Durabilité à 4-5 ans : Etudes Partner 3 & Evolut Low Risk

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Etat des lieux avant la publication de ces 2 études

- **A partir des études Partner 1-2 et US Corevalve high-risk/Surtavi à 5 ans**:

  - Mortalité : très élevée (30-65%) et similaire entre TAVI et chirurgie
  - IA : + fréquente après un TAVI
  - Mismatch : + fréquent après chirurgie
  - Thrombose : rare
  - Endocardite : similaire entre TAVI et chirurgie
  - SVD : > RVA (Sapien XT) et < RVA (Corevalve)
  - Réinterventions : + fréquentes après TAVI (Sapien XT et Corevalve)

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ORIGINAL INVESTIGATIONS

3-Year Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis

Letters

RESEARCH LETTER

4-Year Outcomes of Patients With Aortic Stenosis in the Evolut Low Risk Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

This article was published on October 24, 2023, at NEJM.org.

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Plan de présentation

- Critère de jugement principal
- Paramètres hémodynamiques
- Détériorations valvulaires : SVD, IA, mismatch, thrombose, endocardite, réintervention (critères VARC-3)
- A partir des publications (Partner 3 à 5 ans: NEJM, US Corevalve à 3-4 ans: JACC) **ET** présentations TCT 2023
- Comparaisons: TAVI versus chirurgie et non pas Sapien 3 vs Corevalve Evolut R/Pro

