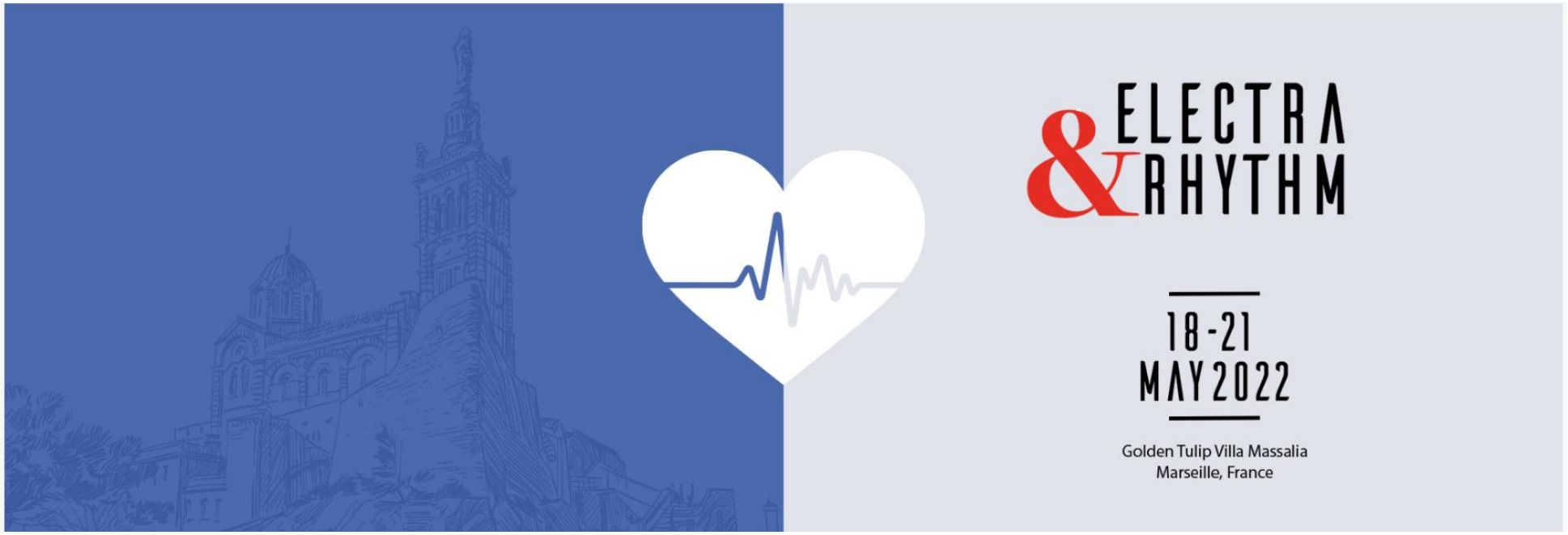
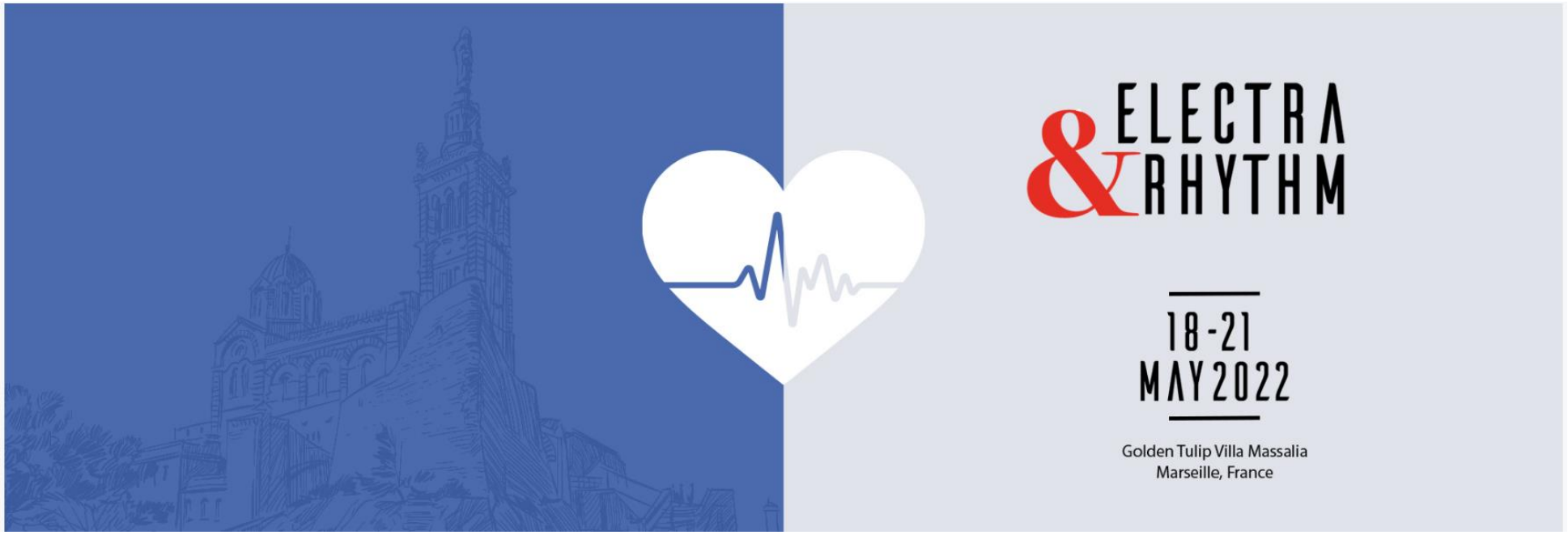



# Which patient should I implant after TAVI ?

Dr Didier IRLES - Annecy




**Speaker : Didier IRLES, Annecy**

☑ No disclosure

# Pacemaker requirement

*The most common complication after TAVI*

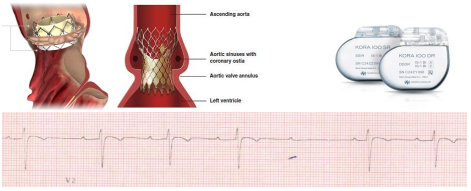
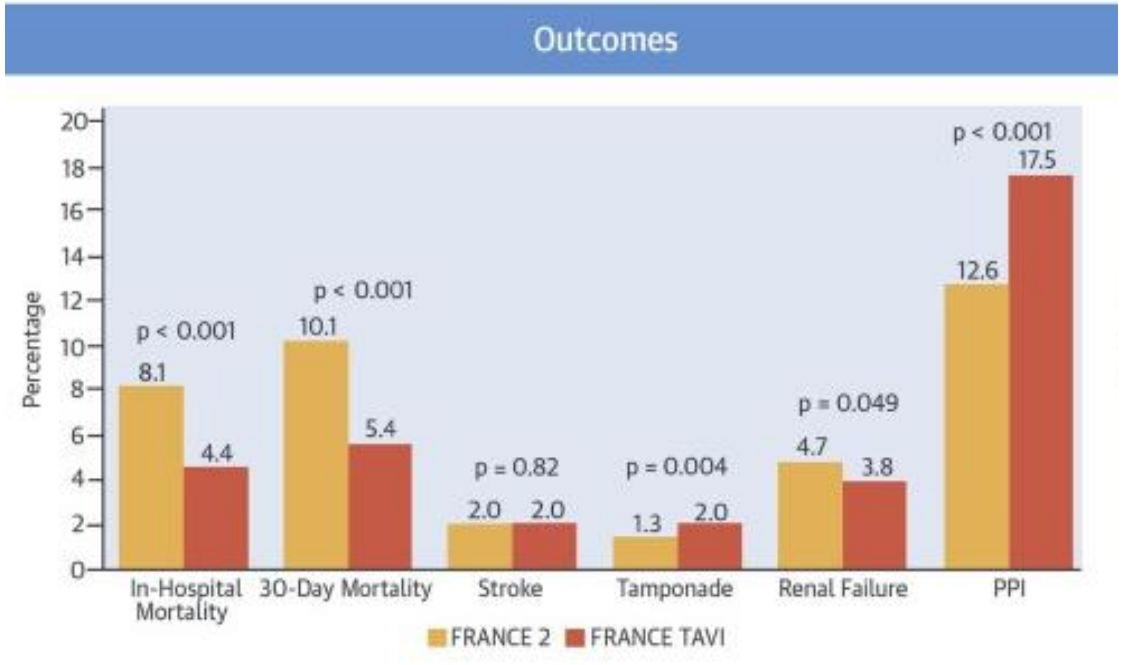


