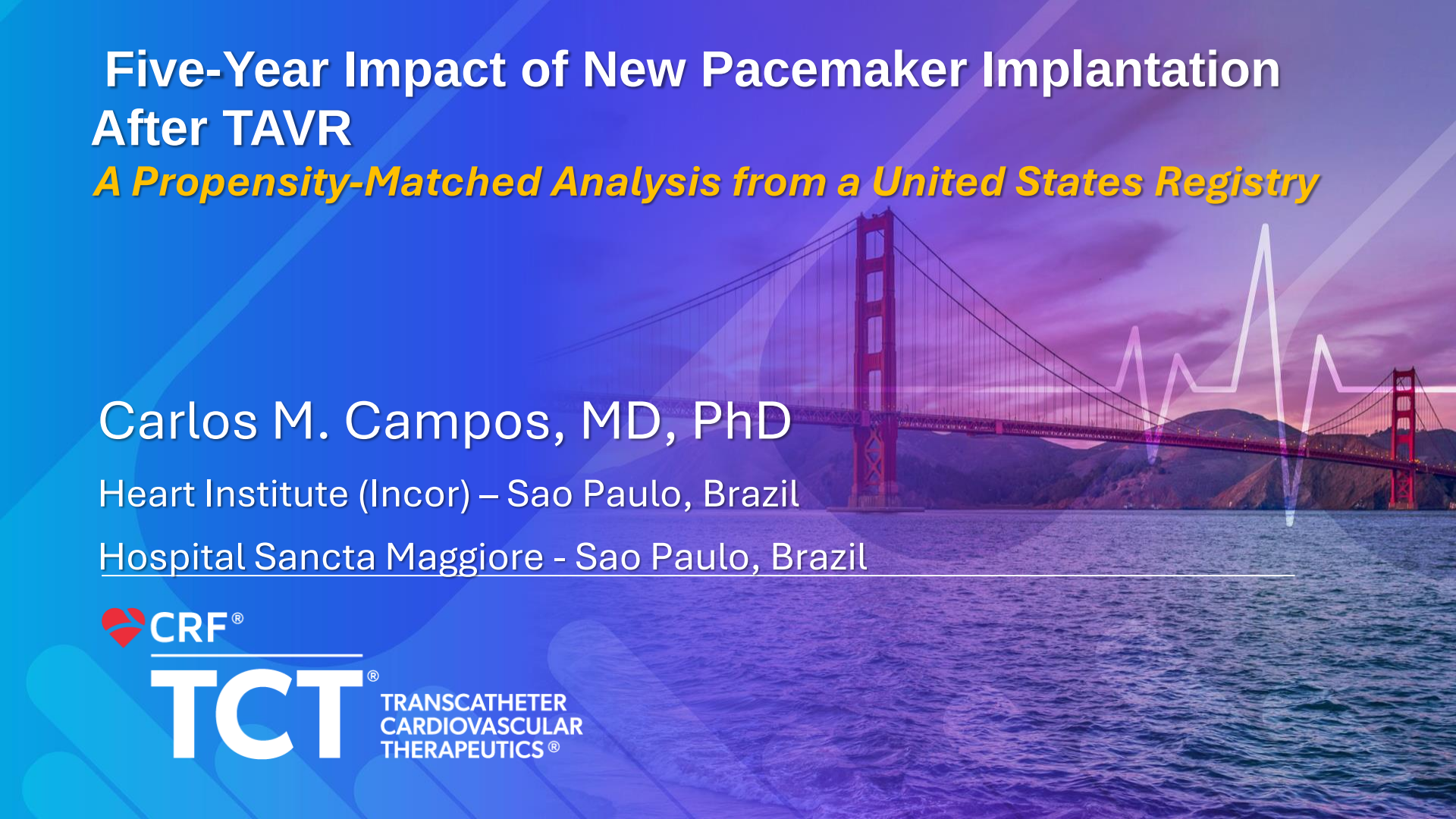
Five-Year Impact of New Pacemaker Implantation After TAVR

A Propensity-Matched Analysis from a United States Registry



Carlos M. Campos, MD, PhD

Heart Institute (Incor) – Sao Paulo, Brazil

Hospital Sancta Maggiore - Sao Paulo, Brazil

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Disclosure of Relevant Financial Relationships

Speaker/Proctor:	Boston Scientific
Speaker/Proctor:	Abbott Vascular
Speaker:	Terumo
Speaker/Proctor:	Nipro

