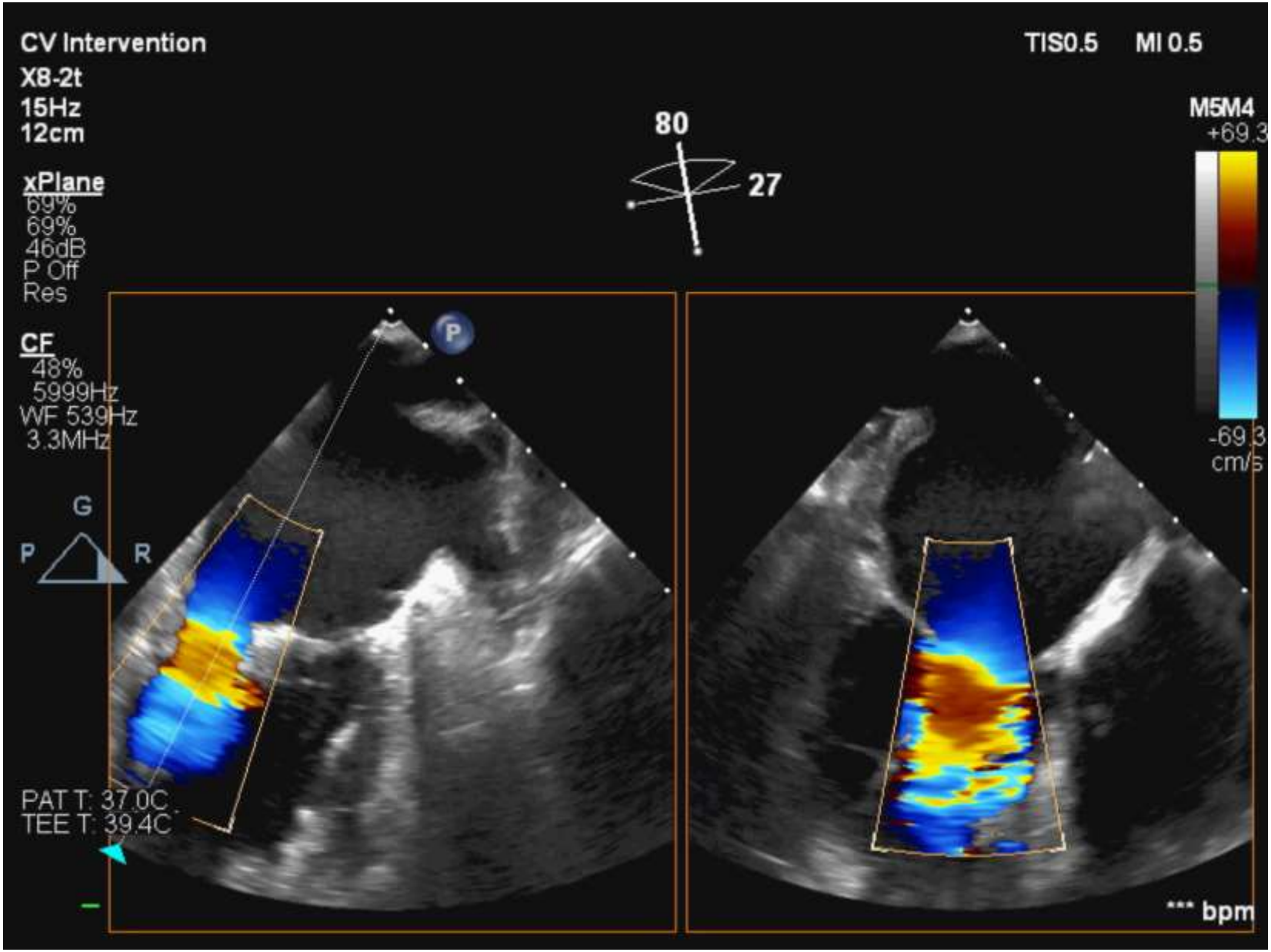
MitraClip

Case : KL

- 98 year old woman active, lives independently
- Slow decline over the past year with SOB
- MV prolapse with chordal rupture with RV pressure of 34.
- MitraClip: LA pressure of 30 v, post 10. 3-4+ MR to trace.


CV Intervention
X8-2t
11Hz
8.1cm
TIS0.4 MI 0.7
95
185
M5M4
+69.3
-69.3
cm/s
xPlane
65%
65%
46dB
P Off
Res
CF
48%
5999Hz
WF 539Hz
3.3MHz
G
P
R
PAT T: 37.0C
TEE T: 38.9C
*** bpm

