

# The Relationship Between Race and Post-TAVR Bleeding Outcomes: Analysis from the Trans-Pacific TAVR (TP-TAVR) Registry

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# Disclosure of Relevant Financial Relationships

I, Meghana Iyer, DO NOT have any financial relationships to disclose.

# Outline

- Background
  - Race-Stratified Differences in TAVR
  - Cardiovascular Health of Asian American Patients
- Methodology
- Results
- Conclusions + Discussion

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# Race-Stratified Differences in TAVR

**Figure 1** Low-Risk Patients Receiving TAVR in the "Real-World vs. Pivotal Trials

	TVT Registry	Low Risk Trial #1	Low Risk Trial #2
<b>Number of Patients Receiving TAVR</b>	8,385 in 2019 (7,101 in 2nd half of 2019)	496 (as treated cohort)	725 (as treated cohort)
<b>Age of Patients</b>	Median 75 years (IQR 70,81)	Mean 73 years	Mean 74 years
<b>Sex</b>	65% Male	67.5% Male	66% Male
<b>Race</b>	93% White	NA	92% White
<b>STS PROM Score</b>	Median 2.3% (IQR 1.6, 3.45)	Mean 1.9%	Mean 1.9%
<b>Baseline NYHA Class 3 and 4</b>	48.9%	31.2%	25.1%
<b>Femoral Access</b>	97.8%	100%	100%
<b>Length of Hospital Stay</b>	Median 1 (IQR 1,2)	Mean 3 days	NA
<b>In-Hospital Mortality</b>	0.5%	0.4%	NA

