

Antithrombotic Strategy Variability In **A**Trial Fibrillation
and **O**bstructive Coronary Disease **R**evascularized with PCI

THE AVIATOR-2 INTERNATIONAL REGISTRY

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on behalf of the AVIATOR-2 Investigators



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Mount
Sinai
Heart

Disclosures

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Background

- Patients with atrial fibrillation (AF) undergoing percutaneous coronary intervention (PCI) present unique challenges given the number of potential antithrombotic strategies, treatment durations and overlap in ischemic and bleeding risk.
- Existing tools to estimate risk (CHA₂DS₂VASc and HAS BLED) were developed in AF cohorts that are distinct from PCI populations.
- Therapeutic approaches and factors influencing clinical decisions in a contemporary AF/PCI cohort are not well characterized.

Study Schema

Index
PCI

- All-comer PCI
- Non-valvular AF
- Multicenter, multinational

Physician
Questionnaire

What is your subjectively perceived risk of adverse ischemic cardiac outcome for your patient?

Very low Low Intermediate High Very High

What is your subjectively perceived risk of adverse bleeding outcome for your patient?

Very low Low Intermediate High Very High

Patient
Questionnaire

With my heart condition, I am most worried about:

- a) Stent related problem b) Heart attack c) Stroke
d) Major Bleeding e) Frequent blood testing f) Death

I am convinced of the importance of my prescription medication:

Disagree Completely Disagree Mostly Not Sure Agree Mostly Agree Completely

One year f/u

MACCE
BARC 2-5

Study Aims & Objectives

- *Baseline*

- To profile antithrombotic strategies in a contemporary AF/PCI cohort
- To examine the level of agreement between subjective and empiric assessments of risk
- Identify factors influencing choice of antithrombotic therapy.

- *Longitudinal*

- Characterize adherence patterns over time and in relation to treatment strategy
- Quantify the predictive value of risk scales on discriminating composite ischemic (MACCE - all-cause death, MI, def/prob ST, stroke, CD-TLR) and bleeding events.

Statistical Considerations

- *Analytic Approach*

- Patients groups according to antithrombotic regimen at discharge
- One-year event rates estimated using the KM method
- ROC curves to assess risk discrimination. Ordinal logistic regression to model association between risk scale and antithrombotic strategy

- *Sample Size and Power*

- Power calculation required total sample of 2500 patients to detect a HR for non-triple Rx versus triple Rx of 0.73
- Study stopped enrollment due to lack of funding, resulting in a final cohort of 514 patients

Baseline Characteristics – Overall

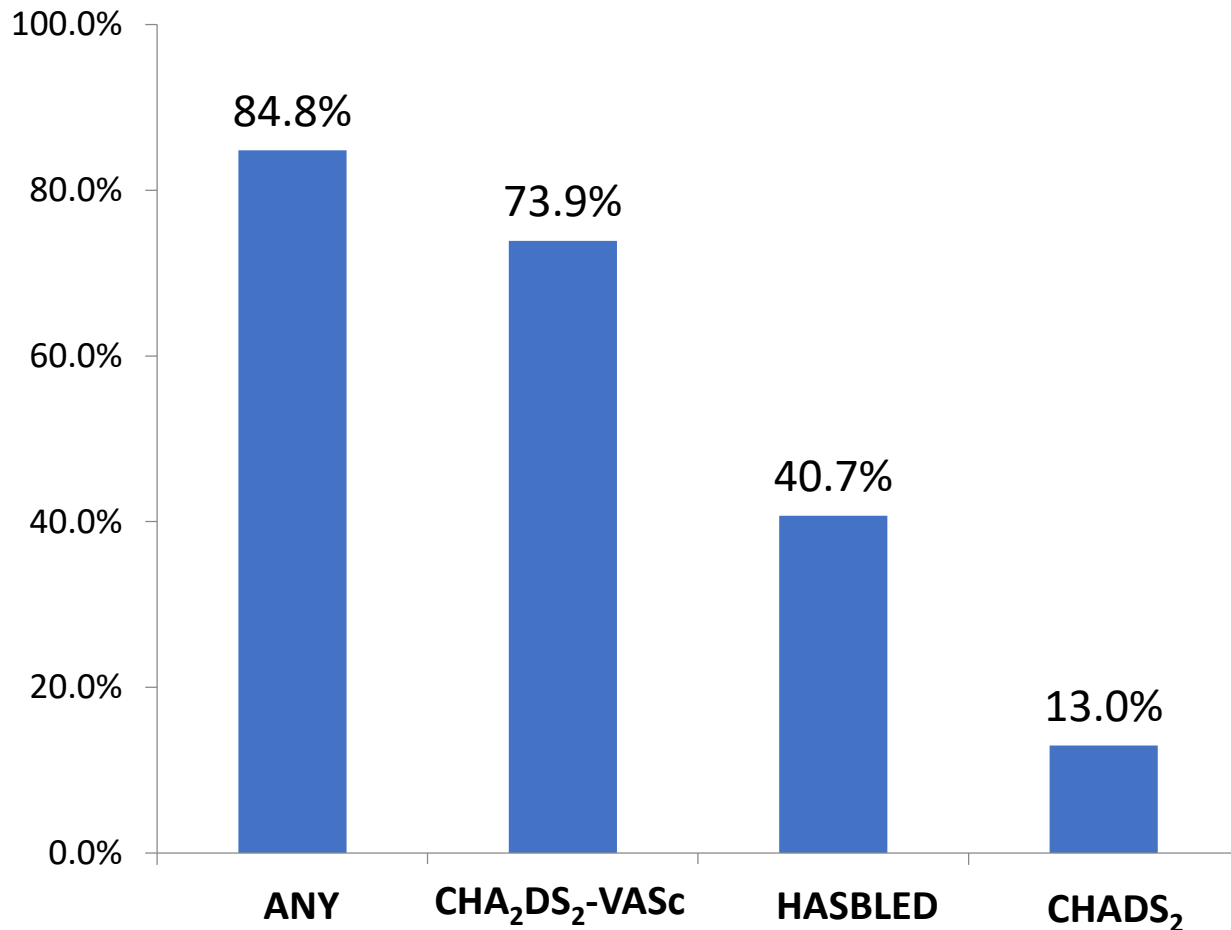
n=514

Age (years)	73.09 ± 9.01
Female Sex	132 (25.7%)
Caucasian Race	450 (87.5%)
Diabetes Mellitus	199 (38.7%)
eGFR < 60 ml/min/1.73m ²	232 (45.1%)
Previous MI	136 (26.5%)
Previous Stroke	14 (2.7%)
ACS presentation	261 (50.8%)
CHA ₂ DS ₂ -VASc	4.23 ± 1.32
HASBLED	2.99 ± 0.7