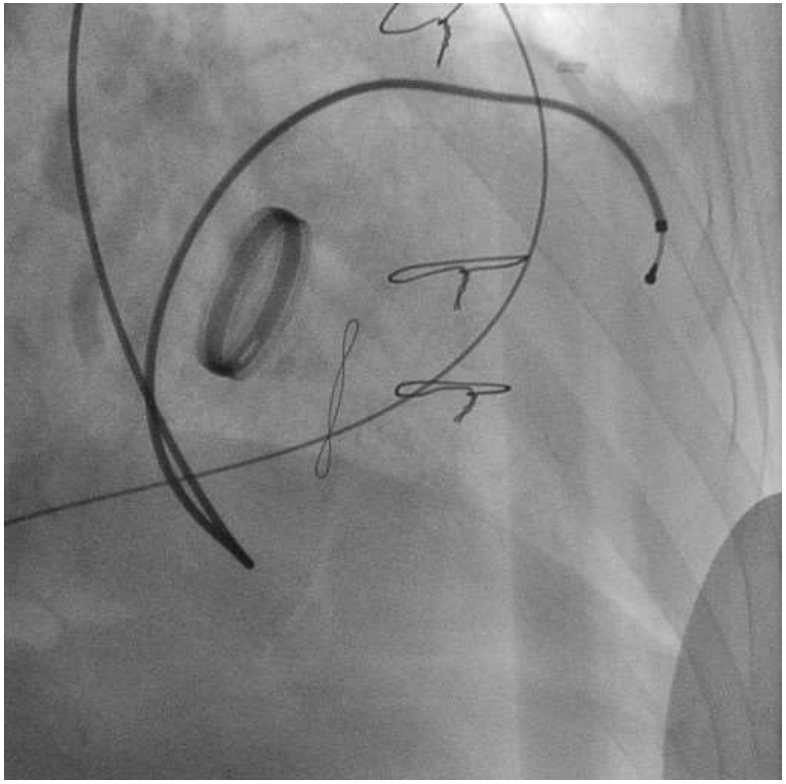

CV Intervention
X8-2t
30Hz
11cm
3D Beats 1
TIS0.2 MI 0.2
M5
0 140 180
3D Zoom
2D / 3D
% 66 / 49
C 46 / 30
Res
PAT T: 37.0C
TEE T: 39.5C
*** bpm

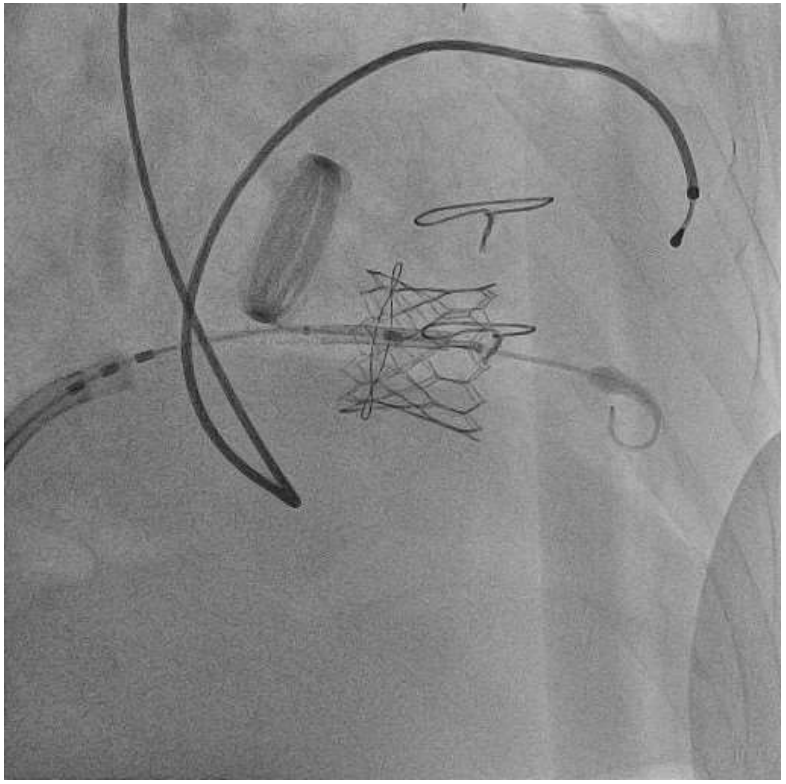

CV Intervention
X8-2t
15Hz
12cm
TIS0.5 MI 0.5
M5M4
+69.3
80
27
xPlane
69%
69%
46dB
P Off
Res
CF
48%
5999Hz
WF 539Hz
3.3MHz
G
P
R
-69.3
cm/s
PAT T: 37.0C
TEE T: 39.4C
*** bpm

