Comparative Effectiveness of AVR Strategies in Low-Risk AS

A Causal Analysis in a Real-World Cohort

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Disclosures

Funding & relationships

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Off-label use: None.

Background

Background

Why this matters

Severe AS is the leading structural-heart indication for an intervention.

PARTNER 3 and Evolut Low Risk demonstrated TAVR non-inferiority in low-risk patients.

FDA expanded TAVR indication on **August 16, 2019.**

~80%

of low-risk SAVR-eligible patients now receive TAVR

Evidence gap

- Real-world generalizability of low-risk trials remains uncertain.
- Current observational studies raise safety concerns but interpretation limited by residual confounding

Mack MJ et al. NEJM 2019, Popma et al. NEJM 2019

Objectives & Hypothesis

TAVR vs SAVR

Comparative effectiveness in Real-world low-risk AS

Causal Methods

Quasi-experimental design to address unmeasured confounding

TAVR

Transcatheter
Aortic Valve Replacement

≈

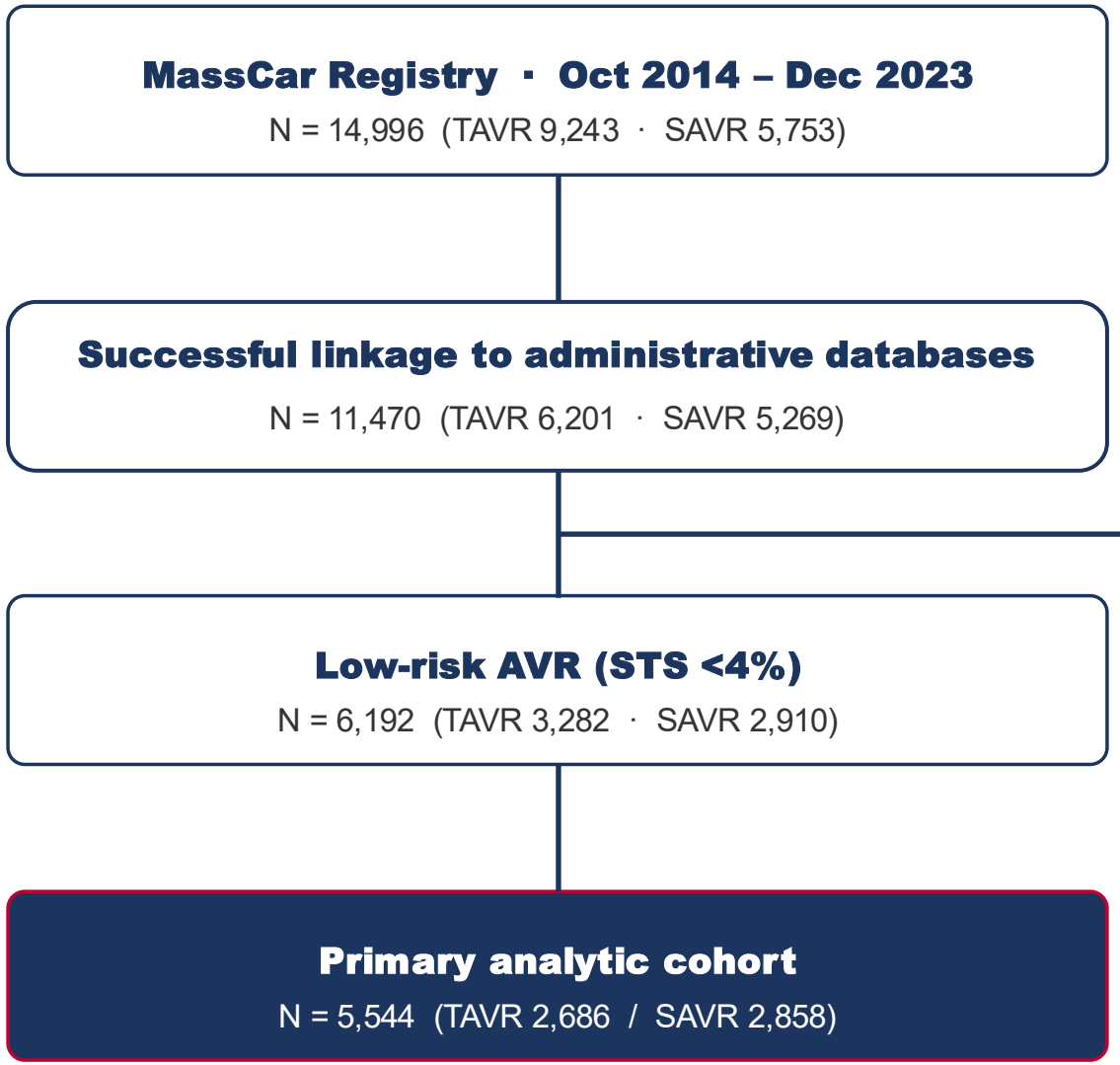
SAVR

Surgical
Aortic Valve Replacement

Comparable short- and long-term MACE once unmeasured confounding is addressed

Methods

Study Population



Exclusion criteria

- STS-PROM > 4% or missing
- Prior aortic valve replacement
- Alternate access TAVR
- Emergency / salvage status
- Active endocarditis
- Hostile chest or porcelain aorta
- Combined SAVR + aortic surgery

Methods | How each approach handles confounding

The challenge: TAVR patients are on average older and sicker than SAVR patients.
Inadequately adjusted comparison conflates the effect of the valve with who received it (confounding).

Cox Regression

Multivariable adjustment

WHAT IT DOES
Adjust the comparison for each risk factor we measured (age, diabetes, heart function, etc.).

ANALOGY
Like asking: "If two patients were the same age and had the same diseases, who does better?"

STRENGTH / LIMITATION
Only adjusts confounders we measured. Hidden differences still bias the result.

IPTW

Propensity-score weighting

WHAT IT DOES
Reweight patients so the TAVR and SAVR groups look statistically identical on measured factors.

ANALOGY
Like rebuilding a fair comparison by giving extra "voting weight" to rare patient types in each arm.

STRENGTH / LIMITATION
Also limited to measured factors. Cannot fix unmeasured confounding.

IV Analysis

FDA approval time as natural RCT

WHAT IT DOES
Compare patients treated JUST BEFORE vs. JUST AFTER FDA approval (8/16/2019).

ANALOGY
Approval date is like a coin flip — it changed access to TAVR but did not change who patients are.

STRENGTH / LIMITATION
Validity depends on strong assumptions.

Disagreement between them points to unmeasured confounding.

Results

Baseline Characteristics | Unadjusted

Variable	TAVR (n=2,686)	SAVR (n=2,858)	SMD
Follow-up, median (Q1, Q3), y	2.4 (1.2, 4.0)	5.7 (3.2, 7.6)	—
Age, mean (SD), y	77.1 (7.7)	66.7 (10.7)	1.11
Female, %	37.2	26.7	0.23
NYHA Class, %			
I	7.6	19.6	0.36
II	38.3	53.4	0.31
III	50.8	22.7	0.61
IV	3.3	4.3	0.05
Cerebrovascular disease, %	12.5	7.4	0.17
Obesity (BMI ≥ 30), %	41.0	39.3	0.04
Diabetes, %	31.3	25.7	0.13
Hypertension, %	85.8	78.4	0.19
Atrial fibrillation, %	27.1	18.9	0.20
Prior PCI, %	20.6	10.4	0.29
3-vessel CAD, %	12.7	12.6	0.00
Proximal LAD ≥ 70%, %	9.5	13.4	0.12
Left main stenosis ≥ 50%, %	4.6	1.2	0.20
Aortic regurgitation (mod/severe), %	16.0	35.8	0.46
Mitral regurgitation (mod/severe), %	21.6	10.9	0.29

SMD = standardized mean difference; NYHA = New York Heart Association class; CAD = coronary artery disease; LAD = left anterior descending; PCI = percutaneous coronary intervention.

Unadjusted: substantial imbalance. TAVR patients are older with more comorbidities; many variables exceed SMD 0.10 (red)

