

# TAVI “Actualidad Argentina”

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# Objetivos de la Presentacion

- Revisión de Guidelines
- Revisión de Data en Registro LATAM
- Situación en otros países.
- TAVR distribución por dispositivos en ARG,
- Problemática y desafíos del TAVR en ARG.

# Guidelines Internacionales

- Las Guidelines son Guidelines.
- Las Guidelines.
  - No son documentos legales.
  - No son documentos inflexibles y mandatorios.
  - Siempre deben estar por debajo del criterio clínico

FLEXIBILIDAD



# Ultimas actualizaciones

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**CLINICAL PRACTICE GUIDELINE: FULL TEXT**

## 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Clinical Practice Guidelines

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Revised 2020

ESC  
European Society  
of Cardiology

European Heart Journal (2021) 00, 1–72  
doi:10.1093/eurheartj/ehab395

ESC/EACTS GUIDELINES

## 2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

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Revised 2021

# Que dicen las Guías

## SAVR o TAVI para EAo Severa

○ Heart

Deci

○ SAVR

○ TAVI

TAVI o SAVR

○ Pacie

○ Pacientes < 75 años de riesgo

intermedio

### Aortic Stenosis

- SAVR preferred:
  - Any indication for AVR, but unsuitable anatomy for trans-femoral TAVI
- TAVI preferred:
  - Patients of any age with high or prohibitive surgical risk
- Neither TAVI nor SAVR in patients with predicted life expectancy <12 months

|         |     |         |     |
|---------|-----|---------|-----|
| class I | A   | class I | B   |
| class I | A   | class I | A   |
| class I | C   | ---     | --- |
| ---     | --- | class I | B   |

# Que dicen las Guías

## Latin America - SOLACI/SIAC 2021

### Main recommendation

Conditional recommendation, based on moderate certainty of evidence ⊕⊕⊕○



For patients with severe symptomatic aortic stenosis from 75 years of age eligible for transfemoral approach



Panel **suggests** the use of TAVI over SAVR

### Recommendation meaning

Transfemoral TAVI is the best course of action for most elderly patients with severe symptomatic aortic stenosis in Latin America, while SAVR may be considered a better course of action in some scenarios or patients

Conditional recommendations highlight the importance of being familiarized with:

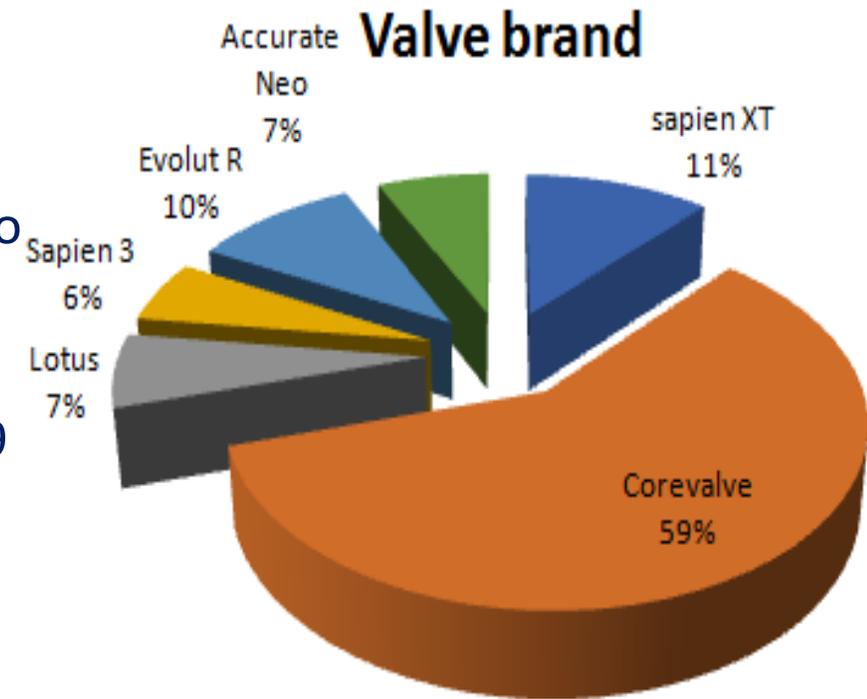
- The evidence supporting this recommendation
- Expert or Heart Team discussion of TAVR candidates
- Integrating patients values and preferences through shared decision-making

Context-specific costs considerations play an important role in the final decision