Selected Survey Responses

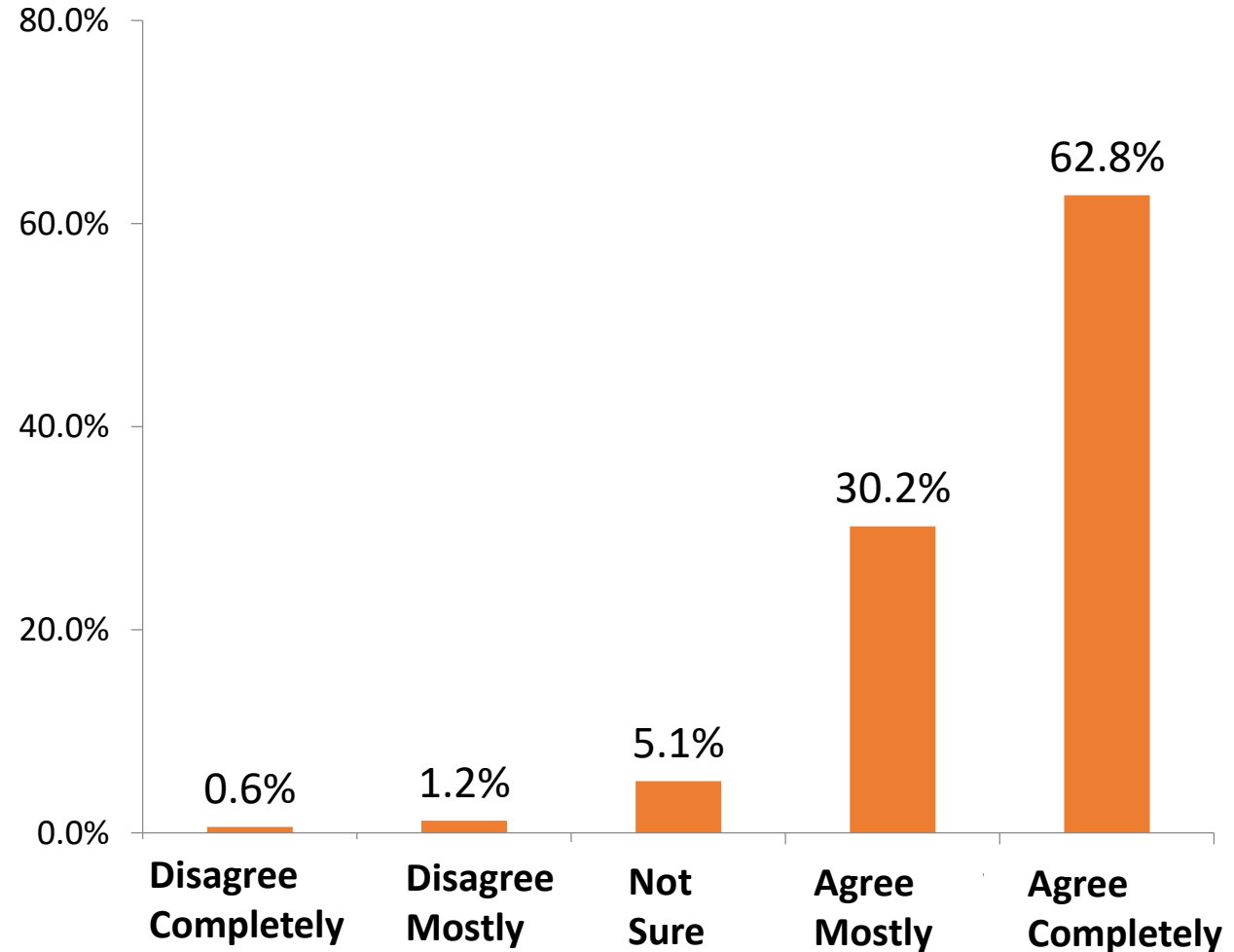
Physician Questionnaire

Which risk scores influenced your decision?



