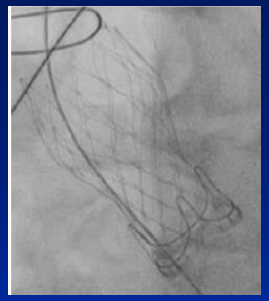

Valve in Valve Aórtico

Diego Grinfeld

Mayo de 2019

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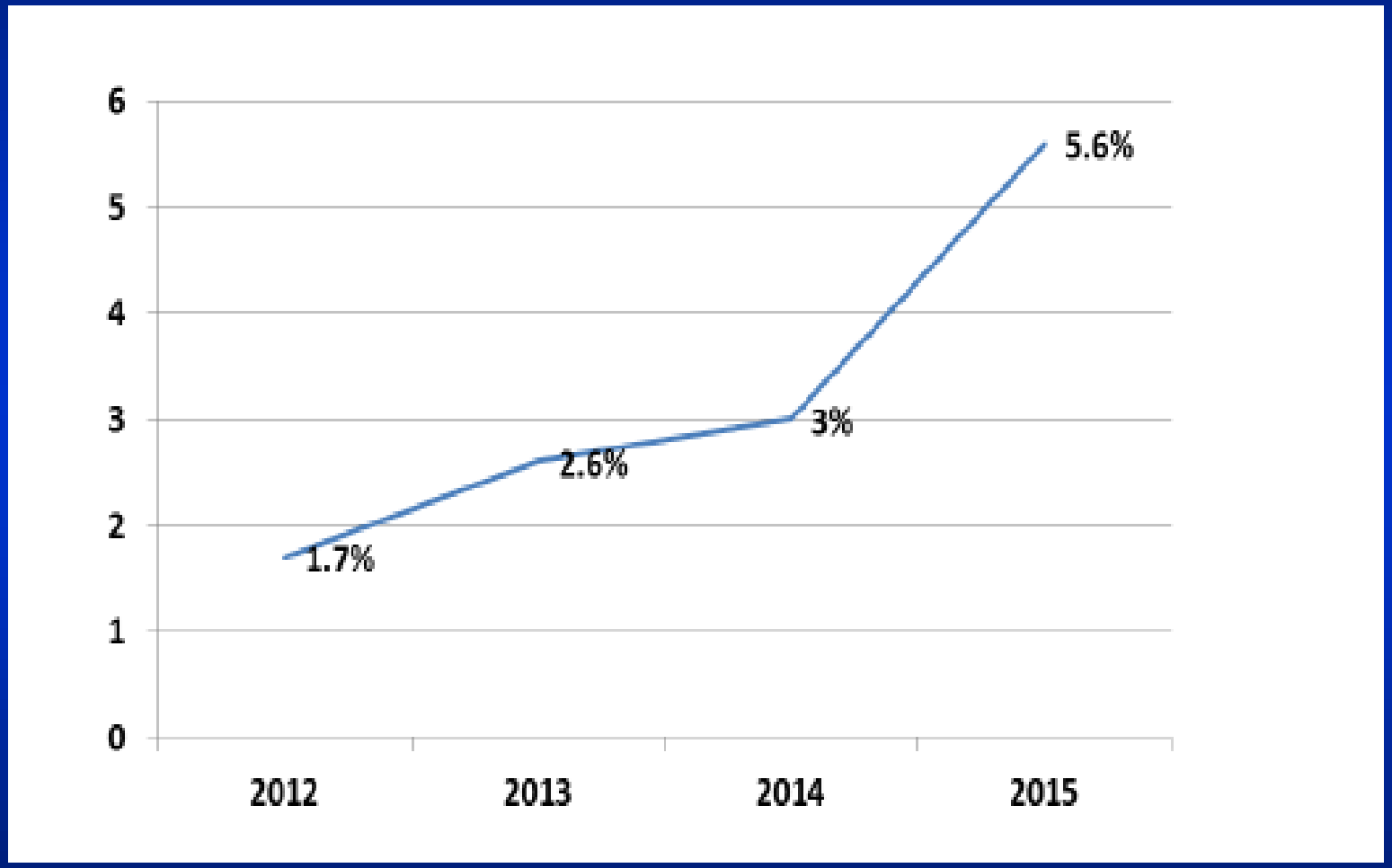
HEMODINAMIA
HOSPITAL ESPAÑOL

Introducción

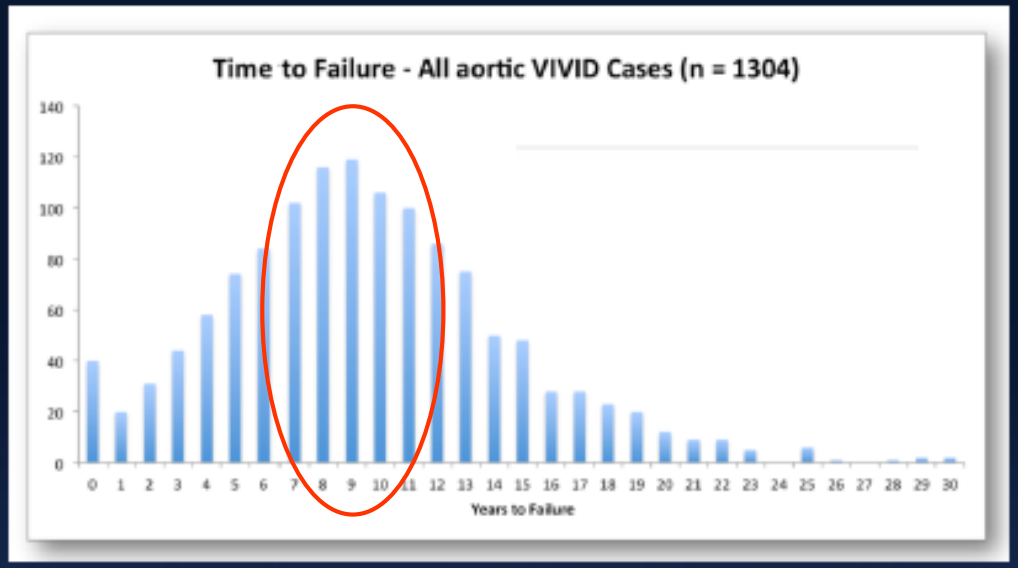
- **La mejoría en la durabilidad de las válvulas biológicas y el interés en disminuir los riesgos de sangrado han llevado a un aumento en la utilización de prótesis biológicas quirúrgicas.**
- **Cuando estás bioprótesis fallan, el diagnóstico diferencial que debe hacerse incluye: Panus, trombosis, endocarditis, error técnico, mist match y deterioro de la prótesis.**
- **La opción de re cirugía conlleva un riesgo de mortalidad opertoria del 5-11% y se eleva a un 15% con enfemdad coronaria concomitante (*), por lo que la terapéutica de ViV está creciendo…**

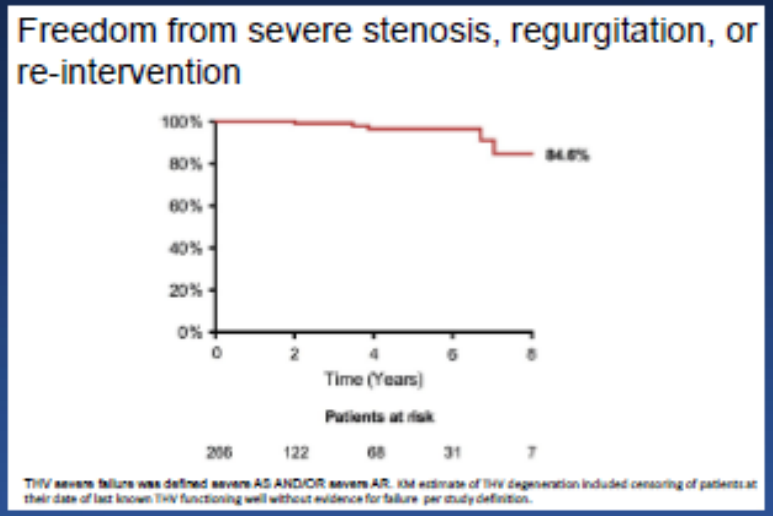
* Jones V. J Thorac Cardiovasc Surg 2001;122:913

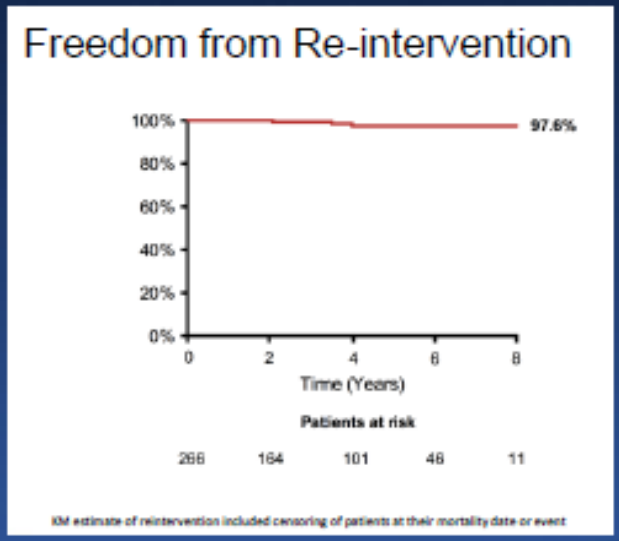
Incremento de ViV



Durabilidad de Válvulas Biológicas vs. TAVI

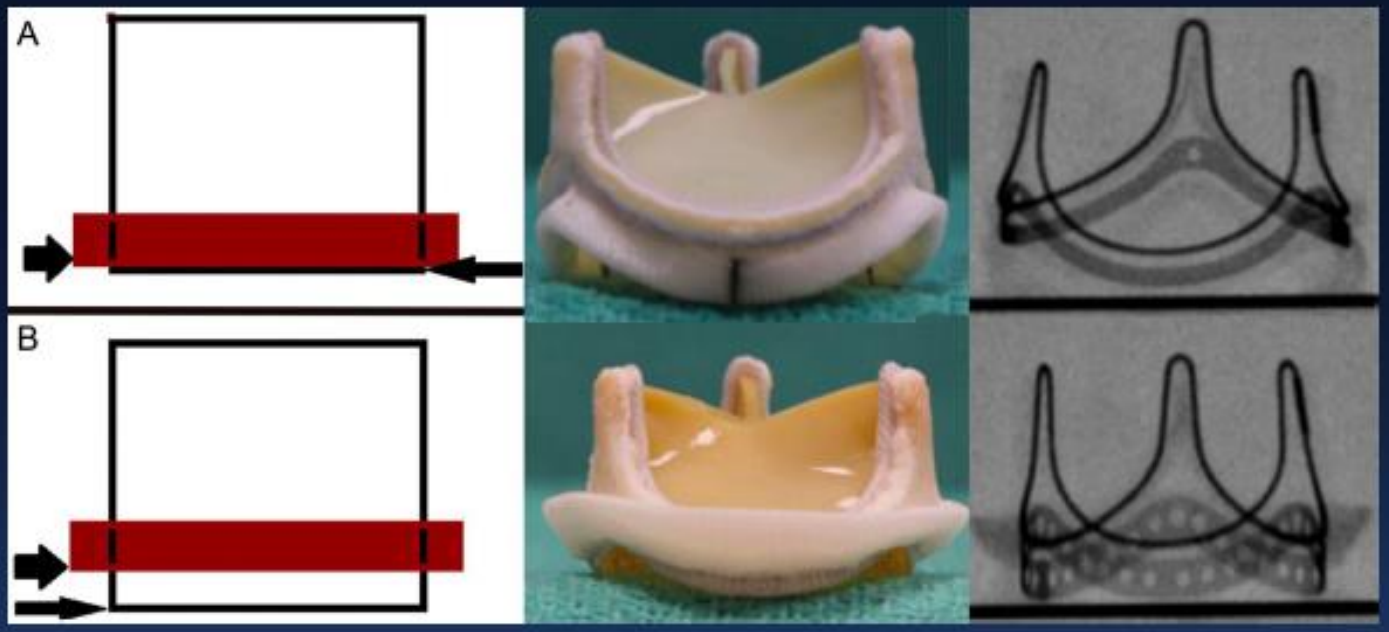






Tipos de Bioprótesis Quirúrgicas

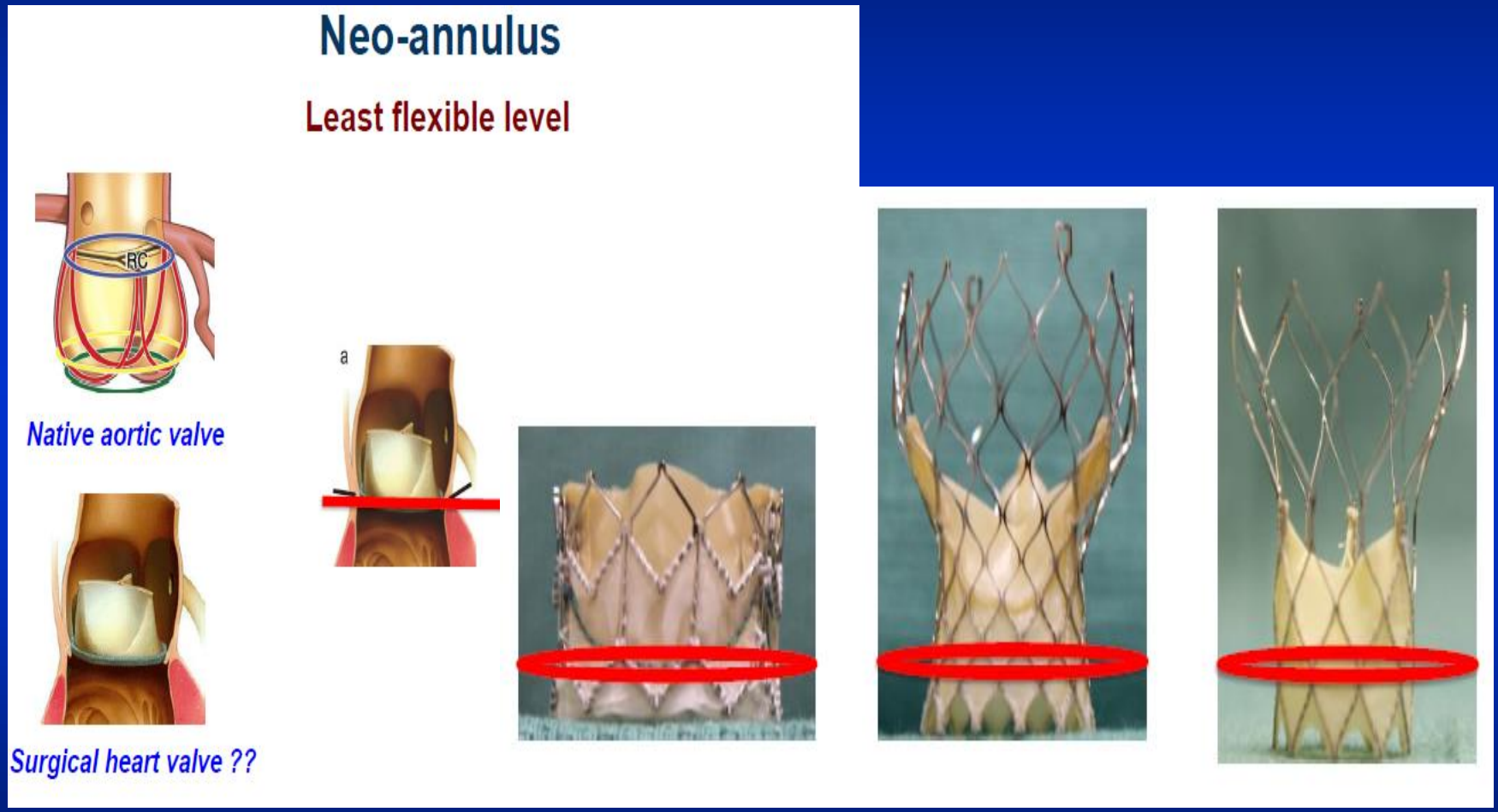
Tipos de Bioprótesis Quirúrgicas



- A) Supra-Annular design = Sewing ring lowest point of valve (Magna; Edwards Lifesciences)
- B) Intra-Annular design = sewing ring is higher than the valve (Perimount; Edwards Lifesciences)

El Anillo de Sutura es el que nos da el lugar de anclaje

Es el Neo annulus



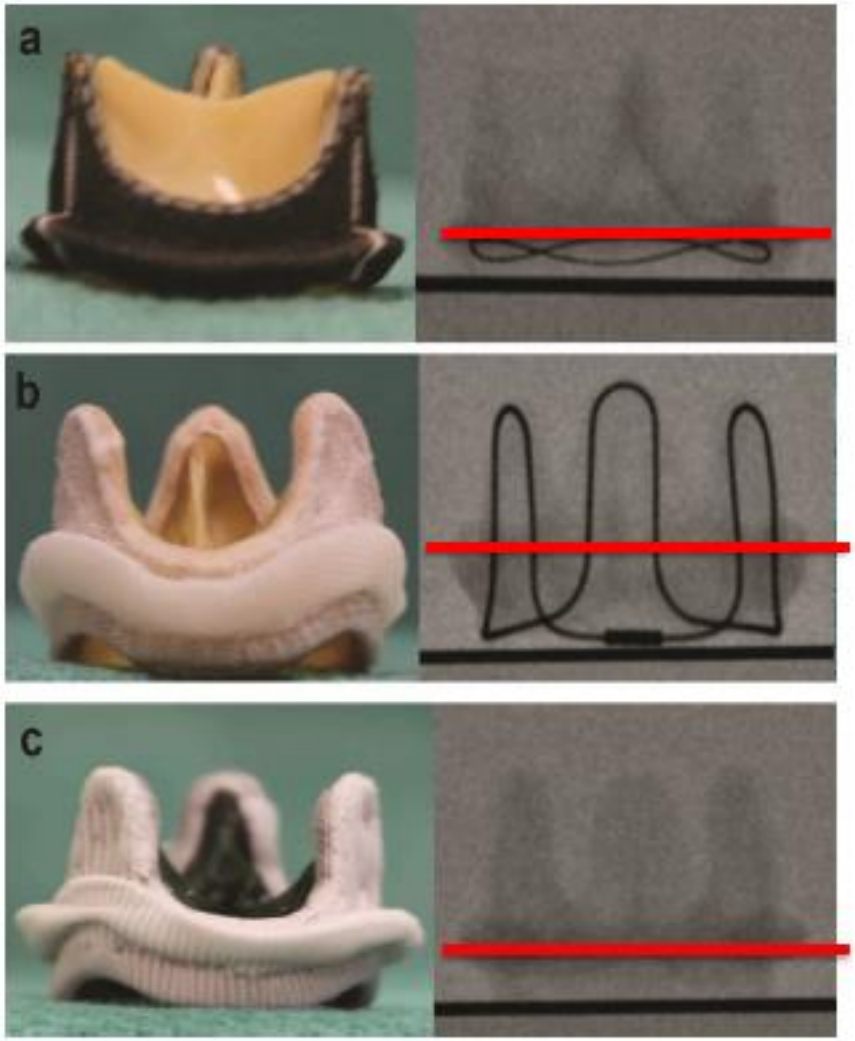
Donde esta el anillo de sutura ???

- Fluoroscopy

Sewing ring marker

Stent frame marker

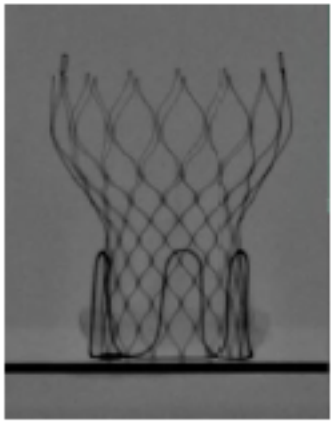
No marker

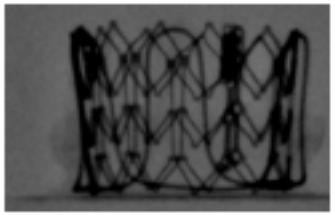


Cual es la posición apropiada para el implante ?