**Table 2. Clinical End Points at 30 Days and at 12 Months.***

| End Point | 30 Days | | | 12 Months | | |
|---|---|---|---|---|---|---|
| | TAVR | Surgery | Difference, TAVR–Surgery (95% BCI) | TAVR | Surgery | Difference, TAVR–Surgery (95% BCI) |
| | % of patients | | percentage points | % of patients | | percentage points |
| Death from any cause or disabling stroke | 0.8 | 2.6 | −1.8 (−3.2 to −0.5) | 2.9 | 4.6 | −1.8 (−4.0 to 0.4) |
| Death from any cause | 0.5 | 1.3 | −0.8 (−1.9 to 0.2) | 2.4 | 3.0 | −0.6 (−2.6 to 1.3) |
| Death from cardiovascular cause | 0.5 | 1.3 | −0.8 (−1.9 to 0.2) | 1.7 | 2.6 | −0.9 (−2.7 to 0.7) |
| All stroke | 3.4 | 3.4 | 0.0 (−1.9 to 1.9) | 4.1 | 4.3 | −0.2 (−2.4 to 1.9) |
| Disabling | 0.5 | 1.7 | −1.2 (−2.4 to −0.2) | 0.8 | 2.4 | −1.6 (−3.1 to −0.3) |
| Nondisabling | 3.0 | 1.7 | 1.2 (−0.3 to 2.9) | 3.4 | 2.2 | 1.1 (−0.6 to 2.9) |
| Transient ischemic attack | 0.6 | 0.8 | −0.2 (−1.2 to 0.7) | 1.7 | 1.8 | −0.2 (−1.6 to 1.3) |
| 30-Day composite safety end point† | 5.3 | 10.7 | −5.4 (−8.3 to −2.6) | NA | NA | NA |
| Life-threatening or disabling bleeding | 2.4 | 7.5 | −5.1 (−7.5 to −2.9) | 3.2 | 8.9 | −5.7 (−8.4 to −3.1) |
| Major vascular complication | 3.8 | 3.2 | 0.6 (−1.4 to 2.5) | 3.8 | 3.5 | 0.3 (−1.7 to 2.3) |
| Acute kidney injury stage 2 or 3 | 0.9 | 2.8 | −1.8 (−3.4 to −0.5) | 0.9 | 2.8 | −1.8 (−3.4 to −0.5) |
| Atrial fibrillation | 7.7 | 35.4 | −27.7 (−31.8 to −23.6) | 9.8 | 38.3 | −28.5 (−32.8 to −24.1) |
| Permanent pacemaker implantation | 17.4 | 6.1 | 11.3 (8.0 to 14.7) | 19.4 | 6.7 | 12.6 (9.2 to 16.2) |
| Myocardial infarction | 0.9 | 1.3 | −0.4 (−1.5 to 0.7) | 1.7 | 1.6 | 0.1 (−1.3 to 1.5) |
| Coronary-artery obstruction | 0.9 | 0.4 | 0.5 (−0.3 to 1.4) | 0.9 | 0.4 | 0.5 (−0.3 to 1.4) |
| Endocarditis | 0.1 | 0.2 | −0.1 (−0.7 to 0.3) | 0.2 | 0.4 | −0.2 (−0.9 to 0.5) |
| Valve thrombosis | 0.1 | 0.1 | 0.0 (−0.4 to 0.4) | 0.2 | 0.3 | −0.1 (−0.9 to 0.5) |
| Aortic reintervention | 0.4 | 0.4 | 0.0 (−0.8 to 0.7) | 0.7 | 0.6 | 0.0 (−1.0 to 0.9) |
| Hospitalization for heart failure | 1.2 | 2.5 | −1.3 (−2.8 to 0.1) | 3.2 | 6.5 | −3.4 (−5.9 to −1.0) |

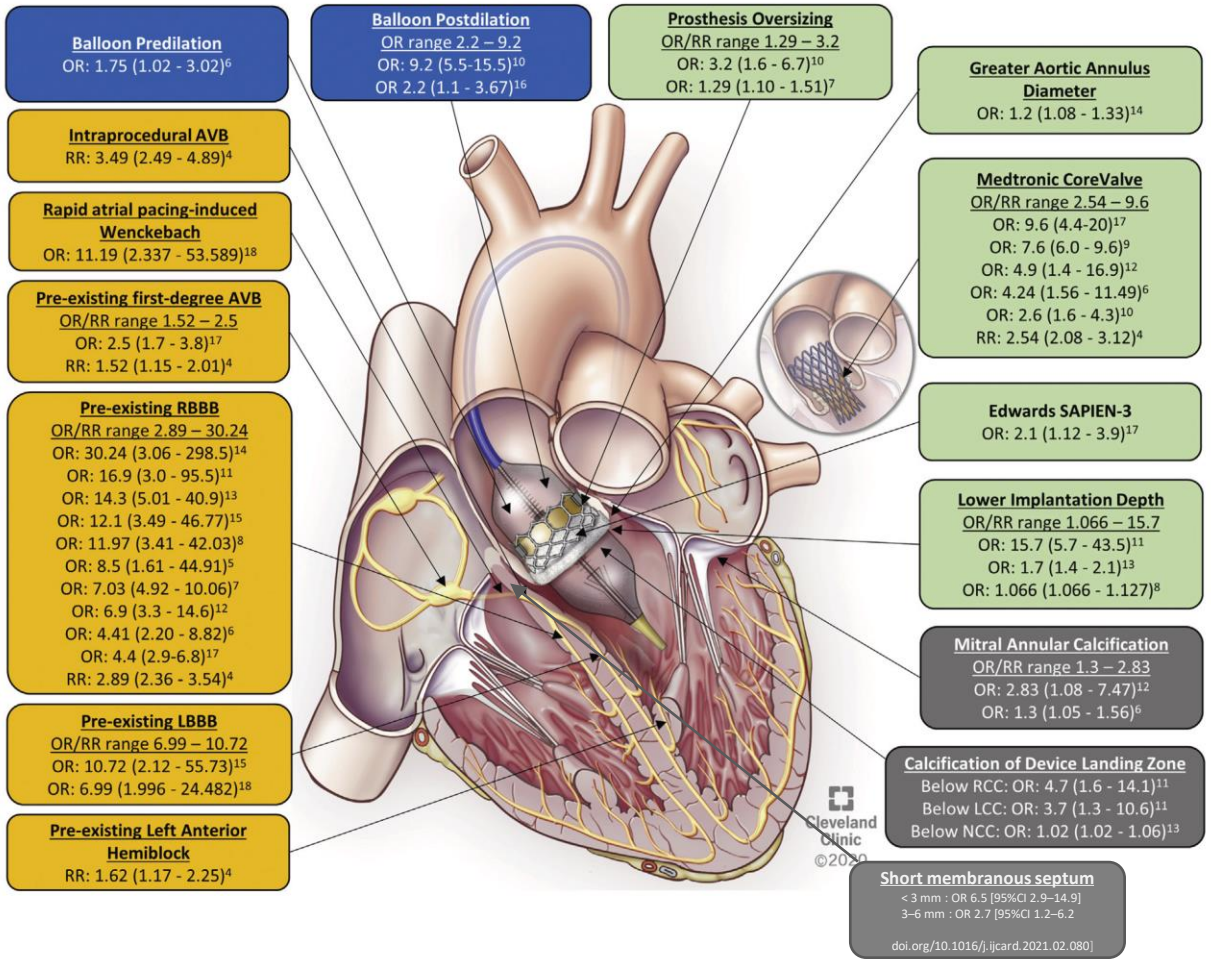
***Popma JJ et al*. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients**. N Engl J Med. 2019 May 2;380(18):1706-1715. doi: 10.1056/NEJMoa1816885.

