

**The real world?
Health insurance data to guide personalization in CV disease.**

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„The paradox of a clinical trial is that it is the best way to assess whether an intervention works, but is arguably the worst way to assess who will benefit from it.“

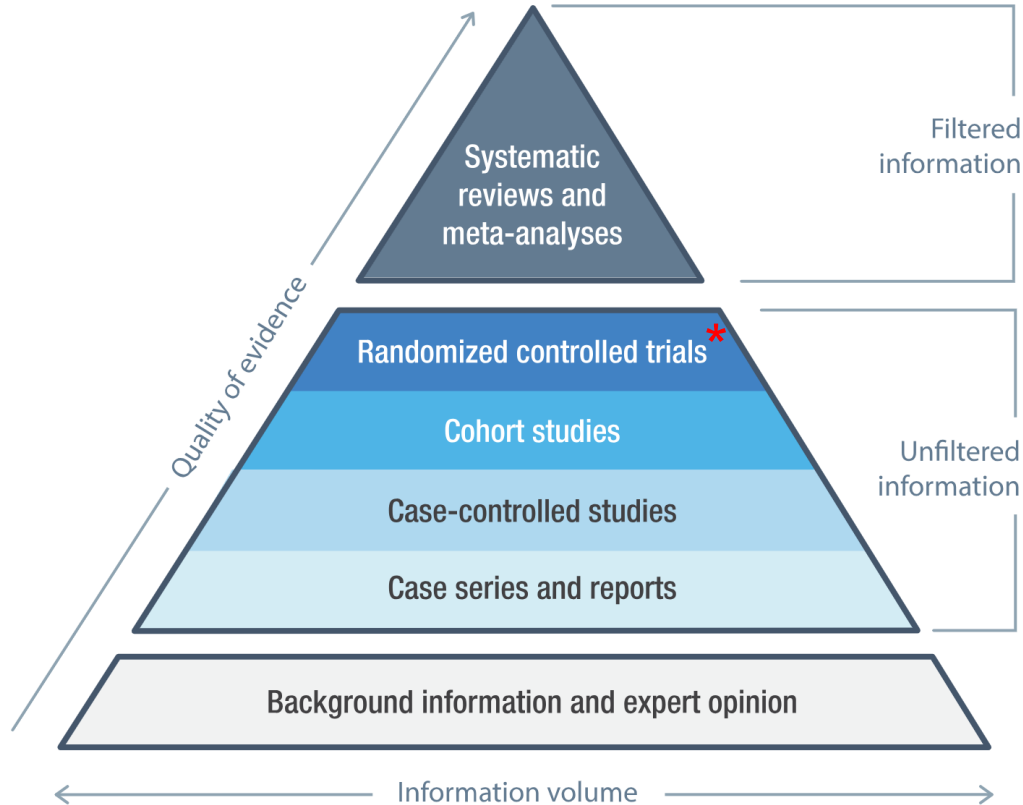
The Real World Patient



RCT Patient



Evidence Based Medicine





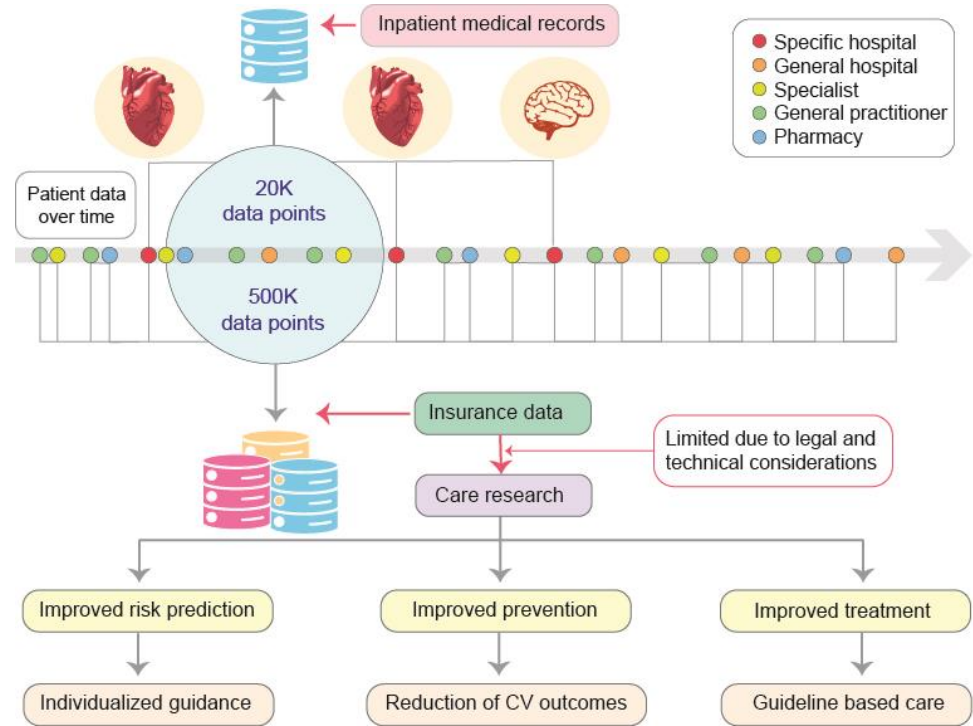
- Confirmation of **RCT results**
- Generalizability of **RCT results**
- Unmet **treatment needs**
- **Risk estimation** of future CV events
- **Effectiveness and safety** of treatments
- **Compliance** to guidelines
- Implications for **guideline implementation**



