

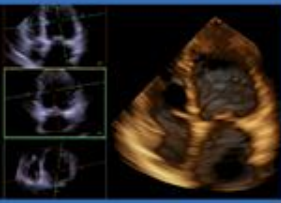
EuroValve  
April 26-27, 2018



# Aortic valve replacement: what's the future

Experience in aortic valve  
replacement with Trifecta  
bioprosthesis

[www.eurovalvecongress.com](http://www.eurovalvecongress.com)



# EuroValve

April 26-27, 2018



## Faculty disclosure

*Rafael Llorens MD, PhD, FECS  
Hospiten Rambla. S/C de Tenerife, Spain*

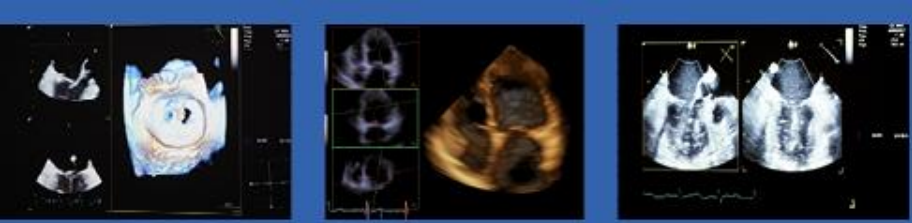
*José Albors MD  
Hospital del Vinalopó. Alicante, Spain*

*I disclose the following financial relationships:*

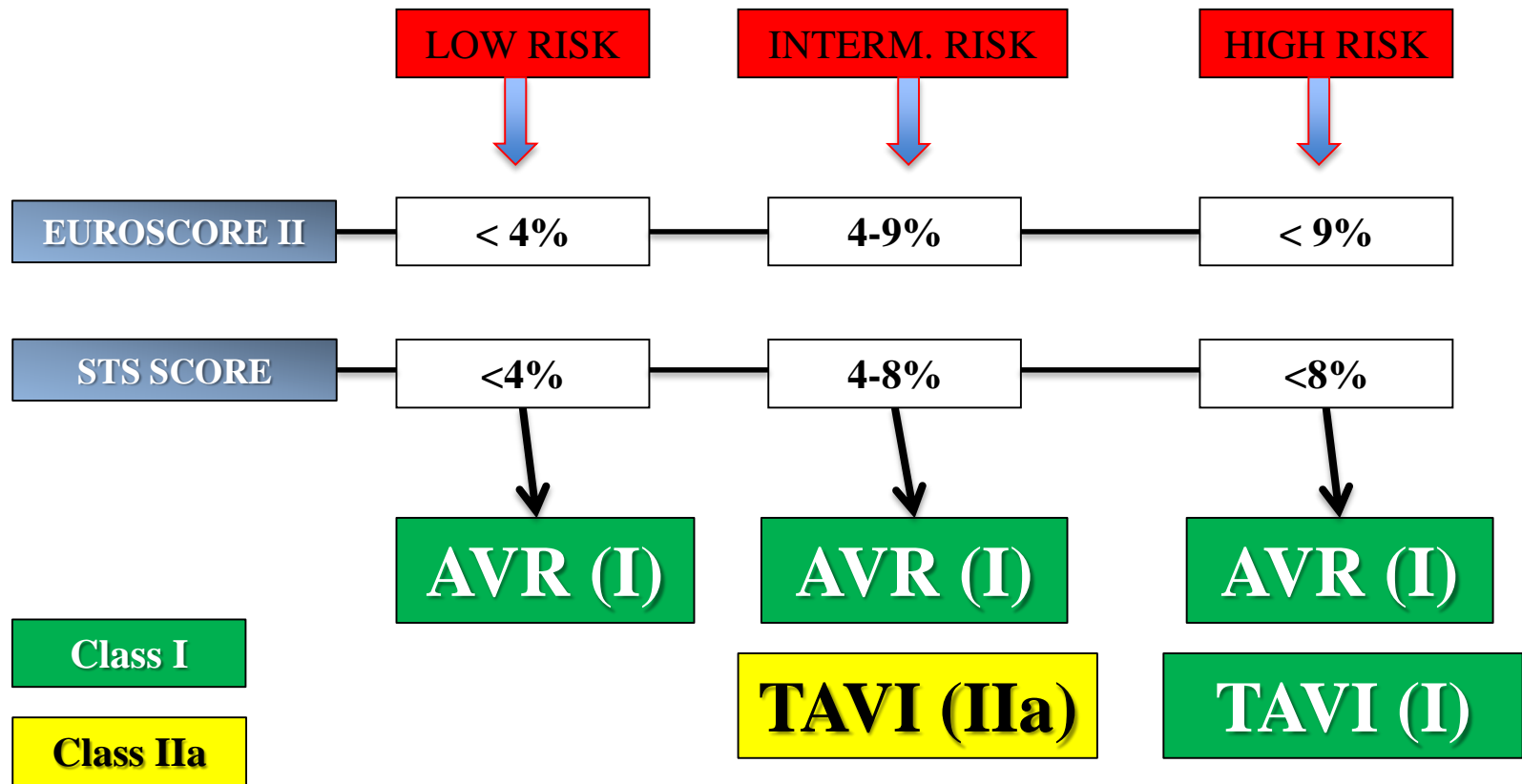
**No financial relationships** to disclose

Just a cardiac surgeon

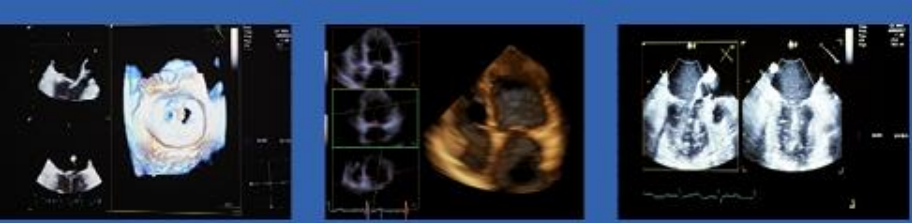
[www.eurovalvecongress.com](http://www.eurovalvecongress.com)



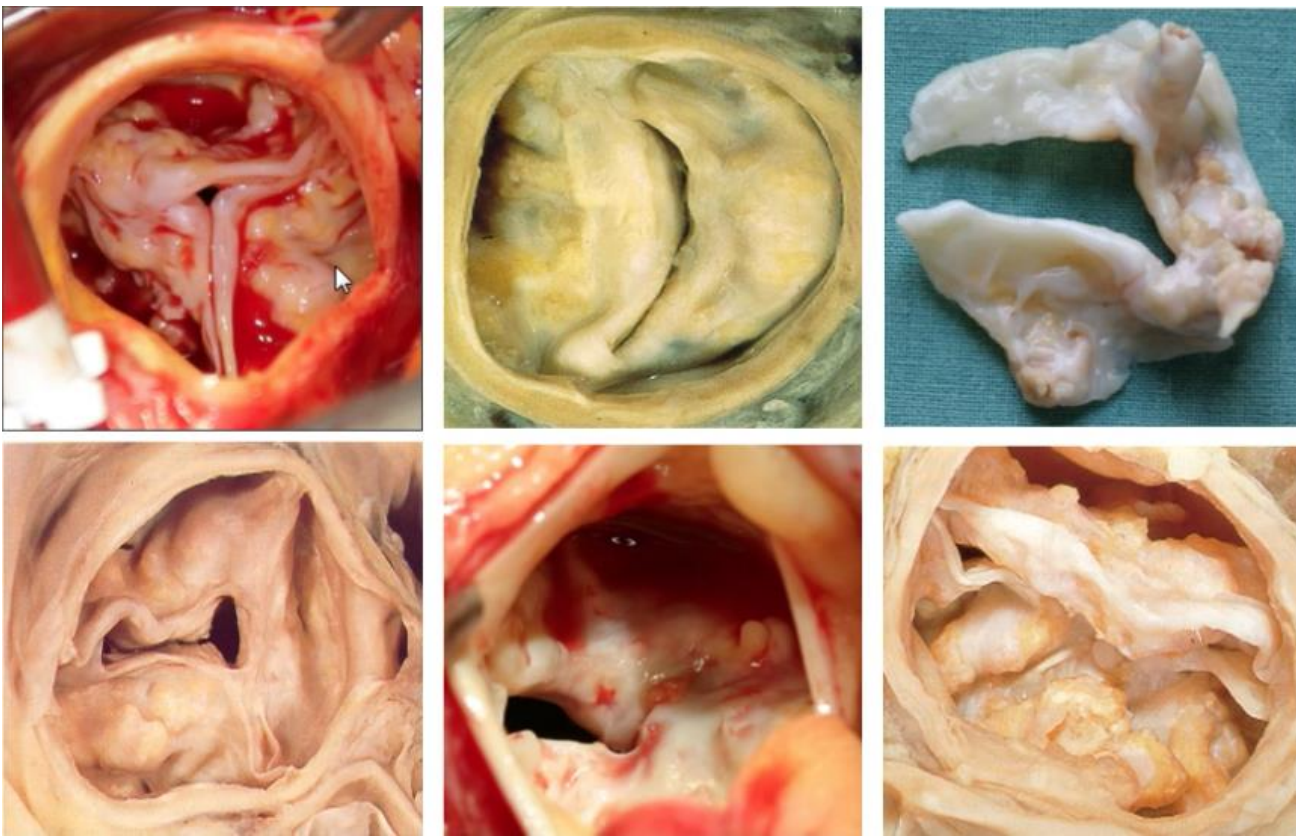
## 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

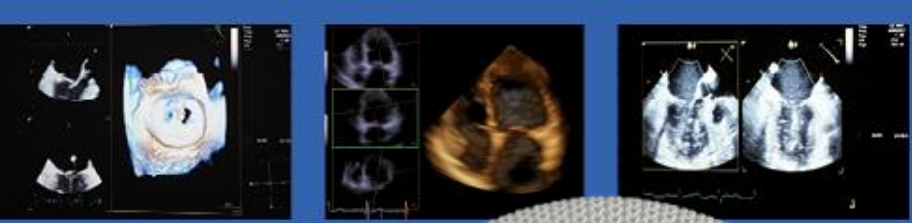


*Choice of TAVR Versus Surgical AVR in the Patient With Severe Symptomatic AS. Stage D*



