

## Providence St. Joseph Health

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# Differential Impact of Bleeding Avoidance Strategies on Risk-Adjusted PCI-Related Bleeding Rates Within a Large Multistate Health System

Tyler J. Gluckman, *Providence St. Joseph Health*

Kateri Spinelli, *Providence St. Joseph Health*

Lian Wang, *Providence St. Joseph Health*

John Petersen, *Providence St. Joseph Health*

Paul P. Huang, *Providence St. Joseph Health*, et al.



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## Background

- Percutaneous coronary intervention (PCI)-related bleeding is associated with increased morbidity, mortality, and cost<sup>1</sup>
- Trans-radial access (RAD), bivalirudin (BIV), and vascular closure devices (VCD) represent strategies to reduce PCI-related bleeding
- The relative impact of these bleeding avoidance strategies (BAS) across bleeding risk strata has not been previously reported

## Objective

- Using real-world data from a large multistate health system, we sought to evaluate the impact of BAS either individually or in combination among patients undergoing PCI with varying levels of bleeding risk

## Methods

- Retrospective cohort analysis of 74,953 PCIs within a multistate healthcare system from 2009Q3-2017Q4
- Exclusion criteria included non-index PCI, patients who died the same day or were missing data related to bleeding, patients who underwent CABG surgery during the same episode of care, and patients with undetermined BAS due to missing data
- Bleeding risk was assessed per the NCDR CathPCI bleeding model<sup>2</sup>; procedures were stratified into six bleeding risk groups to achieve balanced risk between BAS in each group: 1<sup>st</sup> quartile, 2<sup>nd</sup> quartile, 3<sup>rd</sup> quartile, 75th-90<sup>th</sup> percentile, 90th-97.5<sup>th</sup> percentile, and top 2.5<sup>th</sup> percentile
- Within each risk stratum, multivariable regression modeling was used to assess the impact of BAS on bleeding with the logit of predicted risk as a factor and Bonferroni adjustment to control for multiple comparisons