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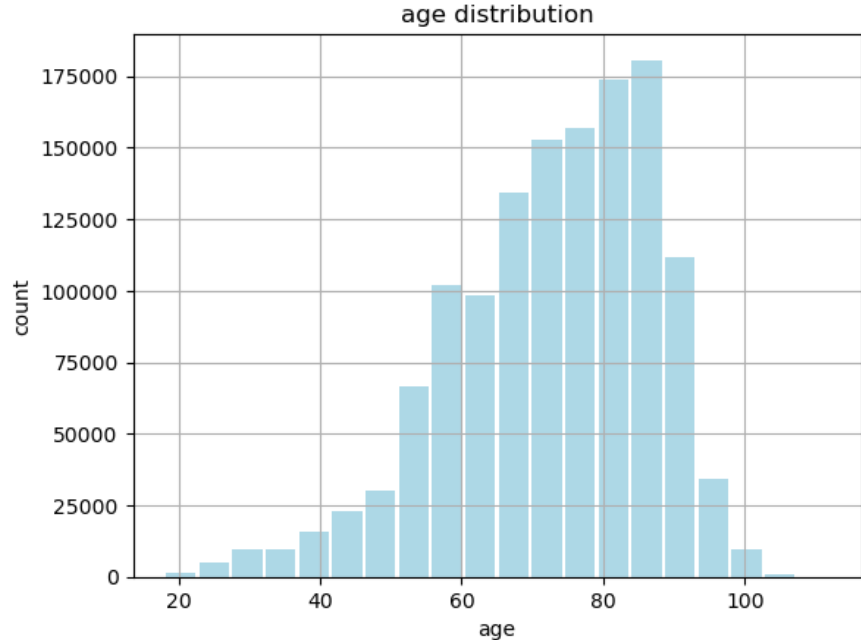
Health insurance (big) data

- Big part of the exponentially growing amount of medical data (zettabytes)
- Reflecting the real world (compared to clinical trials)
- Increasing scientific interest to gain information from health insurance claims data





- Individuals with atherosclerosis (n=1.3 mio, sex distribution 1:1)
- Follow-Up period 2012-2021
- CV-relevant data (demographics, ICD10, OPS, medication, ...)



ORIGINAL ARTICLE

Ticagrelor or Prasugrel in Patients with Acute Coronary Syndromes

BACKGROUND

The relative merits of ticagrelor as compared with prasugrel in patients with acute coronary syndromes for whom invasive evaluation is planned are uncertain.

METHODS

In this multicenter, randomized, open-label trial, we randomly assigned patients who presented with acute coronary syndromes and for whom invasive evaluation was planned to receive either ticagrelor or prasugrel. The primary end point was the composite of death, myocardial infarction, or stroke at 1 year. A major secondary end point (the safety end point) was bleeding.

RESULTS

A total of 4018 patients underwent randomization. A primary end-point event occurred in 184 of 2012 patients (9.3%) in the ticagrelor group and in 137 of 2006 patients (6.9%) in the prasugrel group (hazard ratio, 1.36; 95% confidence interval [CI], 1.09 to 1.70; $P=0.006$). The respective incidences of the individual compo-

Prasugrel was superior to ticagrelor in ACS patients to prevent MACE within 1 year

