



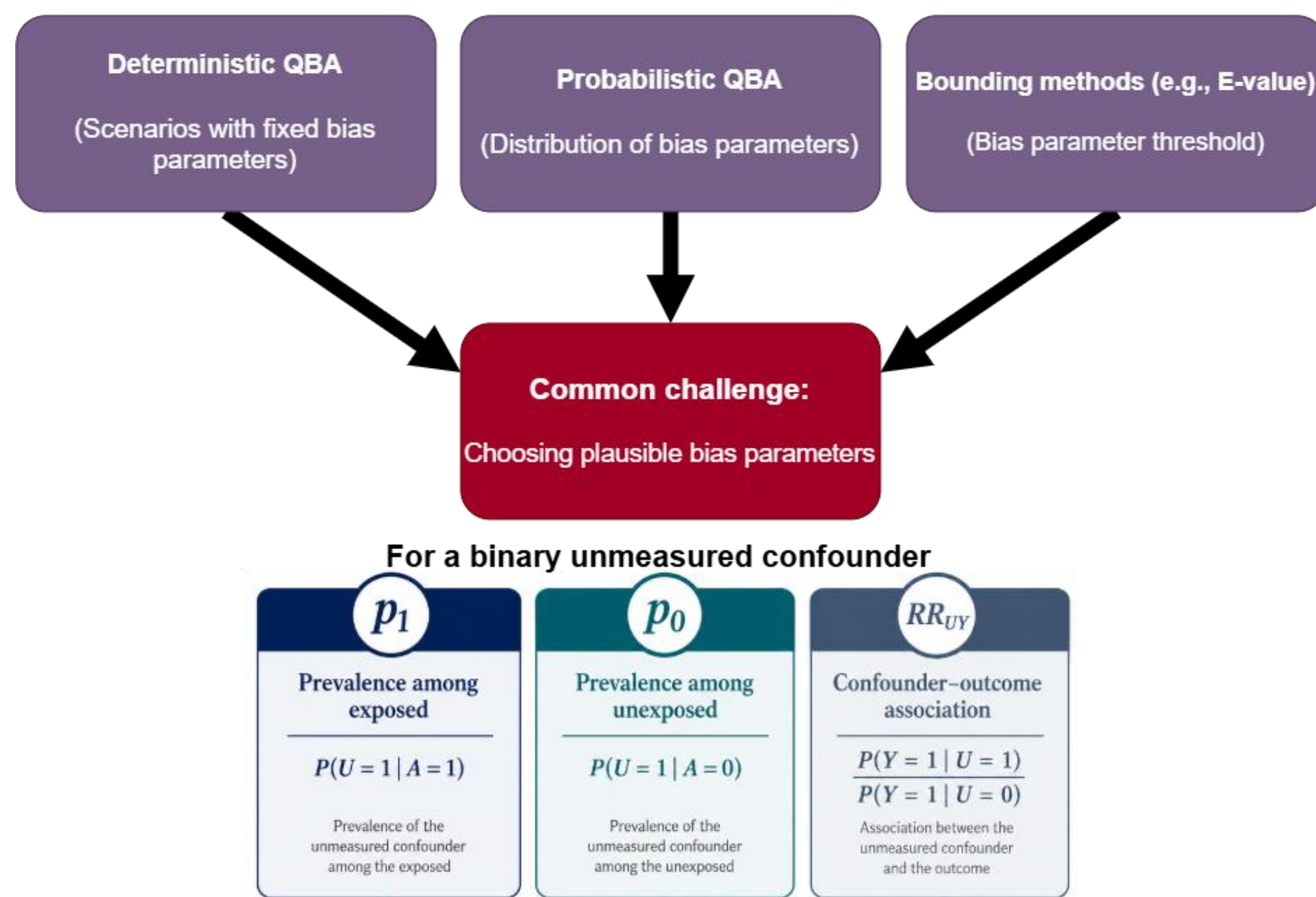
A data-informed quantitative bias analysis framework for causal estimates from real-world evidence using simulated observational data

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Background

- Real-world evidence (RWE) informs clinical and policy decisions, but causal estimates from observational data can be biased due to unmeasured confounding
- Quantitative bias analysis (QBA) can assess the potential impact of unmeasured confounding, but results depend heavily on the bias parameters assumed
- A key challenge is choosing plausible parameter values

