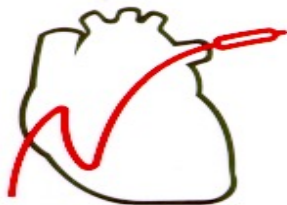


E. Infante de Oliveira

Serviço de Cardiologia
HSM, CHLN, CAML

UNIDADE DE



CARDIOLOGIA
DE
INTERVENÇÃO



HOSPITAL DE
SANTAMARIA

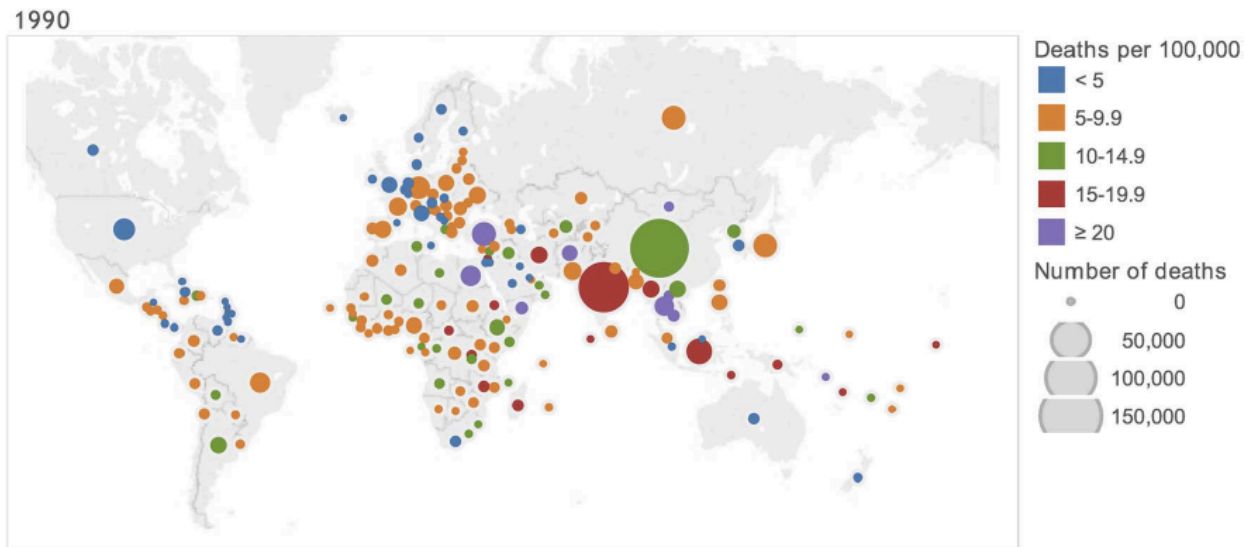
Novas Fronteiras em Cardiologia

Insuficiência mitral, onde estamos e para onde vamos?

17 de Fevereiro de 2017

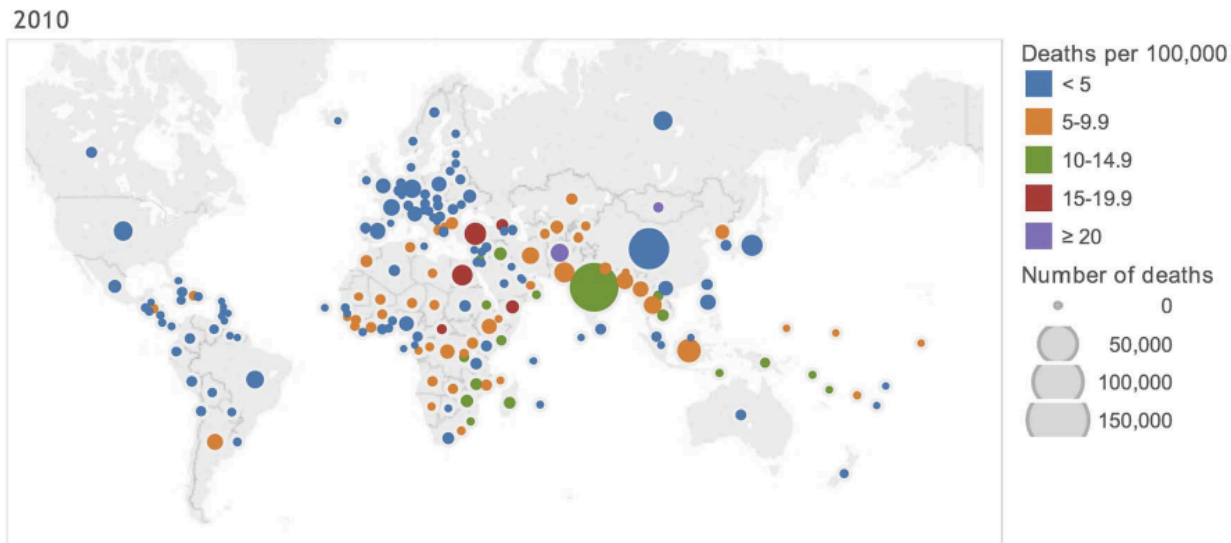
Modern Epidemiology of Heart Valve Disease

(rheumatic heart disease mortality rate)

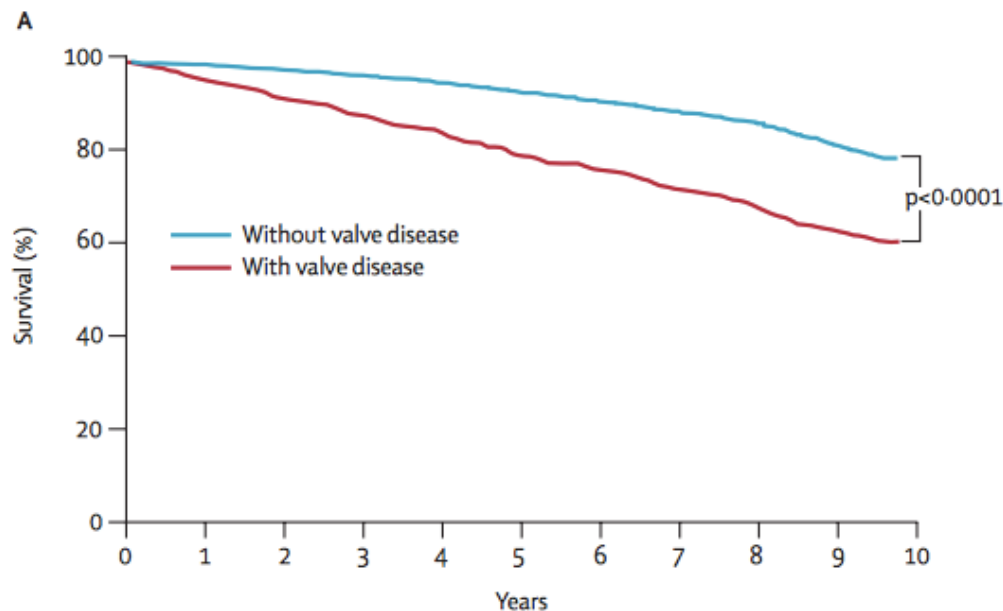
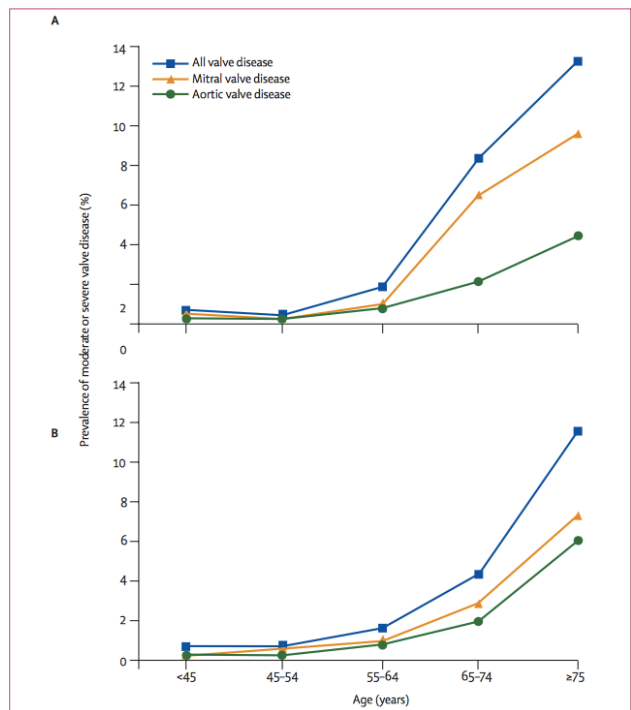


Modern Epidemiology of Heart Valve Disease

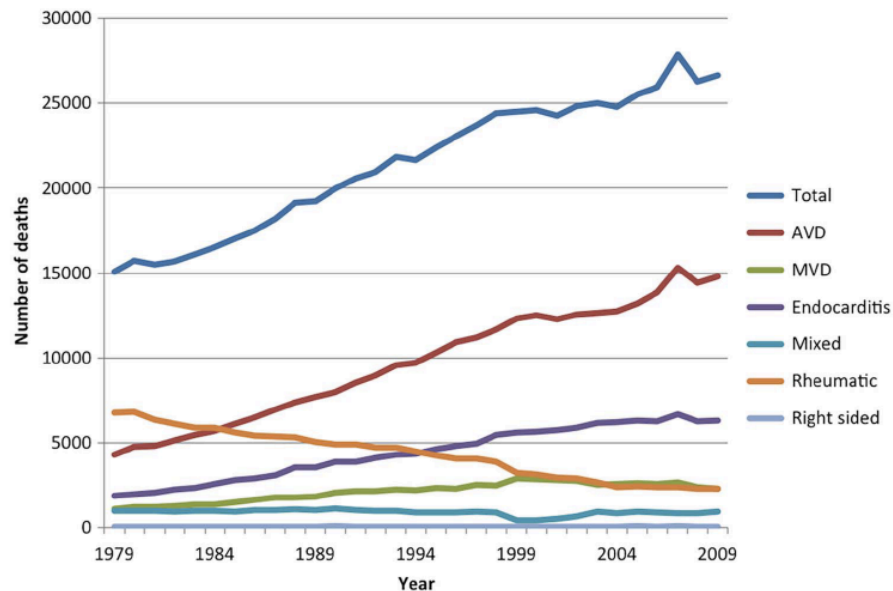
(rheumatic heart disease mortality rate)



