

Measuring
Concordance of Drug
Class-to-Class
Comparison
Between
Observational Data
and the FAERS Data

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INTRO

- Leverage results of 2019 LEGEND-HTN study¹ by Suchard et al.
- Pairwise comparison of 4 first-line anti-hypertension drug classes
- Total of 46 health outcomes of interest (HOI)

METHODS

Data Source

- FDA Adverse Event Reporting System (FAERS) 2014Q3 – 2020Q1
- Over 80MM drug reactions across more than 7MM cases

Entity & Concept Mapping

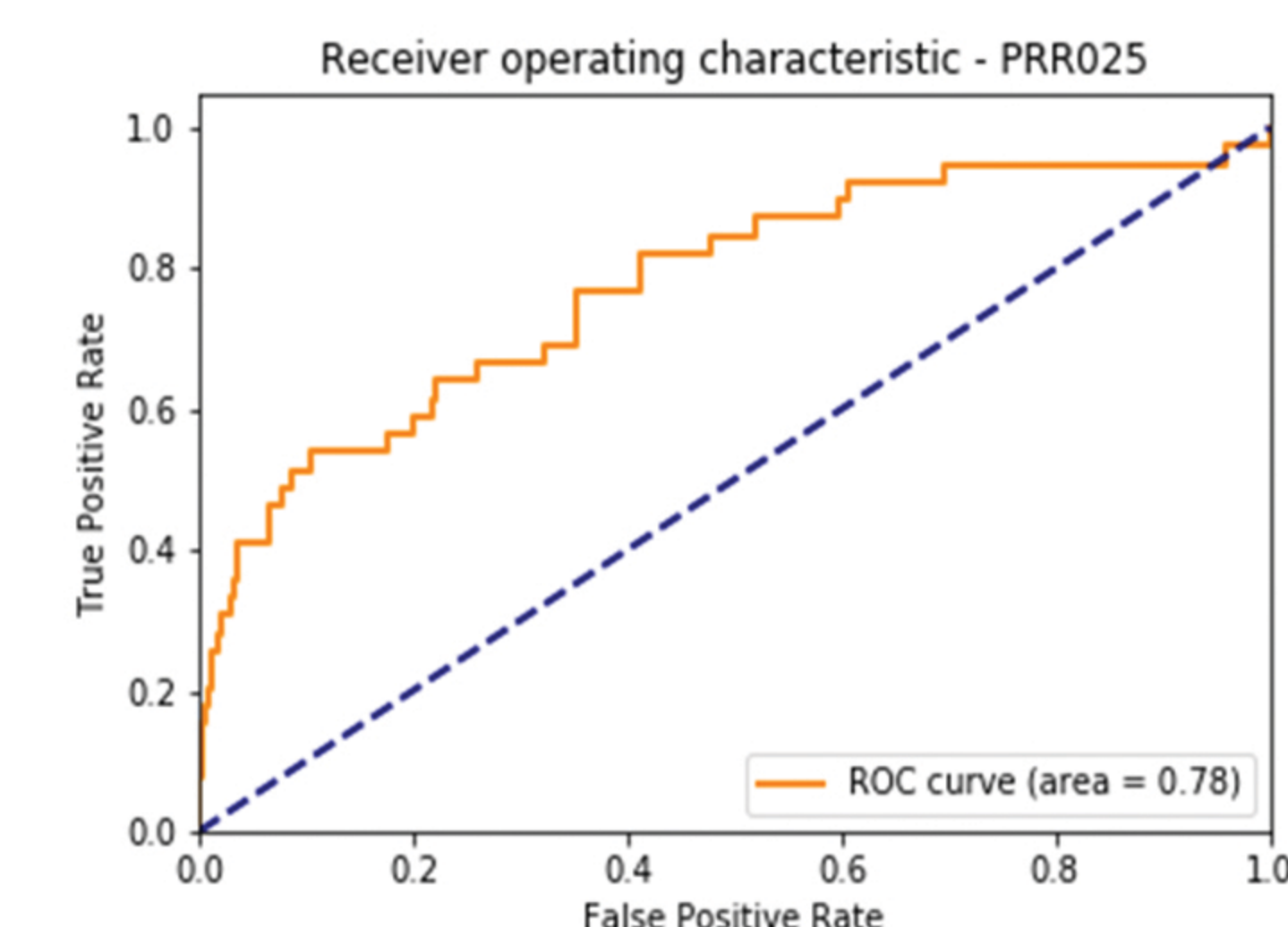
- 46 HOIs → MedDRA PTs
- 4 drug classes → WHO ATC Level 4

Framing

- Treat calibrated Suchard results as the gold standard, with a binary response: significant Yes vs. No
- Use lower bound of 95% CI of disproportionality measure as class discriminators (IC025, PRR025)
- Measure concordance via AUROC

RESULTS

- AUROC of 0.77 and 0.78 using IC025 and PRR025, respectively



Strong concordance between
LEGEND-HTN findings based on
claims & EHR data, and
disproportionality measures
based on FAERS spontaneous
data.



