Decreasing Permanent Pacemaker Implantation Rates in the STS/ACC TVT Registry with a Supra-annular Self-expanding Transcatheter Heart Valve

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DECREASING PPI RATES IN TVT REGISTRY

DISCLOSURES

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below:

Financial Relationship:	**Company:**
Advisory Board	Boston Scientific, Medtronic, Opsens
Speaker's Bureau	Abiomed, Boston Scientific, Medtronic
Proctor	Abiomed, Baylis, Medtronic

Medtronic personnel performed all statistical analyses and assisted with the graphical display of the data presented.

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BACKGROUND

- The number of patients treated for aortic stenosis by transcatheter aortic valve replacement (TAVR) continues to grow. However, rates of conduction disturbances and pacemaker implants are variable.

- Improved procedural success and lower complication rates have been achieved with improved technique in deployment and new iterations of the self-expanding Evolut transcatheter valve (Evolut R, Evolut PRO and Evolut PRO+).

- This analysis looked at pacemaker rates over time for TAVR procedures using the Evolut platform.

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METHODS

- Patients who underwent a TAVR procedure using an Evolut R, Evolut PRO or Evolut PRO+ valve between July 2018 and June 2021 were included.
- Patients who underwent TAVR in a failed surgical valve or a TAV in TAV were included in this analysis.
- In-hospital PPI rates are reported by quarter as proportions and 30-day PPI rates are reported as Kaplan-Meier estimates.
- A Cox regression model was used to determine potential predictors of a new PPI within 30 days of the TAVR procedure.

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Study Demographics

	All N=54,014
Age (years)	79.3 ± 8.8
Body surface area (m^2)	1.9 ± 0.3
Male (%)	49.2
Diabetes mellitus	37.7
History of hypertension	90.8
Peripheral vascular disease	23.6
Previous stroke	10.5
Chronic lung disease/COPD	35.1
Coronary artery bypass surgery	17.8
Prior percutaneous coronary intervention	30.2

Mean ± SD or %.

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Procedural Characteristics

	All N= 54,014
Hybrid cath lab or cath lab	44.6
General anesthesia	42.5
Iliofemoral approach	95.4
Procedure time, min	79 [59, 107]
Valve size implanted	
23 mm	8.1
26 mm	30.5
29 mm	40.0
34 mm	21.1
Device implanted successfully	99.1
Post-procedure hospital stay, days	2 [1, 3]
Discharged home	90.3

Median [1st, 3rd quartile].