Background

- New permanent pacemaker implantation (PPI) is a well-known consequence of transcatheter aortic valve replacement (TAVR)
- The clinical implications of PPI following TAVR remain debated[1-4]
- This study evaluates the impact of new PPI during the index hospitalization on in-hospital and 5-year clinical outcomes

1.Eur Heart J. 2020;41(29):2771-2781.
2.Cardiovasc Interv. 2024;17(11):1325-1336.
3.JACC Cardiovasc Interv. 2015;8(1 Pt A):60-69.
4. JACC Cardiovasc Interv. 2021;14(19):2173-2181.

Methods

- We conducted a retrospective, propensity-matched cohort study utilizing data from the **STS/ACC TVT Registry**
- The study period spanned June 2015 to September 2024
- Patients undergoing elective, **transfemoral TAVR with a balloon-expandable valve** (BEV - specifically SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra Resilia, Edwards Lifesciences, Irvine, CA)

Methods

- The study population was divided into two cohorts: **(1) patients requiring new PPI following TAVR** during the index hospitalization (PPI group), and **(2) those who did not require PPI post-procedure** (NPM group) as the control
- We excluded patients with a **pre-existing pacemaker**, undergoing **redo-TAVR or valve-in-valve** (ViV) procedures, **TAVR via alternative access routes** (e.g., transapical, transaortic), and **emergency TAVR cases**

Data Analysis

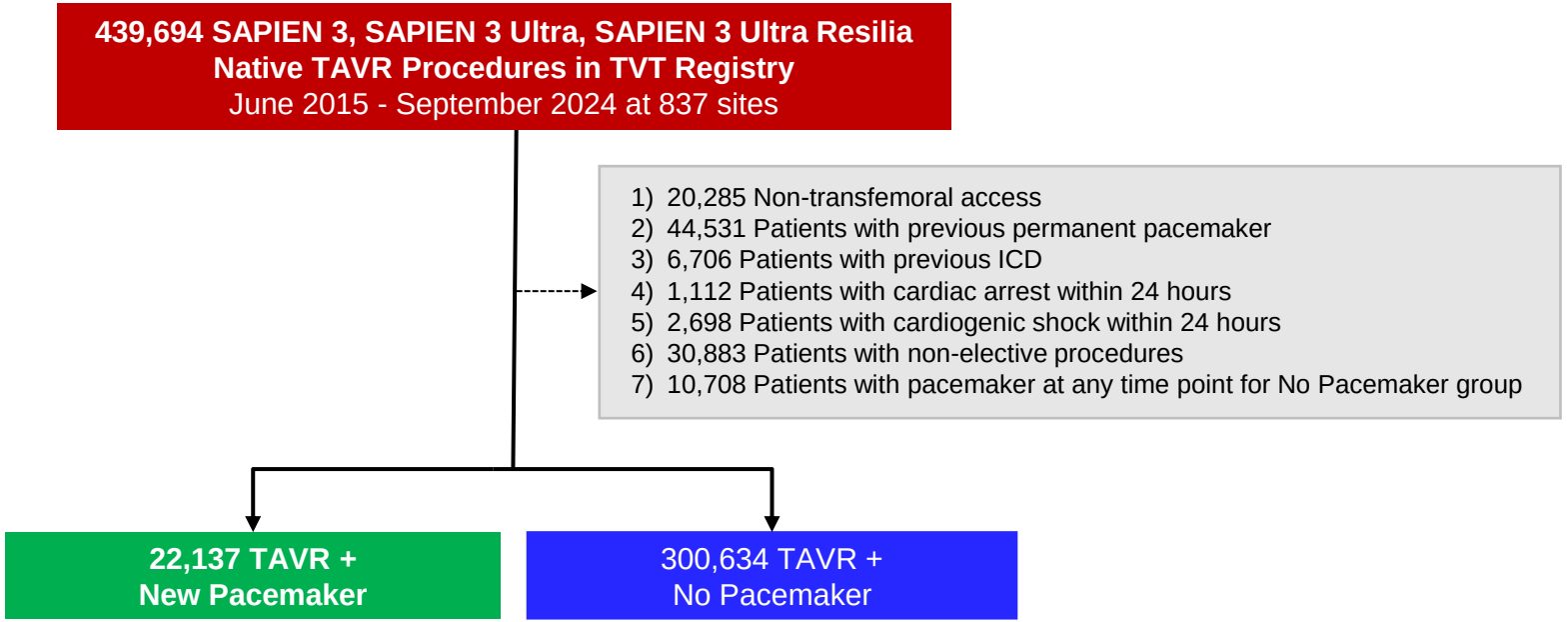
- Continuous variables were presented as mean (standard deviation) or median (interquartile range) and were compared between groups using the two-sample t-test or Wilcoxon rank sum test
- Categorical variables were presented as frequencies and percentages and were compared using the χ^2 or Fisher's exact test
- The 30-day, 1-year, and 3-year adverse event rates were based on Kaplan-Meier estimates