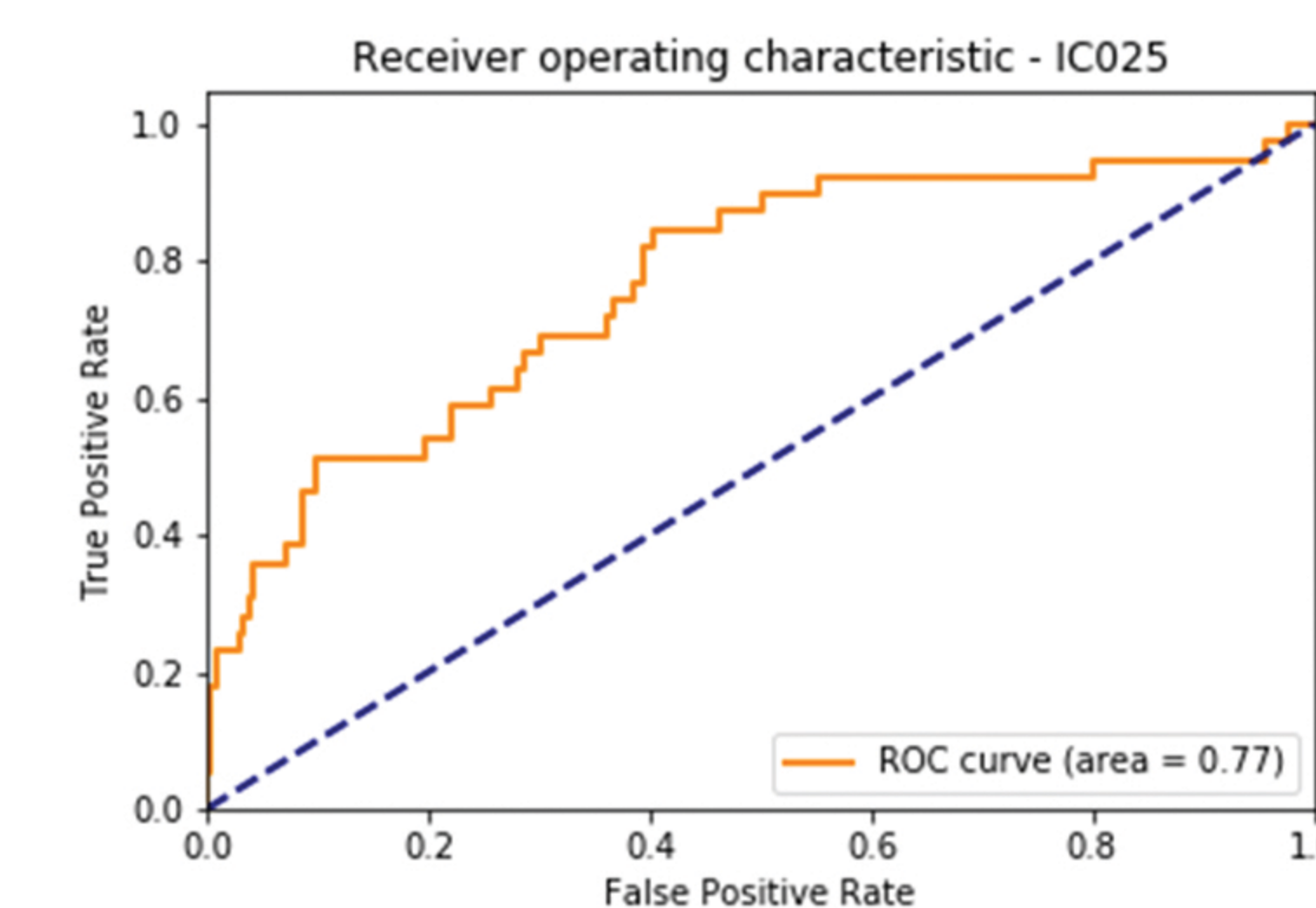
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Mapping Examples

HOI	MedDRA PTs
Abdominal pain	Abdominal Pain, Abdominal Pain Upper, Abdominal Pain Lower
Abnormal weight gain	Abnormal Weight Gain
Abnormal weight loss	Abnormal Loss Of Weight, Weight Decreased
Acute pancreatitis	Pancreatitis, Acute Pancreatitis
⋮	⋮

Drug Class	WHO ATC Level 4 Class
Thiazide or thiazide-like diuretics	Thiazides, plain
Angiotensin-converting enzyme inhibitors	ACE inhibitors, plain
Angiotensin receptor blockers	Angiotensin ii antagonists, plain
Dihydropyridine calcium channel blockers	Dihydropyridine derivatives

ROC Curve for IC025



2x2 Contingency Table

Experienced HOI

Took Drug in Class A	Experienced HOI	
	Yes	No
Yes	<i>a</i>	<i>b</i>
No	<i>c</i>	<i>d</i>

$$a + b + c + d =$$

patients taking drug in class A or B

¹Suchard MA, et al. Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis. *Lancet*.

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