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CONGRESO COLEGIO COLOMBIANO
DE HEMODINAMIA E INTERVENCIONISMO CARDIOVASCULAR

XXIV JORNADAS SOLACI - 8VAS. REGIÓN ANDINA



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SOLACI
SOCIEDAD
LATINOAMERICANA
DE CARDIOLOGIA
INTERVENCIONISTA

TARIO
de

TAVI EN INSUFICIENCIA AORTICA



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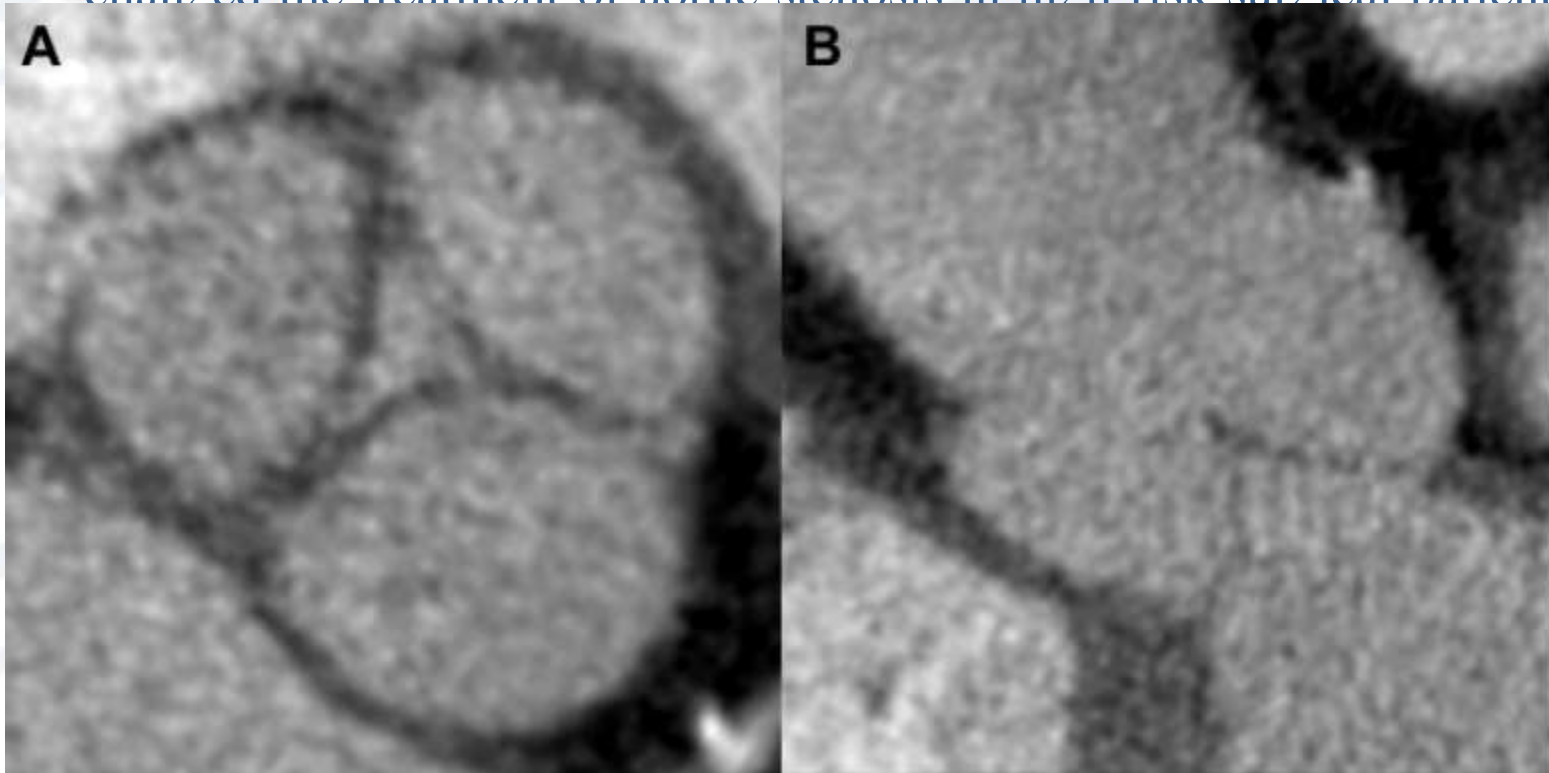
CONFLICTO DE INTERESES

- Proctor de Corevalve
- Miembro advisory board Medtronic

Conclusions—Early SVD is frequent in Mitroflow bioprosthesis (models 12A/LX), especially for small sizes (19 and 21 mm) and reduces overall survival. An unpredictable accelerated pattern of SVD constitutes a life-threatening condition. In view of the large number of Mitroflow valves implanted worldwide, one can expect an epidemic of SVD and valve-related deaths, which represents a major public health issue, especially in the elderly. Hence, a close follow-up with yearly echocardiography after Mitroflow implantation is advisable. An urgent redo surgery should be discussed in patients with severe SVD even though still asymptomatic.