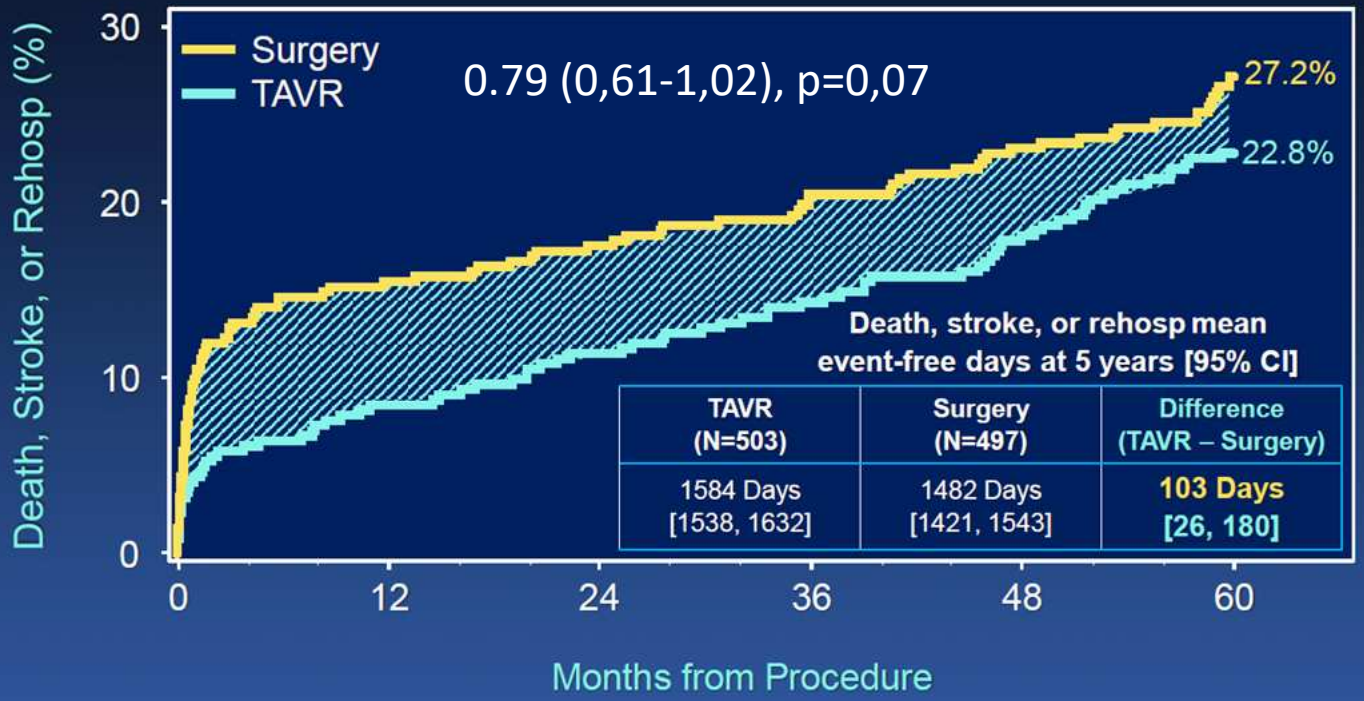
Patient Disposition to 5 Years

Randomized: N = 1000

Allocated to TAVR N = 503	Allocated to Surgery N = 497
Did not receive allocated intervention (n=7) • Died before treatment: 0 • Exclusion criteria found after randomization: 1 • Withdrew: 6	Did not receive allocated intervention (n=43) • Died before treatment: 0 • Exclusion criteria found after randomization: 8 • Withdrew: 35
Procedure Initiated (AT) N = 496	Procedure Initiated (AT) N = 454
1 Withdrawal	11 Withdrawals 1 Lost to f/u
1-year follow up N = 99.8% (495/496)	1-year follow up N = 97.4% (442/454)
11 Withdrawals 15 Lost to f/u	31 Withdrawals 10 Lost to f/u
5-year follow up N = 94.6% (469/496)	5-year follow up N = 88.3% (401/454)
Total 18 withdrawals 16 Lost to f/u	**Total** 77 withdrawals 11 Lost to f/u

91.6% of patients available for primary endpoint analysis at 5 years

Restricted Mean Event-free Survival Time (Days)



All-cause Death

Number at risk:

TAVR	496	490	478	460	438	405
Surgery	454	427	409	394	379	346

Causes of Death 0-5 Years

CV Causes

Cause, No. of pts	TAVR	Surgery
Cardiac Cause	**8**	**9**
Acute MI	0	2
Cardiac Arrest	2	1
Cardiogenic Shock	0	1
CHF	2	3
Endocarditis	0	1
Sudden Cardiac Death	4	1
Non-coronary Vascular Conditions	**11**	**6**
Procedure-related	2	2
Stroke	3	4
Traumatic Head Injury from Fall	**6**	**0**
Unknown	**7**	**6**
Totals	**26**	**21**

Non-CV Causes

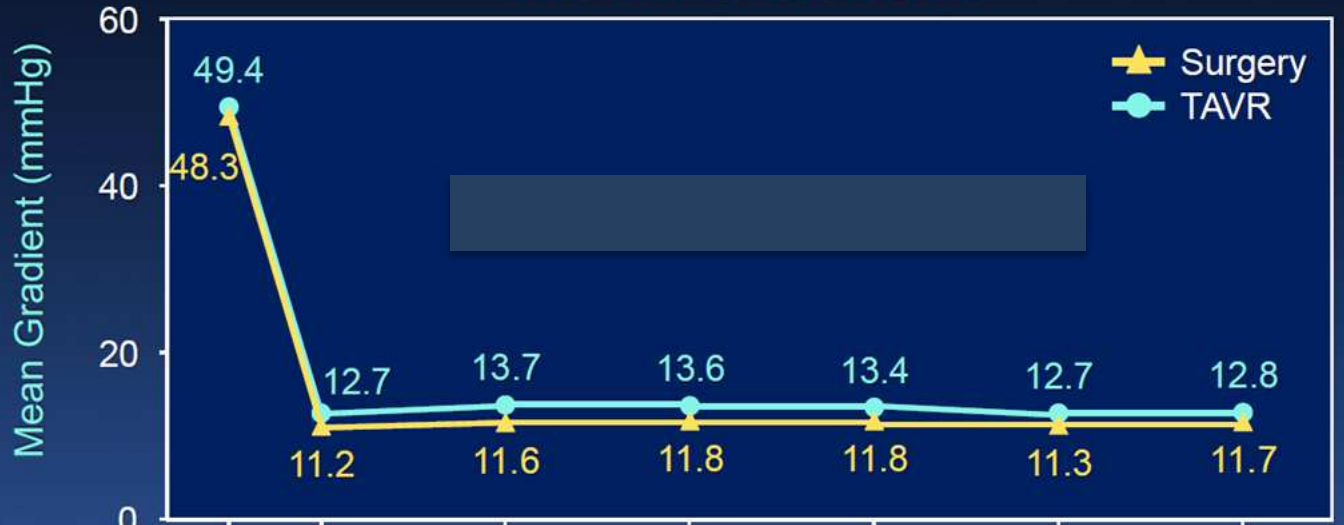
Cause, No. of pts	TAVR	Surgery
Cancer	**9**	**5**
COVID-19	**3**	**1**
Cirrhosis	1	0
MVA	1	1
Parkinson's Disease	0	1
Respiratory Failure*	3	4
Sepsis	**4**	**1**
Suicide	1	0
Totals	**22**	**13**

