

Late Clinical Outcomes with Balloon Expandable Valves in Small Annulus Patients from the PARTNER Trials

Rebecca T. Hahn, MD, on behalf of the PARTNER Trial
Investigators

Disclosures

Rebecca T. Hahn, MD

Within the prior 24 months, I have had a financial relationship with the following:

<u>Nature of Financial Relationship</u>	<u>Company</u>
Speaker/Honoraria	Abbott Structural, Baylis Medical, Edwards Lifesciences, Medtronic, Philips Healthcare, and Siemens Healthineers
Institutional Contracts	Abbott Structural, Anteris, Edwards Lifesciences, Medtronic, and Novartis

All Financial Relationships have been mitigated.
Faculty disclosure information can be found on the app

Background

- Despite reports of higher mean gradients and rates of PPM at 30-days post TAVR with BEVs, multiple studies in patients with small aortic annuli (CT annular area ≤ 430 mm²) show similar short term clinical outcomes between BEVs and SEVs.¹⁻⁴
- Regardless of annulus size, the impact of PPM and mean gradient on mortality, stroke, and HF hospitalization (HFH) after TAVR remains controversial.
- 5-year follow-up from the PARTNER 2 S3i registry and PARTNER 3 trial revealed no association between severe PPM or MG ≥ 20 mmHg and clinical outcomes or valve durability.^{5,6}

Objective

- To compare 5-year outcomes in low- and intermediate-risk AS patients receiving a SAPIEN 3 BE TAVR
 - Small vs. Large Annulus
 - Small Annulus
 - Mean gradient (MG)
 - Prosthesis-patient mismatch (PPM)

Outcomes

Primary Endpoint

- Composite of all-cause death, disabling stroke, and HFH at 1 and 5 years

Additional Outcomes

- Aortic valve reintervention and bioprosthetic valve failure (BVF)
- Impact of 30-day MG and 30-day PPM on longer-term outcomes

Analysis Populations

Small vs Large Annulus

Symptomatic Severe Aortic Stenosis Patients in the PARTNER 2 S3i registry (n=870) or PARTNER 3 RCT (n=485)

1355 patients who received
SAPIEN 3 TF-TAVR

476 (35%) pts with CT
systolic aortic annular
area ≤ 430 mm²

879 (65%) pts with CT
systolic aortic annular
area >430 mm²

PRIMARY ENDPOINT AT 5 YEARS:
Non-hierarchical composite of all-cause death, disabling stroke, or HF hospitalization

Baseline Characteristics

Small vs Large Annulus

% or mean \pm SD

Demographics & Key Echo Characteristics†	Annulus \leq 430 (476)	Annulus $>$ 430 (879)	Other Comorbidities†	Annulus \leq 430 (476)	Annulus $>$ 430 (879)
Age (years)*	79.6 \pm 7.1	78.7 \pm 7.8	Creatinine $>$ 2mg/dL	8.0%	8.7%
Female Sex*	75.0%	16.2%	Atrial Fibrillation*	18.7%	34.1%
STS Score*	4.3 \pm 1.9	3.9 \pm 1.9	Pacemaker	6.9%	9.7%
LVEF (%)*	66.3 \pm 15.8	59.7 \pm 13.7	NYHA Class III or IV	57.4%	57.7%
AVA Index (cm ² /m ²)*	0.37 \pm 0.08	0.38 \pm 0.08	CAD*	45.8%	58.2%
Mean Gradient (mmHg)*	48.8 \pm 12.9	46.3 \pm 12.7	Hypertension	88.2%	90.2%
Annular Area (mm ²)*	376.7 \pm 41.9	518.3 \pm 58.0	Aortic Regurgitation	5.9%	5.4%