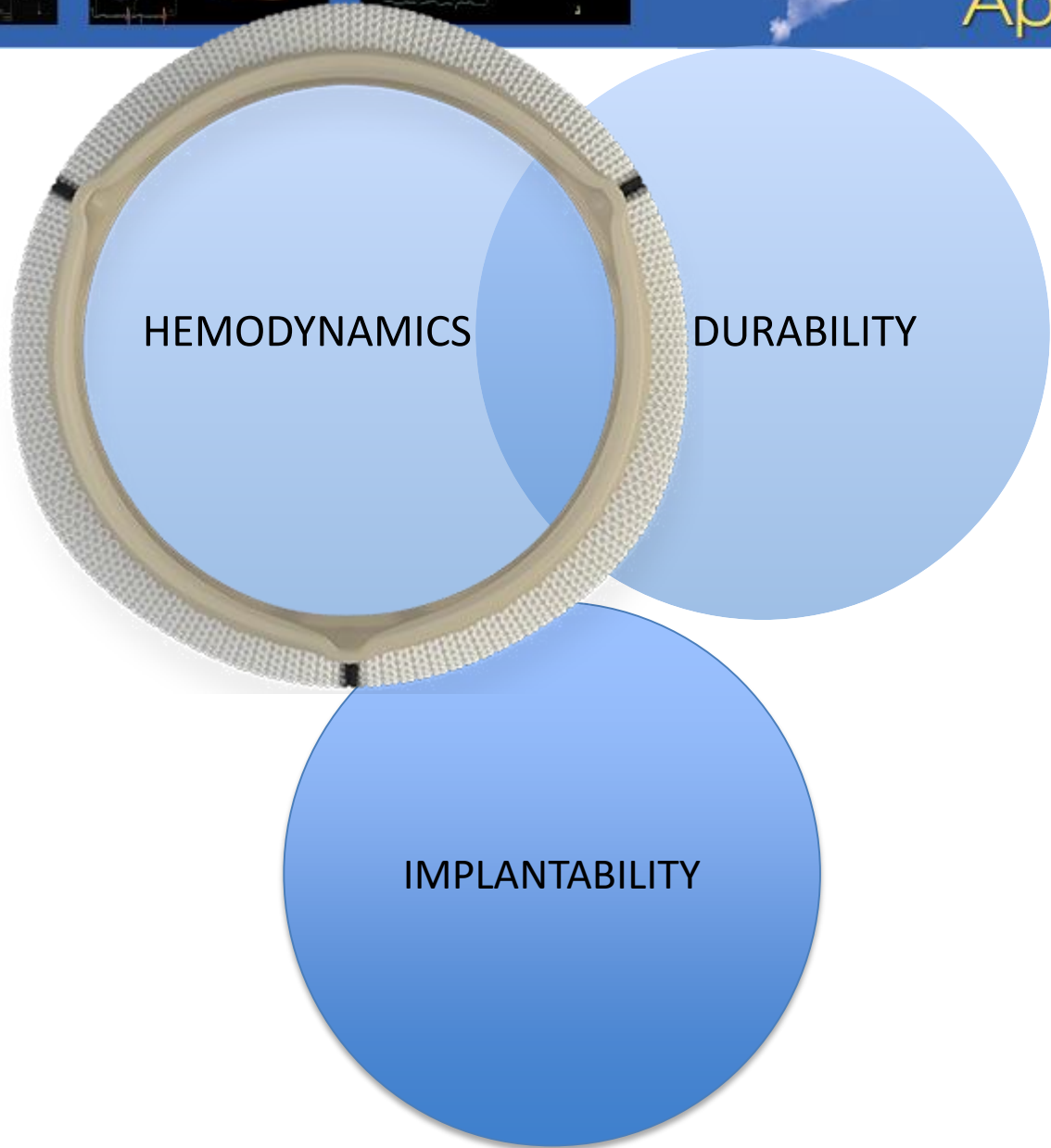
## Surgical AVR is still the gold standar for aortic valve stenosis





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Published Freedom from Reop. SVD



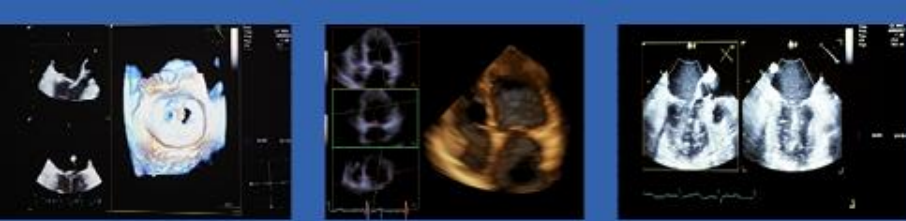
GERMANY<sup>18</sup>  
**97.9%** AT 5 YEARS



FRANCE<sup>19</sup>  
**98%** AT 5 YEARS



NORTH AMERICA<sup>17</sup>  
**97.3%** AT 6 YEARS



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European Heart Journal (2012) 33, 1518–1529  
doi:10.1093/eurheartj/ehs003

**CLINICAL RESEARCH**

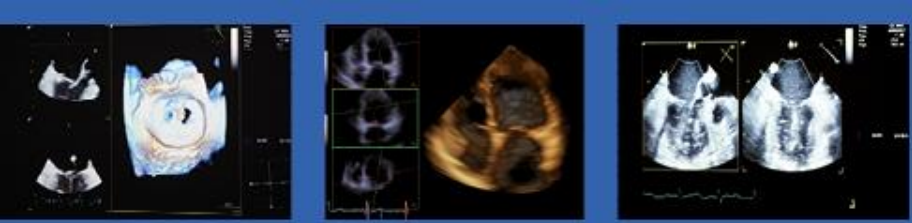
*Cardiac surgery*

## The impact of prosthesis–patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years

Stuart J. Head<sup>1\*</sup>, Mostafa M. Mokhles<sup>1</sup>, Ruben L.J. Osnabrugge<sup>1,2</sup>, Philippe Pibarot<sup>3</sup>, Michael J. Mack<sup>4</sup>, Johanna J.M. Takkenberg<sup>1</sup>, Ad J.J.C. Bogers<sup>1</sup>, and Arie Pieter Kappetein<sup>1</sup>

### Conclusions

- PPM is associated with an increase in all-cause mortality and cardiac-related mortality over long-term follow-up
- efforts to prevent PPM should receive more emphasis to improve long-term survival after AVR
- Patients suffering from mismatch after AVR are twice as likely to undergo reoperation for SVD than those without mismatch



## TARGETS OF THE DESIGN

### **Improvement of hemodynamic parameters**

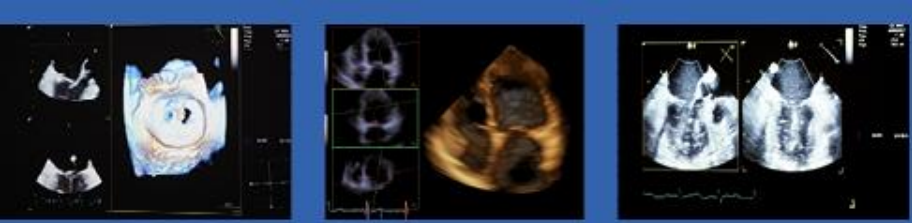
- Increasing orifice effective area, cylindric opening
- Titanium stent with intrinsic distensibility



### **Increasing the durability**

- Reducing the graze and the structural damage
- Minimize stress of leaflets.
- Reduce fibrosis and calcification, Linx™ anticalcification (AC) technology





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**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**  
**July 2010 – March 2018: 1606 Patients**

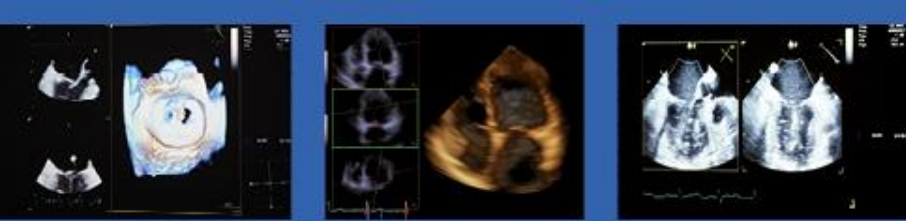
**TRIFECTA: July 2010 - Feb. 2016: 1118 patients**



**TRIFECTA GT: Feb. 2016 - March 2018: 488 patients**







**EuroValve**  
April 26-27, 2018

**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**

**July 2010 – March 2018: 1606 Patients**

**Age: 74,4 (39-91)**

**Gender. M: 962p (61.8%), F: 644p (38,2%)**

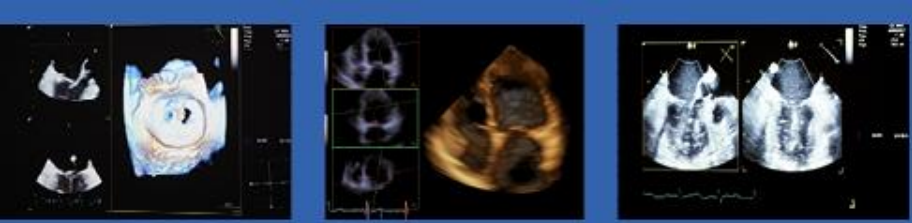
**Weight: 76,4 Kg (44-120)**

**Height: 1,60 m (1,42-1,95)**

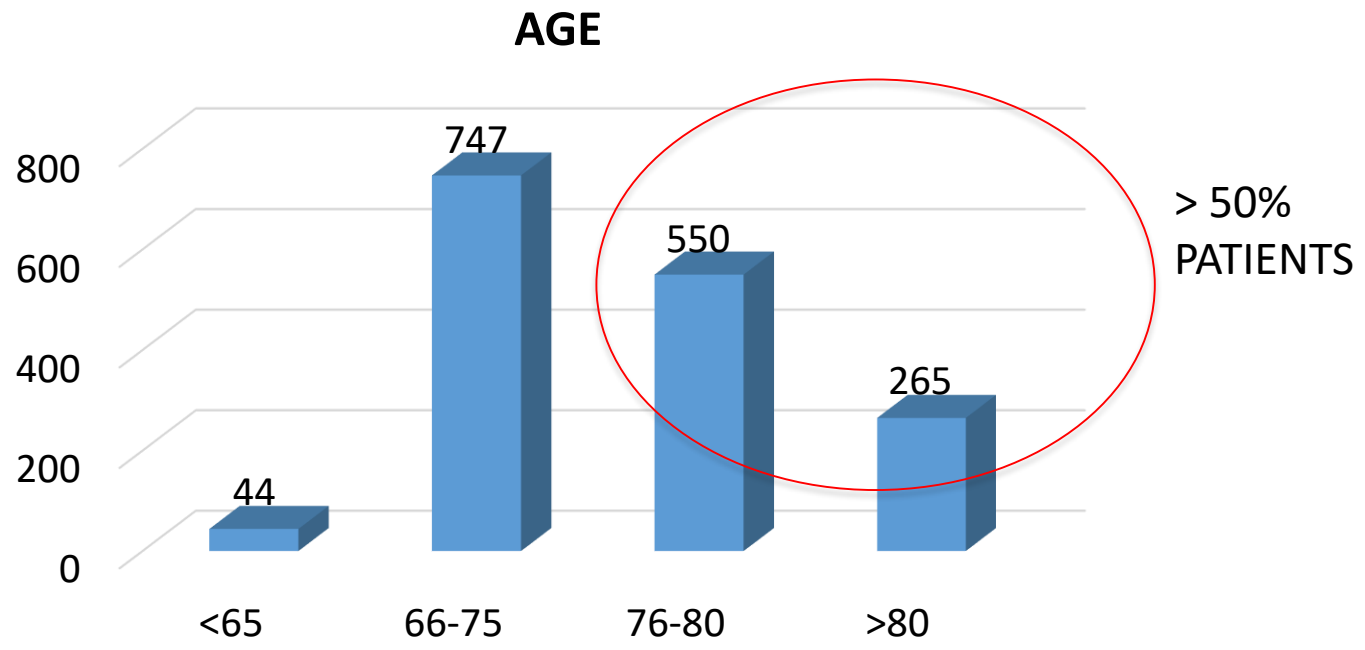
**BSA: 1,80 m<sup>2</sup> (1,29-2,43)**

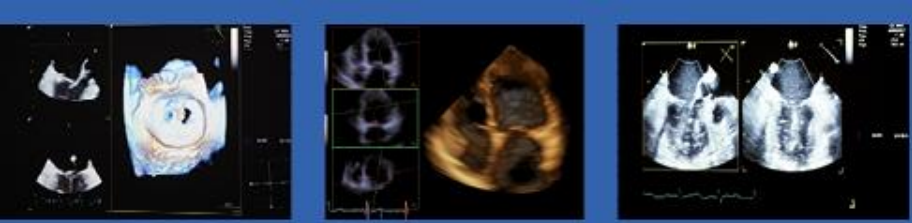
**BMI: 28,6 Kg/m<sup>2</sup> (18,1-58,1)**