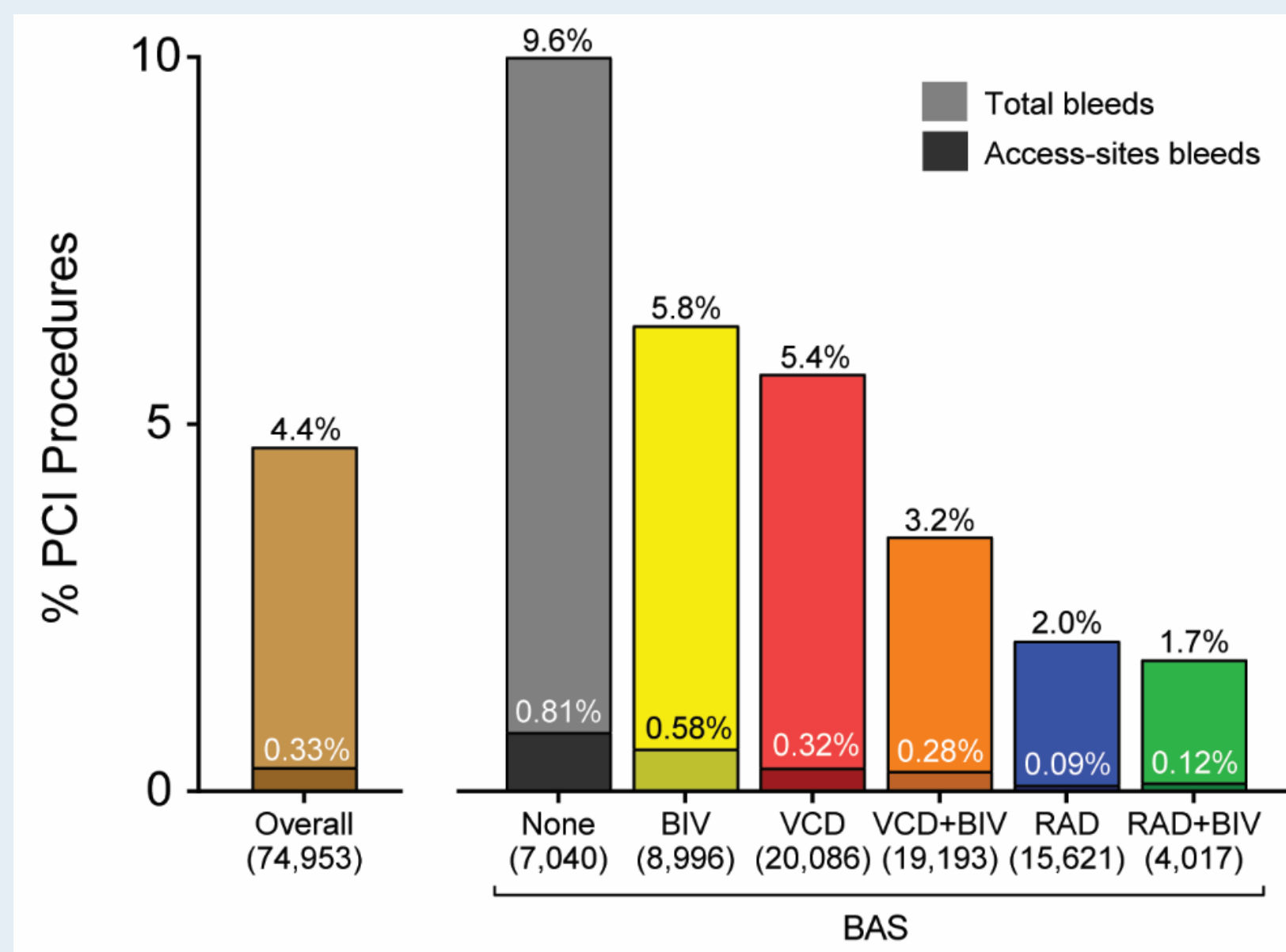
**Table 1: Demographics**

Variable	Overall	No BAS	BIV	VCD	BIV+VCD	RAD	RAD+BIV
# (%) of procedures	74,953	7,040 (9.4%)	8,996 (12.0%)	20,086 (26.8%)	19,193 (25.6%)	15,621 (20.8%)	4,017 (5.4%)
Age, yrs	66 (58, 74)	67 (58, 76)	67 (59, 75)	66 (58, 75)	65 (57, 74)	65 (57, 73)	65 (57, 72)
Female	27.6	31.2	30.1	26.3	27.9	25.9	27.9
BMI, kg/m <sup>2</sup>	28.9	28.7	28.8	28.7	28.7	29.4	29.8
DM	34.5	36	34.4	35.7	33.4	33.4	35.5
PVD	11	17.2	13.7	10.9	9	9.7	9.6
Prior PCI	38.2	38.7	41.8	38.5	38.9	35.1	37.5
Prior CABG	15.8	21.4	21.4	19.3	17.1	6.1	8
Prior MI	31	32.9	32.5	33.1	30.1	28.2	28.4
Renal failure	2.5	4.2	2.6	3.5	2.3	1.2	0.6
Pre-PCI Hb, g/dl	13.9	13.7	13.8	13.9	13.8	14	13.9
Elective	36.6	30.1	41	33.9	38.2	36.7	42.8
Urgent	40.4	36.6	34.7	39.9	40.6	45.1	43.9
Emergent	22.5	31.7	23.2	25.8	20.8	18	13
ACS	78.8	85	80.1	79.8	76.6	76.9	77.2
STEMI	20.5	28.3	19.8	24.1	19.2	16.3	12.6
Shock	3.2	8.7	4.5	3.5	2.1	1.5	1.1
MCS	2.3	7.1	3.9	2.5	1.0	1.0	0.7
GP 2b/3a inhibitor	15.5	32.7	6.9	24.9	7.5	12.1	9
CathPCI mortality risk score, %	0.3 (0.1, 1)	0.6 (0.2, 1.7)	0.3 (0.1, 1.0)	0.4 (0.2, 1.1)	0.3 (0.1, 0.8)	0.3 (0.1, 0.7)	0.2 (0.1, 0.6)
CathPCI bleeding risk score, %	4.2 (2.7, 8.7)	5.7 (3.1, 11.5)	4.2 (2.3, 8.7)	4.9 (2.7, 10)	4.2 (2.3, 7.5)	3.6 (2.3, 7.5)	3.6 (2.3, 6.5)