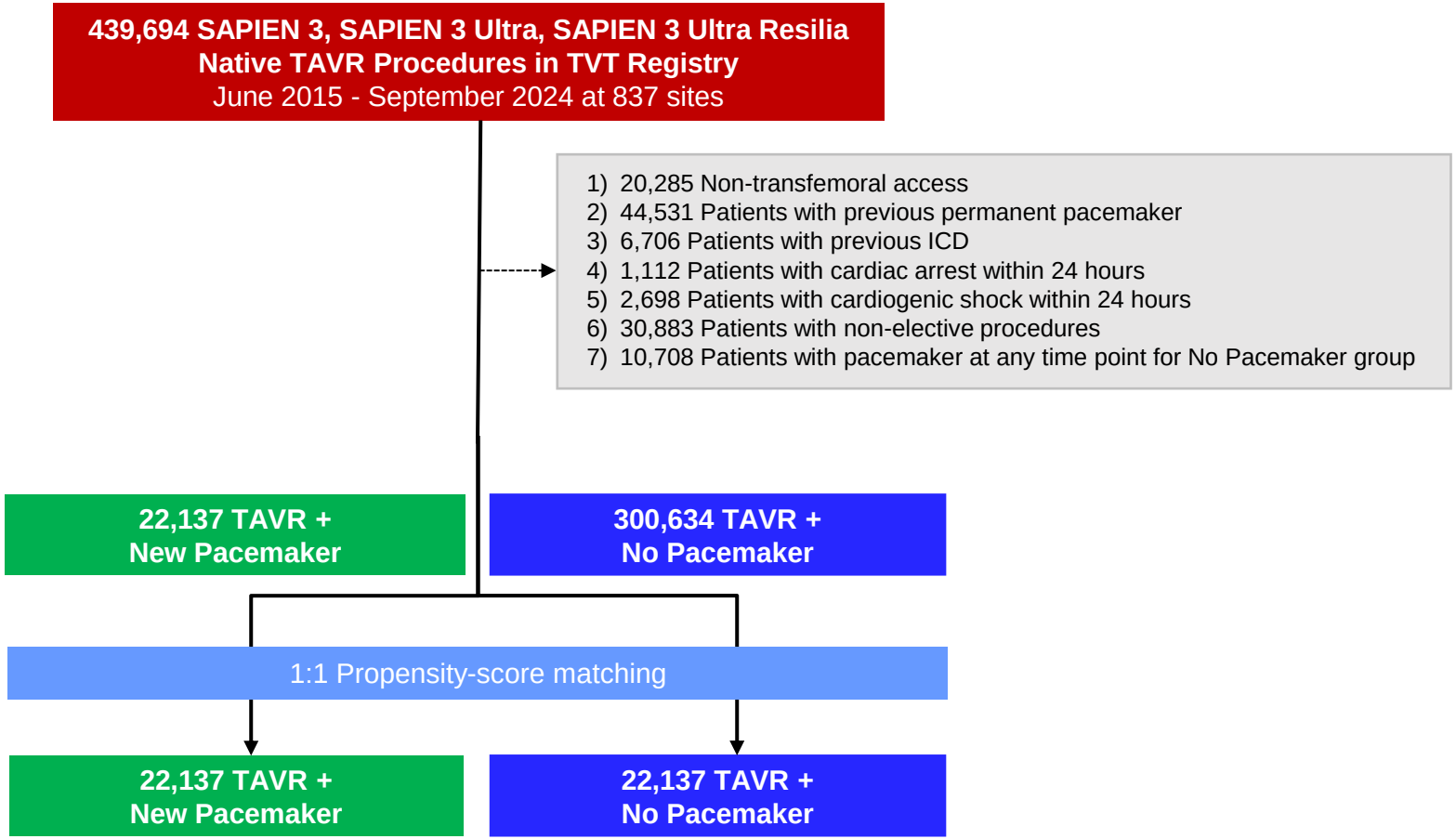
Propensity Score Matching

- We performed 1:1 propensity score matching between the PPI and control groups to address potential confounding
- Propensity scores were estimated using logistic regression based on a comprehensive set of baseline clinical and procedural variables