**Euroscore II: 6,52% (0,5-59,6)**

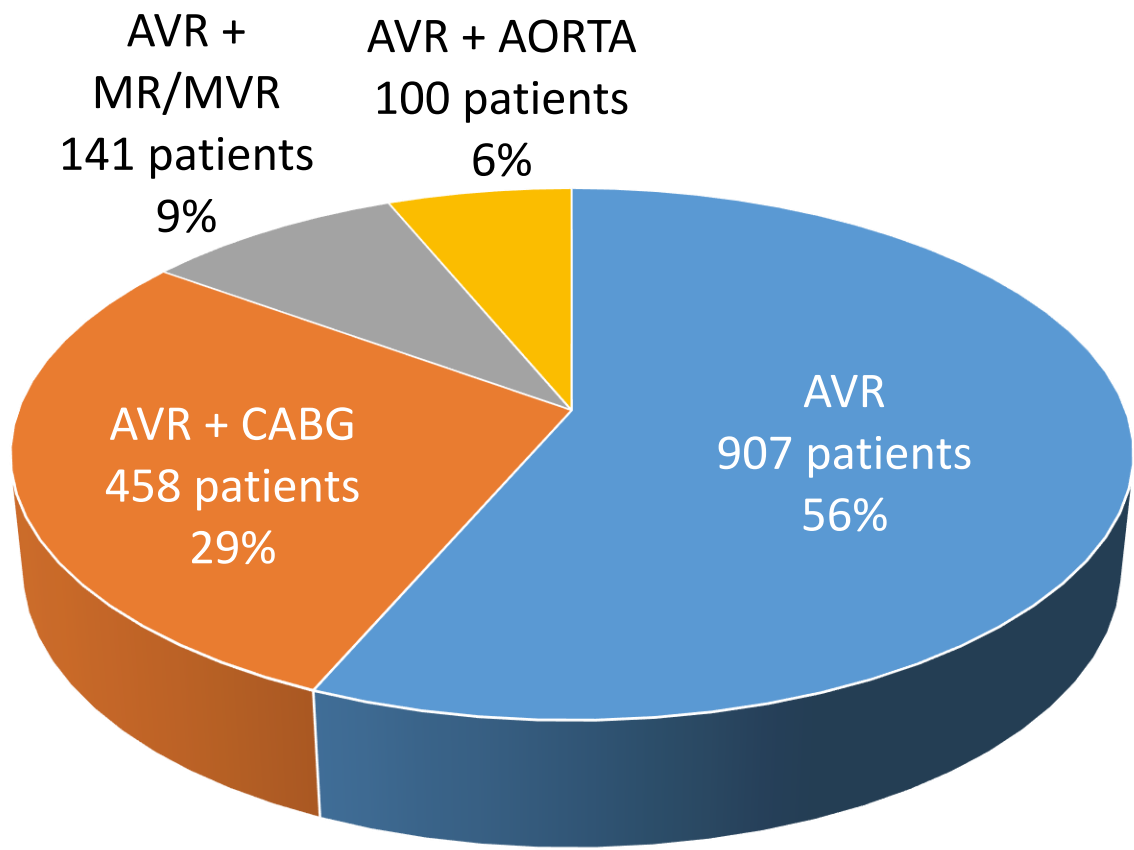


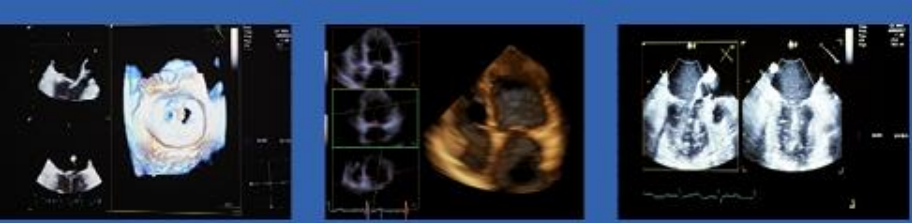
**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**  
**July 2010 – March 2018: 1606 Patients**





**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**  
**July 2010 – March 2018: 1606 Patients**



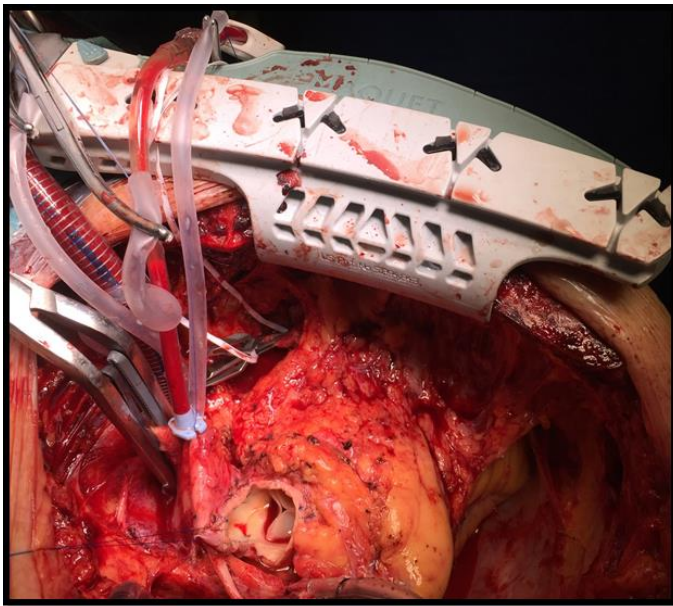


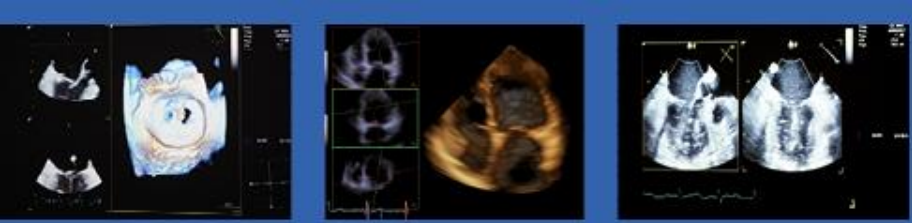
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**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**  
July 2010 – March 2018: 1606 Patients

**HIGH RISK GROUPS**

- **ENDOCARDITIS: 63 patients (4 %)**
- **REDO: 92 patients (5.7 %)**  
(including redoCABG patent grafts)