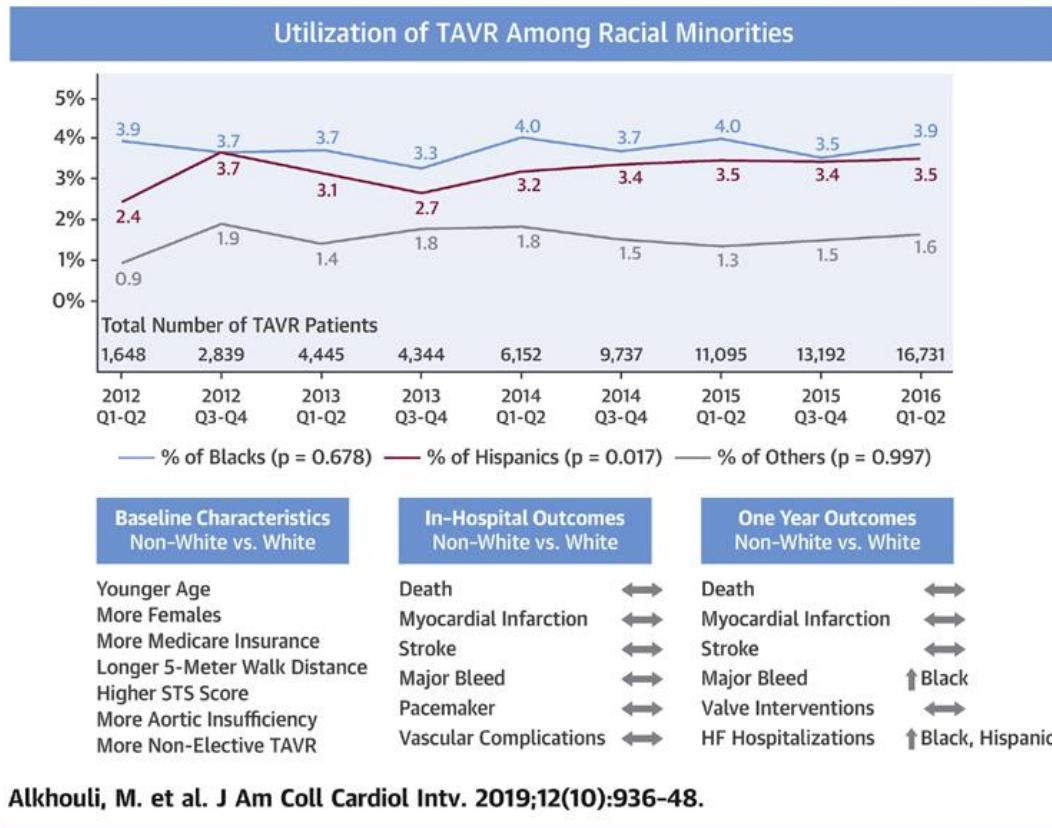
# Race-Stratified Differences in TAVR

**Figure 1** Low-Risk Patients Receiving TAVR in the "Real-World vs. Pivotal Trials

	TVT Registry	Low Risk Trial #1	Low Risk Trial #2
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<b>Age of Patients</b>	Median 75 years (IQR 70,81)	Mean 73 years	Mean 74 years
<b>Sex</b>	65% Male	67.5% Male	66% Male
<b>Race</b>	93% White	NA	92% White
<b>STS PROM Score</b>	Median 2.3% (IQR 1.6, 3.45)	Mean 1.9%	Mean 1.9%
<b>Baseline NYHA Class 3 and 4</b>	48.9%	31.2%	25.1%
<b>Femoral Access</b>	97.8%	100%	100%
<b>Length of Hospital Stay</b>	Median 1 (IQR 1,2)	Mean 3 days	NA
<b>In-Hospital Mortality</b>	0.5%	0.4%	NA

# Race-Stratified Differences in TAVR

**CENTRAL ILLUSTRATION:** Race-Stratified Differences in the Use and Outcomes of TAVR in the United States



# Cardiovascular Health of Asian-American Patients

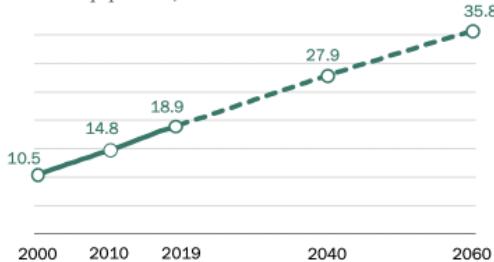
**Asian Americans were the fastest-growing racial or ethnic group in the U.S. from 2000 to 2019 ...**

*U.S. population change by race and ethnicity, in thousands*

	2019	2000	Change '00-'19	% Change '00-'19
Asian	18,906	10,469	8,437	81%
Hispanic	60,572	35,662	24,910	70
NHPI	596	370	226	61
Black	41,147	34,406	6,742	20
White	197,310	195,702	1,608	1
Total	328,240	282,162	46,077	16

**... and their population is projected to pass 35 million by 2060**

*Asian American population, in millions*

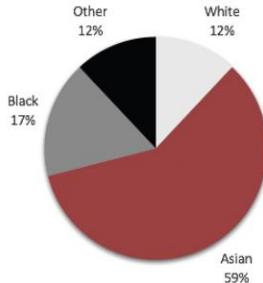


Note: NHPI is the acronym for Native Hawaiian and Pacific Islander. White, Black, Asian and NHPI individuals include those who report only being one race and are not Hispanic. Hispanics are of any race. Population figures rounded to nearest 1,000. American Indian and Alaska Native and multiracial groups not shown.

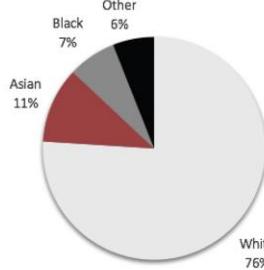
Source: Pew Research Center analysis of U.S. Intercensal population estimates for 2000-2009, U.S. Census Bureau Vintage 2019 estimates for 2010-2019, and Census Bureau 2017 population projections for 2020-2060.