Introduction

- Transcatheter aortic valve implantation (TAVI) has substantially changed the treatment of aortic stenosis in high-risk surgical patients



migration

Transcatheter Aortic Valve Implantation for Pure Severe Native Aortic Valve Regurgitation

J Am Coll Cardiol 2013;

Patients = 43

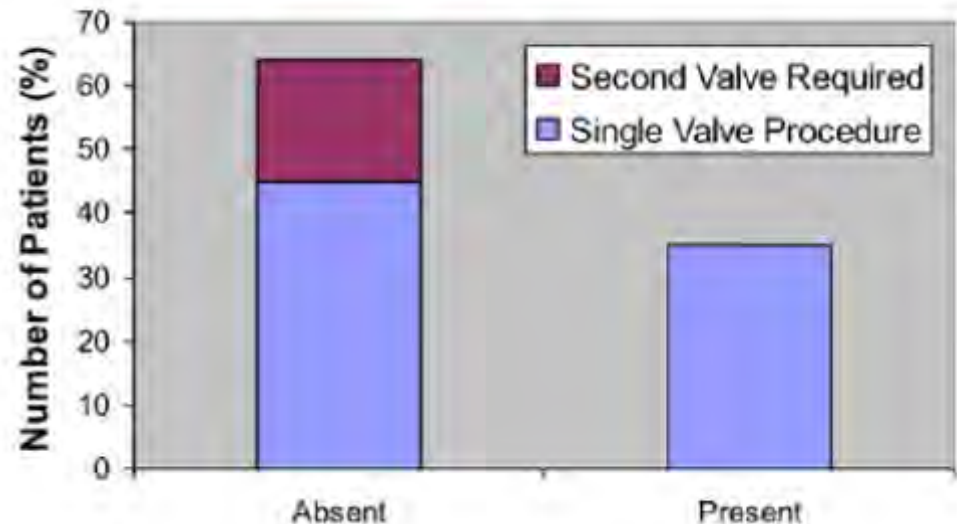
Table 2 Mechanism of Aortic Regurgitation

Degenerative	27 (62.8)
Post-endocarditis	6 (14.0)
Aortic aneurysm	4 (9.3)
Aortic valve cusp restriction due to rheumatoid vasculitis, Takayasu's arteritis, unknown	3 (7.0)
Post-radiotherapy	2 (4.7)
Chronic dissection	1 (2.3)

Outcome according to VARC

Valve implanted	97,7%
2 valve needed	18,6%
CV Mortality 30 days	2,3%
CV Mortality 12 mon	10,7%
Major stroke 30 days	4,7%

Relationship Between Aortic Valve Calcification and Need for a Second Valve



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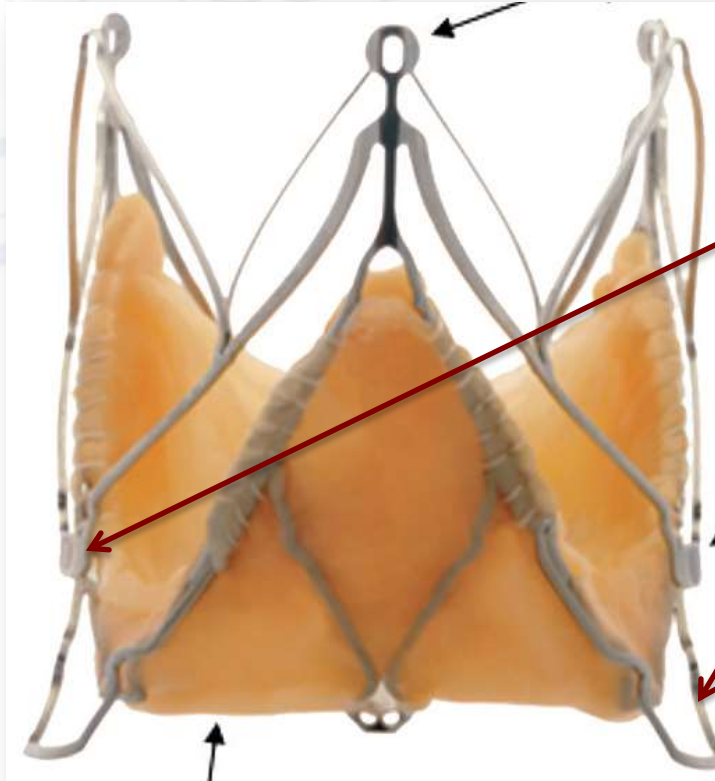
This registry analysis demonstrates the feasibility and potential procedure difficulties when using TAVI for severe NAVR.

Outcome according to VARC

Valve implanted	97,7%
2 valve needed	18,6%
CV Mortality 30 days	2,3%
CV Mortality 12 mon	10,7%
Major stroke 30 days	4,7%

Acceptable results may be achieved in carefully selected patients who are deemed too high risk for conventional surgery, but the possibility of requiring 2 valves and leaving residual aortic regurgitation remain important considerations.

