

EWOLUTION - Efficacy and safety of LAAO in patients with prior ischemic and hemorrhagic stroke

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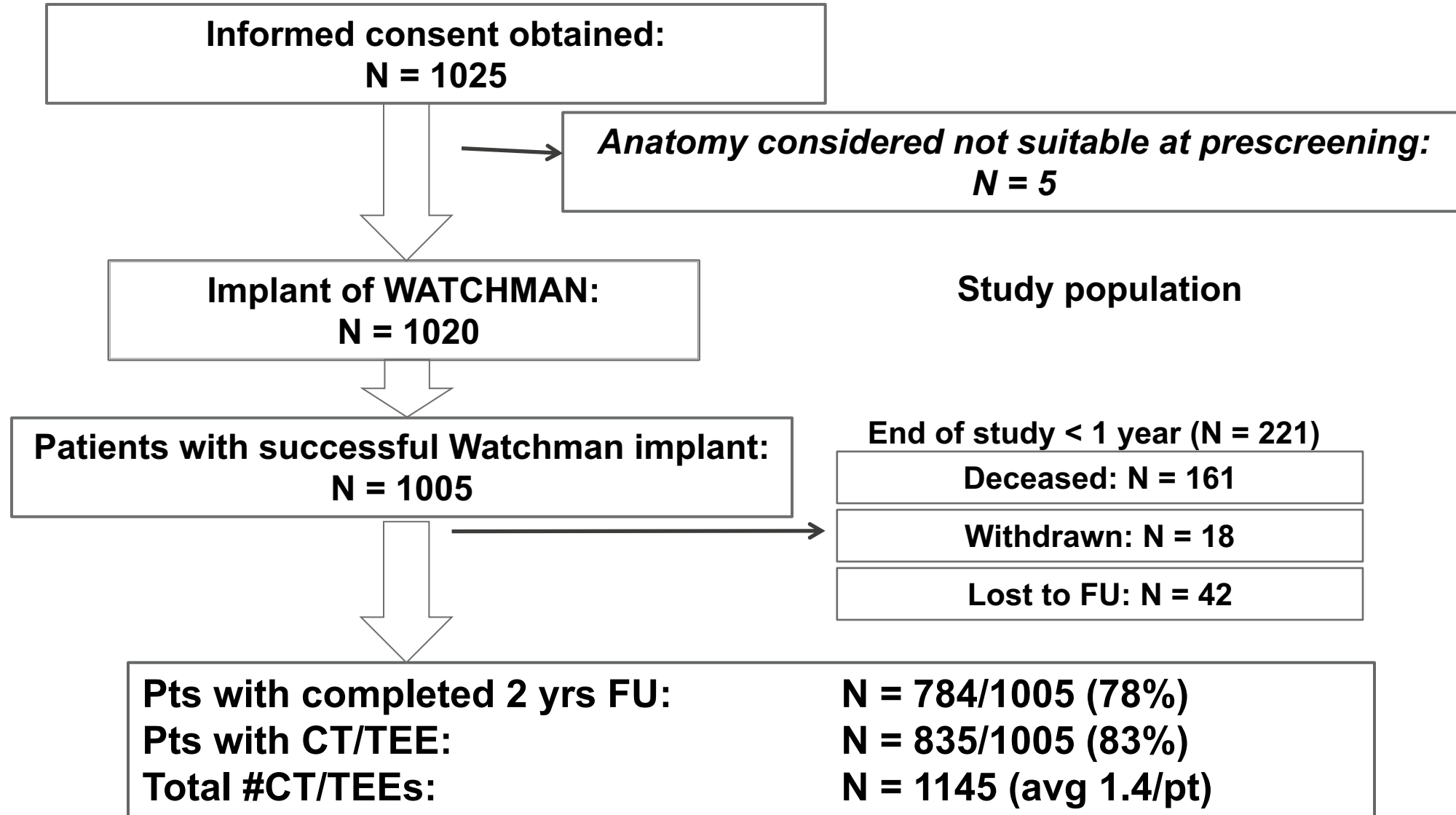
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on behalf of all the EWOLUTION investigators

Registry on WATCHMAN Outcomes in Real-Life Utilization: EWOLUTION

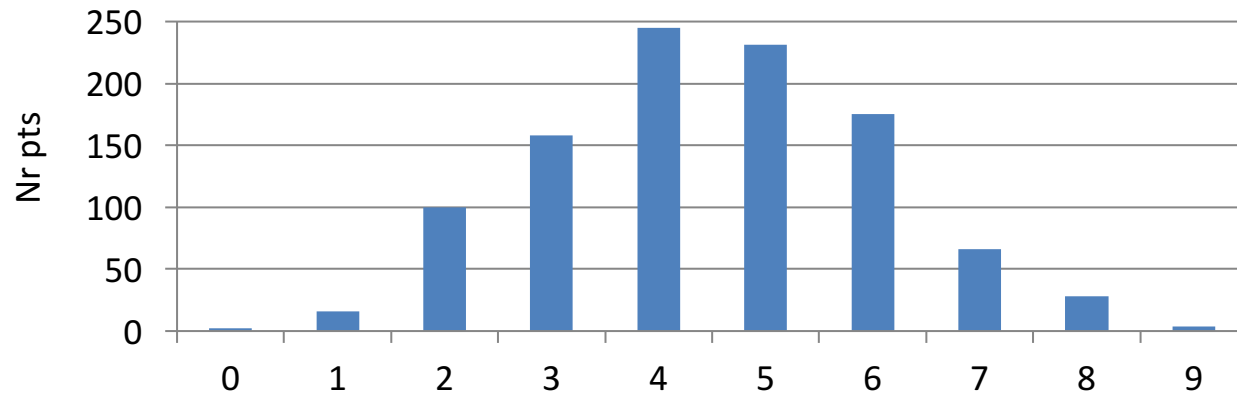
Study Objective:	Collect real-world WATCHMAN LAAO experience outside of selected populations in prior RCT
Study Design:	Prospective, single-arm, multi-center registry of the Watchman LAA Closure Technology
Primary Endpoint:	Primary analysis includes procedural success and safety, incidence of stroke, bleeding, and death after 2 yr of FU Investigator and Medical Safety Group for adjudication
Patient Population:	>1000 patients
Number of Sites:	47 throughout Europe, Russia and Middle East
Enrollment:	Started October 2013 - Completed May 2015
Follow-up:	Standard practice at participating centers <ul style="list-style-type: none">• Normally 1-3 months post-procedure• Annually thereafter for a total of 2 years