Baseline Characteristics | Pre- & Post-IPTW

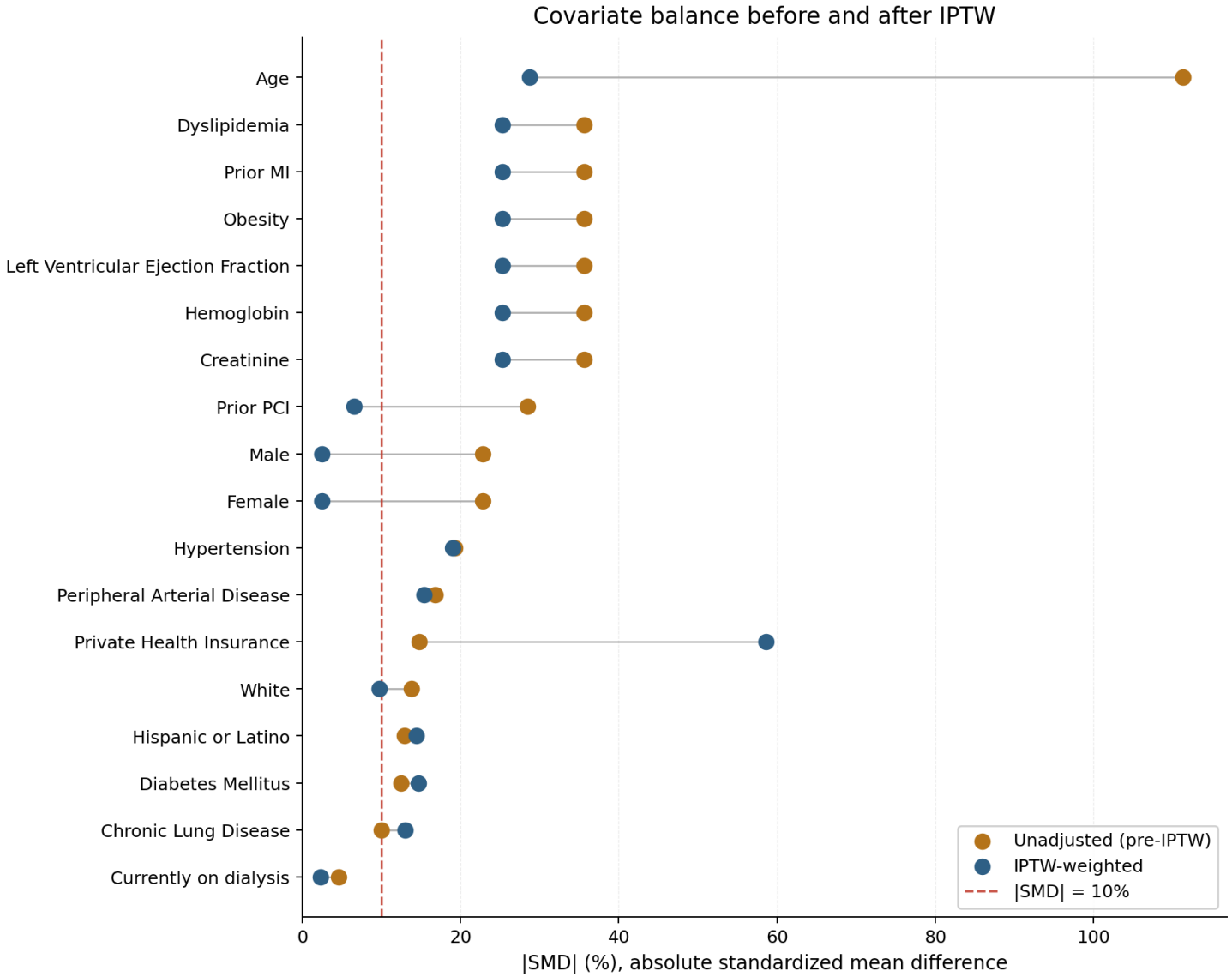
	Pre-weighting (unadjusted)			Post-weighting (IPTW)		
Variable	TAVR (n=2,686)	SAVR (n=2,858)	SMD	TAVR weighted	SAVR weighted	SMD
Age, mean (SD), y	77.1 (7.7)	66.7 (10.7)	1.11	67.2 (12.9)	70.5 (9.9)	0.29
Female, %	37.2	26.7	0.23	28.5	29.6	0.03
NYHA Class, %						
I	7.6	19.6	0.36	10.2	19.1	0.25
II	38.3	53.4	0.31	31.1	58.0	0.56
III	50.8	22.7	0.61	55.7	20.0	0.79
IV	3.3	4.3	0.05	3.0	3.0	0.00
Cerebrovascular disease, %	12.5	7.4	0.17	15.6	8.3	0.23
Obesity (BMI ≥ 30), %	41.0	39.3	0.04	36.2	41.8	0.11
Diabetes, %	31.3	25.7	0.13	22.2	28.6	0.15
Hypertension, %	85.8	78.4	0.19	74.5	82.3	0.19
Atrial fibrillation, %	27.1	18.9	0.20	28.0	20.4	0.18
Prior PCI, %	20.6	10.4	0.29	16.4	14.1	0.07
3-vessel CAD, %	12.7	12.6	0.00	9.5	14.9	0.17
Proximal LAD ≥ 70%, %	9.5	13.4	0.12	6.7	21.0	0.42
Left main stenosis ≥ 50%, %	4.6	1.2	0.20	3.7	2.3	0.08
Aortic regurgitation (mod/severe), %	16.0	35.8	0.46	38.1	25.2	0.28
Mitral regurgitation (mod/severe), %	21.6	10.9	0.29	14.5	14.0	0.01

SMD = standardized mean difference; STS-PROM = STS Predicted Risk of Mortality; NYHA = New York Heart Association; CAD = coronary artery disease; LAD = left anterior descending; PCI = percutaneous coronary intervention.

Pre: substantial imbalance — TAVR older with more comorbidities

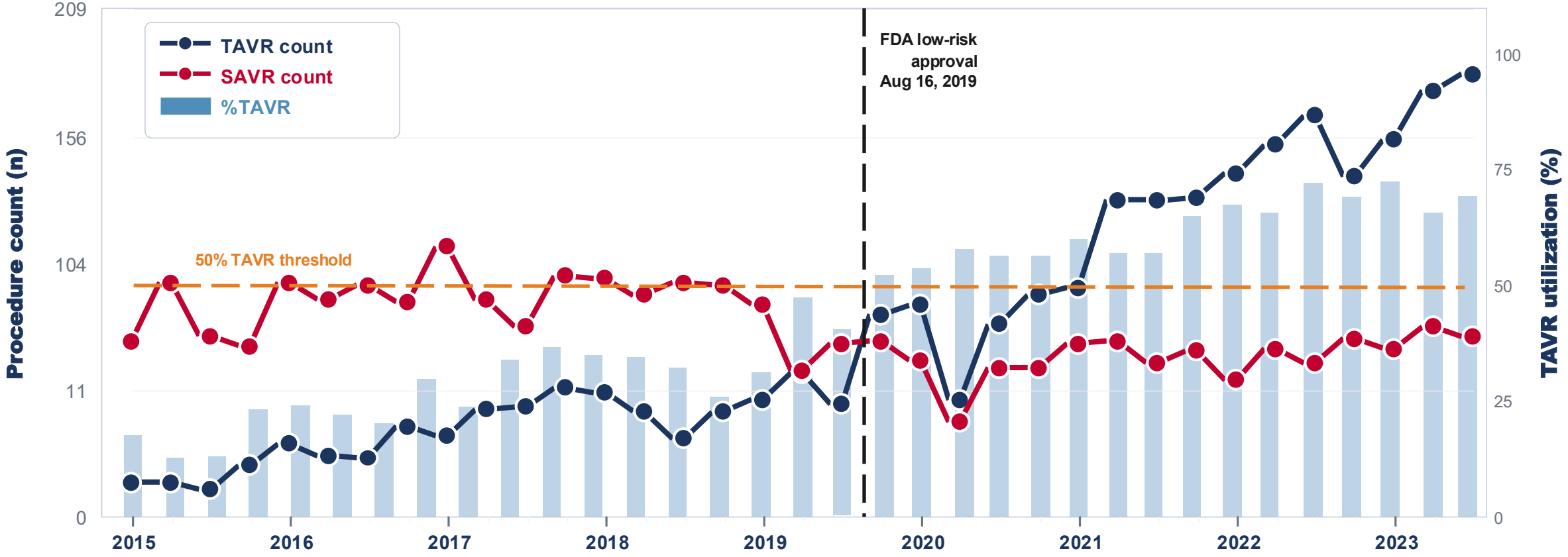
Post: residual imbalance — TAVR younger but with more comorbidities (NYHA IV, Proximal LAD, and AI).

Baseline Characteristics | Pre- & Post-IPTW



AVR Procedure Trends in Low-Risk AS

TAVR vs SAVR Procedure Trends Over Time



TAVR use rose and SAVR use declined. Crossover occurred Q4 2019. >50% utilization after FDA approval

Baseline Characteristics | Instrument TAVR use (>50%)

Variable	<50% TAVR	>50% TAVR	SMD (%)
Age, mean ± SD, y	70.2 ± 10.9	73.0 ± 10.4	26.0
Female, %	30.8	32.6	3.9
NYHA Class, %			
I	9.4	11.8	7.9
II	41.1	43.4	4.7
III	44.2	42.0	-4.6
IV	5.3	2.8	-12.6
Cerebrovascular disease, %	6.3	11.2	17.6
Obesity (BMI ≥ 30), %	41.9	38.8	-6.3
Diabetes, %	26.2	30.1	8.7
Atrial fibrillation/flutter, %	21.6	25.5	9.3
Prior PCI, %	12.8	17.2	12.3
3-vessel CAD, %	13.0	12.4	-1.9
Left main stenosis ≥ 50%, %	2.6	3.4	4.1
Aortic regurgitation (mod/severe), %	22.6	22.3	-0.7
Mitral regurgitation (mod/severe), %	11.4	14.9	10.5