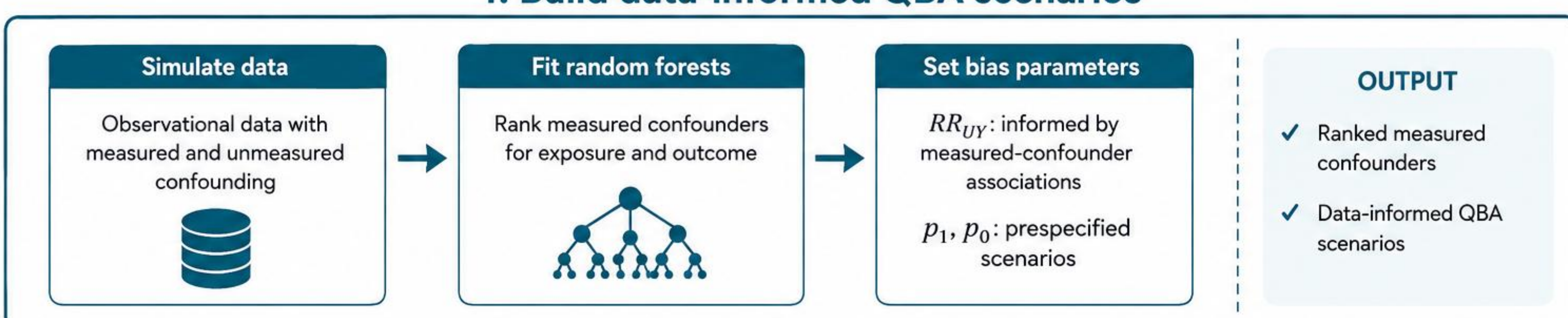


Objectives

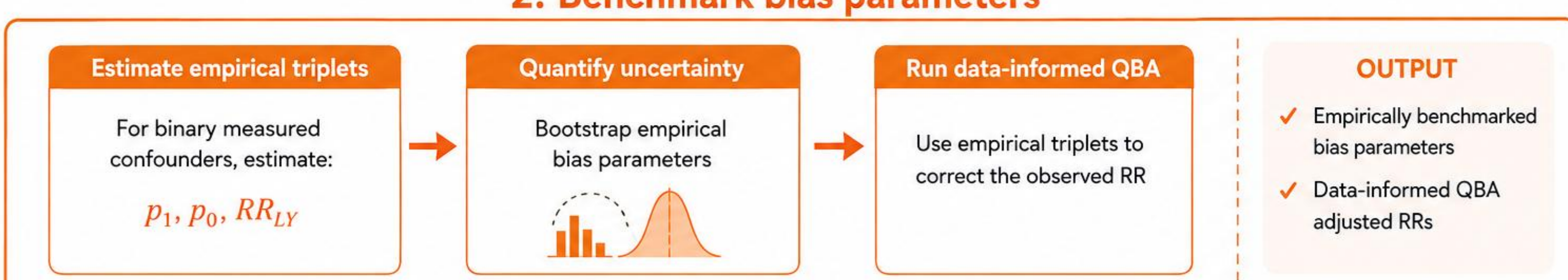
- Develop a data informed QBA approach that benchmarks bias parameters against measured confounders
- Compare data-informed QBA with deterministic QBA, probabilistic QBA, and the E-value
- Evaluate performance against the known data-generating causal estimate and assess robustness to model specification

