Aspirin Versus Clopidogrel Following TAVR: a TVT Propensity Matched Analysis

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Disclosure of Relevant Financial Relationships

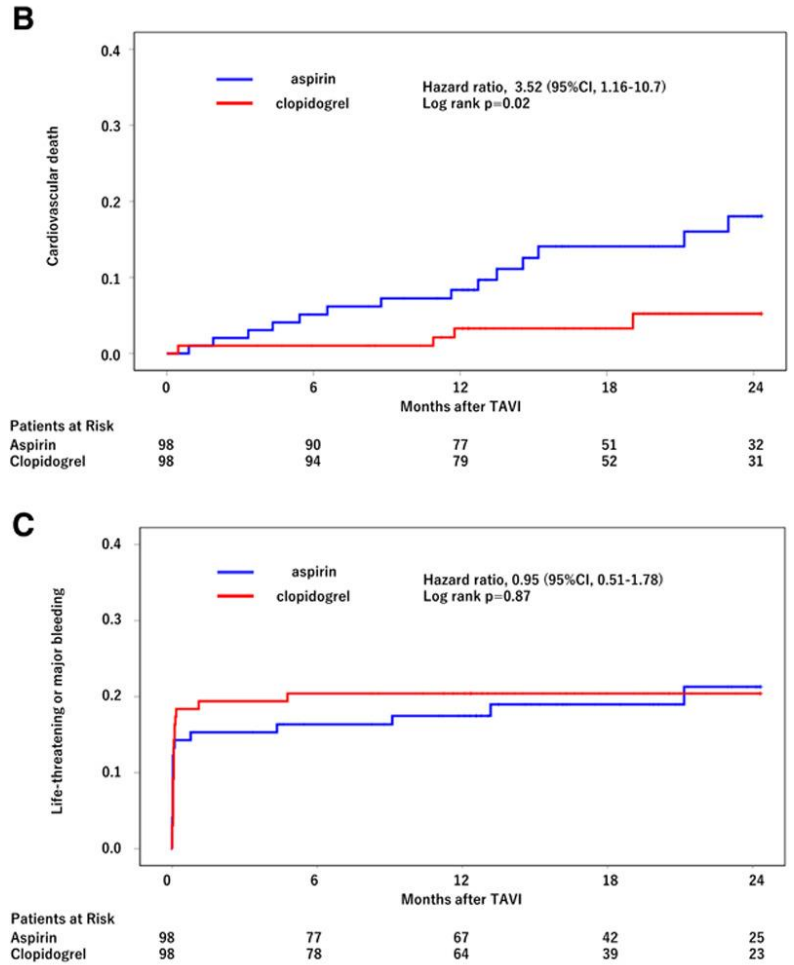
I, Yuri B. Pride, MD, DO NOT have any financial relationships to disclose.

Background

- Optimal antiplatelet therapy following transcatheter aortic valve replacement (TAVR) among patients without an indication for dual antiplatelet therapy (DAPT) or anticoagulation is unknown
- US Guidelines
  - Class 2a: Aspirin 75-100 mg daily
  - Class 2b: 3-6 months of DAPT with aspirin and clopidogrel or warfarin with a goal INR of 2.5 among patients at low bleeding risk
- European guidelines
  - Class I: SAPT, does not specify aspirin or clopidogrel

Background

- A small propensity matched analysis (98 pairs) from a Japanese registry demonstrated a significant decrease in cardiovascular (CV) death without an increase in major bleeding
- Trials and meta-analyses of clopidogrel have demonstrated improved CV outcomes and no increase in major bleeding among patients with CAD