EWOLUTION – complete 2 year patient flow



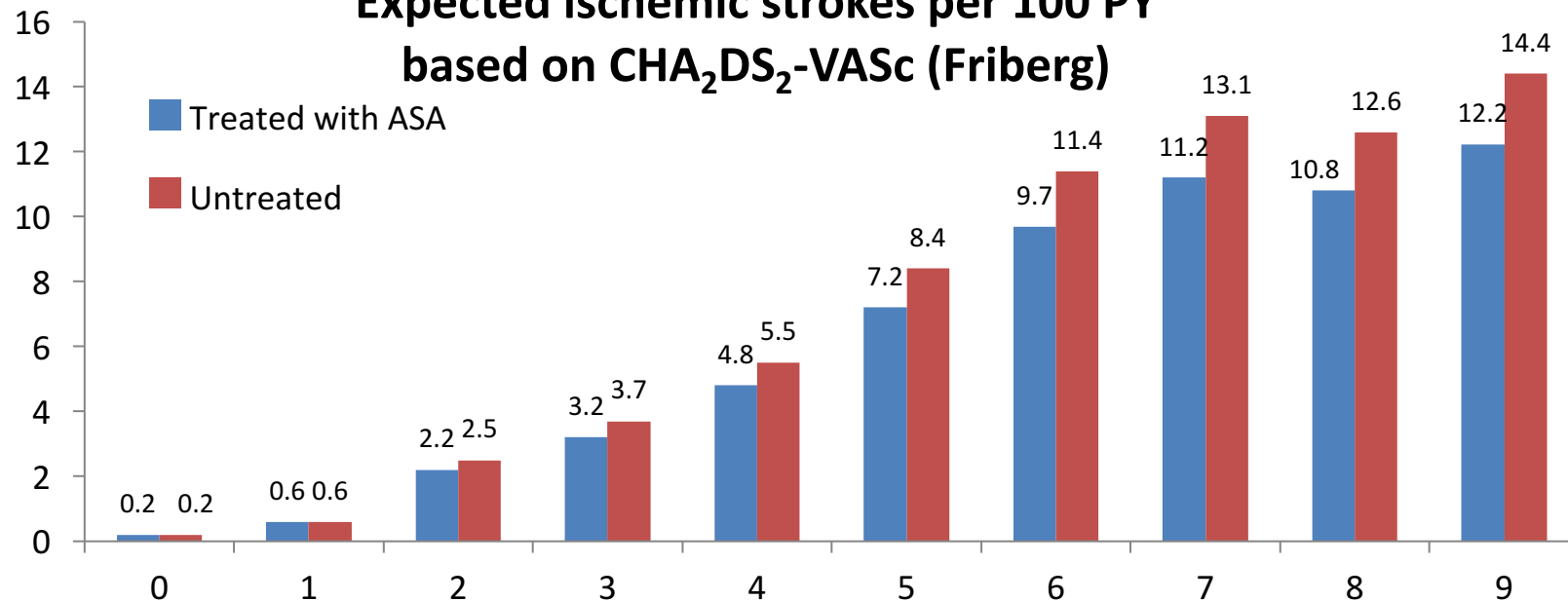
EWOLUTION – Stroke risk profile in AF patients

CHA₂DS₂-VASc distribution in EWOLUTION

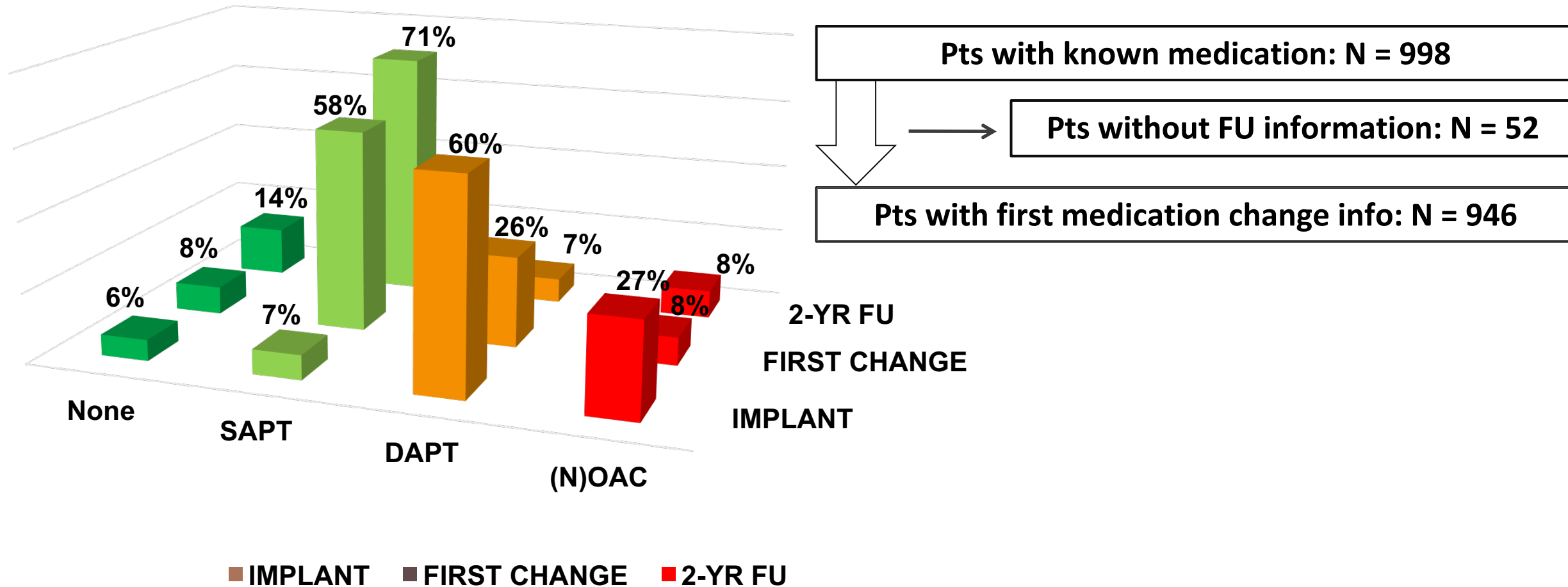


CHA ₂ DS ₂ -VASc score ≥ 5	49%
HAS-BLED ≥ 3	40%
Major Bleeding/predisposition bleeding	39%
Contra-indication (N)OAC	73%

