ProEducar-SOLACI

Mitral Valve Interventions: Current Data and Future Expectations.

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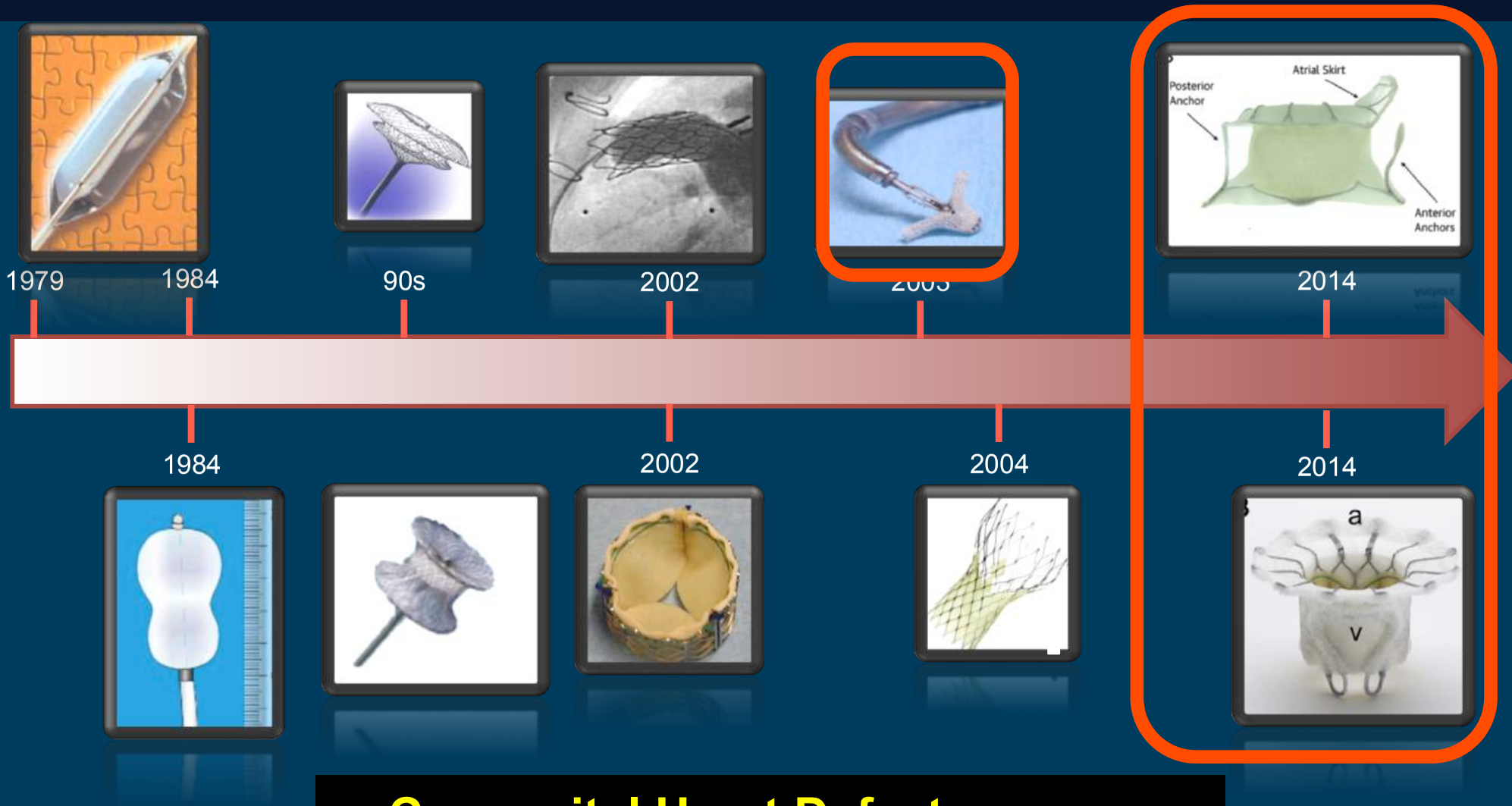
SOLACI CACI`17 ARGENTINA

In partnership with tct

Disclosures

- ✓ Proctor and Consultant for Edwards-Lifesciences and Medtronic.

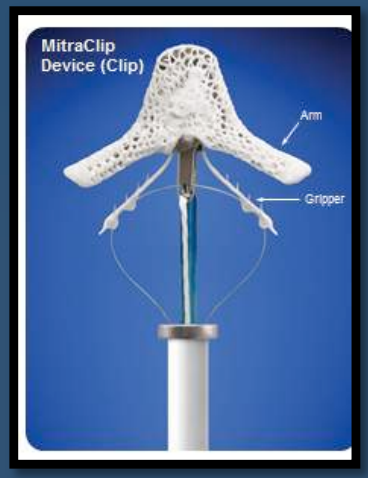
TRANSCATHETER THERAPIES in STRUCTURAL HEART



- Congenital Heart Defects
- Valve Therapies
- Heart Failure
- LAA closure devices