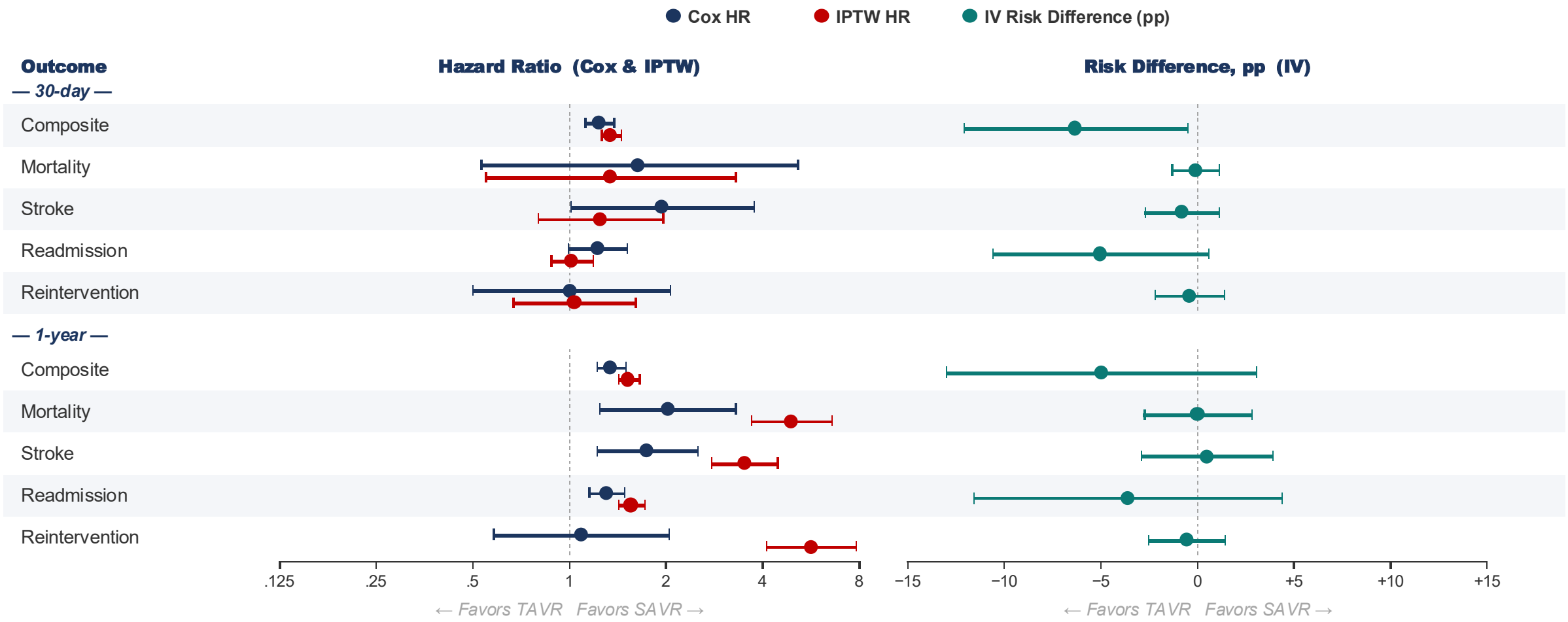
IV = instrumental variable; SMD = standardized mean difference; NYHA = New York Heart Association class; CAD = coronary artery disease; LAD = left anterior descending; PCI = percutaneous coronary intervention.; red = |SMD| > 10%.

Instrument Strength

F = 152.65

(cluster-robust, ≫ 10 threshold)

Outcomes | By Method

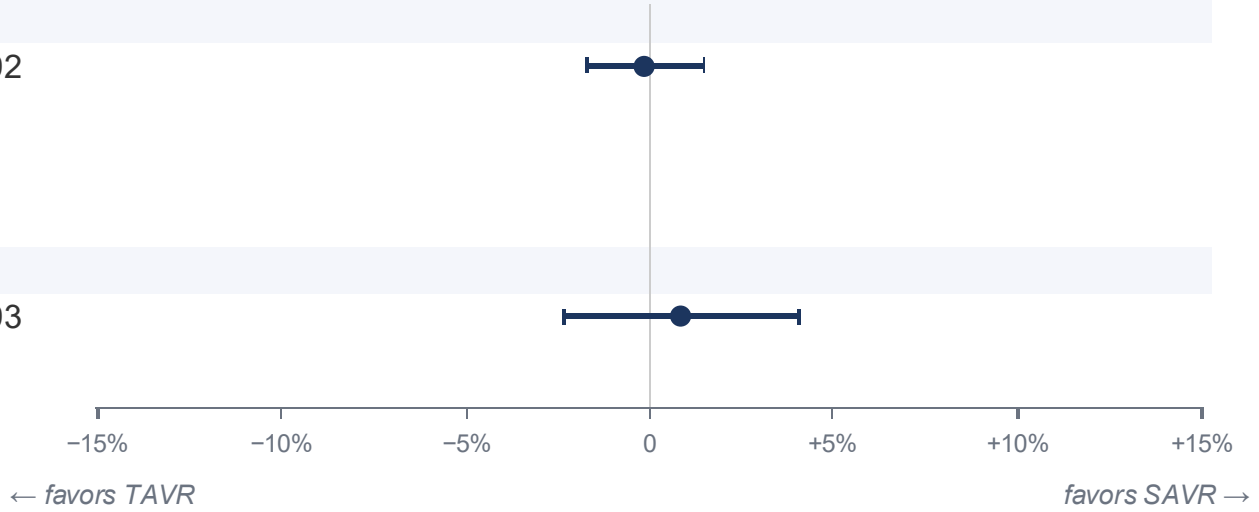


HR = hazard ratio (Cox & IPTW, $\log_2$ scale, null = 1); RD = IV risk difference in pp (linear, null = 0). Bar = 95% CI. IV instrument = FDA low-risk TAVR approval date.

Outcomes| IV Analysis Falsification Endpoint

Outcome	RD (95% CI), %	p-value	Risk difference (TAVR – SAVR)
— 30-day —			
Pneumonia	−0.11 (−1.69, +1.47)	p = 0.892	
— 1-Year —			
Pneumonia	+0.87 (−2.32, +4.06)	p = 0.593	

RD = risk difference (pp); CI = 95% confidence interval.



Pneumonia — a negative-control outcome unrelated to valve-replacement method — shows no difference at 30 days and 1 year, supporting instrument validity and no residual confounding

Conclusions

Conclusions

1

STEP 1

Traditional methods

Cox regression & IPTW

TAVR showed worse outcomes vs SAVR

But TAVR patients were sicker at baseline — imbalance was concerning for residual unmeasured confounding.

2

STEP 2

Quasi-experimental methods

Instrumental-variable analysis

TAVR showed similar outcomes to SAVR

FDA low-risk TAVR approval date as instrument accounts for unmeasured confounding.
Consistent with PARTNER 3 & Evolut Low-Risk RCTs / supports guideline recommendations.

3

STEP 3

Future directions

Confirm, Expand, Replicate

Use alternate causal methods to confirm the finding;
Expand follow-up duration;
Replicate in a national cohort.

Thank you. Questions?

Grant Sponsors

SCAI Society for Cardiovascular Angiography & Interventions

Edwards

Study Sites

Beth Israel Lahey Health

Mass General Brigham

Coordinating Center

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology

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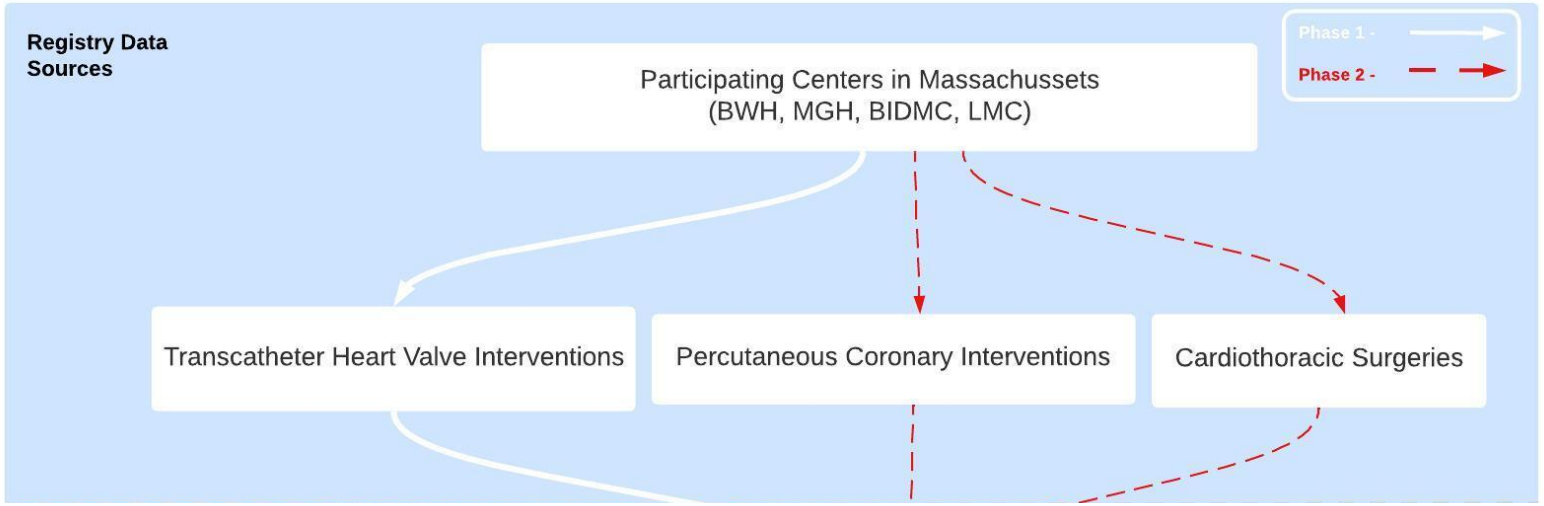
Supplement

MassCar Registry Data Sources



Data linkage

- Deterministic link to records (date · hospital · age · sex)