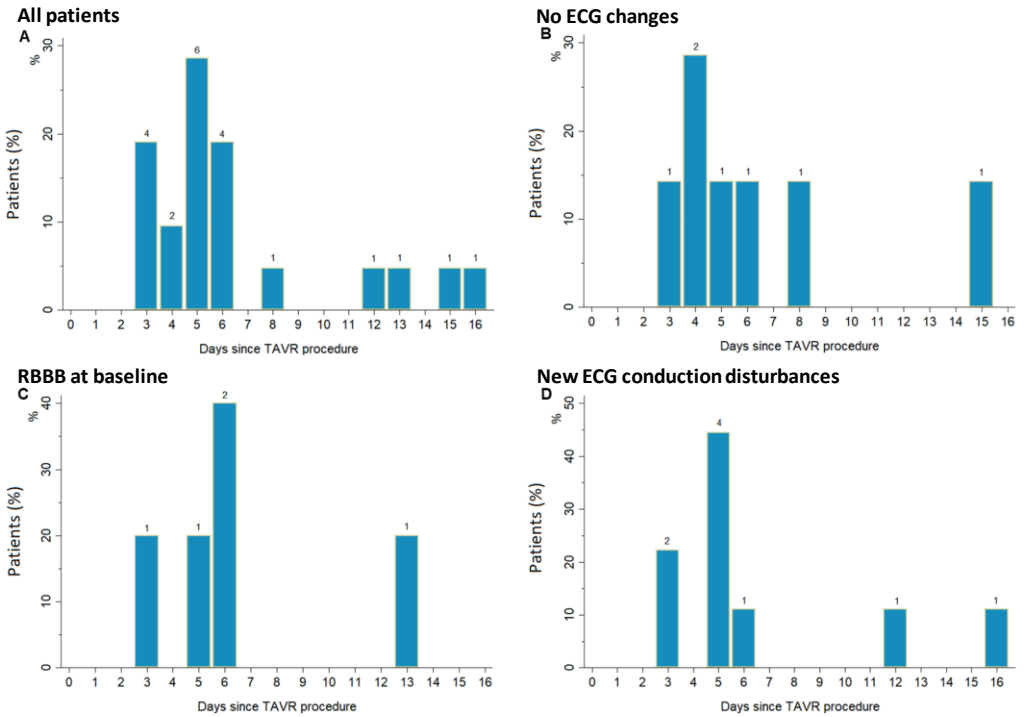



***Auffret V et al.* Temporal Trends in Transcatheter Aortic Valve Replacement in France: FRANCE 2 to FRANCE TAVI.** J Am Coll Cardiol. 2017 Jul 4;70(1):42-55. doi: 10.1016/j.jacc.2017.04.053.

# Pacemaker requirement

## *A complex question*



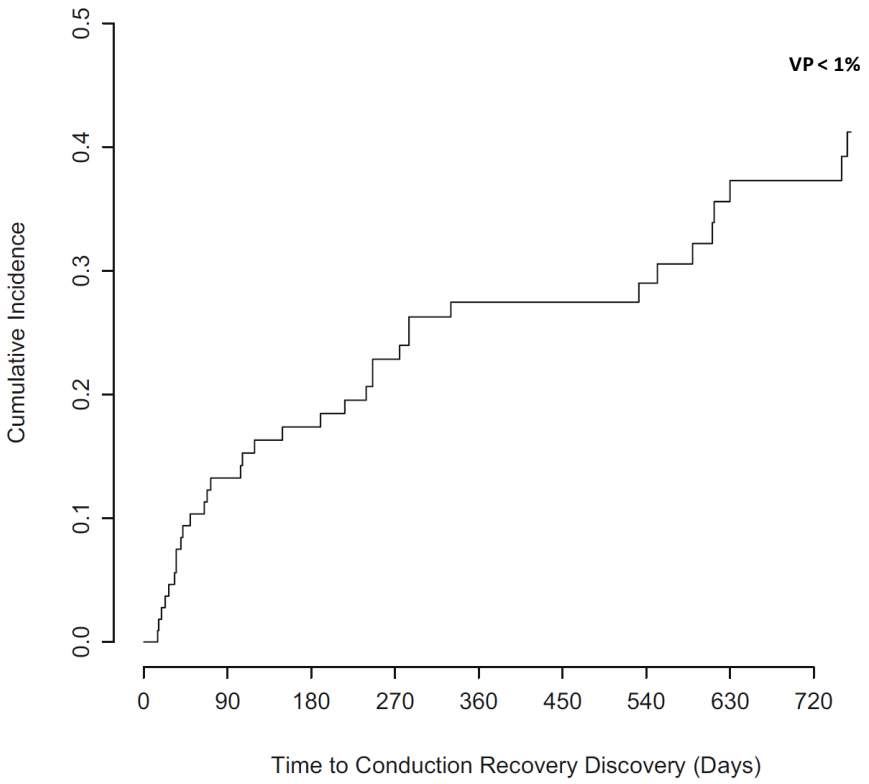




***Sammour Y et al.*** **Incidence, Predictors, and Implications of Permanent Pacemaker Requirement After Transcatheter Aortic Valve Replacement**. JACC Cardiovasc Interv. 2021 Jan 25;14(2):115-134. doi: 10.1016/j.jcin.2020.09.063..

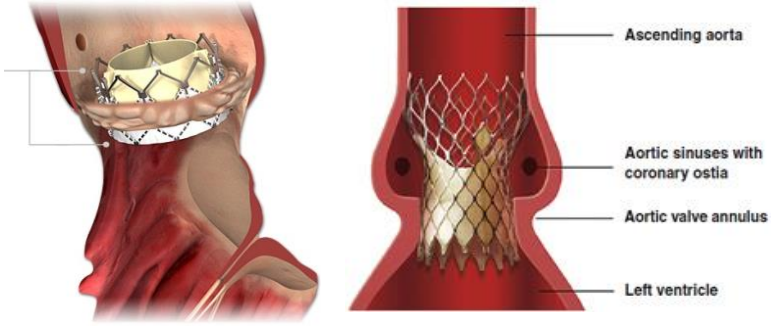
***Muntané-Carol G et al.*** **Ambulatory Electrocardiographic Monitoring Following Minimalist Transcatheter Aortic Valve Replacement.** JACC Cardiovasc Interv. 2021 Dec 27;14(24):2711-2722. doi: 10.1016/j.jcin.2021.08.039. PMID: 34949396.

# Pacemaker requirement

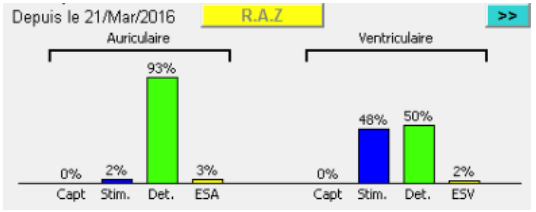
## *A complex question*




***Phan DQ, Goitia J et al.*** **Predictors of conduction recovery after permanent pacemaker implantation following transcatheter aortic valve replacement.** J Interv Card Electrophysiol. 2021 Aug;61(2):365-374. doi: 10.1007/s10840-020-00813-y.