Expected ischemic strokes per 100 PY based on CHA₂DS₂-VASc (Friberg)

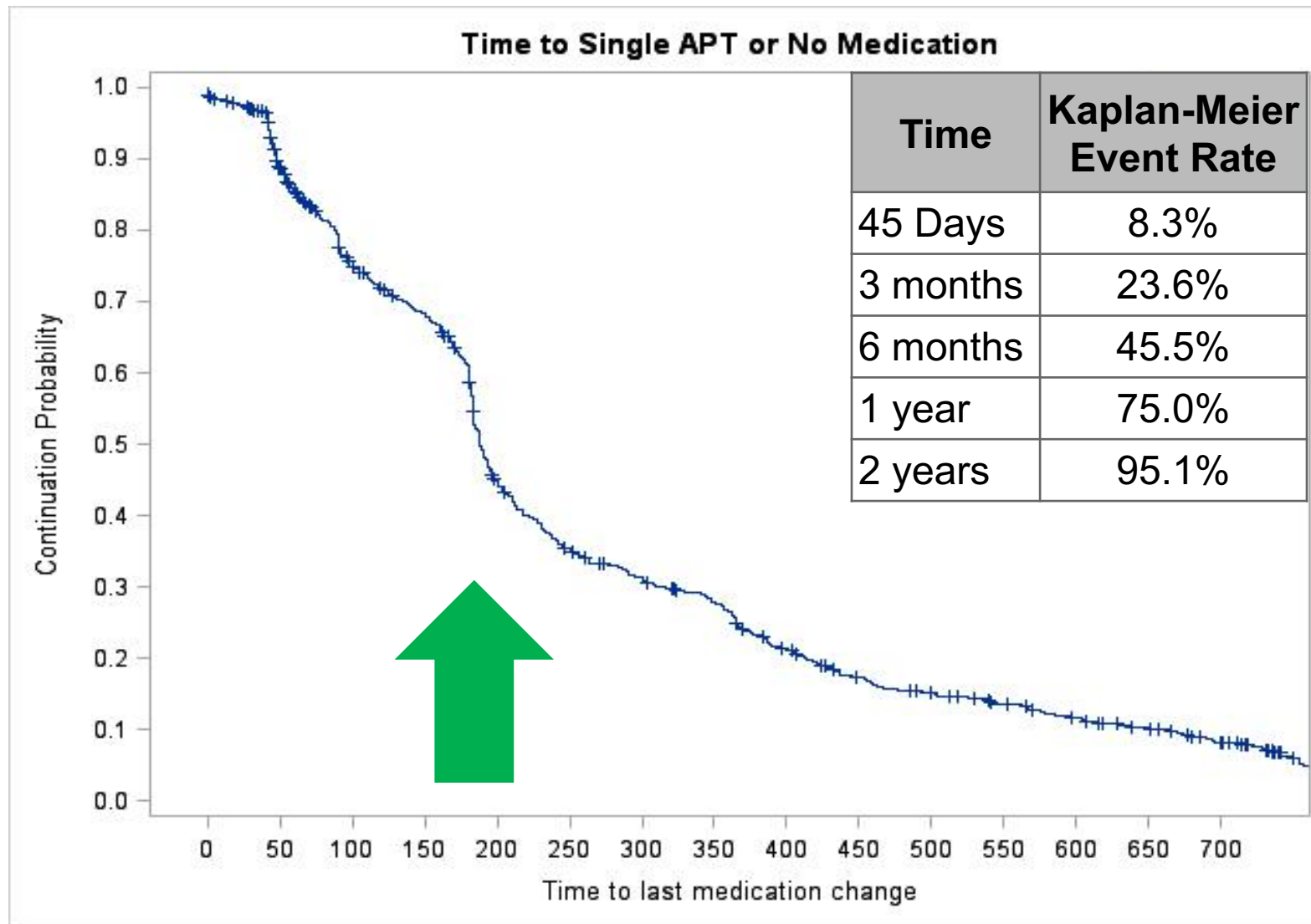


EWOLUTION – OAT at Follow-Up



After 2 years 85% of pts were on SAPT or nothing

Time to final single APT or nothing

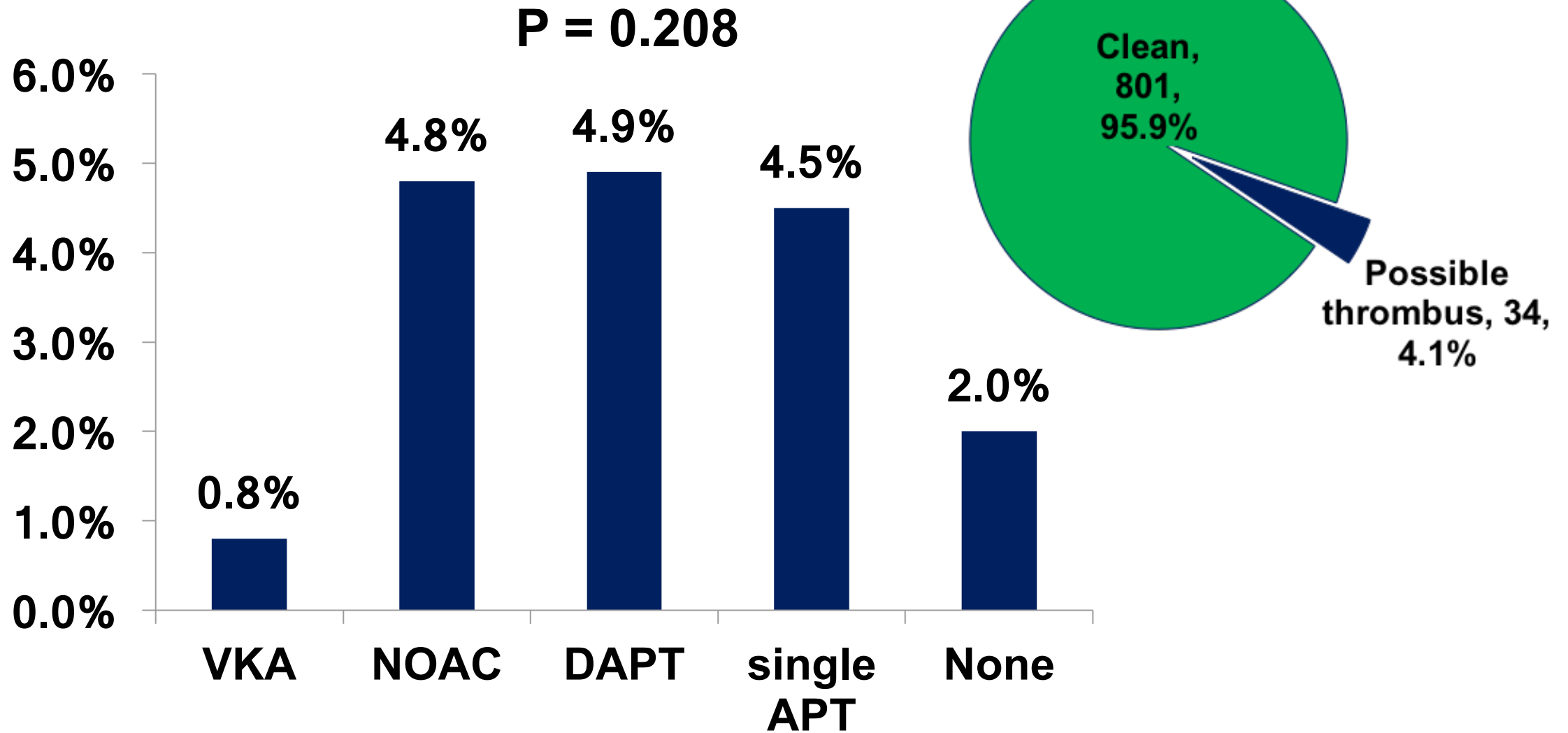


EWOLUTION – High risk subgroup characteristics