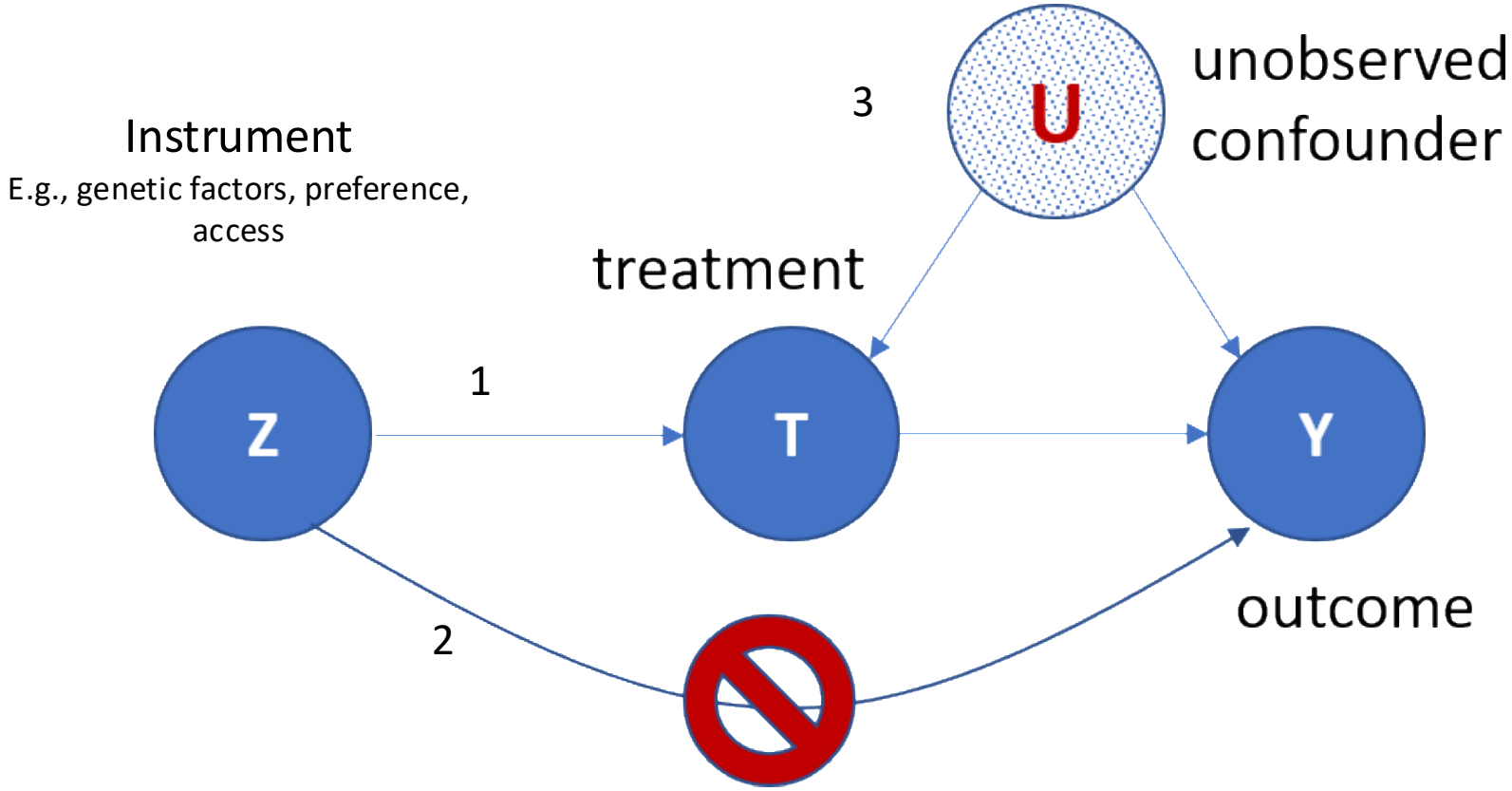
APCD = All-Payer Claims Database · CHIA = MA Center for Health Information & Analysis · FFS = Fee-for-Service · LMC = Lahey · NDI = National Death Index · RVRS = Registry of Vital Records

Analytical Approaches

	Traditional adjustment	IPTW	IV analysis
Pros	Familiar regression framework	Easy to implement Keeps all patients	Handles unmeasured confounding
Cons	Limited covariates adjustment Does not handle unmeasured confounding	Unstable with extreme weights Does not handle unmeasured confounding	Wider confidence intervals Assumption testing not always possible
Assumptions	Correct outcome mode No unmeasured confounding	Correct PS model Positivity (overlap) No unmeasured confounding	Valid instrument - site-year TAVR utilization ≥ 50% threshold (relevance, exclusion, exchangeability)

Imbens GW & Lemieux T. J Econom 2008;142:615–35.
Li L, et al. Med Res. 2013;22(1):14–30. · Elze MC, et al. JACC. 2017;69(3):345–357.

Instrumental Variable Analysis

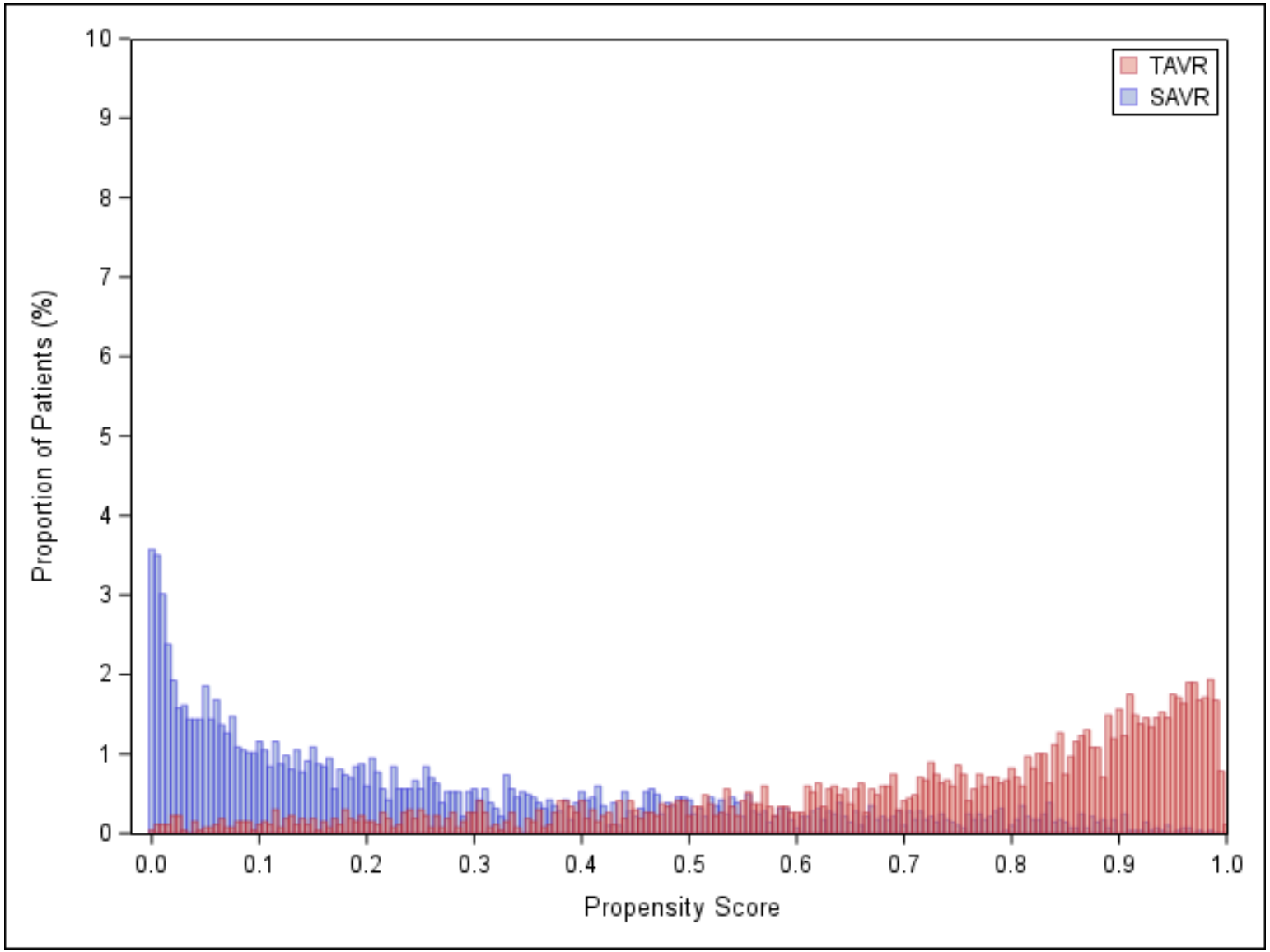


Outcomes | Unadjusted

Outcome	TAVR, %	SAVR, %	p-value
Primary composite (stroke + AV reintervention + readmission + death)			
Composite	53.8%	42.8%	<0.0001
Components			
Stroke	10.1%	7.7%	0.002
AV reintervention †	1.7%	2.9%	0.002
Readmission	55.8%	39.5%	<0.0001
All-cause mortality	13.4%	10.9%	0.003
Procedural & peri-procedural			
Pacemaker implantation ‡	18.6%	6.7%	<0.0001
New dialysis	0.30%	0.31%	NR
Post-proc aortic dissection ¶	0.13%	0%	NR
Post-op mean AV gradient, mmHg ⁂	11.8 (5.9)	8.4 (4.3)	NR
Length of stay, median (IQR), days	2 (1–3)	6 (5–8)	<0.0001

Composite, components, and all-cause mortality reflect full follow-up (TAVR median 873 d, SAVR 2,075 d). Red = p < 0.05. † AV reintervention counts sensitive to differential follow-up between arms. ‡ Pacemaker = ~1-year window (CHIA + TVT/STS combined). ¶ Aortic dissection denominators include non-Lahey STS sites. ⁂ Post-op mean gradient from STS v2.7/2.8 (some v<2.7 missing).