Covariates used for 1:1 propensity score matching: Age, sex (male), Race (White), body mass index, operator reason for procedure, valve size, prior percutaneous coronary intervention, prior coronary artery bypass graft surgery, prior stroke, carotid stenosis, peripheral arterial disease, hypertension, diabetes, chronic lung disease, immunocompromise, porcelain aorta, atrial fibrillation, creatinine, hemoglobin level, estimated glomerular filtration ratio, aortic valve mean gradient, left ventricular ejection fraction, aortic regurgitation (<mild, moderate, severe), mitral regurgitation (<mild, moderate, moderate-to-severe, severe), tricuspid regurgitation (<mild, moderate, severe), NYHA functional class III/IV, 5-meter walk test, KCCQ-OS score, STS, home oxygen, currently on dialysis, cardiogenic shock with 24h, prior TIA, endocarditis, heart failure within 2 weeks, prior MI, left main stenosis ≥ 50%, proximal LAD ≥ 70%, number of diseased vessels and hostile chest.

Study Flowchart for Patient Selection and Propensity Score


439,694 SAPIEN 3, SAPIEN 3 Ultra, SAPIEN 3 Ultra Resilia
Native TAVR Procedures in TVT Registry
June 2015 - September 2024 at 837 sites
1) 20,285 Non-transfemoral access
2) 44,531 Patients with previous permanent pacemaker
3) 6,706 Patients with previous ICD
4) 1,112 Patients with cardiac arrest within 24 hours
5) 2,698 Patients with cardiogenic shock within 24 hours
6) 30,883 Patients with non-elective procedures
7) 10,708 Patients with pacemaker at any time point for No Pacemaker group
22,137 TAVR +
New Pacemaker
300,634 TAVR +
No Pacemaker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22,137 TAVR + New Pacemaker
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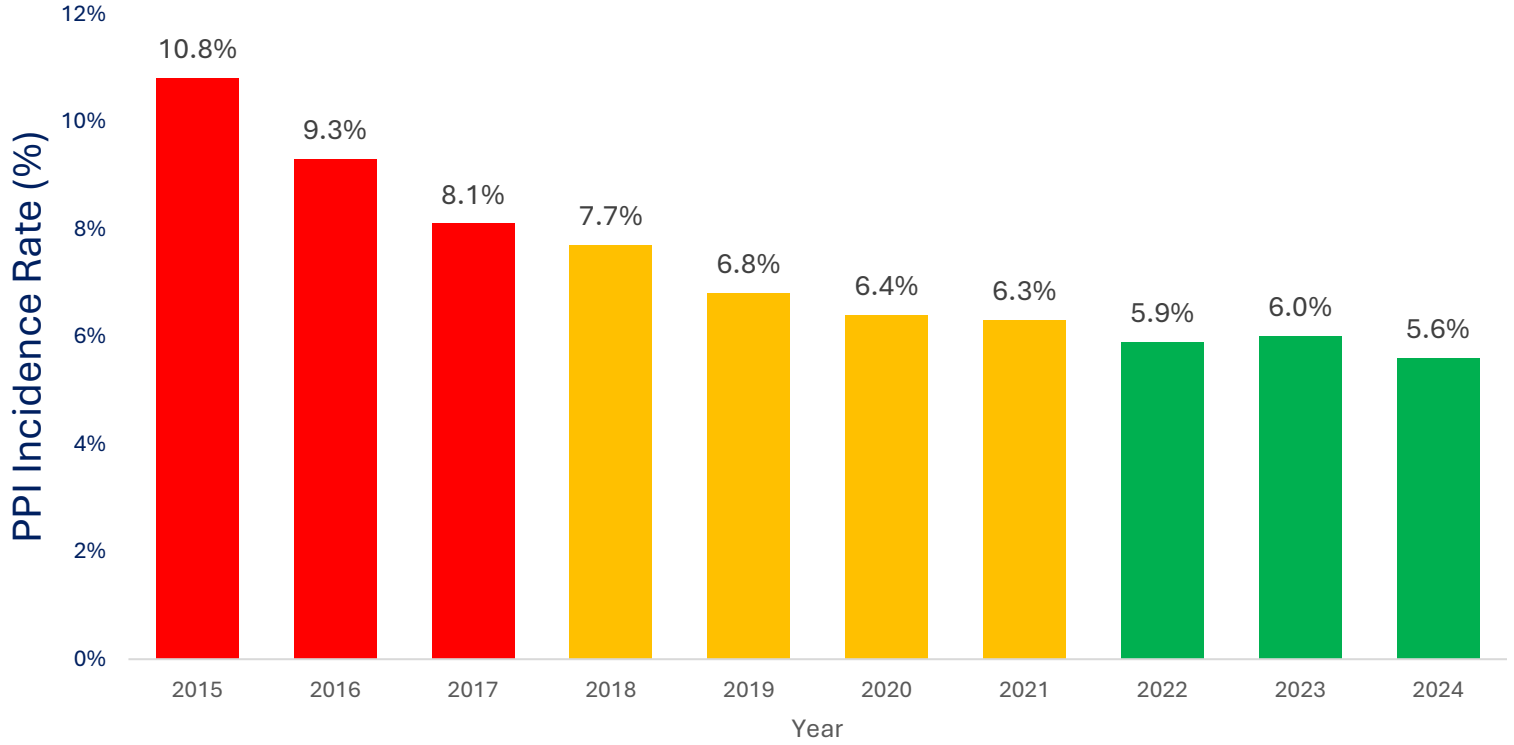
1:1 Propensity-score matching
22,137 TAVR + New Pacemaker
22,137 TAVR + No Pacemaker