Kobari et al., Circ Cardiovasc Interv, 2021;14, 5

Goals

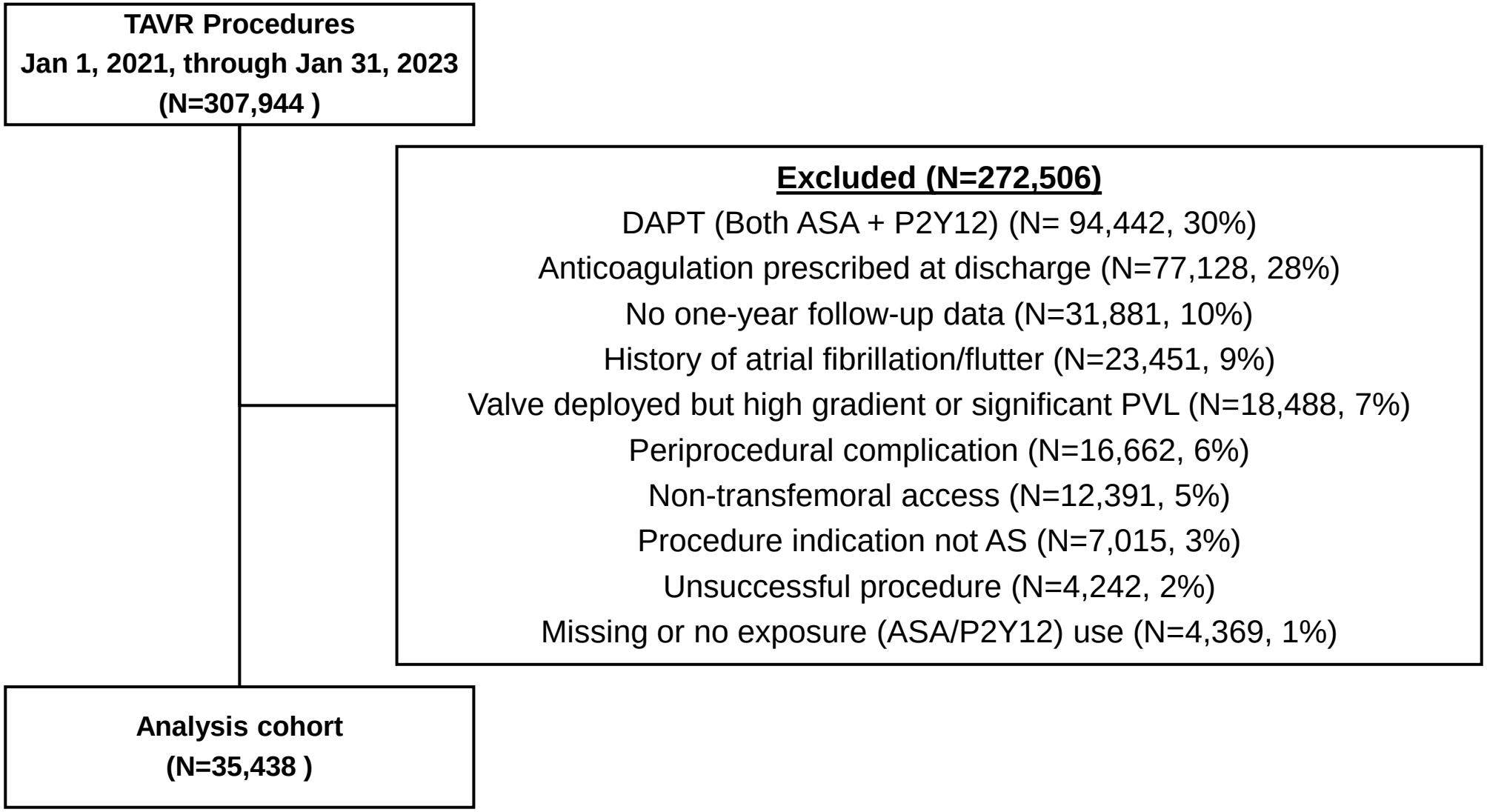
- To assess whether clopidogrel monotherapy is superior to aspirin monotherapy to reduce major adverse cardiovascular events (MACE) without increasing major bleeding in the first year following successful transfemoral TAVR