Mitral Dysfucntion

Failure

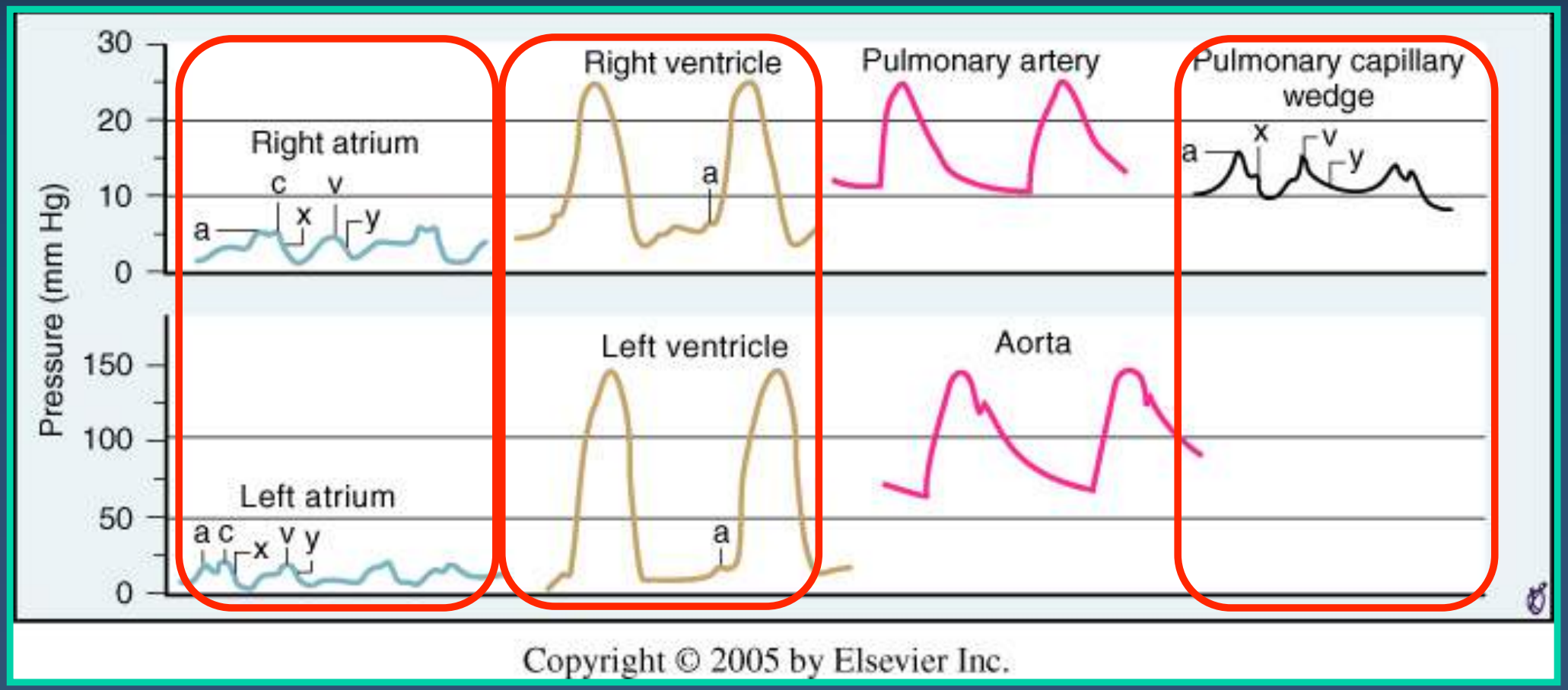


Both

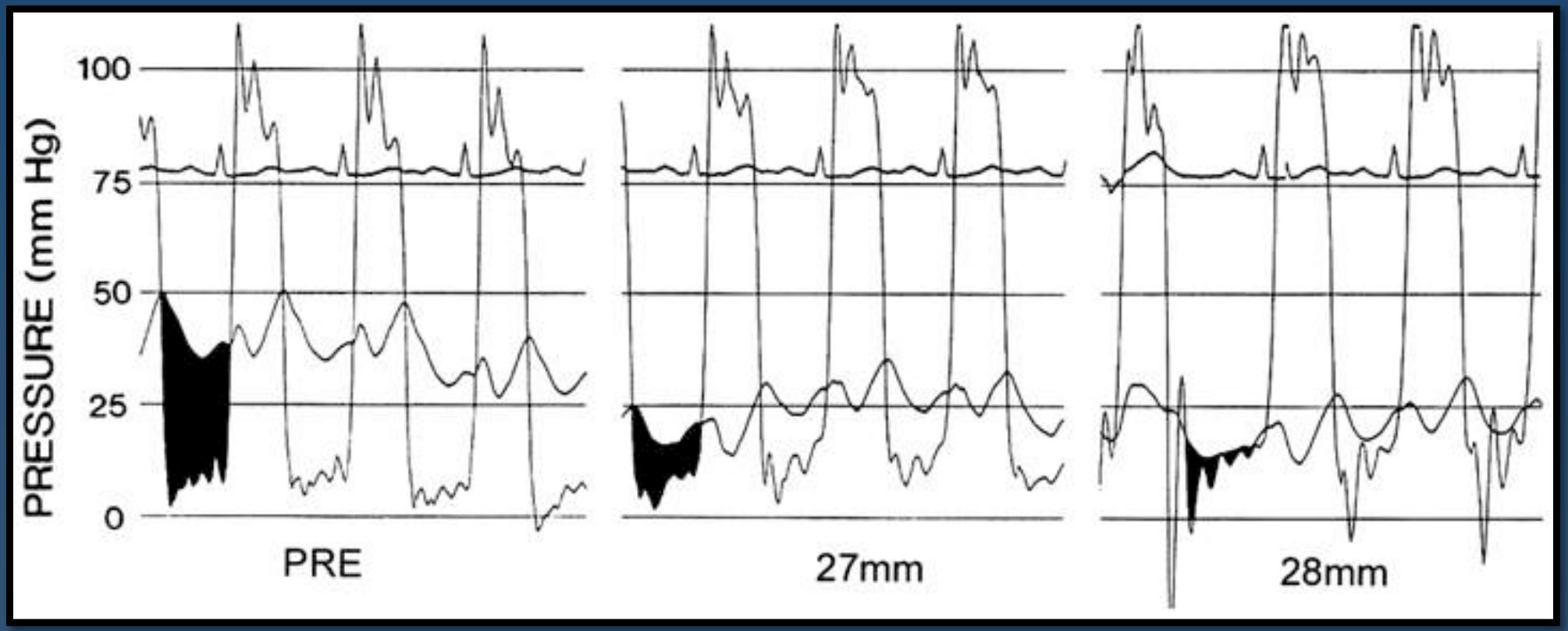
Stenosis

Nombela-Franco, Ribeiro HB, et al. Rev Esp Cardiol. 2013

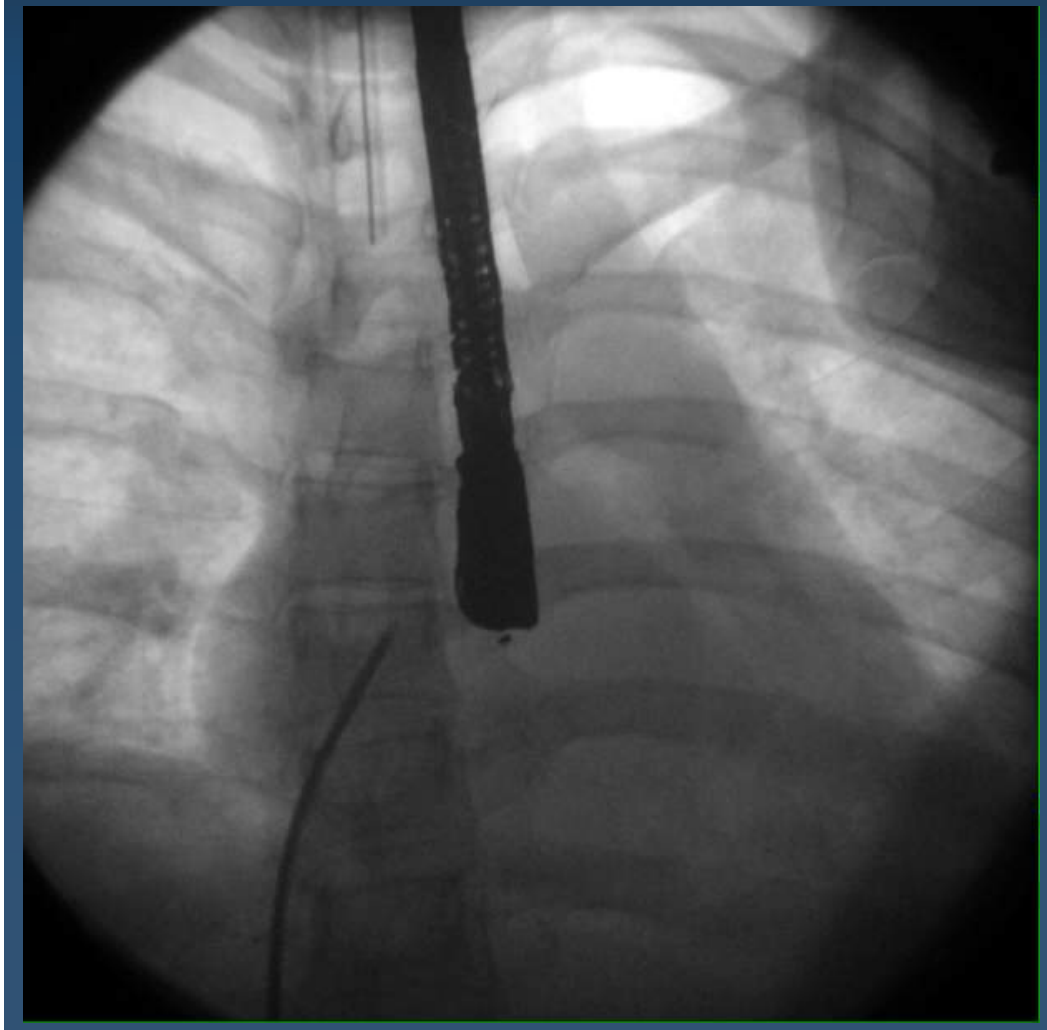
CURVAS DE PRESSÃO



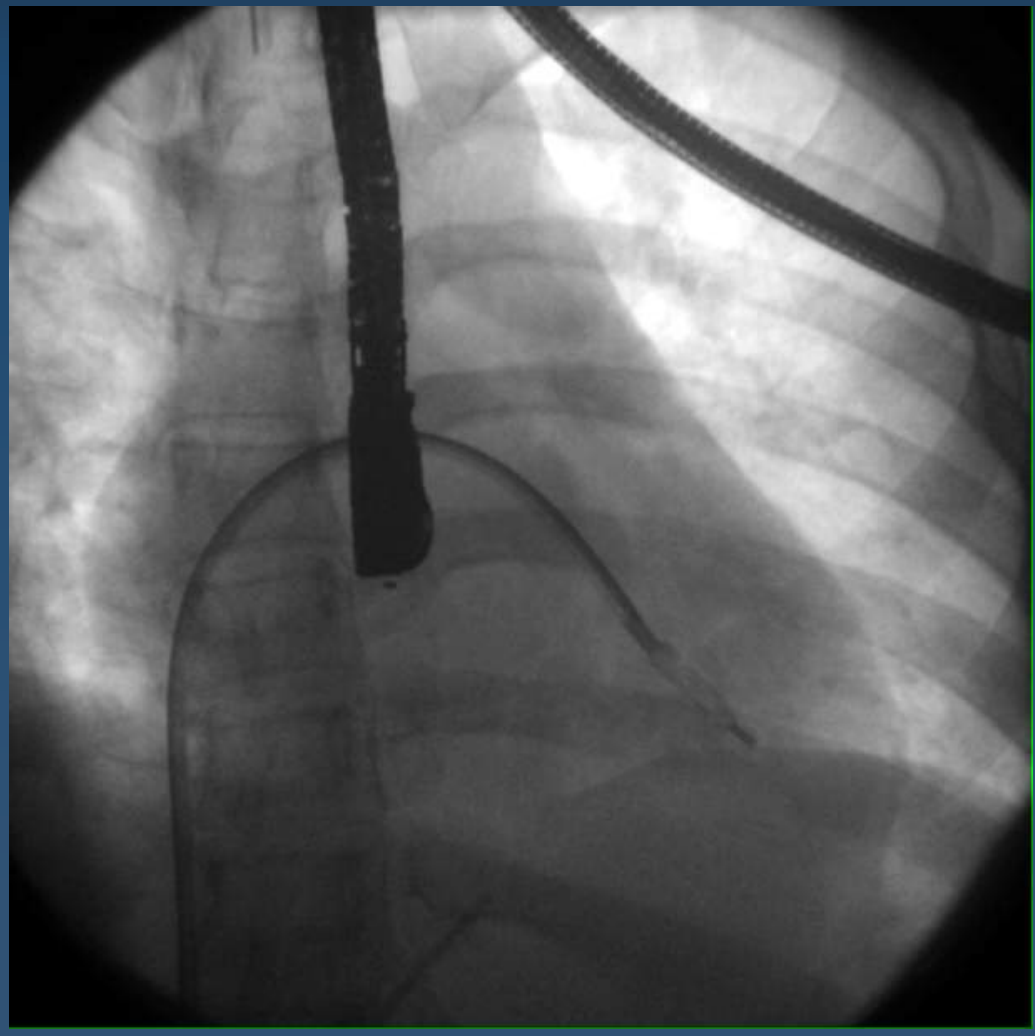
GD ESTENOSE MITRAL PRÉ E PÓS VALVULOPLASTIA