* = $p < 0.05$, unpaired *t*-test

Echocardiographic Outcomes

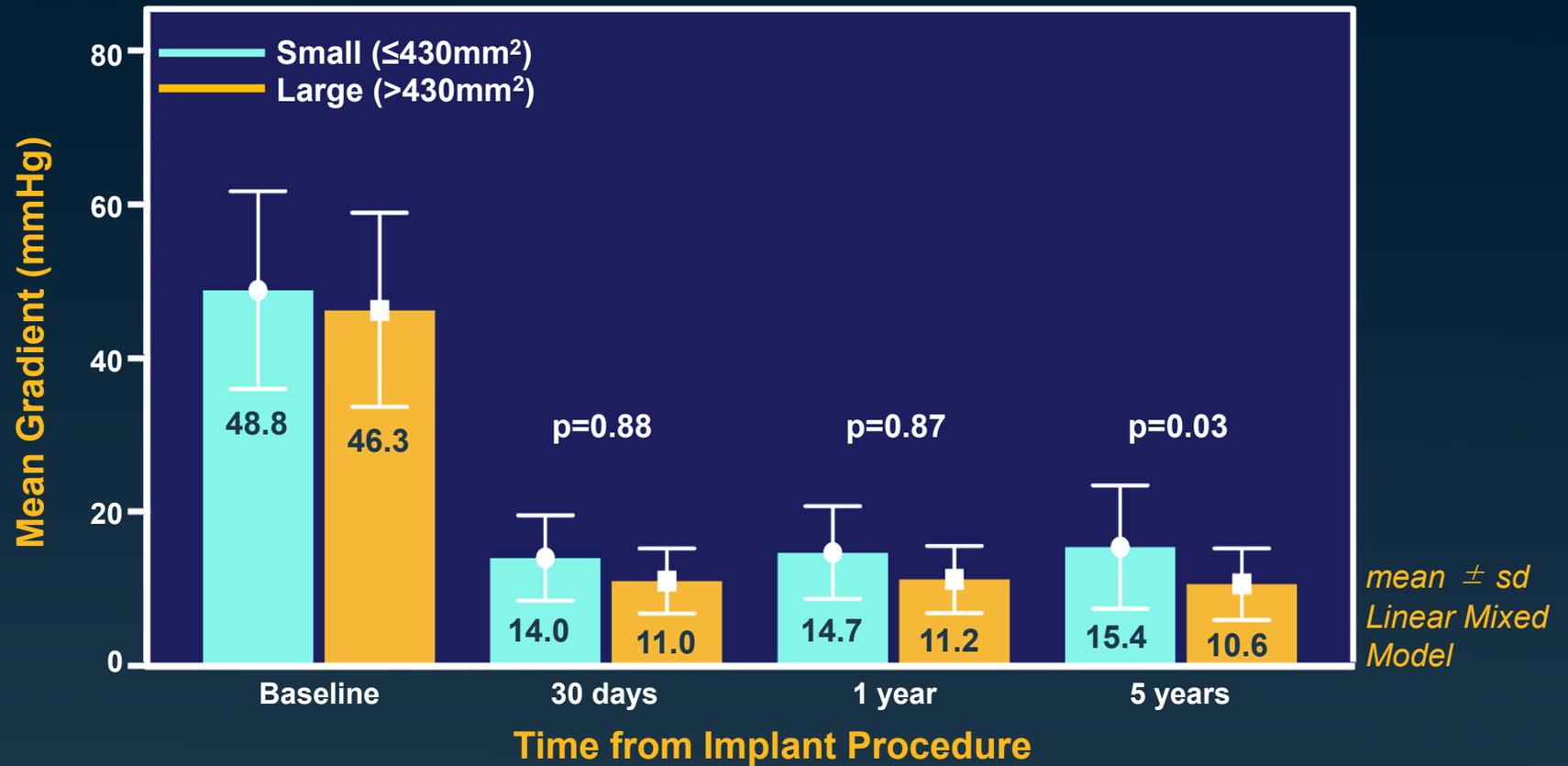
Small vs Large Annulus

% or mean \pm SD

Echocardiographic Variable (30d) †	Annulus \leq 430	Annulus $>$ 430	p-value
AVA (cm ²)	1.46 \pm 0.27 (432)	1.83 \pm 0.36 (826)	<0.0001
AVA Index (cm ² /m ²)	0.81 \pm 0.17 (432)	0.91 \pm 0.20 (826)	<0.0001
Mean Gradient (mmHg)	14.01 \pm 5.53 (459)	11.01 \pm 4.21 (855)	<0.0001
LVEF (%)	65.8 \pm 9.66 (411)	59.3 \pm 11.69 (806)	<0.0001
SVI (mL/m ²)	42.0 \pm 8.10 (432)	40.3 \pm 9.06 (827)	0.0007
Prosthesis-Patient Mismatch			<0.0001
None	238/432 (55.1%)	588/827 (71.1%)	
Moderate	146/432 (33.8%)	205/827 (24.8%)	
Severe	48/432 (11.1%)	34/827 (4.1%)	