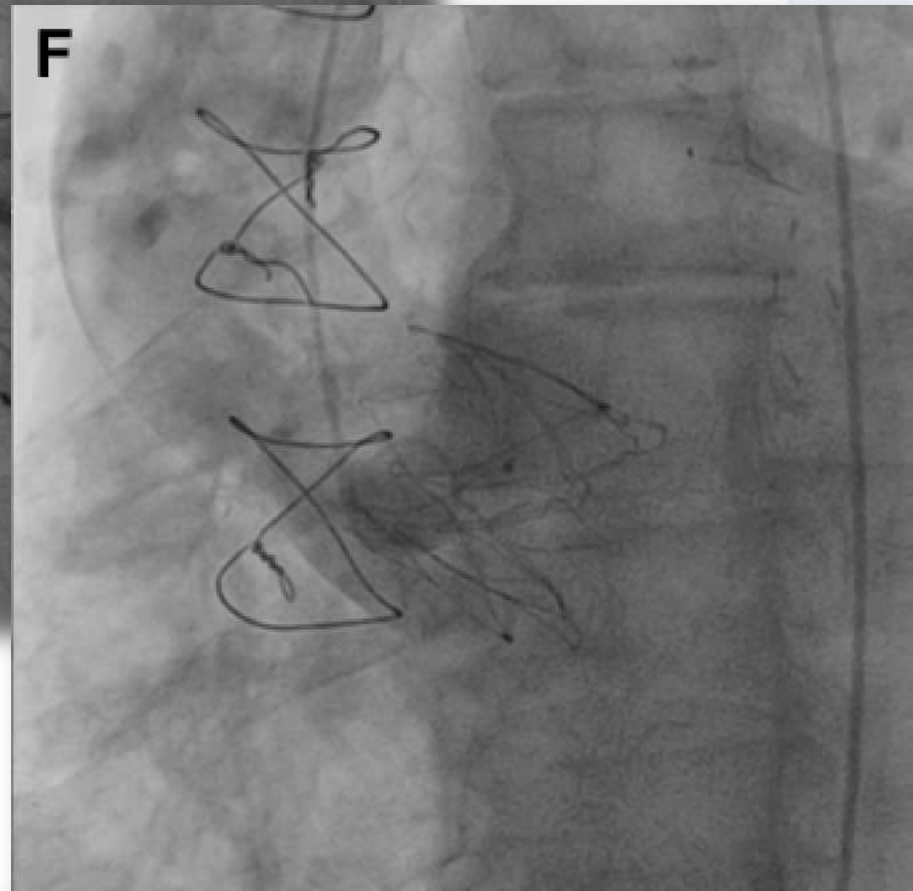
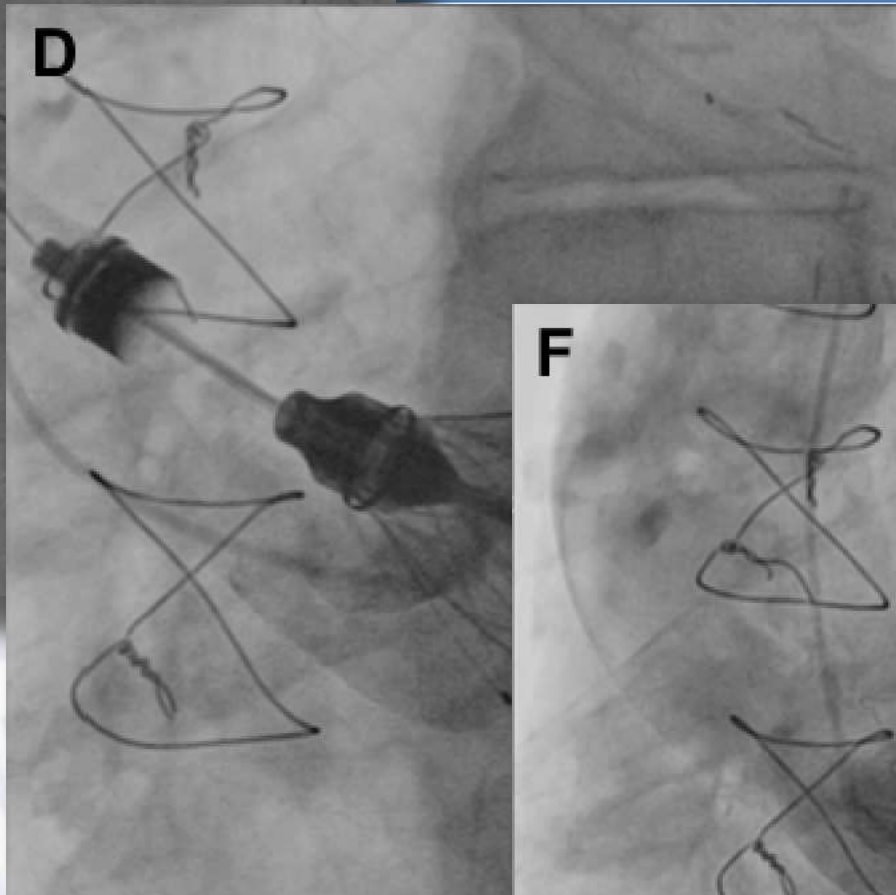
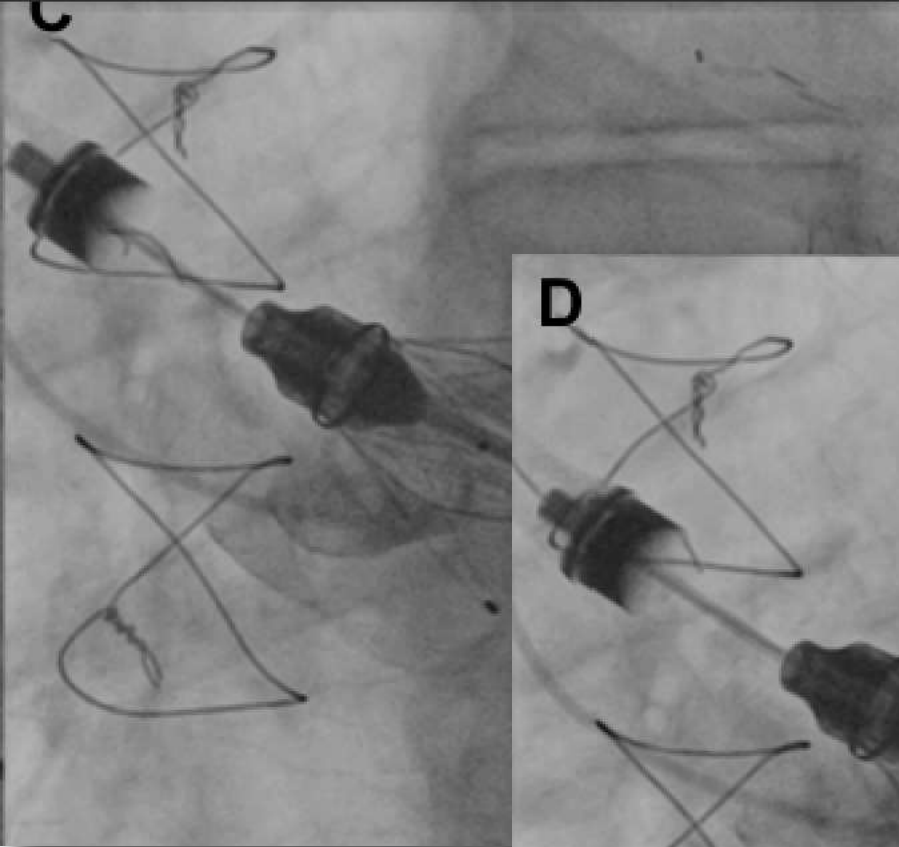
Key design features