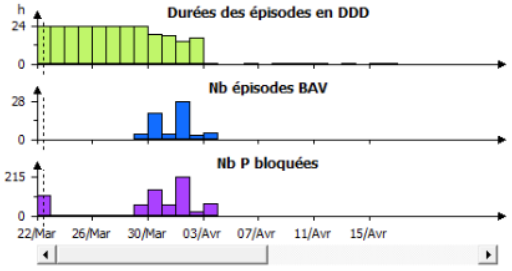


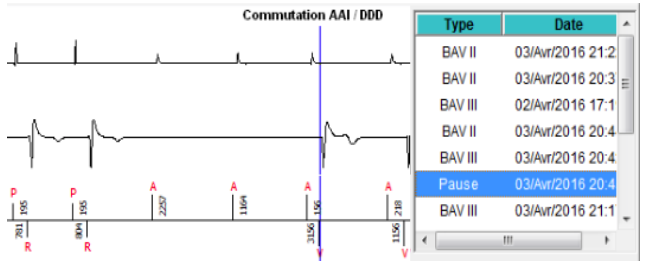





Synthèse des Episodes de BAV

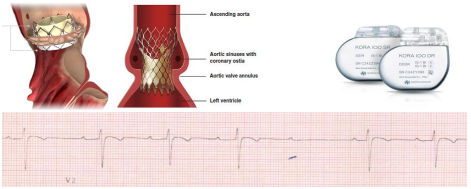
| | Jour | | Nuit | Total |
|---|---|---|---|---|
| | Jour effort | Jour repos | | |
| Pause | - | - | - | - |
| BAV I | 1 (0%) | 120 (36%) | 210 (63%) | 331 |
| BAV II | - | 55 (79%) | 15 (21%) | 70 |
| BAV III | - | 4 (80%) | 1 (20%) | 5 |
| **Episodes BAV** | - | **114 (52%)** | **106 (48%)** | **220** |



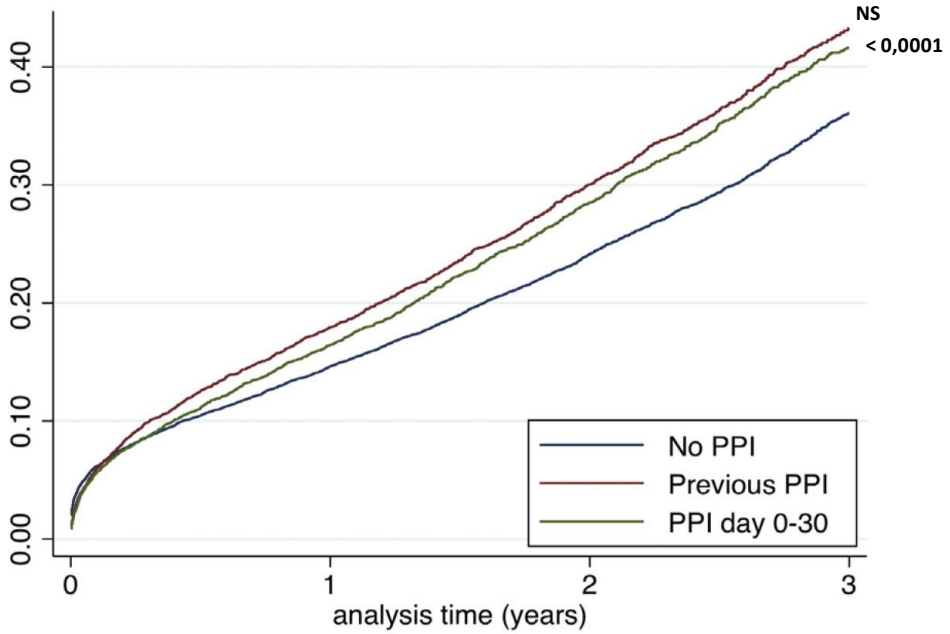



# Pacemaker implantation

*Impact on mortality and heart failure ?*



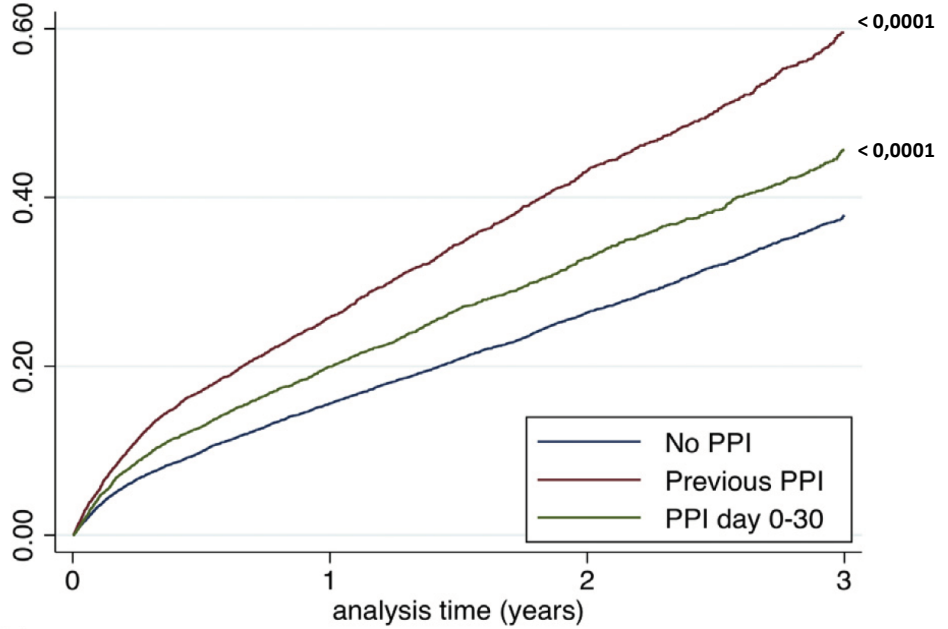
**All-cause death**




Number at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| No PPI = | 16511 | 14867 | 11827 | 9346 | 7194 | 5381 | 3919 |
| Previous PPI = | 6362 | 5610 | 4390 | 3475 | 2685 | 2039 | 1488 |
| PPI day 0-30 = | 6549 | 5859 | 4514 | 3457 | 2679 | 2013 | 1463 |

**Hospitalization for heart failure**



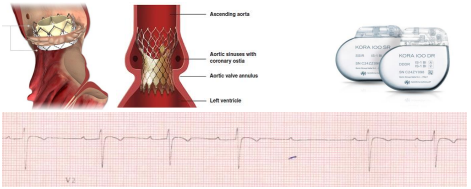

Number at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| No PPI = | 16412 | 13562 | 10413 | 8005 | 5956 | 4310 | 3043 |
| Previous PPI = | 6310 | 4820 | 3600 | 2706 | 1986 | 1462 | 1027 |
| PPI day 0-30 = | 6524 | 5236 | 3875 | 2875 | 2168 | 1602 | 1130 |

***Clementy N et al.*** **Outcomes associated with pacemaker implantation following transcatheter aortic valve replacement: A nationwide cohort study**. Heart Rhythm. 2021 Dec;18(12):2027-2032. doi: 10.1016/j.hrthm.2021.06.1175.