Balão de INOUE – Valvoplastia – Estenose Mitral



Transseptal



Valvoplastia

Indicações de VMPB

- **SINTOMÁTICOS:**
  - Área valvar ≤ 1,5cm²
  - Morfologia favorável e/ou Alto risco cirúrgico
  - Ausência de Trombo nos átrios e Insuficiência Mitral ≤ 2+

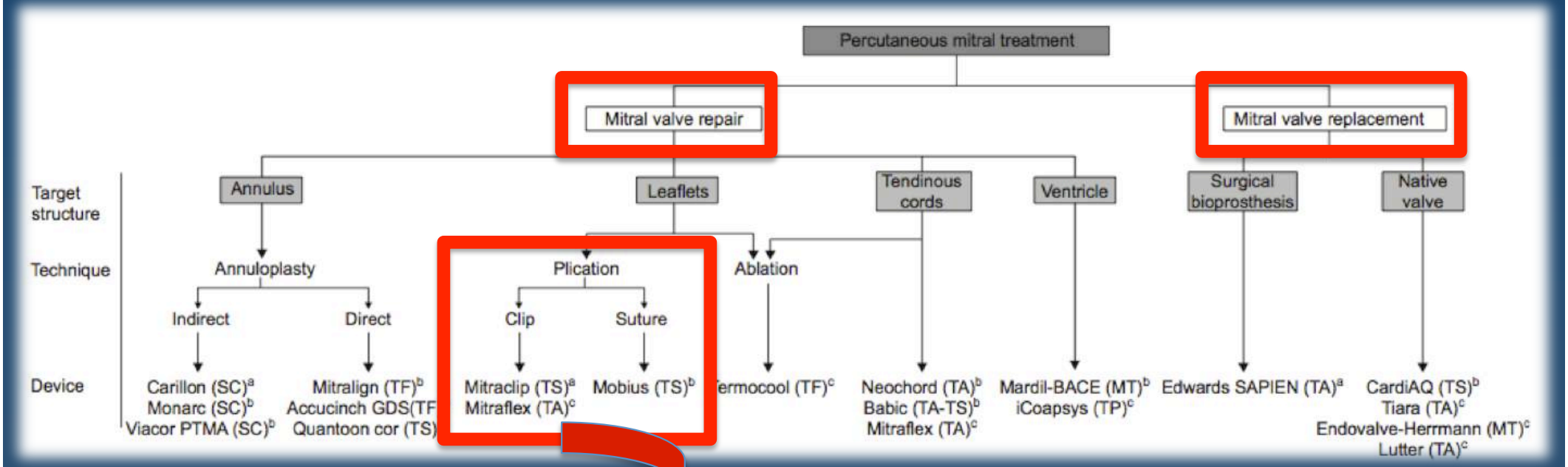
- **ASSINTOMÁTICOS (todos presentes):**
  - Área valvar ≤ 1,5cm²
  - Morfologia favorável
  - PSAP > 50mmHg no repouso ou > 60mmHg no exercício, ou Fibrilação Atrial de início recente
  - Ausência de Trombo nos átrios e Insuficiência Mitral ≤ 2+

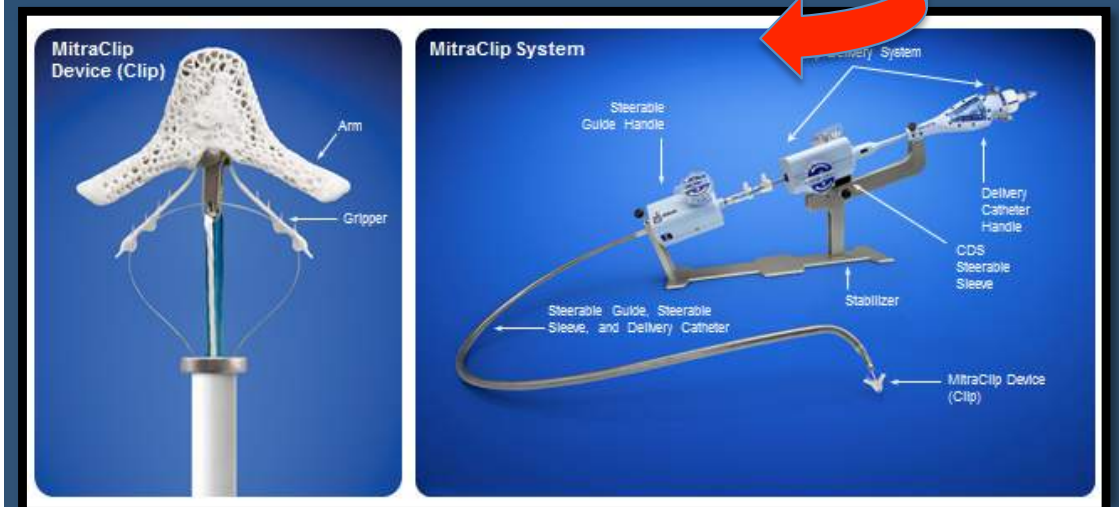
- Score Wilkins*: ≤ 8
- Subvalvar: ≤ 2

*Wilkins GT, et al. Br Heart J 1988;60:2992

Insuficiência Mitral

Minimally Invasive Mitral Therapies
Mitral Insufficiency





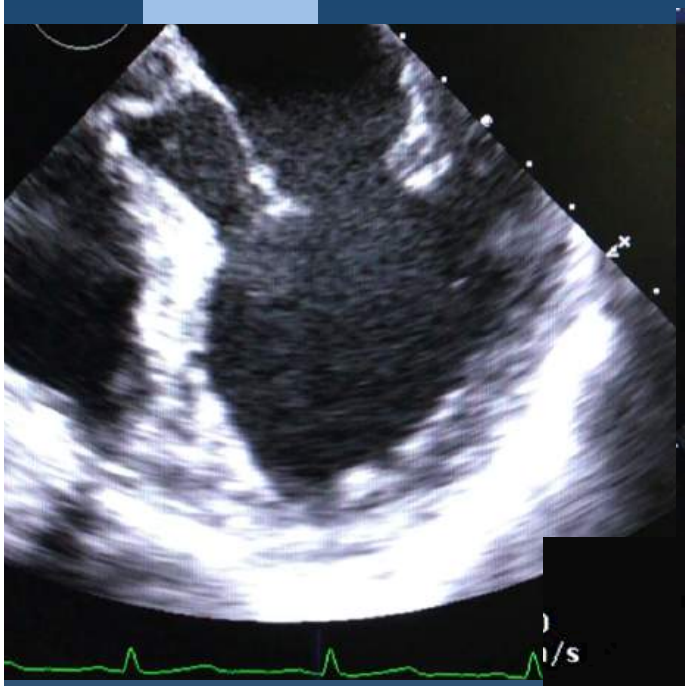
Nombela-Franco, Ribeiro HB, et al. Rev Esp Cardiol. 2013