Patient Questionnaire

I am convinced about the importance of my therapy

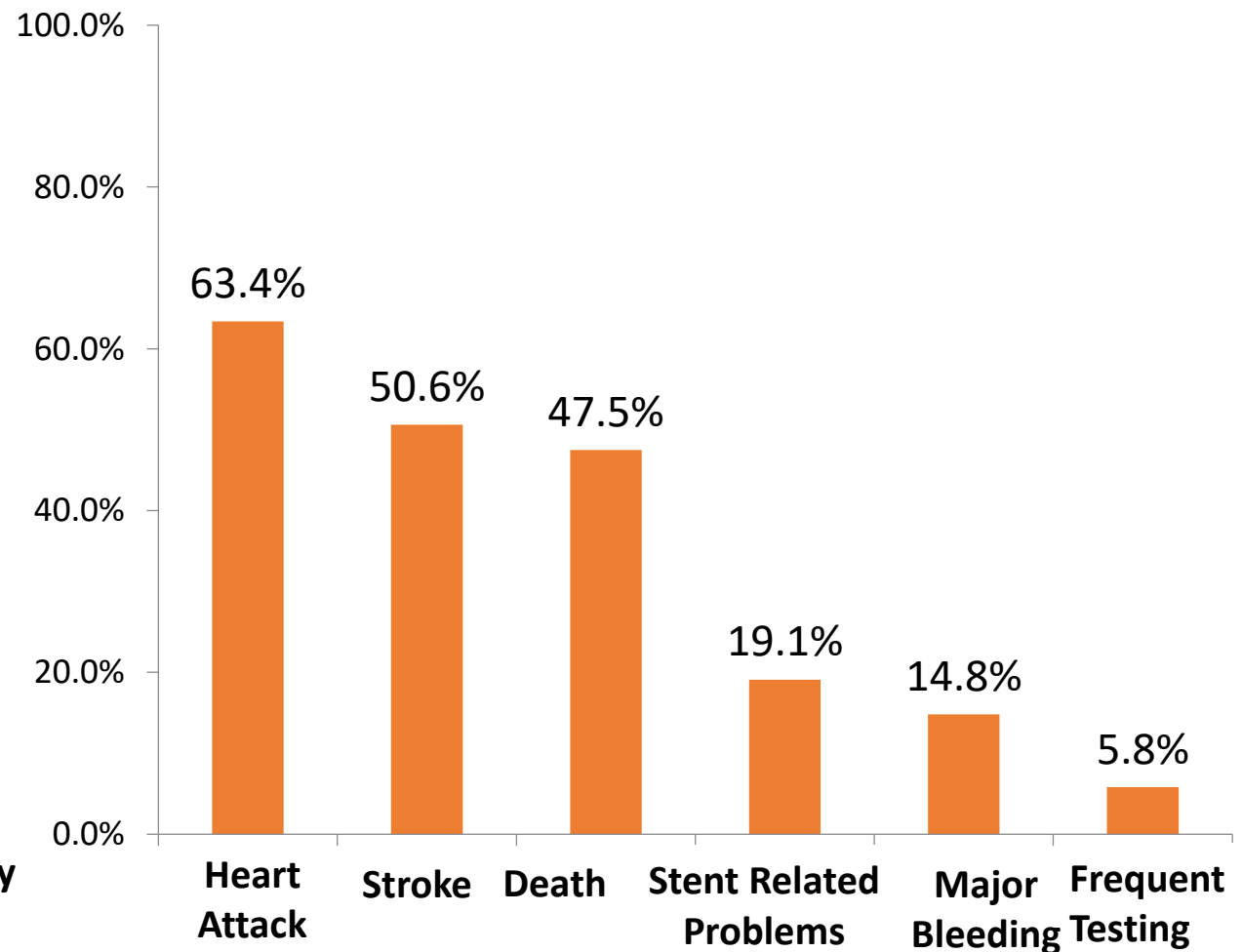
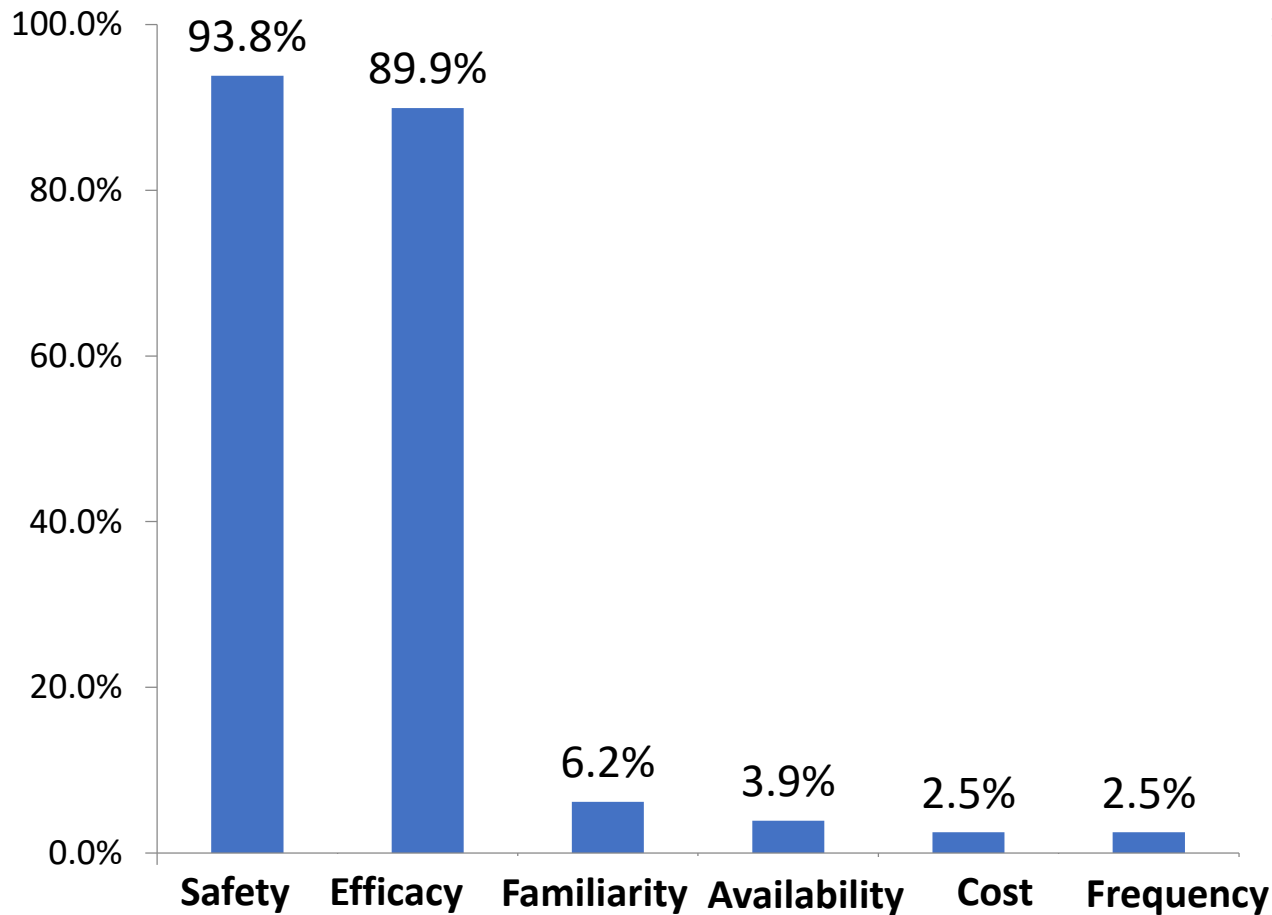


Selected Survey Responses

Physician Questionnaire

Patient Questionnaire

Which 2 factors were the most important in making your decision *With my heart condition, I am most worried about (Select 2)*



Pharmacotherapy at Discharge

ENROLLED
N – 514

508

Triple Therapy

(OAC + P2Y₁₂ + ASA) = 338 (66.5%)

Dual Therapy

(OAC + P2Y₁₂) = 65 (12.8%)

DAPT

(ASA + P2Y₁₂) = 105 (20.7%)