Burden of valvular heart diseases in the developed countries



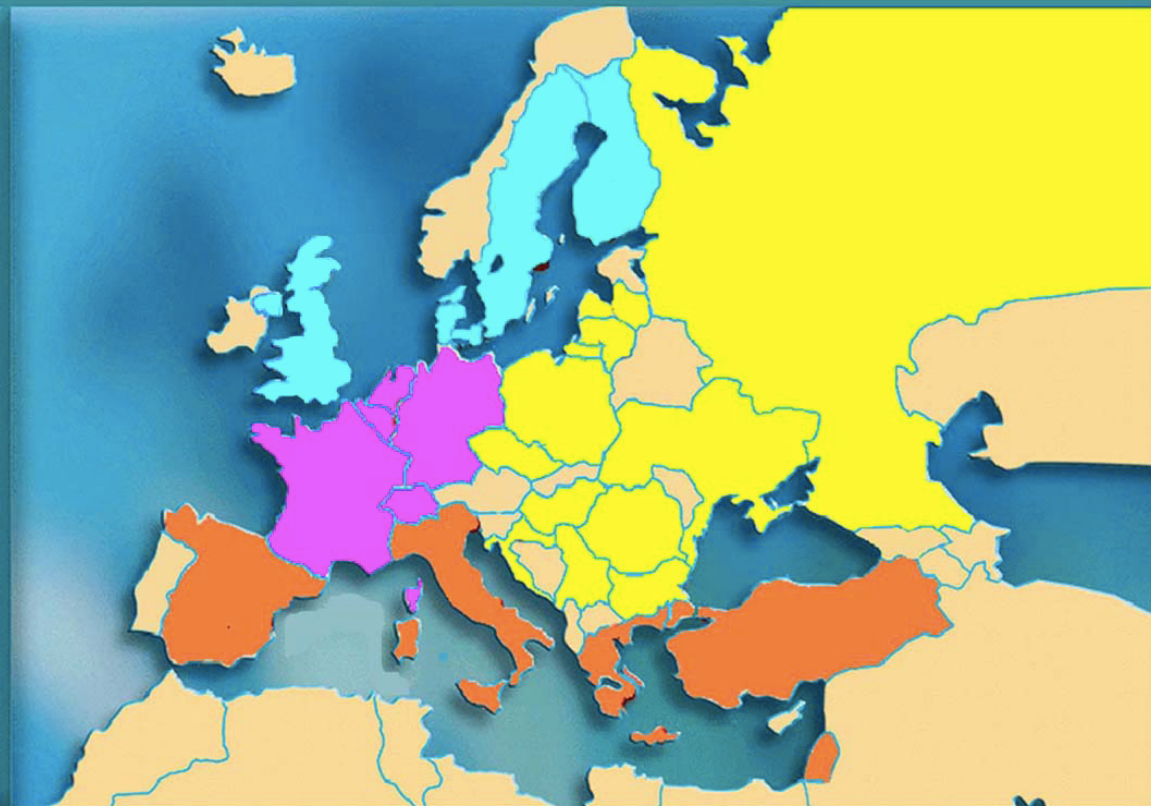
Modern Epidemiology of Heart Valve Disease



Euro Heart Survey on Valvular Heart Disease

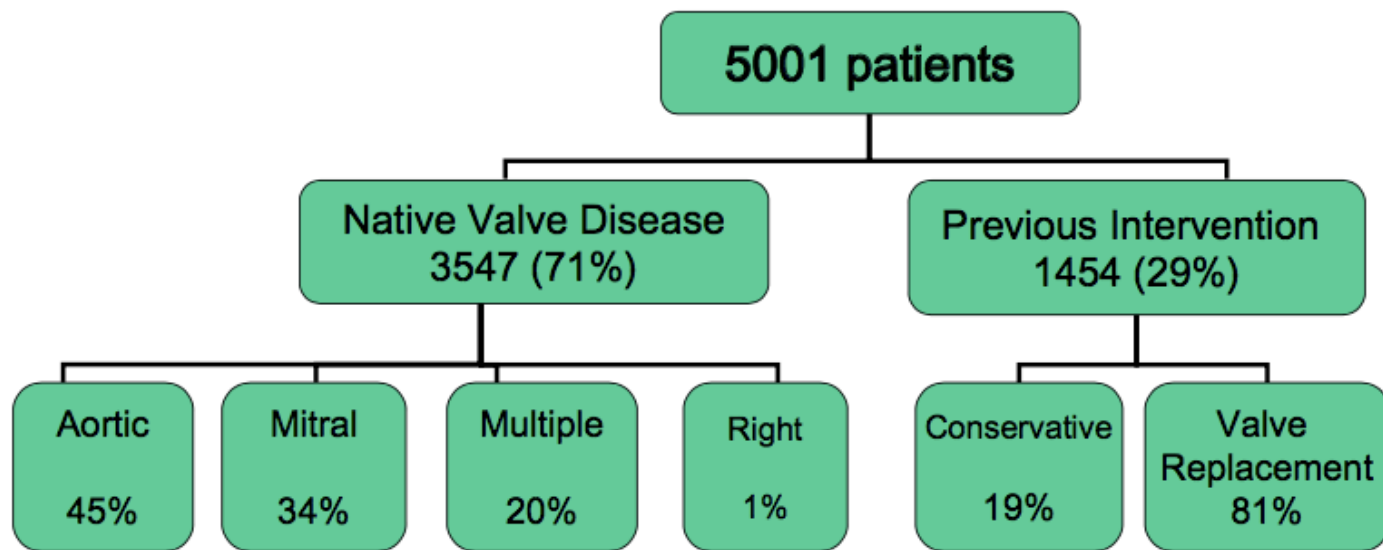


Euro Heart Survey

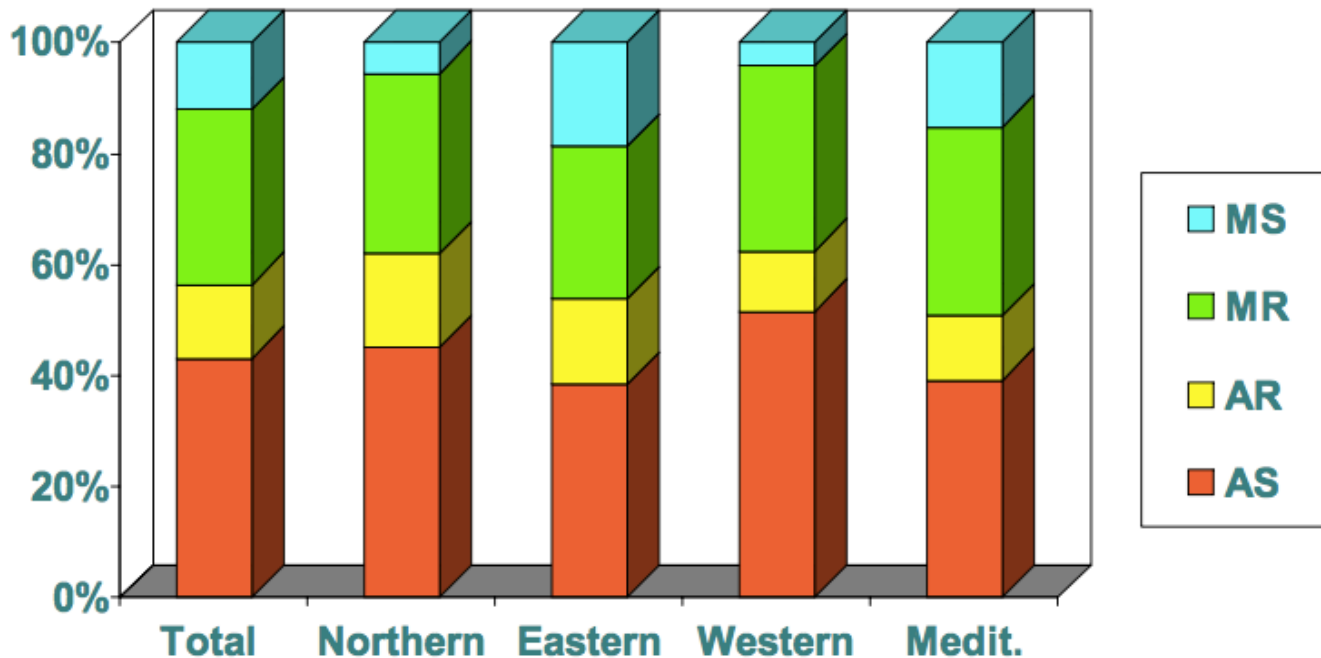


Investigating Centres

Type of VHD

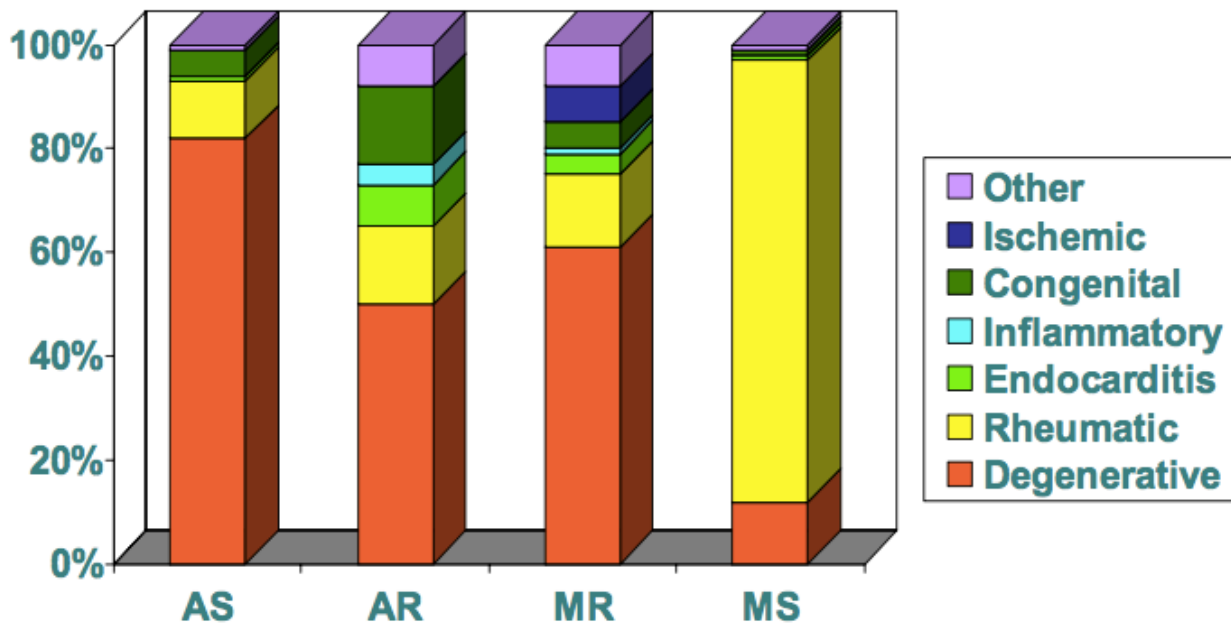


Single Native Valve Disease



Single Native Valve Disease

Etiology



Functional Mitral Regurgitation

Table 1. Prevalence of secondary mitral regurgitation in chronic heart failure with left ventricular dysfunction

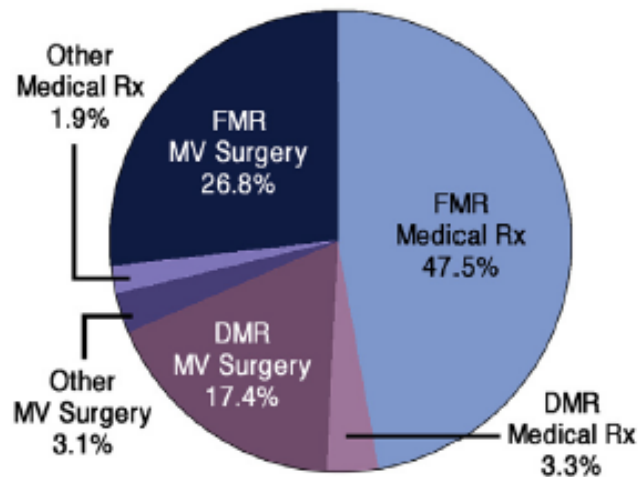
	n	Mean age, years	Mean LVEF (%)	Recruitment	Ischemic heart disease, %	MR, %	MR severity
Varadarajan et al. ³²	370	65	21	Heart failure clinic	39	94	15% grade 3/4; 14% grade 4/4
Rossi et al. ³³	1256	67	32	Hospitalized patients in 4 centres	61	73	24% severe*
Agricola et al. ³⁴	198	66	33	Hospital cohort	0	65	50% severe*
Bursi et al. ³⁵	469	60	30	Outpatient clinic in 2 centres	36	95	30% grade 3/4; 14% grade 4/4
Deja et al. ³⁶	1212	60	27	Randomized trial (99 centres); indication for CABG and EF < 35%	100	64	18% moderate or severe

CABG, coronary artery bypass grafting; EF, ejection fraction; LVEF, left ventricular EF; MR, mitral regurgitation.