Mitral and Tricuspid Valve Replacement


Filter: Filter 4

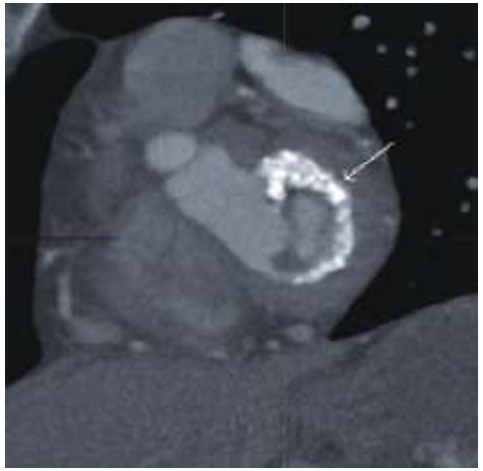
Tricuspid Valve Intervention



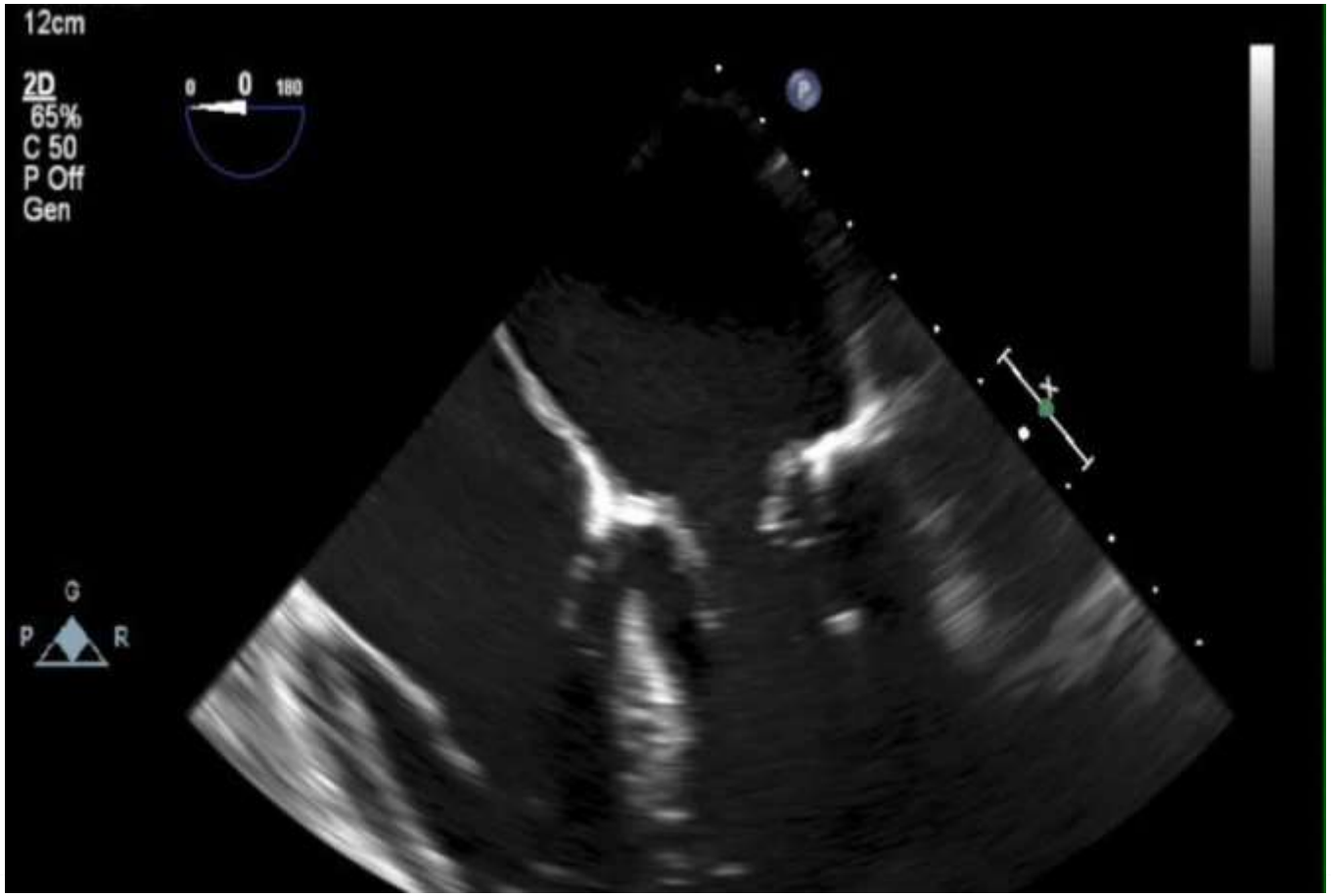


MAC

- Severe Mitral annular calcification
  - Suture placement can be difficult
  - Valve placement can be difficult
- Can it provide an anchor for THV?