DOAC – 54.1%
VKA – 45.9%
CLOP – 95.6%
TICA/PRAS – 4.4%
ASA – 100%

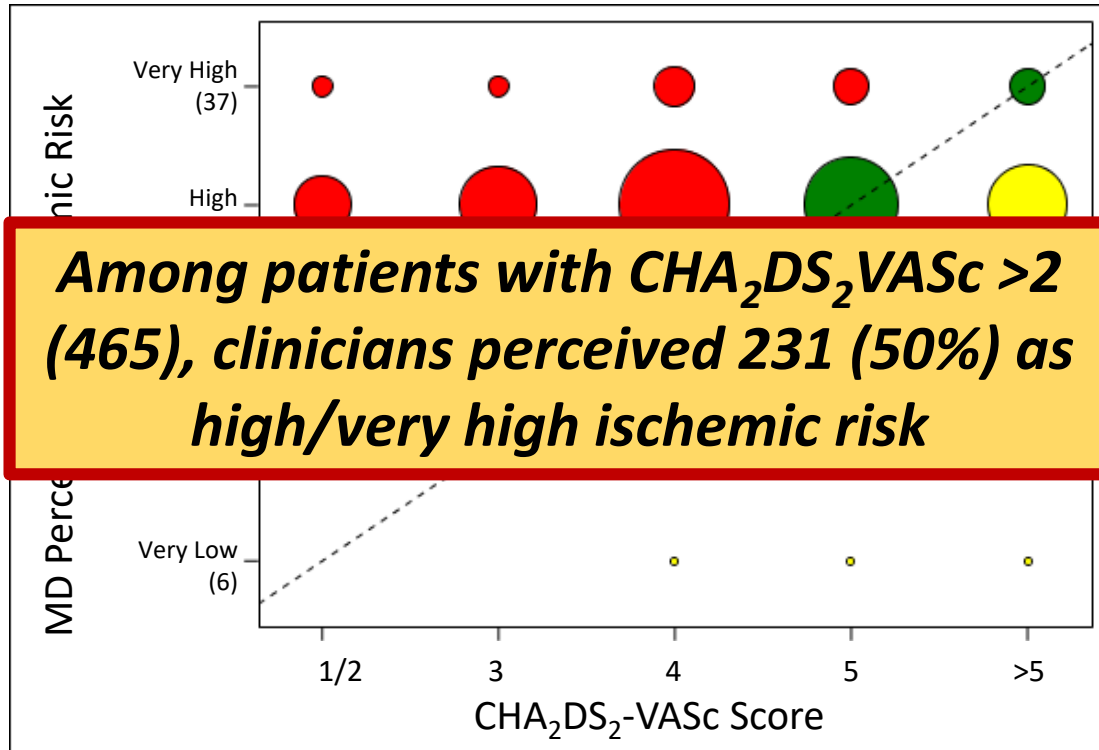
DOAC – 72.3%
VKA – 27.7%
CLOP – 92.3%
TICA/PRAS – 4.6%
ASA – 3.1%

CLOP – 85%
TICA/PRAS – 15%
ASA – 100%

* 6 patients were discharged on monotherapy with Dabigatran and are not included in this analysis.

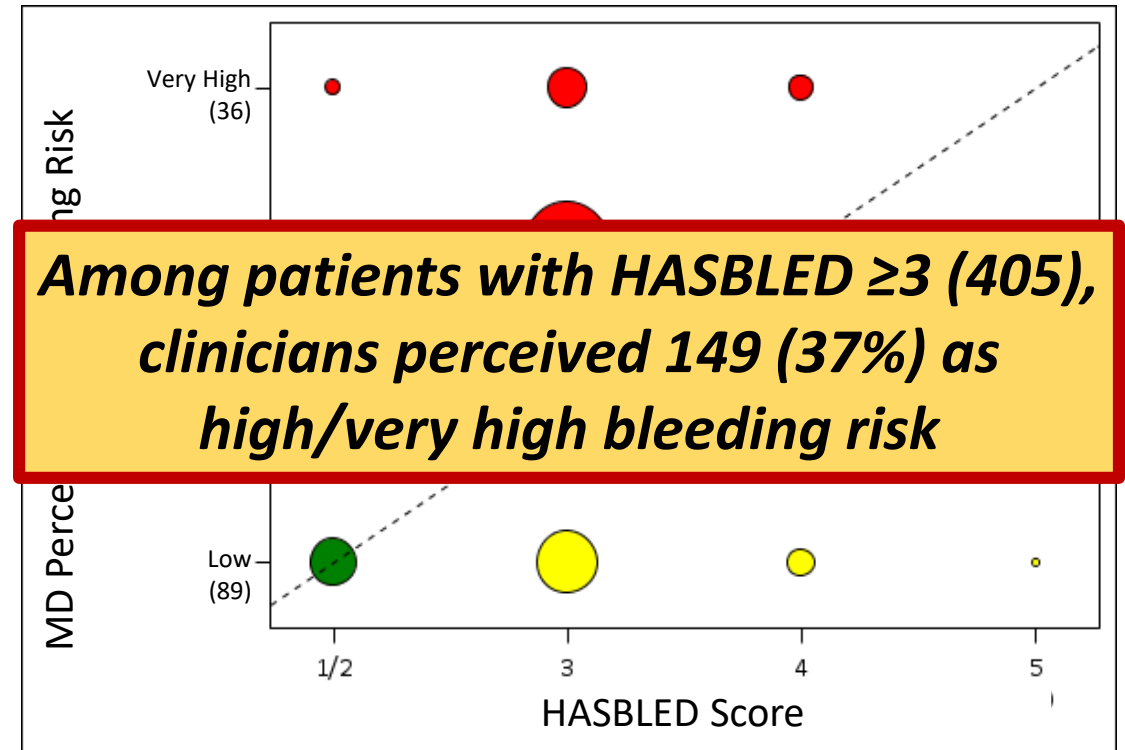
Empiric and Subjective Risk Agreement

ISCHEMIC RISK



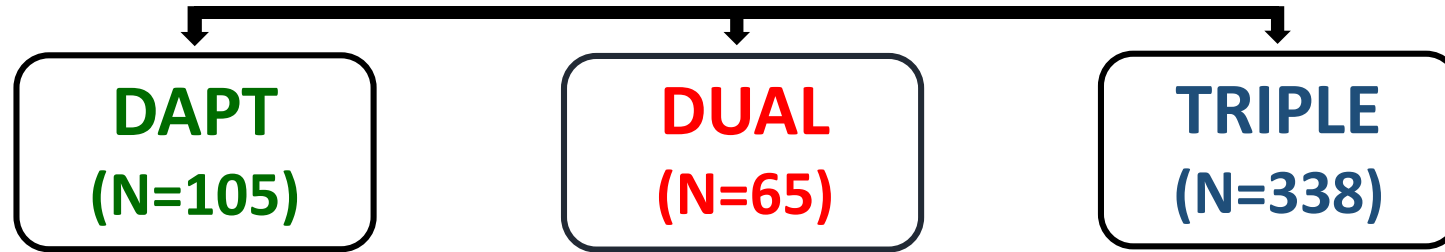
Concordance: 139 (27.0%)

BLEEDING RISK



Concordance: 197 (38.4%)