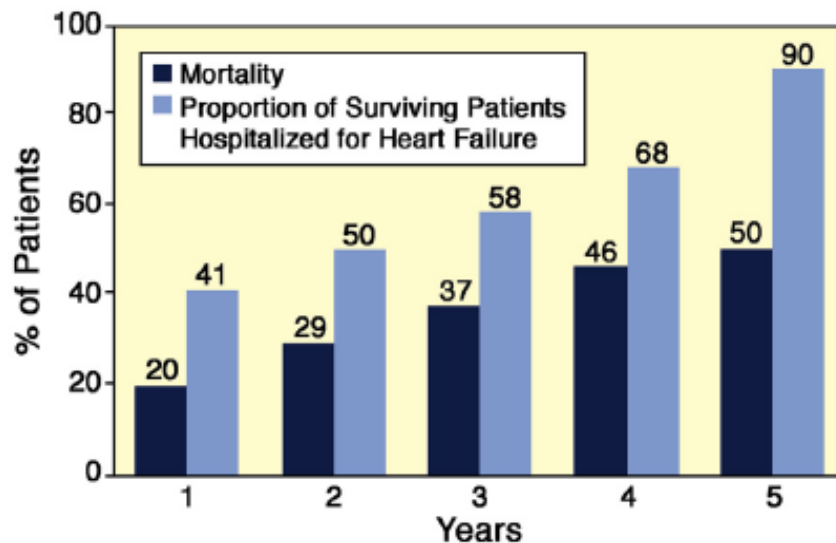
* Effective regurgitant area $\geq 0.20 \text{ cm}^2$ and/or regurgitant volume $> 30 \text{ mL}$.

Outcomes of Unoperated Severe MR

A Medically treated patients with severe MR



B



Mitral Regurgitation in Portugal

- **EPICA study - 130.000 patients with HF and compromised EF**
- **considering a 4% prevalence of severe MR**
- **we should expect a total of 5.200 patients**

Prevalence of chronic heart failure in Southwestern Europe: the EPICA study. Eur J Heart Fail. 2002 Aug;4(4):531-9.
Mitral regurgitation in patients with advanced systolic heart failure. J Card Fail. 2004;10:285-91.

Heart Failure Devices in Portugal

- Portuguese National Registry on Cardiac Electrophysiology, 2013 and 2014
- ICDs 779 / CRTs 477 – total 1256

(moderate or severe MR in 1/3 = 414 patients)

Mitral Disease in Portugal

- 2.572 valvular surgeries in 2015 (Portugal)
- 15% MR surgeries (386 patients) according w/ European Survey

	2011	2012	2013	2014	2015	Δ 2011-15
Cirurgia CARDÍACA - Total	5918	5937	6266	6114	6403	8,20%
Coronárias	1864	1779	1851	1890	1724	-7,51%
c/ CEC	1024	938	913	907	823	
s/ CEC	840	841	938	983	901	
Valvulares	1923	2182	2161	2349	2572	33,75%

Transcatheter MV Repair: **Device Landscape 2016**

Edge-to-edge

- MitraClip***
- MitraFlex

Coronary sinus annuloplasty

- Cardiac Dimensions Carillon**
- Cerclage annuloplasty

Direct annuloplasty and basal ventriculoplasty

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

MV replacement

- Edwards CardiAQ*
- Edwards Fortis*
- Neovasc Tiara*
- Abbott Tendyne*
- Medtronic Intrepid*
 - HighLife*
 - MVValve*
 - Cephea
- NCSI NaviGate
 - St. Jude
- Micro Interventional
- Valtech CardioValve
 - ValveXchange
 - MitrAssist
- Braile Quattuor
 - Caison
- Direct Flow
- Sinomed Accufit

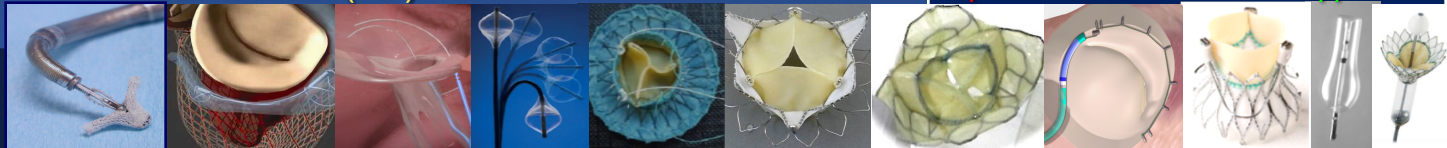
MV replacement (cont)

- MitralHeal
- HT Consultant Saturn
- Lutter valve
- Transcatheter Technologies
 - Tresillo
 - Venus
 - Verso
- Transmural Systems

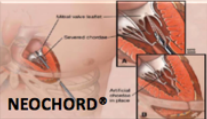
Other approaches

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

*In patients *CE mark *FDA approved



Devices for TMV repair with CE approval

Device	Target of therapy	Year of CE mark	Current number of patients treated	Surgical background	Vascular access
 MITRACLIP®	Leaflet coaptation	2008	> 40.000	Edge-to-edge repair	Transfemoral
 NEOCHORD®	Chordae implantation	2013	> 300	Chordae implantation	Transapical
 CARILLON®	Indirect annuloplasty	2009	> 100	No	Transjugular
 CARDIOBAND®	Direct annuloplasty	2015	> 100	Flexible ring	Transfemoral
 MITRALIGN®	Direct annuloplasty	2016	> 100	Commissuroplasty	Transarterial retrograde

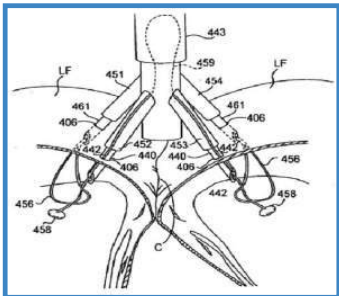
TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

Mitraclip Therapy: a new hope

The original Alfieri concept



- Double-orifice suture technique developed by Prof. Ottavio Alfieri
- First published results in 1998 illustrated proven benefit in selected pathologic conditions

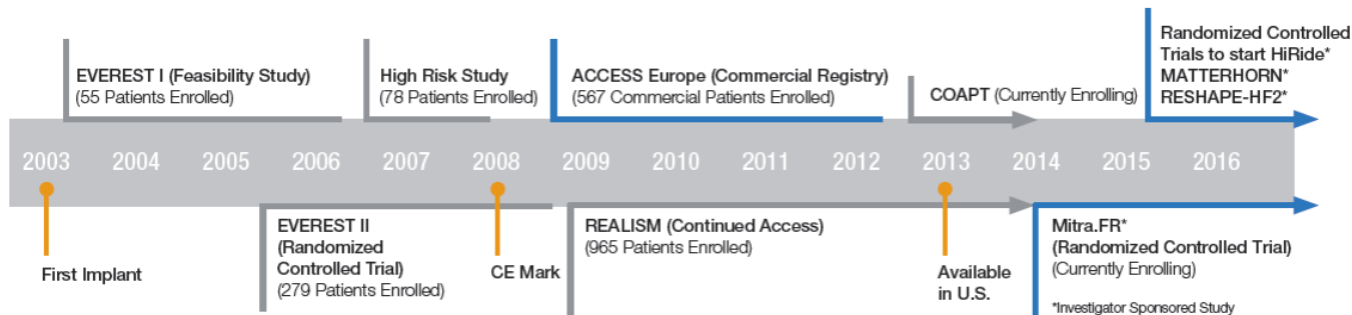


- Dr. Fred St. Goar, interventional cardiologist had patient successfully treated with edge-to-edge surgery
- Conceived several ideas for percutaneous valve repair
- Founded Evalve 1999 in to develop minimally invasive approach to treat mitral regurgitation based on the Alfieri technique

TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

Mitraclip Therapy: a new hope

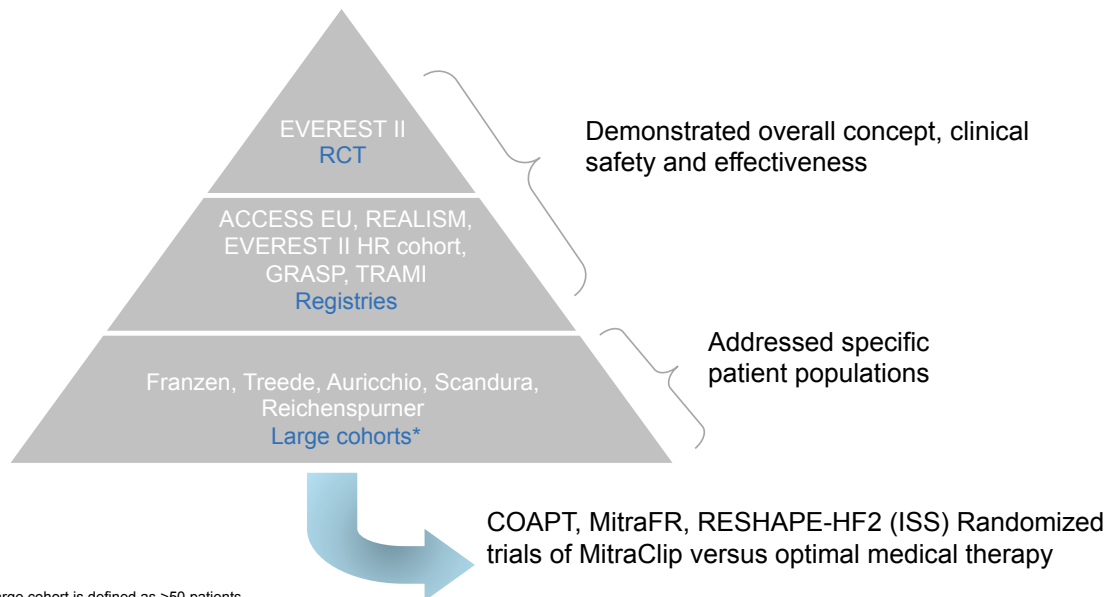
The way to the mainstream



TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

Mitraclip Therapy: a new hope

Growing Body of Clinical Evidence



*large cohort is defined as >50 patients

Saikus et al. TRAMI Registry EHJ 2012; Grasso et al. GRASP Registry Am J Cardiol. 2013 May
Treede H et al. J Thorac Cardiovasc Surg. 2011 Oct 26; Auricchio et al. PERMIT-CARE J Am Coll Cardiol. 2011; 58(21):2183-9; Scandura et al. J. Am. S. Echo 2012; / Franzen O et al. Eur J Heart Fail 2011; 13(5):569-576
Reichenspurner, H. et al. Eur J Cardiothoracic Surgery. 2013; July 17;

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

“Percutaneous edge-to-edge procedure may be considered in patients with symptomatic severe primary MR who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a ‘heart team’, and have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C).”