# TRYTOM registry

Minimalistic Approach versus Standar Approach in Transcatheter Aortic Valve Implantation. Insights from a Latin-American Registry

- We aim to compare safety and efficacy of patients undergoing transfemoral TAVI (TF-TAVI) with Minimalistic Approach (MA) to those with Standar Approach(SA).
- 1133 patients from 4 Latam Countries and 7 centers, from 2009 to 2020.
- Safety and efficacy outcomes were evaluated at 30-days according to *VARC-2 criteria*

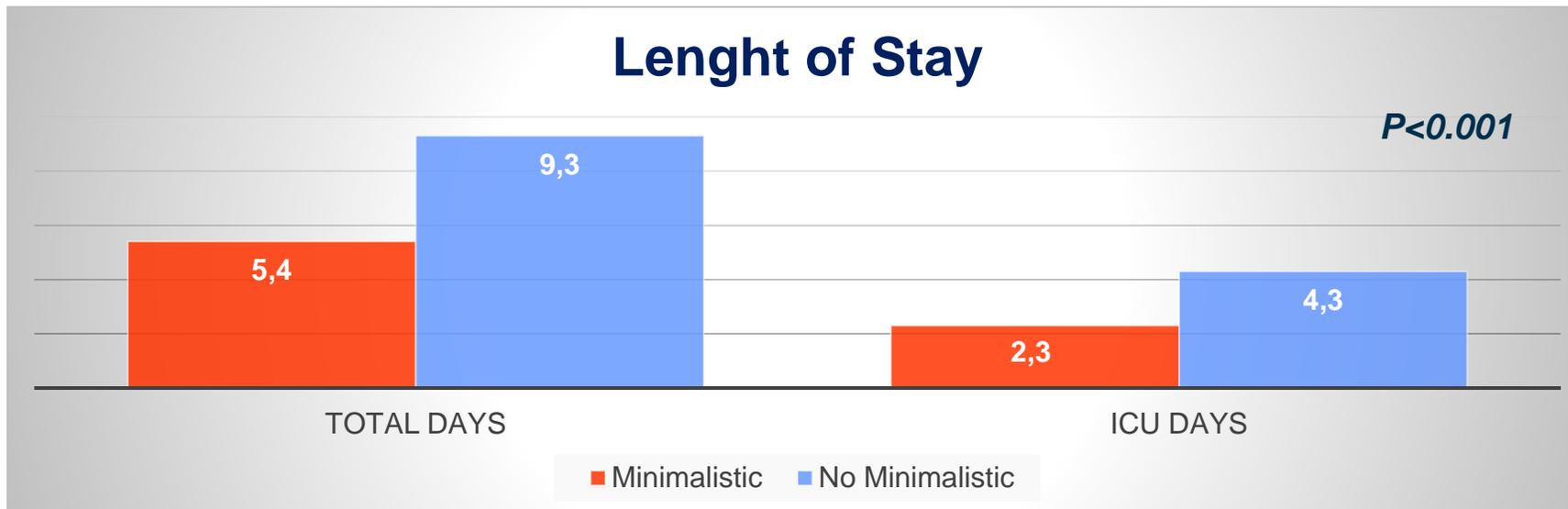


# RESULTADOS

|                              | <b>MA</b><br><b>n = 576</b> | <b>SA</b><br><b>n = 557</b> | <b>PValue</b> |
|------------------------------|-----------------------------|-----------------------------|---------------|
| Age, yrs $\pm$ SD            | 79.4 $\pm$ 7.03             | 80.4 $\pm$ 7.38             | 0.016         |
| STS risk score               | 5.36                        | 6.0                         | 0.08          |
| Emergency procedures (%)     | 0,5                         | 16                          | 0.0001        |
| NYHA IV (%)                  | 76 (13,2)                   | 118 (21.2)                  | 0.0001        |
| Use of vasoactive drugs      | 10.6%                       | 11.8%,                      | 0.682         |
| Device success               | 93.3%                       | 93%                         | 0.884         |
| Moderate to severe AR        | 7.9%                        | 6.3%                        | 0.61          |
| 30-day mortality rates       | 4.3%                        | 5.2%                        | 0.494         |
| Major bleeding               | 5.6%                        | 9.4%                        | 0.036         |
| Major vascular complications | 4.7%                        | 8.5%                        | 0.011         |