*Due to chronic respiratory disease or pneumonia

THE PARTNER 3 TRIAL

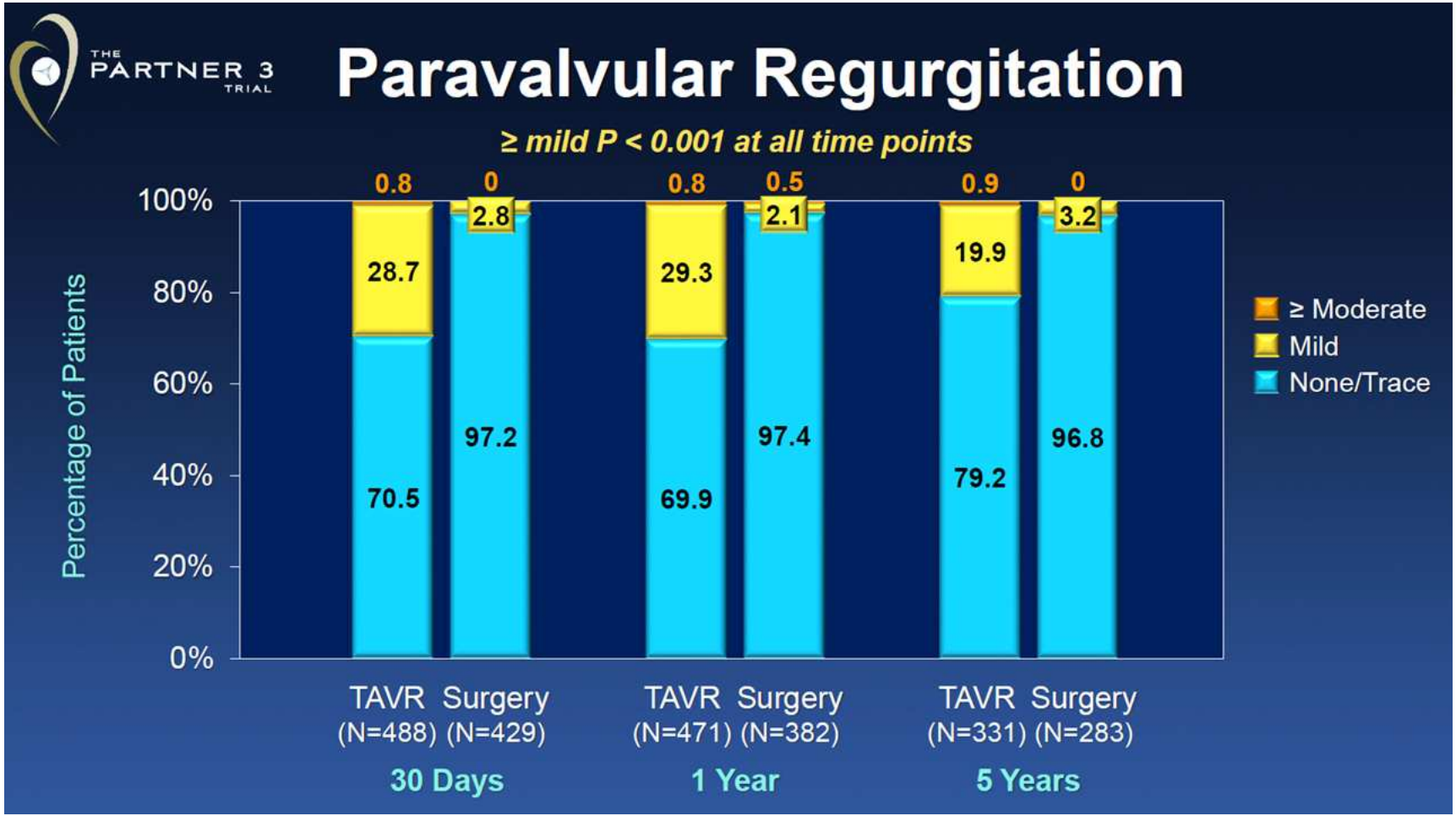
Valve Hemodynamics

Mean Gradient



No. of Echos:

TAVR	483	492	474	437	372	348	329
Surgery	442	432	391	360	304	305	282


THE PARTNER 3 TRIAL
Paravalvular Regurgitation
≥ mild P < 0.001 at all time points
Percentage of Patients
100%
80%
60%
40%
20%
0%
0.8
28.7
70.5
0
2.8
97.2
0.8
29.3
69.9
0.5
2.1
97.4
0.9
19.9
79.2
0
3.2
96.8
≥ Moderate
Mild
None/Trace
TAVR Surgery
(N=488) (N=429)
30 Days
TAVR Surgery
(N=471) (N=382)
1 Year
TAVR Surgery
(N=331) (N=283)
5 Years

Valve Thrombosis

THE PARTNER 3 TRIAL

No. of patients

Clinically Significant Valve Thrombosis	0 – 5 Years	
	TAVR	Surgery
Valve Thrombosis Events*	**13 events in 12 pts†**	**1 event in 1 pt**
Clinical Sequelae Related to Thrombosis		
Death	0	0
Stroke (all ischemic)	3	0
Disabling	1	0
Non-disabling	2	0
Stage 2 or 3 HVD	8	0
Occurred after 1 year	11†	1
Resolved with Anticoagulation	7	0

