



Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

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PCR

First look at long-term durability of transcatheter heart valves:

Assessment of valve function up to 10-years after implantation

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Potential conflicts of interest

Speaker's name: Danny Dvir

☒ **I have the following potential conflicts of interest to report:**

Consultant: EDWARDS LIFESCIENCES, MEDTRONIC, ST. JUDE MEDICAL

- Transcatheter aortic valve implantation (TAVI) is increasingly performed in younger patients and in those at lower surgical risk.
- As a result, more patients are expected to survive long after transcatheter heart valve (THV) implantation.
- However, THV durability has only been assessed over the short- and intermediate-term.

**We aimed to evaluate the long-term risk
for THV degeneration after TAVI**

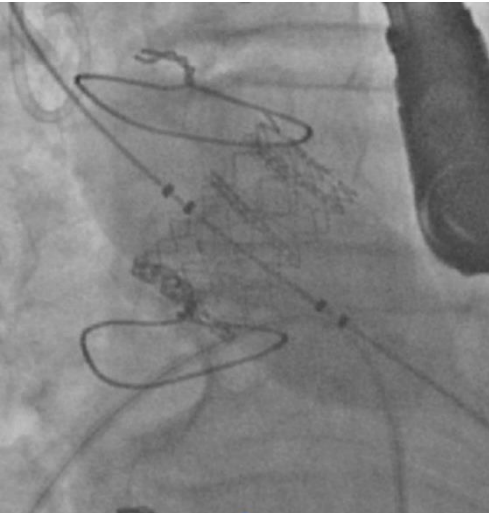
- The analysis consisted of patients that underwent TAVI more than 5 years ago: April 2002- April 2011 (range of time since TAVI: 5-14 years).
- **Sites:**
 - St. Paul's Hospital. Vancouver, Canada
 - Hôpital Charles Nicolle. Rouen, France
- **Inclusion Criteria:**
 - Patients that underwent TAVI before May 2011.
 - Balloon-expandable devices (Cribier Edwards, Edwards SAPIEN, SAPIEN XT).
- **Exclusion criteria:**
 - More than one THV implanted in the aortic position.
 - THV used to treat a failed surgical valve (valve-in-valve).
 - Device failure \leq 30 days after TAVI (\geq moderate stenosis OR regurgitation).
 - Patient mortality within \leq 30 days after TAVI.
 - Infective endocarditis in the aortic position after TAVI.
 - Non balloon-expandable THV devices.
 - Insufficient echocardiographic follow-up (\leq 90 days after TAVI)

- **Degeneration definition** in the current analysis:
At least moderate regurgitation AND/OR mean gradient $\geq 20\text{mmHg}$, which did not appear within 30 days of the procedure and is not related to endocarditis.
- Long-term echocardiographic exams performed during house visits.



Pathological examinations

2006: Edwards SAPIEN

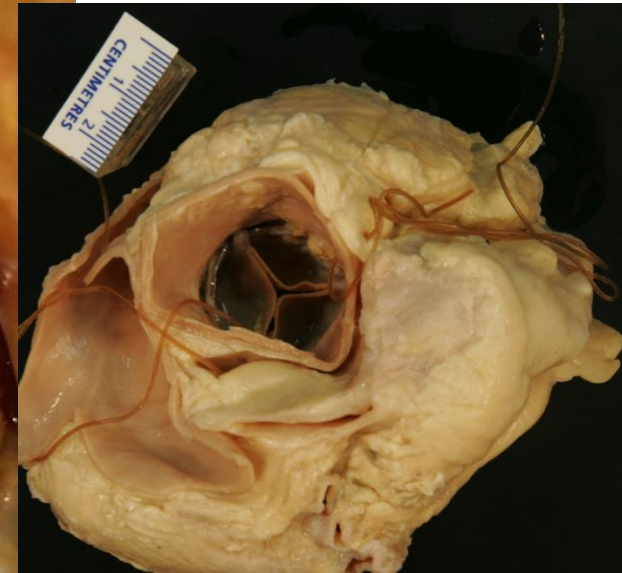
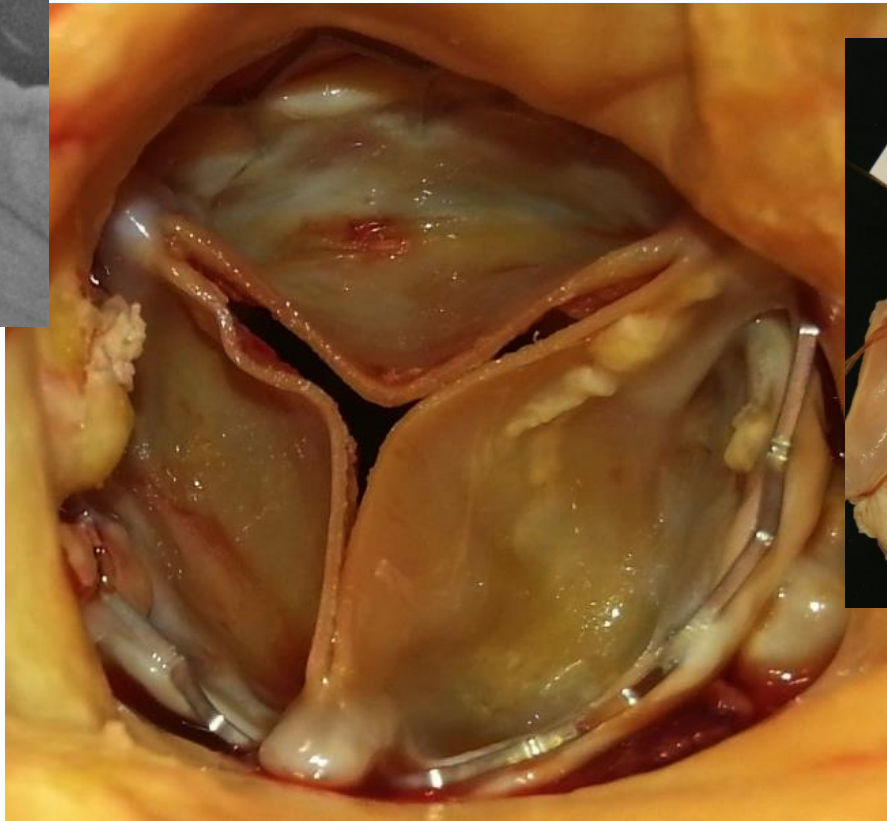


2013 (7-years post TAVI):

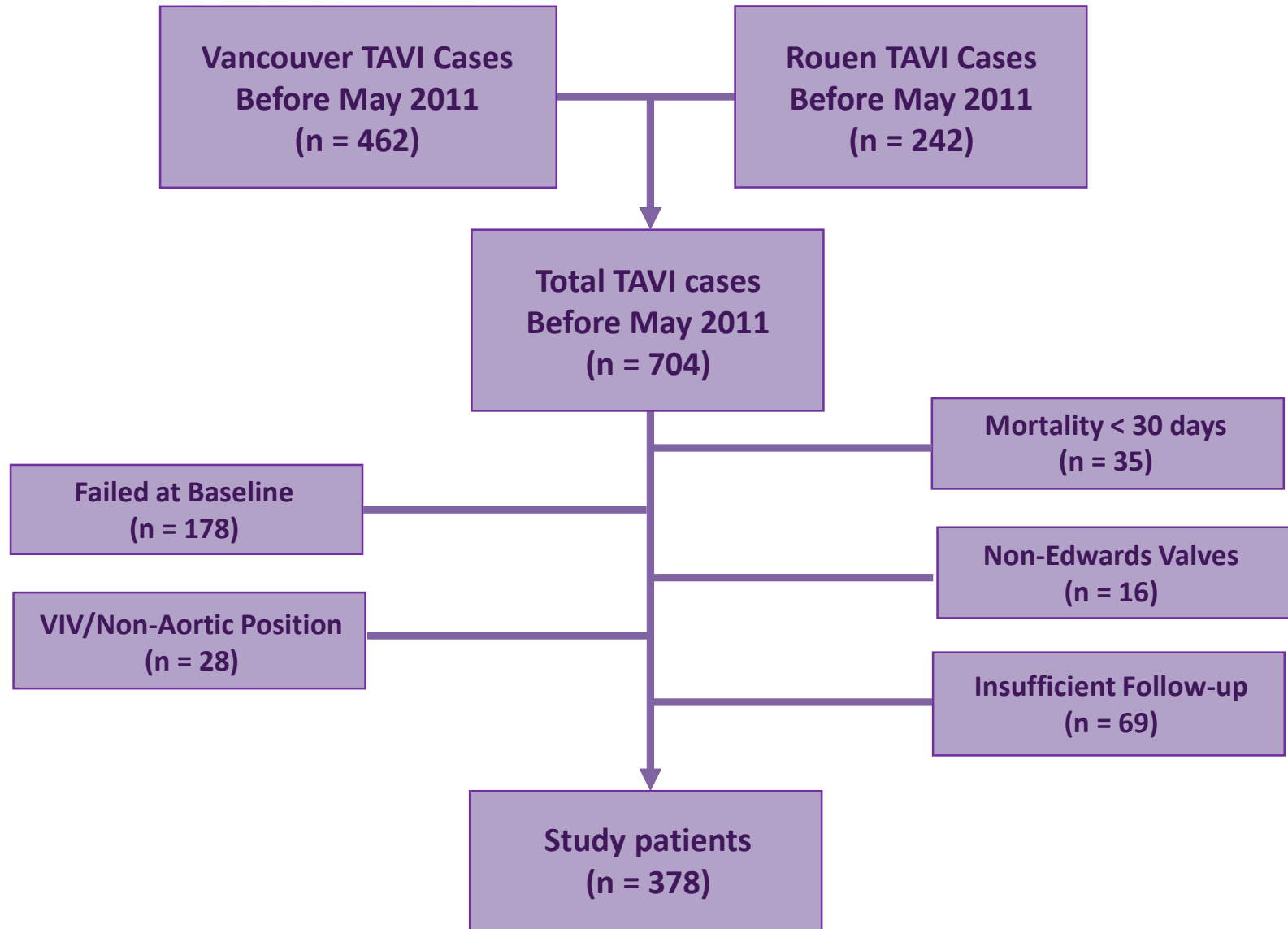
Non cardiac cause of death.