Supplement | Propensity Score Distribution



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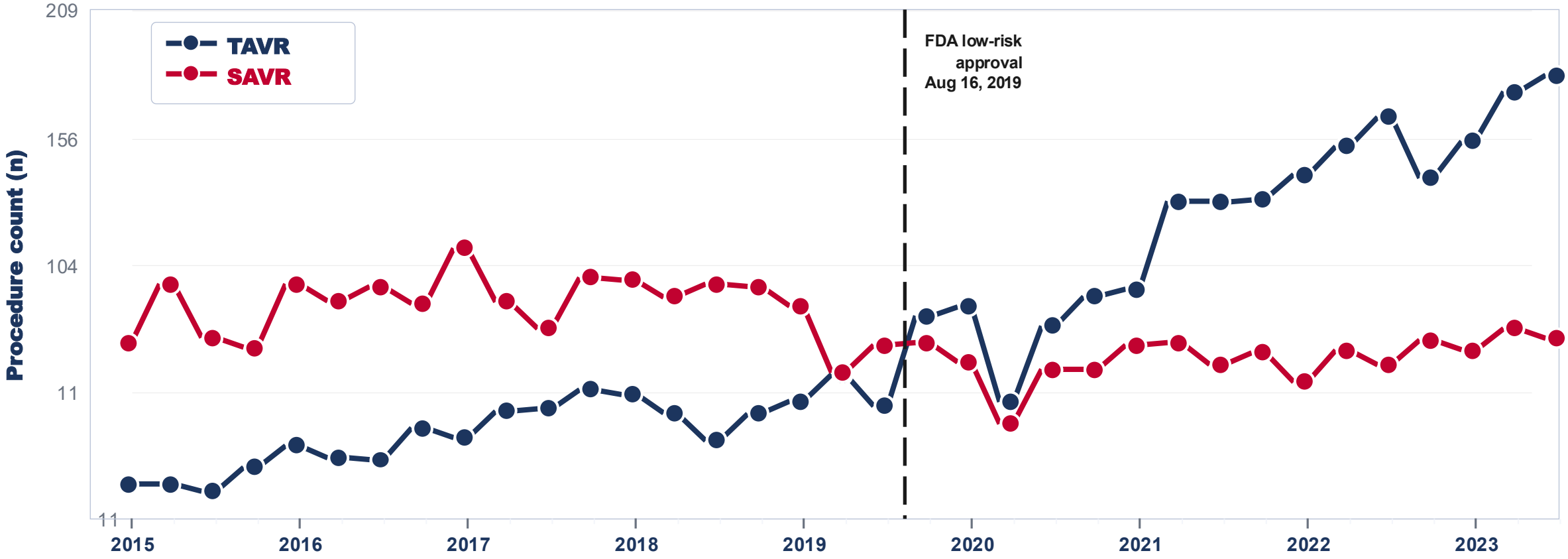
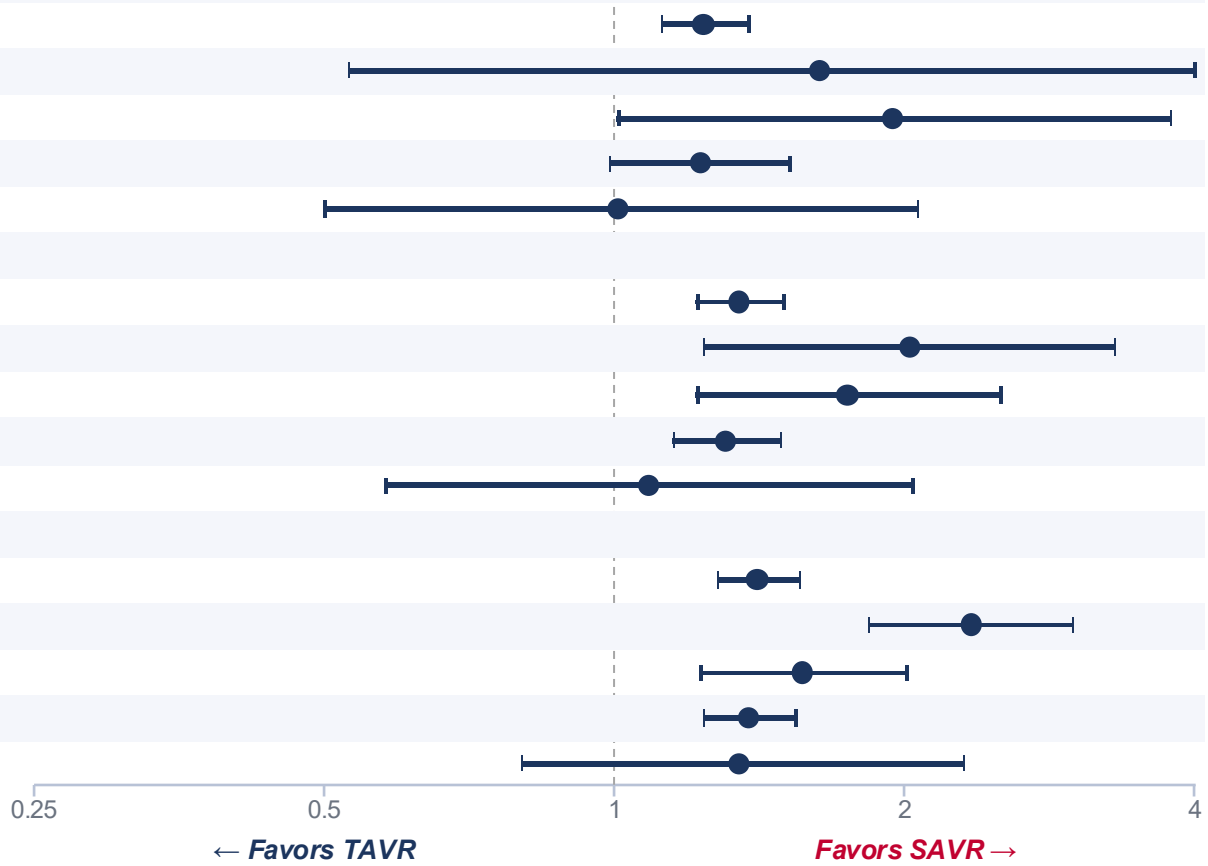


TAVR counts rose and SAVR counts declined. Crossover occurred Q4 2019.

Outcomes | Multivariable Cox

Outcome	HR (95% CI)
— 30-day —	
Composite	**1.24 (1.12, 1.38)**
All-cause mortality	1.64 (0.53, 5.15)
Stroke	**1.95 (1.01, 3.78)**
Readmission	1.23 (0.99, 1.52)
Reintervention	1.01 (0.50, 2.06)
— 1-Year —	
Composite	**1.35 (1.22, 1.50)**
All-cause mortality	**2.03 (1.24, 3.31)**
Stroke	**1.75 (1.22, 2.52)**
Readmission	**1.31 (1.15, 1.49)**
Reintervention	1.09 (0.58, 2.04)
— 5-Year —	
Composite	**1.41 (1.28, 1.56)**
All-cause mortality	**2.35 (1.84, 2.99)**
Stroke	**1.57 (1.23, 2.01)**
Readmission	**1.38 (1.24, 1.54)**
Reintervention	1.35 (0.80, 2.30)



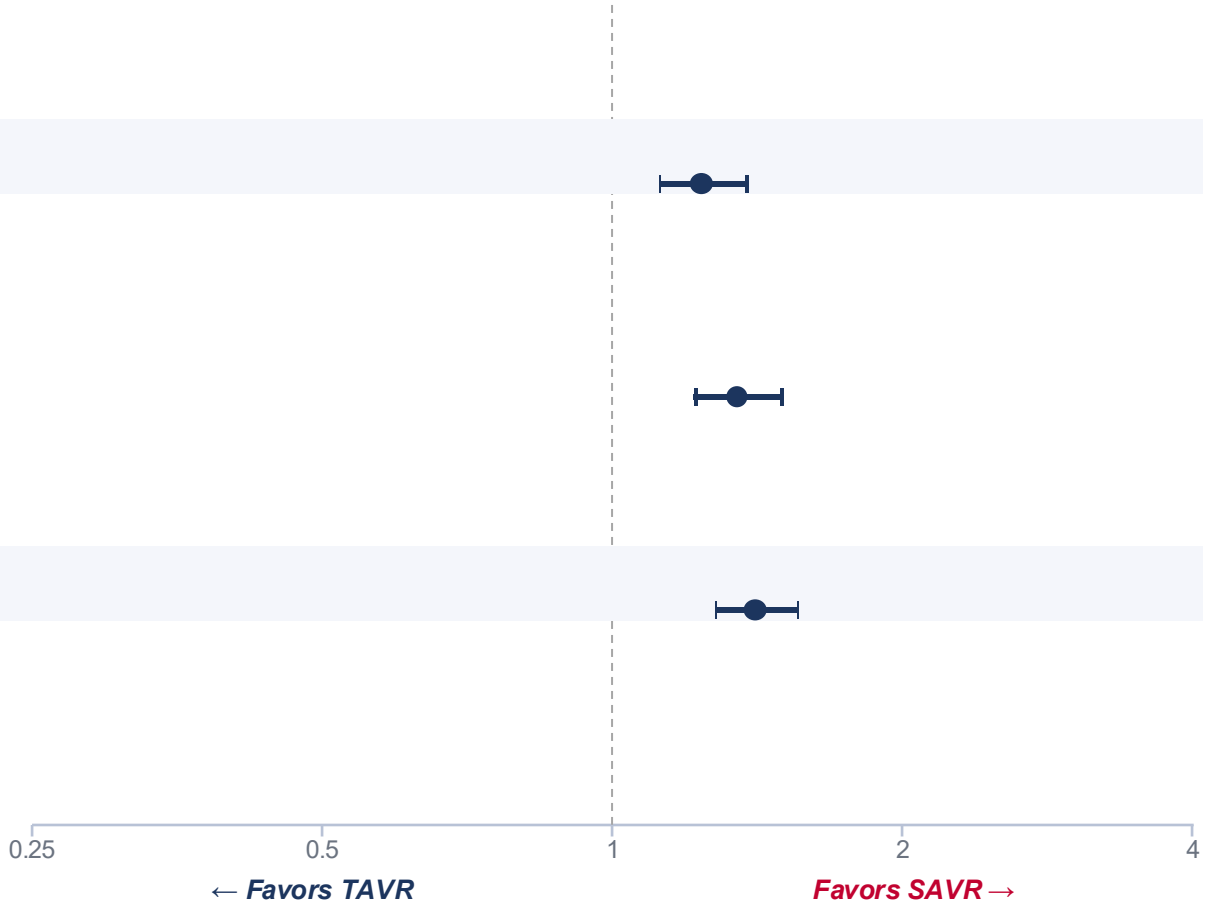
Multivariable Cox proportional hazards models, adjusted for demographics and comorbidities