*All patients had confirmatory imaging

†1 patient had 2 events; the first occurred POD 40, the second POD 371 (both Stage 1 HVD)

Endocarditis

Endocarditis Events	0 – 5 Years	
	TAVR	Surgery
No. of Patients (KM rate)	**6 (1.3%)**	**8 (2.0%)**
Clinical Events Within 30 Days		
Death	0*	1
Stroke (all ischemic)	1	2
Disabling	1†	1
Non-disabling	0	1
AV Reintervention (all surgical explants)	1	4

*1 patient died due to cancer (non-CV)
†1 patient had 3 strokes

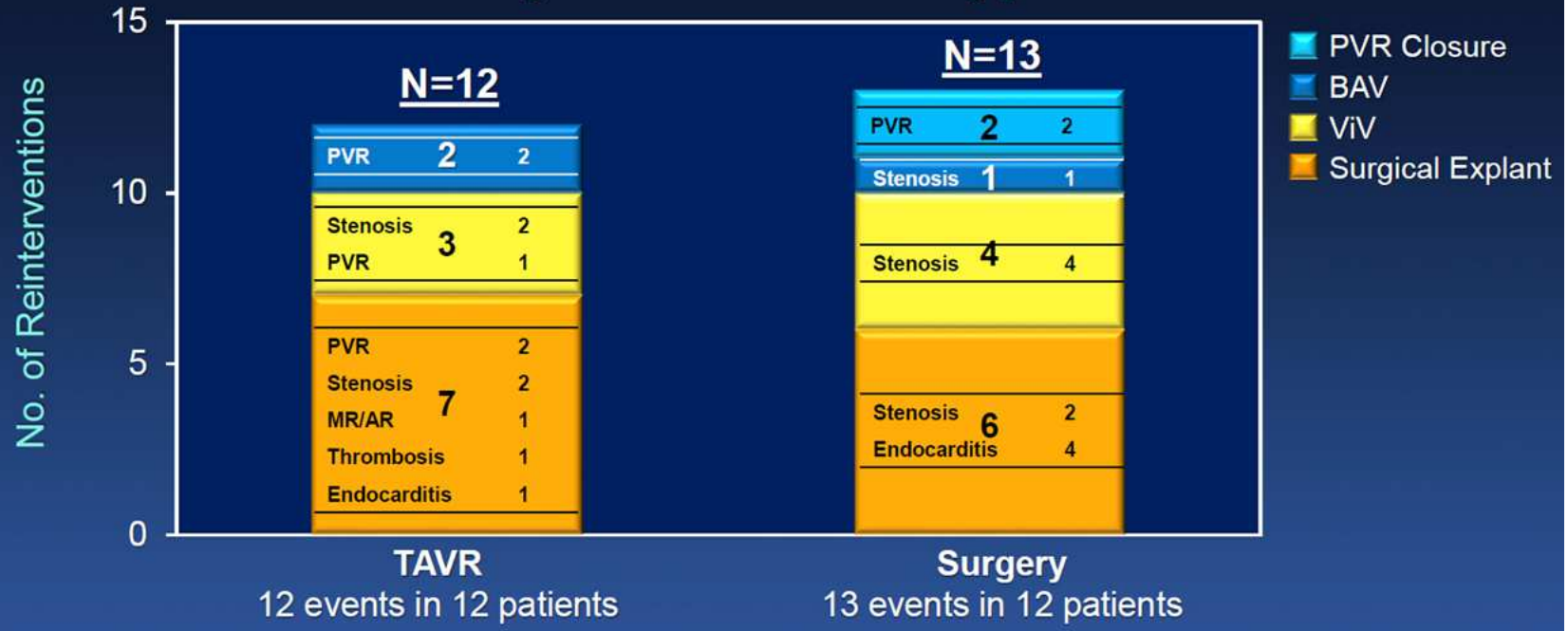
THE PARTNER 3 TRIAL Stage 2/3 SVD to 5 Years (VARC 3)

Number at risk:

TAVR	496	490	476	454	428	387
Surgery	454	426	407	385	366	332

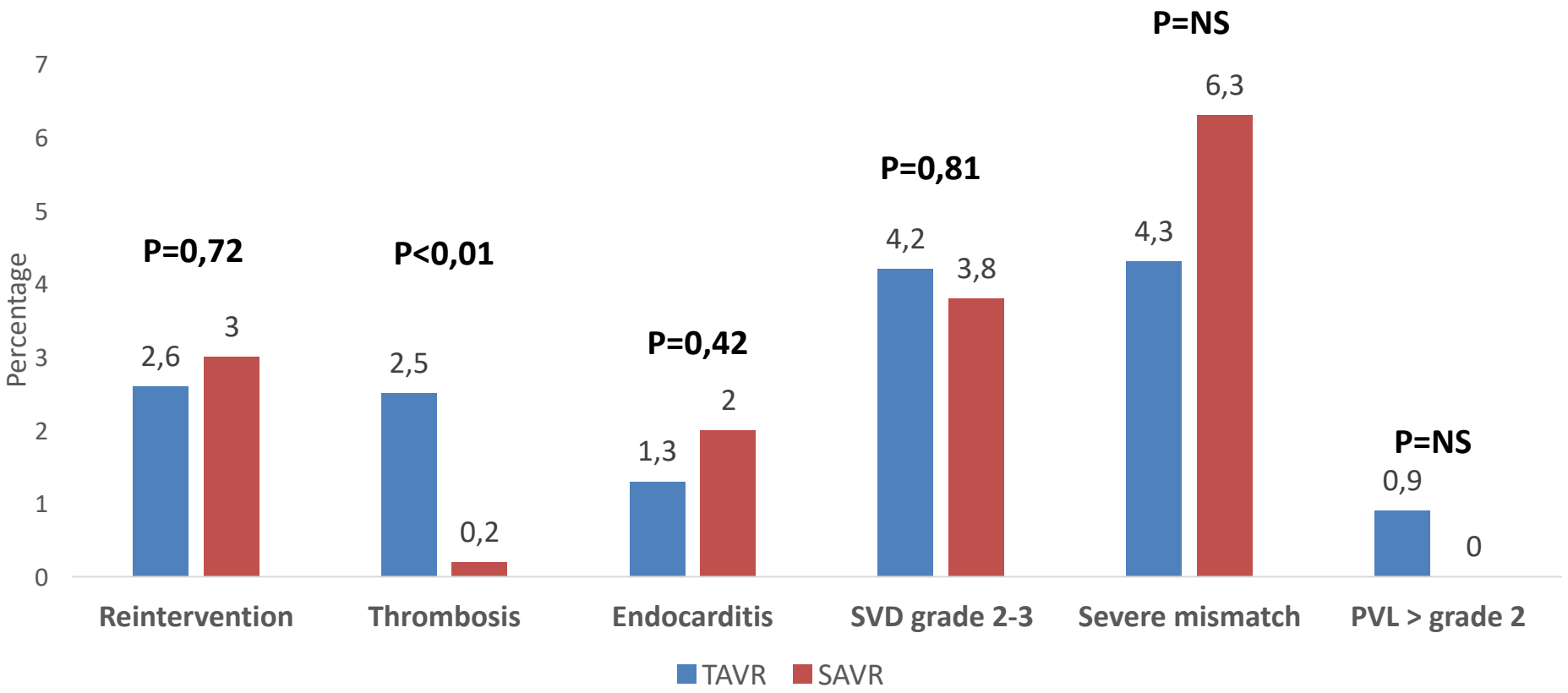
THE PARTNER 3 TRIAL AV Reinterventions 0 – 5 Years

By Cause and Type



Through 5-year follow-up, 7 TAVR and 6 Surgery patients required surgical explantation

Indicence of Valve deterioration in Partner 3 study



EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

Study Design

Evolut™ Low Risk Trial

Patients with Severe AS
Low risk of death (<3%) from surgery
Anatomy suitable for both TAVR and SAVR

Screening Committee
Confirmed eligibility

1:1 Randomization
May 2016 to May 2019
1414 Patients

Clinical Events Committee
Echo Core Laboratory

Evaluable status[a] at 4Y
94.7% TAVR
89.2% Surgery

	Start	1	2	3	4	5	6	7	8	9
TAVR N=730		724	715	704	691					
SAVR N=684		652	634	624	610					