PEW RESEARCH CENTER

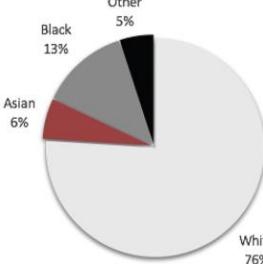
**Global Population**  
Total Population = 7.6 billion people



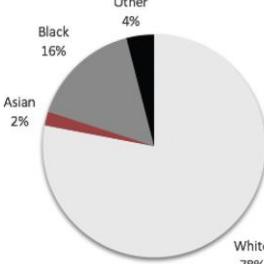
**Global Racial Participation in Clinical Trials**  
Total Participants = 292,537 people



**US Population**  
Total Population = 328,239,523 people



**US Racial Participation in Clinical Trials**  
Total Participants = 102,596 people



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# Trans-Pacific TAVR (TP-TAVR) Registry

## Sex-Specific Disparities in Clinical Outcomes After Transcatheter Aortic Valve Replacement Among Different Racial Populations



Mijin Kim, MD,<sup>a</sup> Do-Yoon Kang, MD,<sup>a</sup> Jung-Min Ahn, MD,<sup>a</sup> Juyong Brian Kim, MD,<sup>b</sup> Alan C. Yeung, MD,<sup>b</sup> Takeshi Nishi, MD,<sup>b</sup> William F. Fearon, MD,<sup>b</sup> Eric P. Cantey, MD,<sup>c</sup> James D. Flaherty, MD,<sup>c</sup> Charles J. Davidson, MD,<sup>c</sup> S. Christopher Malaisrie, MD,<sup>d</sup> Hwa Jung Kim, MSc,<sup>d</sup> Jinho Lee, MD,<sup>a</sup> Jinsun Park, MD,<sup>a</sup> Hoyun Kim, MD,<sup>a</sup> Suji Cho, MD,<sup>a</sup> Yeonwoo Choi, MD,<sup>a</sup> Seung-Jung Park, MD,<sup>a</sup> Duk-Woo Park, MD,<sup>a</sup>

## Racial Differences in the Incidence and Impact of Prosthesis-Patient Mismatch After Transcatheter Aortic Valve Replacement



Hanbit Park, MD,<sup>a,\*</sup> Jung-Min Ahn, MD,<sup>a,\*</sup> Do-Yoon Kang, MD,<sup>a</sup> Juyong Brian Kim, MD,<sup>b</sup> Alan C. Yeung, MD,<sup>b</sup> Takeshi Nishi, MD,<sup>b</sup> William F. Fearon, MD,<sup>b</sup> Eric Page Cantey, MD,<sup>c</sup> James D. Flaherty, MD,<sup>c</sup> Charles J. Davidson, MD,<sup>c</sup> S. Christopher Malaisrie, MD,<sup>d</sup> Sehee Kim, PhD,<sup>d</sup> Sung-Cheol Yun, PhD,<sup>d</sup> Euihong Ko, MD,<sup>a</sup> Seung-Ah Lee, MD,<sup>a</sup> Dae-Hee Kim, MD,<sup>a</sup> Ho Jin Kim, MD,<sup>a</sup> Joon Bum Kim, MD,<sup>a</sup> Suk Jung Choo, MD,<sup>a</sup> Duk-Woo Park, MD,<sup>a</sup> Seung-Jung Park, MD,<sup>a</sup>

## Race-Specific Impact of Conventional Surgical Risk Score on 1-Year Mortality After Transcatheter Aortic Valve Replacement



Hoyun Kim, MD,<sup>a,\*</sup> Do-Yoon Kang, MD,<sup>a,\*</sup> Jung-Min Ahn, MD,<sup>a</sup> Juyong Brian Kim, MD,<sup>b</sup> Alan C. Yeung, MD,<sup>b</sup> Takeshi Nishi, MD,<sup>b</sup> William F. Fearon, MD,<sup>b</sup> Eric P. Cantey, MD,<sup>c</sup> James D. Flaherty, MD,<sup>c</sup> Charles J. Davidson, MD,<sup>c</sup> S. Christopher Malaisrie, MD,<sup>d</sup> Nayoung Kim, MSc,<sup>d</sup> Mijin Kim, MD,<sup>a</sup> Jinho Lee, MD,<sup>a</sup> Jinsun Park, MD,<sup>a</sup> Yeonwoo Choi, MD,<sup>a</sup> Seung-Jung Park, MD,<sup>a</sup> Duk-Woo Park, MD,<sup>a</sup>

