

Infectious complications of new cardiovascular devices

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Disclosure of potential conflicts of interest

Emanuele Durante Mangoni, MD PhD

- My Institution has received research funding for my group from **MSD, Pfizer**
- I have received personal fees or participated in advisory boards or have been in the speaker's bureau of **Pfizer, MSD, Angelini, Bio-Merieux, Abbvie, Sanofi-Aventis, Medtronic, and DiaSorin.**

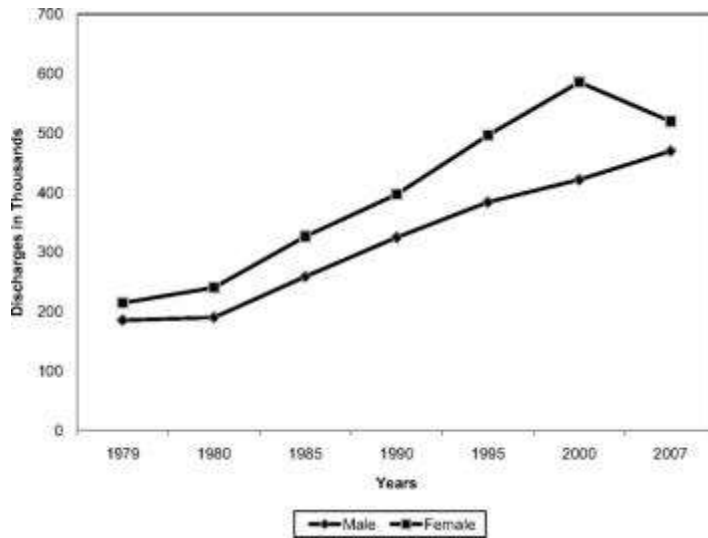
Heart Failure Epidemic

2% of people affected, worldwide
10% over 70 yrs

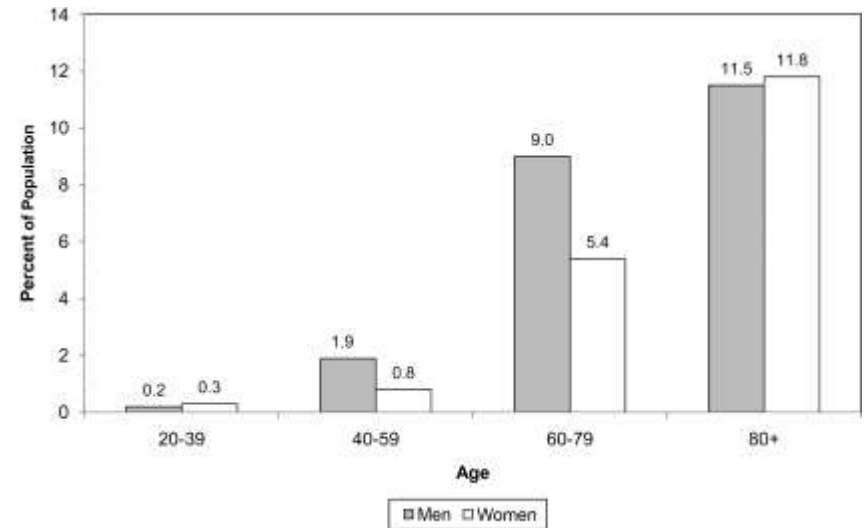
Spread of CV risk factors
Better care of Myocardial Infarction
Efficacy of HF drugs

—————→ Constant rise in incidence

**Hospital discharges for heart failure
(United States: 1979–2007)**



**Prevalence of heart failure by age
(National Health and Nutrition Examination Survey: 2005–2008)**



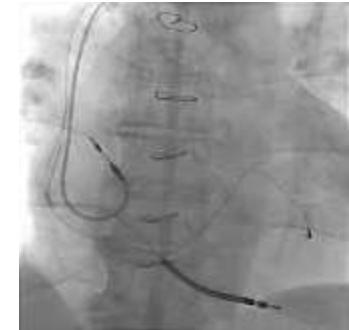
Increasing placement of Intracardiac Devices



PMK

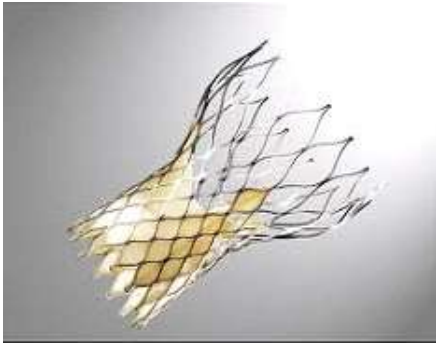


AICD



CRT-D/P

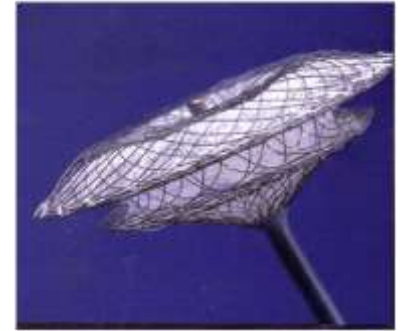
Increasing placement of new Intracardiac Devices



TAVI



MitraClip



**Septal closure
devices**



**Percutaneous
Pulm Valve**



**Leadless
TPS**

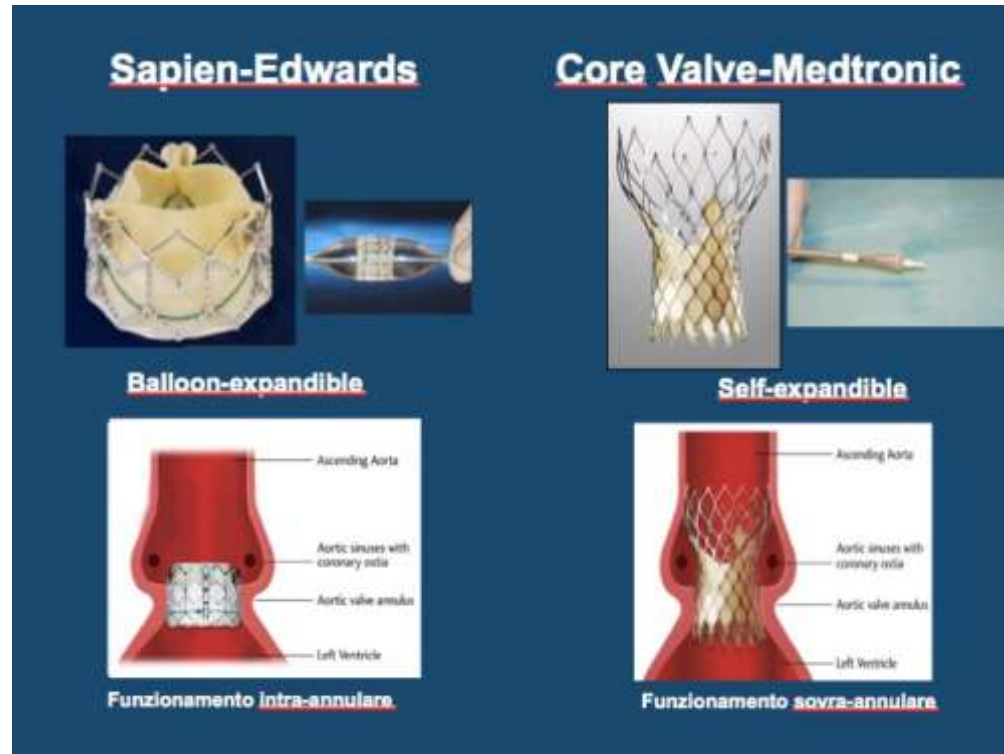


**Atrial Appendage
Closure devices**

Endocarditis on TAVI (transcatheter aortic valve implants)

Less PMK

More PMK





Infective endocarditis in patients with an implanted transcatheter aortic valve: Clinical characteristics and outcome of a new entity[☆]



Juan M. Pericas^{a,*,**}, Jaume Llopis^b, Carlos Cervera^a,

Study Design

- ❑ Literature Review: Pubmed search using the words “TAVI”, “TAVR” and endocarditis
- ❑ From 2009 to July 2013
- ❑ 56 cases (25 from large series and 31 from case reports).
- ❑ Statistical analysis of 31 cases:
 - ❑ Descriptive analysis
 - ❑ Risk factors for acquisition
 - ❑ Risk factors for mortality

TAVI Endocarditis: Risk Factors and Clinical Features

Advanced age median 81 yrs (78-85) M/F 1:1

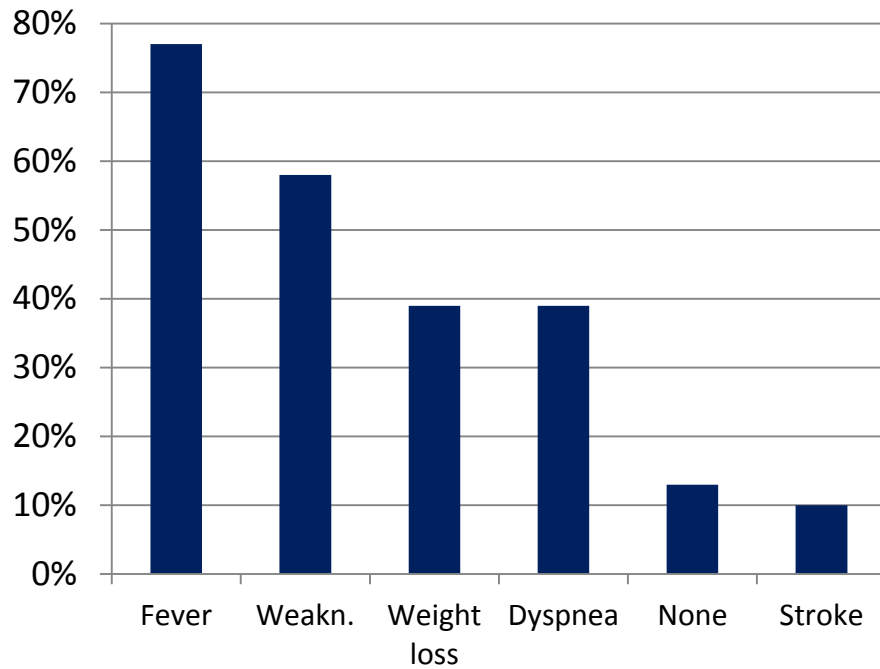
TAVI Endocarditis: Epidemiology

Acquisition

Nosocomial	39%
Health-care related	32%
Community (late onset)	29%

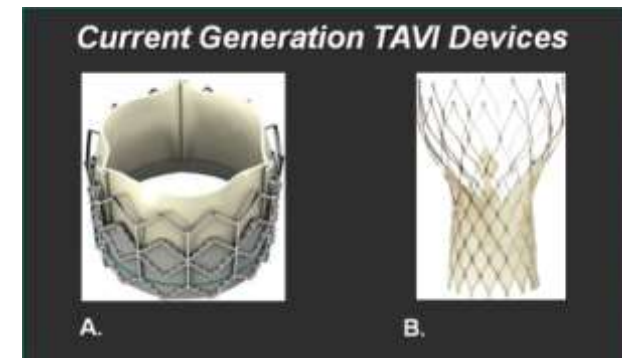
TAVI Endocarditis: Clinical Presentation