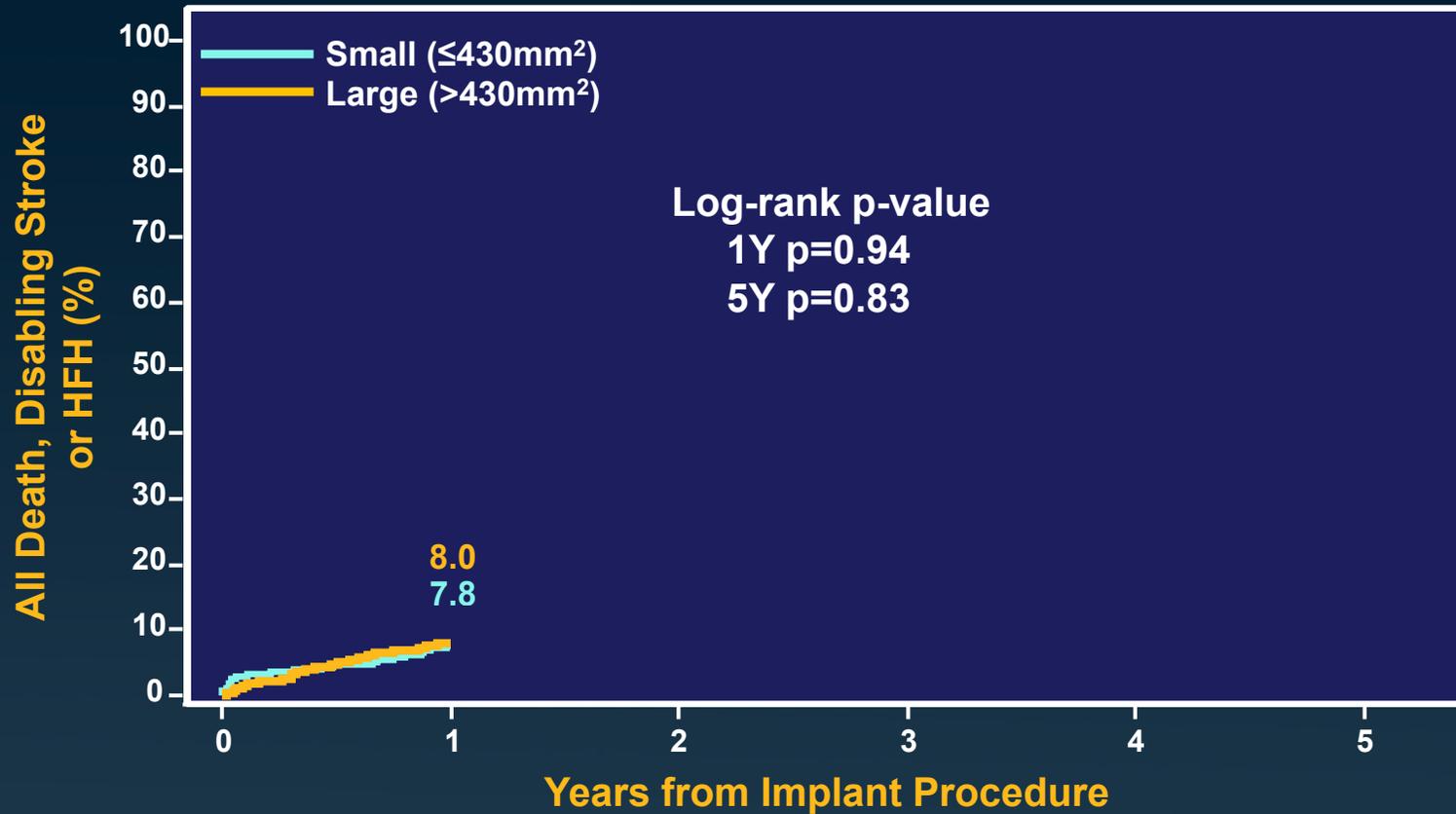
Mean Gradient

Small vs Large Annulus



Primary Endpoint

Small vs Large Annulus

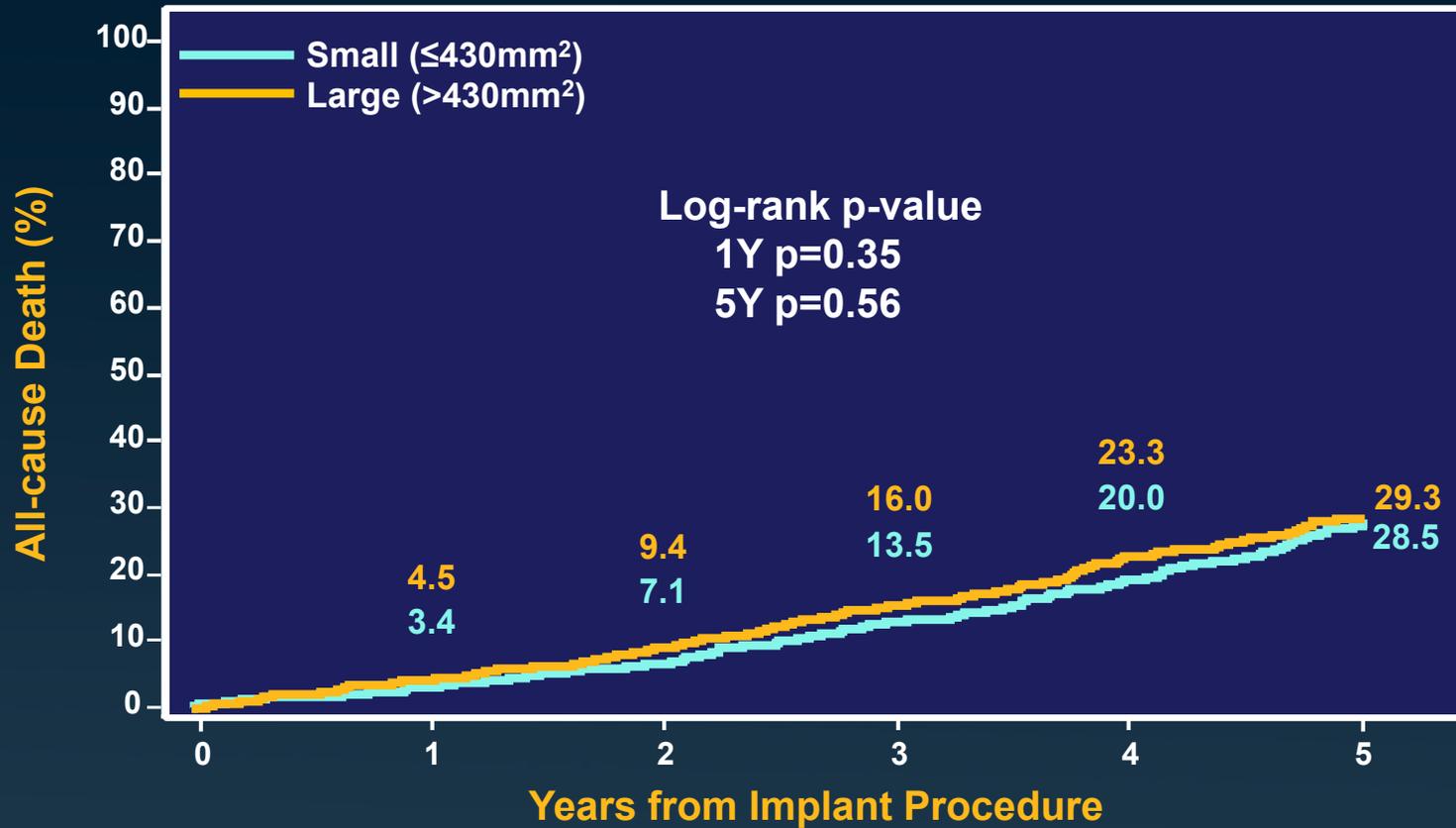


No. at Risk

Small	476	432	395	349	304	233
Large	879	799	730	657	562	443

All-cause Death

Small vs Large Annulus



No. at Risk

Small	476	451	425	384	340	254
Large	879	830	773	699	603	486

Risk Adjusted Outcomes

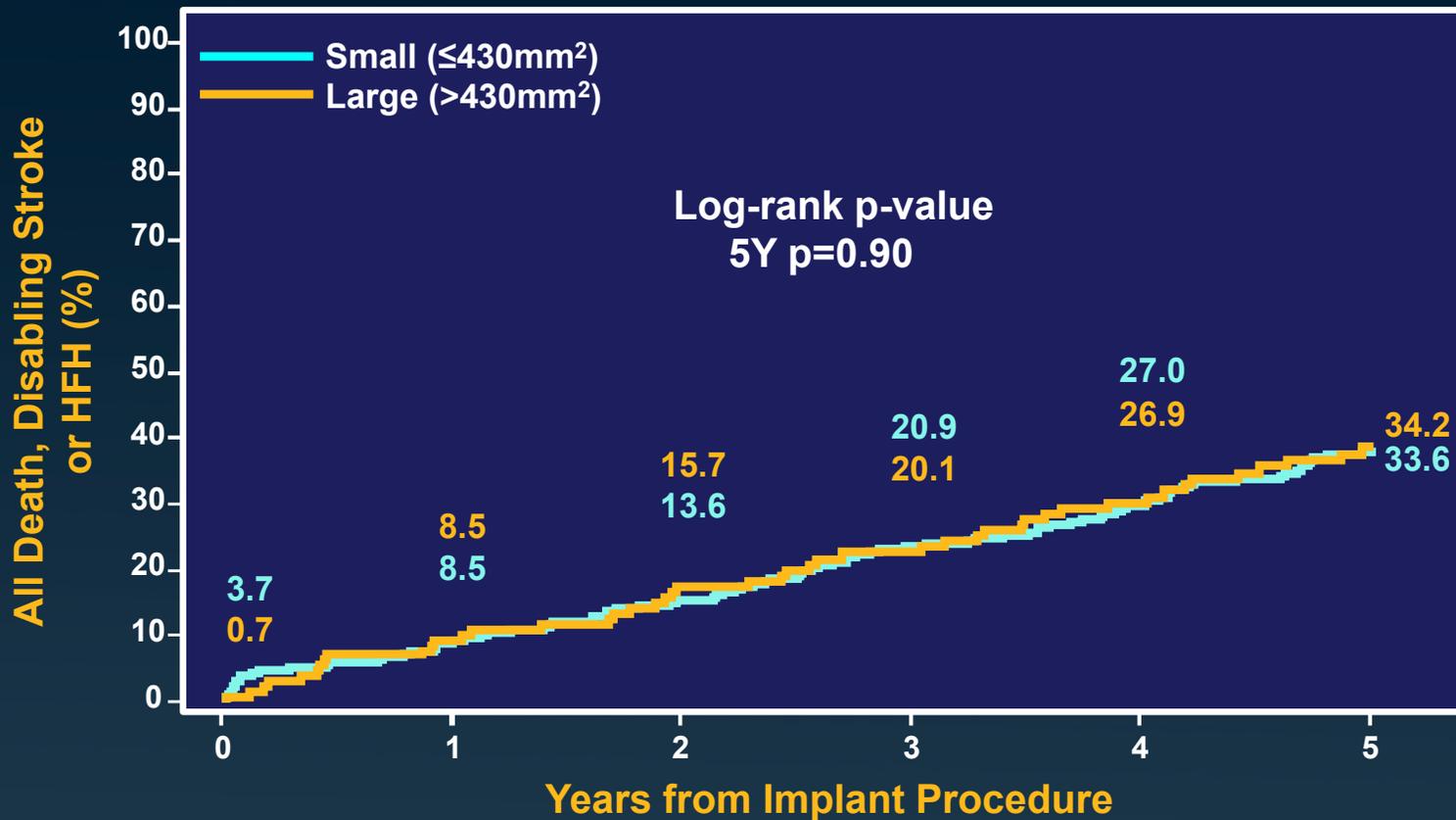
Small vs Large Annulus

5-Year Outcomes

	Adjusted Relative Risk [%95 CI]	Adjusted p-value
All-cause Death or Disabling Stroke or HFH	0.9 [0.5, 1.7]	0.68
All-cause Death	0.9 [0.5, 1.8]	0.76