**TABLE 1** Baseline Demographic and Clinical Characteristics Stratified by Gender and Race

	Overall Patients (N = 1,412)			Asian Patients (n = 581)			Non-Asian Patients (n = 831)		
	Male (n = 755)	Female (n = 657)	P Value	Male (n = 294)	Female (n = 287)	P Value	Male (n = 461)	Female (n = 370)	P Value
<b>Demographics</b>									
Age, y	80 ± 8	81 ± 8	0.04	80 ± 6	80 ± 5	0.20	80 ± 9	81 ± 9	0.06
Body mass index, kg/m <sup>2</sup> <sup>a</sup>	26.8 ± 5.9	26.4 ± 6.4	0.11	23.7 ± 3.3	24.3 ± 3.9	0.04	28.7 ± 6.3	28.0 ± 7.4	0.02
STS score <sup>b</sup>	4.7 ± 3.4	5.4 ± 3.5	<0.001	3.8 ± 2.7	4.5 ± 3.4	<0.001	5.3 ± 3.7	6.1 ± 3.5	<0.001
NYHA functional class III/IV heart failure <sup>c</sup>	317 (41.7)	295 (44.9)	0.20	90 (30.6)	116 (40.4)	0.01	225 (48.8)	179 (48.4)	>0.99
<b>Comorbidities</b>									
Diabetes mellitus	337 (44.6)	253 (38.5)	0.02	169 (57.5)	137 (47.7)	0.02	168 (36.4)	116 (31.4)	0.12
Hypertension	642 (85)	574 (87.4)	0.20	257 (87.4)	251 (87.5)	>0.99	385 (83.5)	323 (87.3)	0.13
Current smoking	55 (7.3)	14 (2.1)	<0.001	38 (12.9)	9 (3.1)	<0.001	17 (3.7)	5 (1.4)	0.04
Hyperlipidemia	579 (76.7)	467 (71.1)	0.02	226 (76.9)	211 (73.5)	0.30	353 (76.6)	256 (69.2)	0.02
Prior MI	108 (14.3)	52 (7.9)	<0.001	15 (5.1)	17 (5.9)	0.70	9.3 (20.2)	35 (9.5)	<0.001
Prior PCI	264 (35)	141 (21.5)	<0.001	98 (33.3)	63 (22)	0.002	166 (36)	78 (21.1)	<0.001
Prior CABG	185 (19.6)	30 (4.6)	<0.001	21 (7.1)	10 (3.5)	0.05	127 (27.5)	20 (5.4)	<0.001
Prior stroke	89 (11.8)	71 (10.8)	0.60	44 (15)	33 (11.5)	0.29	45 (9.8)	38 (10.3)	0.80
History of atrial fibrillation or flutter	242 (32.1)	161 (24.5)	0.002	44 (15)	28 (9.8)	0.06	198 (43.0)	133 (35.9)	0.04
Peripheral vascular disease	143 (18.9)	84 (12.8)	0.002	12 (4.1)	10 (3.5)	0.70	131 (28.4)	74 (20.0)	0.01
Chronic lung disease	104 (13.8)	73 (11.1)	0.13	37 (12.6)	24 (8.4)	0.10	67 (14.5)	49 (13.2)	0.60
Current dialysis	32 (4.2)	21 (3.2)	0.30	12 (4.1)	11 (3.8)	0.90	20 (4.3)	10 (2.7)	0.20

# Trans-Pacific TAVR (TP-TAVR) Registry

- International, multi-center prospective registry comprising patients who underwent TAVR between 2015-2019 across ASAN (Korea), Stanford, Northwestern (n=1412)
- Patients were stratified by documented race/ethnicity (White, Black, Hispanic, Asian, Other)
- Primary outcome: bleeding complications, defined by Valve Academic Research Consortium (VARC) criteria
  - Grade I: minor, Grade II: major, Grade III: “more than major”, Grade IV: life-threatening
- Predictors of bleeding events were analyzed by multivariable logistic regression, with sensitivity analyses performed to assess robustness