Symptoms

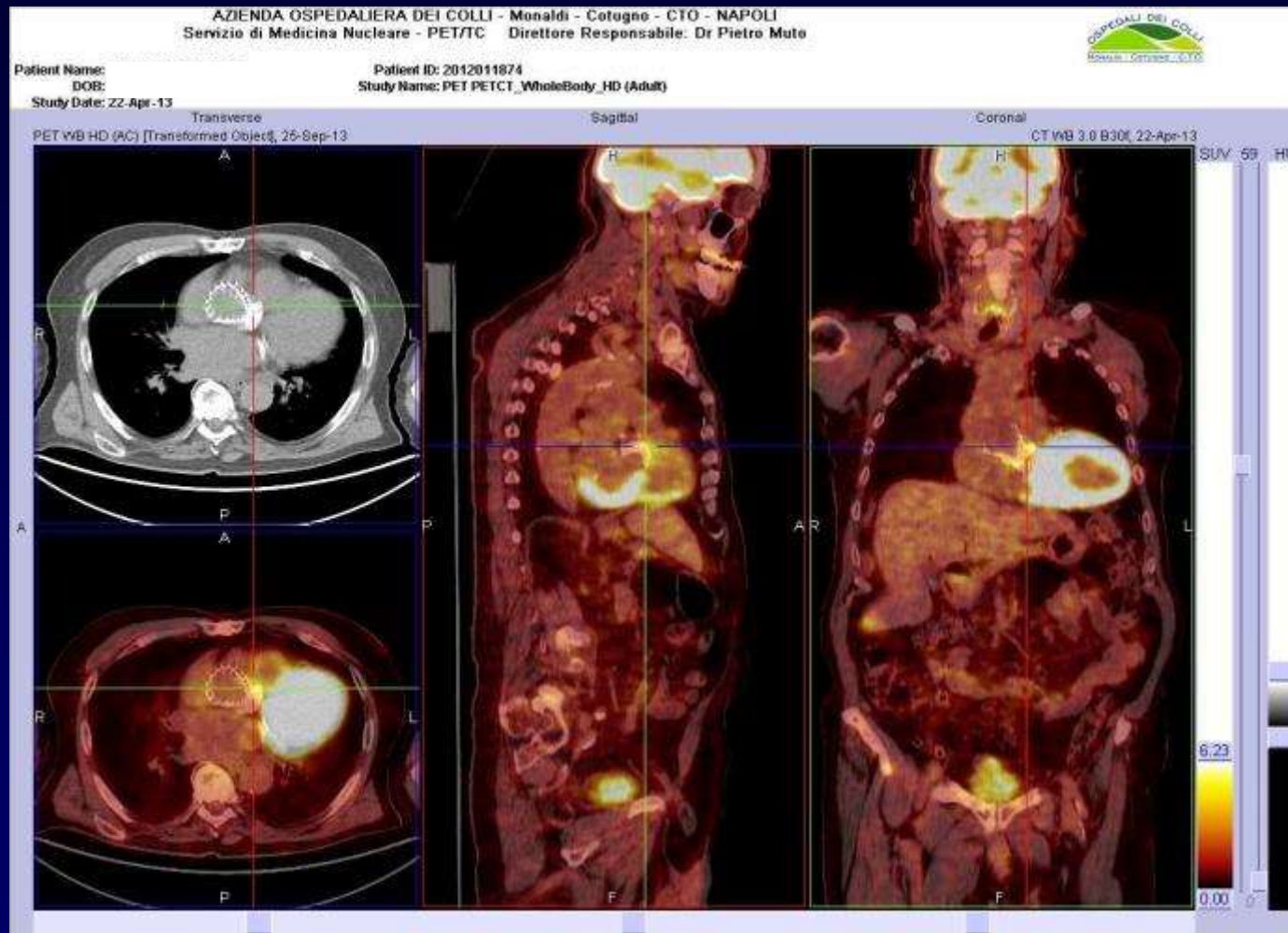


TAVI Endocarditis: Echocardiography

Presence of vegetations	52%
Vegetation size, median	15 mm
Perivalvular abscess/fistula	45%
Mitral valve vegetation	13%



18FDG-PET-CT scan: usefulness in TAVI-IE diagnosis



18FDG-PET-CT scan: usefulness in TAVI-IE diagnosis



SUV max = 4.5

TAVI Endocarditis: Treatment and Outcome

		Mortality = 35%
Antimicrobials alone	68% *	45%
Antimicrobials + Surgery	32%	10%

* long-term suppressive in 12%

Prosthetic Valve Endocarditis After Transcatheter Aortic Valve Implantation

by Niels Thue Olsen, Ole De Backer, Hans G.H. Thyregod, Niels Vejlstrup, Henning Bundgaard, Lars Søndergaard, and Nikolaj Ihlemann

18/509 patients with TAVI-PVE during a median follow-up period of 1.4 years

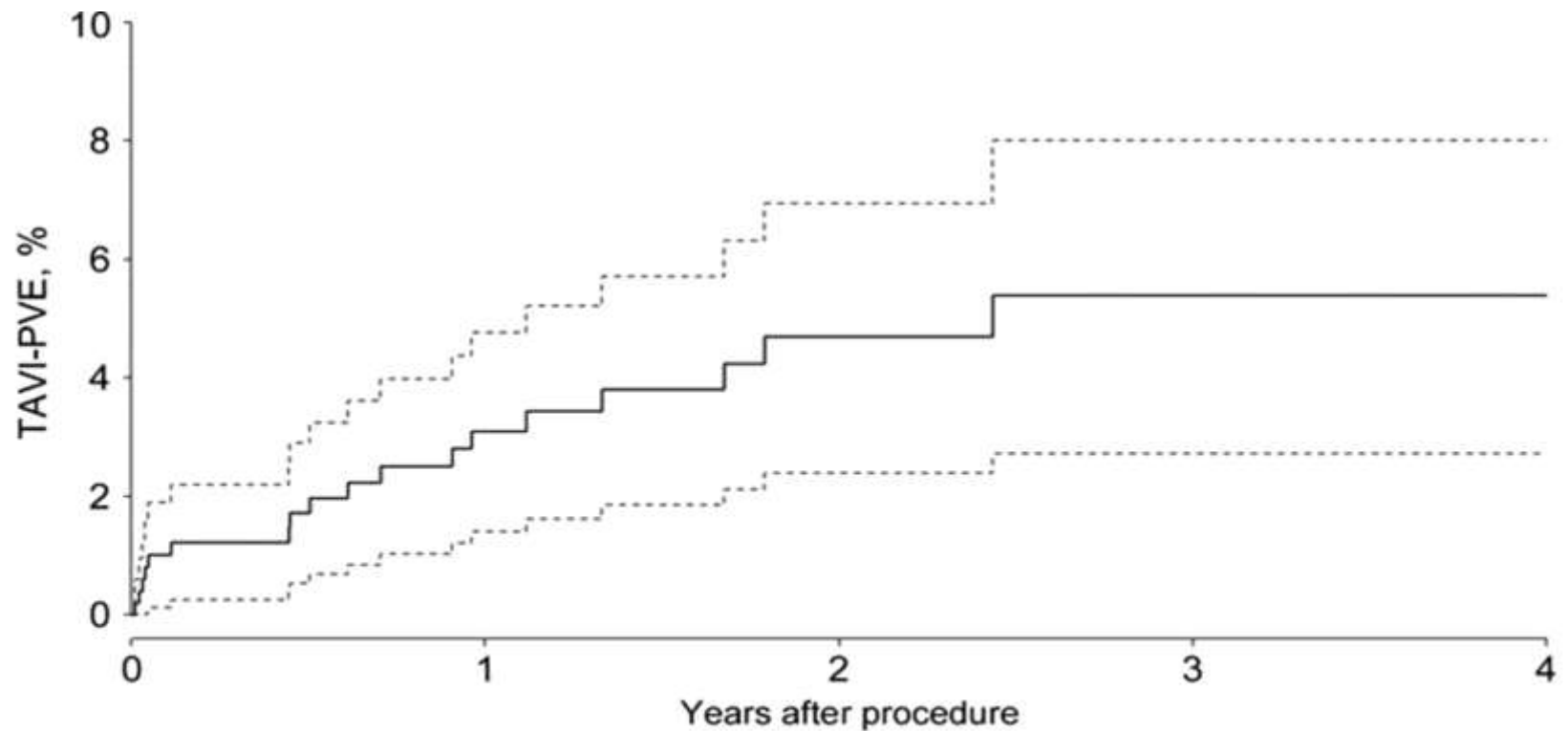
TAVI-PVE was most frequent in the first year after implantation