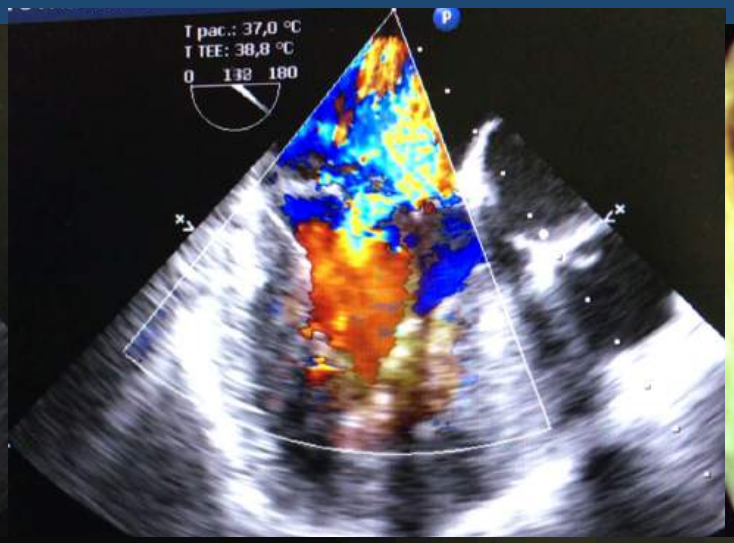
MitraClip Technique

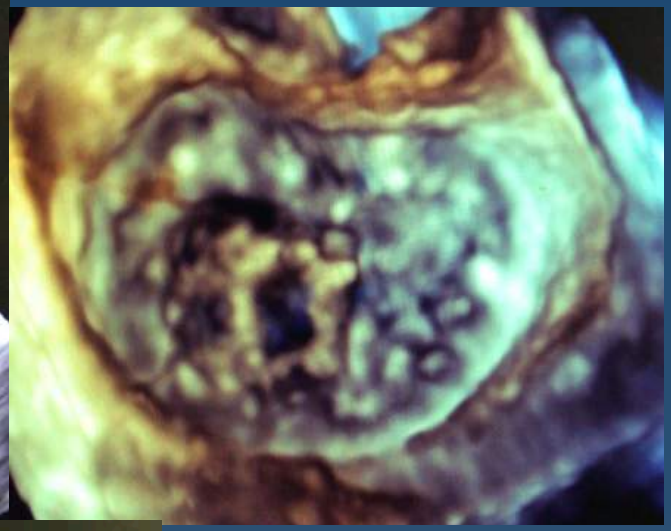
Exemplo de Prolapso - MitraClip

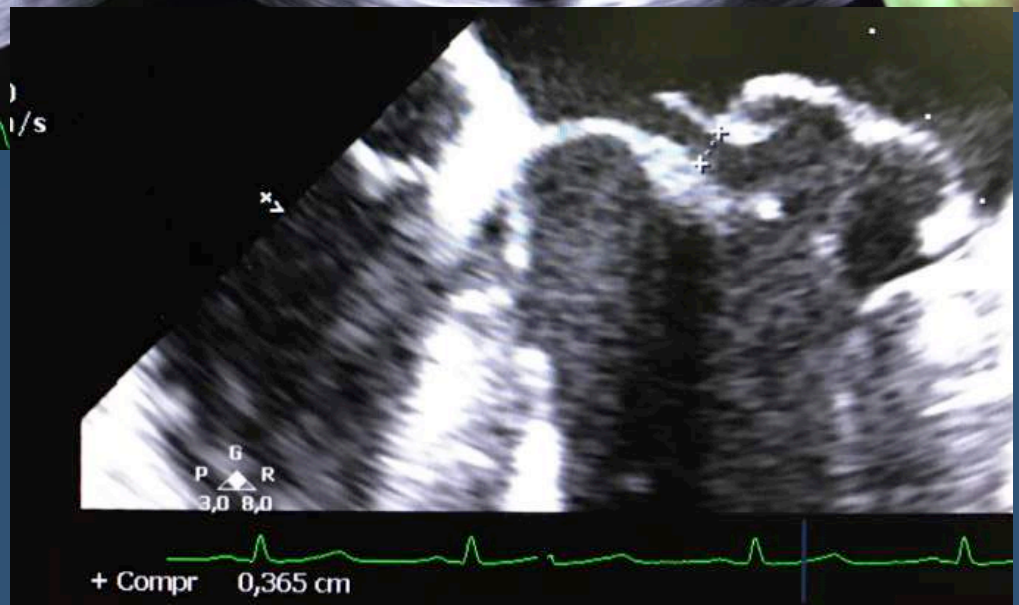
Mulher, 67a, radioterapia prévia de mama (tórax “congelado), neoplasia ativa e bom prognóstico (>2 anos), prolapso P2+ruptura corda (NYHA 3).

Pré





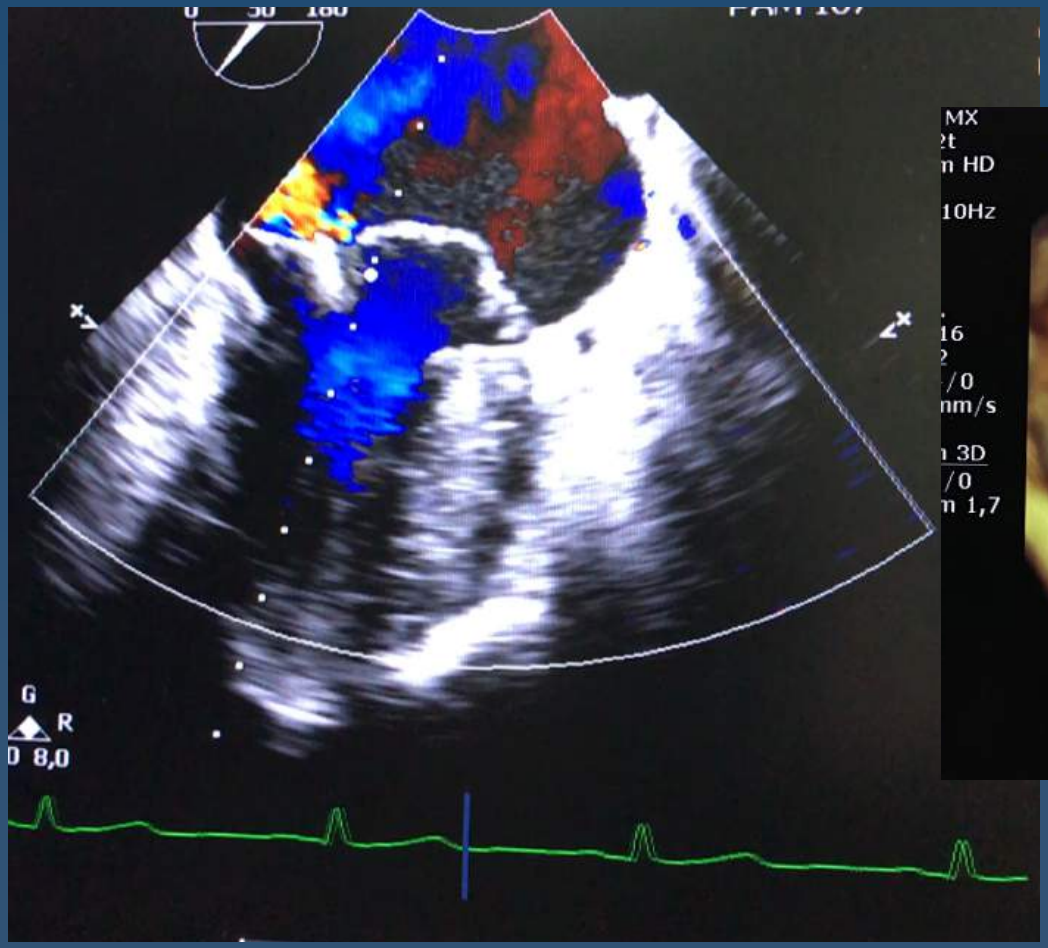


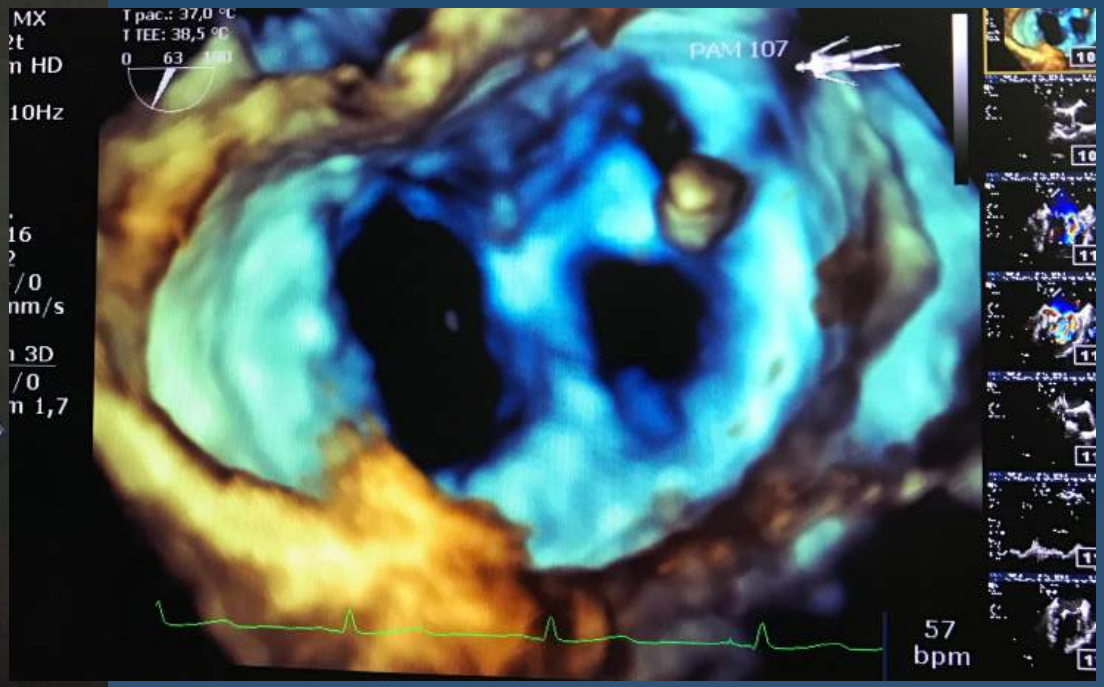


Exemplo de Caso

Mulher, 67a, radioterapia prévia de mama (tórax “congelado), neoplasia ativa e bom prognóstico (>2 anos), prolapso P2+ruptura corda (NYHA 3).