Porcine aortic root / Nitinol

- Contains three so-called feelers that should be planted in the proper coronary cusp.
- The **JenaClip™** is an intrinsic mechanism to clip the JenaValve prosthesis onto the native valve leaflets for active fixation.
- Repositionable and retrievable

Is the only transcatheter heart valve design with a [CE MARK EXPANSION FOR SEVERE AORTIC](#) insufficiency in 2013



Transapical Implantation of a Second-Generation Transcatheter Heart Valve in Patients With Noncalcified Aortic Regurgitation

JACC Cardiovasc. Interv 2013; 6:590–597



Trans Apical 5 patients

30 days results	%
Procedural success	100
Death	0
Access complications	NA
> mild A Regurgitation	0
All Stroke	NA
New PM	NA

Jena valve Prosthesis May Be A Reasonable Option In These Specific Patients Due To Its Unique Stent Design, Clipping The Native Aortic Valve Leaflets

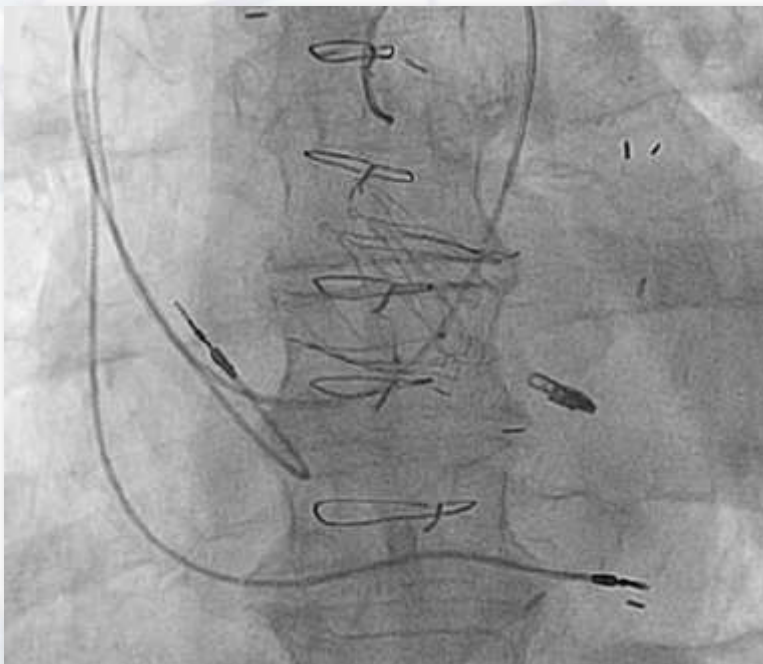
Transcatheter aortic valve implantation of a second-generation valve for pure aortic regurgitation: procedural outcome, haemodynamic data and follow-up