Minimal atheroma/calcification. Normal leaflet thickness.

Non-degenerated



Methods



Patient characteristics at TAVI

(n=378)

Baseline characteristics	
Age (years)	82.6 ± 7.5
Gender (female)	53.2%
Diabetes mellitus	26.7%
Hypertension	74.3%
Peripheral vascular disease	28.6%
Renal failure (GFR<60cc/min)	46.3%
Previous myocardial infarction	36.2%
Atrial fibrillation	39.6%
Previous Stroke	13.4%
Chronic lung disease	28.3%
Permanent pacemaker	15.6%
Coronary artery disease	63.8%
Previous bypass surgery	27.2%

Calculated risk scores	
EuroScore II	5 ± 4.5
STS PROM (%)	8.3 ± 4.9
Body size measures	
Height (cm)	165.6 ± 9.9
Weight (kg)	70.4 ± 15.9
Body mass index (kg/cm ²)	25.6 ± 5.1
Echo parameters	
Aortic valve area (cm ²)	0.65 ± 0.17
Aortic valve mean gradient (mmHg)	42.3 ± 16.3
Baseline LVEF (%)	55.1 ± 13.9
Aortic valve regurgitation	
None	15.0%
Mild	52.5%
Moderate	29.5%
Moderately Severe	2.5%
Severe	0.5%

Procedural characteristics and early outcomes (n=378)

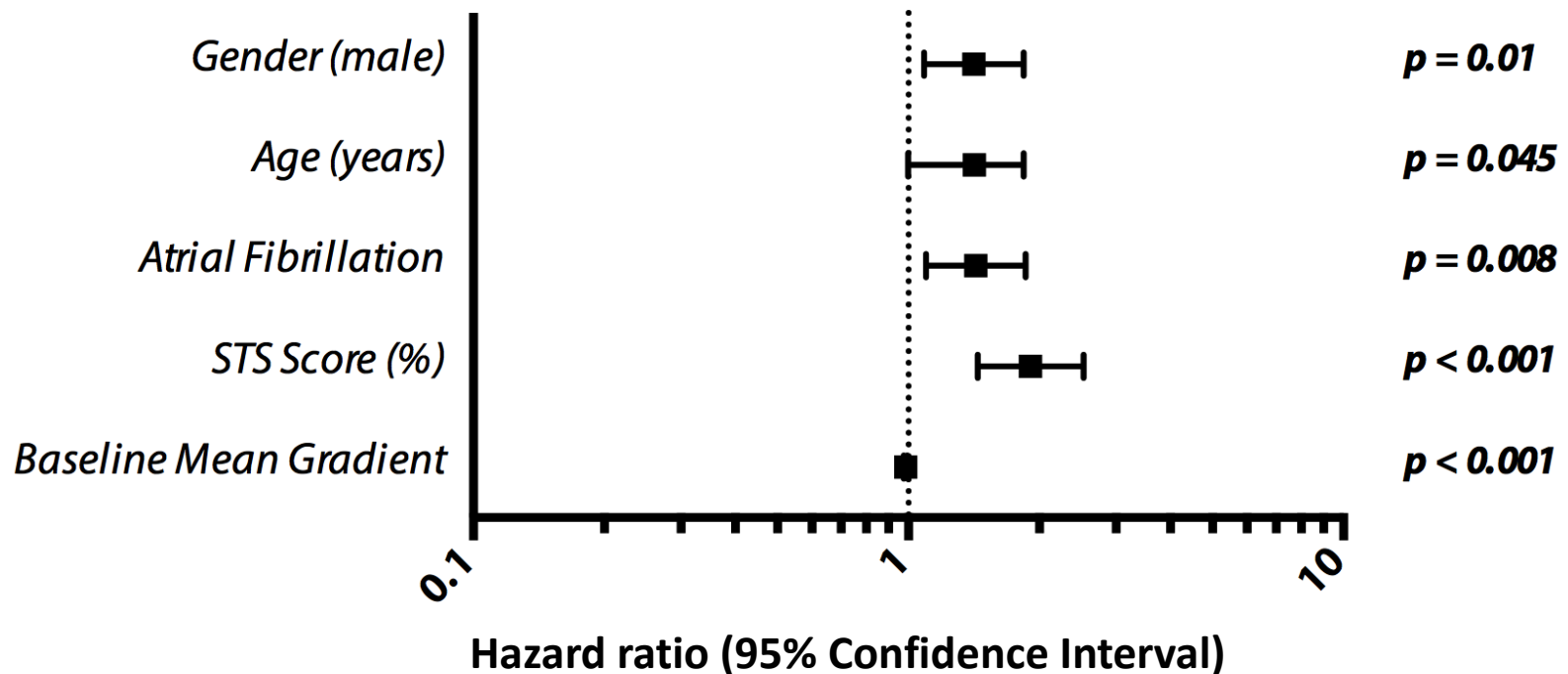
Procedural characteristics	
Transcatheter heart valve	
Cribier-Edwards	14.3%
Edwards SAPIEN	49.7%
SAPIEN XT	36.0%
Device diameter (mm)	24.9 ± 1.6
Access	
Transfemoral	68.5%
Transapical	28.7%
Transseptal	2.8%
General Anesthesia	89.2%
TEE usage	67.3%

30-day outcomes	
Vascular complication (VARC II)	
Minor	7.9%
Major	9.8%
Major / Life-threatening bleeding (VARC II)	14.0%
Major Stroke (VARC II)	1.6%
Need for pacemaker	8.0%
Warfarin Use at Discharge	31.6%
Aortic valve area (cm ²)	1.62 ± 10.1
Aortic valve mean gradient (mmHg)	10.1 ± 3.5
Left ventricular ejection fraction (%)	58 ± 12.6
Final aortic regurgitation	
None	28.0%
Mild	72.0%

Patient survival after TAVI

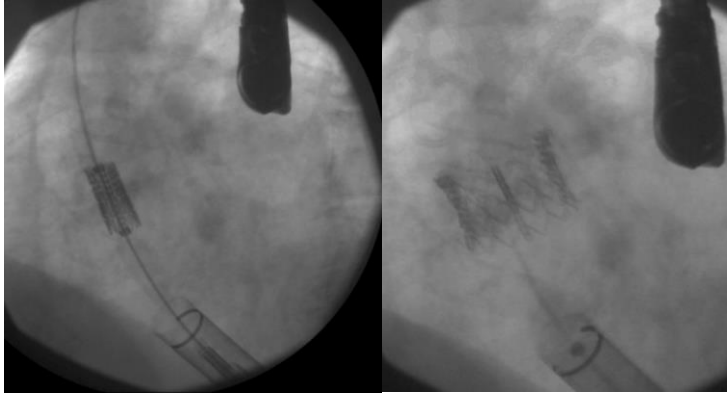
Median survival time was 51 months, IQR 22-75 months.
2 patients survived 10 years