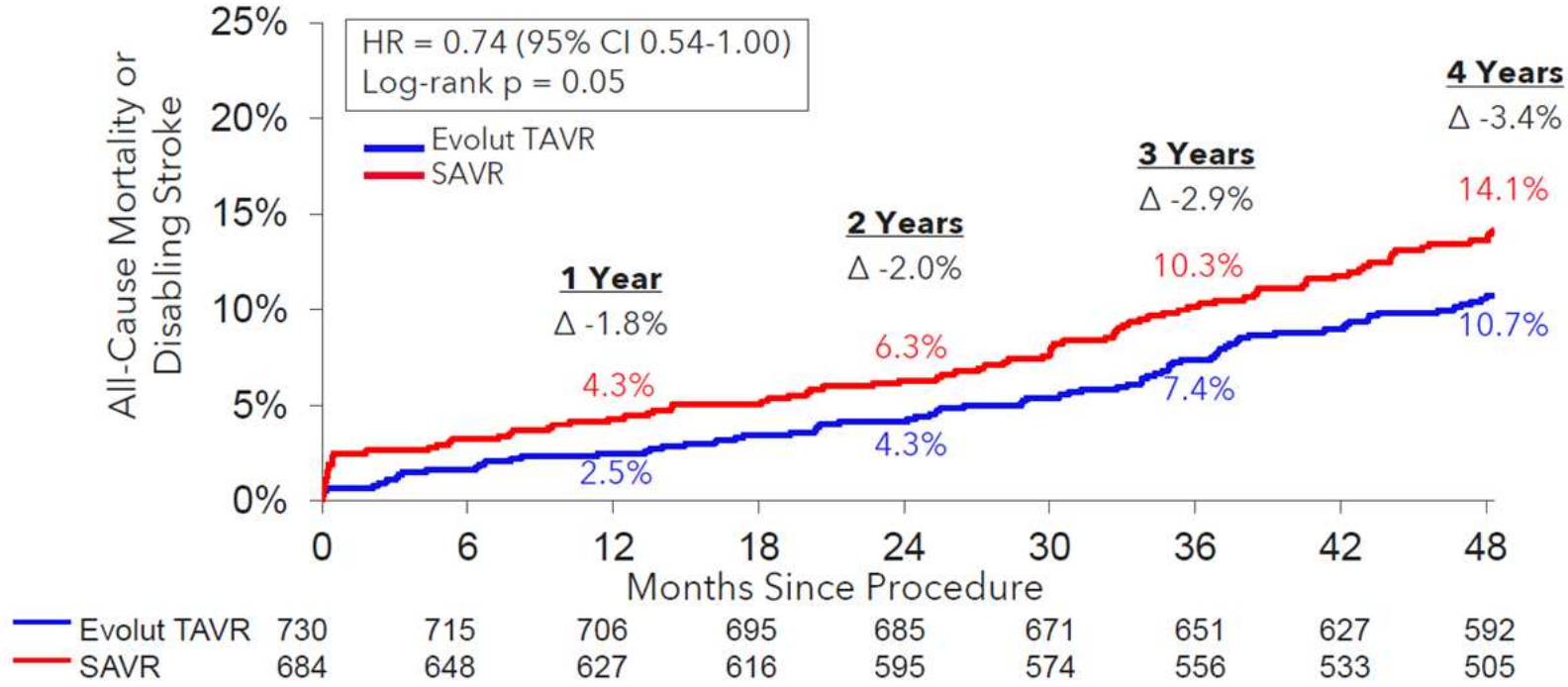
Years of Follow-Up

Evolut R → Evolut PRO

EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

Primary Endpoint: All-Cause Mortality and Disabling Stroke

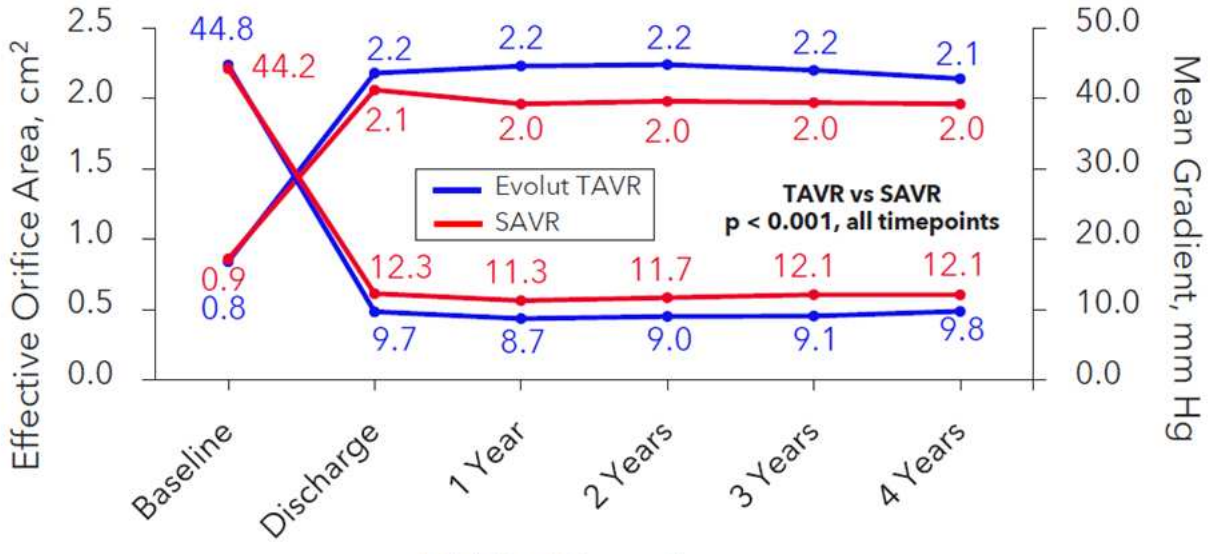
26% Relative Reduction in Hazard for Death or Disabling Stroke (p = 0.05) with Evolut TAVR vs SAVR and the Curves Continue to Separate Over Time



EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

Comparative Hemodynamics

Significantly Better Hemodynamics with Evolut TAVR vs SAVR



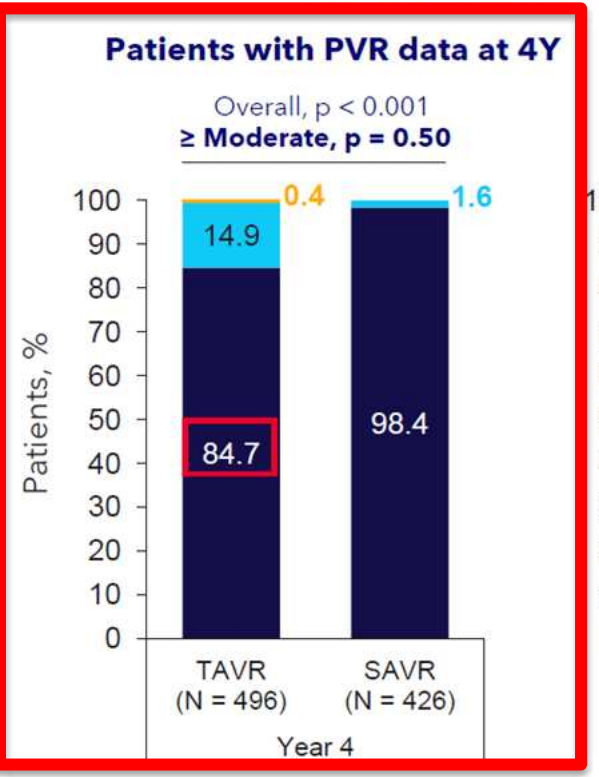
No. of Patients						
TAVR EOA	637	576	565	535	493	438
SAVR EOA	596	406	525	434	397	372
TAVR MG	717	703	662	607	547	497
SAVR MG	679	632	597	514	457	438

EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

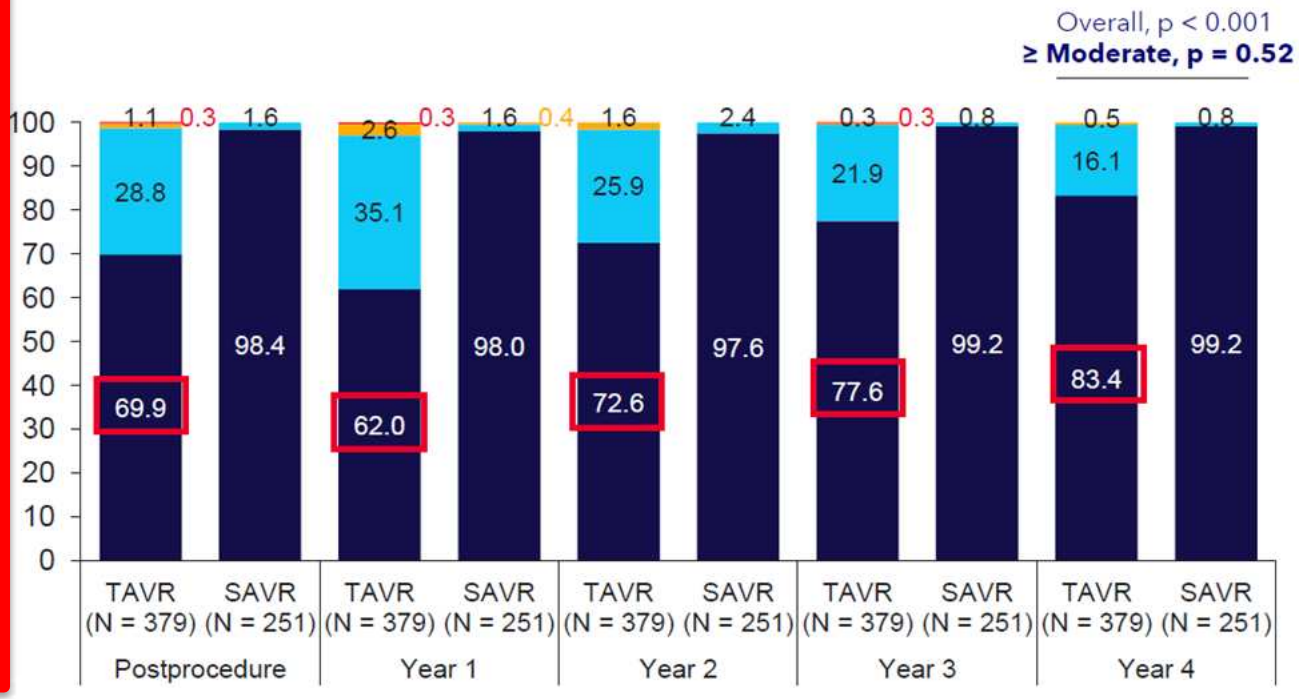
Paravalvular regurgitation

No Difference Between Groups in Moderate or Greater PVR

Patients with PVR data at 4Y

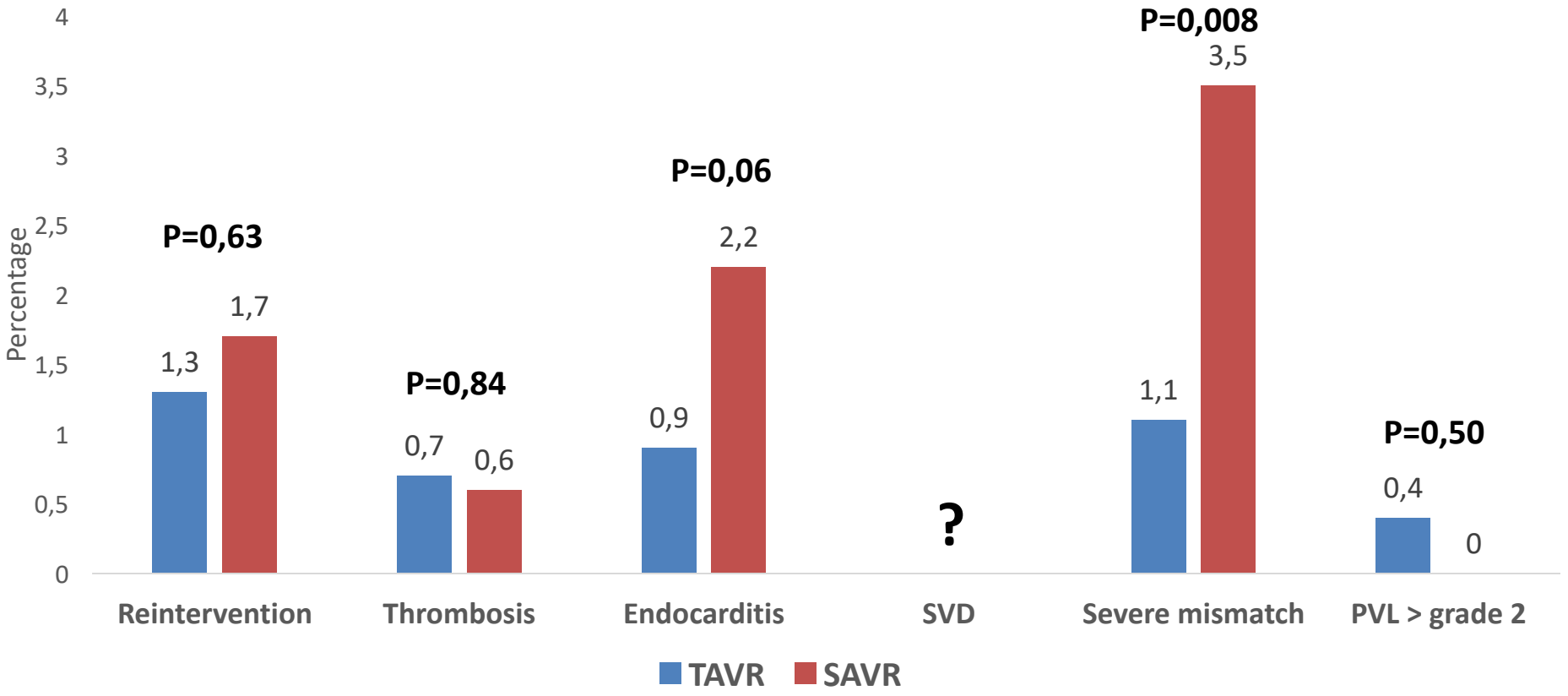


Patients with PVR data at all visits (paired data)



None/Trace Mild Moderate Severe

Indicence of Valve deterioration in Evolut Low risk study



Conclusions

- **Résultats rassurants en terme de durabilité** des bioprothèses aortiques implantées par voie percutanée **par rapport aux bioprothèses chirurgicales**

- Plus de **thrombose avec les prothèses délivrables au ballonnet par rapport à la chirurgie, notamment au delà de 1 an**

- **Les données concernant la SVD (dégénérescence) sont rassurantes** mais ne sont pas disponibles pour l'étude US Corevalve avec des **taux de réintervention similaires entre le TAVI et la chirurgie**

- **La mortalité à 5 ans est faible et d'environ 10%** (vs 30-40% en cas de risque intermédiaire vs 55-65% chez les hauts risques)

- **Les résultats à plus long terme (10 ans) sont donc attendus et permettront de définitivement comparer la durabilité des bioprothèses percutanées AVEC les bioprothèses chirurgicales**