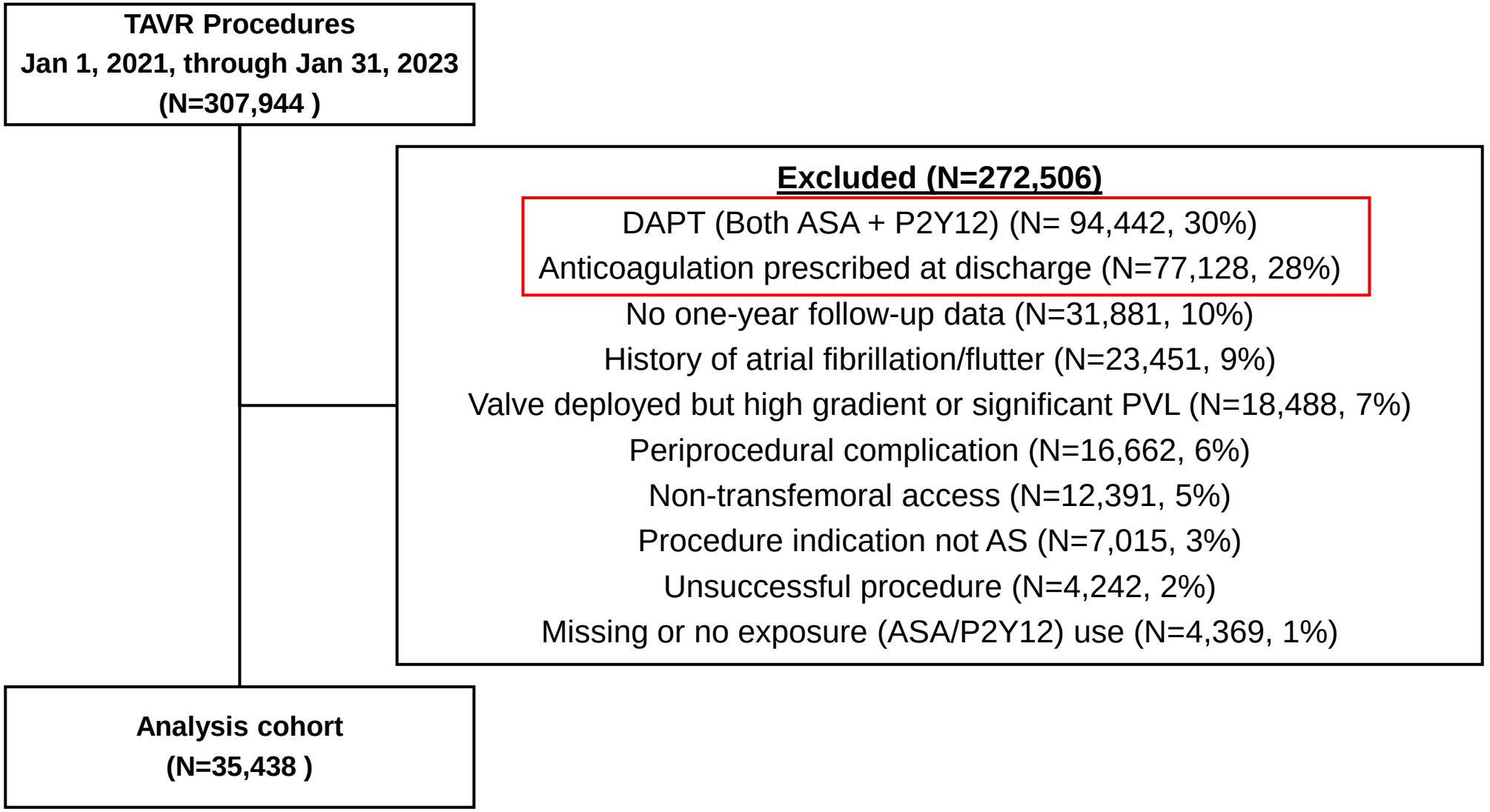
Methods

- Utilized the STS/ACC TVT Registry
- Inclusion
  - Successful transfemoral TAVR from January 1, 2021- January 31, 2023
    - Success defined as mean gradient <20 mmHg, peak transvalvular velocity <3.0 m/s, no moderate or severe aortic regurgitation following implantation
- Exclusion
  - Periprocedural/in-hospital stroke, Valve Academic Research Consortium-3 (VARC-3) life-threatening bleeding, coronary obstruction, major vascular complication, unresolved acute valve thrombosis or repeat procedure
  - Prescribed DAPT or oral anticoagulation at discharge

