Assessing Therapeutic Equivalence of Brand and Generic Drugs Using Observational Data.

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Abstract:

Although generic drugs are required to be bioequivalent to brand, generic producers are not required to establish therapeutic equivalence through clinical trials. We describe a method to assess therapeutic equivalence of brand and generic drugs using insurance claims data with the anti-depressant venlafaxine. We use time to drug failure as an outcome. Generic market entry is typically followed by a large shift among new users towards initiation on generic, with little overlap in initiation times of brand and generic users. This creates temporal confounding when observed survival times are affected by changes over time in unmeasured variables. There is also time varying confounding. Our method addresses both of these concerns by applying Regression Discontinuity to counterfactual survival curves, with a discontinuity in the probability of initiation to generic at the date when generic becomes available. The survival curves themselves are estimated using G-Computation to account for the time-varying confounding.