17 patients (94%) were treated conservatively and 1 with surgery

4 patients (22%) died from endocarditis or complications of treatment

*Circ Cardiovasc Interv
Volume 8(4):e001939
April 14, 2015*

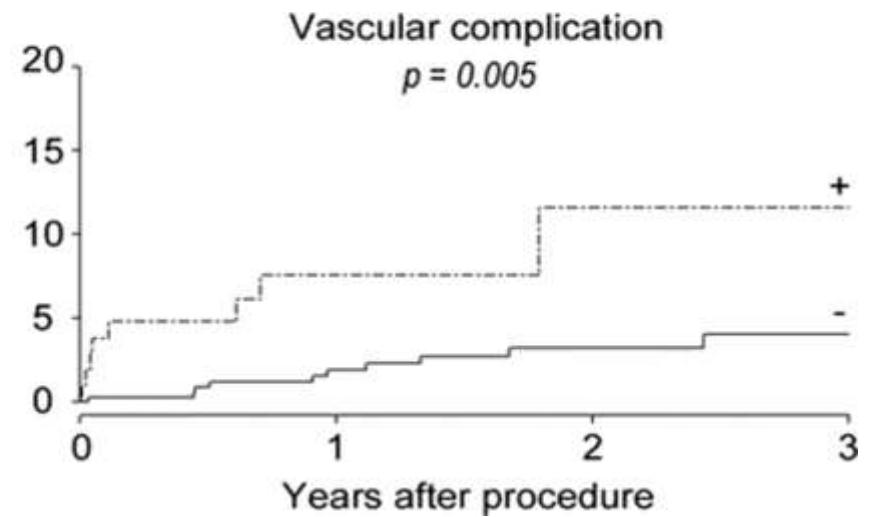
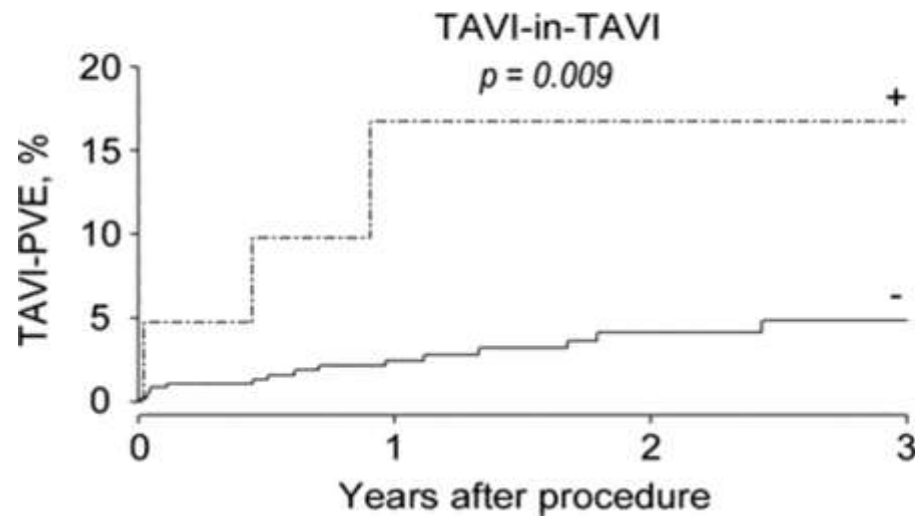
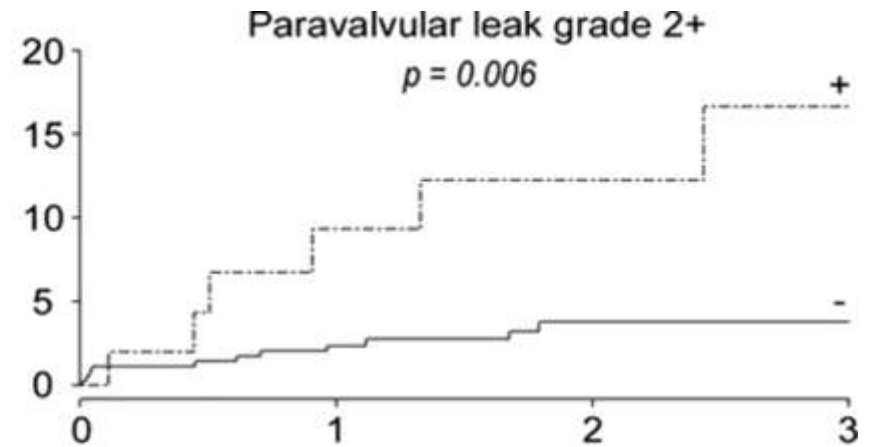
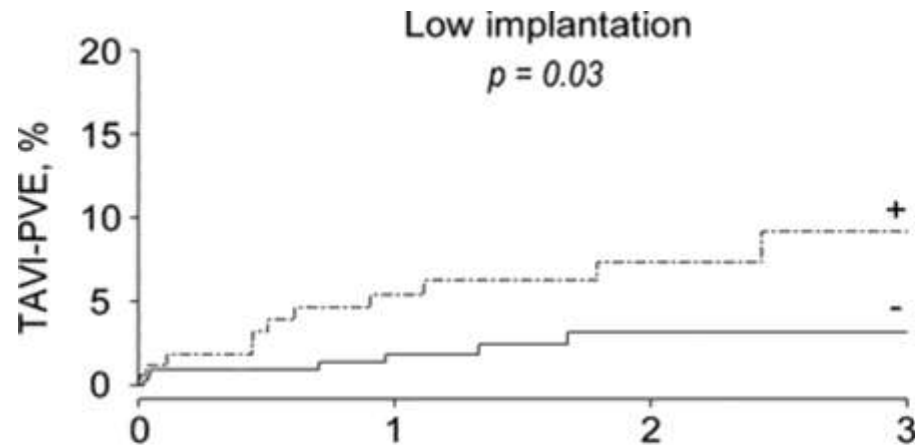
Kaplan–Meier estimate of overall transcatheter aortic valve implantation (TAVI) prosthetic valve endocarditis (PVE) incidence.



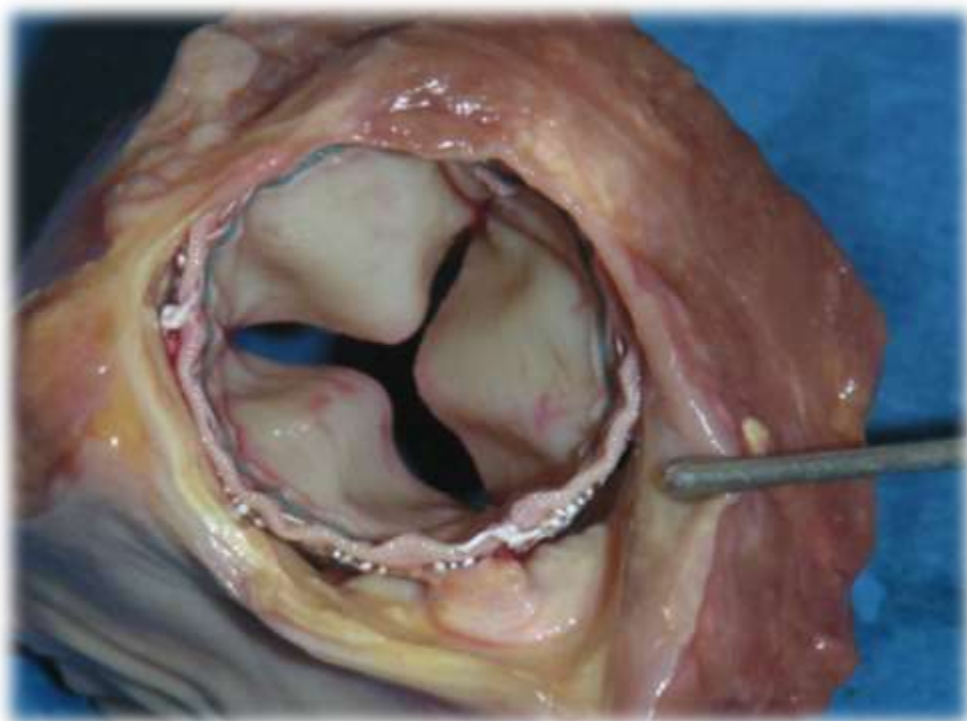
No. at Risk	509	318	182	99	37
No. events	-	13	17	18	18
Cum. incid.	-	3.1%	4.7%	5.4%	5.4%

Niels Thue Olsen et al. Circ Cardiovasc Interv. 2015;8:e001939

Kaplan–Meier curves for different procedural risk factors.



Niels Thue Olsen et al. Circ Cardiovasc Interv. 2015;8:e001939



Infective Endocarditis After Transcatheter Aortic Valve Implantation

Results From a Large Multicenter Registry

Ignacio J. Amat-Santos, MD; David Messika-Zeitoun, MD, PhD; Helene Eltchaninoff, MD;

Multicenter registry including 53 pat (mean age, 79±8 years; men, 57%) with TAVI-IE.

Mean time from TAVI was 6 months.

Self-expandable CoreValve (HR, 3.12; 1.37–7.14; $p=0.007$) was associated with IE.

Microorganisms were *CoNS* (24%), *S. aureus* (21%), *enterococci* (21%).

Vegetations present in 77% of patients (valve leaflets, 39%; stent frame, 17%; mitral valve, 21%).

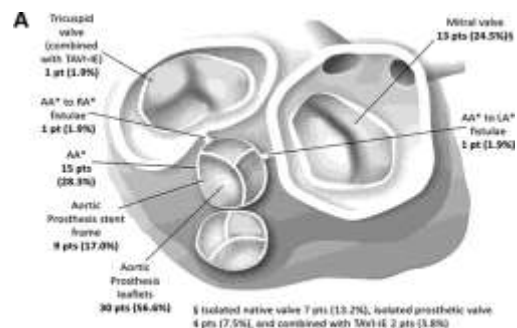
At least 1 complication of IE occurred in 87% of patients (heart failure in 68%).

Only 11% of patients underwent valve intervention (valve explantation and valve-in-valve procedure in 4 and 2 patients, respectively).

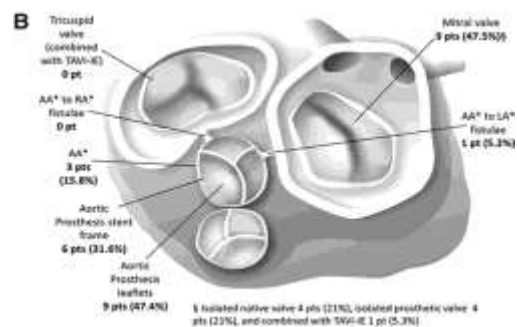
The mortality rate in hospital was 47.2% and increased to 66% at the 1-year follow-up.