Medication Adherence Over Time



30 DAYS

98.1%

ASA = 98.1%
P2Y₁₂ = 100%

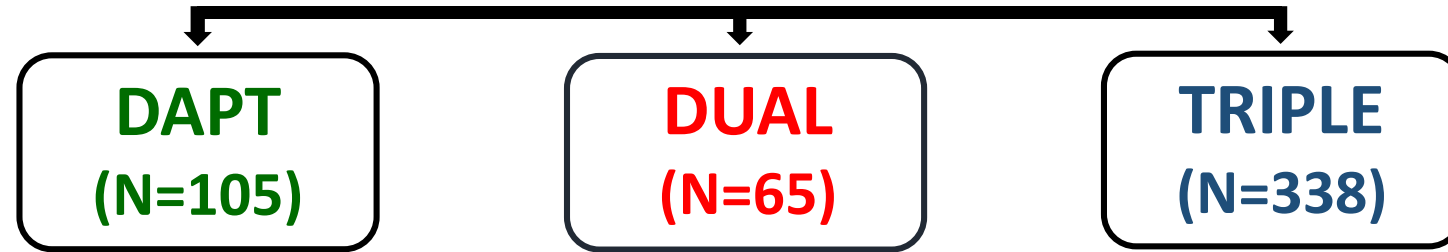
96.9%

P2Y₁₂ = 98.4%
DOAC = 98.5%
VKA = 100%

90.4%

ASA = 92.5%
P2Y₁₂ = 99.7%
DOAC = 98.8%
VKA = 99.4%

Medication Adherence Over Time



30 DAYS

98.1%

96.9%

90.4%

6 MONTHS

↓
94.1%

↓
88.8%

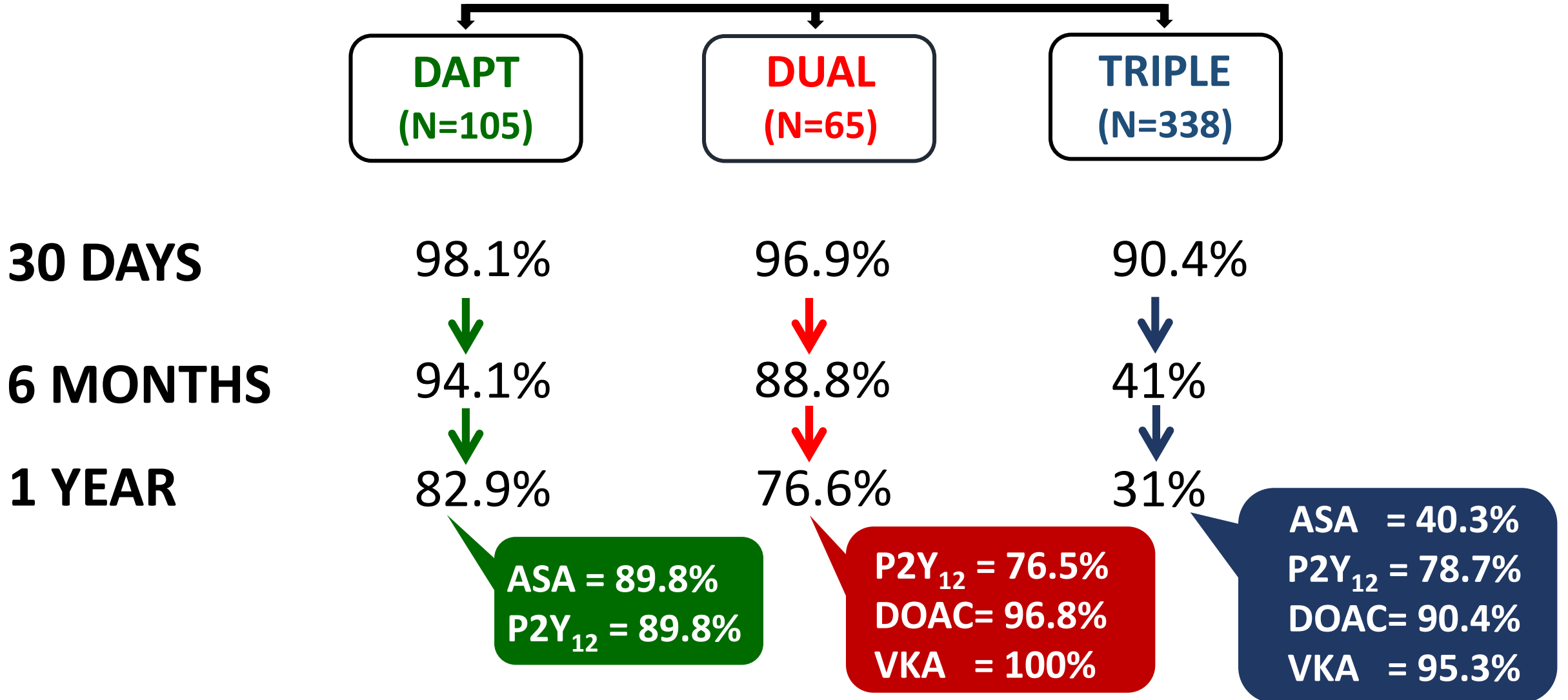