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# Table 1: Demographic and Baseline Characteristics of Study Population

	White	Black	Hispanic	Asian	Other	Unknown	p-value
<b>N</b>	727	14	51	581	17	22	
<b>Center (%)</b>							<0.05
Northwestern	357 (49.1)	8 (57.1)	12 (23.5)	7 (1.2)	0 (0.0)	14 (63.6)	
Stanford	370 (50.9)	6 (42.9)	39 (76.5)	38 (6.5)	17 (100.0)	8 (36.4)	
ASAN	0 (0.0)	0 (0.0)	0 (0.0)	536 (92.3)	0 (0.0)	0 (0.0)	
<b>Female (%)</b>	316 (43.5)	8 (57.1)	26 (51.0)	287 (49.4)	9 (52.9)	11 (50.0)	0.2875
<b>CAD (%)</b>	558 (76.8)	12 (85.7)	43 (84.3)	186 (32.0)	9 (52.9)	13 (59.1)	<0.05
<b>PAD (%)</b>	181 (24.9)	3 (21.4)	15 (29.4)	22 (3.8)	3 (17.6)	3 (13.6)	<0.05
<b>Anticoagulant Use</b>	374 (52.4)	7 (50.0)	24 (47.1)	429 (73.8)	6 (35.3)	12 (54.5)	0.256
<b>P2Y12 Inhibitor</b>	604 (84.5)	13 (92.9)	42 (82.4)	464 (79.9)	13 (76.5)	17 (77.3)	<0.05
<b>Aspirin</b>	106 (14.8)	2 (14.3)	4 (7.8)	14 (2.4)	2 (11.8)	5 (22.7)	<0.05
<b>Coumadin</b>	101 (14.1)	1 (7.1)	7 (13.7)	106 (18.2)	2 (11.8)	1 (4.5)	0.195
<b>DOAC</b>	374 (52.4)	7 (50.0)	24 (47.1)	429 (73.8)	6 (35.3)	12 (54.5)	0.256

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<b>Female (%)</b>	316 (43.5)	8 (57.1)	26 (51.0)	287 (49.4)	9 (52.9)	11 (50.0)	0.2875
<b>CAD (%)</b>	558 (76.8)	12 (85.7)	43 (84.3)	186 (32.0)	9 (52.9)	13 (59.1)	<0.05
<b>PAD (%)</b>	181 (24.9)	3 (21.4)	15 (29.4)	22 (3.8)	3 (17.6)	3 (13.6)	<0.05
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<b>DOAC</b>	374 (52.4)	7 (50.0)	24 (47.1)	429 (73.8)	6 (35.3)	12 (54.5)	0.256

	Asians (n=581)	Non-Asians (n=831)
<b>PAD (%)</b>	22 (3.8)	205 (24.7)
<b>P2Y12 Inhibitor Use (%)</b>	464 (79.9)	689 (82.9)

## Table 2: Bleeding Outcomes

	White	Black	Hispanic	Asian	Other	Unknown	p-value
<b>N</b>	727	14	51	581	17	22	
<b>Minor bleeding (%)</b>	19 (2.6)	0 (0.0)	0 (0.0)	72 (12.4)	0 (0.0)	2 (9.1)	<0.05
<b>Major bleeding (%)</b>	10 (1.4)	1 (7.1)	2 (3.9)	105 (18.1)	0 (0.0)	0 (0.0)	<0.05
<b>More than major bleeding (%)</b>	30 (4.1)	2 (14.3)	2 (3.9)	142 (24.4)	0 (0.0)	1 (4.5)	<0.05
<b>Life threatening bleed (%)</b>	10 (1.4)	1 (7.1)	0 (0.0)	36 (6.2)	0 (0.0)	0 (0.0)	<0.05
<b>In-Hospital Death (%)</b>	14 (1.9)	0 (0.0)	1 (2.0)	7 (1.2)	0 (0.0)	0 (0.0)	0.769
<b>Death (%)</b>	120 (16.5)	3 (21.4)	5 (9.8)	58 (10.0)	2 (11.8)	4 (18.2)	<0.05
<b>In-Hospital MI (%)</b>	4 (0.55)	0 (0.0)	1 (2.0)	8 (1.4)	0 (0.0)	0 (0.0)	0.4247
<b>In-Hospital Stroke (%)</b>	16 (2.2)	0 (0.0)	0 (0.0)	16 (2.8)	0 (0.0)	1 (4.5)	0.723