Correlates for mortality after TAVI



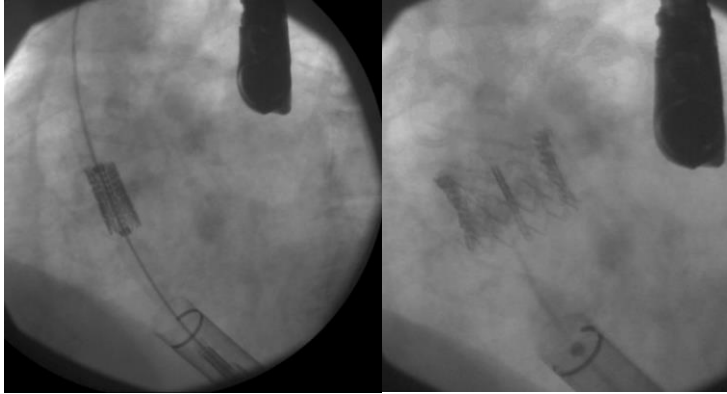
10-year follow up after TAVI

2006- Cribier Edwards



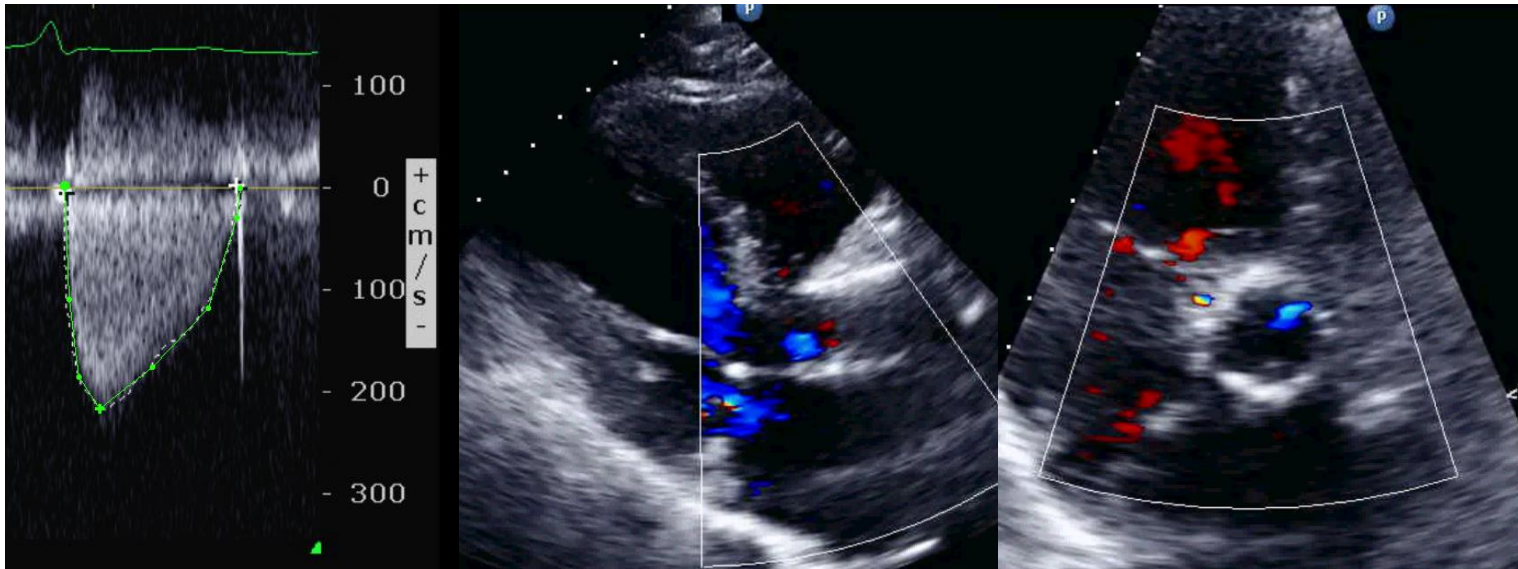
10-year follow up after TAVI

2006- Cribier Edwards



2016

(10 year post TAVI):
97 year-old Female
NYHA II

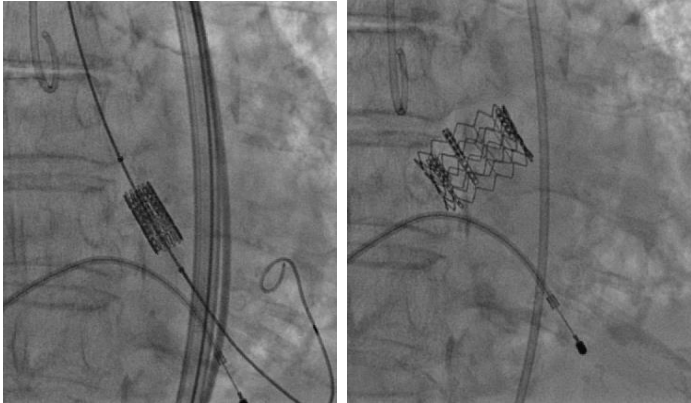


Mean gradient 10mmhg (LVEF 50%).