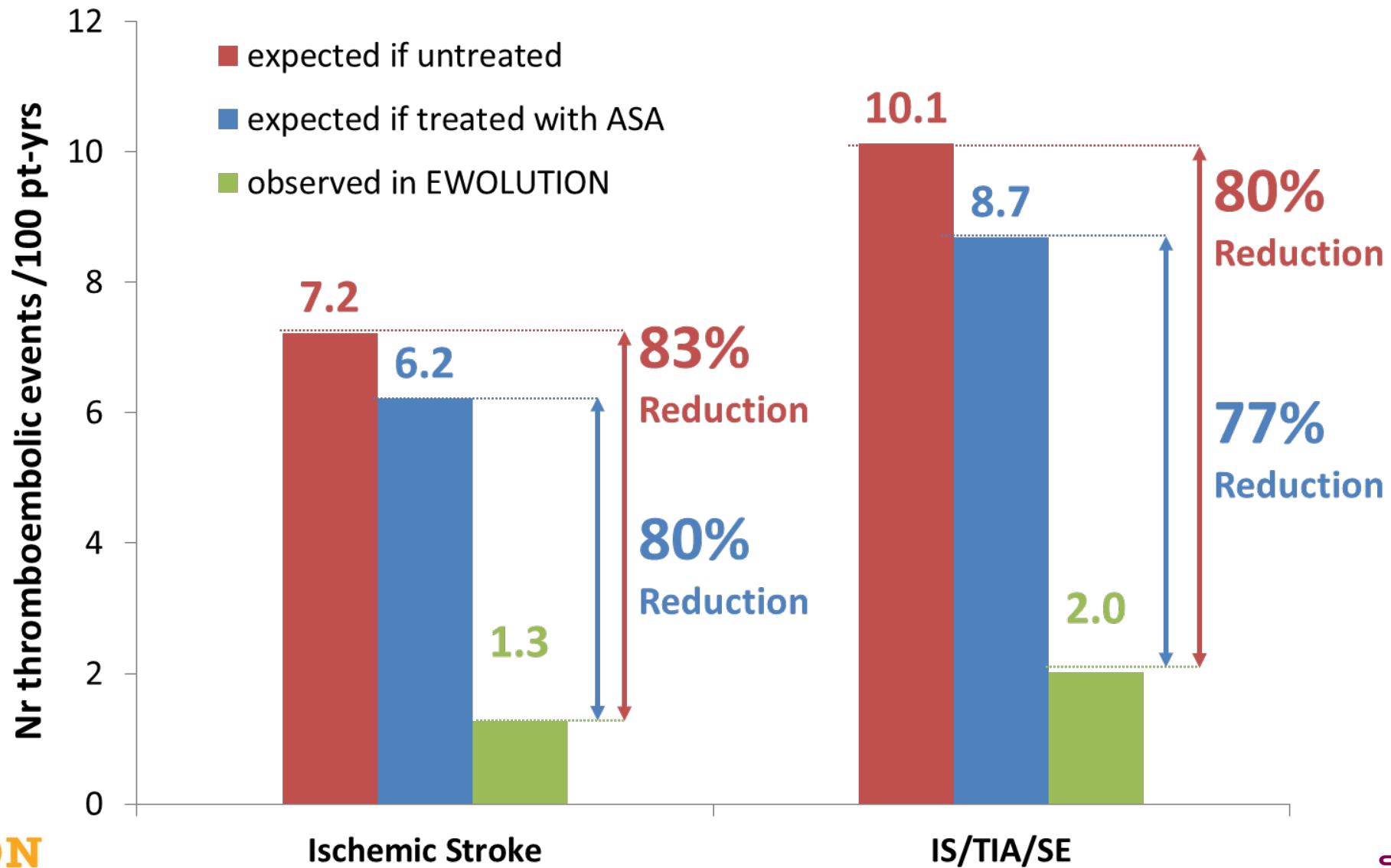
Post implant medications	N	CHA ₂ DS ₂ -VASc	HAS-BLED	(N)OAC	single/ none	DAPT
EWOLUTION all pts	1020	4.5	2.3	27%	14%	60%
Hx ischemic stroke/TIA	311	5.5	2.6	29%	15%	56%
Hx hemorrhagic stroke	153	5.4	2.8	11%*	27%	62%
Hx Major Bleed	318	4.8	3.2	15%	17%	67%