“The percutaneous mitral clip procedure may be considered in patients with symptomatic severe secondary MR despite optimal medical therapy (including CRT if indicated), who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a team of cardiologists and cardiac surgeons, and who have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C).” *page 25*

ACC/AHA 2014 Guidelines for the Management of Patients With Valvular Heart Disease

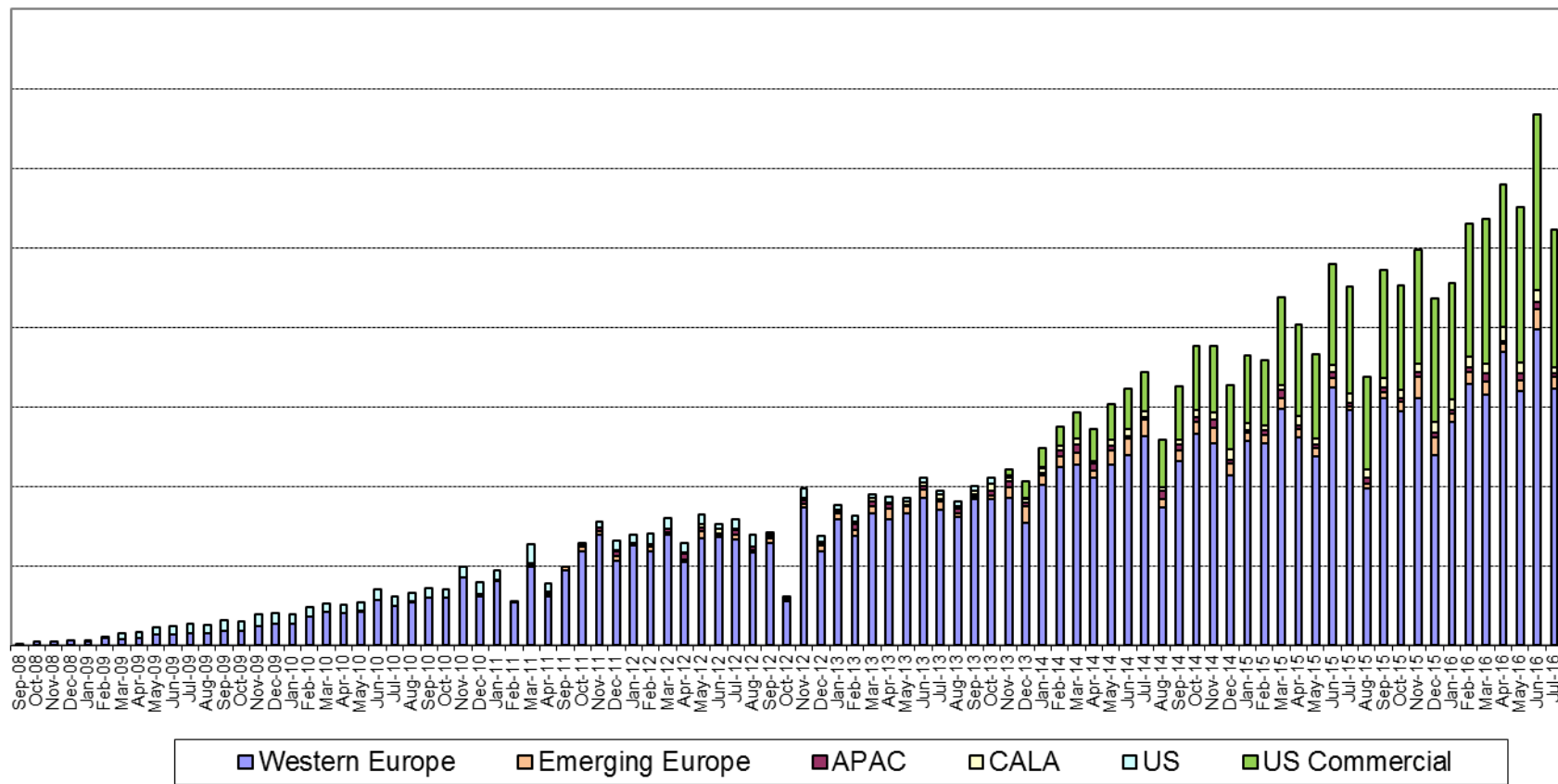
Nishimura, RA et al.

2014 AHA/ACC Valvular Heart Disease Guideline

MV repair is reasonable in asymptomatic patients with chronic severe primary MR (stage C1) with preserved LV function (LVEF >60% and LVESD <40 mm) in whom the likelihood of a successful and durable repair without residual MR is >95% with an expected mortality rate of <1% when performed at a Heart Valve Center of Excellence	IIa	B	(149, 203, 205-209)
MV repair is reasonable for asymptomatic patients with chronic severe nonrheumatic primary MR (stage C1) and preserved LV function in whom there is a high likelihood of a successful and durable repair with 1) new onset of AF or 2) resting pulmonary hypertension (PA systolic arterial pressure >50 mm Hg)	IIa	B	(154, 205, 210-215)
Concomitant MV repair is reasonable in patients with chronic moderate primary MR (stage B) undergoing cardiac surgery for other indications	IIa	C	N/A
MV surgery may be considered in symptomatic patients with chronic severe primary MR and LVEF ≤30% (stage D)	IIb	C	N/A
MV repair may be considered in patients with rheumatic mitral valve disease when surgical treatment is indicated if a durable and successful repair is likely or if the reliability of long-term anticoagulation management is questionable	IIb	B	(194, 202, 203)
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities	IIb	B	(216)
MVR should not be performed for treatment of isolated severe primary MR limited to less than one half of the posterior leaflet unless MV repair has been attempted and was unsuccessful	III: Harm	B	(195-198)

Global MitraClip Experience

Implantation Procedures

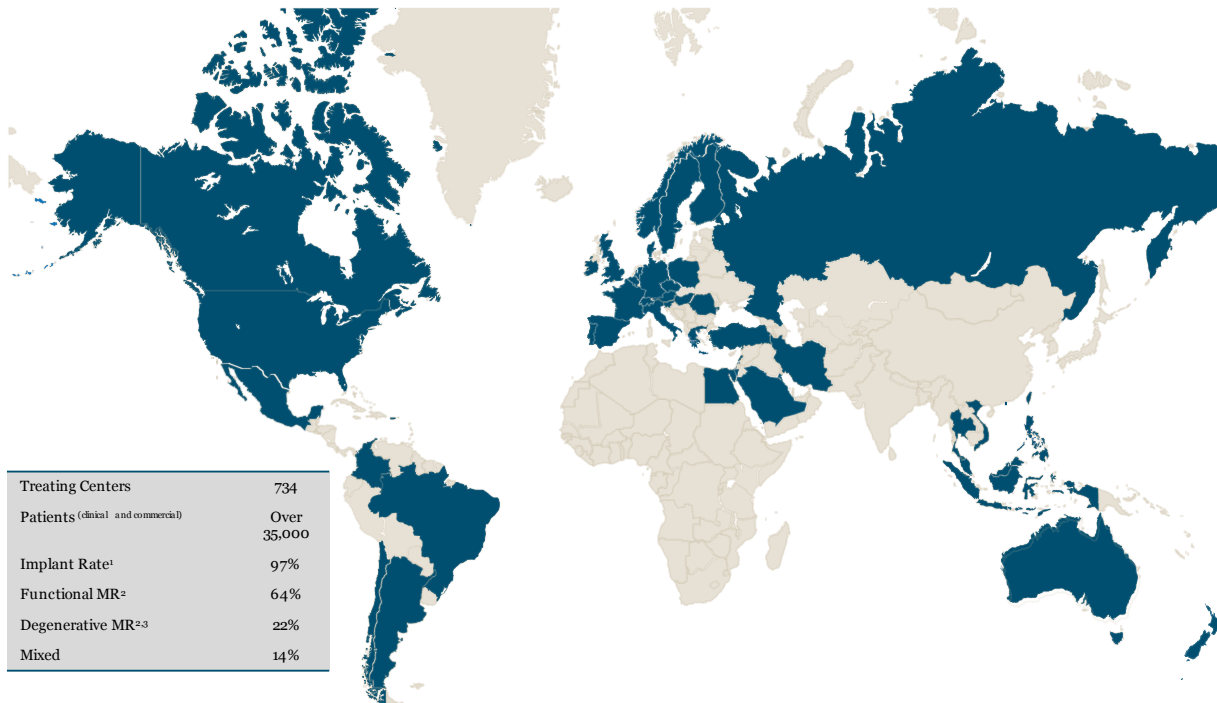


1. Includes clinical and commercial procedures as of 31/07/2016. Source: Data on file at Abbott Vascular

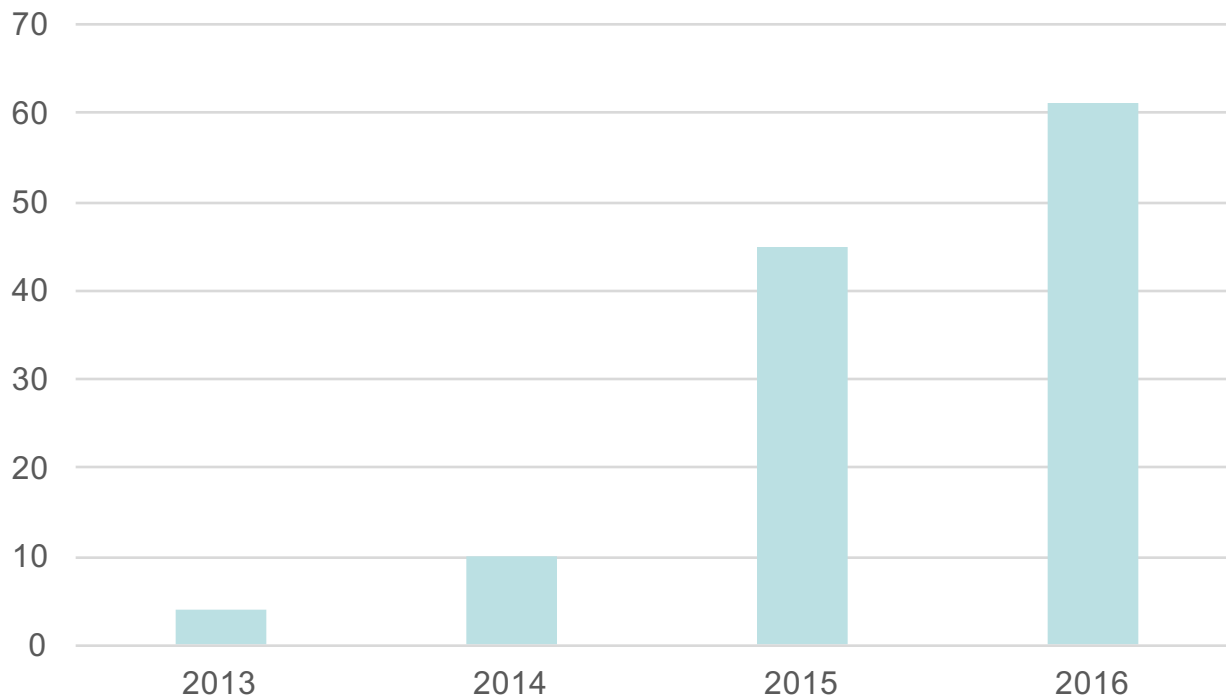
TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