# RESULTADOS

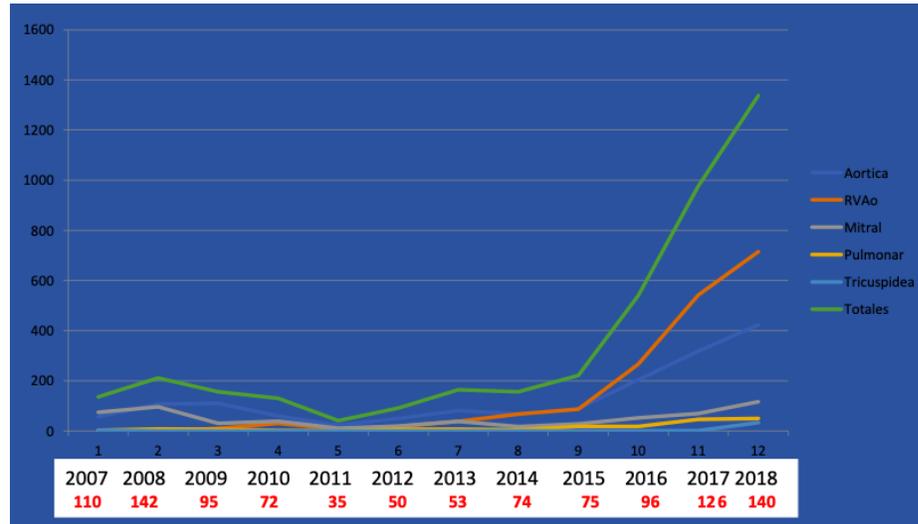
|                       | <b>MA</b><br><b>n = 576</b> | <b>SA</b><br><b>n = 557</b> | <b>PValue</b> |
|-----------------------|-----------------------------|-----------------------------|---------------|
| Permanent Pacemaker   | 25.4%                       | 24.4%                       | 0.87          |
| Echo Guided Procedure | 56.1%                       | 52.9%                       | 0.377         |
| Transesophageal Echo  | 12.9%                       | 72.9%,                      | 0.0001        |



# Procedimientos Valvulares CACI

REGISTRO VOLUNTARIO CACI  
PROCEDIMIENTOS GENERALES  
AÑO 2018

| TERAPEUTICA EN VALVULOPATIAS ADQUIRIDAS |      |        |          |             |         |
|---|------|--------|----------|-------------|---------|
| Aortica                                 | RVAo | Mitral | Pulmonar | Tricuspidea | Totales |
| 56                                      | 0    | 74     | 3        | 3           | 136     |
| 107                                     | 0    | 96     | 8        | 0           | 211     |
| 110                                     | 10   | 30     | 6        | 0           | 156     |
| 59                                      | 30   | 39     | 2        | 0           | 130     |
| 23                                      | 7    | 11     | 0        | 0           | 41      |
| 49                                      | 17   | 19     | 6        | 0           | 91      |
| 81                                      | 38   | 38     | 7        | 0           | 164     |
| 68                                      | 67   | 17     | 4        | 0           | 156     |
| 88                                      | 87   | 28     | 18       | 0           | 221     |
| 204                                     | 266  | 52     | 18       | 0           | 540     |
| 318                                     | 542  | 69     | 46       | 1           | 976     |
| 423                                     | 715  | 116    | 50       | 33          | 1337    |



2019: 1516 TAVI

2021: 1561 TAVI

28 / 1.000.000 habitantes

29 / 1.000.000 habitantes

# TAVR en Otros Países de LATAM

EDITORIAL

## Transcatheter implantation of aortic valve bioprosthesis: changing paradigms

 Fábio Sândoli de Flávio

In Brasil, aortic valve implantations by catheter started being used in January 2008 and, despite the lack of coverage by public and private health systems, we have seen a significant increase in the use of this treatment in the country. It is estimated that, in 2019, approximately 2,000 TAVIs will be conducted in Brasil. This number, which represents approximately ten TAVIs for every million inhabitants per year, is still minimal compared to some European countries or the United States, where 100 to 150 for every million inhabitants take place per year. This represents a considerable challenge, since the vast majority of institutions in Brasil have less than ten procedures per year and, therefore, are still learning the method. In a recent international multicenter publication that included Brazilian data, we found that for an institution can achieve excellence, at least 50 cases per year are required.<sup>3</sup> Less than five medical centers in Brasil have that number.