- Valve should be positioned based on neo-annulus
  - Sapien XT – 10-15% below
  - CoreValve – 4-5mm below

- Malposition leads to improper seal and anchoring
  - Too high
    - Embolization
  - Too low
    - PVL
    - Poor hemodyanamics

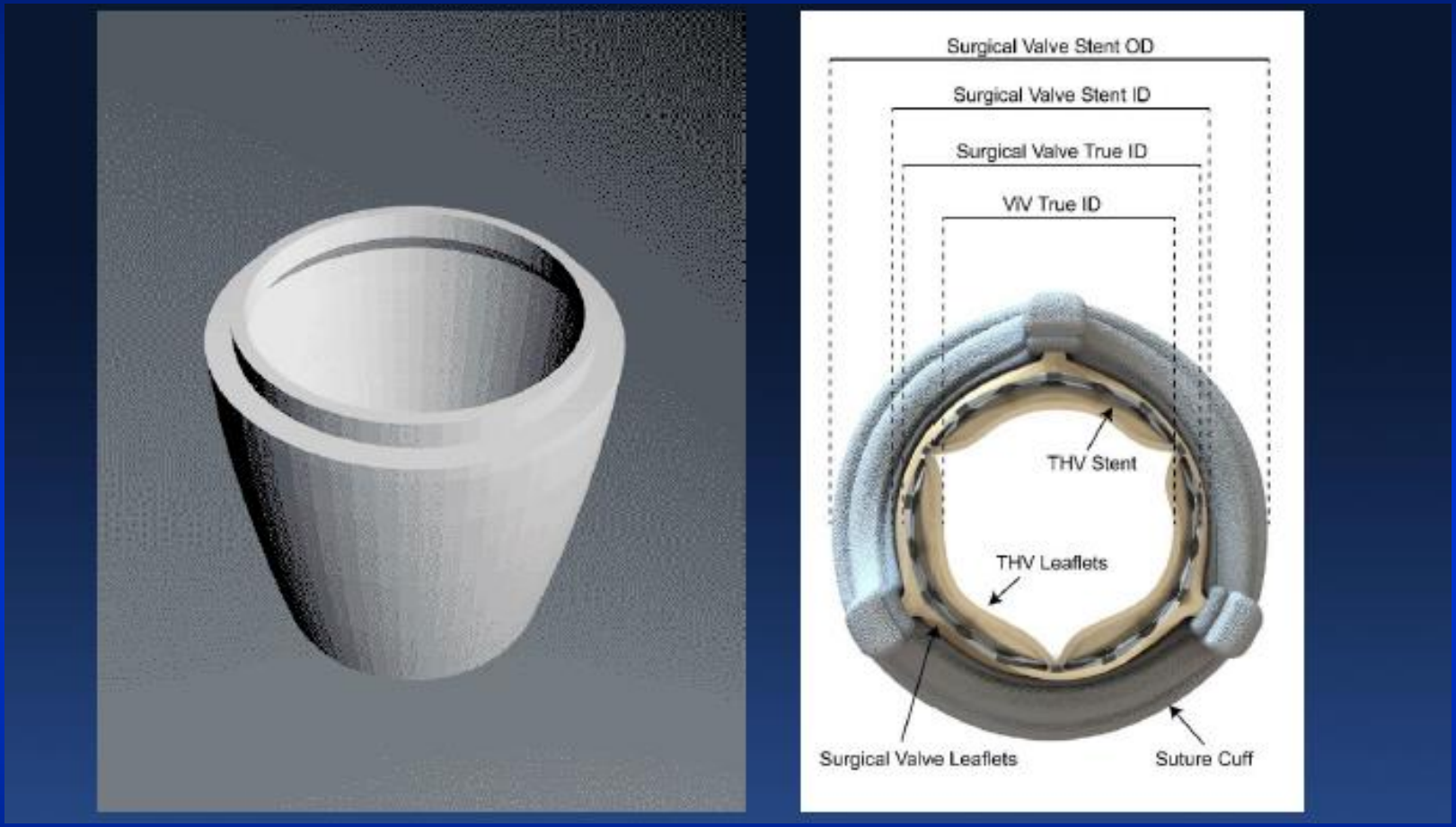




Puntos Principales en el procedimiento de VinV Aórtico

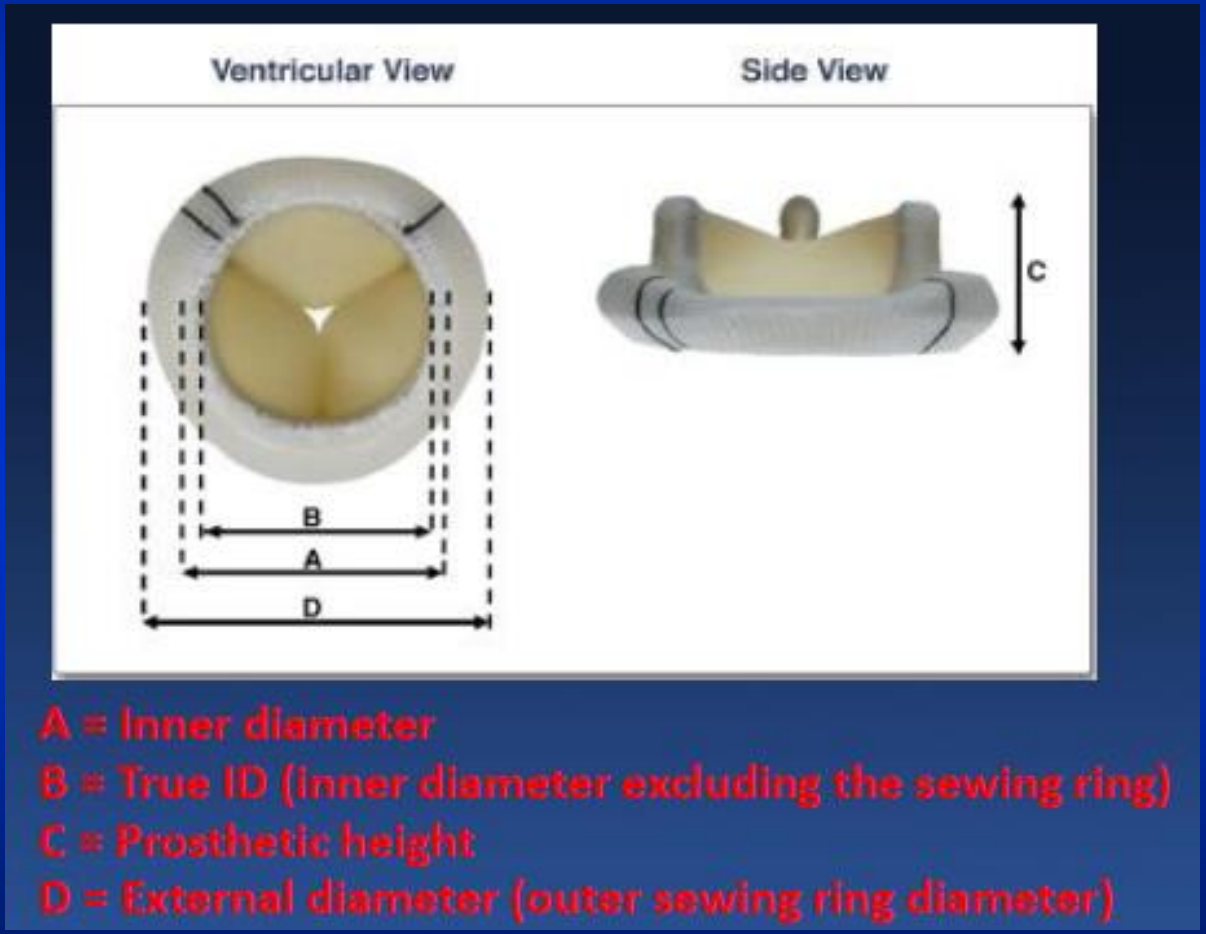
- **Medición y posicionamiento de la prótesis**
- **Mala posición o error en la medición producen:**
  - **Leaks y embolizaciones**
  - **Oclusión coronaria aguda**
  - **Estenosis Residual con gradientes elevados**

ViV no es solamente “poner una valvual detro de otra”…



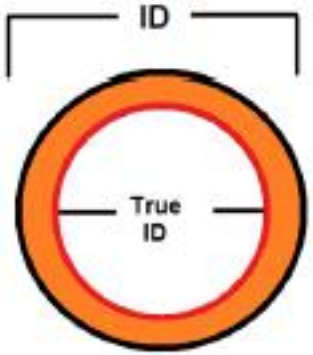
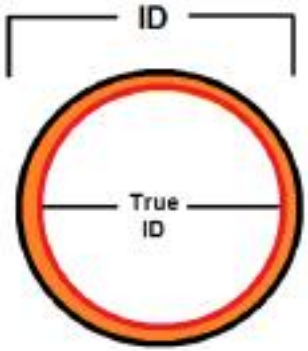
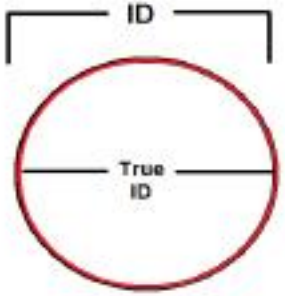
Se crea una situación hemodinámica deficiente e inferior

La primera medida que debemos tomar par ViV es el díámetro interno verdadero



Valve	Nominal size	Stent ID	True ID
Aspire	25	23	21
CE Standard	25	23	21
Mitroflow	25	21	21
Perimount	25	24	23
Trifecta	25	23	22

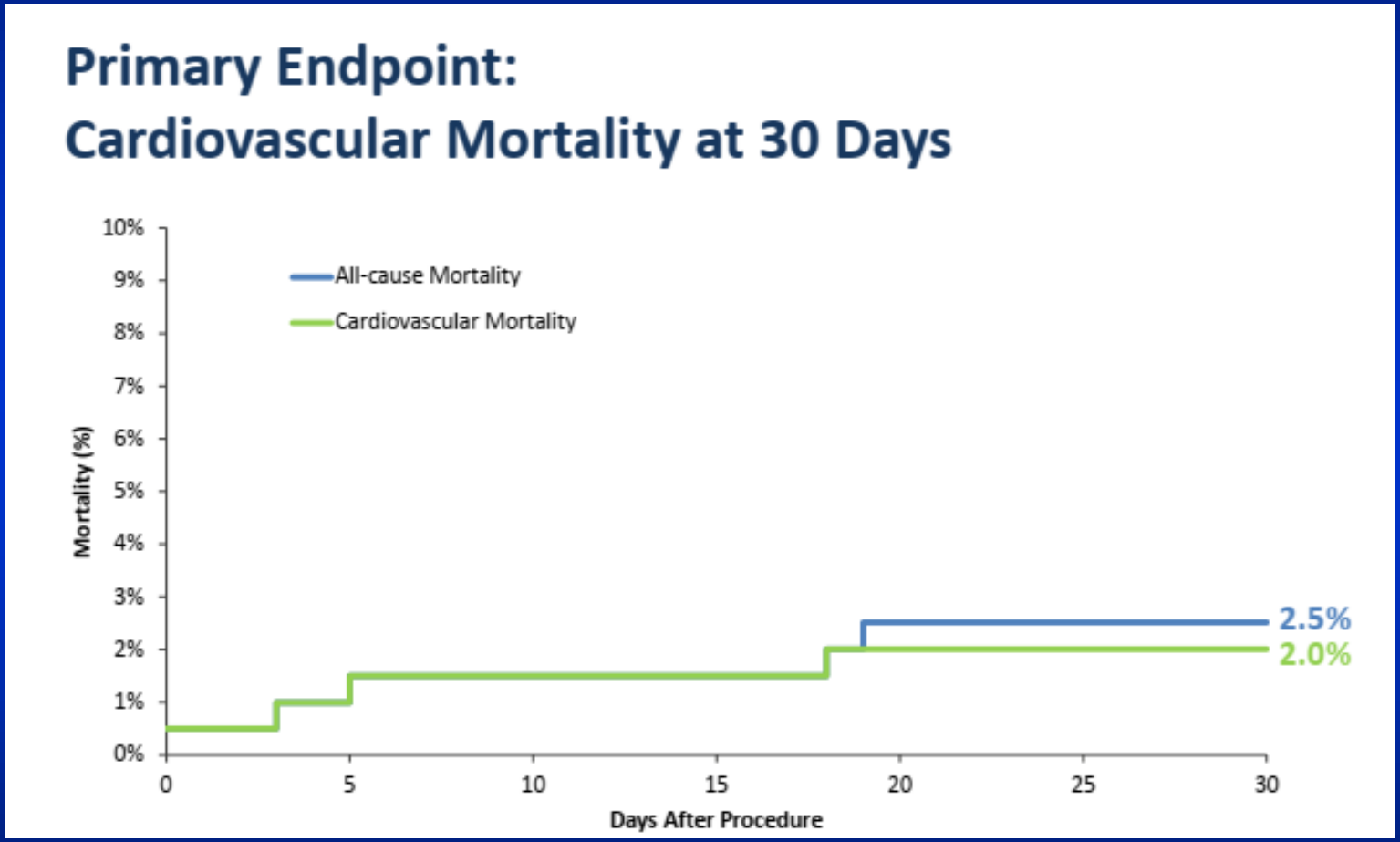
Por Ejemplo, en 3 Tipos de Válvulas tenemos 3 diámetros verdaderos diferentes

Porcine Leaflets Mounted inside	Pericardial Leaflets Mounted inside	Pericardial Leaflets Mounted outside
		
		
True ID = Stent ID – 2mm	True ID = Stent ID – 1mm	Stent ID = True ID

EVIDENCIAS

Resultados a 30 días del “prospective VIVA post-market study”

Evolute R

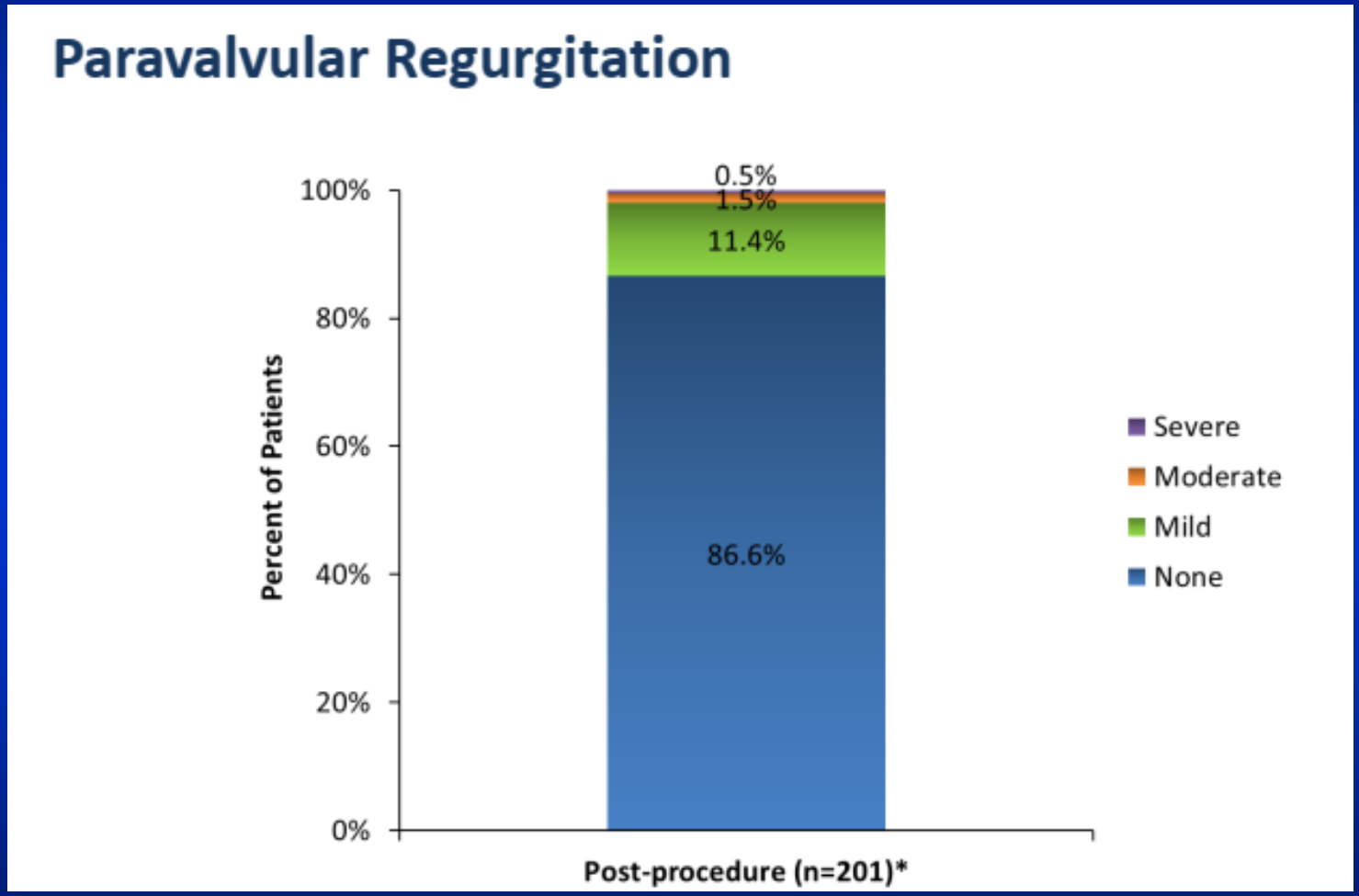


Ran Kornowsk. TVT 2018

DG - D#15

Resultados a 30 días del “prospective VIVA post-market study”