## Table 2: Asian patients experience a higher burden of bleeding events

	White	Black	Hispanic	Asian	Other	Unknown	p-value
<b>N</b>	727	14	51	581	17	22	
<b>Minor bleeding (%)</b>	19 (2.6)	0 (0.0)	0 (0.0)	<b>72 (12.4)</b>	0 (0.0)	2 (9.1)	<0.05
<b>Major bleeding (%)</b>	10 (1.4)	1 (7.1)	2 (3.9)	<b>105 (18.1)</b>	0 (0.0)	0 (0.0)	<0.05
<b>More than major bleeding (%)</b>	30 (4.1)	2 (14.3)	2 (3.9)	<b>142 (24.4)</b>	0 (0.0)	1 (4.5)	<0.05
<b>Life threatening bleed (%)</b>	10 (1.4)	1 (7.1)	0 (0.0)	36 (6.2)	0 (0.0)	0 (0.0)	<0.05
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<b>Death (%)</b>	120 (16.5)	3 (21.4)	5 (9.8)	58 (10.0)	2 (11.8)	4 (18.2)	<0.05
<b>In-Hospital MI (%)</b>	4 (0.55)	0 (0.0)	1 (2.0)	8 (1.4)	0 (0.0)	0 (0.0)	0.4247
<b>In-Hospital Stroke (%)</b>	16 (2.2)	0 (0.0)	0 (0.0)	16 (2.8)	0 (0.0)	1 (4.5)	0.723

# Table 3: Multivariable-Adjusted Odds Ratios for Any Bleeding Events (Composite of Grades I-IV Bleeding Events)

	Odds Ratio (95% CI)	p-value
<b>NYHA Functional Class (vs Class I)</b>		
Class II	0.862 (0.098-7.568)	0.8935
Class III	1.273 (0.145-11.197)	0.8237
Class IV	0.915 (0.051-16.404)	0.9534
<b>Age</b>	1.004 (0.969-1.041)	0.8071
<b>Gender (Male vs Female)</b>	0.740 (0.388-1.409)	0.3586
<b>Race (Asian vs non-Asian)</b>	5.767 (1.184-28.082)	0.0299*
<b>PAD (Yes vs No)</b>	1.421 (0.658-3.070)	0.3776
<b>Aspirin Use (Yes vs No)</b>	0.829 (0.262-2.623)	0.7501
<b>P2Y12 Inhibitor Use (Yes vs No)</b>	0.875 (0.373-2.055)	0.7590
<b>Coumadin Use (Yes vs No)</b>	0.783 (0.269-2.278)	0.6524
<b>DOAC Use (Yes vs No)</b>	0.784 (0.233-2.637)	0.6524

**Table 3: Asian race is an independent predictor of increased bleeding events, compared to non-Asian race**

	Odds Ratio (95% CI)	p-value
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Class II	0.862 (0.098-7.568)	0.8935
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## Table 4: Multivariable-Adjusted Odds Ratios for Grade II (Major) Bleeding Events