↓
41%

ASA = 96.1%
P2Y₁₂ = 98%

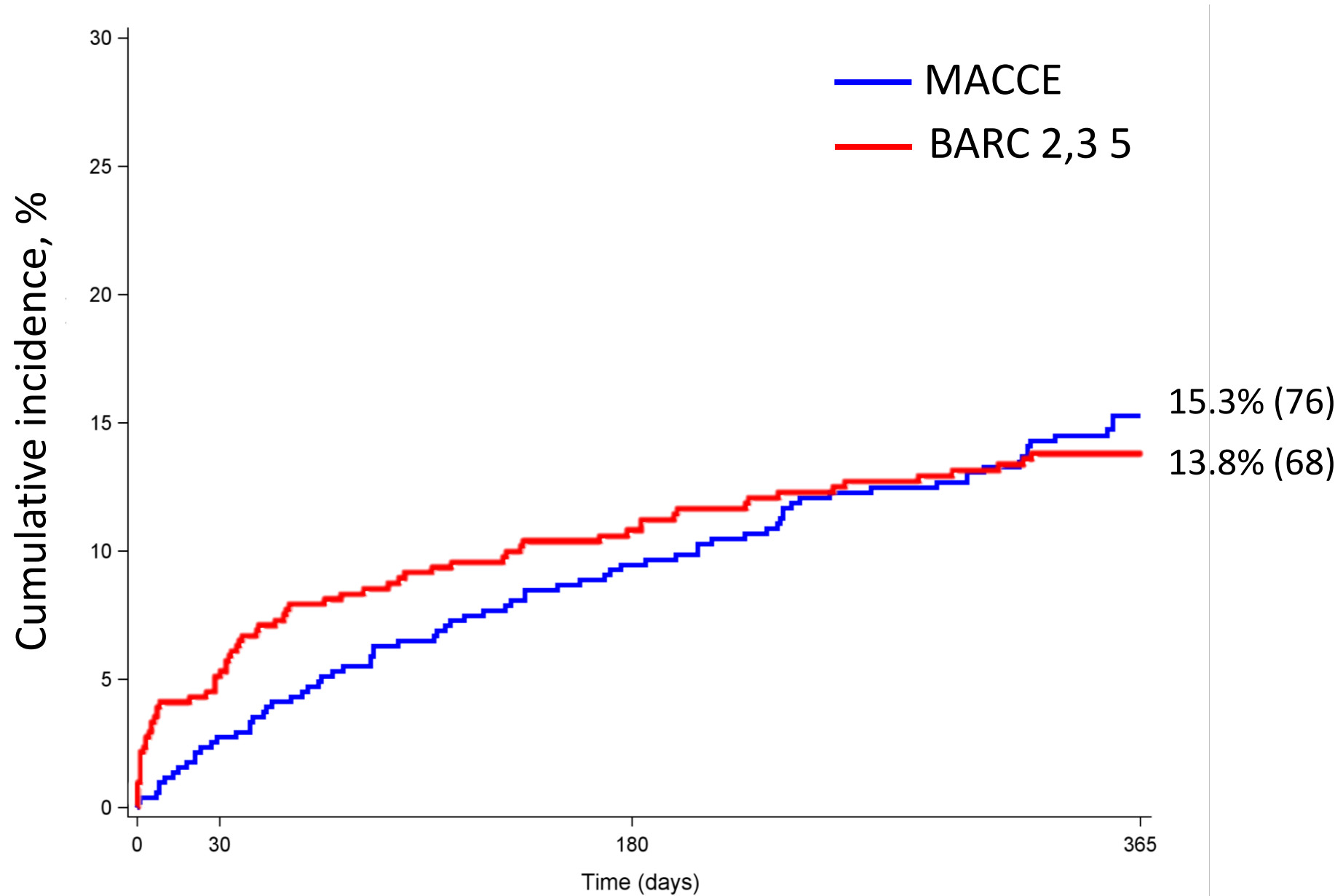
P2Y₁₂ = 90.4%
DOAC = 96.8%
VKA = 100%

ASA = 49.3%
P2Y₁₂ = 93.2%
DOAC = 95.4%
VKA = 97.3%

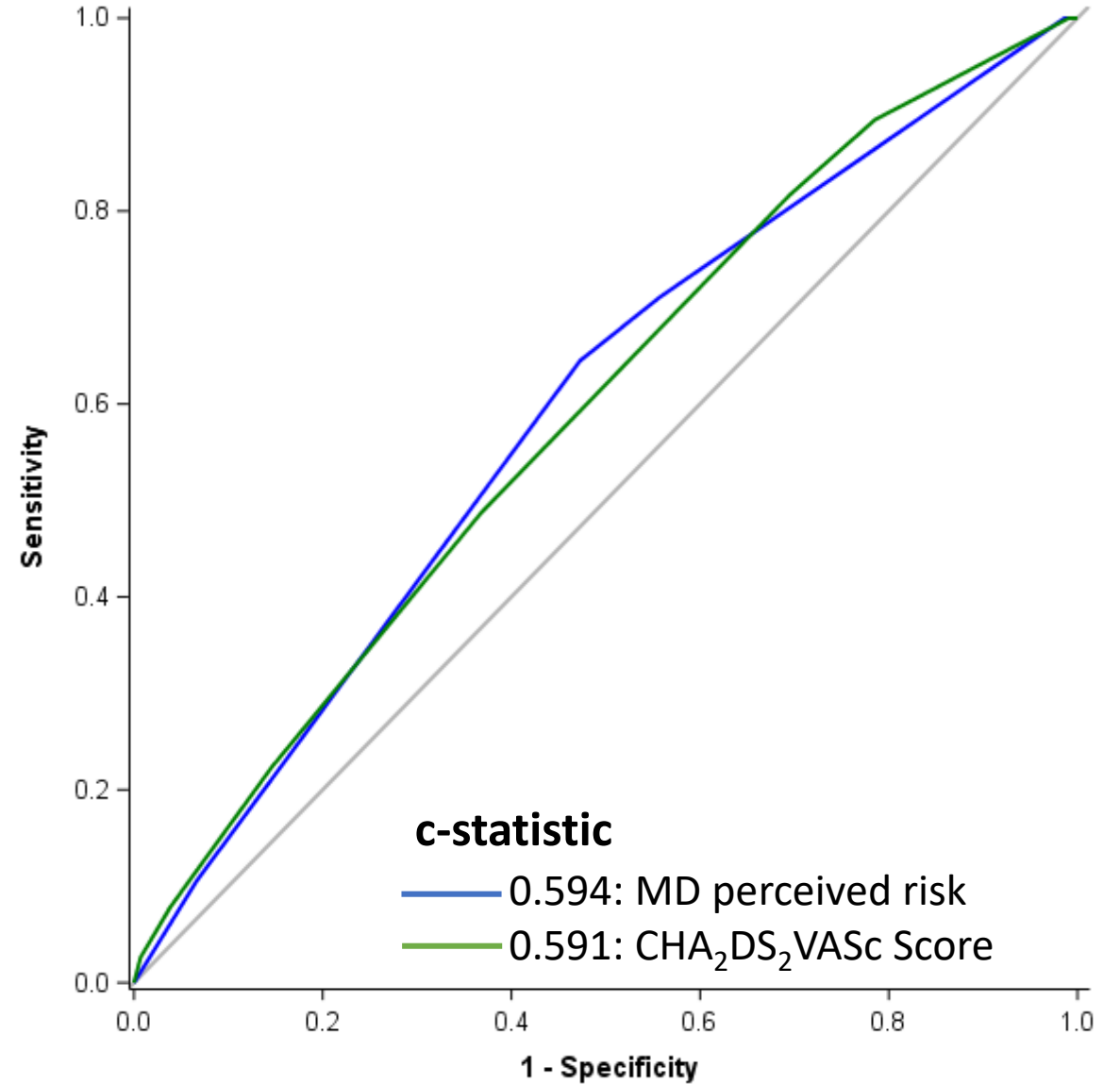
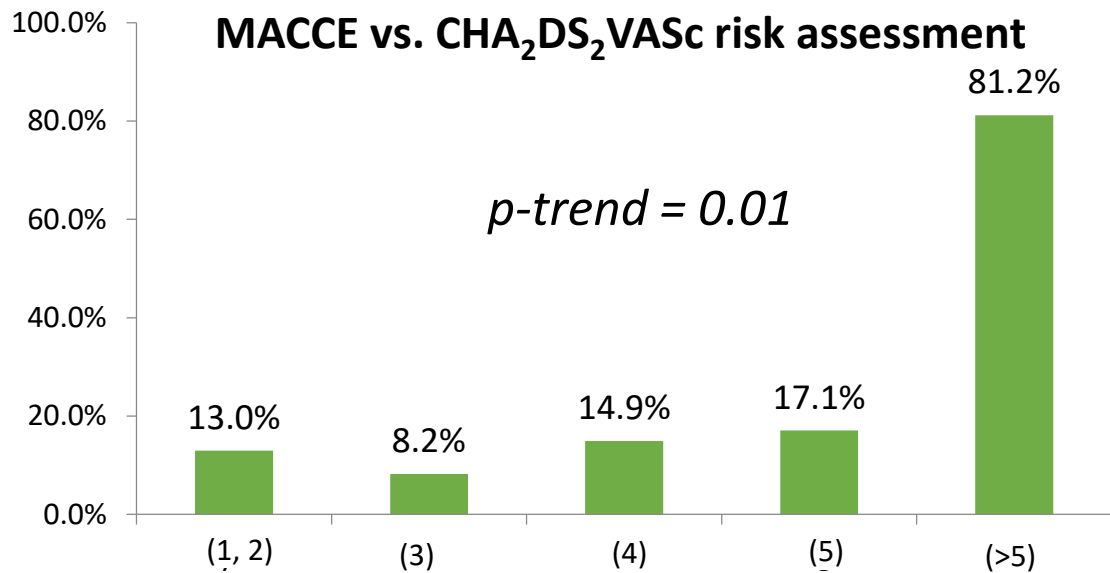
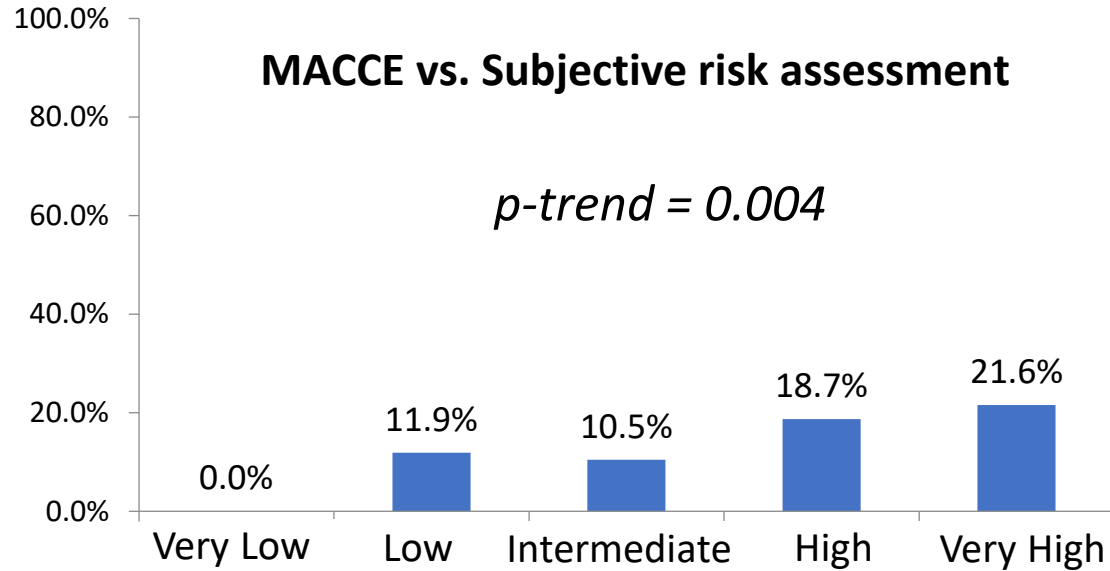
Medication Adherence Over Time