IPTW suggests TAVR worse across most outcomes

likely reflects residual confounding (older, sicker TAVR cohort)

Multivariable Cox | Primary Outcome

Outcome	HR (95% CI)	Hazard ratio (TAVR vs SAVR)
30-day	1.24 (1.12, 1.38)	
1-year	1.35 (1.22, 1.50)	
5-year	1.41 (1.28, 1.56)	

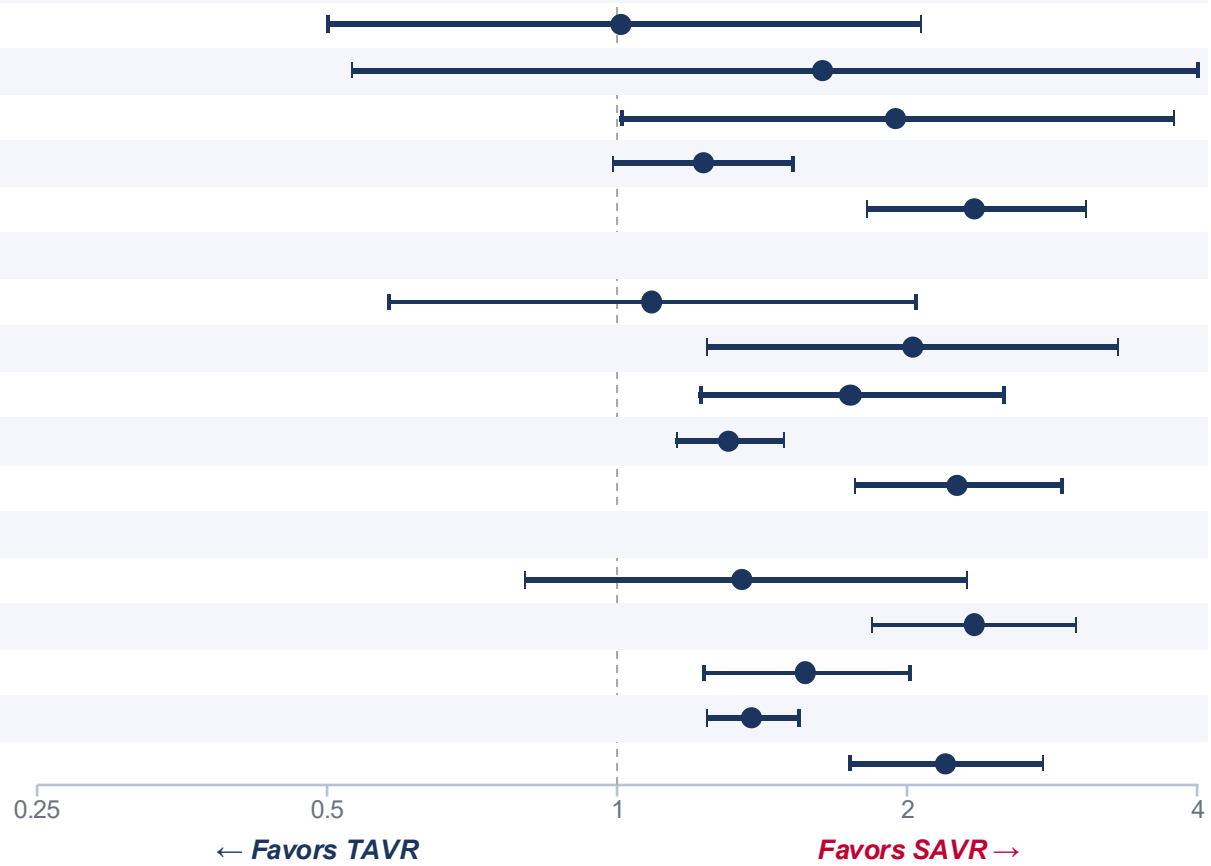


Multivariable Cox proportional hazards models, adjusted for demographics and comorbidities

Multivariable Cox Regression suggests TAVR worse across most outcomes
likely reflects residual confounding (older, sicker TAVR cohort).

Multivariable Cox | Secondary Outcomes

Outcome	HR (95% CI)
— 30-day —	
Reintervention	1.01 (0.50, 2.06)
All-cause mortality	1.64 (0.53, 5.15)
Stroke	**1.95 (1.01, 3.78)**
Readmission	1.23 (0.99, 1.52)
Pacemaker	**2.35 (1.81, 3.05)**
— 1-Year —	
Reintervention	1.09 (0.58, 2.04)
All-cause mortality	**2.03 (1.24, 3.31)**
Stroke	**1.75 (1.22, 2.52)**
Readmission	**1.31 (1.15, 1.49)**
Pacemaker	**2.25 (1.76, 2.88)**
— 5-Year —	
Reintervention	1.35 (0.80, 2.30)
All-cause mortality	**2.35 (1.84, 2.99)**
Stroke	**1.57 (1.23, 2.01)**
Readmission	**1.38 (1.24, 1.54)**
Pacemaker	**2.19 (1.74, 2.76)**

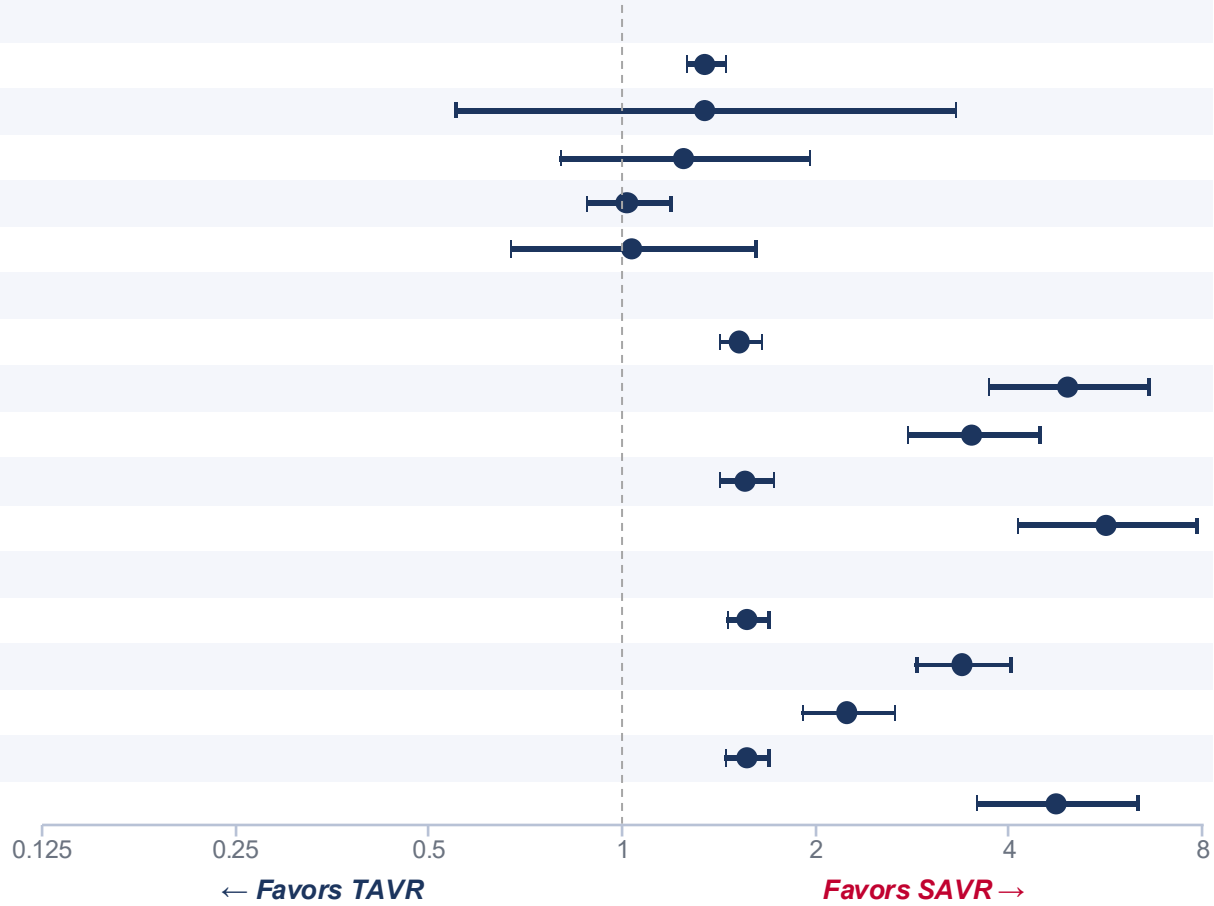


Multivariable Cox proportional hazards models, adjusted for demographics and comorbidities

Multivariable Cox Regression suggests TAVR worse across most outcomes
likely reflects residual confounding (older, sicker TAVR cohort).

Outcomes | IPTW Analysis

Outcome	HR (95% CI)
— 30-day —	
Composite	**1.35 (1.26, 1.45)**
All-cause mortality	1.35 (0.55, 3.31)
Stroke	1.25 (0.80, 1.96)
Readmission	1.02 (0.88, 1.19)
Reintervention	1.04 (0.67, 1.61)
— 1-Year —	
Composite	**1.53 (1.42, 1.65)**
All-cause mortality	**4.95 (3.71, 6.60)**
Stroke	**3.52 (2.78, 4.46)**
Readmission	**1.56 (1.42, 1.72)**
Reintervention	**5.69 (4.12, 7.85)**
— 5-Year —	
Composite	**1.57 (1.46, 1.69)**
All-cause mortality	**3.40 (2.87, 4.02)**
Stroke	**2.25 (1.91, 2.65)**
Readmission	**1.57 (1.45, 1.69)**
Reintervention	**4.75 (3.57, 6.34)**



IPTW suggests TAVR worse across most outcomes
likely reflects residual confounding (sicker TAVR cohort)

HR = hazard ratio; CI = confidence interval; IPTW = inverse probability of treatment weighting; long-term = 5-yr follow-up; HR axis on log scale; null at HR = 1.