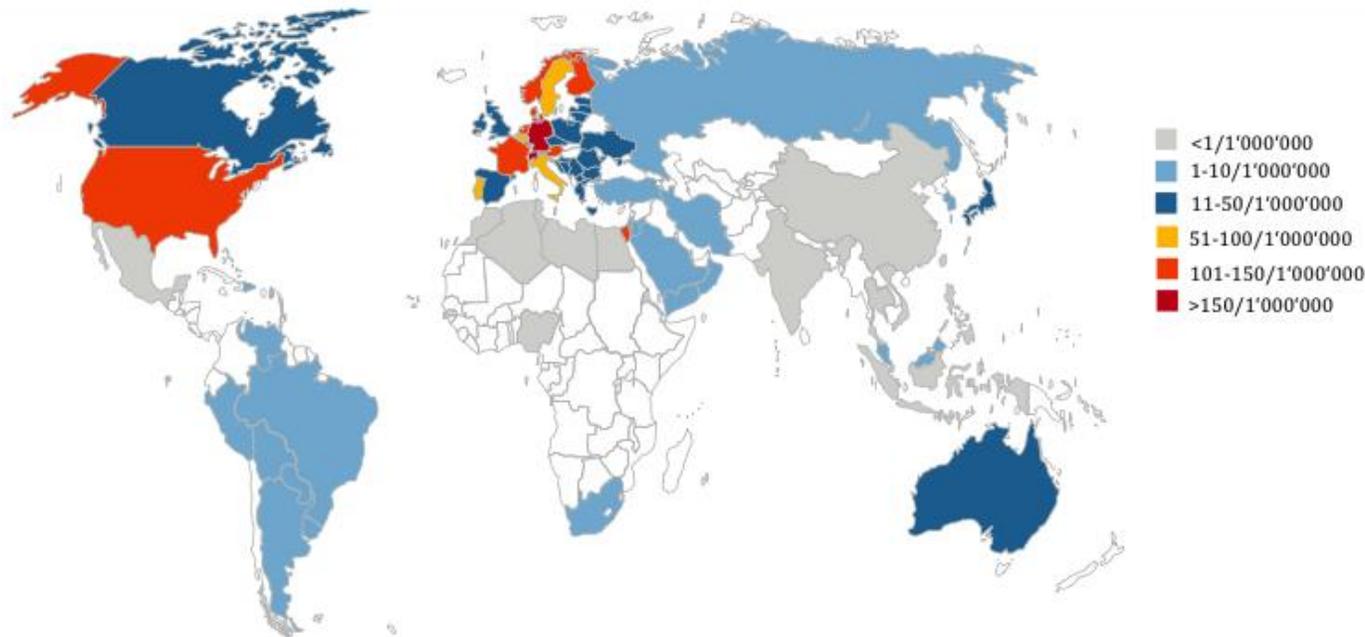
# TAVR en Europa y USA

## Expansion of transcatheter aortic valve implantation: new indications and socio-economic considerations

Thomas Pilgrim and Stephan Windecker\*

### TAVR Procedure Volumes In the United States

The annual volume of TAVR has increased each year and in 2019 TAVR volume (72,991) exceeded all forms of SAVR (57,626), coinciding with the U.S. Food and Drug Administration (FDA) approval of TAVR for low-risk patients. The number of TAVR procedures performed per site varies, but as the number of sites performing TAVR has increased, the total annual volume has increased. In 2019 sites performed 84 TAVR procedures on average with 161 sites performing less than 50 cases. An expert consensus document published by stakeholders — including the ACC and STS — included a recommendation of a 50-case annual threshold minimum for sites performing TAVR.



USA 222 / 1.000.000 habitantes

**Take home figure** Geographical dispersion of TAVI. TAVI implantation per 1 000 000 inhabitants. Estimates for Q1–Q4 2017 (Western Europe) or Q4 2016–Q3 2017 (all other regions) including moving annual total (MAT) data. Data are subject to end of year adjustment. Source: BIBA Medical.