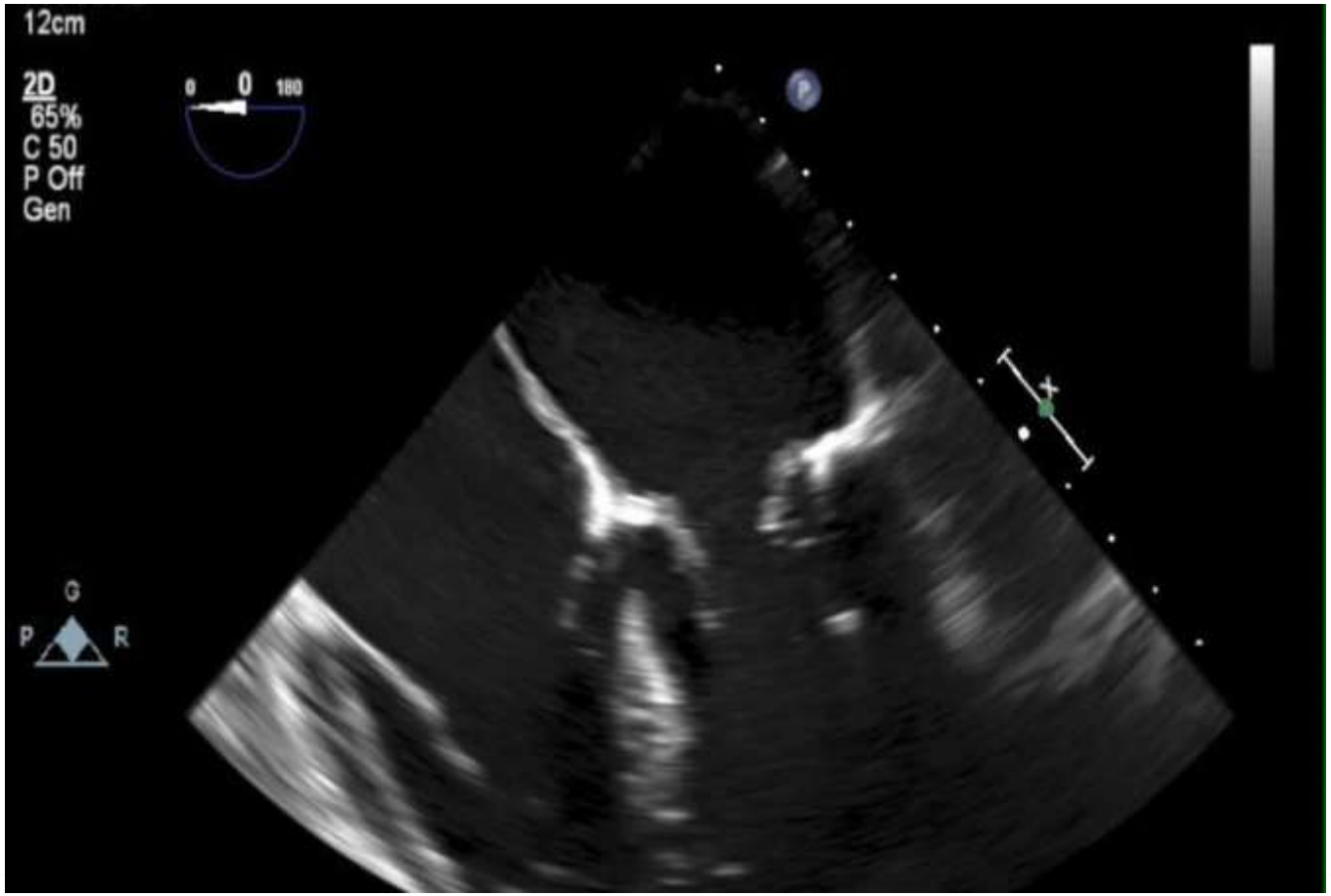


THV in MAC



Courtesy from Vinnie Bapat

THV in MAC



Courtesy from Vinnie Bapat

Scope of the Problem

TABLE 2. Estimated structural heart disease opportunity: United States

	Patient population	Currently treated
Mitral regurgitation		
Moderate to severe	2,300,000[2,3]	48,000*[2]
Severe	220,000[2,3]	
Aortic stenosis		
All grades	749,000[2,4]	79,000[2]
Severe	125,000†[2,4,5]	
Tricuspid regurgitation		
Moderate to severe	1,600,000‡[2,3]	<8000*[2]

<1% of patients with moderate or severe TR undergoing surgery annually.

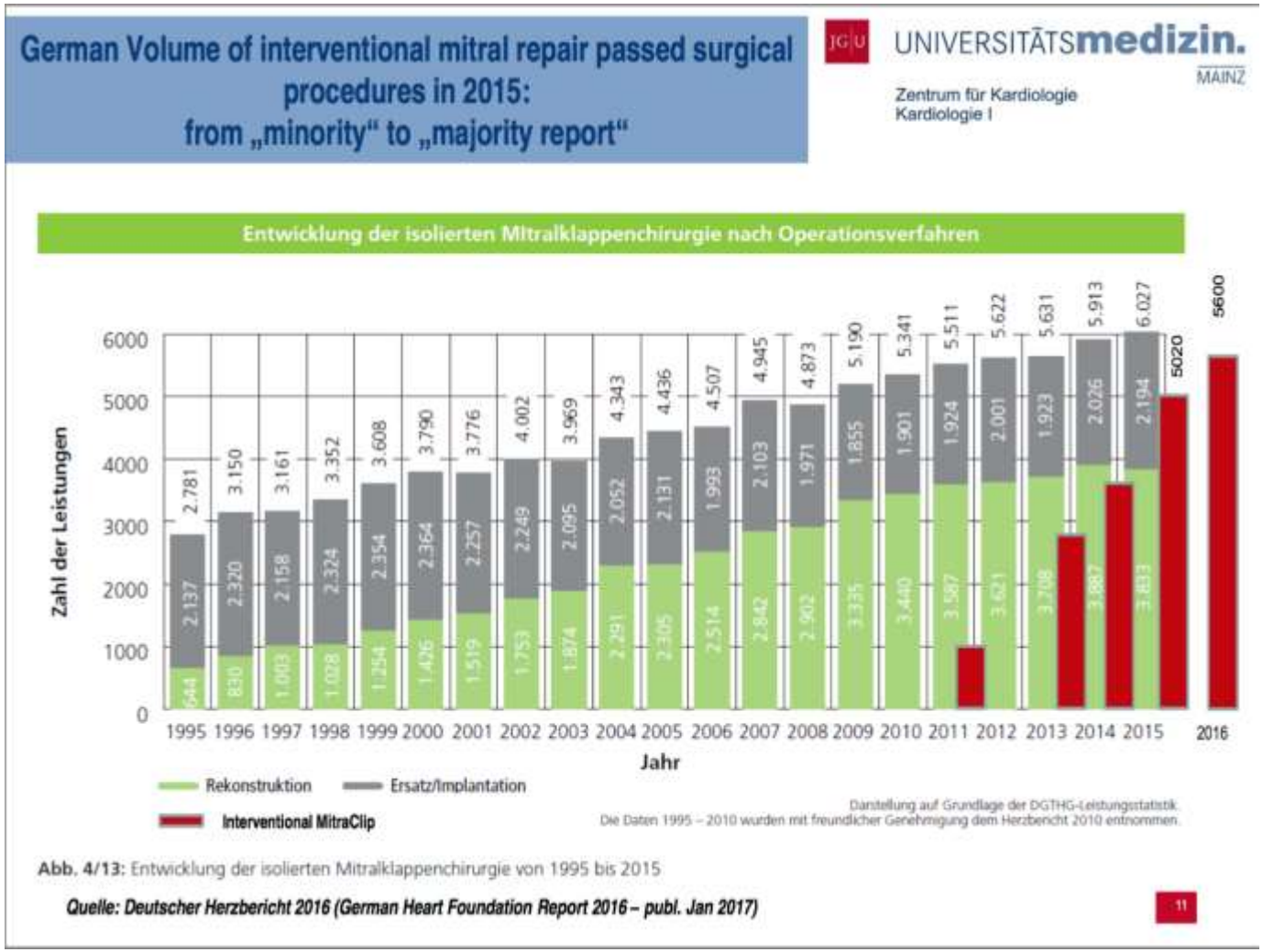
Surgery rarely performed (16±5%) 5-years after diagnosis

Stuge O. et al. *Thorac Cardiovasc Surg* 2006; 132: 1258-61

Needs Findings in MV and TV Interventions

- Mitral Stenosis:
  - Present: Inoue Balloon Valvuloplasty
  - Need: Calcific MS (+/- MAC) Solution: TMVR
- Mitral Regurgitation:
  - Present: Mitraclip
  - Need: Calcific valve tip and immobile valve Solution: TMVR
  - Need: Functional MR Solution: ? Mitraclip
- Tricuspid Stenosis:
  - Extremely rare
- Tricuspid Regurgitation:
  - Enigma
- V-in-V in Mitral and Tricuspid Positions
  - Doable with current technology
  - Need: non-transapical route