Evolute R

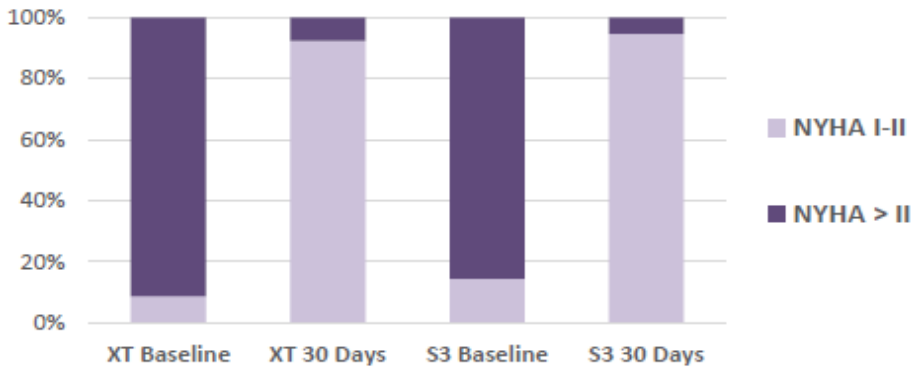


Ran Kornowsk. TVT 2018

Registro VIVID

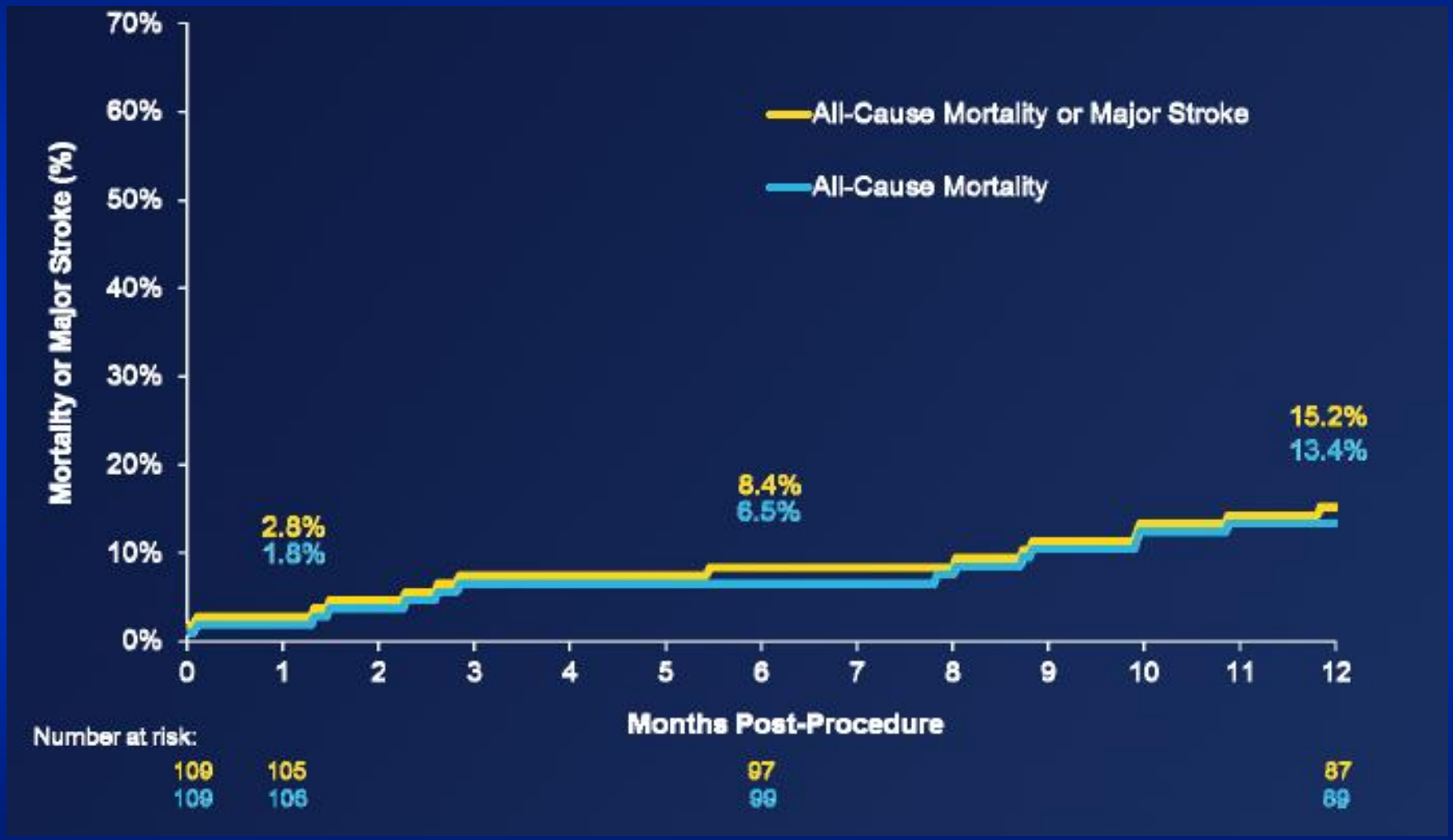
Resultados Peri Procedimiento

	SAPIEN 3 n = 156	SAPIEN XT n = 156	P
Major stroke	0.6%	1.3%	0.56
Major/life-threatening bleeding	1.9%	3.2%	0.72
Major vascular complication	1.9%	1.9%	0.97
Acute kidney injury (stages II/III)	3.8%	3.8%	1.0
Permanent pacemaker implantation	6%	1.4%	**0.04**
All-cause mortality (at 30 days)	2%	2.6%	0.71



COREVALVE US TRIAL

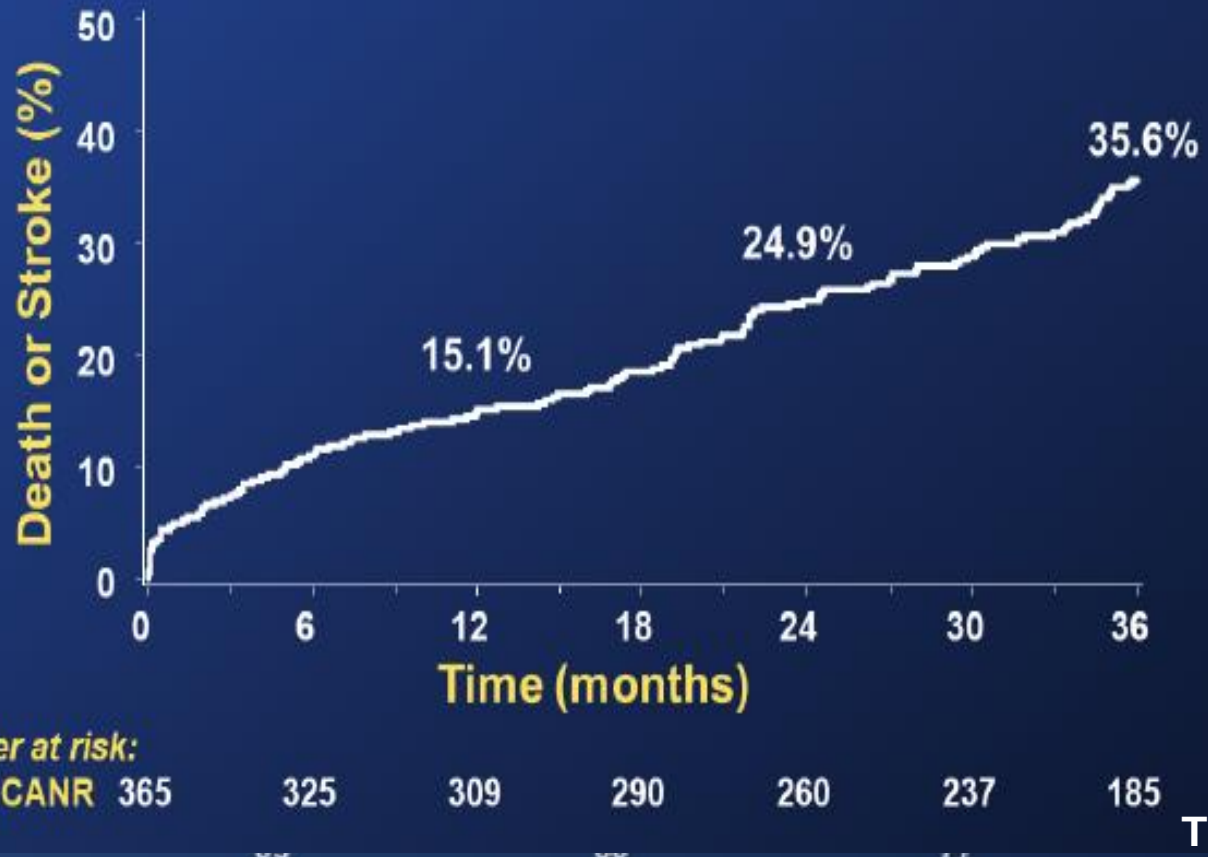
Mortalidad Total o Stroke a 12 meses



DG - D#18

Regitro ViV Partner II

End Point Primario- Mortalidad + Stroke a 36 meses



TCT 2018

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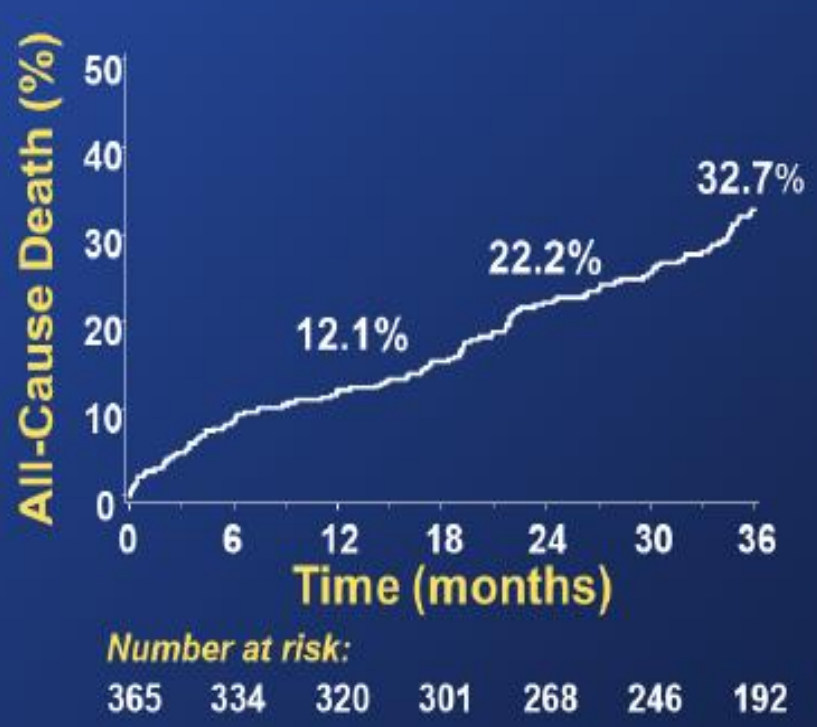
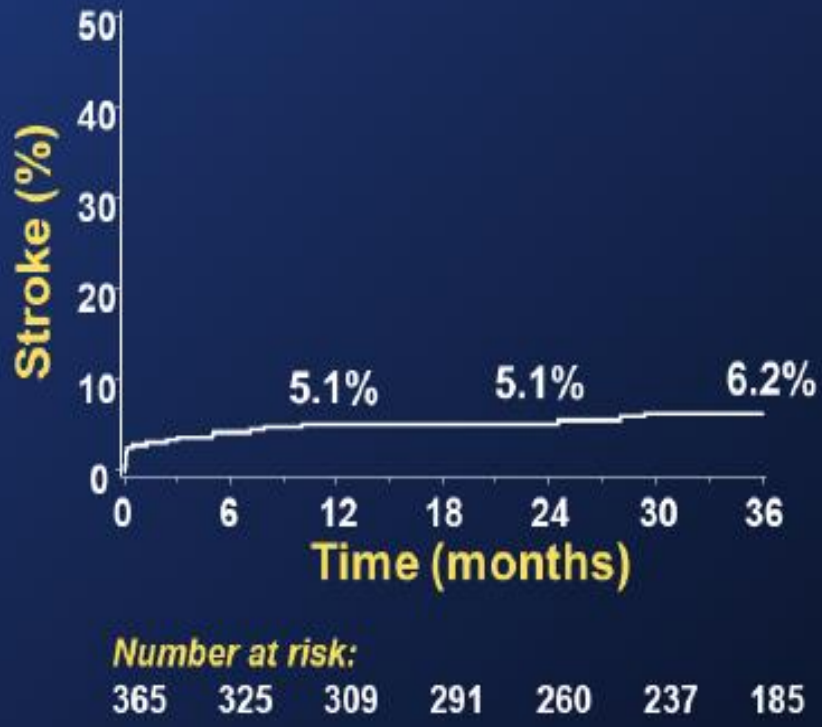
Registro ViV Partner II

Mortalidad y Stroke

THE PARTNER II TRIAL





TCT 2018

DG - D#20

Registro ViV Partner II (media de STS 9.1% y media edad 79 a)
Características de la Válvula y Procedimiento

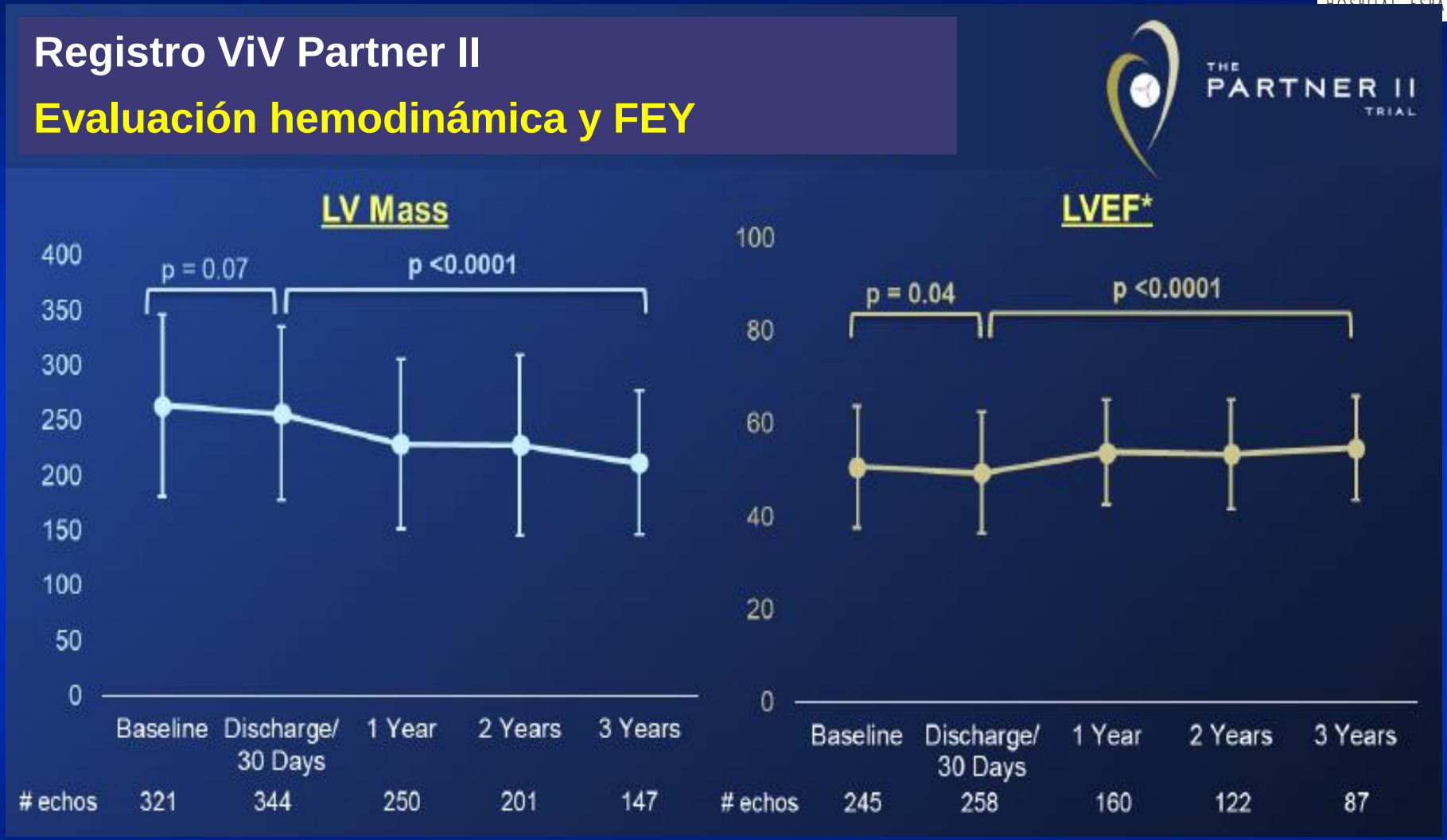
THE PARTNER II TRIAL

Surgical Bioprosthesis Age	%
< 5 years	6.8
5-10 years	27.2
> 10 years	66.0
Mode of Degeneration	
Stenosis	55.0
Regurgitation	23.7
Mixed	21.2
Surgical Valve Type	
Bioprosthetic Stented	93.1
Other	6.9

Labeled Surgical Valve Size	%
21mm	26.7
22-25mm	12.6
>25mm	59.2
Implanted THV Size	
23mm	69.0
26mm	31.0
Access	
Transfemoral	75.8
Transapical	24.2

Registro ViV Partner II

Evaluación hemodinámica y FEY



TCT 2018

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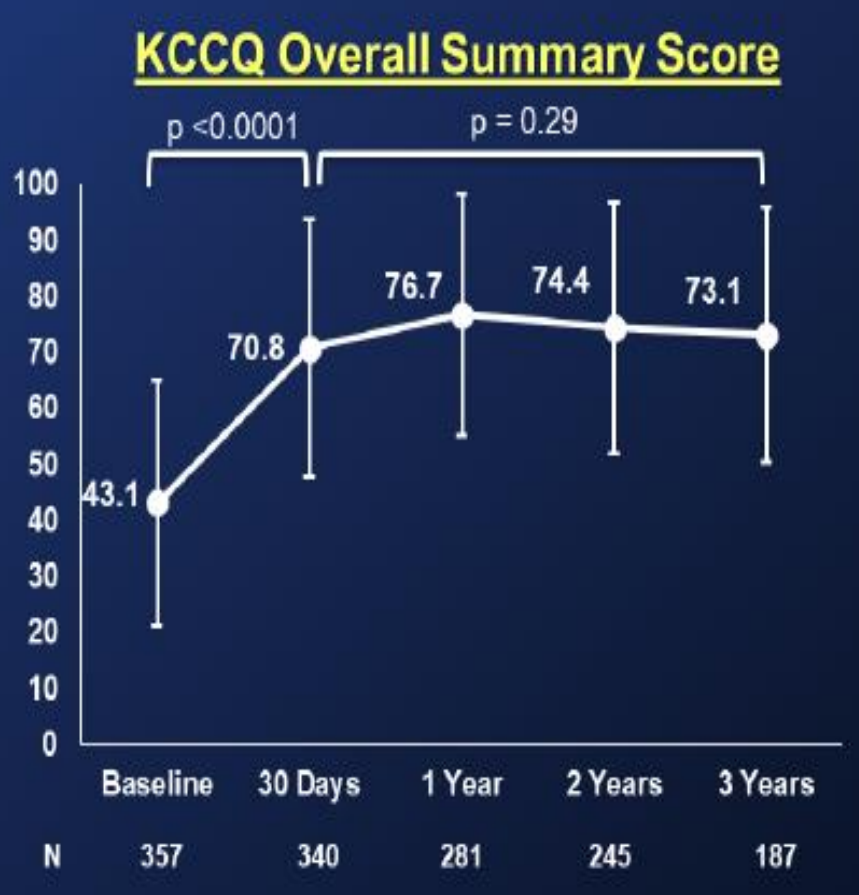
Registro ViV Partner II