# CENTROS DE TAVR EN ARGENTINA

## Argentinean Registry TAVR: 35 Institutions

### CORDOBA

- SANATORIO ALLENDE
- HOSPITAL PRIVADO DE LA COMUNIDAD
- FUSAVIM
- HOSPITAL DE CORDOBA
- SANATORIO VELEZ SARSFIELD
- CLINICA SUCRE

### SANTA FE

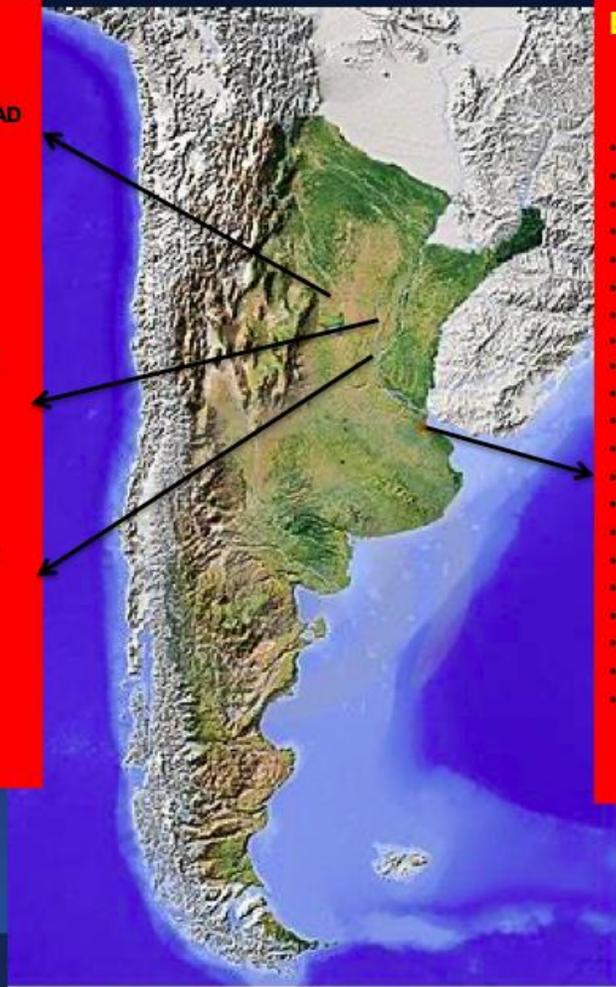
- INSTITUTO DE DIAGNOSTICO SANTA FE
- SANATORIO GARAY