IE complications such as heart failure ($p=0.037$) and septic shock ($p=0.002$) were associated with increased in-hospital mortality.

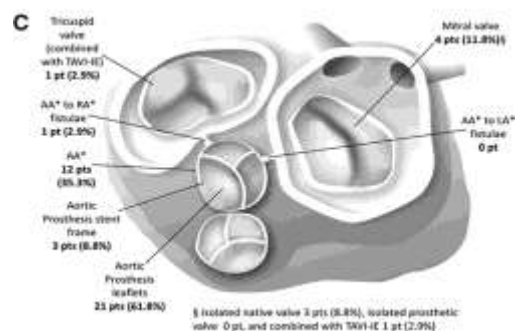
Schematic representation of the location of infective endocarditis (IE) in patients with previous transcatheter aortic valves



OVERALL (n=53)



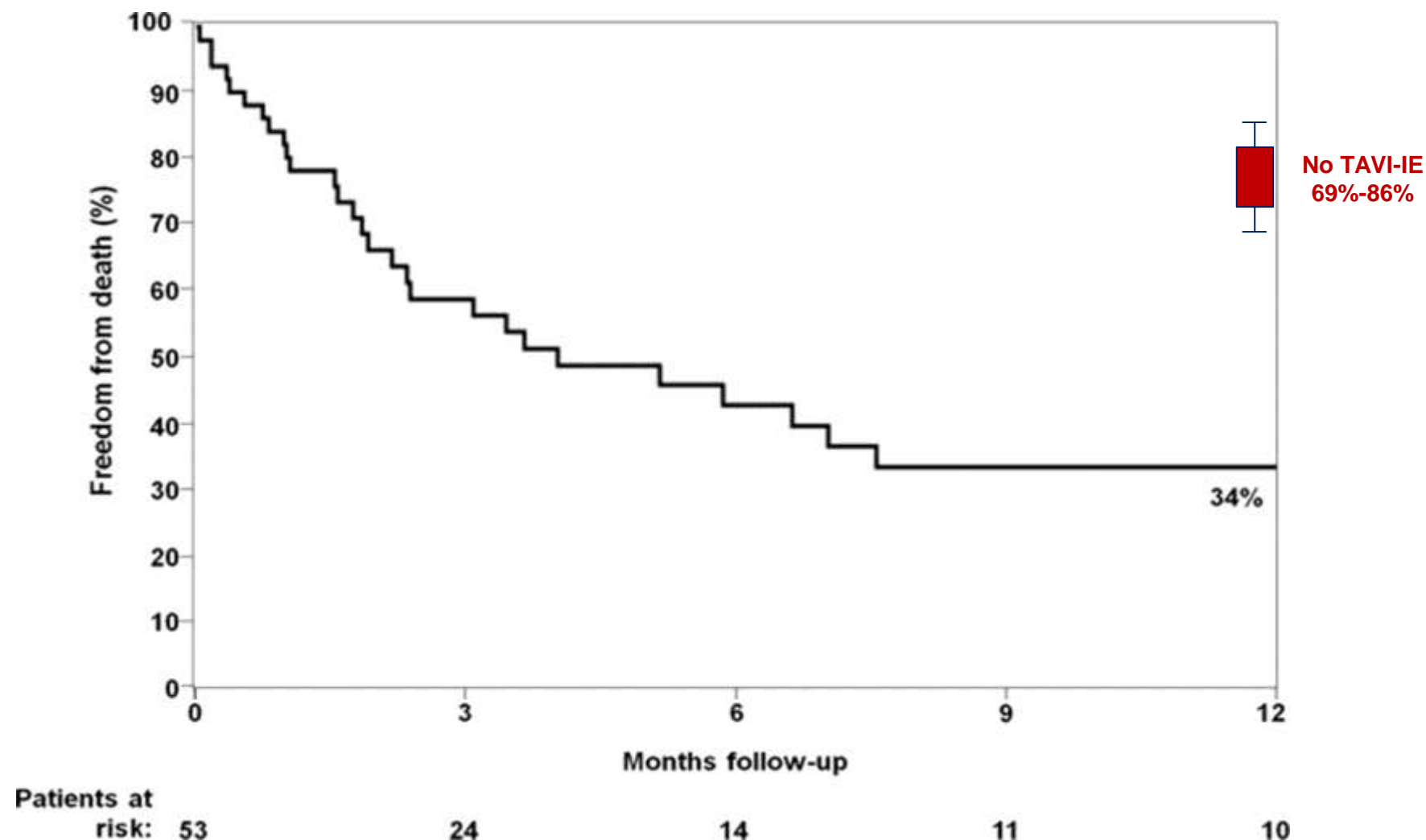
Self-expandable CoreValve (n=19)



Balloon-expandable Edwards valve (n=34)



Kaplan–Meier survival curves at the 12-month follow-up in patients diagnosed with infective endocarditis (IE) after transcatheter aortic valve implantation (time 0 represents the time of IE diagnosis)



MITRACLIP

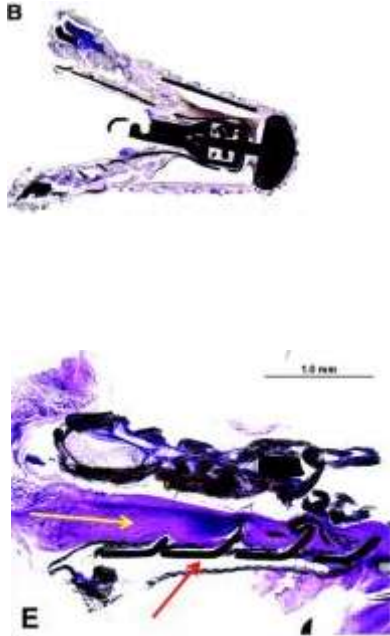
NEW OPTION FOR INOPERABLE SEVERE MITRAL REGURGITATION
(BOTH PRIMARY AND SECONDARY)



Histo-pathological Healing Response of Explanted MitraClip Devices

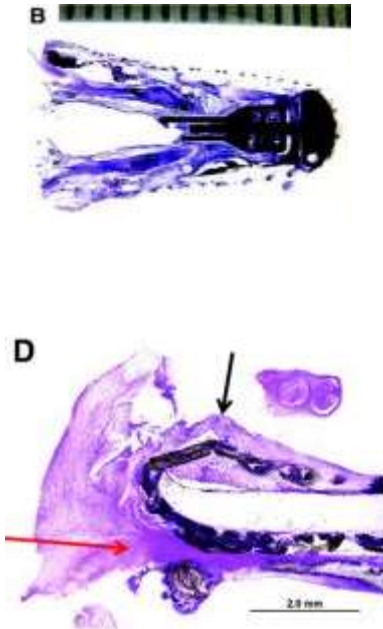
Clinical Perspective

Acute response (<30 days)



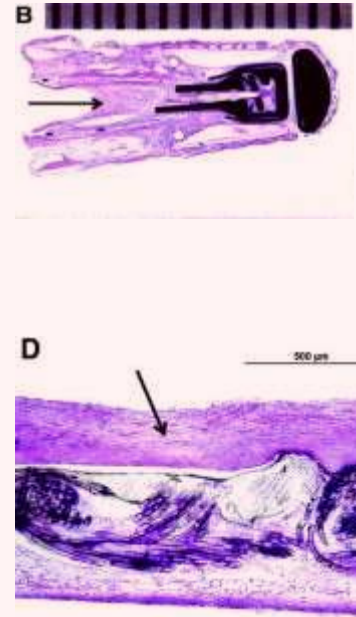
Fibrin & Platelets

Subacute response (31 to 90 days)



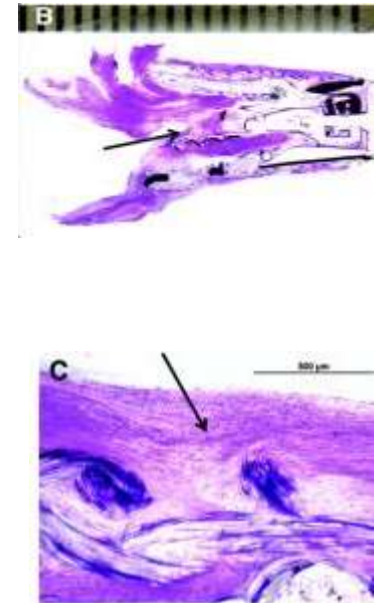
**Granulation tissue
Fibrous pannus**

Chronic response (91 to 300 day)

