



Real Real World Evidence

George Hripcsak, David Madigan, Patrick Ryan, Martijn Schuemie, Marc Suchard

<http://www.ohdsi.org>

“The sole cause and root of almost every defect in the sciences is this: that whilst we falsely admire and extol the powers of the human mind, we do not search for its real helps.”

— Novum Organum: Aphorisms [Book One], 1620, Sir Francis Bacon



Thromb Haemost 2016; 116(05): 975-986
DOI: 10.1160/TH16-05-0403



Stroke, Systemic or Venous Thromboembolism

Schattauer GmbH

Real-world comparison of major bleeding risk among non-valvular atrial fibrillation patients initiated on apixaban, dabigatran, rivaroxaban, or warfarin

A propensity score matched analysis

Gregory Y. H. Lip, Allison Keshishian, Shital Kamble, Xianying Pan, Jack Mardekian, Ruslan Horblyuk, Melissa Hamilton

When comparisons were made between NOACs, matched rivaroxaban patients had a significantly higher risk of major bleeding (HR: 1.82; 95 % CI: 1.36–2.43) compared to apixaban patients.



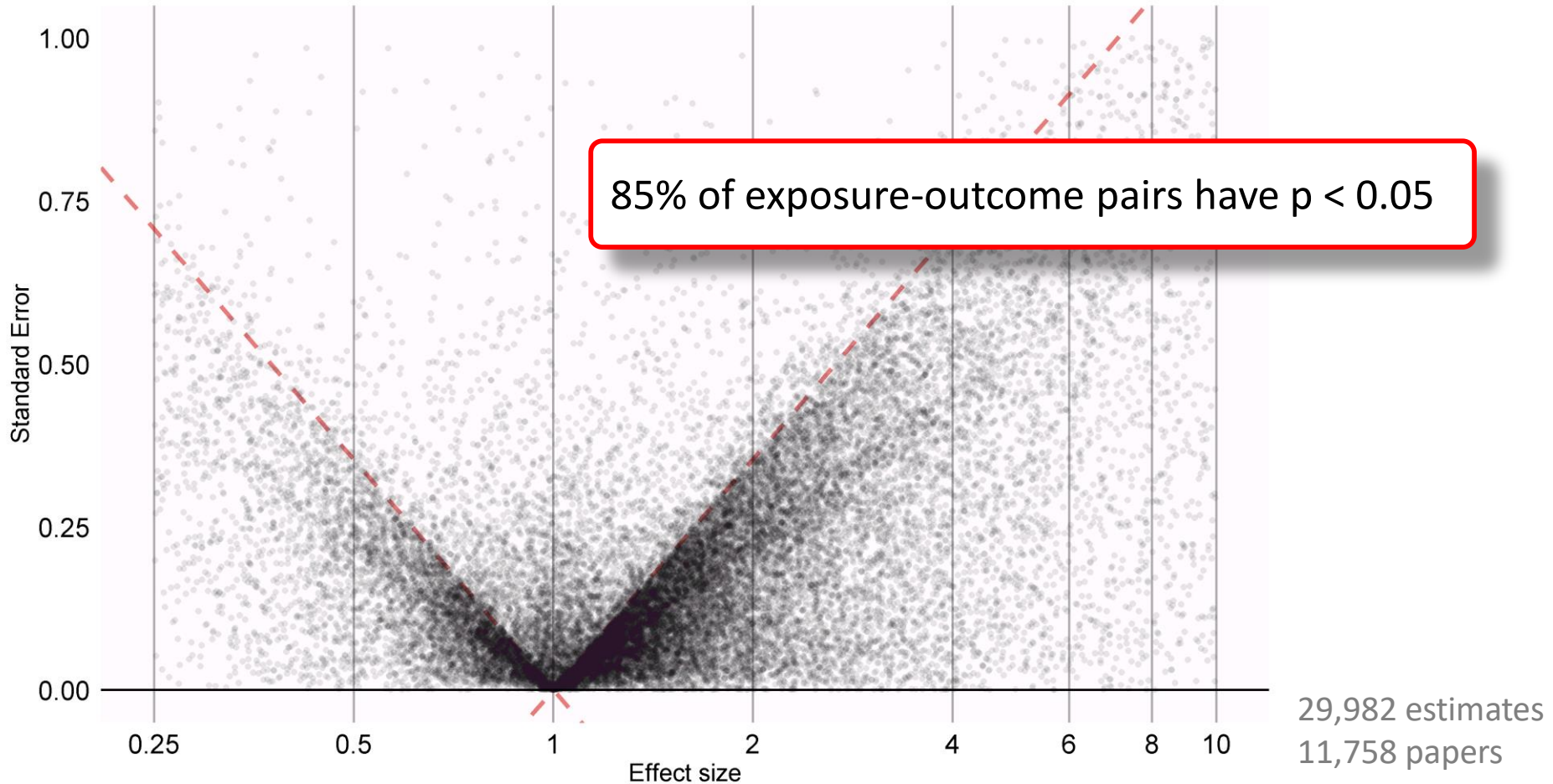
Studies ignore...