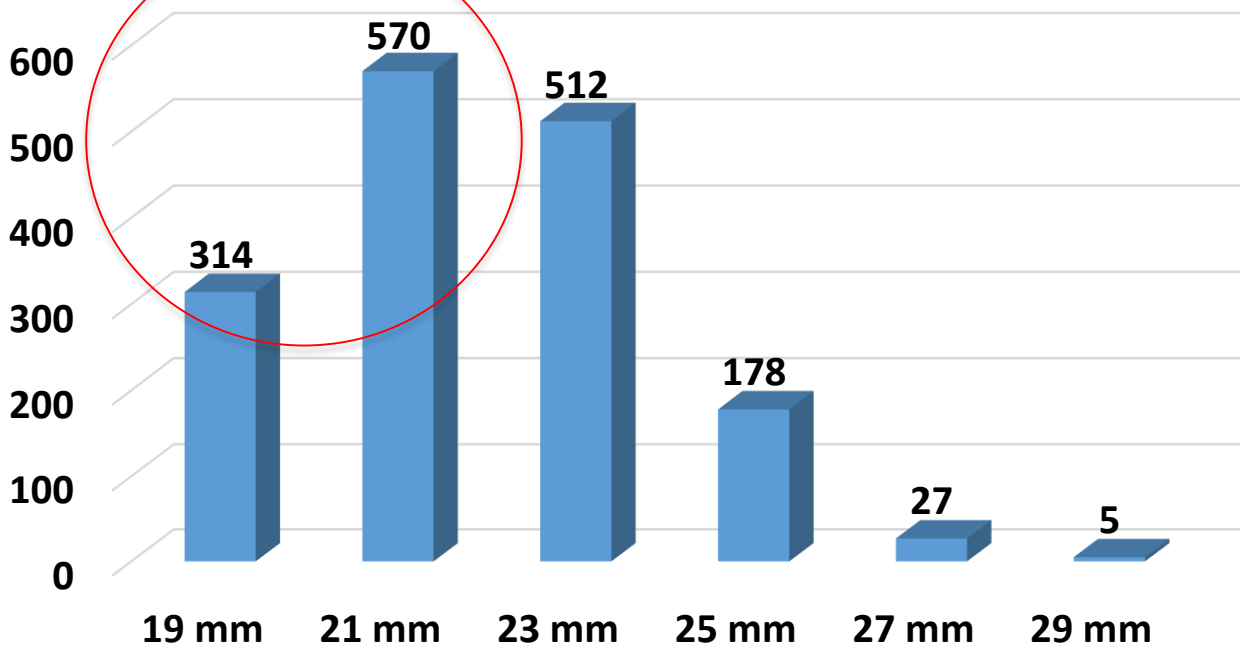


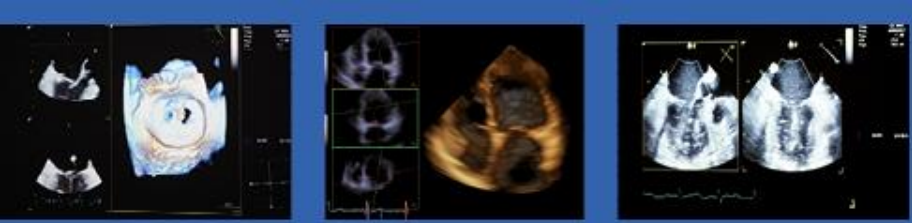


**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**  
**July 2010 – March 2018: 1606 Patients**

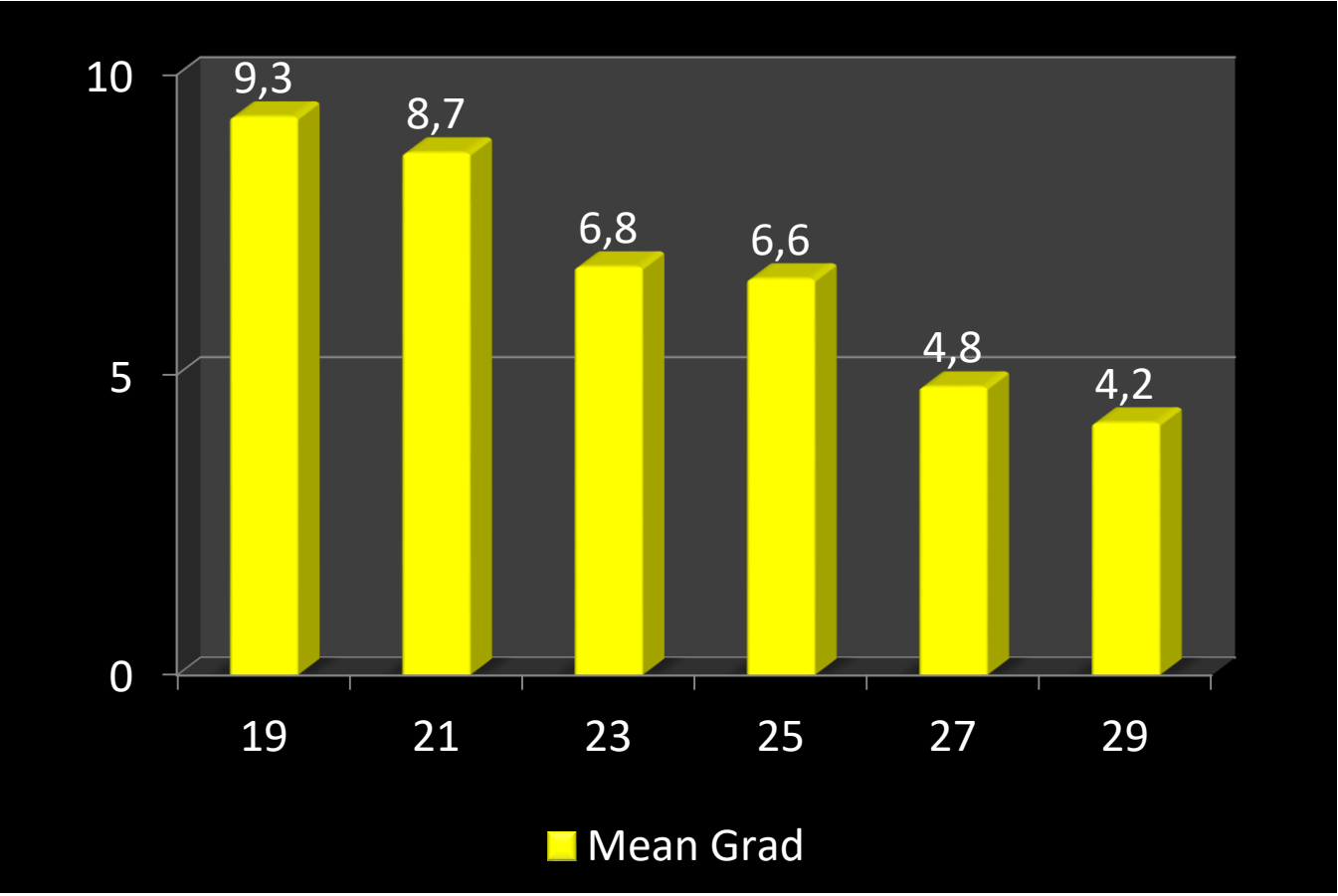
**Prostheses size**

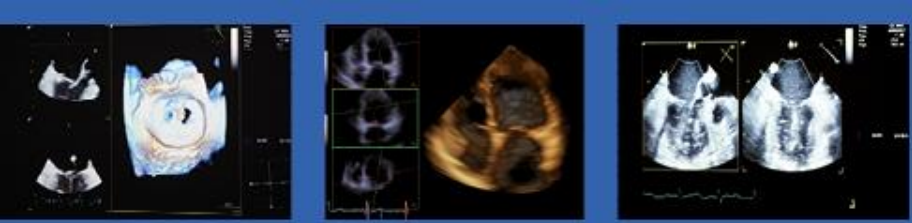
> 50%  
PATIENTS  
SMALL  
ANNULUS





**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**  
**July 2010 – March 2018: 1606 Patients**



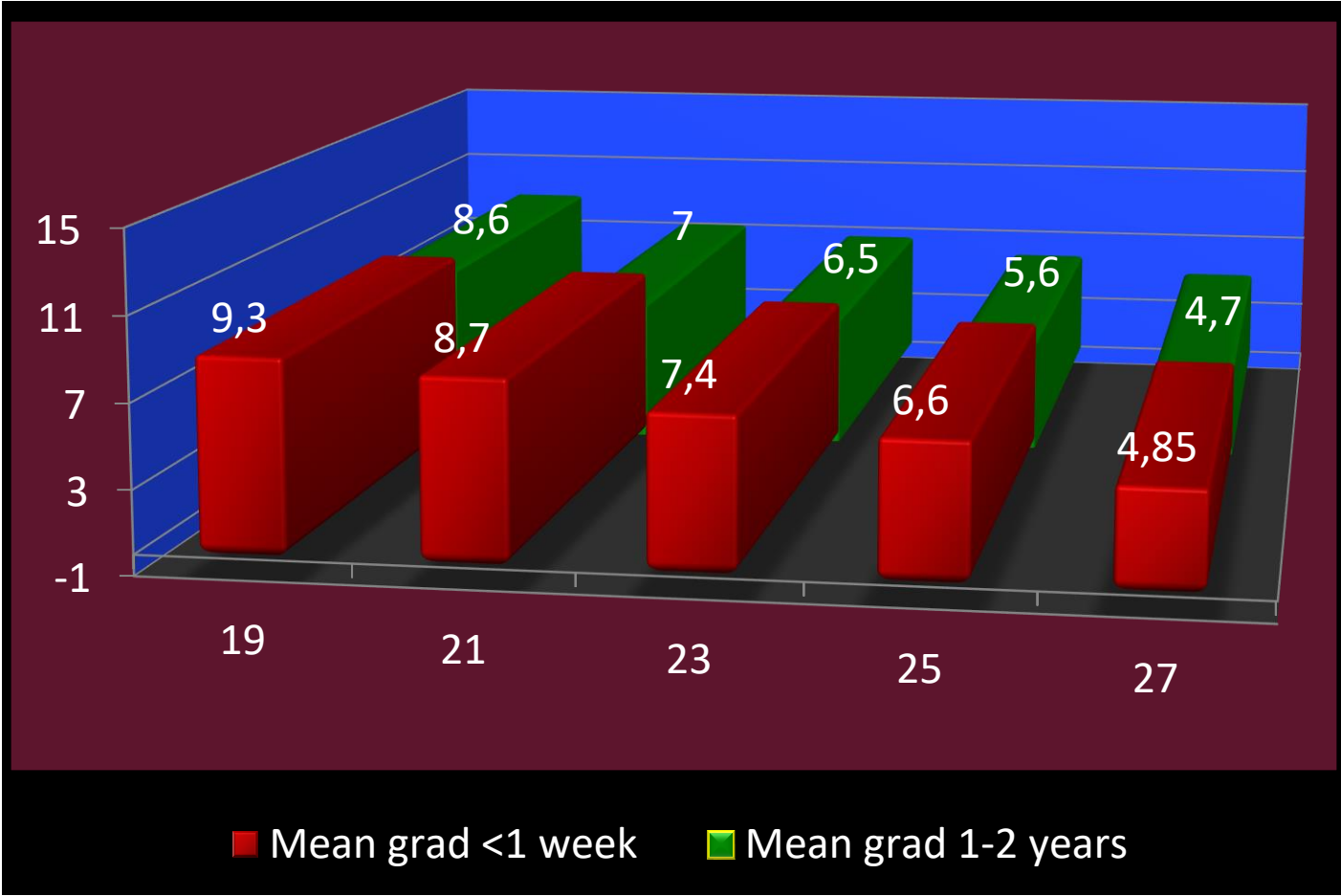


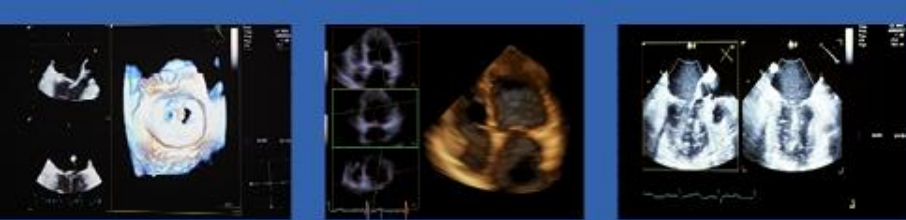
# EuroValve

April 26-27, 2018

## TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ

July 2010 – March 2018: 1606 Patients



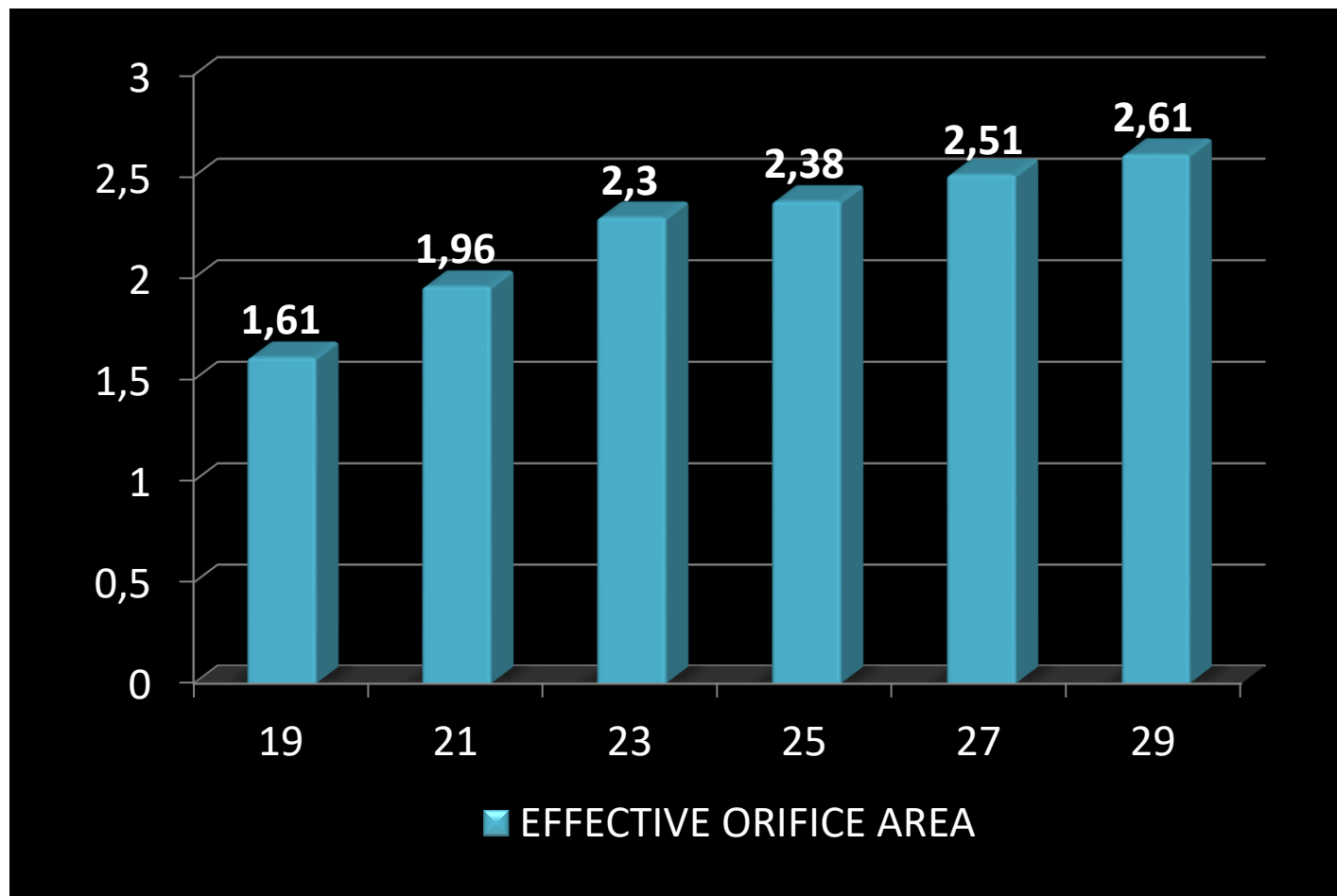


# EuroValve

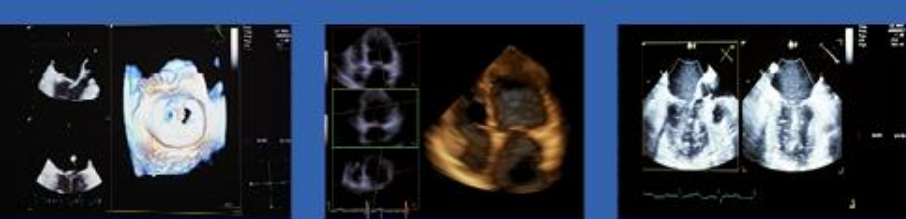
April 26-27, 2018

**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**

**July 2010 – March 2018: 1606 Patients**







# EuroValve

## April 26-27, 2018

### Effective Orifice Area Index (EOAI) Calculator

*In Vivo: Trifecta Valve EOA data*

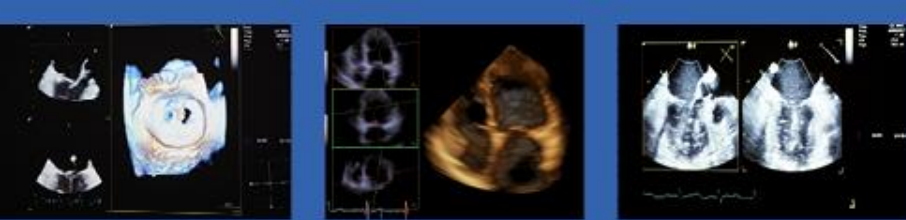
Valve Size (mm)	19 n = 60	21 n = 151	23 n = 190	25 n = 129	27 n = 38	29 n = 13
Average EOA <sup>1</sup> (cm <sup>2</sup> )	1.41	1.63	1.81	2.02	2.20	2.35
BSA (m <sup>2</sup> )						
0.6	2.35	2.72	3.02	3.37	3.67	3.92
0.7	2.01	2.33	2.59	2.89	3.14	3.36
0.8	1.76	2.04	2.26	2.53	2.75	2.94
0.9	1.57	1.81	2.01	2.24	2.44	2.61
1.0	1.41	1.63	1.81	2.02	2.20	2.35
1.1	1.28	1.48	1.65	1.84	2.00	2.14
1.2	1.18	1.36	1.51	1.68	1.83	1.96
1.3	1.08	1.25	1.39	1.55	1.69	1.81
1.4	1.01	1.16	1.29	1.44	1.57	1.68
1.5	0.94	1.09	1.21	1.35	1.47	1.57
1.6	0.88	1.02	1.13	1.26	1.38	1.47
1.7	0.83	0.96	1.06	1.19	1.29	1.38
1.8	0.78	0.91	1.01	1.12	1.22	1.31
1.9	0.74	0.86	0.95	1.06	1.16	1.24
2.0	0.71	0.82	0.91	1.01	1.10	1.18
2.1	0.67	0.78	0.86	0.96	1.05	1.12
2.2	0.64	0.74	0.82	0.92	1.00	1.07
2.3	0.61	0.71	0.79	0.88	0.96	1.02
2.4	0.59	0.68	0.75	0.84	0.92	0.98
2.5	0.56	0.65	0.72	0.81	0.88	0.94

EOAI<sup>2</sup> = EOA/BSA

EOAI > 0.85 cm<sup>2</sup>/m<sup>2.2</sup>

EOAI > 0.65 cm<sup>2</sup>/m<sup>2</sup> to EOAI ≤ 0.85 cm<sup>2</sup>/m<sup>2.2</sup>

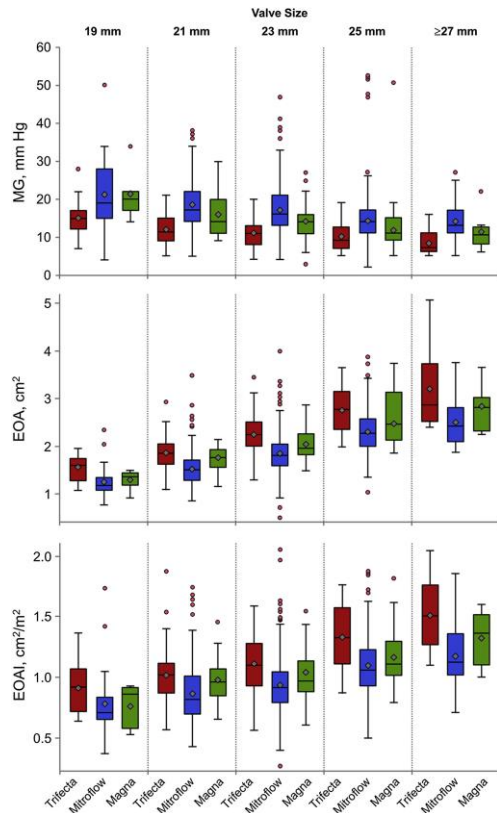
EOAI ≤ 0.65 cm<sup>2</sup>/m<sup>2.2</sup>



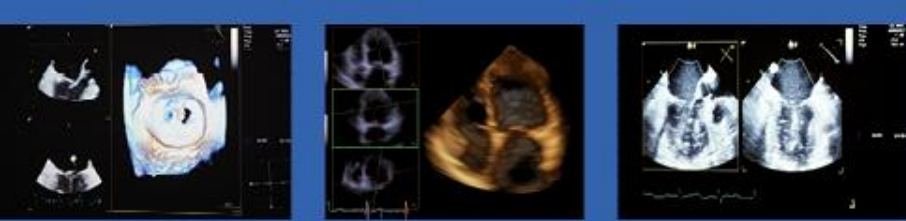
## Comparison of early hemodynamic performance of 3 aortic valve bioprostheses

Murat Ugur, MD, Rakesh M. Suri, MD, DPhil, Richard C. Daly, MD, Joseph A. Dearani, MD, Soon J. Park, MD, Lyle D. Joyce, MD, PhD, Harold M. Burkhart, MD, Kevin L. Greason, MD, and Hartzell V. Schaff, MD