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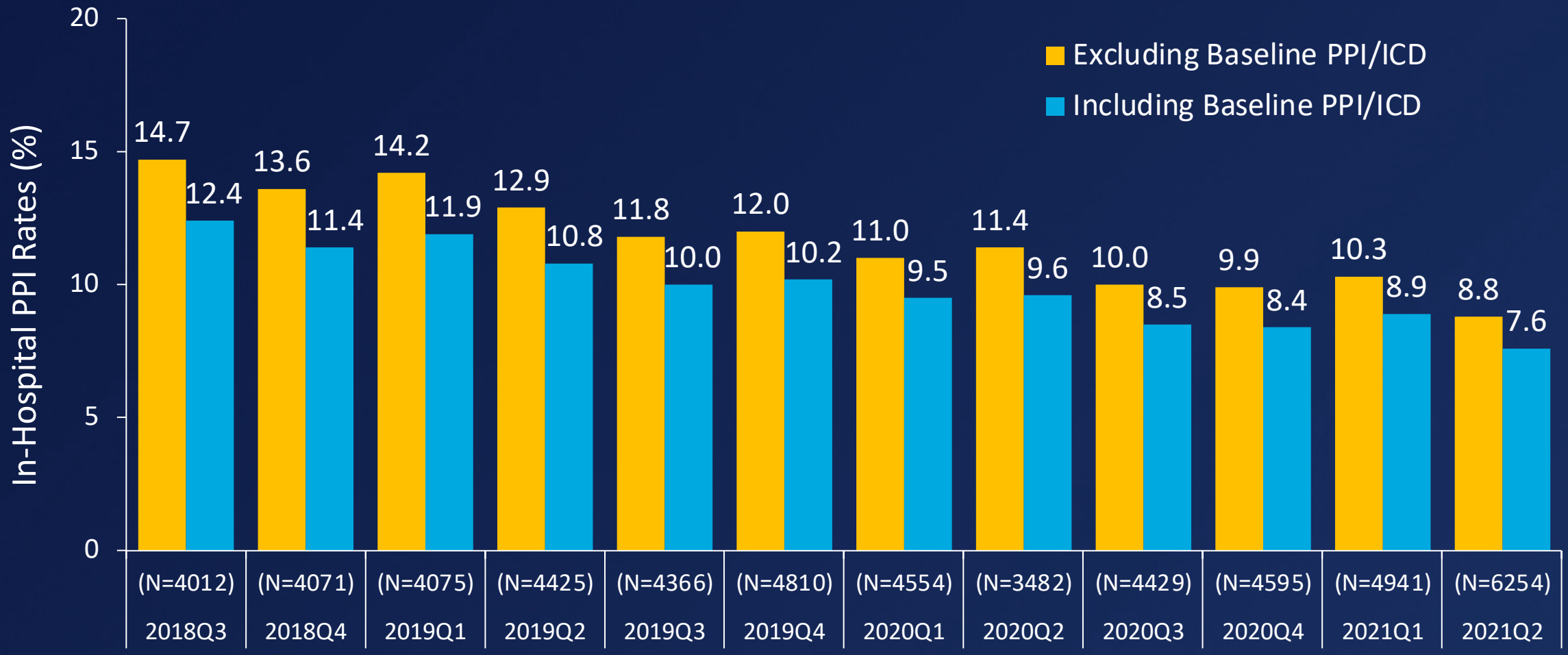
In-hospital Pacemaker Rates by Quarter



ICD, implantable cardioverter; PPI, permanent pacemaker implantation. Quarterly PPI rate trending at in-hospital encompasses all patients including TAV-in-SAV and TAV-in-TAV, which may benefit in providing lower PPI rates. Bars encompass PPI rates of each quarter starting at 2018Q3 and ending at 2021Q2.