- Selection bias
- Measurement error
- Model misspecification
- Multiple modeling
- Unmeasured confounding

Artisanal, non-reproducible, non-evaluatable process



Observational research results in literature





A New Approach

- Reproducible, systematized, open source approach at scale
- Negative controls
 - Drugs and outcomes “known” to have no causal association
 - Literature, product labels, spontaneous reports
 - Empirical p-values
- Positive Controls
 - Inject signals onto negative controls with known effect size
 - Calibrated confidence intervals



OHDSI

OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

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Welcome to OHDSI!

The Observational Health Data Sciences and Informatics (or OHDSI, pronounced "Odyssey") program is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics. All our solutions are open-source.

OHDSI has established an international network of researchers and observational health databases with a central coordinating center housed at Columbia University.

Read more [about us](#), [about our goals](#), and how you can [help support the OHDSI community](#).

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ACHILLES Released



OHDSI released its first open-source software application, ACHILLES, at the 2014 EDM Forum in San Diego, CA. Congratulations to the ACHILLES

OHDSI on YouTube



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THE LANCET

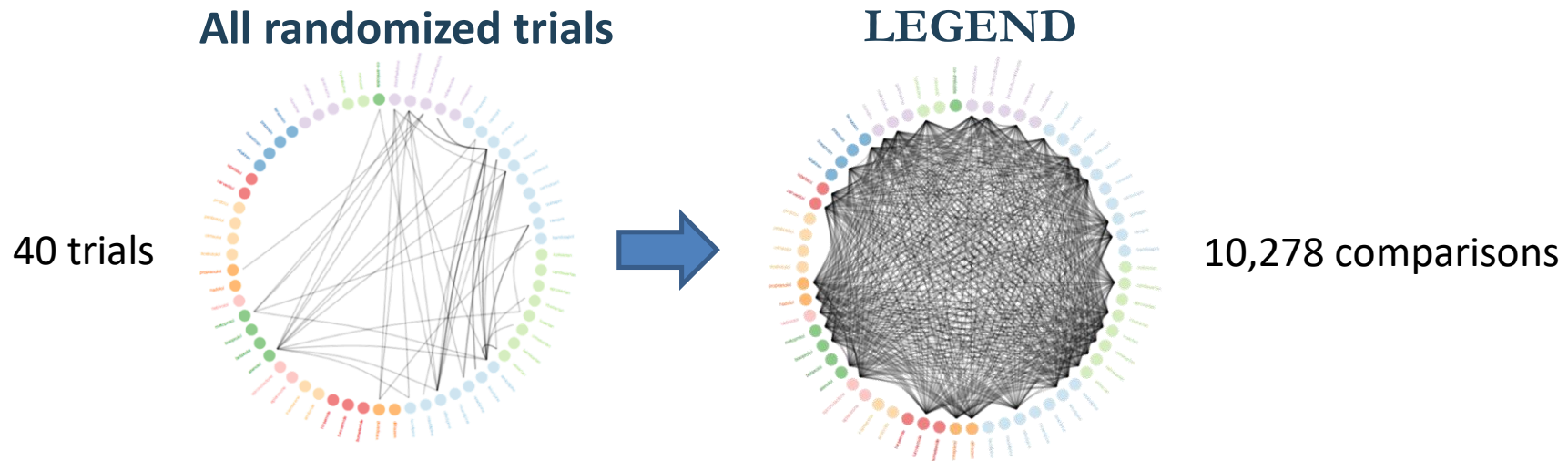
Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis

Marc A Suchard, Martijn J Schuemie, Harlan M Krumholz, Seng Chan You, RuiJun Chen, Nicole Pratt, Christian G Reich, Jon Duke, David Madigan, George Hripcsak, Patrick B Ryan

All pairwise comparisons of 39 drugs, 58 outcomes, 9 databases



LEGEND Large-scale Evidence Generation and Evaluation in a Network of Databases



<https://github.com/OHDSI/LEGEND>



Concluding thoughts

- An international community and global data network can be used to generate real-world evidence in a secure, reliable and efficient manner
- Common data model critically important
- Much work remains on establishing (and improving) actual operating characteristics of current approaches to causal inference