Mitraclip Therapy: a new hope

MitraClip – the way to the mainstream (> 40,000 patients treated)



MitraClip Portugal



MITRACLIP PORTUGAL



Ano	Casos Espanha	Casos Portugal	Casos Italia
2014	82 (2 clips/milhão hab)	10 (1clip/ 1 milhão hab)	613 (10.2 clips/milhão hab)
2015	160 (3.5 clips/milhão hab)	45 (4.5 clips/ milhão hab)	713 (11.9 clips/milhão hab)

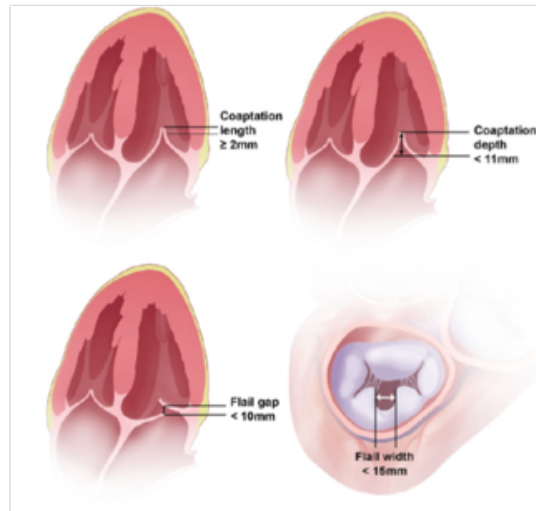
TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

Mitraclip Therapy: a new hope

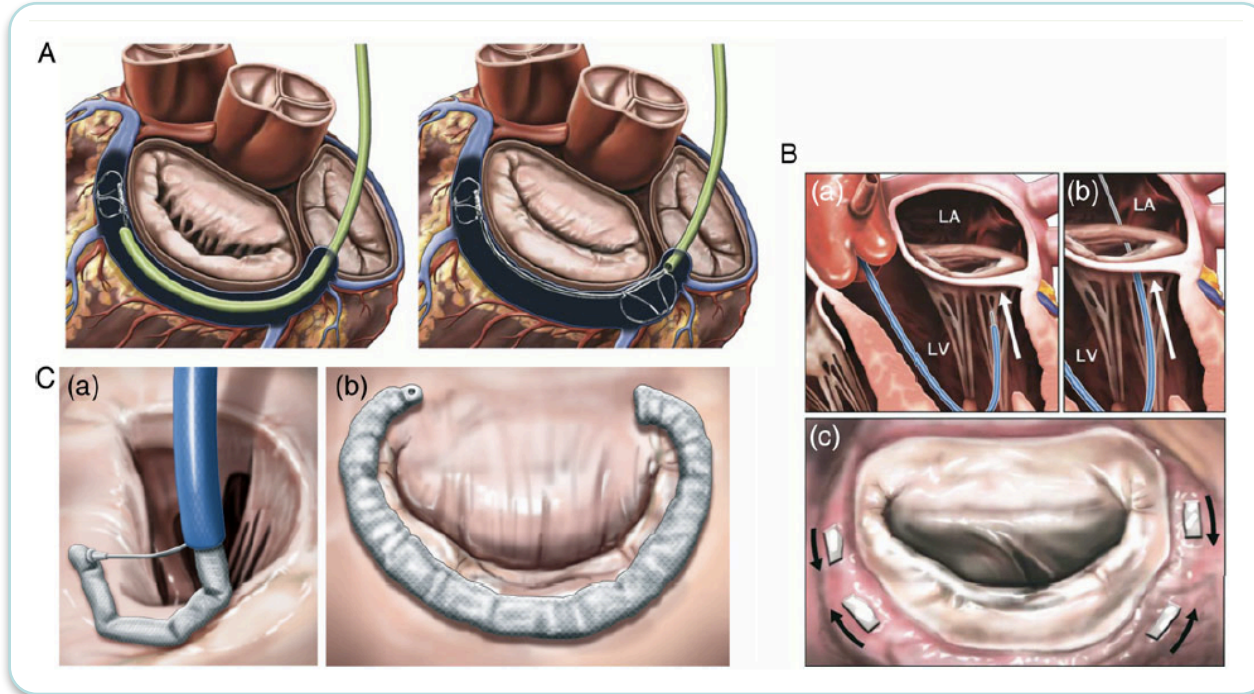
Anatomical restrictions

Recommended criteria¹

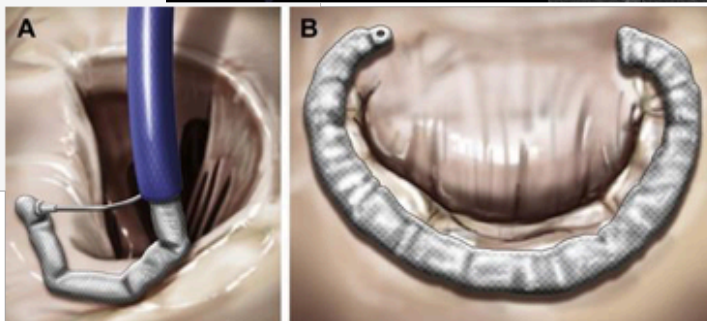
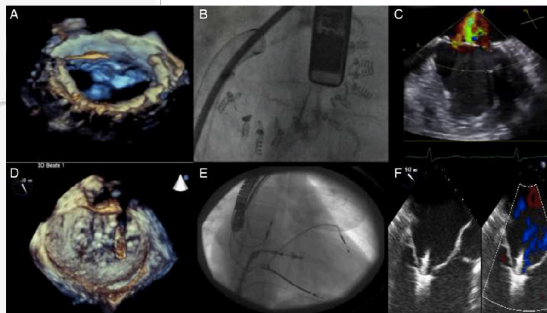
- Moderate to severe MR (Grade 3 or more out of 4 grades)
- Pathology in A2-P2 area
- Coaptation length > 2 mm (depending on leaflet mobility)
- Coaptation depth < 11 mm
- Flail gap < 10 mm
- Flail width < 15 mm
- Mitral valve orifice area $> 4\text{cm}^2$ (depending on leaflet mobility)
- Mobile leaflet length > 1 cm

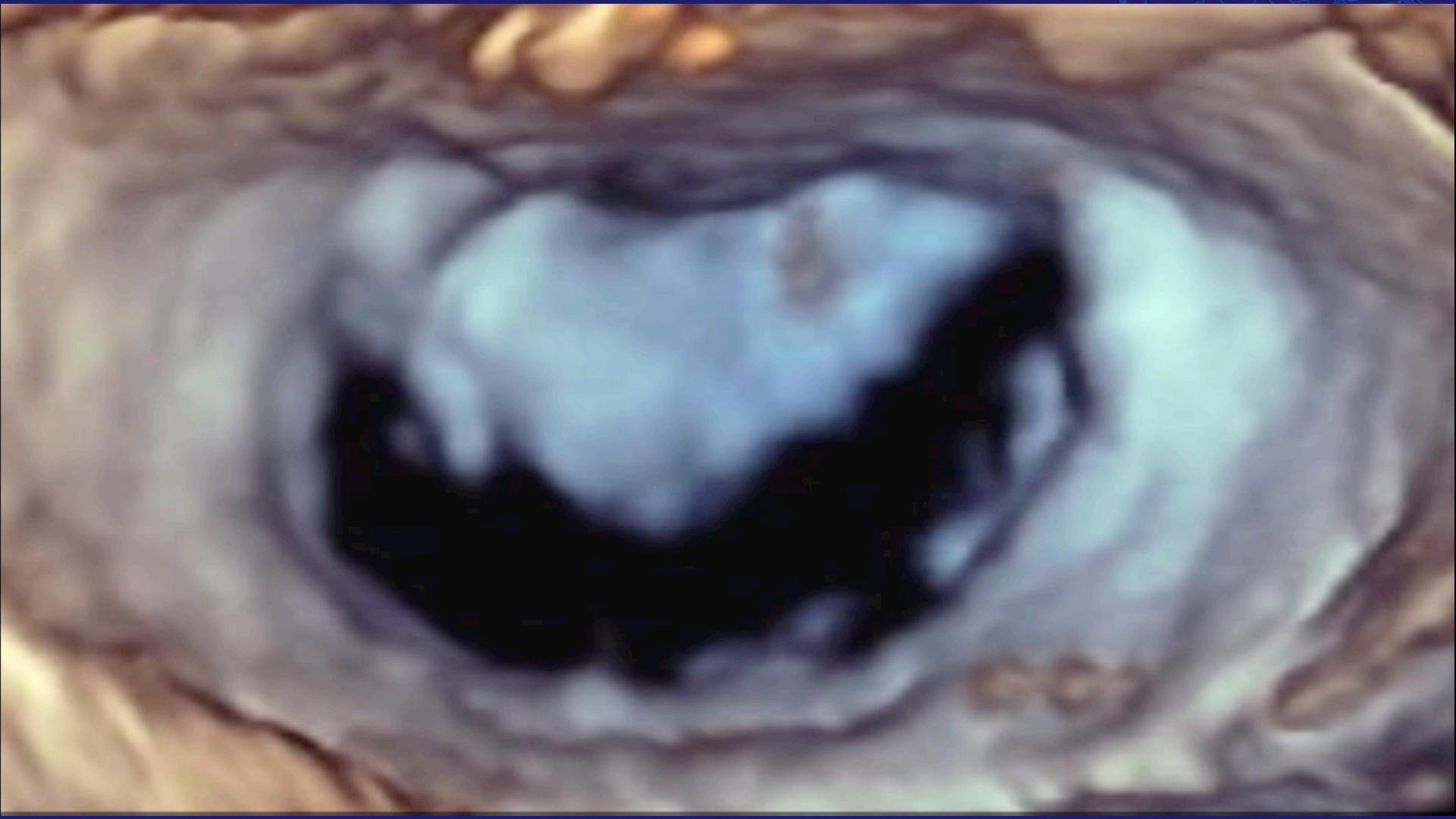


Annuloplasty – the next step:



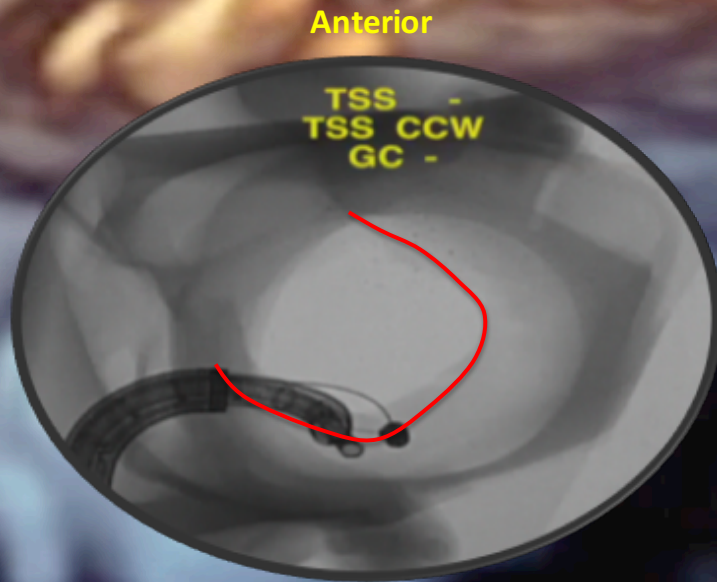
Cardioband





TSS CW rot
TSS +\ -
GC +/-
P1

TSS +
GC +/-

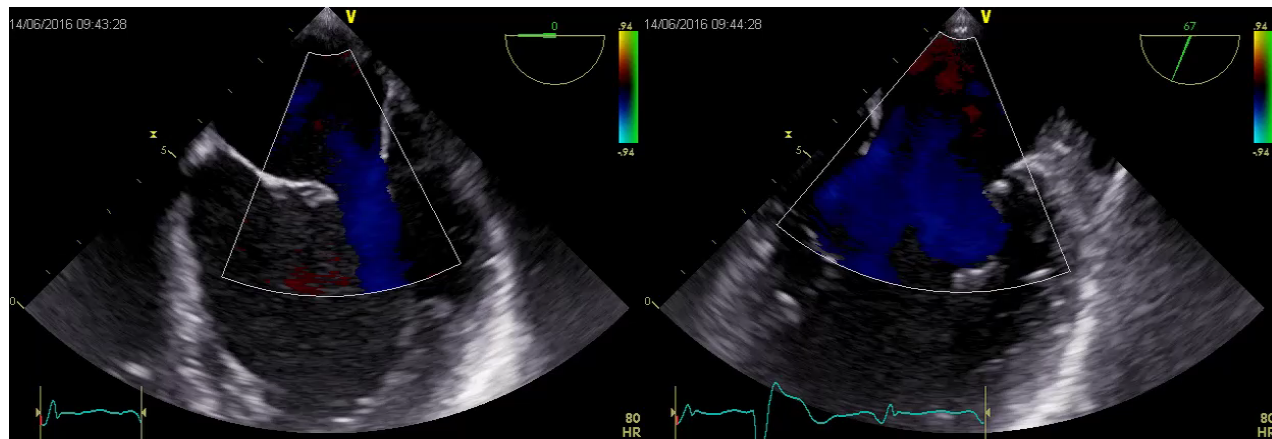


System pull Back
GC +/-
P2

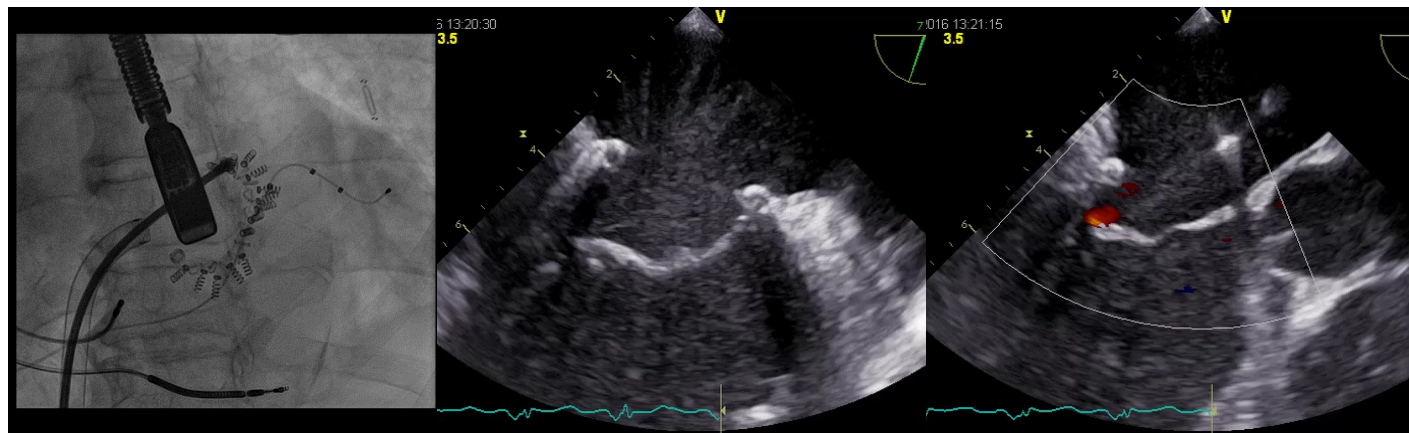
Posterior

GC - \ +
TSS CCW rot.
P3
GC + hooking
TSS -

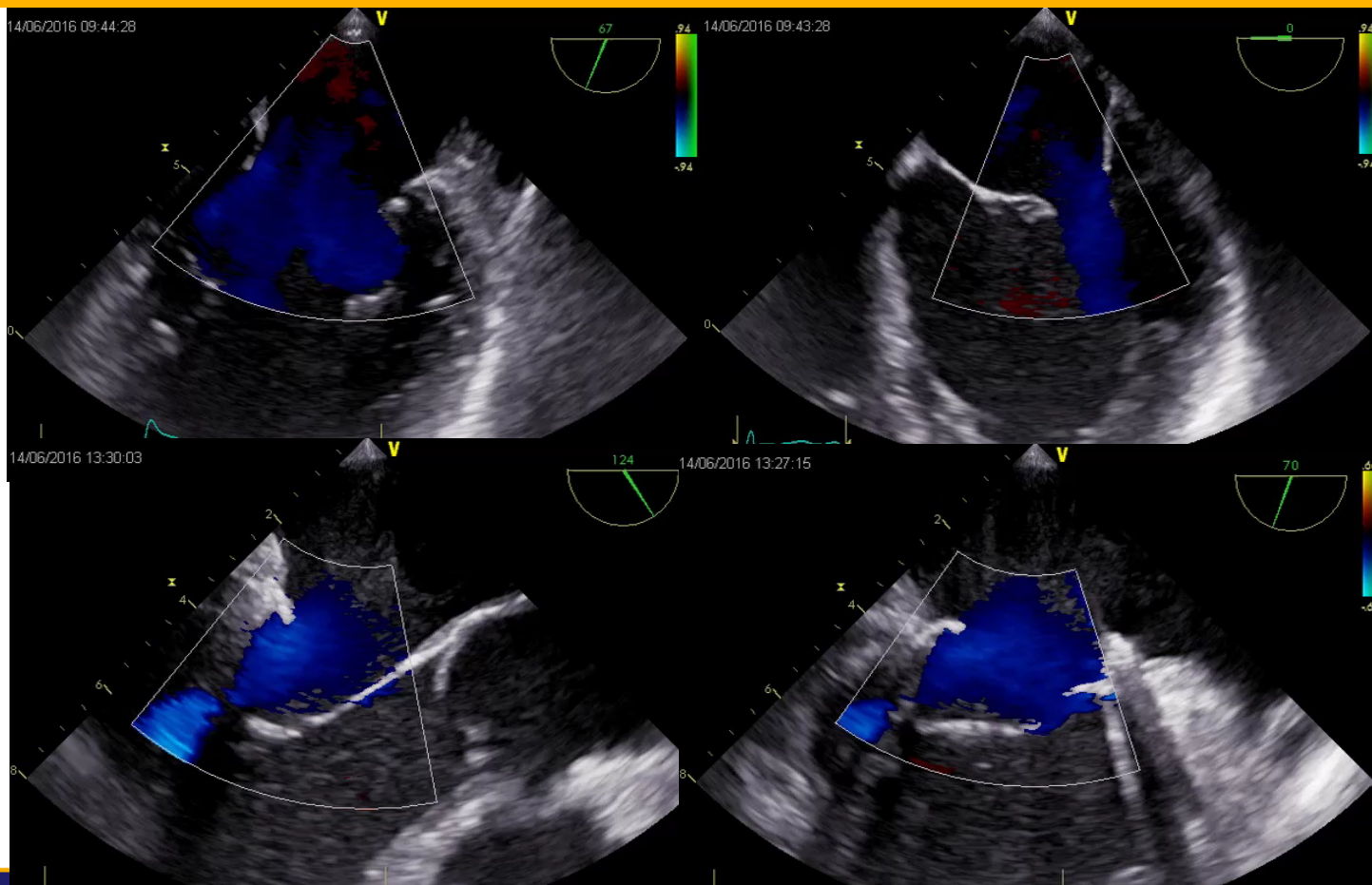
Baseline



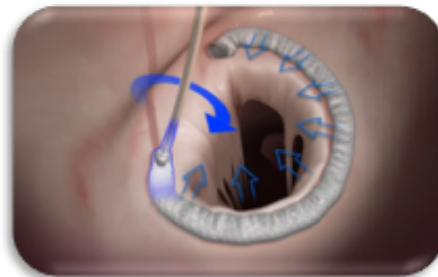
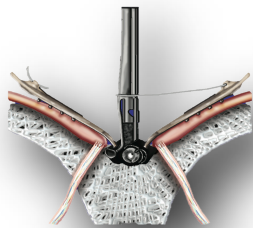
**3.5cm
15 anchors
contraction**



Baseline



**Final after
4.5cm
contraction**



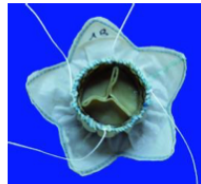
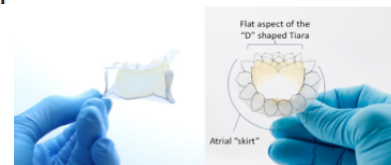
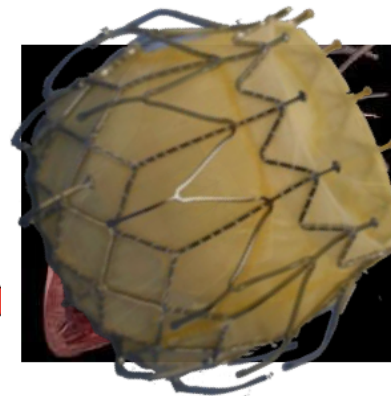
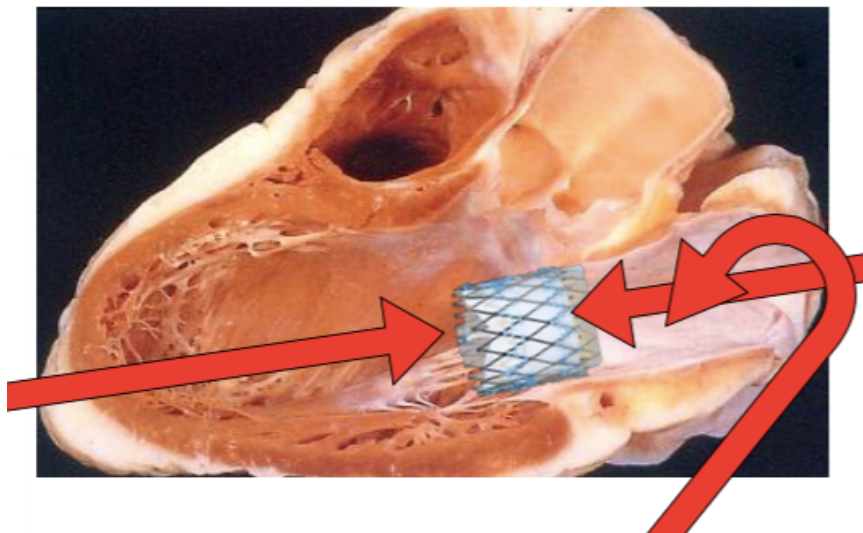
Percutaneous Direct Annuloplasty With Cardioband to Treat Recurrent Mitral Regurgitation After MitraClip Implantation