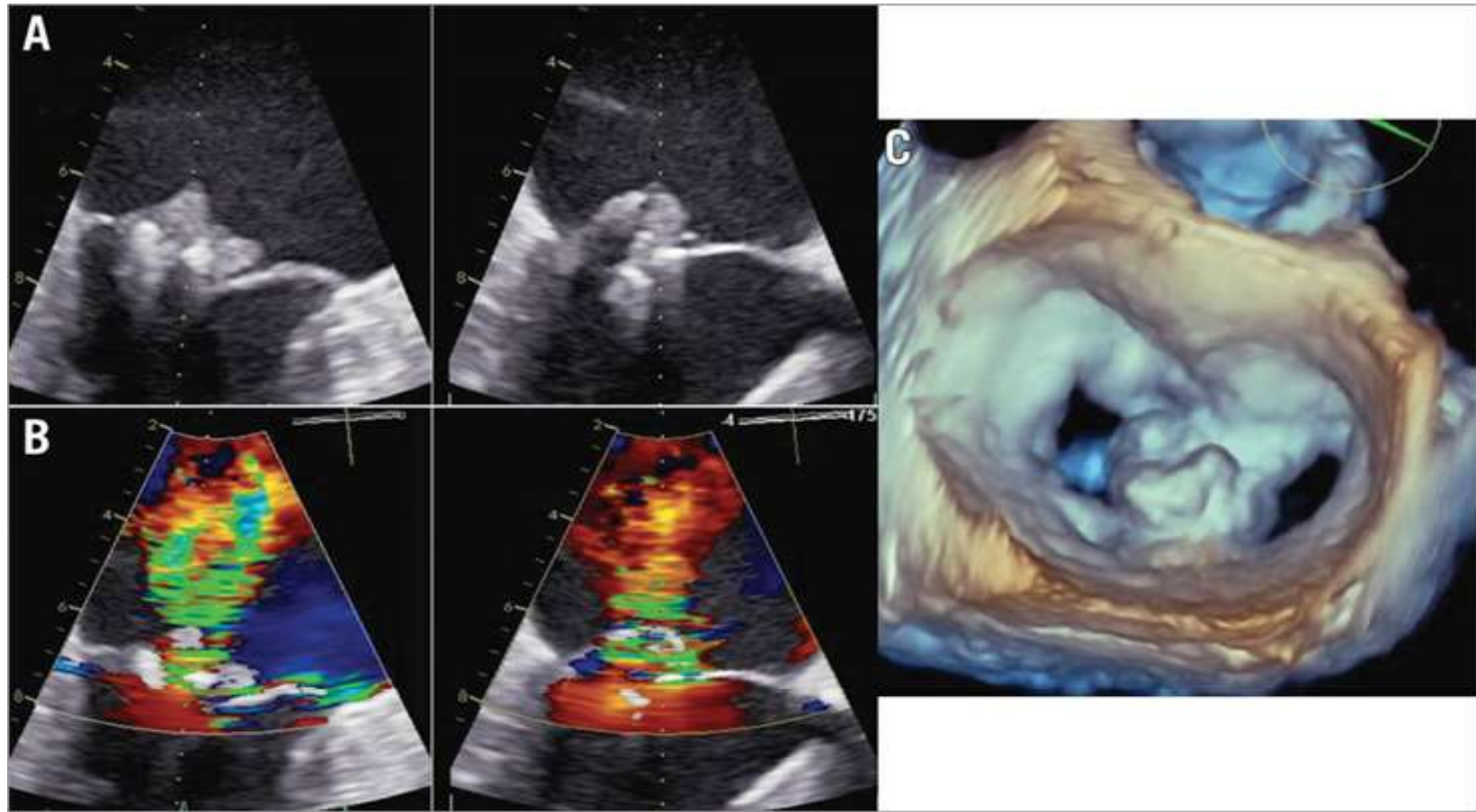


Bridges

Long-term response (>300 days)




**Collagen rich matrix
Complete encasement**



EuroIntervention 2015; 11(3):351-4.

Severe infective endocarditis after MitraClip implantation treated by cardiac surgery

Percutaneous Repair or Surgery for Mitral Regurgitation

	MITRACLIP	SURGERY
	N=184	N=95
 ENDOCARDITIS	2 (1.1%)	0 (0%)
GANGRENE	1 (0.5%)	0 (0%)
PNEUMONIA	5 (2.7%)	4 (4.2%)
SEPSIS	1 (0.5%)	1 (1.1%)
UTI	1 (0.5%)	0 (0%)
VIRAL INFECTIONS	1 (0.5%)	0 (0%)

Infective endocarditis following transcatheter edge-to-edge mitral valve repair: A systematic review

Lluís Asmarats MD, Tania Rodriguez-Gabella MD, Chekrallah Chamandi MD, Mathieu Bernier MD, Jonathan Beaudoin MD, Kim O'Connor MD, Eric Dumont MD, ... See all authors ▾

First published: 10 May 2018 | <https://doi.org/10.1002/ccd.27632>

Studies published 2003 to 2017

10 publications, 12 patients with definite IE (median age 76 years, 55% men)

Mean logistic EuroSCORE 41%

IE occurred **early (<12 months) in 9 patients (75%); <1 month in 5 patients (42%)**

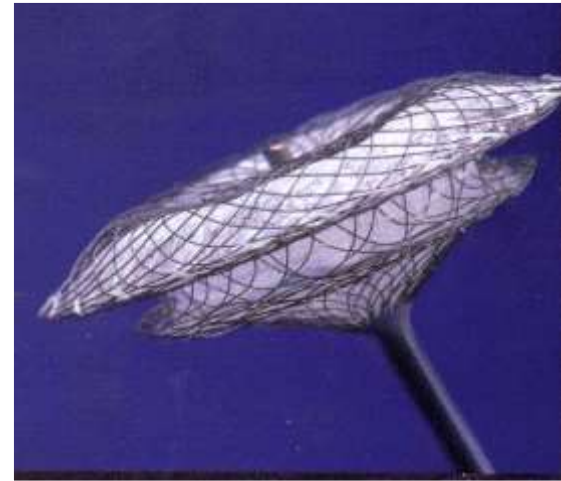
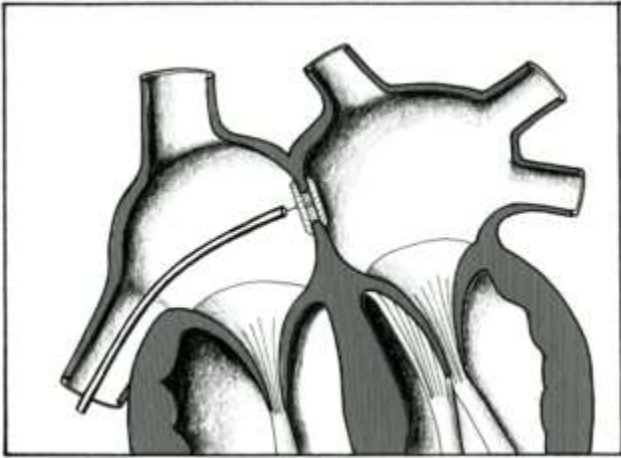
****Staphylococcus aureus** was the causal microorganism in 60% of cases**

****Severe mitral regurgitation** was present in 11 cases**

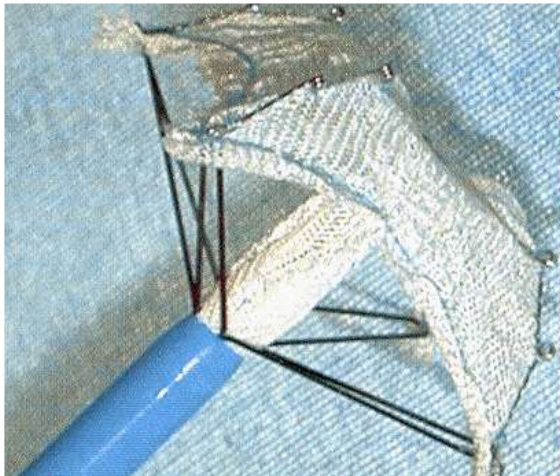
****Surgical MVR** was performed in 67% patients**

****Mortality** associated with the IE episode was 42%**

ASD & VSD closure devices



Amplatzer



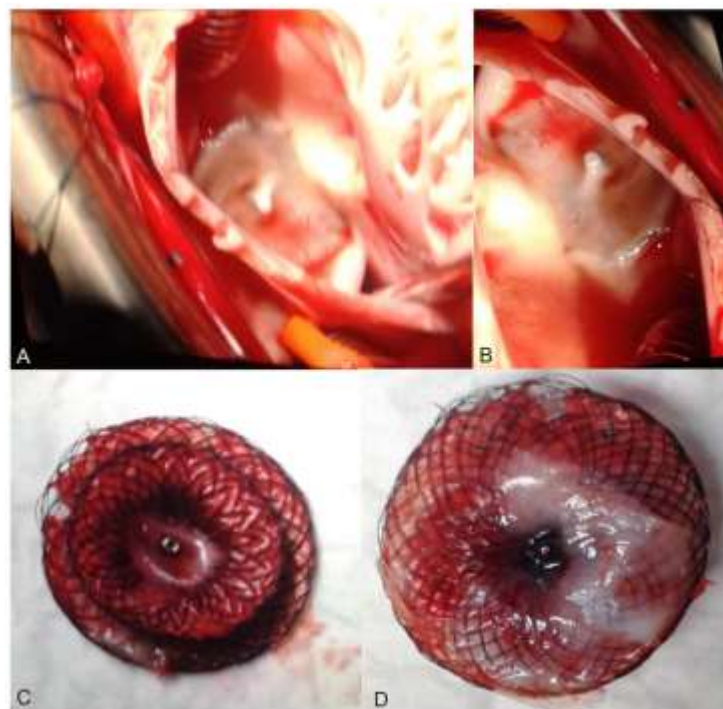
Starflex



Helex

Infective Endocarditis After Device Closure of Atrial Septal Defects: Case Report and Review of the Literature

Pascal Amedro,^{1,2*} MD, PhD, Camille Soulatges,¹ MD, and Alain Fraisse,³ MD, PhD



Endothelialization

Absent

5

Incomplete

3

Present

3

Not specified

10

Infective Endocarditis After Device Closure of Atrial Septal Defects: Case Report and Review of the Literature

Pascal Amedro,^{1,2*} MD, PhD, Camille Soulatges,¹ MD, and Alain Fraisse,³ MD, PhD

ASD closure device-related endocarditis (N=21 cases)

Patient age 1-76 years (median 42 yrs)

From 2 days up to 11 years after device implantation

Mainly Staphylococcus aureus (10 of 21 cases)

Vegetations: LA 10 cases; LA + RA 6 cases

Device surgically removed in 18 pts >> incomplete neo-endothelialization

2 patients died (9.5% - both surgical)

Infective Endocarditis After Device Closure of Atrial Septal Defects: Case Report and Review of the Literature

Pascal Amedro,^{1,2*} MD, PhD, Camille Soulatges,¹ MD, and Alain Fraisse,³ MD, PhD