* More pts on SAPT/none p<0.001)

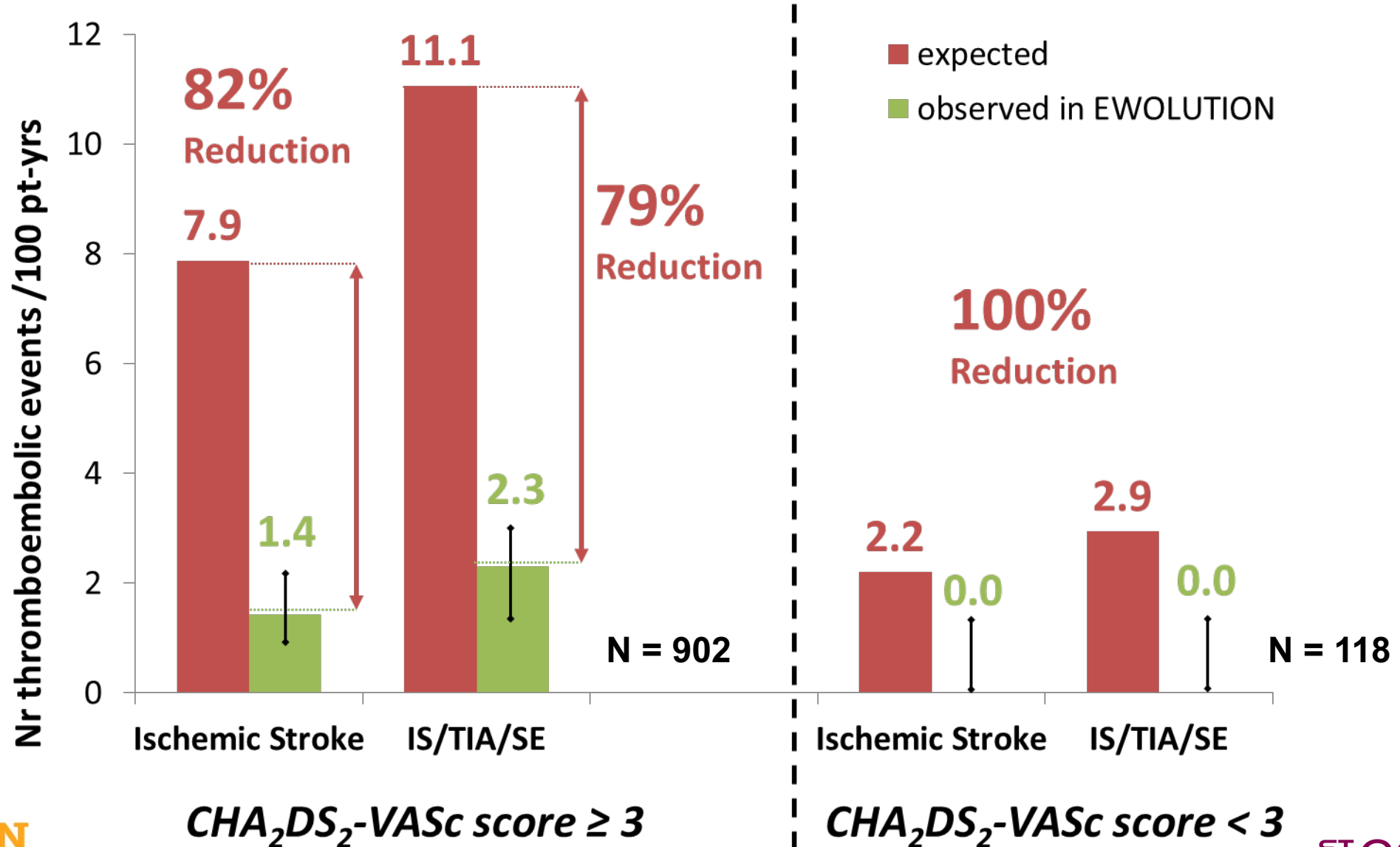
Device thrombus and medication – no relation