Trial Emulation – Rules

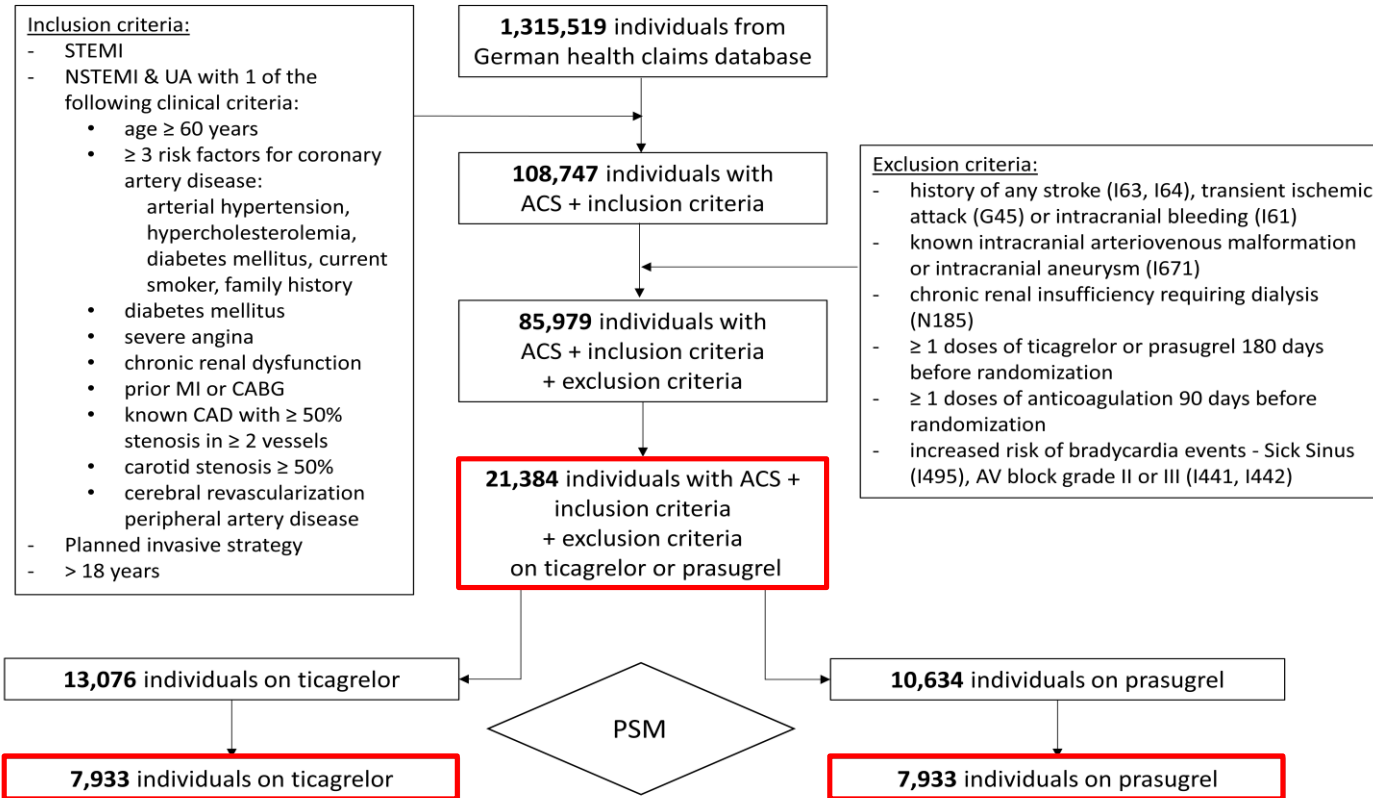
- ✓ Published protocol with pre-defined analysis plan
- ✓ Propensity based matching of relevant factors
- ✓ Check points (sample size, covariate balance, sensitivity analysis)
- ✓ Separation of programmers and analysts from influence

Limitations of matching and why the ,big' is relevant

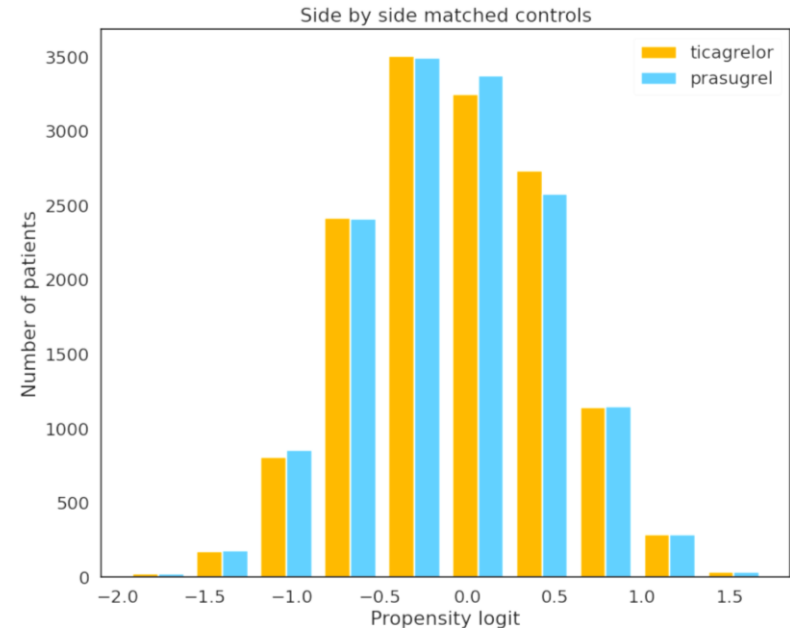


Male
Born in 1948
Raised in the UK
Married twice
Lives in a castle
Wealthy & famous