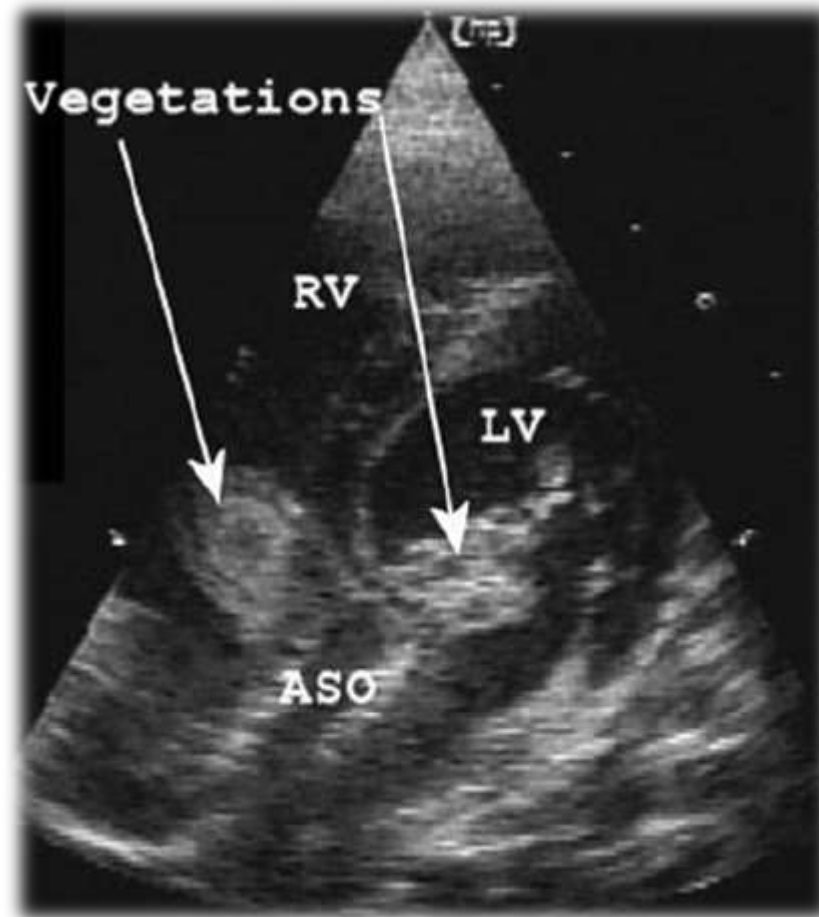
Treatment

Antibiotics only

3

Surgical removal of device

18



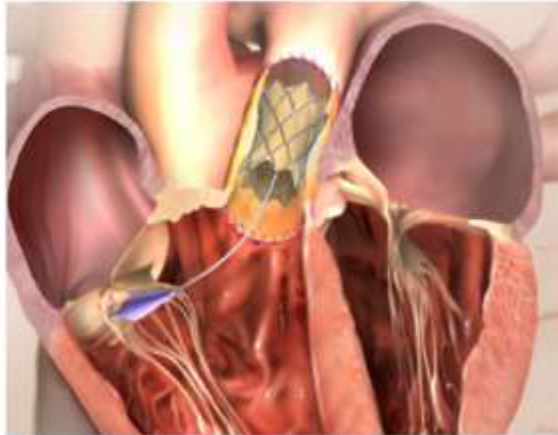
Growing issue

Surgically-/percutaneously corrected Congenital Heart Disease

- **Shunts, tubes, closing devices**
- **Many of these patients are young adults (GUCH)**

Percutaneous pulmonary artery valvulated conduits (for RV efflux disease)

18, 20, and 22 mm
double Balloons



Melody TPV n >5000



23 mm
SAPIEN



26 mm
SAPIEN



Edwards Sapien valves n >300

French national survey on infective endocarditis and the Melody™ valve in percutaneous pulmonary valve implantation

Expérience nationale française sur endocardite infectieuse et valvulation pulmonaire percutanée par Mélody™

Sophie Malekzadeh-Milani^{a,*}, Ali Houeijeh^b,

incidence of infective endocarditis

	Global
Number of patients	365
Mean follow-up (years)	3.3
Patient-years	ND
Number of patients with IE	43
Cumulative incidence of IE ^a	11.8 (8.5–15.9)
Annulized incidence of IE ^a	3.55 (0–4.77)

Mean interval between PPVI and

15 patients required intravenous
7 patients had early intervention
24 patients had surgical valve re-

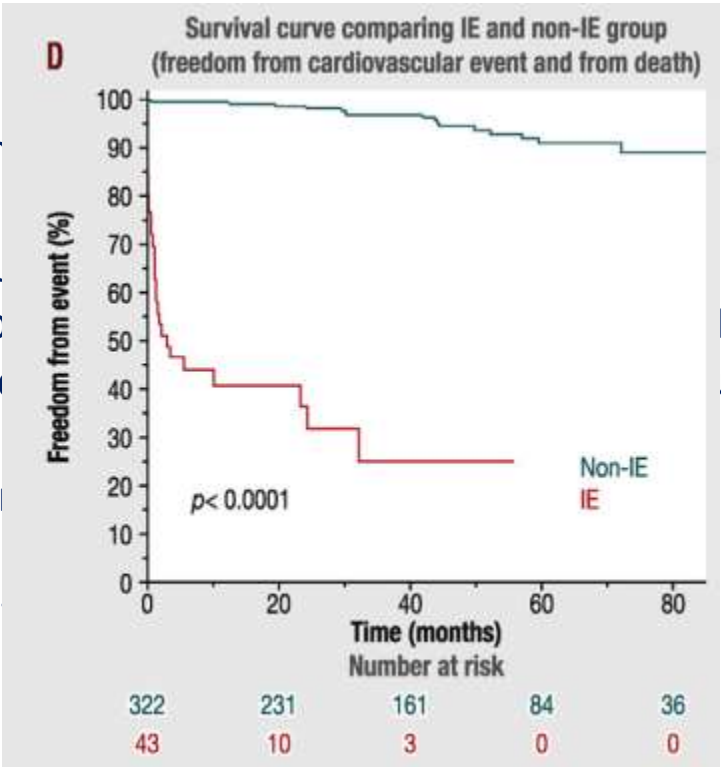
Staphylococcus aureus IE requi

3 pts died before any treatment

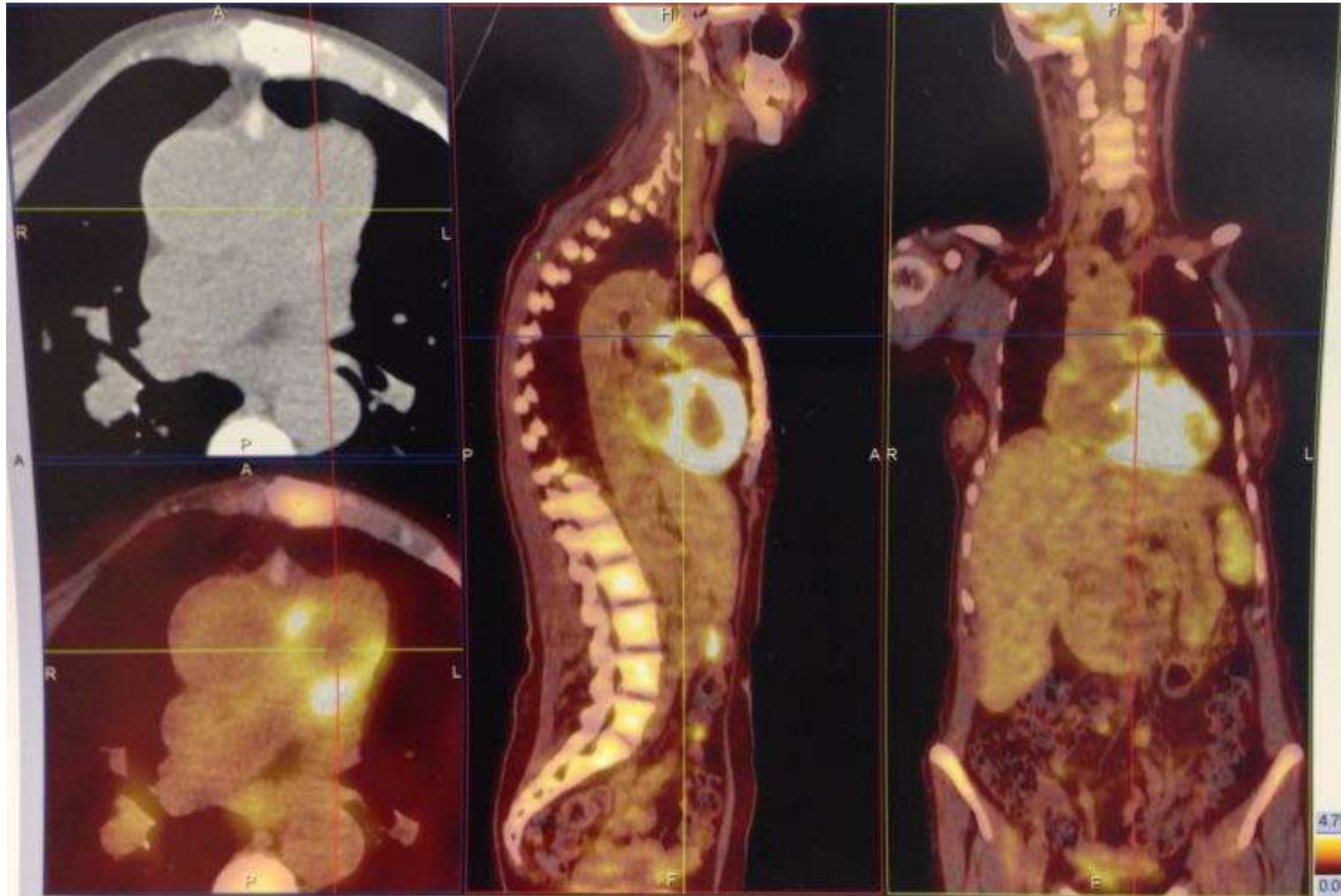
to 7.3 years).

RV outflow tract obstruction.
(urgently; nine electively).

mortality rate of 14%.