Azeem Latib, MBCh^{a,b} Marco B. Ancona, MD,^b Luca Ferri, MD,^b Matteo Montorfano, MD,^b Antonio Mangieri, MD,^b Damiano Regazzoli, MD,^b Francesco Giannini, MD,^b Fabrizio Monaco, MD,^d Manuela Giglio, MD,^e Stefano De Servi, MD,^f Ottavio Alfieri, MD,^c Antonio Colombo, MD,^{a,b} Eustachio Agricola, MD^b

J Am Coll Cardiol Interv. 2016; doi: 10.1016/j.jcin.2016.06.028

TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

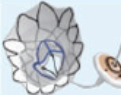
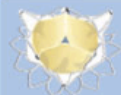
Replacement



TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

Replacement

TVT: Mitral Valves and Human Implants (Oct. 2015)

Company	Product, Year of first human implant	Access side	Development Status	N pts, clinical implants	
Edwards	Fortis, 2014	TA	Stopped	>20	
Tendyne	Lutter, 2014	TA	Clinical	17	
Neovasc	Tiara, 2014	TA	Clinical	8	
CardiaQ – Edwards	2012	TA, TS	Clinical	9	
Twelve-Medtronic	Intrepid, 2015	TA	Clinical	?	Picture not available

NEWS • INTERVENTIONAL

Edwards Lifesciences Pauses Transcatheter Mitral Valve Study to Work Out Design Issues

In a call with investors, Edwards remained vague about the design complication, but was optimistic the trial will continue.

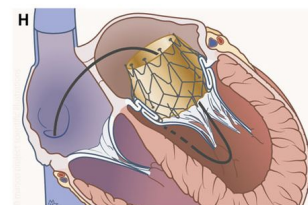
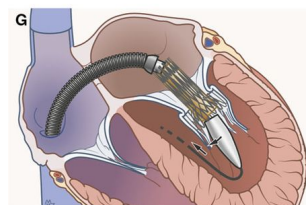
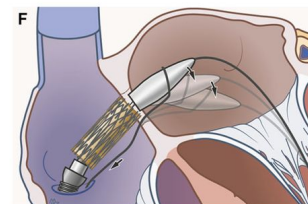
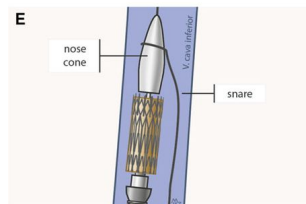
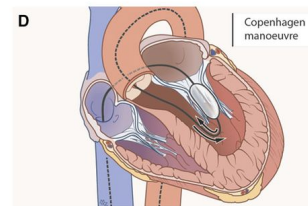
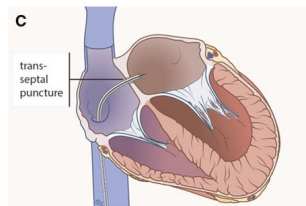
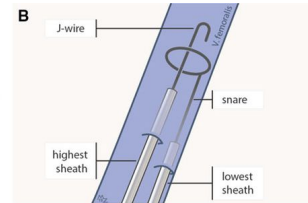
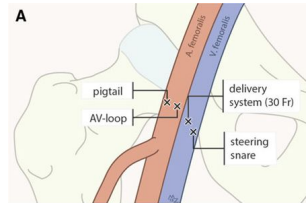


By [Michael O'Riordan](#) | February 07, 2017

A



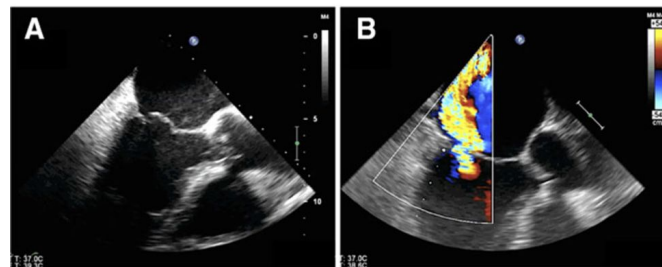
B



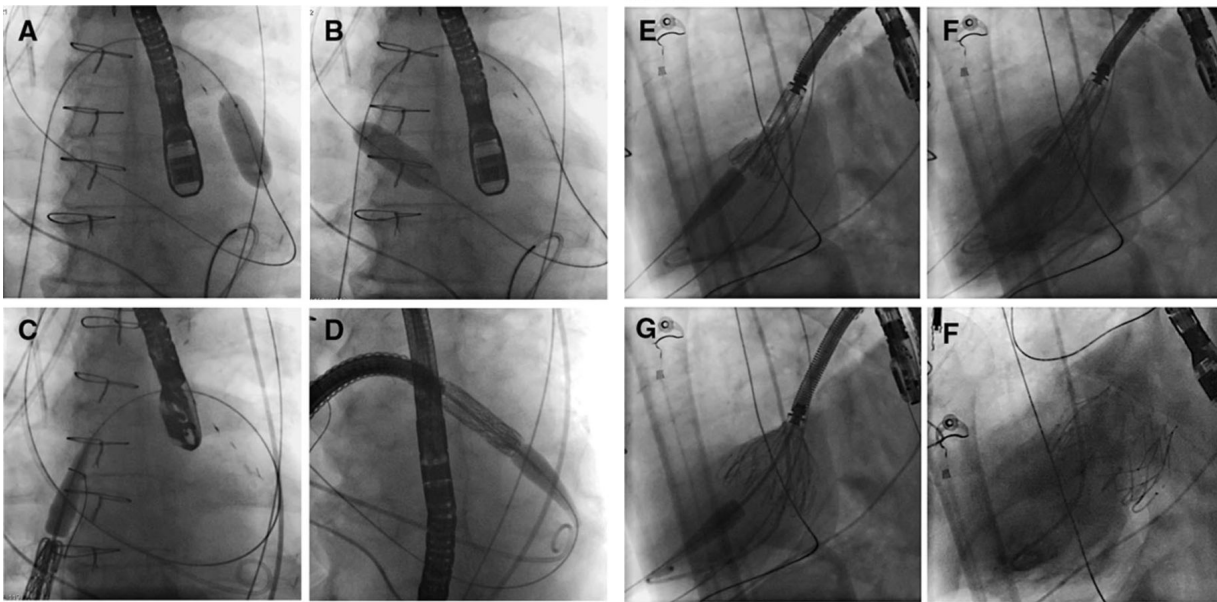
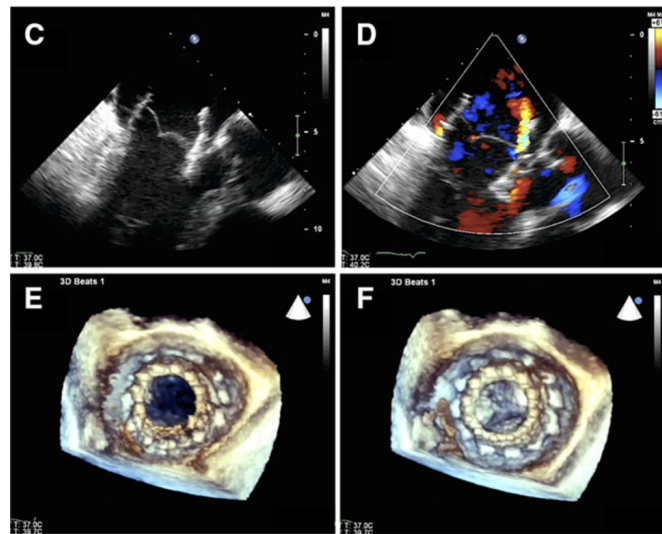
First-in-Human Case of Transfemoral CardiAQ Mitral Valve Implantation

Circulation: Cardiovascular Interventions. 2015;8:e002135

Before TMVI



After TMVI



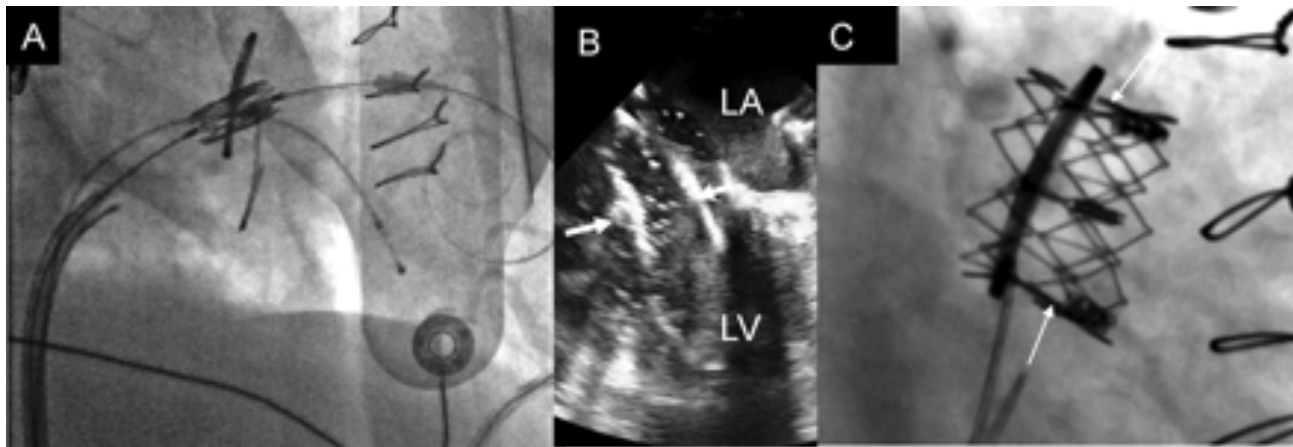
TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

Special indications:

Valve-in-Valve Mitral

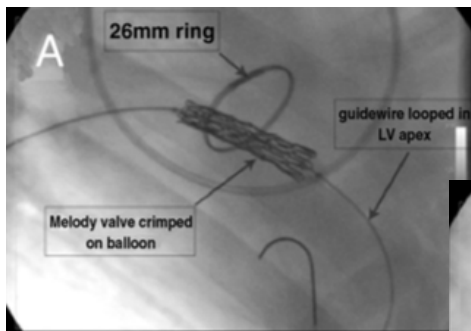
Circulation Cardiovascular Interventions August 2011 vol. 4 no. 4 396-398