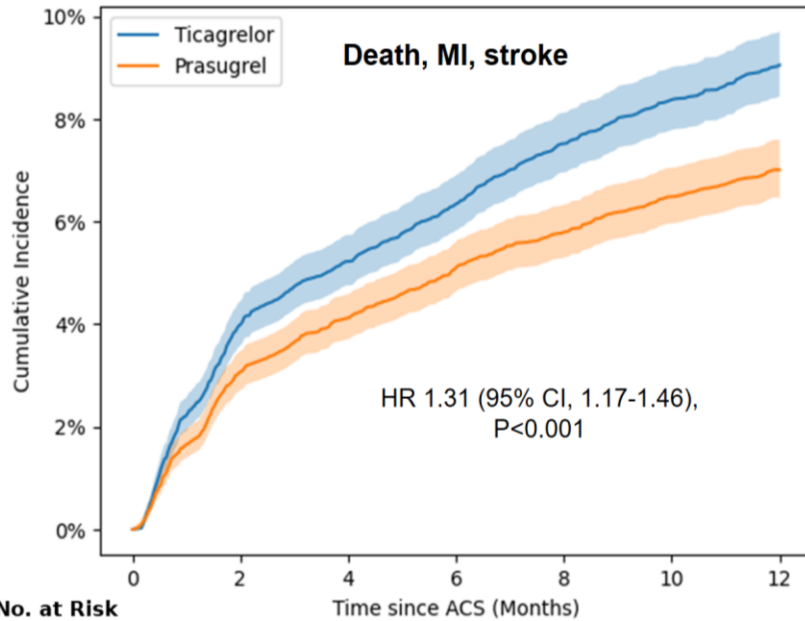




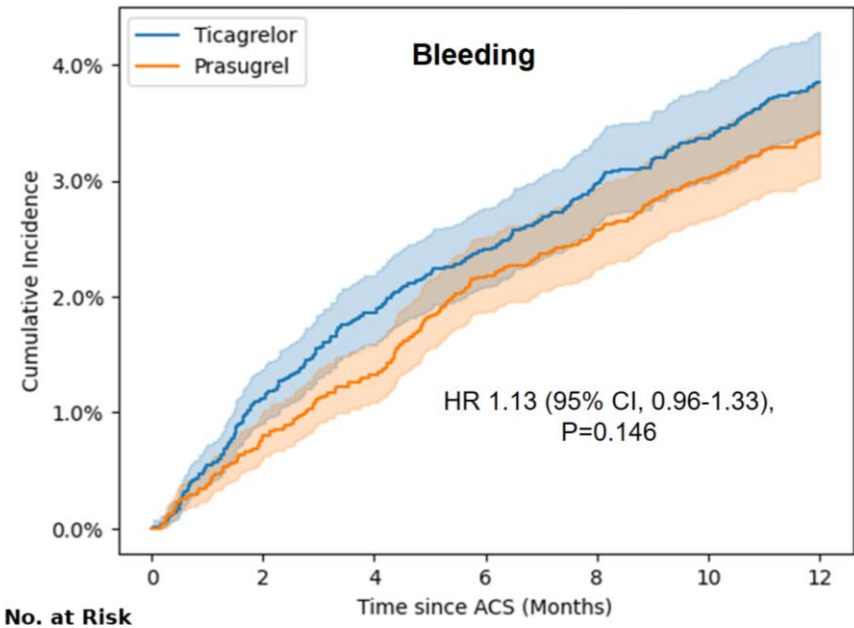
Characteristic	Ticagrelor Group (n=7,933)	Prasugrel Group (n=7,933)
Age (mean)	62.51 ± 11.38	62.54 ± 10.15
Male	5943 (74.91%)	5920 (74.62%)
Cardiovascular risk factors		
Diabetes	2643 (33.32%)	2554 (32.19%)
Use of Insulin	577 (7.27%)	527 (6.64%)
Current smoker	2050 (25.84%)	2005 (25.27%)
Hypertension	6278 (79.14%)	6295 (79.35%)
Hyperlipidemia	6060 (76.39%)	6020 (75.89%)
Medical history		
Myocardial Infarction	1175 (14.81%)	1153 (14.53%)
PCI	211 (2.66%)	223 (2.81%)
CABG	6 (0.08%)	11 (0.14%)
Comorbidities		
Chronic kidney disease	992 (12.50%)	987 (12.44%)
Obesity	1908 (24.05%)	1867 (23.53%)
ACS diagnosis at admission		
Unstable angina	569 (7.17%)	560 (7.06%)
NSTEMI	2782 (35.07%)	2737 (34.50%)
STEMI	4582 (57.76%)	4636 (58.44%)