*The Journal of Thoracic and Cardiovascular Surgery* Volume 148, Issue 5, Pages 1940-1946 (November 2014)



	Trifecta	Mitroflow	Magna	P value
Mean gradient (mmHg)	11.4	16.9	14.1	< 0.001
EOA (cm <sup>2</sup> )	2.22	1.85	2.09	< 0.001
iEOA (cm <sup>2</sup> /m <sup>2</sup> )	1.14	0.96	1.07	< 0.001



## Management of small aortic annulus in the era of sutureless valves: A comparative study among different biological options



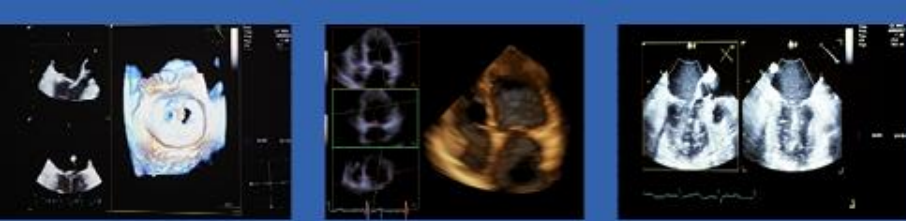
Aly Ghoneim, MD, Ismail Bouhout, MD, MSc, Philippe Demers, MD, MSc, Amine Mazine, MD, MSc, Mary Francispillai, MD, Ismail El-Hamamsy, MD, PhD, Michel Carrier, MD, MBA, Yoan Lamarche, MD, MSc, and Denis Bouchard, MD, PhD

J Thorac Cardiovasc Surg. 2016 Oct;152(4):1019-28

	Trifecta	Mitroflow	Perceval (sutureless)	P value
Mean gradient (mmHg)	10.3	19.4	17.3	< 0.001
EOA (cm <sup>2</sup> )	1.62	1.22	1.26	< 0.001
iEOA (cm <sup>2</sup> /m <sup>2</sup> )	1.00	0.74	0.79	< 0.001

*Results:* The Trifecta bioprostheses displayed the lowest mean aortic gradient compared with other stented prosthesis (7.1 mm Hg) and no severe prosthesis-patient mismatch.

*Conclusions:* In our study, stentless AVR and Trifecta bioprostheses had the best hemodynamic outcomes.

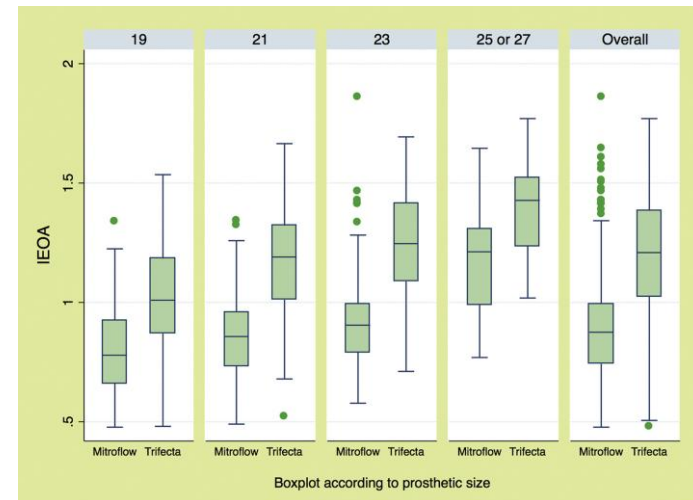
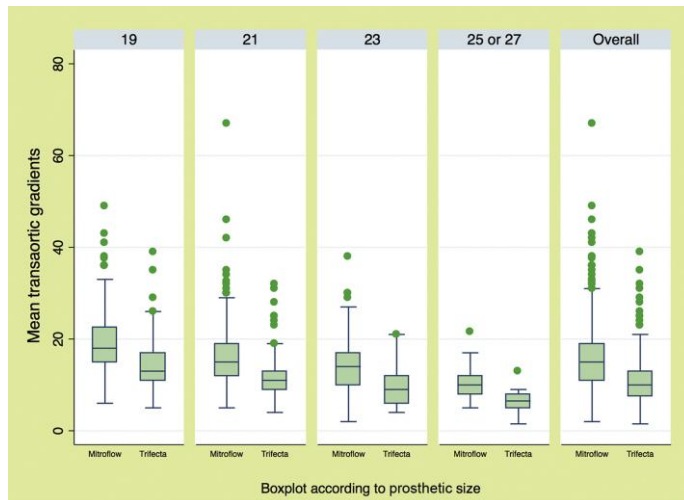


## The Prevalence of Patient-Prosthesis Mismatch Can Be Reduced Using the Trifecta Aortic Prosthesis

Daniel Hernandez-Vaquero, MD, PhD, Rocio Diaz, MD, Isaac Pascual, MD, PhD, Jose Rozado, MD, Jesus M. De la Hera, MD, PhD, Victor Leon, MD, PhD, Pablo Avanzas, MD, PhD, Maria Martín, MD, PhD, Daniel García-Iglesias, MD, David Calvo, MD, PhD, Jacobo Silva, MD, PhD, and César Moris, MD, PhD

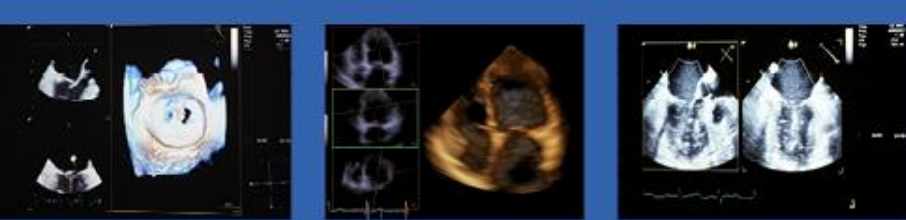
Heart Area, Central University Hospital of Asturias, Oviedo; and Department of Medicine, University of Oviedo, Spain

*The Annals of Thoracic Surgery* Volume 105, Issue 1, Pages 144-151



**Results.** Any degree of mismatch was present in 5.9% of the Trifecta group and in 42.4% in the Mitroflow group

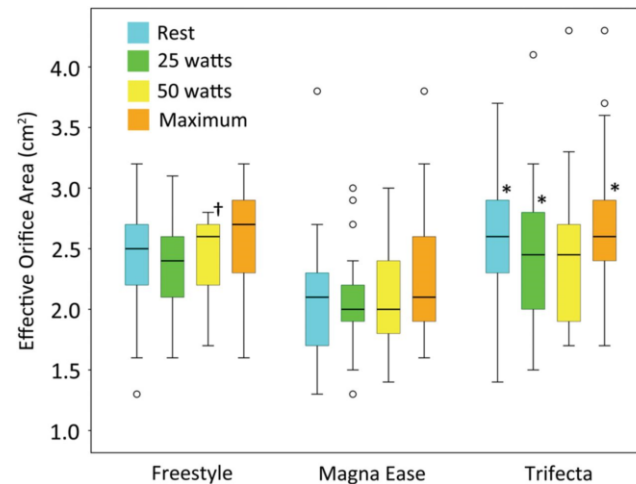
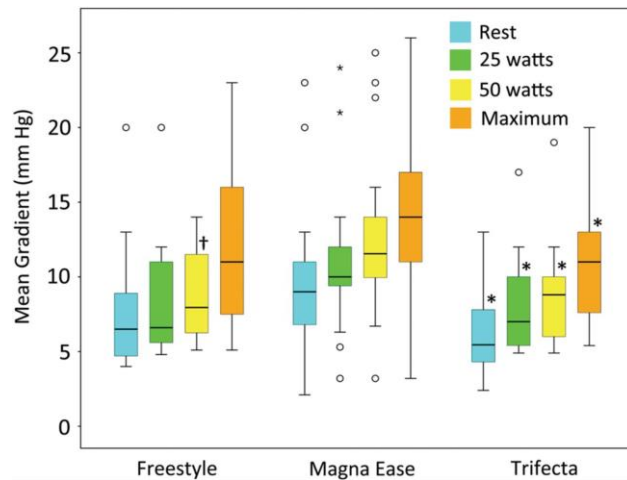
**Conclusions.** The prevalence of patient-prosthesis mismatch using the Trifecta aortic prosthesis is extraordinary low.