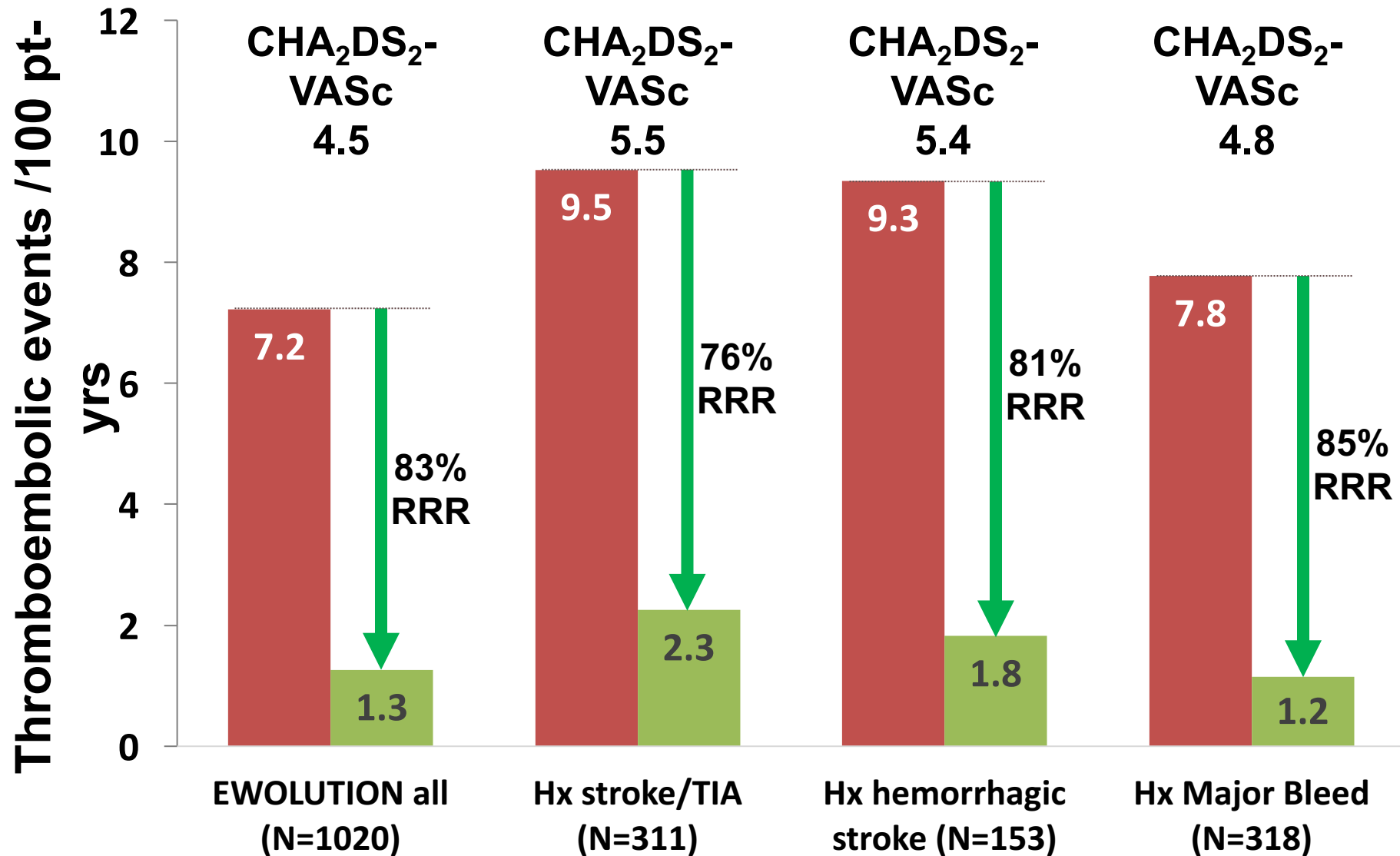
EWOLUTION – Thrombo-embolic event rates



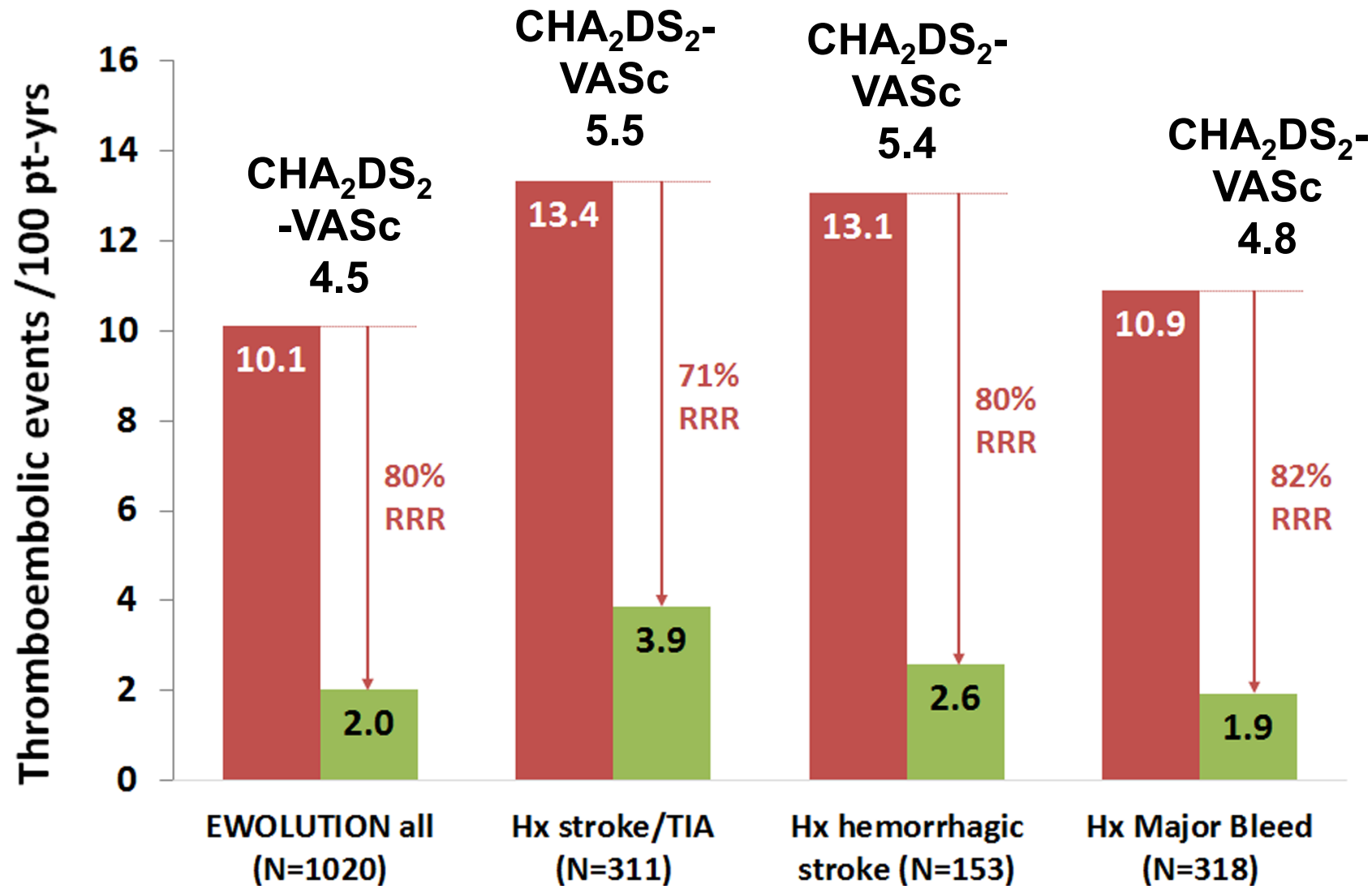
EWOLUTION – No Stroke/TIA/SE in low risk patients