Cambios en CF y Calidad de Vida

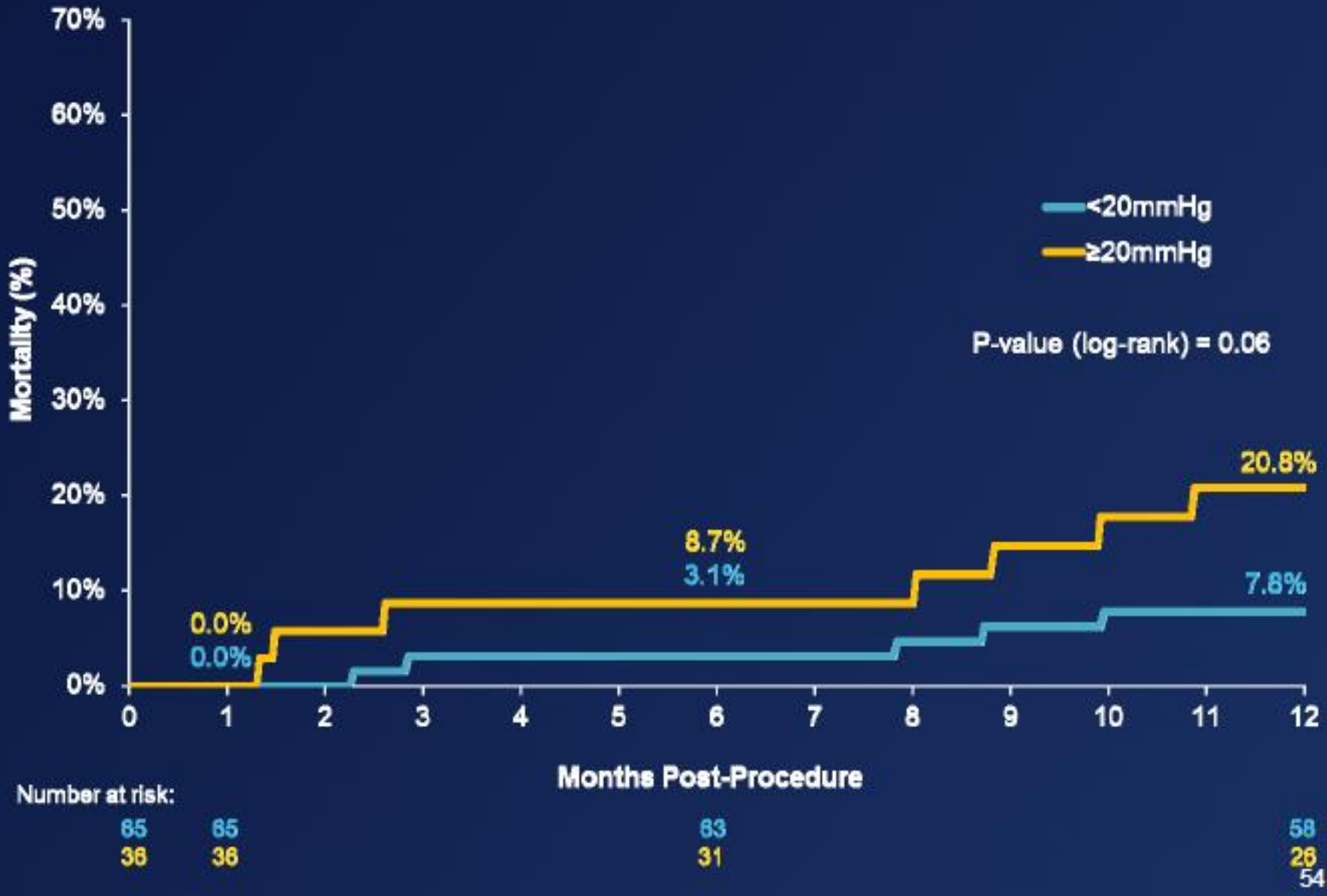
THE PARTNER II TRIAL



DG - D#23

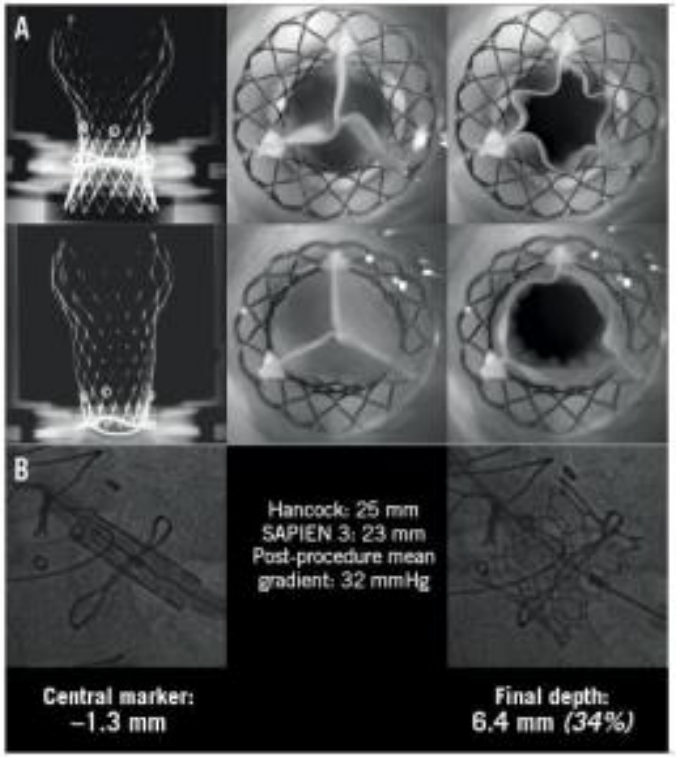
TCT 2018

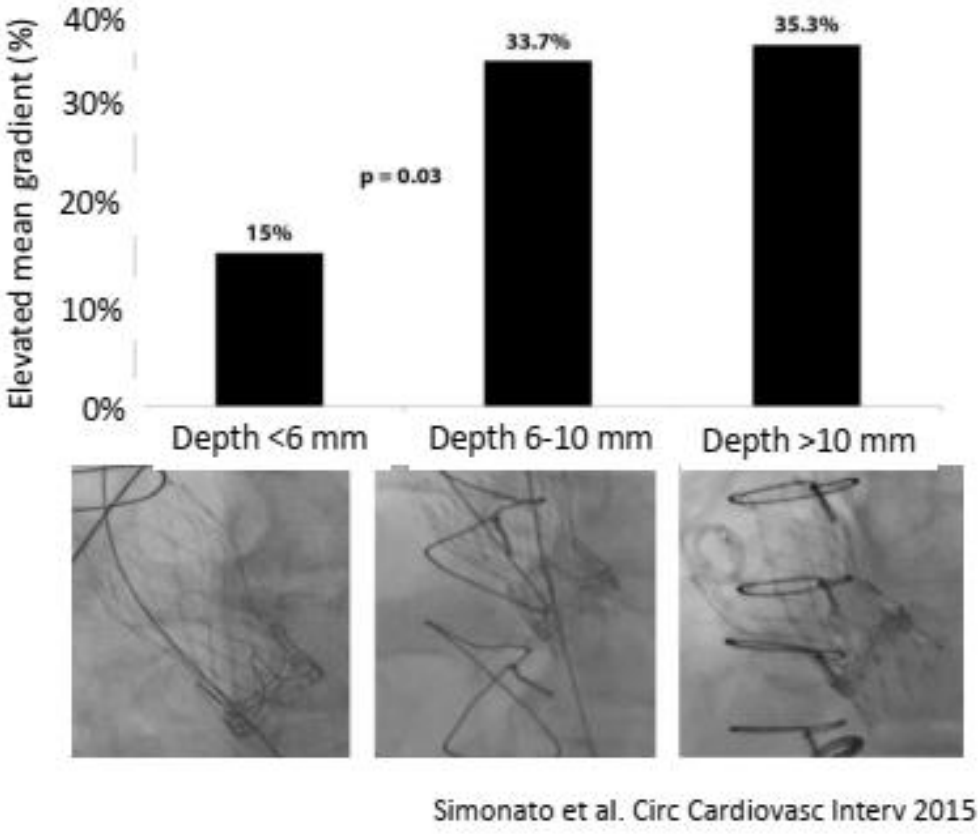
All-Cause Mortality by Discharge Gradient



2019 PCR tokyo valves

El Implante Alto da Gradientes más Bajos



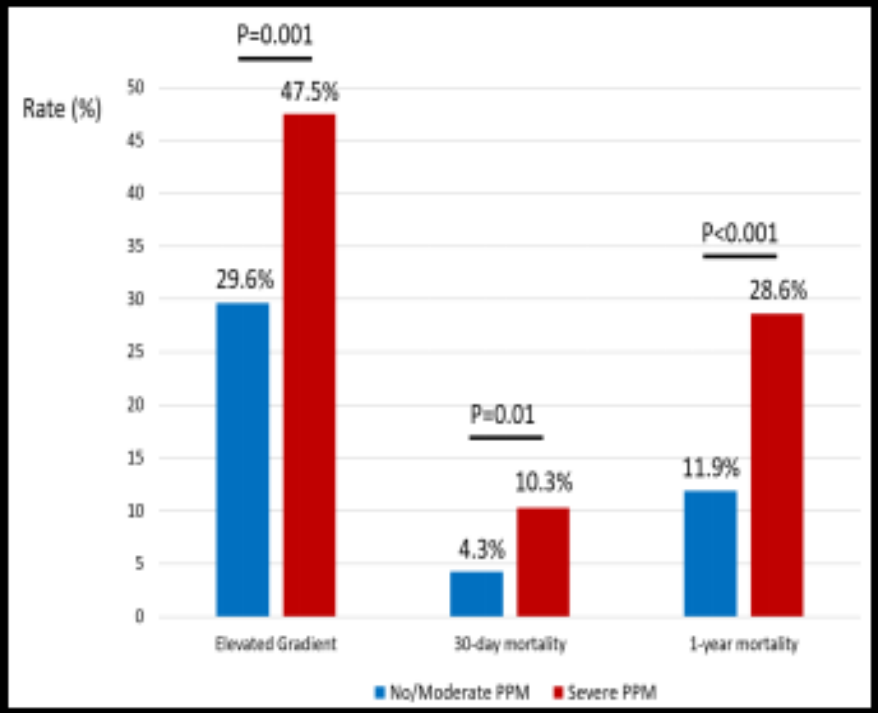


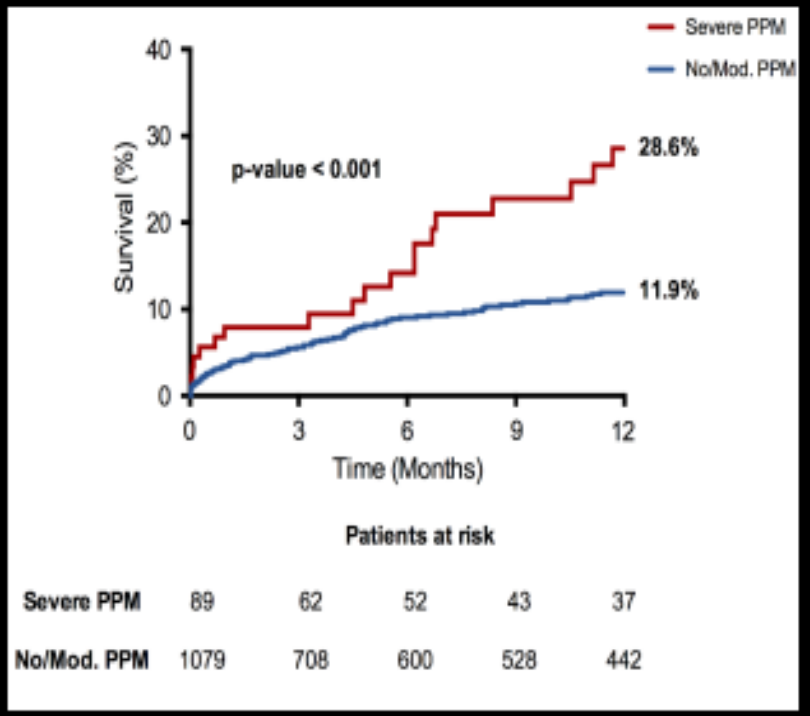
Lars Sondergaard, Tokio Vakves 2019

Impacto de MMatch Previo en Mortalidad de ViV:

Registro VIVID

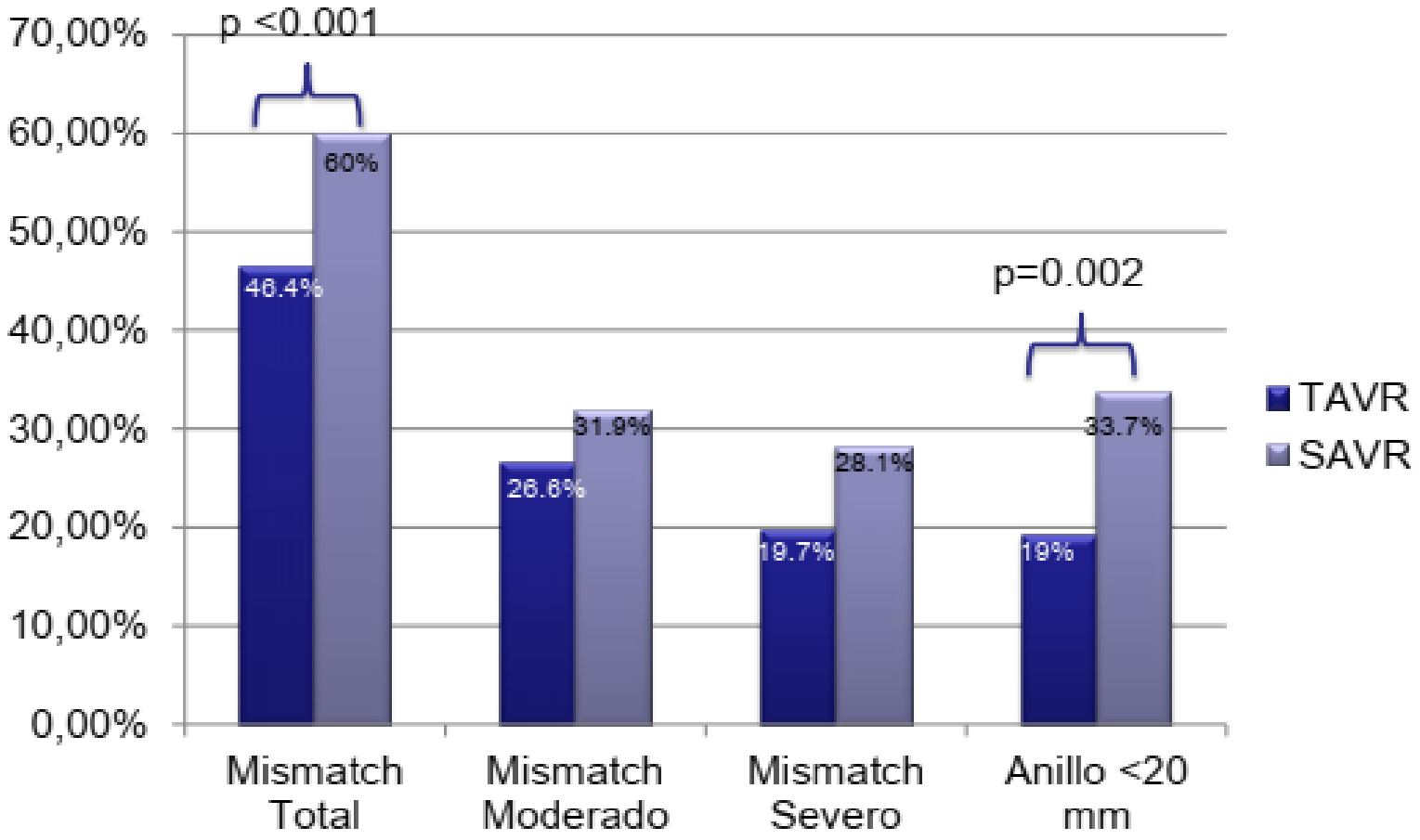
1,168 patients; 89 (7.6%) patients with severe PPM of the surgical valve





Pibarot et al. EuroPCR 2017

Mayor Mismatch luego de la Cirugía



Pibarto P. JACC 2014;64:1323

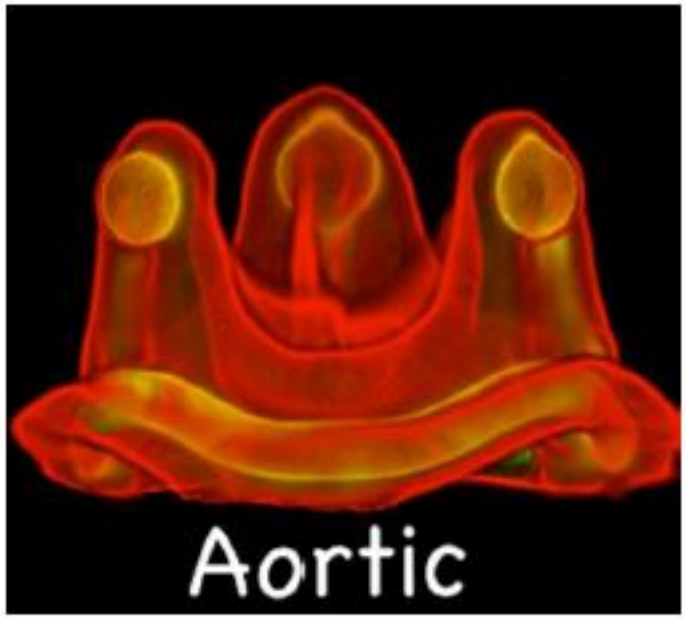
Resumen VinV

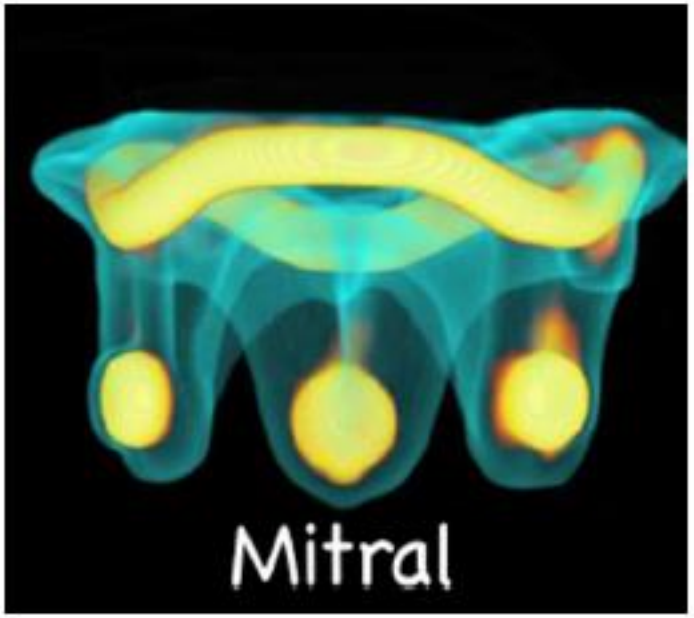
- **El procedimiento de VinV puede realizarse con diferentes dispositivos y con buenos resultados.**
- **Estos resultado empeoran cuando se trata de válvulas pequenas.**
- **Las válvulas stentless se asocian con mayor porcentaje de mal posicionamiento y obstrucciones coronarias, pero con menor gradiente residual.**

Resumen VinV 2

- **Le insuficiencia peri valvular y el gradiente residual son el talón de Aquiles del VinV.**
- **Los gradientes elevados podrían reducirse con implantes más altos.**
- **La oclusión coronaria es una complicación que se presenta con mayor frecuencia que en los TAVR en anillo nativo.**

Valve in Valve Apps





App Store
Google market

VIV Aortic
VIV Mitral

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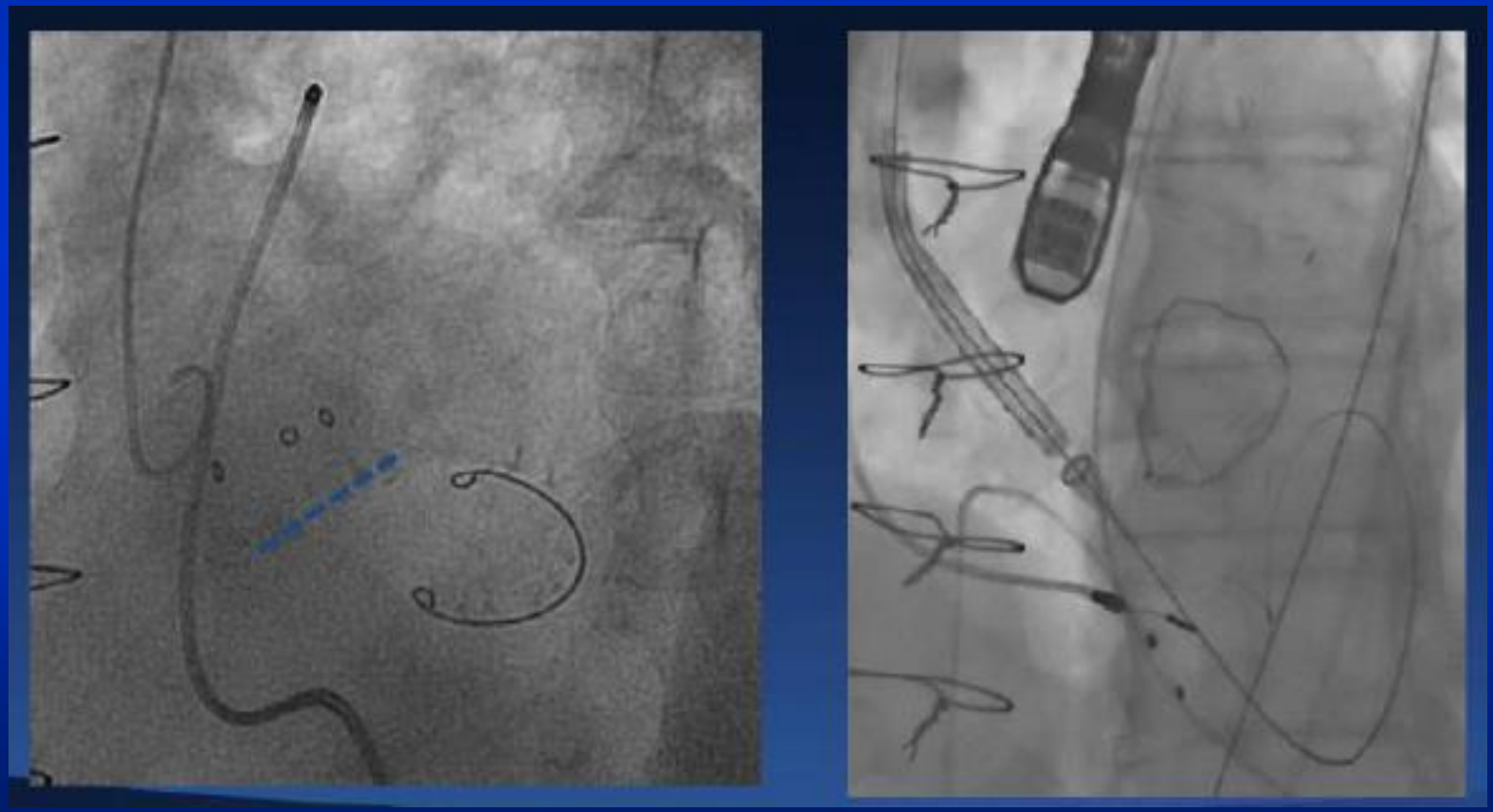
HEMODINAMIA
HOSPITAL ESPAÑOL

Muchas Gracias !!!