Primary Outcomes

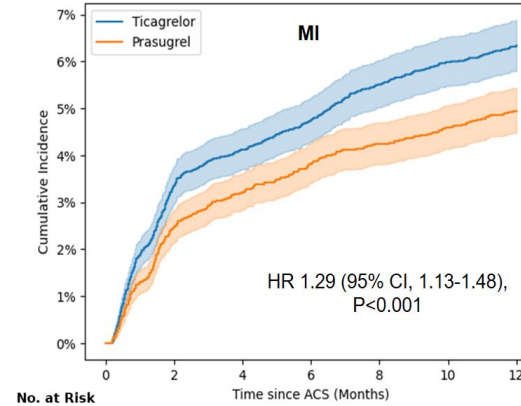
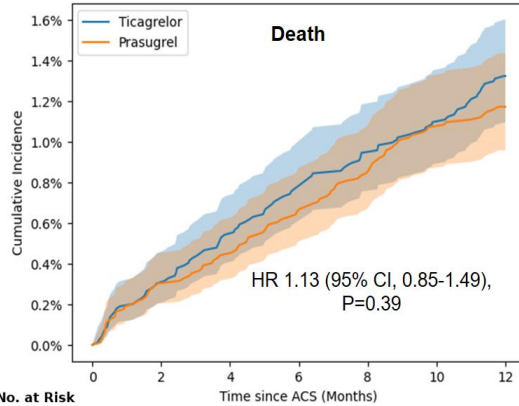


No. at Risk	0	2	4	6	8	10	12
Prasugrel	7933	7691	7607	7530	7475	7419	7377
Ticagrelor	7933	7618	7519	7431	7337	7270	7215



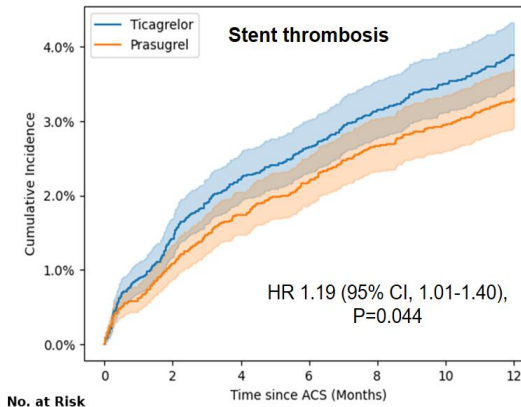
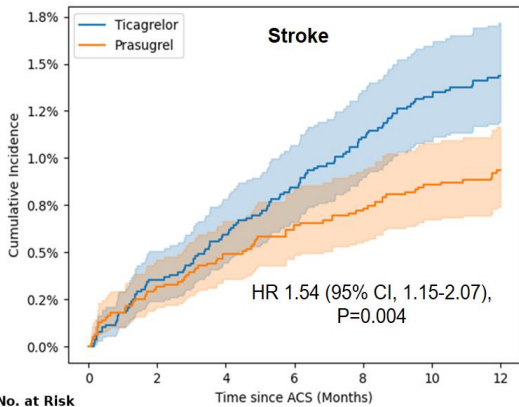
No. at Risk	0	2	4	6	8	10	12
Prasugrel	7933	7850	7795	7712	7666	7615	7577
Ticagrelor	7933	7823	7752	7693	7635	7594	7542