Primary Endpoint

Females, Small vs Large Annulus

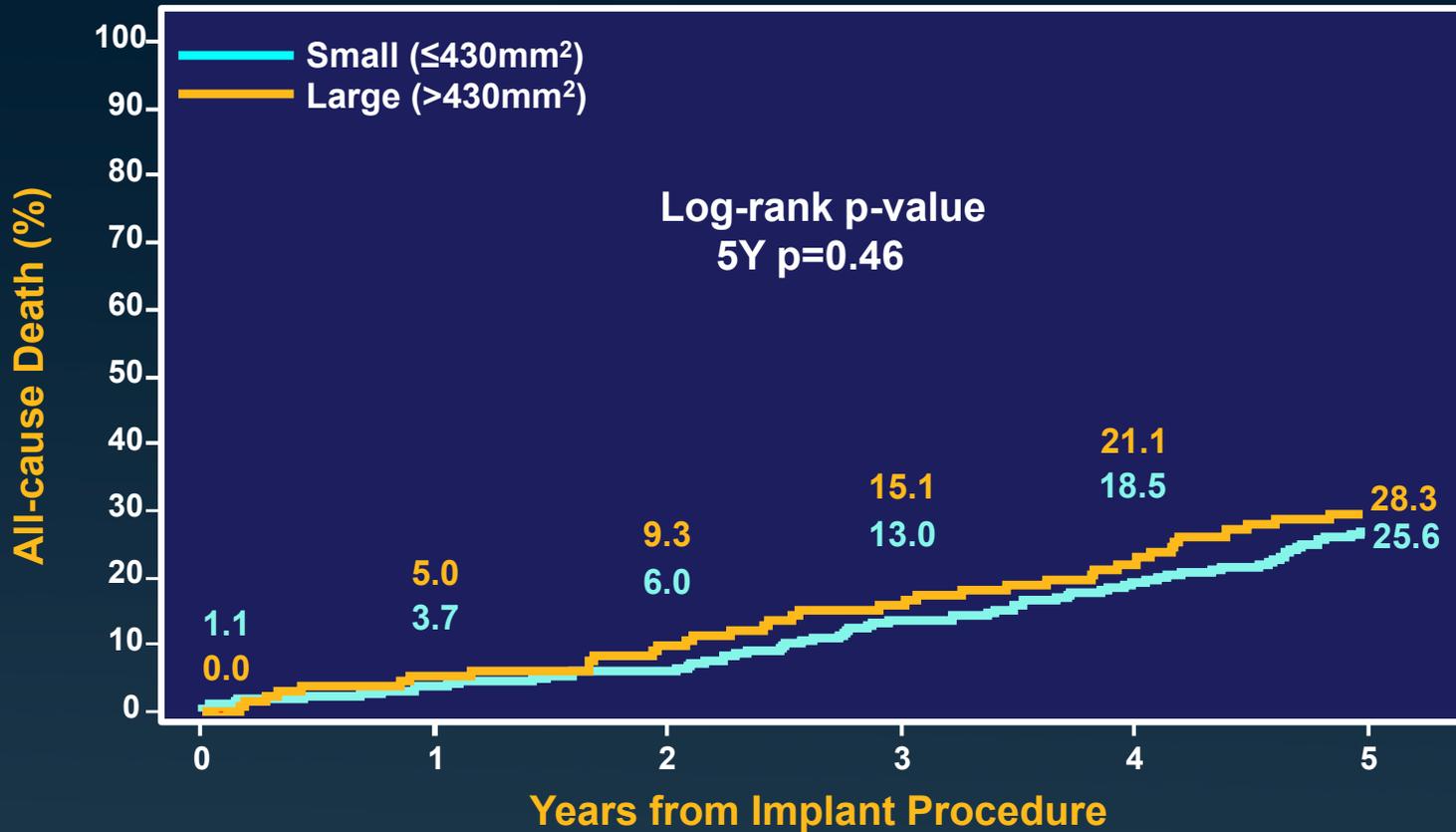


No. at Risk

	0	1	2	3	4	5
Small	357	323	299	266	234	183
Large	142	128	117	109	95	78

All-cause Death

Females, Small vs Large Annulus

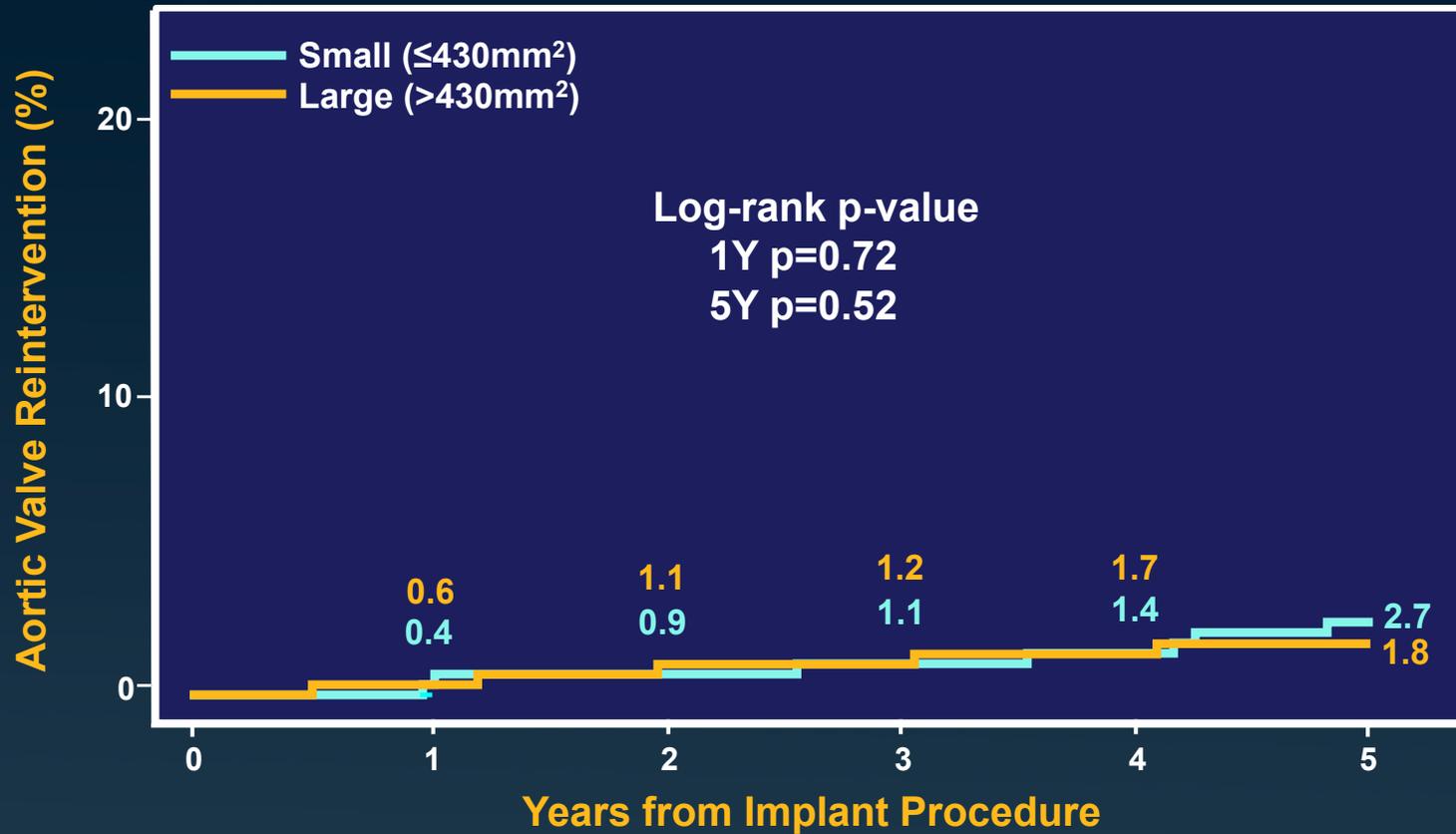


No. at Risk

	0	1	2	3	4	5
Small	357	338	324	292	261	200
Large	142	133	126	116	103	86

Aortic Valve Reintervention

Small vs Large Annulus

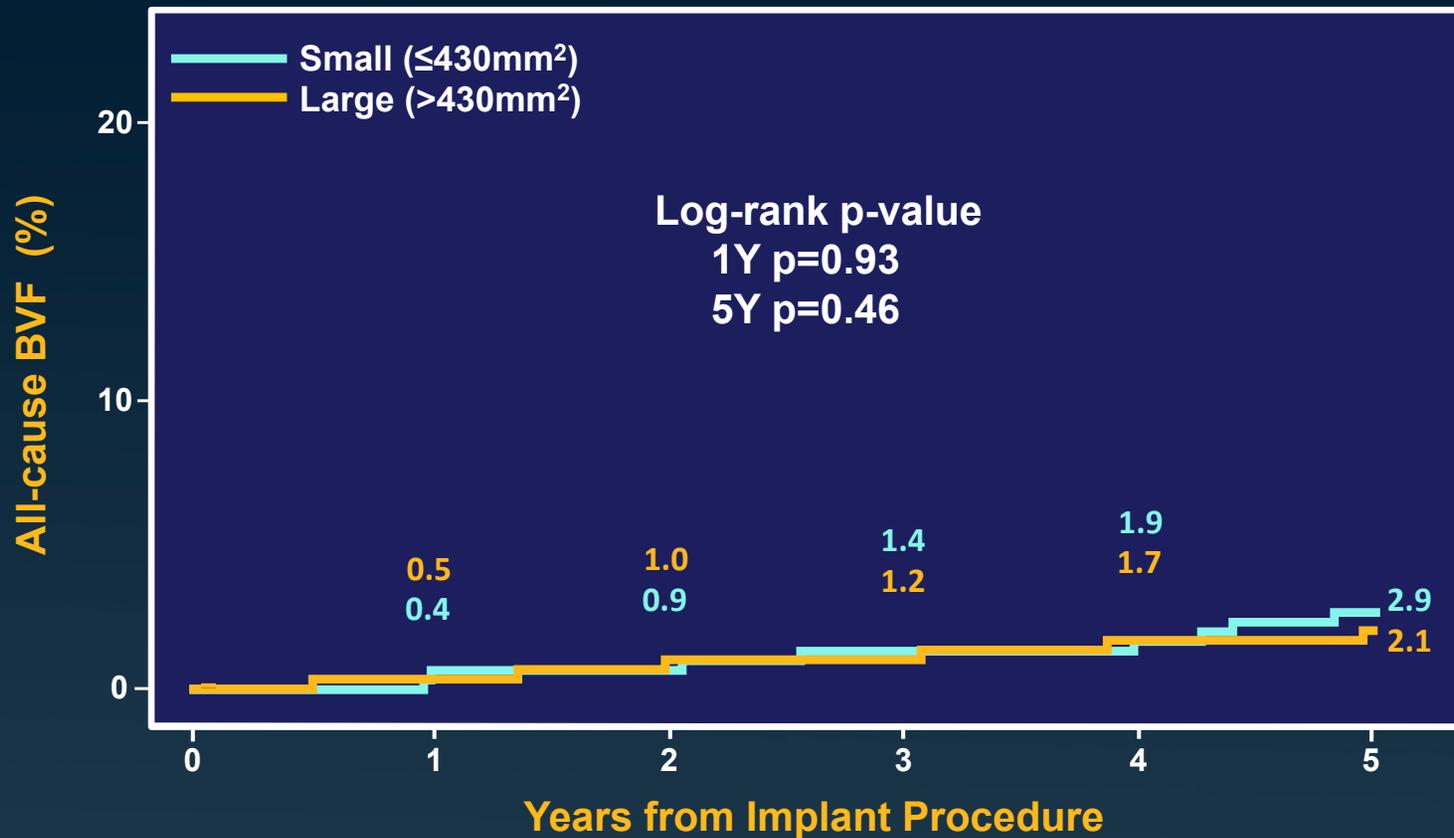


No. at Risk

	0	1	2	3	4	5