Pós





Worldwide MitraClip Experience

Study	Population	N*
EVEREST I (feasibility)	Feasibility	55
EVEREST II (pivotal)	Roll-in	60
EVEREST II (pivotal)	Randomized	184
EVERES		78
REALISM		899
Compass		66
ACCESS Europe Phase I	Non-randomized	567
ACCESS Europe Phase II	Non-randomized	286
Commercial Use	Commercial	>50,000
Total		**>50,000**

BRAZIL: 120 CASOS
JAN - 2015

EVEREST II Randomized Clinical Trial

279 Patients enrolled at 37 sites

Significant MR (3+ -4+)
73% DMR, 27% FMR
Specific anatomical criteria

Randomized 2:1

Device Group
MitraClip System
N=184

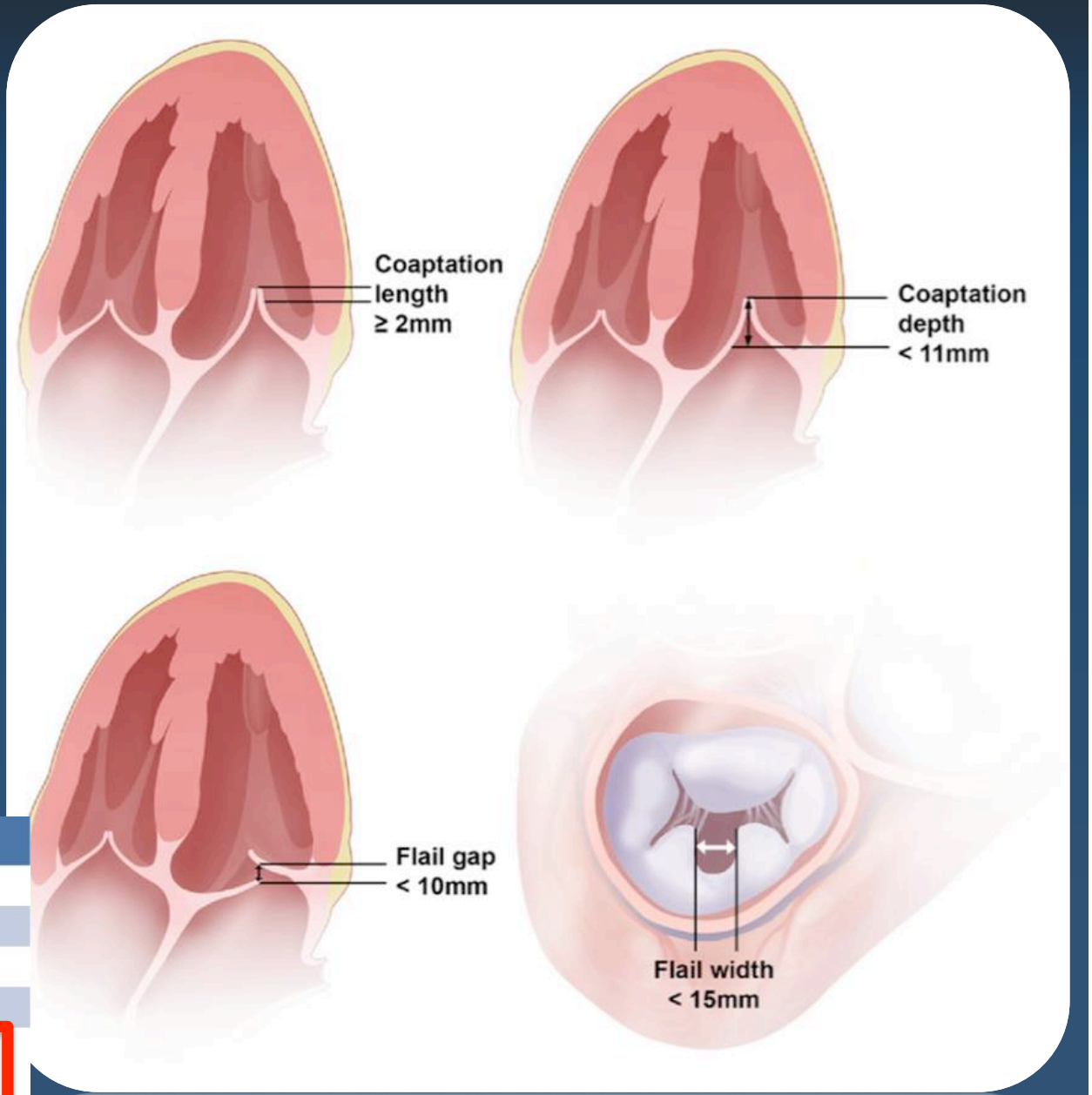
Control Group
Surgical Repair or Replacement
N=95

Echocardiography Core Lab and Clinical Follow-Up
Baseline, 30 days, 6 months, 1 year, 18 months, and annually through 5 years

Feldman T et al. NEJM 2011;364:1395-406

MitraClip Criteria According to EVEREST - II

- No rheumatic MR or SAM
- Jet - origin from the central 2/3 of the valve
- Etiology: degenerative or functional
- Sufficient leaflet tissue for coaptation



DISPOSITIVO MITRACLIP	
Comprimento do Clip Fechado	Máximo de 15 mm
Largura da Pinça em 120º	Mínimo de 17 mm
Largura do Clip em 180º	Máximo de 20 mm
Largura do Braço	Máximo de 5 mm
Comprimento do Braço (Comprimento de Captação)	Máximo de 9 mm

European Heart Journal – Cardiovascular Imaging (2013) **14**, 935–949
doi:10.1093/ehjci/jet060

REVIEW

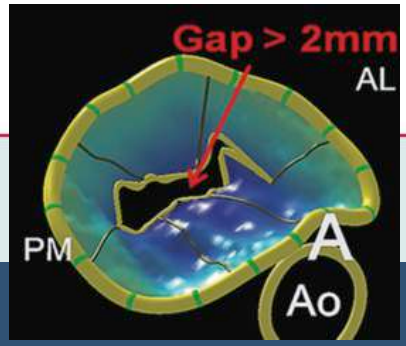
Peri-interventional echo assessment for the MitraClip procedure

Nina C. Wunderlich[1,2]* and Robert J. Siegel[3]*

Table 2 Morphological characterization for MitraClip eligibility

Ideal valve morphology for a MitraClip procedure (*Figure 2*)	Unsuitable valve morphology for a MitraClip procedure (*Figure 3*)
MR originating from the mid portion of the valve (degenerative or functional aetiology)	Perforated mitral leaflets or clefts, lack of primary and secondary chordal support
Lack of calcification in the grasping area	Severe calcification in the grasping area
MVA >4 cm^2	Haemodynamically relevant mitral stenosis
Length of posterior leaflet ≥ 10 mm	Length of posterior leaflet <7 mm
Non-rheumatic or endocarditic valve disease	Rheumatic valve disease—with restriction in systole und diastole or endocarditic valve disease
Flail-width <15 mm, flail-gap <10 mm	
Sufficient leaflet tissue for mechanical coaptation: coaptation depth <11 mm, coaptation length >2 mm	Gap between the leaflets >2 mm

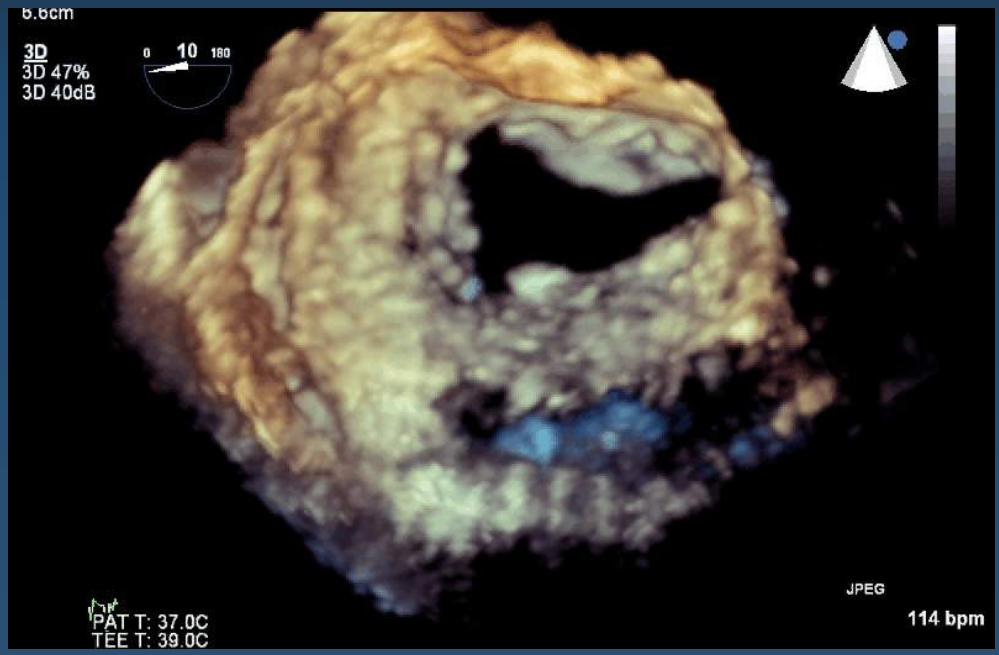
Adapted from the EVEREST criteria and the Abbott training centre experience.
MR, mitral regurgitation; MVA, mitral valve area.