PPI Incidence Rate (%)
12%
10%
8%
6%
4%
2%
0%
10.8%
9.3%
8.1%
7.7%
6.8%
6.4%
6.3%
5.9%
6.0%
5.6%
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
Year

Baseline Characteristics
N=322,771

	New Discharge Pacemaker (n=22137)	No New Pacemaker (n=300634)	P-value
Age (year)	80.2 ± 8.0 (22136)	78.5 ± 8.3 (300582)	<0.0001
Male	62.8% (13904/22133)	57.4% (172460/300605)	<0.0001
STS risk score (%)	4.9 ± 4.0 (21678)	4.2 ± 3.5 (294937)	<0.0001
BMI (kg/m^2)	30.2 ± 13.3 (22072)	29.9 ± 11.8 (299935)	0.001
Hypertension	91.3% (20204/22132)	89.9% (270082/300572)	<0.0001
Diabetes mellitus	42.2% (9331/22127)	37.5% (112674/300497)	<0.0001
Currently on dialysis	3.9% (869/22117)	3.0% (8937/300281)	<0.0001
Chronic lung disease	29.8% (6570/22084)	26.8% (80532/299972)	<0.0001
Hostile chest	3.7% (821/22131)	3.1% (9262/300534)	<0.0001
Prior PCI	31.3% (6922/22120)	29.1% (87559/300488)	<0.0001
Prior CABG	16.6% (3684/22128)	12.6% (37832/300523)	<0.0001
Prior stroke	11.0% (2429/22127)	9.8% (29448/300542)	<0.0001
Prior TIA	7.4% (1629/22122)	6.7% (20020/300351)	<0.0001
Previous cardiac surgeries	17.7% (3890/22034)	13.4% (40009/299196)	<0.0001
Peripheral arterial disease (PAD)	20.3% (4481/22126)	17.7% (53239/300509)	<0.0001
Prior MI	17.9% (3968/22112)	15.7% (47092/300378)	<0.0001

Unadjusted Clinical Outcomes
In Hospital

	New Discharge Pacemaker (n=22137)	No New Pacemaker (n=300634)	P-value
All-cause mortality	0.9% (200/22137)	0.7% (2172/300634)	0.002
Cardiac death	0.5% (101/22137)	0.4% (1325/300634)	0.74
Stroke	1.4% (305/22137)	1.0% (3154/300634)	<0.0001
Aortic valve re-intervention	0.2% (40/22137)	0.1% (187/300634)	<0.0001
Life-threatening bleeding – derived	0.9% (209/22137)	0.5% (1649/300634)	<0.0001
Major vascular complication	1.5% (327/22137)	1.0% (2964/300634)	<0.0001
New requirement for dialysis	0.6% (125/22137)	0.1% (446/300634)	<0.0001