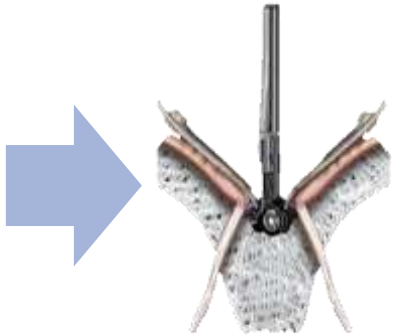
More transcatheter than surgical MV interventions in Germany



courtesy of S. Von Bardeleben

COMBINATION THERAPY

Baseline



Courtesy from F. Maisano

Transcatheter MV Tx : Device Landscape 2017

Edge-to-edge
- MitraClip***
- Pascal*
- MitraFlex

Coronary sinus annuloplasty
- Cardiac Dimensions Carillon**
- Cerclage annuloplasty

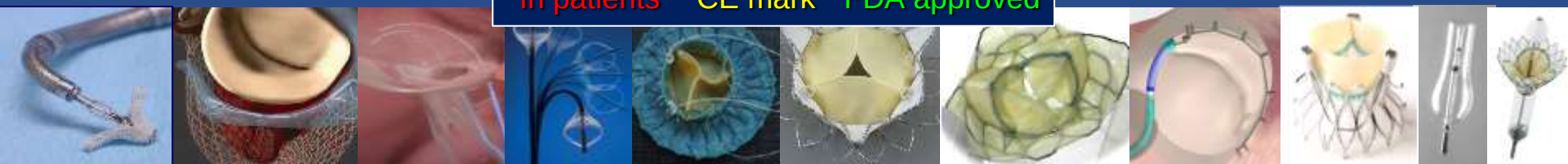
Direct annuloplasty
- Mitralign TAMR**
- Valtech Cardioband**
- GDS Accucinch*
- Millipede IRIS*
- MVRx ARTO*
- Mardil BACE*
- Mitraspan TASRA*
- Valcare Amend*
- Micardia enCor*
- Cardiac Implants RDS
- QuantumCor (RF)
- Valfix

MV replacement
- Edwards CardiAQ*
- Edwards Fortis*
- Neovasc Tiara*
- Abbott Tendyne*
- Medtronic Intrepid*
- HighLife*
- MValve*
- Caisson*
- Cephea
- NCSI NaviGate
- St. Jude
- Micro Interventional
- Valtech CardioValve
- ValveXchange
- MitrAssist
- Braile Quattuor
- Direct Flow
- Sinomed Accufit
- Corona MVR w/Amend ring

MV replacement (cont)
- MitralHeal
- HT Consultant Saturn
- Lutter valve
- Transcatheter Technologies Tresillo
- Venus
- Verso
- Transmural Systems
- 4C

Other approaches
- NeoChord DS 1000**
- Harpoon neochords*
- Babic chords*
- Middle Peak Medical*
- St. Jude leaflet plication*
- Cardiosolutions Mitra-Spacer*
- Mitralix*
- Valtech Vchordal
- Coramaze Mitramaze