Methods

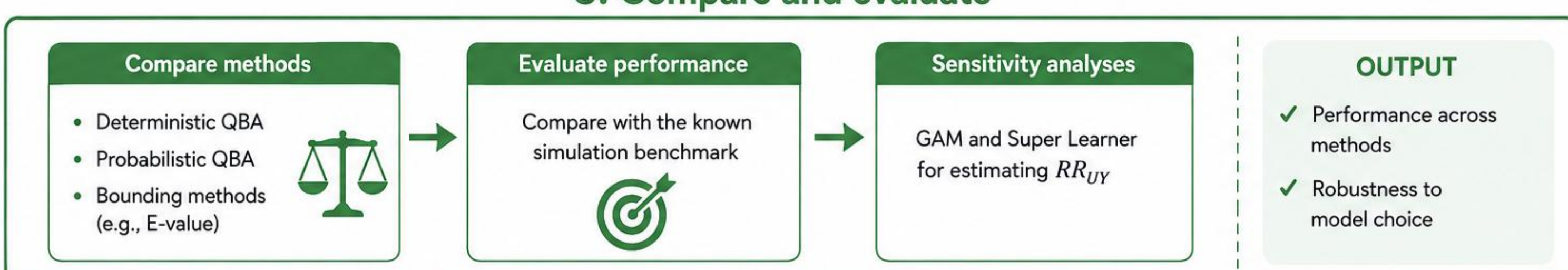
1. Build data-informed QBA scenarios



2. Benchmark bias parameters

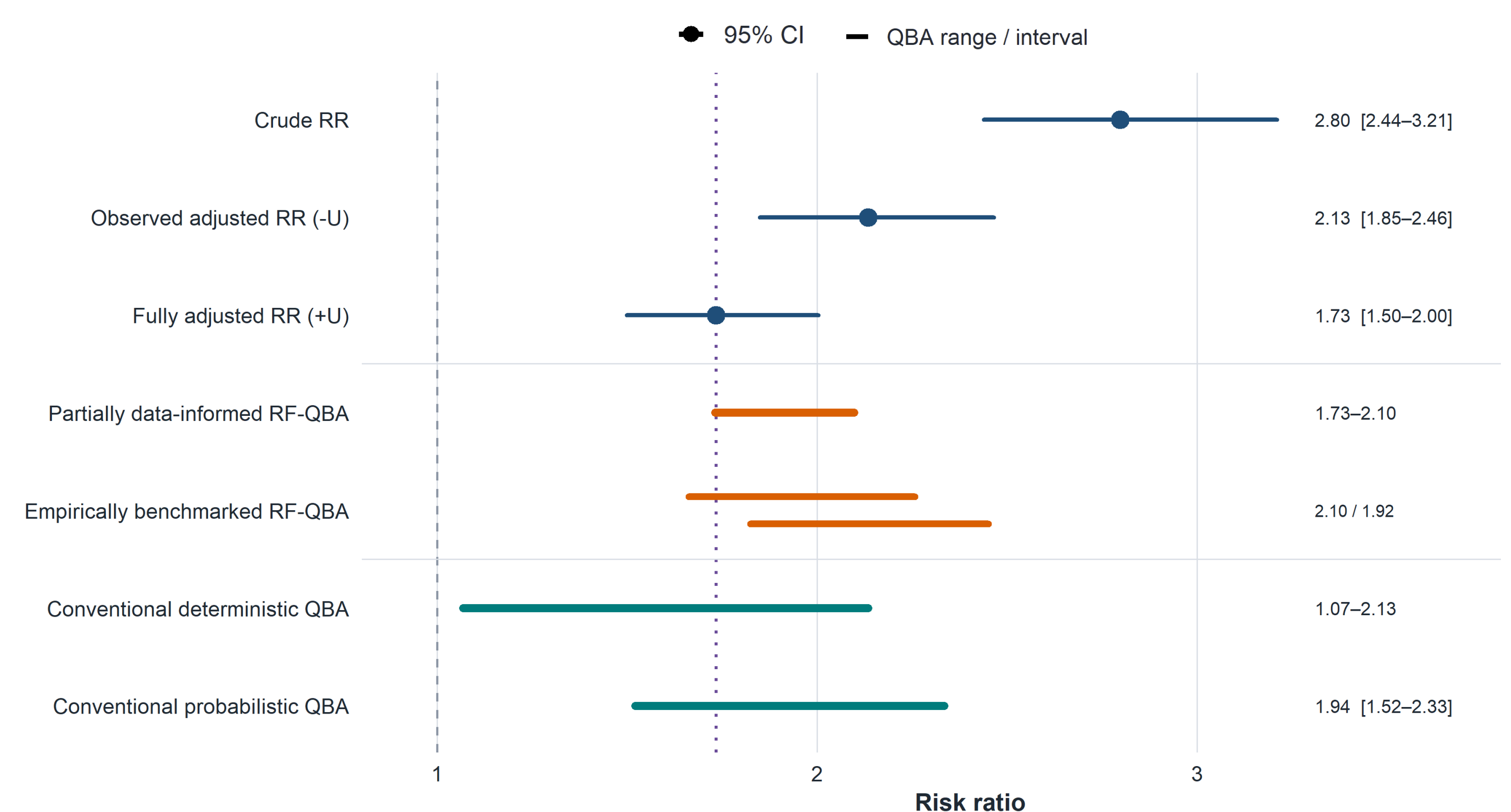


3. Compare and evaluate



Results

Figure 1. Risk ratio estimates across causal effect and quantitative bias analyses: Data-informed QBA attenuated the observed RR toward the fully adjusted estimate