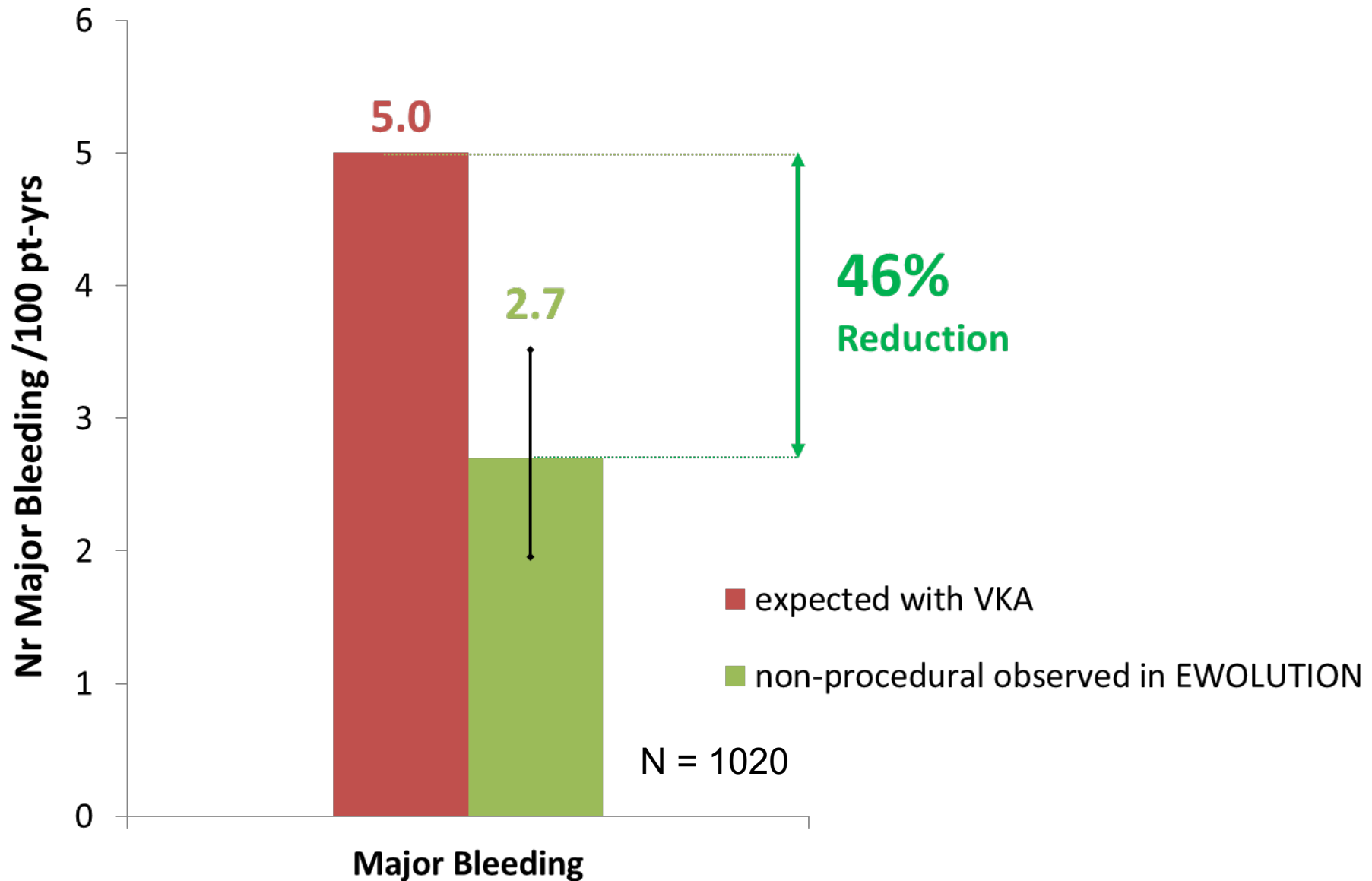
EWOLUTION – Stroke in high risk subgroups



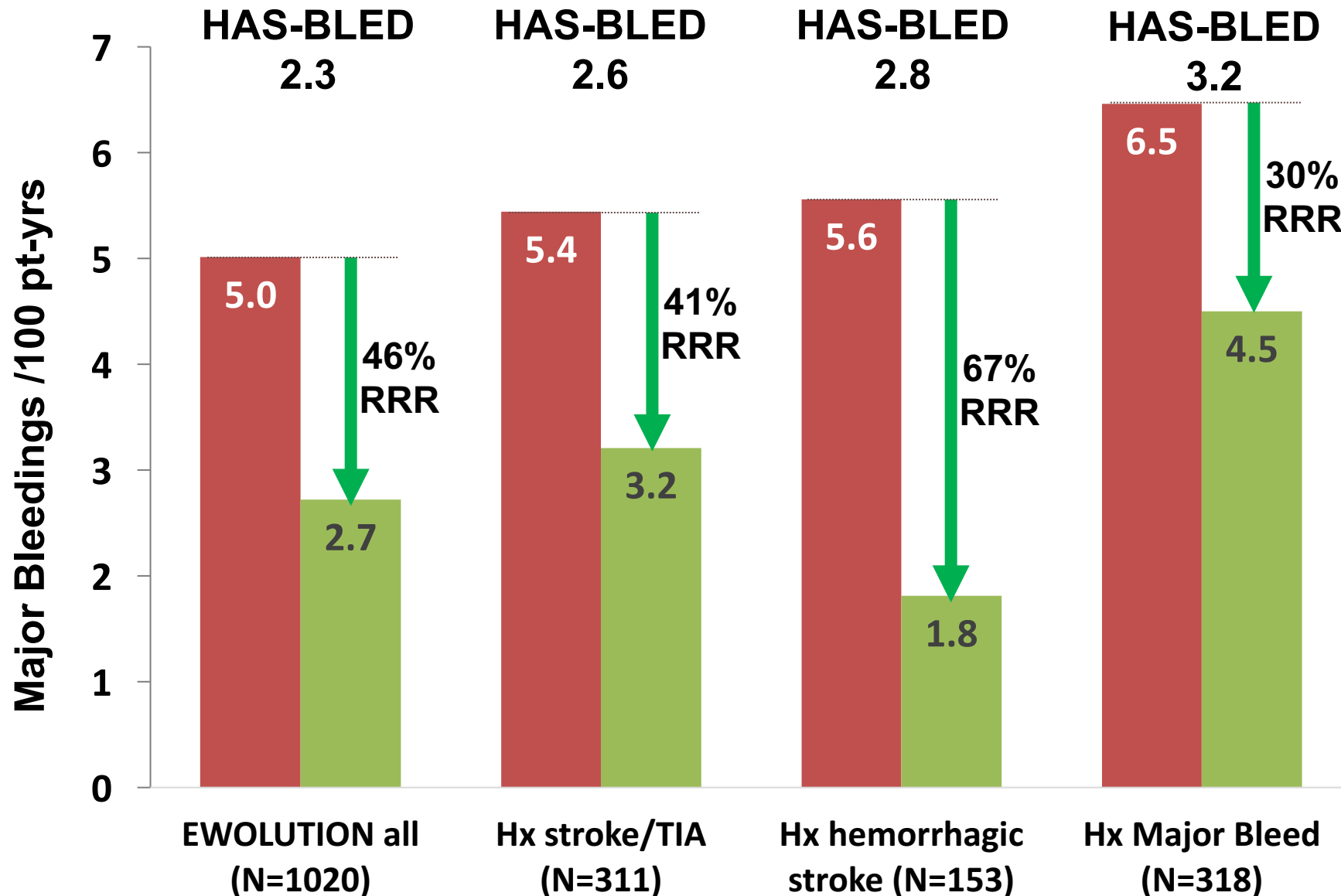
EWOLUTION – Stroke/TIA/TE in high risk subgroups