*In patients *CE mark *FDA approved

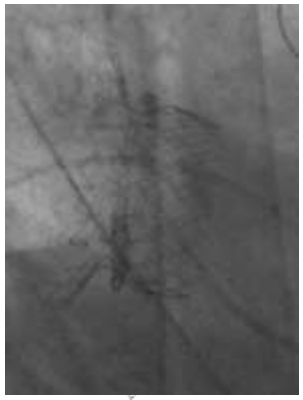


CardiAQ Edwards

Neovasc Tiara

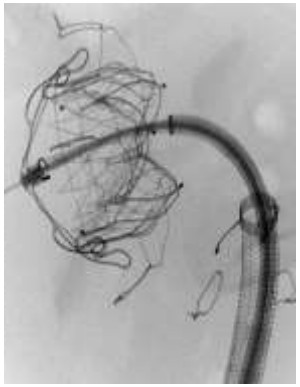
Edwards Fortis

Tendyne
Abbott



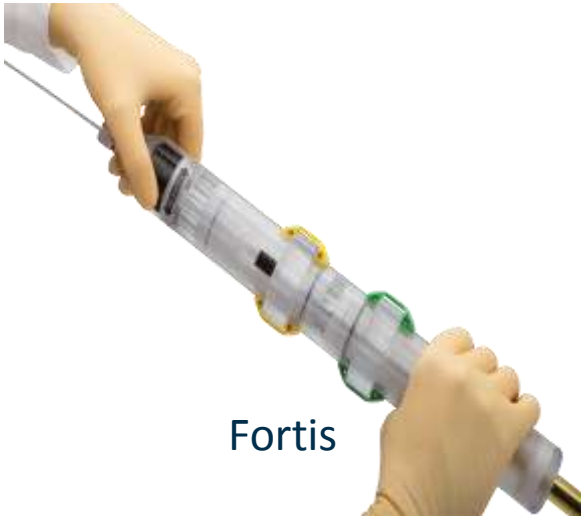
HighLife

Medtronic Intrepid



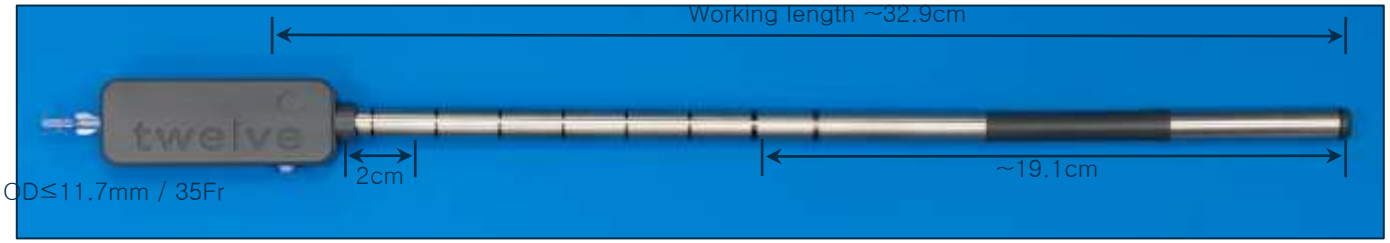
Caisson

Transapical delivery catheters



Fortis

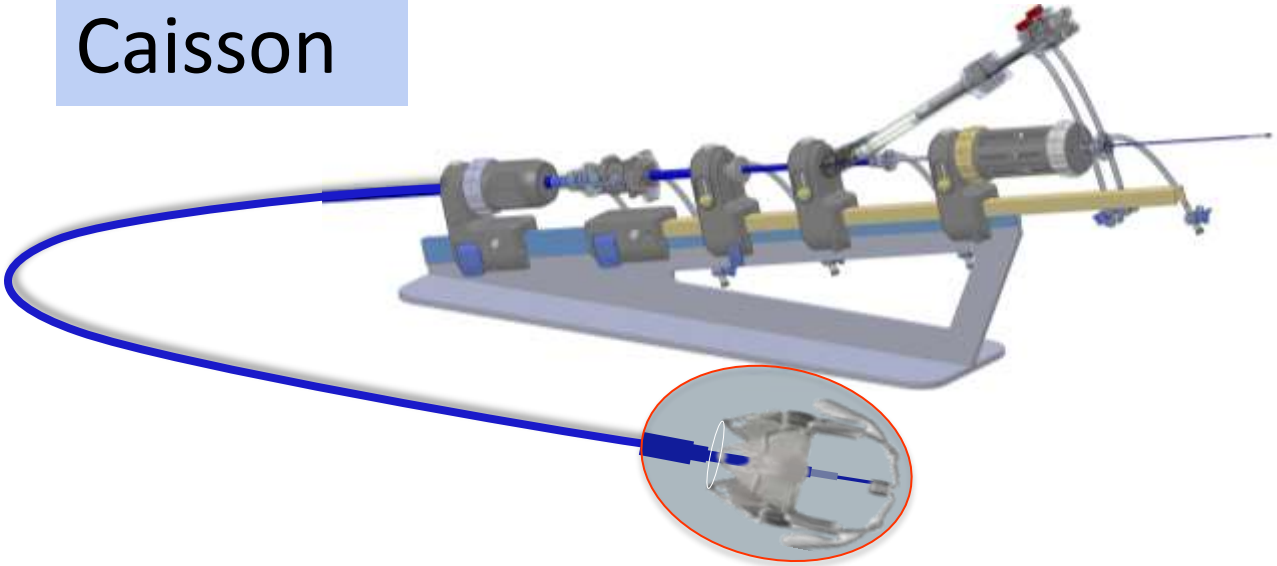
Intrepid



Tiara

Approaches to transseptal delivery

Caisson



Similar to MitraClip

CardiAQ

Similar to Commander

Design features

	CardiAQ	Fortis	Tiara	Tendyne	Intrepid	HighLife	Caisson
Nitinol frame	✓	✓	✓	✓	✓	✓	✓
Trileaflet pericardial valve	✓	✓	✓	✓	✓	✓	✓
Asymmetric valve	-	✓	✓	✓	-	-	✓
Fixation	anchors	paddles	anchors	tether	barbs	ring	feet
Apical access	✓	✓	✓	✓	✓	✓	-
Transseptal access	✓	-	-	working on it	working	working	✓
Recapturable	-	-	partly	fully	partly	party	fully