IPTW | Primary Outcome

Outcome	HR (95% CI)	Hazard ratio (TAVR vs SAVR)
30-day	1.35 (1.26, 1.45)	
1-year	1.53 (1.42, 1.65)	
5-year	1.57 (1.46, 1.69)	

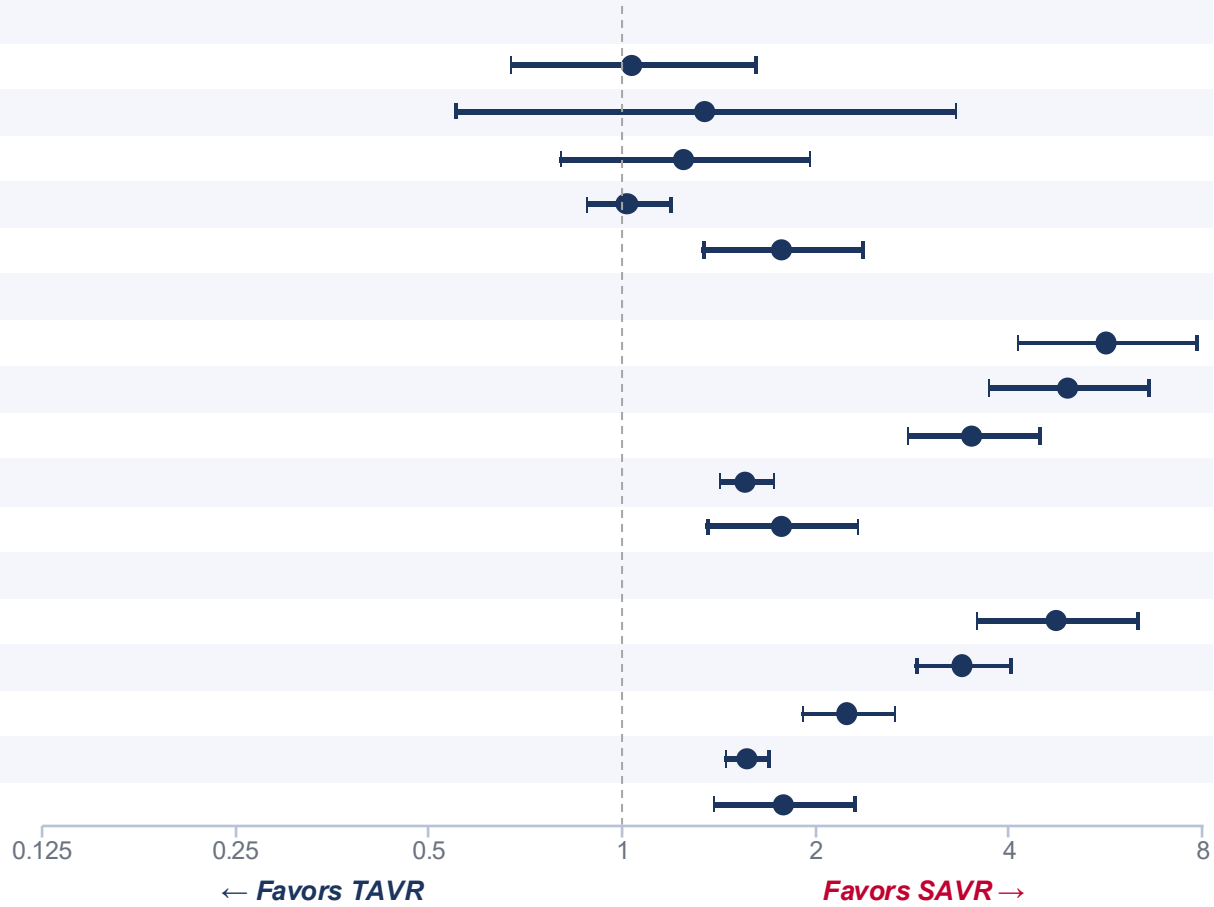
HR = hazard ratio; CI = confidence interval; IPTW = inverse probability of treatment weighting;

IPTW suggests TAVR worse across most outcomes

likely reflects residual confounding (older, sicker TAVR cohort); reintervention NS.

IPTW | Secondary Outcomes

Outcome	HR (95% CI)
— 30-day —	
Reintervention	1.04 (0.67, 1.61)
All-cause mortality	1.35 (0.55, 3.31)
Stroke	1.25 (0.80, 1.96)
Readmission	1.02 (0.88, 1.19)
Pacemaker	**1.46 (1.21, 1.77)**
— 1-Year —	
Reintervention	**5.69 (4.12, 7.85)**
All-cause mortality	**4.95 (3.71, 6.60)**
Stroke	**3.52 (2.78, 4.46)**
Readmission	**1.46 (1.22, 1.75)**
Pacemaker	**5.69 (4.12, 7.85)**
— 5-Year —	
Reintervention	**4.75 (3.57, 6.34)**
All-cause mortality	**3.40 (2.87, 4.02)**
Stroke	**1.47 (1.24, 1.74)**
Readmission	**1.57 (1.45, 1.69)**
Pacemaker	**4.75 (3.57, 6.34)**



HR = hazard ratio; CI = confidence interval; IPTW = inverse probability of treatment weighting;

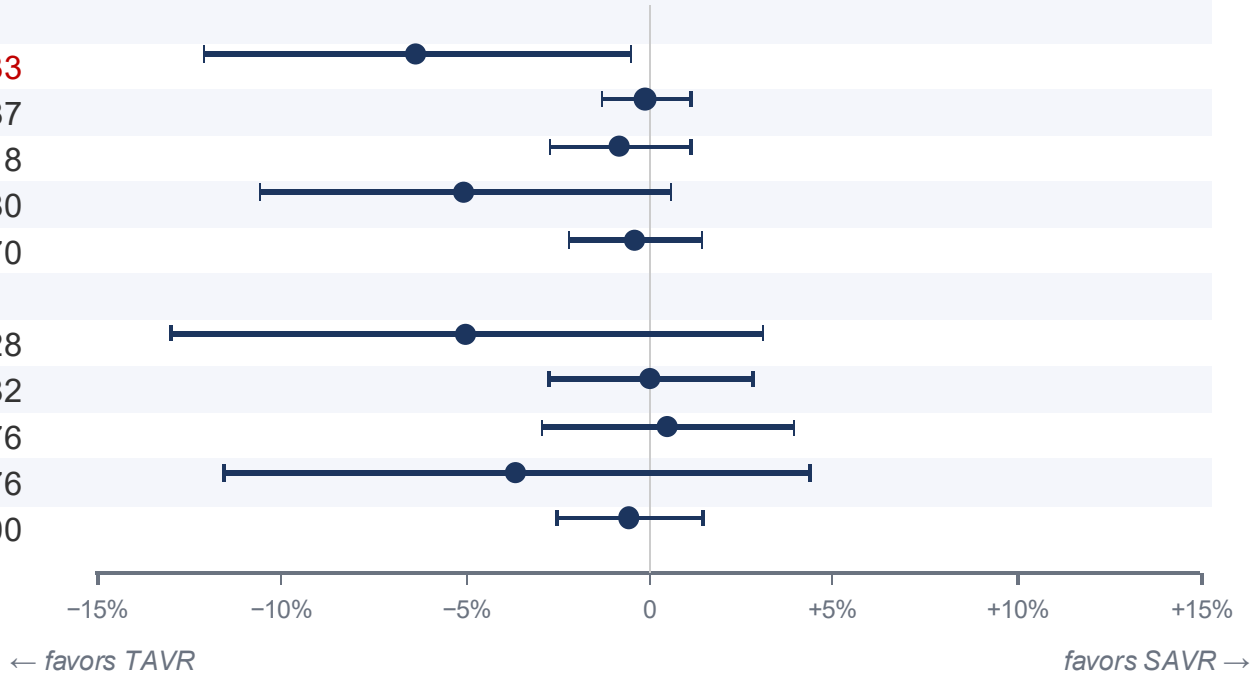
IPTW suggests TAVR worse across most outcomes

likely reflects residual confounding (older, sicker TAVR cohort); reintervention NS.