PET-CT scan in a ToF patient with pulmonary artery Contegra bioprosthesis valvulated graft



Micra - Leadless Trans-catheter Pacing System

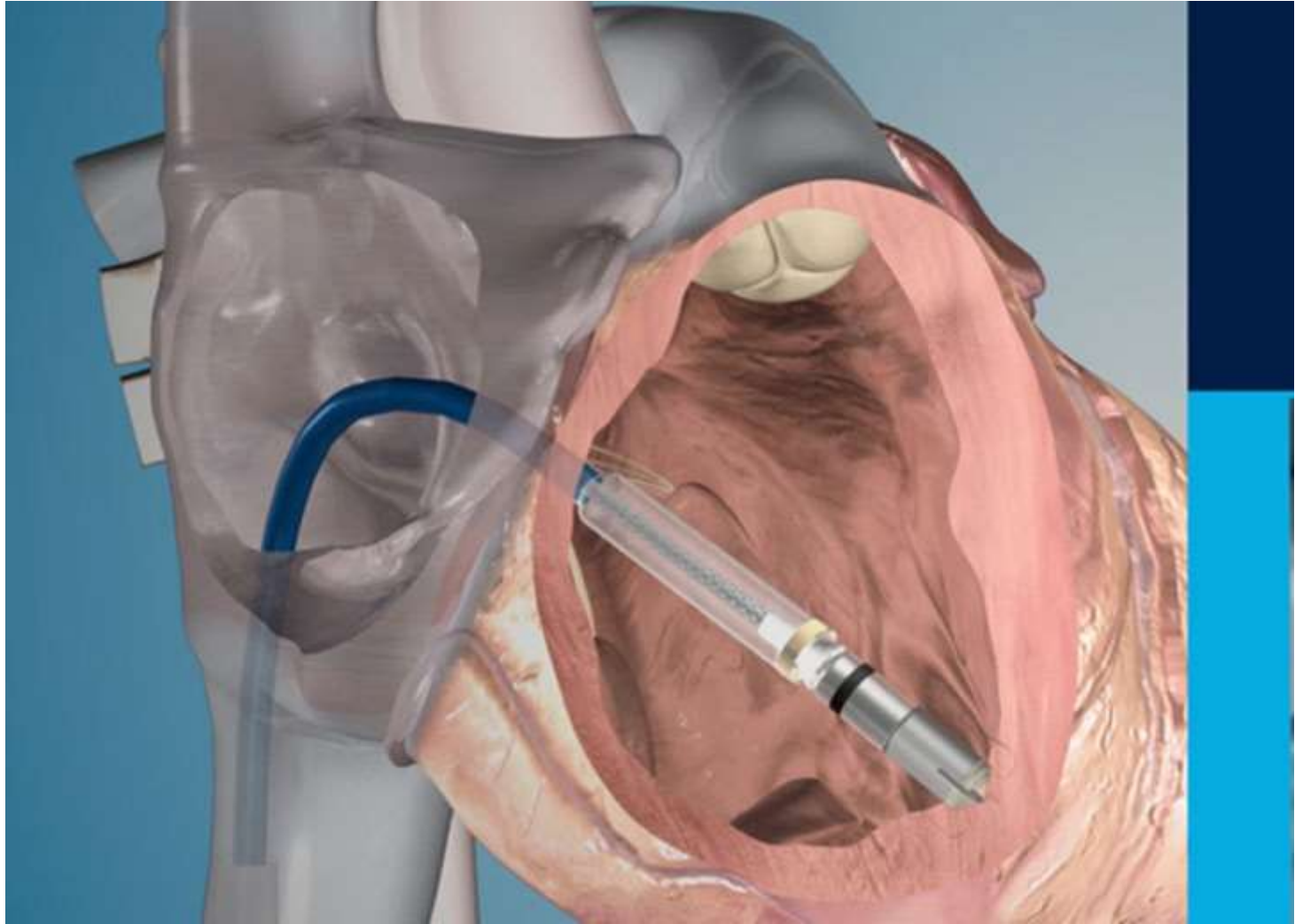








Figure 1: Images demonstrating the miniature size of the Micra™ Transcatheter Pacing System.



To retrieve, or not to retrieve: System revisions with the Micra transcatheter pacemaker

Eric Grubman, MD, FHRS,^{*} Philippe Ritter, MD,[†] Christopher R. Ellis, MD, FHRS,[‡]
Michael Giocondo, MD,[§] Ralph Augostini, MD, FHRS,^{||} Petr Neuzil, MD,[¶]
Bipin Ravindran, MD,[#] Anshul M. Patel, MD, FHRS,^{**} Pamela Omdahl, MBA,^{††}
Karen Pieper, BS,^{††} Kurt Stromberg, MS,^{††} J. Harrison Hudnall, BS,^{††}
Dwight Reynolds, MD, FHRS,^{††} for the Micra Transcatheter Pacing Study Group

the TVP group (123 revisions in 117 patients). TPS revisions occurred 5–430 days postimplant for elevated pacing thresholds, need for alternate therapy, pacemaker syndrome, and prosthetic valve endocarditis; none were due to device dislodgment or device-related infection. TPS was disabled and left in situ in 7 cases, 3 were retrieved percutaneously (range 9–406 days postimplant), and 1 was surgically removed during aortic valve surgery.

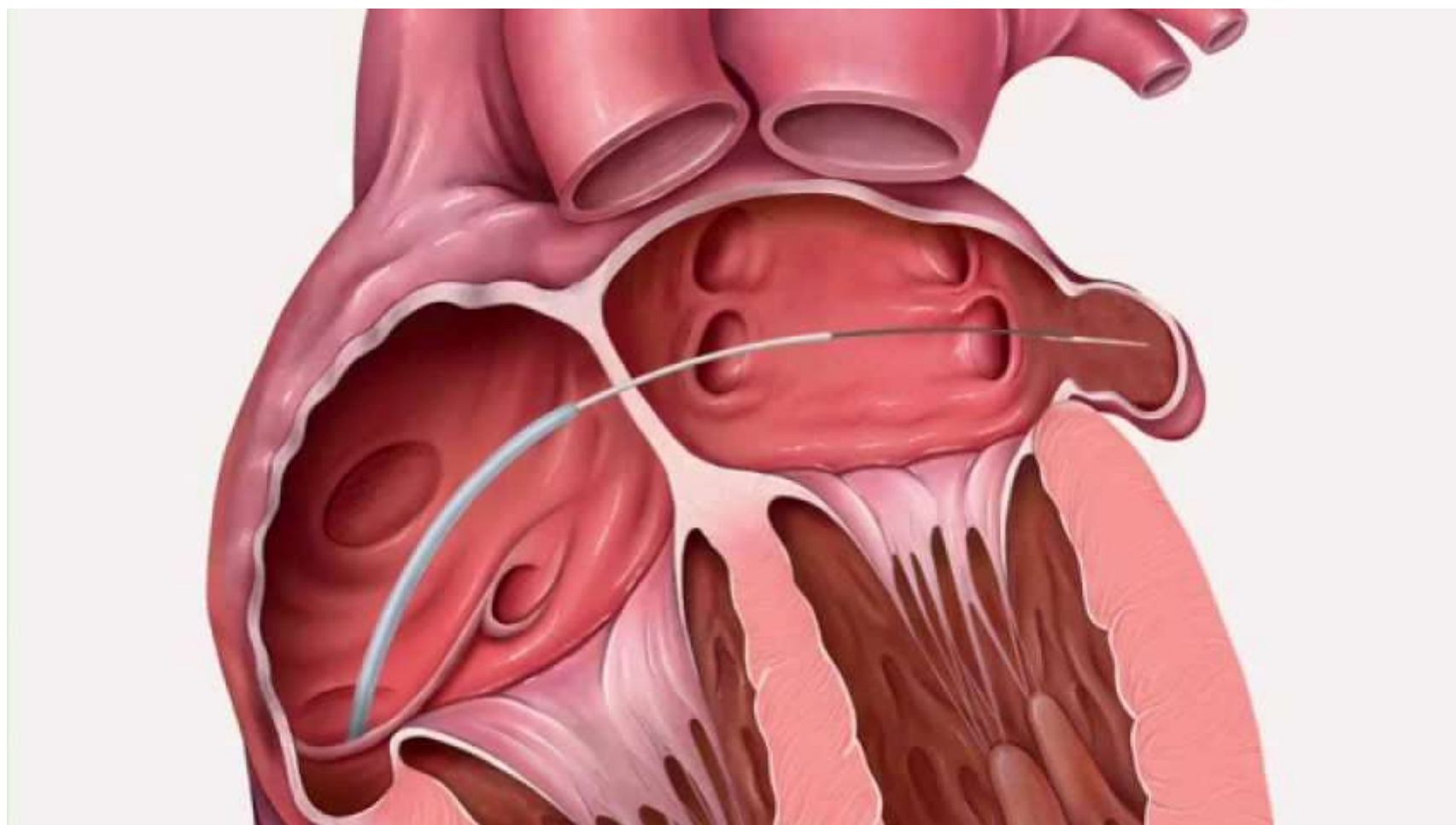
A leadless pacemaker in the real-world setting: The Micra Transcatheter Pacing System Post-Approval Registry ^e

Paul R. Roberts, MD,^{*} Nicolas Clementy, MD,[†] Faisal Al Samadi, MD,[‡] Christophe Garweg, MD,[§] Jose Luis Martinez-Sande, MD,^{||} Saverio Iacopino, MD,[¶] Jens Brock Johansen, MD, PhD,^{**} Xavier Vinolas Prat, MD,^{††} Robert C. Kowal, MD, PhD, FHRS,^{‡‡§§} Didier Klug, MD, PhD,^{||||} Lluís Mont, MD, PhD,^{¶¶} Jan Steffel, MD, FHRS,^{***} Shelby Li, MD,^{§§} Dirk Van Osch, MPH,^{†††} Mikhael F. El-Chami, MD, FHRS^{‡‡‡}

TPS implanted in 792 patients
149 implanters
96 centers
20 countries

Study end point:
system or procedure-related major complications
at 30 days post implant

repositioning. Sepsis was reported in 1 patient within 48 hours of the implant procedure and was successfully treated using intravenous antibiotics, without the need for device removal. There was no major complication related to telem-
suspect that the small size, lack of proximity to a cutaneous incision, and late encapsulation will all positively influence a reduced infection rate. Similarly, the rate of device