	Model 1		Model 2	
	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
<b>Age</b>	1.000 (0.937-1.067)	0.9931	0.996 (0.933-1.062)	0.9030
<b>Gender (Male vs Female)</b>	1.091 (0.342-3.476)	0.8833	1.075 (0.334-3.457)	0.9040
<b>PAD (Yes vs No)</b>	3.381 (1.085-10.541)	0.0357*	3.375 (1.061-10.730)	0.0393*
<b>Aspirin Use (Yes vs No)</b>	0.574 (0.103-3.216)	0.5280	0.546 (0.010-3.137)	0.4975
<b>P2Y12 Inhibitor Use (Yes vs No)</b>	3.168 (0.583-17.208)	0.1817	3.710 (0.672-20.491)	0.1326
<b>Coumadin Use (Yes vs No)</b>	4.831 (0.846-27.594)	0.0765	5.025 (0.875-28.844)	0.0702
<b>DOAC Use (Yes vs No)</b>	1.314 (0.102-16.950)	0.8341	1.410 (0.107-17.965)	0.7913

## Table 4: Multivariable-Adjusted Odds Ratios for Grade II (Major) Bleeding Events

	Model 1		Model 2	
	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
<b>Age</b>	1.000 (0.937-1.067)	0.9931	0.996 (0.933-1.062)	0.9030
<b>Gender (Male vs Female)</b>	1.091 (0.342-3.476)	0.8833	1.075 (0.334-3.457)	0.9040
<b>PAD (Yes vs No)</b>	<b>3.381 (1.085-10.541)</b>	<b>0.0357*</b>	<b>3.375 (1.061-10.730)</b>	<b>0.0393*</b>
<b>Aspirin Use (Yes vs No)</b>	0.574 (0.103-3.216)	0.5280	0.546 (0.010-3.137)	0.4975
<b>P2Y12 Inhibitor Use (Yes vs No)</b>	3.168 (0.583-17.208)	0.1817	3.710 (0.672-20.491)	0.1326
<b>Coumadin Use (Yes vs No)</b>	4.831 (0.846-27.594)	0.0765	5.025 (0.875-28.844)	0.0702
<b>DOAC Use (Yes vs No)</b>	1.314 (0.102-16.950)	0.8341	1.410 (0.107-17.965)	0.7913

## Table 4: PAD remains an independent predictor of bleeding events, even after adjustment for race

	Model 1		Model 2	
	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
Age	1.000 (0.937-1.067)	0.9931	0.996 (0.933-1.062)	0.9030
Gender (Male vs Female)	1.091 (0.342-3.476)	0.8833	1.075 (0.334-3.457)	0.9040
Race (Asian vs non-Asian)			<b>8.848 (0.761-102.86)</b>	<b>0.0815</b>
PAD (Yes vs No)	<b>3.381 (1.085-10.541)</b>	<b>0.0357*</b>	<b>3.375 (1.061-10.730)</b>	<b>0.0393*</b>
Aspirin Use (Yes vs No)	0.574 (0.103-3.216)	0.5280	0.546 (0.010-3.137)	0.4975
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# Outline

- Background
  - Race-Stratified Differences in TAVR
  - Cardiovascular Health of Asian American Patients
- Methodology
- Results
- Conclusions + Discussion

# Limitations

- Observational nature of the registry limits causal inference.
  - Current analysis is performed on slightly under-powered dataset: Required sample size to achieve 80% power at  $\alpha = 0.05$  was 1,648 for total population (these analyses were performed on n=1412 patients)
  - Ongoing work: expand international centers represented in TP-TAVR database (TORCH Registry, China). Internal validation with Stanford cohort.
- PAD diagnosis was based on chart documentation and may be subject to underreporting, especially in East Asian centers.
- Some models had wide confidence intervals due to low event counts in subgroups.
- Bleeding adjudication may have varied between international centers.

# Conclusions

- **Asian race is strongly and independently associated with increased bleeding risk.**
- **P2Y12 inhibitor use is extensive among Asians.** Its use may contribute to elevated bleeding risk, as supported by interaction analysis.
- **PAD is associated with increased risk of major (Grade II) bleeding.**
- Racial and clinical factors interact to influence bleeding risk following TAVR.
- Caution about “one-size-fits-all” approach to antiplatelet therapy preceding and following TAVR.
- Potential underdiagnosis or misclassification of PAD in Asian individuals – differences in diagnostic practices, access to vascular imaging, or true biologic variation.

# Thank you for your attention!

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