Unadjusted Clinical Outcomes

1 year

	New Discharge Pacemaker (n=22137)	No New Pacemaker (n=300634)	P-value
All-cause mortality	12.5% (2090)	8.3% (18403)	<0.0001
Cardiac death	2.7% (456)	1.9% (4327)	<0.0001
Stroke	2.7% (517)	2.9% (7170)	0.57
Aortic valve re-intervention	0.5% (84)	0.3% (659)	<0.0001
Life-threatening bleeding - derived	1.6% (307)	1.1% (2729)	<0.0001
Major vascular complication	1.8% (377)	1.2% (3607)	<0.0001
New requirement for dialysis	0.9% (175)	0.4% (961)	<0.0001
Any readmissions	30.9% (5272)	24.8% (55916)	<0.0001
New onset of atrial fibrillation	4.4% (751)	2.8% (6504)	<0.0001

Propensity Score Matching

Baseline Characteristics

	New Discharge Pacemaker (n=22137)	No New Pacemaker (n=22137)	P-value
Age (year)	80.2 ± 8.0 (22136)	80.2 ± 7.9 (22135)	0.81
Male	62.8% (13904/22133)	62.6% (13846/22135)	0.56
STS risk score (%)	4.9 ± 4.0 (21678)	4.9 ± 4.0 (21708)	0.87
BMI (kg/m^2)	30.2 ± 13.3 (22072)	30.0 ± 13.1 (22082)	0.053
Hypertension	91.3% (20204/22132)	91.3% (20195/22131)	0.89
Diabetes mellitus	42.2% (9331/22127)	42.6% (9422/22123)	0.37
Currently on dialysis	3.9% (869/22117)	3.9% (870/22098)	0.97
Chronic lung disease	29.8% (6570/22084)	30.3% (6693/22084)	0.20
Hostile chest	3.7% (821/22131)	3.6% (798/22125)	0.56
Immunocompromise present	6.7% (1377/20455)	6.9% (1402/20316)	0.50
Endocarditis	0.4% (89/22128)	0.4% (84/22123)	0.70
Prior PCI	31.3% (6922/22120)	30.9% (6845/22123)	0.42
Prior CABG	16.6% (3684/22128)	16.4% (3631/22128)	0.50
Prior stroke	11.0% (2429/22127)	11.0% (2427/22129)	0.97
Prior TIA	7.4% (1629/22122)	7.3% (1607/22108)	0.70
Previous cardiac surgeries	17.7% (3890/22034)	17.2% (3782/22035)	0.17