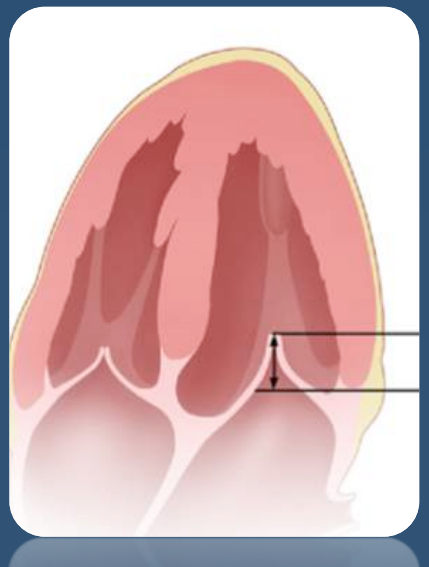
MitraClip Should be Avoided

Barlow's

Cleft



Stenosis



Comprimento Folheto Posterior < 7mm

EVEREST II RCT: MitraClip Device

30 day Modified* Major Adverse Event Rate by Etiology

Intention to Treat

30 Day MAE	# (%) Patients experiencing event	
	Percutaneous (N=180)	Surgery (N=94)
Death	2 (1.1%)	2 (2.1%)
Major St		)
Re-opera		)
Urgent /		)
Myocardi		
Renal Fa		
Deep Wo		
Ventilatic		)
New Ons		
Septicem		
GI Comp		
Transfus		%)
TOTAL		

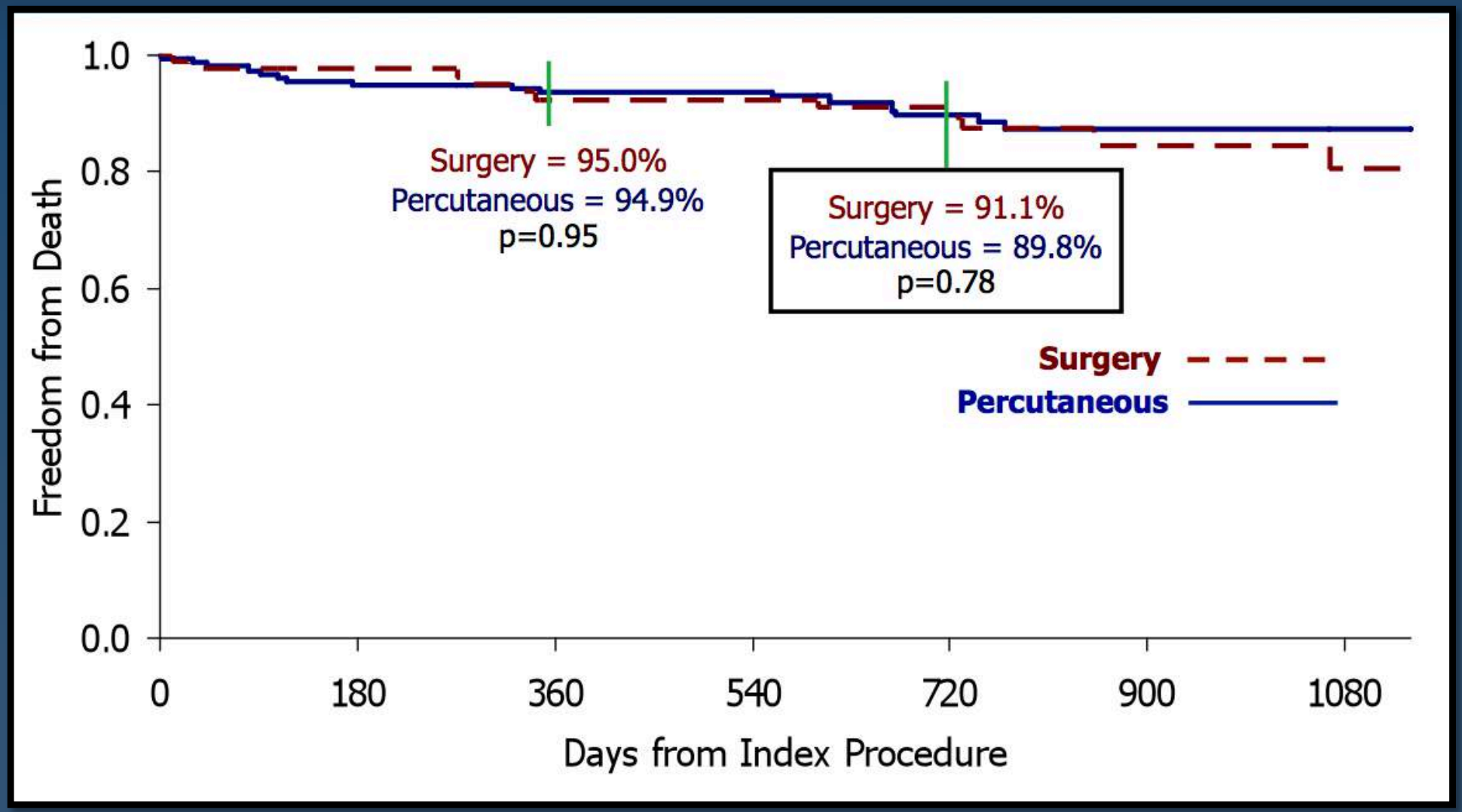
- CLIP IS SAFER THAN SURGERY IN HIGH-RISK PATIENTS;
- Very few events after 30 days

9%

p<0.001; (95% CI: -20.7%, -45.0%)