# Pacemaker requirement

*A complex question*

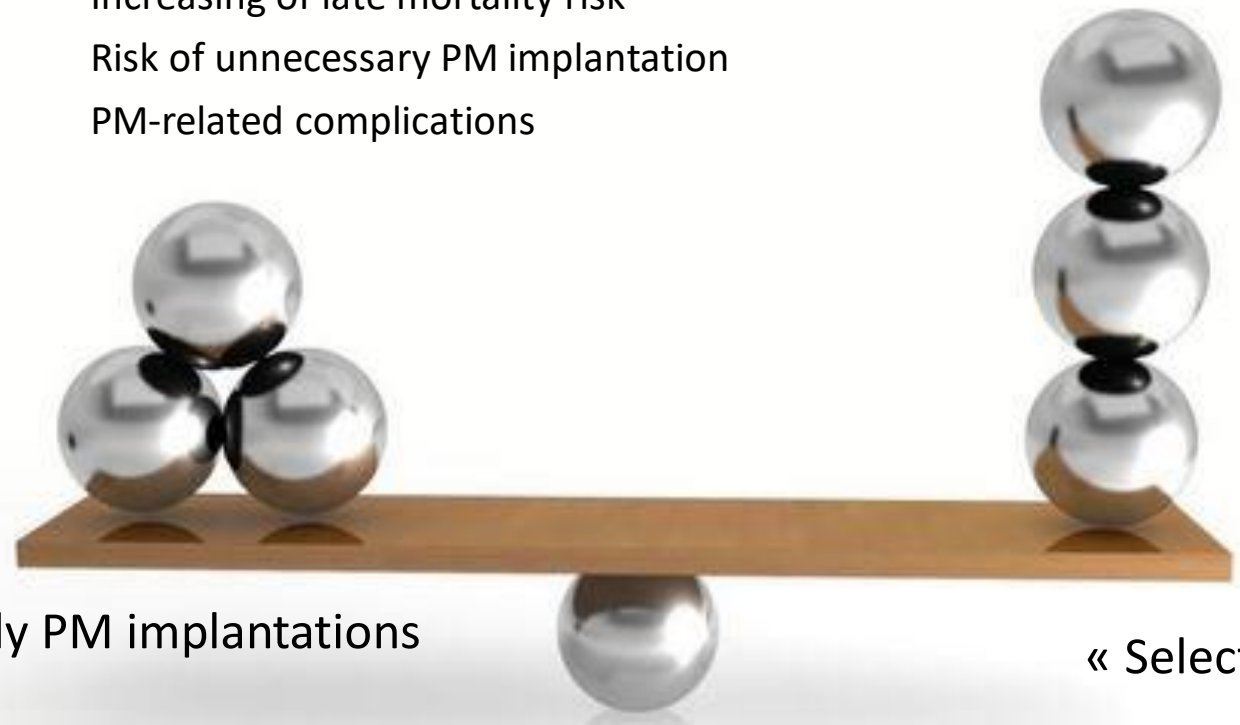


Increasing of late HF risk

Increasing of late mortality risk

Risk of unnecessary PM implantation

PM-related complications



Risk of late PM implantation

Risk of late syncope or sudden death ?

Prolonged bed rest (temporary pacing)

Prolonged hospitalization

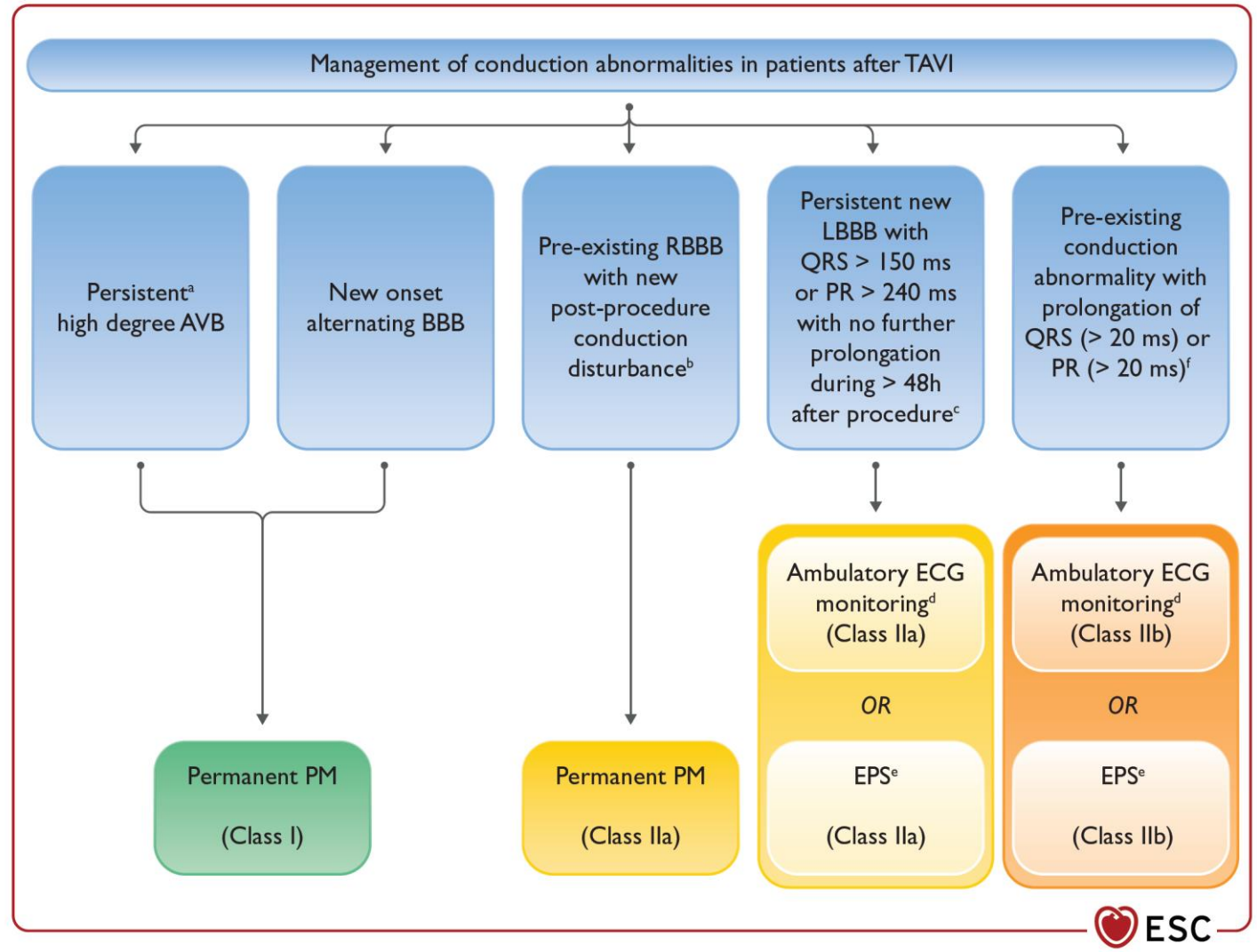
Prolonged ECG monitoring

Large and early PM implantations

« Selected » PM implantations

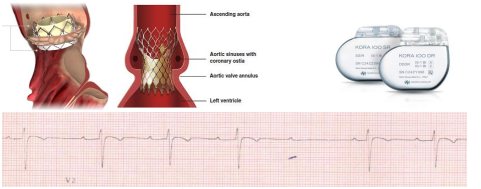
# Pacemaker implantation

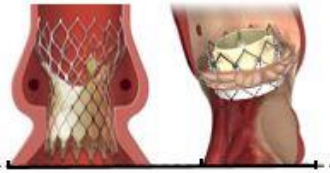
*What do 2021 guidelines advise ?*




- Low risk patients
- Moderate risk patients
  - PM implantation may be considered in RBBB patients with new CD (IIa)
  - ILR or EPS may be considered (IIa-IIb)
- High risk patients
  - HG-AVB or alternating block after TAVI
  - PM implantation (I)

# So, which patient should I implant after TAVI ??





Prospective, Observational, Multicenter Study
19 French Hospitals

**Day 0**

Pacemaker implantation due to atrioventricular conduction disorders

High-grade 83 %

Low-grade 17 %

SafeR® Mode activated

Study Inclusion

STIM TAVI

**Day 7**

Patients implanted with a pacemaker after TAVI (*n* = 588)

Exclusion criteria (*n* = 315)

Patients enrolled in STIMTAVI (*n* = 273)

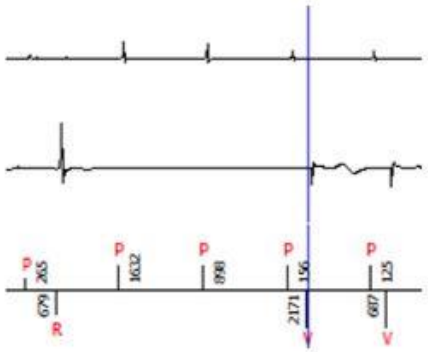
Primary endpoint not evaluable (*n* = 76)

No pacemaker interrogation file available (*n* = 29)

SafeR® mode analysis duration <250 days *and* primary endpoint not validated (*n* = 47)

Patients with evaluable primary endpoint (*n* = 197)

**Primary Endpoint : ≥ one *late* (beyond Day 7) high-grade atrioventricular blocks (HG-AVB)**
***Pacemaker-diagnosed Episodes - Central Independent Adjudication Process***




| | | |
|---|---|---|
| Oversizing | 3.26 (.88-12.11) | .053 |
| HG-AVB during TAVI | 1.68 (.67-4.20) | .271 |
| HG-AVB after TAVI during D0-D1 | 3.25 (1.57-6.74) | .001 |
| HG-AVB after TAVI during D2-D6 | 4.13 (2.06-8.31) | <.001 |