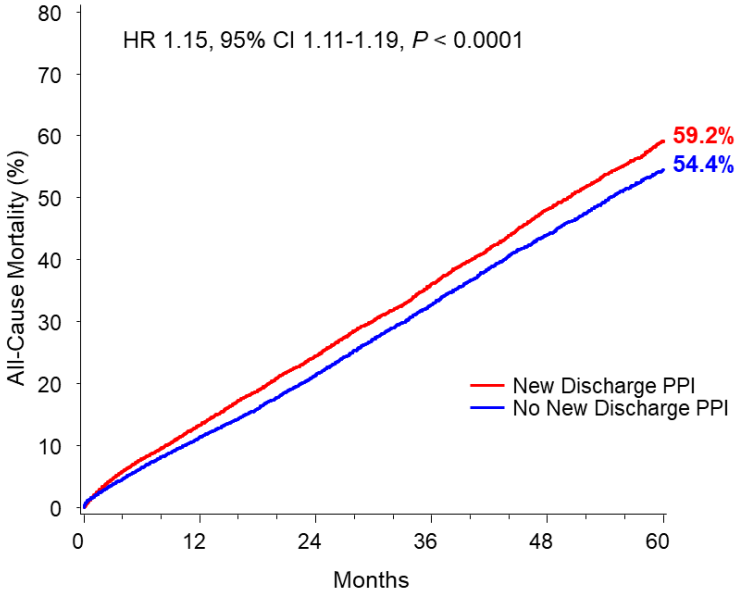
In Hospital Outcomes

	New Discharge Pacemaker (n=22137)	No New Pacemaker (n=22137)	P-value
All-cause mortality	0.9% (200/22137)	0.9% (208/22137)	0.69
Cardiac death	0.5% (101/22137)	0.5% (117/22137)	0.28
Stroke	1.4% (305/22137)	1.2% (267/22137)	0.11
Hemorrhagic	0.0% (7/22137)	0.0% (8/22137)	0.80
Ischemic	1.2% (272/22137)	1.1% (246/22137)	0.25
Undetermined	0.1% (27/22137)	0.1% (17/22137)	0.13
Aortic valve re-intervention	0.2% (40/22137)	0.1% (16/22137)	0.001
Life-threatening bleeding	0.9% (209/22137)	0.5% (121/22137)	<0.0001
Major vascular complication	1.5% (327/22137)	1.1% (248/22137)	0.0009
New requirement for dialysis	0.6% (125/22137)	0.2% (40/22137)	<0.0001
New onset of atrial fibrillation	3.1% (565/18153)	1.7% (298/17834)	<0.0001

1 Year Outcomes

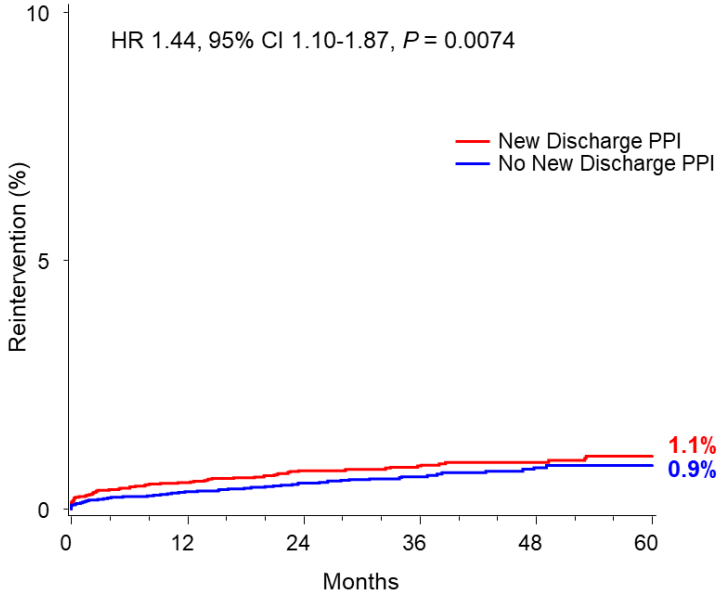
	New Discharge Pacemaker (n=22137)	No New Pacemaker (n=22137)	P-value
All-cause mortality	12.5% (2090)	10.4% (1698)	<0.0001
Cardiac death	2.7% (456)	2.2% (381)	0.01
Stroke	2.7% (517)	3.3% (599)	0.009
Hemorrhagic	0.3% (49)	0.3% (50)	0.88
Ischemic	2.2% (428)	2.8% (514)	0.003
Undetermined	0.3% (48)	0.2% (42)	0.55
Aortic valve re-intervention	0.5% (84)	0.3% (46)	0.001
Life-threatening bleeding – derived	1.6% (307)	1.1% (211)	<0.0001
Major vascular complication	1.8% (377)	1.4% (299)	0.003
New requirement for dialysis	0.9% (175)	0.5% (87)	<0.0001
Any readmissions	30.9% (5272)	27.7% (4596)	<0.0001
New onset of atrial fibrillation	4.4% (751)	2.9% (475)	<0.0001

5-Year Outcomes
All-Cause Mortality



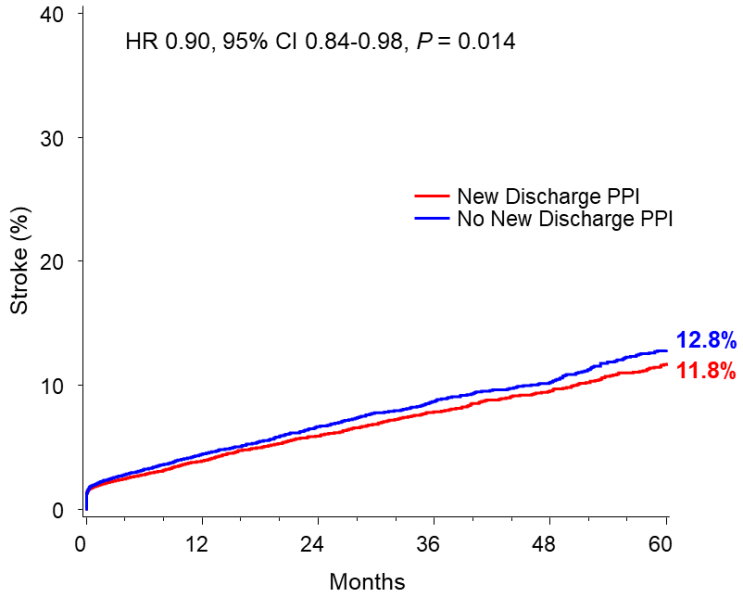
No. at risk:						
New Discharge PPI	22,137	13,987	6,570	4,404	2,626	1,370
No New Discharge PPI	2,2137	1,3865	6,523	4,334	2,558	1,342