Secondary Outcomes



No. at Risk

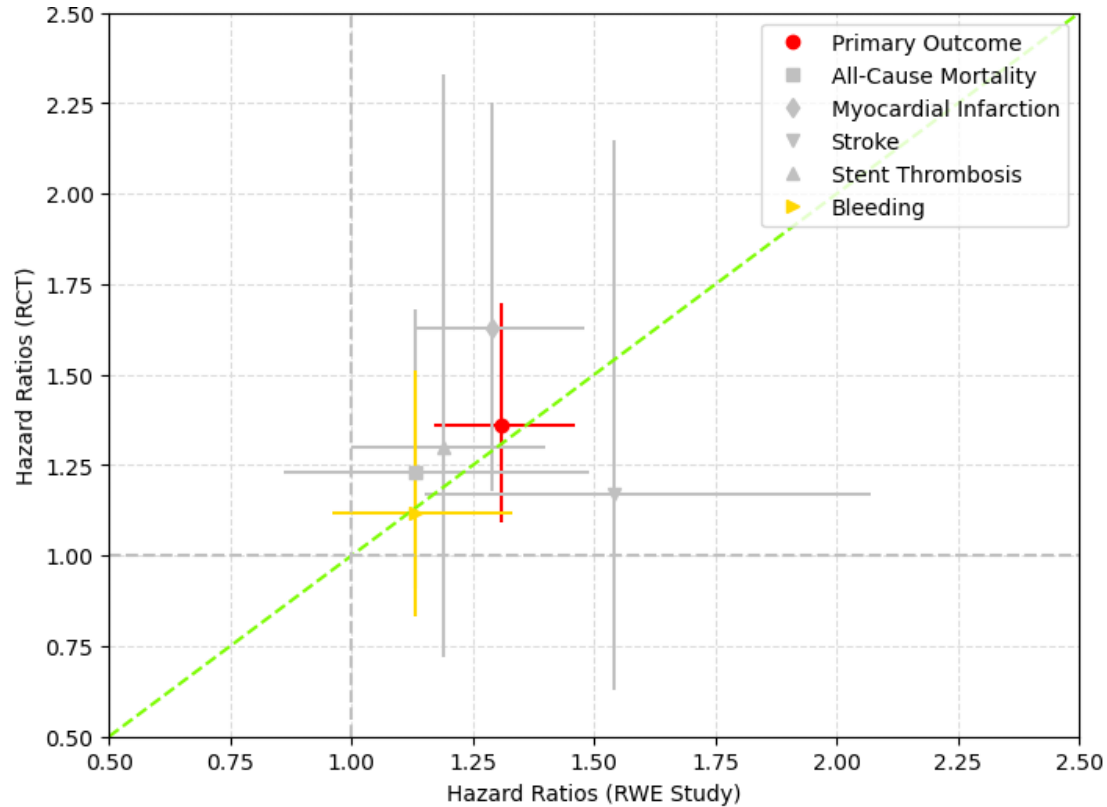
No. at Risk



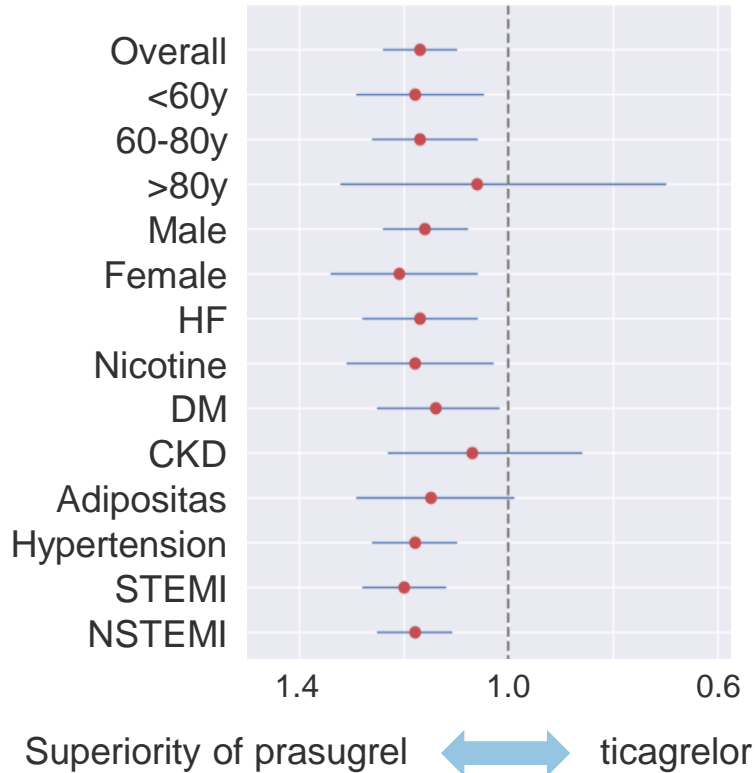
No. at Risk

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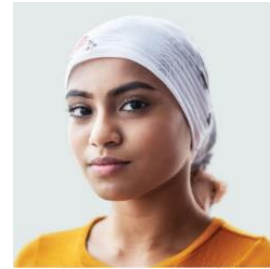
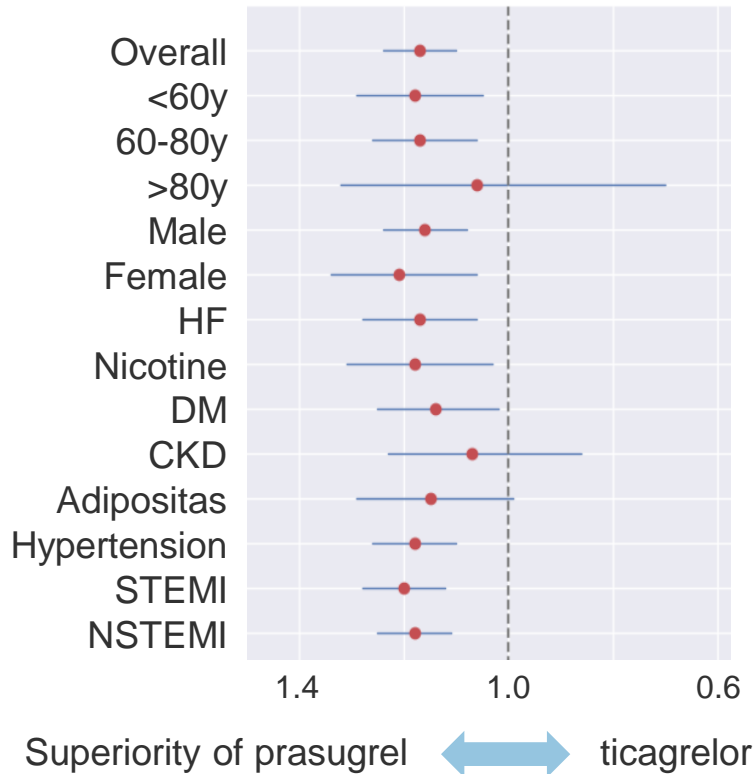
RCT vs RWD