### ROSARIO

- INSTITUTO CARDIOVASCULAR ROSARIO
- SANATORIO PLAZA
- HOSPITAL ITALIANO

### CORRIENTES

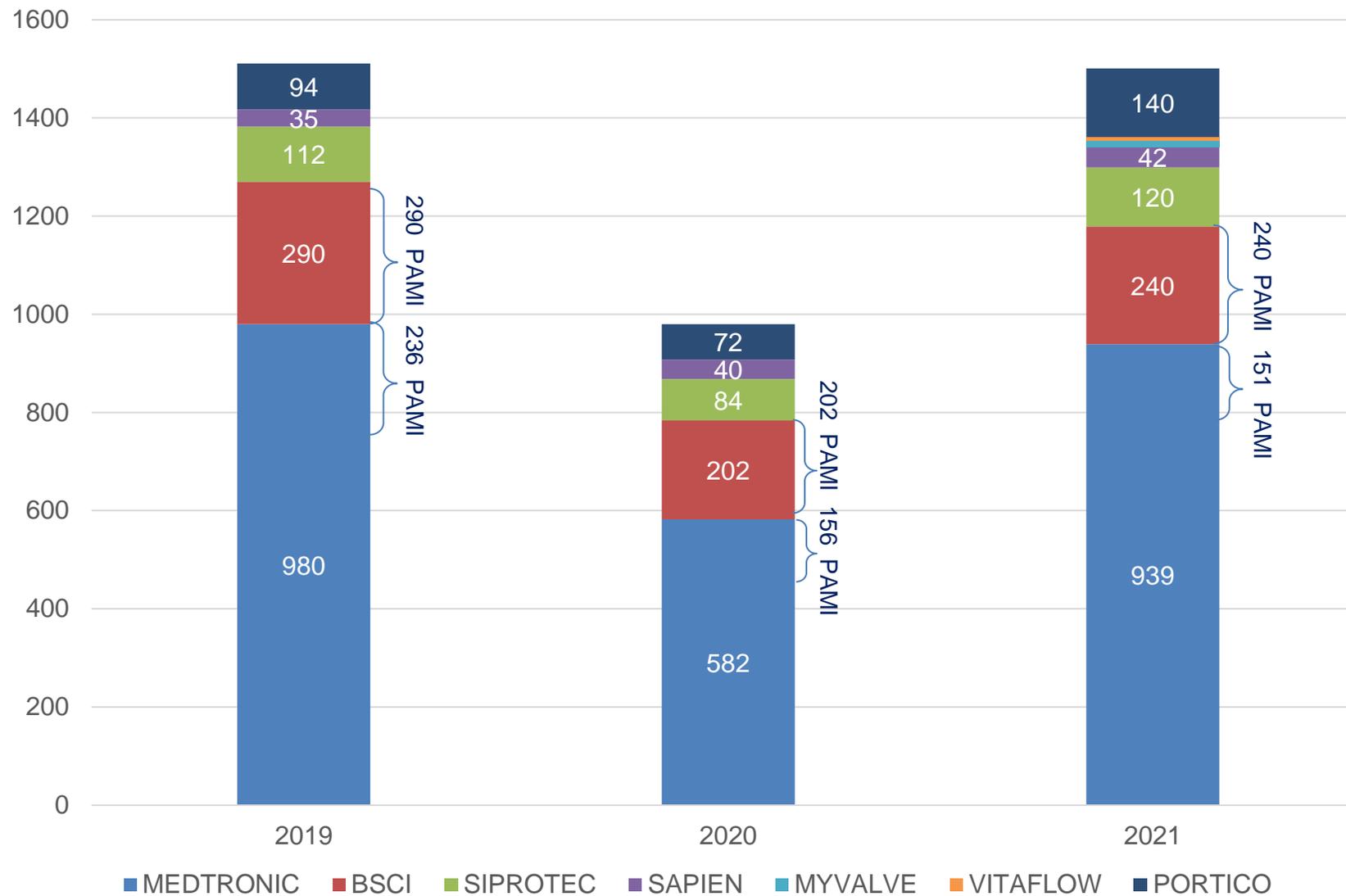
- INSTITUTO DE CARDIOLOGIA CABRAL



### BUENOS AIRES

- FUNDACION FAVALORO
- HOSPITAL ALEMAN
- HOSPITAL BRITANICO DE BS AS
- HOSPITAL ESPAÑOL DE BS AS
- HOSPITAL ESPAÑOL DE LA PLATA
- HOSPITAL JUAN A FERNANDEZ
- HOSPITAL ITALIANO DE BS AS
- INSTITUTO CADIOVASCULAR DE BS AS
- INSTITUTO MOD. DE ALTA COMPLEJIDAD
- ANATORIO BURZACO
- SANATORIO GUEMES
- SANATORIO OTAMENDI
- HOSPITAL DEL CRUCE
- HOSPITAL DEL SUR BAHIA BLANCA
- CLINICA SAN CAMILO
- CLINICA ADVENTISTA
- CLINICA SAGRADA FAMILIA
- INSTITUTO FLENI
- SANATORIO LAS LOMAS
- SANATORIO TRINIDAD PALERMO
- HOSPITAL UNIVERSITARIO UAI

# CANTIDAD DE TAVR EN ARGENTINA



# CANTIDAD DE TAVR Distribución x centro

83 centros informaron haber realizado TAVI en 2018  
54,6% de los centros participantes en el Registro

| Número de TAVI 2018 | Número de Centros |
|---------------------|-------------------|
| 1 - 5               | 48                |
| 6 - 10              | 16                |
| 11 - 20             | 08                |
| 21 - 40             | 07                |
| > 41                | 04                |

# Problemáticas del TAVI en Argentina

- Escasa penetración de la práctica en relación a otras regiones, a pesar de un fuerte cuerpo de evidencia.
- Escaso reconocimiento por parte de las autoridades sanitarias del impacto clínico del TAVI.
- Numerosos centros con escaso volumen de procedimientos. Tecnologías y resultados dispares.
- Ausencia de datos que reflejen los resultados clínicos del TAVI a nivel nacional.
- Costo de los dispositivos en nuestro país.



# Desafíos del TAVI en Argentina

- Instrumentar las herramientas que faciliten el acceso a TAVI a un número de pacientes significativamente mayor.
- Proporcionar a las autoridades sanitarias, financiadores de salud, auditores, resultados clínicos del TAVI en nuestro país. (Registros)
- Promover políticas para reducir los impuestos a las prótesis TAVI.
- Concientizar sobre los costos asociados a la cirugía de RVAo, (internaciones prolongadas, rehabilitación cardiovascular, reinternaciones)

Muchas Gracias