

CORONARIE E VALVOLE CARDIACHE. NUOVE POSSIBILITA' DI TRATTAMENTO NON CHIRURGICO

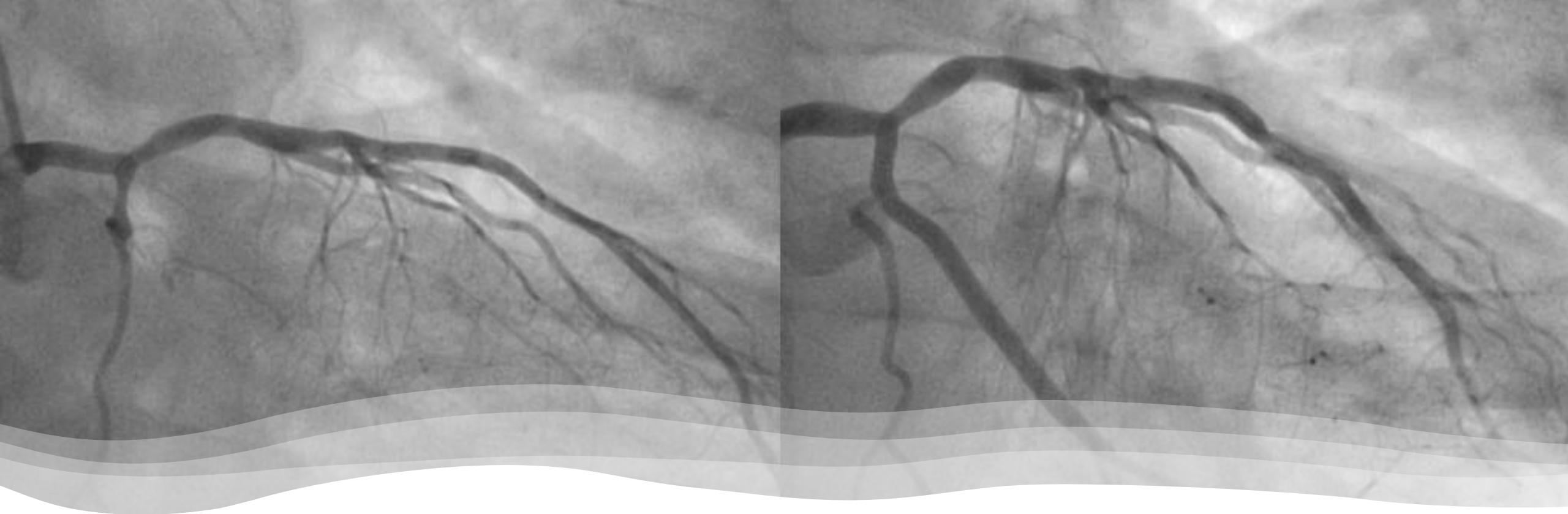
Dr Lorenzo Monti
Humanitas Research Hospital
Rozzano (MI)

Sviluppo tecnologico in cardiologia

→ nuove possibilità terapeutiche

In quanto nuove, le metodiche descritte sono tuttora oggetto di studio e validazione

1. Occlusioni coronariche croniche («CTO»)
2. Stenosi valvolare aortica
3. Malattie delle altre valvole



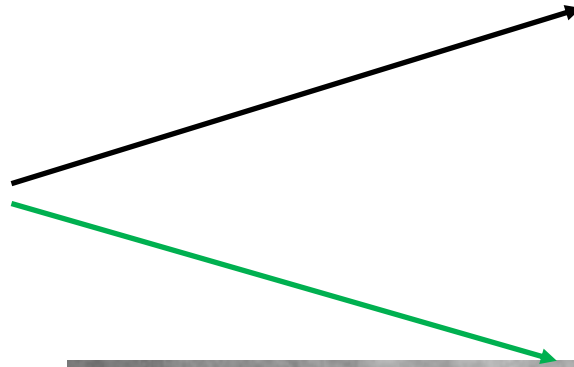
Le occlusioni coronariche croniche

PREVALENZA: Occlusioni totali croniche (CTO) di una coronaria o di sue diramazioni si osservano con una prevalenza di circa il 15-20% nella popolazione sottoposta ad angiografia coronarica

GESTIONE: solo una bassa percentuale di CTO viene ad oggi sottoposta a procedura coronarica percutanea (PCI).

- elevata complessità tecnica
- incidenza di complicanze periprocedurali

Ma se il vaso
si è chiuso
senza che il
paziente se
ne
accorgesse...



Good collaterals

The vessel is already totally occluded; it can't get any worse

Let's open up other vessels and this will reduce the overall burden of ischemia

Send the patient for CABG

No hard evidence to support CTO PCI

CTO PCI is a very costly and risky procedure with high failure and complication rates



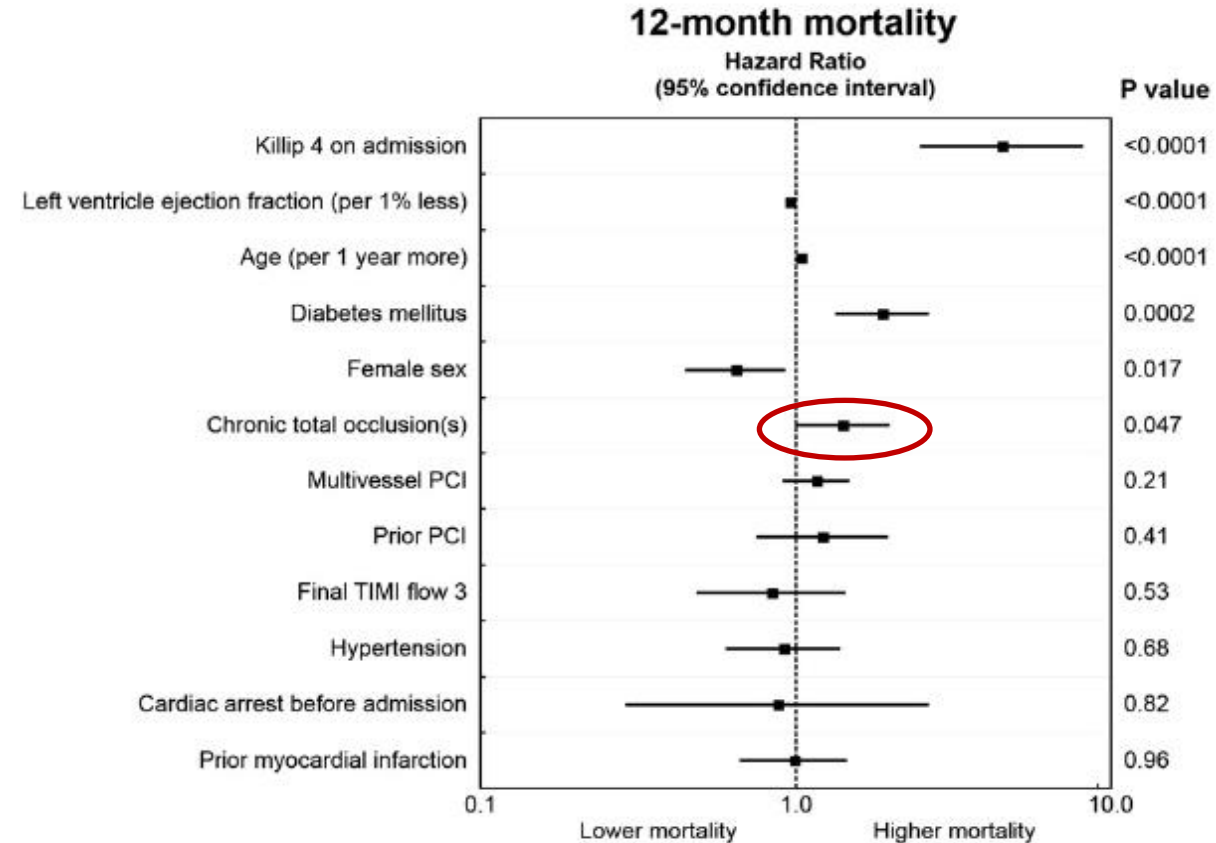
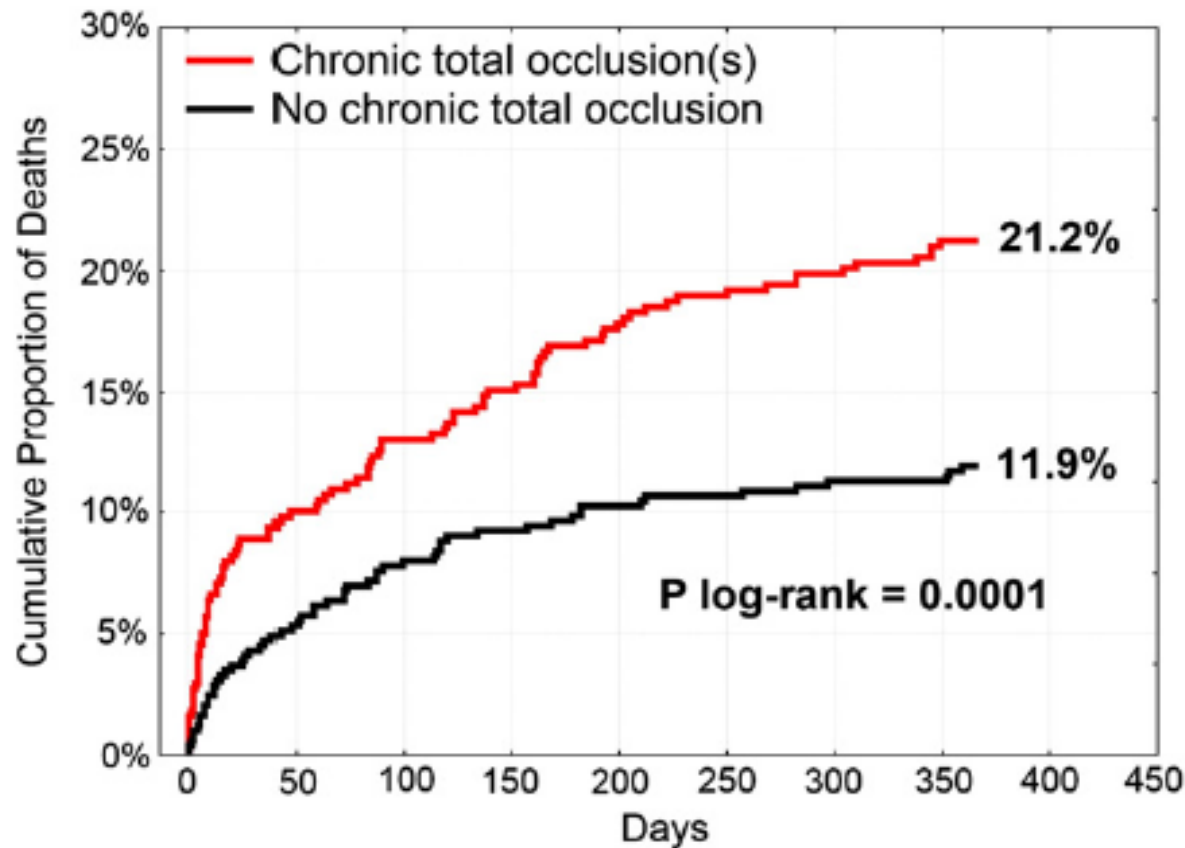
Se il vaso è già chiuso, non può peggiorare...!

Che fare?

Per uscire (anche da questo) dilemma,
servono dati e non opinioni

1: dati di prognosi

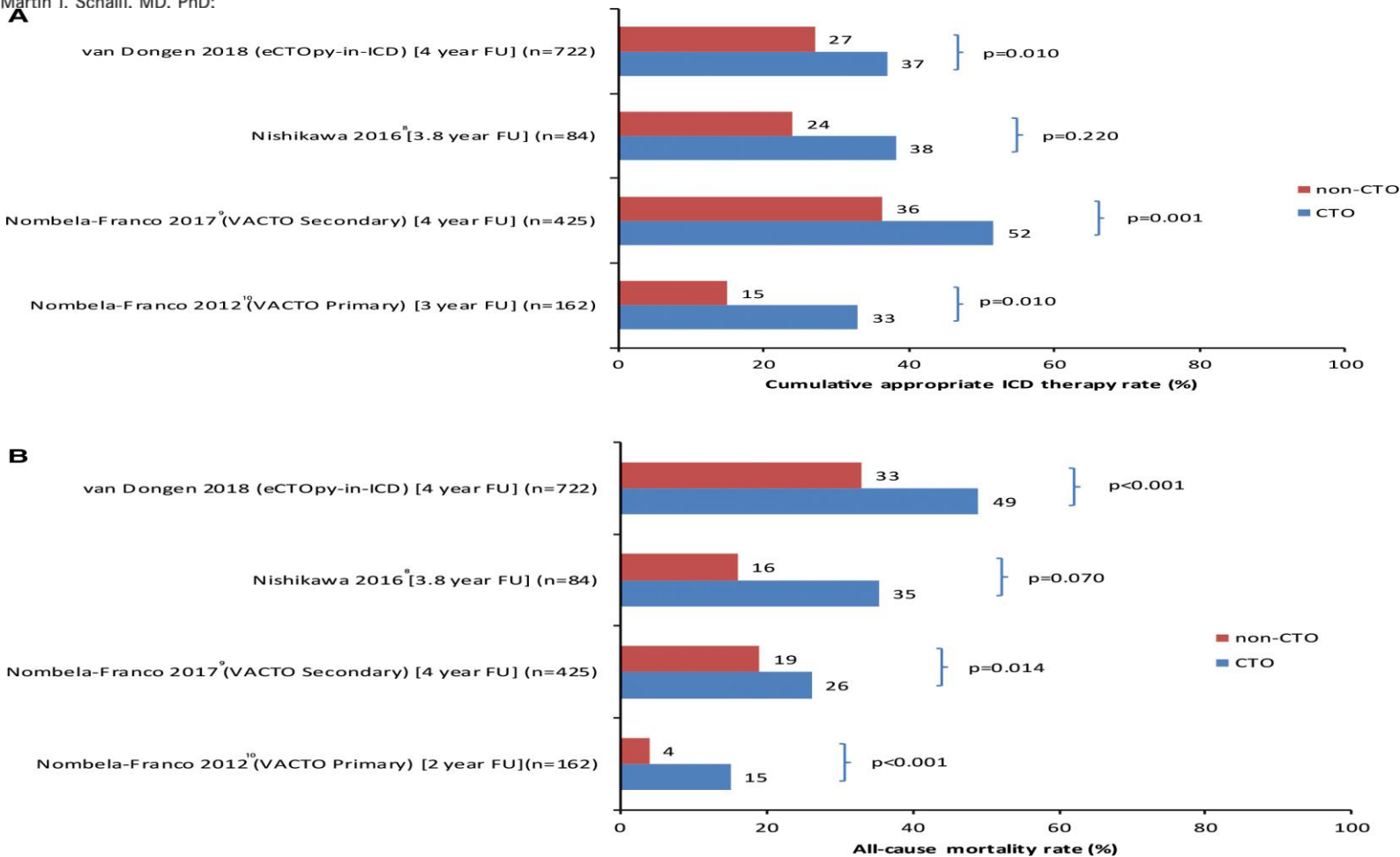
Impact of chronic total occlusion artery on 12-month mortality in patients with non-ST-segment elevation myocardial infarction treated by percutaneous coronary intervention (From the PL-ACS Registry)☆



Evaluation of the Impact of a Chronic Total Coronary Occlusion on Ventricular Arrhythmias and Long-Term Mortality in Patients With Ischemic Cardiomyopathy and an Implantable Cardioverter-Defibrillator (the eCTOpy-in-ICD Study)

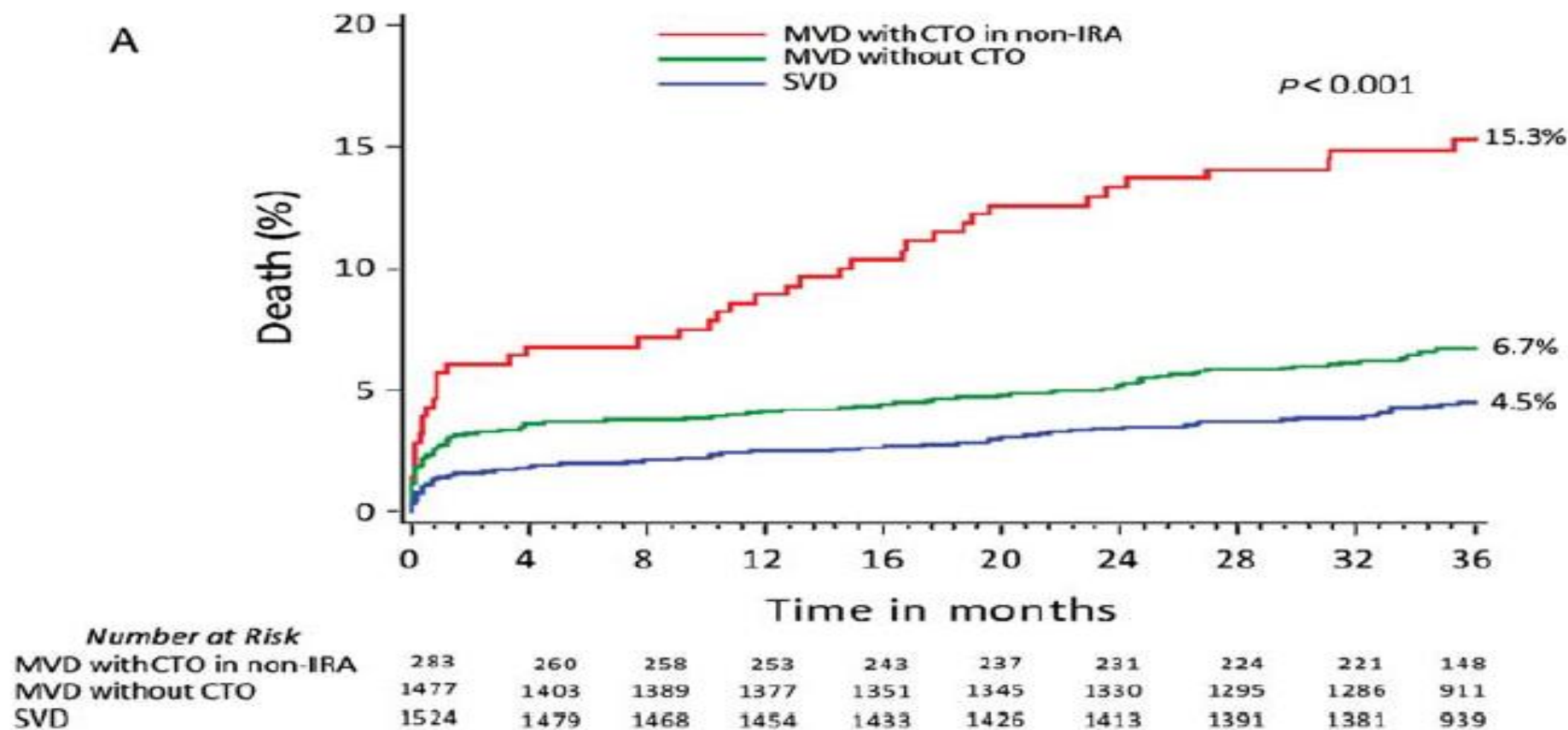
Ivo M. van Dongen, MD;* Dilek Yilmaz, MD;* Joëlle Elias, MD; Bimmer E. P. M. Claessen, MD, PhD; Ronak Delewi, MD, PhD; Reinoud E. Knops, MD, PhD; Arthur A. M. Wilde, MD, PhD; Lieselot van Erven, MD, PhD; Martin I. Schalij, MD, PhD; José P. S. Henriques, MD, PhD

The vessel is already totally occluded; it can't get worse



Van Dongen et al. JAHA 2018

Prognostic impact of a chronic total occlusion in a non-infarct-related artery in patients with ST-segment elevation myocardial infarction: 3-year results from the HORIZONS-AMI trial



The vessel is already totally occluded; it can't get worse

FACT

Presence of a CTO = worse outcomes

TO IMPROVE SYMPTOMS

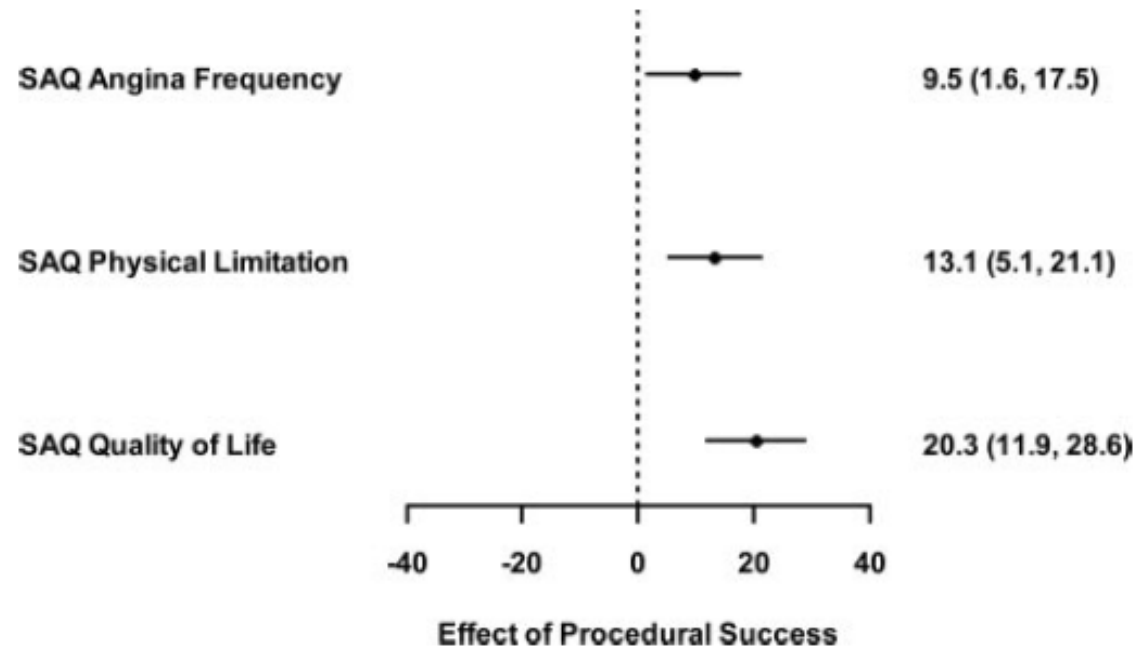
CTO patients have rarely angina, they often complain dyspnea, weakness, atypical symptoms

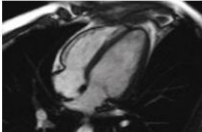
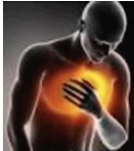
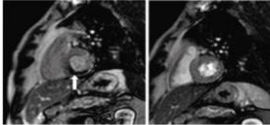
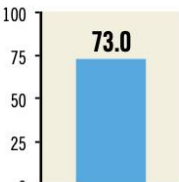
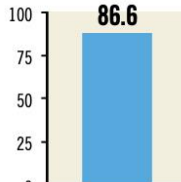
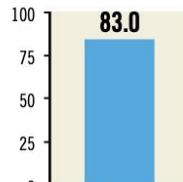
....Or they limit their physical activity

Quantifying the Early Health Status Benefits of Successful Chronic Total Occlusion Recanalization

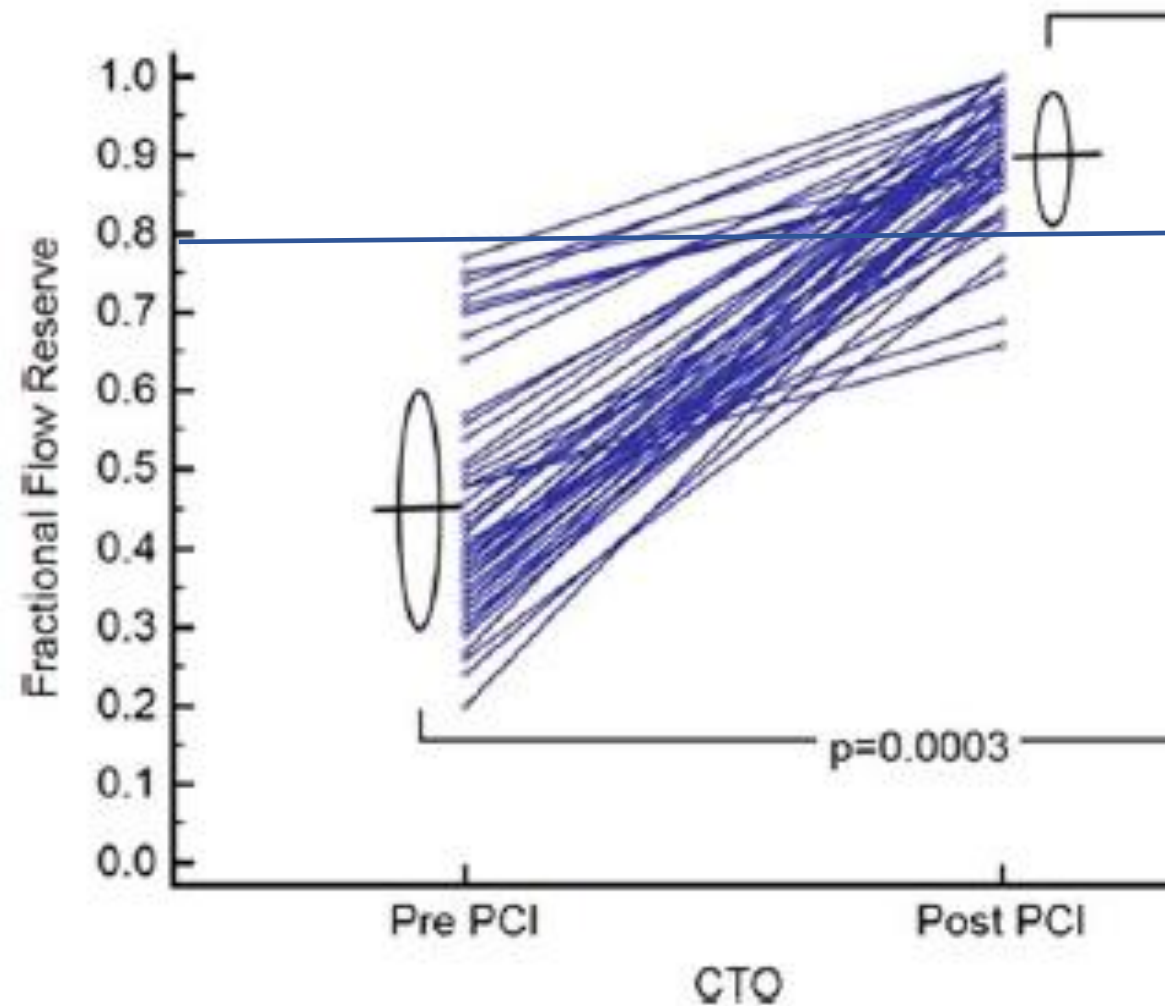
Results From the FlowCardia's Approach to Chronic Total Occlusion Recanalization (FACTOR) Trial