Interactive CardioVascular and Thoracic Surgery (2014) 1–6

Trans Apical JENA valve

10 patients

2 MitraClips 1 Amplatzer

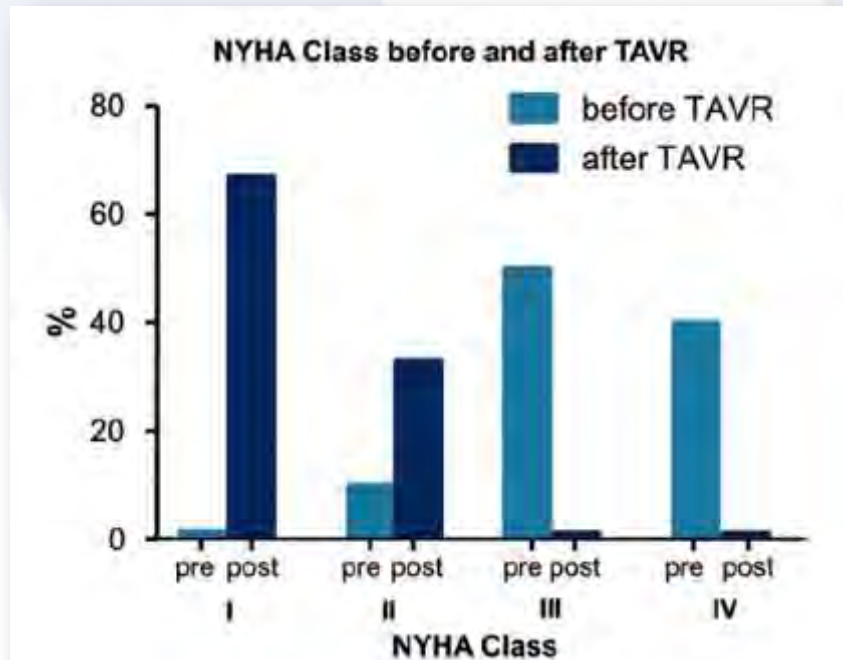
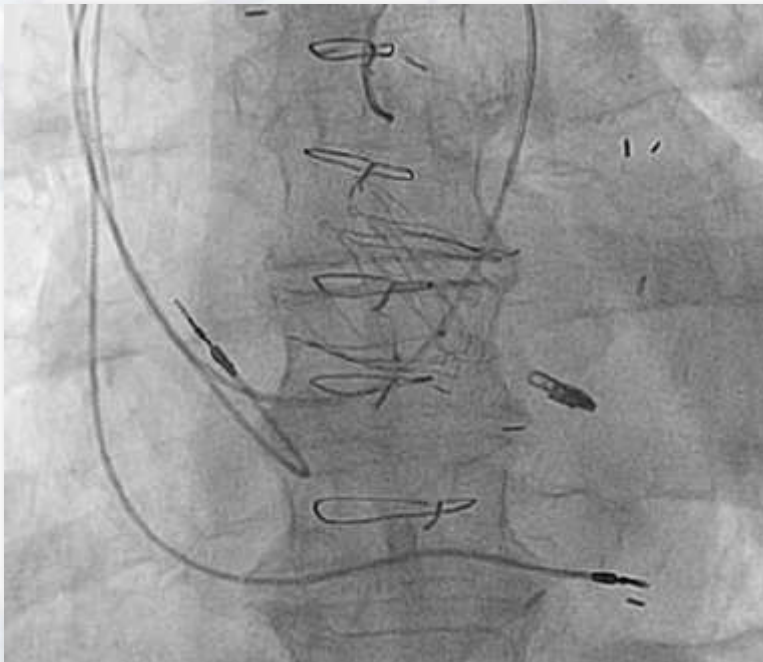


30 days results	%
Procedural success	100
Death	30 (3)
Access complications	0
> mild A Regurgitation	0
All Stroke	0
New PM	20 (2)

Transcatheter aortic valve implantation of a second-generation valve for pure aortic regurgitation: procedural outcome, haemodynamic data and follow-up

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Trans Apical JENA valve



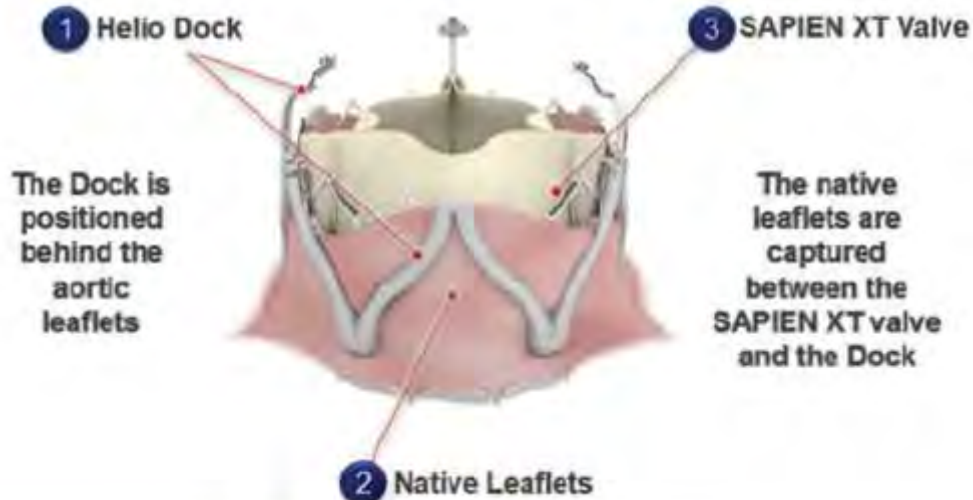
Treatment of AR by a TA TAVI approach with the Jena valve is technically feasible with satisfying short-term results concerning haemodynamics and device success

Feasibility trial reports deployment of new device for TAVI in aortic insufficiency