5-Year Outcomes
Reintervention



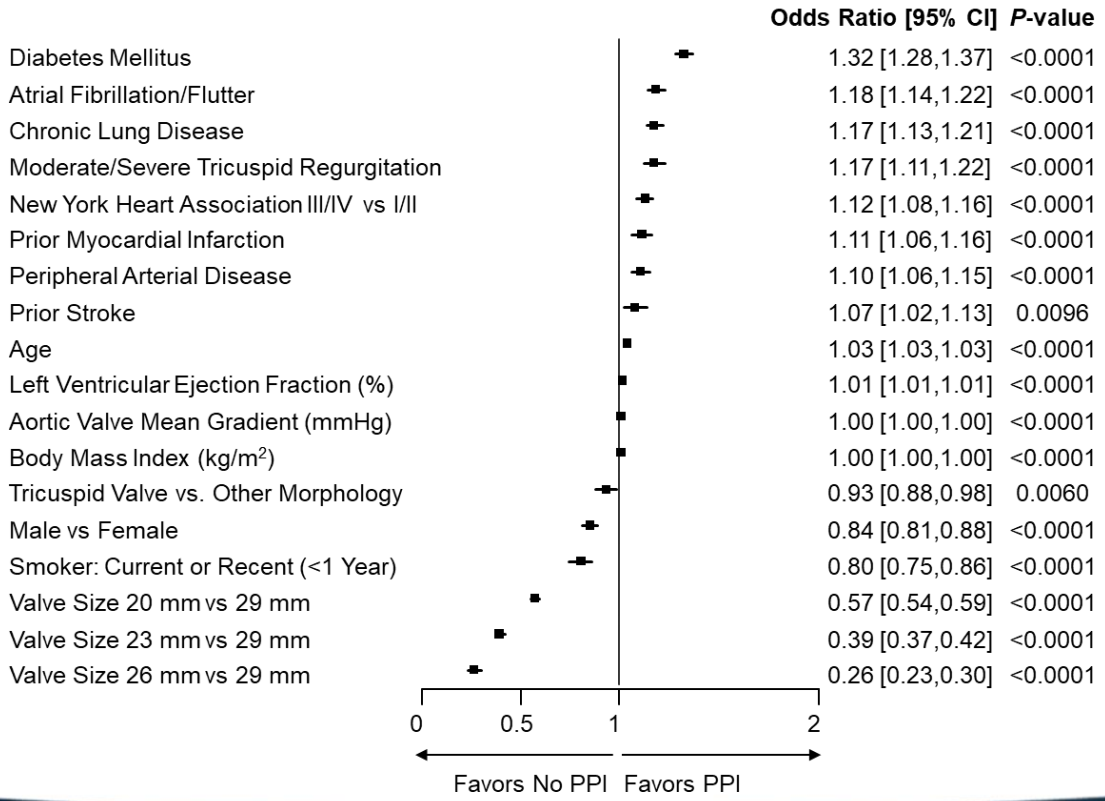
No. at risk:						
New Discharge PPI	22,137	13,919	6,523	4,367	2,598	1,353
No New Discharge PPI	22,137	13,819	6,491	4,306	2,536	1,326

5-Year Outcomes
Stroke



No. at risk:						
New Discharge PPI	22,137	13,578	6,283	4,163	2,463	1,274
No New Discharge PPI	22,137	13,390	6,205	4,074	2,388	1,235

Predictors of In-Hospital Pacemaker



Conclusions

- This large, real-world analysis with BEV demonstrates PPI requirement was low, but it was associated with increased procedural complications and sustained elevations in mortality and valve reintervention over five years
- Careful patient selection, device type, and procedural planning should be used to minimize the incidence of PPI