Problema 1:
Mala posición de la válvula

Las prótesis biológicas no suelen tener calcio y
las "Stentless" no tiene marcas o anillo para orientarse

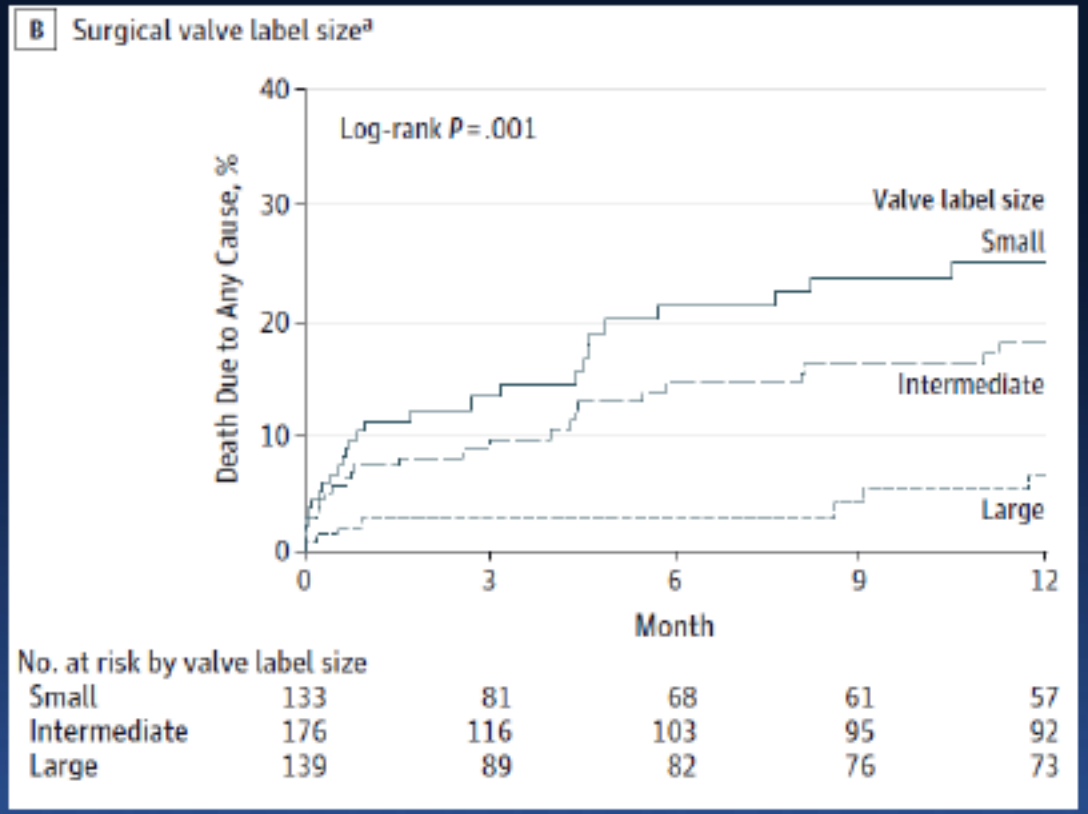


Problema 2: Sub Expansión

La estenosis y los anillos chicos afectan la sobrevida

Mortalidad Post VinV Aórtico

The smaller the surgical valve, the higher the mortality!



Problema 3:
Oclusión Coronaria

Con las Válvulas Stentless
el riesgo de oclusión coronaria es mayor

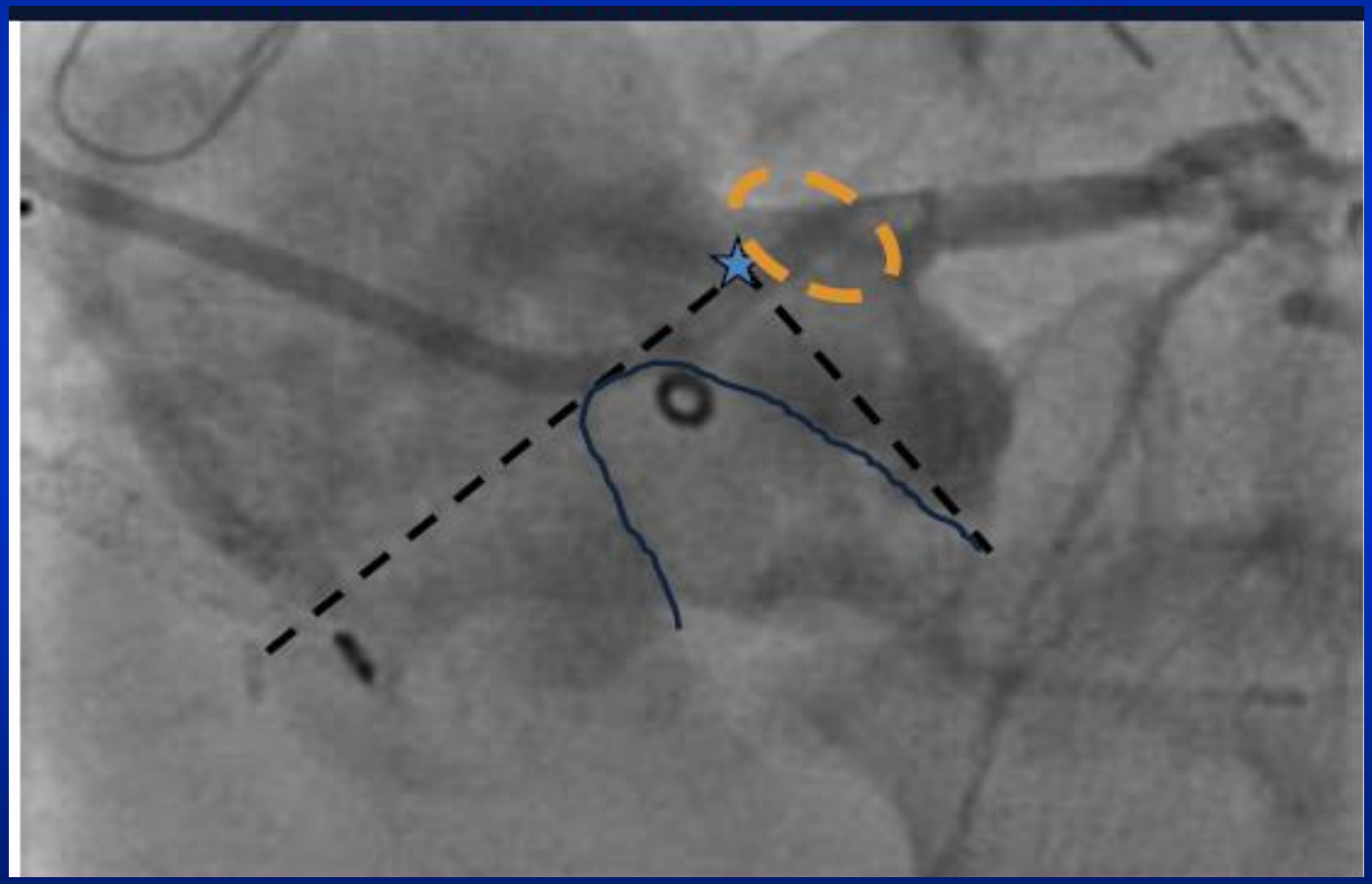


Table 3. Computed-Tomographic Assessment for Coronary Occlusion With Valve-in-Valve

Coronary and bypass graft parameters
Stenosis in coronary ostia
Patency of bypass grafts
Aortic root parameters
Sinus of Valsalva diameter
Sinus height
Bioprosthesis
Leaflet thickness, significant pannus calcification, or bulkiness
Post height
Bioprosthesis–root relationship
Sewing ring plane to coronary ostial height (if below coronary ostia less important)
Distance from a virtual ring defined by the posts to the sinus of Valsalva
Distance from a virtual ring defined by the posts to coronary ostia
VTC distance: virtual THV to coronary ostia (ring at the level of the top of the posts and in a size of THV device to be implanted): high risk <3 mm, intermediate risk 3–6 mm, low risk >6 mm

THV indicates transcatheter heart valve; and VTC, virtual THV-coronary distance.

"To Split or Not to Split?" The role of BASILICA to reduce the risk of coronary obstruction during TAVR

Adam Greenbaum, MD, *Vasilis Babaliaros, MD*
Emory University, Atlanta, GA, USA

Danny Dvir MD,
University of Washington, Seattle, WA, USA

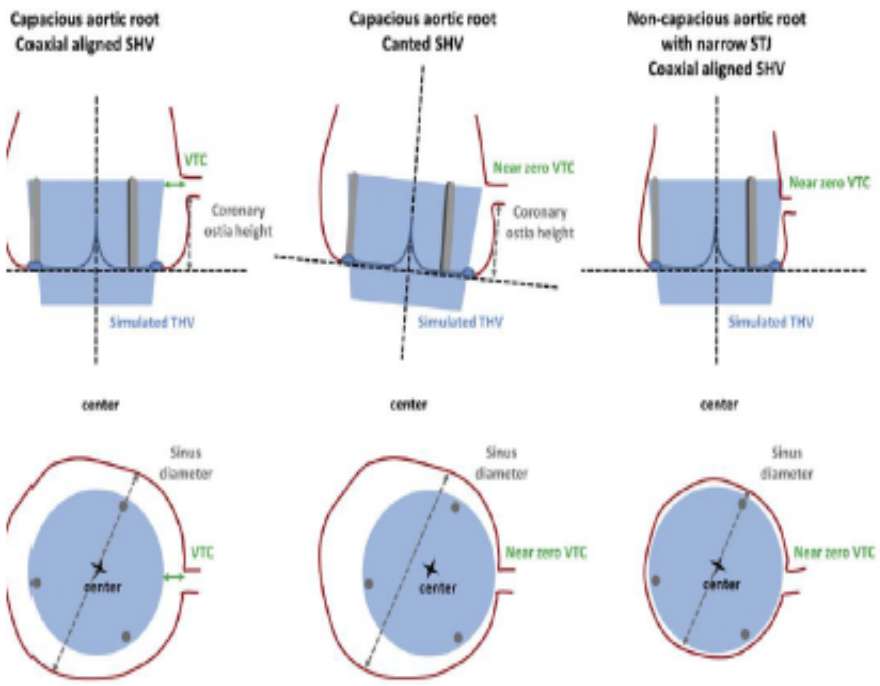
Toby Rogers PhD, BM BCh
Medstar Hospital, Washington, DC

Jaffar Khan, BM BCh, Robert Lederman, MD
NHLBI, NIH, Bethesda, MD, USA

Predicting coronary obstruction is complicated

Table 1. Possible Risk Factors for Coronary Obstruction After Valve-in-Valve Implantation

Anatomic factors
Low-lying coronary ostia
Narrow sinotubular junction/low sinus height
Narrow sinuses of Valsalva
Previous root repair (eg, root graft and coronary reimplantation)
Bioprosthetic valve factors
Supra-annular position
High leaflet profile
Internal stent frame (eg, Mitroflow, Trifecta)
No stent frame (homograft, stentless valves)
Bulky leaflets
Transcatheter valve factors
Extended sealing cuff
High implantation



Coronary height <12mm
Sinus width <30mm
VTC <4mm

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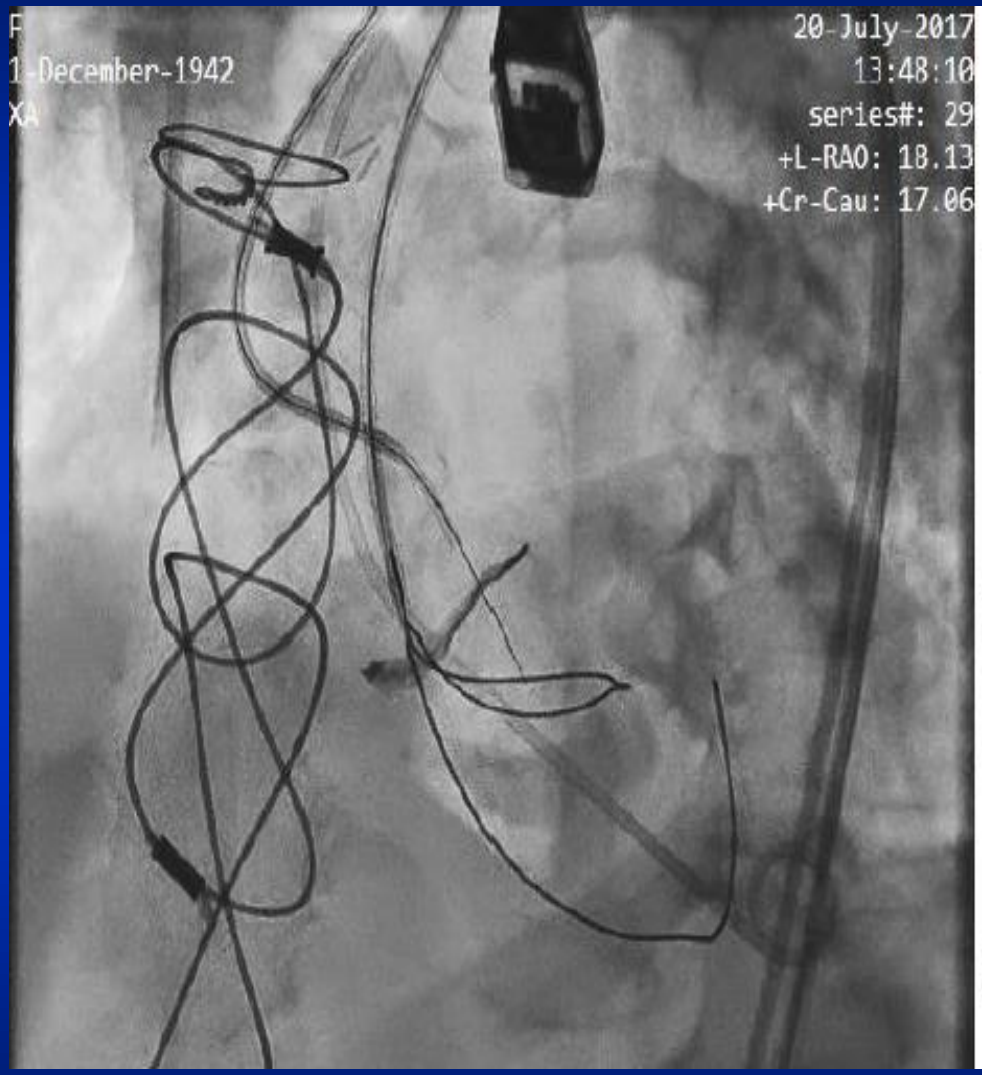
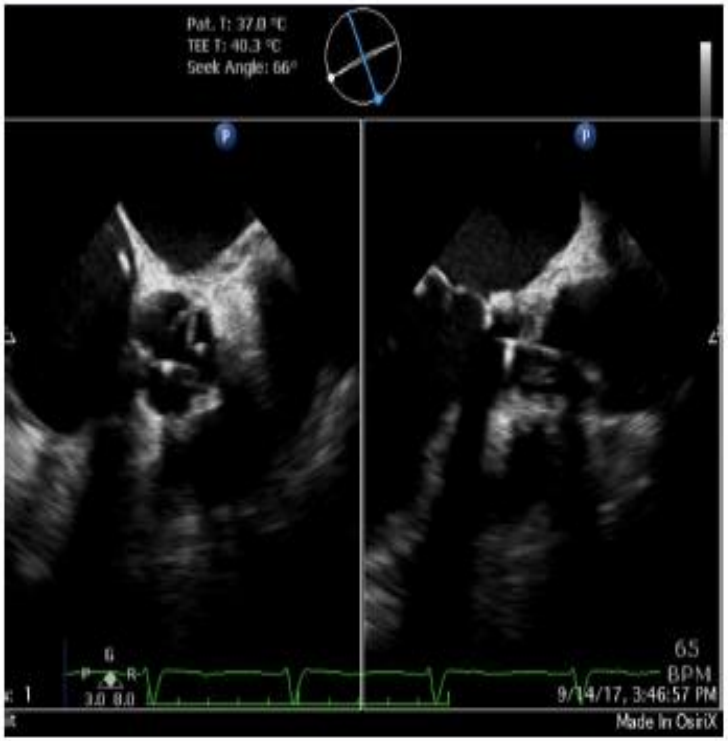


Leaflet traversal with Astato guidewire into Gooseneck snare

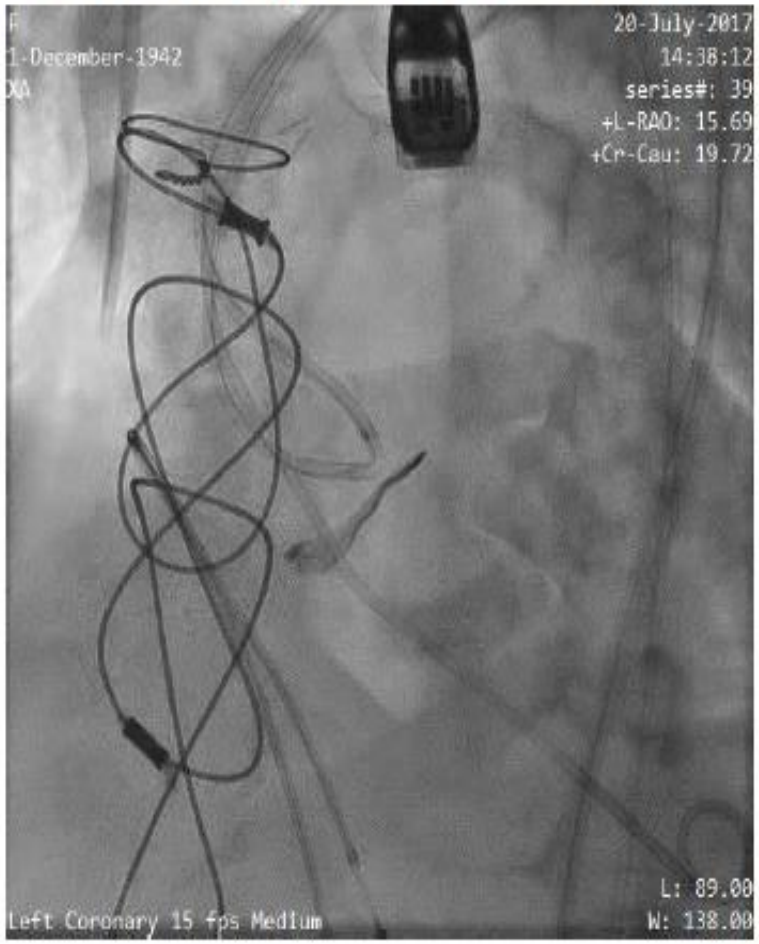


DG - D#39

Novel prevention of coronary obstruction

BASILICA

- Pros
  - Directly addresses the leaflet issue
  - No alteration in post TAVR antiplatelet/OAC regimen
  - Easier future access to coronaries
  - Not affected by BVF
- Cons
  - Requires an additional skillset
  - Risk of embolism?