Outcomes | IV Analysis

Outcome	RD (95% CI), %	p-value
— 30-day —		
Composite	−6.31 (−12.10, −0.52)	p = 0.033
All-cause mortality	−0.09 (−1.31, +1.13)	p = 0.887
Stroke	−0.79 (−2.70, +1.12)	p = 0.418
Readmission	−5.00 (−10.58, +0.59)	p = 0.080
Reintervention	−0.39 (−2.18, +1.40)	p = 0.670
— 1-Year —		
Composite	−4.96 (−13.01, +3.09)	p = 0.228
All-cause mortality	+0.03 (−2.74, +2.80)	p = 0.982
Stroke	+0.50 (−2.93, +3.92)	p = 0.776
Readmission	−3.59 (−11.55, +4.36)	p = 0.376
Reintervention	−0.53 (−2.52, +1.45)	p = 0.600

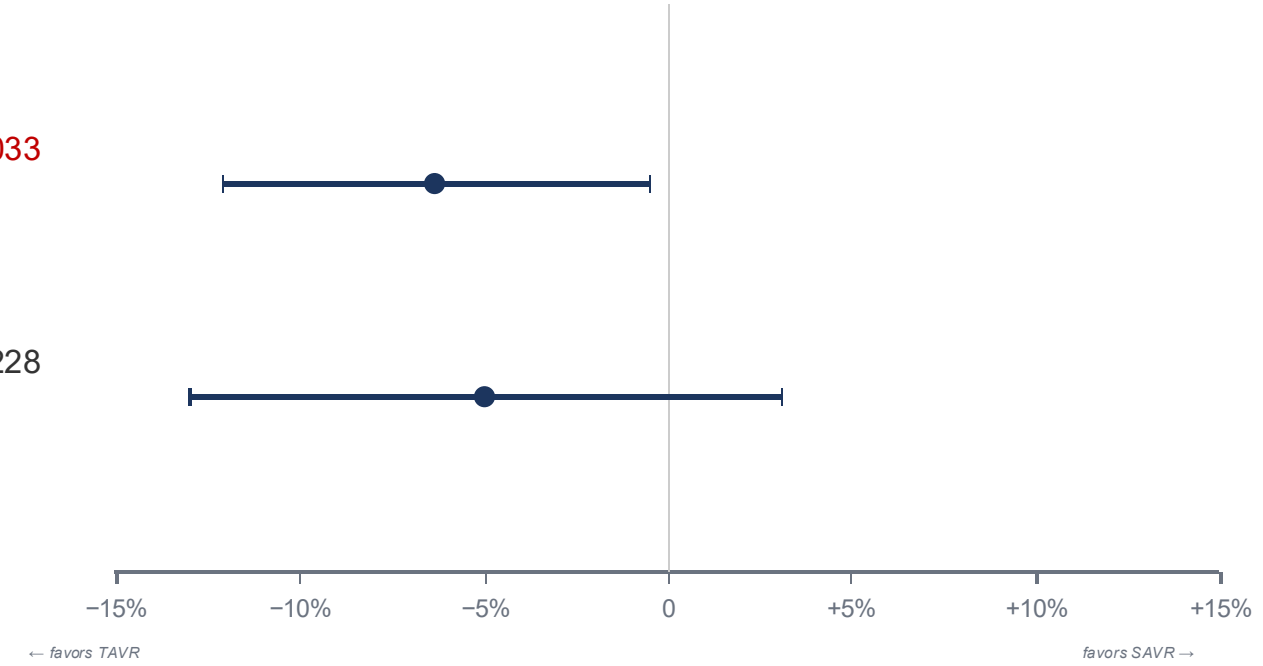
RD = risk difference (percentage points); CI = confidence interval.



IV analysis shows decrease in composite outcome at 30 days driven by readmission & no difference in at 1 year *consistent with low-risk TAVR RCTs.*

IV Analysis | Primary Outcome

Outcome	RD (95% CI), %	p-value	Risk difference (TAVR – SAVR)
30-day	−6.31 (−12.10, −0.52)	p = 0.033	
1-year	−4.96 (−13.01, +3.09)	p = 0.228	

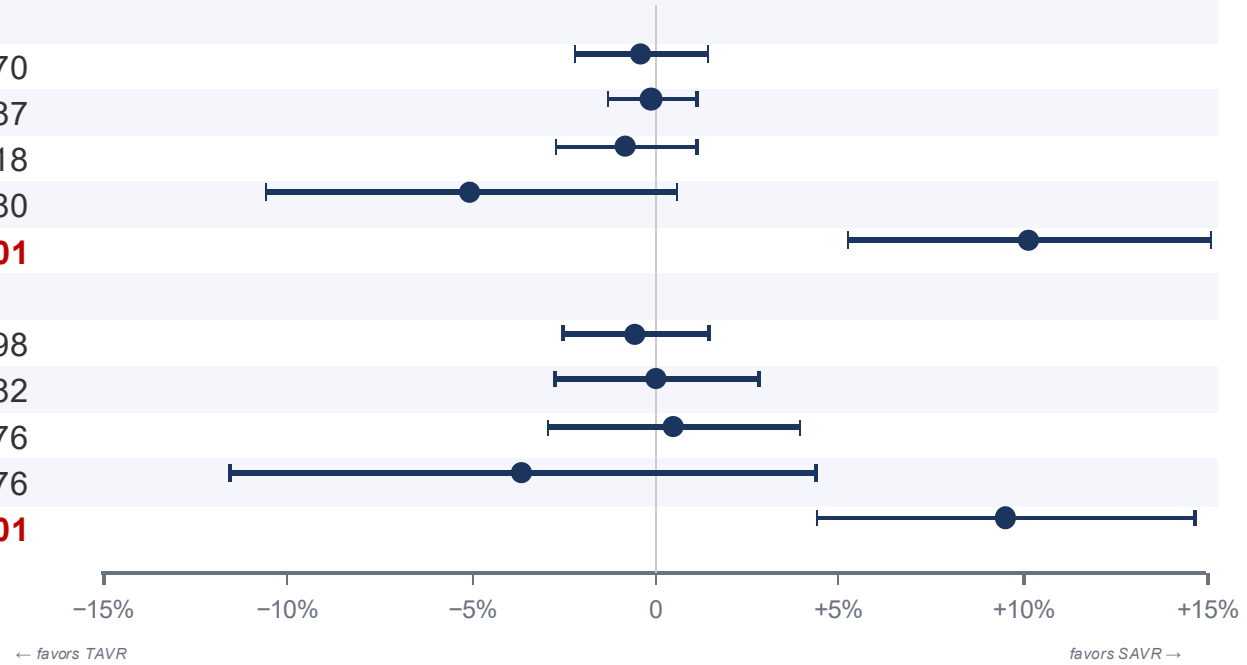


IV analysis (FDA low-risk approval date as instrument): null effects at 30 days and 1 year — consistent with low-risk TAVR RCTs.

IV = instrumental variable (FDA low-risk TAVR approval date 8/16/2019 as instrument; 1st-stage F = 152.65); RD = risk difference (percentage points); CI = confidence interval.

IV Analysis | Secondary Outcomes

Outcome	RD (95% CI), %	p-value
— 30-day —		
Reintervention	−0.39 (−2.18, +1.40)	p = 0.670
All-cause mortality	−0.09 (−1.31, +1.13)	p = 0.887
Stroke	−0.79 (−2.70, +1.12)	p = 0.418
Readmission	−5.00 (−10.58, +0.59)	p = 0.080
Pacemaker	**+10.15 (+5.21, +15.10)**	**p < 0.001**
— 1-Year —		
Reintervention	−0.53 (−2.52, +1.45)	p = 0.598
All-cause mortality	+0.03 (−2.74, +2.80)	p = 0.982
Stroke	+0.50 (−2.93, +3.92)	p = 0.776
Readmission	−3.59 (−11.55, +4.36)	p = 0.376
Pacemaker	**+9.53 (+4.40, +14.65)**	**p < 0.001**



IV analysis (FDA low-risk approval date as instrument): null effects at 30 days and 1 year — consistent with low-risk TAVR RCTs.

IV = instrumental variable (FDA low-risk TAVR approval date 8/16/2019 as instrument; 1st-stage F = 152.65); RD = risk difference (percentage points); CI = confidence interval.

Outcome | By Method

Outcome	Cox HR (95% CI)	IPTW HR (95% CI)	IV RD, pp (95% CI)
30-DAY			
Composite adverse event	**1.24 (1.12, 1.38)**	**1.35 (1.26, 1.45)**	**−6.31 (−12.10, −0.52)**
All-cause mortality	1.64 (0.53, 5.15)	1.35 (0.55, 3.31)	−0.09 (−1.31, +1.13)
Stroke	**1.95 (1.01, 3.78)**	1.25 (0.80, 1.96)	−0.79 (−2.70, +1.12)
Readmission	1.23 (0.99, 1.52)	1.02 (0.88, 1.19)	−5.00 (−10.58, +0.59)
Reintervention	1.01 (0.50, 2.06)	1.04 (0.67, 1.61)	−0.39 (−2.18, +1.40)
1-YEAR			
Composite adverse event	**1.35 (1.22, 1.50)**	**1.53 (1.42, 1.65)**	−4.96 (−13.01, +3.09)
All-cause mortality	**2.03 (1.24, 3.31)**	**4.95 (3.71, 6.60)**	+0.03 (−2.74, +2.80)
Stroke	**1.75 (1.22, 2.52)**	**3.52 (2.78, 4.46)**	+0.50 (−2.93, +3.92)
Readmission	**1.31 (1.15, 1.49)**	**1.56 (1.42, 1.72)**	−3.59 (−11.55, +4.36)
Reintervention	1.09 (0.58, 2.04)	**5.69 (4.12, 7.85)**	−0.53 (−2.52, +1.45)

HR = hazard ratio (Cox & IPTW); RD = risk difference in percentage points (IV); CI = 95% confidence interval. IV instrument = FDA low-risk TAVR approval date (8/16/2019); 1st-stage F = 152.65. Bold red = statistically significant (CI excludes null).

Cox and IPTW show higher hazard with TAVR
IV shows no difference at 30-day and 1-yearl; consistent with low-risk TAVR RCTs.

Supplement | Pacemaker risk by method

Timepoint	Cox adj. HR (95% CI)	IPTW adj. HR (95% CI)	IV RD, pp (95% CI)
30-day	**2.35 (1.81, 3.05)**	**1.46 (1.21, 1.77)**	**+10.15 (+5.21, +15.10)**
1-year	**2.25 (1.76, 2.88)**	**1.46 (1.22, 1.75)**	**+9.53 (+4.40, +14.65)**
5-year	**2.19 (1.74, 2.76)**	**1.47 (1.24, 1.74)**	**+8.29 (+2.87, +13.72)**

All four methods agree: TAVR carries substantially higher pacemaker risk at 30 days, 1 year, and 5 years — every estimate is statistically significant.

Cox and IPTW report adjusted hazard ratios; IV (FDA low-risk TAVR approval date, 8/16/2019) reports risk differences in percentage points. All values bold red = statistically significant (CI excludes null). Adjusted for demographics and comorbidities.