Mild AR

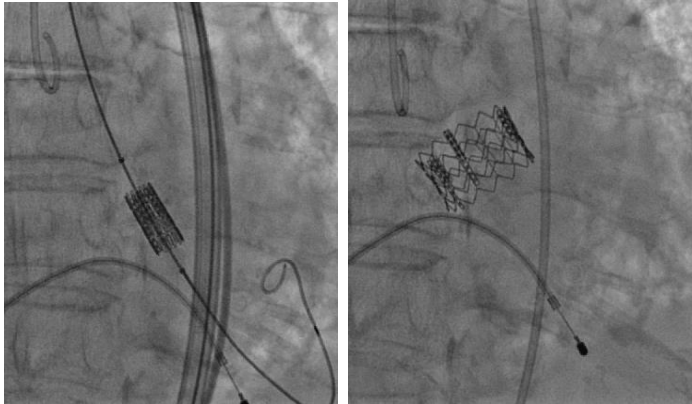
10-year follow up after TAVI

2006- Cribier Edwards



10-year follow up after TAVI

2006- Cribier Edwards

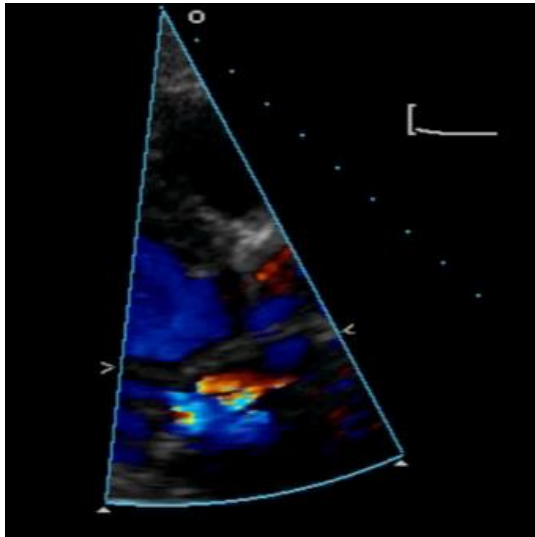


2016

(10 year post TAVI):
96 year-old Female
NYHA III

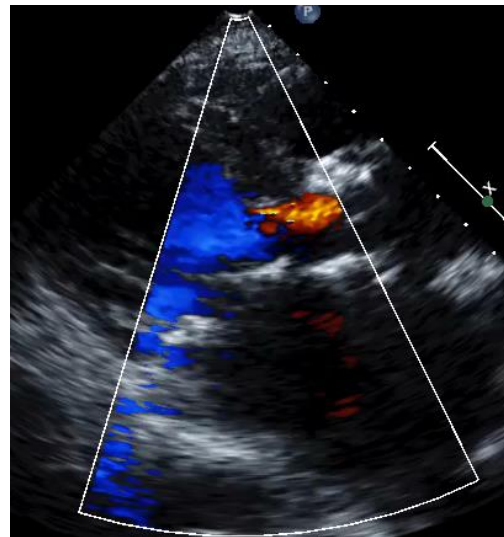


1 year post TAVI

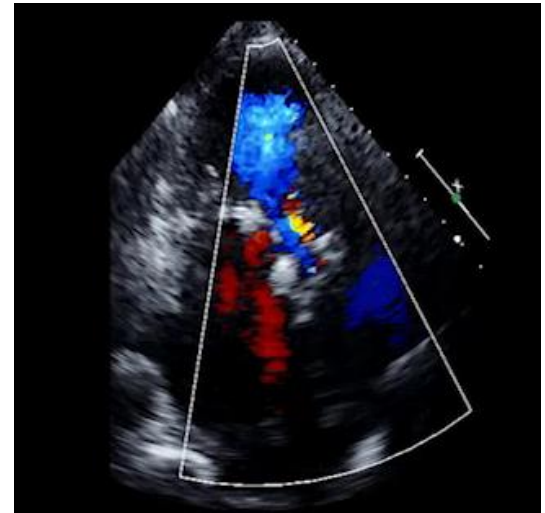


Trivial AR

6 years post TAVI

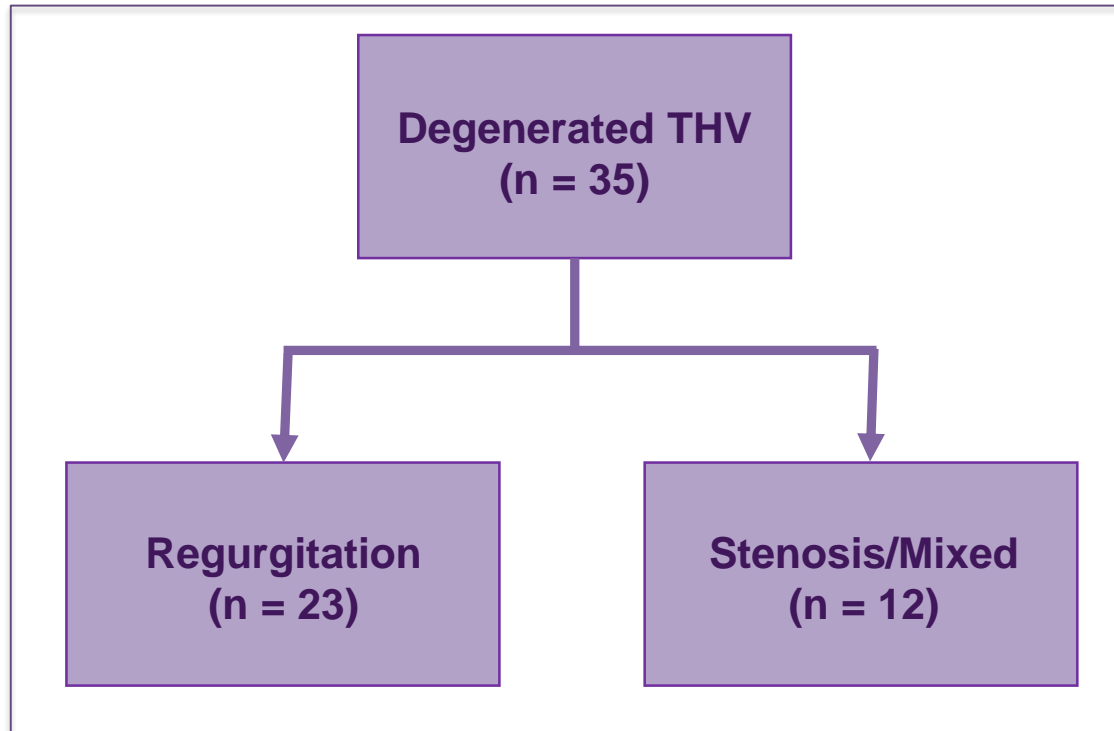


Mild AR



Moderate intravalvular AR
Mean gradient 13mmhg (LVEF 50%)

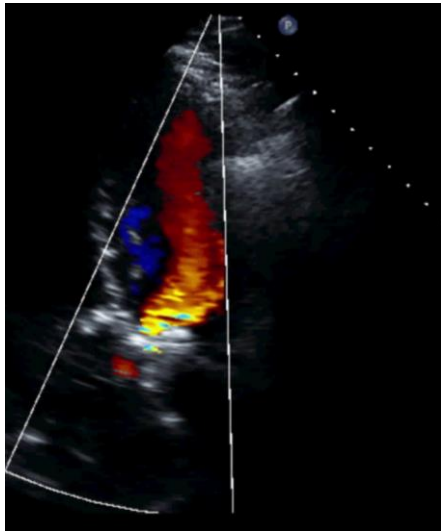
THV degeneration



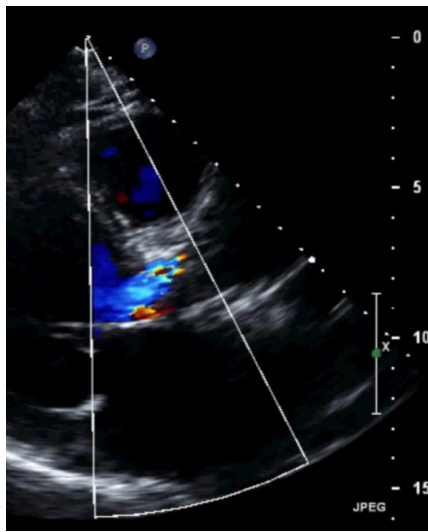
- Time to degeneration: median of 61months (IQR 36-79months).
- **Degenerated valves:**
 - Cribier Edwards (n=3, 8.6%)
 - Edwards SAPIEN (n=19, 54.3%)
 - SAPIEN XT (n=13, 37.1%)

Degeneration with regurgitation (8 different patients)