Small	476	449	422	389	335	257
Large	879	826	765	692	595	479

VARC-3 Bioprosthetic Valve Failure

Small vs Large Annulus

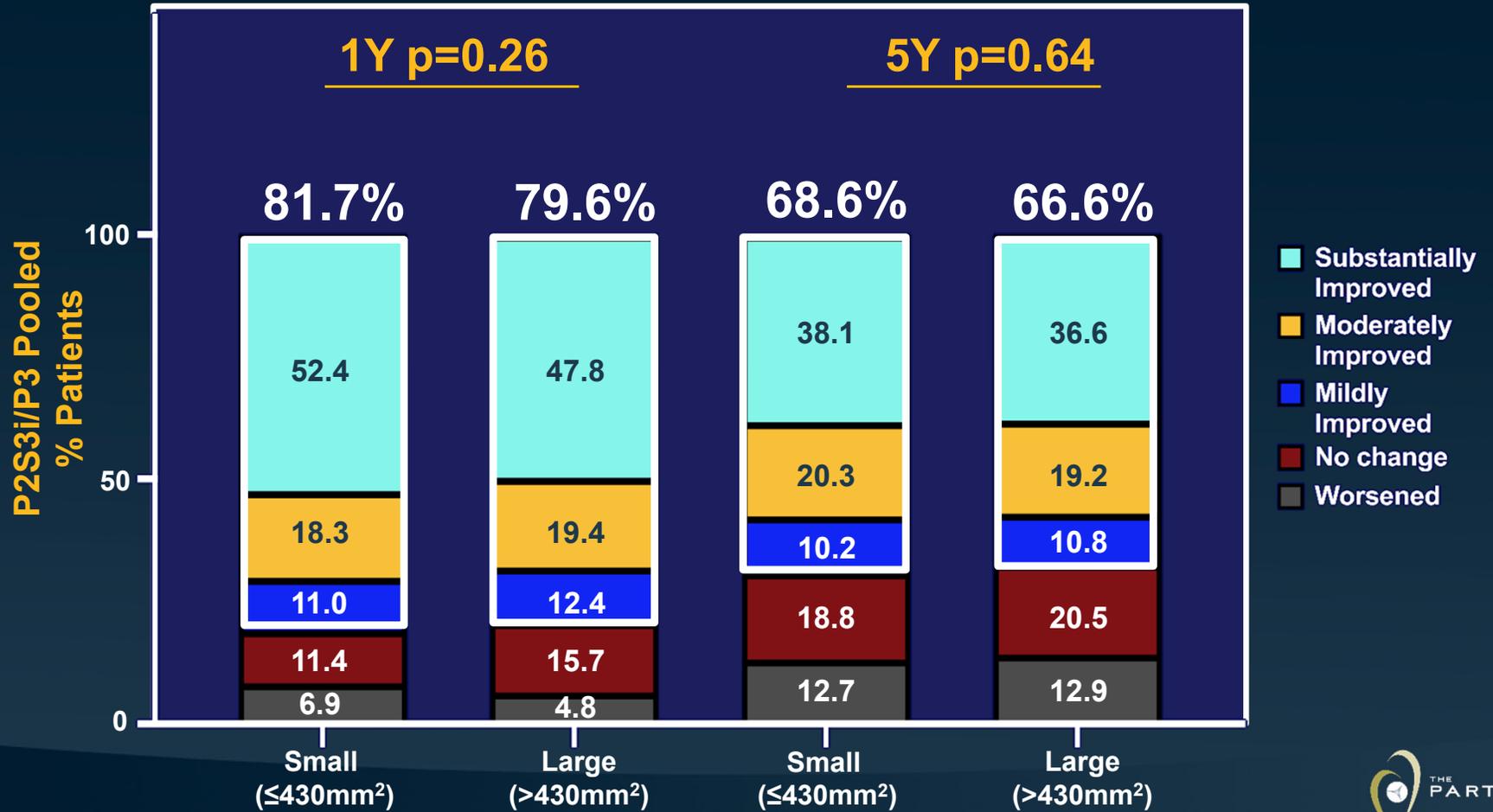


No. at Risk

Small	476	449	422	379	333	246
Large	879	827	766	691	594	477

Quality of Life in Survivors

Intermediate and Low Risk Patients



Analysis Populations

Small Annulus, MG <20 vs ≥20mmHg

Symptomatic Severe Aortic Stenosis Patients in the PARTNER 2 S3i registry (n=870) or PARTNER 3 RCT (n=485)