## Randomized comparison of exercise haemodynamics of Freestyle, Magna Ease and Trifecta bioprostheses after aortic valve replacement for severe aortic stenosis<sup>†</sup>

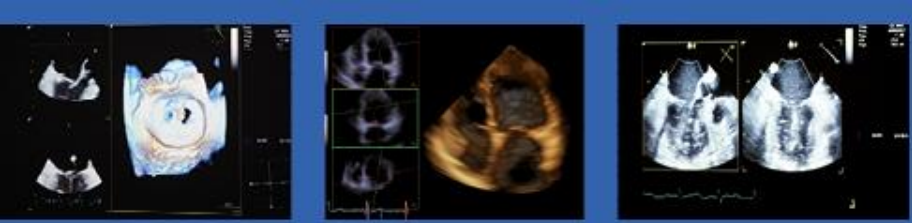
David S. Bach<sup>a,\*</sup>, Himanshu J. Patel<sup>b</sup>, Theodore J. Kolias<sup>a</sup> and G. Michael Deeb<sup>b</sup>

European Journal of Cardio-Thoracic Surgery, Volume 50, Issue 2, 1 August 2016, Pages 361–367



**RESULTS.** Trifecta had better haemodynamics compared with Magna Ease. With exercise, significant differences between groups were evident in peak velocity at 50 watts and peak exercise; mean gradient at 25 watts, 50 watts and maximal exercise; and EOA at 25 watts and at peak exercise; all with haemodynamic superiority of Trifecta compared with Magna Ease.

**CONCLUSIONS.** There were small but significant differences between groups, with favourable haemodynamics associated with Trifecta compared to Magna Ease, and no significant differences between Trifecta and Freestyle. The Trifecta valve appears to offer haemodynamics similar to a stentless valve without the technical complexity of stentless valve implantation.



# EXCELLENT HEMODYNAMICS

Measure size appropriately

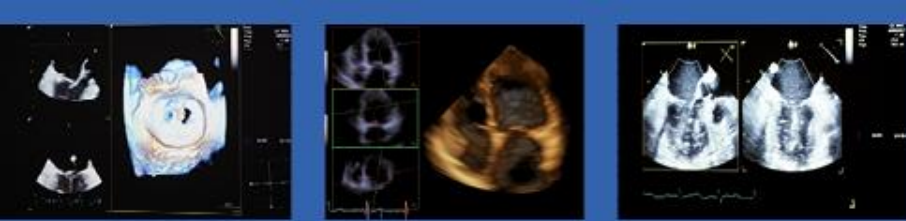
No need to oversize



[J Thorac Cardiovasc Surg. 2017 Sep;154\(3\):820-821. doi: 10.1016/j.jtcvs.2017.05.004.](#)

**Bigger valve size is not always better.**

[Goldman S<sup>1</sup>.](#)



# EuroValve

April 26-27, 2018

## Evaluation of Hemodynamic Performance of Aortic Valve Bioprostheses in a Model of Oversizing



John D. Cleveland, MD, Michael E. Bowdish, MD, Carol E. Eberhardt, BS, Wendy J. Mack, PhD, James A. Crabtree, BS, Thomas A. Vassiliades, MD, Alan M. Speir, MD, Yogesh A. Darekar, MS, Amy E. Hackmann, MD, Vaughn A. Starnes, MD, and Robbin G. Cohen, MD, MMM

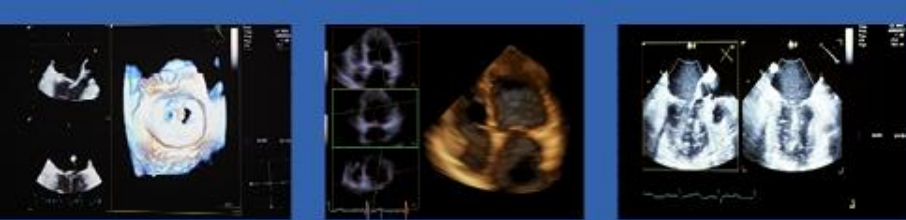
Departments of Surgery and Preventive Medicine, Keck School of Medicine of USC, University of Southern California, Los Angeles; Medtronic, PLC, Irvine, California; and Inova Heart and Vascular Institute, Falls Church, Virginia

*Ann Thorac Surg* 2017;103:1866–77

**Methods.** Three sizes each (21, 23, and 25 mm) of 5 aortic bioprostheses (**Magna ; Trifecta; Epic; Mosaic and Hancock**) were tested on a mock annulus in a pulsatile aortic simulator.

**After the annulus was sized to match each valve, the annulus was decreased by 3 mm and then by 6 mm to simulate oversizing.**

We measured the effective orifice area and the mean pressure gradient



# EuroValve

## April 26-27, 2018

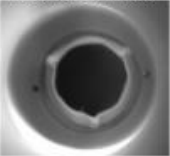
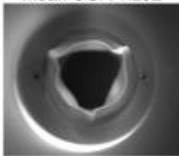
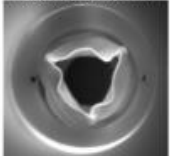
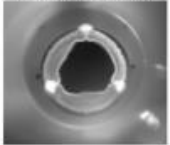
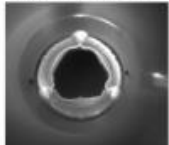
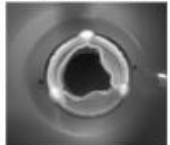
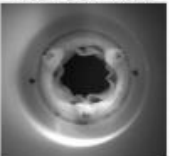
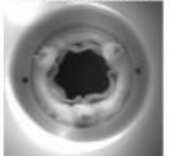
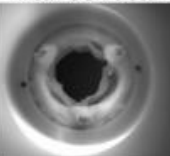
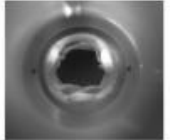
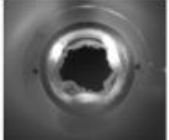
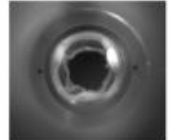
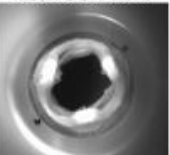
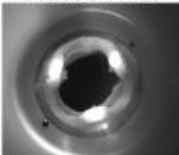
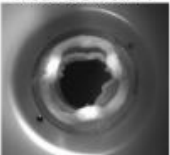
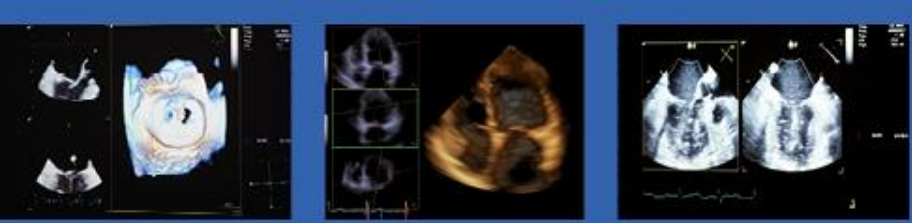
Slow Motion Video Assessment of GOA (cm <sup>2</sup> ) for 21mm Valves			
Annulus	N	N-3mm	N-6mm
St. Jude Triecta, 21mm	Mean GOA 1.705 	Mean GOA 1.292 	Mean GOA 0.727 
Edwards Magna, 21mm	Mean GOA 1.638 	Mean GOA 1.571 	Mean GOA 1.149 
St. Jude Epic, 21mm	Mean GOA 1.022 	Mean GOA 1.054 	Mean GOA 0.862 
Medtronic Mosaic, 21mm	Mean GOA 1.143 	Mean GOA 1.143 	Mean GOA 0.741 
Medtronic Hancock II, 21mm	Mean GOA 1.079 	Mean GOA 1.128 	Mean GOA 0.771 

Fig 4. Representative high-speed photographs at maximal valvular opening for all 21-mm valves tested. The geometric orifice area (GOA) was assessed through an internally developed computer program to measure area encompassed by leaflet edges. (Magna, Edwards Lifesciences, Irvine, CA; Triecta and Epic, St. Jude, St. Paul, MN; Mosaic and Hancock II, Medtronic, Minneapolis, MN.)