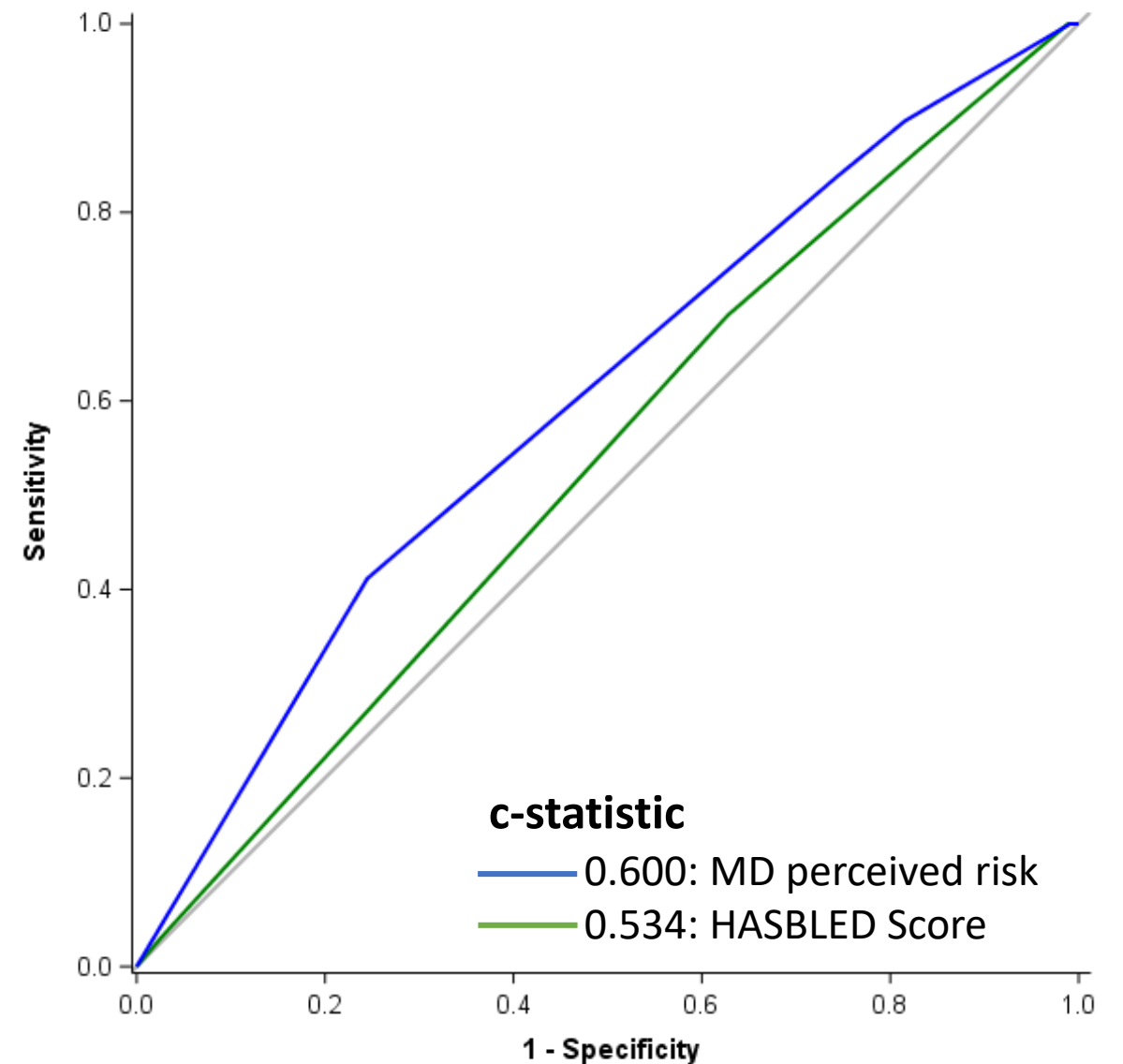
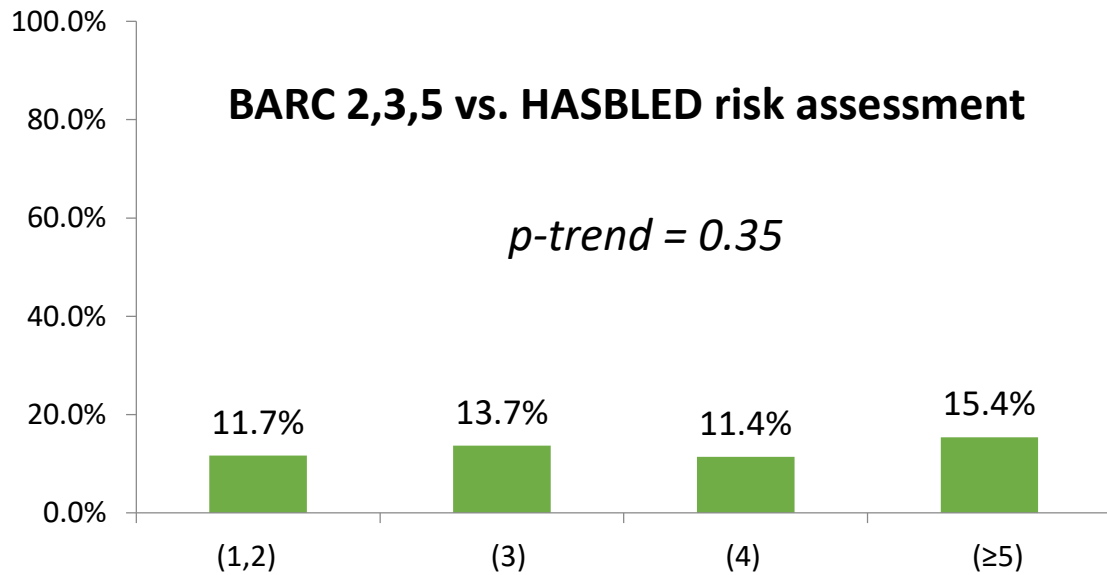
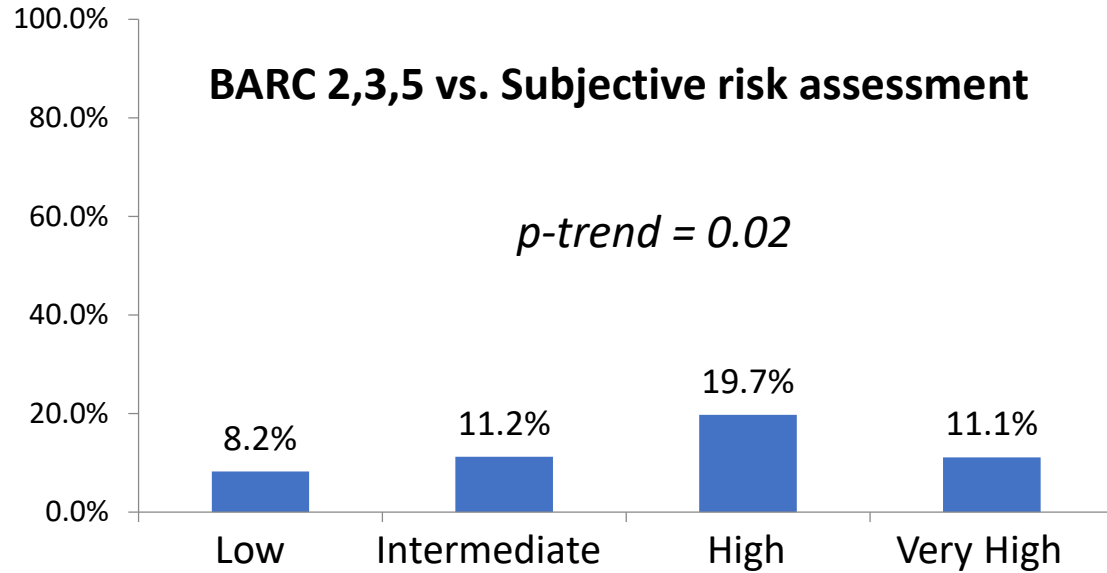
One-Year Event Rates