E-value: 3.69 to explain away the observed RR; 3.10 to shift the lower 95% CI limit to the null

Figure 2. Empirical confounder space: Stronger measured-confounder benchmarks produced greater bias correction

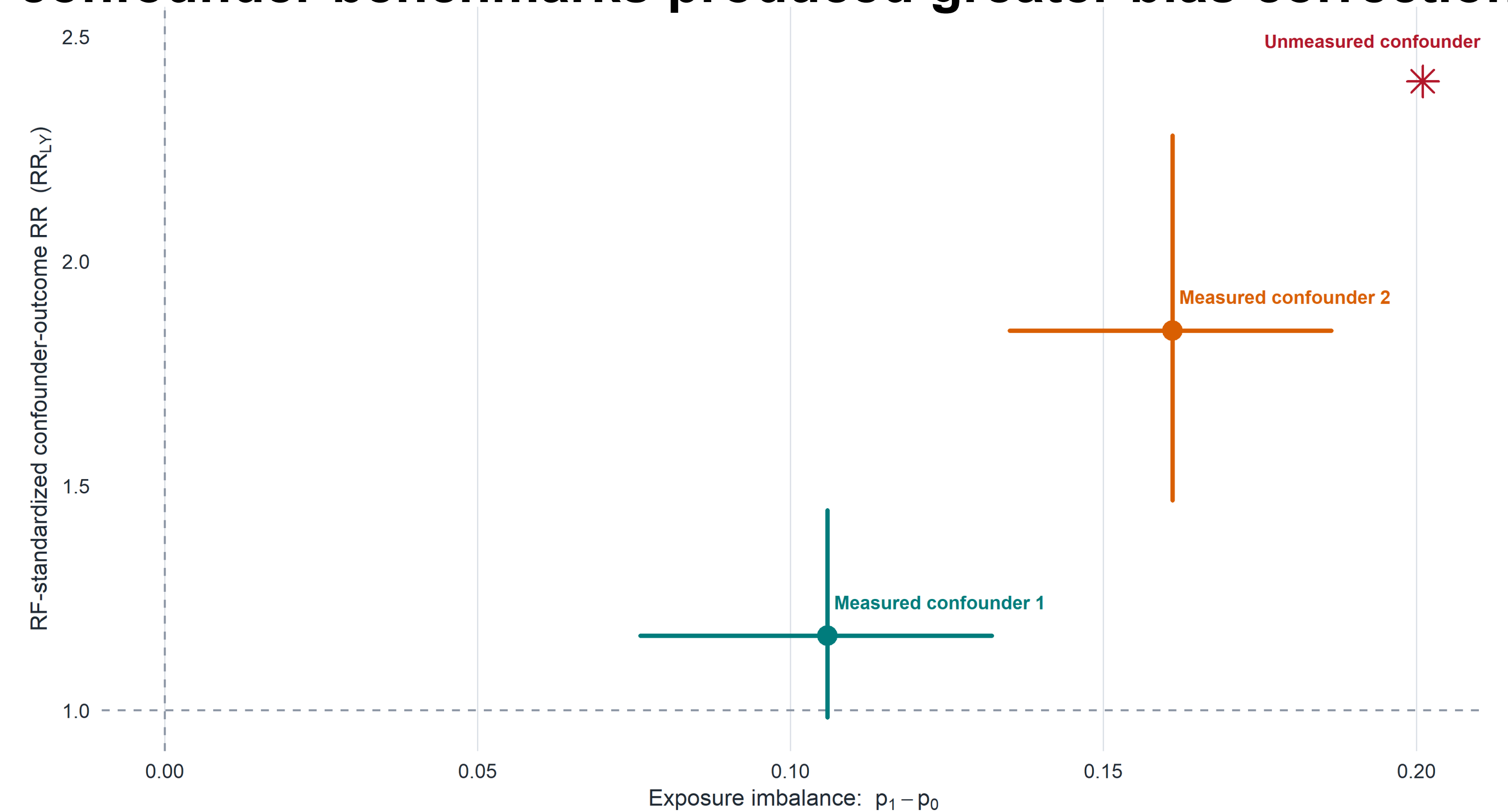
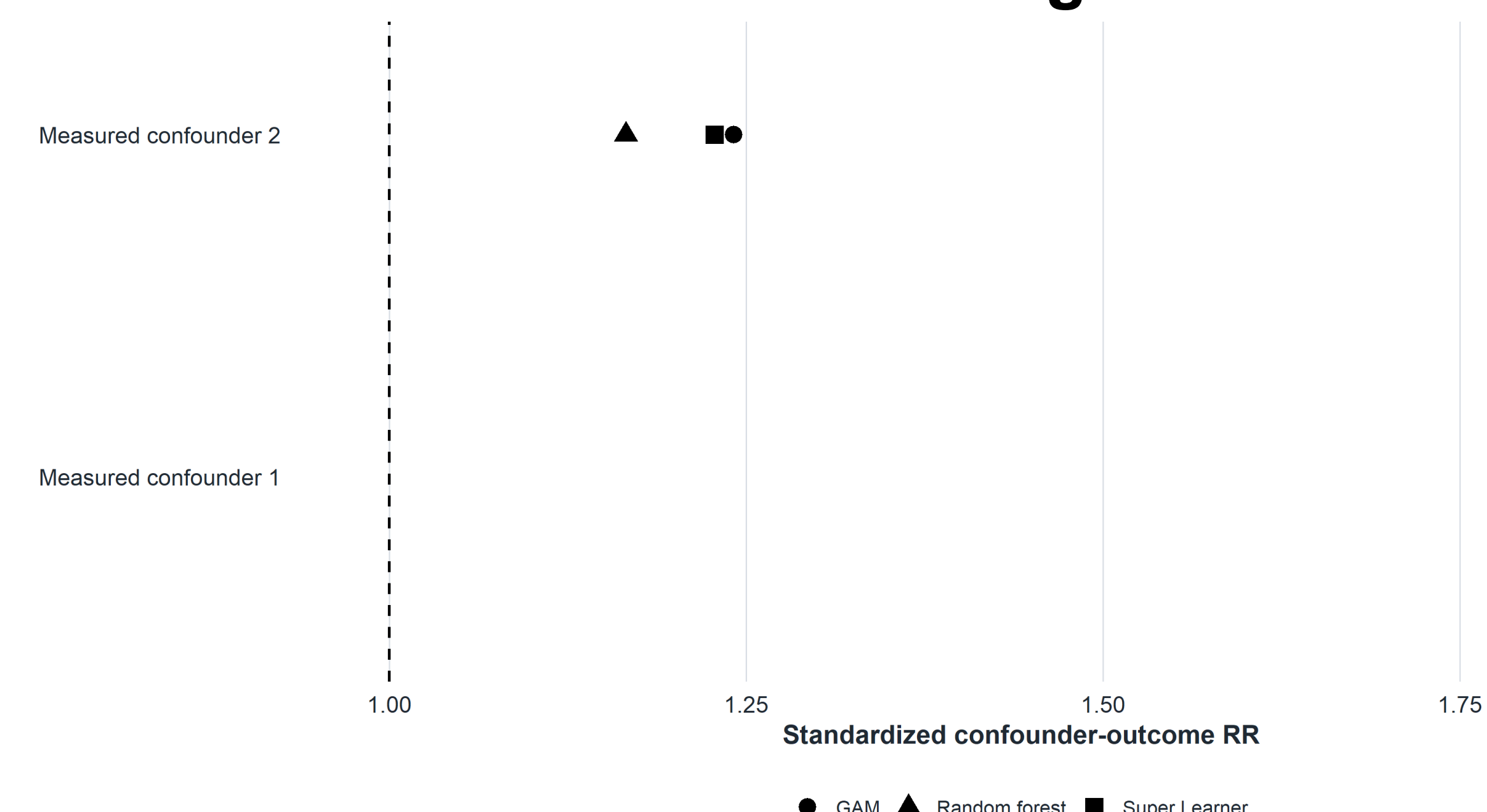


Figure 3. Model robustness check on empirically benchmarked confounder-outcome risk ratios: Random Forest model choice did not change estimates



Conclusion

- Data-informed QBA moved estimates closer to fully adjusted RR
- Empirical benchmark estimates were robust to model specification
- Future work:** integrate with external evidence and expert elicitation, including Bayesian bias analysis approaches, and evaluate the framework in real-world causal analyses