J. Aaron Grantham, MD; Philip G. Jones, MS; Louis Cannon, MD; John A. Spertus, MD, MPH

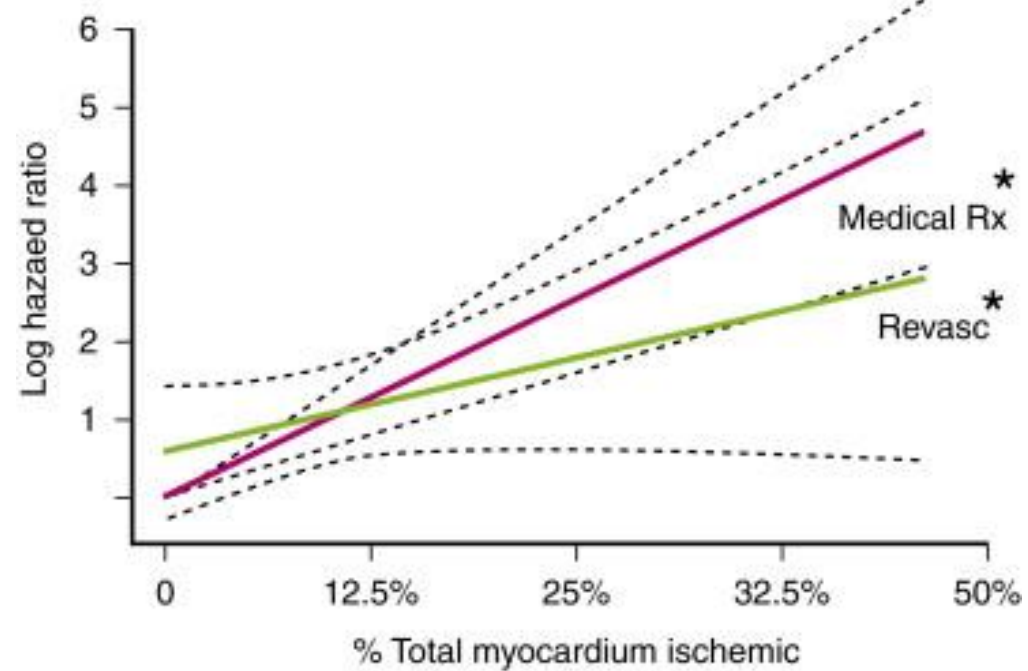


	EXPLORE	EUROCTO	IMPACTOR-CTO																																													
Location & design	Europe & Canada  Multicentre RCT (14 centres)	Europe  Multicentre RCT (28 centres)	Russia  Single-centre RCT																																													
N patients	304	407	72																																													
Study population	Patients with STEMI treated with PCI with a non-infarct-related CTO	SCAD CTO patients with symptoms and/or ischaemia and viability	Patients with isolated dominant RCA CTO and stable angina																																													
Primary endpoint	 LVEF and LVEDV by CMR	 QoL (SAQ, EQ-5D)	Stress Rest  Δ MIB by adenosine stress CMR																																													
Follow-up period	4 months	1 year	1 year																																													
Mean J-CTO score	2 $\pm$ 1	1.82 $\pm$ 1.07	1.92 $\pm$ 0.86																																													
Success rate	 73.0 EXPLORE	 86.6 EUROCTO	 83.0 IMPACTOR-CTO																																													
Positive/negative RCT																																																
Major findings	<table><thead><tr><th></th><th>PCI</th><th>OMT</th></tr></thead><tbody><tr><td>MACE</td><td>No difference</td><td></td></tr><tr><td>QoL</td><td>N/A</td><td></td></tr><tr><td>Ischaemia reduction</td><td>N/A</td><td></td></tr><tr><td>LVEF and LVEDV</td><td>No difference</td><td></td></tr></tbody></table> PCI of a CTO located in the LAD may improve LVEF and clinical outcome		PCI	OMT	MACE	No difference		QoL	N/A		Ischaemia reduction	N/A		LVEF and LVEDV	No difference		<table><thead><tr><th></th><th>PCI</th><th>OMT</th></tr></thead><tbody><tr><td>MACE</td><td>No difference</td><td></td></tr><tr><td>QoL</td><td>Better</td><td></td></tr><tr><td>Ischaemia reduction</td><td>N/A</td><td></td></tr><tr><td>LVEF and LVEDV</td><td>N/A</td><td></td></tr></tbody></table>		PCI	OMT	MACE	No difference		QoL	Better		Ischaemia reduction	N/A		LVEF and LVEDV	N/A		<table><thead><tr><th></th><th>PCI</th><th>OMT</th></tr></thead><tbody><tr><td>MACE</td><td>No difference</td><td></td></tr><tr><td>QoL</td><td>Better</td><td></td></tr><tr><td>Ischaemia reduction</td><td>N/A</td><td></td></tr><tr><td>LVEF and LVEDV</td><td>N/A</td><td></td></tr></tbody></table>		PCI	OMT	MACE	No difference		QoL	Better		Ischaemia reduction	N/A		LVEF and LVEDV	N/A	
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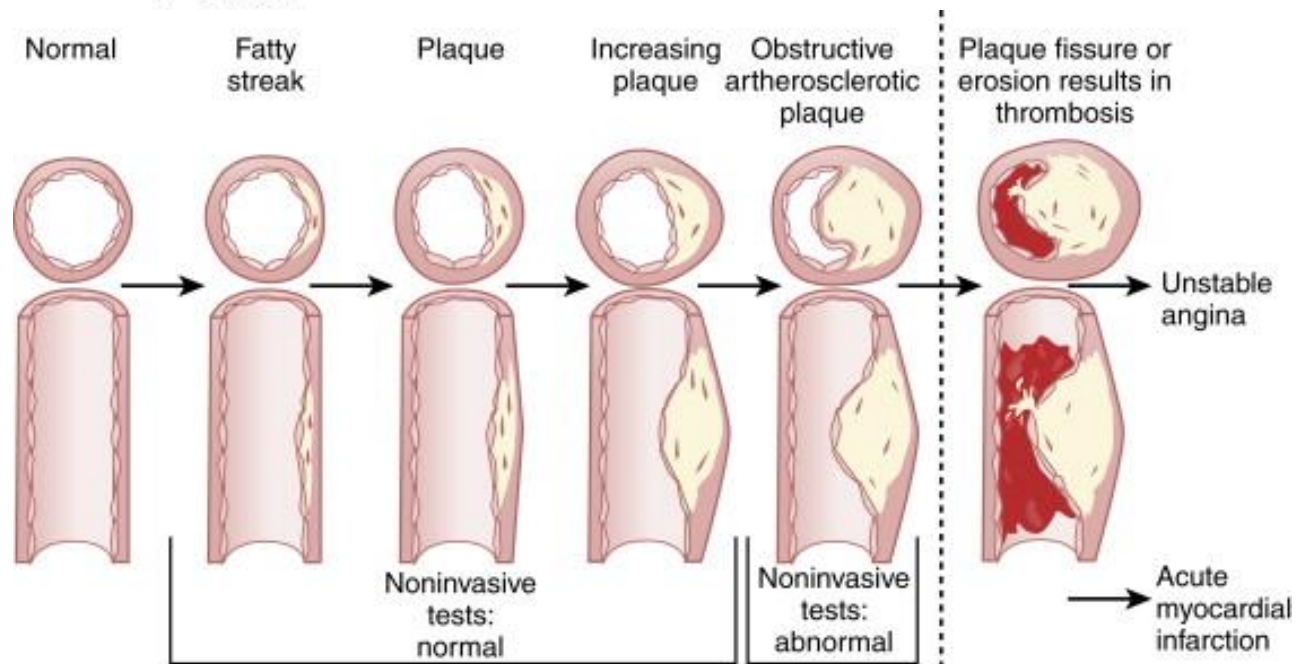
Presenza di ISCHEMIA miocardica
Il miocardio sotteso ad una CTO è sempre ischemico



**Se una coronaria
è completamente
chiusa, il flusso a
valle
dell'occlusione
non può essere
normale**

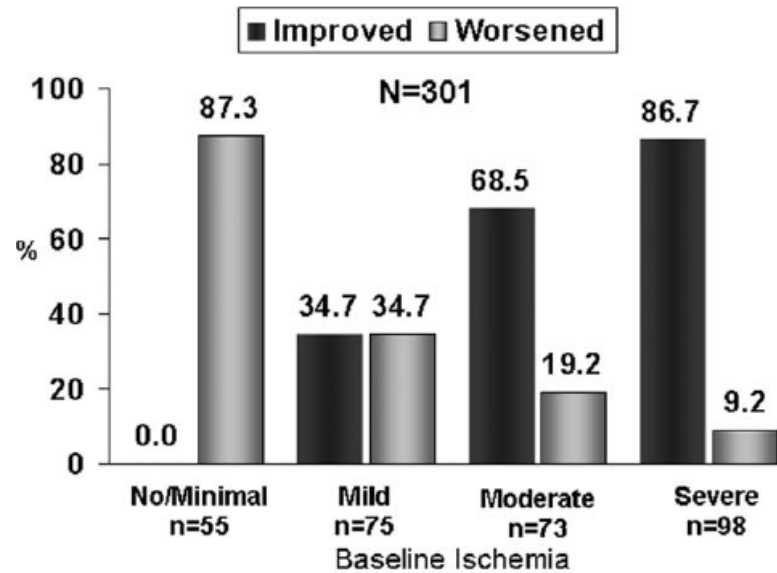
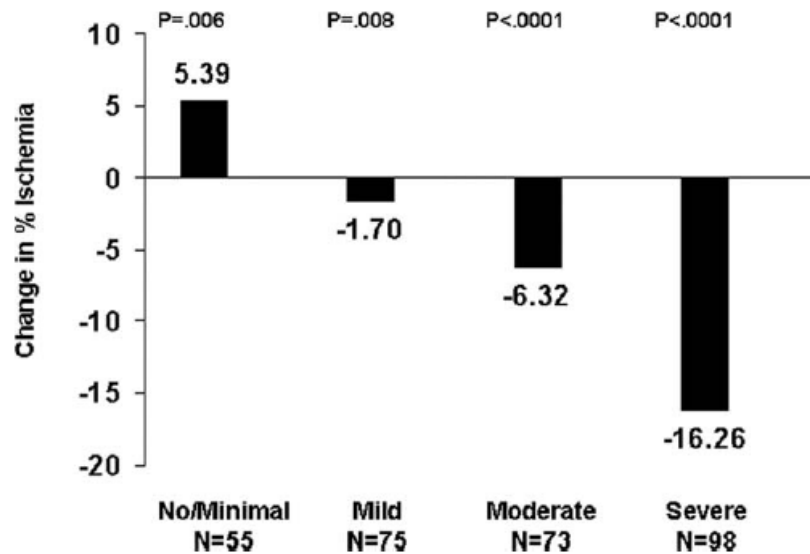


* $P < .001$



CTO PCI: Reduction of ischemic burden

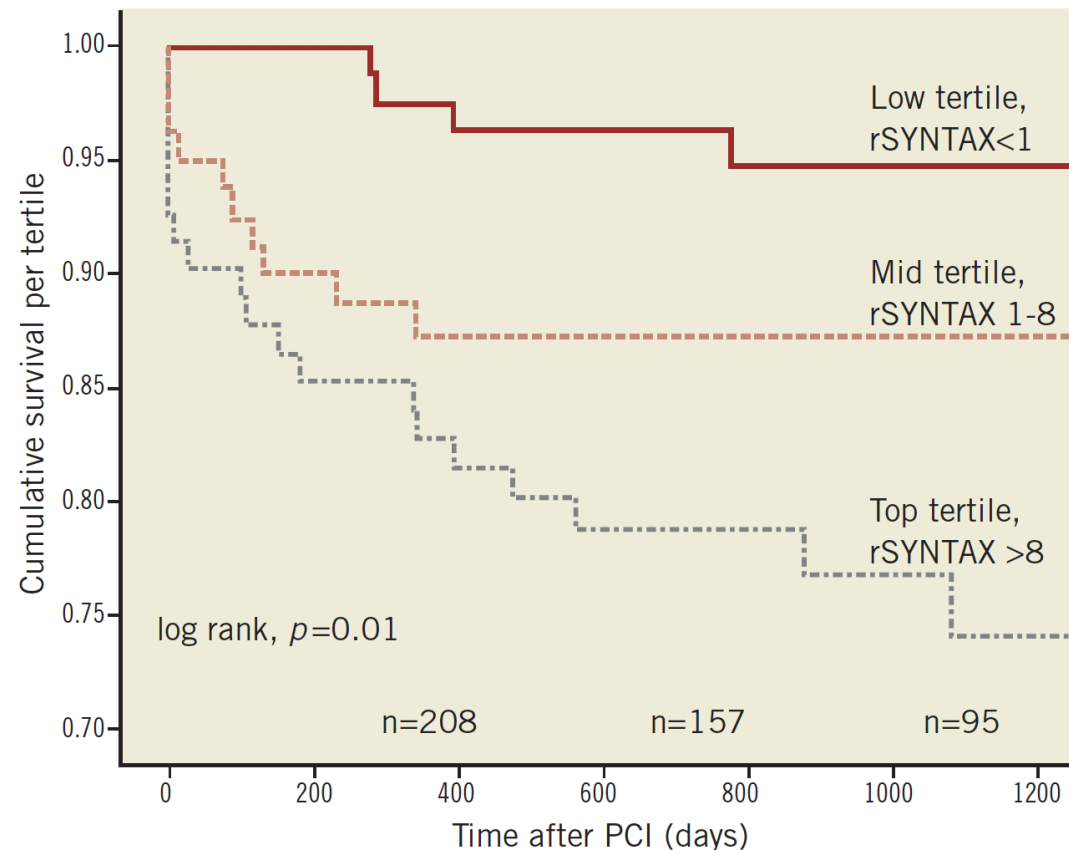
Changes in Myocardial Ischemic Burden Following Percutaneous Coronary Intervention of Chronic Total Occlusions



301 patients
undergoing
SPECT/PET before
and after CTO
recanalization

- The mean reduction in myocardial ischemic burden after CTO PCI was $6.2\% \pm 6.0\%$
- **ischemic burden > 12.5% predictive of improvement in myocardial ischemic burden following CTO PCI**
- Ischemic burden < 6.25% predictive of worsening ischemia following CTO PCI
- **patients with 5% reduction in ischemic burden post-PCI experienced fewer clinical events, in particular death and TVR**

Let's open other vessels; this will reduce the overall ischemic burden



Leading causes for incomplete revascularization

Anatomical: CTO
Clinical: too sick

Let's open other vessels; this will reduce the overall ischemic burden

FACT

Incomplete revascularization = worse outcomes

When considering the decision between CABG and PCI, completeness of revascularization should be prioritized.^{131,132,134–136}

Ila

B

Send the patient for CABG

Fefer et al JACC 2012

Patients with Coronary
Artery Disease
N = 14,439

CTO
18.4%

Treatment of Patients
with CTOs
N = 1,697

CABG
26%

Medical
Therapy
44%

Non-CTO
PCI
20%

Attempted
CTO-PCI
10%

Current Perspectives on Coronary Chronic Total Occlusions

The Canadian Multicenter Chronic Total Occlusions Registry

Paul Fefer, MD,*† Merrill L. Knudtson, MD,‡ Asim N. Cheema, MD, PhD,§
P. Diane Galbraith, BN, MSc,‡ Azriel B. Osherov, MD,* Sergey Yalonetsky, MD,*
Sharon Gannot, BS,† Michelle Samuel,* Max Weisbrod,* Daniel Bierstone,* John D. Sparkes, MSc,*
Graham A. Wright, PhD,* Bradley H. Strauss, MD, PhD*

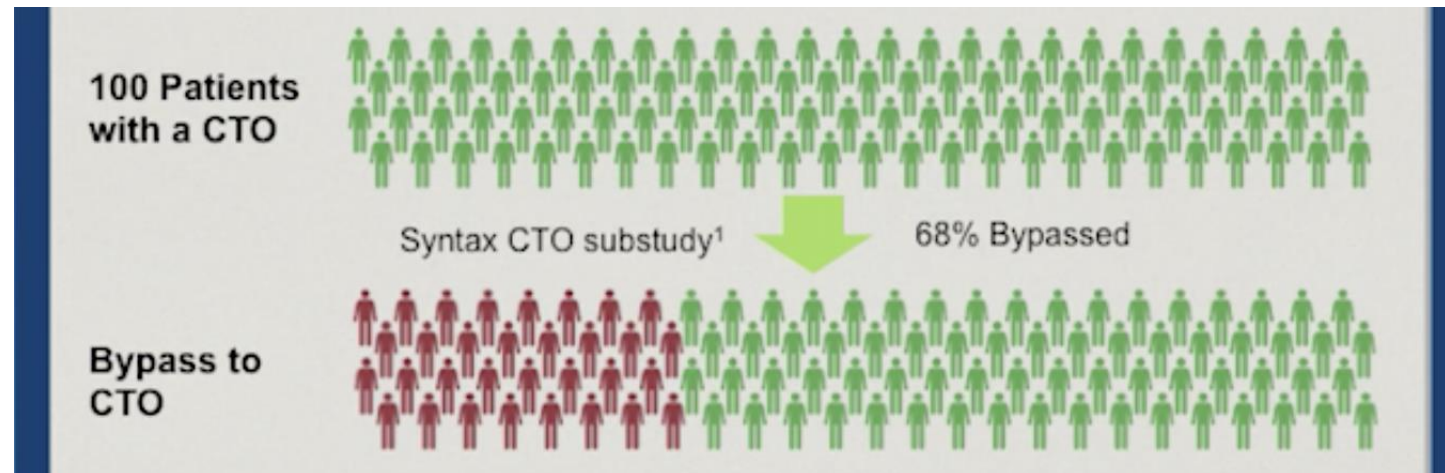
Toronto, Ontario, and Calgary, Alberta, Canada; and Tel Aviv, Israel

40% previous MI in CTO territory

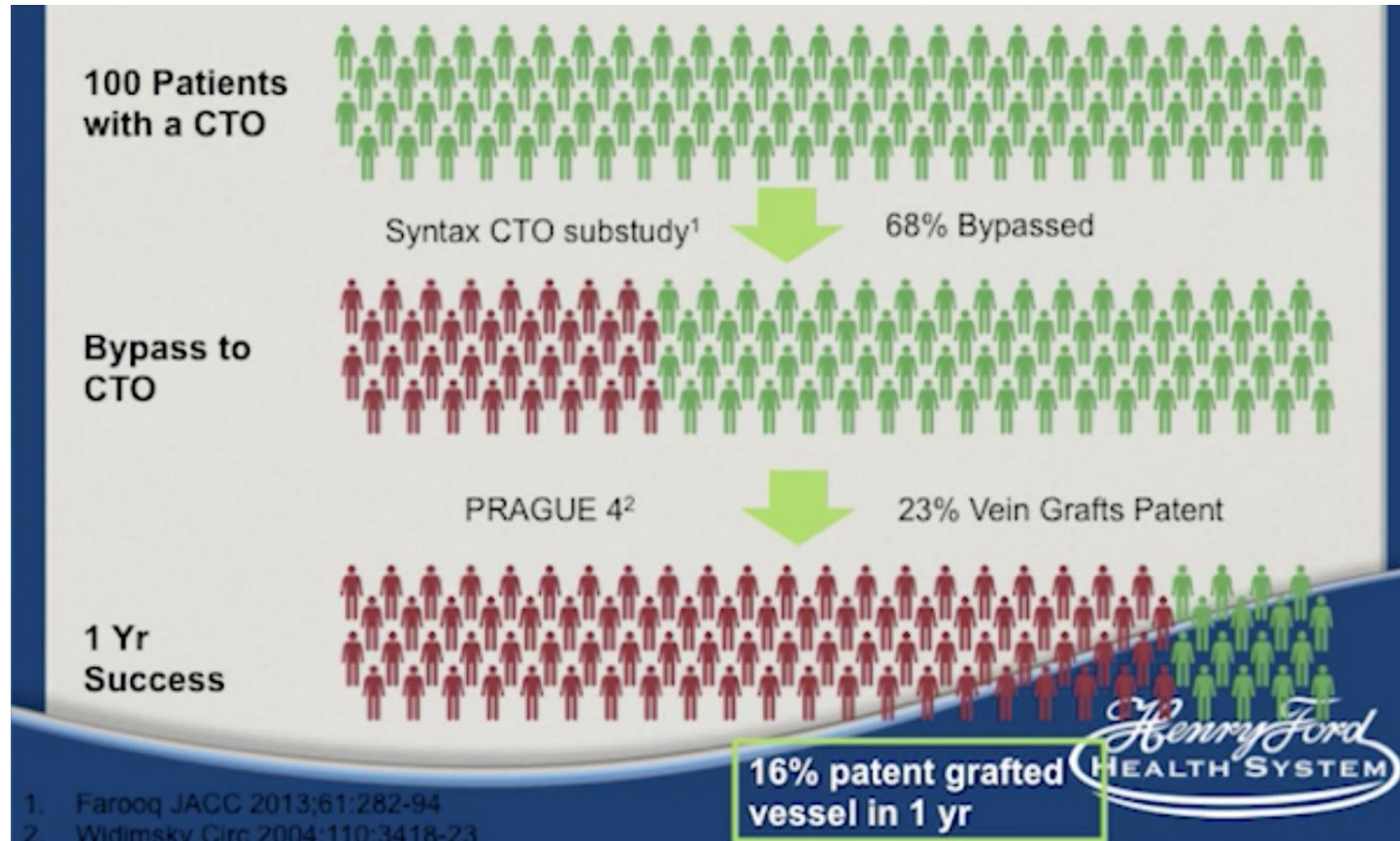
26% Q waves in CTO MI territory

> 50% Normal LV function

Gestione con bypass della CTO

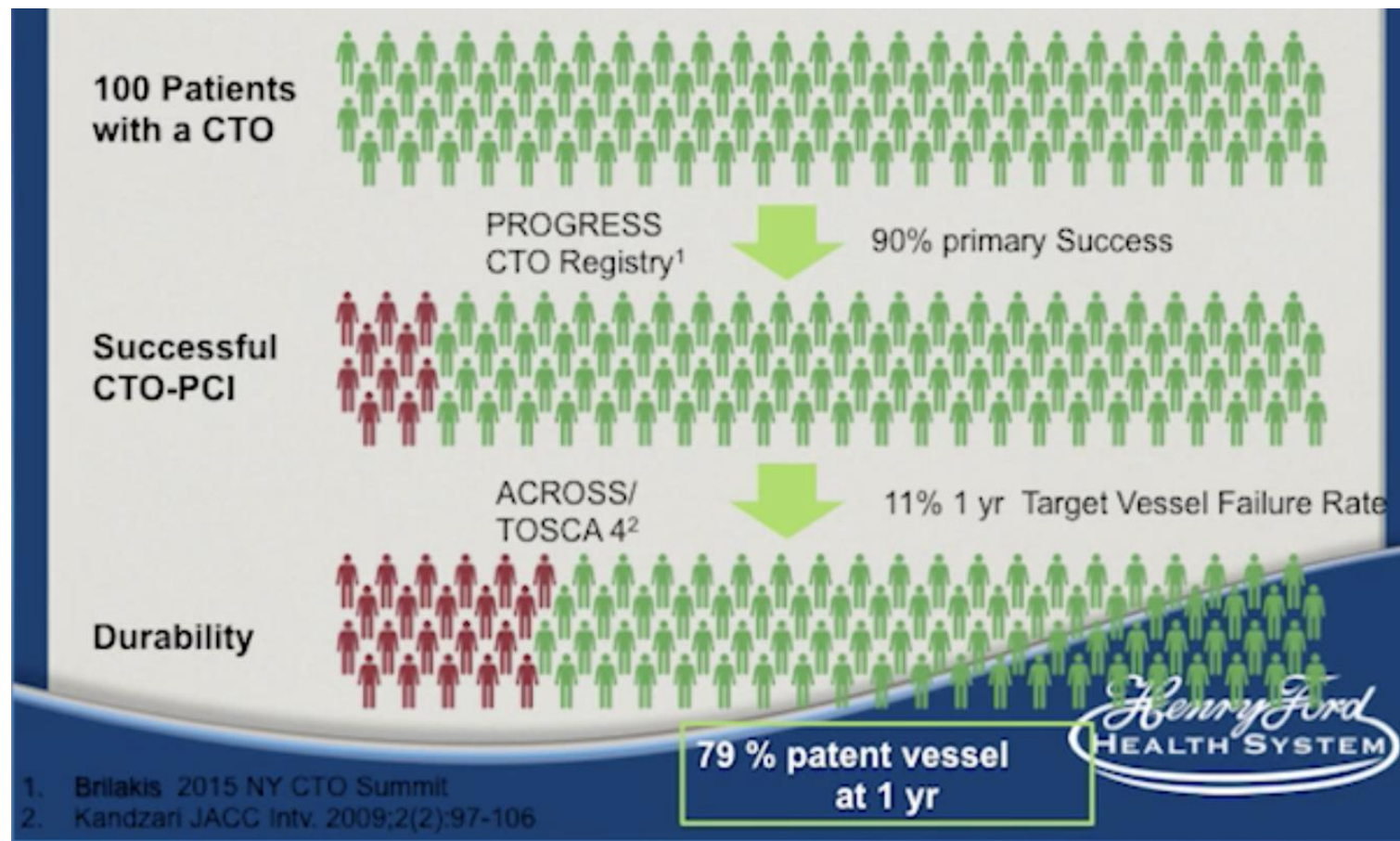


Gestione con bypass della CTO



Courtesy of Khaldoun AlAswad

Gestione con angioplastica della CTO



Courtesy of Khaldoun AlAswad

Gestione con bypass della CTO

FACT

Can be a valid option especially in certain scenarios:

- Low surgical risk
- MVD + CTO
- High Syntax score
- AND the CTO Vessel will be grafted!