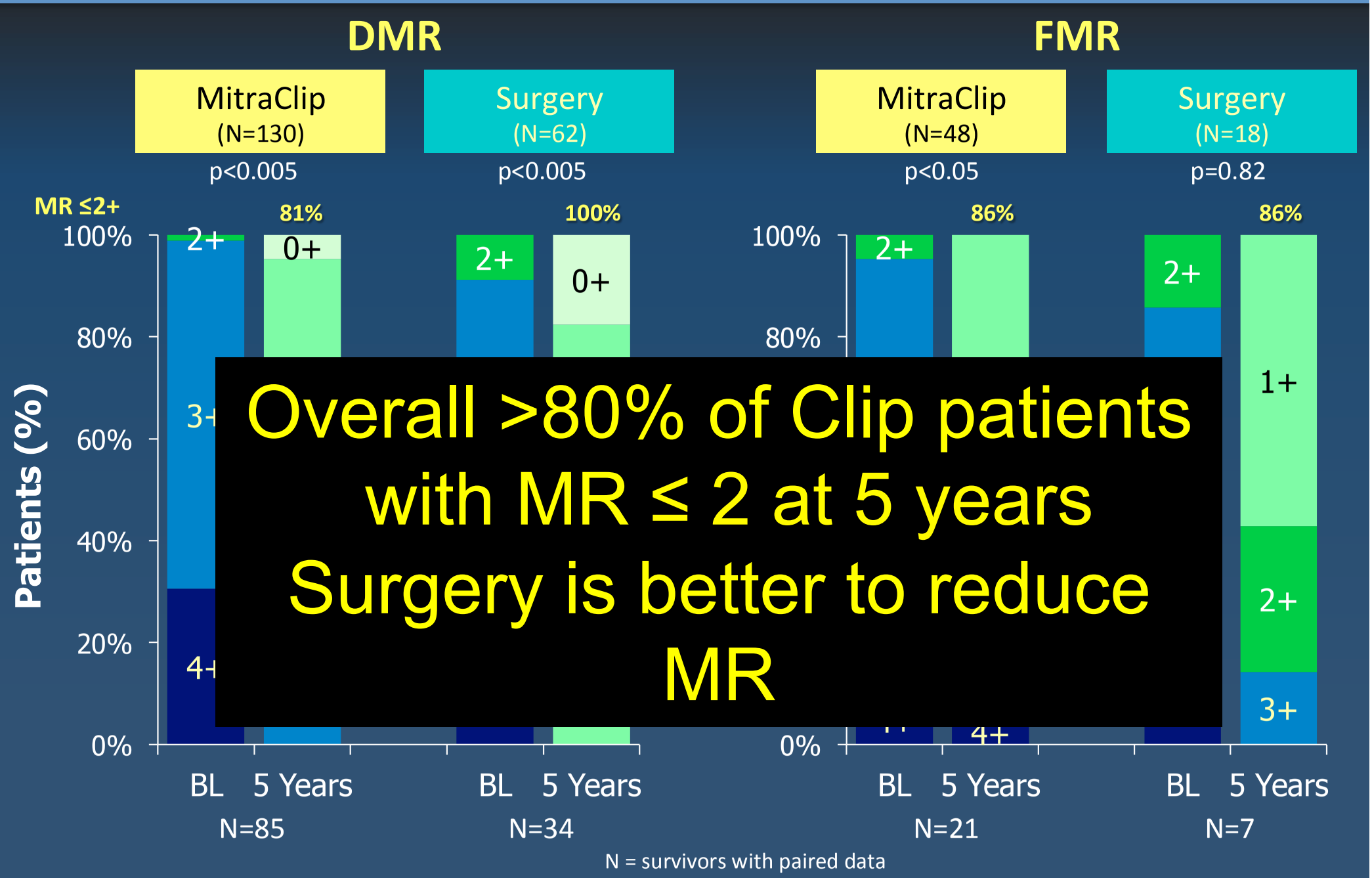
Kaplan-Meier Freedom from Death

Intention to Treat



EVEREST II RCT

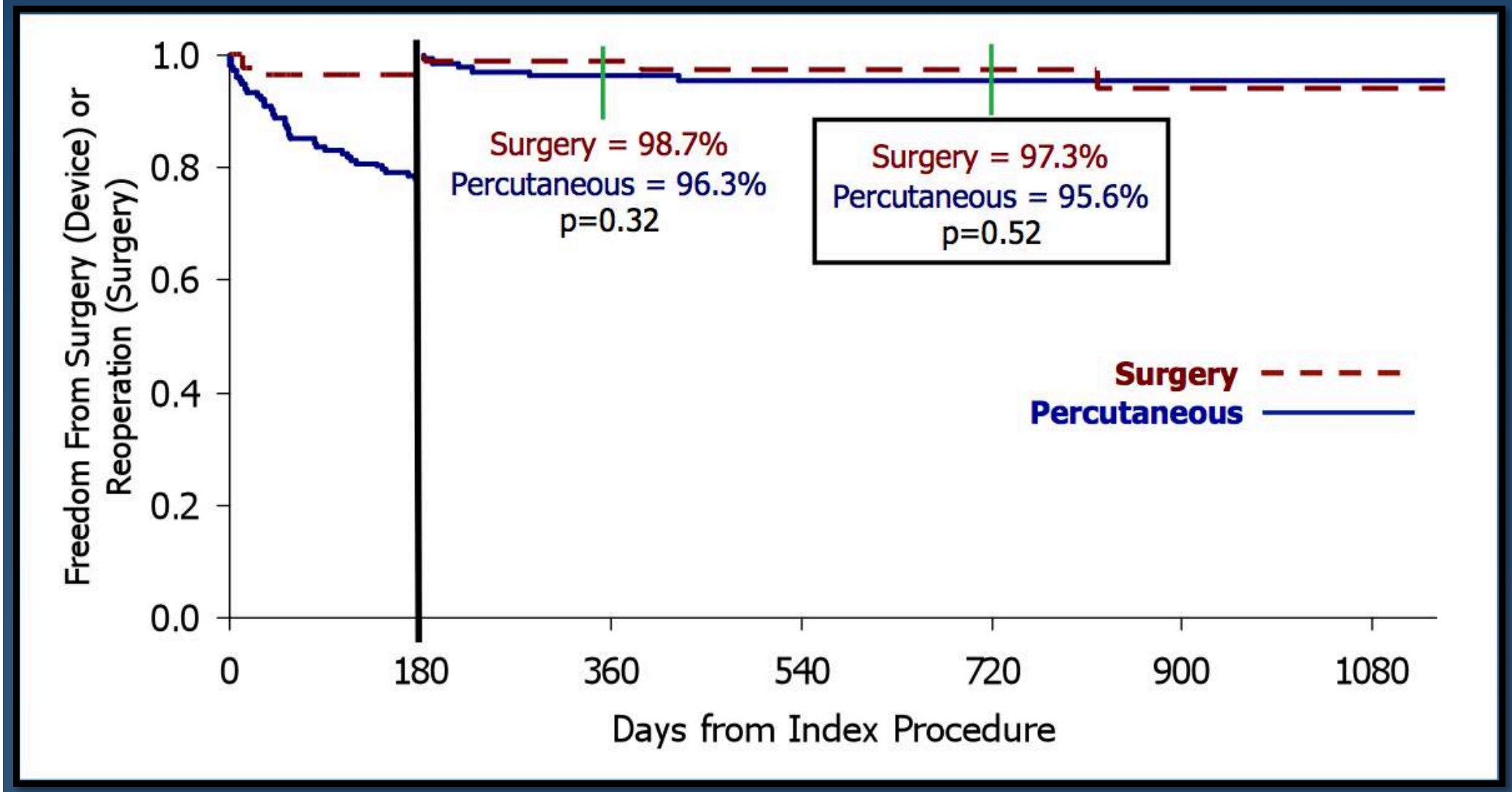
MR Grade at 5 Years According to MR Etiology



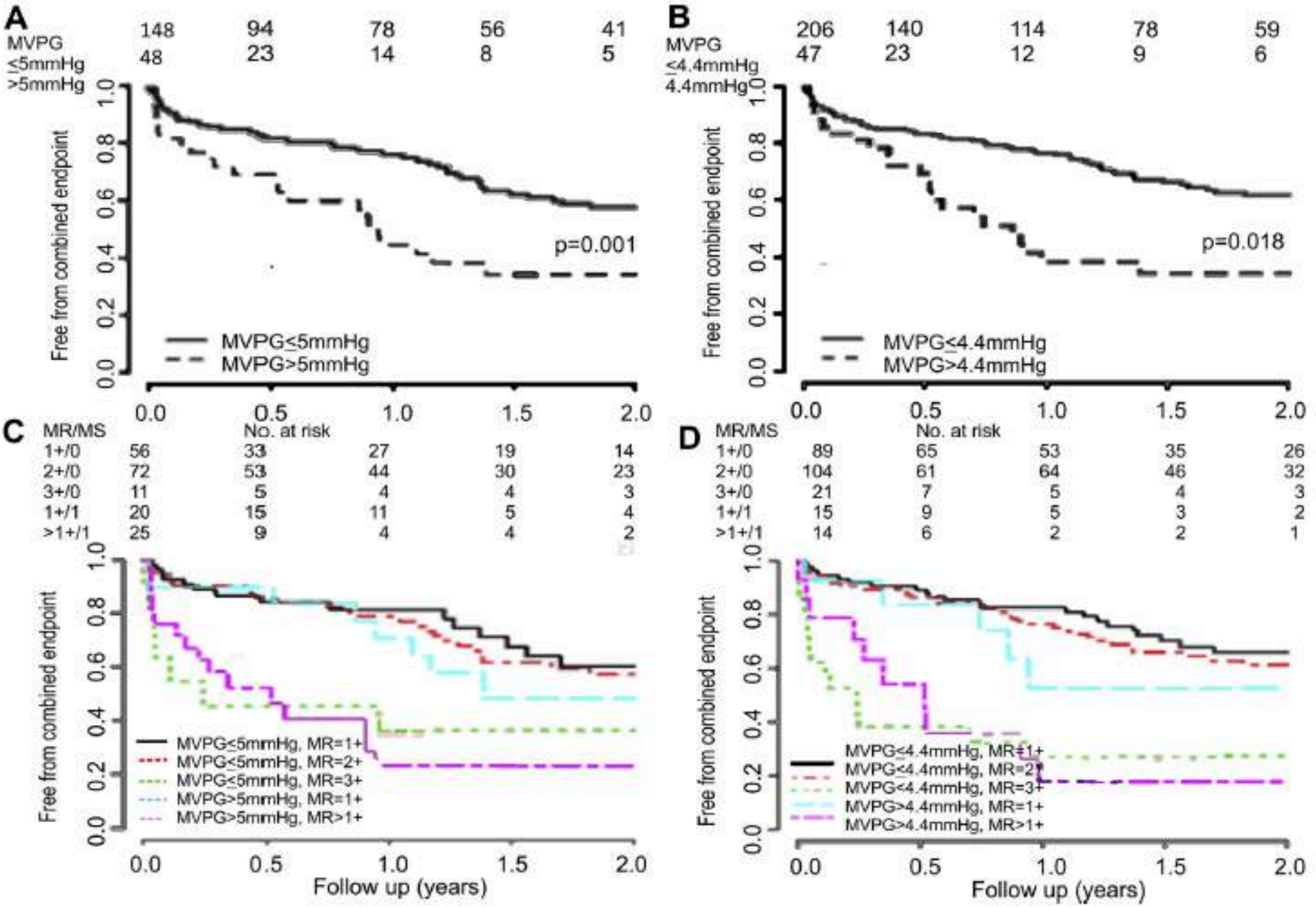
Saibal Kar. EuroPCR 2014

Landmark Analysis of KM Freedom from MV Surgery (Percutaneous)/Re-operation (Surgery)

Intention to Treat



EVEREST II RCT



Neuss M et al. JACC Cardiovasc Interv 2017;10:931-939.

Catheterization and Cardiovascular Interventions 84:129–136 (2014)

Safety and Efficacy of the MitraClip® System for Severe Mitral Regurgitation: A Systematic Review

Kairav Vakil,[1*] MD, Henri Roukoz,[1] MD, Mohammad Sarraf,[2] MD, Balaji Krishnan,[1] MD, Mark Reisman,[3] MD, Wayne C. Levy,[4] MD, and Selcuk Adabag,[5] MD, MS

- Total of 16 studies, including **2,980 patients** (age 73.7 years; 63.3% males)
- Acute procedural success: 91.4%
- Procedural mortality: 0.1%, and 30-day of 4.2%; 1-year 15.8%
- Major procedural adverse outcomes was relatively low with blood transfusion accounting for most events.
- Efficacy: MR ≥ 3 MR reduced from 96.3% to 14.7% ($P < 0.001$), and those with NYHA class III/IV reduced from 83.2% to 23.4% ($P < 0.001$).

Guidelines ACC/AHA - 2017

IIb	**B**	**Transcatheter mitral valve repair may be considered for severely symptomatic patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal GDMT for heart failure (HF) (124).**	2014 recommendation remains current.

