

Addressing Bias in Observational Studies Using Real-world Data: An Example of Using Two Designs in One Study to Examine Risk of Self-harm Associated with Antidepressant Use

Abstract

Observational studies based on real-world data are essential to understanding the benefits and risks of therapy or intervention. They supplement the body of evidence generated from randomized controlled trials, which are often limited to a small number of events, short observation periods, and stringent inclusion/exclusion criteria. However, observational studies are susceptible to various sources of bias such as indication bias, channeling bias, and residual confounding. Using a study on antidepressant use and the risk of self-harm in people with depression as an example, Dr Luo will discuss methodological challenges encountered when trying to disentangle the effect of antidepressants on self-harm risk from the core symptoms of depression itself. In this study, longitudinal electronic health records of 48,724 individuals with depression diagnoses from public hospitals in Hong Kong were used. Two study designs - cohort analysis and a self-controlled case series design – were adopted to address biases. In this seminar, the pros and cons of each study design and corresponding statistical models in the context of suicide research will be illustrated. The strengths and limitations of observational studies based on electronic medical records will also be discussed.