Caveats

- A substantial percentage of CTO vessels are not grafted
- Graft patency rates are low
-

Scarsa evidenza scientifica a favore di CTO PCI

Circulation

ORIGINAL RESEARCH ARTICLE



Randomized Trial Evaluating Percutaneous Coronary Intervention for the Treatment of Chronic Total Occlusion

The DECISION-CTO Trial

Editorial, see p 1684

Seung-Whan Lee*
Pil Hyung Lee, MD*

Primary endpoint: Mortality and MI

Limitations:

- Underpowered: prematurely terminated (65%)
- randomization was done before non-CTO PCI
- 77% of the OMT arm received PCI to non-CTO vessel
- 20% crossover (OMT to CTO PCI arm)
- Symptoms and residual ischemia not evaluated after non-CTO

Scarsa evidenza scientifica a favore di CTO PCI



ESC

European Society
of Cardiology

European Heart Journal (2018) 39, 2484–2493
doi:10.1093/eurheartj/ehy220

CLINICAL RESEARCH

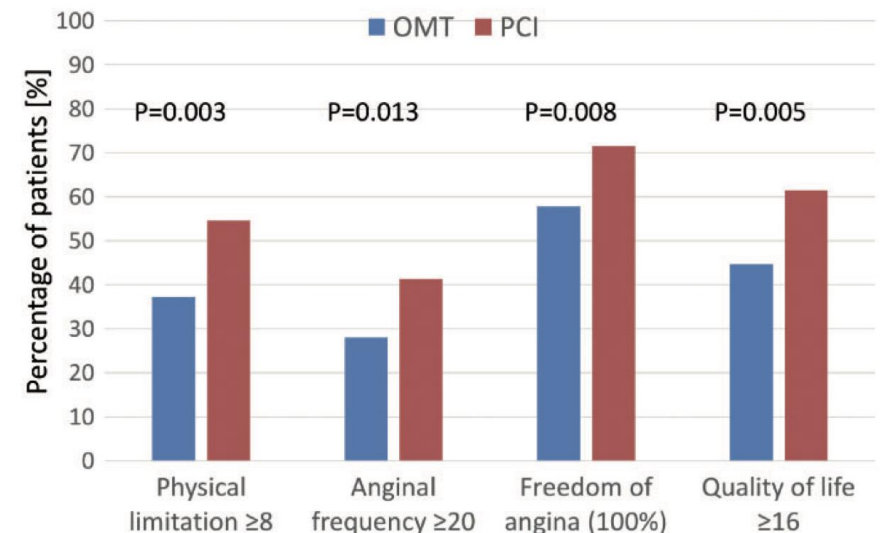
Interventional cardiology

A randomized multicentre trial to compare revascularization with optimal medical therapy for the treatment of chronic total coronary occlusions

Gerald S. Werner^{1*}, Victoria Martin-Yuste², David Hildick-Smith³, Nicolas Boudou⁴, Georgios Sianos⁵, Valery Gelev⁶, Jose Ramon Rumoroso⁷, Andrejs Erglis⁸, Evald Høj Christiansen⁹, Javier Escaned¹⁰, Carlo di Mario¹¹, Thomas Hovasse¹², Luis Teruel¹³, Alexander Bufe¹⁴, Bernward Lauer¹⁵, Kris Bogaerts¹⁶, Javier Goicolea¹⁷, James C. Spratt¹⁸, Anthony H. Gershlick¹⁹, Alfredo R. Galassi²⁰, and Yves Louvard¹²; for the EUROCTO trial investigators[†]

Primary endpoint: QoL (SAQ):

- Underpowered: prematurely terminated (35%)
- Many highly symptomatic patients not randomized
- PCI to CTO performed >4w after PCI to non-CTO vessel
-



Scarsa evidenza scientifica a favore di CTO PCI

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<http://dx.doi.org/10.1016/j.jacc.2016.07.744>

Percutaneous Intervention for Concurrent Chronic Total Occlusions in Patients With STEMI

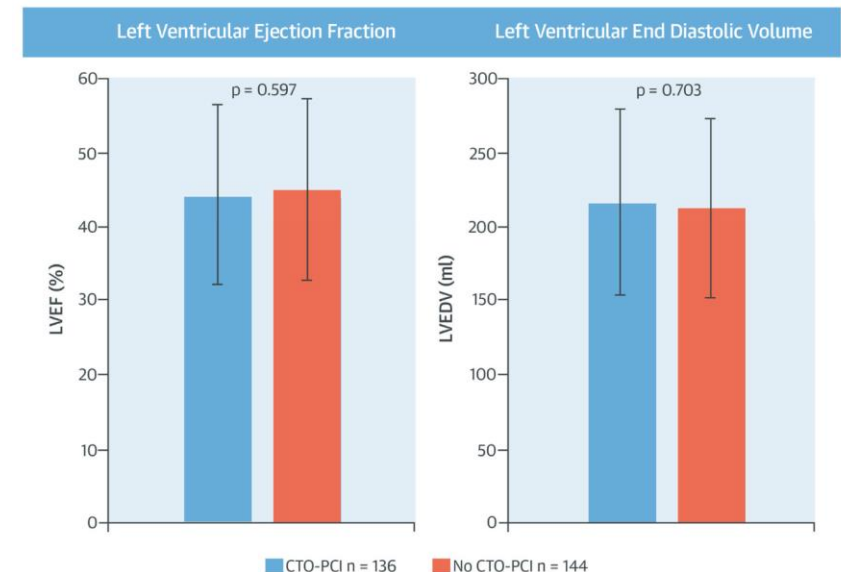


The EXPLORE Trial

José P.S. Henriques, MD, PhD,^a Loes P. Hoebers, MD,^a Truls Råmunddal, MD, PhD,^b Peep Laanmets, MD,^c
Erlend Eriksen, MD,^d Matthijs Bax, MD,^e Dan Ioanes, MD,^b Maarten J. Suttorp, MD, PhD,^f
Bradley H. Strauss, MD, PhD,^g Emanuele Barbato, MD, PhD,^h Robin Nijveldt, MD, PhD,ⁱ
Albert C. van Rossum, MD, PhD,^j Koen M. Marques, MD, PhD,ⁱ Joëlle Elias, MD,^a Ivo M. van Dongen, MD,^a
Bimmer E.P.M. Claessen, MD, PhD,^a Jan G. Tijssen, PhD,^a René J. van der Schaaf, MD, PhD,^j
for the EXPLORE Trial Investigators

Primary endpoint: LVEF and LVEDV

- Selection bias: 14 sites, 7 years
- Symptoms, ischemia and viability not tested
-

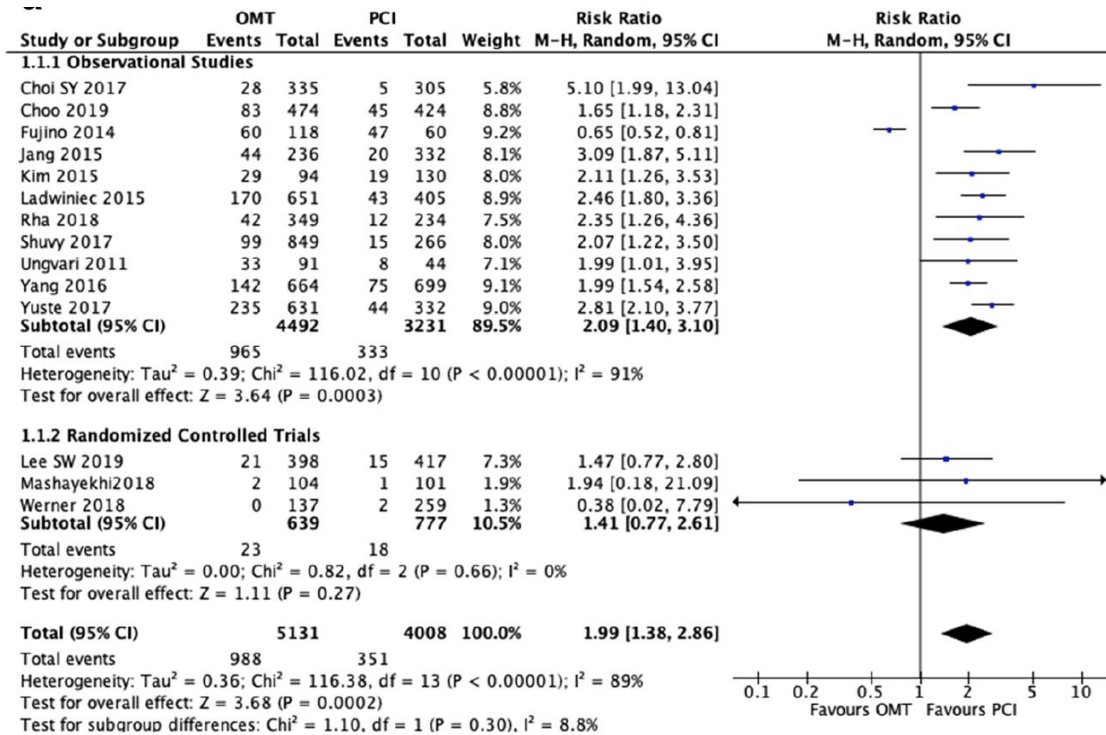




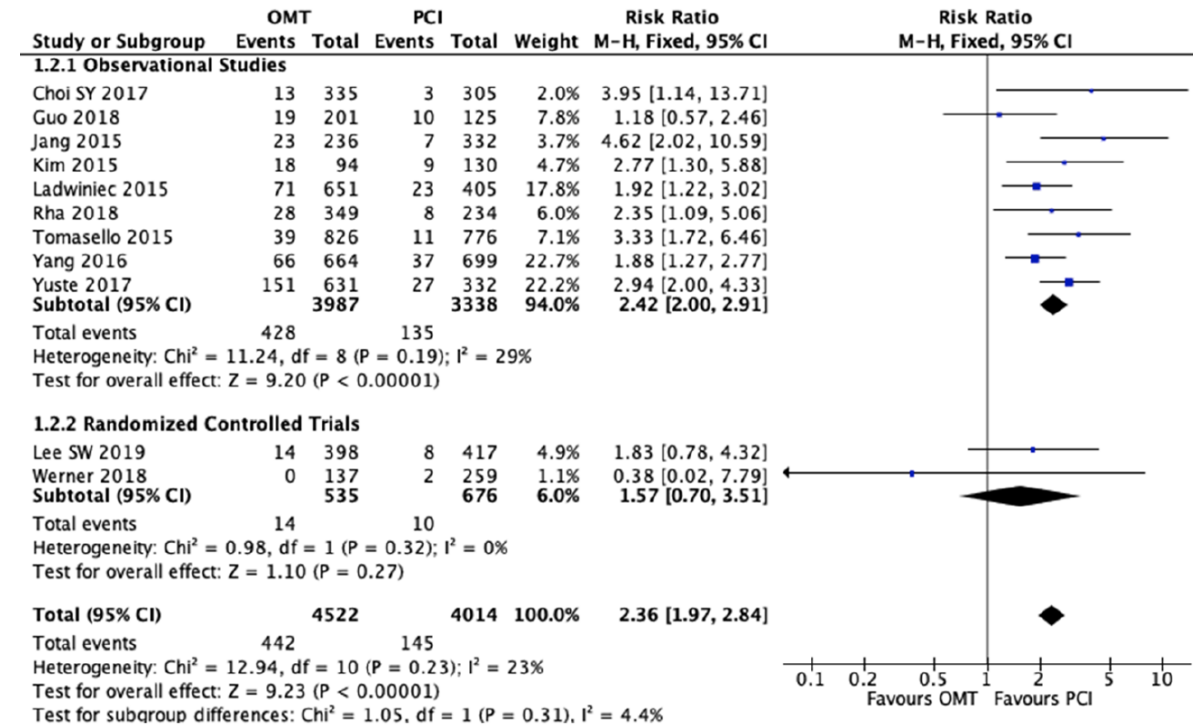
Percutaneous Coronary Intervention Versus Medical Therapy for Chronic Total Occlusion of Coronary Arteries: A Systematic Review and Meta-Analysis

Ka Hou Christien Li^{1,2,3} · Ka Hei Gabriel Wong^{1,2} · Mengqi Gong⁴ · Tong Liu⁴ · Guangping Li⁴ · Yunlong Xia⁵ · Jeffery Ho^{2,6} · Luis Nombela-Franco⁷ · Abhishek C. Sawant⁸ · Simon Eccleshall⁹ · Gary Tse^{1,2} · Vassilios S. Vassiliou^{9,10,11}

All-cause mortality

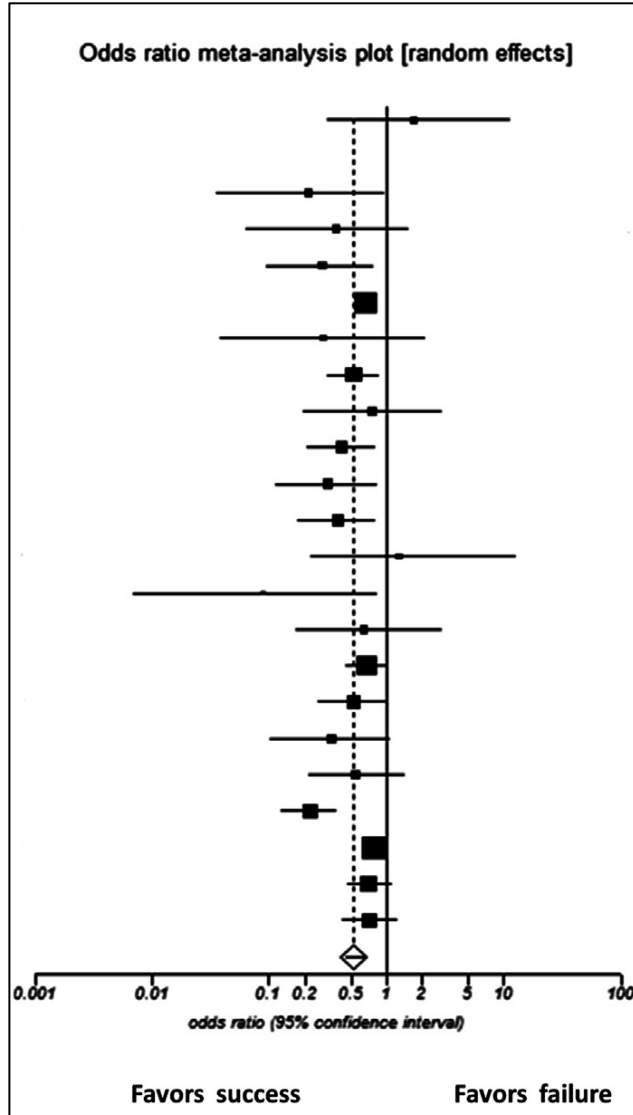


Cardiac death



Scarsa evidenza scientifica a favore di CTO PCI..?

Successful vs. Failed CTO PCI



- 29,315 CTO PCI, follow-up of 3.11 years
- Procedural success: 71% (range 51% - 87%).
- successful CTO PCI was associated with
 - lower mortality (odds ratio [OR] 0.52, 95% CI 0.43 to 0.63)
 - less residual angina (OR 0.38, 95% CI 0.24 to 0.60)
 - lower risk for stroke (OR 0.72, 95% CI 0.60 to 0.88)
 - less need for CABG (OR 0.18, 95% CI 0.14 to 0.22)
 - lower risk for MACE (0.59, 95% CI 0.44 to 0.79).
 - No difference in the incidence of target vessel revascularization (OR 0.66, 95% CI 0.36 to 1.23) or myocardial infarction (OR 0.73, 95% CI 0.52 to 1.03).

Scarsa evidenza scientifica a favore di CTO PCI

FACT

- Limited and inadequately designed/conducted RCT currently available
- Data from multiple registries strongly support CTO PCI
- <25% of current guidelines recommendations based on RCT

Percutaneous revascularization of CTOs should be considered in patients with angina resistant to medical therapy or with a large area of documented ischaemia in the territory of the occluded vessel.^{629,659–663}

IIa

B

2018 ESC Myocardial Revascularization Guidelines

CTO PCI è una procedura impegnativa, con elevate possibilità di insuccesso e di complicazioni

JACC: CARDIOVASCULAR INTERVENTIONS
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CLINICAL RESEARCH

CORONARY

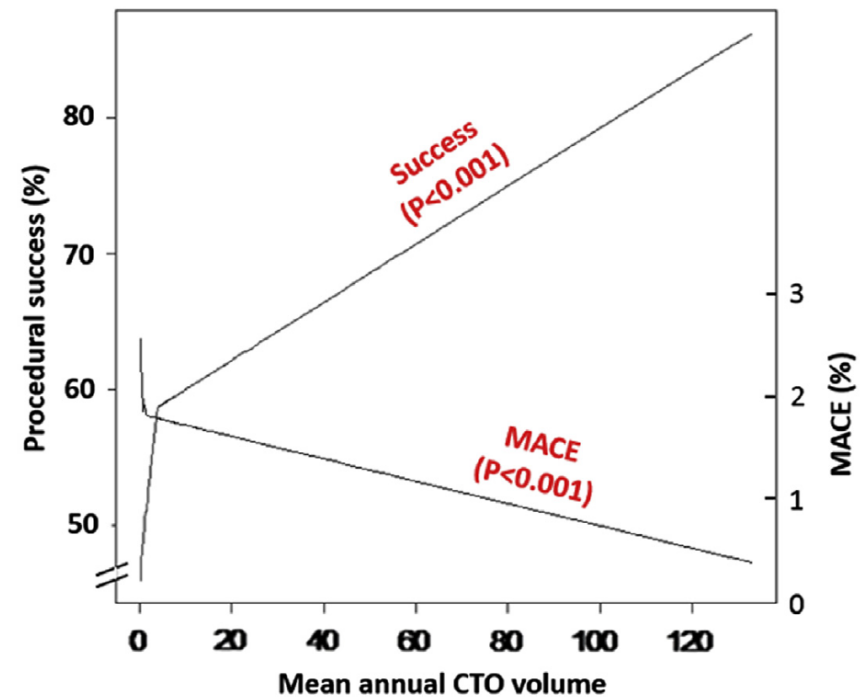
Procedural Outcomes of Chronic Total Occlusion Percutaneous Coronary Intervention

A Report From the NCDR (National Cardiovascular Data Registry)

Emmanouil S. Brilakis, MD, PhD,* Subhash Banerjee, MD,* Dimitri Karpaliotis, MD,† William L. Lombardi, MD,‡
Thomas T. Tsai, MD, MSc,§ Kendrick A. Shunk, MD, PhD,|| Kevin F. Kennedy, MS,¶ John A. Spertus, MD,¶
David R. Holmes, Jr, MD,# J. Aaron Grantham, MD¶



FIGURE 4 Operator CTO PCI Volume Association With Procedural Success and Complications



Conclusioni - CTO

- Avere una CTO significa prognosi peggiore
- Popolazione sottotrattata
- Se trattata ha prognosi migliore
- Se effettuata in centri ad alto volume e da operatori esperti, la riapertura di una CTO può essere ottenuta con elevata probabilità (>90%) e con un accettabile rischio di complicanze (<3%)
- Vanno favoriti i pazienti con sintomi resistenti alla terapia e con elevata quota di ischemia miocardica.

Deciding to perform CTO PCI should depend on the patient's clinical presentation and risk benefit ratio and not the patient's anatomy, as experienced operators using contemporary CTO PCI techniques can be expected to be successful in the great majority of patients (90%), even among the most complex CTO lesions.

Nuovi sviluppi in Cardiologia Interventistica Strutturale

Interventi sulle valvole

TAVR/BAV
MitraClip/TMVR
Tricuspid
PVL



Interventi non valvolari

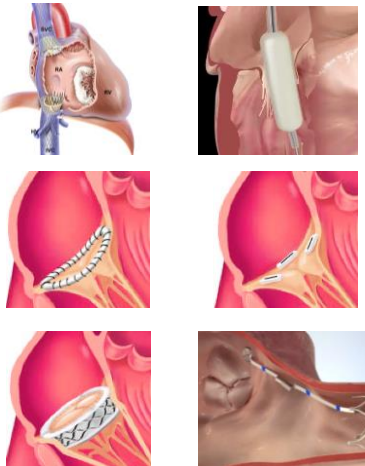
Adult Congenital
LAAC
HF therapies
Other

Percutaneous technologies are the future for the treatment of heart valve diseases

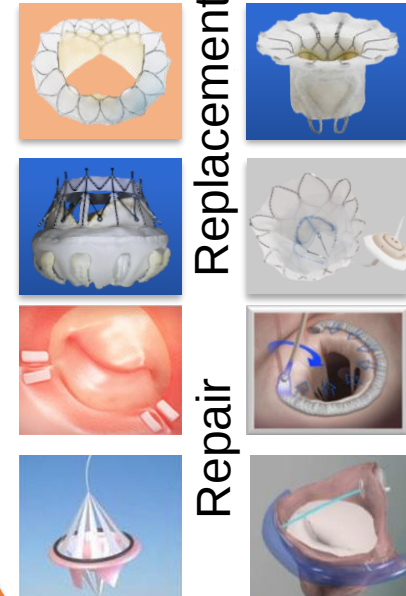
Pulmonary Valve



Tricuspid



Mitral Valve



Aortic Valve



2017: A YEAR OF CELEBRATIONS

**40 YEARS OF CORONARY
ANGIOPLASTY**

**15 YEARS OF TRANSCATHETER
AORTIC VALVE IMPLANTATION**



ANDREAS GRÜNTZIG



ALAIN CRIBIER

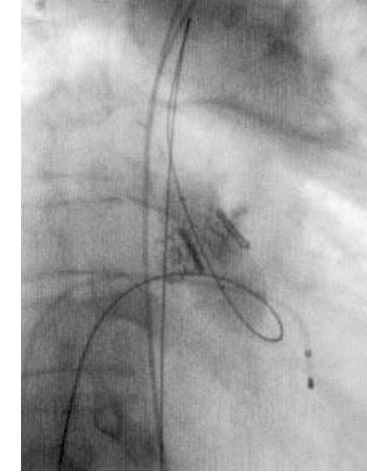
FIRST PATIENT TO UNDERGO PTCA

Grüntzig A. *The Lancet* 1978;1:263



FIRST PATIENT TO UNDERGO TAVI

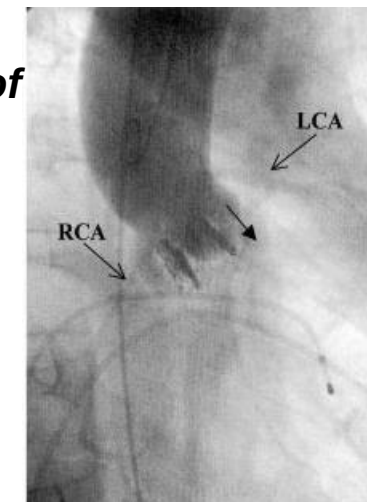
Cribier A. et al. *Circulation*. 2002 Dec 10;106(24):3006-8



2002

***Progressive worsening of
acute limb ischemia :***

- ***Leg amputation 4 months after TAVI***
- ***No post-operative recovery***

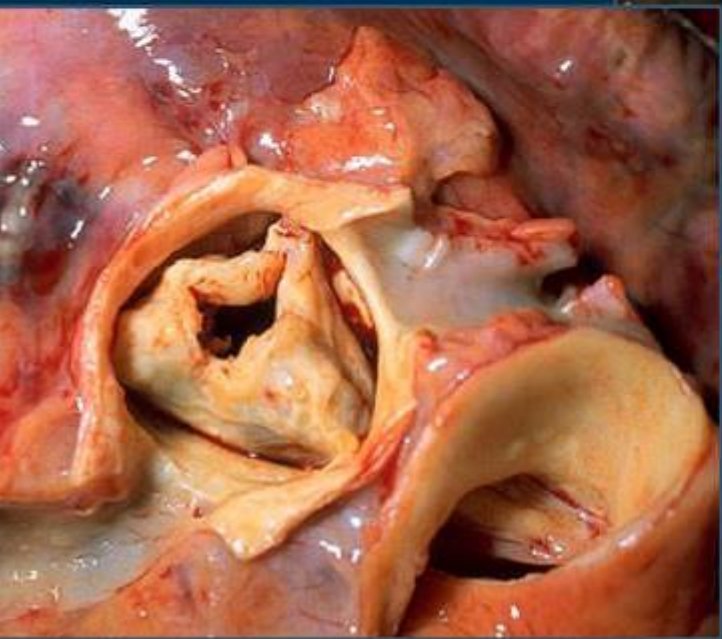




- Stenosi aortica senile calcifica



- Stenosi aortica su aor



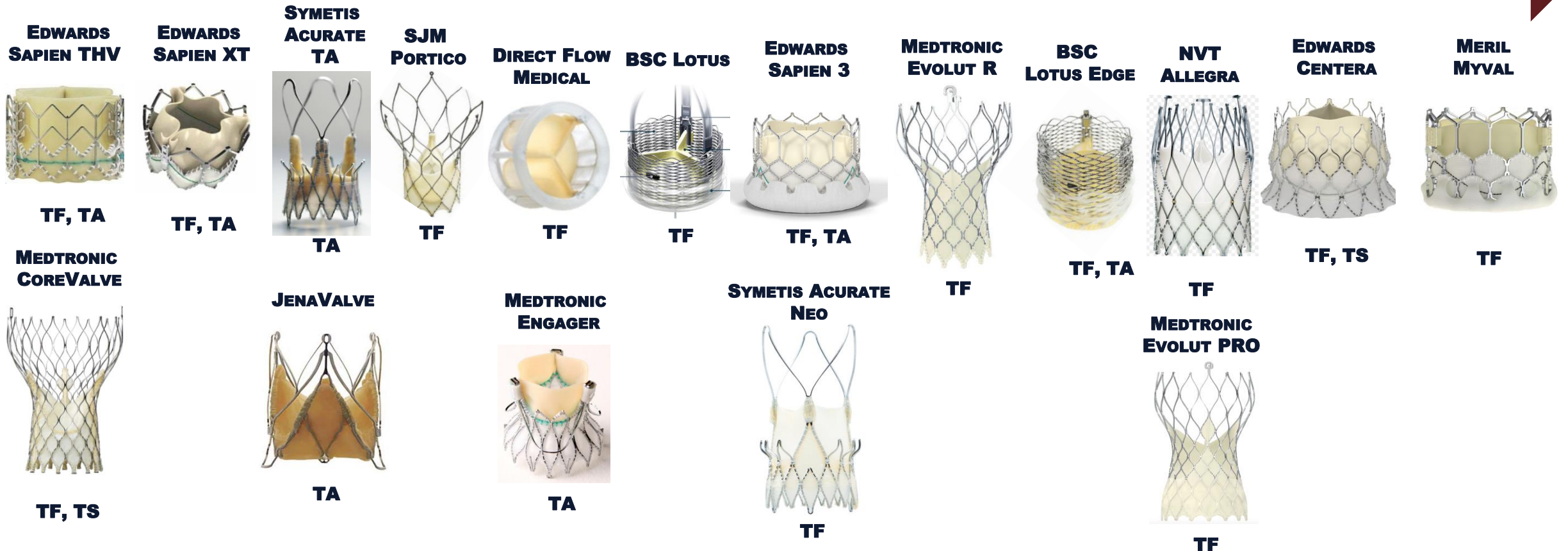
- Stenosi aort

Aorta

17 YEARS OF TAVI (2002 – 2019)

PROSTHESIS WITH CE – MARK APPROVAL

2007 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019



A large, solid orange diamond shape is centered on the page. It has a soft drop shadow, making it appear to float slightly above the white background.