Methods

- Analytic approaches
  - Instrumental variable analysis
    - Approximates randomization via natural experiments
    - Instrument utilized was the hospital-level preference for aspirin, defined as the proportion of patients receiving aspirin as SAPT at a given hospital
  - Inverse probability weighting
    - Reduces bias by creating population in which treatment assignment is independent of observed covariates


TAVR Procedures
Jan 1, 2021, through Jan 31, 2023
(N=307,944)
Excluded (N=272,506)
DAPT (Both ASA + P2Y12) (N= 94,442, 30%)
Anticoagulation prescribed at discharge (N=77,128, 28%)
No one-year follow-up data (N=31,881, 10%)
History of atrial fibrillation/flutter (N=23,451, 9%)
Valve deployed but high gradient or significant PVL (N=18,488, 7%)
Periprocedural complication (N=16,662, 6%)
Non-transfemoral access (N=12,391, 5%)
Procedure indication not AS (N=7,015, 3%)
Unsuccessful procedure (N=4,242, 2%)
Missing or no exposure (ASA/P2Y12) use (N=4,369, 1%)
Analysis cohort
(N=35,438)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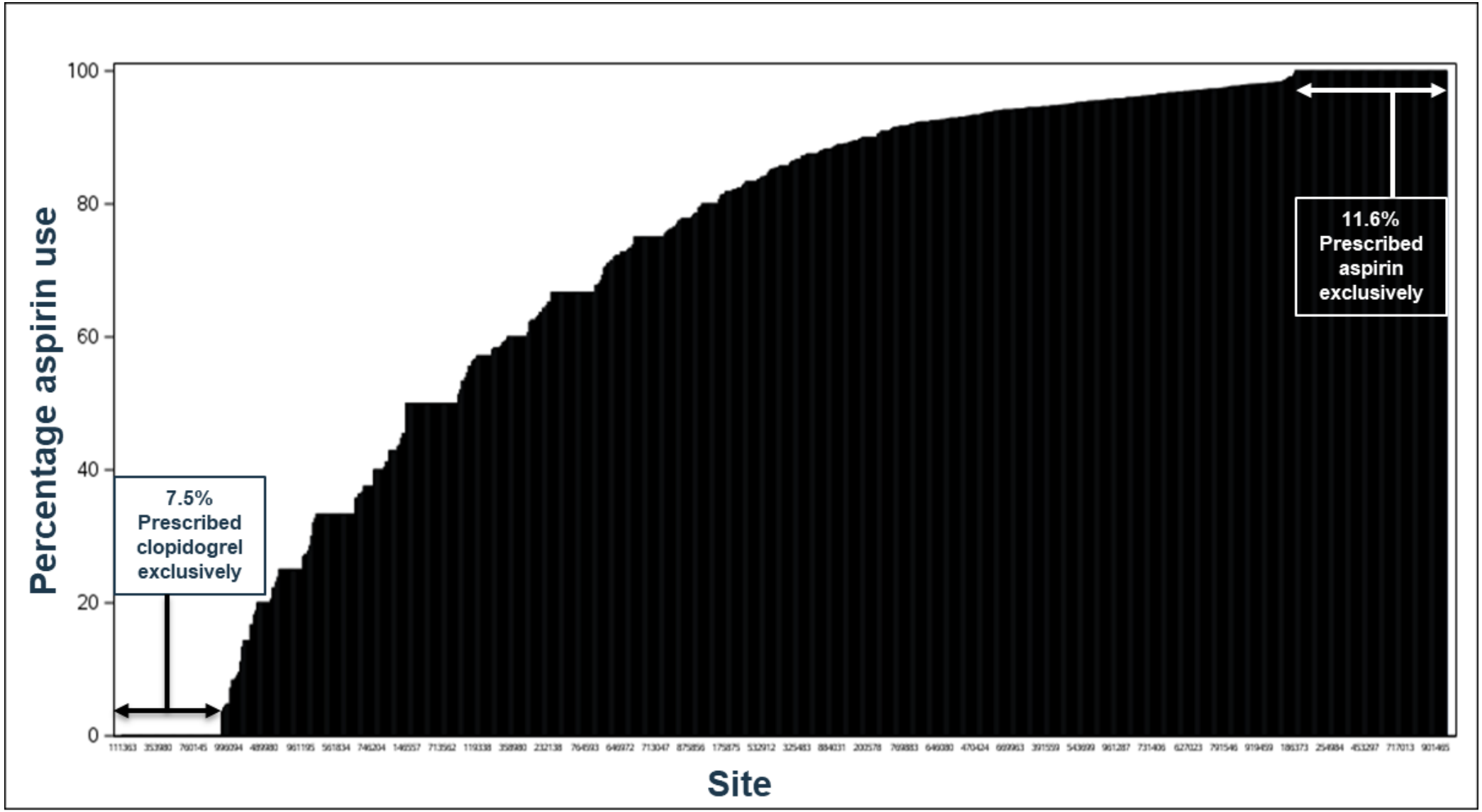