Values are median (interquartile range) or %  
 BMI = body mass index, PCI = percutaneous coronary intervention, CABG = coronary artery bypass graft, MI = myocardial infarction, Hb = hemoglobin, ACS = acute coronary syndrome, STEMI = ST-segment elevation myocardial infarction, MCS = mechanical circulatory support

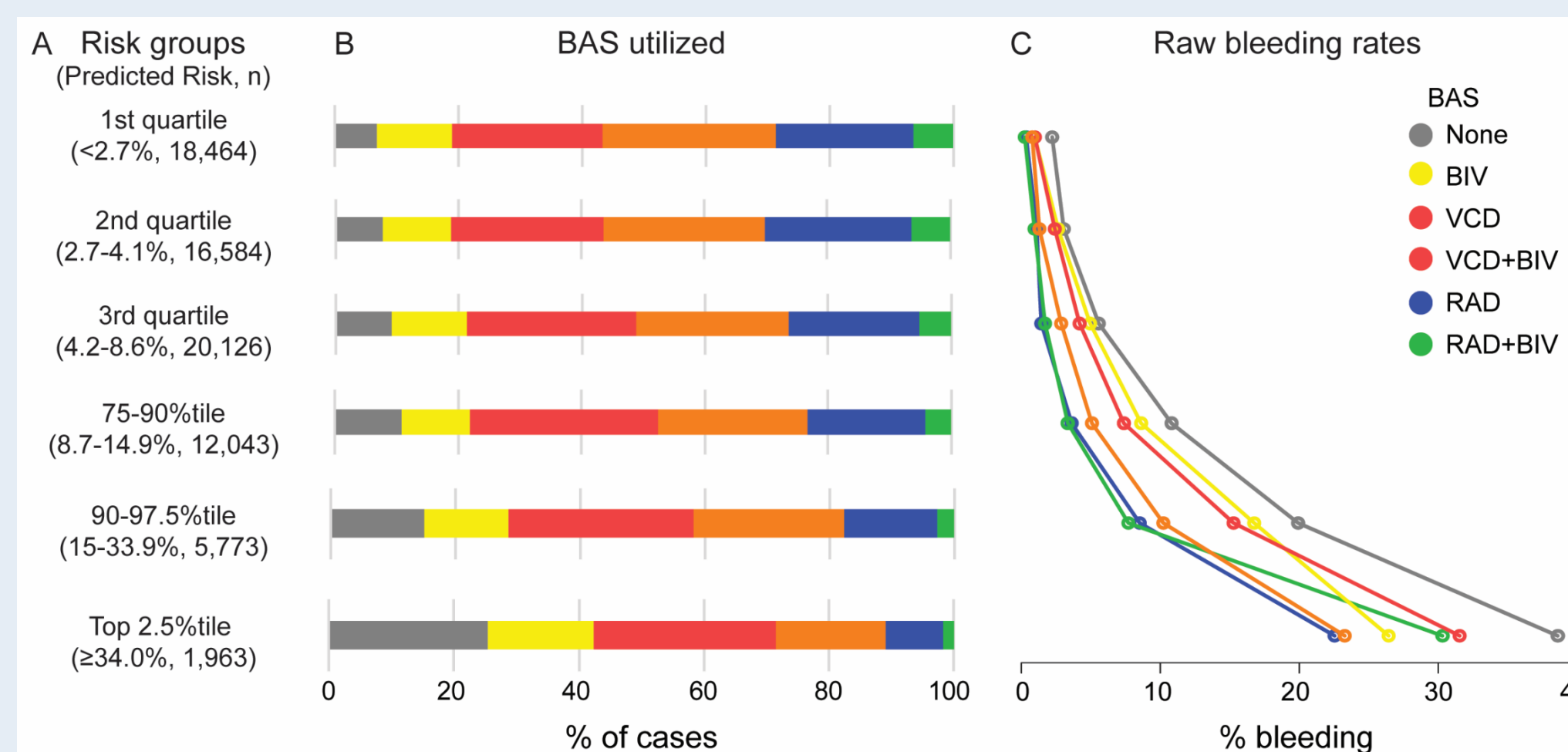
## Results

- Raw PCI-related bleeding rates were 4.4% overall and 9.6%, 5.8%, 5.4%, 3.2%, 2.0%, and 1.7% in patients receiving no BAS, BIV, VCD, VCD + BIV, RAD, and RAD + BIV, respectively (Figure 1)