“Craking” del anillo valvular protésico

Cuando se estima que el gradiente residual será muy elevado luego del TAVI debido a que el anillo de la prótesis quirúrgica es muy pequeño

Balón de Kevlar de Alta Presión

Images and Case Reports in Interventional Cardiology

Fracturing the Ring of Small Mitroflow Bioprostheses by High-Pressure Balloon Predilatation in Transcatheter Aortic Valve-in-Valve Implantation

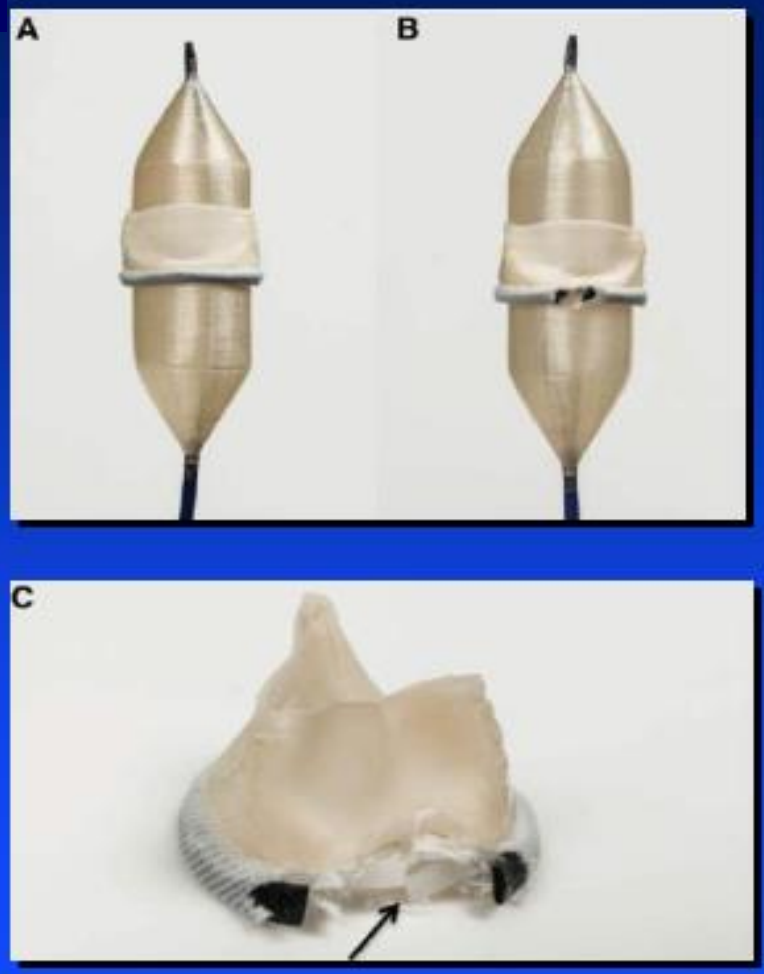
Jens Erik Nielsen-Kudsk, MD, DMSc; Evald Høj Christiansen, MD, PhD; Christian Juhl Terkelsen, MD, DMSc; Bjarne Linde Nørgaard, MD, PhD; Kaare Troels Jensen, MD, PhD; Lars Romer Krusell, MD; Mariann Tang, MD; Kim Terp, MD; Kaj-Erik Klaaborg, MD; Henning Rud Andersen, MD, DMSc

Early deterioration of Mitroflow aortic bioprostheses (Sorin Group Inc), particularly small sizes 19 and 21 mm, has been reported.[1] Treatment of failing bioprostheses by transcatheter valve-in-valve (ViV) therapy has become an alternative to repeat surgery.[2,3] However, ViV treatment is problematic with small surgical bioprosthesis because of a further reduction in the effective valve orifice. One way to overcome this challenge may be to fracture the ring of the surgical valve by high-pressure balloon dilatation before implanting a larger size transcatheter valve. The feasibility of this approach was recently reported for an Edwards Perimount bioprosthesis (19 mm) in the pulmonic position.[4] We report the first cases in vitro and in man of high-pressure balloon dilatation to fracture the ring of small dysfunctional Mitroflow aortic bioprostheses followed by transcatheter ViV implantation.

The Mitroflow bioprosthesis is build from a bovine pericardial sheet sutured to the outside of an acetyl stent to form the leaflet. The stent is made from self-inflating

heart valve in vitro in one of the fractured 21 mm Mitroflow bioprostheses.

After in vitro testing and informed consent, we performed this procedure in 2 patients with small Mitroflow bioprostheses (19 and 21 mm) and high risk to redo surgery (Table). High-pressure balloon predilatation by an ATLAS Gold balloon led to fracturing of the stent ring of the Mitroflow valves with subsequent successfully ViV with an SAPIEN XT valve 20 mm (19 mm Mitroflow) and a SAPIEN III 23 mm valve (21 mm Mitroflow; Table). The procedures were performed in general anesthesia guided by fluoroscopy and TEE. Rapid right ventricular pacing (180 bpm) and cardiopulmonary support (CPS 2 l/min; right atrium to left femoral artery) were used during the high-pressure balloon predilatation and at the time of ViV implantation. The Mitroflow valve ring fractured at a pressure of 16 atm (Mitroflow 19 mm) and 11 atm (Mitroflow 21 mm) evident by a sudden drop in inflation pressure and resolution of the waist in the balloon with expan-



Nielsen-Kudsk JE, et al. Circ Cardiovasc Intv 2015

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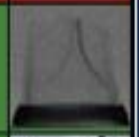
How to Perform BVF

First, check to see if the surgical valve can be fractured

Manufacturer/ Brand	Valve Size	Bard TRU Balloon Fracture/Pressure	Bard Atlas Gold Balloon Fracture/Pressure	Appearance After Fracture
St. Jude Trifecta 	19 mm	NO	NO	
	21 mm	NO	NO	
St. Jude Biocor Epic 	21 mm	YES / 8 ATM	YES / 8 ATM	
Medtronic Mosaic 	19 mm	YES / 10 ATM	YES / 10 ATM	
	21 mm	YES / 10 ATM	YES / 10 ATM	
Medtronic Hancock II 	21 mm	NO	NO	
Sorin Mitroflow 	19 mm	YES / 12 ATM	YES / 12 ATM	
	21 mm	YES / 12 ATM	YES / 12 ATM	
Edwards MagnaEase 	19 mm	YES / 18 ATM	YES / 18 ATM	
	21 mm	YES / 18 ATM	YES / 18 ATM	
Edwards Magna 	19 mm	YES / 24 ATM	YES / 24 ATM	
	21 mm	YES / 24 ATM	YES / 24 ATM	

How to Perform BVF

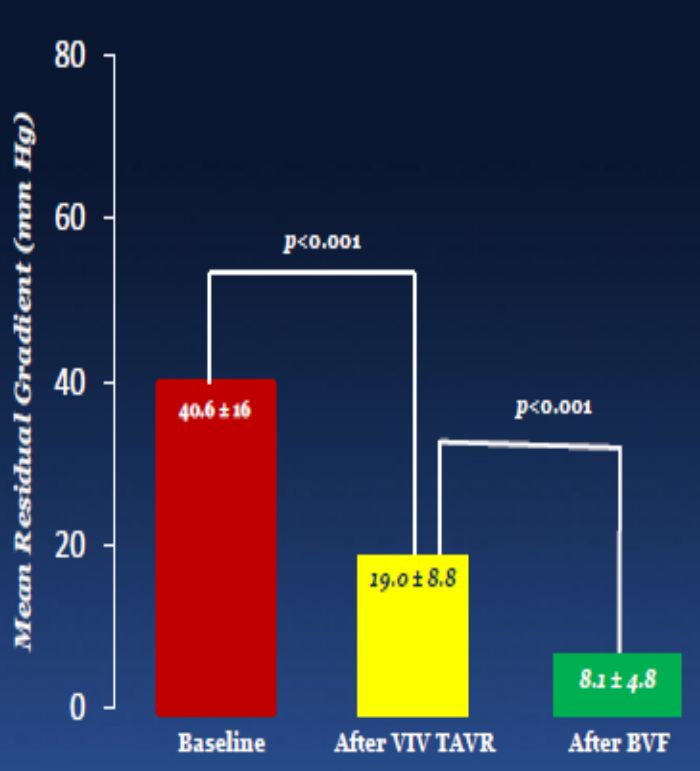
... or remodeled

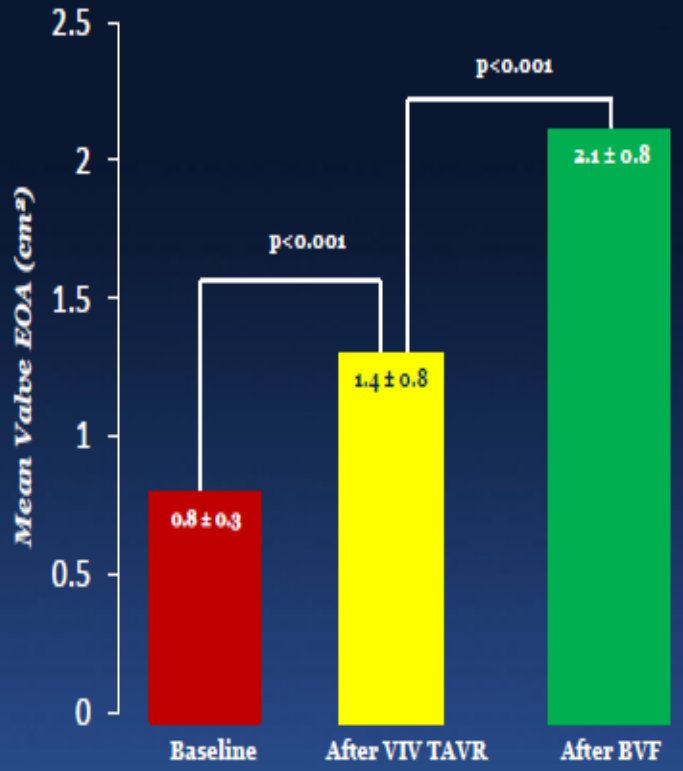
Valves that can be fractured	Valves that can be remodeled	Valves that cannot be fractured or remodeled
Biocor Epic	Carpentier-Edwards Standard	Avalus
Magna	Carpentier-Edwards SAV	Hancock II
Magna Ease	Inspiris	
Mitroflow	Perimount (older generation)	
Mosaic	Trifecta	
Perimount (newer generation)		

Circ Cardiovasc Interv. 2018

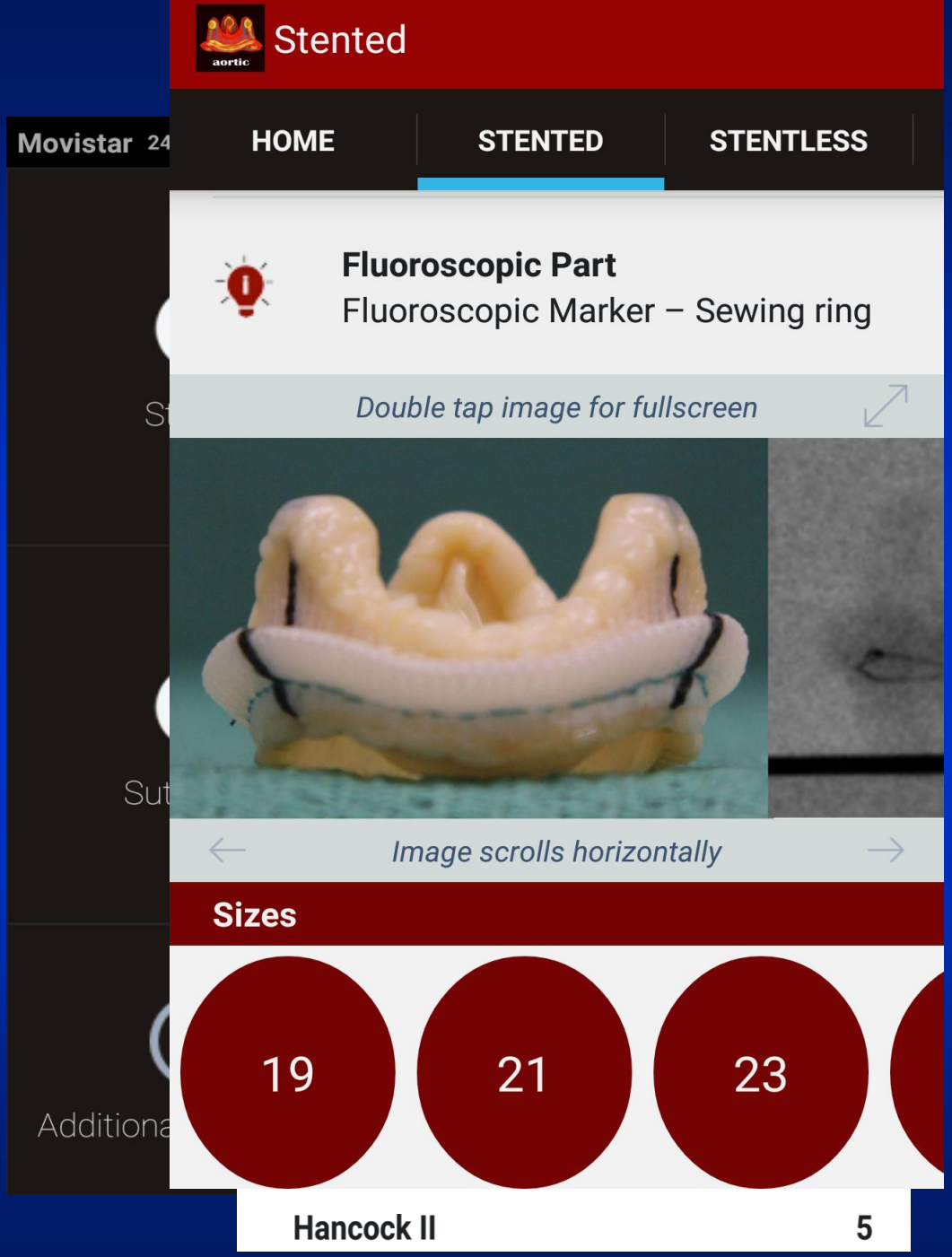
Clinical Results

66 Patients undergoing VIV TAVR followed by BVF



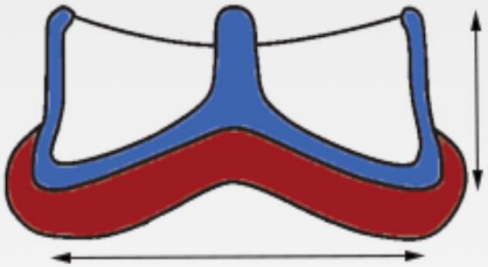


Presented by Keith B. Allen, Western Thoracic Society Annual Meeting, 2018


Stented
HOME
STENTED
STENTLESS
Fluoroscopic Part
Fluoroscopic Marker – Sewing ring
Double tap image for fullscreen
Image scrolls horizontally
Sizes
19
21
23
Hancock II
5

Stented

HOME | STENTED | STENTLESS



Ht: 16

Stent ID: 23

True ID 20.5

THV Selector

Stented

HOME | STENTED | STENTLESS

TAVI Valve Choices For:

Biocor / Epic Supra, 23

Sapien 23	Core Valve 23
Portico 23	Jena 23
Lotus 23	S3 23
Accurate TA S	Accurate NEO S

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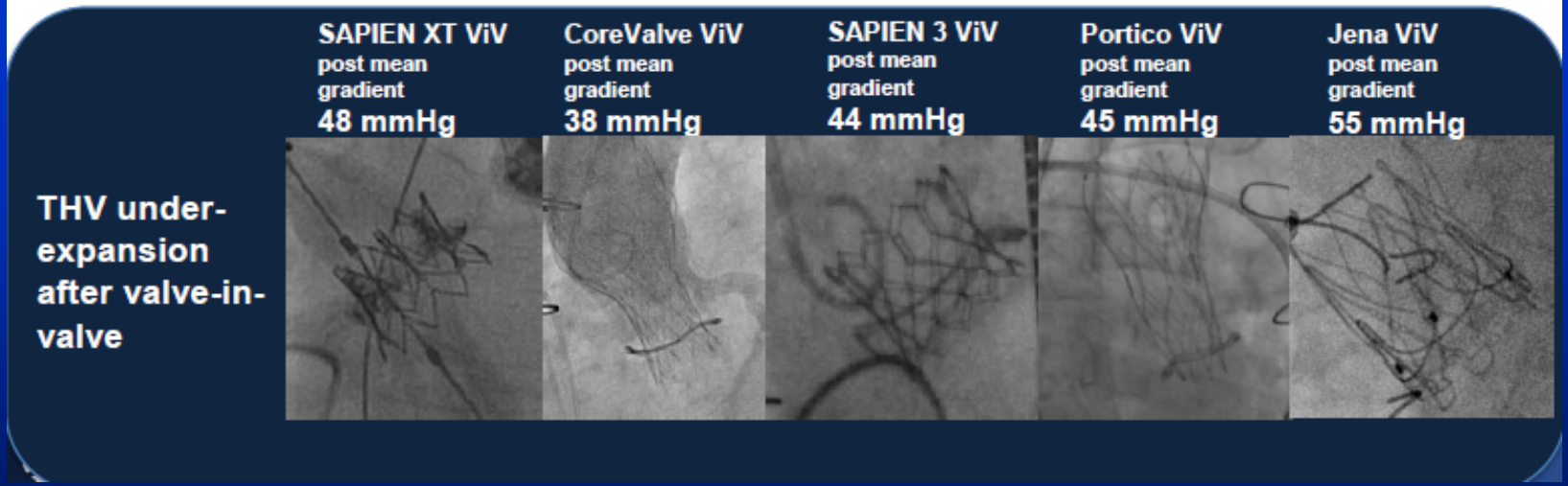
- **Esta APP nos permite elegir la valvula correcta, en cuanto a tamano y diseno.**
- **Nos ayuda a lograr una posición correcta y segura**
- **Siempre partiendo del conocimiento de la bioprotesis quirúrgica utilizada**

Limitations of current therapeutic options

- Transcatheter valve implantation for the treatment of failed surgical bioprosthetic valves (valve-in-valve) is an appealing less invasive alternative to reoperation.