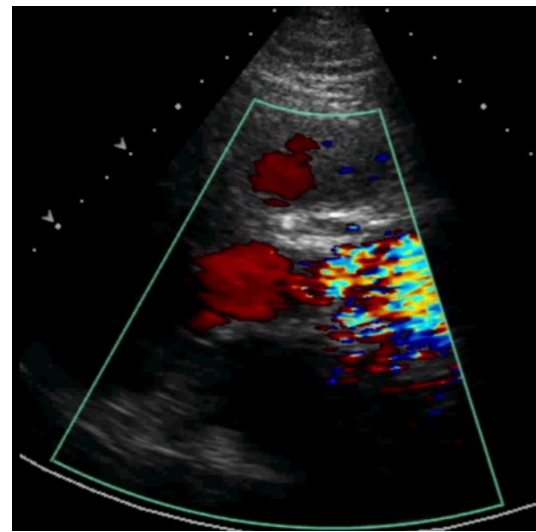
2 years post TAVI



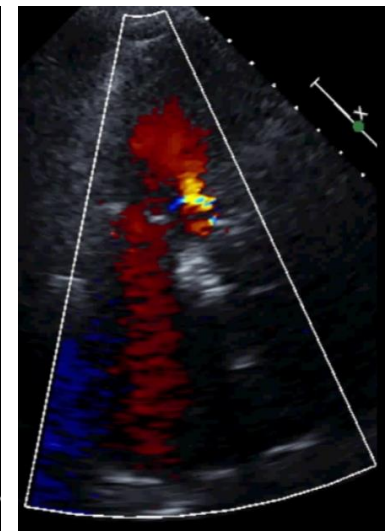
2.5 years post TAVI



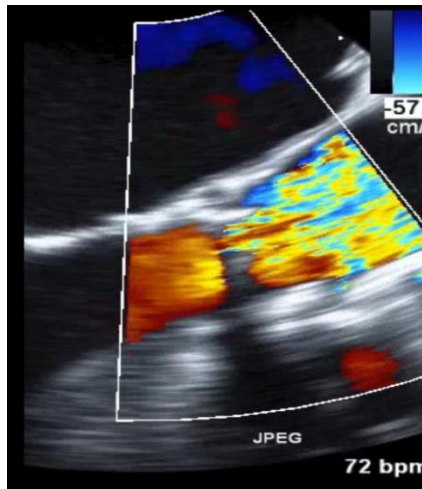
6.5 years post TAVI



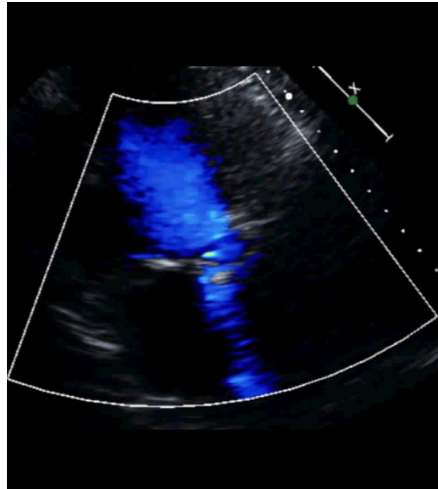
5 years post TAVI



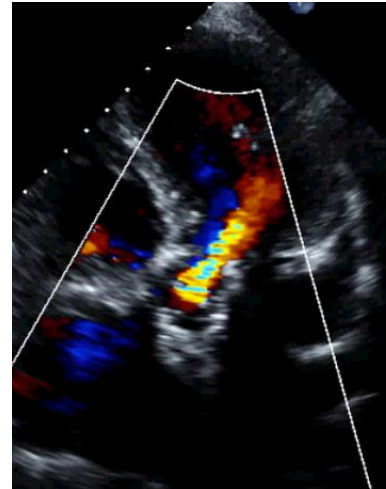
3 years post TAVI



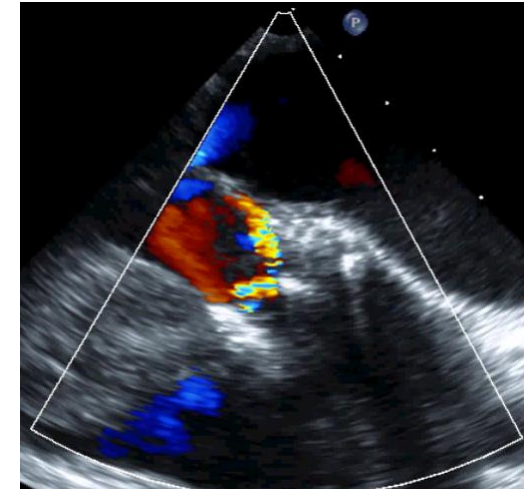
5 years post TAVI



7 years post TAVI

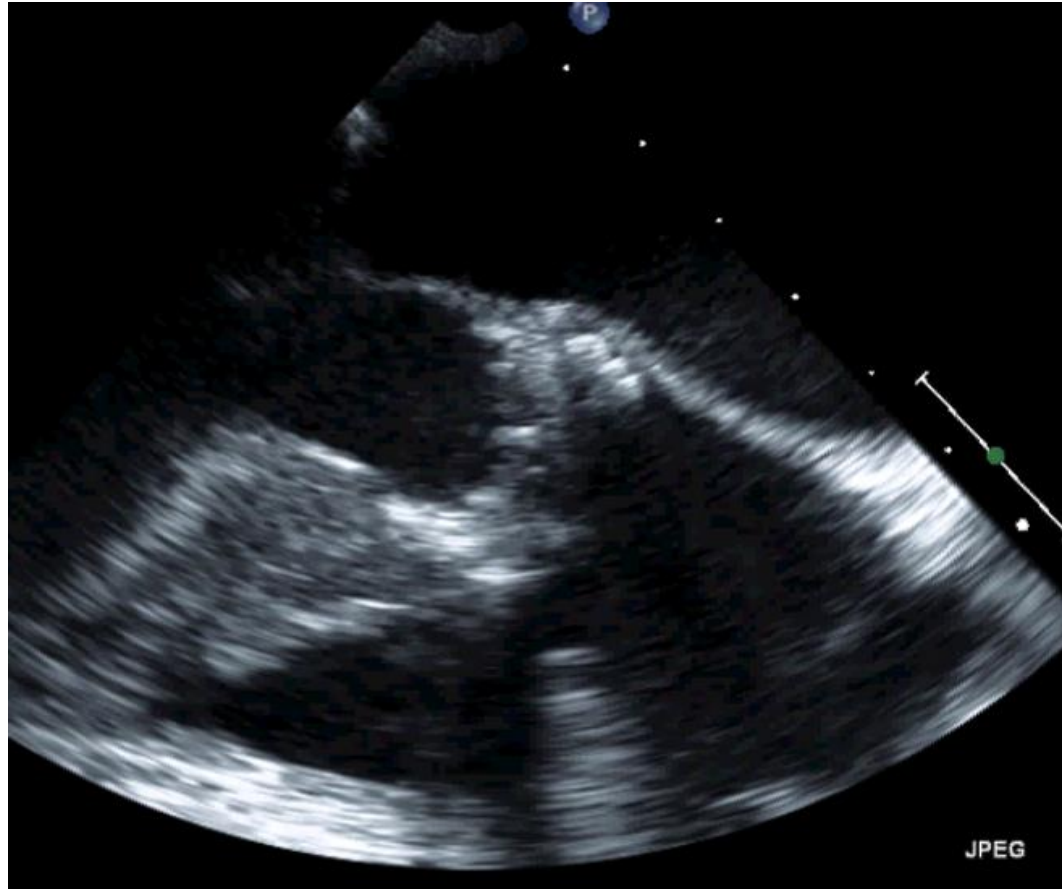


7 years post TAVI



Degeneration with stenosis

7 years post TAVI



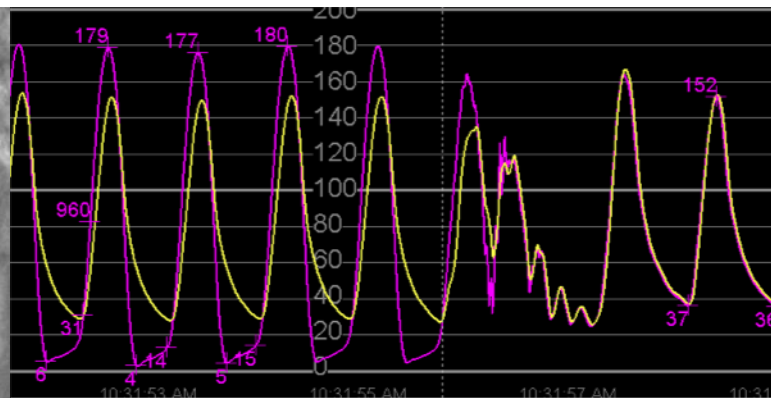
Calcified bulky leaflets. Mobility is severely reduced

Degeneration with stenosis (2 different patients)

**Immediately
after TAVI**

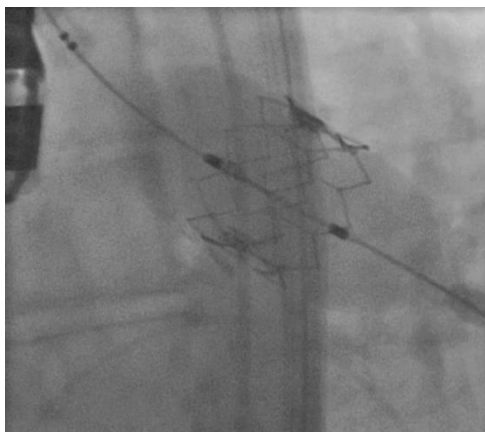


6.5 year after TAVI



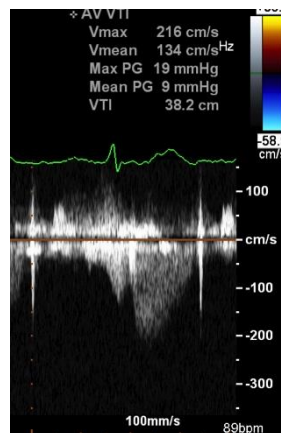
Mean gradient 32mmHg and pullback,
AR index=7. LVEF 35%