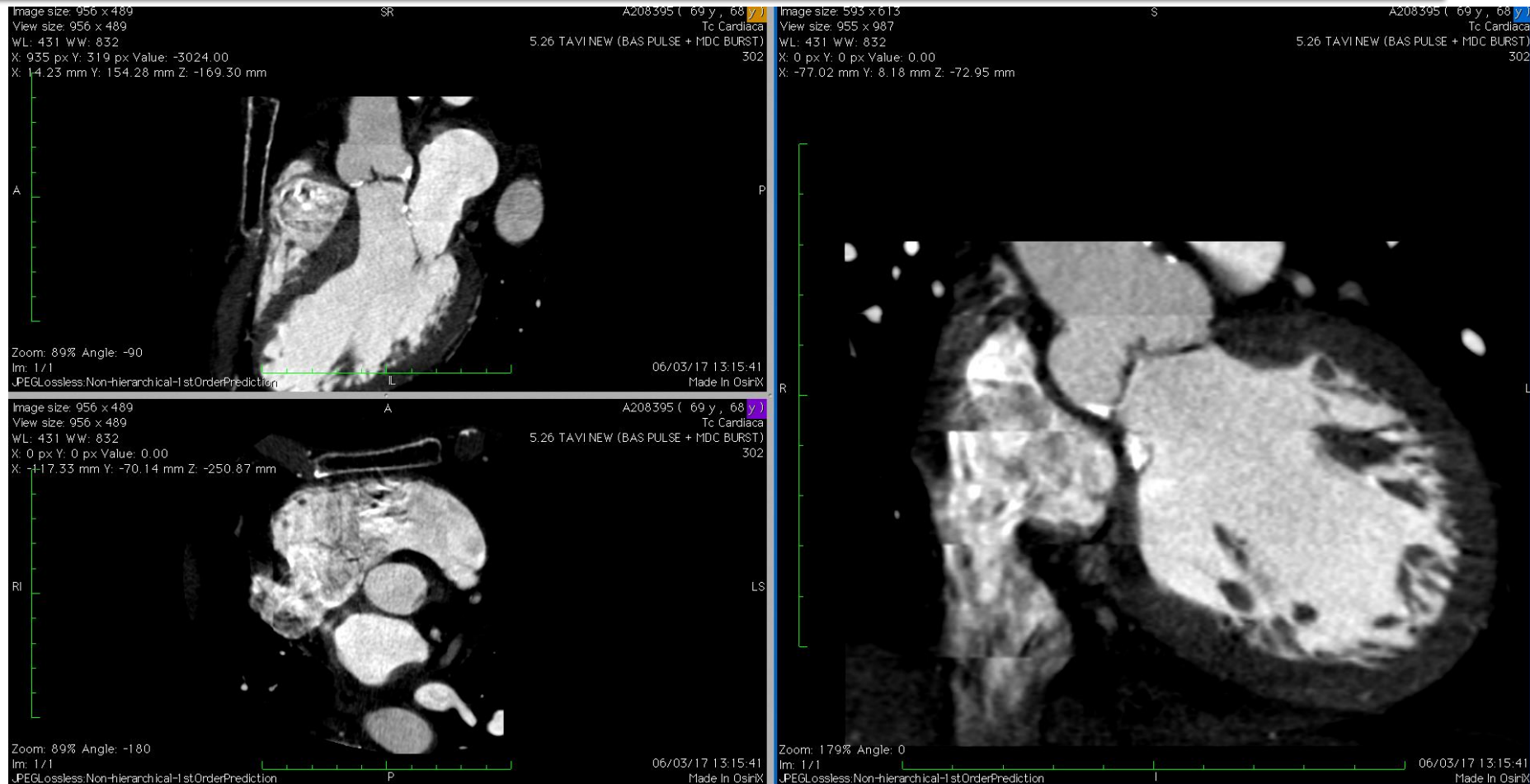
Esempio TAVI

Caso clinico

Patient Characteristics

- 80-year-old male
- Hypertension
- No other Comorbidities. Normal renal function
- NYHA II
- Severe symptomatic aortic stenosis
 - Mean gradient=55mmHg, PAP=20mmHg, EF=60%
 - No mitral or tricuspid valve disease
- STS score 1.4%; Logistic EuroScore II 0.98%
- (If 85-yrs old: STS 1.9% , LogES II 1.13%)

CT scan



Area 423 mm²
Perimeter 73.8 mm

Normal coronaries

CT scan





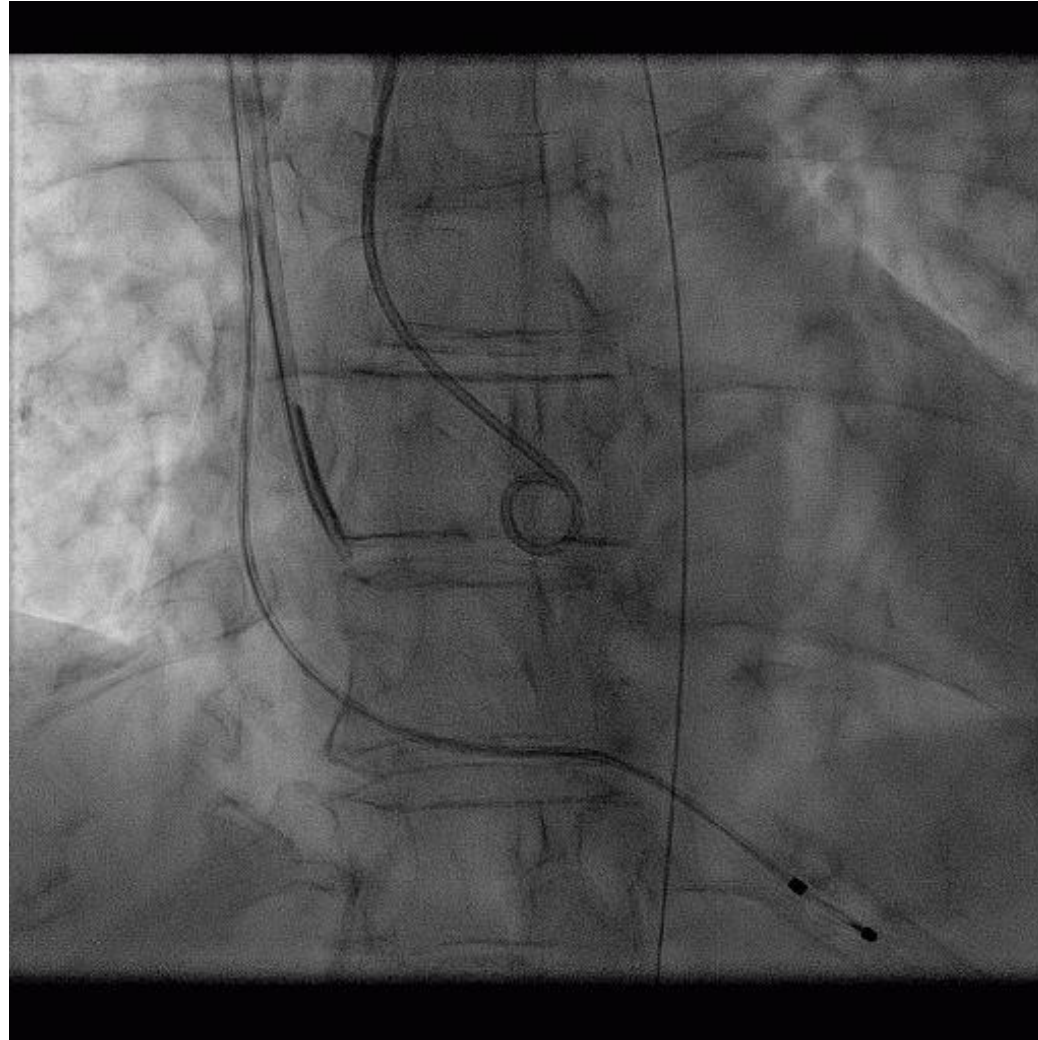
TAVI procedure



Therapeutic Right femoral access



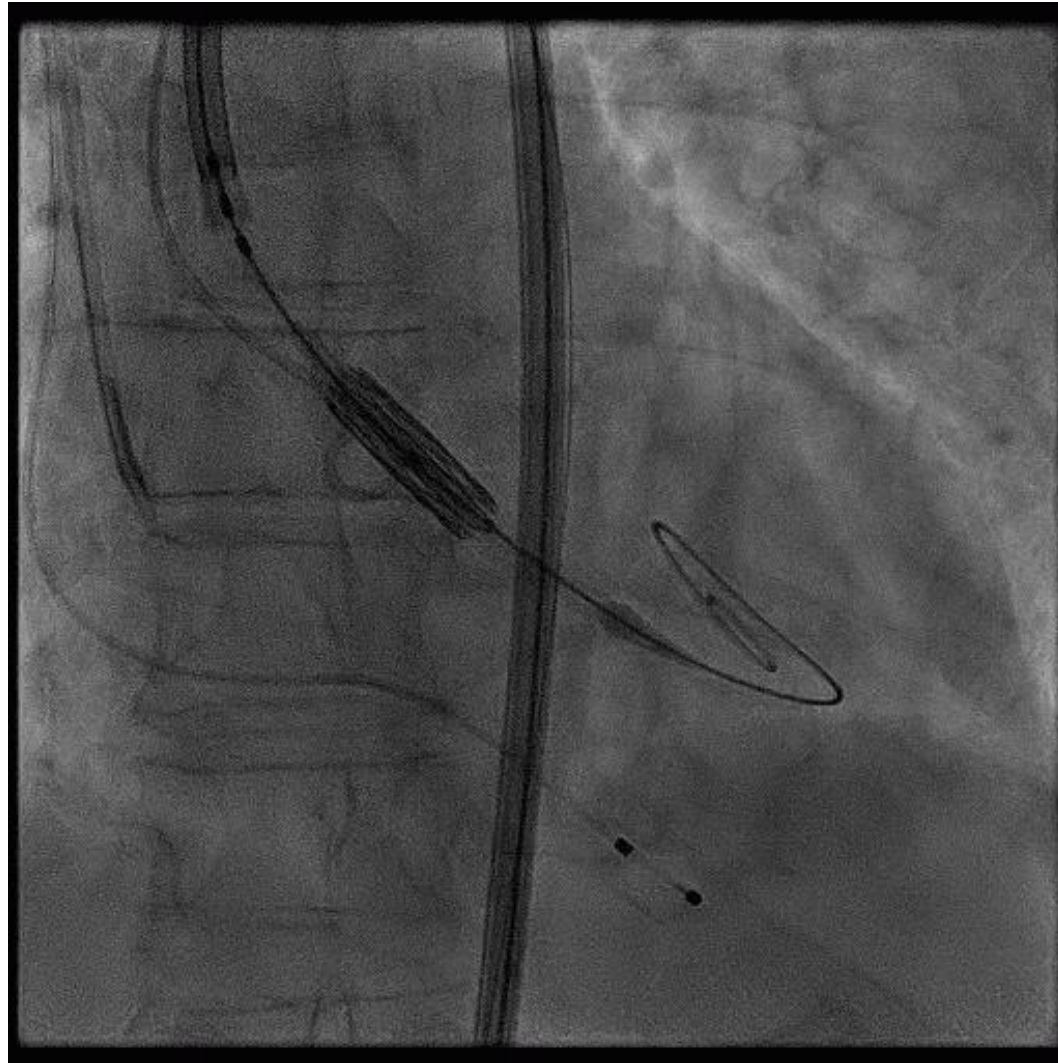
TAVI procedure



Severe Aortic Stenosis and Regurgitation



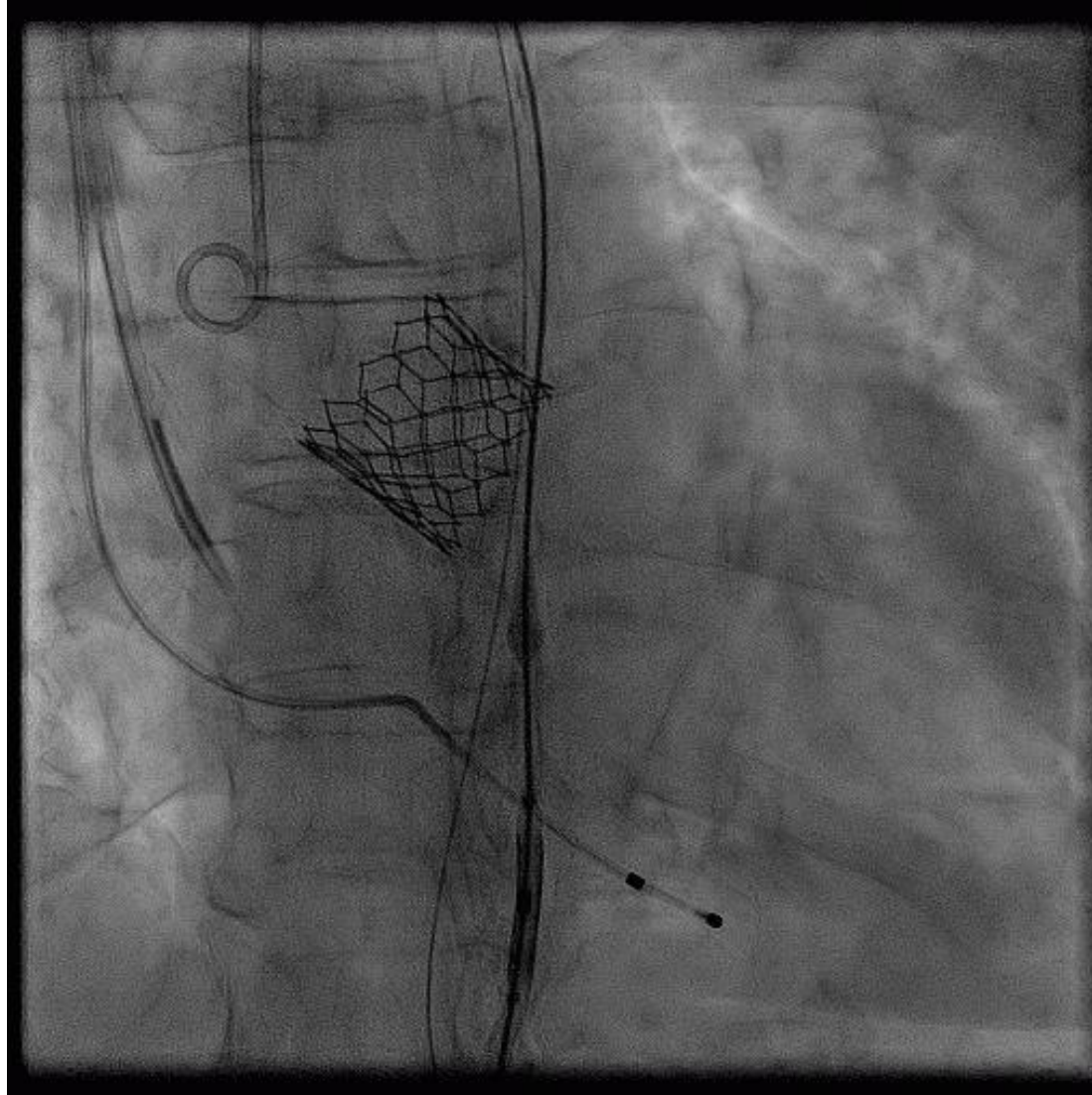
TAVI procedure



Edwards Sapien 3 26 mm implantation



TAVI procedure



No paravalvular Leak



TAVI procedure



Right femoral access angiography after
closure by Proglide

Performance Benchmarks for Expert Valve Centers

	Current	Future
• All-cause mortality	$\leq 3\%$	$< 1\%$
• Major (disabling) strokes	$\leq 2\%$	$\leq 1\%$
• Major vascular complications	$\leq 5\%$	$\leq 2\%$
• New permanent pacemakers	$\leq 10\%$	$\leq 8\%$
• Mod-severe para-valvular regurgitation	$\leq 5\%$	0%

Patient name :

Xxx Xxx

Patient hospital ID :

Xxx

Case ID:

TAV000024

Select patient

Anatomy

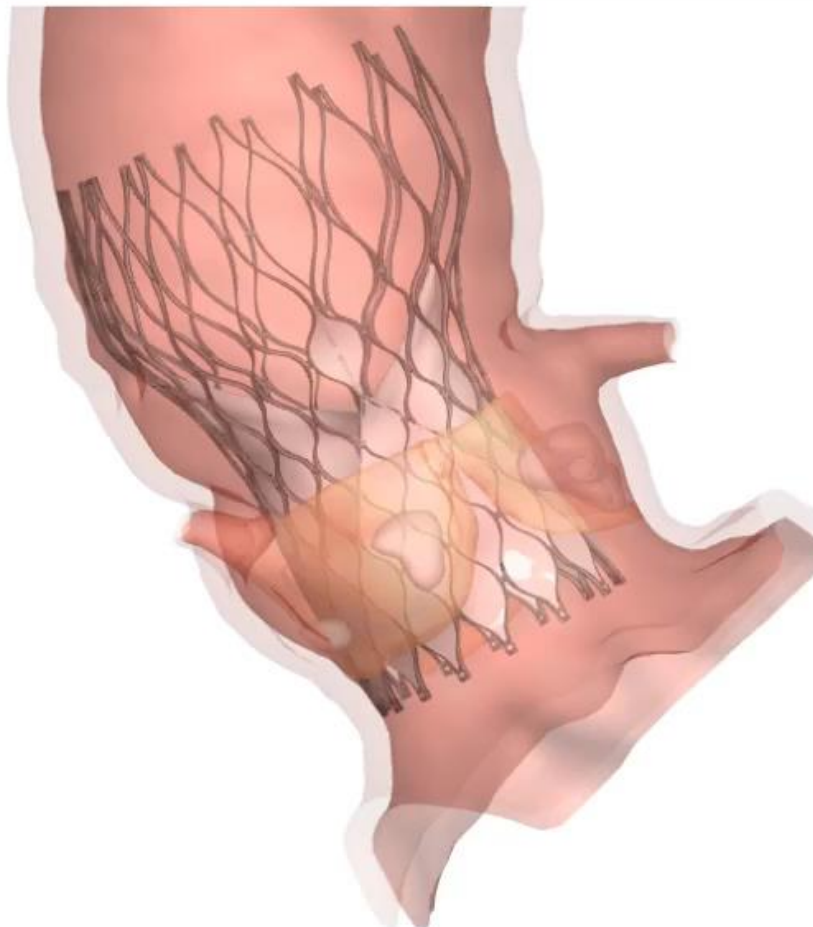
Treatment options

Simulation

Discussion

Report

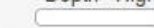
History



Transparency



Depth - High



Alignment



Deformation



Malapposition



Par. regurgitation



Reset camera

Add a viewport

Simulation data

Simulated device

CV26

Calcium-LCA ostium distance

6 mm

Calcium-RCA ostium distance

9 mm

Implantation depth NCC

3 mm

Implantation depth LCC

5 mm

Paravalvular regurgitation

22 ml/s

Patient name :
Xxx Xxx

Patient hospital ID :
Xxx

Case ID:
TAV000039

Select patient

Anatomy

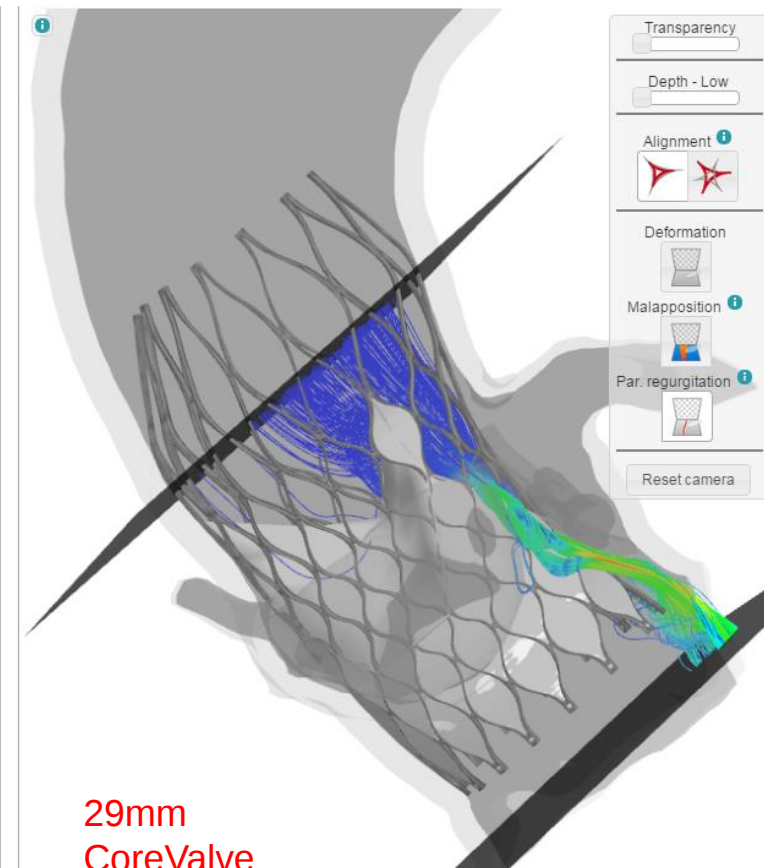
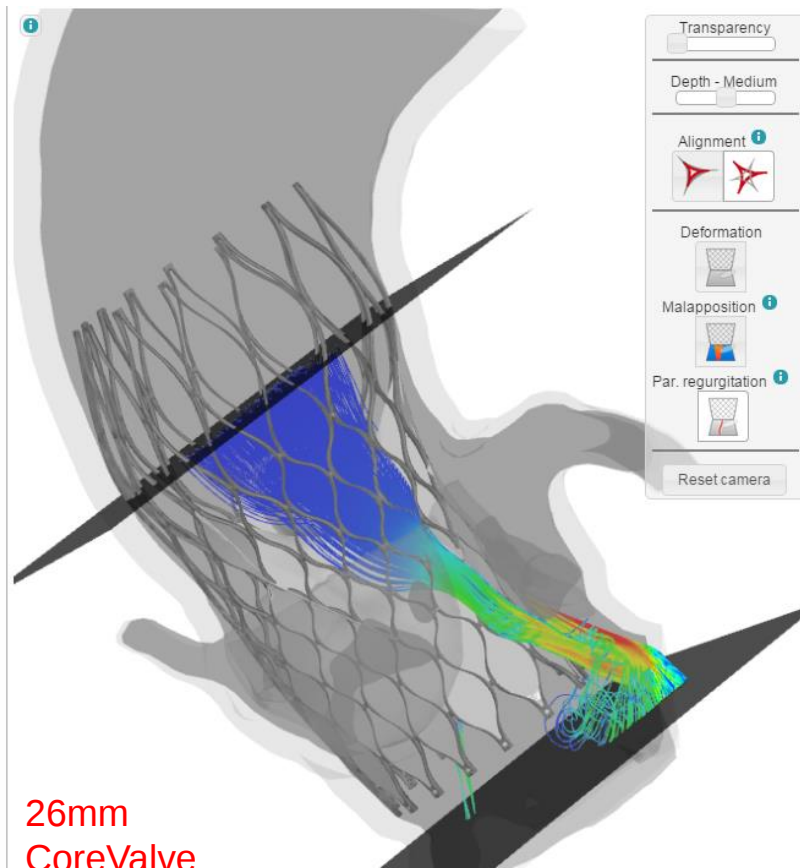
Treatment options

Simulation

Discussion

Report

History



Hide a viewport

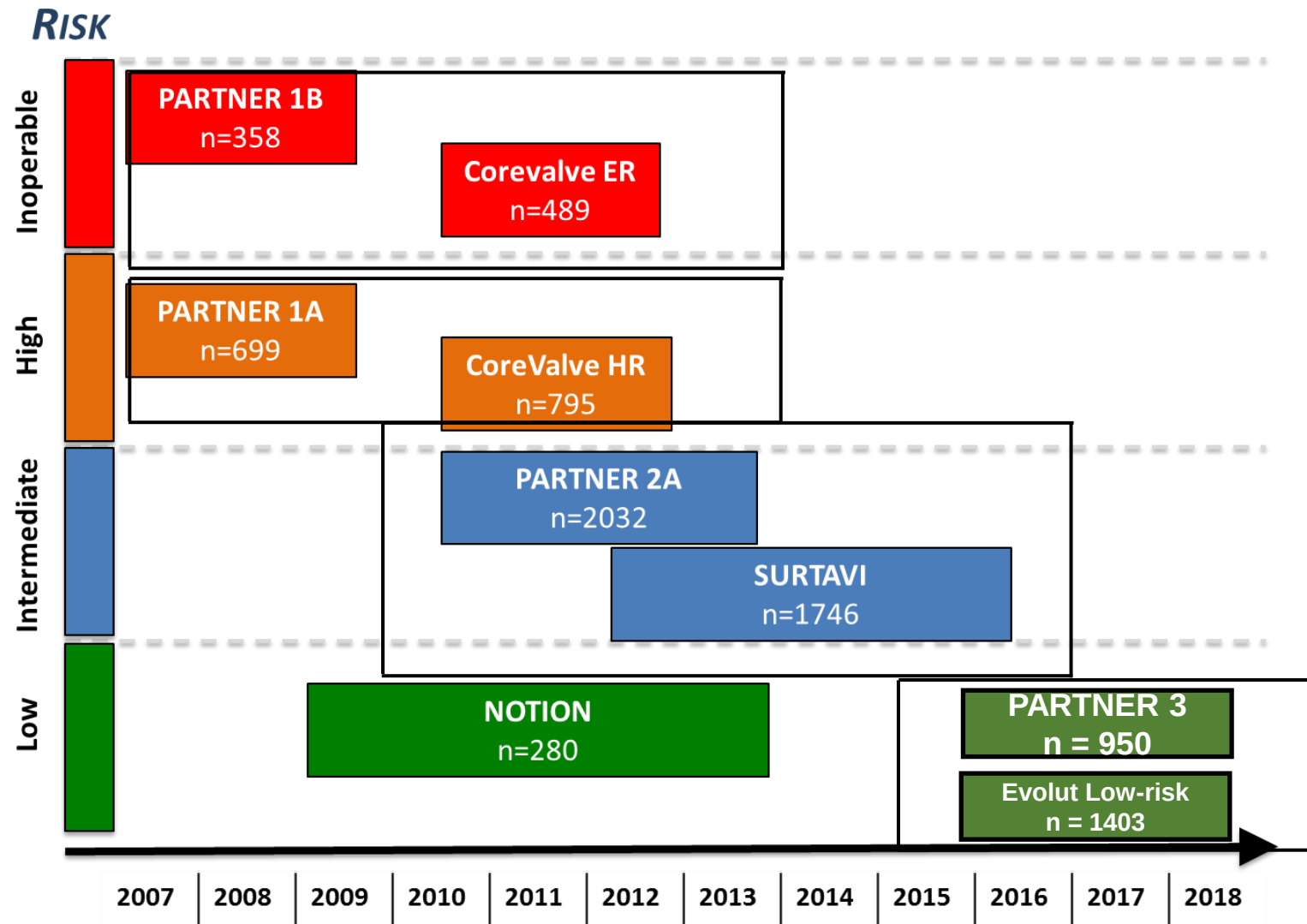
Simulation data

Simulated device	CV26
Calcium-LCA ostium distance	6 mm
Calcium-RCA ostium distance	8 mm
Implantation depth NCC	7 mm
Implantation depth LCC	6 mm
Paravalvular regurgitation	38 ml/s

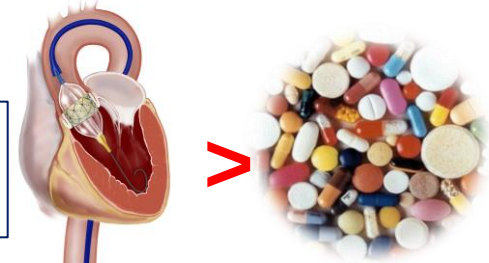
Simulated device	CV29
Calcium-LCA ostium distance	5 mm
Calcium-RCA ostium distance	8 mm
Implantation depth NCC	11 mm
Implantation depth LCC	8 mm
Paravalvular regurgitation	14 ml/s

Perimeter-based annulus diameter: 22.8mm

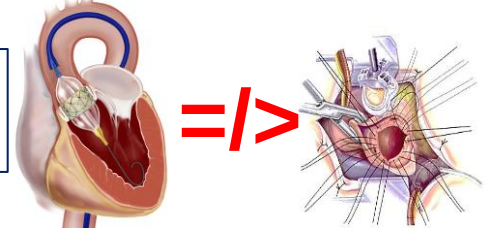
THE EVOLUTION OF CLINICAL EVIDENCE



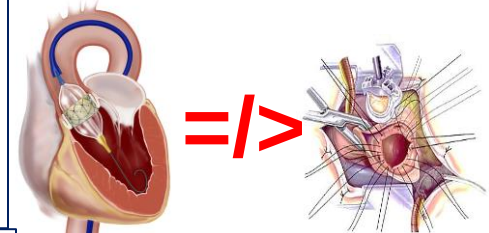
**TAVI superior
to medical Rx**



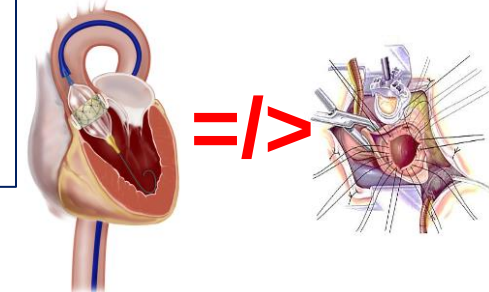
**TAVI noninferior or
superior to SAVR**