- A major limitation of valve-in-valve is under-expansion, due to the non-elastic physical characteristics of surgical valve rings.



ESC Guidelines for AVR and bioprosthesis 2013

Choice of the aortic/mitral prosthesis : in favour of a bioprosthesis

	Class	Level
A bioprosthesis is recommended according to the desire of the informed patient.	I	C
A bioprosthesis is recommended when good quality anticoagulation is unlikely (compliance problems, not readily available) or contraindicated because of high bleeding risk (prior major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation).	I	C
A bioprosthesis is recommended for reoperation for mechanical valve thrombosis despite good long-term anticoagulant control.	I	C
A bioprosthesis should be considered in patients for whom future redo valve surgery would be at low risk.	IIa	C
A bioprosthesis should be considered in young women contemplating pregnancy.	IIa	C
A bioprosthesis should be considered in patients aged > 65 years for prosthesis in aortic position or > 70 years in mitral position, or those with life expectancy lower than the presumed durability of the bioprosthesis.	IIa	C

Bioprothesis are used and are recommended today by guidelines.
With Class I and class IIa level of evidence C recommendations.

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 & European Journal of Cardio-Thoracic Surgery 2012 - doi:10.1093/ejcts/ezs455).

www.escardio.org/guidelines

EACTS

EUROPEAN SOCIETY OF CARDIOLOGY

CASO

- **Paciente femenina de 77 años con antecedentes de estenosis aórtica severa por degeneración de válvula biológica protésica quirúrgica colocada hace 6 años, sintomática por disnea en CF III-IV.**
- **HTP moderada, I. Tric leve, I. Mitral Moderada, EPOC. Internaciones por insuficiencia cardíaca.**
- **Euroscore 2: 9.25, Euroscore Logístico:13.9; STS: 28.7**
- **Válvula EPIC 21 (St Jude)**
- **TCMS: Diámetro: 21; Area: 260 ; Senos: 30**
  TCI: 0.9 ; CD: 2.4

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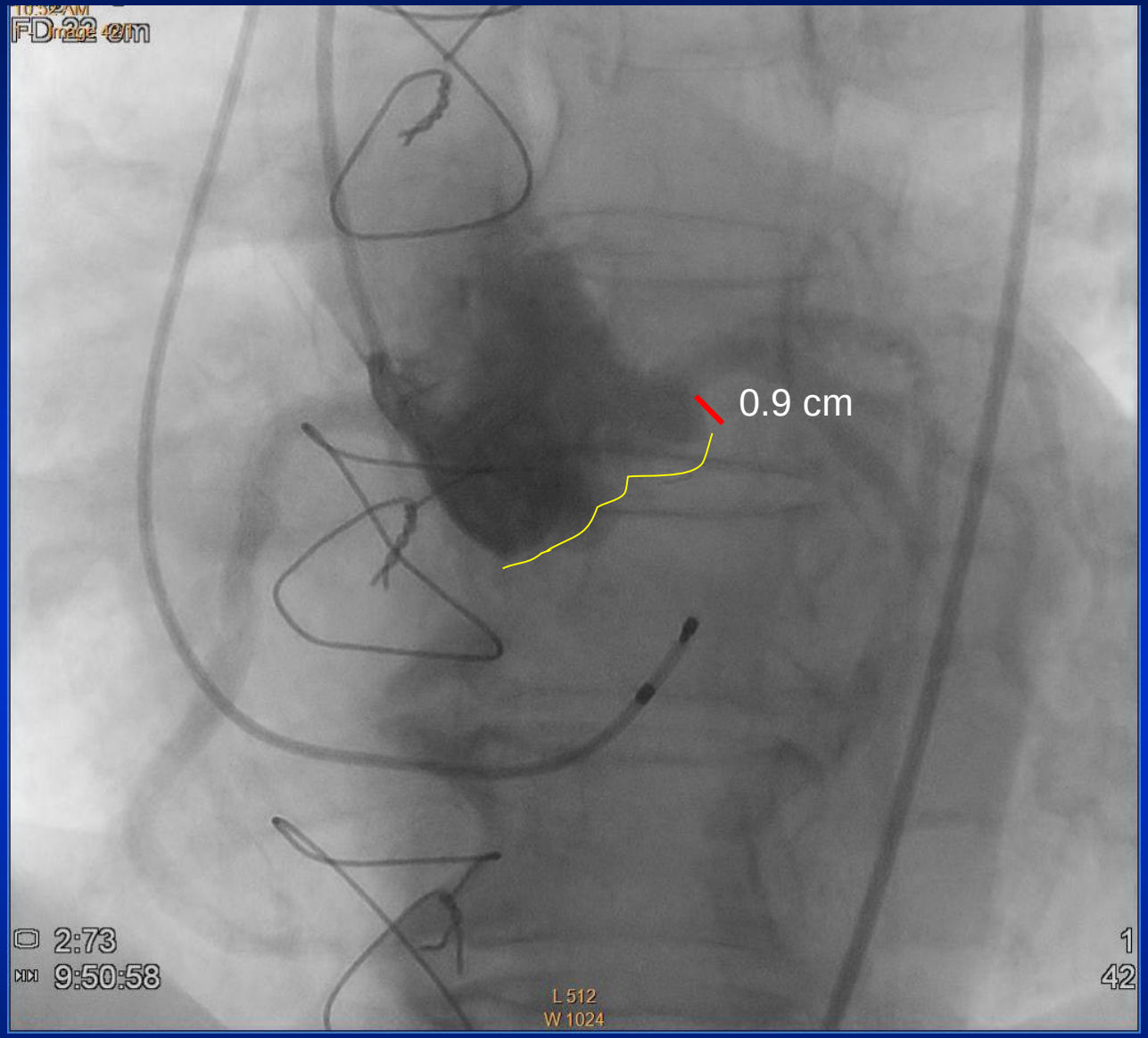

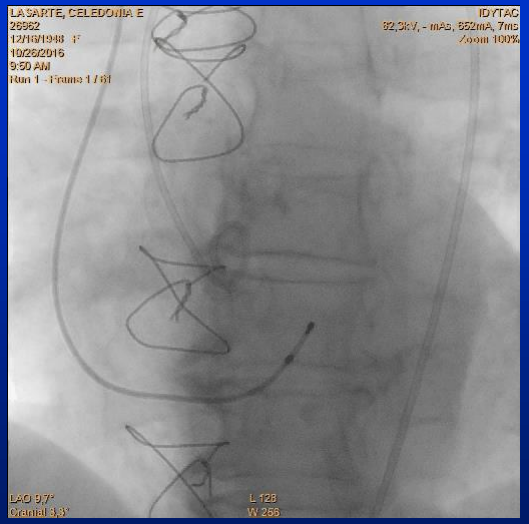

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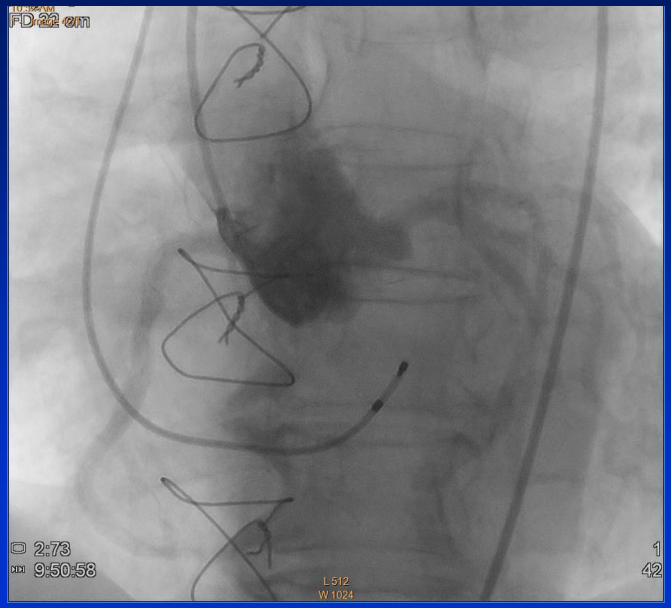

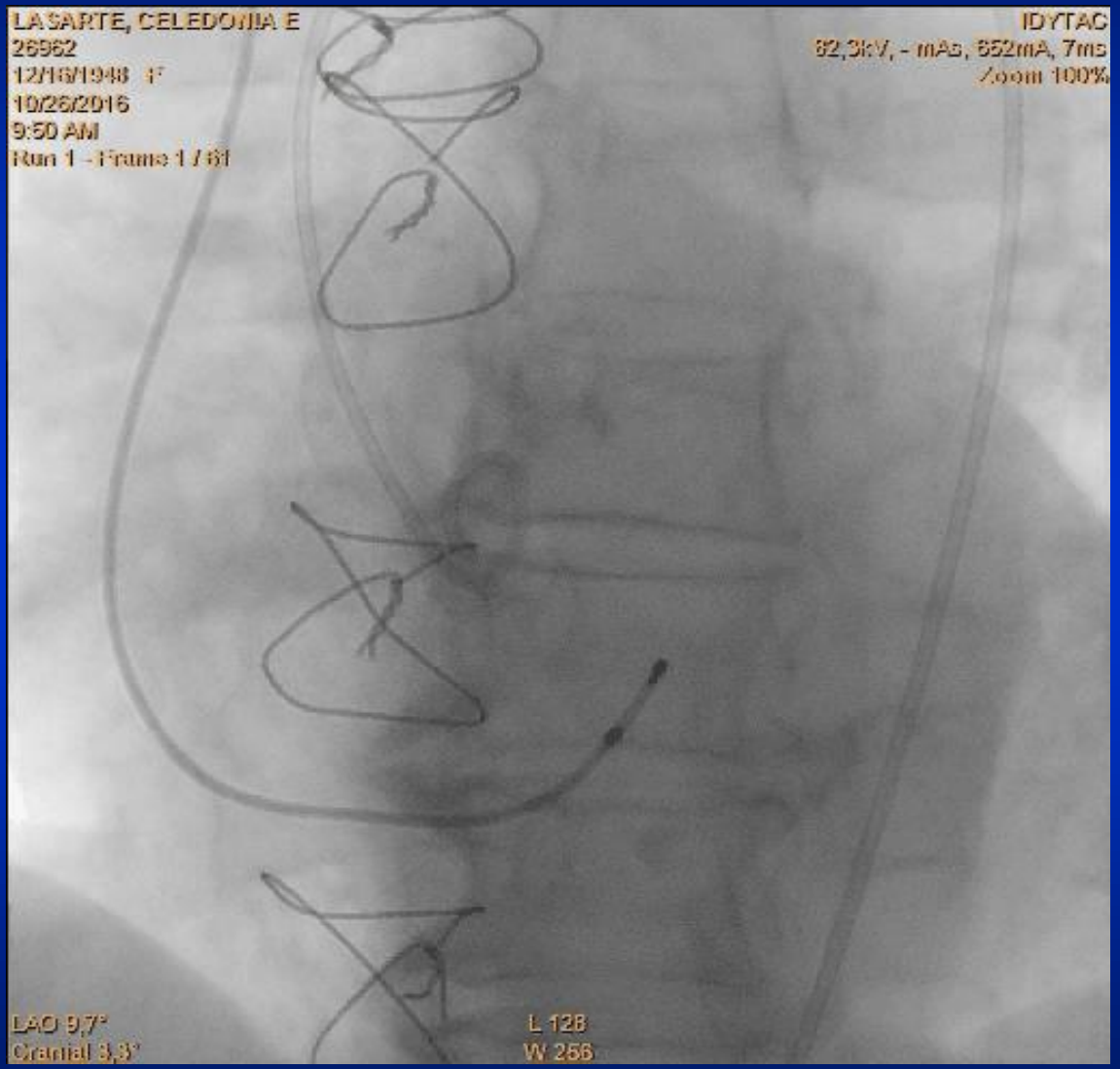

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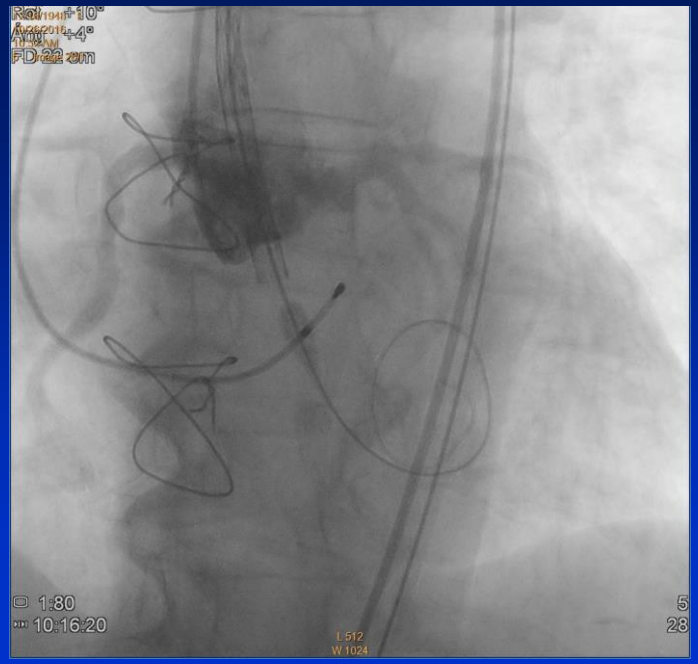

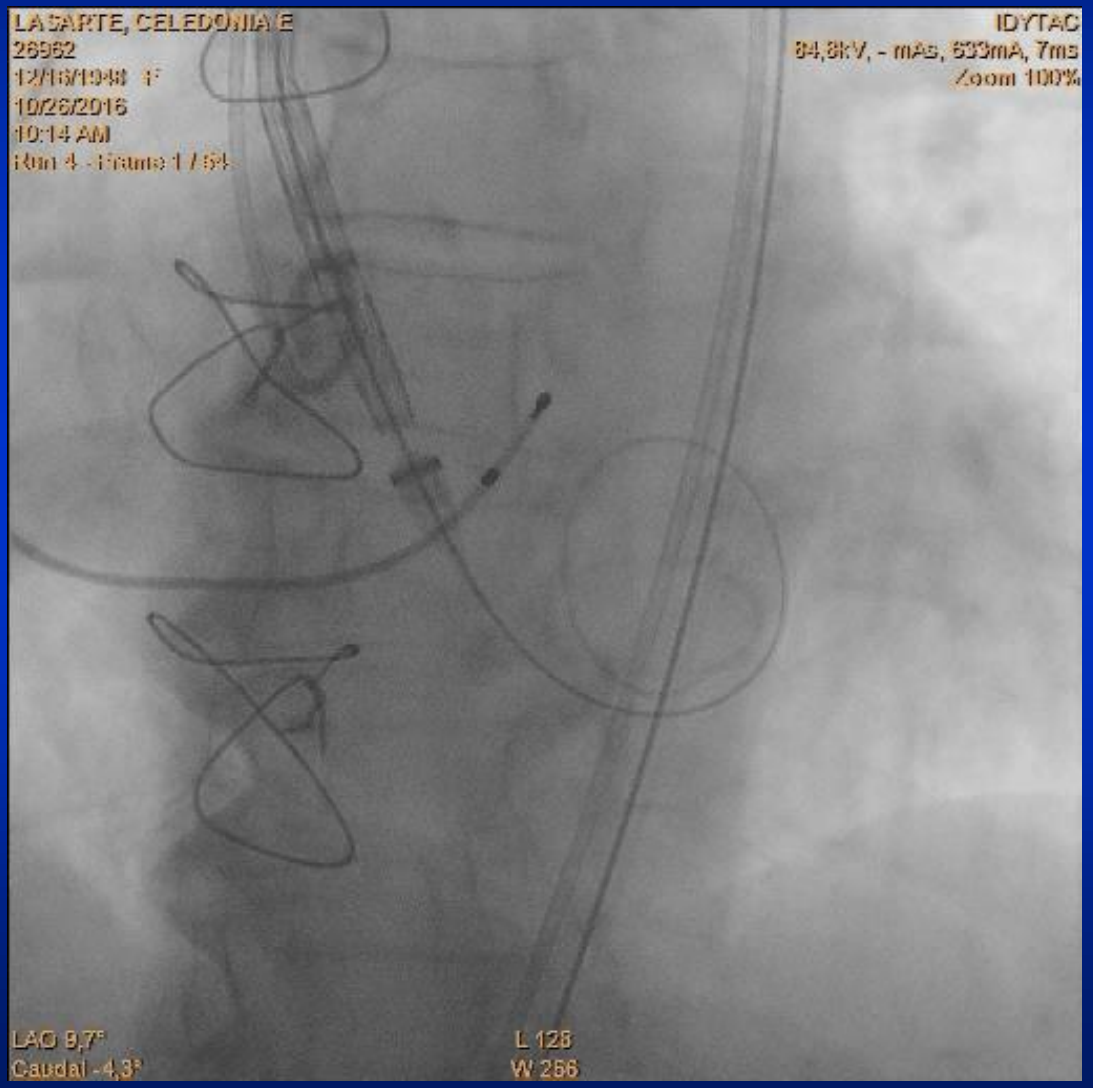

COREVALVE 23

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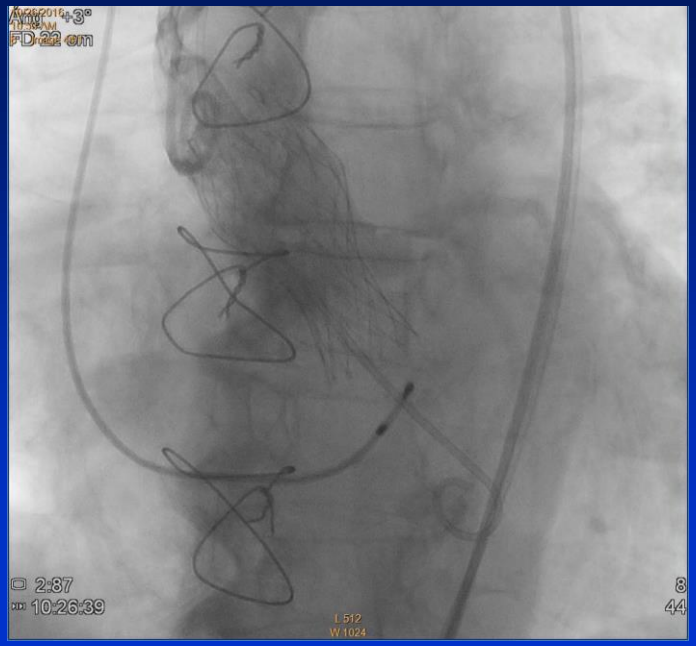
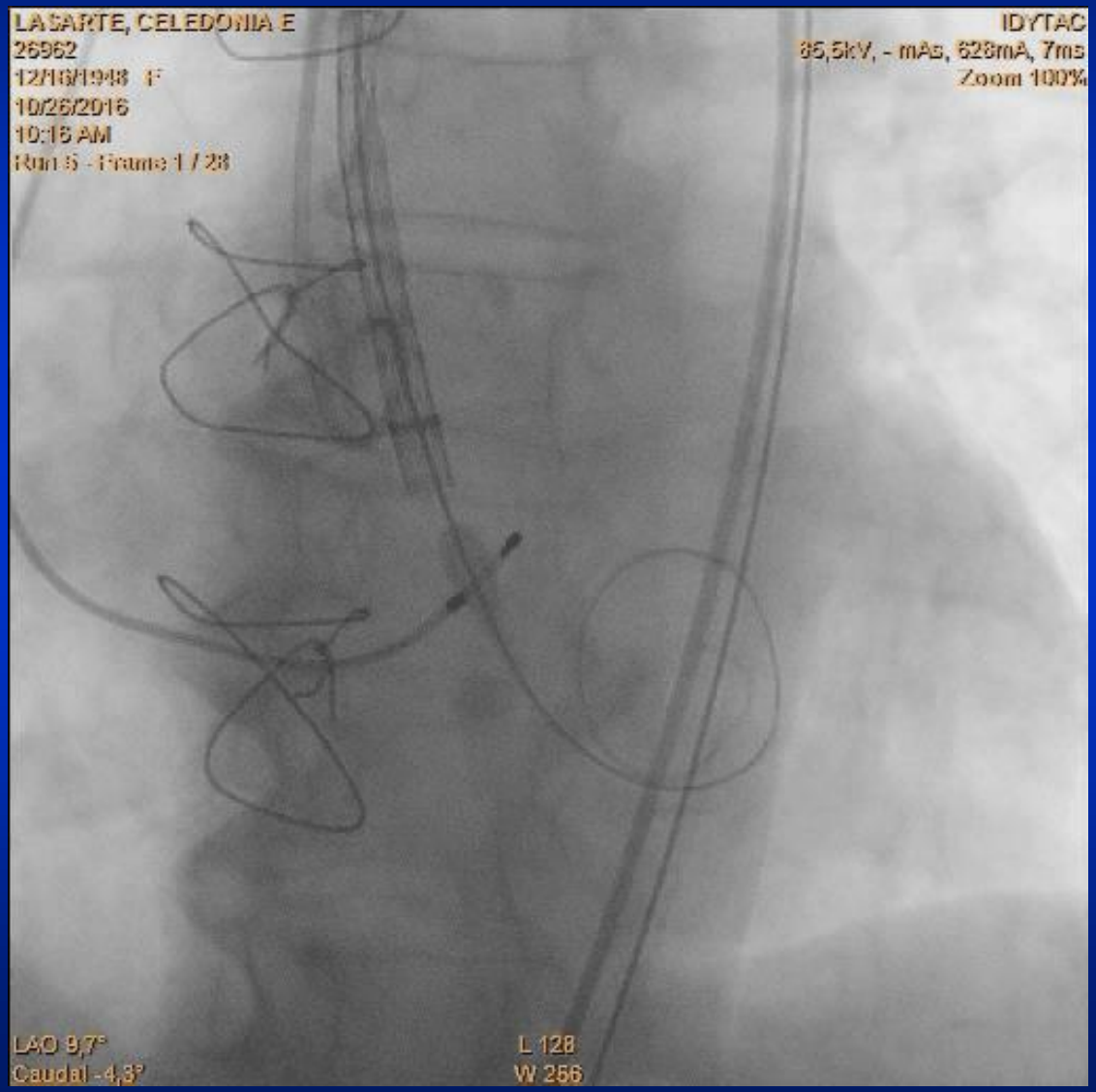