# EuroValve

April 26-27, 2018

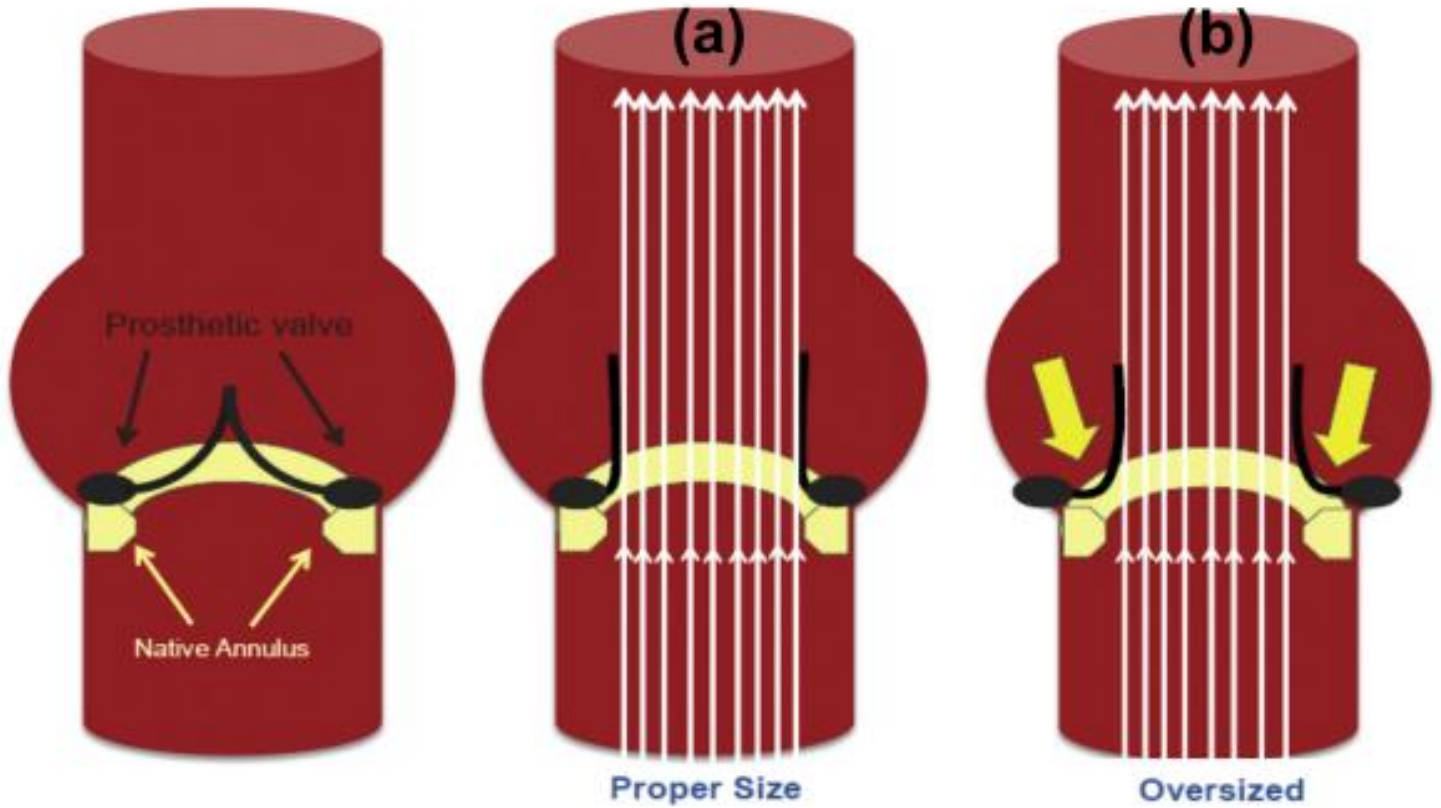
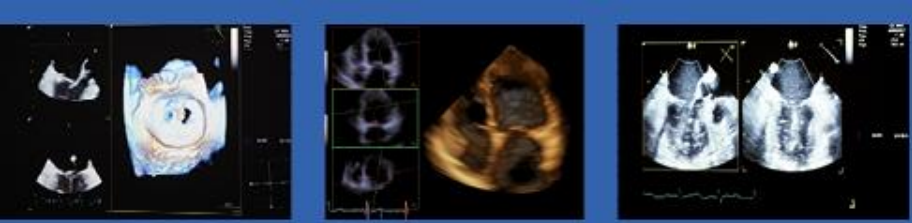
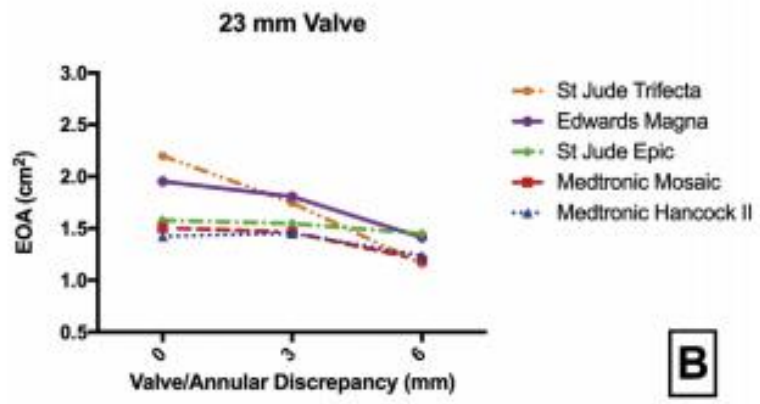
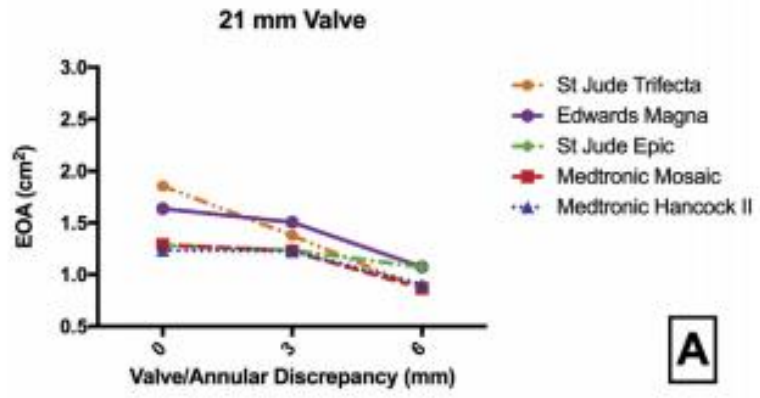
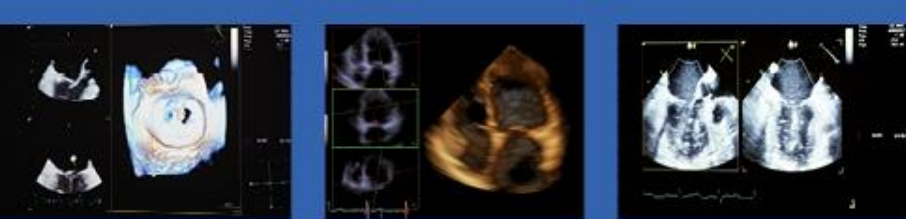


Fig 9. Schematic drawing represents supraannular prosthetic valve placement with (a) proper sizing vs (b) oversizing. In the oversized setting, the valve leaflet hinge point shifts inward.



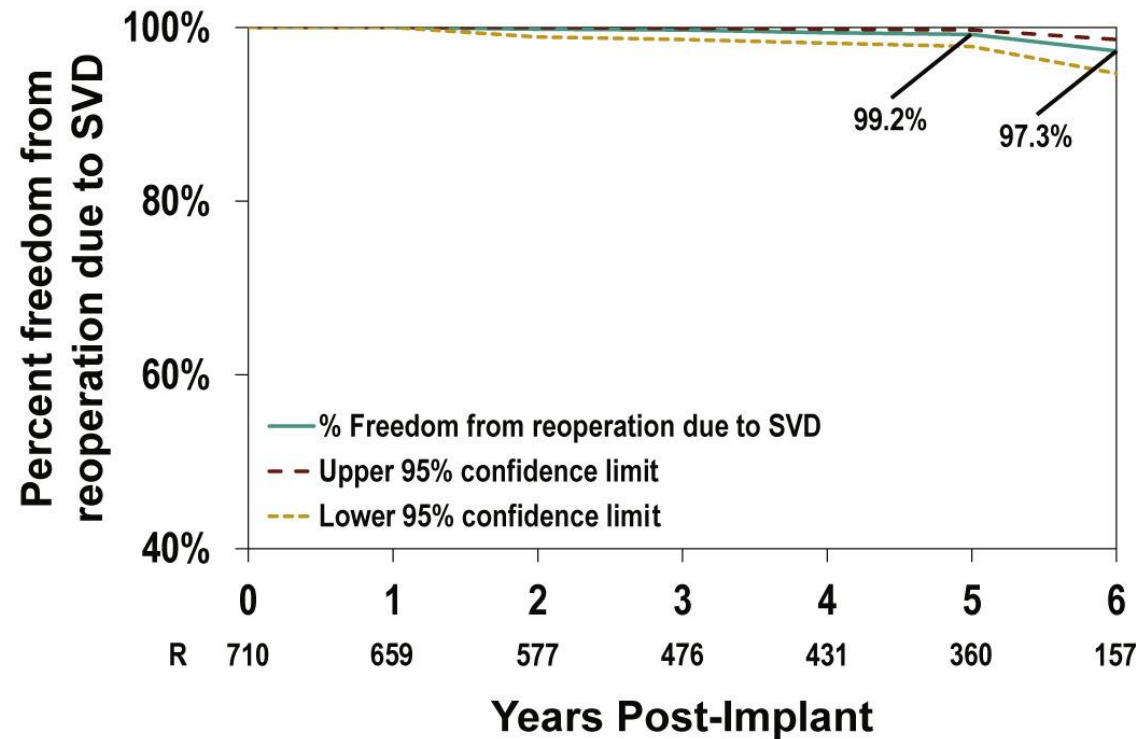
## Effective Orifice Area





# EuroValve

## April 26-27, 2018



Freedom from reoperation due to structural valve deterioration was 97.3% at 6 years.

### Central Message

Excellent hemodynamic performance and durability was maintained through 6 years of follow-up.

### Perspective

Use of bioprosthetic aortic heart valves has steadily increased in recent years. The availability of a bioprosthetic aortic heart valve that has excellent hemodynamic performance and durability is particularly attractive when encountering a small aortic annulus.

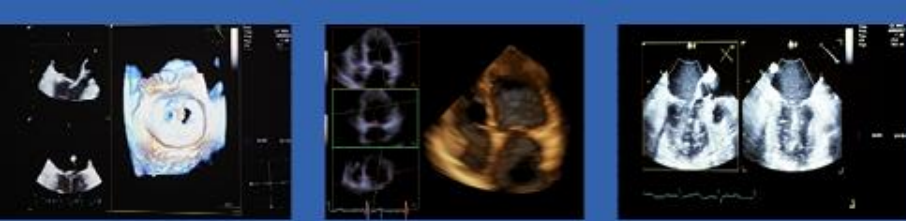
## Midterm, multicenter clinical and hemodynamic results for the Trifecta aortic pericardial valve



Scott Goldman, MD,<sup>a</sup> Anson Cheung, MD,<sup>b</sup> Joseph E. Bavaria, MD,<sup>c</sup> Michael R. Petracek, MD,<sup>d</sup> Mark A. Groh, MD,<sup>e</sup> and Hartzell V. Schaff, MD<sup>f</sup>

*The Journal of Thoracic and Cardiovascular Surgery*  
 Volume 153, Issue 3, Pages 561-569.e2 (March 2017)

**>200,000** patients  
 implanted with Trifecta



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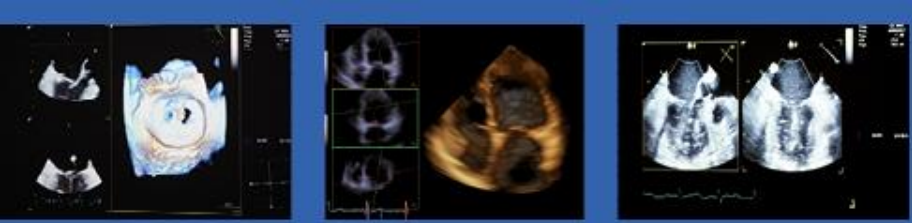
**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**

**July 2010 – March 2018: 1606 Patients**

## **STRUCTURAL DYSFUNCTION: 6 patients**

### **Mechanisms for SVD:**

- Pannus overgrowth (2 p)
- Leaflet tear(4 p)
- Leaflet calcification
- Stent deformation



# EuroValve

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## IMPLANTABILITY

### NEW HOLDER

Prevents stent deformation and adds leaflet protection during implantation

### SOFT SEWING CUFF

Minimizes needle penetration, suture drag, and parachuting forces

### SCALLOPED CUFF

Follows contour of annulus, allowing valve to sit lower in anatomy

### SUTURE MARKERS

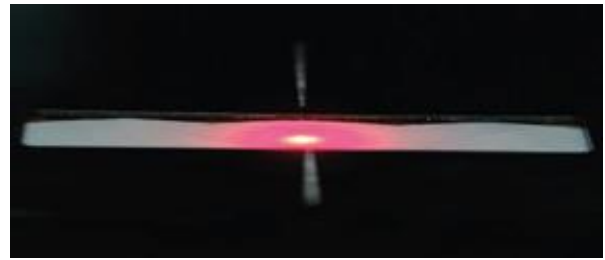
Aids in optimal needle placement and spacing



## DURABILITY

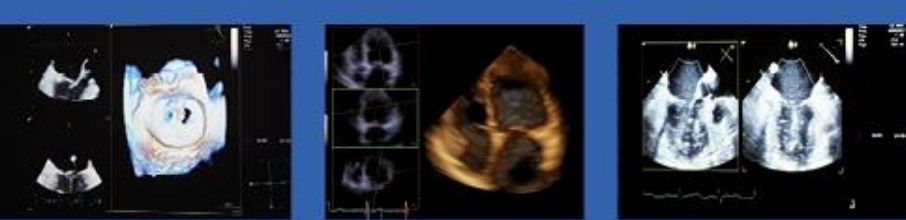
### FIBER ALIGNMENT TECHNOLOGY

Ensures uniform tissue mechanical properties and higher resistance to fatigue related tissue degradation



### TITANIUM BAND

Enhances strength and improves visualization for future valve interventions



# EuroValve

April 26-27, 2018

## Trifecta™ GT Post Market Clinical Follow-up

The objective of this study is to evaluate the safety and performance of the Trifecta™ GT (Glide Technology) valve through 5 year follow-up in a prospective, multi-center, real-world setting. This study is intended to satisfy post-market clinical follow-up requirements of CE Mark in Europe.