European Heart Journal 2013; 34: 2578

Trans Apical or Trans Femoral

First 4 patients

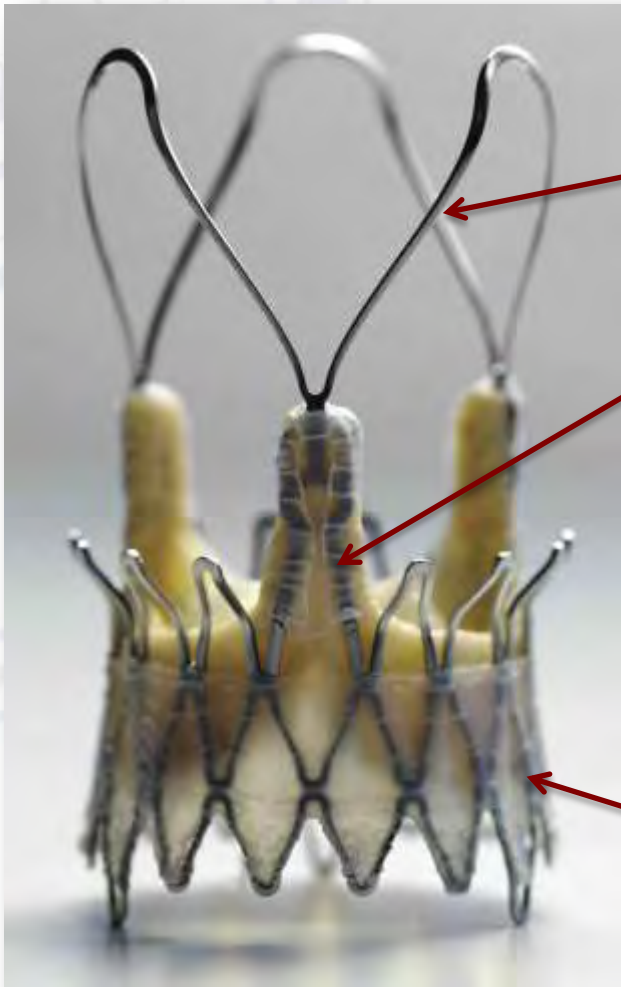


30 days results	%
Procedural success	100
Death	0
Access complications	0
> mild A Regurgitation	0
All Stroke	25 (1)
New PM	NA

Transapical Transcatheter Aortic Valve for Severe Aortic Regurgitation

J Am Coll Cardiol Intv 2014

Key design features



Porcine / Nitinol

- The distal/aortic edge of the frame contains three stabilisation arches.
- The upper-crown segment of the stent contains the valve leaflets (which are also placed supra-annularly) and provide supra-annular anchoring.
- The lower crown is the stent edge that minimally resides within the left ventricular outflow tract.
- A PET sealing skirt is mounted around the intra-annular part of the stent.
- 18 Fr sheath compatible.

Transapical Transcatheter Aortic Valve for Severe Aortic Regurgitation

J Am Coll Cardiol Intv 2014



Porcine / Nitinol

A

Comorbidities	Etiology of AR
<u>Previous aortic surgery</u> , systemic hypertension, neurological dysfunction	Secondary AR after failed aortic root repair
<u>CABG surgery 2006</u> , diabetes, previous multiple PCIs, systemic hypertension, obesity, severe COPD (FEV ₁ , 53.4%, steroids, long-term use of bronchodilators)	Sclerotic-degenerative
<u>Previous aortic surgery with persisting aortic type B dissection</u> , severe COPD (FEV ₁ , 47.5%, long-term use of bronchodilators), renal insufficiency, systemic hypertension	Secondary AR after failed aortic root repair
<u>CABG surgery 2001</u> , dialysis, systemic hypertension	Sclerotic-degenerative
<u>Previous PCI</u> , systemic hypertension, atrial fibrillation, peripheral artery disease, obesity	Sclerotic-degenerative
<u>Severe COPD</u> (FEV ₁ 51.2%, long-term use of bronchodilators), renal insufficiency, previous PCI, systemic hypertension, atrial fibrillation	Sclerotic-degenerative
<u>Emergency TAVR with preoperative inotropes</u> , previous PCI, cardiac tamponade due to catheterization	Sclerotic-degenerative
<u>Previous PCI</u> , cardiac decompensation	Sclerotic-degenerative

Transapical Transcatheter Aortic Valve for Severe Aortic Regurgitation

J Am Coll Cardiol Intv 2014



Porcine / Nitinol

Aortic Regurgitation (TA)

8 consecutive Patients

30 days results	%
Procedural success	100
Death	0
V. complications	0
< mod A Regurgitation	0
All Stroke	0
New PM	0

Transapical Transcatheter Aortic Valve for Severe Aortic Regurgitation

J Am Coll Cardiol Intv 2014



Porcine / Nitinol

Aortic Regurgitation (TA)