Percentage aspirin use
100
80
60
40
20
0
7.5%
Prescribed
clopidogrel
exclusively
11.6%
Prescribed
aspirin
exclusively
Site

Patient characteristics

- Patients discharged on clopidogrel had significantly higher rates of multiple comorbidities
- Also more likely to have been performed at lower volume centers

	ASPIRIN (N=31,173)	CLOPIDOGREL (N=4,265)	*P-VALUE*
Age, median (IQR)	78 yrs (72-84 yrs)	79 yrs (73-85 yrs)	<0.001
Female sex	45.3%	49.8%	<0.001
Hypertension	87.5%	89.8%	<0.001
Diabetes mellitus	35.2%	38.0%	<0.001
Carotid stenosis	10.4%	13.2%	<0.001
CAD			
Proximal LAD stenosis ≥70%	6.0%	7.6%	<0.001
LM stenosis ≥50%	3.3%	3.5%	0.555
Prior MI	10.8%	13.2%	<0.001
Prior PCI	13.0%	25.3%	<0.001
Chronic lung disease	19.9%	23.3%	<0.001
Hospital characteristics			
TAVR volume, median (IQR)	57.7 (30.1-99.7)	26.3 (11.8-74.5)	<0.001
Number of beds, median (IQR)	505 (334-712)	505 (336-783)	0.616
Teaching hospital	68.9%	66.6%	0.003