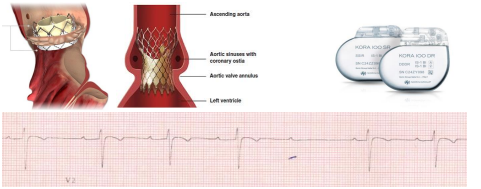
**Year 1**

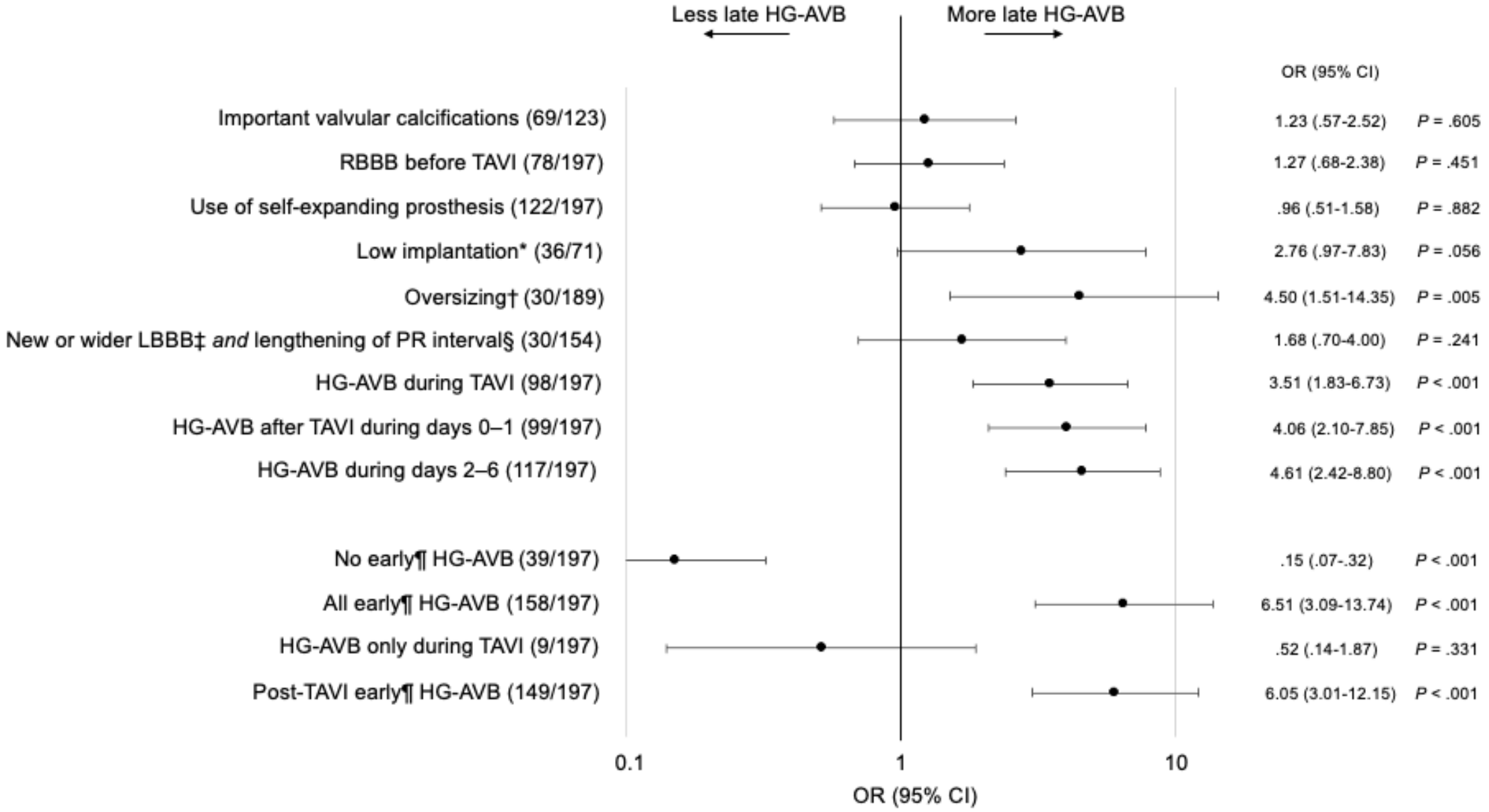
≥ One *late* HG-AVB — 70.1 %

No *late* HG-AVB — 29.9 %

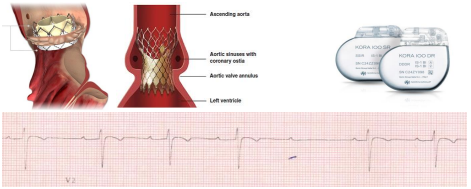
***Irles D et al.*** **Evolution of high-grade atrioventricular conduction disorders after transcatheter aortic valve implantation in patients who underwent implantation of a pacemaker with specific mode-that minimizes ventricular pacing-activated.** J Cardiovasc Electrophysiol. 2021 May;32(5):1376-1384. doi: 10.1111/jce.14970.