8 consecutive Patients

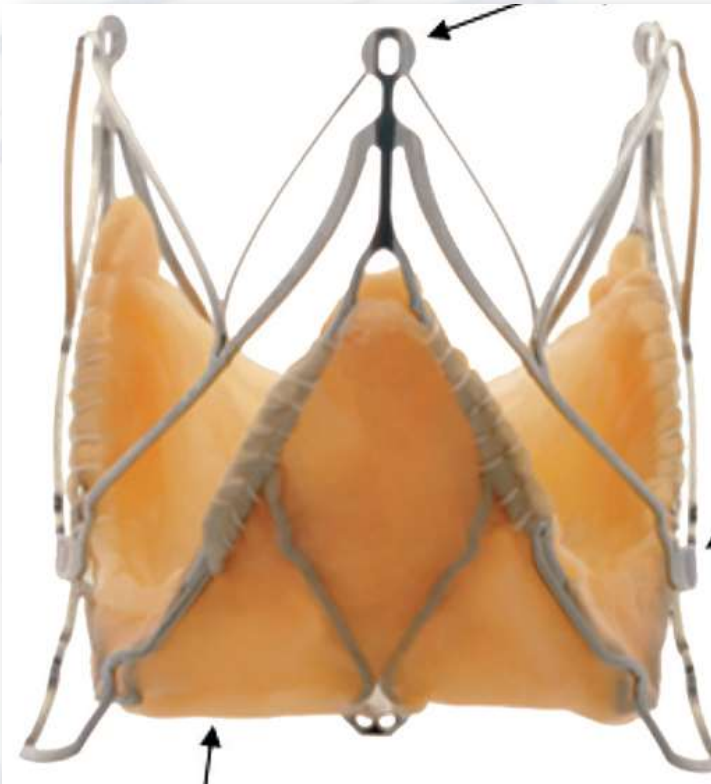
- The valve hemodynamic findings were satisfactory and comparable to conventional valves.
- Furthermore, the specific architecture of the bioprosthesis lends itself to secure annular placement and alignment in the native anatomy of the noncalcified aortic valve

Initial German Experience With Transapical Implantation of a Second-Generation Transcatheter Heart Valve for the Treatment of Aortic Regurgitation

J Am Coll Cardiol Intv 2014

Aortic Regurgitation (TA)

31 Patients / 9 German centers

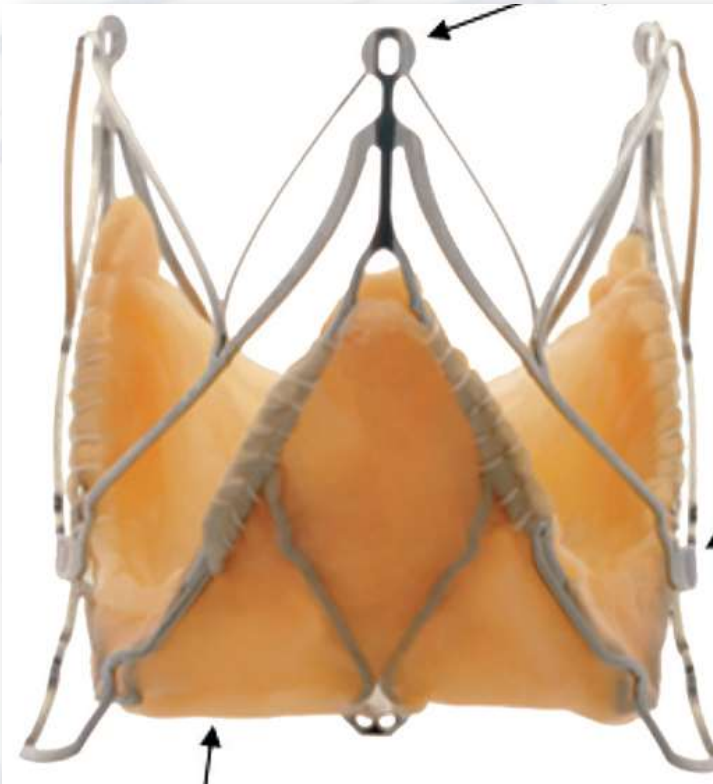


30 days results	%
Procedural success	96,8
Death	13
V. complications	0
< mod A Regurgitation	0
All Stroke	0
New PM	6,4% (2)
Valve in valve	10% (3)

Jena Valve transcatheter heart valve as a reasonable option in this subset of patients

Initial German Experience With Transapical Implantation of a Second-Generation Transcatheter Heart Valve for the Treatment of Aortic Regurgitation

J Am Coll Cardiol Intv 2014



- Aortic regurgitation remains a challenging pathology for TAVI.
- This multicenter study revealed the Jena Valve transcatheter heart valve as a reasonable option in this subset of patients.
- However, a significant early non cardiac mortality related to the high-risk population emphasizes the need for careful patient selection.

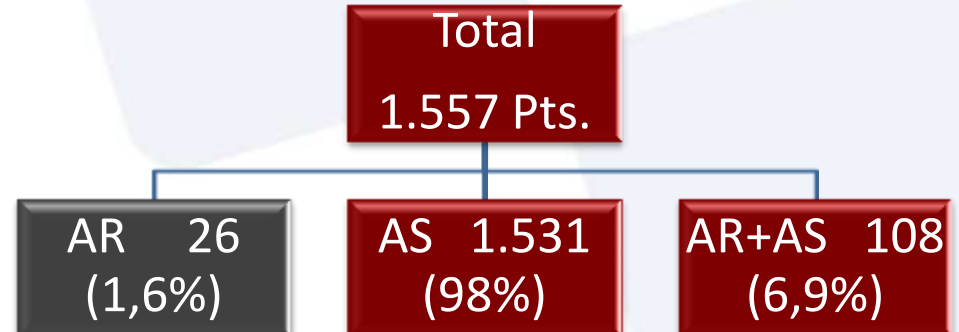
CoreValve implantation for severe aortic regurgitation: a multicentre registry