**Immediately
after TAVI**



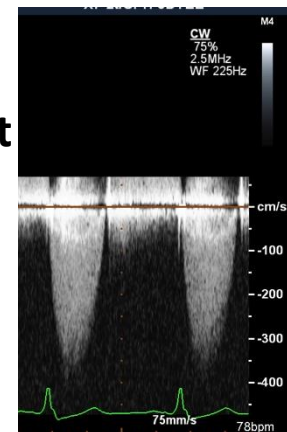
1 year after TAVI

**Mean gradient
9mmHg**



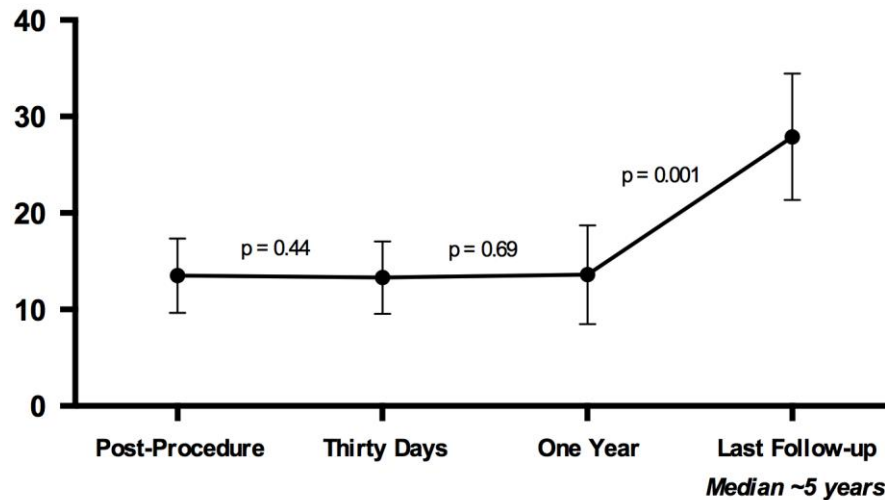
4 years after TAVI

**Mean gradient
35mmHg**

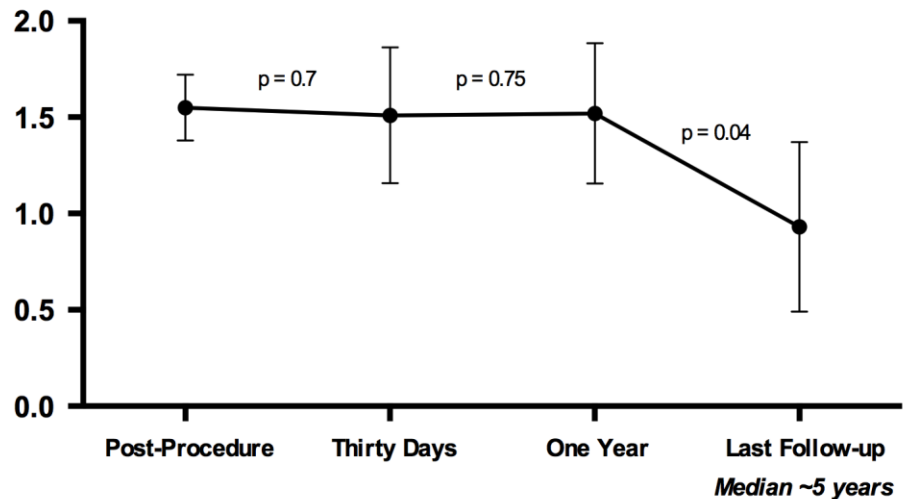


Degeneration with stenosis (n=12)

Aortic valve mean gradient (mmHg)



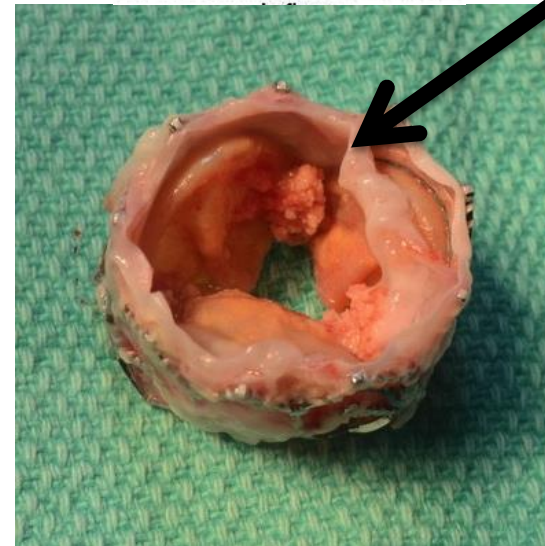
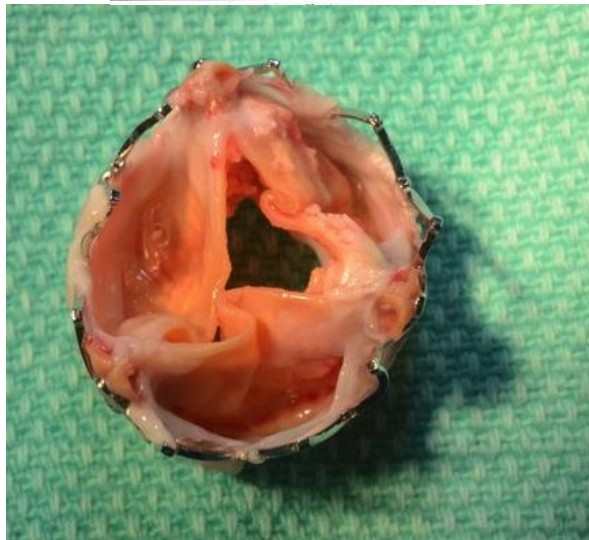
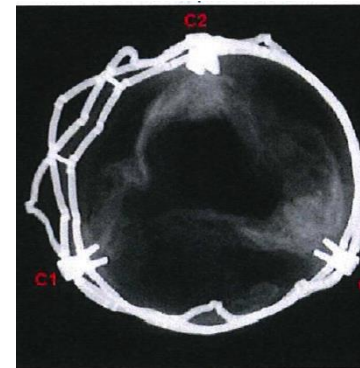
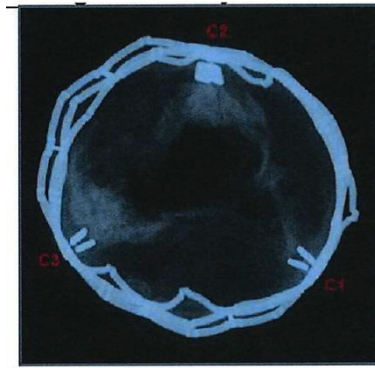
Aortic valve area (cm²)



Stenosis indices appeared only in long-term follow up

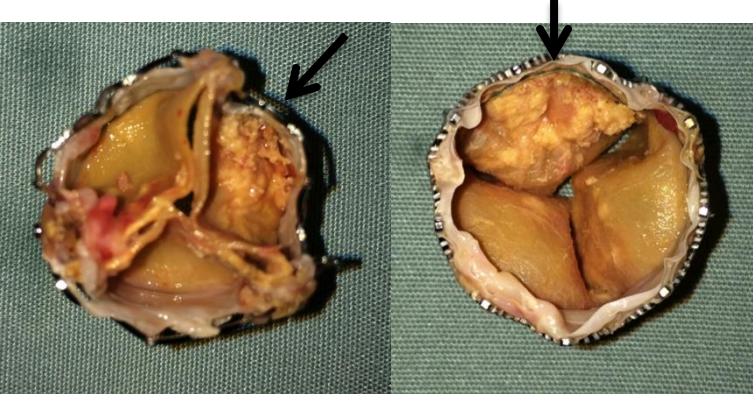
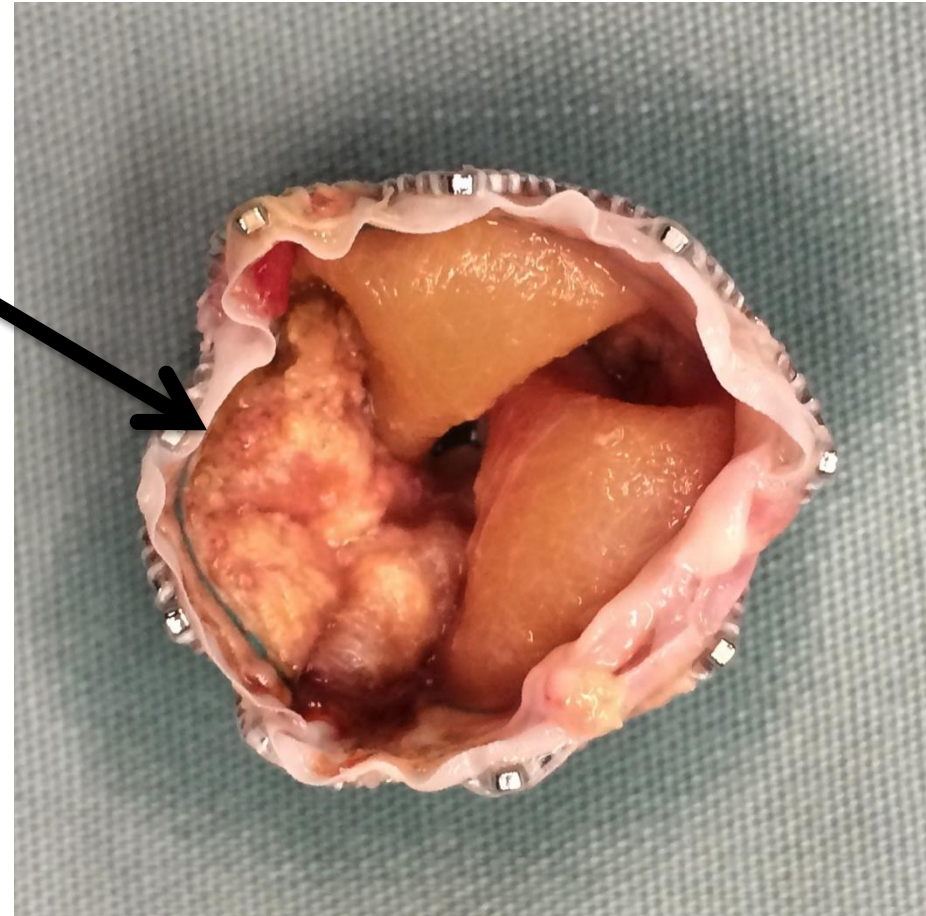
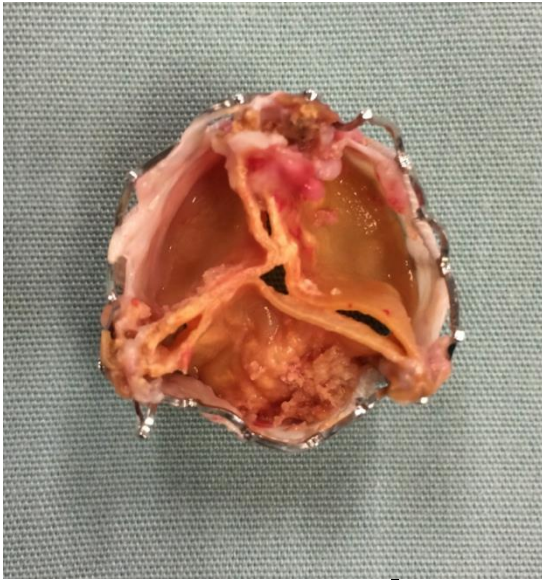
Pathological examinations