Unadjusted analysis

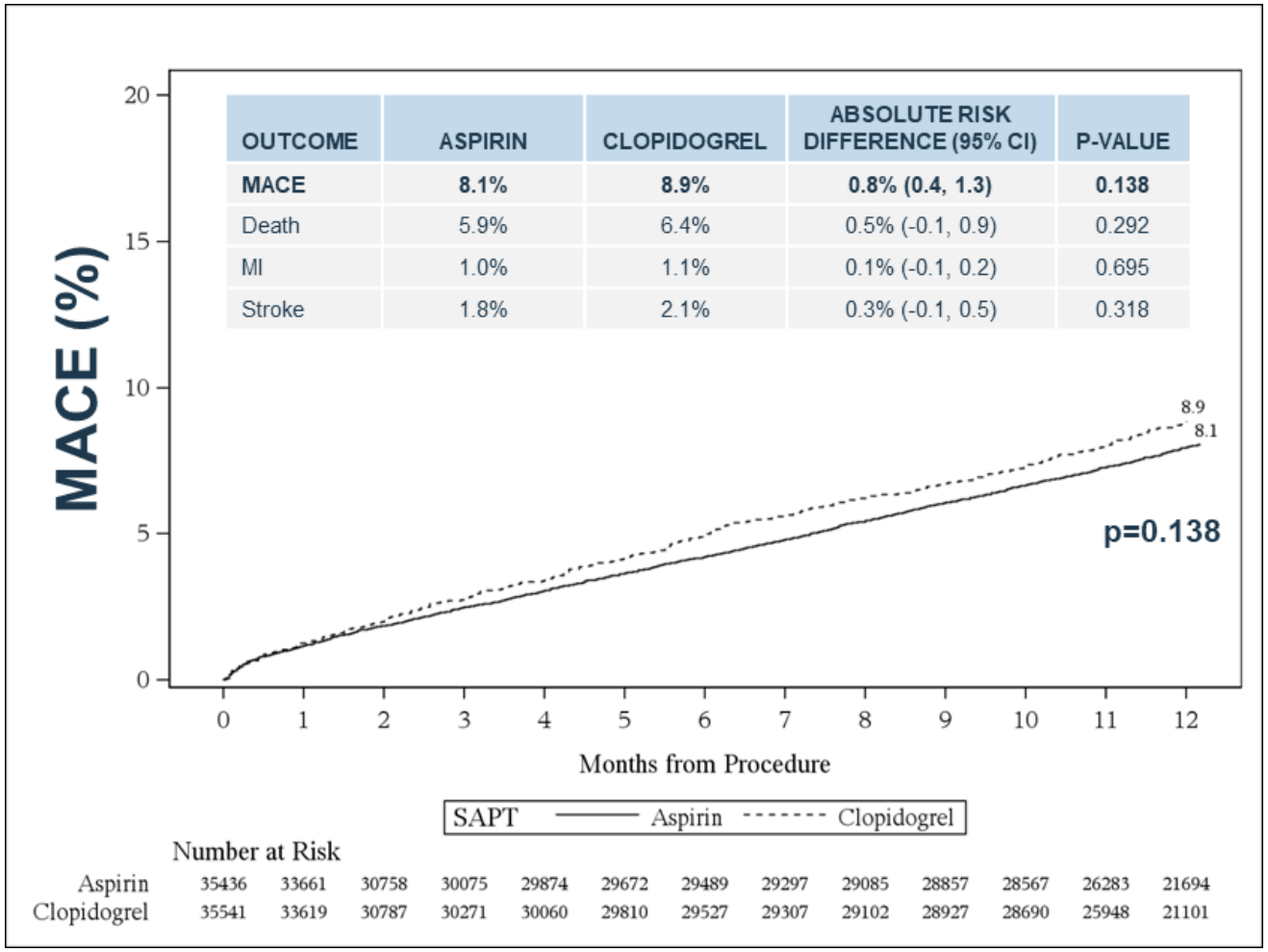
OUTCOME	ASPIRIN N=31,173	CLOPIDOGREL N=4,265	P-VALUE
NACE	2,552 (9.2%)	444 (11.8%)	<0.001
MACE	2,169 (7.9%)	357 (9.6%)	0.001
Major bleeding	551 (1.9%)	113 (2.9%)	<0.001
Death	1,557 (5.8%)	261 (7.1%)	0.003
Myocardial infarction	260 (0.9%)	42 (1.1%)	0.302

Instrumental variable analysis

OUTCOME	ASPIRIN	CLOPIDOGREL	ABSOLUTE RISK DIFFERENCE (95% CI)	P-VALUE
NACE	9.3%	11.1%	1.8% (-0.1, 3.1)	0.090
MACE	8.1%	8.7%	0.6% (-0.5, 2.0)	0.163
Major bleeding	2.0%	3.5%	1.5% (0, 2.2)	0.050
Death	6.0%	6.4%	0.4% (-0.5, 0.8)	0.213
Myocardial infarction	1.0%	1.4%	0.4% (-0.1, 0.8)	0.093