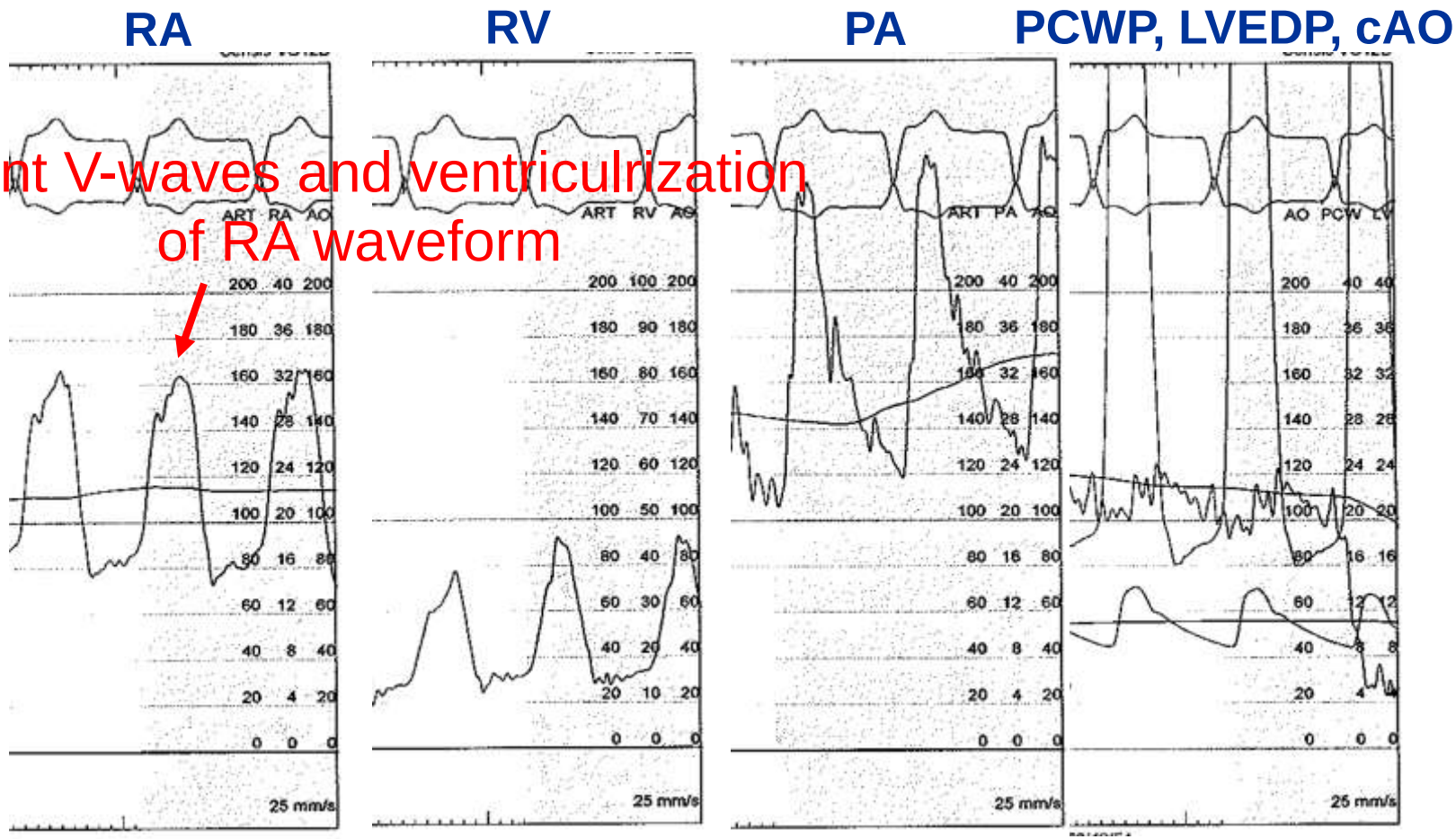
TRICUSPID REGURITATION

Etiology

- Primary (25%)
  - Ebstein's anomaly
  - Carcinoid tumors
  - Infective endocarditis
  - Drug related "Fen-phen" diet pills
  - Radiation therapy
  - Rheumatic
  - Iatrogenic
    - Pacemaker, ICD, Biopsy
- Secondary (75%)
  - Left heart disease
  - Right heart dysfxn
  - Pulmonary hypertension
    - Chronic jung disease
    - Thromboembolism
  - Annular dilation
    - Usually from A-fib