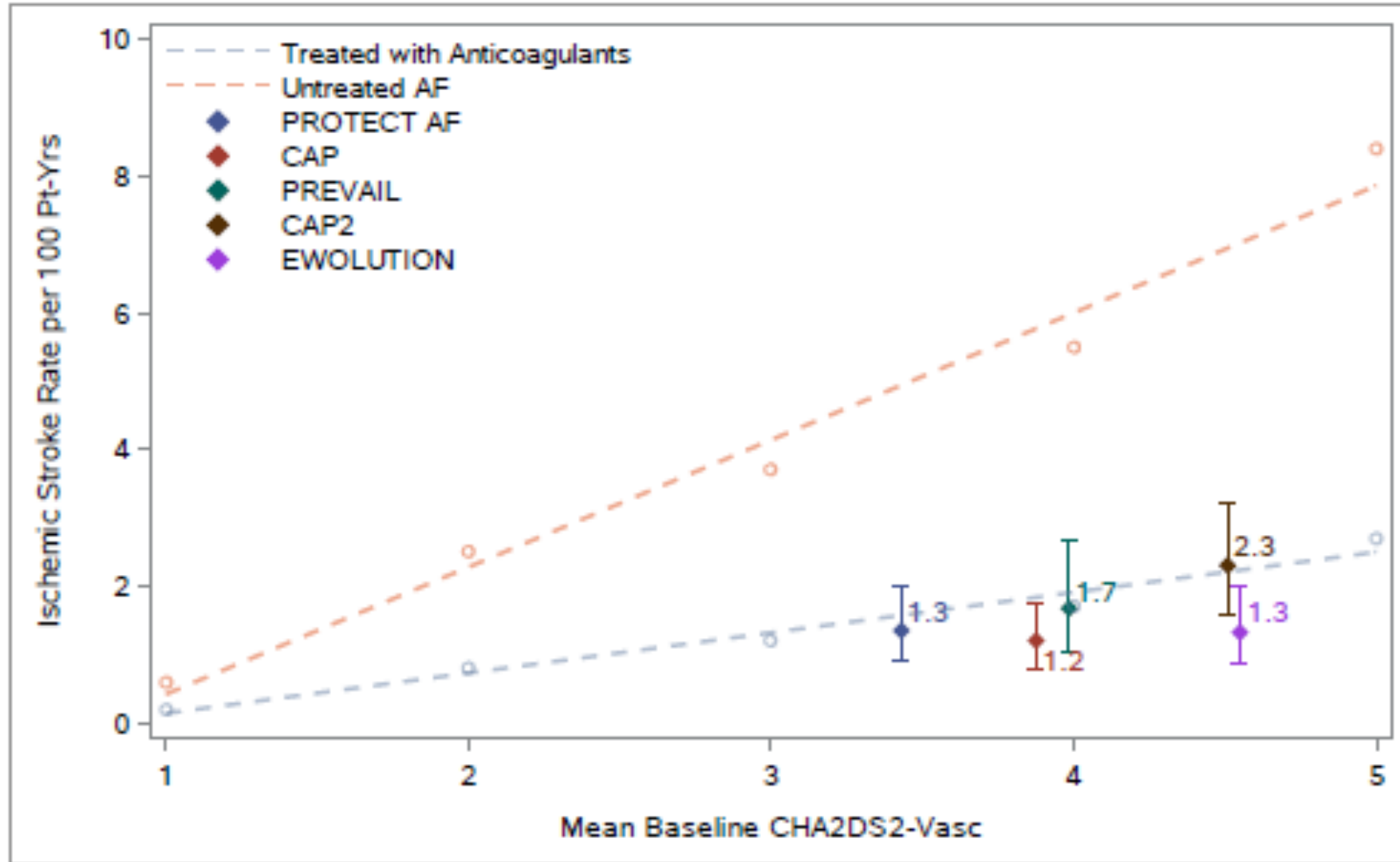
EWOLUTION – Bleeding rates for all pts



EWOLUTION – Bleeding in high risk subgroups



Consistent low stroke rate with WATCHMAN



EWOLUTION - Conclusions

- WATCHMAN LAAC was studied in an all-comers prospective registry with >70% of pts contra-indicated to oral anticoagulation
- Implant and LAA sealing success exceeding that of prior RCT and registries, with lower procedural adverse event rates¹

During the complete 2-year follow-up:

- Most pts were on (D)APT (77%) or no anticoagulation (14%)
- Device-thrombus was low (4.1%) and unrelated to stroke or anticoagulation type
- Ischemic stroke rate was 1.3 per 100 pt-yrs (83% RR reduction)
- Post-procedural major bleeding was 2.7 per 100 pt-yrs (46% RR reduction)
- High risk pts with prior ischemic/hemorrhagic stroke had the same benefit of stroke/TIA/SE prevention and the same low bleeding rates



THANK YOU