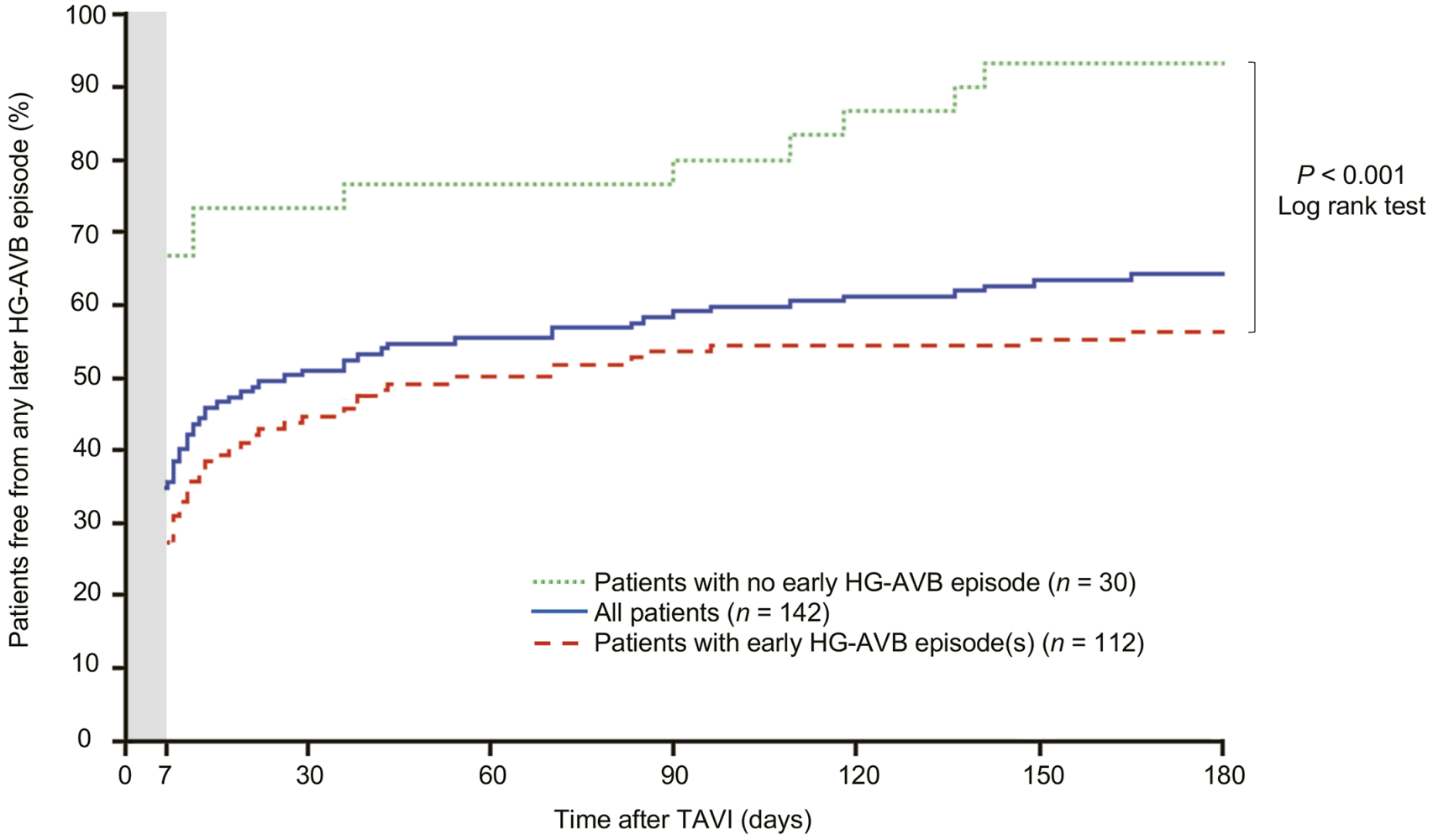
# STIM TAVI Study





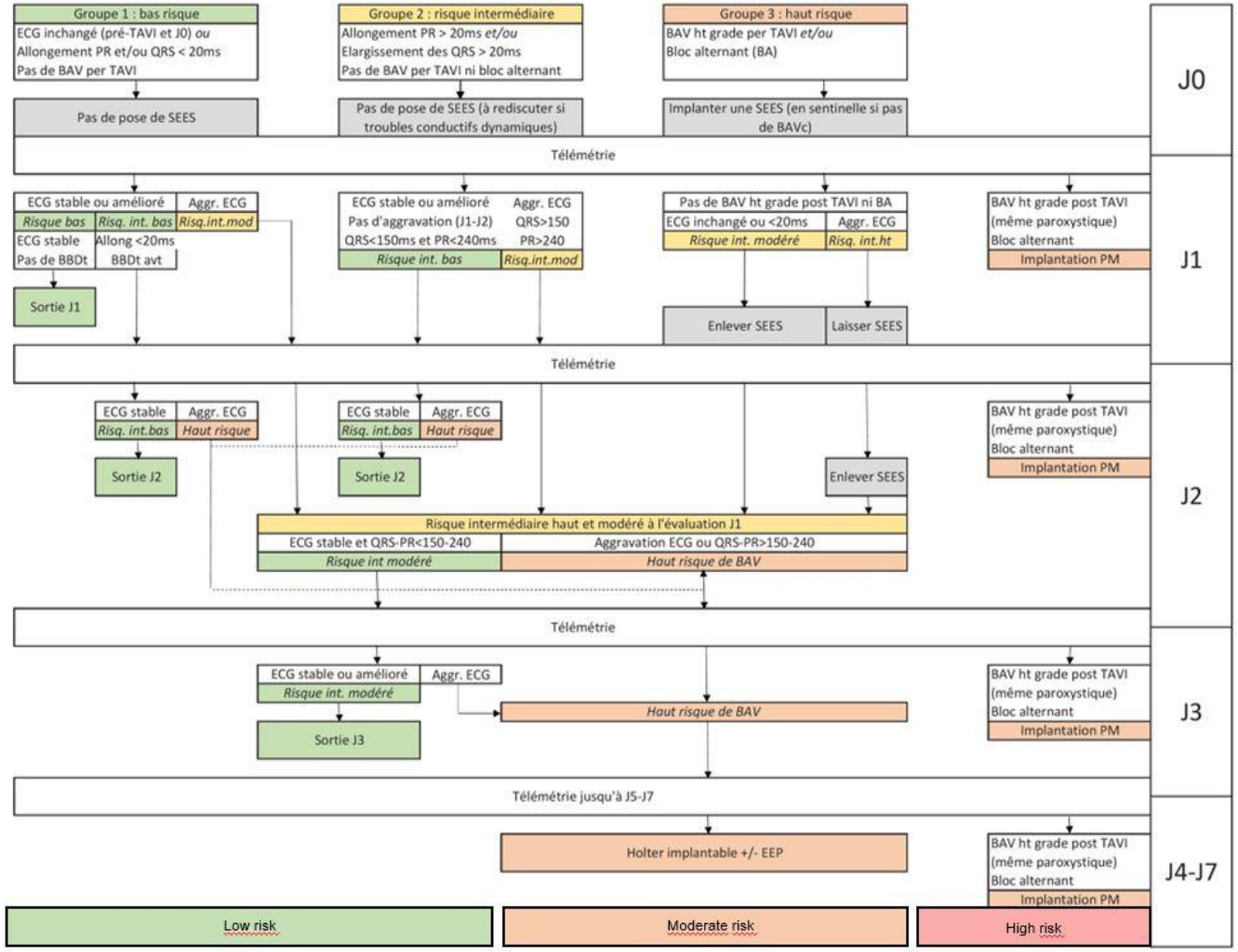
# STIM TAVI Study





# Post-TAVI CD management

## *Annecy Hospital Strategy*



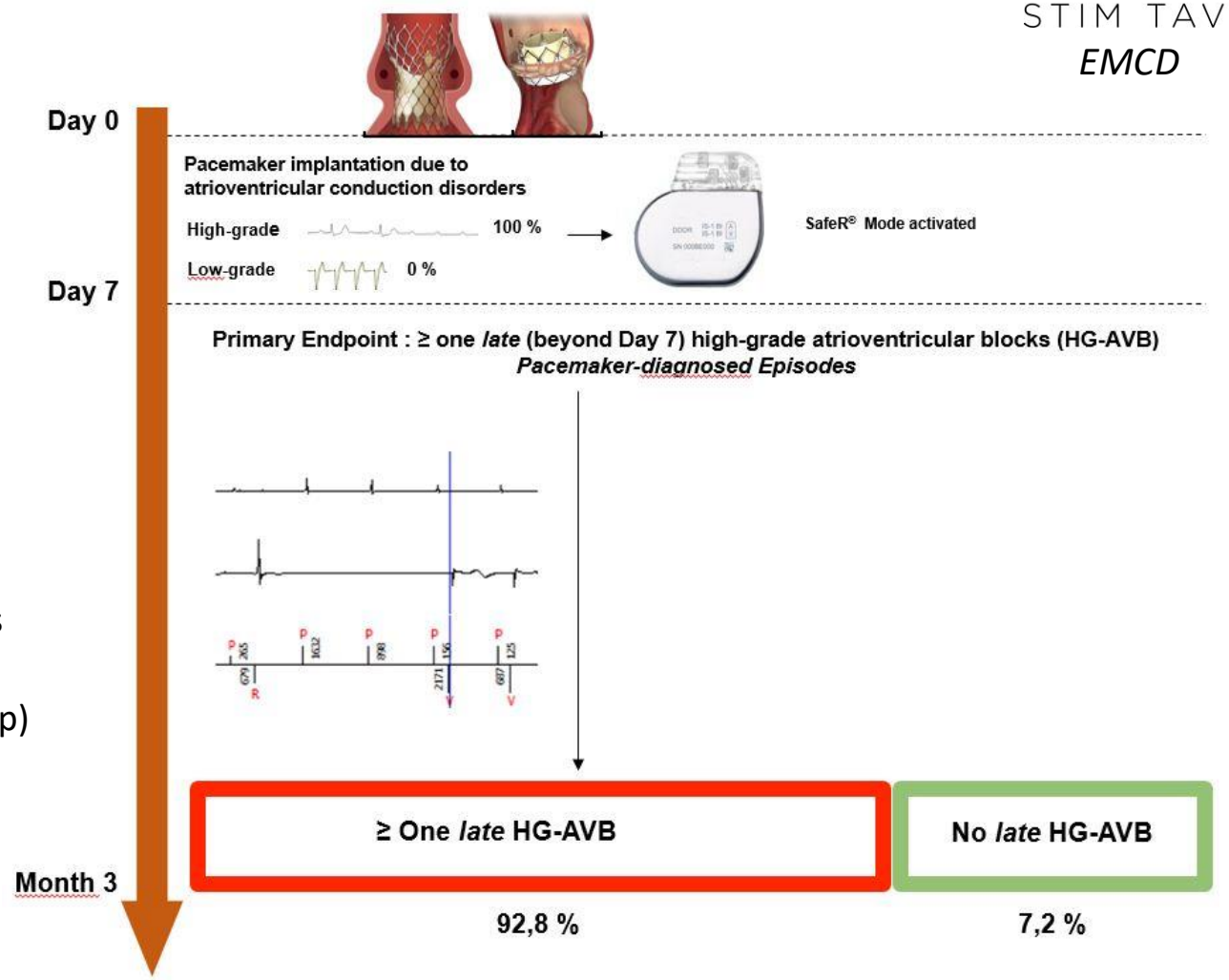

- Low risk patients
  - No RBBB
  - No new CD beyond D1
  - No HG-AVB
  - Early discharge (D1 to D3)
- Moderate risk patients
  - RBBB
  - New CD beyond D1
  - PR>240ms and/or QRS>150ms
  - 7 days ECG monitoring
  - Consider ILR and/or EPS
- High risk patients
  - HG-AVB or aternative block after TAVI
  - PM implantation
- No systematic temporary pacing, early removing