COREVALVE 23



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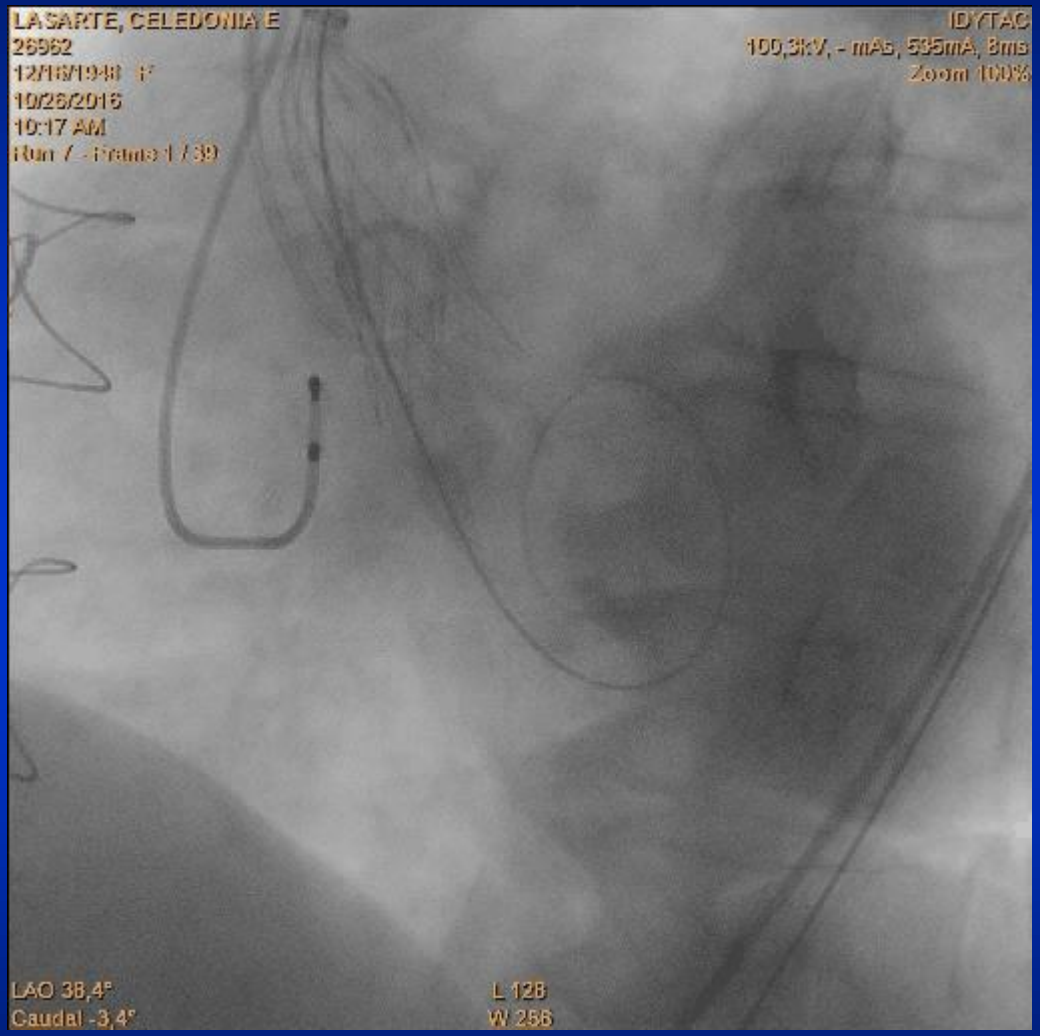
LASARTE, CELEDONIA E
26962
12/16/1948 F
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10:17 AM
Run 7 - Frame 1 / 39
IDYTAC
100,3kV, - mAs, 535mA, 8ms
Zoom 100%
LAO 38,4°
Caudal -3,4°
L 128
W 256

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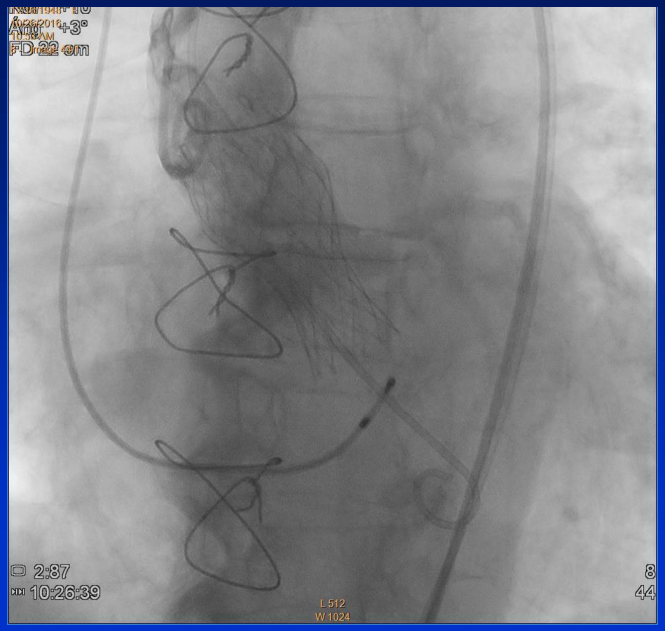
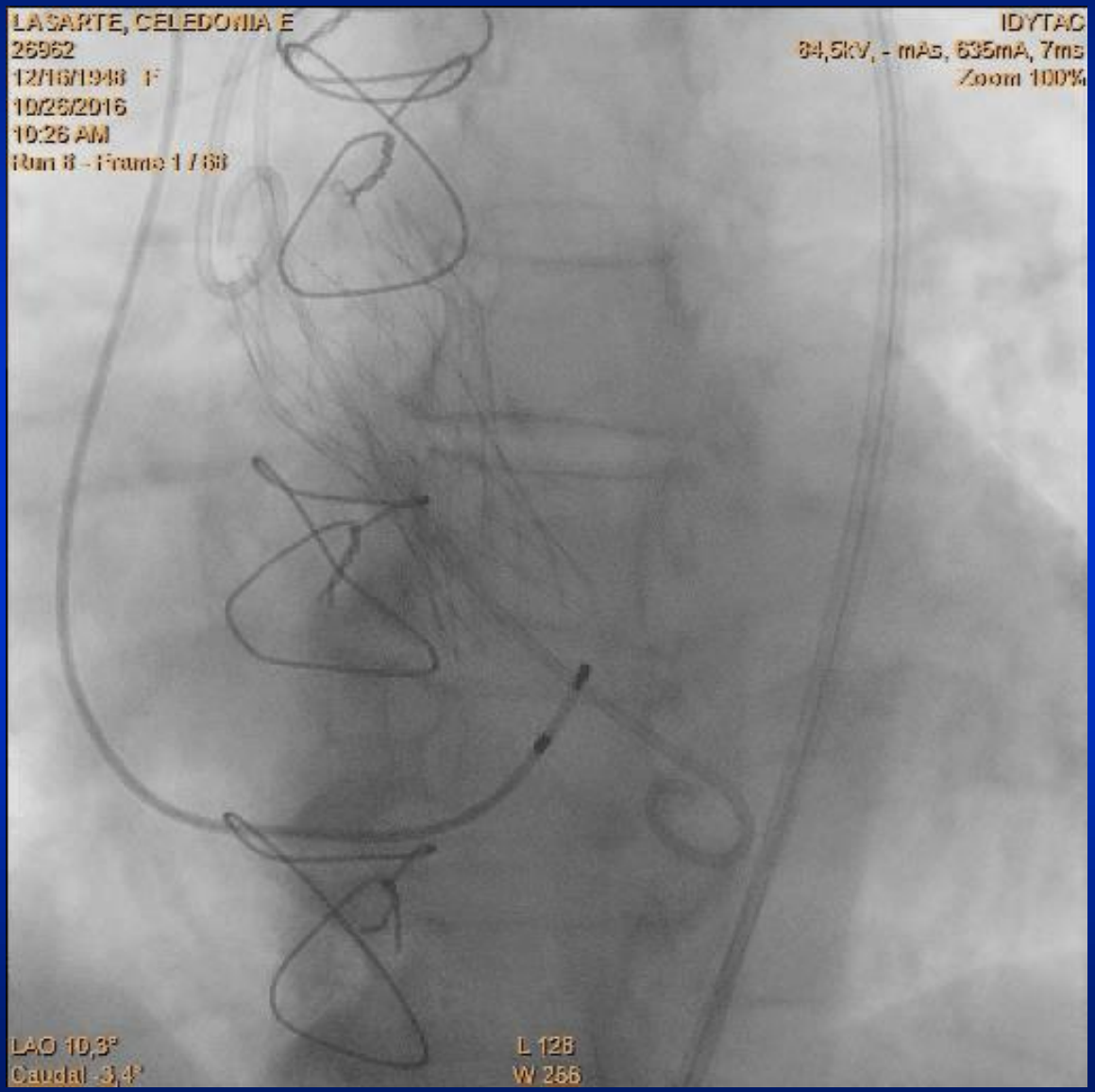


COREVALVE 23

Gradiente

TV Final de 12 mmHg



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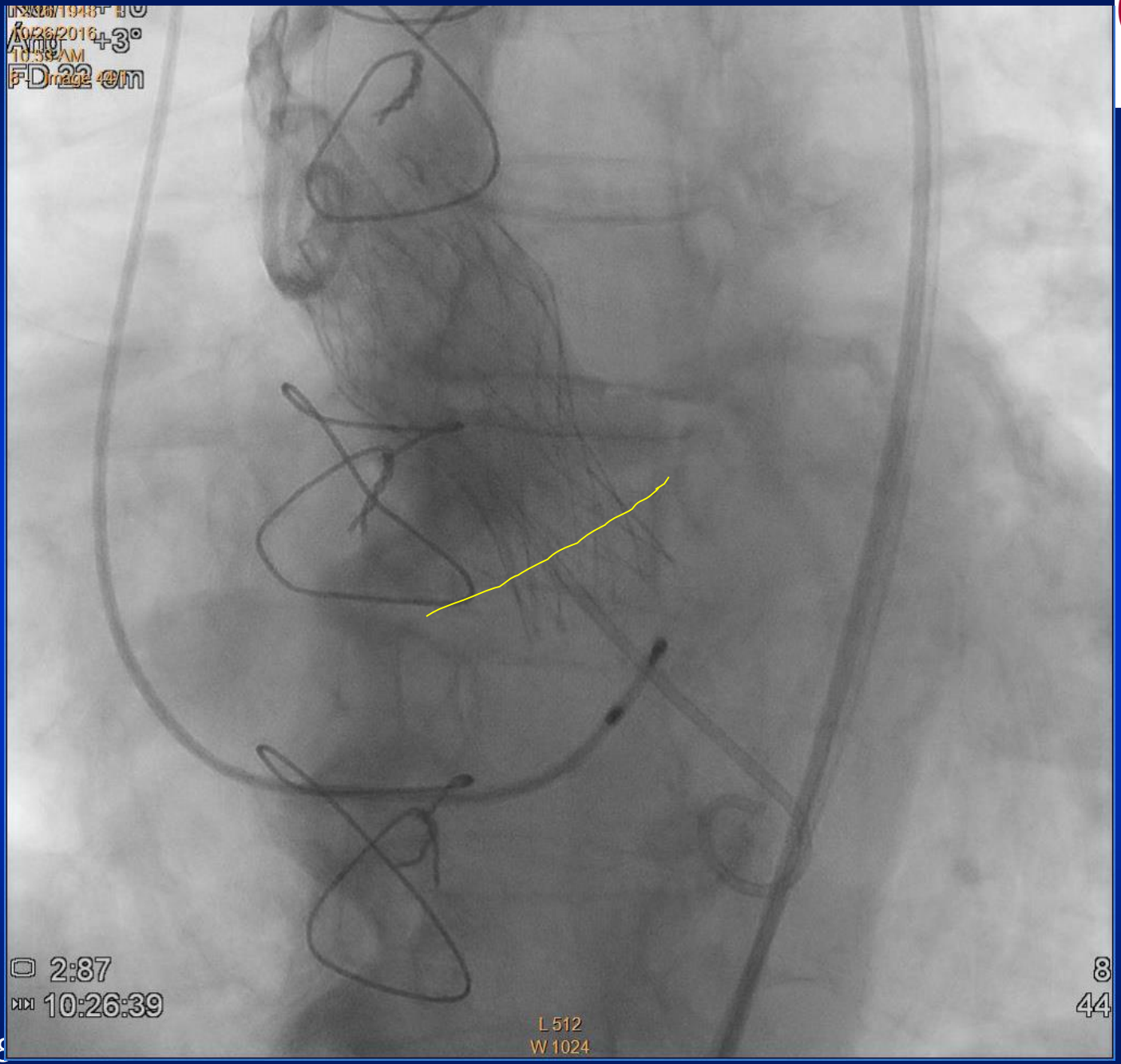

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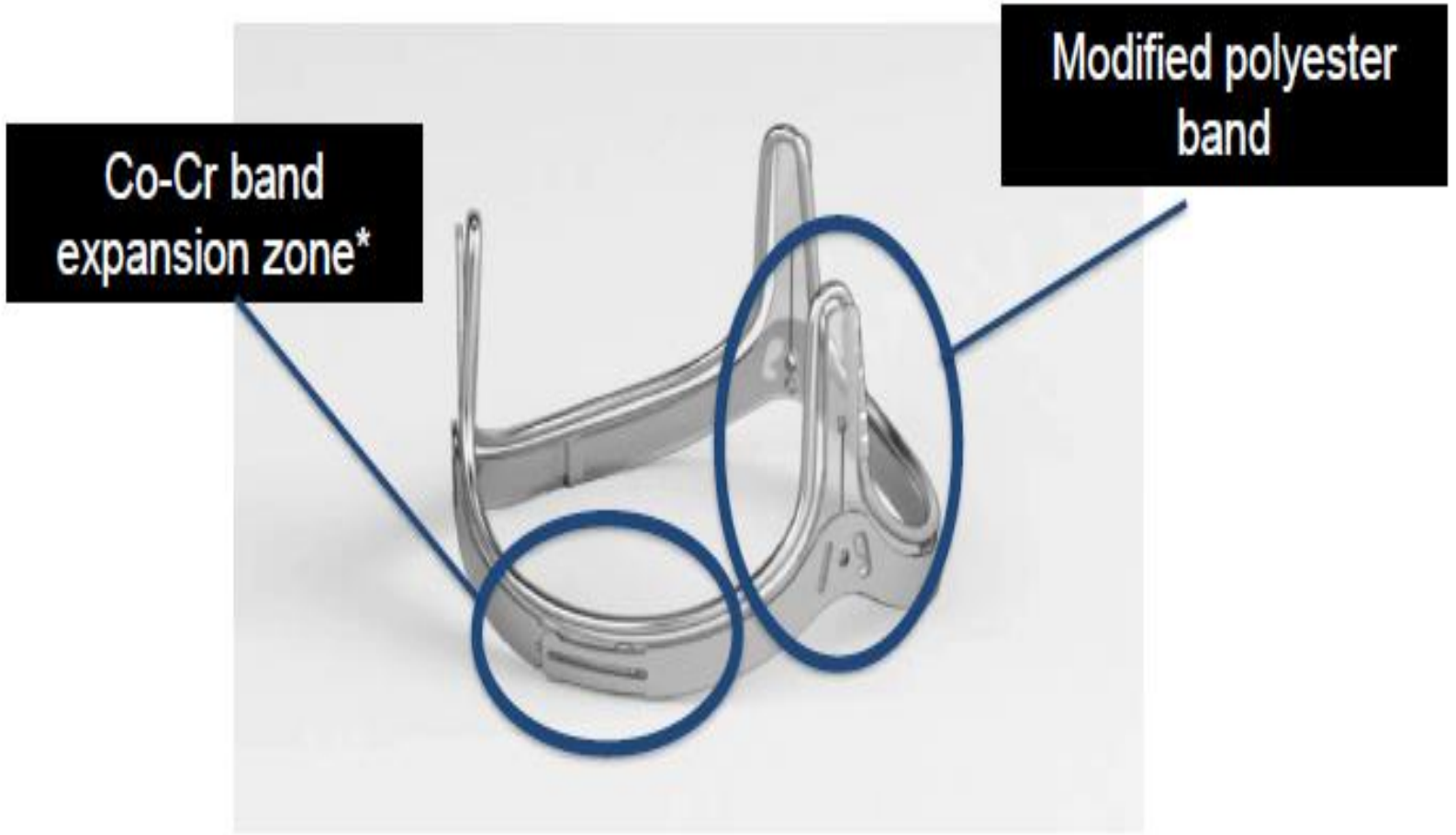

Disclaimer: The valve is an investigational device and not approved for sale in the US

Que hacer en casos complejos

- **Considerar anesteisa general y ETE.**
- **Implantar la válvula siempre viendo los ostiums coronarios.**
- **Se puede proteger el TCI con una cuerda y posicionar un stent para implantar en caso de oclusión coronaria aguda**

O

- **NO HACER EL CASO**