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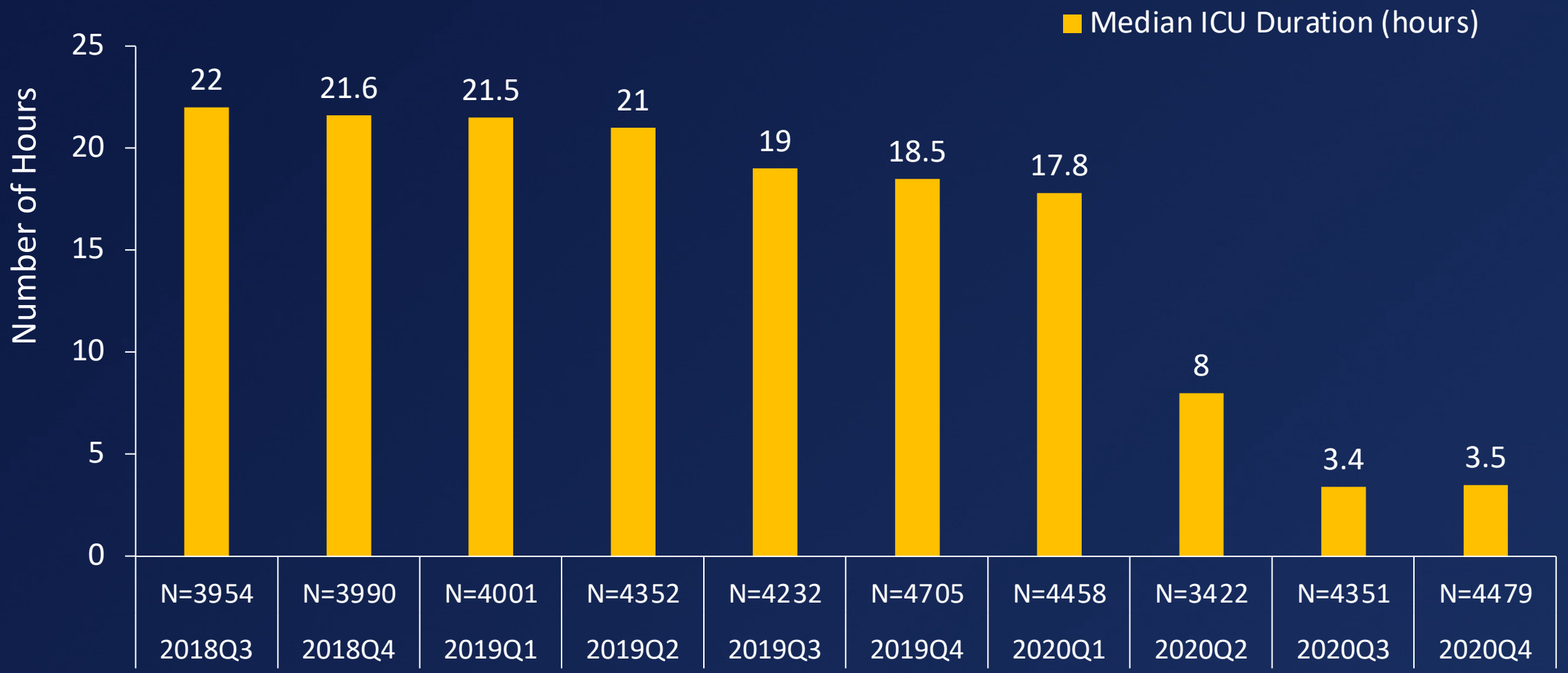
Time in the Intensive Care Unit



Bars encompass ICU duration of each quarter starting at 2018 Q3 through 2020 Q4. 2021 Q1 and 2021 Q2 are not included on this slide because ICU duration was no longer collected by the registry.

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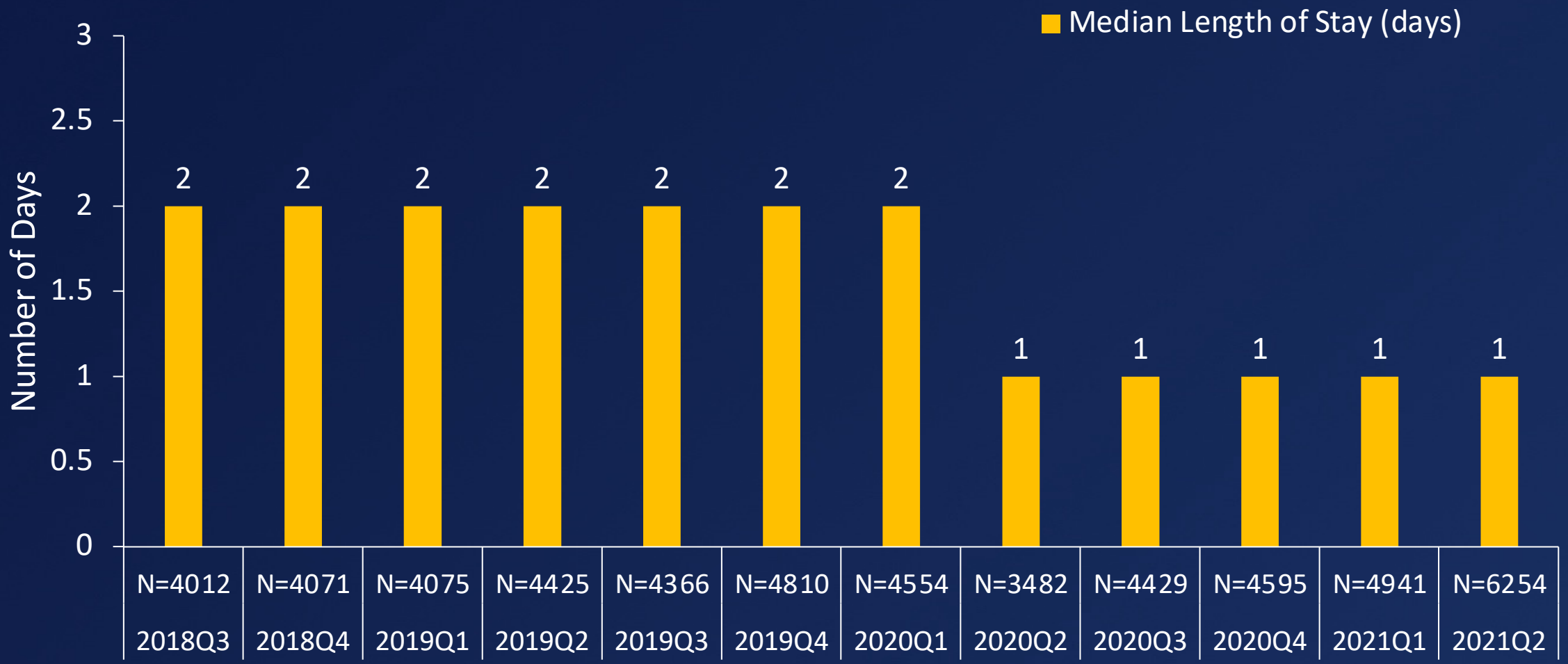
LENGTH OF STAY POST-PROCEDURE