# Post-TAVI risk stratification

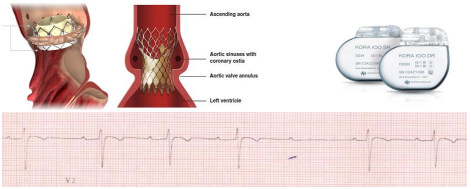
## *Annecy Hospital Strategy*

STIM TAVI
*EMCD*

- Monocentric, observational study
- All one-year TAVI patients
- Follow-up 3 months
- 128 patients
  - Low risk : 77 pts (60%)
  - Moderate risk : 34 pts (26,2%)
  - High risk : 17 pts (13,8%)
- PM implantation :
  - Early : 17 pts (13,1%)
  - Follow-up : 4 pts (2 in LR, 2 in MR group)
- Mean hospitalization duration : 6,3 days (3.7 days according to the protocol)
- Syncope in the FU : 2 pts (1 in LR, 1 at D6 in MR group)
- Death :
  - In hospital : 3 pts (2,3%)
  - Follow-up : 7 pts (5,4%)
  - No sudden cardiac death



# Which patient should I implant after TAVI ??



**High risk patients**

- Post TAVI HG-AVB
- Post TAVI alternating block

↓

**Pacemaker implantation**

**Moderate risk patients**

- HG-AVB during TAVI

**Pacemaker implantation ?**
**Low risk if no post TAVI HG-AVB ?**

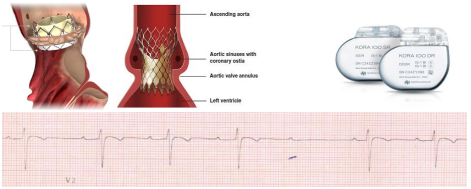
**Low risk patients**

- No new CD
  No previous RBBB
- New early CD
  PR<240-QRS<150

↓ No worsening of CD beyond D1

**Early discharge**
**No pacemaker, no ILR**

# So, which patient should I implant after TAVI ??



High risk patients

Post TAVI HG-AVB

Post TAVI alternating block

Pacemaker implantation

Moderate risk patients

New CD
PR>240-QRS>150

RBBB

New evolutive CD
PR<240-QRS<150

7 days ECG mo
Pacemaker impl

7 days ECG monitoring ?
ILR ? EPS ?

Worsening of CD beyond D1

Low risk patients

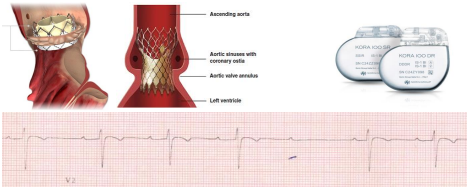
No new CD
No previous RBBB

New early CD
PR<240-QRS<150

No worsening of CD beyond D1

Early discharge
No pacemaker, no ILR

# So, which patient should I implant after TAVI ??



**High risk patients**

- Post TAVI HG-AVB
- Post TAVI alternating block

→ Pacemaker implantation

**Moderate risk patients**

- RBBB
- New evolutive CD PR<240-QRS<150
- New CD PR>240-QRS>150

7 days ECG monitoring

→ Discharge at D7 No pacemaker

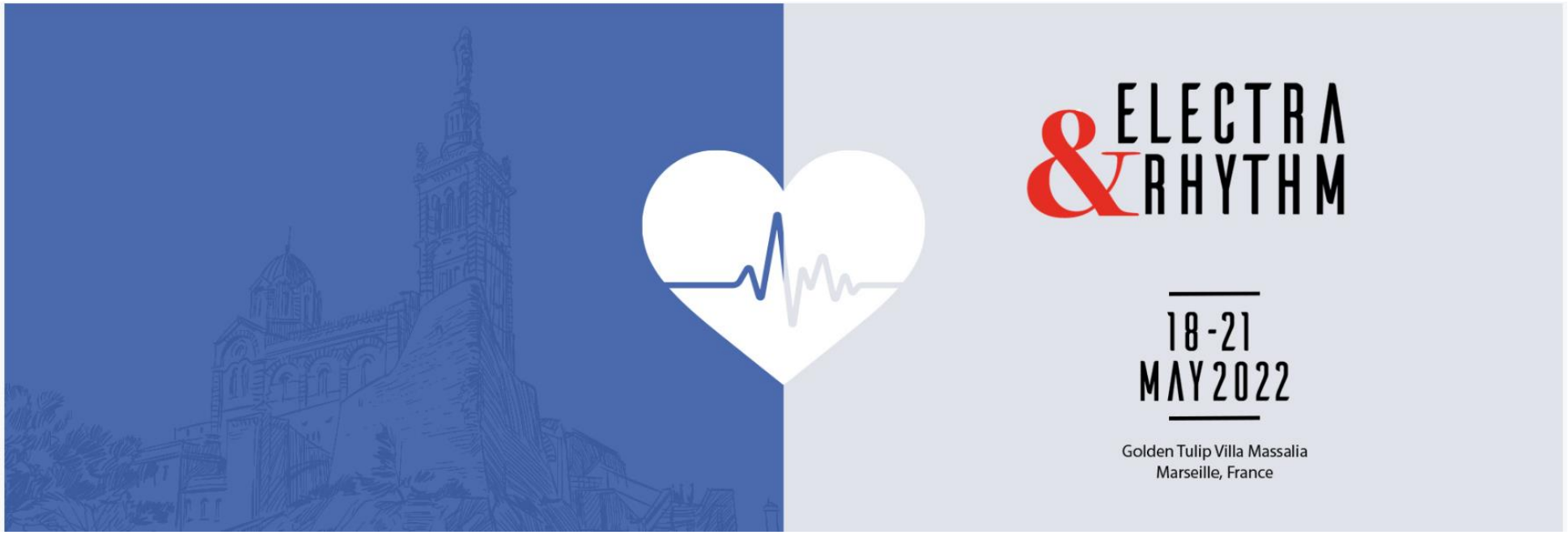
- Consider ILR
- Clinical follow-up

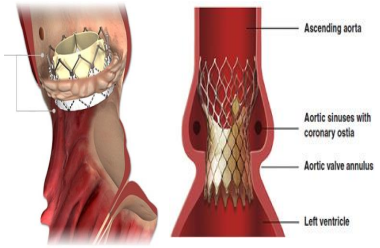
**Low risk patients**

- No new CD No previous RBBB
- New early CD PR<240-QRS<150
- HG-AVB during TAVI

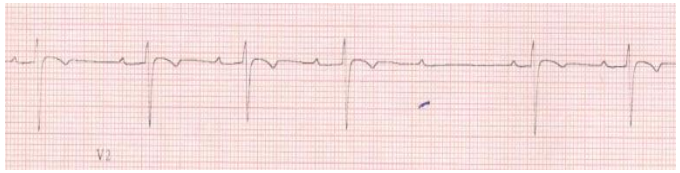
Worsening of CD beyond D1

→ Early discharge No pacemaker, no ILR








# Thank you for your attention