**TAVI
noninferior or
superior
(TF access) to
SAVR**



**Transfemoral
TAVI noninferior
or superior
to SAVR**

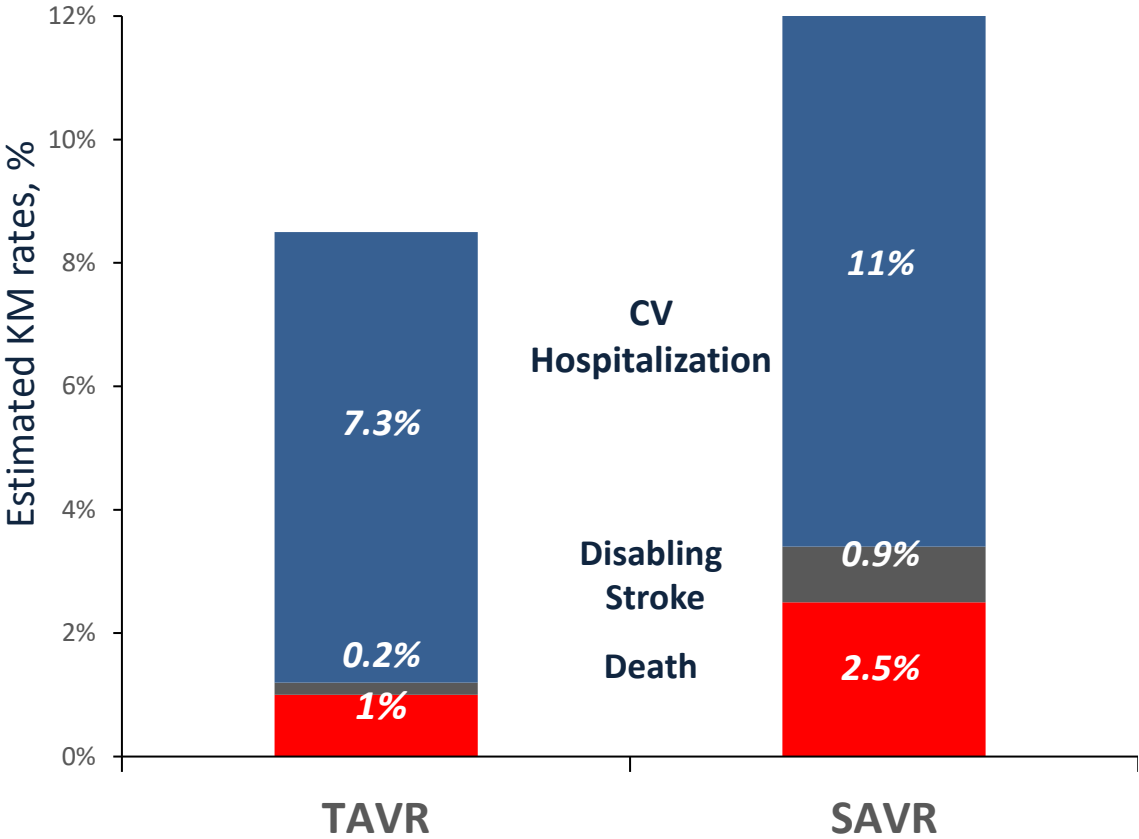


Clinical Implications

Death, Disabling Stroke and Re-Hospitalizations to 1 Year

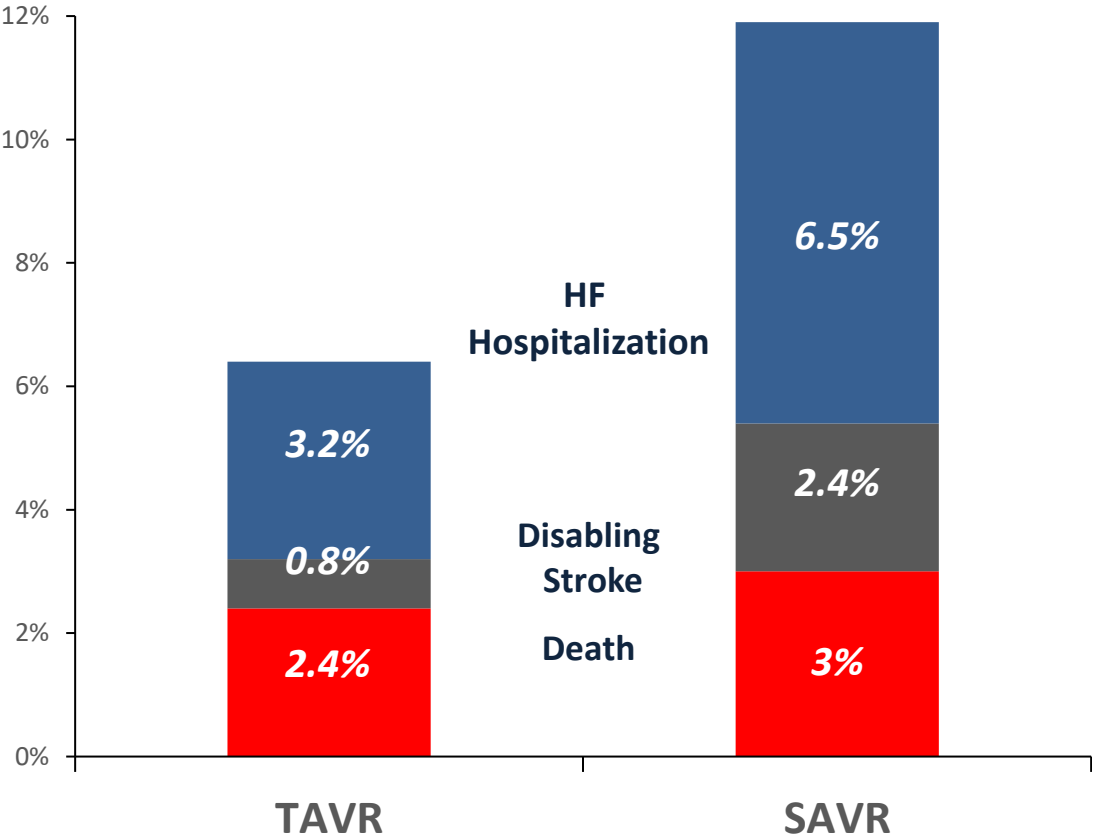
PARTNER 3 Trial

Mack MJ et al, N Engl J Med. 2019 May 2;380(18):1695-1705



Evolut Low-Risk Trial

Popma JJ et al, N Engl J Med. 2019 May 2;380(18):1706-1715



TAVI – SUPERIOR CLINICAL PERFORMANCE

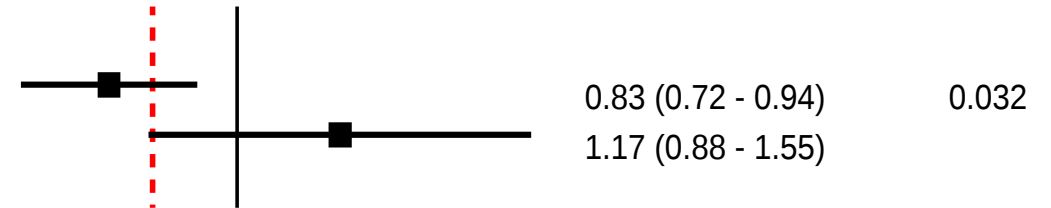
Meta-analysis of 7 RCTs

Siontis G et al, European Heart Journal (2019)

MORTALITY

Access route

Transfemoral
Transthoracic



**17% relative risk reduction
up to 2 years**

0.2

0.5

1

2

5

Favours TAVI

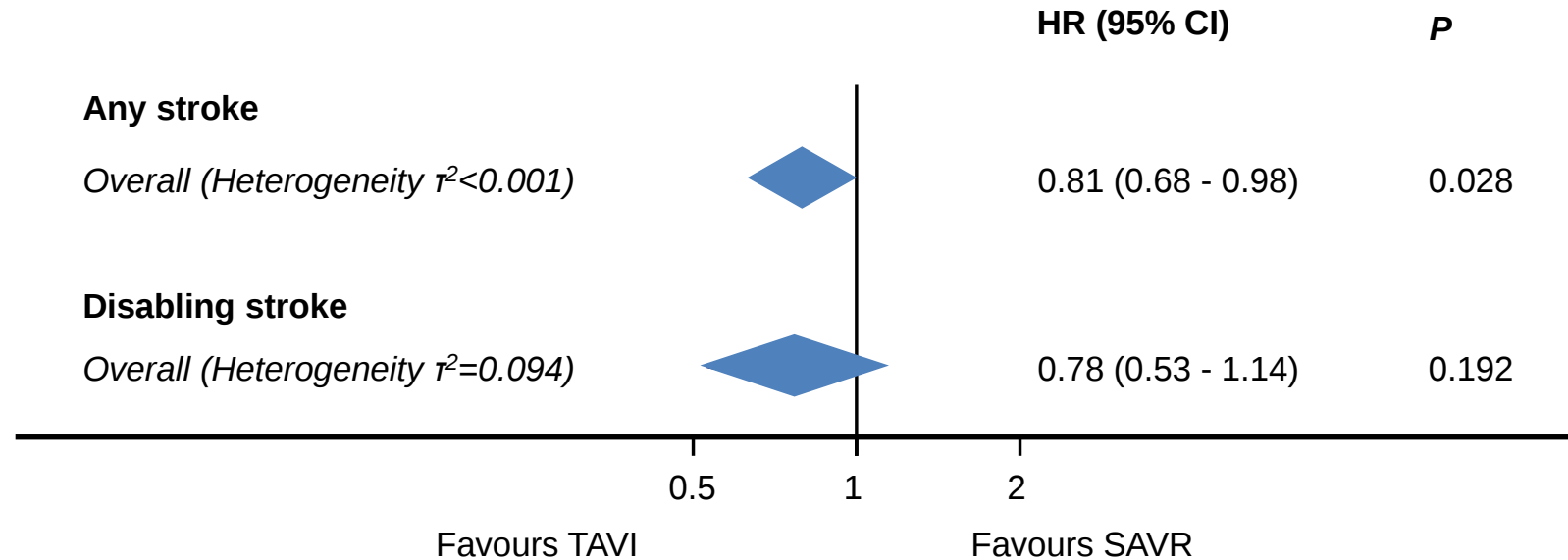
Favours SAVR

TAVI – SUPERIOR CLINICAL PERFORMANCE

Meta-analysis of 7 RCTs

Siontis G et al, European Heart Journal (2019)

STROKE



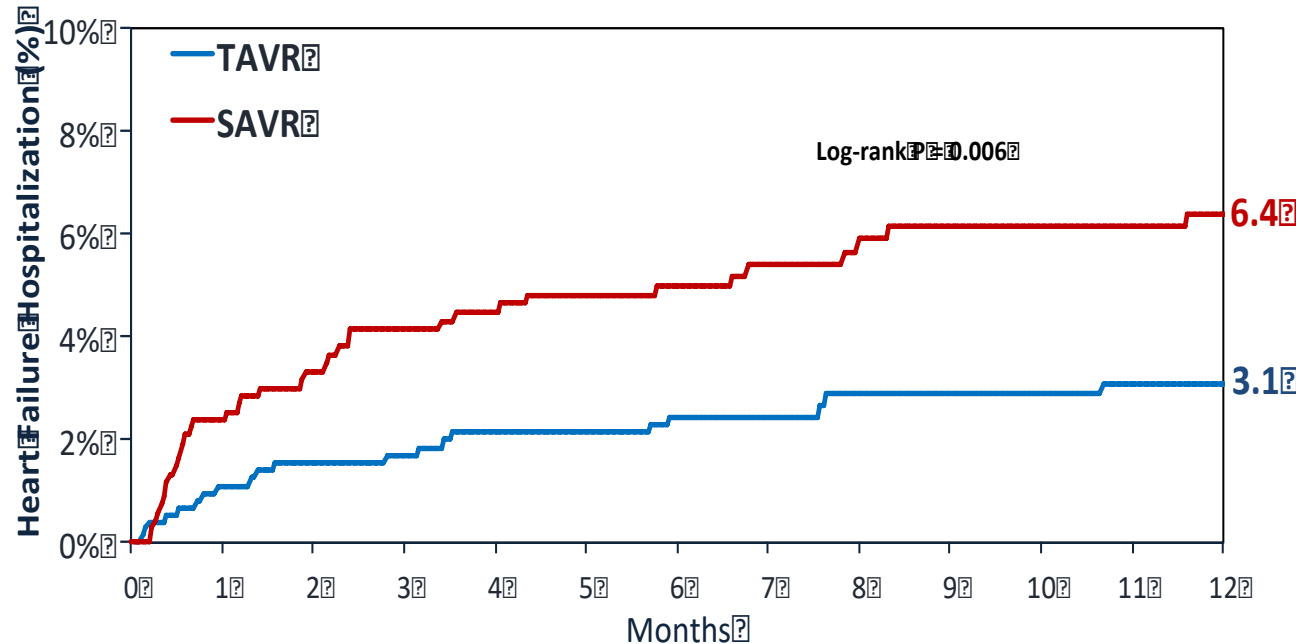
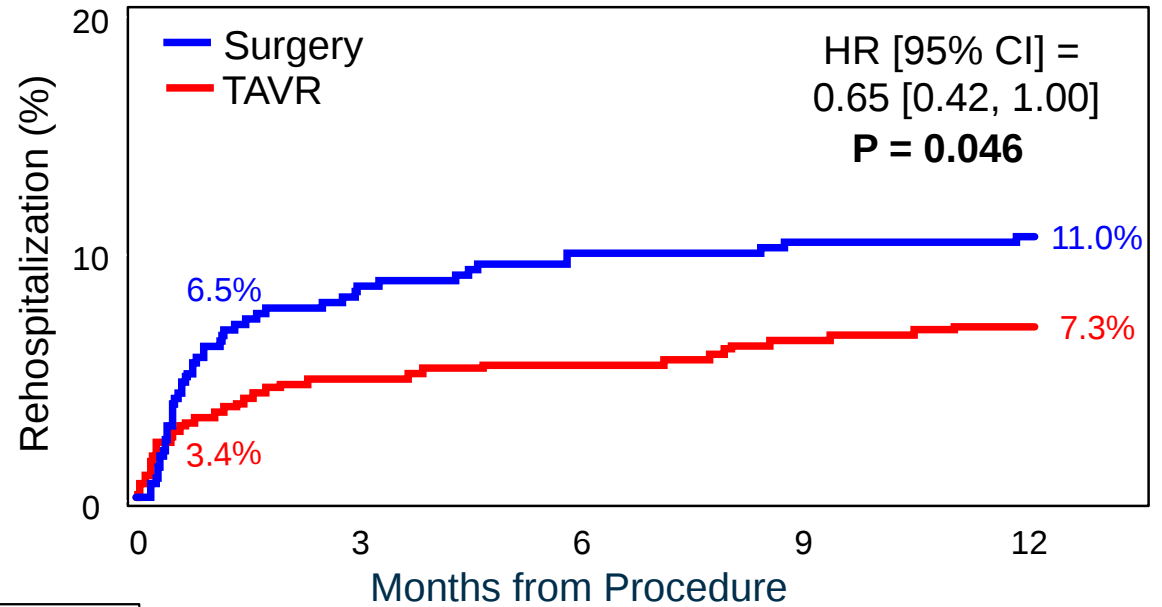
***19% relative risk reduction
up to 2 years***

TAVI – SUPERIOR CLINICAL PERFORMANCE

PARTNER 3 Trial

Mack MJ et al, N Engl J Med. 2019 May 2;380(18):1695-1705

RE-HOSPITALIZATION

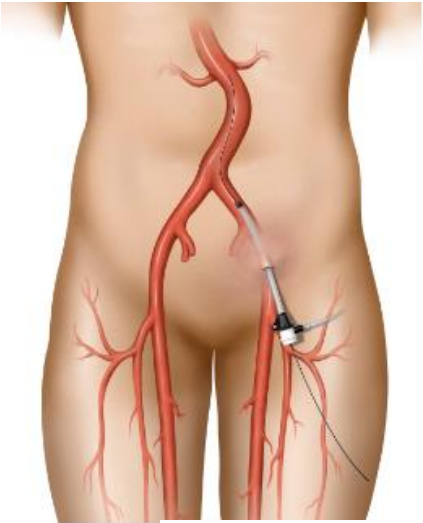


Evolut Low-Risk Trial

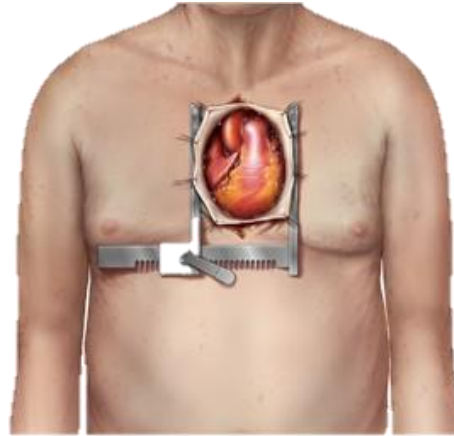
Popma JJ et al, N Engl J Med. 2019 May 2;380(18):1706-1715

TAVI - IMPROVED RESOURCE UTILIZATION

TRANSFEMORAL TAVI



SAVR

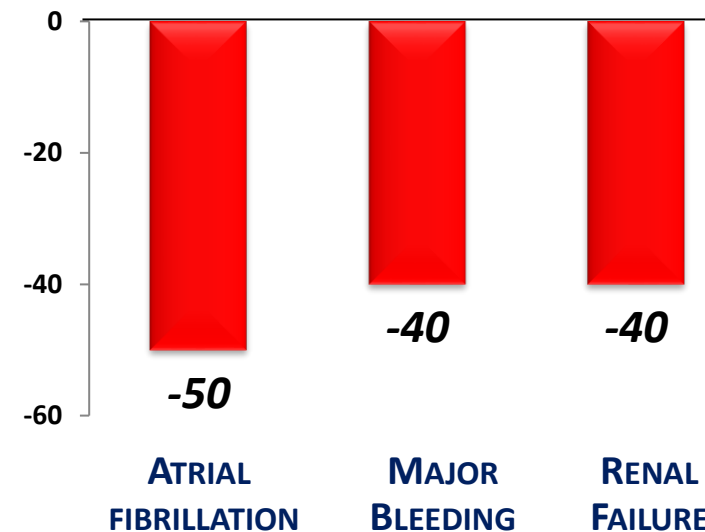


EARLY PERI-PROCEDURE

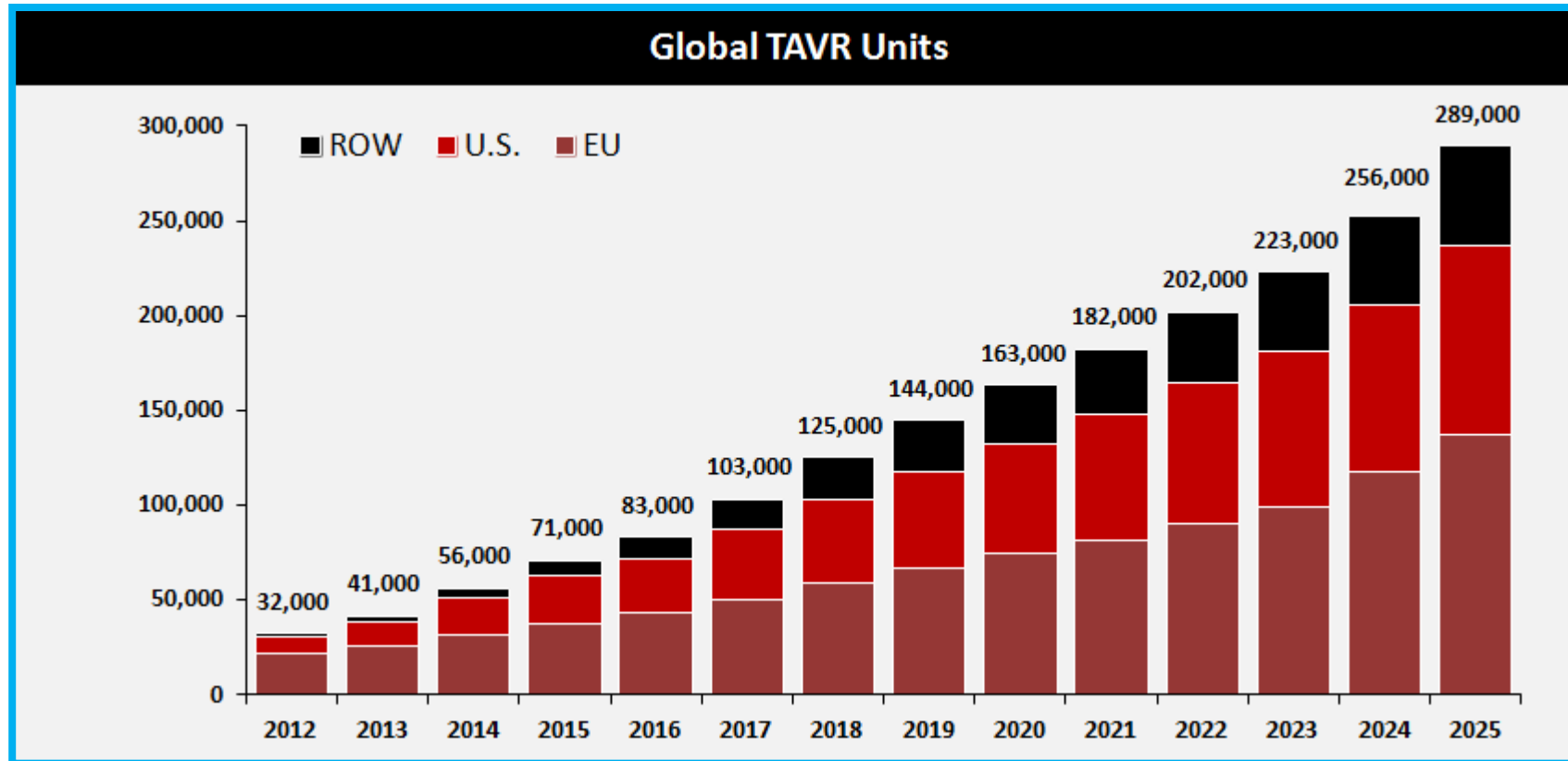


NO	OPEN THORACOTOMY	YES
NO	CARDIOPULMONARY BYPASS	YES
NO	OROTRACHEAL INTUBATION	YES
NO	GENERAL ANESTHESIA	YES
NO	PROLONGED VENTILATION	YES

TAVI vs. SAVR



-15%



In the next 10 years, TAVR growth will increase X4!

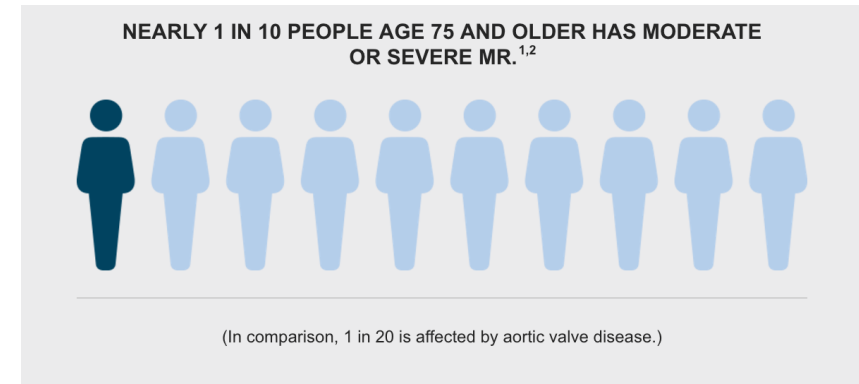
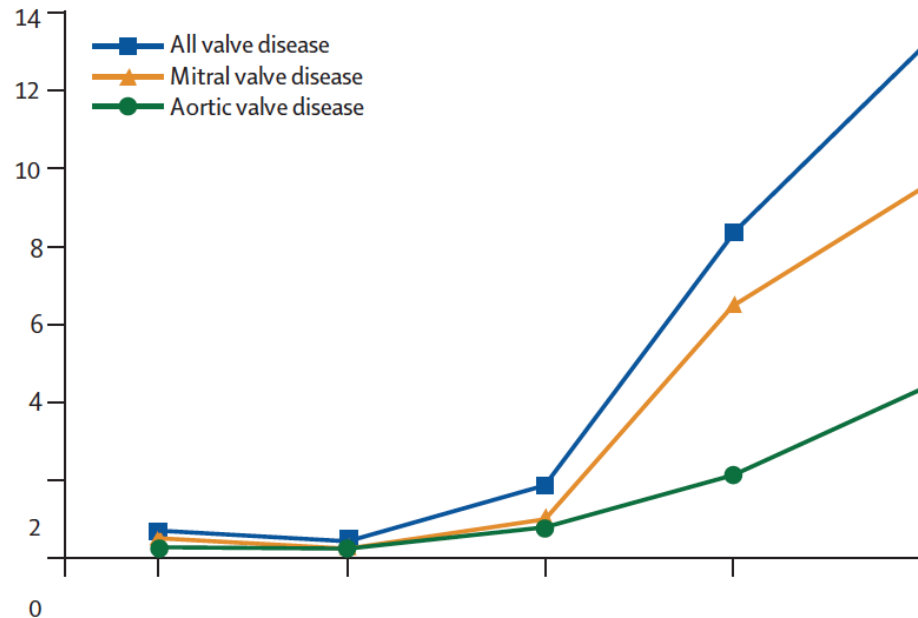
A large, solid orange diamond shape is centered on the page. It has a soft drop shadow, making it appear to float slightly above the white background.

Mitrare

Mitral Valve



Mitral Regurgitation is the most frequent valve disease in Europe & US

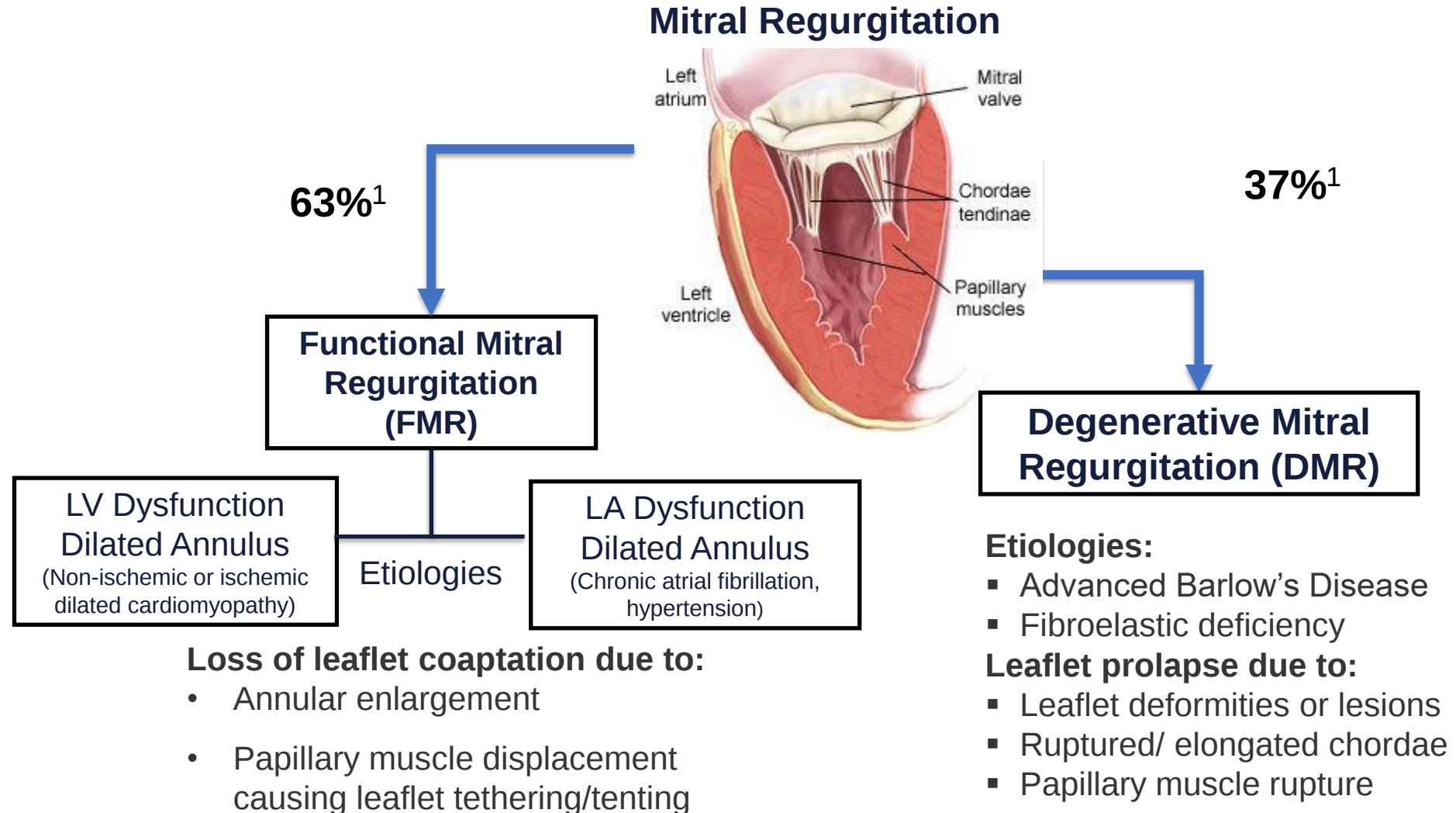


Prevalence of Moderate or Severe Mitral Valve Disease in the US = ~4.2M Patients*

Source: Nkomo et al. Burden of valvular heart diseases: a population-based study, Lancet 2006; 368:

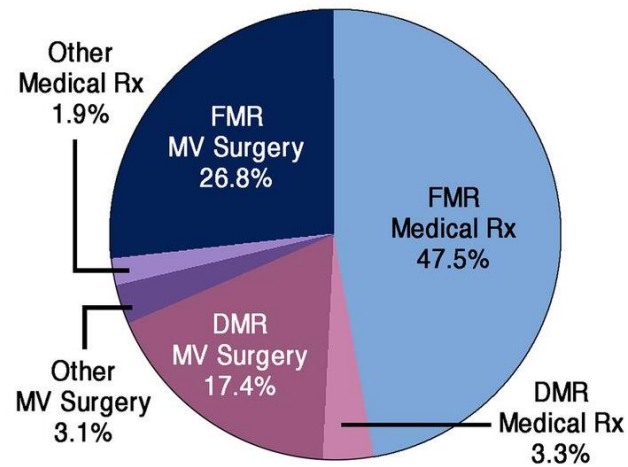
1005-11. 11.7% prevalence (population based studies); US Census Bureau 2016: 248M adults