Bars encompass length of stay of each quarter starting at 2018 Q3 and ending at 2021Q2.

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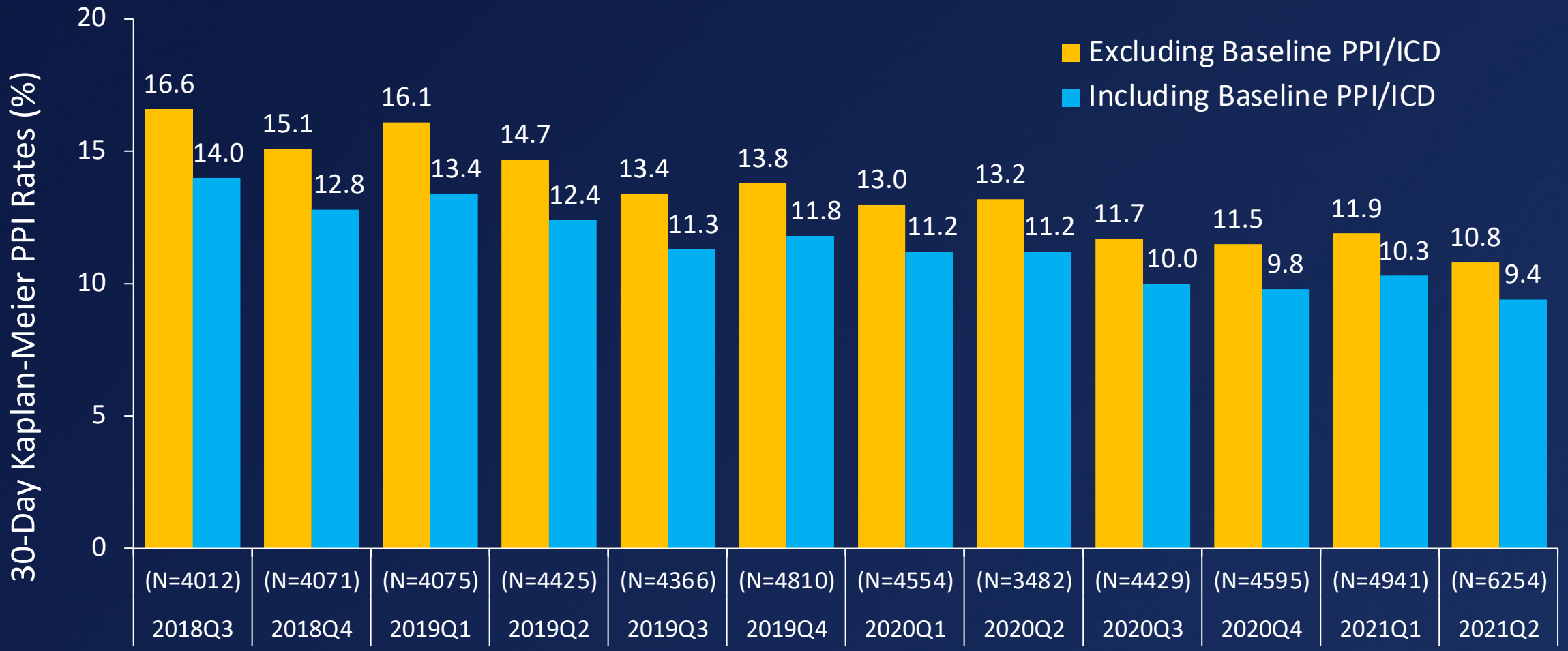
30-Day Pacemaker Rates by Quarter