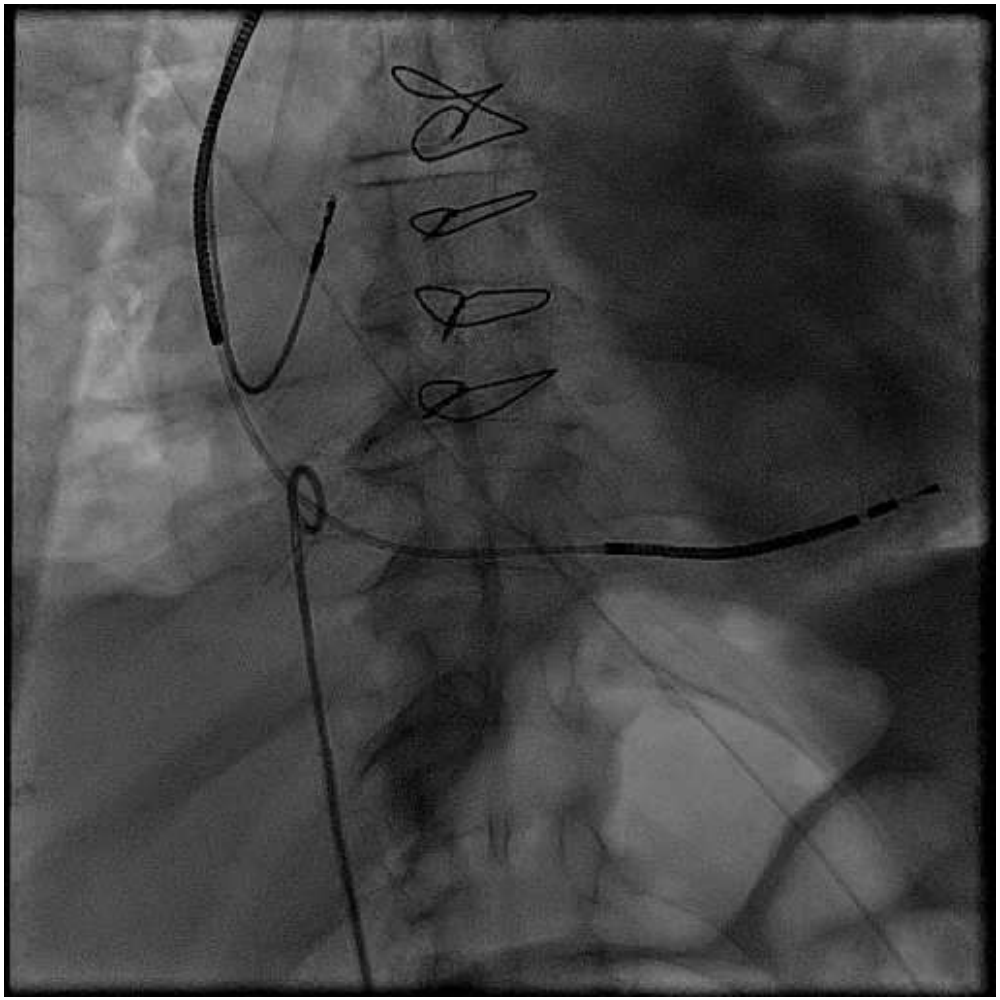
Echocardiography

Hemodynamics



CO=2.3 L/min; CI=1.5 L/min/m^2

Angiography



The Problem

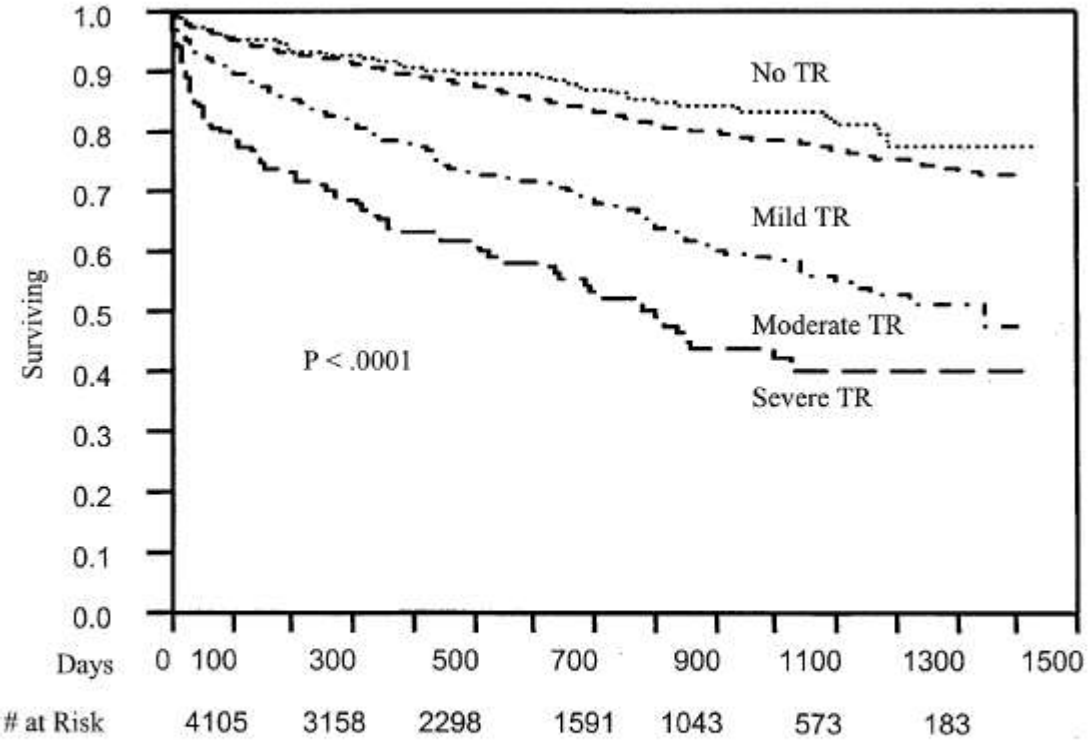


Figure 1. Kaplan-Meier survival curves for all patients with tricuspid regurgitation (TR). Survival is significantly worse in patients with moderate and severe TR.

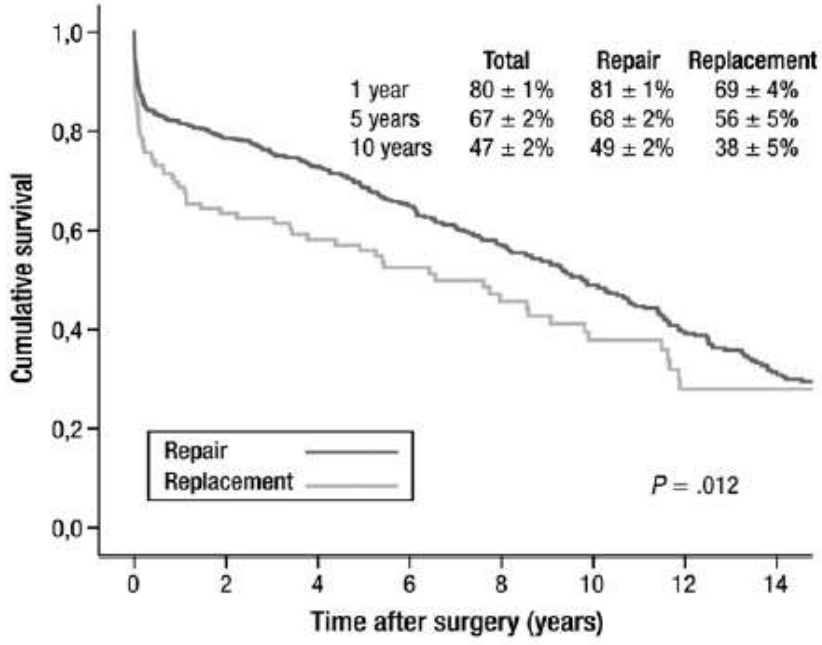
- 1-year survival rates
  - No TR 91.7%
  - Mild TR 90.3%
  - Mod TR 78.9%
  - Severe TR 63.9%
- Independent of:
  - LVEF
  - PA pressure
  - Age
  - RV size
  - IVC dilation

- n=5223 VA patients
- Follow up available for 4 years

Nath J et al. JACC 2004;43:405-9

Surgical Correction

Figure 3



At risk								
Repair	791	475	362	266	196	150	97	65
Replacement	134	67	52	44	32	23	14	10

Unadjusted survival after TV surgery.

- 926 patients undergoing tricuspid valve surgery.
- 126 underwent isolated valve surgery
- Ten-year survival was 49% ± 2% and 38 ± 5% in the repair and replacement groups

Tricuspid repair devices

Device Name	MitraClip	Trialign	TriCinch	Cardioband	Millipede	FORMA Repair System	Caval valve implantation	TRAIPTA
Device Image								
Description	Bicuspidisation of the TV by plicating	Bicuspidisation of the TV by plicating	Bicuspidisation of the TV by cinching	Direct annuloplasty device	Complete semi rigid ring	Spacer to occupy the regurgitant orifice area	Caval valve implantion in vena cava	Pericardial circumferential device
Access	Transfemoral	Transjugular	Transfemoral	Transfemoral	Transfemoral	Transsubclavian	Transjugular/ transfemoral	Transjugular/ transfemoral
Status*	• About 60 patients	• About 15 patients	• About 25 patients	• About 10 patients	• About 2 patients	• About 20 patients	• About 40 patients	• Only pre-clinical data

*** At the moment of reporting from recently international meeting**

A vision for the 2025: a toolbox for a tailored approach