Study Home Page

[My Contact Info](#)

\*\*\*\*\* Congratulations! You are the 1st top enroller for Trifecta GT PMCF \*\*\*\*\*

Your Site Compliance / Overall Study Compliance

Follow up Visit Compliance: 100% / 94.13% In range Follow up Visit Compliance: 100% / 86.93% Deviation Rate per Visit: 0 / .03 Withdrawal Rate per Enrollment: 0 / .04

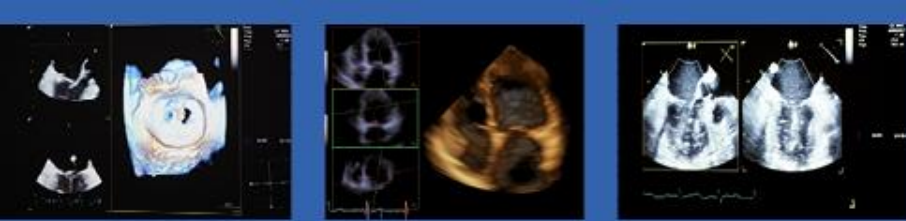
Welcome Albers, Jose - jalbers@vinaloposalud.com

Study: CRD\_837 - Trifecta GT PMCF

Site: SP1638 - Hospital Universitario del Vinalopó

### Study/Site Enrollments





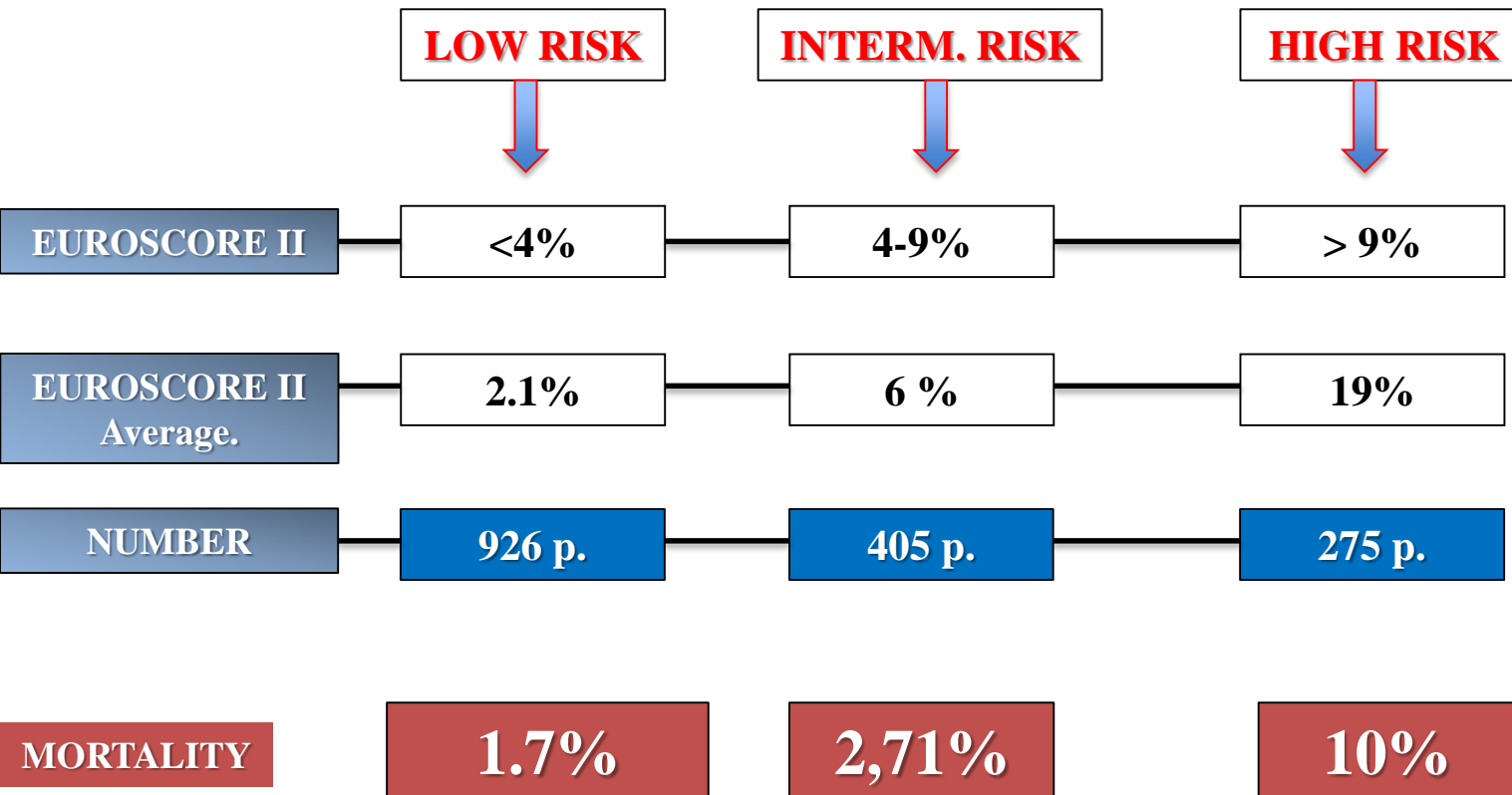
# EuroValve

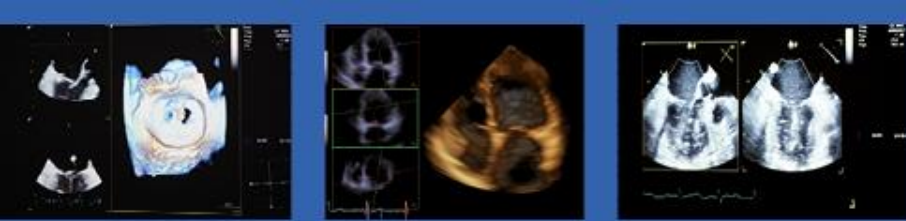
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**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**

**July 2010 – March 2018: 1606 Patients**

## Mortality: 3,5%



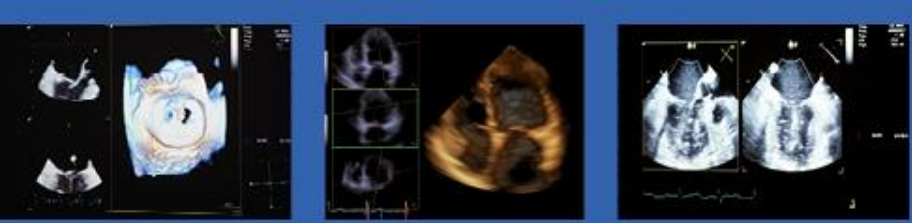


## SAVR IS COST-EFFECTIVE

88 patients Isolated AVR with the Trifecta valve @ Hospital Vinalopó  
year 2014

- Age: 75.44 y (57-89)
- Euroscore II: 4.13% (0.64-41.70 %)
- Hospital costs including prosthesis: 10426.5 euros (7427.5 - 21759.6 euros)





## HEART TEAM

**CARDIAC SURGEON**

**IMAGING CARDIOLOGIST**

**CLINICAL CHARACTERISTICS**

**ANATOMICAL AND TECHNICAL  
ASPECTS. VALVE  
MORPHOLOGY**

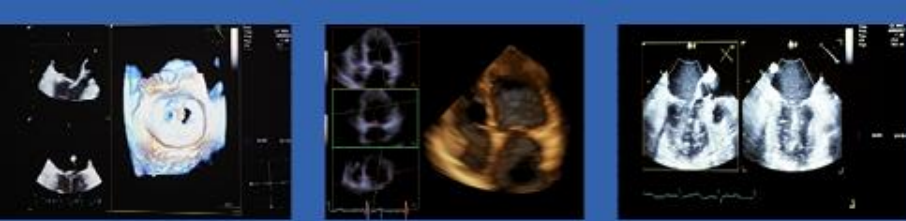
**CONCOMITANT  
PROCEDURES**

**LOCAL EXPERIENCE AND  
RESULTS**

**Critical Care Physician,  
Physiotherapists....**

**INTERVENTIONAL  
CARDIOLOGIST**

**CLINICAL CARDIOLOGIST**



**PORTICO EXPERIENCE. HOSPITEN.**

**July 2010 – March 2018: 3 Patients**

## Indications

1. Acute Trifecta structural dysfunction  
(after 7 years)

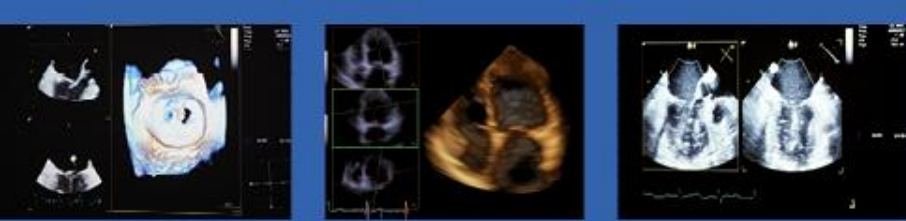
*Acute pulmonary edema, renal insufficiency*

2. Leukaemia. Bilateral amputation

3. Severe frailty

*Euroscore II: 9.28%*





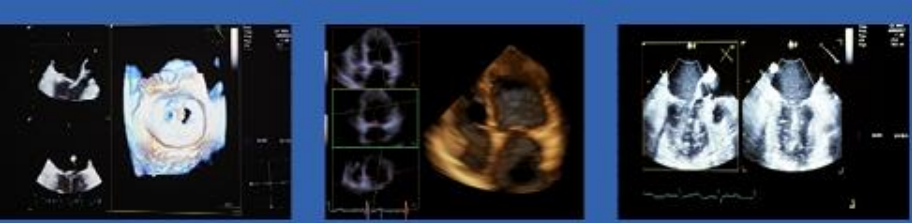
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**TRIFECTA EXPERIENCE. HOSPITEN. HOSPITAL VINALOPÓ**

**July 2010 – March 2018: 1606 Patients**

## **CONCLUSIONS**

- **TRIFECTA IS A PROSTHESIS OF EASY IMPLANT, EVEN IN MICS**
- **THE GRADIENTS AND ORIFICE AREA ARE EXCELLENTS**
- **MISMATCH STILL DOES NOT TAKE PLACE IN SMALL SIZES, WITH POPULATIONS OF SMALL HEIGHT AND HIGH BMI**
- **NO NEED FOR OVERSIZING**
- **THE HEART TEAM SHOULD DETERMINE WHO WILL BENEFIT FROM SAVR / TAVR**



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# THANK YOU FOR YOUR ATTENTION

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[www.cirugiacardiaca.me](http://www.cirugiacardiaca.me)*