Severely calcified valve 2.5 years after TAVI



Pathological examinations

Asymmetric degeneration 5 years after TAVI

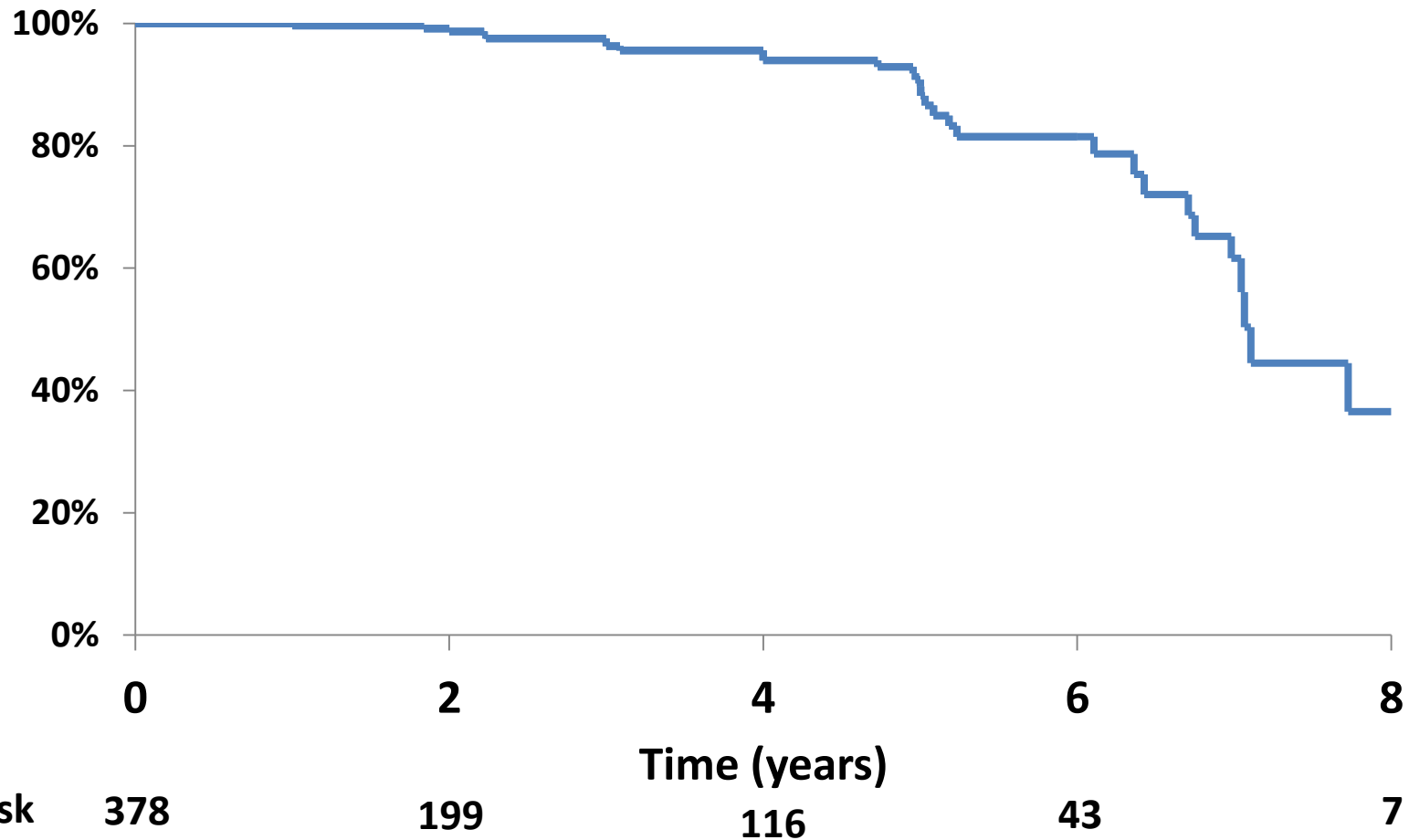


Pathological examinations

Symmetric degeneration 7 years after TAVI



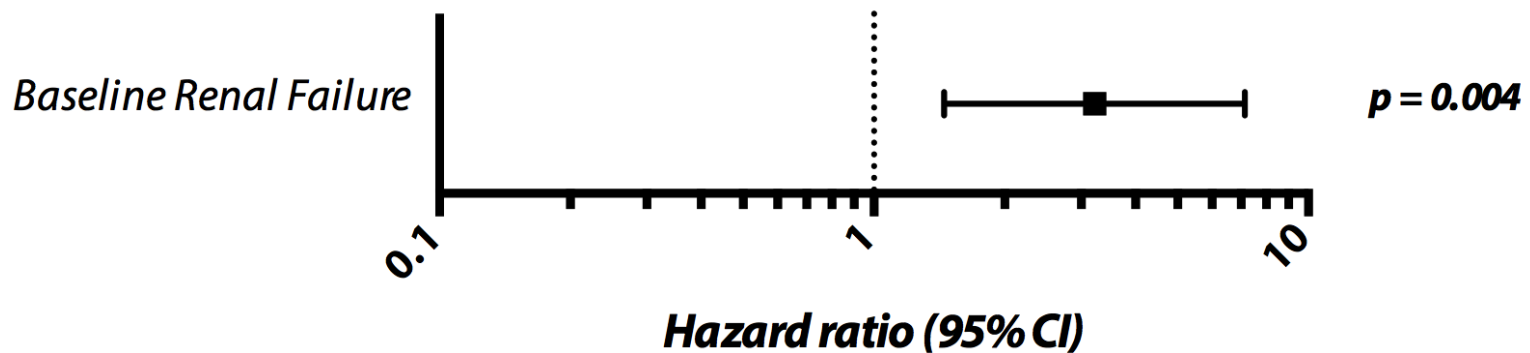
Freedom from THV degeneration



THV degeneration was defined as at least moderate regurgitation AND/OR mean gradient ≥ 20 mmHg, which did not appear within 30 days of the procedure and is not related to endocarditis.

KM estimate of THV degeneration included censoring of patients at their date of last known THV functioning well without evidence for degeneration per study definition.