Aprovação CE Edwards Sapiens XT



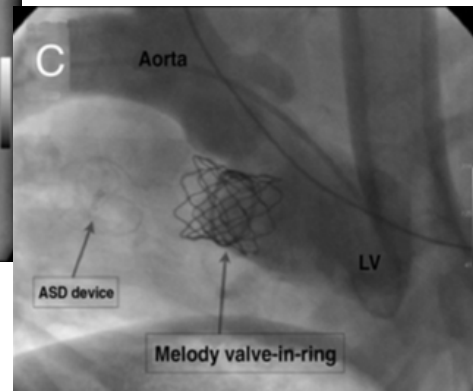
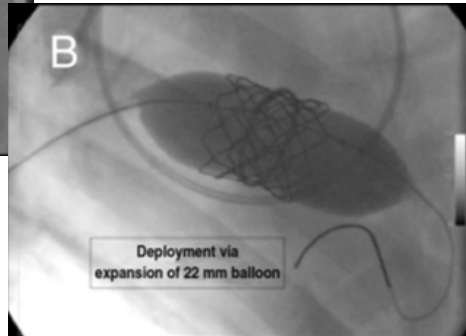
TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

Special indications:



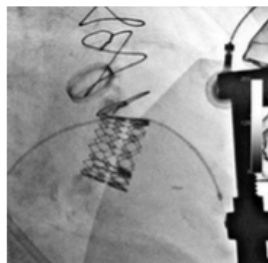
Valve-in-Ring Mitral

JACC 2011 No. 24 Vol.58 2475-80

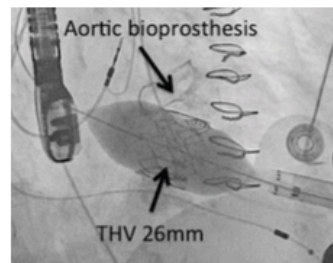


TECHNOLOGICAL INNOVATION: CARDIOLOGY'S BRAVE NEW WORLD

The Calcified Native Valve



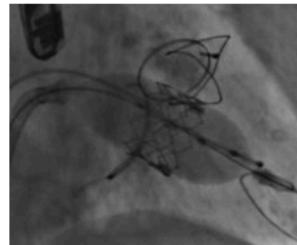
Hassan et al, *Circulation* 2013;128:e74-e76.



Sinning et al, *Eur Heart J* 2013.



Guerrero et al, *CCI* 2014;83:E287-291.



Fassa et al, *JACC Cardiovasc Interv* 2014;7:696-7.

The future of transcatheter mitral valve interventions: competitive or complementary role of repair vs. replacement?

TMVI - transcatheter mitral valve implantation:

Advantages

- Simplicity
- Versatility
- Predictable results

The future of transcatheter mitral valve interventions: competitive or complementary role of repair vs. replacement?

TMVI - transcatheter mitral valve implantation:

Challenges

- Dynamic mitral structure
- Asymmetric anatomy
- Deliverability (profile, rigidity)
- Fixation (not relying on radial force)
- Need for chronic oral anticoagulation (?)
- Risk of LVOT, CS, and LCX obstruction
- Risk of para-valvular leak

The future of transcatheter mitral valve interventions: competitive or complementary role of repair vs. replacement?

TMVRep, transcatheter mitral valve repair:

Advantages

- More natural haemodynamics
- No need for long-term anticoagulation
- Favourable safety profile

The future of transcatheter mitral valve interventions: competitive or complementary role of repair vs. replacement?

TMVRep, transcatheter mitral valve repair:

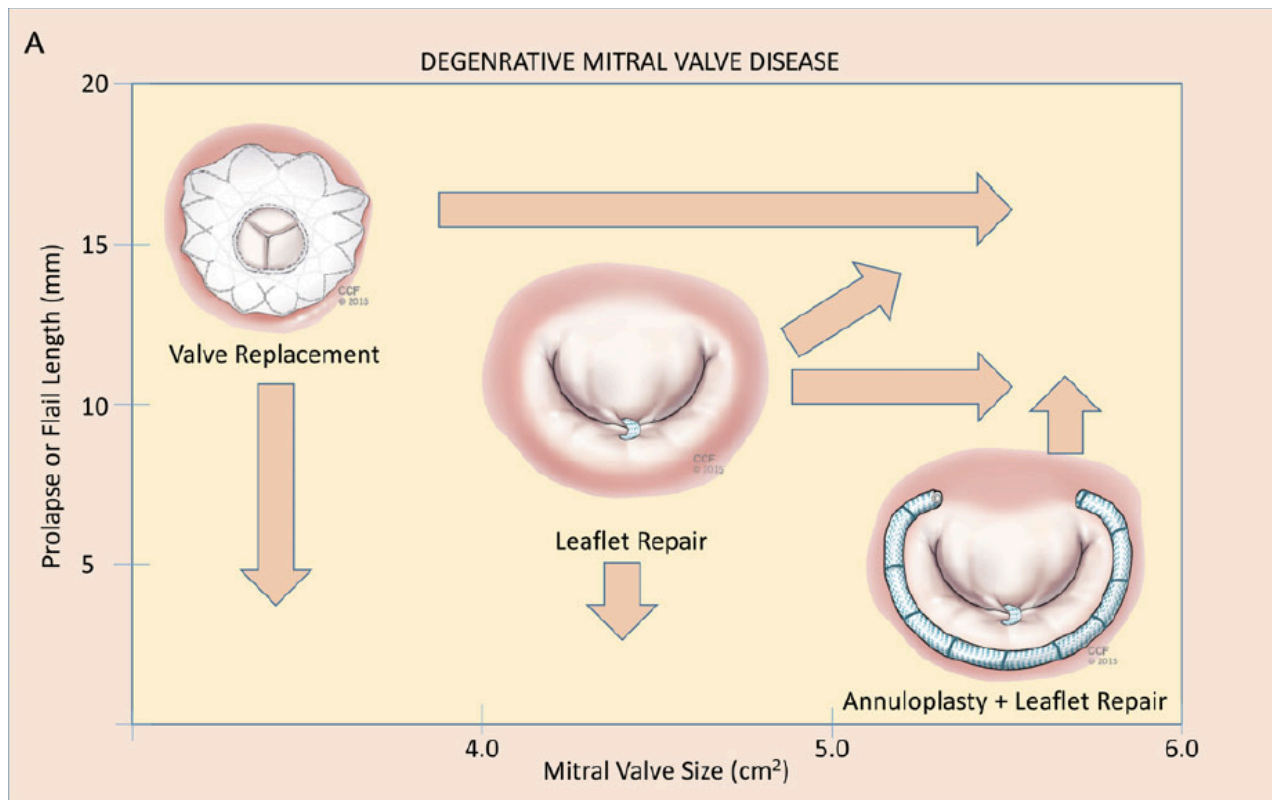
Challenges

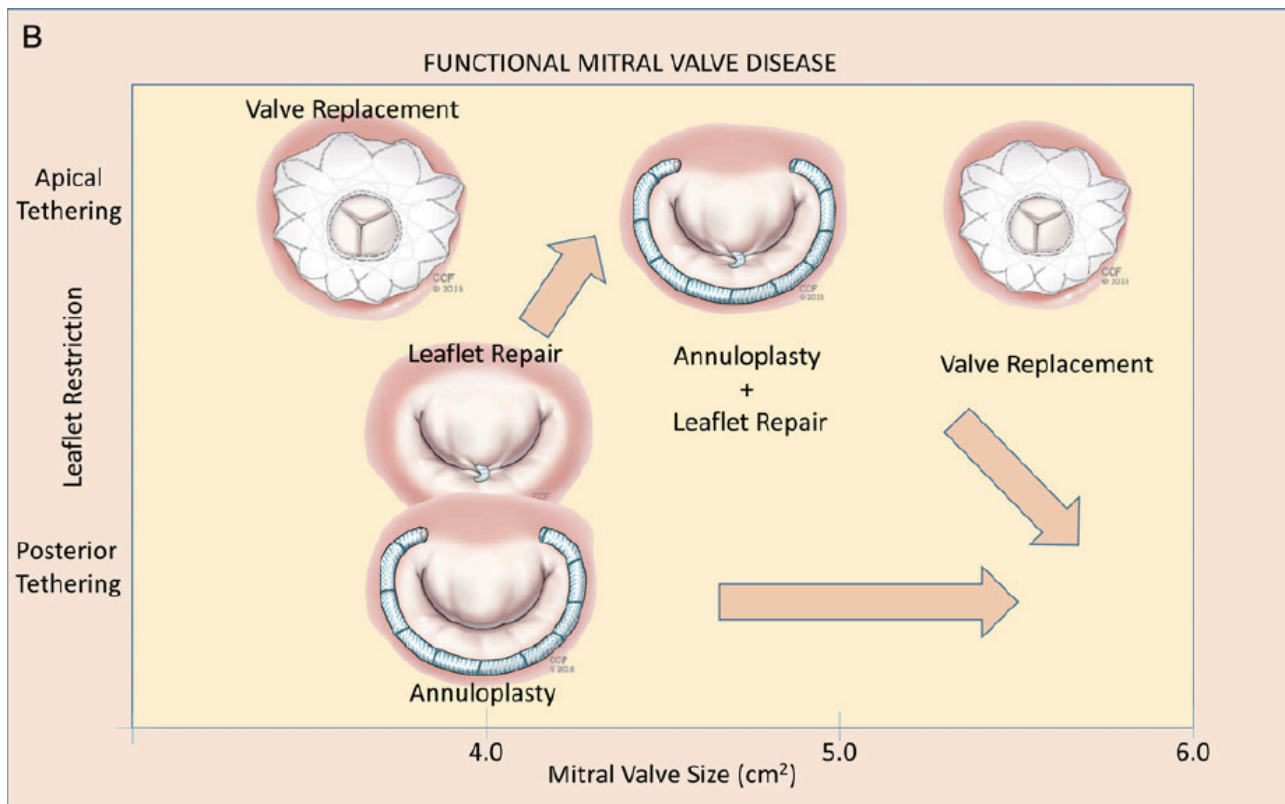
- Need for advanced imaging
- Variability of disease/need for multiple devices
- Possible need for combined therapies
- Steeper learning curve
- Residual/recurrent regurgitation

Believe It: Mitral Valve Repair Beats Replacement for Severe Regurgitation, Registry Shows (MIDA)

Survival: Mitral Valve Repair vs Replacement

	Repair	Replacement	P Value
Operative Mortality			
<i>Overall</i>	1.3%	4.7%	< 0.001
<i>Propensity-Matched</i>	0.2%	4.4%	< 0.001
20-Year Survival			
<i>Overall</i>	46%	23%	< 0.001
<i>Propensity-Matched</i>	41%	24%	< 0.001



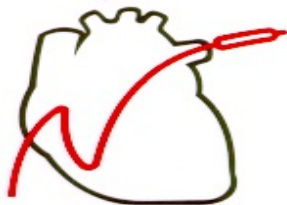




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Novas Fronteiras em Cardiologia

Insuficiência mitral, onde estamos e para onde vamos?

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