Types of Mitral Regurgitation

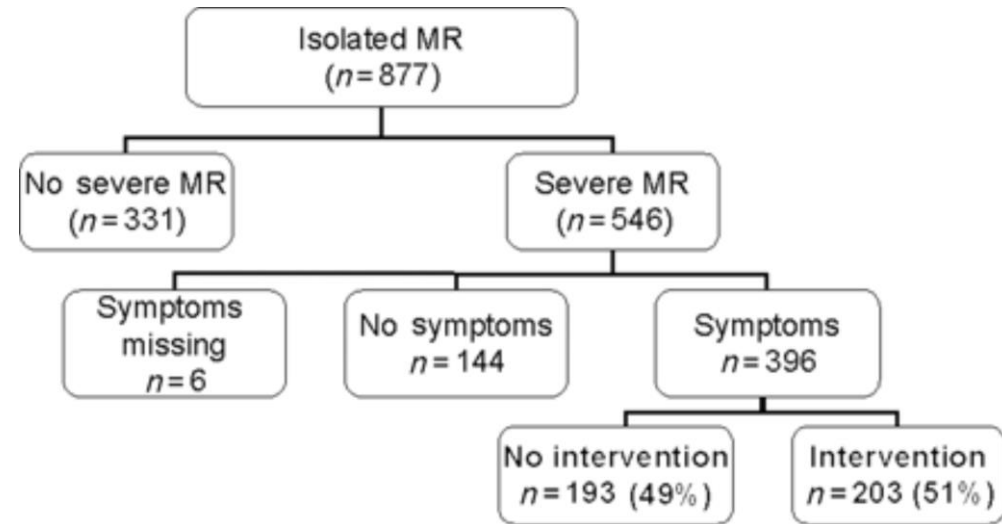


50% of MR patients are treated medically

Medically treated patients with severe MR

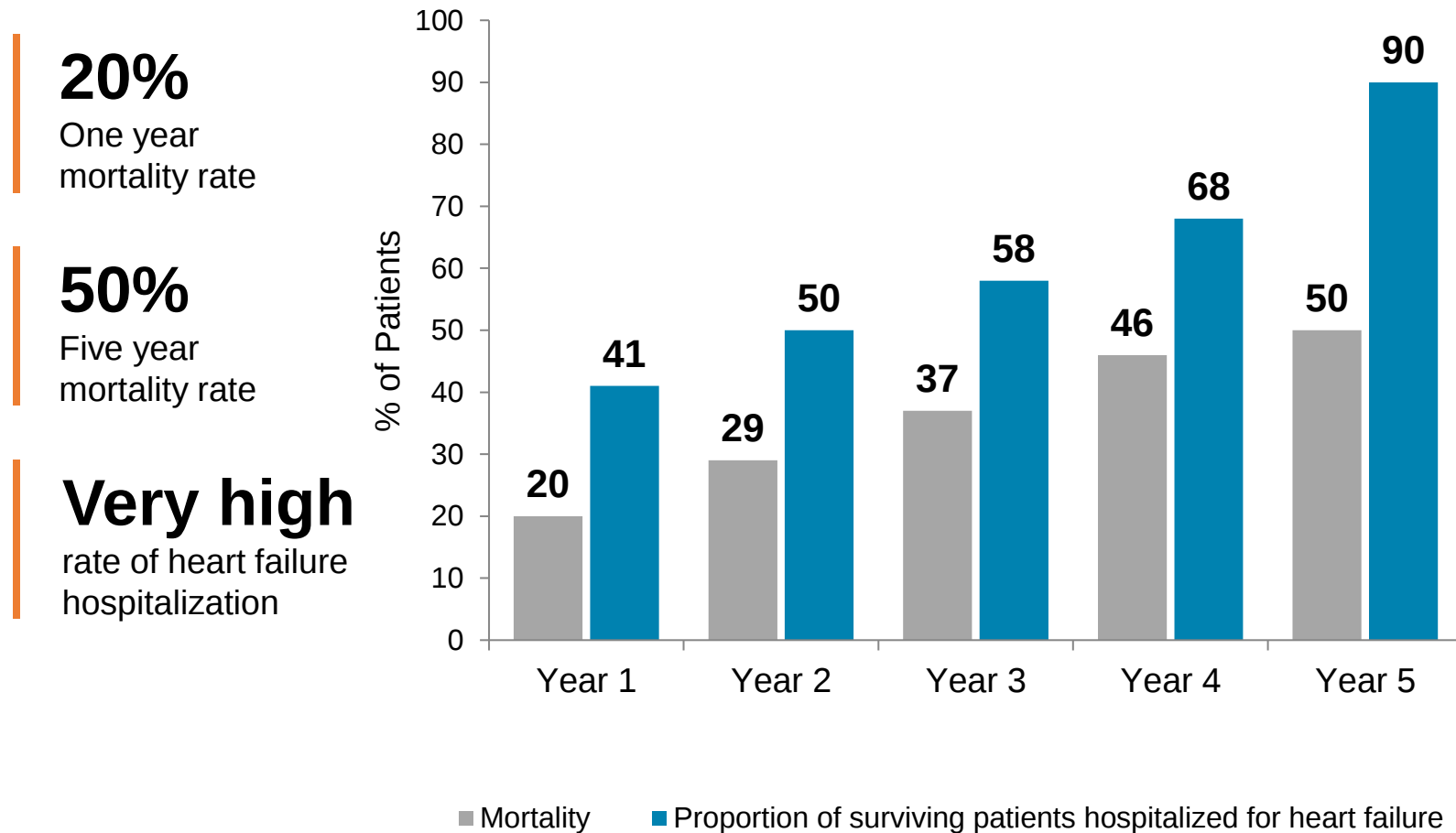


Goel et al. JACC 2014;63:185-186



Mirabel et al. Eur Heart J. 2007;28(11):1358-1365

Medically Managed Patients with Severe MR Have Poor Outcomes



Transcatheter MV Repair: Device Landscape 2018

Edge-to-edge

- MitraClip***
- MitraFlex
- PASCAL

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*
 - MValve*
 - Cephea
- NCSI NaviGate*
 - St. Jude
- Micro Interventional
- Mitraltech 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*
 - Polares*
- St. Jude leaflet plication*
- Cardiosolutions Mitra-Spacer*
 - Valtech Vchordal
 - Mitralix
 - Mitral Bridge

*In patients *CE mark *FDA approved

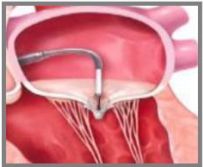


Randomized clinical trials with MitraClip



Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*



EVEREST study

Primary mitral regurgitation



ORIGINAL ARTICLE

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*



MITRA-FR study

Secondary mitral regurgitation



ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

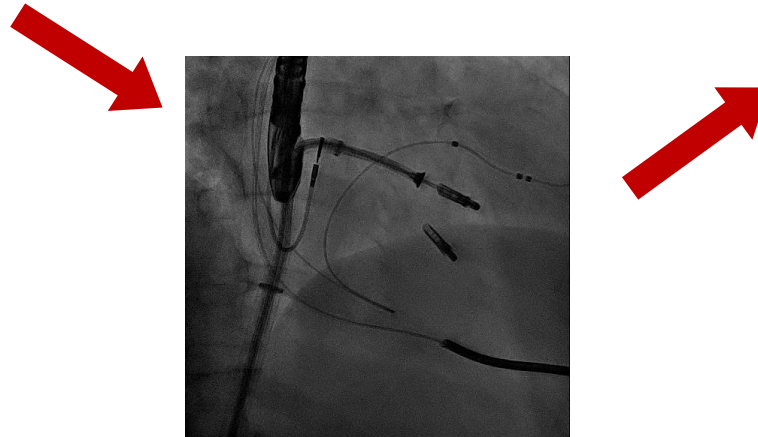
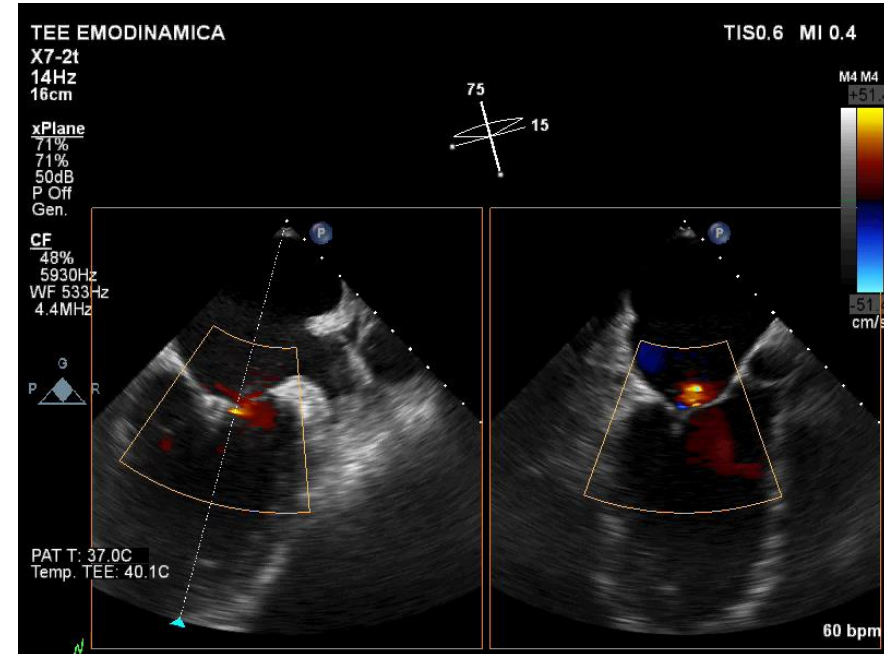
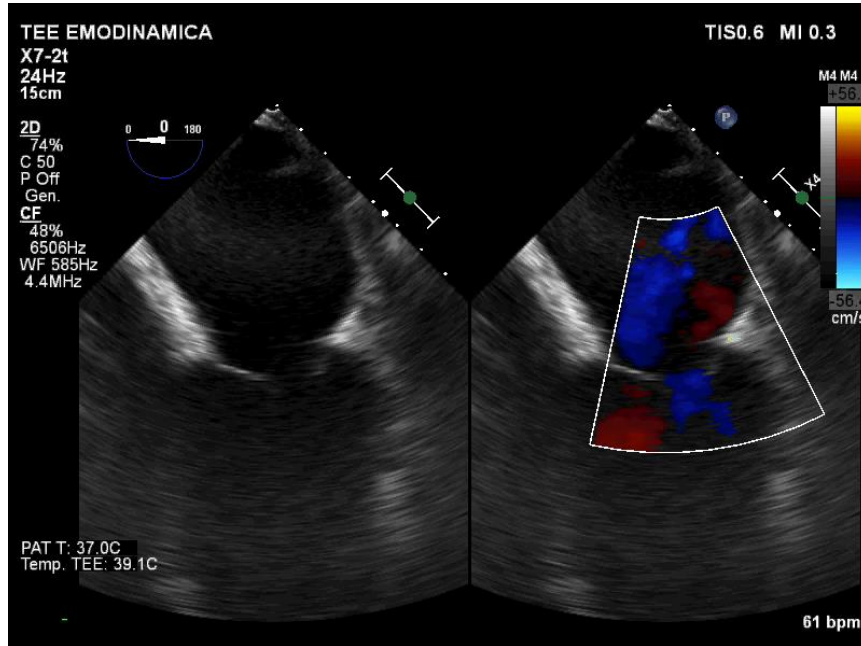
G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*



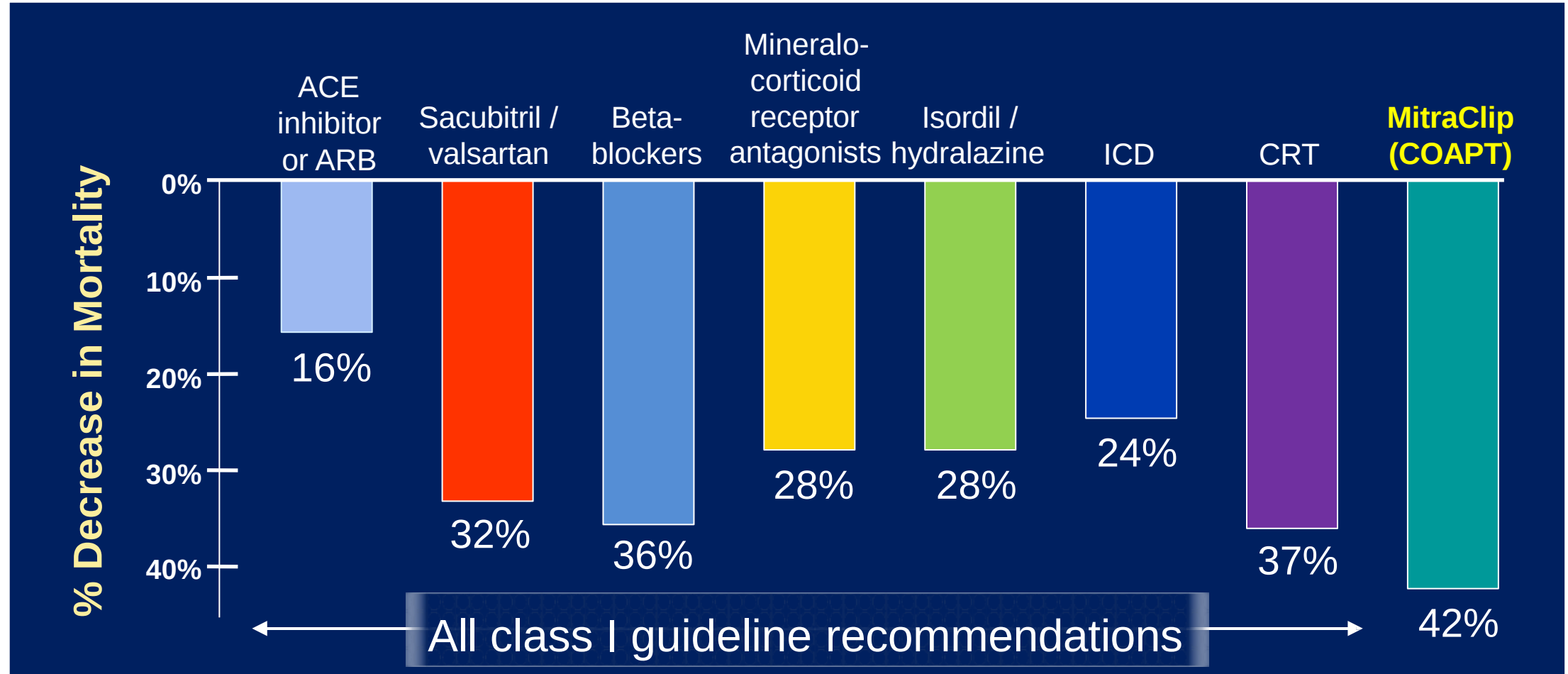
COAPT study

Secondary mitral regurgitation

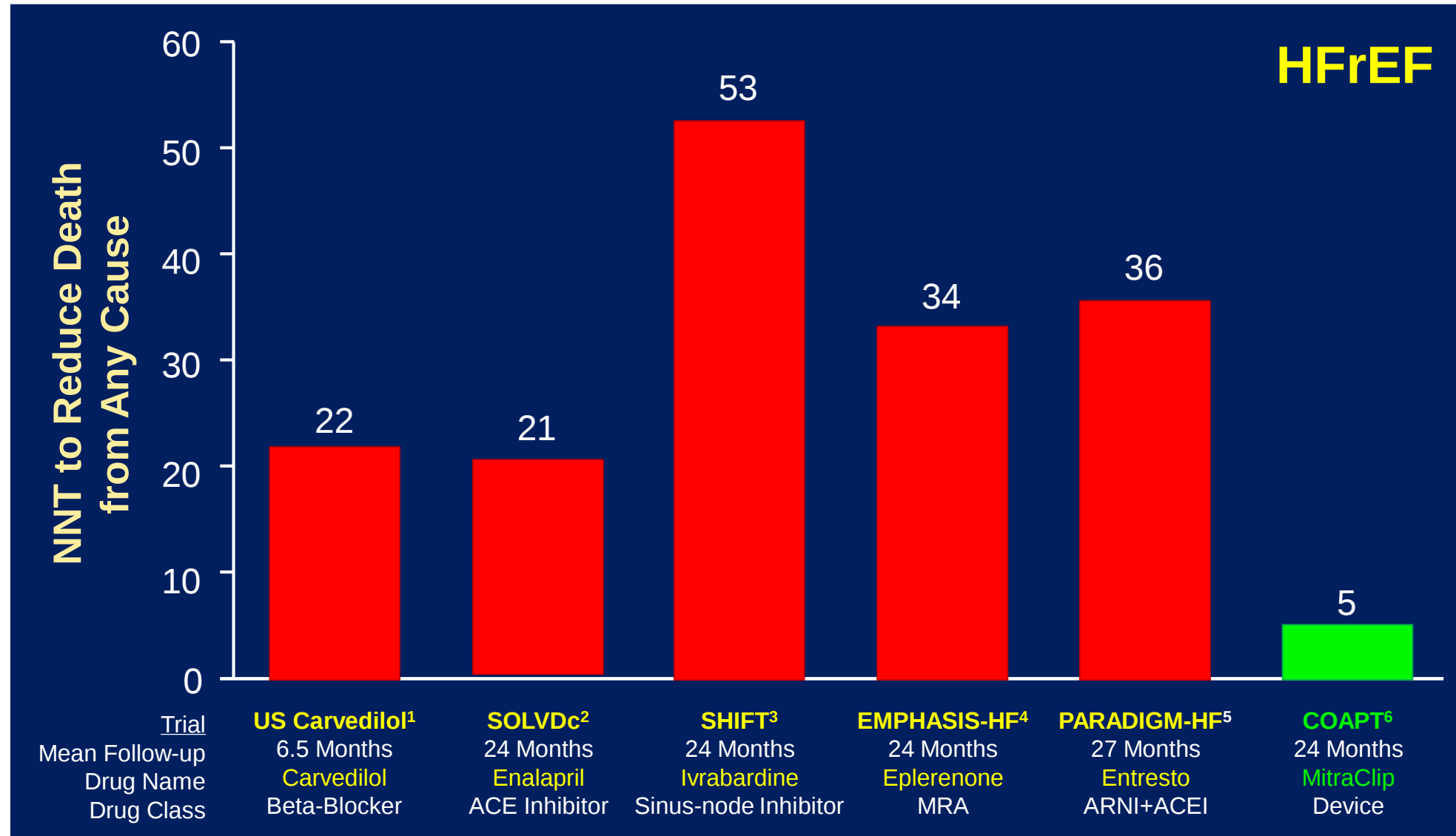
MitraClip - Case Example



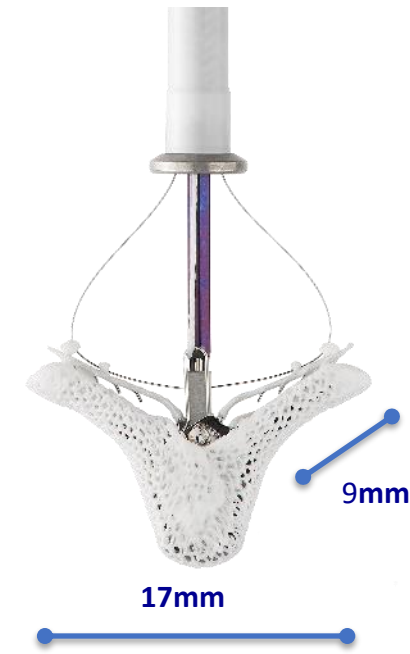
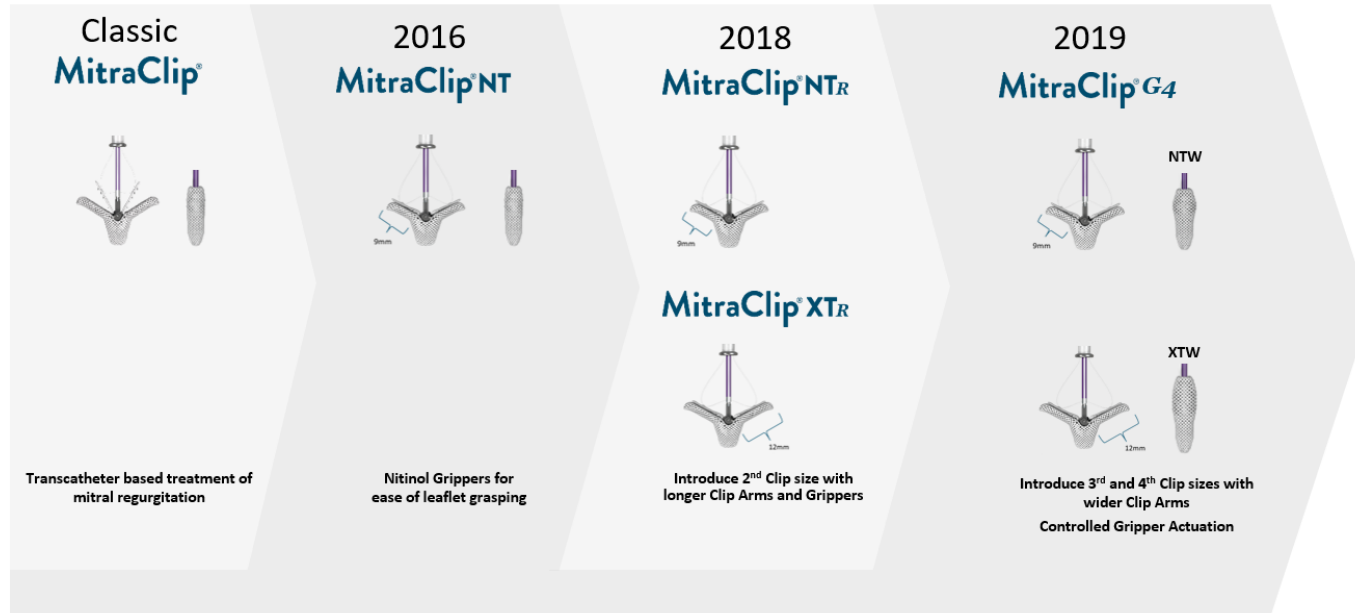
The Mortality Benefit of Therapies for HFrEF



Number Needed to Treat (NNT) to Prevent 1 Death

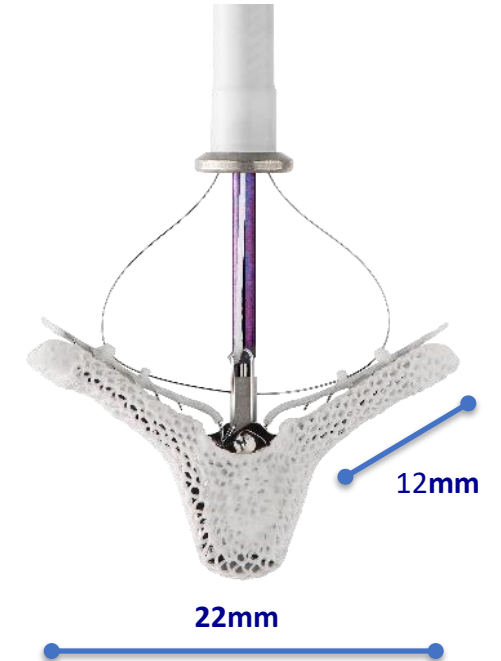


MitraClip™ Evolution - NTR/XTR



NTR

Improved delivery system

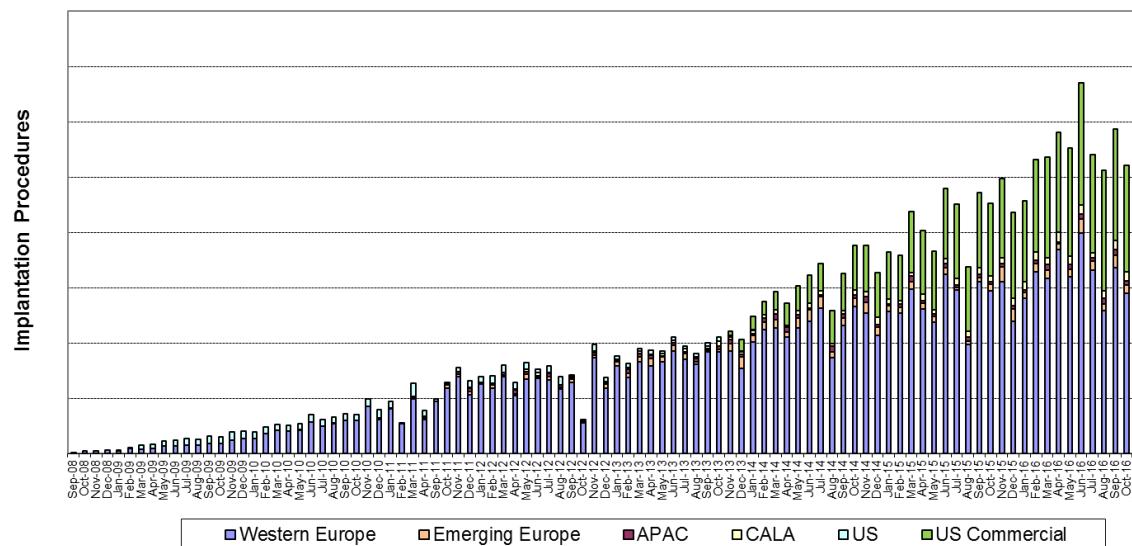


XTR

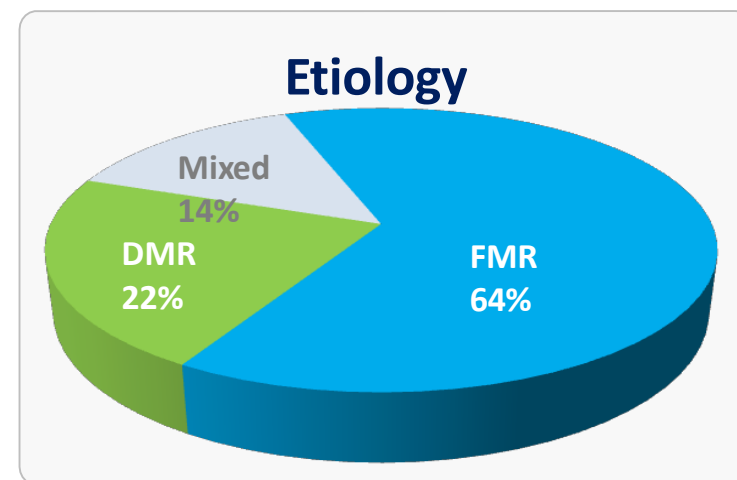
Longer arms, with an improved delivery catheter system