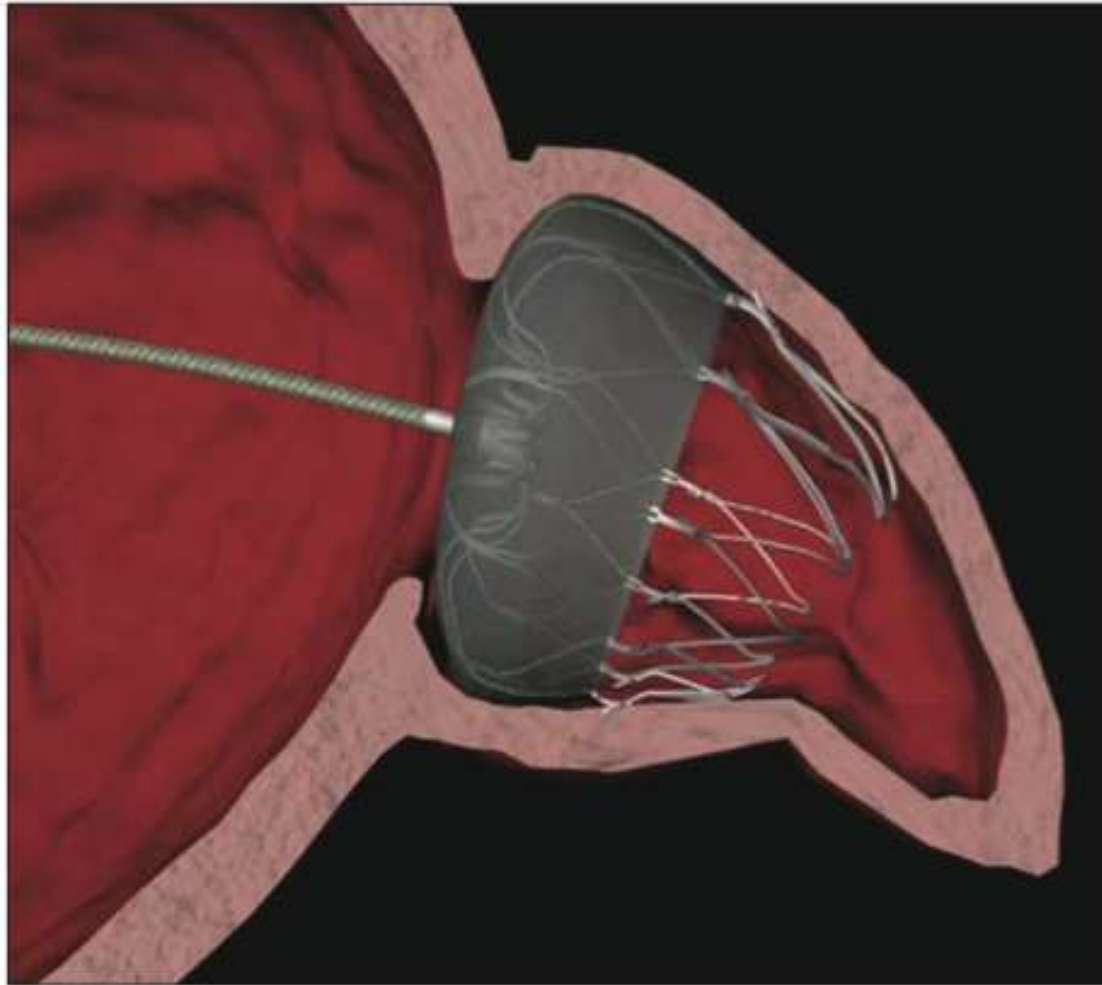
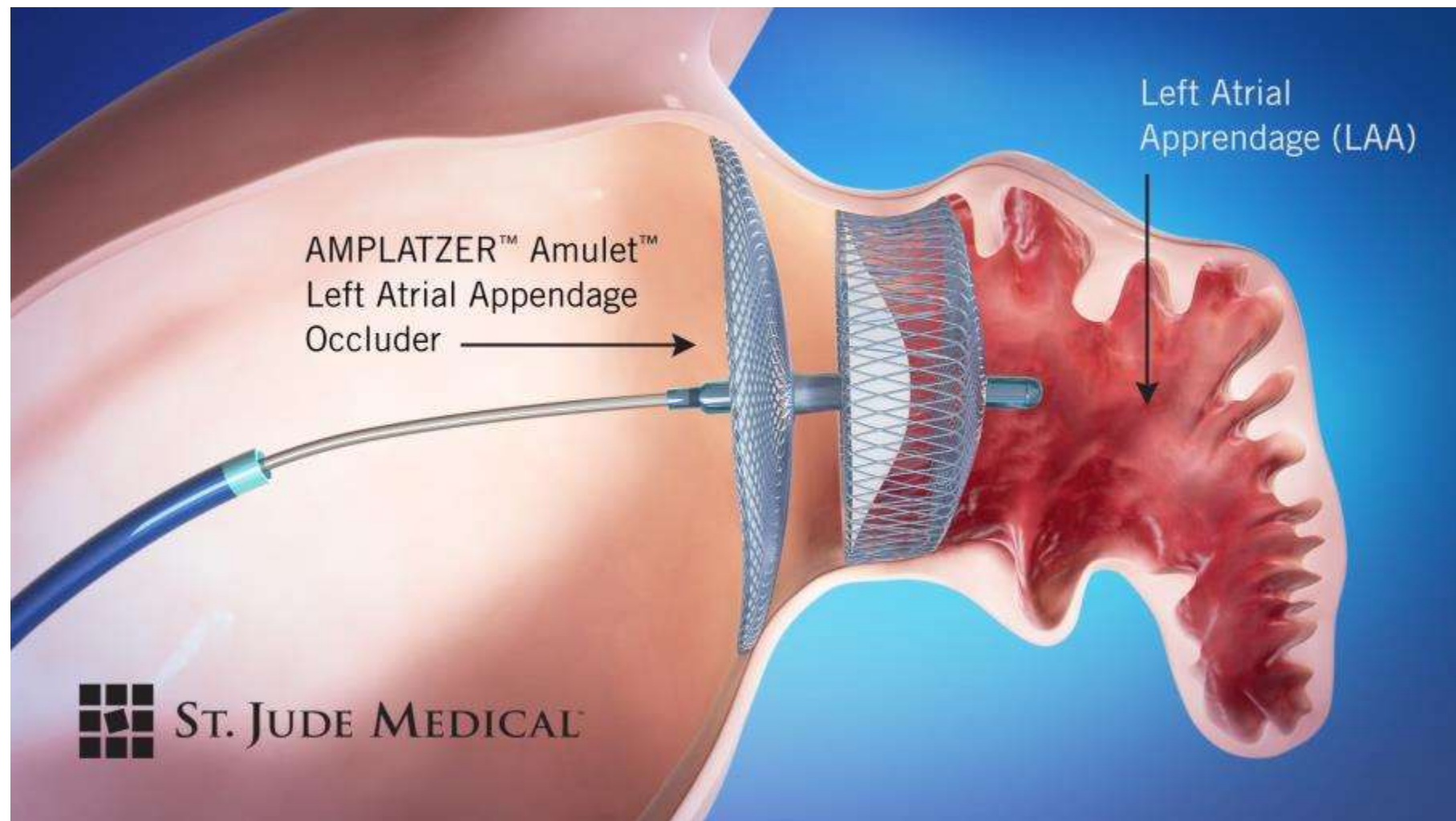


Figure 4:

Illustration of the placement of a WATCHMAN® LAA closure device (used with the permission of Atritech, Inc. ©2011).

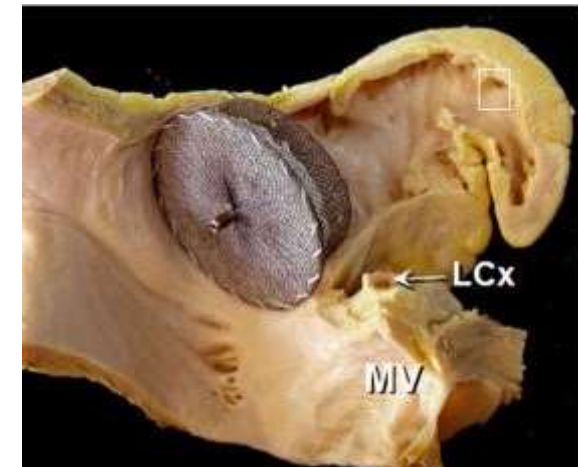
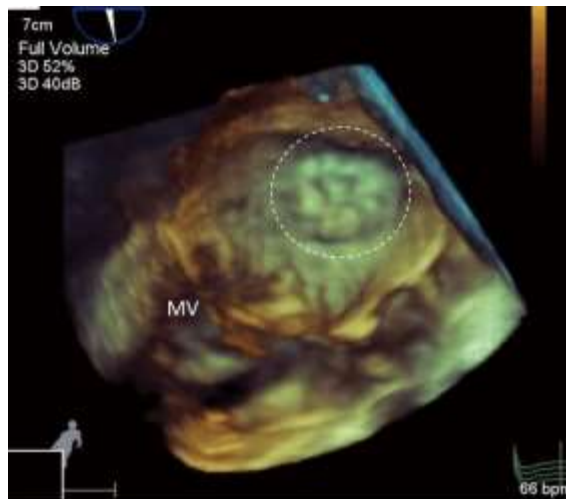


Convexity Subarachnoid Hemorrhage, Pseudomonas Aeruginosa (PA) Infective Endocarditis and Left Atrial Appendage Occluder (LAAO) Device Infection. A Case Report

Monique Boukobza^{1*}, Ibtissem Smaali¹, Xavier Duval² and Jean-Pierre Laissy³

The Open Neuroimaging Journal, 2017, 11, 26-31

IE located at the LAAO is an extremely rare complication. Two recent studies about feasibility and safety with the fourth generation watchman LAAOs failed to detect device infection [13]. Only one case of infection associated with atrial appendage occluder, occurring a few days after implantation has been reported (*staphylococcus aureus*) and was related to lack of sterile conditions during the procedure [9]. IE due to gram-negative bacilli (GNB) represents 4% of all



Transesophageal echocardiographic diagnosis of left atrial appendage occluder device infection

Taiyeb M. Khumri, Joseph B. Thibodeau, and Michael L. Main*

New CVD infectious complications: SUMMARY

- ❑ Growing implant rates cause a current steep increase of new CVD infections
- ❑ ID physicians should learn the different CVD features and be prepared to recognize their infection
- ❑ Tailored preventive measures should be put forward
- ❑ Diagnosis of CVD infection may be challenging, Duke University's criteria may be inaccurate, ESC 2015-based imaging modalities should be exploited
- ❑ Prognosis is poor, often worse than traditional prosthetic valve IE
- ❑ Therapeutic tools are targeted therapy, CVD removal, long term suppressive rx