- Non-access site bleeds accounted for 93% of PCI-related bleeding events overall



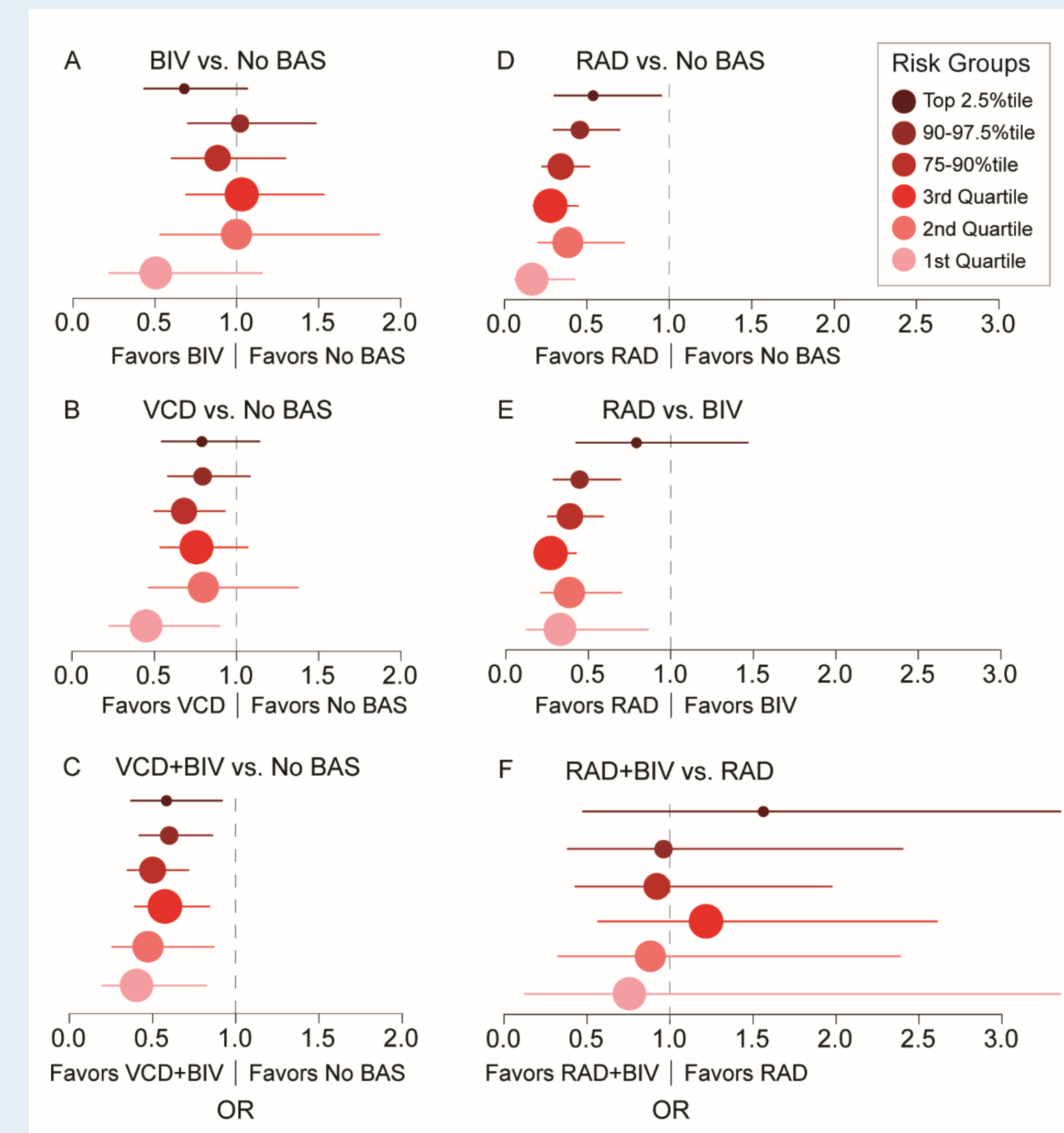
**Figure 1 – Raw bleeding rates.** Absolute rates of PCI-related bleeding (numbers above the bars) and absolute rates of access site bleeding (numbers in white within the bars) for listed BAS. Group sample sizes are in parentheses after the group labels. BAS = bleeding avoidance strategies, BIV = bivalirudin, VCD = vascular closure device, RAD = trans-radial access