1355 patients who received SAPIEN 3 TF-TAVR

476 pts with CT systolic aortic annular area ≤430 mm²

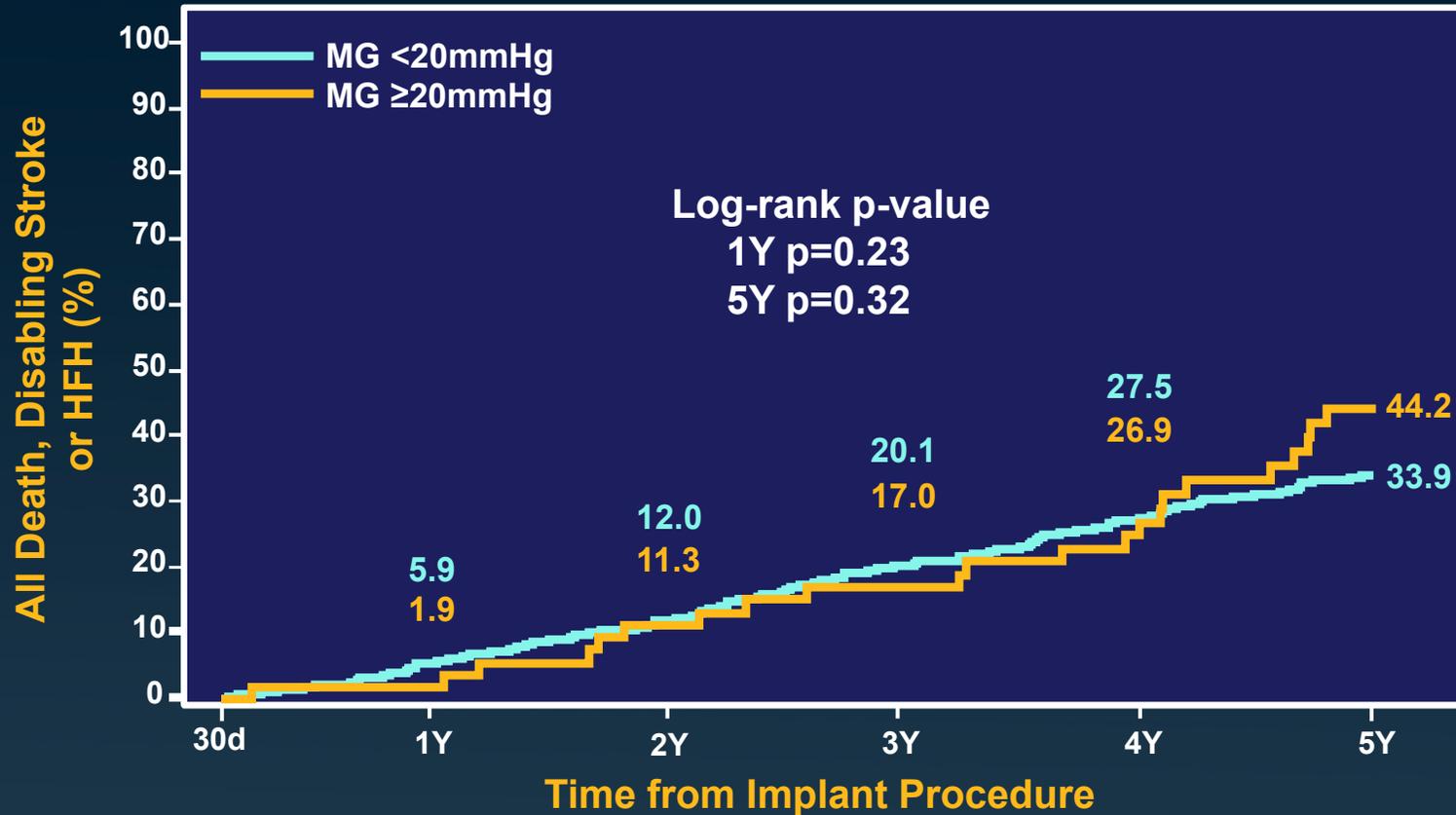
418 (89%) pts 30-day
Mean Gradient <20mmHg

54 (11%) pts 30-day
Mean Gradient ≥20mmHg

PRIMARY ENDPOINT ASSESSED AT 5-YEARS:
Non-hierarchical composite of all-cause death, disabling stroke, or HF hospitalization