Ischemic Risk Prediction



Bleeding Risk Prediction



Limitations

- Registry-based cohort does not allow for causal inference
- Follow-up limited to 1-year
- Specialized centers may limit generalizability
- Insufficient power to detect differences in clinical outcomes

Conclusions

- Antithrombotic choices in AF/PCI patients are highly variable with greater adherence to OAC versus antiplatelet drugs

Novel tools to accurately quantify risk and inform clinical decisions are needed in complex patients with AF requiring PCI

- Validated tools to quantify ischemic and bleeding risk in AF cohorts perform poorly in AF/PCI patients

STUDY ORGANIZATION



Clinical Coordinating Center –	Center of Interventional Cardiovascular Research at Icahn School of Medicine
Global PI –	Dr. Roxana Mehran
Medical Lead –	Dr. Jaya Chandrasekhar and Dr. Ridhima Goel
Project Management –	Clayton Snyder and Alyssa Ramkissoon
AP design –	Dr. Ashish Atreja- Chief Innovation officer, Icahn School of Medicine
Biometrics –	Dr. Usman Baber- lead, Melissa Aquino- Biostatistics
Clinical Events Committee –	Emma Woodoff-Leith (lead)



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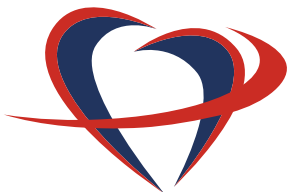
Thank you for your attention

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