EuroIntervention 2014;10:739-745



Italian Registry

October 2008 to January 2013



CoreValve implantation for severe aortic regurgitation: a multicentre registry

EuroIntervention 2014;10:739-745

	AR (26 patients)	AS (1,531 patients)	AS + AR* (108 patients)	<i>p</i> [#]
Age (yrs), mean (SD)	73±10	82±6	81±4	0.02
NYHA III-IV (%)	25 (95)	1,118 (73)	78 (72)	0.01
Log EuroSCORE, mean (SD)	24±8	22±16	23±12	0.09
STS risk score (%)	13.1±2	10±3	11±2	0.08
Diabetes (%)	5 (21)	367 (24)	25 (23)	0.7
Creatinine clearance, ml/min, mean (SD)	48.4 (22.6)	46.9 (21.9)	47.5 (20.7)	0.09

Patients with AR were:

- Younger
- More symptomatic
- Sicker

CoreValve implantation for severe aortic regurgitation: a multicentre registry

EuroIntervention 2014;10:739-745

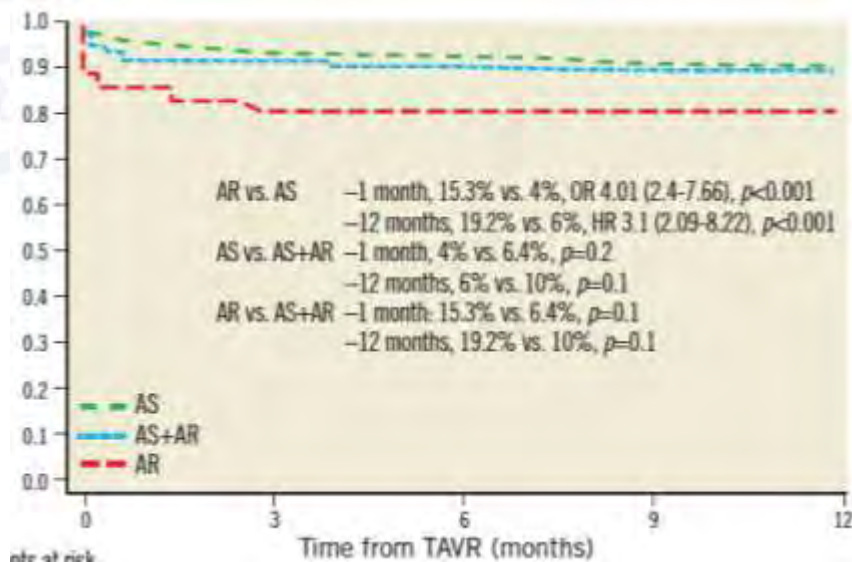
Procedural data

	AR (26 patients)	AS (1,531 patients)	AS+AR* (108 patients)	<i>p</i> [#]
+ Post-procedural paravalvular leak ≥ 2 (%)	23	4	4	<0.01
- Residual transaortic gradient >15 mmHg, N (%)	0	15 (1)	0	0.1
- Post-dilation, N (%)	3 (10)	199 (13)	13 (12)	0.7
+ "Valve-in-valve", N (%)	5 (19.2)	69 (4.5)	5 (4.6)	<0.001
- Device success, %	76.9	96	96	0.006

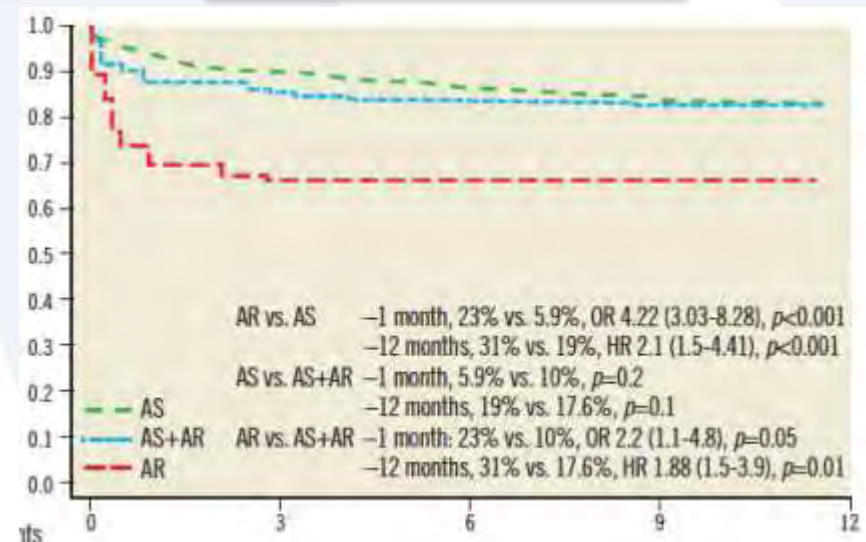
CoreValve implantation for severe aortic regurgitation: a multicentre registry

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Cardiovascular mortality



All cause mortality



The present study shows that TAVR may have a beneficial role, considering the ominous prognosis of inoperable patients

Summary

- Transcatheter aortic valve implantation (TAVI) is feasible in patients with AR.
- Patients with AR present specific technical issues during implantation considering that this subset of patients often shows a large LV outflow tract, large aortic roots and non calcified annulus.
- The possibility of requiring 2 valves and leaving residual aortic regurgitation remain important considerations.
- Probably specific devices with active fixation mechanisms could obtain best results.
- Only specifically designed studies may provide insights into this issue



Muchas gracias por su atención