Primary Endpoint

Small Annulus, MG <20 vs ≥20mmHg

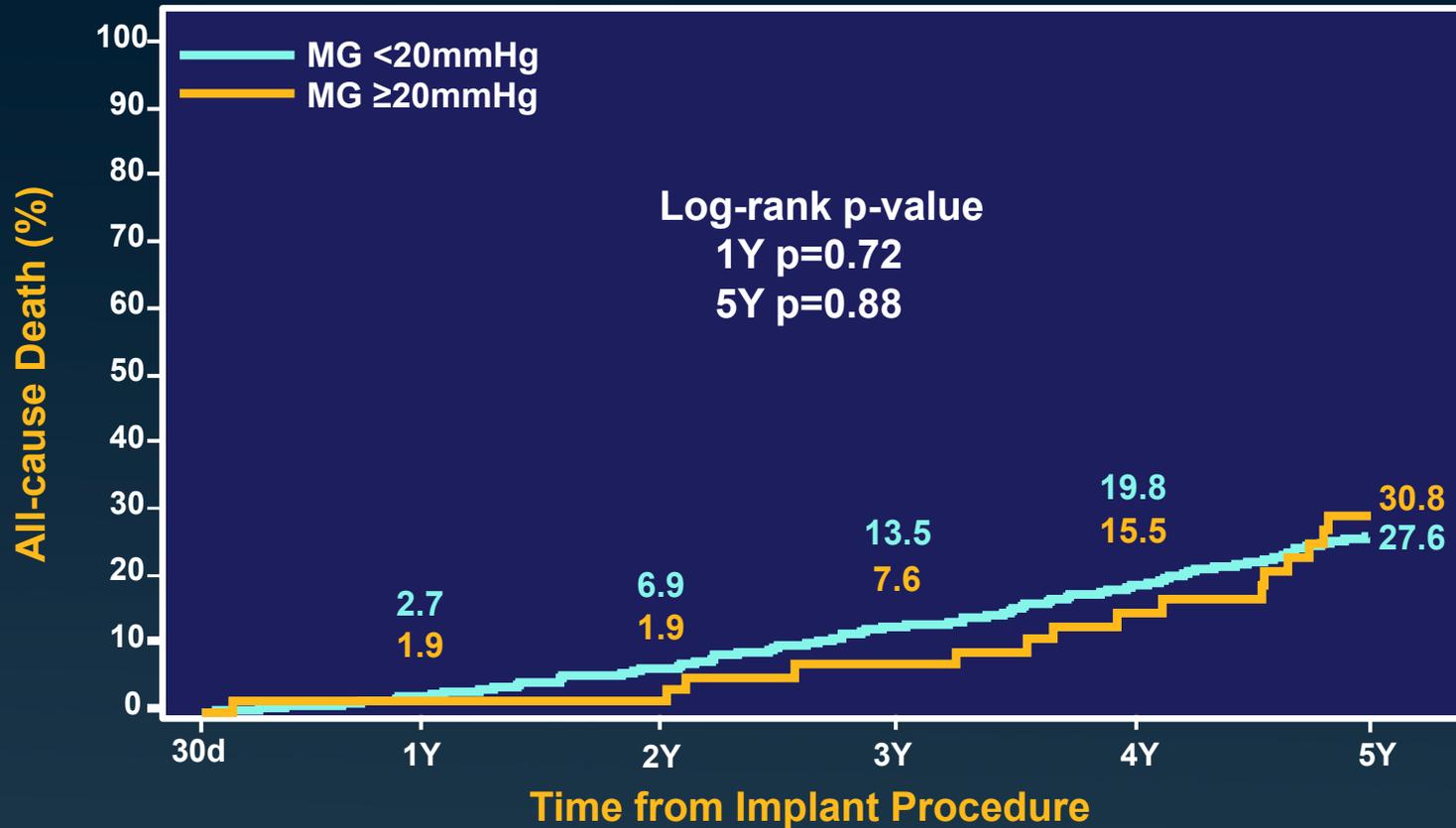


No. at Risk

	30d	1Y	2Y	3Y	4Y	5Y
<20mmHg	414	384	353	311	271	210
≥20mmHg	54	53	47	43	36	23

All-cause Death

Small Annulus, MG <20 vs ≥20mmHg



No. at Risk

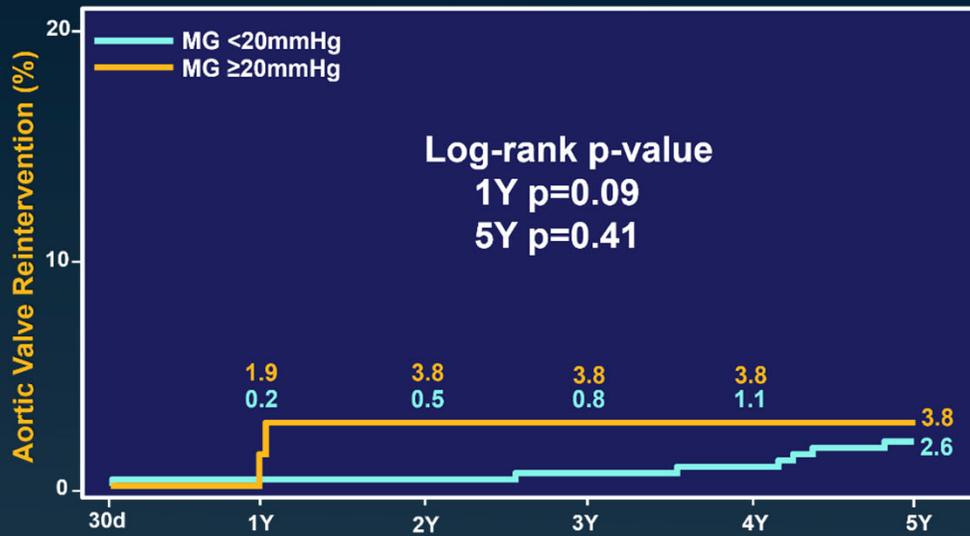
	30d	1Y	2Y	3Y	4Y	5Y
<20mmHg	414	396	372	335	298	225
≥20mmHg	54	53	52	48	41	28

Valve Durability

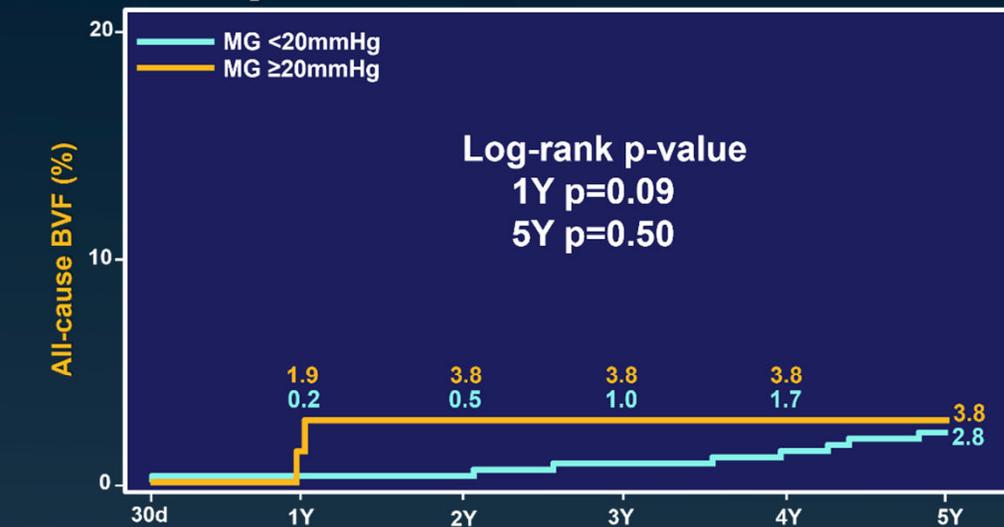
Small Annulus, MG <20 vs ≥20mmHg

VARC-3

Aortic Valve Reintervention



Bioprosthetic Valve Failure



No. at Risk

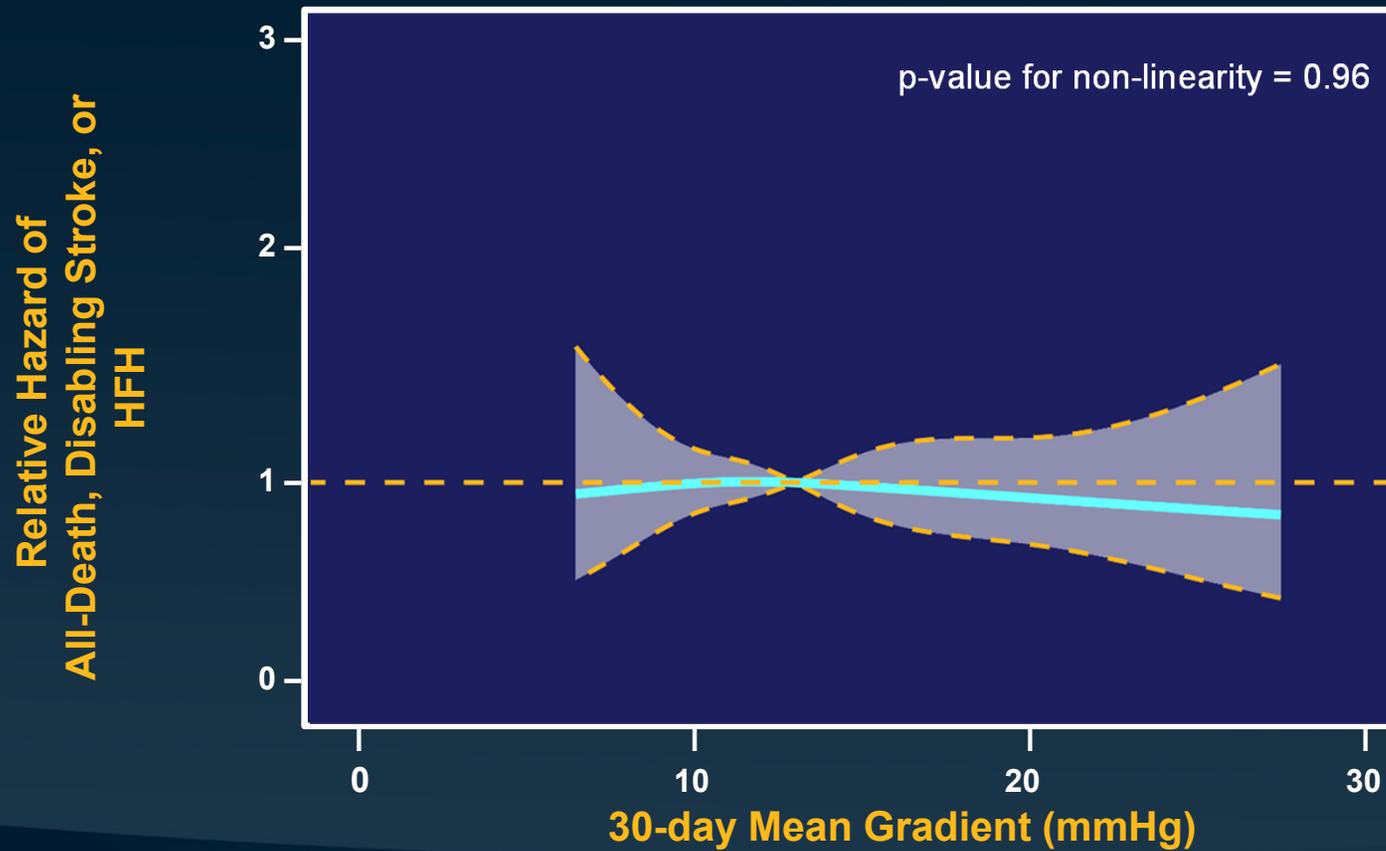
Time from Implant Procedure	30d	1Y	2Y	3Y	4Y	5Y
<20mmHg	414	395	371	333	295	220
≥20mmHg	54	52	50	46	39	26