- The six risk groups had predicted bleeding rates of <2.7%, 2.7-4.1%, 4.2-8.6%, 8.7-14.9%, 15.0-33.9% and ≥34.0% (Figure 2)
- A risk-treatment paradox was observed, with greatest underuse of BAS among those at greatest bleeding risk
- In addition, use of RAD, VCD + BIV and RAD + BIV progressively decreased as bleeding risk increased



**Figure 2 – Predicted risk stratification.** (A) Predicted bleeding risk groups, stratified by the NCDR CathPCI bleeding risk model (B) use of BAS across strata of predicted bleeding risk (C) raw rates of bleeding for BAS across strata of predicting bleeding risk. Abbreviations defined in Figure 1.

- For those treated with a single BAS, only RAD use was associated with a significantly lower risk of PCI-related bleeding across all risk strata, compared to no BAS (Figure 3)
- Compared to no BAS, VCD + BIV use was associated with a significantly lower risk of PCI-related bleeding; this benefit was not observed when a VCD or BIV was used alone
- RAD use was associated with a significantly lower risk of PCI-related bleeding compared to BIV across all bleeding risk groups except for those at the top 2.5<sup>th</sup> percentile
- Addition of BIV to RAD did not lower the risk of PCI-related bleeding across any of the bleeding risk groups, compared to RAD alone



**Figure 3 – Risk-adjusted bleeding rates.** Multivariate analysis of bleeding outcomes (adjusted for GP 2b/3a inhibitor use) comparing BIV to no BAS (A), VCD to no BAS (B), VCD + BIV to no BAS (C), RAD to no BAS (D), RAD to BIV (E) and RAD + BIV to RAD (F). The marker size is representative of the sample size for each risk group. Odds ratios and 95% confidence intervals are displayed. Abbreviations defined in Figure 1.

## Conclusions

- Further efforts should be directed at maximizing use of bleeding avoidance strategies, particularly among those at higher bleeding risk
- If only a single intervention is used, trans-radial access represents the preferred bleeding avoidance strategy to minimize PCI-related bleeding
- While the addition of bivalirudin to a vascular closure device is associated with significantly reduced bleeding, bivalirudin does not convey this same benefit when added to trans-radial PCI