ICD, implantable cardioverter; PPI, permanent pacemaker implantation. Quarterly PPI rate trending at 30-day encompasses all patients including TAV-in-SAV and TAV-in-TAV, which may benefit in providing lower PPI rates. Bars encompass PPI rates of each quarter starting at 2018 Q3 and ending at 2021Q2.

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MULTIVARIABLE PREDICTORS OF NEW PPI WITHIN 30 DAYS

	Hazard Ratio (95% CI)	P-Value from Cox Model
Quarter implanted[a]	0.97 (0.96–0.98)	<0.001
Conduction defect	2.20 (2.08–2.32)	<0.001
Home oxygen	1.14 (1.04–1.26)	0.008
Diabetes mellitus	1.13 (1.07–1.19)	<0.001
Atrial Fibrillation / Atrial Flutter	1.11 (1.05-1.17)	0.0004
Total time in procedure room, 15 min	1.06 (1.05–1.07)	<0.001
Valve size implanted		
23 mm vs 34 mm	0.74 (0.64–0.85)	<0.001
26 mm vs 34 mm	0.64 (0.59–0.69)	<0.001
29 mm vs 34 mm	0.82 (0.77–0.88)	<0.001
Previous transcatheter aortic valve replacement	0.44 (0.24–0.80)	0.007
Previous surgical aortic valve replacement	0.25 (0.21–0.30)	<0.001

[a]Quarter was forced into the multivariable cox model. The variables were selected from univariable predictors with a p value ≤ 0.15 and with ≤15% missing values. Stepwise method was used. Univariable predictors included male, STS score, diabetes, creatinine level > 2mg/dl, coronary artery bypass surgery, conduction defect, atrial fibrillation/atrial flutter, home oxygen, previous transcatheter aortic valve replacement, previous surgical aortic valve replacement, left ventricular ejection fraction < 50%, moderate to severe mitral regurgitation, implanted valve size, oversizing, procedure time, general anesthesia, more than 1 valve used, number of procedures per center and quarters. Procedures with pacemaker or ICD at baseline are not included. Conduction Defect was defined as right or left bundle branch block, sick sinus syndrome, or 1st, 2nd or 3rd degree heart block on ECG.

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CONCLUSIONS

- Real-world experience in TAVR with a supra-annular self-expanding valve demonstrated decreasing in-hospital PPI rates from 2018 to 2021, with a most recent rate of 7.6%.
- Factors that predict patients receiving a pacemaker are existing conduction defects/atrial fibrillation, home oxygen, larger valve size, or diabetes.
- Reductions in pacemaker rates are multifactorial but are likely impacted by the experience level of the practicing physician, improved care pathways and adoption of novel implantation techniques such as the cusp overlap technique.

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