Guiding personalized treatment?

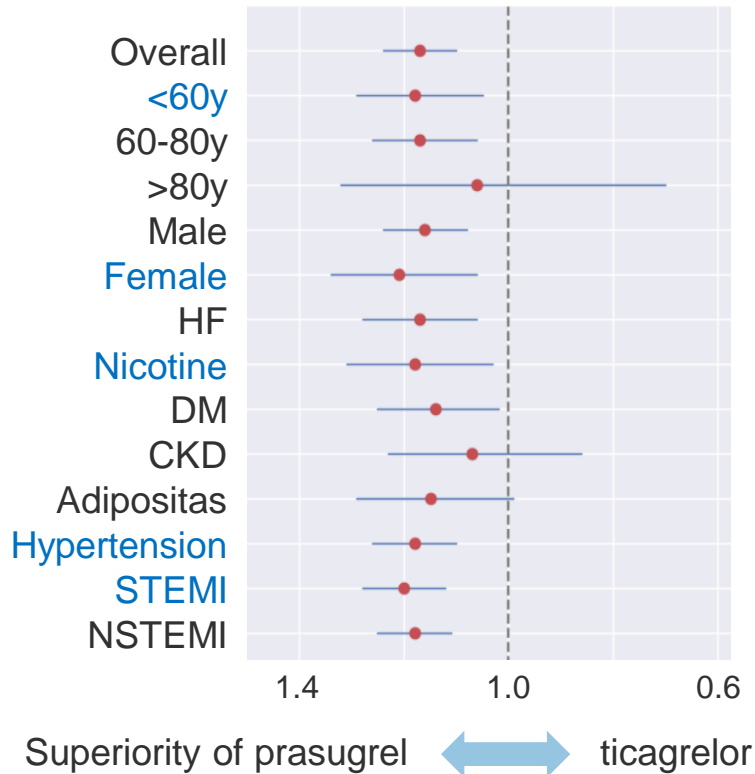


Guiding personalized treatment?