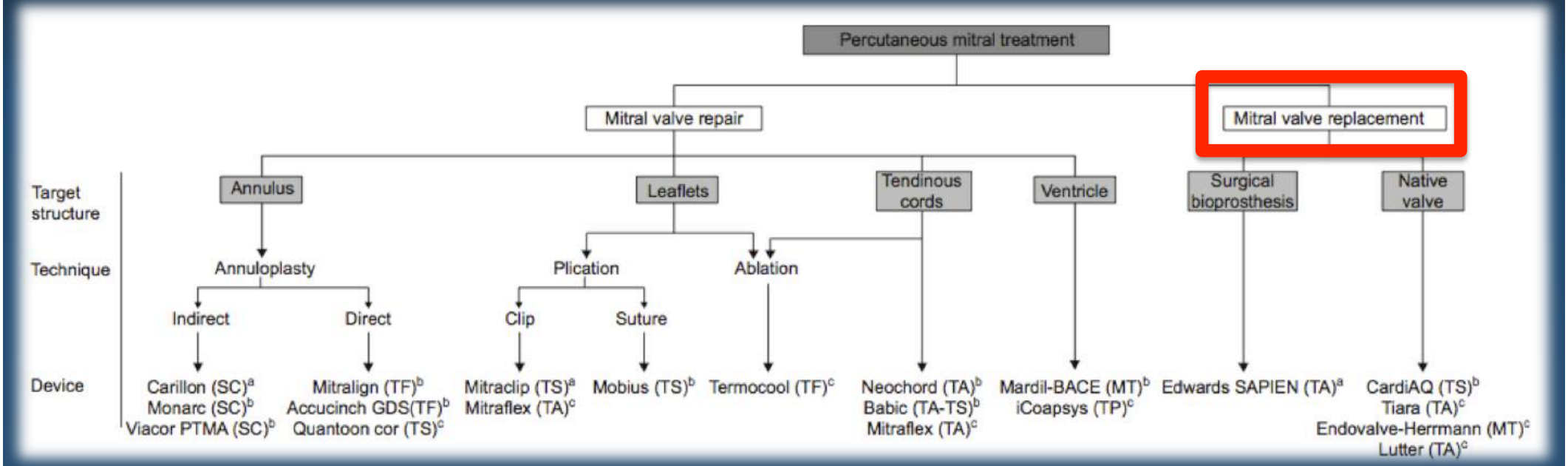
- NYHA III e IV
- Insuficiência mitral primária (Secundária??)
- Anatomia favorável
- Alto risco cirúrgico

Nishimura RA, et al. JACC 2017. doi: 10.1016/j.jacc.2017.03.011.

Comparison of MitraClip RCTs in FMR

	COAPT	RESHAPE-HF
N patients, sites	430 @ 75 US sites	800 @ 75 EU sites
Control arm	Medical Rx	Medical Rx
FMR grade (core lab)	3+ - 4+	3+ - 4+
NYHA class	II, III, or ambulatory IV	III or ambulatory IV
Other inclusion criteria	HF hosp <12 mos or BNP ≥400 pg/ml or nT-proBNP ≥1600 pg/ml	-
LVEF	≥20% - ≤50%	≥15% - ≤40%
LV volumes	LVESD ≤70 mm	LVEDD ≥55 mm
Primary efficacy endpoint (superiority)	Recurrent HF hospitalization (ITT)	Death or recurrent HF hospitalization (ITT)
Primary safety endpoint (noninferiority)	SLDA, device embolizations, endocarditis/MS/device-related complications requiring non-elective CV surgery, LVAD, OHT	-
Health economics	Assessed	Assessed

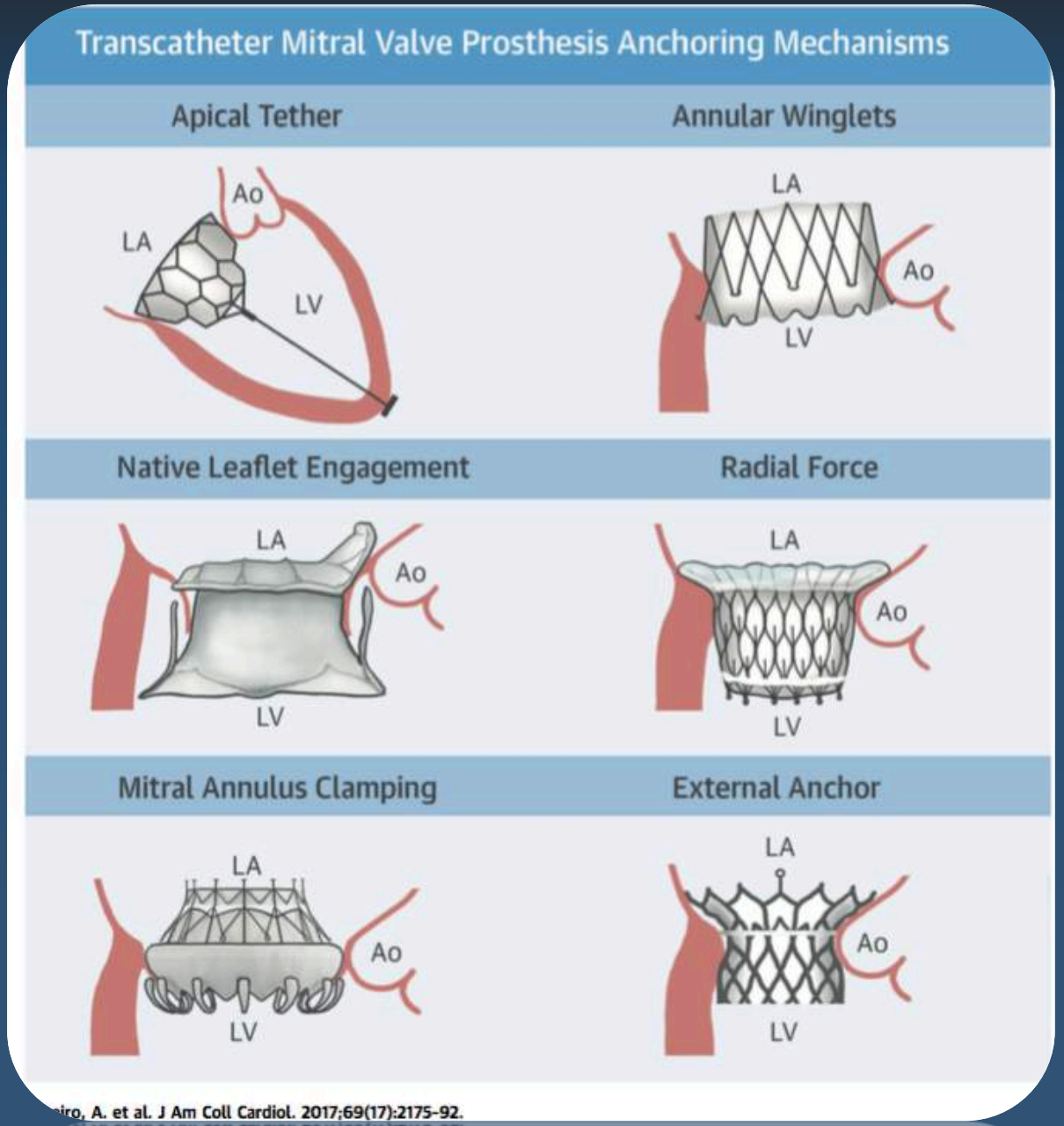
Minimally Invasive Mitral Therapies



- **Secondary MR**
  - Coronary sinus annular devices
  - Direct annuloplasty
  - Septal shortening devices
- **Primary MR**
  - Percutaneous neochords

Nombela-Franco, Ribeiro HB, et al. Rev Esp Cardiol. 2013

Transcatheter Mitral Valve Replacement

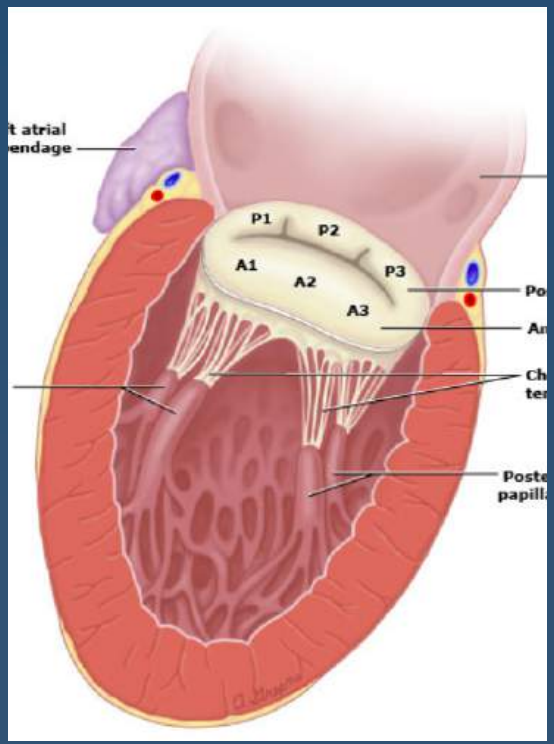


iro, A. et al. J Am Coll Cardiol. 2017;69(17):2175-92.

Regueiro A, et al. JACC 2017

Transcatheter Mitral Valve Replacement

- **TMVR is not TAVR in another position**
  - MV annulus is a more complex 3D structure without the fibrous calcified support with AV and the LA-LV pressure delta is much greater than LV-Ao
- **TA access is still cardiac surgery**
- **Valve Thrombosis**
- **LVOT Obstruction**
- **Peri-Valvular MR**
- **LA Embolization**
- **LCx/CS Compression**
- **LA Injury**



Conclusions - I

- **Balloon valvuloplasty has been consolidated as an important therapy in mitral stenosis with good anatomy**
- **MitraClip results in clinically significant MR reduction** in a majority of patients
- **MitraClip is safer than surgery** with sorter time to recovery but is less effective than surgery for MR reduction
- **Therefore MitraClip is ideally suited for poor surgical candidates with appropriate anatomy**

Conclusions - II

- For patients with **symptomatic functional MR,** MitraClip will be better evaluated in the **COAPT** and **RESHAPE-HF** randomized trials
- Newer devices have potential but are a long way off
- TMVR may be the future but given the safety profile of MitraClip there may be a roll for both technologies

X