No. at Risk

Time from Implant Procedure	30d	1Y	2Y	3Y	4Y	5Y
<20mmHg	414	395	371	332	293	219
≥20mmHg	54	52	50	46	39	26

Primary Endpoint

Small Annulus, Risk at 5Y according to MG



Analysis Populations

*Small Annulus, 30-day PPM**

Symptomatic Severe Aortic Stenosis Patients in the PARTNER 2 S3i registry (n=870) or PARTNER 3 RCT (n=485)

1355 patients who received SAPIEN 3 TF-TAVR

476 pts with CT systolic aortic annular area ≤ 430 mm²

238 (55%) No PPM

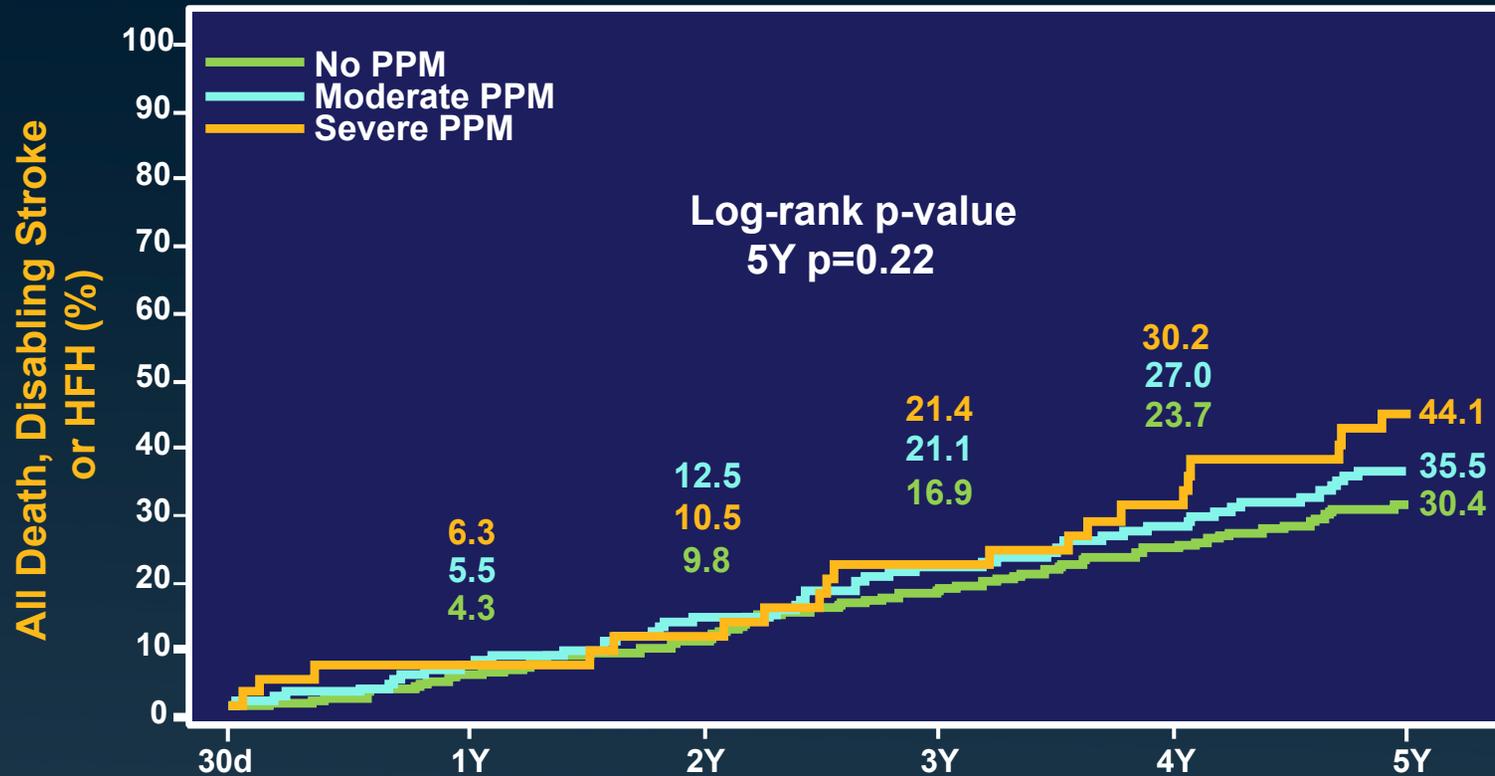
146 (34%) Moderate PPM

48 (11%) Severe PPM

PRIMARY ENDPOINT ASSESSED AT 5-YEARS:
Non-hierarchical composite of all-cause death, disabling stroke, or HF hospitalization

Primary Endpoint

Small Annulus, 30-day PPM



No. at Risk

	30d	1Y	2Y	3Y	4Y	5Y
None	238	225	207	186	162	124
Moderate	146	136	125	108	98	75
Severe	48	45	42	36	30	21

Time from Implant Procedure

Summary and Conclusions

- Clinical outcomes and valve durability were comparable at 5Y between small and large aortic annulus TF-TAVR patients receiving a SAPIEN 3 BEV
- In small annulus patients, neither post-TAVR MG nor 30-day PPM were associated with clinical events at 5 years

Clinical Implications

Through 5-year follow up:

- Clinical outcomes for severe AS patients who received a SAPIEN 3 THV are excellent, irrespective of annulus size
- Despite small annulus patients having higher gradients and rates of PPM at 30-days, there is NO impact on 5-year clinical outcomes or valve durability in patients treated with BEV
- BVF and reintervention rates were consistently low

Thank you!

To all the Investigators,
Heart Teams, and especially,
the 12,000 participating Patients
for 15 years of PARTNER!