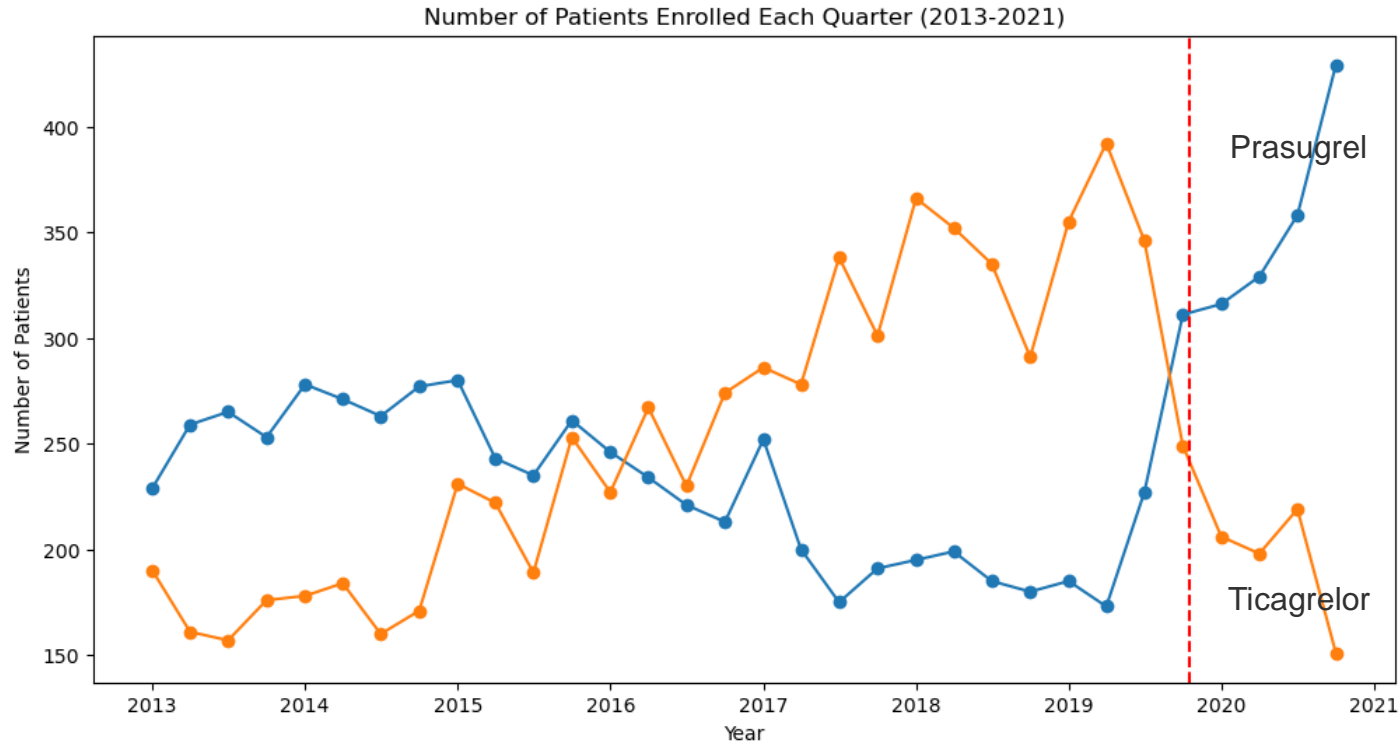
46y, female, STEMI
RF: AH & smoking

Guiding personalized treatment?

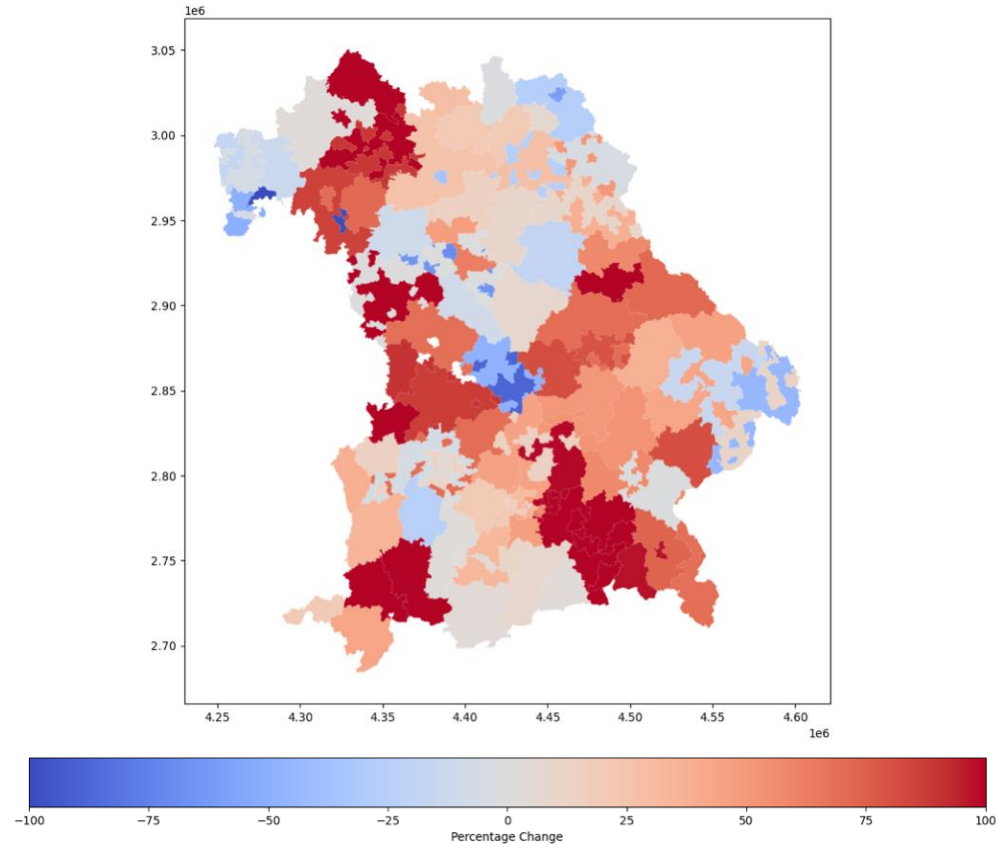


46y, female, STEMI
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What is the relevance for Bavaria?



Prasugrel description prior and after IR5



Conclusion

- RWD are a powerful tool to study the longitudinal **treatment status and compliance** in the broad population
- Emulation of RCTs have the potential to **confirm and extend RCT** data, and might provide insightful guidance in the future
- We confirmed the results of IR5 in the Bavarian population, and our data supports the **generalizability of IR5** in Bavaria
- Measuring the reality of healthcare supply enables to **understand individual and local needs** for optimization of healthcare delivery
- RWD will play a key role in future **guiding policies and interventions** aimed at maximizing the impact of therapeutics



Thank you for your attention!



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