Global MitraClip Experience

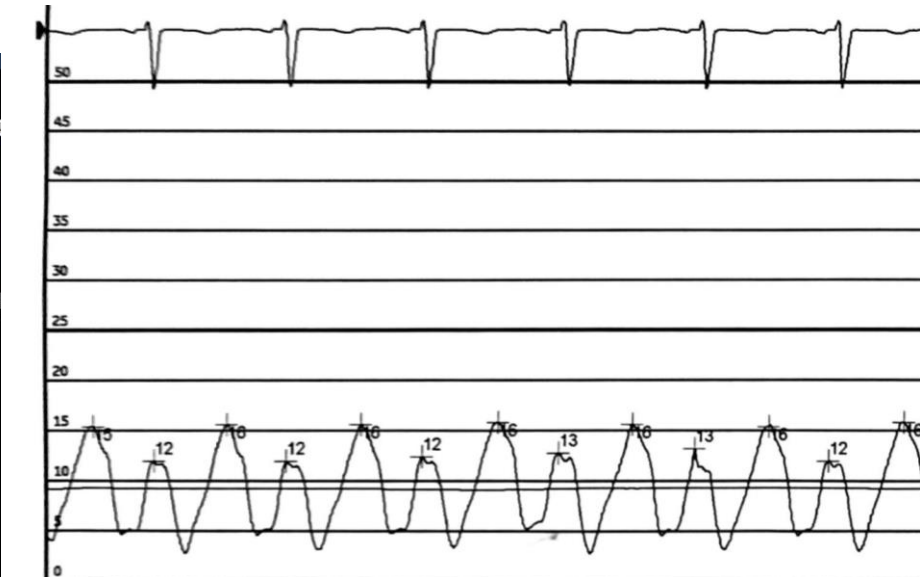
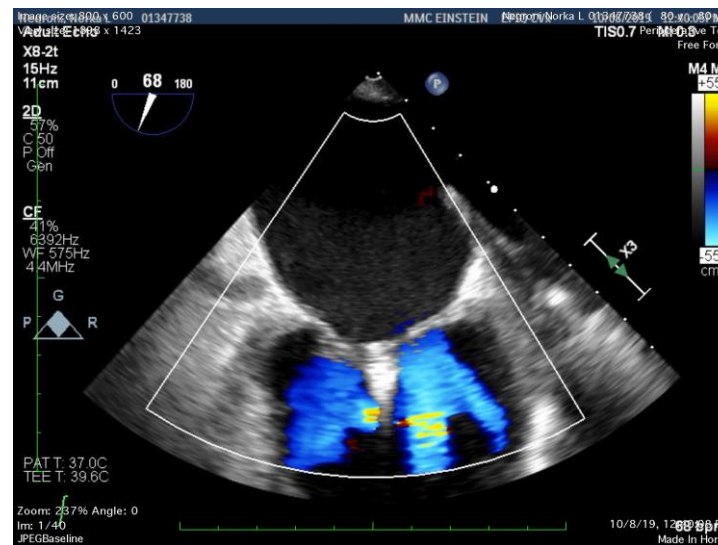
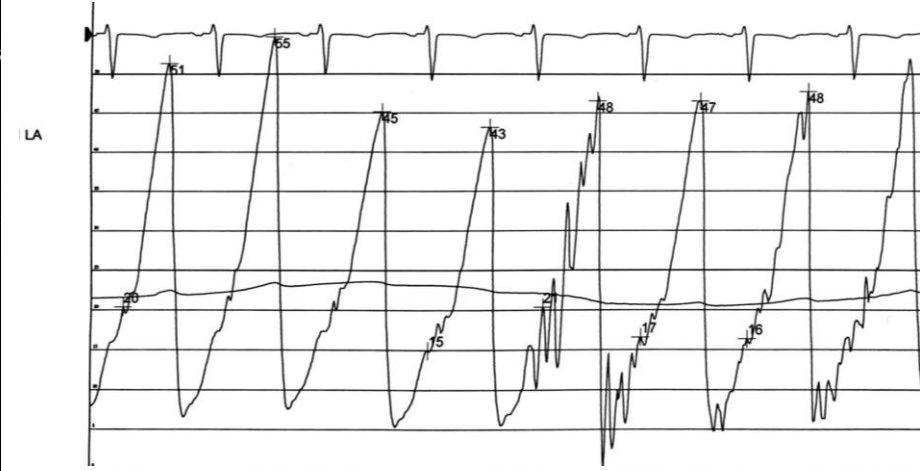
>50000 patients treated



Implant Rate: 97%



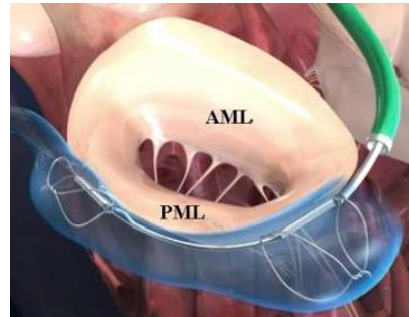
A Typical COAPT patient



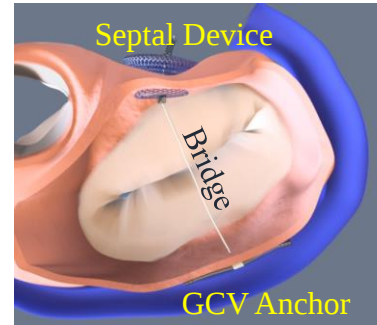
Annuloplasty Devices

* CE mark

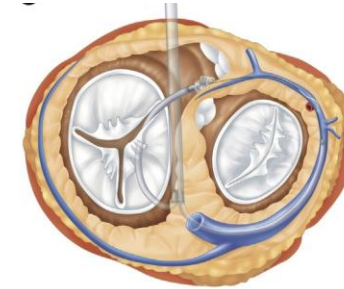
INDIRECT ANNULOPLASTY



Carillon*

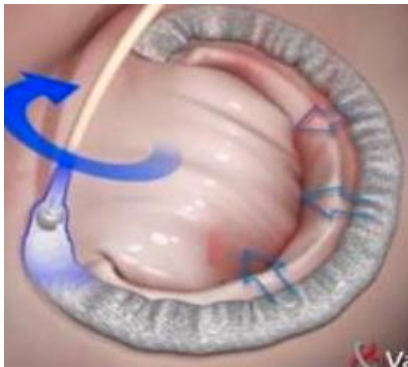


MVRx ARTO



Mitral Loop Cerclage

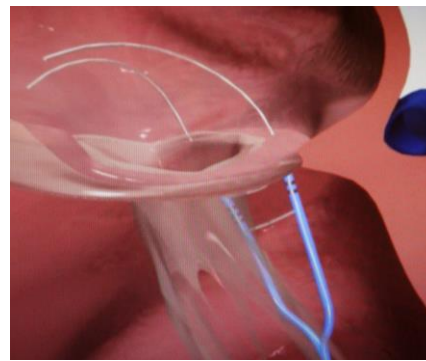
DIRECT ANNULOPLASTY



Cardioband*



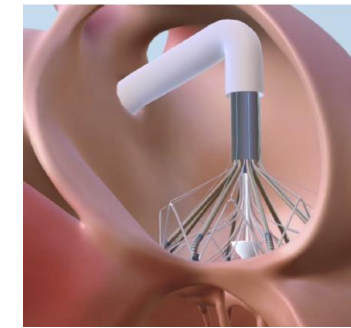
Millipede



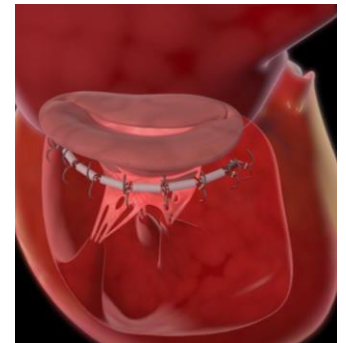
Mitralign*



Valcare



Valfix

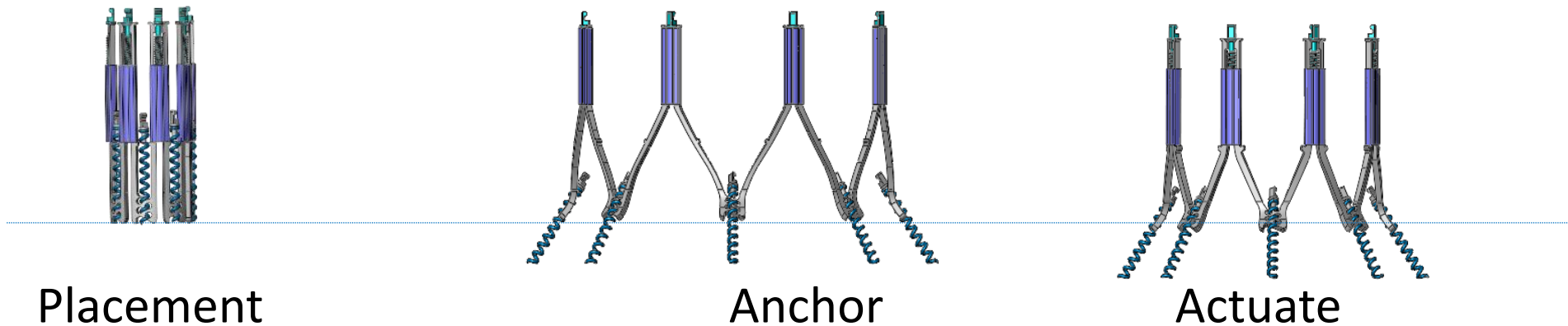


AccuCinch

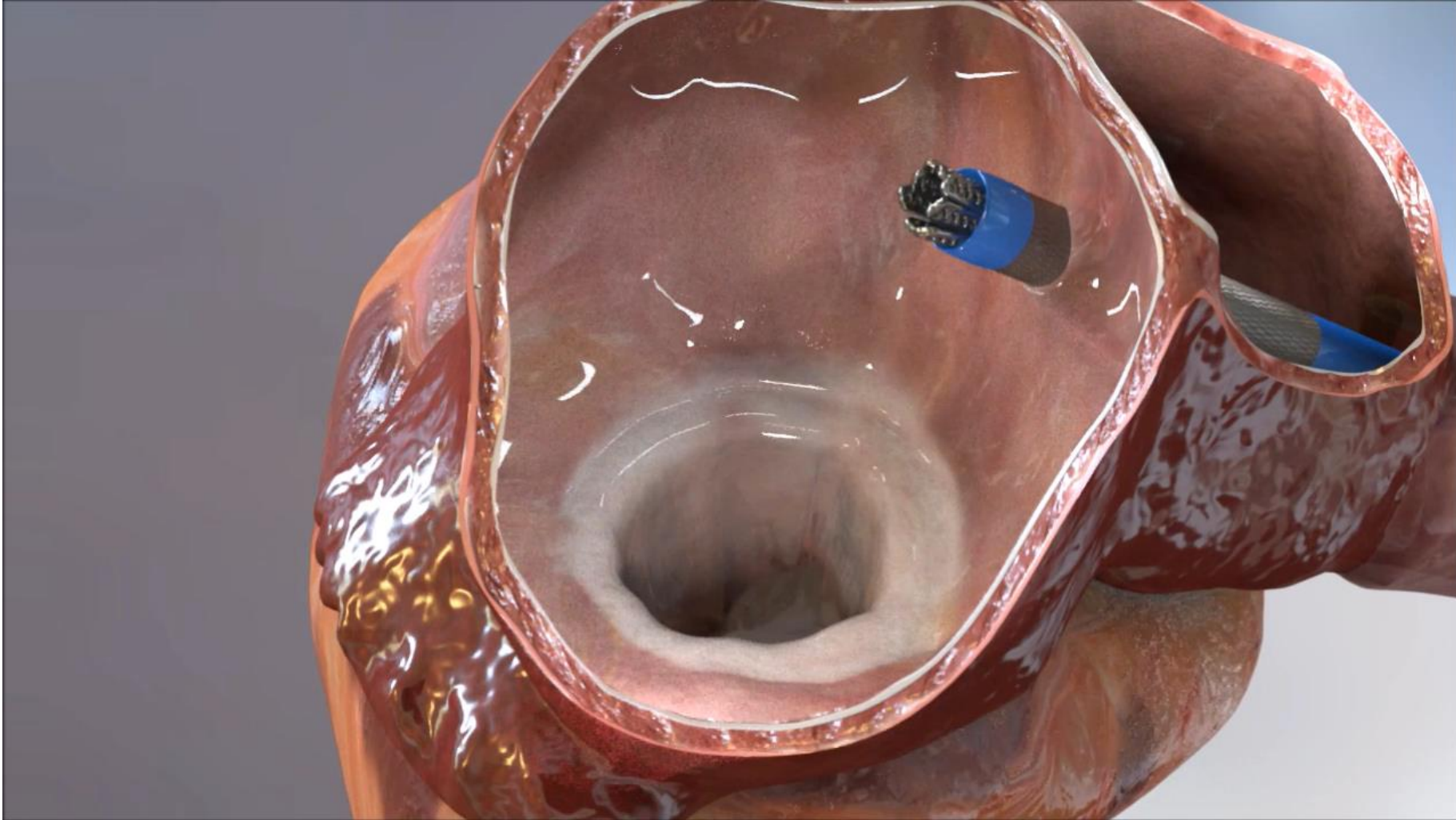
Millipede Transcatheter Annuloplasty Ring System



- Physiologically sound mechanism of action replicates the cornerstone of surgical repair
- **Customizable, repositionable and retrievable**
- Leaves options open for future interventions
- Familiar controls and ICE-guided placement for streamlined procedure
- **Trans-Septal access**



Millipede Transcatheter Annuloplasty Ring System with Integrated ICE Imaging



TMVR Devices



Braile Biomedica



Braile Biomedica



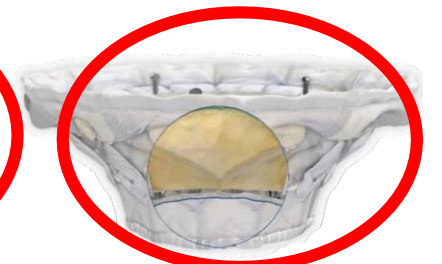
CardiAQ 1st G



CardiAQ Edwards



Cephea



Cardiovalve



Direct Flow Medical



Medtronic Intrepid



M-Valve



Edwards Fortis



HighLife



Edwards M3



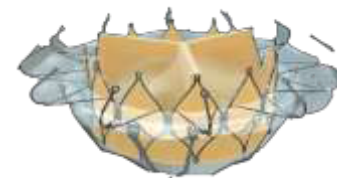
Navigate



Neovasc Tiara



PermaValve MID



Sinomed



Tendyne Abbott



SATURN TMVR



ALTAVALVE



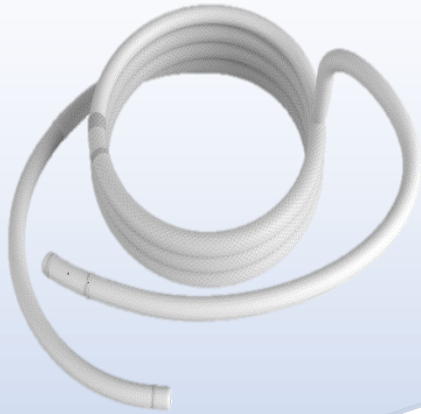
Caission

Others: MitraHeal, Mitrasist, Mehr Medical, Mitracath, Mitralix MAESTRO, Nakostech, St. George ATLAS, Transcatheter Technologies Tresillo

Edwards SAPIEN M3 System

Dock Delivery

SAPIEN M3
Dock

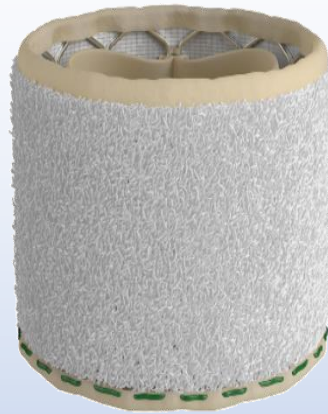


SAPIEN M3 Dock Delivery
System



Valve Delivery

SAPIEN M3 Valve



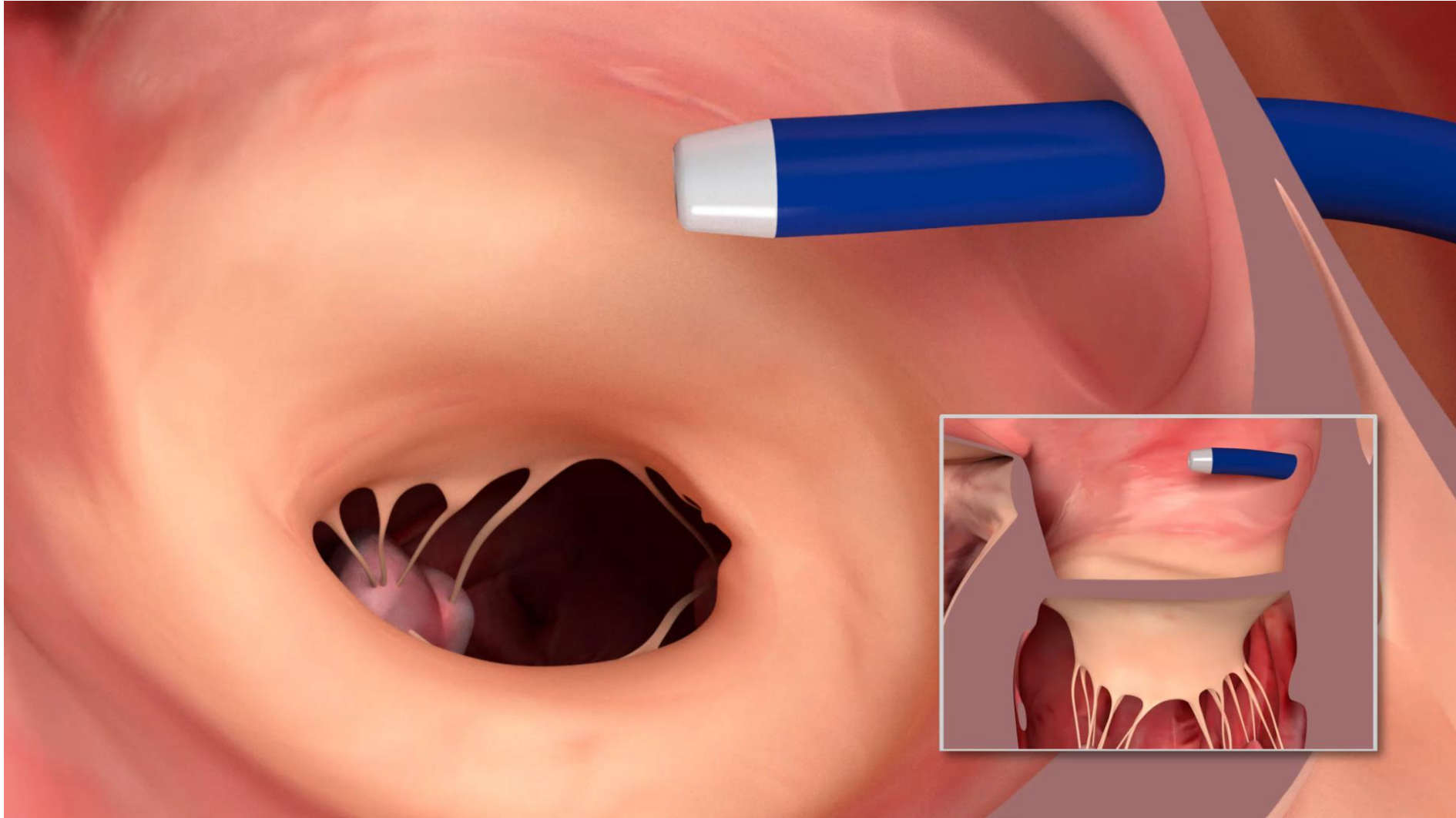
Commander Delivery System

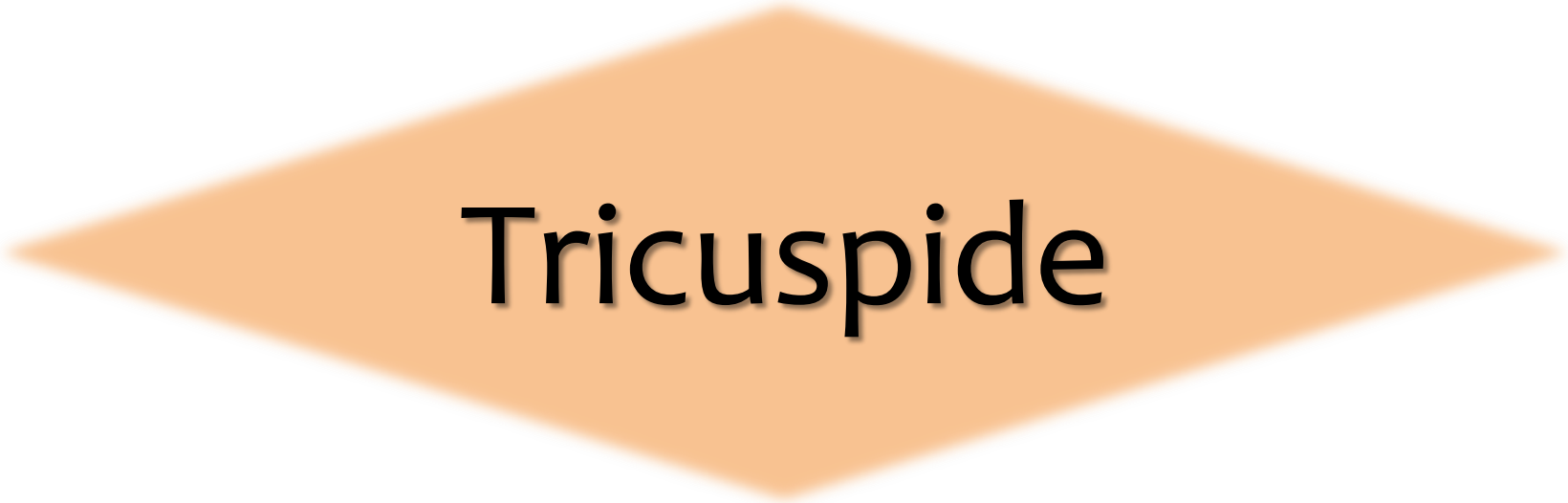


Final Implant



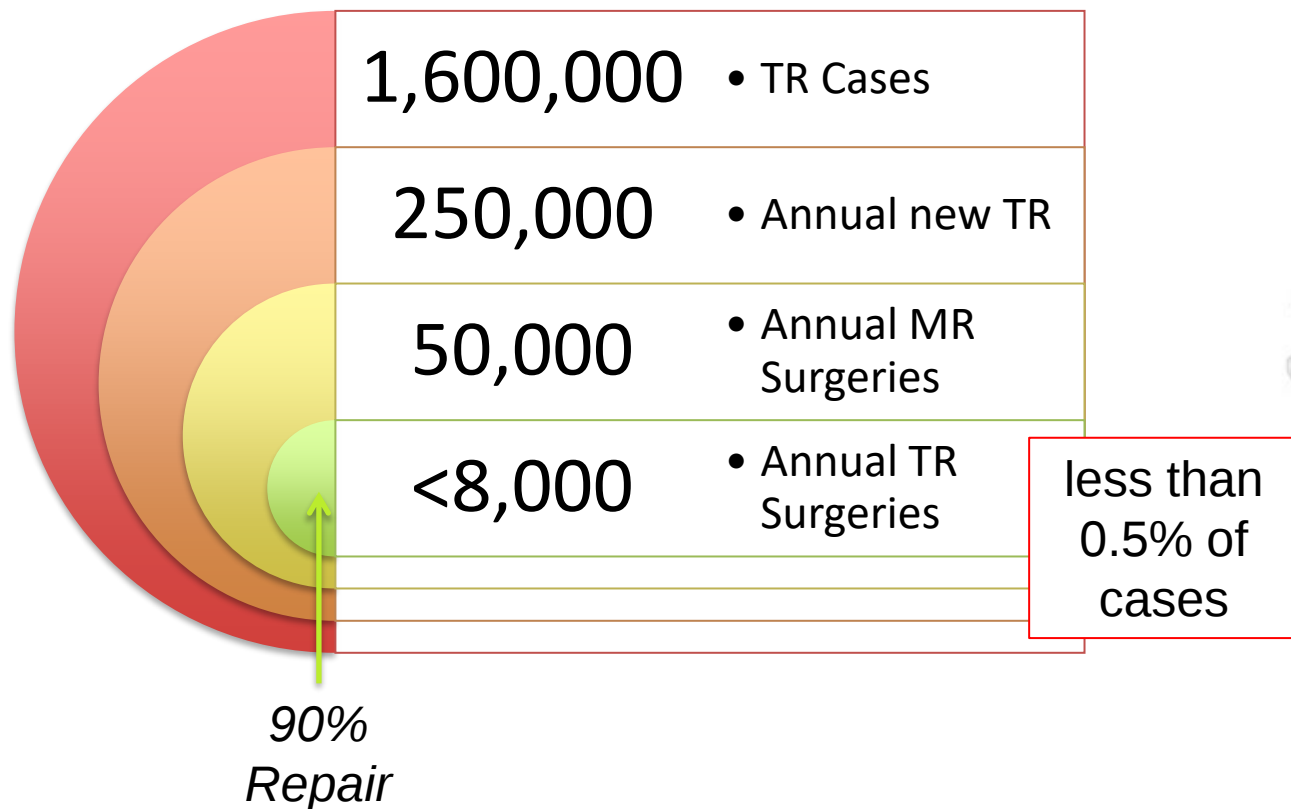
SAPIEN M3 SYSTEM: DOCK 2-STEP SYSTEM



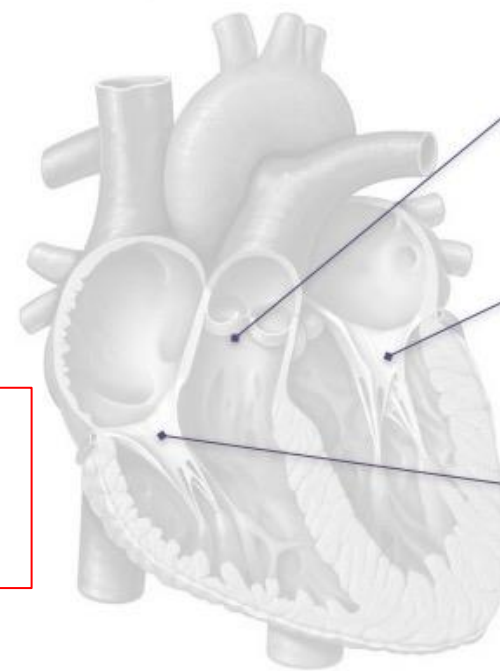


Tricuspid

Prevalence of TR



Moderate/Severe Heart Valve Disease >65 years, n=4753



Aortic Stenosis
Prevalence: 1.9% (TBC) Newly diagnosed: 0.7% (TBC)
Mitral Regurgitation
Prevalence: 3.5% Newly diagnosed: 2.4%
Tricuspid Regurgitation
Prevalence: 2.6% Newly diagnosed: 1.7%

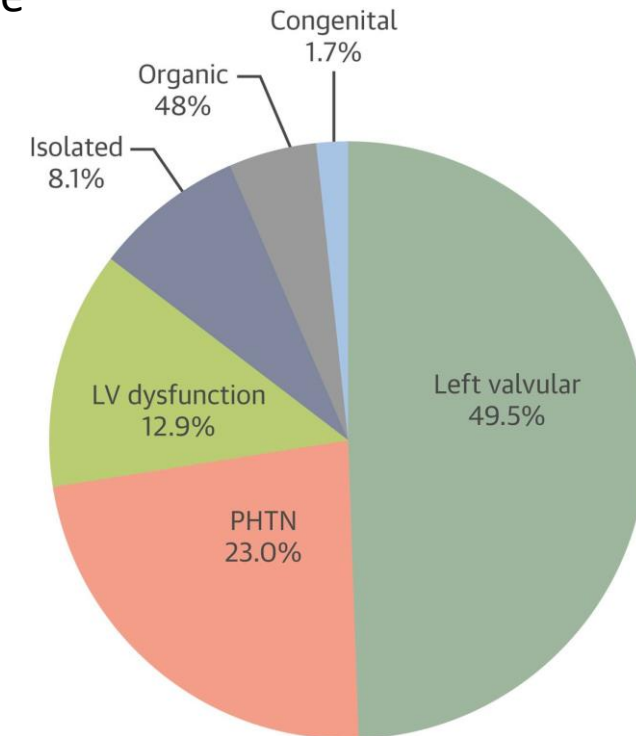
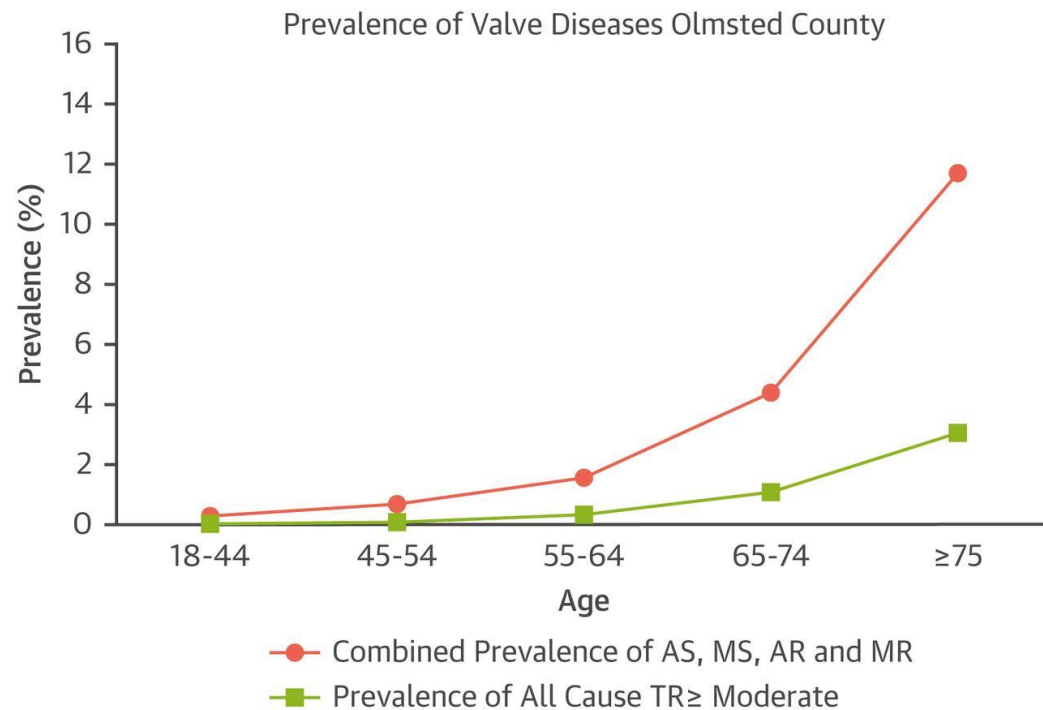
d'Arcy J et al. Eur Heart J 2016.

Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573
Stuge O, Liddicoat J. J Thorac Cardiovasc Surg. 2006 Dec;132(6):1258-61

Prevalence and Causes of TR in community setting

417 community residents were diagnosed with greater or equal to moderate TR

All-cause TR (0.55%) was about one-fourth of all left-sided valvular disease

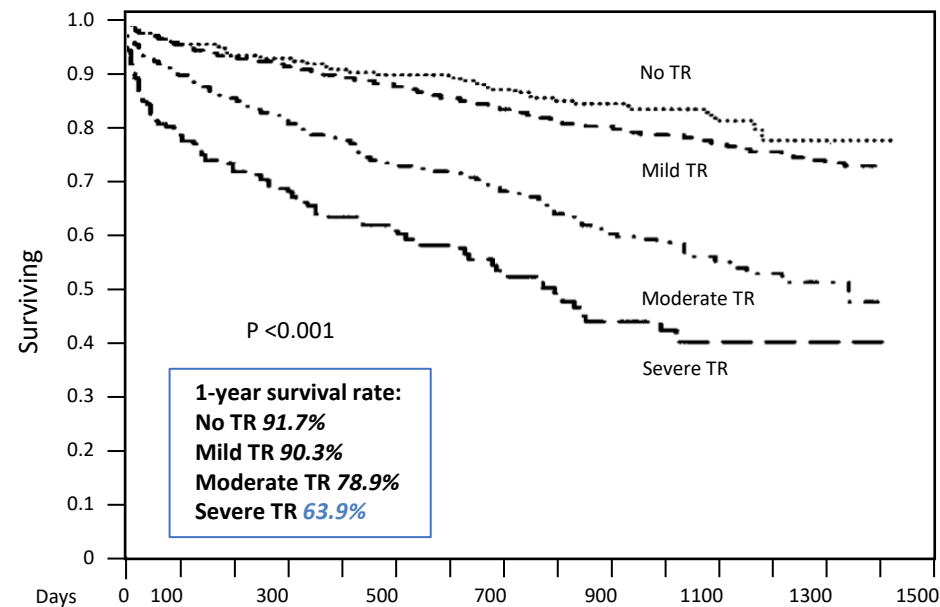


Only 2.6% of patients ever had tricuspid valve surgery during follow-up

Prognosis of TR

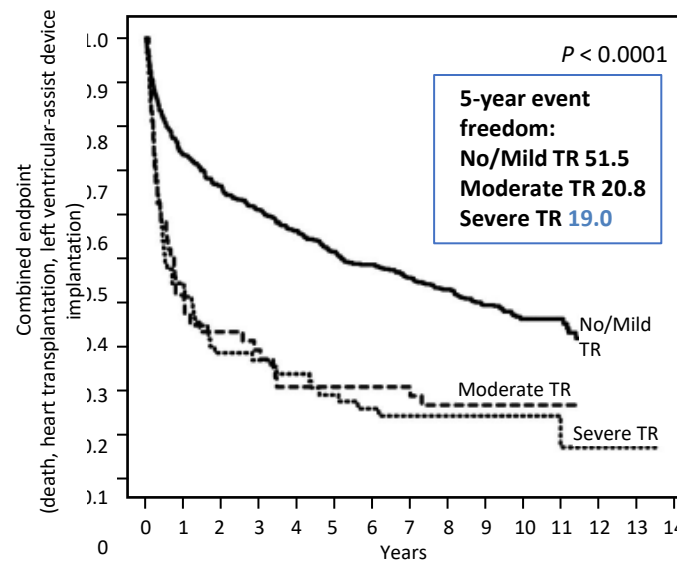
Tricuspid valve disease is a severe condition with impact on long term survival, esp in patients with chronic heart failure & LV dysfunction

Retrospective analysis of 5,223 patients (age 66.5 ± 12.8 years) adjusted for age, LVEF, inferior vena cava size, and RV size and function



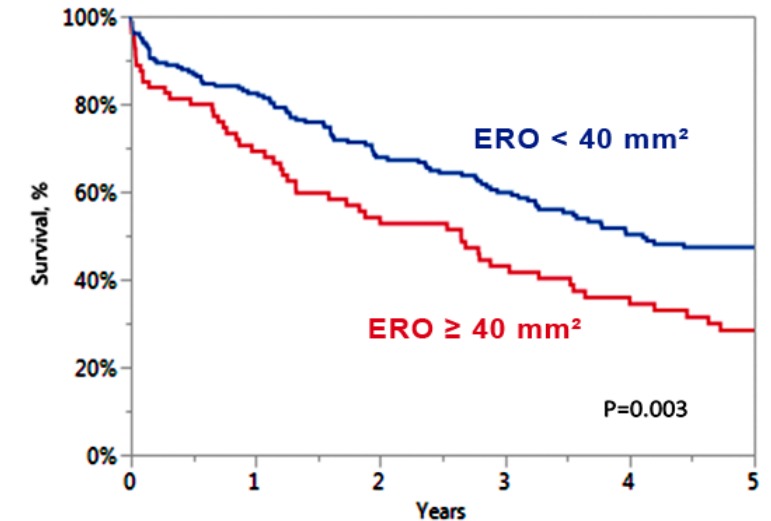
Nath et al. *J Am Coll Cardiol* 2004;43:405–09

Prospective analysis of 576 consecutive patients with CHF (age 56.4 ± 11.2 years)



Neuhold et al. *Eur Heart J* 2013;34:844–52

Retrospective analysis of 291 patients with LVEF < 50% and Functional TR (age 70 ± 12 yrs; EF $31 \pm 10\%$)



Topilsky et al. *Eur Heart J* 2018 Jul 27

Table 1. Clinical and Echocardiographic Features of Patients With Tricuspid Regurgitation

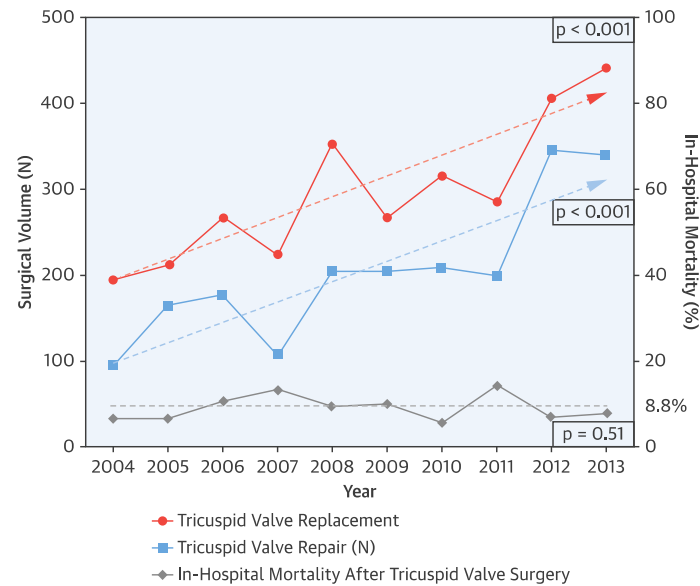
	No TR (n = 600)	Mild TR (n = 3,804)	Moderate TR (n = 620)	Severe TR (n = 199)	p Value
Age (yrs)	62.2 ± 12.8	66.0 ± 12.6	71.9 ± 11.7	71.9 ± 12.4	< 0.0001
LVEF (%)	57.3 ± 9.1	55.4 ± 11.6	47.1 ± 15.6	40.4 ± 17.2	< 0.0001
RV dilation	8%	11%	35%	66%	< 0.0001
RV dysfunction	3%	8%	30%	61%	< 0.0001
Dilated IVC	6%	11%	44%	76%	< 0.0001

Surgical outcomes of TV surgery

5,005 isolated TV operations between 2004-2013
 (~20% of cases in US)

TV repair in 40.8%: TV replacement in 59.2%

CENTRAL ILLUSTRATION Temporal Trends in Surgical Volume and Mortality for Isolated Tricuspid Valve Surgery



Zack, C.J. et al. J Am Coll Cardiol. 2017;70(24):2953-60.

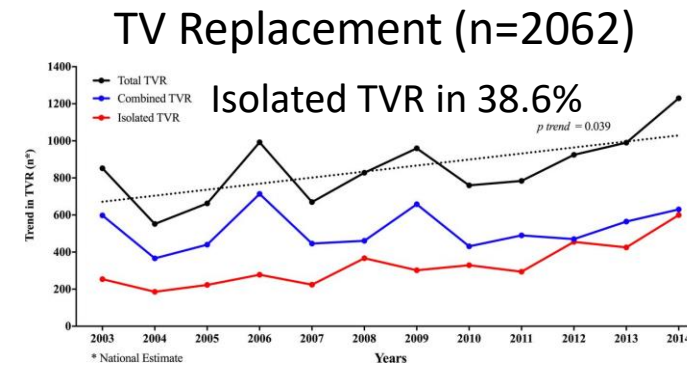
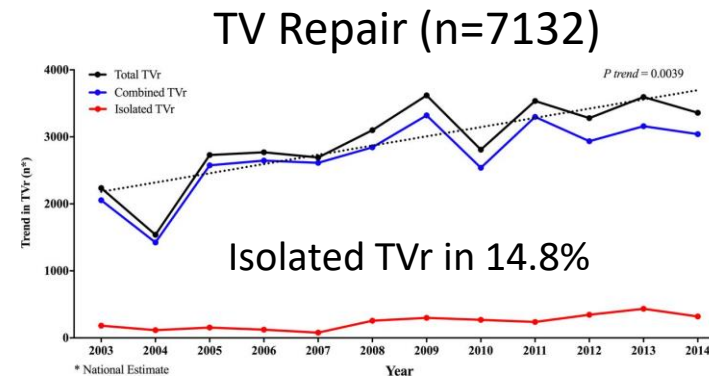
In-Hospital Mortality is still 8.8%

TABLE 3 Multivariate Logistic Regression for Predictors of In-Hospital Death in Patients Undergoing Isolated Tricuspid Valve Surgery From 2004 to 2013

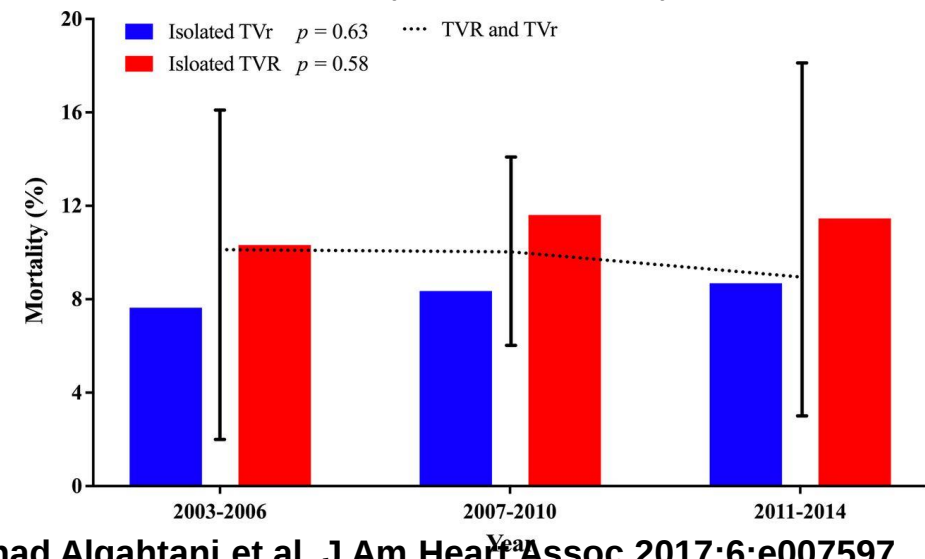
Comorbidity	Odds Ratio	95% CI	p Value
Coagulopathy	2.37	1.44-3.82	<0.001
Hypertension	0.40	0.27-0.63	<0.001
End-stage renal disease	3.15	1.41-7.05	0.005
Age ≥ 60 yrs	2.02	1.22-3.34	0.006
Tricuspid valve replacement*	1.91	1.18-3.08	0.009
Charlson comorbidity index	1.58	0.93-2.67	0.09

12,567 patients undergoing TV Repair & Replacement between 2003-2014

No of patients undergoing TV surgery for TR increased by **48%** from 3100 in 2003 to 4600 in 2014



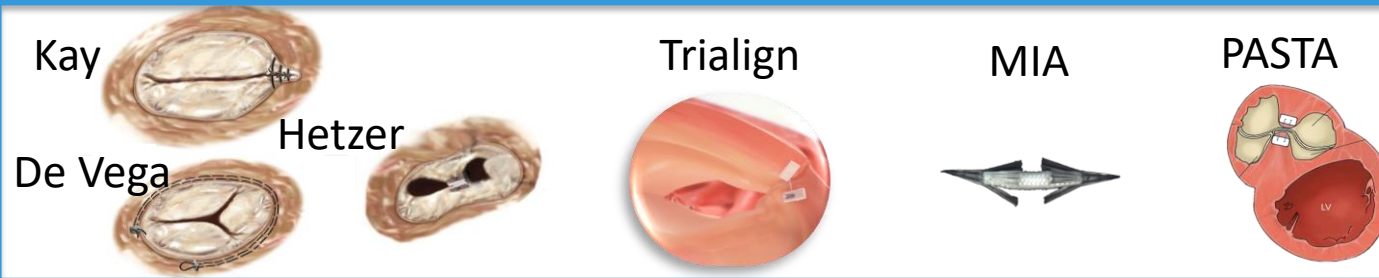
In-Hospital Mortality



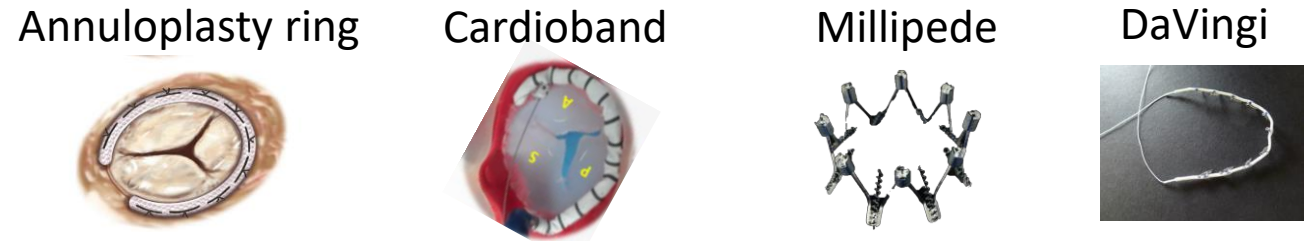
Fahad Alqahtani et al. J Am Heart Assoc 2017;6:e007597

Transcatheter Tricuspid Landscape

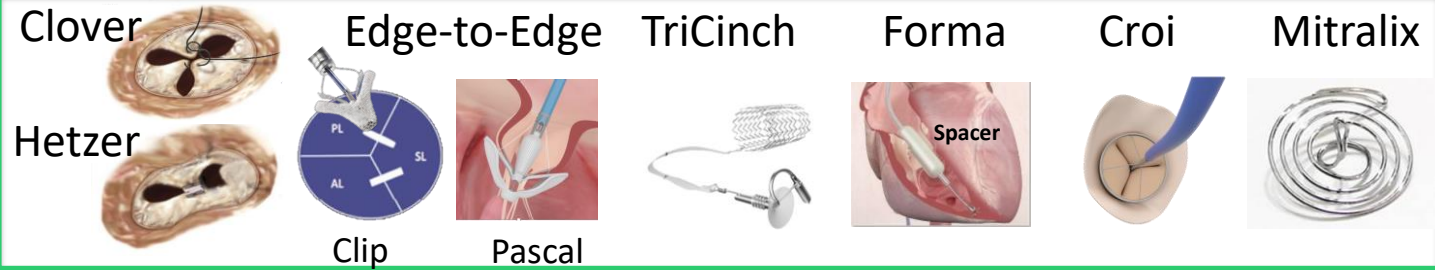
Direct Suture Annuloplasty



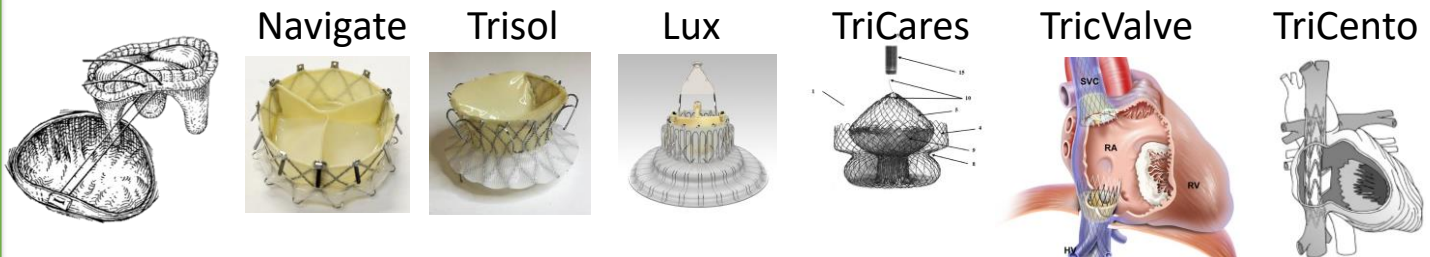
Direct Ring Annuloplasty



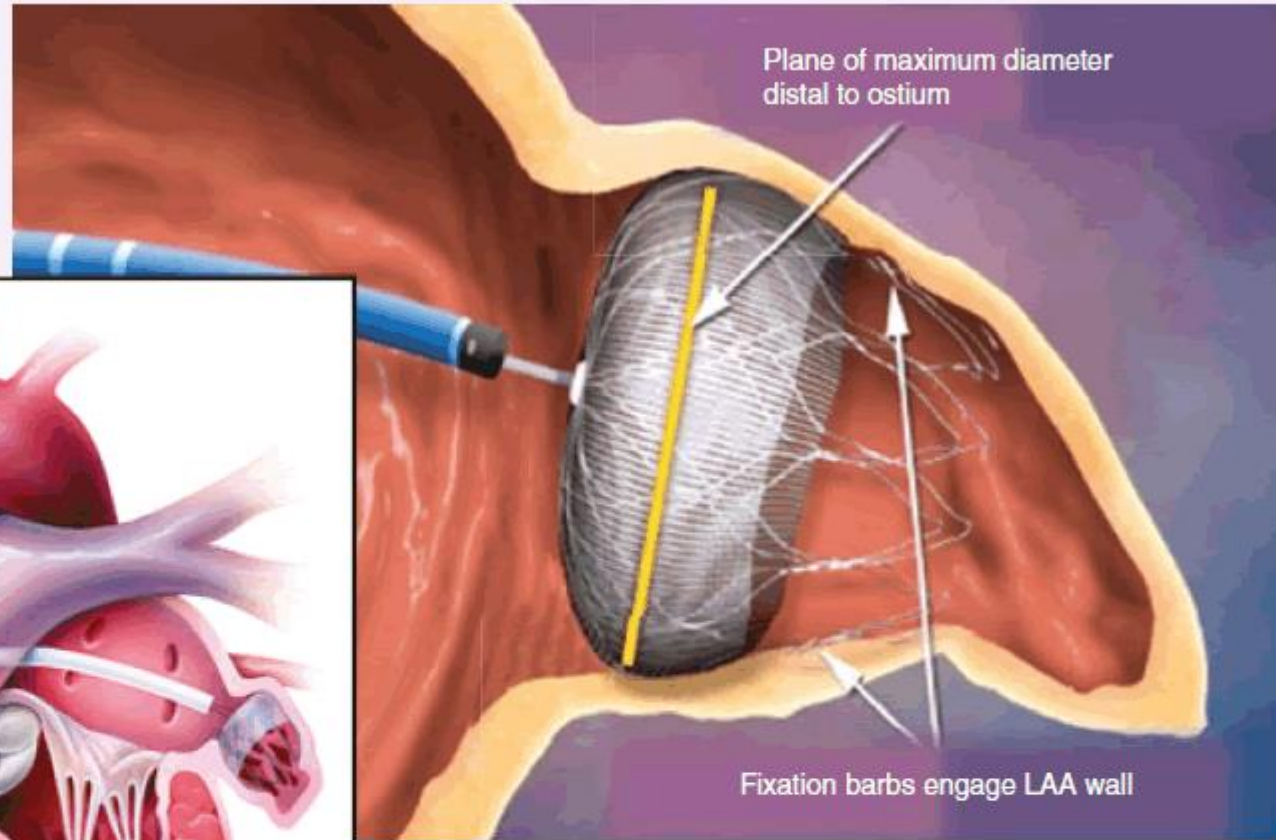
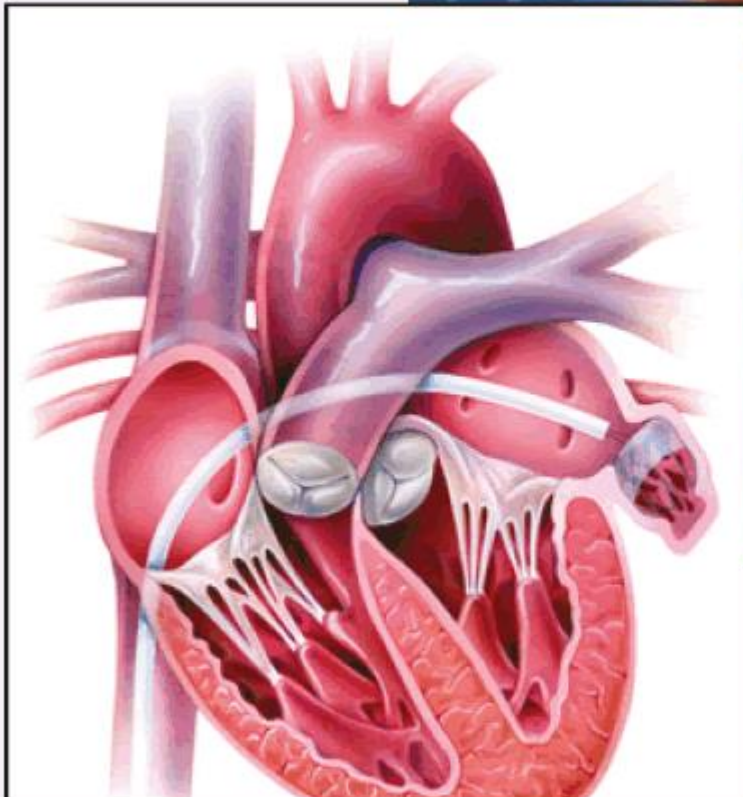
Coaptation Enhancement



Valve Replacement



Un'ultima possibilita'....



In caso di fallimento della terapia: ictus in terapia
anticoagulante

Indicazioni alla chiusura dell'auricola

In caso di severi sanguinamenti in terapia anticoagulante

sinistra

In alternativa alla terapia anticoagulante in pazienti ad
elevato rischio emorragico (varici esofagee, angiomi
cerebrali...)

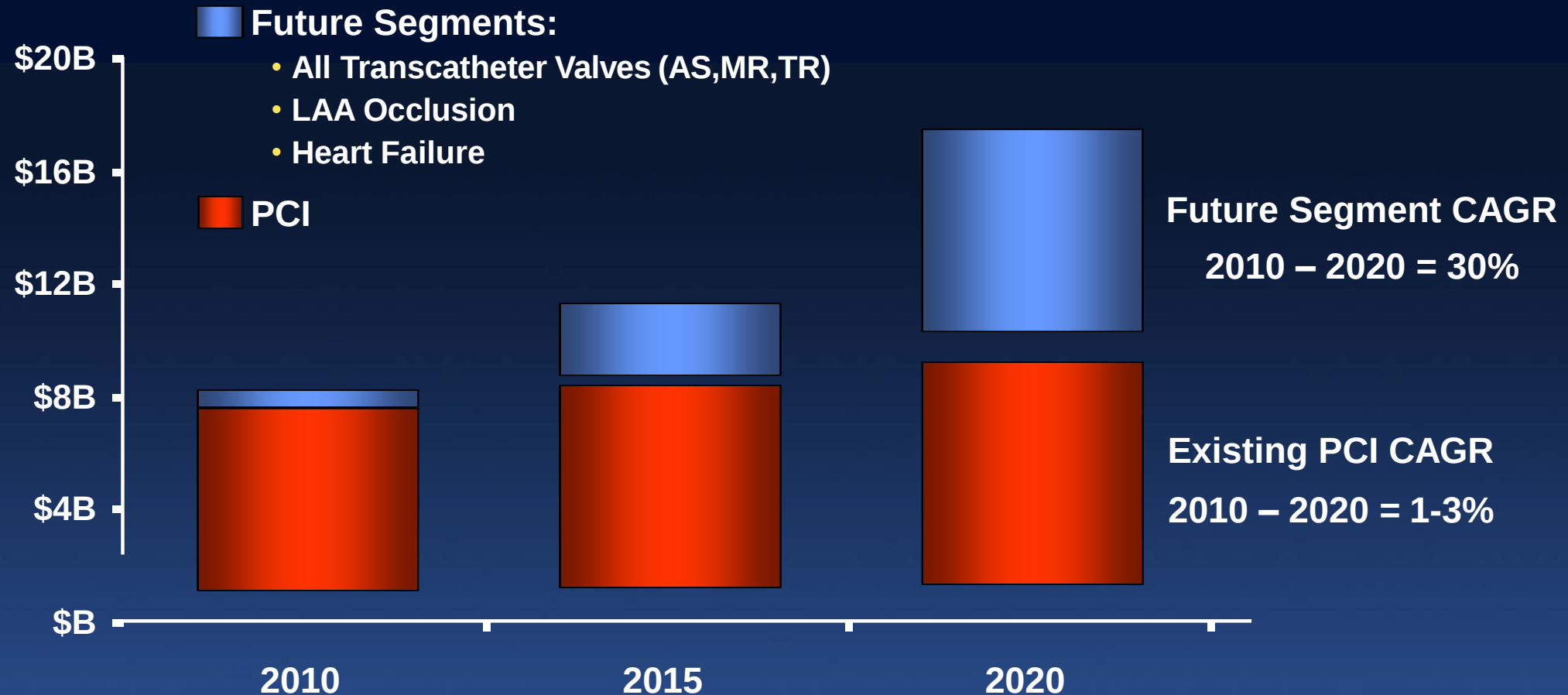
Mitraclip

La cardiologia oggi, in sala di emodinamica

Trattamento dell'insufficienza mitralica e
tricuspидale: riduzione di anello e
ventricolo,
sostituzione delle valvole AV

La cardiologia domani, in sala di emodinamica

WW \$ Cardiology Market Trends



- New market segments may exceed PCI market size by 2020
- Emergence of future segments relies on technology and clinical data

OUS markets will lead and exceed the size of US markets

Grazie per l'attenzione