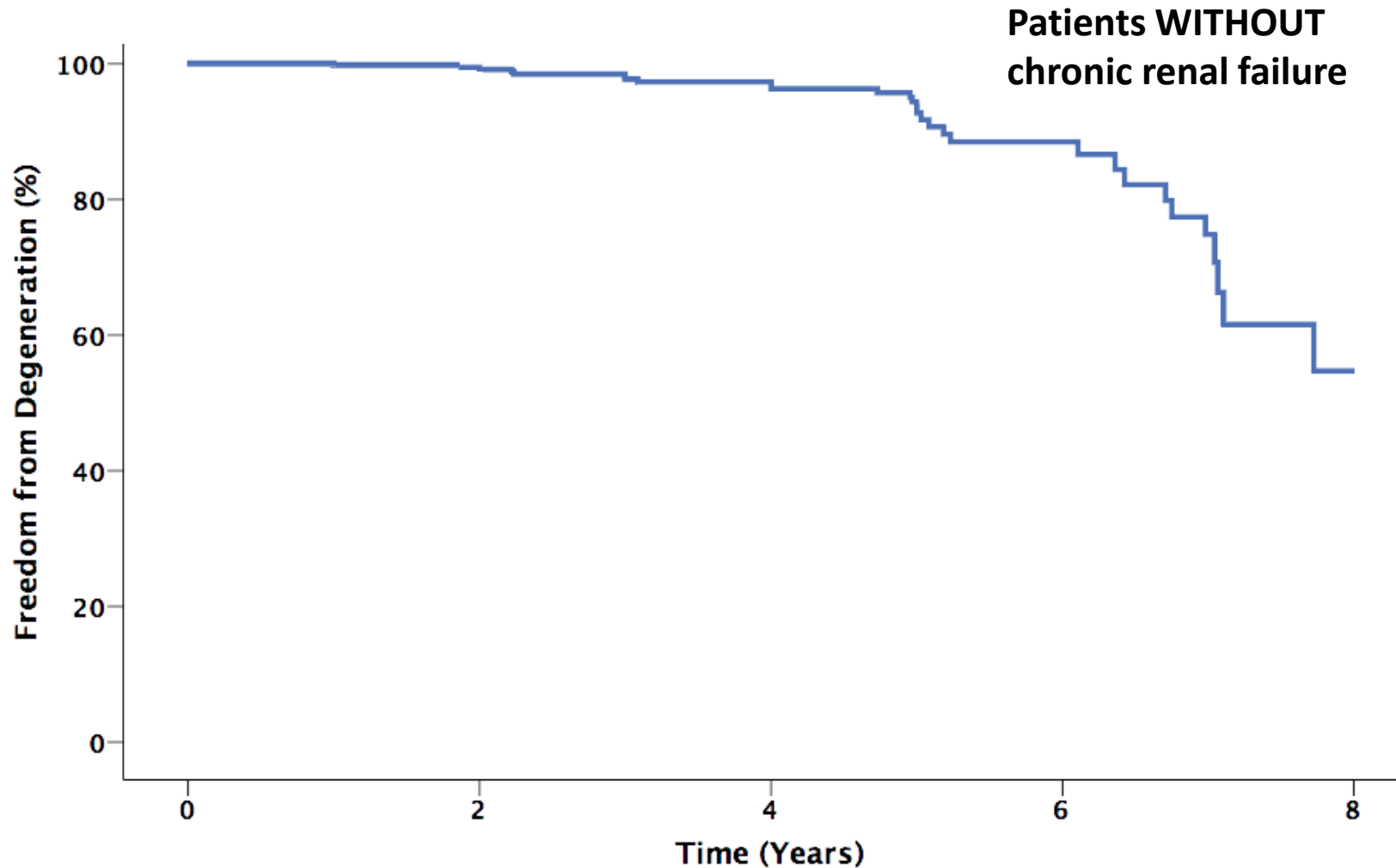
Correlates THV degeneration



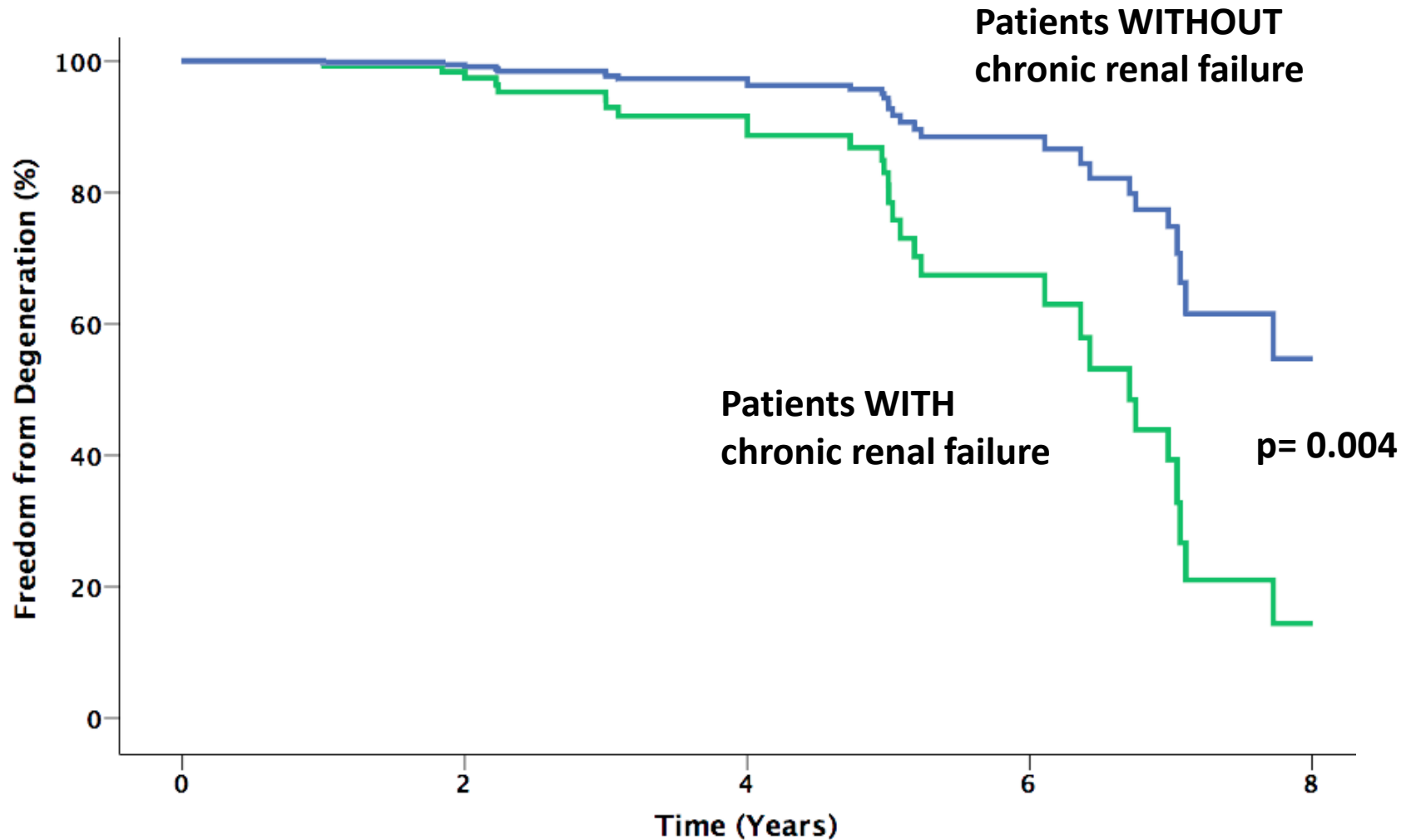
Baseline renal failure (GFR<60cc/min) was the strongest correlate for THV degeneration
HR=3.22, CI 1.45-7.15, $p=0.004$

Correlates included in the model: patient age, gender, baseline EOA, baseline LVEF, BMI, renal failure, THV type, THV size, anticoagulation treatment (i.e. Warfarin) after TAVI.

Freedom from THV degeneration



Freedom from THV degeneration



Summary

- **The current analysis includes a first look at long-term durability after TAVI, evaluating cases performed 5-14 years ago with early-generation balloon-expandable THV devices.**
- **In this preliminary report, a significant increase in degeneration rate was observed between 5-7 years after TAVI.**
- **Estimate of THV degeneration (resulting in at least moderate stenosis AND/OR regurgitation) was ~50% within 8 years.**
- **Renal failure was the strongest correlate of THV degeneration.**

Clinical implications

- **The risk for structural valve degeneration after TAVI should be considered, especially when treating relatively young patients and those at lower surgical risk.**
- **Physicians must be mindful of limitations of the bioprostheses they implant and whether these valves can be safely/effectively treated by a transcatheter approach (valve-in-valve), if these valves fail years later.**
- **Future studies should explore long-term durability of next generation and other THV platforms.**

VALID Registry

VAlve Long-term durability International Data

We are looking forward to collaborating with other centers!

**Please contact us:
ddvir@providencehealth.bc.ca**



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