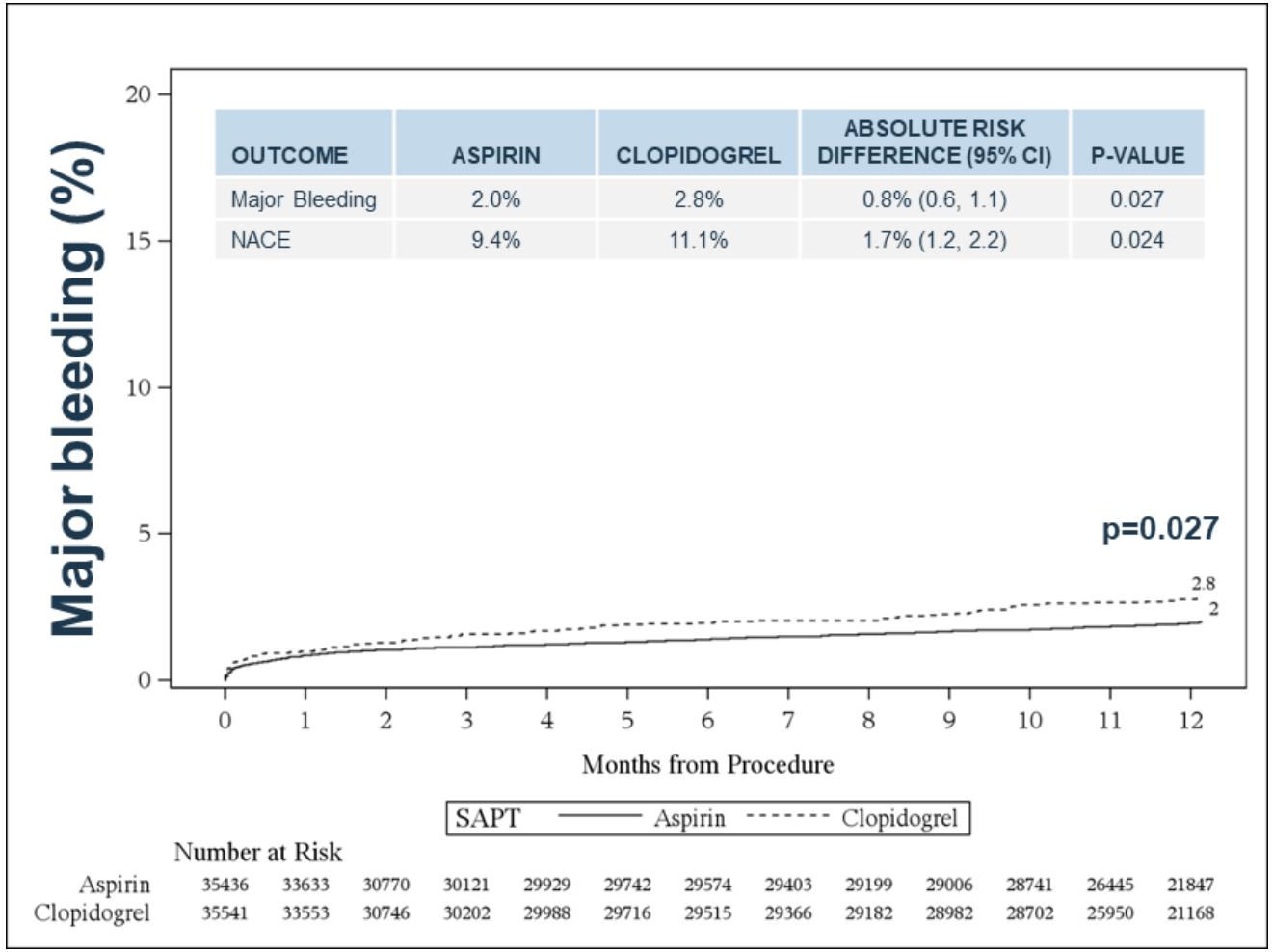
Propensity weighted analysis

OUTCOME	ASPIRIN	CLOPIDOGREL	ABSOLUTE RISK DIFFERENCE (95% CI)	P-VALUE
MACE	**8.1%**	**8.9%**	**0.8% (0.4, 1.3)**	**0.138**
Death	5.9%	6.4%	0.5% (-0.1, 0.9)	0.292
MI	1.0%	1.1%	0.1% (-0.1, 0.2)	0.695
Stroke	1.8%	2.1%	0.3% (-0.1, 0.5)	0.318



Propensity weighted analysis

OUTCOME	ASPIRIN	CLOPIDOGREL	ABSOLUTE RISK DIFFERENCE (95% CI)	P-VALUE
Major Bleeding	2.0%	2.8%	0.8% (0.6, 1.1)	0.027
NACE	9.4%	11.1%	1.7% (1.2, 2.2)	0.024



Summary

- Among patients undergoing uncomplicated transfemoral TAVR without an indication for DAPT or oral anticoagulation, use of clopidogrel was associated with no difference in MACE and a significantly higher risk of major bleeding when compared to aspirin monotherapy in two separate analyses used to control for differences in baseline characteristics
- These data support the use of aspirin monotherapy among patients undergoing uncomplicated transfemoral TAVR

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